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Politiques de Santé

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

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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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ADDRESSES
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PUBLISHING
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EDITORIAL

Health Services and Policy Research in Canada: An Editor's Reflections

Healthcare Policy is a vibrant and growing Canada-focused health services and policy journal. As I mark my two-year anniversary as volunteer editor-in-chief of *Healthcare Policy*, I can say that I have had the privilege to see the scope and breadth of researchers' progress on important health system problems. From this vantage point, a number of trends are worth summarizing for the journal's readers.

The readership of *Healthcare Policy* has grown enormously during the pandemic. Research manuscripts and Discussion and Debate articles have experienced at least a doubling of monthly reads over the past two years. Most readers are from Canada, though there are signs that the manuscripts are increasingly being accessed from a number of English-speaking countries, including the UK, Australia and the US. This increase in readership was unanticipated, though it is good news for the publisher, for the journal's authors and for the impact of the manuscripts.

One change that has been introduced to *Healthcare Policy* is the addition of rejoinder articles. Each Discussion and Debate article that is accepted is paired with a rejoinder that raises complementary policy issues or provides counterpoints to the original article's thesis. In my opinion, the rejoinders have greatly enriched the discussions on policy and enhanced the profile of the Discussion and Debate articles.

The journal's popularity as an outlet for Canada-focused research has induced a corresponding increase in workload for the journal's hard-working editors and staff. With its strong team and with the continuing support of independent peer reviewers, the duration between submission and completion of peer review has reduced in spite of the increased volume of submissions. The time from submission to decision is now averaging 12 weeks.

When the pandemic began early during my tenure as editor-in-chief, I expected *Healthcare Policy* to be deluged with manuscripts devoted to the impact of the COVID-19 pandemic on health and healthcare. This has not happened at the level I had anticipated, and I weigh possible causes: First, and most probable, is that Canadian research on

COVID-19–related health services and policy is being submitted elsewhere. Second, with almost two years of the pandemic behind us, Canadian Institutes of Health Research's (CIHR's) deluge of COVID-19–related funding has not yet borne fruit for health services and systems research. Possibly, data are being collected and manuscripts have yet to be authored, but if this is the case, the "lag" between funding decisions and actionable health services and policy research is regrettably long. Finally, it could be that many Canadian health services and policy researchers did not pivot their research programs toward COVID-19–related health services and policy research. Irrespective of the reasoning, I look forward to bold health policy articles being submitted.

Patterns in Research Manuscript Submission

A pattern is evident from the health services and policy research submissions made to *Healthcare Policy*. There is overrepresentation of research teams and manuscripts from Ontario, which could be attributed to a disproportionately active research community in this province. There have been few submissions addressing health services and policy issues that confront the north, the prairies and the Atlantic provinces and I would like to see more submissions from these regions.

I naively anticipated that research topics would align into common themes such as mobile health technologies, or healthcare sectors such as hospital-based care. This has not happened yet and is probably a reflection of the diversity of academics' research interests across the country, the intersection of CIHR's quixotic funding programs and the provinces' diverse health delivery networks. Instead, we routinely see manuscripts exploring aspects of drug policy, though very few focus on policy issues in other sectors, such as access to dental care or the quality of long-term care. Over the next year, I would like to encourage more submissions from a broader range of policy-relevant topics and sectors, such as the health of the workforce and mental healthcare.

A significant proportion of manuscripts submitted to *Healthcare Policy* are returned to authors for revision after editorial review due to the lack of fulsome policy analysis. For this journal, it is not enough to say, "Policy makers will find these results interesting." As outlined in the instructions for authors, all submissions must have an analysis that thoroughly addresses key policy issues associated with the research findings, otherwise the manuscripts will be directed elsewhere.

The Current State and Need for Research

There are worrisome signals regarding healthcare in provinces and territories. Some say it is in shambles, while others are more pragmatic. The COVID-19 pandemic has revealed some successes – the structures and processes of acute care remain intact, and many Canadians continue to receive urgent and acute care. The counterpoint to this resilience is that massive reforms do not appear on the horizon for long-term care, and wait lists for elective surgery are surging, with no clear remedy at hand from provincial and territorial governments.

It is not for me to predict how the course of the pandemic will unfold over this year as Omicron causes a backtracking on 2021's hard-earned progress. However, health services and systems research is urgently needed to fill the gaps in knowledge and provide policy makers with evidence-guided options.

As the editor-in-chief, I look forward to *Healthcare Policy* expediting health services and systems research that addresses high priority policy problems in critical areas of healthcare delivery. Prospective authors should contact the editor if they have questions regarding their "fit" with *Healthcare Policy*.

In This Issue

This issue is led by a Discussion and Debate article focused on the issue of conflict of interest among members of the federally convened COVID-19 Vaccine Task Force. Drawing from publicly available information, Lexchin (2022a) identifies gaps in the declaration and management of conflicts of interest of Task Force members. Inferring that the government may not receive the best advice, the article recommends further transparency in the reporting and minimizing of potential conflicts of interest.

In a rejoinder to that article, Grundy (2022) emphasizes the importance of transparency in conflict of interest reporting, though the author makes the point that transparency itself is not sufficient for advisory committees. Grundy suggests that to improve the public's trust in decision making, members' conflicts or commercial relationships should be evaluated from the perspective of "risk." Grundy's recommendation has the practical effect of highlighting that some disclosed conflicts of interest are low risk and that committees should be carefully assessing their members' risks most likely to influence decision making.

A Data Matters article by Kiran et al. (2022) explores the impact of homelessness on COVID-19 positivity. Based on a single-site cross-sectional study in Ontario, this study found that people experiencing homelessness were significantly more likely to test positive for COVID-19. The article discusses the need for health system strategies specific to reducing COVID-19 transmission among people experiencing homelessness, such as improved ventilation and testing in shelters.

This issue includes a second Data Matters article that focuses on contemporaneous efforts to monitor and report pharmaceutical company payments to healthcare providers and organizations. Lexchin (2022b) found that financial payment reporting was not comprehensive or transparent in Canada. Contrasting reporting requirements in other countries with that of Canada's, the article recommends that reporting be made obligatory and more detailed for an understanding of financial entanglements between pharmaceutical companies and healthcare organizations and individual providers.

A research manuscript by Limoges et al. (2022) measures self-reported mental health issues faced by healthcare providers during the COVID-19 pandemic. Using a cross-sectional design and semi-structured interviews among staff at two Ontario hospitals, healthcare providers were asked to recount their experiences with the pandemic. Stress, occupational

fatigue and depression were identified as negative consequences of COVID-19–related workplace and social policies. The authors propose a multi-pronged approach to support healthcare providers, including staff involvement in local rapid cycle improvement teams and macro-level engagement in policy making.

The emergence of private payment for concierge-type primary care is explored by Bodner et al. (2022). An environmental scan was used to identify the prevalence of private-pay primary care clinics across Canada. The authors conclude that active surveillance of this delivery model by provinces is needed to ensure that equitable access to primary care is not undermined and provincial legislation is not being violated.

This issue's final research manuscript advocates for the adoption of life-cycle regulation and reimbursement decisions for drugs and vaccines in Canada. Authored by McPhail et al. (2022), the authors describe that life-cycle approaches that are based on gathering and reporting post-market data are far more dynamic than the regulatory or reimbursement decisions that are currently dominant. The authors describe that post-market clinical trials are often not completed in a timely manner, nor does Health Canada robustly monitor on-market drugs. The authors conclude that stronger mechanisms are needed to support conditional regulatory approvals while ethics and data issues are resolved.

JASON M. SUTHERLAND, PHD
Editor-in-Chief

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ÉDITORIAL

Recherche sur les services et les politiques de santé au Canada : réflexions d'un rédacteur en chef

Politiques de Santé est une revue en pleine croissance et dynamique axée sur les politiques et les services de santé au Canada. Alors que je célèbre mon deuxième anniversaire en tant que rédacteur en chef bénévole de la revue, je peux dire que j'ai eu le privilège de constater l'avancée des chercheurs sur les problèmes importants du système de santé. De ce point de vue, un certain nombre de tendances méritent d'être énumérées pour nos lecteurs.

Le lectorat de *Politiques de Santé* s'est accru énormément pendant la pandémie. Les manuscrits de recherche et les articles de discussion et de débat ont connu pas moins du double des lectures mensuelles au cours des deux dernières années. La plupart des lecteurs viennent du Canada, bien qu'il y ait des signes que les articles sont de plus en plus consultés à partir d'un certain nombre de pays anglophones, dont le Royaume-Uni, l'Australie et les États-Unis. Cette augmentation du lectorat était inattendue, même si c'est une bonne nouvelle pour l'éditeur, pour les auteurs et pour l'impact de leurs articles.

Un des changements apportés à la revue *Politiques de Santé* est l'ajout de répliques à certains articles. Ainsi, chaque article accepté pour la section Discussions et débats s'accompagne d'une réplique qui soulève des questions politiques complémentaires ou qui fournit un contrepoint à la thèse avancée. Selon moi, ces répliques enrichissent considérablement les discussions d'ordre politique et elles améliorent le profil des articles de la section Discussions et débats.

La popularité de la revue en tant que vecteur pour la recherche axée sur le Canada a donné lieu à une augmentation de la charge de travail des réviseurs et du personnel. Grâce à sa solide équipe et au soutien des évaluateurs indépendants, la durée entre la soumission et l'achèvement de l'examen par les pairs a été réduite, et ce, malgré l'augmentation du volume de soumissions. Le délai entre la soumission et la décision est maintenant de 12 semaines en moyenne.

Lorsque la pandémie a commencé, au début de mon mandat de rédacteur en chef, je m'attendais à ce que *Politiques de Santé* soit inondé de manuscrits consacrés à l'impact de la pandémie de la COVID-19 sur la santé et les soins de santé. Cela ne s'est pas produit au niveau que j'avais prévu, et j'en évalue les causes possibles : premièrement, et la plus probable, c'est que la recherche canadienne sur les services et les politiques de santé liés à la COVID-19 est soumise ailleurs. Deuxièmement, avec près de deux ans de pandémie derrière nous, le déluge de financement lié à la COVID-19 offert par les Instituts de recherche en santé du Canada (IRSC) n'a pas encore porté fruit dans la recherche sur les services et les systèmes de santé. Il est possible que des données soient encore recueillies et que des manuscrits n'aient pas encore été parachevés. Si tel est le cas, le « décalage » entre, d'une part, les décisions de financement et, d'autre part, une recherche utile pour les services de santé est malheureusement bien long. Enfin, il se pourrait que de nombreux chercheurs canadiens n'aient pas orienté leurs programmes de recherche vers la recherche sur les services et les politiques de santé liés à la COVID-19. Indépendamment de la raison, j'ai hâte de recevoir des articles audacieux sur les politiques de santé.

Tendances dans les soumissions de manuscrits de recherche

Une tendance se dégage dans les soumissions de recherche faites à *Politiques de Santé*. Il y a une surreprésentation d'équipes de recherche et de manuscrits provenant de l'Ontario, ce qui pourrait s'expliquer par une communauté de recherche disproportionnellement active dans cette province. Il y a eu peu de soumissions sur les services et les politiques de santé auxquels sont confrontés le Nord, les Prairies ou les provinces de l'Atlantique et j'aimerais recevoir plus de soumissions de ces régions.

J'avais naïvement cru que les sujets de recherche s'aligneraient sur des thèmes communs tels que les technologies de santé mobiles ou encore sur des secteurs tels que les soins en milieu hospitalier. Cela ne s'est pas encore produit et cela reflète probablement la diversité des intérêts de recherche des universitaires à travers le pays, de même que l'intersection des programmes de financement chimériques des IRSC et les divers réseaux de services de santé des provinces. Au lieu de cela, nous voyons régulièrement des manuscrits abordant les politiques en matière de médicaments, bien que très peu se concentrent sur des questions politiques dans d'autres secteurs, tels que l'accès aux soins dentaires ou la qualité des soins de longue durée. Au cours de l'année à venir, j'aimerais encourager davantage de soumissions provenant d'un plus large éventail de sujets et de secteurs pertinents pour les politiques, tels que la santé de la main-d'œuvre et les soins de santé mentale.

Une proportion importante des manuscrits soumis à *Politiques de Santé* sont renvoyés aux auteurs pour révision après examen en raison du manque d'analyse approfondie des politiques. Pour cette revue, il ne suffit pas de dire : « Les décideurs trouveront ces résultats intéressants ». Comme indiqué dans les instructions aux auteurs, toutes les soumissions doivent comprendre une analyse qui traite en profondeur des questions politiques clés associées aux résultats de la recherche, sinon les manuscrits seront dirigés ailleurs.

L'état actuel et le besoin de recherche

Il y a des signaux inquiétants concernant les soins de santé dans les provinces et les territoires. Certains disent que c'est la pagaille, tandis que d'autres sont plus pragmatiques. La pandémie de la COVID-19 a révélé certains succès – les structures et les processus de soins de courte durée restent intacts et de nombreux Canadiens continuent de recevoir des soins urgents et de courte durée. Le contrepoint à cette résilience est qu'aucune réforme massive n'apparaît à l'horizon pour les soins de longue durée et que les listes d'attente pour les chirurgies non urgentes augmentent sans que les gouvernements provinciaux et territoriaux n'aient de solution claire à portée de main.

Ce n'est pas à moi de prédire comment l'évolution de la pandémie se déroulera cette année, car le variant omicron fait reculer les progrès durement gagnés en 2021. Cependant, la recherche sur les services et les systèmes de santé est nécessaire de toute urgence pour combler les lacunes dans les connaissances et pour fournir aux décideurs des options fondées sur les données probantes.

En tant que rédacteur en chef, j'attends avec impatience que *Politiques de Santé* accélère la recherche qui aborde des problèmes politiques hautement prioritaires dans les domaines critiques de la prestation des services de santé. Les auteurs potentiels devraient communiquer avec l'éditeur s'ils ont des questions concernant l'« adéquation » de leur travail avec *Politiques de Santé*.

Dans le présent numéro

Ce numéro s'ouvre avec un article de la section Discussions et débats axé sur la question des conflits d'intérêts parmi les membres du groupe de travail sur les vaccins contre la COVID-19, convoqué par le fédéral. S'appuyant sur des informations accessibles au public, Lexchin (2022a) identifie des lacunes dans la déclaration et la gestion des conflits d'intérêts chez les membres du groupe de travail. En déduisant que le gouvernement pourrait ne pas recevoir les meilleurs conseils, l'article recommande une plus grande transparence dans le signalement et la minimisation des conflits d'intérêts potentiels.

Dans la réplique à cet article, Grundy (2022) souligne l'importance de la transparence dans les rapports sur les conflits d'intérêts, bien que l'auteur souligne que la transparence n'est pas suffisante en soi pour les comités consultatifs. Grundy suggère que pour améliorer la confiance du public dans la prise de décision, les conflits ou les relations commerciales des membres devraient être évalués du point de vue du « risque ». La recommandation de Grundy a pour effet pratique de souligner que certains conflits d'intérêts divulgués présentent un faible risque et que les comités devraient évaluer attentivement les risques de leurs membres les plus susceptibles d'influencer la prise de décision.

Un article de Kiran et al. (2022), dans la section Question de données, explore l'impact de l'itinérance sur la positivité à la COVID-19. Basée sur une étude transversale à site unique en Ontario, cette étude révèle que les personnes en situation d'itinérance sont beaucoup plus

susceptibles d'être testées positives à la COVID-19. L'article traite de la nécessité de stratégies spécifiques pour réduire la transmission de la COVID-19 chez les personnes sans abri, telles qu'une ventilation améliorée et des tests dans les refuges.

La section Question de données présente un deuxième article qui se concentre sur les efforts actuels pour surveiller et signaler les paiements des sociétés pharmaceutiques aux fournisseurs de soins et aux organisations de santé. Lexchin (2022b) constate qu'au Canada, les rapports sur les paiements financiers ne sont ni complets ni transparents. En comparant les exigences de déclaration d'autres pays à celles du Canada, l'article recommande que la déclaration soit obligatoire et plus détaillée afin de mieux comprendre l'enchevêtrement financier entre les sociétés pharmaceutiques, les organisations de santé et les fournisseurs de soins.

Un article de recherche par Limoges et al. (2022) mesure les problèmes de santé mentale autodéclarés par les fournisseurs de soins de santé pendant la pandémie de la COVID-19. À l'aide d'une conception transversale et d'entrevues semi-structurées auprès du personnel de deux hôpitaux ontariens, les fournisseurs de soins de santé ont été invités à raconter leur expérience pendant la pandémie. Le stress, la fatigue professionnelle et la dépression ont été désignés comme des conséquences négatives des politiques sociales et du lieu de travail dans le contexte de la COVID-19. Les auteurs préconisent une approche à plusieurs volets pour soutenir les fournisseurs de soins de santé, notamment l'implication du personnel dans les équipes locales d'amélioration rapide et leur engagement dans l'élaboration des politiques.

Bodner et al. (2022) explorent l'émergence du paiement privé pour les soins primaires « de conciergerie ». Une analyse environnementale a été employée pour déterminer la prévalence des cliniques de soins primaires payantes au Canada. Les auteurs concluent qu'une surveillance active de ce modèle par les provinces est nécessaire pour s'assurer que l'accès équitable aux soins primaires ne soit pas compromis et que la législation provinciale ne soit pas violée.

Le dernier article de recherche préconise l'adoption du cycle de vie dans la réglementation et dans les décisions de remboursement pour les médicaments et les vaccins au Canada. Rédigé par McPhail et al. (2022), l'article montre que les stratégies du cycle de vie basées sur la collecte et la communication de données post-commercialisation sont beaucoup plus dynamiques que les décisions réglementaires ou de remboursement qui prédominent actuellement. Les auteurs observent que les essais cliniques post-commercialisation ne sont souvent pas terminés en temps opportun et que Santé Canada ne surveille pas rigoureusement les médicaments sur le marché. Les auteurs concluent que des mécanismes plus solides sont nécessaires pour soutenir les approbations réglementaires conditionnelles pendant que les problèmes d'éthique et de données sont résolus.

JASON M. SUTHERLAND, PhD
Rédacteur en chef

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Letter to the Editor

Canada's System of Liability Coverage in the Event of Medical Harm: Is It Time for No-Fault Reform?
Shoo K. Lee, Brian H. Rowe, Colleen M. Flood and Sukhy K. Mahl
Healthcare Policy 17(1), August 2021

As an active participant in discussing improvements to the canadian medical liability system, the Canadian Medical Protective Association (CMPA) read with interest the article noted.

We were surprised that the authors did not undertake a more systematic literature review of the current medical liability system or consider reforms other than the no-fault model. We also noted the significant omission of any discussion regarding the role of hospitals and other healthcare professionals in the medical liability system.

Conversations regarding the implementation of a Canadian no-fault medical liability system have been ongoing for years. The CMPA has continuously reviewed international data related to no-fault models, including some comprehensive reports (Armstrong and Tess 2008; Farrell et al. 2010). Our analysis reveals that a no-fault model has several key challenges to achieving an equitable and sustainable medical liability system and that it would not necessarily enhance patient safety (Davis et al. 2003).

There is a significant amount of context missing from information cited from CMPA's annual reports (2016, 2017, 2018, 2019 and 2020). Most importantly, neither is the CMPA subsidized nor does it receive any government or taxpayer funding. The CMPA collects membership fees directly from physicians. Governments reimburse them for a portion of their fees. Provincial or territorial medical associations negotiate reimbursement agreements on behalf of the physicians. The CMPA is not a party to these negotiations. The CMPA is the leading provider of patient safety-related medical education to Canadian physicians.

When a patient initiates a claim against a CMPA member, the CMPA assists the member's defence as long as the care is medically defensible. If experts conclude that the standard of care was not met and this failure harmed the patient, appropriate financial compensation to the patient or family is provided. In the last five years, approximately over *one third* of cases proceeding through the medico-legal process were resolved with compensation to patients and their families. While the total annual amount varies, the CMPA has paid *$1.1 billion* in patient compensation over this period on behalf of its members.

A medical liability system is generally considered effective when it takes into consideration the social, cultural, legal and economic environment (The World Bank 2013). While we believe that the existing Canadian system has been more resilient and sustainable than the authors suggest, there is room for improvement. The CMPA supports civil justice reforms including alternative dispute resolution, improved case management and proportionality in dispute adjudication – all aimed at bringing cases to early and fair resolution and reducing costs for all parties.

However, it is unlikely that a no-fault model would address the current deficiencies in our medical liability system. In those jurisdictions where complete no-fault systems have been effective, there is an extensive social welfare system, and compensation related to medical injury is largely a "top up" of a comprehensive benefit package (e.g., Sweden and New Zealand) (*Act [1993: 387] on Support and Service for Certain Disabled People*; Kachalia et al. 2008). This type of system does not exist in Canada. The implementation of a no-fault model in Canada would require significant investment in community care resources and would not enhance patient safety (Davis et al. 2003; The World Bank 2013).

The CMPA will continue to advocate for medical liability model improvements and focus efforts on enhancing patient safety, which helps to decrease system costs and improve patient outcomes (Simon and Jansen 2009; Slawomirski et al. 2017; Yang et al. 2018).

LISA CALDER, MD, MSc, FRCPC
CEO, Canadian Medical Protective Association

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Response to the Letter to the Editor

We thank Dr. Calder for her response on behalf of the Canadian Medical Protective Association (CMPA) to our article (Lee et al. 2021), and we appreciate the opportunity to address her comments.

Dr. Calder claims that we did not undertake a full systematic review. Systematic reviews are distinct research undertakings beyond the objective of this manuscript. Importantly, bias and conflict of interest need to be avoided, and we propose that an organization with a vested interest in the topic is not the appropriate author of such a systematic review. If indeed CMPA has literature that supports their case, we ask them to release such information for critical review. Dr. Calder also critiques our article on the grounds that no-fault compensation would not improve patient safety. We disagree. Countries such as New Zealand and Sweden have had no-fault systems, which do not compromise patient safety, in place for over 40 years, and provide a model for how Canada can do this.

With so few cases of medical negligence brought relative to the estimated numbers of patients injured due to medical error, tort law does not deter or prevent medical error (Flood and Thomas 2011). Dr. Calder further claims that a no-fault system cannot be implemented in Canada because it lacks a comprehensive social welfare system as, for example, in Sweden and New Zealand. In fact, New Zealand ranks much closer to Canada than Sweden in its level of social spending as a percentage of the gross domestic product, suggesting this is not a determinative factor (OECD 2022). More importantly, Canadians would be better served if the majority of funding were used to compensate patients directly instead of litigating claims.

Dr. Calder claims that the CMPA is not directly paid by governments, nor does it participate in negotiations for fee reimbursements related to medical liability. The reality is that almost all medical liability costs come out of the public purse, irrespective of how the money is routed. The CMPA states that one third of cases proceeding through the medico-legal process are resolved with compensation to patients and their families; however, this neglects the vast majority of injured patients who did not undertake medical liability claims, many because they lack the resources to litigate. In fact, it has been estimated that only 2% of injured patients ever receive compensation for injuries caused by negligent physicians (Silversides 2008). Judicial notice has also been taken of CMPA's "scorched earth" policy (*Frazer v. Haukioja*, 2008) of strangling patient claims at their inception (Gibson 2016) and the fact that "plaintiffs don't have the war chest and endurance of professional defendants" (*Ornstein v. Starr*, 2011). A no-fault system could compensate far more injured patients instead of only those with the resources needed to win their medico-legal battle with the CMPA.

We appreciate that any no-fault proposal would see a reduced role for the CMPA. However, we believe that this is outweighed by the extant evidence in favour of no-fault as well as another important dimension that our tort system fails to address: both patients and medical professionals involved in litigation proceedings experience tremendous emotional stress. Since the publication of our article, we have received communications from patients who have been involved in malpractice claims who state how much they suffered in the process, and wished that a no-fault system had been in place instead. Despite the CMPA's claims, the time for reform is now.

Sincerely,

SHOO K. LEE, MBBS, FRCPC, PHD, DHC, OC
BRIAN H. ROWE, MD, MSC
COLLEEN M. FLOOD, PHD, LLM, SJD, FRSC, FCAHS
SUKHY K. MAHL, MBA

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COVID-19 Vaccine Task Force and Conflicts of Interest

Groupe de travail sur les vaccins contre la COVID-19 et conflits d'intérêts

JOEL LEXCHIN, MSc, MD
Professor Emeritus
School of Health Policy and Management, York University
Associate Professor
Department of Family and Community Medicine
University of Toronto
Toronto, ON

Abstract
Early in the COVID-19 pandemic, the federal government established a COVID-19 Vaccine Task Force to provide it with recommendations on a wide variety of issues related to vaccines. This article explores how the conflicts of interest of the Task Force members are declared and managed and what the implications are for the advice that they offer to the government. The Canadian government needs to go beyond just managing conflicts and work toward eliminating them on the Task Force.

Résumé
Au début de la pandémie de la COVID-19, le gouvernement fédéral a créé le groupe de travail sur les vaccins contre la COVID-19, qui avait comme tâche de formuler des recommandations sur une grande variété de questions liées aux vaccins. L'article explore comment les conflits d'intérêts des membres du groupe de travail sont déclarés et gérés et quelles en sont les répercussions sur les conseils qu'ils donnent au gouvernement. Le gouvernement du Canada doit aller au-delà de la simple gestion des conflits et s'efforcer de les éliminer au sein du groupe de travail.

Introduction
In June 2020 – relatively early during the COVID-19 pandemic – the federal government created

the COVID-19 Vaccine Task Force with a one-year mandate to provide it with advice around a range of vaccine-related issues. These included prioritizing vaccine projects seeking support for activities in Canada, attracting promising non-Canadian vaccine candidates to Canada or partnering with developers of non-Canadian vaccine candidates and facilitating solutions to manufacture the most promising COVID-19 vaccines in Canada (National Research Council for Canada 2020a). In setting up the Task Force, the government made a conscious decision to include people who may have current or past ties with companies engaged in vaccine research and/or manufacturing (National Research Council for Canada 2020a).

This article explores whether conflicts of interest (COIs) of Task Force members are fully disclosed, how they are managed, what the possible implications are for the advice that the Task Force has offered and, finally, how the issue of COIs could be dealt with in a more coherent way.

Discussion

The government seemed comfortable with its decision to include people with COIs on the Task Force because according to its webpage, it had "a robust process in place to manage potential conflicts of interests. The process related to this advice is in line with similar task forces around the world" (National Research Council for Canada 2020a). As part of that process, members of the Task Force were "required to sign a Conflict of Interest and Confidentiality Agreement and to disclose activities and interests that could place them in a COI situation with respect to the work of the Task Force" (National Research Council for Canada 2020b). COI items fell into nine categories including direct and indirect scientific interests, financial interests, employment and interests of family members and other personal involvement. In addition, at each meeting, the Task Force members were required to declare their interests. From the government website, it is not clear who is responsible for deciding if the COI should preclude someone from taking part in the discussions and voting, but it appears to be someone in Industry, Science and Economic Development Canada. More importantly, the criteria used for what is a relevant COI are not disclosed.

The voluntary nature of the Task Force means that the federal ethics commissioner does not have the authority to oversee the COIs of members and explains why the COIs of the Task Force members are not listed on the public registry maintained by the commissioner (WWWHive 2020).

Up until May 31, 2021, the Task Force held 11 meetings between June 22, 2020, and March 9, 2021 (not counting follow-up discussions), and considered proposals and/or research from 17 companies (National Research Council for Canada 2021). Table 1 gives the dates of the meetings and the proposals that were discussed. The website that provided this information does not give any details about the nature of the discussions or about the recommendations to the government.

There have been a total of 13 members, two of whom have resigned for separate reasons. Gary Kobinger, who worked with the Winnipeg team that developed a successful

Ebola vaccine, left because of a lack of transparency in making public the COIs of the Task Force members (Dougherty 2020). The reason why Shelly Deeks, who works for Public Health Ontario, left the Task Force was not made public (National Research Council for Canada 2021).

TABLE 1. Dates of Task Force meetings and proposals considered

Dates of meetings	Proposal(s) considered
June 22, 2020 (Follow-up discussions on July 3, 2020, and July 16, 2020)	Biodextris, Providence Therapeutics, Glycovax Pharma, Symvivo, IMV Inc.
June 22, 2020 (Follow-up discussions on July 3, 2020, July 16, 2020, and March 9, 2021)	Entos
June 22, 2020 (Follow-up discussion on June 29, 2020)	Precision Nanosystems
June 22, 2020 (Follow-up discussions on June 25, 2020, and October 22, 2020)	Medicago
June 25, 2020	AstraZeneca, Pfizer
June 26, 2020	Variation Biotechnologies Inc.
June 26, 2020 (Follow-up discussion on July 16, 2020)	Treadwell Therapeutics
June 29, 2020	AstraZeneca, Pfizer
July 3, 2020	Moderna, Inc.
July 23, 2020	Novavax
July 28, 2020	Johnson & Johnson/Janssen
August 6, 2020	Pfizer
September 3, 2020	Sanofi/GSK
December 10, 2020	Novavax
March 9, 2021 (Follow-up discussion on March 12, 2021)	VIDO

Of the Task Force members, only one has not declared a COI at any of the meetings. For the remaining 12 members, the number of COI declarations has ranged from one per person to 12 for one individual (median = 1, interquartile range = 1, 3). Table 2 (available online at www.longwoods.com/content/26732) provides all the details about the COIs that the members disclosed at the meetings. No search was conducted for other sources of COI statements.

Conflicts held by chairs and co-chairs are generally considered to be the most relevant because these are typically the people with the most power on a committee or task force. For this reason, the report from the United States (US) Institute of Medicine (now the National Academy of Medicine) recommended that chairs and co-chairs of clinical guideline committees should be completely free of any COI (IOM 2011). The co-chair of the Task Force, Joanne Langley, is the person with the 12 COI declarations (National Research Council for Canada 2021). Langley has, among other activities, worked with Variation Biotechnologies Inc. (a global biopharmaceutical company) on vaccines, collaborated on research projects outside of clinical trials with scientists from Sanofi – a French healthcare company – served as a consultant to Sanofi on influenza vaccines in 2018 and holds the CIHR-GSK Chair in pediatric

vaccinology at Dalhousie University in Halifax, NS. Yet neither these nor the rest of her 12 COIs were deemed to have direct, material linkages and, therefore, not considered conflicts and recusal was not deemed necessary. Langley has also been a scientific colleague of Medicago's (a Canadian biotechnology company) medical officer for several decades and is planning to work with this person in the Canadian Immunization Research Network on the clinical development program of a vaccine developed by the National Research Council to prevent invasive disease due to *Haemophilus influenzae* type A. This also was not felt to be a conflict, but "in an abundance of caution, [she] recused herself from deliberations and recommendations" (National Research Council for Canada 2021).

In a September 2020 interview with Global News, Langley was asked whether there should be more transparency in COI declarations. Her reply was that the government ministers receiving advice could see what was disclosed "… and whether or not the ministers decide to make that public, really, it's not for me to say … I would have to review all the kinds of information that everyone has given to say, is it fair to make that public when people are doing this? It's volunteer service" (WWWHive 2020).

The other co-chair, Marc Lievonen, was the president of the Canadian branch of Sanofi Pasteur – a vaccine manufacturer – for 17 years until 2016, still holds $500 (all amounts are in Canadian dollars unless otherwise indicated) worth of shares in the company (National Research Council for Canada 2021) and was previously a director of the Canadian biotech company Oncolytics Biotech and the Canadian pharmaceutical companies Acerus Pharmaceuticals and Quest PharmaTech, chair of Rx&D (the former name of the lobbying group representing the multinational pharmaceutical companies based in Canada) and chair of BIOTECanada, the association representing Canada's biotechnology companies. He is currently a director of the Canadian biotechnology company OncoQuest Pharmaceuticals Inc. and Biome Grow Inc., a cannabis company (Mark Lievonen 2021). When the Task Force discussed the vaccine that was under development by Sanofi and GSK (a pharmaceutical manufacturing giant), Lievonen's COI was not deemed relevant and recusal was not considered necessary, although he, similar to Langley, recused himself "in an abundance of caution" (National Research Council for Canada 2021).

Besides recognizing when a COI has been disclosed, it is also important to recognize when a COI exists but has not been disclosed. Michel de Wilde is listed on his LinkedIn webpage as being a senior vice-president for Sanofi Pasteur from 1999 to 2013 and a senior advisor to the company's chief executive officer from 2013 to 2016. He is also a current advisory board member for CureVac, a European bioresearch firm in talks with the European Union to supply the vaccine it is developing (Michel de Wilde 2021; WWWHive 2020). de Wilde did not attend the meeting where the vaccine from Sanofi and GSK was discussed, and this may be why his COI with Sanofi is not disclosed on the Task Force's webpage (National Research Council for Canada 2021). The Task Force has not discussed any product or research by CureVac and this may account for the absence of any mention of de Wilde's COI with this company. However, he is a board member of Variation Biotechnologies Inc., and this was labelled a COI; as such

he did not participate in the discussion about or recommendation regarding this company (National Research Council for Canada 2021).

Table 3 summarizes seven different types of conflicts, although sometimes the declarations are vague, making it difficult to characterize the nature of the COI. For example, Langley declared on eight different occasions that her university was involved in research with a company, but it was not clear if she personally was participating in the research projects. In total, out of 30 declarations of COIs, 21 were not considered relevant, 4 were not considered relevant but the members still recused themselves and the remaining 5 were considered relevant.

TABLE 3. Summary of different types of conflicts

	Type of conflict						
	Previous or current employment with company	**Collaborated on research with company**	**University collaborating with company**	**Company board member**	**Commercial relationship with company**	**Directly or indirectly owns shares in company**	**Previous relationship with company employee**
Number declared	3	11	8	1	4	1	2

The process of declaring and managing the COIs of Task Force members is flawed. First, the information in the conflict of interest and confidentiality agreements is not made public; the only information disclosed is what is declared at the individual meetings. This practice of minimal disclosure of information about a COI is typical of declarations of people serving on Health Canada advisory committees and panels. In that case, members give yes or no answers to questions about COIs in eight categories but no monetary sums are mentioned and no companies are named (Lexchin 2019).

The situation with de Wilde illustrates another important flaw in the process of declaring a COI; if a member is absent from a meeting or if a particular company is never discussed, then the COI is never revealed. The practice of treating a COI as a discrete event fails to take into consideration that a COI is not based on isolated relationships with a single company but is a process that reflects an understanding of the nature of interactions between individuals and industry and how those interactions can affect decision making in general. Second, the process for deciding what is and is not a relevant COI is not articulated and, as such, decisions can seem arbitrary and possibly biased. Finally, when it comes to dealing with COIs, the government does not seem to have gone beyond the concept that declaring a COI is all that is required for ensuring that the Task Force recommendations are free from bias. There are no minutes released from the Task Force meetings so the public cannot see the tenor of the discussions and what views individual members took; the final recommendations coming out of the various meetings are also kept secret. As such, it is not possible to see what influence, if any, the COIs may have had on the final decisions made by the Task Force.

There are better models for managing COIs. The Canadian Agency for Drugs and Technology in Health (CADTH) requires expert committee and panel members to declare direct and indirect financial and intellectual interests. A summary of the member's expertise, experience, affiliations and COI declarations is posted and publicly available on the CADTH website. The declaration form asks members for the name of the party that they have a conflict with and for the monetary value of the benefit in dollar ranges (e.g., $0–5,000, $5,001–10,000) (CADTH n.d.). Company names are disclosed on the website but not the monetary value of the benefits. In the US, experts may not participate on Food and Drug Administration (FDA) advisory committees if their financial COI is in excess of US$50,000, although the FDA can grant waivers under specific conditions. COI declarations and waivers are publicly available on the FDA website and a COI is reported in dollar ranges (e.g., US$0–5,000, US$5,001–10,000) (U.S. Department of Health and Human Services FDA 2014).

Transparent declaration of a COI is only a first step. The *Physician Payments Sunshine Act* (S.301 – *Physician Payments Sunshine Act* of 2009) in the US requires drug and medical device companies to declare any payments to physicians of $10 or more (Centers for Medicare & Medicaid Services 2013). Since its implementation in 2013, there has not been any subsequent discernable changes in the behaviour of either companies or physicians nor has there been any substantial change in policies regarding the relationship between doctors and industry (Lexchin and Fugh-Berman 2021). Jerome Kassirer, the former editor of the *New England Journal of Medicine*, critiqued the fixation on "the wrong problem," that is, the lack of transparency and "expressed concern that the need to eliminate commercial conflicts, especially from oversight bodies that assess the integrity of medical data, was being excluded as a public policy option" (Wilson 2014: e11).

Transparency alone will not mitigate the effects of COIs on advice that experts give (Cain et al. 2005). The situation in Australia shows that it is possible to go beyond just the declaration of COIs. In April 2020, the Australian government funded its National COVID-19 Clinical Evidence Taskforce (n.d.) to provide rapid, evidence-based and continually updated advice on Australia's health response to the COVID-19 pandemic (National COVID-19 Clinical Evidence Taskforce 2022). It ran its proposed COI standards by an independent panel (of which I was and still am a member) and based partly on our input developed a COI policy that required both the committee chair and more than 50% of the Taskforce to be free of any conflicts. All Taskforce members have to declare COIs over the previous five years and any individuals who have significant conflicts, such as receiving grants from entities that have commercial interests of AUS$5,000 or more per annum in the topic under discussion, have to cease their involvement with the Task Force. The COI policy and the names of the four people on the independent panel are publicly available (National COVID-19 Clinical Evidence Taskforce n.d.). Since then, the panel has been consulted regularly about individuals' decision-making roles, whether they should be allowed to participate on the Taskforce and whether the requirements of the policy are being met.

The federal government is currently spending $170 million to upgrade and build a new

facility in Montreal, QC, that will produce a vaccine made by the American biotechnology company Novavax, starting probably in early 2022 (Ling and Walsh 2020). It has recently announced the investment of $415 million into an influenza vaccine manufacturing plant owned by Sanofi (Walsh 2021) and $190 million into the expansion of a Mississauga medical facility that will eventually be able to make 640 million doses yearly of an mRNA COVID-19 vaccine when the expansion is completed in 2024 (Ballingall 2021). The size of the investments and their implications for Canada's ability to respond to the ongoing COVID-19 pandemic and future pandemics that are sure to come is evidence that the federal government needs to be assured that it is getting the best unbiased advice on how to spend taxpayers' money to help ensure public health.

Conclusion

COVID-19 has caused over 25,000 deaths in Canada, derailed our healthcare system and caused enormous psychological and economic damage. One of the keys to controlling the pandemic and stabilizing our mental, physical and economic health is vaccines. This commentary shows that some of the current Task Force members have substantial COIs. In the absence of more transparency about the nature of those COIs and about the content of the Task Force's discussions and recommendations, there is no guarantee about the quality of the advice that the Task Force is delivering. Finally, instead of just managing the COIs, the government should be working toward minimizing them on its Task Force.

Correspondence may be directed to: Joel Lexchin, School of Health Policy and Management, York University, 4700 Keele St., Toronto, ON M3J 1P3. Joel can be reached by e-mail at jlexchin@yorku.ca.

Conflicts of Interest

From 2017 to 2020, Joel Lexchin received payments for being on a panel at the American Diabetes Association, for talks at the Toronto Reference Library, for writing a brief in an action for the side-effects of a drug for Michael F. Smith, lawyer, and a second brief on the role of promotion in generating prescriptions for Goodmans LLP. Lexchin also received payments from the Canadian Institutes of Health Research (CIHR) 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 CIHR 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 the University of Toronto Press and James Lorimer & Co. Ltd., for books he has written.

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Commentary – From Transparency to Accountability: Finding Ways to Make Expert Advice Trustworthy

Commentaire – De la transparence à l'imputabilité : trouver des moyens de rendre les conseils d'experts dignes de confiance

QUINN GRUNDY, PhD, RN
Assistant Professor
Lawrence S. Bloomberg Faculty of Nursing
University of Toronto
Toronto, ON

Abstract

Declining public trust in government and expert advice is a public health priority, given its impact on vaccination uptake, adherence to guidelines and social cohesion. In the context of the COVID-19 Vaccine Task Force, conflicts of interest that can threaten public trust are handled primarily through disclosures. However, this places the onus on the public to discern the relevance, severity and impact of these conflicts and does little to address whose interests guide decision making. Alternatively, expert advisory committees should adopt more trustworthy strategies, including promoting independence from commercial and political interests.

Résumé

La baisse de confiance du public dans le gouvernement et les conseils d'experts est une question d'ordre prioritaire pour la santé publique compte tenu de son impact sur la vaccination, sur le respect des directives et sur la cohésion sociale. Dans le cadre du groupe de travail sur les vaccins contre la COVID-19, les conflits d'intérêts susceptibles de menacer la confiance du public sont principalement traités par la divulgation. Cependant, cela oblige le public à discerner la pertinence, la gravité et l'impact de ces conflits et il y a peu de précisions sur les intérêts qui guident la prise de décision. Par ailleurs, les comités consultatifs d'experts devraient adopter des stratégies plus fiables, notamment la promotion de l'indépendance vis-à-vis des intérêts commerciaux et politiques.

Introduction

Lexchin (2022a) carefully documents the ways that the Canadian COVID-19 Vaccine Task Force considered members' conflicts of interest, whether and how they were reported and what actions were taken to mitigate the risk that personal or third-party commercial interests might compromise the integrity of the decision-making process. The Task Force initially took the need for public transparency for granted, assuming that oversight by a governmental secretary was sufficient and that as experts, leaders and volunteers, members were entitled to public trust (Lexchin et al. 2020). What emerges from Lexchin's (2022a) analysis is that transparency alone will be insufficient to ensure public trust in their recommendations and subsequent policy action. Instead, expert advisory committees should shift their focus to ways they can be trustworthy, including strategies to promote independence from commercial and political interests and accountability to the public they were tasked to serve.

A Crisis of Trust

As we near the two-year mark in the global COVID-19 pandemic, public trust in scientists, the government and its institutions is under threat. With critical implications for compliance with public health measures, vaccine uptake and social cohesion (Algan et al. 2021), waning public trust in government, healthcare and scientific institutions can be characterized as a "crisis of trust" (Goldenberg 2021). While social media and its targeted misinformation campaigns present a significant public health challenge, Goldenberg (2021) argues for greater scrutiny and intervention in relation to other root causes of public mistrust – namely, systemic medical racism and the commercialization of health research, including the high prevalence of conflicts of interest among clinicians and researchers. Currently, however, expert groups, health regulators and public health leadership continue to locate the trust deficit within the public – often attributing it to a lack of information or misunderstanding – instead of critically examining whether their actions and decision making is, in fact, trustworthy (Goldenberg 2021).

The dominance of disclosure as the means to address commercial influence within healthcare and scientific research follows a similar logic. Many Organisation for Economic Co-operation and Development countries (though not Canada) have introduced "sunshine" legislation requiring pharmaceutical and medical device companies to publicly report all payments to health professionals with the hope that public transparency might serve as a deterrent to inappropriate relationships – while allowing productive and beneficial activities to continue – and a form of *caveat emptor* for members of the public (Fabbri et al. 2018; Grundy et al. 2018). Scientific journals, clinical guideline development groups and expert committees advising health product regulators now routinely require that members disclose conflicts of interest arising from financial relationships with commercial entities interested in the outcome of research or decision making (Grundy et al. 2020a). Disclosure requirements are largely premised on the assumption that public trust is dependent upon "how transparently an author's relationships and activities ... are handled" and that, ultimately, transparency

is necessary to enable a reader's "own judgments regarding whether an author's relationships and activities are pertinent to a paper's content" (ICMJE 2021). While promoting skepticism (which may indeed be warranted), placing the onus on members of the public to judge the credibility and integrity of evidence or scientific advice does little to build public trust.

Disclosure Is More Than an Exercise in Risk Management

Transparency is necessary but insufficient for maintaining public trust. Disclosures are frequently missing, incomplete, inconsistent and inaccessible (Grundy et al. 2020b). In other cases, authors flood statements with long lists of financial relationships (one statement disclosed payments from 42 different entities, including 23 drug and medical device companies), biographical information or ambiguous descriptors – for example, including 130 different ways of stating there were no conflicts of interest (Grundy et al. 2020b). Consequently, public conversation about the problem of conflicts of interest within health and scientific institutions is fixated on the adequacy of disclosure processes instead of ways to ensure the integrity and independence of evidence-led processes.

When disclosure processes are implemented to merely inform the public about the *existence* of conflicts of interests, it may have unintended consequences such as increasing pressure to comply with biased advice (Loewenstein et al. 2012) or normalizing the extent of industry relationships. For example, as Lexchin (2022a) documents following public scrutiny and the resignation of one member, the Task Force adopted a disclosure process, clearly defining the types of interests requiring disclosure (National Research Council of Canada 2020b). However, though Task Force members clearly and comprehensively disclosed all relationships between themselves or their institutions and vaccine manufacturers, without understanding the context, relevance and nature of the risk, the disclosures could instead be read as a colourful description of the myriad and diverse commercial relationships within the scientific enterprise (National Research Council of Canada 2021). A highly comprehensive approach to disclosure may also have a flattening effect, suggesting that everyone is equally "biased" and obscuring the relationships that pose a serious risk to the integrity or independence of the Task Force's process (Grundy 2021).

From Transparency to Accountability

The true value of public disclosure is in its ability to enable accountability. Public transparency around the existence and management of conflicts of interest enables the public to compare a committee's actions around conflicts of interest to their intentions, assess congruence and hold committees accountable. Goldenberg (2021) argues that the public needs to have confidence in the knowledge, competence and moral integrity of individual experts and also maintain confidence that their advice and activities will further public interest and not alternate agendas that are unjust or oppressive. Trust is built and maintained when the public can be confident that an expert group will do what they say they will do, and that these actions are consistent with the public's best interests.

This congruence between what an institution says it will do, what the public relies on it to do and what it actually does is the notion of institutional integrity (Marks 2019). Lexchin (2022a) points out that while the Task Force made conflict of interest disclosures and corresponding management actions public, the meeting minutes were not published, which would have been helpful to understand why the disclosed interest was relevant, what was at stake within the deliberations and the positions taken or to trace the line of decision making. Rather than using this information to detect "bias," enhanced transparency (such as documenting meeting minutes) around the committee's purpose, the role of evidence within the decision-making framework, efforts to ensure independence and the underlying values guiding recommendations could bolster the trustworthiness of the process. Though the scientific community emphasizes objectivity in decision making (Goldenberg 2015; Intemann and de Melo-Martín 2016), risk of "bias" is not the only consideration in the context of evidence-led advisory processes. For example, expert advice related to vaccine research, development and manufacture should also include considerations of equity, stewardship of public resources, environmental impact, human rights and independence.

Enhanced transparency and management of conflicts of interest of individual members is, thus, just one facet of ensuring the integrity of the Task Force and public trust in its activities. The federal government publicly set out the Task Force's mandate, which included identifying and prioritizing activities related to vaccine research, development, manufacturing and supply chain coordination (National Research Council of Canada 2020a). While committing to an evidence-led approach with critical implications for public health, this advisory process required consideration of numerous additional non-scientific elements including logistical, economic, commercial, social, political and cultural factors. Recognizing the need for multiple perspectives and different forms of expertise, the government made a conscious decision to include people who may have current or past ties with companies engaged in vaccine research and/or manufacturing (National Research Council of Canada 2020a). What requires greater emphasis is the primary obligation or purpose that unites these diverse perspectives, which is necessary to enable evaluation, in the first instance, of whether secondary interests indeed create a conflict of interest. Scientific institutions are focused on identifying and disclosing secondary interests that might compromise the primary obligation or interest of an expert entrusted to make decisions on behalf of patients or the public. However, the primary obligation or interest at stake is typically much more implicit and vaguely referenced as the "public interest" (Grundy et al. 2020a), or in this case "to protect the health and safety of Canadians during the pandemic" (National Research Council of Canada 2020a).

An explicit, clear and measurable primary interest is necessary to determine the relevance or severity of disclosed interests (WHO 2014). For example, in the *Handbook for Guideline Development*, the World Health Organization (WHO) clearly identifies the publics to which guideline developers are accountable and their guiding primary interest, which is generally to "serve WHO's Member States by producing recommendations that improve the health and well-being of populations, globally or in specific areas or countries"

(WHO 2014: 57). Specific guideline-development committees can then operationalize this obligation for a specific context, community and set of population health outcomes against which all decision making can be scrutinized.

In some cases, the interests or relationships of individual experts might pose too high a risk of compromising the committee's primary obligation. Expert committees should clearly identify what interests or relationships are considered high risk and prioritize the selection of members who are free from such conflicts of interest. To ensure that evidence-led processes are independent from political and commercial interests but still have access to the necessary expertise (located in industry, for example) may require the development of creative strategies such that independent committees have access to, but do not necessarily include, such expertise.

Conclusion

To address the growing crisis of mistrust, expert health and scientific committees must clearly identify the communities they serve, the values they will prioritize and the explicit role that evidence will play within their decision-making framework, recognizing that evidence-led processes are inherently value-laden (Goldenberg 2015; Intemann and de Melo-Martín 2016). For an expert committee, such as the Task Force, with a mandate that has critical implications for public trust but also the prospect of incredible commercial gain (or loss), independence as a quality of decision making and evidence-led processes is a requisite for accountability and public trust. Moving beyond disclosure, expert committees must consider additional strategies including diversifying our notion of who can be an "expert" as well as clear, consistent selection criteria for experts, including those who are free or willing to divest from conflicting commitments deemed high risk.

Declaration

The author is a member of the conflict of interest panel for the Cochrane Collaboration and the four-person independent panel tasked with evaluating the implementation of the conflict of interest policy for the Australian National COVID-19 Clinical Evidence Taskforce.

Correspondence may be directed to: Quinn Grundy, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Suite 130, 155 College St, Toronto, ON, M5T1P8. Quinn can be reached by e-mail at quinn.grundy@utoronto.ca.

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Association of Homelessness with COVID-19 Positivity among Individuals Visiting a Testing Centre: A Cross-Sectional Study

Lien entre itinérance et positivité à la COVID-19 chez les personnes visitant un centre de dépistage : une étude transversale

TARA KIRAN, MD, MSc
Scientist
MAP Centre for Urban Health Solutions
Family Physician and Associate Professor
Department of Family and Community Medicine
St. Michael's Hospital
Toronto, ON

AMY CRAIG-NEIL, MSc
Research Coordinator
MAP Centre for Urban Health Solutions
St. Michael's Hospital
Toronto, ON

PAUL DAS, MD, MSc
Family Physician and Assistant Professor
Department of Family and Community Medicine
St. Michael's Hospital
Toronto, ON

JOEL LOCKWOOD, MD
Staff Physician and Assistant Professor
Division of Emergency Medicine
Faculty of Medicine
Department of Emergency Medicine
St. Michael's Hospital
Toronto, ON

RI WANG, MMATH
Statistician
MAP Centre for Urban Health Solutions
St. Michael's Hospital
Toronto, ON

NIKKI NATHANIELSZ, BSc
Medical Student
MD program
Faculty of Medicine
University of Toronto
Toronto, ON

Association of Homelessness with COVID-19 Positivity among Individuals Visiting a Testing Centre

ESTHER ROSENTHAL, MD
Family Physician and Lecturer
Department of Family and Community Medicine
St. Michael's Hospital
Toronto, ON

STEPHEN W. HWANG, MD, MPH
Director and Scientist
MAP Centre for Urban Health Solutions
St. Michael's Hospital
Staff Physician and Professor
Division of General Internal Medicine
Department of Medicine
University of Toronto
Toronto, ON

Abstract
Among those visiting a testing centre in Toronto, ON, between March and April 2020, people experiencing homelessness (n = 214) were more likely to test positive for COVID-19 compared with those not experiencing homelessness (n = 1,836) even after adjustment for age, sex and medical co-morbidity (15.4% vs. 6.7%, $p < 0.001$; odds ratio [OR] 2.41, 95% confidence interval [CI: 1.51, 3.76], $p < 0.001$).

Résumé
Parmi ceux qui ont visité un centre de dépistage à Toronto, en Ontario, entre mars et avril 2020, les personnes en situation d'itinérance (n = 214) étaient plus susceptibles d'être testées positives à la COVID-19 que celles qui ne sont pas en situation d'itinérance (n = 1 836), même après ajustement selon l'âge, le sexe et la comorbidité (15,4 % c. 6,7 %, p < 0,001 ; rapport des cotes [RC] 2,41, intervalle de confiance à 95 % [IC : 1,51, 3,76], p < 0,001).

Introduction
In any given year, more than 235,000 people in Canada experience homelessness (Gaetz et al. 2016). People experiencing homelessness are thought to be at a higher risk of acquiring COVID-19 as lack of safe housing makes it difficult to practise physical distancing, hand hygiene and other preventive measures (Perri et al. 2020). Shelter residents are particularly at risk, given congregation in an enclosed space. People experiencing homelessness also have higher rates of chronic conditions, making them more vulnerable to COVID-19 complications (Fazel et al. 2014).

Early in the pandemic, some regions began conducting mobile outreach testing in shelters and detected high rates of infection among asymptomatic residents, especially when there was a known positive case in the shelter (Baggett et al. 2020; Mosites et al. 2020). However, it is unclear how often people experiencing homelessness were visiting testing centres and how their test positivity rates differed from that of others visiting the same centre.

The St. Michael's Hospital COVID-19 Assessment Centre (CAC) was one of 116 testing centres that were opened in Ontario shortly after the pandemic began. It is located in Toronto's urban core where a large proportion of the city's homeless population resides. An

estimated 8,715 of Toronto's 2.9 million residents experienced homelessness on a given night in 2018 and approximately 80% live in the city's 75 shelters (City of Toronto 2018). This study examines the association between homelessness and test positivity among people seen at the CAC.

Method

We conducted a retrospective chart audit of all patients tested for COVID-19 at the St. Michael's Hospital CAC from its opening on March 16, 2020, until April 30, 2020. Testing was free for all individuals regardless of whether they presented a provincial health insurance card. Testing criteria changed according to provincial government direction (Ministry of Health and Long-Term Care 2022) and was largely limited to symptomatic people who were at high risk of acquiring COVID-19 due to vulnerable residence, occupation or high-risk exposure (Ministry of Health and Ministry of Long-Term Care 2022). Vulnerable residence included those unhoused or in homeless shelters. In mid-April, asymptomatic individuals began being tested in specific circumstances (e.g., local outbreak, clinical exposure). We did not include results from the CAC's outreach testing done at shelters that we have reported on separately (Kiran et al. 2021).

Age, sex and health insurance number (if available) were collected at the time of registration. Other data were collected on a standardized form by registered nurses, nurse practitioners or physicians in the CAC. The form included data on symptoms, medical co-morbidities and vulnerable residence based on patients' self-report. We classified people as homeless if the checkboxes for "shelter" or "unhoused" were marked in the CAC chart or if the hospital registration address field contained "no fixed address" or the name or address of a shelter; we manually cross-referenced the address field with a list of shelter addresses in Toronto that we compiled based on publicly available information. Testing results were abstracted from an electronic spreadsheet kept by the CAC. Patients who had more than one test during the study period were categorized as testing positive if any of their results came back positive; we used the data collection form associated with the positive test. Three patients were excluded because their test result was reported as "cancelled," "leaked" or "unavailable."

We used a Chi-squared test or Mann–Whitney test to compare demographics, medical co-morbidities, symptoms and test positivity between people who did and did not experience homelessness. We performed a logistic regression analysis to estimate the odds of testing positive for COVID-19 for people who were and were not homeless after adjustment for age, sex and medical co-morbidity. We used Microsoft Access to collect chart audit data and R version 4.0 for analyses.

Results

Between March and April 2020, 214 (10.4%) of 2,050 unique individuals who were tested at the St. Michael's Hospital CAC were homeless. People experiencing homelessness were

more likely to be male (75.7% vs. 37.0%, $p < 0.001$) and less likely to have a health insurance card (71.5% vs. 97.6%, $p < 0.001$) (Table 1). There was no statistical difference in mean age, but the age distribution was different ($p < 0.001$), with fewer people experiencing homelessness between ages 25 and 49. There were no statistical differences in reported symptoms but people experiencing homelessness were more likely to have at least one medical co-morbidity (70.3% vs. 53.4%, $p < 0.001$) and abnormal vital sign (38.1% vs. 26.0%, $p < 0.01$) compared with those not experiencing homelessness.

TABLE 1. Comparison of demographic characteristics, symptoms, medical co-morbidity and vital signs between people who did and did not experience homelessness

Characteristics	Homeless (n = 214)	Not homeless (n = 1,836)	All (n = 2,050)	p value
Age, median (IQR)	40.3 (31.0–55.5)	41.7 (32.1–54.0)	41.5 (32.1–54.1)	0.64
Age category				<0.001
0–15	4 (1.9%)	14 (0.8%)	18 (0.9%)	
16–24	23 (10.8%)	90 (4.9%)	113 (5.5%)	
25–49	111 (51.9%)	1,130 (61.6%)	1,241 (60.5%)	
50–64	58 (27.1%)	497 (27.1%)	555 (27.1%)	
65+	18 (8.4%)	105 (5.7%)	123 (6.0%)	
Sex				<0.001
Female	52 (24.3%)	1,155 (63.0%)	1,207 (59.0%)	
Male	162 (75.7%)	678 (37.0%)	840 (41.0%)	
Health insurance card available	153 (71.5%)	1,792 (97.6%)	1,945 (94.9%)	<0.001
Symptoms				
Any symptoms	172 (83.1%)	1,563 (85.8%)	1,735 (85.6%)	0.34
No symptoms	35 (16.9%)	258 (14.2%)	293 (14.5%)	0.85
Cough	100 (48.3%)	892 (49.0%)	992 (48.9%)	0.26
Fever	27 (13.0%)	193 (10.5%)	220 (10.8%)	1.00
Shortness of breath	25 (12.1%)	229 (12.6%)	254 (12.5%)	1.00
Other	91 (44.0%)	827 (45.4%)	918 (45.3%)	
Medical co-morbidity				
Any co-morbidity	135 (70.3%)	911 (53.4%)	1,046 (55.1%)	<0.001
No co-morbidity	57 (29.7%)	796 (46.6%)	853 (44.9%)	
Chronic lung disease	25 (13.0%)	179 (10.5%)	204 (10.7%)	0.85
Diabetes	14 (7.3%)	133 (7.8%)	147 (7.7%)	0.24
Heart disease or stroke	14 (7.3%)	83 (4.9%)	97 (5.1%)	0.76
Immunosuppressed	9 (4.7%)	61 (3.6%)	70 (3.7%)	1.00
Smoker	85 (44.3%)	190 (11.1%)	275 (14.5%)	<0.001
Other	66 (34.4%)	485 (28.4%)	551 (29.0%)	0.39
Any abnormal vital sign*	48 (38.1%)	288 (26.0%)	336 (27.2%)	<0.01

*Abnormal vital sign is defined as heart rate > 110, oxygen saturation < 92% and/or respiratory rate > 24. IQR = interquartile range.

People experiencing homelessness were more likely to test positive for COVID-19 compared with those not experiencing homelessness (15.4% [n = 33] vs. 6.7% [n = 123], $p < 0.001$). People experiencing homelessness had higher odds for testing positive even after

adjustment for age, sex and the presence of any medical co-morbidity (OR 2.41, 95% CI: [1.51, 3.76], $p < 0.001$) (Table 2).

TABLE 2. Adjusted odds* of people experiencing homelessness testing positive for COVID-19 compared with people not experiencing homelessness

Description	Covariate	OR	*p* value	Lower 95%	Upper 95%
Homelessness	Homeless vs. not homeless	2.41	<0.001	1.51	3.76
Age	Per increase of one year	1.00	0.73	0.99	1.01
Sex	Male vs. female	1.12	0.52	0.78	1.60
Any medical co-morbidity	Any co-morbidities vs. no co-morbidities	0.99	0.97	0.69	1.43

*Adjusted for age, sex and any medical co-morbidity.

Discussion

In this study of individuals visiting a COVID-19 testing centre early in the pandemic, people experiencing homelessness had more than twice the odds of testing positive than those not experiencing homelessness. The higher positivity was present even when accounting for differences in age, sex and medical co-morbidity. Moreover, people experiencing homelessness comprised approximately 10% of all visits to the testing centre, far above the estimated proportion of people experiencing homelessness in Toronto.

Our findings are consistent with those from other studies. Several studies from the US have confirmed high rates of COVID-19 in shelter settings (Yoon et al. 2021). A study from France found that more than half of individuals living in homeless shelters in a region had seropositivity for SARS-CoV-2, with higher rates among those living in crowded settings (Roederer et al. 2021). A study using administrative data in Ontario found higher rates of testing and test positivity among people experiencing homelessness compared with those who were housed (Richard et al. 2021). Our own study of on-site testing at 20 shelter locations found a 14% positivity rate when there was at least one known COVID-19 case in the shelter and a 2% positivity rate among shelters with no known cases – relatively high proportions given that 90% of those tested were asymptomatic (Kiran et al. 2021).

Our study has strengths and limitations. We analyzed data from a large sample from a region with the highest rates of homelessness in Canada. However, data were from a single testing centre early in the pandemic when testing was largely limited to symptomatic individuals living or working in high-risk settings and when testing criteria and our understanding of COVID-19 transmission was rapidly evolving. As such, our results – including testing and positivity rates among people experiencing homelessness – may not be generalizable to other jurisdictions and subsequent waves of COVID-19. Shelters directed residents with symptoms to get tested, which would have additionally influenced testing and positivity rates (healthcare workers and others in the comparison group may have been similarly compelled). People self-reported being homeless, the gold standard for identification. Some

people may have been reluctant to disclose their status but that would have biased our findings to the null. We did not ask people to distinguish the type of homelessness. For example, the pandemic has seen a growth in people living in makeshift encampments as many people experiencing homelessness perceived these to be safer than shelters. But it is unclear whether infection rates in encampments truly differ from shelter settings and more research is needed to understand this.

Conclusion

Our results confirm that people experiencing homelessness are at high risk of COVID-19. Targeted efforts are needed to reduce transmission rates, particularly in shelters and other congregate settings that have seen numerous outbreaks in Canada and around the globe. We need improved ventilation in shelters, given new understanding that aerosol transmission is responsible for much of the spread of COVID-19 (Greenhalgh et al. 2021). We also need better testing for COVID-19 in shelters, including surge testing when there is a known outbreak (Rogers et al. 2020) and use of rapid antigen testing to screen residents in the absence of an outbreak (Kiran et al. 2021).

Perhaps most important and timely, our results support prioritizing those who are homeless – and staff who work with them – to receive a complete COVID-19 vaccine series in a timely way. Vaccinating people who are homeless poses unique logistical challenges. Vaccination efforts will also need to address distrust of the healthcare system, which is common among people experiencing homelessness due to their past experiences of marginalization, dehumanization and exclusion (Magwood et al. 2019). It is encouraging that some early reports suggest that levels of vaccine hesitancy among people experiencing homelessness are no higher than that of the general population (Longchamps et al. 2021). Nonetheless, focused strategies will be needed to build vaccine confidence among people who are homeless; these efforts should involve individuals and organizations that have established relationships with and have earned the trust of people experiencing homelessness in their community.

The ultimate solution to reducing COVID-19 rates among those who are homeless is to end homelessness itself through the creation of permanent stable housing. Since the time of our study, city governments across Canada – from Toronto to Montreal to Vancouver – have moved thousands of individuals experiencing homelessness into spaces that allow for physical distancing, for example, by converting low occupancy hotels into isolation sites (City of Toronto 2020). This rapid housing of the homeless population is unprecedented and offers a potential path to ending homelessness after the pandemic (Hwang 2020). In the meantime, research is needed to understand models of success and whether these efforts have lowered the rates of COVID-19 infection – and morbidity and mortality more broadly – among people who are unhoused.

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Correspondence may be directed to: Tara Kiran, Health Centre at 80 Bond, 80 Bond Street, Toronto, ON M5B 1X2. Tara can be reached by phone at 416 864 3011 or by e-mail at tara.kiran@utoronto.ca.

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Pharmaceutical Company Payments to Healthcare Professionals and Healthcare Organizations in Canada: An Observational Study

Paiements des entreprises pharmaceutiques aux professionnels de la santé et aux organisations de soins de santé au Canada : une étude observationnelle

JOEL LEXCHIN, MSc, MD
Professor Emeritus
School of Health Policy and Management
York University
Associate Professor
Department of Family and Community Medicine
University of Toronto
Toronto, ON

Abstract

Starting in 2017, retroactive to 2016, Innovative Medicines Canada (IMC) – the lobby group representing most of the large research-based pharmaceutical companies operating in Canada – initiated a voluntary system for companies to annually report on payments that they make to healthcare providers and organizations. Over the five years that the system has been in operation, 10 companies reported spending almost $345 million. The largest payments were to healthcare providers. Four companies spent more than $10 million in one or more years. The names of people and organizations receiving the payments and their purpose are not disclosed. Even if IMC makes disclosures mandatory for all its members, those reforms will not be enough to ensure transparency of company payments.

Résumé

Depuis 2017, avec effet rétroactif sur 2016, Médicaments novateurs Canada (MNC) – le lobby représentant la plupart des grandes entreprises de recherche pharmaceutique en activité au Canada – propose aux entreprises un système volontaire de déclaration annuelle des

paiements qu'elles versent aux fournisseurs et aux organismes de santé. Au cours des cinq années de fonctionnement du système, 10 entreprises ont déclaré avoir dépensé près de 345 millions de dollars. Les paiements les plus importants étaient destinés aux fournisseurs de soins de santé. Quatre entreprises ont dépensé plus de 10 millions de dollars en une ou plusieurs années. Les noms des personnes et des organisations recevant les paiements ne sont pas divulgués, pas plus que ne le sont les objectifs visés. Même si MNC rendait les divulgations obligatoires pour tous ses membres, ces réformes ne suffiraient pas à assurer la transparence des paiements des entreprises.

Introduction

Starting in 2017, retroactive to 2016, Innovative Medicines Canada (IMC) – the lobby group representing most of the large research-based pharmaceutical companies operating in Canada – initiated a voluntary system for companies to report annually on payments that they made in each of three categories: fees for healthcare professional (HCP) services, funding to healthcare organizations (HCOs) and sponsorship of Canadian HCPs' travel to international conferences (IMC 2021). The disclosures do not name HCPs or HCOs that received payments, the amounts that were given or the specific purpose of the payments.

When the disclosures started, 10 companies out of the then 45 in the organization's membership agreed to participate. The president of IMC said that the revelations were only the first step in increased transparency and that more companies were expected to disclose payments in the coming years (Grant 2017). However, since that time, there has not been any increase in the amount of information disclosed or in the number of companies participating.

Transparency and comprehensiveness in reporting of payments to HCPs and HCOs is important because it is required for investigating the effects of these payments on the practices and priorities of HCPs and HCOs. This study looks at the disclosures from 2016 to 2020, inclusive of the period, to examine total payments and payments by individual companies.

Method

IMC does not collect and collate the individual company disclosures into a single database. Disclosures for 2016 to 2018 – inclusive of the period – were proactively collected from the websites of each of the participating companies when the disclosures were made public. A search for disclosures for 2019 and 2020 was conducted on July 21, 2021, and repeated on December 31, 2021. All companies except GlaxoSmithKline (GSK) only make their most recent report public. If 2019 reports were not found on the companies' website, then the Wayback Machine or websites cached in Google search results were used to try to find reports. If those searches were unsuccessful, then companies were contacted directly by phone.

Amounts and the purpose of the payments were entered into an Excel spreadsheet. All amounts are in Canadian dollars. Only descriptive data are reported.

As all the data were publicly available, ethics approval was not required.

Results

Data were complete for all 10 companies for 2016 to 2018 and for 2020. Reports for 2019 were available on the websites for six companies and were retrieved using the Wayback Machine for two companies and cached Google search results for one company. One company was contacted by phone, and it provided the requested information.

Total annual payments by the 10 companies continued to increase from 2016 to 2019, peaking at $78,011,769 in 2019, but dropped to $66,645,686 in 2020. In the first four years, payments to HCPs were the largest category of expenditure, but were smaller than payments to HCOs in 2020: $27,731,966 versus $38,248,515, respectively. Payments by all companies over all five years totalled $344,397,082 (Table 1).

TABLE 1. Yearly payments by category and total from 2016 to 2020*

Year		2016	2017	2018	2019	2020	Total
Number of companies reporting		10	10	10	10	10	
Category of spending	Fee for HCP services	29,405,492	40,800,836	42,350,594	42,194,518	27,731,526	182,482,966
	Funding to HCOs	17,437,126	32,186,088	32,156,149	33,959,672	38,248,515	153,987,550
	Sponsorship of Canadian HCPs' travel	1,540,025	1,827,082	2,036,235	1,857,579	665,645	7,926,566
	Total	48,382,643	74,814,006	76,542,978	78,011,769	66,645,686	344,397,082

*Amounts in Canadian dollars.

From 2016 to 2020, AbbVie and Novartis were the leading spenders at $60,189,119 and $48,202,003, respectively (Table 2). Four companies reported spending a total of more than $10 million in one or more years. Bristol Myers Squibb, Eli Lilly and GSK did not make any payments for travel in any year. Purdue only made travel payments in 2016 and Merck made no travel payments in 2020 (data not shown).

TABLE 2. Overall company spending by year*

	AbbVie	Amgen	Bristol Myers Squibb	Eli Lilly	Gilead	GSK	Merck	Novartis	Purdue	Roche
2016	6,445,000	5,781,000	3,825,380	1,938,191	2,310,418	2,134,820	9,410,667	4,895,217	3,062,000	8,579,950
2017	13,017,000	10,858,910	7,272,710	5,876,870	5,138,171	2,618,198	9,107,905	10,796,345	2,305,019	7,822,878
2018	13,338,000	10,988,899	5,761,004	6,798,596	4,153,188	3,496,982	8,735,483	12,313,470	1,819,667	9,137,689
2019	12,698,888	9,766,149	6,485,053	9,691,611	3,933,330	3,368,853	6,857,129	11,488,248	1,758,319	11,964,189
2020	14,690,231	9,534,388	6,040,730	7,682,866	3,353,761	4,678,891	4,683,686	8,708,723	1,060,976	6,200,434
Total 2016–2020	60,189,119	46,929,346	28,940,554	31,988,134	18,888,868	16,297,744	38,794,870	48,202,003	10,005,981	43,705,140

*Amounts in Canadian dollars.

Discussion

This is the first analysis of payments in Canada made by drug companies to HCOs and HCPs. The 10 companies that reported have collectively spent almost $345 million in payments to HCPs, HCOs and HCPs' travel from 2016 to 2020, inclusive of the period. Four individual companies spent over $10 million in some years for all three categories of payments. Payments to HCPs was the largest category in each year except for 2020. Analysis of who the recipients of payments were, what drugs the payments were related to and the association of prescribing behaviour as a result of the payments is not possible.

While industry disclosure of payments in Canada lacks both transparency and comprehensiveness, the situation in other countries is decidedly uneven. As documented by Mulinari et al. (2021), reporting in Europe is a mixture of self-regulatory industry reporting in some countries and public regulation in others, sometimes in combination with self-regulation (e.g., Finland and Spain). In some countries, such as the UK and Ireland, there are centralized databases, whereas in others disclosures are published as PDFs on individual company websites, making it very difficult to comprehend the entire national picture. In these countries (e.g., Germany, Italy, Sweden and Switzerland), it is necessary for researchers to download reports individually and then use custom-made scripts to extract and combine data. In many European countries, physicians can opt out of having their individual payments released, leading to a situation where the rate of individualized disclosure was less than 20% in Germany compared to about 60% in Ireland and the UK, 70% in Italy and Switzerland and 80% in Sweden (Mulinari et al. 2021). Except in countries where reporting is mandated by law – for example, France and Portugal – self-regulation means that companies that are not part of the main industry association are not necessarily required to report payments.

At one point, Australia was a leader in transparently reporting on industry payments. Beginning in 2007, Medicines Australia's Code of Conduct required member companies to publicly report their spending on educational events for HCPs, including spending for "educational" events attended by HCPs from many disciplines. "In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia amended its Code to require public reporting of the amounts paid to individual, identified HCPs. At the same time, however, the requirements to report on spending for educational events were watered down" (Parker et al. 2019), meaning that expenditures on food and beverages, which constituted over a third of previously reported spending on HCPs, were hidden.

The strongest and most comprehensive reporting requirements are those under the *Physician Payments Sunshine Act* (S.301 – *Physician Payments Sunshine Act of 2009*) in the US. The Act mandates that pharmaceutical and medical device companies report gifts or any other transfer of value of US$10 or greater to physicians and teaching hospitals to the Open Payments database maintained by the Centers for Medicare and Medicaid Services (Lexchin and Fugh-Berman 2021). The types of payments that need to be reported include consulting fees, honoraria, gifts, entertainment, food and beverages, travel and lodging, education,

research, charitable contributions, royalties or licenses, ownership or investment interests, speakers' fees and grants. Importantly, the value of samples is missing from the Open Payments database (in 2016, samples were valued at $13.5 billion [Schwartz and Woloshin, 2019]), and currently payments to HCPs other than doctors do not have to be reported (Grundy et al. 2018).

The combination of data from the Open Payments database and prescribing information from Medicare Part D, the plan that partially covers the cost of outpatient prescription drugs for US citizens who are eligible for Medicare (Medicare.gov n.d.), has revealed that industry gifts (including meals and speaking, consulting and other financial opportunities) influence physicians' therapeutic choices. Meals and other small gifts increased prescriptions for targeted drugs compared to competing drugs, in four different drug classes (De Jong et al. 2016). A large study of over 150,000 physicians found that those who received any gifts – even a few meals – from drug or device manufacturers prescribed a higher percentage of branded drugs and devices, overall, than physicians who received no gifts (Ornstein et al. 2016). Industry payments to physicians are associated with increased prescribing of branded drugs including expensive branded drugs with uncertain medical benefit (Sharma et al. 2018), and reduced prescribing of generic drugs (Fleischman et al. 2016). Marketing of opioid products to physicians was associated with increased opioid prescribing (Robbins et al. 2019; Zezza and Bachhuber 2018).

There are limitations to this study. There was no way to verify the accuracy of the information on companies' websites. The amounts reported may not be reflective of non-IMC members or other members of IMC.

Conclusion

IMC member companies spend considerable sums annually on payments to HCPs and HCOs, but the limited nature of the disclosures restricts the analysis of how that money is being spent and who is receiving it. At a minimum, IMC should make disclosures by all of its members mandatory and more detailed by requiring recipients (individuals and organizations) to be named, the purpose of the donation and the types of HCPs receiving the payments (e.g., doctors, nurses, respiratory technicians, etc.) to be identified and any related product to be named. Furthermore, in order to make it easier for researchers and others to analyze the data, IMC should collate and post disclosures on a central website. However, these reforms by IMC would still be half measures because they would not apply to many of the companies that are not part of its membership. Before the Ontario election in 2019, the government was finalizing regulations for Bill 160, which required that all drug and device manufacturers that provided a "transfer of value" to all individuals who were members of a regulated healthcare profession, HCOs and patient groups report those transfers to a public registry (Hoskins 2017). The legislative process stopped when the government changed post-election. This type of legislation should be picked up at the federal level to improve the transparency of company payments and to allow for an analysis of their effects.

Conflicts of Interest

From 2017 to 2020, Joel Lexchin received payments for being on a panel at the American Diabetes Association, for talks at the Toronto Reference Library, for writing a brief in an action for the side-effects of a drug for Michael F. Smith, lawyer, and a second brief on the role of promotion in generating prescriptions for Goodmans LLP. Lexchin also received payments from the Canadian Institutes of Health Research (CIHR) 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 CIHR 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 the University of Toronto Press and James Lorimer & Co. Ltd. for books he has written.

Correspondence may be directed to: Joel Lexchin, School of Health Policy and Management, York University, 4700 Keele St., Toronto, ON M3J 1P3. Joel can be reached by e-mail at jlexchin@yorku.ca.

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RESEARCH PAPER

Effects of the COVID-19 Pandemic on Healthcare Providers: Policy Implications for Pandemic Recovery

Effets de la pandémie de la COVID-19 sur les fournisseurs de soins de santé : répercussions politiques pour la reprise

JACQUELINE LIMOGES, PhD, RN
Associate Professor
Athabasca University
Athabasca, AB
Faculty
Georgian College
Barrie, ON

JESSE McLEAN, PhD
Research Manager
Royal Victoria Regional Health Centre
Barrie, ON

DANIEL ANZOLA, MD
Research Associate
Department of Research and Innovation
Georgian College
Barrie, ON

NATHAN J. KOLLA, MD, PhD, FRCPC
Research Chair in Forensic Mental Health Science
Waypoint Centre for Mental Health Care
Penetanguishene, ON
Clinician Scientist
Centre for Addiction and Mental Health
Toronto, ON

Abstract

Background: Notably higher rates of mental health issues have been reported among healthcare providers (HCPs) during the COVID-19 pandemic. Concerns over the impact of policy decisions on the well-being of HCPs is growing, yet it remains underexplored in the literature.

Method: HCPs from a 301-bed mental health hospital and a 408-bed acute care community hospital, both located in central Ontario, participated in interviews (N = 30) and answered open-ended questionnaires (N = 88) to provide their experiences with the COVID-19 pandemic.

Results: Using interpretive description methods, we found that public health policies and other strategies intended to mitigate COVID-19 transmission variably impacted HCP well-being and professional practice.

Discussion: Pandemic-related policies contributed to HCP stress by changing the healthcare environment and clinical practice. Understanding HCP experiences is key for leaders, policy makers and health system planners to deal with the current state, recovery and preparation for future pandemics. Direct input into policy development, implementation and evaluation from HCPs may support their well-being.

Résumé

Contexte : Des taux nettement plus élevés de problèmes de santé mentale ont été signalés chez les fournisseurs de soins de santé pendant la pandémie de la COVID-19. Les inquiétudes concernant l'impact des décisions politiques sur le bien-être des professionnels de la santé augmentent, mais elles restent sous-étudiées dans la littérature.

Méthode : Les fournisseurs de soins de santé d'un hôpital de santé mentale de 301 lits et d'un hôpital communautaire de soins de courte durée de 408 lits, tous deux situés dans le centre de l'Ontario, ont participé à des entrevues (N = 30) et ont répondu à des questionnaires ouverts (N = 88) pour faire part de leur expérience dans le contexte de la pandémie de la COVID-19.

Résultats : À l'aide de méthodes de description interprétative, nous avons observé que les politiques de santé publique et d'autres stratégies visant à atténuer la transmission de la COVID-19 avaient un impact variable sur le bien-être et la pratique professionnelle des fournisseurs de soins de santé.

Discussion : Les politiques liées à la pandémie ont contribué au stress des fournisseurs de services de santé en modifiant l'environnement des soins et la pratique clinique. Comprendre l'expérience des fournisseurs de soins est essentiel aux dirigeants, aux décideurs et aux planificateurs du système de santé pour faire face à l'état actuel, au rétablissement et à la préparation à d'éventuelles pandémies. La contribution directe des fournisseurs de soins à l'élaboration, à la mise en œuvre et à l'évaluation des politiques peut contribuer à leur bien-être.

Introduction

During the very early period of the COVID-19 pandemic, health leaders and governments were alerted to the dramatic impact that the pandemic would have on health system capacity and mental health of healthcare providers (HCPs). As the pandemic monopolized human and financial resources in clinical settings, increasing evidence suggested that HCPs, who we defined as working directly with patients, were experiencing significant negative psychosocial and physical consequences. Indeed, notably higher rates of mental health issues, such as insomnia, anxiety, stress, fatigue, burnout, depression, somatization, obsessive-compulsive symptoms and post-traumatic stress disorder, have been reported among HCPs since the onset of the pandemic (Abbas et al. 2021; Bansal et al. 2020; Crowe et al. 2021; Greenberg et al. 2021; Lapum et al. 2021; Pappa et al. 2020; Tiete et al. 2021). One study of registered nurses providing critical care to COVID-19 patients found that 38% of participants had symptoms of post-traumatic stress disorder, 57% had mild to severe depression and 57% had anxiety (Crowe et al. 2021). Alarmingly, in another study, nearly one in five nurses and more than one in seven clinicians in intensive care units reported thoughts of self-harm or suicide (Greenberg et al. 2021). The declining psychosocial and physical state of HCPs is particularly concerning as prior to the pandemic, these groups were already considered vulnerable to occupational stress and burnout (Stelnicki et al. 2020). Understanding the sources of these challenges is crucial for pandemic recovery.

Studies that explored HCPs during the second and third waves reveal no abatement of psychological burden or burnout in HCPs (Gonçalves et al. 2021; Nishimura et al. 2021a, 2021b; Tan et al. 2020). There is growing concern that the protracted crisis may cause lasting harm to HCPs and the health system (Greenberg and Raferty 2021; Lorente et al. 2021). The mental health and psychological well-being of front-line HCPs has been attributed to workplace issues such as work overload, reduced or insufficient staffing, lack of infectious disease experience or training, personal protective equipment (PPE) shortages, compassion fatigue and shared trauma (Arnetz et al. 2020; Greenberg et al. 2021; Iheduru-Anderson 2021; Khajuria et al. 2021; Manzano García and Ayala Calvo 2021; Werner et al. 2020). Perceived fear regarding occupationally acquired infection and bearing responsibility for the health of one's family, friends and colleagues is common among HCPs. Moreover, as the pandemic has progressed, HCPs have faced additional occupational strains from an influx of patients with higher clinical acuity as a result of cancelled or delayed procedures (Abbas et al. 2021; Gomez-Ramiro et al. 2021; Hartnett et al. 2020).

Healthcare policy decisions that were made during the pandemic impact psychosocial and physical health, social harms and opportunity costs (Crowe et al. 2021; Gilson et al. 2020; Glover et al. 2020). Policies created at the national, provincial and institutional level to shield people from the risk of COVID-19 and to avoid overwhelming the healthcare system altered the healthcare environment (Glover et al. 2020; Gomez-Ramiro et al. 2021; Limoges et al. 2021). For example, there were policies restricting visitors in all patient care areas and those restricting mobility such as the stay-at-home order and the six-feet physical

distancing requirements, whereby patients could not leave their rooms or units even for fresh air and that prevented any type of patient group exercise or psychological therapy. Additionally, there were also government orders/directives, such as those requiring hospitals to manage long-term care and retirement facilities in outbreak, that placed strains on healthcare workers. Given that the work environment has a strong influence on nurse burnout and patient outcomes such as patient mortality, failure to rescue and prolonged length of stay (Schlak et al. 2021), added burdens from the pandemic responses are concerning.

This qualitative study included participants from two distinct parts of a non-urban health system: a large psychiatric hospital and a large acute care community hospital, both located in Ontario. These two facilities were chosen because they are the two largest healthcare facilities in the region, they represent different types of healthcare services and the researchers had access to these facilities. We opted to use two distinct types of facilities knowing that this would enable a detailed analysis of the local and extra-local factors influencing HCPs during the pandemic. The purpose of the study was to describe HCPs' experiences with the pandemic and to understand their education and support needs. The research findings are used to generate recommendations and strategies to support policy development, implementation and evaluation for the pandemic recovery. Now – more than two years into the pandemic – leaders, policy makers and health system planners need knowledge to deal with the fatigue, burnout and negative health outcomes during the current state and prepare for pandemic recovery.

Method

One-to-one semi-structured interviews and online open-ended questionnaires were used to elicit perceptions and experiences of HCPs working during the COVID-19 pandemic to answer the following research questions:

1. What are the experiences and psychological needs of HCPs that have arisen from the COVID-19 pandemic restrictions?
2. How have the COVID-19 experiences of HCPs influenced professional practices, relationships with patients and inter- and intraprofessional collaborations?
3. What types of educational interventions and supports could address the needs of HCPs during the pandemic recovery period?

The online open-ended questions were similar to the interview questions and were offered as a way to promote participation and flexibility for shift workers (Box 1). The questions were modified slightly to reflect the name of the facility and type of care provided; otherwise, the questions were very similar. The research questions were used to write the interview and online questions in a way that would enable participants to use their own words to explain their experiences and ideas.

BOX 1. Sample interview questions from the online questionnaire

- What were your experiences with the COVID-19 pandemic and the restrictions?
- What changed for you in the way you interact with patients and other HCPs as a result of the pandemic restrictions?
- How have the pandemic restrictions impacted you and your professional practice?
- What strategies and supports would assist you at this time and as the pandemic ends?

Recruitment and participant description

Participants were recruited from the Waypoint Centre for Mental Health Care, a 301-bed specialty mental health hospital located in Penetanguishene, ON, and the Royal Victoria Regional Health Centre (RVH), a 408-bed acute care community hospital located in Barrie, ON. All actively employed and/or affiliated HCPs from Waypoint (N = 740) and RVH (N = ~2,500) were invited through e-mailed invitations to participate in the study. Through convenience sampling, 30 people were interviewed, and 88 people answered open-ended questionnaires online (see Table 1 for participant breakdown). Those from Waypoint participated in the study between August 18, 2020, and November 18, 2020, which was after the first wave of the pandemic, while those from RVH participated between December 23, 2020, and February 15, 2021, during the second wave of the pandemic. Informed consent was obtained prior to data collection. Participants received an e-gift card as a token of appreciation. The study was approved by the Research Ethics Boards of RVH, Waypoint Centre for Mental Health Care and Georgian College (Ref R20-006, HPRA#20.07.02, and #1920-97, respectively).

Methodology and analysis

Qualitative data came from transcripts of the semi-structured interviews and written answers to the online open-ended questions. Analysis of the qualitative data was informed by Thorne's interpretive description, a pragmatic method well-suited to knowledge production for health practice disciplines (Thorne 2016). Interpretive description enabled an analysis of how the pandemic was influencing the participants' experience, disciplinary epistemology, practice and practice setting. Analyses with interpretive descriptive methods involve exploring broader social experiences, including personal and social relations and policy. When participants described their experiences, if further clarification on the influences to the experience were required, probing questions were asked.

Open coding and peer debriefing guided the comparison of memos, codes and salient categories. RQDA (a qualitative analysis software application) was used to organize the data and to provide an audit trail of coding and data analysis. Participant data were read and re-read until agreements on common themes and understanding of the experience were reached by two independent researchers. Methodological and investigator triangulation enhanced the trustworthiness, credibility and reliability of the findings (Thorne 2016). Triangulation was carried out with interviews and online open-ended questionnaires, coding and analysis by an interprofessional research team and by data collection at two distinct sites over two different

TABLE 1. Participant demographics

Variable		Questionnaire		Interviews		Total
		RVH (Community hospital)	Waypoint (Psychiatric hospital)	RVH (General hospital)	Waypoint (Psychiatric hospital)	
Profession	Nursing	36 (76.6%)	34 (82.9%)	11 (73.3%)	9 (60.0%)	90 (76.3%)
	Physician	2 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)
	Other	3 (6.4%)	4 (9.8%)	1 (6.7%)	0 (0.0%)	8 (6.8%)
	Allied health	6 (12.8%)	3 (7.3%)	3 (20.0%)	6 (40.0%)	18 (15.3%)
	Total	47 (100%)	41 (100%)	15 (100%)	15 (100%)	118 (100%)
Age	<30	13 (27.7%)	14 (34.1%)	0 (0.0%)	1 (6.7%)	28 (23.7%)
	31–50	29 (61.7%)	15 (36.6%)	9 (60.0%)	6 (40.0%)	59 (50.0%)
	51–65	5 (10.6%)	12 (29.3%)	6 (40.0%)	8 (53.3%)	31 (26.3%)
	Total	47 (100%)	41 (100%)	15 (100%)	15 (100%)	118 (100%)
Experience (total)	<5	16 (34.0%)	14 (34.1%)	1 (6.7%)	2 (13.3%)	33 (28.0%)
	6–10	11 (23.4%)	12 (29.3%)	3 (20.0%)	1 (6.7%)	27 (22.9%)
	11–15	7 (14.9%)	5 (12.2%)	4 (26.7%)	4 (26.7%)	20 (16.9%)
	16–20	8 (17.0%)	6 (14.6%)	4 (26.7%)	2 (13.3%)	20 (16.9%)
	>20	5 (10.6%)	4 (9.8%)	3 (20.0%)	6 (40.0%)	18 (15.3%)
	Total	47 (100%)	41 (100%)	15 (100%)	15 (100%)	118 (100%)
Experience at site	<5	24 (51.1%)	16 (39.0%)	4 (26.7%)	2 (13.3%)	46 (39.0%)
	6–10	14 (29.8%)	10 (24.4%)	3 (20.0%)	1 (6.7%)	28 (23.7%)
	11–15	2 (4.3%)	1 (2.4%)	4 (26.7%)	4 (26.7%)	11 (9.3%)
	16–20	5 (10.6%)	8 (19.5%)	2 (13.3%)	2 (13.3%)	17 (14.4%)
	>20	2 (4.3%)	6 (14.6%)	2 (13.3%)	6 (40.0%)	16 (13.6%)
	Total	47 (100%)	41 (100%)	15 (100%)	15 (100%)	118 (100%)
Race/ ethnicity*	White	42 (89.4%)	36 (90.0%)	14 (93.3%)	12 (92.3%)	104 (90.4%)
	N	88		30		118

*Small numbers in race/ethnicity have not been presented to protect identity.

time points wherein the region was in different levels of lockdown and with different infection rates. The data were analyzed inductively using answers to individual questions while considering the data as a whole to find individual and common experiences. The findings reflect common themes on how the pandemic restrictions impacted HCPs and their perceptions of helpful strategies to navigate the pandemic and the pandemic recovery.

Findings

Analysis of the data at the individual and group level revealed common experiences and yielded three findings. First, the common experiences and struggles of HCPs that are linked to

policies are described. Second, the impact of policy implementation strategies, communication techniques and frequent policy revisions on HCPs is detailed. Third, participant needs and recommendations related to policy development and implementation are discussed.

Demographic characteristics across both sites were similar and are provided in Table 1. Most participants identified as white, female, working-on-site nurses, were between 31 and 50 years of age and lived with other people, such as children or a spouse.

Policies driving pandemic fatigue and burnout

When participants were asked to describe how the pandemic influenced their personal and professional lives, they provided detailed accounts of their challenges. As expected, they recounted the fear of the contagion, especially at the very beginning of the pandemic and during periods of high COVID-19 infection rates. With the protractions of the pandemic, their concerns multiplied. HCPs named and linked various policies as the source or antecedent to their deepening fatigue, emotional upheaval and mounting distress and anxiety.

The participants explained how government policies that limited mobility (such as the stay-at-home orders and six-feet physical distancing) led to agency policies that required the cancellation of group therapy and recreational activities and the requirement for all patients to remain in their room. Patient confinement, with few opportunities to exercise, move freely or socialize, had a negative impact on patient health. Mobility restrictions were particularly challenging for patients with paranoia and/or depression, yet al. patients had to comply with the policies. Witnessing patient hardship exacted a high toll on HCPs, with many discussing burnout, fatigue and stress. This quotation explains the toll:

> Staff call in sick more, staff are stressed more, [there is] more crying, [they are] more upset [and there are] more thoughts of inability to care for people … It's almost [as if] you think you are not good enough. Staff feel like they [are] alone and isolated in that they do not have help. Even though we are all there.

The physical distancing requirement directly impacted HCPs in a surprising way. While necessary to limit the spread of COVID-19, it disrupted social patterns and the taken-for-granted emotional support provided during rest breaks. Participants indicated that social time was so important to de-stress during difficult times. Without these small social exchanges, work began to feel like a grind. A participant explained as follows:

> It [has] been really hard, it's like [this]: wake up in the morning, go to work, come home and then go to sleep, and it starts all over again because I do [not] have time, and I do [not] even have colleagues that I used to have. It's not easy to do this type of job in the way that it [is] happening.

Another policy that had impacted the well-being of HCPs, particularly those in the acute care hospital, was the no visitor/no volunteer policy. Witnessing patient loneliness and lack of social supports during serious and sometimes life-altering hospitalizations alone was emotionally draining. A participant stated as follows:

> Whenever they have a life-changing situation, whether it is great news or bad news, they do not have the people they want at the bedside. I cannot even imagine the torment that [it] is for patients. Yes, I can support the patient, and I want to be able to support the family as well. And yet I cannot.

Furthermore, HCPs had to intensify their work pace so that they could provide their usual care in addition to providing supports that would typically be given by visitors/family members. HCPs were already taxed by the heavy workload, short staffing and extra requirements from donning and doffing PPE. A nurse participant from the community hospital explained, "When they stopped families from being able to visit, it made things really challenging. We're like the patient's link now." HCPs quickly realized that they could not even come close to replacing the essential supports offered by close family and friends. This caused them to question the merits of policy decisions:

> It makes me question some of the decisions that are being made from a pandemic perspective. I am sure some of the decisions are based in science and some of them are based on logic, [but] some of them are based on fear, [such as] the visiting hours and the visiting protocols. I really think that we have underestimated the gravity of our work, and I really do not think having a loved one at the bedside should be a choice to be honest. I really do not. It is not right. It was a mistake to restrict families.

HCPs were challenged to see patients suffering alone, felt pressure from intense and unrelenting workloads and felt strained from witnessing the negative effects of loneliness and boredom in patients.

The pandemic pay policy was particularly impactful for the allied health participants (such as physiotherapists and social workers). The pandemic pay policy was implemented in Ontario to recognize and reward HCPs with a four-dollar-per-hour pay increase. Yet, for many, it had an unintended consequence. Participants, such as physiotherapists and social workers, who did not receive pandemic pay said that their exclusion made them feel devalued. During a time when HCPs were all sacrificing and working strenuously with patients, feeling devalued was difficult to cope with. A participant explained:

> The nurses got pandemic pay [and] the housekeeping staff did, but the dietary staff didn't. How is that fair? They're in the front line[s] too … People just want to feel

> valued and that someone [has] actually paid attention to what they're doing. And I don't know how to solve that part. If I knew how to solve that, I'd bottle it and sell it. I think that the biggest piece is for people to feel valued and connected and appreciated.

HCPs relayed how the pandemic was impacting every aspect of their practice as seen in this quotation:

> It is every moment we breathe, every moment we do anything at work – it is [a] pandemic. You can see the stressors on our leaders too. It definitely does [affect] them. Patients … how they are reacting … [y]ou can see anxiety [they face]. Not having family or their supports within the hospital – they have to face [the] illness and surgery by themselves now. And of course, it is being reflected upon us. Our restrictions [stretch] as far as where we have our luncheons … everything has changed for us. It is very stressful – your temperament can be very short sometimes. There are times whe[n] I have cried, which I have never done at my job before. I cannot say enough about [the] stress of what the pandemic has put on the workplace.

Policy communication and implementation-shaped experience

Regardless of when someone joined the study, strong emotions were linked to the ways in which the policies were communicated and implemented during the initial days and during the continuation of the pandemic. This quotation explains the same:

> What we need are consistencies. I find some of the messaging that we got were inconsistent. And that is what really causes angst.

The pandemic itself created a situation of low control, and participants felt little was done to address these feelings during the implementation of the policies that were meant to support safe practice. This quotation shows the common experience with policy-driven changes:

> At work, it's extremely stressful. The two biggest things that I found [are] that the restrictions changed day to day and they seemed to be reactive and arbitrary decisions. All the changes made it stressful. [The way] management [communicated] to the front lines was a very directive approach.

HCPs were not always sure that they were doing things right. A participant explained, "Nobody was really sure if they were [donning] PPE [the right way]. From day to day, everything changed hospital wide and we were really unsure if we were doing the right thing. [That was] [s]tressful."

They also relayed feelings of insecurity and lack of confidence in the development of the policies, pondering whether they were carefully developed with evidence or common sense. In situations where there was already a lack of trust, the frequent changes in policy fuelled strong feelings of concern and anxiety. A participant explained:

> It feels like the rules and the policies change constantly. One example I have, where I used to feel safe and now I do not, is about a month ago, we could not cohort COVID patients in a room because they told us [there] was too much viral load in one area for staff members, and [they say] it is not safe. But now we are out of rooms, and so now they have changed the policy, and it is completely safe now to cohort four patients. And they do cohort up to four COVID patients. So it feels like they change the policy whenever they feel like it. They keep telling us we're safe, but they keep changing, and so it is hard to believe them. I find that super frustrating.

The constant changes in policy and the lack of HCP input into policy creation, implementation or evaluation were stressful to HCPs. Participants relayed how trying to stay current with changing policies was exhausting and anxiety provoking.

HCPs' needs vis-à-vis policy

All participants understood the need for the pandemic restrictions and associated policies, and all participants were willing to follow the rules. However, HCPs struggled because policies were solely focused on controlling the spread of COVID-19 and did not adequately address holistic patient care or the practice environment. In general, HCPs found that patient suffering was extreme and very distressing to witness. Participants wanted a process where they could provide their expertise during policy development so that the policies could be "least restrictive." HCPs also wanted a concurrent strategy to develop new care approaches to mitigate the impact of policy on practice. They wanted an opportunity to engage in clinical innovation to counteract the negative impact of policy. This quotation reveals the need to focus on patient care and patient health outcomes: "If all we are thinking about is COVID, then we are not spending enough time working on the day-to-day care delivery that is necessary for the patient." Participants anticipated that had they been able to develop new care strategies to counteract the restrictive pandemic policies, the situation would have been better for patients and, therefore, themselves. This quotation illustrates the need to consider more than just COVID-19: "They [patients] can't put their health on hold."

Participants understood the reasons for the one-directional policy development and implementation at the very start of the pandemic. But with the duration and mounting evidence showing the psychosocial, physical and emotional harm to patients and HCPs, they wanted to move from emergency crisis mode to a mode of sustainable health delivery that would address high-quality patient care and burnout. This change would require their input into policy.

Discussion

The ongoing pandemic is having widespread and profound impact on HCPs practising in mental health and acute care settings. The similarity of perceptions and experiences between HCPs working at two distinct hospital settings and across different time points in the pandemic (Anzola et al. 2022) prompted an exploration of the data for extra-local reality constructors. Importantly, the impact of policy, policy implementation and policy evaluation emerged as strong influencers to HCP experiences. Policies developed at the government level, such as the emergency stay-at-home orders, led to institutional policies that restricted visitors and required new practices for infection control, such as the six-feet physical distancing measure. Other government policies, such as the pandemic pay policies, directly impacted HCPs and their sense of belonging to the team. Ultimately, the government and institutional policies shaped clinical practice, the work environment and the HCP and patient experiences. The lasting impact of the early pandemic period, the ever-changing policies and the poor communication of policy changes between decision makers and HCPs at the point of care requires consideration. Burnout and stress transcend the fear of the COVID-19 contagion and the challenges of caring directly for patients diagnosed with COVID-19 (Crowe et al. 2021; Tiete et al. 2021). The findings from this study highlight unintended negative consequences linked to policies and how HCPs could contribute to policies aimed at pandemic recovery.

Policy makers at the provincial, federal and institutional levels faced a significant challenge when making pandemic decisions and policies to curb the spread of COVID-19. Information was evolving rapidly about the infectiousness and seriousness of COVID-19, and decisions had to be made quickly. As we move to pandemic recovery and prepare for the next crisis or pandemic, recognizing policy as discourse and as a constructor of experience is essential. Furthermore, challenges following policies during the pandemic were linked to major depression in front-line health workers (Hennein et al. 2021). HCPs felt frustrated by the pandemic response and often felt abandoned. A similar finding was reported by Crowe et al. (2021). Recognizing the lasting impact of policy on wellness and experience signals its powerful influence on HCPs, and ideally this would be addressed at the government and institutional level during policy development. Alternative decision-making patterns can guide transparent policy making that includes a balanced perspective that can support better policy and policy outcomes (Berger et al. 2021).

The findings from this study can be used to initiate a more collaborative and relational approach to policy development and implementation to include input from the individual, institutional and government levels. Regular communication and support can increase confidence in decisions and feelings of control, both of which were associated with lower burnout rates during the current and past pandemics (Goulia et al. 2010; Manzano García and Ayala Calvo 2021; Nickell et al. 2004). By recognizing the interconnections among policies, the work setting and HCP experience, networks of collaboration can be formed to ensure that the intended effects of policy are achieved with minimal negative consequence (Gilson et al.

2020; Hennein et al. 2021). Addressing the fact that nurses who carry the burden of front-line work and who are mostly removed from policy development can be an important step (Anders 2021). Their front-line knowledge and experience of implementing policy can and should be utilized by policy makers (Anders 2021). Nurses can advocate for patients as they have firsthand knowledge of the patient experience, are widely trusted as professionals and would be a credible source of knowledge. Nurses and other HCPs from the point of care need to play a larger role in developing workplace policy (Anders 2021).

Participants in this study revealed high levels of occupational fatigue, poor inter-shift recovery and loneliness while at work. There is evidence validating the cumulative negative impact from the subsequent waves of the pandemic as well (Nishimura et al. 2021a, 2021b; Tan et al. 2020), which align with our findings. Additionally, participants in the study explained how the lack of social interaction with colleagues made work feel more arduous and lonelier. Loneliness during the pandemic has been associated with higher rates of depression in HCPs (Wang et al. 2021). High acute and chronic fatigue levels are associated with higher occurrences of care left undone (Min et al. 2021) and, thus, is a concern in healthcare that should be addressed. As such, pandemic fatigue is a significant concern for pandemic recovery, employee resignation and the sustainability of our healthcare system. Bettering health and well-being and addressing workplace challenges can enhance the quality of care and the sustainability of working conditions (Yildirim et al. 2021), which can ultimately influence workforce retention. Good work environments can attenuate the relationship between nurse burnout and patient mortality, failure to rescue and length of stay (Schlak et al. 2021). Developing, implementing and evaluating policies with HCPs from the point of care and ensuring mitigation strategies, such as clinical innovation and new skills development, can offset the changes to the healthcare environment that impact patients and HCPs (Anders 2021; Hennein et al. 2021).

Changing the approach to policy development, implementation and evaluation so that it includes the experience and expertise of HCPs from the point of care is an important step needed to recover from the pandemic. Engaging HCPs in policy requires a multi-pronged strategy involving short- and long-term interventions. The YoderWise Framework for Planned Policy Change was shown as a useful model to support nurses to engage in policy during the COVID-19 pandemic (Anders 2021). Well-developed protocols and standard operating procedures at the government and institutional level will ensure that even during times of crisis, adequate consultation with those who practise at the point of care is used. HCP perspectives are essential to properly inform policy makers and policy for health system reform, regulatory changes, care coordination and policies for pandemic recovery.

There are practical strategies that can support stronger collaboration during policy development and implementation, and these are particularly important to consider during the pandemic recovery phase. HCPs are exhausted, and many are contemplating resignation and early retirement. Clear signals that the system and the policies that drive the system are changing could support retention and the sustainability of the health system. At the institutional

level, this could occur by recruiting members from policy and procedure committees to obtain input from HCPs on policy needs, the impact of policy implementation and strategies to mitigate unintended consequences. Rapid cycle improvement teams, usually located in institutional quality and safety departments, can be deployed to engage HCPs in processes to identify and implement innovations to offset policy consequences. Traditional and social media strategies can be used to gather feedback from HCPs, patients and stakeholders to inform policy. At the government level, ensuring that practising HCPs are consulted in the earliest phases of policy development can support impactful policies. A longer-term strategy involves additional education of HCPs during undergraduate and graduate education for crisis management and policy development, with opportunities to participate in each step in the policy process.

Learning from the COVID-19 pandemic and previous infection control challenges, such as the severe acute respiratory syndrome (SARS) outbreak in 2003 and H1N1 influenza pandemic in 2009, can ensure greater preparation for future crises. The COVID-19 pandemic experiences reported in this study are similar to the situations with H1N1 and SARS, such as issues related to information sharing. In previous pandemics, the importance of clear information and direction was raised, showing how clear information sharing was associated with lowered stress (Goulia et al. 2010; Matsuishi et al. 2012; Nickell et al. 2004). A repeat of these less-than-ideal practices, now over three pandemics, points to the need for integrated and system-wide change. Policy makers at the local, government and institutional level, as well as healthcare managers, need to consider how workplace factors, such as availability of PPE, staff training prior to re-deployment and mental health supports, can improve the experience and well-being of HCPs. This is crucial in the event of future COVID-19 waves and other pandemics (Khajuria et al. 2021). The lack of preparation for an inevitable pandemic, especially after recent experiences with SARS and H1N1, may have lasting implications (Brophy et al. 2021). Additionally, given the historical experience and the association of known stresses with providing healthcare during a pandemic (Goulia et al. 2010; Matsuishi et al. 2012; Nickell et al. 2004), pre-empting the next crisis is important (Brophy et al. 2021).

Conclusion

This study explored the experiences of HCPs who work in two distinct health sectors and covered two different time points in the pandemic. The professional practice and well-being of HCPs have been significantly impacted by the pandemic and pandemic-related policies. The duration and magnitude of the COVID-19 pandemic is compounding the need for health system planners, policy makers and health leaders to consider sustainable strategies to support healthcare providers. The pandemic is often described as an unprecedented event, yet during two previous pandemics (SARS and H1N1), HCPs had similar experiences and researchers had reported findings and recommendations similar to those discussed in this paper.

In the very early pandemic period, health leaders and governments were alerted to the dramatic impact that the pandemic would have on health system capacity and HCPs. Ensuring that the lessons learnt from the COVID-19 pandemic are implemented is crucial.

This article highlights the need for a policy development, implementation and evaluation cycle at both the government and institutional level that includes the HCPs from the point of care, so that they can provide input into policy and mitigation strategies. Policy developed with and for HCPs can reduce pressure and ensure a sustainable workforce and health system. The findings in this study can support recovery from the COVID-19 pandemic and guide inter-pandemic capacity building. There are opportunities to integrate the findings from this study in undergraduate and graduate education, leadership and policy development programs and use them for health leaders involved in institutional and government policy development. The lessons from this pandemic can inform pandemic preparedness policies and protocols, which will ultimately support HCP and patient well-being and a sustainable health system. The following is an overview of recommendations for practice:

- Develop clear communication channels and supports for HCPs to ensure that they are aware and confident of policy changes.
- Include HCPs from the point of care in policy development, implementation and evaluation.
- Develop a concurrent process for clinical innovation and HCPs' education/training to mitigate the negative consequences of policies on patients and HCPs.
- Develop systematic approaches to collect data on HCPs' intent to leave/resign and engage in collaborative strategies that support pandemic recovery.
- Ensure that lessons from SARS, H1N1 and COVID-19 outbreaks are included in education programs that prepare leaders and policy advisors/writers.

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Correspondence may be directed to: Jacqueline Limoges. Jacqueline can be reached by e-mail at jacqueline.limoges@athabascau.ca.

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RESEARCH PAPER

Exploring Privatization in Canadian Primary Care: An Environmental Scan of Primary Care Clinics Accepting Private Payment

Exploration de la privatisation dans les soins primaires au Canada : une analyse de l'environnement des cliniques de soins primaires qui acceptent le paiement privé

AIDAN BODNER, BSc
Research Assistant
Faculty of Health Sciences
Simon Fraser University
Burnaby, BC

SARAH SPENCER, MSc, MPH
Research Coordinator
Faculty of Health Sciences
Simon Fraser University
Burnaby, BC

M. RUTH LAVERGNE, PhD
Associate Professor
Primary Care Research Unit, Department of Family Medicine
Dalhousie University
Halifax, NS

LINDSAY HEDDEN, PhD
Assistant Professor
Faculty of Health Sciences
Simon Fraser University
Burnaby, BC
Assistant Scientific Director
Michael Smith Health Research BC
Vancouver, BC

Abstract

Background: Private payment within primary care has not received extensive scrutiny, despite the emergence of "concierge" primary care services.
Objective: We conducted an environmental scan to explore the nature of private payment for primary care across Canada.
Method: We extracted data from clinic websites on funding models, range of services provided and whether they were independent or part of a chain. We conducted a thematic analysis of service advertisements.
Results: We identified 83 private clinics across six provinces, predominately in urban areas. Private payment-only clinics offered the widest range of services and advertisements emphasised timely, comprehensive care.
Conclusion: The extent to which these clinics and bundling of primary care with privately paid wellness services impact patients' access to care should be the subject of future research.

Résumé

Contexte : Le paiement privé dans le cadre des soins primaires n'a pas fait l'objet d'un examen minutieux, et ce, malgré l'émergence de services de soins primaires « de conciergerie ».
Objectif : Nous avons effectué une analyse environnementale pour explorer la nature du paiement privé des soins primaires au Canada.
Méthode : Nous avons extrait, à partir des sites Web des cliniques, des données sur les modèles de financement, sur la gamme de services fournis et sur le type de cliniques, à savoir si elles étaient indépendantes ou faisaient partie d'une chaîne. Nous avons procédé à une analyse thématique des annonces de services offerts.
Résultats : Nous avons identifié 83 cliniques privées dans six provinces, principalement dans les zones urbaines. Les cliniques privées payantes offraient la plus large gamme de services et leurs annonces mettaient l'accent sur des soins complets et en temps opportun.
Conclusion : La mesure dans laquelle ces cliniques et le regroupement des soins primaires avec des services de bien-être privés ont un impact sur l'accès des patients aux soins devrait faire l'objet de recherches futures.

Background and Objective

Introduction

Concern about privatization within Canadian healthcare is long-standing, and regulations controlling the growth of parallel systems of privately funded healthcare are increasingly being challenged (Hurley 2020). Against the backdrop of Supreme Court rulings in *Chaoulli v. Quebec (Attorney General)* (2005) and *Cambie Surgeries Corporation v. British Columbia (Attorney General)* (2020), private clinics have been increasingly bold in delivering both publicly and privately funded services (Costain 2017; Flood 2005; Ontario Health Coalition 2017). Recent evidence on private clinics in Canada indicates that they have tended to focus

on providing diagnostic and surgical services; however, the number of clinics offering privately funded primary care may also be growing (Graff-McRae 2017; Isabelle and Stabile 2020; Ontario Health Coalition 2017). Clinics can charge membership or à la carte fees for non-insured services, which may have the effect of limiting access to publicly funded services for non-members (Born and Laupacis 2011). Recent reporting has indicated that these practices are widespread across corporate or boutique clinics operating in Alberta and Ontario (Graff-McRae 2017; Ontario Health Coalition 2017). A thriving parallel private primary care system creates a drain on the supply of physicians and other healthcare professionals, catering to a wealthier clientele at the expense of accessibility based on need and exacerbating ongoing primary care shortages. Furthermore, two-tiered primary care is in clear opposition to the *Canada Health Act* (1985) – namely, the Universality Criterion, which establishes access to medically necessary services under uniform terms and conditions, and the Accessibility Criterion, which ensures access is not impeded by additional charges or other means. The current extent of private payment for primary care services has not been formally investigated.

Context

Services provided in primary care settings include health promotion, illness and injury prevention, diagnosis and treatment of common illness and injury and referral to and coordination with specialty services (Flood and Archibald 2001). Primary care in Canada is largely provided through physician-led clinics, with non-physician health professionals integrated through various models of team-based practice (CFPC 2017; Peckham et al. 2018). It is typically publicly funded and privately delivered, with physicians operating independent businesses while receiving remuneration through provincial health insurance plans (Hutchison et al. 2011). Primary care services deemed medically necessary by insurers are free at point of care to insured patients, while exempted services such as cryotherapy for warts and benign skin lesions, excision of benign moles, vaccines for travel and most medical forms and sick notes are commonly paid for by patients privately. This is in accordance with the *Canada Health Act* (1985), which applies only to services deemed medically necessary. Some clinics may choose to request a "block" annual payment to cover these services, but this fee cannot be an obligatory precursor to receiving insured services (Reid 2017). The extent to which this is enforced is unknown. Regardless, "block" annual payments framed as memberships for non-insured services may have the effect of limiting access to publicly funded services for non-members (Born and Laupacis 2011).

Provincial ministries of health regulate private payment for publicly insured services using a variety of mechanisms. Most provinces prohibit physicians who have "opted in" to the public system from direct billing patients for covered services (Flood and Archibald 2001; Marchildon 2020). Extra-billing, where patients are charged an extra fee for services covered in the public plan, is directly prohibited in all but New Brunswick and Prince Edward Island (Flood and Archibald 2001). The elimination of public subsidies, either through price-based

or status-based disincentives, deter physicians from choosing to opt out of the public plan in most provinces; however, there is provincial variability in terms of the specific methods used, including how rapidly physicians can opt out and in (Flood and Archibald 2001). Provincial health legislation is reinforced within practice standards and codes of conduct created by provincial physician licencing bodies. The specific content of these standards, similar to provincial health legislation, varies by province.

This mix of variable provincial policies and regulations has largely discouraged the development of a parallel system of privately funded primary care; however, the emergence of "boutique," "concierge," or "wellness" clinics (henceforth referred to as "private clinics") that deliver primary care while also charging membership fees and/or marketing services that require patients to pay out-of-pocket (beyond the common exempted services mentioned above) may indicate that private payment within primary care clinics warrants attention.

While reports have documented the operation of corporate or boutique clinics in Alberta and Ontario, we do not yet have national information on the extent of these practices (Graff-McRae 2017; Ontario Health Coalition 2017). Online directories of private clinics exist to direct patients to services (https://www.findprivateclinics.ca/), but details offered, funding models used and how clinics describe and advertise their services to patients have not been documented. As long as fees charged by clinics are not obligatory precursors to receiving publicly insured services, operation of these clinics may be legal and in accordance with the *Canada Health Act* (1985). Based on the understanding that private payment affects both accessibility and equity in healthcare (Bambra et al. 2014; Colombo and Tapay 2004; Dahlgren 2014; Gelormino et al. 2011; Hopkins and Cumming 2001; Thomas et al. 2020; Tuohy et al. 2004), private clinics raise concerns about equity in access to primary care and may signal the need for more active surveillance of private payment and possible regulatory reform.

Objective

We conducted an environmental scan to document the extent and nature of primary care clinics offering privately paid services beyond common uninsured services. We documented the services offered and funding models used and explored how these clinics advertise their services to patients.

Method

Search strategy

We sought to identify primary care clinics offering privately paid services beyond those that are commonly excluded from provincial health insurance plans (Appendix 1: Table A1, available online at www.longwoods.com/content/26727). We identified clinics from two existing published lists, supplemented with structured Google searches conducted between November 2019 and June 2020. We also hand-searched websites of identified clinics for

links to additional, potentially relevant clinics. Published lists include FindPrivateClinics.ca and the source list for an existing report on private care in Canada titled *Private Clinics and the Threat to Public Medicare in Canada: Results of Surveys with Private Clinics and Patients* (Ontario Health Coalition 2017). FindPrivateClinics.ca is an online directory of private clinics and health professionals, sortable by province and specialty (https://www.findprivateclinics.ca/). The Ontario Health Coalition's (OHC's) report summarizes the results of a survey conducted between fall 2016 and spring 2017 in which researchers called all identified private clinics (136 clinics in nine provinces) to assess the extent to which they are charging user fees for medically necessary services (Ontario Health Coalition 2017). Searches on FindPrivateClinics.ca and the list of clinics identified in the OHC report were conducted by screening each clinic listed, province by province.

We supplemented the two above-mentioned sources using a structured Google search. We performed an exploratory background search to develop a suitable list of search terms. Each potential term in the list was concatenated with "Canada" to determine the strongest search string. The strongest strings were those that returned the greatest number of websites matching the inclusion criteria. This resulted in the final search string: "personalized" OR "executive" OR "concierge" AND "general practitioner" OR "family medicine" OR "health clinic" AND "province." Before provincial searches were conducted, we set a custom geolocation code within each province through the "Developer Tools" option on Google Chrome to ensure location searches were performed in their respective provinces (Basques 2018). For each provincial search, we scanned all pages of results until we reached redundancy to locate relevant clinics.

Eligibility criteria

To be included, clinics had to provide and advertise private pay-for-all services or services that would not be reimbursable by provincial health insurance (over and above those in Appendix 1: Table A1) and/or charge patients clinic membership fees. To determine whether clinics marketed services that required private payment by patients, we compared service listings and associated fees on each clinic website to provincial insurance service fee schedules. Included clinics also had to have at least one physical location in a Canadian province or territory and have an English website.

We excluded clinics that had no practising physicians – e.g., those led by a naturopath or nurse practitioner. We also excluded those with no physical location, such as virtual e-health services, and those for which a referral is required for a patient to secure an appointment.

Data extraction

We extracted the following data from the websites of each included clinic: number of primary care physicians and non-MD healthcare professionals employed, geographic location(s), number of locations, provision of e-health services, membership options, cost of membership (if applicable), cost of appointments and services advertised.

We classified clinics as "private payment only," "public insurance plus private payment" or "not stated." Clinics that did not explicitly state their funding model ("not stated") either advertised services outside provincial health insurance plans or explicitly advertised the limited or exclusive nature of services, which was highly suggestive of their private nature, but did not post fee schedules that would allow us to determine their pay structure. We used census metropolitan areas (CMAs), census agglomerations (CAs) and non-CMAs/non-CAs to define the rurality of clinic locations. CMAs are cities with populations of 100,000 or more, while CAs have populations of at least 10,000 and non-CMAs/CAs have populations below 10,000 (Statistics Canada 2016). We labelled clinics as "stand-alone" if they had only a single physical location or as a "chain" if they operated two or more locations.

We grouped individual services into the following categories: general medical services, alternative medical services, medical office services, mental health services, lifestyle services, medical testing, pharmacy, rehabilitation and specialty services (full groupings are included in Appendix 1: Table A2, available online at www.longwoods.com/content/26727). Service categories were defined and added iteratively to ensure comprehensive documentation; once a new category was added, clinics were retrospectively re-assessed to examine whether they offered services within that category. We assumed that clinics that were part of a larger chain operated under the same organizational and payment model unless differences were specified by individual locations. Individual services that were advertised at fewer than five clinics were excluded from the categorization. Finally, we abstracted text from clinic websites promoting any aspect of services offered for thematic analysis.

Analysis

QUANTITATIVE DESCRIPTIVE ANALYSIS

We analyzed differences in service categories offered, comparing stand-alone clinics and chain clinics, as well as payment models using χ^2 tests (or Fisher's exact test when the numbers were small). Some chain clinic locations did not individually report services provided. These clinics were excluded from this analysis. All statistical analyses were performed using RStudio (https://www.rstudio.com/).

THEMATIC ANALYSIS OF SERVICE ADVERTISEMENTS

We analyzed service advertisements thematically, with broad themes drawn from all clinic advertisements (Trotter and Namey 2015). In the development of our coding framework, advertisements were classified per existing deductive themes, with new classifications added inductively if none of the pre-existing options were appropriate (Clarke and Braun 2014; Green and Thorogood 2018). This approach was continued until all service advertisements were categorized. We then defined each theme and selected representative quotes. We also scrutinized existing themes for similarity of concepts and amalgamated and redefined similar themes to better represent the category. To ensure reliability, a second reviewer coded the

TABLE 1. Distribution of private clinics and their key features by province[a] (*n* [%])

Feature	Province[a]						Total (*N*)
	BC	AB	ON	QC	NS	NFLD	
Private clinics	13 (15.7)	14 (16.9)	24 (28.9)	30 (36.1)	1 (1.2)	1 (1.2)	83
Number of physicians	56 (20.5)	71 (26.0)	76 (27.8)	66 (24.2)	4 (1.5)	0 (0.0)	273
Number of physicians per capita (Statistics Canada 2020)[b]	1.09	1.60	0.52	0.77	0.41	0	
CMA	13 (16.0)	12 (14.8)	24 (29.6)	30 (37.0)	1 (1.2)	1 (1.2)	81
CA	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1
Non-CMA/Non-CA	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1
Fee schedule present	8 (26.7)	5 (16.7)	5 (16.7)	12 (40.0)	0 (0.0)	0 (0.0)	30
Private payment only	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)	0 (0.0)	0 (0.0)	10
Public insurance plus private payment	8 (36.4)	7 (31.8)	5 (22.7)	2 (9.1)	0 (0.0)	0 (0.0)	22
Membership options[c]	10 (23.3)	8 (18.6)	9 (20.9)	14 (32.6)	1 (2.3)	1 (2.3)	43
Membership Costs (C$)[d] (Median[*SD*])	1,950 (1,289.4)	3,150 (1,702.9)		1,199 (1,709.3)			
E-health options	7 (20.0)	4 (11.4)	10 (28.6)	12 (34.3)	1 (2.9)	1 (2.9)	35
Chain locations	4 (8.3)	6 (12.5)	14 (29.2)	23 (47.9)	0 (0.0)	1 (2.1)	48

[a] Provinces and territories with no clinics (Saskatchewan, Manitoba, New Brunswick, Prince Edward Island, Yukon, Northwest Territories and Nunavut) were excluded from the Table.

[b] Per 100,000 population.

[c] Membership options listed for all available packages.

[d] Median membership costs are obtained from all prices listed for full-membership packages (excluding bonus or add-on packages and packages for common uninsured services) (Polyclinic 2020; Doctors of BC 2016; Fédération des médecins omnipraticiens du Québec 2020; New Brunswick Medical Society 2019; Nova Scotia Medical Services Insurance 2014) offered for individual adults. Number of clinics included in median and standard deviation calculations, $n = 14$.

BC = British Columbia; AB = Alberta; ON = Ontario; QC = Quebec; NS = Nova Scotia; NFLD = Newfoundland and Labrador.

advertisements independently with the final coding framework, and any conflicts were reconciled (Joffe and Yardley 2004). We counted the total occurrence of each theme across the clinic websites to determine which themes were most commonly represented.

Ethics approval

As this study involved the collection and analysis of publicly available data and did not involve contacting individuals, consideration and approval by an ethics review board was not required.

Results

We initially identified 119 clinics: six clinics in the OHC report; 52 clinics through FindPrivateClinics.ca; and an additional 61 clinics from our Google search. Two additional clinics were identified through a hand search. We subsequently excluded 38 clinics that did not meet our inclusion criteria, leaving 83 included clinics. Among the clinics we excluded, 29 only accepted private payment for selected services commonly excluded from provincial

health insurance plans, seven clinics had a French-only website, one clinic did not offer a private payment option and one clinic did not offer primary care services.

We identified clinics in British Columbia, Alberta, Ontario, Quebec, Nova Scotia, and Newfoundland and Labrador (Table 1). A total of 273 physicians were listed on clinic websites, ranging from four in Nova Scotia to 76 in Ontario. More than half (57.8%) of all the clinics identified were a part of 13 larger chains operating mostly in Quebec and Ontario. The remaining 35 (42.2%) were standalone. All but two (97.6%) were located in densely populated areas (CMAs).

Payment model

Though many clinics advertised services that would not be reimbursable under provincial health insurance, most websites (61.4%) did not explicitly state their payment model. A quarter (26.5%) included a combination of private payment and public insurance, and 12% of clinics operated on a private-pay-only model (Table 2). All 10 private-pay-only clinics were located in Quebec.

TABLE 2. Payment model distribution among chain and standalone clinics (*n* [%])

	Clinic type			
Payment model	**Chain 48 (57.8)**	**Standalone 35 (42.2)**	**Total**	***p* value**
Private payment only	8 (16.7)	2 (5.7)	10 (12.0)	0.0126
Public insurance plus private payment	7 (14.6)	15 (42.9)	22 (26.5)	
Not stated	33 (68.8)	18 (51.4)	51 (61.4)	

In all, 43 (51.8%) clinics listed costs for memberships. Median (*SD*) costs for full-membership packages ranged between provinces as follows: British Columbia: $1,950.00 ($1,289.4); Alberta: $3,150 ($1,702.9); and Quebec: $1,199 ($1,709.3). Ontario, Nova Scotia and Newfoundland and Labrador did not have clinics that advertised membership fees.

Chain and standalone clinics differed in their funding models. Standalone clinics were more likely to operate using public insurance plus private payment (42.9% vs. 14.6% of chain clinics). Chain clinics were more likely to operate on a solely private payment model (16.7% vs. 5.7%) or not state a funding model (68.8% vs. 51.4%).

Services delivered

Most (91.6%) clinics listed the services they offered. Nine chain locations that did not list services were excluded from this analysis. General medical services such as assessments and diagnostic services were advertised by all 76 clinics. Specialty services were advertised by 64 clinics (84.2%), and lifestyle optimization services by 63 clinics (82.9%). E-health options were offered by 35 clinics.

TABLE 3. Service category distribution by clinic type and funding model (*n* [%])

	Clinic type				Funding model				
Service category[a]	**Chain 41 (53.9)**	**Standalone 35 (46.1)**	**Total**	***p* value***	**Private payment only 10 (13.2)**	**Public insurance plus private payment 22 (28.9)**	**Not stated 44 (57.9)**	**Total**	***p* value****
Alternative medical services	18 (43.9)	26 (74.3)	44 (57.9)	0.0147	10 (100.0)	14 (63.6)	20 (45.5)	44 (44.7)	0.0029
General medical services	16 (39.0)	24 (68.6)	40 (52.6)	0.0192	9 (90.0)	14 (63.6)	17 (38.6)	40 (52.6)	0.0057
Cognitive health services	24 (58.6)	28 (80.0)	52 (68.4)	0.0786	9 (90.0)	15 (68.2)	28 (63.6)	52 (68.4)	0.3019
Medical office services	29 (70.7)	20 (57.1)	49 (64.5)	0.3205	10 (100.0)	14 (63.6)	25 (56.8)	49 (64.5)	0.0242
Lifestyle optimization services	31 (75.6)	32 (91.4)	63 (82.9)	0.1285	9 (90.0)	18 (81.8)	36 (81.8)	63 (82.9)	1
Medical testing services	37 (90.2)	22 (62.9)	59 (77.6)	0.0099	10 (100.0)	15 (68.2)	34 (77.3)	59 (77.6)	0.133
Pharmacy services	2 (4.9)	6 (17.1)	8 (10.5)	0.1333	0 (0.0)	4 (18.2)	4 (9.1)	8 (10.5)	0.3667
Rehabilitation services	5 (12.2)	14 (40.0)	19 (25.0)	0.0116	2 (20.0)	10 (45.5)	7 (15.9)	19 (25.0)	0.0352
Specialty services	32 (78.0)	31 (88.6)	63 (82.9)	0.3635	10 (100.0)	20 (95.5)	33 (75.0)	63 (82.9)	0.0374

[a]For clinic type and funding model analysis, general medical services *p* value = 1.
*Fisher's exact test was used for the analysis of pharmacy services.
**Fisher's exact test was used for the analysis of all funding models.

Chain and standalone clinics differed in terms of the services they offered (Table 3). Stand-alone clinics provided proportionally more alternative medical services and rehabilitation services compared to chain clinics but were less likely to advertise that they provided diagnostic testing.

Comparison by funding model also yielded significant differences (Table 3). Clinics with a private-only payment model provided proportionally more alternative medical services, general medical services and medical office services compared to clinics with a public insurance plus private payment or an unstated payment model.

Service advertisements

Representative quotes from advertisement themes are presented in Table 4, available online at www.longwoods.com/content/26727. Themes included a focus on comprehensive services (49 clinics [59.0% of total clinics identified]), followed by timely service provision

(34 [41.0%]), quality (29 [34.9%]), personalized care (26 [31.3%]) and prevention (26 [31.3%]). Additional themes included an individual's control over their own health outcomes (17 [20.5%]), health optimization (16 [19.3%]), alternative medicine (11 [13.3%]) and cosmetic services (7 [8.4%]). One clinic (Corporate Health Services, ExcelleMD, Calgary, AB) advertised services with a comprehensive focus stating, "We offer a range of à la carte services in one place, letting you make the most of your time by minimizing your travel and wait times."

Discussion

Through a robust search, we sought to describe the scope of private payment for primary care in Canada. We found 83 physician-led clinics across six provinces that explicitly marketed services that required private payment, 48 of which were part of larger chains. More than half charged membership fees. These clinics were clustered within urban areas and offered a broad range of services with advertising that emphasized convenience, comprehensiveness and personalization.

Building off previous research, there is a visible continued presence of private payment for primary care services (Graff-McRae 2017; Isabelle and Stabile 2020; Ontario Health Coalition 2017). This raises concerns about equity in access to care, which is achieved when access is based on need and not one's ability to pay (Whitehead 1991). Parallel private systems can threaten equitable access to healthcare services (Dahlgren 2014; Leatherman and Sutherland 2008; Tuohy et al. 2004), and evidence suggests that even modest user fees or copayments can have a detrimental effect on access, particularly for lower-income households (Kesselheim et al. 2015; Law et al. 2019; Schoen et al. 2010).

The content of service advertisements by clinics suggests a target patient group seeking a broad range of medical services coupled with highly individualized care. Advertisements created strong narratives surrounding what health should look like and the standard at which a patient should expect to receive care. Thematic elements of advertisements include time (both rapid access to services and longer appointments), optimization of health and personalization of services (Bambra et al. 2005). These themes may reflect the fact that despite decades of targeted investment, the public system remains unable to consistently provide whole-person, integrated care; boutique clinics are capitalizing on this gap.

The extent to which the clinics we identified were operating in violation of specific provincial health legislation is beyond the scope of this work; however, the challenges to accessibility and equity remain a concern. For example, in one case, the annual fee charged by a wellness clinic not only provided access to services not covered within provincial health insurance – e.g., physiotherapy, massage therapy – but also provided the opportunity to queue jump for publicly provided colonoscopy screening (Vertes 2013). It is simply "not credible that C$10,000/year was the price of massage and dietary advice and had no bearing on an expectation of expedited access to public resources" (Reid 2017: 158). Provincial ministries of health should undertake more active surveillance or investigations to determine whether,

through membership fees, user fees and extra-billing for publicly covered services, the clinics we have identified are operating in violation of provincial health insurance legislation.

We found a clear clustering of clinics within urban areas. This is consistent with literature on healthcare systems that include a formalized means for parallel private provision, highlighting the profit-driven nature of private providers (Dahlgren 2014; Dickman et al. 2017). Additionally, both greater inequality and the propensity of patients in urban locations to pay a fee for medical services have been associated with the growth of urban-based clinics (Isabelle and Stabile 2020).

The influx of options for private payment also creates potential challenges with respect to physician integrity and conflict of interest. Bundling publicly insured services with alternative wellness services, for example, creates situations where physicians can financially profit from coercing patients into using privately paid services that may be unnecessary and are not evidence based. Furthermore, as larger numbers of physicians are selling products or services, there are risks that publicly funded services become available only to those patients who can afford the expensive "add-ons" (Reid 2017). This may pose a particular challenge in cases where clinics are owned and operated by corporations rather than physicians as physicians in corporate clinics may face pressure to recommend specific privately paid services provided by their clinics.

The observation that all private-pay-only clinics are in Quebec is consistent with factors unique to the Quebec setting, where physicians can more rapidly opt in and out of the public system. These fully opted-out clinics operate in full accordance with the *Canada Health Act* (1985) and are not in a position to coerce patients to pay privately for non-insured services in order to access publicly insured services. However, the potential conflict in this setting is similar to fully opted-out delivery of private specialist services, wherein opting out exacerbates shortages within the public system and creates demand for private services.

Provincial physician colleges have practice standards to address the bundling of insured and uninsured services. Some of these standards point out the need for clear communication with patients about which services are covered and which are associated with a fee (eg., CPSBC 2019) but are otherwise silent on the inherent conflict of interest. Other provincial practice standards do mention the conflict directly (e.g., CPSO 2017), but focus more on the selling of medical devices or products, rather than on delivering uninsured services for a profit. In both cases, practice standards should be strengthened to address the bundling of insured and uninsured services and the inherent conflict therein.

Boutique wellness clinics and executive clinics may pose an additional challenge with respect to primary care physician supply. Corporate-owned clinics, in particular, provide an attractive employment model for family physicians, offering competitive remuneration, regular predictable work hours and little administrative burden while catering to wealthy, worried and well patients. To the extent that these models proliferate, they may compete for the supply of physicians providing comprehensive primary care in urban areas, particularly to lower-income Canadians and individuals with complex, chronic illnesses.

Chain clinics comprised a significant proportion of total clinics discovered in the scan, and these clinics provided more diagnostic services than standalone clinics. This suggests a growing interest in family medicine by big businesses who see potential for profit (Brown 2020; Centre for Primary Care 2019; MacLeod 2020a, 2020b). Concerns have already been raised about challenges with continuity of care and unnecessary testing within corporate virtual care and brick-and-mortar clinics, and there is a clear tension between profits and patient care (Brown 2020; MacLeod 2020b; McCracken et al. 2019).

Limitations

We relied exclusively on data sourced from clinic websites, which results in a number of potential limitations. For example, clinics may not be completely comprehensive in their listing of services or charges. Additionally, for some chain clinic websites, we noted discrepancies in reporting with respect to physician practice locations; often, physician numbers and locations were reported but it was unclear at which locations physicians practised. Thus, caution is warranted in the interpretation of service and physician counts. Furthermore, we have not attempted to fully survey the scope and content of block fees within our search, and some variability by province is expected. It is possible that, within block fee arrangements, clinics may be charging patients inappropriately either by placing surcharges on publicly funded services or by charging an unreasonably large amount for the supplemental services covered. Block fees also raise concerns about informed consent, wherein patients may feel pressured by their physicians to agree to pay (Reid 2017).

The data collected for the scan represent a single cross section and are thus only representative of the collection period. We are unable to comment on broader trends in the availability of private payment over time. Furthermore, information regarding clinics and their services may not be representative past its date of extraction. Variation may also extend to fluidity in what is covered under provincial health insurance plans, such as expansion to include e-health services during the COVID-19 pandemic in Ontario (Ontario Ministry of Health and Ministry of Long-Term Care 2021). Additionally, our search was limited to bricks-and-mortar primary care clinics and, therefore, excluded stand-alone virtual walk-in clinics. There is, however, significant potential for private payment for primary care services within these models, and regulations around these services vary by province (Matthewman et al. 2021).

Our search was conducted in English. While we captured clinics in Quebec whose websites were available in English and French, our search would not have picked up any clinics that offered services in French only. We are underestimating the number of clinics with private payment in Quebec in particular. Furthermore, as the search was limited to physician-led clinics, we did not capture the range of providers increasingly represented in providing primary care services, such as nurse practitioners (DiCenso et al. 2010), and those providers who may also be delivering services privately. The scan only captured private payment for primary care services; thus block fees charged by clinics for uninsured services were

not captured. It may be that clinics offering block fees do not follow provincial billing guidelines for uninsured services (Born and Laupacis 2011; Daw et al. 2020). We did not directly examine clinic ownership. As noted above, large, for-profit corporations may be playing expanded roles in clinic ownership and delivery of both publicly and privately funded care and this requires future-focused research. Finally, while results raise concerns about access to care and potential harms to patients through feeling pressured to pay for supplemental services, more research is needed to explore patient experiences and the impacts of clinics directly.

Conclusion

Parallel private payment for primary care services is occurring in at least 83 clinics across six Canadian provinces as identified through this environmental scan. The extent to which these clinics impact patients' access to care and supply of physicians and other healthcare professionals should be the subject of future research. Similarly, the introduction of membership fees, bundling of public primary care with wellness services and the corporatization of family medicine should all be the subject of both future research and robust investigation by both provincial policy makers and provincial physician regulatory colleges. Findings should also prompt consideration of gaps in public delivery of primary care that private services are addressing, with a view to strengthening equitable and public delivery of high-quality primary healthcare.

Correspondence may be directed to: Lindsay Hedden, Simon Fraser University, Faculty of Health Sciences, 8888 University Drive, Burnaby, BC V5A 1S6. Lindsay can be reached by e-mail at lindsay_hedden@sfu.ca.

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RESEARCH PAPER

The Importance of and Challenges with Adopting Life-Cycle Regulation and Reimbursement in Canada

Importance et défis de l'adoption du cycle de vie dans la réglementation et le remboursement au Canada

MELANIE McPHAIL, JD, LLM
Research Associate
Faculty of Health Sciences
Simon Fraser University
Vancouver, BC

CHRISTOPHER McCABE, PhD
CEO, Institute of Health Economics
Professor, Health Economics
Faculty of Medicine and Dentistry
University of Alberta
Edmonton, AB

DEAN A. REGIER
Senior Scientist, Canadian Centre for Applied Research in Cancer Control (ARCC)
Cancer Control Research, BC Cancer
Associate Professor, School of Population and Public Health
University of British Columbia
Vancouver, BC

TANIA BUBELA, BSc (HONS), PhD, JD, FCAHS, FRSC
Professor and Dean
Faculty of Health Sciences
Simon Fraser University
Vancouver, BC

Abstract
Regulatory and reimbursement decisions for drugs and vaccines are increasingly based on limited safety and efficacy evidence. In this environment, life-cycle approaches to evaluation are needed. A life-cycle approach grants market approval and/or positive reimbursement decisions based on an undertaking to conduct post-market clinical trials that address evidentiary uncertainties, relying on the collection and analysis of post-market data. In practice, however, both conditional regulatory and reimbursement decisions have proven problematic. Here we discuss some of the regulatory implications and unsettled ethical and pragmatic issues, taking lessons from the recent experiences of Israel in rapidly approving the Pfizer-BioNTech COVID-19 vaccine.

Résumé
Les décisions réglementaires et de remboursement des médicaments et des vaccins reposent de plus en plus sur des données limitées quant à leur innocuité et leur efficacité. Dans ce contexte, des approches visant l'évaluation du cycle de vie sont nécessaires. Une approche axée sur le cycle de vie accorde l'approbation de mise en marché ou les décisions de remboursement moyennant l'engagement de mener des essais cliniques post-commercialisation qui traitent les incertitudes concernant les données en s'appuyant sur la collecte et l'analyse de données post-commercialisation. Dans la pratique, cependant, les décisions réglementaires conditionnelles et les décisions de remboursement se sont avérées problématiques. Nous discutons ici de certaines des répercussions réglementaires et des problèmes éthiques et pragmatiques non résolus, en tirant les leçons de l'expérience dans l'approbation rapide du vaccin Pfizer-BioNTech COVID-19 en Israël.

Introduction
Health Canada has initiated public engagement on a national strategy to balance equitable access to high-cost drugs for rare diseases (HCDRDs) with sustainable Canadian healthcare systems. The engagement process seeks feedback to ensure reimbursement decisions are informed by the best available evidence including alternative regulatory approval and reimbursement models, an expert panel to make ongoing recommendations, a national data system to capture real-world data and independent networks to facilitate data sharing (Health Canada 2020). Regulatory and reimbursement decisions for HCDRDs and for new drugs more broadly, especially in oncology, are increasingly accepting of and reliant on limited and emerging safety and efficacy evidence. This shift is partly due to new treatment paradigms that target patient subpopulations based on genetic or other biomarkers and pressures to accelerate patient access to new drugs (Breckenridge et al. 2016; Davis et al. 2016; Gibson et al. 2015). We argue that in this environment, life-cycle approaches to evaluation are needed because they trade static regulatory and reimbursement decisions for dynamic decision making. A life-cycle approach relies on the collection and analysis of post-market data, using platforms and methods that are designed to update and refine decisions based on

pre-specified decision rules. In practice, however, both conditional regulatory and reimbursement decisions have proven problematic. Post-market evidence does not necessarily accrue to sufficiently address uncertainties and reversing positive decisions rarely occurs, even when indicated (Pease et al. 2017; van de Wetering et al. 2017). Here we discuss some of the associated regulatory implications and unsettled ethical and pragmatic issues, taking lessons from the recent experiences of Israel in rapidly approving the Pfizer-BioNTech COVID-19 vaccine.

What Are the Origins of Life-Cycle Regulatory and Reimbursement Approaches?

The origins of the life-cycle approach are often attributed to the Institute of Medicine's (2007) report, which recommends that assessing the benefits and risks of drugs should be ongoing throughout their entire market life. The report was initiated following several highly salient drug withdrawals in the years prior and led to new powers to evaluate drugs in the post-market setting (Psaty et al. 2012). Similarly, in the context of reimbursement decisions, a life-cycle approach trades a one-time assessment for adaptive health technology assessment processes across the drug's life cycle to better align funding decisions with ongoing evidence generation (Gutiérrez-Ibarluzea et al. 2017; Husereau et al. 2016). The commonality between both approaches is the recognition of and attempt to mitigate evidentiary uncertainties that exist at the time of initial assessment. Over the past few decades, many jurisdictions have implemented policy and regulatory reforms in support of adopting a life-cycle approach to balance the often-opposing goals of providing timely patient access to new drugs, encouraging industry innovation and requiring comprehensive safety and efficacy data (Eichler et al. 2012). Striking the appropriate balance has become increasingly challenging with the rise of "niche" drug development, which targets small patient populations (Davis et al. 2016; Gibson et al. 2015).

What Are the Current Regulatory and Reimbursement Mechanisms in Canada that Support a Life-Cycle Approach?

Current knowledge of research and development pipelines of HCDRDs and oncology drugs predict increased reliance on conditional regulatory approvals, such as Canada's Notice of Compliance with Conditions (NOC/c) policy. This approvals process grants market access to promising drugs with the proviso that additional confirmatory trials are conducted to enhance evidence of a drug's safety and/or efficacy. The approval may be withdrawn if the trials fail to support a favourable benefit–risk profile or address outstanding uncertainties (Health Canada 2016). However, the NOC/c policy has been criticized for insufficient enforcement of confirmatory trials (Lexchin 2007).

Canada's NOC/c policy is not enshrined in statute or regulation; instead, conditional approvals rely on an agreement by manufacturers to fill evidentiary gaps after market approval in the form of a confidential letter of undertaking. From a statutory standpoint,

a drug granted approval under the NOC/c policy generally has the same market access as one granted an unconditional regulatory approval. As a result, Health Canada has had limited legal authority to enforce the completion of post-market clinical trials, instead leaving manufacturers to self-regulate. This has resulted in drugs approved under the NOC/c policy remaining on market for many years without fulfilling the agreed-upon clinical trials (Law 2014). The same has been found for post-market trials in the US (Herder 2019). Without robust enforcement mechanisms, there is little incentive for manufacturers to complete confirmatory trials once they are approved, and evidentiary uncertainties remain unaddressed. The European Medicines Agency is an outlier in how it manages conditional regulatory approvals; conditional approvals are limited to one year, and approvals must be renewed annually if there are still outstanding obligations. Automating review of conditional approvals is a relatively minor adjustment that could improve oversight and avoid "dangling" approvals that remain on market despite clinical trials that failed to confirm clinical benefit (Beaver and Pazdur 2021). Since the passing of Vanessa's Law (*Protecting Canadians from Unsafe Drugs Act* 2014), Health Canada has acquired new powers that encourage on-market evaluation of drugs, including the power to order manufacturers to provide information, conduct tests and assessments and monitor experience of approved drugs. However, these powers are discretionary and intended to be used as a last resort only when a manufacturer is not willing to comply voluntarily (Health Canada 2021). It remains to be seen whether these new regulatory powers will result in more responsive on-market decision making.

While regulatory approval of drugs is solely within the jurisdiction of the federal government, deciding whether a drug will be covered by a public drug plan is the responsibility of each individual province. Under conditional reimbursement schemes, payers agree to reimburse a drug based on the collection of further evidence either to confirm its cost-effectiveness or to identify the subpopulations most likely to benefit from its use. On reassessment of the evidence, the drug can be delisted or reimbursement criteria can be refined to optimize the value realized within a limited budget (Piatkiewicz et al. 2018). In Canada, conditional reimbursement schemes have not been adopted widely due to restrictive legislative frameworks and fear of loss of provincial autonomy (Morgan et al. 2013b). Exceptions are product listing agreements (PLAs) through the pan-Canadian Pharmaceutical Alliance. PLAs are increasingly used to negotiate confidential prices for new drugs but their adoption across jurisdictions has been inconsistent and, perhaps more importantly, PLAs do not include mechanisms for on-market evaluation and reassessment (Morgan et al. 2013a).

What Are the Current Barriers to Adopting a Life-Cycle Approach?

Based on the current structure of Canada's healthcare systems, there are various ethical, practical and regulatory barriers to adopting a life-cycle approach. Dynamic decision making based on post-market surveillance requires data generation in studies or clinical trials that blur the line between research and clinical care. Data generation may be required that exceeds standard of care. For example, additional diagnostic tests or monitoring visits may

be necessary to collect data sufficient for decision making. If characterized as research, institutional ethics review is required; if characterized as clinical care, consent processes need to acknowledge the uncertain risk and benefit profiles over the life cycle of a conditionally approved or reimbursed drug. There is a lack of consensus about the appropriate standard of consent in the post-market setting: Is it the higher standard required in research settings or the more flexible standard permitted in clinical care and health-system utilization of patient data for quality improvement (Largent et al. 2011)? Additionally, privileged access to an intervention that is contingent on participation in a post-market research protocol may be viewed as coercive, particularly where no other treatment options are available. Many of these concerns can be mitigated by comprehensive disclosure and consent requirements prior to initiating treatment. Patient privacy is also a factor as patient data are collected, shared and analyzed for research and regulatory decision-making purposes, in addition to patient care (Holland and Hope 2012). Public acceptance of health data sharing remains unsettled. While research suggests that participants and patients are generally supportive of sharing their personal health information for research purposes, many individuals distrust institutions that collect and share health information, representing a gap that should be addressed prior to widespread adoption (Darquy et al. 2016; Milne et al. 2019; Platt et al. 2018).

Practical issues also emerge. Once a drug is approved and marketed, it may become difficult to enroll patients in clinical trials or other data collection efforts because patients are able to access the drug outside clinical trials (Eichler et al. 2008). As a result, conditional approvals may undermine the required evidence-collection efforts to remove the conditions. Issues also arise from inadequacies in the design and analysis of post-market studies, which often necessitate departure from randomized controlled trials powered appropriately to enable causal inference (Davis et al. 2016). Administration, implementation and evaluation of conditional regulatory and reimbursement schemes are not well developed. It is unclear who should be responsible for the funding, design and implementation of data collection and analysis efforts. Placing the data collection burden on the manufacturer in the post-market environment raises concerns about clinical trial manipulation, lack of transparency and conflicts of interest (Light and Lexchin 2021). These concerns may be ameliorated through real-world evidence generated from routine clinical care. However, shifting the burden of evidence generation to health systems or government agencies may introduce new concerns. For example, post-market evidence would likely need to be shared with manufacturers to enable them to secure regulatory approval or reimbursement in different jurisdictions. Post-market data systems for HCDRDs, in particular, will need to be interoperable across multiple institutions and/or jurisdictions, requiring substantial investments and appropriate consent processes. In parallel, progress is needed in developing and standardizing health database terminology, coding, validation and statistical methods before real-world data derived from electronic health databases can be relied upon for regulatory and reimbursement decision making (Moore and Furberg 2015).

Finally, enforcement and evaluation of post-market data collection has been largely underwhelming. Most conditional regulatory and reimbursement agreements are commercial in nature, and therefore confidential, making it difficult to hold parties accountable for the promises made or to evaluate the decisions made based on post-market data collection. While the threat to withdraw funding or approval exists in theory, withdrawing a drug from the market or delisting it from a drug plan is difficult administratively and unpopular politically (Vitry et al. 2015). As a result, drugs may remain on the market or be reimbursed despite evidence that they provide little or no clinical benefit (Government of Canada 2019). There is a lack of consensus on the best way to manage patients who do respond positively to a drug that is withdrawn or defunded. Clear decision rules and exit strategies will be required prior to initiating post-market evidence generation (Pace et al. 2021). Both federal and provincial governments have a responsibility to enforce reassessments based on iterative evidence collection for approval and reimbursement decisions, respectively. A balance needs to be found between encouraging transparency and accountability and protecting commercial interests and promoting innovation. To this end, clear decision-making processes, dispute resolution mechanisms and evaluation frameworks should be built into conditional regulatory approvals and reimbursement agreements.

What Can We Learn from the Pfizer–Israel COVID-19 Vaccine Agreement?

The COVID-19 pandemic has highlighted the importance of conditional regulatory approvals and other accelerated pathways in conjunction with supporting post-market data collection infrastructure. Recently, a redacted version of the Real-World Epidemiological Evidence Collaboration Agreement (the Agreement) was released that covers the purchase of the Pfizer-BioNTech COVID-19 vaccine for use in Israel (Israel Ministry of Health 2021). The parties agreed to "share information and data regarding the distribution, administration and use of the [vaccine], including to track its benefits" (Israel Ministry of Health 2021). The parties agreed to share epidemiological data collected through the Israeli Ministry of Health's vaccination program in aggregate form to be jointly analyzed by the parties. The Agreement clarified that all data would continue to be owned by the Ministry of Health, regardless of transfer, but Pfizer was granted rights under the agreement to use the data for research and development purposes, regulatory submissions and scientific or other legitimate publications. The parties agreed to jointly prepare and publish results from the project in academic journals. The Agreement lists the data endpoints the parties will collaborate on, including subgroup analyses, as well as the specifics of the weekly data transfers including confirmed COVID-19 cases, hospitalizations, severe and critical cases, ventilator use, deaths, symptomatic cases, total vaccinees with demographic data and case counts by demographic.

Israel was able to enter into this type of agreement as a result of its robust national healthcare database, which contains data collected through health maintenance organizations. In addition, all healthcare providers in Israel also use electronic health records (EHRs), and the entire Israeli population is covered by the state's healthcare system (Lovis and

Gamzu 2015). Israel is, therefore, better positioned than many other countries, especially federated countries such as Canada, with respect to post-market surveillance infrastructure. However, ethical concerns about the Agreement have been raised. Specifically, Israeli privacy expert Tehilla Shwartz Altshuler from the Israel Democracy Institute has expressed concern with respect to individual privacy if subgroup analyses are utilized, as well as the risk of exposure in the event of a cyber-attack when data are shared with a company outside of the health system (*France 24* 2021).

While the Agreement may be perceived as a positive step toward the integration of real-world data with regulatory decision making, it also highlights the outstanding issues and concerns that must be addressed before conditional agreements can be adopted more widely. Unlike Israel, most other countries, including Canada, do not have the requisite data infrastructure to collect and share data efficiently. Health data collection is the responsibility of each province, and as a result, health data are siloed within jurisdictions and institutions and EHRs have been inconsistently adopted and implemented. There remains limited capacity to share information across and within jurisdictional borders because of restrictive data and privacy laws and policies, and even if data were able to flow more freely, a lack of harmonization in systems would likely hinder interoperability (Katz et al. 2018).

Concluding Thoughts

Despite continued interest in adopting a life-cycle approach, many of the concerns discussed above have prevented the expected benefits from being realized in practice. The lack of success to date can be attributed to maladapted systems and infrastructure rather than a reflection of the value of a life-cycle approach. There have been some efforts to increase cooperation between the regulatory and reimbursement processes in Canada, such as the aligned review process between Health Canada, the Canadian Agency for Drugs and Technologies in Health and the Institut national d'excellence en santé et en services sociaux (Government of Canada 2018). However, to benefit from a life-cycle approach, Canada's health, regulatory and reimbursement systems and supporting data infrastructures need to be modernized. Enforcement and accountability measures need to be implemented that can identify and remove drugs that fail to confirm clinical benefit and/or cost-effectiveness while respecting the needs of individual patients for whom there is evidence of valuable benefit. While the new powers under Vanessa's Law (*Protecting Canadians from Unsafe Drugs Act* 2014) are an important step to improving Health Canada's ability to monitor the on-market performance of drugs, stronger mechanisms are needed to support the widespread adoption of conditional regulatory and reimbursement mechanisms. Finally, multi-stakeholder deliberative platforms and processes are needed to resolve the ethical concerns associated with the widespread use of administrative health data collection in the post-market setting. Ethical concerns need to be resolved in the traditional separation of clinical care and clinical research, and the equity interests of specific patient groups need to be weighed against the sustainability of health systems. While Israel's agreement with Pfizer highlights the benefits of having the ability to

capture population-level data to support healthcare planning, it also emphasizes the need to better understand and settle outstanding privacy and ethical concerns with trading data for access to new drugs.

Correspondence may be directed to: Tania Bubela. Tania can be reached by e-mail at tbubela@sfu.ca.

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