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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.

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

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

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

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EDITORIAL

Health Data: Desert, Deluge, or Discovery?

It's not often that data policy and infrastructure make the news, but a multi-part series in *The Globe and Mail* (Andrew-Gee and Grant 2019) last month highlighted a range of data deficits – from local vaccination rates to wait times for mental health services.

The reporters invited Canadians to weigh in on data gaps that affect Canadians. In doing so, they prompted us to consider 'which questions are we not asking?' and 'who are we not asking questions of?' Responses flooded my Twitter feed. The range of gaps cited, and the passion of their advocates, highlighted the many important data deficits that exist in the health sector and elsewhere.

These data deserts co-exist with data deluges. I often hear complaints about difficulties in keeping up with a tsunami of health research, "indicatoritis" from overwhelming reporting systems, as well as the challenges of managing floods of patient information that was not accessible in the past. Likewise, increased digitization in the health sector generates gigabytes of new data every day. Data storage capacity is no longer a significant limitation in most cases. And increasingly sophisticated methods to analyze data locked in unstructured text, medical images, and monitoring devices offer potential new sources of insight.

Looking ahead, privacy-by-design will continue to be an important foundation for responsible data collection and analysis. Respondent burden is another significant consideration. Personally, I answer almost every survey that I am sent and have consented to participation in a myriad of research studies because I have used so much data generously contributed by others. But declining response rates for many surveys suggest that not everyone shares this compulsion.

The challenge is also as much about effectively using the data that we have as about acquiring more. By choosing to focus in one area – whether in terms of data collection, analysis, or use – often, we implicitly choose not to devote resources or attention elsewhere. Growing analytic capacity and the ability to act in a meaningful way on the results matters too. This dynamic is key to the success of rapid-learning health systems.

Authors in this issue of the journal have taken up the challenge. For instance, Joel Lexchin starts us off with an analysis of the potential impact on drug expenditures of a

two-year extension in data protection for biologics. Marie-Josée Fleury, Guy Grenier and Lambert Farand contribute a study on how satisfied patients presenting for mental health reasons are with the care that they receive in emergency departments. And Anne Girault and colleagues explore responses to pay-for-performance methods in hospitals in France. Other authors offer new perspectives on important policy questions, such as mental health and addictions strategy, regulating mobile health solutions, and integrated knowledge translation in public health.

Whatever your particular health policy interests, I hope that the writings in this issue will help to deepen your thinking about a question already on your radar or to open a door to an area of data, practice, or policy that was not.

JENNIFER ZELMER, PhD
Editor-in-Chief

Reference

Andrew-Gee, E. and T. Grant. 2019 (January 26). "In the Dark: The Cost of Canada's Data Deficit." *The Globe and Mail*. Retrieved February 15, 2019. <https://www.theglobeandmail.com/canada/article-in-the-dark-the-cost-of-canadas-data-deficit/>.

ÉDITORIAL

Les données sur la santé : désert, déluge ou découverte ?

Ce n'est pas tous les jours que la politique et l'infrastructure des données font la manchette. Le mois dernier, une série d'articles dans le *Globe and Mail* (Andrew-Gee et Grant 2019) présentait nombre de lacunes en matière de données, allant des taux de vaccination aux temps d'attente pour obtenir des services de santé mentale.

Les journalistes y invitaient les lecteurs à jauger l'ampleur des lacunes statistiques qui peuvent affecter les Canadiens. Cette lecture m'a portée à me demander « quelles questions ne sont pas posées?» et « à qui ne pose-t-on pas les questions?». Les réponses n'ont pas tardé à affluer sur mon compte Twitter. L'ampleur des lacunes mentionnées et la passion des militants ont permis de mettre en évidence plusieurs importantes lacunes de données dans le secteur de la santé ou ailleurs.

Ces déserts de données côtoient des déluges de données. J'entends souvent parler, en effet, des difficultés de se tenir à jour dans le raz-de-marée des recherches en santé, de l'«indicateurite» des systèmes de déclaration envahissants ainsi que des défis liés à la gestion du flot d'informations sur les patients qui n'étaient pas disponibles auparavant. Dans le même ordre d'idées, la numérisation croissante du secteur de la santé génère chaque jour des gigaoctets de nouvelles données. La capacité de stockage des données n'est plus un facteur limitant qu'on peut évoquer. Des méthodes de plus en plus complexes pour analyser les données enchâssées dans des textes non structurés, des images médicales ou des dispositifs de contrôle offrent de nouvelles sources à exploiter.

La protection de la vie personnelle à même la conception des projets continuera d'être un des fondements de la collecte et de l'analyse des données. Et le fardeau du répondant est un autre aspect important dont il faut tenir compte. Personnellement, je réponds à presque tous les sondages que je reçois et j'ai accepté de participer à une myriade d'études de recherche parce que j'utilise moi-même tellement de données généreusement fournies par autrui. Mais les taux de réponse en baisse de plusieurs questionnaires laissent voir que tout le monde ne partage pas cette habitude.

L'utilisation efficace des données et l'acquisition de nouvelles données comportent toute deux leur lot de défis. En optant pour centrer ses efforts dans une sphère – que ce soit la collecte de données, l'analyse ou l'utilisation des données – on choisit souvent implicitement

de ne pas consacrer les ressources ou l'intérêt ailleurs. Les capacités accrues d'analyse et la possibilité d'agir de diverses façons sur les résultats sont aussi deux aspects importants. Cette dynamique est la clé du succès des systèmes de santé en apprentissage accéléré.

Dans ce numéro, les auteurs ont relevé le défi. Par exemple, Joel Lexchin ouvre le bal avec une analyse de l'impact potentiel sur les dépenses en médicaments d'une prolongation de deux ans de la protection des données pour les produits biologiques. Marie-Josée Fleury, Guy Grenier et Lambert Farand proposent une étude sur le taux de satisfaction envers les services reçus aux urgences chez les patients qui s'y présentent pour des raisons de troubles mentaux. Quant à Anne Girault et ses collègues, ils explorent la réaction face au mode de paiement à la performance dans les hôpitaux français. D'autres auteurs présentent de nouveaux points de vue sur d'importantes questions d'ordre politique, telles que la stratégie de santé mentale et de lutte contre les dépendances, la réglementation des technologies mobiles en santé ou encore l'application des connaissances intégrée dans le domaine de la santé publique.

Quels que soient vos centres d'intérêt en matière de politiques de santé, j'espère que les articles du présent numéro vous aideront à approfondir votre réflexion sur une question qui vous habite déjà ou vous permettront d'ouvrir la porte à un nouvel ensemble de données, une pratique ou une politique qui vous avait échappé.

JENNIFER ZELMER, PhD
Rédactrice en chef

Référence

Andrew-Gee, E. et T. Grant. 2019 (26 janvier). "In the Dark: The Cost of Canada's Data Deficit." *The Globe and Mail*. Consulté le 15 février 2019. <https://www.theglobeandmail.com/canada/article-in-the-dark-the-cost-of-canadas-data-deficit>.

Increase in Drug Spending in Canada Due to Extension of Data Protection for Biologics: A Descriptive Study

Accroissement des dépenses en médicaments au Canada en raison d'une prolongation de la protection des données pour les produits biologiques : une étude descriptive

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Abstract

Introduction: Biologics are currently protected from competition by eight years of data protection. The renegotiated North American Free Trade Agreement (NAFTA) increases data protection from 8 to 10 years. This study investigates the effect of such an extension on drug spending in Canada.

Methods: A list of currently available biologics eligible for data protection along with their 2017 sales was compiled. Two years were added to the current expiration date of data protection to see if it exceeded patent protection, and any theoretical change in spending due to delayed competition was calculated. The number of biologics approved after January 1, 1995, that have competition and the time until competition started was analyzed. Theoretical competition due to increased data protection for biologics where data protection has already expired was examined.

Results: Depending on how much of the market is captured by biologic competitors and how strong the patents are, lost savings from data protection extension could range from $0 to $305.8 million. One biologic competitor currently on the market could theoretically have been affected by an increase in data protection. Increased data protection would have had minor effects on products that have already lost data protection.
Discussion: The potential impact on drug expenditures of a two-year extension in data protection is highly variable. Possible increases in spending on biologics strengthen the rationale for a national pharmacare plan where monopsony buying power would help to control drug prices overall and offset increased spending on biologics.

Résumé

Introduction : Les produits biologiques bénéficient actuellement d'une protection des données de huit ans afin de les protéger de la concurrence. Cette protection passe de huit à dix ans dans le cadre du nouvel Accord de libre-échange nord-américain (ALENA). La présente étude s'intéresse aux effets d'une telle prolongation sur les dépenses en médicaments au Canada.
Méthode : Nous avons compilé une liste des produits biologiques actuellement admissibles en vertu de la protection des données, de paire avec leurs ventes en 2017. Deux années ont été ajouté à la date d'expiration de la protection des données actuelle pour voir si elle dépassait la protection conférée par le brevet; et tout changement théorique de dépense dû au report de la concurrence a été calculé. Nous avons analysé le nombre de produits biologiques approuvés après le 1er janvier 1995 et qui sont soumis à la concurrence ainsi que le temps écoulé avant le début de la concurrence. Nous avons examiné la concurrence théorique due à l'accroissement de la protection des données des produits biologiques pour lesquels ladite protection est effectivement périmée.
Résultats : Dépendamment de la part du marché captée par les concurrents des produits biologiques et selon la solidité des brevets, la perte d'économie due à la prolongation de la protection des données se situe entre 0 et 305,8 millions de dollars. Un concurrent actuellement sur le marché pourrait théoriquement être affecté par un accroissement de la protection des données. Cet accroissement aurait des effets mineurs sur les produits qui ont déjà perdu la protection des données.
Discussion : L'impact potentiel d'une prolongation de deux ans de la protection des données sur les dépenses en médicaments est très variable. De possibles augmentations des dépenses pour les produits biologiques sont autant d'arguments en faveur d'un plan national d'assurance médicaments dans lequel le pouvoir d'achat d'un monopsone aiderait à contrôler le coût général des médicaments et à compenser les dépenses accrues pour les produits biologiques.

Introduction

Originator drugs in Canada are protected by two types of intellectual property. Patents on both the product and the process used to make the product last for 20 years from the time that the patent is filed. Companies typically file multiple patents for a single drug, but not all patents are equal and some may not block generic entry. The second type of intellectual property is data protection. In this case, the data in question are the results of the pre-market clinical trials undertaken by the company to have the drug approved by Health Canada for marketing.

In order to qualify for data protection, drugs have to satisfy two conditions: they need to be new chemical entities, i.e., contain a medicinal ingredient never sold before in Canada, and the data supporting the approval of these drugs should have required considerable effort to generate, where considerable effort is defined as the use of clinical trials to produce the data (Health Products and Food Branch 2017). Data protection gives the originator company eight years of market exclusivity with the possibility of an additional six months if it has conducted pediatric clinical trials (Health Products and Food Branch 2017).

The recently concluded renegotiated NAFTA increases data protection for biologics to 10 years (Government of Canada 2018). Biologics include, among others, gene therapies, viral and bacterial vaccines and products produced through biotechnology (Health Canada 2018), and between 2008 and 2017, biologics went from accounting for 16% ($1.9 billion) in sales of patented medicines in Canada to 42% ($7.0 billion) (Patented Medicine Prices Review Board 2018). Competitors for biologics in Canada are referred to as subsequent entry biologics (SEBs).

Only drugs approved after the agreement comes into effect will be affected by the increase in data protection. The aim of this study is to examine currently marketed biologics to estimate the possible future changes in drug expenditures as a result of the increase in data protection.

Methods

Three methods were used to determine what effect extension in data protection might have on spending on biologics:

1. top-selling biologics that are on the market and currently subject to data protection were identified, and the impact of a two-year delay in the appearance of SEBs on sales was estimated;
2. biologics approved between January 1, 1995, and March 31, 2018, were examined to determine if any of them would have been affected by a change from 8 to 10 years of data protection; and
3. biologics with expired data protection were examined to determine if a two-year extension in data protection would have meant that data protection expired after the period of patent protection ended.

1. *Impact of two-year extension of data protection on top-selling biologics that are currently subject to data protection*

SELECTION OF BIOLOGICS

A list of the top-selling biologics in Canada was compiled from two sources. The names and 2017 annual sales for the top 10 selling biologics were taken from the 2017 annual report from the Patented Medicine Prices Review Board (PMPRB) (Patented Medicine Prices Review Board 2018). An additional seven biologics were listed in a slide presentation from the PMPRB (PMPRB nd). The 2017 sales of five of these additional drugs came from the annual report of the Canadian subsidiary of IQVIA, a human data science company (IQVIA 2018), whereas 2016 sales for the other two were available from the PMPRB slide presentation.

DETERMINATION OF DATA PROTECTION AND PATENT EXPIRATION

These 17 drugs were then searched in the Register of Innovative Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs/register.html) that lists which drugs have data protection and the expiry date of that protection. Patent expiration dates for drugs listed in the Register were obtained from the Patent Register Database (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/patent-register/database-download.html). If a drug was covered by more than one patent, then the expiration dates of all of the patents were recorded. Searches of the Register of Innovative Drugs and the Patent Register Database were done on September 29, 2018. Patents that expired before September 29, 2018, were not included.

CALCULATION OF LOST SAVINGS DUE TO DATA PROTECTION EXTENSION

Two years (730 days) were added to the expiration date for data protection. Instances where patent expiration occurred before the extended data protection expired were recorded. The theoretical loss in savings from SEBs was calculated by taking the mean 26% price reduction from currently available SEBs (PMPRB nd) and then applying that percent to the 2017 sales of the biologics. Uptake of SEBs is highly variable depending on the country. In Canada, after one to two years, SEBs only capture 1%–3.5% of the market, whereas the median market share for all Organisation for Economic Co-operation and Development (OECD) countries is 50%, rising to 85% for the five OECD countries with the highest uptake (PMPRB nd). Calculations of lost savings from the two additional years of data protection were made assuming that the SEBs would capture 25%, 50%, 75% and 100% of the market.

2. *Length of time before biologic is subject to competition*

Starting in 1995, Health Canada began identifying newly approved biologics in annual reports (available by directly contacting Health Canada at publications@hc-sc.gc.ca). From

these reports, the generic names of biologics, excluding vaccines, immunization agents and diagnostic agents, approved from January 1, 1995, to March 31, 2018, and the date when these drugs were approved (received a Notice of Compliance) were recorded. The existence of an SEB for these biologics as of December 31, 2018, was determined by consulting the Drug Product Database (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp), and if there was an SEB, its date of marketing was recorded. The time between the approval of the biologic and the marketing of the SEB was computed in days.

3. *Biologics with expired data protection*

Drugs with expired data protection are also listed in a section of the Register of Innovative Drugs. The names of all biologics in this section were recorded along with the date on which data protection ended. Two years were added to this date to account for the extension in the renegotiated trade agreement. The Patent Register Database was then consulted, and expiry dates for patents were recorded to see whether patent protection or the extended data protection would expire first. The Drug Product Database was used to determine if any of the drugs had competition from an SEB as of December 31, 2018.

STATISTICS

Descriptive data are reported, and all calculations were done using Excel (version 16.20 for Macintosh).

ETHICS

No patients were involved, and all data were publicly available. Therefore, ethics approval was not sought.

Results

Impact of two-year extension of data protection on top-selling biologics that are currently subject to data protection

Table 1 gives the names of the 17 biologics and their 2017 sales. Out of the 17 biologics only two were listed in the Register of Innovative Drugs – aflibercept and pertuzumab–trastuzumab with current data protection expiration dates of November 8, 2021, and April 12, 2021, respectively. Aflibercept was covered by two patents, one of which expires before the current end of data protection and one after. This situation would not change with the additional two years of data protection (Table 2 – available online at www.longwoods.com/content/25796). Pertuzumab–trastuzumab is covered by 10 patents that expire between December 10, 2018, and January 28, 2029. With the two-year extension of data protection, three of those patents would expire before data protection ends (Table 2).

TABLE 1. List of biologics and 2017 annual sales

Generic name	Name of originator	Sales ($ million) in 2017
Infliximab	Remicade	941
Adalimumab	Humira	706
Aflibercept	Eylea	403
Etanercept	Enbrel	319
Ranibizumab	Lucentis	319
Rituximab	Rituxan	252
Ustekinumab	Stelara	185
Pertuzumab–trastuzumab	Perjeta–Herceptin	185
Trastuzumab	Herceptin	185
Immune globulin (human)	Gamunex	168
Insulin glargine	Lantus	167
Omalizumab	Xolair	131
Bevacizumab	Avastin	116
Epoetin alfa	Eprex	104
Filgrastim	Neupogen	100
Natalizumab	Tysabri	50 (2016)
Follitropin alfa	Gonal-F	14 (2016)

Source: PMPRB (4, 5); IQVIA (6).

Depending on how much of the market is captured by SEBs, lost savings because of data protection extension for these two products theoretically could range from $0 (patents necessary to keep SEBs off the market expire after extended data protection) to $24.1 million (data protection for pertuzumab–trastuzumab only and only 25% of the market is captured) to $305.8 million (both SEBs capture 100% of the market). Lost savings under this scenario would start on December 4, 2021, (current data expiration for pertuzumab–trastuzumab) and end on August 11, 2023, (extended data expiration for aflibercept), that is, a time span of 940 days.

Length of time before biologic is subject to competition

From January 1, 1995, to March 31, 2018, there were a total of 139 biologics approved by Health Canada. Out of these, nine had competitors (one product, infliximab, had two competitors), and the mean time to competition was 5,426 days (95% confidence interval 4441, 6411). One of these competitors (glucagon and ribosomal DNA origin) was marketed after eight years of data protection for the original biologic started but before 10 years

(Table 3 – available online at www.longwoods.com/content/25796). In this case, the extra two years of data protection could potentially have delayed the marketing of the SEB. Seventy-eight of the biologics were approved after January 1, 2009, and some of them may acquire competition after the current eight years of data protection but before a 10-year period.

Biologics with expired data protection

There were 17 biologics with expired data protection, but one product was not listed in the Patent Register Database leaving 16 for analysis. In three cases, data protection already exceeded patent protection, and the additional two years could have theoretically further delayed competition. In seven cases, patent protection would have exceeded 10 years of data protection. In five cases, where drugs had multiple patents, even without the additional two years of data protection, it was unclear whether data or patent protection would have expired first, and the situation was not changed with extended data protection. In one case, again where the drug had multiple patents, if data protection were eight years, it would have expired before patent protection, but with the additional two years, it was unclear which would have expired first (Table 4 – available online at www.longwoods.com/content/25796). There was no competition for any of the 17 drugs as of December 31, 2018.

Discussion

Even with 10 years of data protection, patent protection might continue to be the most important factor in delaying competition for biologics. The potential impact on overall Canadian drug expenditures of a two-year extension in data protection is highly variable, ranging from no increase to a high of $305.8 million over slightly more than two and a half years depending on the strength of patent protection and whether those patents are challenged in court. These amounts are based on drugs currently available in the market and cannot predict spending on new biologics that will appear and be subject to extended data protection. However, the cost of some of these future biologics could be considerable. In 2006, only one of the top 10 patent medicines by sales was a biologic, whereas by 2017, seven were biologics (PMPRB 2018). In addition, depending on how the new agreement is eventually interpreted, the criteria for eligibility for data protection may be expanded, thereby increasing the number of drugs that qualify for it. Finally, as previously mentioned, patents can be challenged in court whereas data protection cannot be. Therefore, in cases where it appears that data protection will expire before patents, successful challenges may mean that data protection will actually last longer than patents.

The possibility that there will be any substantial increase in expenditures also needs to take into account findings about existing competition for biologics and theoretical

competition for biologics where data protection has already expired. Both of these results indicate a minimal effect of an additional two years of data protection. Out of nine biologics (of 139 approved) that had competition as of December 31, 2018, only one SEB might have been delayed if data protection was 10 years instead of 8. In the other eight cases, competitors appeared after the expiration of 10 years of data protection, indicating that patent protection was potentially the more important of the two. However, 78 biologics were approved after January 1, 2009, that is, before the expiration of a 10-year period for data protection, and if the extended period were already in effect, it is possible that competition for some of these might theoretically be delayed.

For 16 drugs where data protection had already expired, the additional two years would have changed the status for one product, going from a situation where data protection expired before patent protection to a situation where it was unclear which would have expired first because of the existence of multiple patents. In five other cases, also where drugs had multiple patents, with eight years of data protection, it was unclear which was more important, and two more years of data protection might have further delayed competition, again depending on which patent was the strongest. There were three drugs where data protection already exceeded patent protection, and in these three instances, competition could have theoretically been further delayed by two more years of data protection.

Finally, at present, the market share of SEBs in Canada is quite small (PMPRB nd), so even if extra data protection delays the introduction of competition for most biologics, the impact on spending might be quite small because there are currently few savings from SEBs.

Limitations

The assumption was made that competition among SEBs would not affect savings, that is, that SEBs do not compete on price. It was also assumed that sales of the originator biologics would remain stable during the extra two years of data protection. For the products where data protection had already expired, there were no publicly available data to use to estimate theoretical changes in spending in the cases where the additional two years of data protection might have made a difference in the marketing of a competitor.

Conclusion

Any changes in spending on biologics because of the additional two years of data protection will only affect biologics approved after the renegotiated NAFTA takes effect. At this point, a definitive answer about increases in expenditures is unknown, and the range could be from trivial to substantial. However, the possibility of a large increase, even if this possibility is small, should prompt the federal government to take a precautionary principle approach and take action to guard against increases through the creation of a national pharmacare program. Such a program would create a situation where monopsony buying power can be used to control the prices of drugs in general. The Parliamentary Budget Office report on

the cost of a pharmacare plan estimated that prices could be reduced by 25% (Office of the Parliamentary Budget Officer 2017). Reductions in overall prices would help to offset any increases in spending on biologics due to the two-year delay in the introduction of SEBs.

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The Regulatory Challenge of Mobile Health: Lessons for Canada

Le défi de la réglementation des technologies mobiles en santé : leçons pour le Canada

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Abstract

Mobile health (mHealth) is the provision of health or medical services enabled by portable devices. This field is rapidly expanding as the global market for mobile devices grows. mHealth "apps" pose benefits and risks to their users that governments have attempted to address through regulation. There is substantial variability across regulatory bodies in the scope, specificity and robustness of mHealth regulations, with Canada's regulatory framework lacking in two major domains: (1) specificity of existing regulations for mHealth and (2) regulatory clarity for what apps require regulation. If Canada is to be a leader in digital

health, it requires a new framework that encourages the growth of an mHealth market that can bring innovative solutions to contemporary healthcare challenges while maximizing user benefits and minimizing harms.

Résumé

On entend par «technologies mobiles en santé» la prestation de services médicaux ou de santé facilitée par les appareils portables. Ce domaine est en rapide expansion, de paire avec la croissance du marché mondial pour les appareils mobiles. Les applications mobiles en santé présentent des avantages ainsi que des risques pour les usagers, risques que les gouvernements tentent d'atténuer au moyen de réglementations. Il existe, entre les divers organismes de réglementation, d'importantes variations en matière de portée, de spécificité et de solidité des réglementations visant les technologies mobiles en santé. Au Canada, le cadre réglementaire présente des lacunes dans deux domaines d'importance : (1) la spécificité des règlements en vigueur pour les technologies mobiles en santé et (2) la clarté de la réglementation quant à savoir quelle application nécessite une réglementation. Si le Canada souhaite devenir un leader en santé numérique, il faudra un nouveau cadre de travail qui favorise la croissance d'un marché pour les technologies mobiles en santé, lequel apporterait des solutions novatrices aux défis actuels en matière de services de santé tout en maximisant les avantages et en minimisant les dommages pour les usagers.

Introduction

Mobile health (mHealth) is the use of portable devices, such as smartphones and tablets, for the provision of health or medical services (Cortez et al. 2014). These services are defined broadly, encompassing diagnosis and management of conditions and support for general health, well-being and fitness (Cortez et al. 2014). Services tend to be provided in one of three ways: (1) software applications ("apps") that allow users to enter and receive information, (2) pre-existing hardware (e.g., microphones, cameras) installed on portable devices and (3) external devices attached to portable devices that receive/generate information of interest (e.g., an attachment allowing a smartphone to read an electrocardiogram).

As mobile device use increases worldwide, so does the use of mHealth, creating new medical and legal challenges. These challenges include the demand to protect consumers from the risks of mHealth apps while at the same time leveraging mHealth services to improve healthcare delivery, quality and safety on both personal and population levels. Despite Canada's allocation of $800 million to innovation networks and clusters to bolster market competitiveness or through more grassroots funding initiatives, such as the Canadian Medical Association's Joule Program that helps physicians develop, market and adopt new patient care technologies, Canada still lacks a dedicated regulatory framework for mHealth (CMA 2017; Morneau 2017). Not only do regulatory frameworks provide assurances of

safety, they also establish credibility for tools among patients and providers and can be structured to align to other international standards; together, these facilitate market access.

In this discussion paper, we provide an overview of the emerging field of mHealth, the current mHealth regulatory landscape in Canada and a brief comparison of Canadian regulation with that of other jurisdictions, and we address the major regulatory deficiencies related to software apps in Canada, providing concrete regulatory considerations. We believe that Canada can be a leader in mHealth, but only with a specific, clear and enforced set of standards that is in concordance with international regulatory efforts.

The Rise of mHealth

By 2020, an estimated 2.6 billion people globally will use mHealth apps, generating a market estimated at US$31 billion (Research2Guidance 2016). By the end of 2016, over 259,000 apps were available on major app stores for Apple and Android (Research2Guidance 2016). In 2014, 80% of these apps targeted consumers (patients) while 46% addressed primarily fitness and wellness (Research2Guidance 2014). Adoption of this technology more broadly is expected to curtail rising healthcare costs and improve patient care, monitoring, treatment adherence and healthcare access (Research2Guidance 2016). A report commissioned by the Group Spéciale Mobile Association predicted that, by 2017, adoption of mHealth could facilitate treatment of an additional 24.5 million patients and generate €99 billion in savings for the EU (including €65 billion from disease prevention) (PriceWaterhouseCoopers 2013). Data collection via mHealth and peripheral devices has also enabled the rise of the so-called "quantified-self" movement in which users and app manufacturers collect personal biophysical data and which will ultimately become the key source of "Big Data" used to generate personalized evidence-based recommendations (Fernandes et al. 2012).

The rise of mHealth raises concerns around app safety, efficacy and user privacy. Of the 1,500 health apps assessed by the New England Centre for Investigative Reporting, 20% claimed to treat or cure medical conditions, often with little evidence (Sharpe 2012). Examples are plentiful. Dermatological applications have come under particular scrutiny; a validation study found that three out of four apps evaluated misclassified over 30% of melanomas as "unconcerning" (Wolf et al. 2013). In systematic reviews, self-management apps for asthma and diabetes and apps serving as opioid dosing conversion calculators were deficient in measures that could adversely impact patient safety (Demidowich et al. 2012; Haffey et al. 2013; Huckvale et al. 2012). There is minimal involvement of health professionals in app development, and many apps do not adhere to public health guidelines (Cortez et al. 2014). Concerns about adequate protection of user data and privacy have also surfaced. Systematic reviews, and one study of diabetes-specific apps, have found that 30%–80% have no privacy policy or send data to undisclosed third parties – often without notifying users (Ackerman 2013; Blenner et al. 2016; Hutton et al. 2018). The regulatory challenge is to address these legitimate problems while fostering an mHealth market that lives up to its potential to benefit healthcare systems while promoting, rather than stifling, innovation.

Current Canadian Regulatory Landscape and Challenges

Canadian mHealth regulation is overseen by Health Canada (HC). HC and federal and provincial governments rely on non-profit, government-funded organizations, such as the Canadian Agency for Drugs and Technologies in Health (CADTH), to provide evidence, research and analysis and set non-binding regulatory standards to assist with decision-making around healthcare technology regulation and to adopt new digital technologies within healthcare systems (CADTH 2018).

Currently, software apps are subject to HC regulation if they meet the legal definition of a medical device (Health Canada 2015). This definition can be summarized as any technology intended for the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of a person's or animal's body (Health Canada 2015). Regulation and licensing hinges on the categorization of user risk as per HC guidelines and the app's intended use (rather than actual function) as defined by the app manufacturer (Health Canada 2015). The onus of navigating the regulatory landscape falls on app manufacturers who design, develop and label apps rather than app distributors, vendors and mobile platforms (European Commission DG Health and Consumer 2012; Health Canada 2012). Notably absent from regulatory guidelines is software-specific legislation that addresses or recognizes unique aspects of this technology and regulates these accordingly. Furthermore, even applications for certification of devices classified as being of low risk require, on average, 120 days to process (Health Canada 2012). Finally, app developers must contact HC directly to seek any clarification on existing regulations.

Two major challenges to mHealth regulation and adoption thus emerge in reviewing HC's existing regulations: (1) lack of a specific mHealth regulatory framework and (2) lack of clarity in what guidance is available. Both challenges are associated with further concerns.

Canada Lacks a Specific Regulatory Framework for mHealth

First, Canada lacks a regulatory framework specific to mHealth apps. Although the definition of a medical device encompasses mHealth technologies, the regulatory framework remains tethered to the traditional conceptualization of medical devices as hardware and fails to recognize the rapidly evolving nature of software development. It also fails to address the relationship between software performance and hardware functionality, for instance, that the same app can work differently on different versions of the iPhone or on an Android device.

Several issues stem from this. The first is the financial and opportunity costs of app development. While costs and revenues are difficult to establish, in 2012, the average price of an mHealth app was estimated at US$2 and declining, with few users willing to pay over US$10 for an app (Dolan 2012; Research2Guidance 2016). According to a 2016 mHealth market analysis, 60% of app publishers made less than US$10,000 (Research2Guidance 2016). Upfront costs of certification in Canada vary widely, starting at approximately

C$8,000 for those needing a medical device establishment license in addition to C$0–$6,000 depending on the app risk classification for a medical device license (Health Canada 2018). The financial barrier to market entry is therefore evident.

Second, traditional methods of medical device evaluation to establish safety and efficacy are costly and time-intensive and assume that the approved device is relatively static (Chan and Misra 2014). Although this may work for medical equipment, apps are often updated every few weeks, cost little and may function differently on different hardware platforms (Chan and Misra 2014; Danova 2015). This poses a challenge to clinical assessment and to establishing the version of, and platform for, the app being evaluated, particularly as regulations apply to the app and not its associated device (Chan and Misra 2014). Questions arise about how updated versions are evaluated and what constitutes a meaningful alteration to an approved app. Traditional assessment methods are likely to be appropriate only for a small number of apps that function as traditional medical devices and to become a barrier to most software developments and innovations. This is not to suggest that apps should not be assessed for safety and efficacy, but rather to recognize the need for an approach to mHealth evaluation that does not stifle innovation.

Third is the issue of data security (Blenner et al. 2016; Chan and Misra 2014; He et al. 2014). Because app manufacturers and private businesses fall outside the scope of health information legislation such as *Ontario's Personal Health Information Protection Act*, usage of personal health information collected by app manufacturers is essentially unregulated (MOHLTC 2004). This oversight must be addressed if healthcare providers are to use this technology for patient care. Current regulations incentivize mHealth manufacturers to create apps that do not require regulation, leading to a proliferation of health and fitness apps rather than software directed at complex healthcare challenges (Research2Guidance 2014).

Canada Lacks Clarity in Its Guidance Documents for mHealth

A second major challenge is lack of clarity in existing regulations, which provide little in the way of consolidated, comprehensive, easily understandable guidance for app manufacturers who may not be well-versed in legal or regulatory language. The scope of the "medical device" definition results in apps that do little more than replace a paper and pencil to track blood sugar values, for example, being classified as medical devices (Powell et al. 2014). Consequently, many app developers may choose to forego licensing or even be unaware of its existence. The extent of this problem is unknown because of a lack of systematic tracking of available apps and their compliance with HC regulations. The "intended use" caveat for determining which apps are subject to regulation is difficult to interpret and ripe for abuse by those wishing to avoid the licensing process (Krieger 2016; Lewis and Wyatt 2014). For instance, an app that "treats depression" would be deemed a device, but one that "improves mood" may not.

Regulation in Other Jurisdictions

The deficiencies evident in Canada's current mHealth regulatory landscape are not unique, with other historically, linguistically and culturally similar jurisdictions, such as Australia and the European Union, similarly struggling to develop timely legislation specifically addressing the unique strengths and challenges of mHealth. Thus, although Canada, the US, the European Union and Australia share commonalities in their definitions of what constitutes medical devices and assessment of device risk in regulation, only the US Food and Drug Administration (FDA) has taken a truly proactive and transparent approach to developing perhaps the most robust mHealth regulatory system in the English-speaking world by releasing a plan for a Digital Health Software Precertification (Pre-Cert) Program, set to pilot in 2019 (European Commission DG Health and Consumer 2010, 2012; FDA 2018). This program recognizes the unique and rapidly changing aspects of mHealth apps and aims to streamline the regulatory oversight of software-based medical devices (FDA 2017a).

Contrary to Canada's regulatory guidelines, those of the FDA's pilot program are clearly stated in a single, comprehensive document that provides transparency and guidance to developers using software (FDA 2018). The primary difference in the US approach is their view to fast-tracking product review and market entry. Rather than regulating and assessing devices, this pilot program will look at the device manufacturer's record of producing safe, effective devices and their prior commitment to assessing and monitoring device performance once it reaches the consumer (FDA 2018). Those companies meeting pre-determined standards will qualify for a more streamlined pre-market review that in turn allows for faster market entry, regulatory simplicity and timely product availability while providing an avenue for product evaluation in a real-world setting (FDA 2018). Pre-market review will subsequently depend on a number of factors beyond an organization's pre-certification status and level, one of which is software risk stratification (FDA 2018). It is noteworthy that the FDA opted to adopt risk definitions from the International Medical Device Regulators Forum (IMDRF), which perhaps suggests a view to developing international regulatory standards.

In contrast, mobile apps in both Europe and Australia are regulated as medical devices based on their risk assessment category, much as they are in Canada (European Commission DG Health and Consumer 2012; Australian Government Department of Health Therapeutic Goods Administration 2013). Similar to previous FDA efforts, the UK has now developed a guidance document to allow app manufacturers to determine whether their apps are subject to regulation as medical devices, thus giving manufacturers greater clarity into the process (Medicines & Healthcare Products Regulatory Agency 2018). The US remains unique, however, in developing a separate regulatory schema for mHealth regulation.

Discussion

It is clear that innovations in regulatory approach are taking place at both national and international levels. The absence of a dedicated regulatory framework in Canada hinders the development of solutions to current national healthcare challenges and our ability to be a

leader in digital health. This situation creates concerns around patient safety and use of personal health information and is an unnecessary barrier to mHealth innovation and growth. Although there are challenges to regulating a fast-paced industry with thousands of annual new market entrants, we believe that successful mHealth regulation with devoted, simplified and clear guidelines that recognize the unique aspects of mHealth, address standards for testing app safety and efficacy and lay out expectations for personal health data use will have positive consequences for businesses and consumers alike. For businesses specifically, good regulation may reduce barriers to market entry, stimulate innovation and encourage app developers to engage in the regulatory process. Regulation may reduce consumer risk (and potential legal liabilities) and enable product export.

If mHealth is to move into mainstream medical settings, its success will rely heavily on clinician buy-in and the technology's perceived credibility, making certification worthwhile to give app manufacturers a competitive edge. While no definitive regulatory model yet exists, we endorse the FDA's approach of developing a pre-certification program as part of its Digital Health Innovation Plan to streamline pre-market approval and develop more intensive post-market surveillance with a view to developing a dedicated, comprehensive approach to mHealth regulation (FDA 2017b; Gottlieb 2017). Canada would be wise to look to this precedent to develop its own framework that recognizes the challenges of this rapidly growing market and uses government resources appropriately to determine which software to target. The rapid proliferation of mHealth apps makes it infeasible to independently assess all entries onto the market. A pre-certification program is a solution to this problem that allows for oversight combined with a requirement for post-marketing surveillance that benefits businesses, consumers and regulators alike and allows all parties to harness the benefits of this technology while creating an incentive for developers to establish a culture of safety, quality, effectiveness and product surveillance that reduces further regulatory hurdles. A local framework for a more "agile," that is, iterative, evaluation that accounts for the many differences between software and hardware has recently been proposed, and frameworks like this could also form the basis for a more rational maturity-driven approach to regulation (Wilson et al. 2018).

Even with implementation of a regulatory strategy, questions about the future of mHealth remain. This includes the major issue of regulatory enforcement, which is a particular challenge with software that can be easily downloaded across borders while avoiding regulatory oversight. This issue is difficult to solve. Support of nascent international regulatory efforts may create more regulatory and enforcement feasibility. In fact, multinational regulatory integration would allow mHealth technologies to more rapidly enter national markets without creating the need for app reassessment at each new border provided that differences in certain regulatory aspects, including differing standards for data protection in the US, Canada and the EU, can be reconciled. Such efforts are already under way, with the US FDA working with the IMDRF to develop a harmonized approach towards mHealth terminology, device risk classification, clinical evaluation of mHealth apps and quality control around mHealth and software as medical devices (FDA 2017b).

The challenges of regulating non-physical tools in a globally connected world suggests that additional approaches may also be required. There are many existing non-regulatory mechanisms that could be applied to mHealth from not-for-profit entities (e.g., Health on the Net's trustmarks for health information websites or Canada Health Infoway's certification schema for tools such as Electronic Medical Records) or from for-profit corporations (e.g., the policies and procedures governing the inclusion or exclusion of apps on the Apple Store). However, the latter is unlikely to be a viable mechanism in isolation, given the well-publicized problems with both Facebook (i.e., Cambridge Analytica) and Google (i.e., National Health Service health data breach) when corporate goals and priorities were not in alignment with those of consumers (Powles and Hodson 2017).

What is clear, however, is that Canada must expedite reform of its current regulations if it intends to be a contender in the mHealth field, let alone an innovation leader.

Key Points:

(1) mHealth is a rapidly growing field of technology reaching millions of users that has the potential to improve healthcare delivery, but that also carries risks to patients in its current form.
(2) Canada's current regulation of mHealth faces two major challenges: a lack of regulatory specificity and clarity of regulatory guidelines.
(3) For Canada to become a leader in mHealth, it must look to the regulatory steps taken by the US, the current innovator in this field, to develop its own devoted guidelines that strike a balance between protecting users and promoting innovation. It must also actively engage in nascent multinational regulatory efforts, as neither the regulation of this border-traversing technology nor the realization of its benefits with checks on its risks can feasibly be achieved in isolation.
(4) Regulation can ultimately benefit businesses by adopting standards that would reduce barriers to market entry, stimulate innovation, reduce user risk, enable product export and encourage adherence to regulations.

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RESEARCH PAPER

A Fresh Approach to Reform? A Policy Analysis of the Development and Implementation of Ontario's Mental Health and Addictions Strategy

Nouvelle fraîcheur dans la réforme ? Analyse des politiques liées au développement et à la mise en œuvre de la stratégie ontarienne de santé mentale et de lutte contre les dépendances

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Abstract

Background: *Open Minds, Healthy Minds, Ontario's Comprehensive Mental Health and Addictions Strategy* commits to the transformation of mental health and addictions services for all Ontarians.

Objective: We analyzed the formulation and implementation of this Strategy to address the question: What are the prospects for transformative change in Ontario's current approach to mental health and addictions?

Methods: Qualitative policy analysis using interpretive description of key documents of the policy process, drawing on policy network and horizontal governance theory.

Results: Three features set this policy process apart from previous reform efforts: (1) expansion of the state pluralist network to those outside of health, (2) extension of the policy network approach into the Strategy's implementation stage and (3) the combined presence of political and policy leadership.
Conclusions: There is reason for optimism that the approach of the Strategy has increased the prospects for the transformation of Ontario's mental health and addictions system.

Résumé

Contexte : *Esprit ouvert, esprit sain – Stratégie ontarienne globale de santé mentale et de lutte contre les dépendances* représente un engagement envers le changement profond des services de santé mentale et de lutte contre les dépendances pour tous les Ontariens.
Objectif : Nous avons analysé la formulation et la mise en œuvre de cette Stratégie afin de répondre à la question suivante : quelles sont les perspectives de changement profond dans la démarche ontarienne actuelle envers la santé mentale et la question des dépendances?
Méthode : Nous avons effectué une analyse qualitative des politiques, au moyen de la description interprétative de documents clés touchant au processus, en tirant profit du réseau politique et de la théorie de la gouvernance horizontale.
Résultats : Trois caractéristiques font que ce processus politique se démarque des efforts de réforme précédents : (1) l'expansion du réseau provincial multiple au-delà du milieu de la santé, (2) l'étendue de la démarche du réseau politique dans la phase de mise en œuvre de la Stratégie et (3) la présence combinée de leaderships politiques et administratifs.
Conclusion : Il y a des raisons de croire que la démarche adoptée pour la Stratégie a permis d'accroître les perspectives de changement au sein du système ontarien de santé mentale et de lutte contre les dépendances.

Background

Ontario has had a long and challenging history of addressing its populations' mental health and addictions problems. The move towards deinstitutionalization beginning in the 1960s and continuing for over 40 years (Hartford et al. 2003) has increased governments' and communities' awareness of the need to address these problems. However, the provincial government has been slow to respond to this shift, leaving communities poorly resourced and with a community-based mental health system that is fragmented and difficult to navigate (Hartford et al. 2003; Mulvale et al. 2007).

Several authors have examined this lack of progress by analyzing reform efforts and various commissioned reports, task force documents and provincial government policies. Notably, Wiktorowicz (2005) sought to understand why the shift to a community-based system in Ontario has not kept pace with institutional downsizing, with particular focus on the years 2000–2004. Their analysis found that a lack of political will to reallocate funds to

the community and to delegate control for them was the largest barrier to reform. Additional challenges identified were arm's-length and internal government policy processes with varying degrees of authority, a lack of consistent engagement with the policy community and the complexity of intersectoral coordination. Mulvale and colleagues (2007) also identified challenges to reform in their analysis of the role of legacies produced by psychiatric hospital policies stemming from the introduction of psychiatric hospitals in the 1850s and public health insurance in the 1960s.

While some incremental gains have been achieved in terms of investments in community mental health and addictions services since that time, programs still lack capacity to serve all those in need and clients still lack access to a broad range of supports and services (SEEI Coordinating Centre 2009). This may be partly attributable to insufficient funding levels. In 2013–2014, there was an estimated $3.5-billion direct investment from the Ministry of Health and Long-Term Care (MOHLTC) and the Ministry of Child and Youth Services (MCYS) as well as investments from other sectors such as education, justice and housing (Brien et al. 2015). This investment equates to approximately 6.5% of Ontario's health budget, markedly lower than many other countries and lower than the 9% target in *Changing Directions, Changing Lives: The Mental Health Strategy for Canada* (MHCC 2012).

In 2008, the Ontario government once again embarked on a reform process targeting mental health and addictions, this time with the goal of developing a 10-year mental health and addictions strategy. *Open Minds, Healthy Minds, Ontario's Comprehensive Mental Health and Addictions Strategy* (the Strategy) was released in June 2011 (Government of Ontario 2011). The Strategy commits to the "transformation" of mental health and addiction services for all Ontarians. It includes four goals: (1) improve mental health and well-being for all Ontarians; (2) create healthy, resilient, inclusive communities; (3) identify mental health and addictions problems early and intervene; and (4) provide timely, high-quality, integrated, person-directed health and other human services. It has been seven years since the release of the Strategy, so it seems reasonable to take stock of whether Ontario is any further along in realizing the transformation it promised and to assess whether this attempt at reform has been any different from the "frustrated" attempts of the past.

This paper traces the formulation and implementation of the Strategy guided by the question of whether there is something specific about this policy process that increases its prospects for leading to transformative change. We approach this research with two specific objectives in mind: (1) to describe the policy process; and (2) to identify key features that distinguish it from past policy efforts in this area. We draw on relevant policy theory to advance our core argument in the paper that the current Strategy has reasonable prospects for achieving its goals because of the approaches taken for its development and implementation.

Methods

We undertook a qualitative policy analysis using interpretive description (Thorne et al. 2004), which allows the researcher, through reflexive and critical examination, to extend the

descriptive account to one that is also explanatory (Thorne 2016). In this case, interpretive description was particularly useful because it allowed us to critically examine a wide range of documents to create a descriptive account of the policy process, which we then interpreted through the lens of our research question and the theory we drew upon for our analysis.

Conceptual frameworks

We used two recognized theories from the political science field to guide our analysis: (1) policy networks; and (2) horizontal governance. These theories were selected based on a preliminary review of the Strategy and selected policy documents that suggested differences in the size and scale of engagement in both the development and implementation phases of the Strategy. When compared to previous reform efforts, the Strategy gave greater emphasis to the broad and inclusive engagement of stakeholders within and across sectors, as well as across government ministries. It also extended this engagement beyond the policy formulation stage and into the implementation stage. Recognizing these differences, we hypothesized that two key structural features in the Strategy – the mobilization of policy networks and the horizontal coordination of public policies – might increase the prospects for the Strategy to lead to more transformative change of Ontario's mental health system.

POLICY NETWORKS

Policy networks can be simply described as the links that join state and societal actors together in a policy process (Katzenstein 1977). According to Kenis and Schneider (1991), policy networks can "be understood as those webs of relatively stable and ongoing relationships which mobilize dispersed resources so that collective (or parallel) action can be orchestrated towards the solution of a common policy problem" (p. 36). These networks vary according to the number of members and whether the state or the societal actors are perceived as dominant (Howlett and Ramesh 1998). Interest in policy networks continues to grow in part because it reflects important shifts in our forms of governance based on societal changes, including increases in the complexity of society and government, the emerging importance of information and technologies and a better understanding that policy objectives often require implementation support from non-government actors (Pal 2014). For most healthcare issues, a policy network of actors in government and society already exists, but network activation to realize policy goals is more haphazard. The draw of a network approach, Pal suggests, is the thinking that the wider the networks and the more competition among actors, the better the policy outcomes.

HORIZONTAL GOVERNANCE

Horizontal coordination of public policies (or horizontal governance) refers to efforts made within government to coordinate across existing bureaucratic boundaries to solve problems that span bureaucratic jurisdictions. As Pal (2014) notes, horizontal governance is not new in the sense that it has traditionally occurred at high levels of government such as cabinet.

However, he points to a growing interest in horizontality extending to all levels of the government bureaucracy and an increased expectation that departments work together. Hopkins and colleagues (2001) identify the key dimensions of horizontal management as: mobilizing teams and networks, developing shared frameworks, building supportive structures and maintaining momentum. There is some conceptual overlap between the horizontal governance and policy network literatures; however, for the purposes of this study, the former will refer to actors and interactions within government structures and the latter will refer to actors and interactions across government and societal boundaries. Both of these approaches have been described elsewhere in varying forms as either "joined-up government" or "whole-of-government" approaches (Christensen and Laegreid 2007; Davies 2009; Hunt 2005).

Data sources

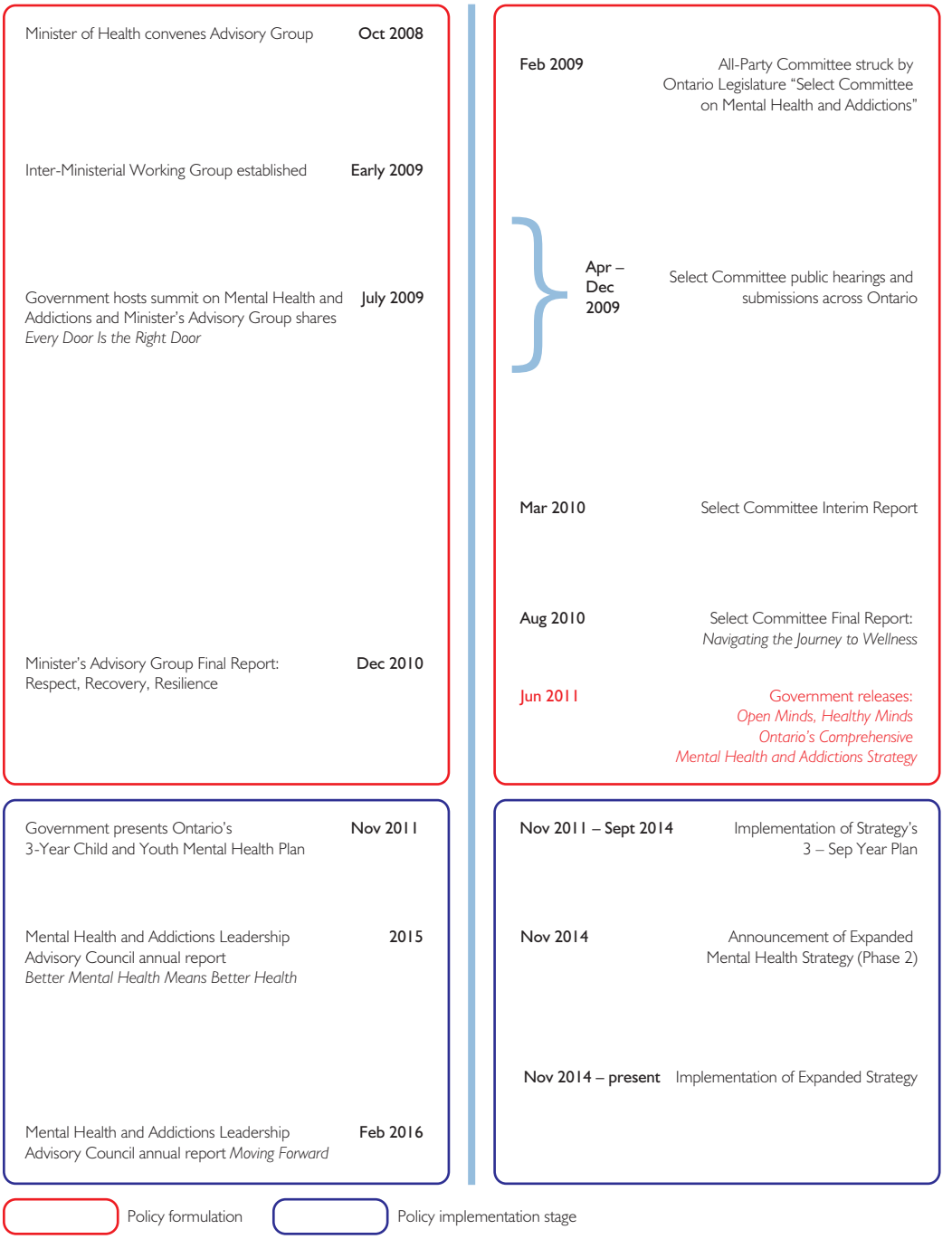
We searched for publicly available documents using the search engine Google and academic documents using PubMed, EBSCOhost and Google Scholar using the key words: mental health, addictions, "Open Minds Healthy Minds," "mental health addictions strategy Ontario," "minister's advisory group," "select committee" and "every door is the right door," in various combinations to identify publicly available documents related to the Strategy. We also reviewed the websites of the Ontario government and key organized interests across sectors, including mental health and addictions (such as Children's Mental Health Ontario), health (such as the Ontario Medical Association), education (such as the Ontario Public School Boards' Association), justice (such as the Ontario Association of Chiefs of Police) and child welfare (such as the Ontario Association of Children's Aid Societies), and we searched the Canadian Newswire for press releases from organized interests. All searches covered the period from 2009 (two years prior to the release of the Strategy) to 2016 (five years after the release of the Strategy). These sources were supplemented with additional documents from the authors' personal files.

The search resulted in 43 documents that included: (1) publicly available government documents and presentations by government officials on the Strategy and related policy formulation and implementation activities; (2) hearing transcripts from the Select Committee on Mental Health and Addictions; (3) academic articles focused on the policy process or outcomes; 4) Canadian Newswire press releases from organized interests; and (5) reports from the Mental Health and Addictions Leadership Advisory Council.

Analysis

To describe the policy process, documents were read in their entirety, sorted and classified as either being related to policy formulation or implementation. A timeline was created to identify key activities and documents according to policy stage (Figure 1). The documents were then analyzed with the goal of identifying key features drawing from relevant theory and using the analytic procedures of interpretive description (Thorne 2016).

FIGURE 1. Timeline of key activities and documents related to policy formulation and policy implementation of Ontario's Mental Health and Addictions Strategy



Results

Description of the policy process

POLICY FORMULATION

We identified three key government actions taken to inform the Strategy development that illustrate a policy network and horizontal governance approach to policy formulation: (1) the appointment of an all-political-party Select Committee; (2) the convening of a group of stakeholders to advise the Minister of Health on strategy development; and (3) the striking of an interministerial working group at the assistant deputy minister (ADM) level across multiple government ministries.

In February 2009, the legislative appointment of an all-party Select Committee on Mental Health and Addictions (Select Committee) to develop a comprehensive mental health and addictions strategy, in structure alone, improved the likelihood that the resulting strategy would be acceptable to and supported by each of the parties in the event of a change in political leadership at the provincial level. The Select Committee began its work in 2009 with three main goals: (1) to determine the mental health and addiction needs of children and young adults, First Nations, Inuit and Metis peoples and seniors; (2) to explore innovative approaches to delivering services in the community; and (3) to identify ways to leverage existing opportunities and initiatives within the current mental health and addictions system (Ontario Legislative Assembly 2010a). The committee held a series of 30 public hearings, toured sites and accepted written submissions from a wide array of organized interests and members of the public. In total, over 230 witnesses presented to the committee providing diverse perspectives from the health and mental health sectors, as well as education, human rights, justice, housing and social care. In addition, 300 written submissions were received. The Select Committee submitted an interim report to the Legislative Assembly of Ontario in 2010 (Ontario Legislative Assembly 2010b) followed by a final report outlining recommendations to the Government in advance of the Strategy six months later (Ontario Legislative Assembly 2010a). While a committee of elected officials alone could be considered an authoritative policy instrument, the committee's engagement with such a broad range of actors demonstrates the additional efforts taken to engage the policy or "issue" network (Mulvale et al. 2014) in the formulation of a policy direction.

The *second action* involved the identification and convening of a Minister's Advisory Group (MAG) in 2008, to provide overall direction and priorities for the Strategy. The MAG comprised stakeholders outside of government, representing a range of individual and organized interests including researchers, service providers, professional associations, consumer groups, the Mental Health Commission of Canada, social development organizations and immigrant services (Government of Ontario 2009). The MAG consulted over 100 Ontarians, held workshops, commissioned five background or "theme group" papers on

different topics and then created a discussion paper *Every Door is the Right Door,* which presented a framework for the proposed strategy (Government of Ontario 2009). Shortly after the discussion paper's release, the Minister of Health and the MAG held a summit, inviting over 1,000 consumers and experts from across Ontario to contribute to the discussion paper. Additional feedback was solicited following the summit through round-table consultations and written submissions. The MAG's final task was to develop recommendations for Ontario's mental health and addictions strategy, which were presented in a 2010 report (Minister's Advisory Group on Mental Health and Addictions 2010). This action put actors with varying interests in a position of power and responsibility in the formulation of policy. It allowed the government access to a wide array of ideas, including research evidence, tacit knowledge of practitioners and stakeholder values.

The *third action* was the creation of an interministerial assistant deputy ministers (ADMs) group, which reflects a horizontal governance approach to policy making. Comprising 14 different ministry ADMs, this group was tasked with identifying and streamlining services, policies and initiatives that address mental health to foster coordination (Government of Ontario 2009). They were also tasked with including mental health as a standing item on existing interministerial meeting agendas.

All told, the policy formulation process took place over almost three years, culminating with the release of the Strategy in June 2011 (Government of Ontario 2011). The scale and scope of this process reflect a deliberate and concerted effort at engaging and mobilizing a very broad policy network for the purposes of policy formulation.

POLICY IMPLEMENTATION

We identified five features of the implementation plan and its subsequent roll-out that illustrate the government's persistence in extending the policy network and horizontal governance approach into the policy implementation process: (1) the dispersion of leadership and accountability for Strategy initiatives across government ministries beyond health; (2) the development of a range of interministerial approaches for ongoing collaboration and coordination across the government ministries; (3) the engagement of actors outside the government structure to lead Strategy initiatives; (4) the appointment of the Mental Health and Addictions Leadership Advisory Council; and (5) the delegation of leadership to the policy network to determine what should be done to meet some of the Strategy goals.

The distribution of the leadership – a key feature of a horizontal governance approach – could be identified in the first wave of implementation of the 22 initiatives across government ministries. While one ministry (MCYS) had overall accountability for the first three years, each particular initiative had an identified program lead in government. In total, four government ministries (MCYS, Ministry of Education, MOHLTC and Ministry of Training, Colleges and Universities) with multiple divisions and programs within those ministries had direct accountability for the initiatives.

Another horizontal governance feature used to support their efforts was the government's articulation of a range of interministerial approaches (Government of Ontario 2013). These included both decision-making and coordination approaches, such as a Deputy Ministers Social Policy Committee that would meet quarterly to discuss priorities including the Strategy, bi-weekly and monthly meetings of interministerial working groups at staff/manager, director and ADM levels and a clear process vetting communications/memos, advisory committee activity, education/training and advisory committee activities through the working groups (Government of Ontario 2013).

The government's implementation approach also included actors outside of the government structure. This is most apparent through the delegation of accountability for many of the Strategy initiatives from ministry programs to policy network actors. For example, the initiative "Provide Nurses in Schools to Support Mental Health Services" was delegated for implementation to the Registered Nurses Association of Ontario. Similarly, in education, the Hamilton Wentworth District School Board was designated lead for "Implement School Mental Health ASSIST Program and Mental Health Literacy Provincially." Within the health area, "Create 18 Service Collaboratives" was delegated to the Centre for Addiction and Mental Health. It should be noted that, in all cases, leads represented well-established institutions. This delegation continued in the second wave of implementation that began in the fourth year of implementation when lead accountability for the Strategy shifted from the MCYS to the MOHLTC. During this period, the government appointed a Mental Health and Addictions Leadership Advisory Council comprising 20 system stakeholders with a mandate to provide implementation advice for three years, from 2014 to 2017. The Council, in turn, identified a number of working groups, led by council members but comprising additional experts from the province on specific topics. This widened the engagement of the policy network even further during the second wave of implementation.

The government also took a networked approach to determine what should be done to meet some of the Strategy goals by creating a $27-million "Mental Health Innovation Fund" aimed at supporting innovative approaches to on-campus mental health service delivery for post-secondary students (Ontario Undergraduate Student Alliance 2014). In 2012, the Ministry of Training, Colleges and Universities solicited proposals from stakeholders based on the objectives of the fund. Thirty-two initiatives were supported as of 2015, led by a variety of actors (Ministry of Advanced Education and Skills Development 2015). Thus, leadership and engagement in the implementation of this particular policy objective was shared with actors who were selected during the process, thus diffusing the responsibility and accountability for improving campus mental health across the system.

Assessing the prospects for transformative change

Our findings identified a number of features of policy network and horizontal governance approaches visible in the Strategy that offer promising prospects for transformative change.

First, in contrast to previous reform efforts that have focused on a narrower set of actors from the mental health and health sectors, the Strategy defined the policy network more broadly and intersectorally, an approach viewed as critical to successfully address wicked problems (Roberts 2000). Involving multiple actors and government ministries through horizontal governance distributes leadership in policy reform, but may also increase collective accountability, making the process less likely to stall at the implementation phase. It may also reduce resistance to implementation among organized interests (as noted by the series of news releases from organizations mainly applauding the release of the Strategy) (Canada Newswire 2011a–g).

A second distinguishing feature is the concerted effort to extend the engagement of the policy network and the horizontal governance approach beyond the policy formulation stage and into implementation. Continuing to mobilize policy network actors into the implementation stage significantly increases the prospects for reform by embedding changes across systems and developing shared ownership at the implementation level. Policy networks are important sinews for implementation and delivery (Pal 2014), so early and continued engagement of relevant actors lays the groundwork for success.

Finally, this process involved both political and policy leadership. The political leadership (the Select Committee) was a unique feature when compared with past policy activity in the mental health and addictions domain. Committee membership from all three main political parties increased the likelihood that the Strategy would be sustained through changes in government.

Discussion

Our findings demonstrate that many of the features of the policy network and horizontal governance approach to policy making were present in the Government of Ontario's Strategy. Notably, our analysis revealed an expansion of the state pluralist network to include both governmental and non-governmental actors beyond those in the health sector. Second, we see examples of the various dimensions of horizontal governance as identified by Hopkins and colleagues (2001). The presence of these features reveals a deep commitment to responding to the challenges of the complex, multi-faceted problem of mental health policy in a comprehensive and collaborative way across multiple sectors and in both the policy formulation and policy implementation stages.

Although our findings offer an optimistic account regarding the potential for transformative change in mental health and addictions in Ontario, there are several limitations to policy network and horizontal governance approaches. One drawback is time. As this case illuminates, using a networked approach can be lengthy because of the coordination of inputs and consensus building required before decisions can be made. This approach may take longer than a centralized authoritative model of policy formulation, which places pressure on governments who want to be seen as "doing something" and making strides towards

reform. This challenge is amplified by relatively short electoral cycles, which can increase the impetus for swift action and constrain the perceived options for implementation. A related challenge is the value conflicts that arise during the policy development and implementation process and the need to create effective resolutions to ethical dilemmas that are encountered, particularly when the policy development and implementation process involves the engagement of such a wide array of actors. Scholars have suggested that network and horizontal approaches can ignore important political value conflicts because of the focus on consensus and partnership, which creates only shallow goal consensus and can result in a replication of silo practices that were meant to be avoided by using these approaches (Davies 2009).

In addition, actors who engage in horizontal and network approaches still must interact with and, to some degree, operate within the authoritative structures that exist in the system. Hierarchical organizations have not been designed for this mode of operation, which can have challenging consequences. For example, joint communications announcing the Strategy implementation initiatives were initially slow to surface. However, once these processes were established, they began to move more swiftly, and a subsequent memo with four ministry signatories was circulated to key actors in a timely way announcing a particular implementation initiative (Srinivasan 2012).

A further potential limitation of the network approach is the boundaries that networks create, resulting in some stakeholders being left out and therefore unable to contribute in a direct way. One example of stakeholders who were excluded from the network in this case was private sector service providers who continue to play a key role in delivering mental health and substance use services that are not covered by publicly funded health insurance plans.

Finally, networks require some form of governance and management. Applying a network approach requires both a different frame of thinking and a different way of acting. Network management has been acknowledged as no easy task (Klijn and Koppenjan 2000). When the government does not use horizontal governance and policy network approaches frequently, additional leadership and individuals with skills in brokering, communication and systems thinking are required. This is a particular challenge with high turnover in bureaucratic positions and leadership and will continue to be a challenge for the Ontario government as it manages the Strategy moving forward.

Underpinning any approach to reform is a need to resource the system appropriately to undertake the reforms and deliver services that meet the needs of citizens. As identified by Bartram and Lurie (2017), and as alluded to earlier, Canada has a long-standing gap in mental health funding relative to the disease burden of mental illnesses and addictions. Any reforms identified through this approach will require appropriate financial investments to ensure success.

Our study included a thorough document analysis but did not include other empirical strategies such as interviews or surveys with relevant actors, which would enrich the

understanding of the intricacies of the policy process related to the Strategy. This analysis is therefore most helpful in identifying the features of the policy process that are salient for future investigation and hypothesis development.

Because the Strategy is only midway through its implementation, there are many avenues for additional exploration as it continues to unfold. Future research should examine and measure the policy outcomes of the Strategy with the aim of specifying the components of the policy network and horizontal governance approach most important in explaining the policy outcomes. Comparative studies that examine Ontario's approach to that of other provinces/states based on either the same subject area (mental health and addictions) or on other similar policy network and horizontal governance approaches would yield additional explanatory power. Furthermore, studies comparing the costs of such approaches with more traditional approaches to health policy development and implementation, and related trade-offs in efficiency and outcomes, would be of value to begin to understand when such approaches are warranted. Moreover, quantitative social network analysis of the policy network could offer important insights into how the structure of the network and the ties among actors affect the policy outcomes (Brandes et al. 1999; Rhodes 2006). Finally, evaluation activities should focus on the changes implemented as a result of the policy, whether those changes address the original problems and if they result in positive outcomes for citizens.

Conclusion

Our analysis suggests that there is reason to be optimistic that the policy formulation and implementation stages of the Strategy as currently constructed have increased the likelihood for transformative change. Further evaluation will be required to determine whether this was enough to improve outcomes for Ontarians.

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RESEARCH PAPER

Satisfaction with Emergency Departments and Other Mental Health Services among Patients with Mental Disorders

Satisfaction envers les urgences et autres services de santé mentale chez les patients atteints de troubles mentaux

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Abstract

Background: Few studies have investigated satisfaction with emergency departments (EDs) among patients with mental health (MH) issues. This study evaluated the use of and satisfaction with EDs and other MH services among 328 patients with MH disorders, as well as specific characteristics of patient satisfaction and dissatisfaction.

Methods: A mixed-methods study was conducted in four EDs located in different administrative healthcare regions of Quebec (Canada).
Results: Patients were highly satisfied with staff attitudes in EDs and other MH services (i.e., hospital in-patient services, outpatient services, community organizations). Major sources of dissatisfaction were the information received in EDs concerning community services and the physical environment or climate in EDs and other MH services.
Conclusion: Dissatisfaction with services may be reduced by extending hours of operation in MH services; promoting collaboration between psychiatrists, family physicians and other primary care providers; further integrating EDs with other healthcare services; and improving the characteristically austere and restrictive atmosphere in EDs.

Résumé

Contexte : Peu d'études se sont penchées sur la satisfaction envers les urgences chez les patients qui s'y présentent en raison de maladie mentale. Cette étude évalue l'utilisation des urgences et autres services de santé mentale, ainsi que la satisfaction, auprès de 328 patients atteints de troubles mentaux. L'étude s'intéresse aussi aux caractéristiques particulières liées à la satisfaction ou à l'insatisfaction des patients.
Méthode : Une étude à méthode mixte a été menée dans quatre services des urgences situés dans différentes régions administratives sanitaires du Québec (Canada).
Résultats : Les patients se sont montrés hautement satisfaits de l'attitude du personnel dans les urgences et autres services de santé mentale (c'est-à-dire, les services aux hospitalisés, les services externes, les organismes communautaires). Les principales sources d'insatisfaction concernent l'information remise par les urgences au sujet des services communautaires ainsi que l'environnement physique ou les conditions ambiantes dans les urgences et autres services de santé mentale.
Conclusion : Le taux d'insatisfaction envers les services pourrait être réduit en prolongeant les heures d'ouverture des services de santé mentale; en favorisant la collaboration entre les psychiatres, les médecins de famille et les autres prestataires de soins primaires; en intégrant davantage les services des urgences aux autres services de santé; et en améliorant l'ambiance typiquement austère et restrictive des services des urgences.

While mental health (MH) services have become more patient-centred, ongoing assessment of patient satisfaction remains important for treatment and service planning (Ruggeri et al. 2006). Studies suggest that patient satisfaction is a major outcome of interest (O'Regan and Ryan 2009), if not the best predictor of service quality (Shipley et al. 2000). Patient satisfaction is, in fact, more reliable than evaluations by MH professionals (Shipley et al. 2000; Woodward et al. 2017) and is strongly related to service use and continuity of care, both viewed as influential in treatment outcomes

(Ruggeri et al. 2006; Woodward et al. 2017). Satisfied patients are more likely to maintain contact with services and comply with medication and treatment regimens, whereas dissatisfied patients drop out from services more frequently (Ruggeri et al. 2006). Because mental disorders often run hand-in-hand with chronic health problems, the long-term and continuous care of affected patients, and their satisfaction with services, is crucial (O'Regan and Ryan 2009). Better understanding of the determinants of patient satisfaction may help improve services.

Research has identified associations between patient satisfaction and service-related factors (Woodward et al. 2017), such as attitudes of MH professionals (Berghofer et al. 2001), and good professional/patient communication (Zahid et al. 2010). Environmental quality (e.g., calm, cleanliness, presence of rules and regulation, which may appear as restrictive measures) also emerged as an important determinant of satisfaction (Berghofer et al. 2001). Reduced wait times and rapid access to services have contributed to higher levels of satisfaction (Eytan et al. 2004; Roper and Manela 2000), as have professional competence (Ruggeri et al. 2007), staff availability (Summers and Happell 2003), continuity of care (Rosenheck et al. 1997) and the quality of information provided by services (Cleary et al. 2009; Zahid et al. 2010).

While studies have assessed satisfaction among patients with MH disorders regarding both hospital (Eytan et al. 2004; Zahid et al. 2010) and community-based (Urben et al. 2015) services, very few have investigated factors associated with satisfaction among patients presenting at EDs for MH reasons (O'Regan and Ryan 2009; Roper and Manela 2000; Summers and Happell 2003). ED services for MH patients involve different operating models. As with other patients, patients with MH disorders may be evaluated in a general ED by an emergency physician, possibly followed by a psychiatric evaluation. Alternatively, patients with MH disorders may be evaluated in a psychiatric ED separate from the general ED. Between these two extremes is the possibility that MH professionals may assess patients in a designated psychiatric location of a general ED or refer them to a psychiatric ED division within the same hospital (Halmer et al. 2015; Zeller 2010).

EDs provide round-the-clock crisis intervention for patients with MH disorders, serving all too often as the main point of entry to specialized MH services (Arfken et al. 2004). Yet, wait times for an MH evaluation in the ED greatly exceed the wait times for a physical examination. In Quebec, 31% of individuals who visit EDs for MH reasons wait eight hours on average before receiving a consultation with a psychiatrist (CSBE 2017). American studies found that wait times for hospital admission were three times longer for patients with MH disorders than for those with other medical conditions (Pearlmutter et al. 2017; Zeller et al. 2014). Considering that the overuse of EDs may reflect gaps in other areas of healthcare delivery (Ruggeri et al. 2006), it is important to identify key factors in patient satisfaction/dissatisfaction with the ED, while taking into account their perspectives on other MH services.

Studies using standardized questionnaires found that most patients with MH disorders were generally satisfied or very satisfied with MH services (Perreault et al. 2006; Williams et al. 1998), with mean satisfaction scores of 80% or higher often reported (O'Regan and Ryan 2009; Summers and Happell 2003; Svensson and Hansson 1994). Williams et al. (1998) contend that such high satisfaction is embedded in the design of evaluations, that is, while the questions guide patients to rate themselves as "satisfied" when services fulfill their overall objectives, any negative aspects remain unreported (Williams et al. 1998). Moreover, while patients with MH disorders expect services to address their problems effectively, they also value other aspects of services, such as positive professional/patient relationships. The use of qualitative methods addresses the limitations inherent in standardized measures by exploring various meanings attached to patient satisfaction. In particular, open questions facilitate expressions of dissatisfaction (O'Regan and Ryan 2009) and highlight areas needing improvement (Perreault et al. 2006). Using mixed methods, this study aimed to: (1) evaluate the satisfaction of 328 patients with MH disorders concerning their use of EDs and other MH services (hospital in-patient services, outpatient services and community organizations) and (2) identify specific aspects of EDs and other MH services with which patients were most, or least, satisfied.

Methods

Study setting

The study was conducted in four EDs that reflected different operating models identified in the literature; they were located in different administrative healthcare regions of Quebec (Canada). The selected EDs were as follows: a psychiatric ED completely separate from the general ED in an MH university institute, which offered no medical services (ED-P); a psychiatric ED that was a division of a general ED located at a separate site (ED-PG-1); a psychiatric ED merged with a general ED (ED-PG-2); and, finally, a general ED where staff included a number of additional MH specialists (ED-G). All sites had in-patient units offering specialized mental healthcare.

Data collection

Participant recruitment occurred between January and June 2017. Site visits were scattered throughout the days and hours that the EDs were operating at peak capacity, according to information provided by ED managers. Clinical team members in the EDs assisted recruitment by evaluating the ability of potential participants to provide informed consent. In cases where patients were too confused to participate in an interview, or were slated for transfer to another hospital unit, the interview was postponed until their MH conditions had stabilized, whether during or after hospitalization. Interviews were conducted in designated offices at the EDs by research assistants trained for this work and supervised by researchers. Patients completed a descriptive questionnaire that was developed based on previous research

(Fortin et al. 2018) and pretested by six ED users. The questionnaire included two standardized scales: (1) the Alcohol Use Disorders Identification Test (AUDIT) (Bohn et al. 1995), measuring alcohol use and sequelae on a five-point Likert scale (10 items); and (2) the Drug Abuse Screening Test-20 (DAST-20) (Carey et al. 2003), measuring consequences of drug use with yes/no responses (20 items). The descriptive questionnaire also included quantitative and qualitative components. The quantitative items concerned socio-demographic and socio-economic characteristics, patient health-related beliefs, self-assessed physical and MH conditions and satisfaction with/utilization of EDs and other MH services. The qualitative items on the questionnaire concerned reasons for ED use and appraisal of EDs and other MH services, including in-patient services, outpatient clinics, day hospitals, local community service centres, walk-in clinics, rehabilitation centres, crisis centres and other services within community organizations, as well as the services of family physicians and private psychologists. All participants provided written consent, and the Douglas Mental Health University Institute research ethics committee approved the multi-site study protocol.

Analysis

The study used a convergent mixed-method design (Pluye and Hong 2014) that integrated quantitative and qualitative data simultaneously. The quantitative data were first screened for missing values, univariate outliers and normality assumptions (skewness and kurtosis). Univariate analyses, including frequency distributions, percentages for categorical variables and central tendency measures for continuous variables (mean values and standard deviations), were performed. Qualitative data collection, and the mixed-method analysis, followed a five-step process: (1) audio-recording of interviews and verbatim transcriptions, (2) preliminary readings by two research team members who read through 10% of the interviews and further separated the data. The team coordinator validated inter-rater reliability at roughly 90%, (3) coding of the remaining 90% of interviews under supervision of the team coordinator, (4) data extraction and integration within units of meaning developed from items in the questionnaire and (5) data analysis (Titscher et al. 2000). Numbers and percentages were calculated for each qualitative variable, separating positive and negative responses, in an effort to assess whether positive or negative responses were more common. All data related to EDs and other MH services were organized into four broad categories, and related sub-categories, as follows: staff attitudes and behaviours, wait times and delays in access to services, physical environment/climate and quality of services received.

Results

Sample characteristics

The participant response rate was 88%, with 328 patients agreeing to participate of 372 invited to the study. Most participants (n = 172; 52%) were recruited at ED-P, versus 89

(27%) at ED-PG-2, 38 (12%) at ED-PG-1 and 29 (9%) at ED-G. A majority of interviews were conducted at the EDs (n = 188; 57%) and the remainder (n = 140; 43%) in in-patient units.

Table 1 – available online at www.longwoods.com/content/25793 – presents participant characteristics. Mean age in this sample was 38.9 years (SD: 15.2). Participants were 51% female; 80% lived in private houses, condos or rental apartments; 80% were single, separated, divorced or widowed; and 62% did not have children. A majority had post-secondary education (56%), were unemployed (67%) and earned less than $40,000/year (70%). Most participants (62%) rated their MH as fair or poor, although 59% considered themselves to be in excellent physical health. Nearly all participants (91%) viewed their presenting problem at the ED as important or very important. The main reasons for ED use included suicidal ideation or attempt (28%), depression (12%) and anxiety (11%). Moreover, 30% engaged in harmful, or hazardous, alcohol use (AUDIT score = 8 or over), and 28% were affected by drug abuse or dependence (DAST-20 score = 6 or more). Some participants (13%) experienced both alcohol and drug disorders. Another 12 participants (4%) admitted to problems with gambling in the previous 12 months (Table 1).

ED and other MH service use

Participants visited EDs for mental disorders or substance use disorders (SUDs) an average of 2.4 times (SD: 3.8) over the 12-month study period. Forty-five (14%) were frequent ED users, defined as four or more ED visits in the previous 12 months. Concerning general service use, 41% of participants reported having poor knowledge of MH or addiction services. A majority (63%) had used services other than EDs for MH or SUD-related reasons over the study period. Most had a family physician (65%), a psychiatrist (55%) or other healthcare provider (e.g., nurse, social worker) (41%) (Table 1).

Satisfaction with ER and other MH services

The quantitative results on satisfaction with services are shown in Table 2 (available online at www.longwoods.com/content/25793). Concerning EDs, most participants agreed somewhat or totally with the suggestion that staff were respectful (95%) and that staff had a good opinion of them/treated them fairly (91%). Most agreed somewhat or totally that EDs provided adequate treatment for their problems (78%) and gave sufficient information on treatment options (77%). Yet, 40% of participants did not consider the information received on community services adequate to their needs.

Concerning other MH services, 90% of participants felt that service providers had a good opinion of them/treated them fairly. A great majority of participants felt that services outside of EDs responded to their needs (238/297; 80%); they were somewhat or totally satisfied with the care received from family physicians (n = 182/213; 85%), psychiatrists (n = 130/147; 88%) or their other providers (n = 130/133; 98%).

Table 3 (available online at www.longwoods.com/content/25793) presents both positive and negative comments from participants concerning services received at the

ED or from other MH services, based on qualitative data. Illustrative quotations are provided in Table 4 (available online at www.longwoods.com/content/25793). Regarding EDs, 286 (87%) of participants made at least one positive comment, and 173 (53%) made at least one negative comment. Most of the positive comments referred to the respect, calm and courtesy shown by ED staff (191/286; 67%) (staff attitudes/behaviours), followed by quality of services (119/286; 42%); empathy and listening ability among ED staff (n = 113/286; 40%) (staff attitudes/behaviours); wait times and access to services (n = 79/286; 28%); and the calm, comfort, cleanliness and security provided by EDs (n = 26/286; 9%) (physical environment/climate). The 173 participants who made at least one negative comment most often criticized EDs for the lack of calm, comfort, cleanliness and security (69/173; 40%); followed by lack of empathy or listening skills on the part of ED staff (n = 57/173; 33%); wait times and delays in accessing services (n = 57/173; 33%); quality of services offered (n = 52/173; 30%); lack of respect from ED staff (n = 45/173; 26%); and rules and regulations (e.g., smoking ban, inspection of personal effects, surveillance), which may appear as restrictive measures (n = 30/173; 17%).

Comments made by 119 participants on the quality of services offered at the ED tended to be positive with respect to follow-up (n = 35/119; 29%), knowledge of MH among ED staff (n = 34/119; 29%) and staff availability (n = 29/119; 24%). Of 52 participants who made at least one negative comment on the quality of ED services, most were critical of information received regarding follow-up (n = 27/52; 52%); staff availability (n = 20/52; 38%); and the availability of activities, meals and socialization (n = 11; 21%).

On the question of other MH services, 226 (69%) participants made at least one positive comment and 183 (56%) at least one negative comment. Concerning the former, a majority appreciated the quality of services (n = 120/226; 53%); followed by appreciation of staff for their respect, calm and courtesy (n = 88/226; 39%); empathy and listening ability of staff (n = 77/226; 34%); service environments characterized as calm, comfortable, clean and safe (n = 10/226; 4%); rules and regulations (n = 9/226; 4%); and reasonable wait times or accessibility of services (n = 8/226; 4%). Among the negative comments provided by 183 participants in relation to other MH services, most involved issues with the quality of services (n = 124/183; 68%); followed by wait times and access to services (n = 61/183; 33%); empathy and listening ability of staff (n = 20/183; 11%); rules and regulations (n = 20/183; 11%); respect, calm and courtesy of staff towards patients (n = 16/183; 9%); and environments that were not calm, comfortable, clean and/or safe (n = 15/183; 8%).

Of 120 participants who made at least one positive comment about the quality of other MH services, most concerned follow-up (n = 53/120; 44%); staff availability (n = 46/120; 38%); and activities, meals and socialization (n = 36/120; 30%). Of 124 who made one or more negative comments about the quality of other MH services, most were critical of follow-up (n = 41/124; 33%); staff MH knowledge (n = 41/124; 33%); staff availability (n = 28/124; 23%); and the capacity of services to meet needs (n = 24/124; 19%).

Discussion

The characteristics of participants in this study were similar to those in previous studies that assessed ED use for MH reasons in Canada, Australia, New Zealand, the UK and elsewhere in Western Europe (Barratt et al. 2016). Most participants had experienced suicidal ideation or attempts, depression, anxiety and SUDs, which are frequent causes of ED use. Many were affected by negative socio-economic conditions related to low income and unemployment, which are thought to exacerbate MH problems. Patients with MH problems frequently visit EDs because they also need help in other areas (i.e., problems with housing, work or social relationships) (Parkman et al. 2017). As well, a large proportion of participants had not used services outside of the ED in the previous 12 months, which is similar to results of American epidemiological studies (Mojtabai et al. 2002).

Levels of satisfaction with both EDs and other MH services were very high, based on the quantitative results, except for the variable on information received in the ED about community services. ED use seemed to result from ignorance of other MH services, especially among the many patients in this study who were not receiving community follow-up from other sources. Previous research conducted in Australia and Kuwait identified substantial dissatisfaction around information provided by MH services (Cleary et al. 2009; Zahid et al. 2010), similar to our results. Other research from the US reported an association between satisfaction with care and provision of information relevant to patient needs (Roper and Manela 2000).

The qualitative data also revealed more positive than negative comments, although the negative comments were particularly important. The use of open questions allowed participants to make more nuanced observations that revealed key factors of dissatisfaction.

Both quantitative and qualitative findings revealed higher levels of satisfaction with respect to professional attitudes and behaviours, which coincides with the literature (Berghofer et al. 2001). Good therapeutic relationships are needed to ensure continuity of care and positive outcomes among patients with MH disorders. By contrast, negative professional attitudes risk increasing emotional distress in patients and undermining treatment (Harris et al. 2016). A lack of communication skills among patients may also provoke stigmatizing attitudes towards them on the part of MH professionals. Negative professional attitudes are particularly directed at frequent ED users or those less compliant with medications or treatment protocols (Harris et al. 2016).

Results also showed that participants preferred the ED to other MH services for MH issues, particularly because of relatively shorter wait times and rapid access to follow-up services in the ED. According to the literature, satisfaction with ED services is inversely related to wait times: the shorter the wait, the greater the patient satisfaction (Roper and Manela 2000). Concerning other MH services, difficulties and dissatisfaction emerged around problems of access, usually related to the lack of evening and weekend hours or problems in booking appointments. This may explain the high use of EDs for non-urgent situations. In addition, the number of negative comments regarding quality of ED services was less than

half the number reported for other MH services, especially in relation to staff knowledge around MH issues, follow-up and the capacity of MH services to meet patient needs. Some patients deplored the lack of MH expertise among family physicians as previously reported (Su et al. 2011). Furthermore, good follow-up and continuity of care improved levels of satisfaction with services (Fortin et al. 2018). This same study also identified an association between patient satisfaction and fewer unmet needs. In fact, ED services were viewed as less satisfactory in comparison with other MH services but only in terms of the activities, meals and socialization provided at the ED. This finding was not entirely surprising, as EDs are not designed to provide the same type of environment as that offered by community organizations (e.g., day centres, self-help groups) serving people with MH problems. One American study reported higher patient satisfaction with EDs that provided opportunities to engage in activities (Roper and Manela 2000). Finally, participant comments around the physical environment and climate in EDs were overwhelmingly negative, both for EDs and MH services. In this study, as in others from the US, patients with MH disorders associated EDs with noise, lack of privacy and loss of freedom (Harris et al. 2016). Patients admitted voluntarily were less affected by rules and regulations, which may appear as restrictive measures, and were generally more satisfied than those admitted under treatment order (Woodward et al. 2017).

Limitations

Certain study limitations should be acknowledged. First, because the results are limited to particular EDs, they may not be generalized to other ED settings (e.g., in rural areas) whether in Quebec or elsewhere. Second, the mixed methodology was not sensitive to possible differences among patients with MH disorders in terms of the various ED operating models. Third, ED-P participants were over-represented in the sample, whereas the number of ED-G participants was low. It is possible that the over-representation of ED-P patients positively influenced results on some dimensions (e.g., quality of services offered) but may have had a negative influence on others (e.g., rules and regulations). Fourth, the mixed-methods design did not allow us to distinguish possible differences in satisfaction among participants in terms of diagnoses. According to the literature, MH disorders, such as SUD or personality disorders, are often associated with both greater utilization of ED services and greater dissatisfaction with the help received (Lawn and McMahon 2015; Parkman et al. 2017). Fifth, the study design did not allow for the measurement of statistical differences in participant satisfaction with EDs and other MH services. Sixth, it was impossible to measure statistical differences between satisfied and unsatisfied participants, as these two groups were not mutually exclusive. Seventh, considerable disparity emerged in the numbers of comments made by participants, as some were less forthcoming than others in their responses. Finally, patient perspectives were sought exclusively, as ED professionals were not invited to complete questionnaires. Yet, patient perspectives concerning satisfaction with services may differ from those of ED professionals, including physicians or managers, who were not included in the study.

Conclusion

This study was innovative in using mixed methods to evaluate satisfaction with EDs and MH services among patients with MH disorders and to further identify specific areas of satisfaction and dissatisfaction with those services. Results show that participants were most satisfied with staff attitudes and behaviours in both EDs and other MH services. Results also revealed greater satisfaction with EDs, particularly in terms of shorter wait times, relative to other MH services, which may explain the high use of EDs by study participants. By contrast, participants tended to view the quality of services outside the ED more critically. Issues also emerged around the physical environment and climate of both EDs and other MH services, which were important sources of dissatisfaction for patients. Moreover, both quantitative and qualitative data revealed a high level of dissatisfaction with information provided about community services available to patients. Recommendations for reducing dissatisfaction with EDs and other MH services might include extending evening and weekend hours in MH services as a way of improving access; and better continuity of care. The expansion of case management programs may also improve client follow-up to ED visits. Further integration of EDs and other MH services through service agreements, use of liaison officers in EDs and shared staff training may also increase awareness among ED professionals of available services for this patient population. Greater collaboration should also be promoted between psychiatrists and family physicians or other primary care providers in the interests of knowledge translation. Finally, it would be important to transform EDs from austere and restrictive environments to more user-friendly sites conducive to individual recovery.

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RESEARCH PAPER

Integrated Knowledge Translation with Public Health Policy Makers: A Scoping Review

Application des connaissances intégrée auprès des décideurs en santé publique : un examen de la portée de la littérature

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Abstract

Integrated knowledge translation (iKT) refers to the engagement of knowledge users (e.g., policy makers, clinicians, patients) as active participants in the research process. Theoretically, this involvement enhances research relevancy and usefulness, thereby supporting health system change. However, evidence to support best practices for iKT is lacking, particularly in a public health context and with non-clinical decision-makers. The objectives of this research were to report how decision-maker involvement in public health iKT research has been described and operationalized and whether the process was evaluated. We conducted a scoping review of published literature from January 2005 to December 2017 and extracted information related to iKT involvement, barriers and facilitators and outcomes.

Studies typically did not distinguish between different kinds of knowledge users, making it impossible to comment specifically on decision-makers' involvement. Authors believed knowledge user involvement was beneficial to the quality and potential impact of research activities, although corroborating evaluation data were unavailable. Broad research–knowledge user partnerships spanning multiple projects, as well as flexible involvement of knowledge users, enhanced engagement and supported the iKT process.

Résumé

L'application des connaissances intégrée (ACi) est une approche qui met à contribution les utilisateurs des connaissances (p. ex., responsables de politiques, cliniciens, patients) en tant que participants actifs au processus de recherche. Théoriquement, ce type de participation accroît la pertinence et l'utilité de la recherche, ce qui favorise le changement dans le système de santé. Toutefois, il y a un manque de données pour étayer les pratiques exemplaires en ACi, en particulier dans le contexte de la santé publique ainsi qu'auprès des décideurs des milieux autres que cliniques. L'objectif de cet examen est, dans un premier lieu, de rendre compte de la façon dont est décrite la participation des décideurs dans les recherches qui mettent en pratique l'ACi et, ensuite, de voir dans quelle mesure le processus a été évalué. Nous avons mené un examen de la portée de la littérature publiée entre janvier 2005 et décembre 2017, puis nous avons extrait les renseignements liés à la participation, aux obstacles, aux facteurs favorables et aux résultats de l'ACi. Les études considérées ne font pas nécessairement la distinction entre les divers types d'utilisateurs des connaissances, ce qui rend impossible un compte rendu sur la participation particulière des décideurs. Les auteurs estiment que la participation des utilisateurs des connaissances présente un avantage pour la qualité et l'impact potentiel des activités de recherche, bien que les données venant corroborer ce fait ne soient pas disponibles. De vaste partenariats multi-projets réunissant chercheurs et utilisateurs des connaissances, de même qu'une flexibilité dans la participation des utilisateurs des connaissances, permettraient d'améliorer l'engagement et d'appuyer les processus de l'ACi.

Background

"Wicked" problems are characterized by multiple causes within complicated and dynamic social and political contexts (Rittel and Webber 1973). Many public health challenges – inactivity, unhealthy eating, problematic substance use, the effect of the environment on health – are "wicked" (Kreuter et al. 2004), thereby requiring the synthesis, interpretation, translation and mobilization of vast bodies of evidence to arrive at optimal solutions (Brownson et al. 2009; Kitson et al. 2013; Lobb and Colditz 2013). Evidence-informed

public health decision-making necessitates the use and adaptation of evidence from applied health research to support public health policy and program development (Boyko 2015; Brownson et al. 2012; Brownson et al. 2006).

One approach to maximizing the effect of evidence on policy and practice is to work with the intended recipients of research evidence: knowledge users (KUs). Participatory models of research (e.g., community-based participatory research, participatory action research) have been used in public health to work with communities to better develop, implement and evaluate research interventions and translate findings into meaningful change (Ahmed and Palermo 2010; Wallerstein and Duran 2010). These methods have been used to develop a sense of community "ownership" of issues and galvanize community action as a method for social change (Israel et al. 1998). Building partnerships between researchers and community stakeholders is a complex and active process, but it can add value to the research process by creating better quality research outputs and enhancing the sustainability of project goals while also building capacity in stakeholder groups (Jagosh et al. 2012).

In Canada, integrated knowledge translation (iKT) is a similar approach that has gained considerable traction (Bowen and Graham 2013; Graham 2012; Kothari and Wathen 2013). iKT has many similarities with participatory methods, including the shared desire to co-create knowledge to improve current conditions (Jull et al. 2017). Both blur the distinction between researchers and research participants; both acknowledge that knowledge development is influenced by values and widen the ambit of "acceptable" knowledge by negotiating perspectives between researcher producers and research users (Jull et al. 2017). Given the history of community-based participatory research, there are also many lessons to inform KT approaches, such as the underlying principles for working together, structures that support this collaboration, the processes for working together and the dynamics of the relationship itself (Lencucha et al. 2010). However, while participatory approaches emphasize community-driven solutions, iKT is intended to generate research-based solutions, and KUs are involved because of their authority to invoke change following the completion of the research (Gagliardi et al. 2016; Kothari and Wathen 2017). Participatory research and iKT also differ in terms of their respective historical motivations (social justice, as opposed to application of knowledge) and social locations (grassroots-/citizen-led, as opposed to health decision-makers) (Jull et al. 2017).

Given the centrality of generating research that are relevant to KUs and can be adopted into practice, there is an expectation of involving KUs throughout the research process, including refining research questions, developing research methods, analyzing findings and sharing results (Graham 2012). Strengthening the relevancy of research findings to KUs can support research-informed decision-making (Innvaer et al. 2002; Oliver et al. 2014); produces research that is more contextually applicable (McLean et al. 2012); improves researcher–KU relationships for future collaborations (Kothari and Wathen 2013); and leads

to better social, research and health services outcomes (Gagliardi et al. 2014).

The translation of knowledge into improved health and health services, and iKT by extension, was enshrined in the act of parliament that created the Canadian Institutes of Health Research (CIHR) (The Government of Canada 2000). The push for KT stemmed from two factors: (1) a growing awareness that active efforts were needed for knowledge to be widely used in policy and practice and; (2) a trend in government and public demand for spending to be more in line with, and accountable to, public good (McLean et al. 2013; Tetroe 2007). Activities have included requiring KT plans as a condition for funding, as well as providing resources and training for KT, including iKT (Graham 2012). Another relatively recent innovation was the 2011 launch of CIHR's Strategic Patient-Oriented Research (SPOR) initiative, designed to strengthen the ability of researchers and health system personnel to work with patients to produce research with a greater likelihood of improving health systems and practices (Strategy for Patient-Oriented Research 2014). While still in its infancy and not without areas for improvement (e.g., clarification of mandate, evaluation of outcomes), the SPOR initiative has been effective at engaging stakeholders and building interest and support for patient-oriented research (KPMG LLP 2016).

Canada is also by no means the only country to create structures and supports to foster relationships between health system partners and encourage the movement from research to influence health system change. The CLAHRC collaborative in the UK comprises multiple university–healthcare organization partnerships and has yielded important insights about the structures and processes, which support the adoption of evidence into practice (Fitzgerald and Harvey 2015; Rycroft-Malone et al. 2016). Other examples of programs or systems enhancing how researchers and other system stakeholders and service users work together include the Australian Prevention Partnership Centre (Wilson et al. 2014) and the World Health Organization-directed Evidence-Informed Policy Networks (EVIPNet) spanning continental communities (World Health Organization 2015).

Policy and decision-makers (PDMs) play a vital role in public health policy development and initiation and are key KUs to consider when conducting public health research. Although the use of research evidence by PDMs can strengthen health system performance and improve individual health outcomes, there are many barriers to its use including poor access to relevant, timely, context-sensitive and understandable research (Innvaer et al. 2002; Lavis et al. 2003; Lavis et al. 2012; Oliver et al. 2014; Orton et al. 2011). While iKT is intended to overcome many of these issues, it also presents additional challenges: iKT activities often require considerable time commitments, may not produce results that lead to immediate policy or practice change and are often not rewarded by traditional academic or PDM advancement structures (Kothari and Wathen 2013). Even in cases of nationally funded iKT research, KU engagement can be "tokenistic" (Sibbald et al. 2014).

While evidence regarding how iKT activities are currently being structured to enhance engagement with KUs is sparse (Kothari and Wathen 2017), there are some emerging best practices. A recent scoping review on iKT in healthcare noted that facilitators reported by

multiple authors included multiple – and varied – opportunities for KUs to contribute to the research, as well as strong leadership and a phased approach to allow time for building shared understanding and early successes (Gagliardi et al. 2016). These are similar to the "3 Ts" reported by Wathen and colleagues (2011) from their four-year KT and exchange project with stakeholders in the area of violence prevention; *talk*, *trust* and *time* were key factors to effectively engaging with stakeholders and enhancing their receptivity to acting on research findings (Wathen et al. 2011). Other potential models for iKT, such as consensus-based approaches (i.e., where researchers and KUs work together to solve problems and determine how their answers can be used) and interorganizational networks, offer new ways for thinking about how iKT research can be successfully conducted (Kothari and Wathen 2017).

However, evidence-informed policy making is more nuanced than simply getting the right evidence into the right hands. Consider public vaccination programs: While PDMs can use evidence to help choose a course of action (e.g., What vaccine does scientific evidence suggest will be most effective at immunizing people from the flu this year?), there are other decisional factors that cannot be found in the research literature (e.g., How much more are we willing to pay for a more effective vaccine?). Moreover, PDMs must also consider *how* a course of action can be most successful in a given setting and consider factors such as equity (e.g., Should we prioritize access for vulnerable populations?) and workforce planning (Are the benefits of a new vaccination protocol worth the costs of new training and safety requirements?), as well as ponder if more far-ranging and fundamental shifts are worth pursuing (e.g., What are the implications of a mandatory vaccination program for healthcare providers?). PDMs must thus consider and prioritize many factors in addition to evidence when deciding on public policy, including political priorities, the political capital required to affect change, the timeline of the commitment, public values, stakeholder input and the optimal return of investing limited resources (Andermann et al. 2016; Cairney and Oliver 2017; Lavis et al. 2009; Liverani et al. 2013; Moat et al. 2013). For example, the "3I+E" framework proposes that *Ideas*, *Interests*, *Institutions* and *External Factors* are the drivers of policy decisions (Lavis et al. 2012); in this conceptualization, research evidence constitutes a single kind of "idea" for how the world should be. Models that conceptualize evidence uptake as a transfer problem between research producers and research users have been criticized for their ignorance of these political factors and processes, and are therefore of limited utility to the policy community (Cairney et al. 2016).

Moreover, given the complexity of health policy making, how PDMs might use evidence is likely to be different from other KU groups (e.g., clinicians) and thus must be supported differently. For example, with near-perfect knowledge of a condition and confounding variables – e.g., allergies, interactions with other medications, risk of complications – a clinician should be able to determine a course of action with a high degree of confidence. This reductionistic logic is challenged in policy settings, where PDMs must consider not just what to do about a perceived problem, but what the problem is, how best to implement a solution that

will be feasible within a contested ideological jurisdiction and whether to prioritize this problem at the expense of limited resources (Cairney and Oliver 2017). Depending on the "phase" of decision-making, PDMs may use evidence to prioritize areas of interest or dispute claims of interest groups for attention (*agenda setting*), reduce uncertainty and improve confidence in options as well as reduce duplication of services (*policy development*) or provide a basis for ongoing program improvement and an impetus for accountability (*monitoring and evaluation*) (Lomas and Brown 2009). In addition, while PDMs can use evidence *instrumentally* to directly inform a policy decision, they may also use it to *conceptually* inform their thinking of an issue or *symbolically* to justify a course of action that was already decided ("decision-informed evidence making") (Amara et al. 2004; Weiss 1979).

Accordingly, successful iKT with PDMs signifies more than just a willing audience for research; aligning the goals and objectives of knowledge producers and KUs is intended to influence the research process such that it is tailored to support the needs of policy makers, and findings are more readily integrated into the decision-making process. Given that a key component of iKT is engaging those who have the authority to apply research findings to a problem, and that the basis of this process is developing a shared understanding so that evidence generated is more likely to be of use amidst other decision factors, learning from existing iKT descriptions stands to support future public health research. Given the primacy of iKT research in Canada as indicated by dedicated resources and funding opportunities (Graham 2012), as well as evidence that meaningful KU engagement is not always achieved (Sibbald et al. 2014), a better understanding of how to successfully conduct iKT research is beneficial to the public health research community. As such, the objectives of this study were to explore how PDMs' involvement in public health iKT research has been described and operationalized in the public health research literature and whether there is convincing evidence for the impacts of an iKT approach.

Methods

To understand how PDMs have been involved in public health iKT research, we conducted a scoping review. A scoping review follows a transparent and replicable process of mapping the literature in a systematic way and is useful for describing unexplored or developing topics and identifying gaps (Arksey and O'Malley 2005; Daudt et al. 2013; Levac et al. 2010). An iterative approach was used to conduct the scoping review, where we critically reflected at every step of the process to adapt our approach (e.g., inclusion criteria, data charting) to best answer the question based on the mapping of the literature (Arksey and O'Malley 2005).

First, a research librarian was consulted to assist in the development of the search strategy for PubMed, CINAHL and EMBASE databases. The searches used the "AND" operator to identify articles across three areas: knowledge translation, public health and policy making (see Appendix A at www.longwoods.com/content/25792 for detailed strategy, including construction of search areas). The search strategy was initially pilot tested to ensure that specific key articles were identified (Arksey and O'Malley 2005). Searches

were limited from January 2005 (two years before the earliest known use of the term iKT the authors could identify) (Graham and Tetroe 2007) to December 2017. We also hand-searched the table of contents of four relevant journals (*Milbank Quarterly*, *Implementation Science*, *Health Research Policy and Systems* and *Evidence & Policy*). In addition to searching databases, a search was carried out through Google Scholar in January 2016 using the term "integrated knowledge translation," as a mix of search engines enables greater capture of articles that may otherwise be missed (Rothfus et al. 2016). Protocol papers that met inclusion criteria were also forward-searched via Google Scholar to identify completed works.

All citations were imported into a reference manager program (RefWorks) where duplicates were removed. Two reviewers independently applied inclusion and exclusion criteria to citation titles and abstracts to select relevant studies for full-text review (Appendix A). As per scoping review methodology, our inclusion criteria were adapted based on our findings. For example, we included overviews of research initiatives even if these did not report results of the primary studies, as they provided valuable detail on the iKT processes used. We also broadened our definition of PDM to include individuals involved across stages of the policy making process, including decision-making (e.g., "politician," "civil servant") (Lavis et al. 2013) as well as policy implementation and evaluation (e.g., "administrator," "manager") (Fafard 2008). Disagreements were resolved through discussion and consensus, with reviewers erring on the side of inclusion to ensure that all relevant studies were captured. Two authors (LL and AB) then independently performed full-text screening.

Data extraction was based on factors or variables identified in the iKT literature, such as how KUs were involved in the research process (e.g., informing the research question; collecting, analyzing and interpreting data, disseminating findings) (Bowen and Graham 2013; Graham 2012; Shen et al. 2016). Other extracted characteristics of the iKT process included the development of the researcher–KU relationship (e.g., trust, mutual learning) (Sibbald et al. 2014) and evaluation of the iKT process (Bhattacharyya et al. 2013). The data extraction form was pilot-tested prior to commencing the full search and adapted iteratively to capture emergent salient details, such as the kind of study (e.g., protocol, single project or overview of a larger research initiative) and challenges and facilitators to the iKT process (Appendix B).

Quality appraisal was conducted using the Mixed Methods Appraisal Tool (MMAT) (Pluye et al. 2011) to describe the quality of identified studies. The MMAT has been previously used in scoping reviews in the field of KT and is useful when included studies span a variety of research designs (Dagenais et al. 2013).

Results

A total of 3,848 citations were screened, of which 232 were advanced for full text review. Twenty-six articles were selected for data extraction; during this process, six were excluded because of their setting (e.g., clinical care), leaving 20 articles in the final review (see Figure 1 for PRISMA Flow Diagram). Included studies spanned a variety of subject areas and

designs (see Table 1 for descriptive characteristics, available online at www.longwoods.com/content/25792). There were three types of article formats: protocols, single studies and descriptive reports providing "overviews" of research programs employing an iKT approach.

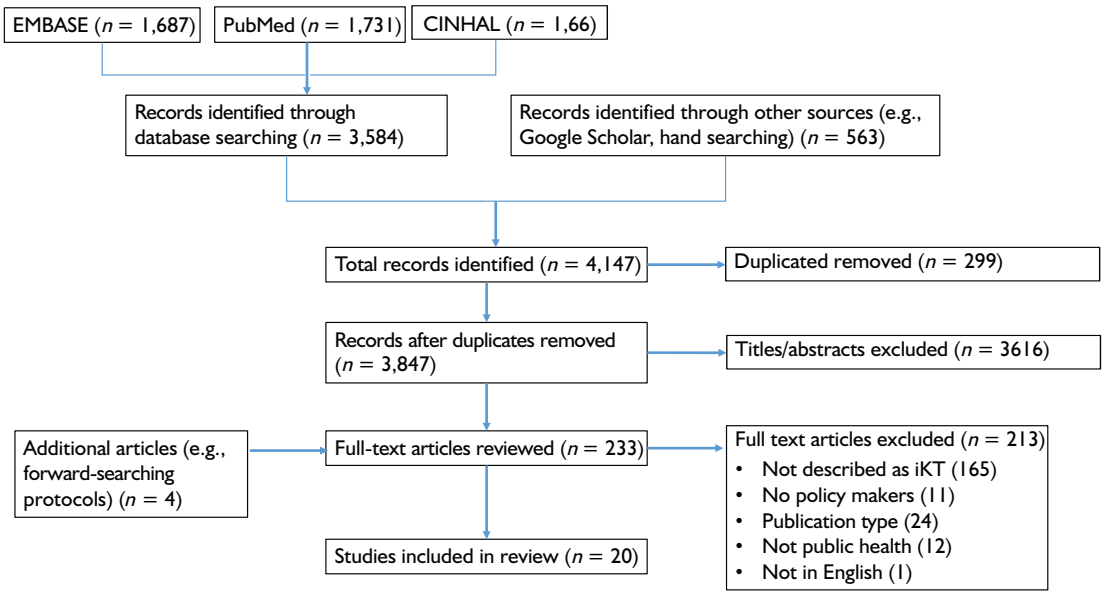
When the affiliation of PDMs was specified, they often represented provincial governments or health authorities, although other policy actors representing the federal government, research funders or policy-related services or agencies (e.g., World Health Organization, Public Health Agency of Canada) were also included (Table 1). Only one project (Oelke et al. 2015) worked solely with PDMs as part of their iKT process, although other stakeholders were to be included at a later phase. Other KUs included health providers, patients and their families, members of the public and representatives from other KT and community health organizations.

With one exception, authors described the involvement of KUs as one entity rather than describing the individual roles of the different groups of KUs in a given project (McGrath et al. 2009). It was therefore not possible to determine the contributions of PDMs relative to other types of KUs; as such, we report on iKT with KUs in general rather than PDMs specifically.

Rationale for iKT

All studies provided reasons for involving KUs (i.e., assumptions about the theoretical merits of iKT), though it was occasionally unclear whether this could be attributed to an iKT approach or to something else (e.g., using community-based participatory research principles). While some introduced the value of KU involvement as a general enhancement to the research process (e.g., multiple perspectives) (Bullock et al. 2010; Henderson et al. 2014; Iyer

FIGURE 1. PRISMA Flow Diagram



et al. 2015; Pelletier et al. 2011; Porter et al. 2012; Valaitis et al. 2012; Welch et al. 2015), others anticipated KUs to assist in research design, such as shaping research questions or deciding research priorities (Bornstein et al. 2017; Hayden et al. 2015; Kothari et al. 2014a; Naqshbandi Hayward et al. 2016) and/or informing methods (e.g., intervention content) (Boivin et al. 2011; McGrath et al. 2009; Wathen et al. 2011). Many believed that involving KUs would improve the use of their research (i.e., enhanced relevance and utility of research findings and adaptability to user contexts) and its spread (i.e., timely and facilitated dissemination, uptake or use of research findings, as well as overcome resistance to new ideas). The majority of rationales stated that KUs would assist in their dissemination or uptake, although in a few cases, some KUs were expected to help implement the research or interpret the findings. This included reducing potential resistance to new ideas (McGrath et al. 2009), understanding their preferences for how best to translate or exchange findings (Henderson et al. 2014) and ensuring relevancy to KU needs (Bullock et al. 2010; Henderson et al. 2013; Kothari et al. 2014a, b; Naqshbandi Hayward et al. 2017; Oelke et al. 2015). In two cases, KUs had requested and funded the research (Bullock et al. 2010; Hayden et al. 2015).

Engaging KUs in Research Process

Authors' descriptions of KU involvement across all aspects of the iKT research were often unclear, making it difficult to discern the level of engagement. Based on unequivocal descriptions of involvement, KUs helped to: (1) develop research questions (Bornstein et al. 2017; Bullock et al. 2010; Hayden et al. 2015; Naqshbandi Hayward et al. 2016; Oelke et al. 2015; Pelletier et al. 2011; Valaitis et al. 2012), (2) inform methods (Bornstein et al. 2017; Bryant et al. 2011; Bullock et al. 2010; Fortin et al. 2016; Hayden et al. 2015; Henderson et al. 2013, 2014; Iyer et al. 2015; McGrath et al. 2009; Porter et al. 2012; Wathen et al. 2011; Welch et al. 2015), (3) collect and analyze data (Boivin et al. 2011; Bornstein et al. 2017; Bryant et al. 2011; Fortin et al. 2016; Iyer et al. 2015; Naqshbandi Hayward et al. 2016; Porter et al. 2012; Valaitis et al. 2012), (4) interpret results and craft the overall message (Boivin et al. 2011; Bornstein et al. 2017; Bullock et al. 2010; Fortin et al. 2016; Hayden et al. 2015; Kothari et al. 2014b; Naqshbandi Hayward et al. 2016; Oelke et al. 2015; Porter et al. 2012; Valaitis et al. 2012; Wathen et al. 2011); and (5) share findings and move research into practice (Boivin et al. 2011; Bornstein et al. 2017; Bullock et al. 2010; Fortin et al. 2016; Hayden et al. 2015; McGrath et al. 2009; Naqshbandi Hayward et al. 2016; Oelke et al. 2015). Out of these five kinds of opportunities, studies reported an average of two involvement activities and ranged from describing none (Kothari et al. 2014b; Rosella et al. 2014) to all five (Bornstein et al. 2017). However, some studies, such as Rosella and colleagues (2014), did mention working with KUs to guide evaluation, which was not captured in our data extraction.

In addition to meetings with KUs (e.g., face-to-face, teleconference, project launch), engagement activities included exchange forums or think tanks, as well as using existing planning events to work with KUs. Other iKT activities included workshops, online

communities and using knowledge brokers. Surveys were used to elicit specific information from KUs, while consultation and small work groups and individual interviews were used to support larger KU engagement efforts; Henderson and colleagues (2014) differentiated between information sharing and formal and informal input-seeking, suggesting that different methods of engagement serve different functions. More general methods of KU contribution included executive or advisory committees, site-specific or local advisory groups and networking events. Strategies for sharing information, plans and research proposals with KUs included regular updates or reports/newsletters, distributing summaries or briefs, media press releases, conferences, presentations, website content and teleconference updates.

Less than half the studies explicitly described the contribution KUs made to the research, such as prioritizing research questions (Hayden et al. 2015), providing contextual information that helped frame the research findings (Bullock et al. 2010), developing quality indicators (Bryant et al. 2011), planning implementation blueprint (Boivin et al. 2011) and centralizing the voices required for determining success (Naqshbandi Hayward et al. 2016). Three studies noted that their methodology evolved or was flexible as a result of working with their KUs (Bornstein et al. 2017; Fortin et al. 2016; Hayden et al. 2015). Table 2 (available online at www.longwoods.com/content/25792) describes the challenges, barriers and facilitators to iKT identified in the included studies. It was unclear whether KUs were co-authors on publications.

Managing Relationships and Challenges

Despite the importance of the relationship with KUs, few studies described existing relationships with KUs or how the iKT partnership developed. Only one study reported on the relationship they had with their main KU (Bullock et al. 2010), although two reported on how their relationship with KUs had changed over time and led to new initiatives (Bornstein et al. 2017; Fortin et al. 2016). The challenges of working with KUs reported by a minority of authors fell into three broad categories: logistics and coordination (e.g., resource use, time, information sharing), negotiating tensions and building shared understanding (e.g., aligning research and policy considerations), and external constraints (e.g., changes in personnel and political priorities). While solutions were not offered for all challenges, authors offered advice as to how they overcame some challenges and would structure future projects.

The time and resources required to do iKT optimally were substantial, although face-to-face meetings were seen as worth the time and cost (Fortin et al. 2016; Hayden et al. 2015; Henderson et al. 2013, 2014; Kothari et al. 2014b; McGrath et al. 2009; Valaitis et al. 2012). Authors recommended budgeting for these activities (McGrath et al. 2009) and that engagement is considered as the project is conceptualized (Henderson et al. 2014). Meeting the information needs of multiple KU partners was also challenging, both in terms of providing timely updates as well as balancing different information needs without privileging some KUs (Bullock et al. 2010; Kothari et al. 2014b; Wathen et al. 2011). Guiding documents such as a memorandum of understanding (Bullock et al. 2010) or governance

structure (Naqshbandi Hayward et al. 2016) can make reporting relationships explicit, thereby enhancing clarity and mitigating the risk of miscommunication or not meeting expectations.

The importance of good communication extended to building a shared understanding of the work. Many authors reported challenges with low involvement of KUs (Fortin et al. 2016; Wathen et al. 2011), ensuring usefulness of research to the KU organization (Kothari et al. 2014b; McGrath et al. 2009; Wathen et al. 2011) and balancing methodological rigour with involvement (Bullock et al. 2010). Again, careful planning was thought to maximize the role of KUs in the project, such as considering how KU involvement could vary according to their willingness or availability (Henderson et al. 2014) as well as across research stages (Valaitis et al. 2012). Technology (e.g., web-based conferencing platforms) was thought to be useful at engaging stakeholders, although knowledgeable support staff were required, and problems with organizational information technology security requirements were encountered (Valaitis et al. 2012). Demands for research to inform program or policy decisions while the research is ongoing could also be serviced by drawing on existing research (Kothari et al. 2014b) or through alternative reporting strategies that can still support decision needs without sacrificing research integrity (McGrath et al. 2009). It was also challenging to situate the iKT portion within a larger policy or program environment; while a memorandum of understanding can help all parties determine how the iKT process aligns with ongoing work, this may take considerable time (e.g., 1–2 years) to complete (Bullock et al. 2010). Also, while some KUs may feel they do not have the expertise to offer meaningful contributions (Henderson et al. 2014), their input is vital for determining how research findings can be successfully integrated into health system practices (McGrath et al. 2009). The development of trust (Bullock et al. 2010; Fortin et al. 2016; Naqshbandi Hayward et al. 2016; Wathen et al. 2011) and mutual learning (Bornstein et al. 2017; Fortin et al. 2016) helped create relationships with the potential for future collaboration.

Finally, external factors may be the most capricious and deleterious to the success of iKT projects. Changes in personnel – both within the research team as well as with KU organizations – requires time and effort to ensure that institutional memory is maintained (Bornstein et al. 2017), trust is built anew and incoming project members are brought up to speed (Bullock et al. 2010). It is possible to maintain relationships through organizational restructuring, although the research team is required to adapt and update their training to continue to understand KU interests and align their work accordingly (Bornstein et al. 2017). Unfortunately, other challenges were left unanswered (e.g., identifying the right stakeholders, competing priorities impeding KU engagement, conflicting priorities, negotiating credit for outputs), so these serve as issues to be aware of for researchers wishing to engage in iKT.

Research Impact

IKT research required extra time and resources, notably for coordinating meetings, maintaining communication and developing tools. Tensions between researchers and KUs

sometimes complicated the research process, such as when the research evidence does not support a desired direction (Wathen et al. 2011). In spite of these challenges, the vast majority of completed projects noted a variety of benefits in line with their rationales for conducting iKT research, such as ensuring research was relevant to KUs and enhancing the sharing and use of findings (Bornstein et al. 2017; Bryant et al. 2011; Fortin et al. 2016; Hayden et al. 2015; Kothari et al. 2014b; McGrath et al. 2009; Porter et al. 2012; Valaitis et al. 2012; Wathen et al. 2011). Other benefits included enhancing methodological feasibility (Henderson et al. 2013, 2014), building partnerships for future collaborations (Bullock et al. 2010; Hayden et al. 2015; Kothari et al. 2014b; McGrath et al. 2009; Valaitis et al. 2012), fostering ownership over knowledge creation (Naqshbandi Hayward et al. 2016) and overcoming differences to better understand each other's constraints and areas of interest (Fortin et al. 2011; Pelletier et al. 2011; Wathen et al. 2011).

Only one study evaluated the iKT process, although its focus was on the partnership process rather than whether iKT affected research use or health outcomes (Kothari et al. 2014b). Those reporting on the ability of KUs to act on research findings believed it to be strong because the research was commissioned by them, or they had actively disseminated the research. Only one study (Wathen et al. 2011) examined knowledge use, finding that research was much more likely to be used conceptually or symbolically than instrumentally (Weiss 1979) and that the kind of use depended on where they were in the decision-making process.

Quality of Studies

The overall quality of studies was low to medium, with an average MMAT score of 50%. However, only 8 out of the 20 studies met the screening criteria for going through quality appraisal (e.g., clear research questions or objectives, data collected address questions or objectives), mainly because of the format of the article (i.e., descriptive articles do not have clear questions or objectives). Therefore, quality appraisal results should be interpreted accordingly. There was variation between study types in terms of being eligible for MMAT scoring as well as the actual score received: "project" reports (4/7 eligible for scoring) had an average MMAT score of 62.5%; "overview" reports (1/9) had a score of 75% and "protocol" reports (3/4) had a score of 25%.

Discussion

This scoping review explored public health iKT research involving PDMs and identified various rationales and strategies for engaging KUs in research. iKT provided means to incorporate KU insight, preferences and concerns to produce feasible, relevant and useful research with the potential to develop future collaborations. The researcher–KU collaboration was enhanced by taking the time to develop trust and mutual respect (Bullock et al. 2010; McGrath et al. 2009; Wathen et al. 2011). Meaningful engagement is crucial to this end:

research is more likely to be used by KUs if they have been consulted to accurately determine their needs, rather than have knowledge that may not meet these needs "translated at them" (Bowen and Graham 2013). Because trust and mutual respect can also be seen as indicators of collaboration, this likely reflects a trust-building cycle: some collaboration is necessary to build trust and respect, which in turn fosters a deeper relationship.

The importance of relationship-building has been noted in the KT literature (Bowen and Martens 2005) as well as reviews or co-creation in community health services (Greenhalgh et al. 2016) and broader interorganizational partnership literature (Winters et al. 2016). It is unclear why relationship-building was only reported in a handful of included studies; this may reflect the belief that relationship-building is not a methodological consideration worth reporting or that there were no conscientious relationship-building activities incorporated in the iKT process; in either case, the reader is not provided with guidance on how to build relationships. This is reflected in both a recent call for an iKT research agenda (Gagliardi et al. 2017) as well as a protocol for a longitudinal program of research examining how iKT works under different circumstances and partnerships (Graham et al. 2018).

Allowing KUs to decide their level of engagement and be flexible about their commitments was thought to let them contribute to the best of their abilities (Bullock et al. 2010; Henderson et al. 2014; Wathen and MacMillan 2015;). Different KUs bring differing levels of ability and expertise to the table, suggesting that careful tailoring of involvement opportunities, rather than seeking to maximize involvement of KUs in all phases of the iKT process, is helpful (Henderson et al. 2013; Wathen and MacMillan 2015). Given the different ways that KUs can be involved (e.g., developing the research question, informing methods, implementing the study, interpreting results and disseminating findings), there is substantial opportunity to determine where KU interests lie and how to best leverage them. Ten of the included studies took the form of "overviews" of programs of research or networks; as these contained multiple projects, they offered multiple opportunities for KU involvement and thus may be better designed to allow KUs to modify their involvement as time and interest permit. Recent Canadian work exploring how engagement was defined among leadership within a policy and service delivery organization found that across hierarchical levels, engagement was defined similarly (Norris et al. 2017). Facilitating participation at the individual level (e.g., determining willingness and varying level of involvement accordingly), connecting around a purpose (i.e., shared vision or goal), and providing opportunities for meaningful interaction and dialogue all align with our findings regarding the importance of a meaningful relationship with KUs. The *"spectrum of public participation"* offered by the international association of public participation (IAP2; iap2.org) has been used to support patient engagement in research (Bellows et al. 2015), and could assist researchers to determine the optimal level of involvement for PDM KUs.

Further, as relationships change with experience, the "maturity" of the partnership (i.e., degree of shared history and understanding) can help determine the appropriate degree of KU involvement (Kothari et al. 2011) (although this was not associated with outcomes

in a recent iKT scoping review; Gagliardi et al. 2016). Existing literature on health services partnerships, such as task and role negotiation, leadership, and conflict management, may also be useful in guiding researcher-PDM collaboration and operationalize iKT processes (Curry et al. 2012; Winters et al. 2016). While formal arrangements (e.g., memorandums of understanding) can help address potential issues, informal mechanisms (e.g., good working personal relationships between researchers and KUs) can support formal mechanisms and thus should not be undervalued (Bullock et al. 2010). Regardless of specific methods used, emphasis on principles of engagement to guide the research process, understanding perspectives beyond the academic world, and drawing on the experiences and perspectives of KUs are crucial for avoiding failure (Greenhalgh et al. 2016).

It is also worth noting that the rationale of involving PDMs in iKT implies the shared goal of using the resulting research to change policy and practice. When the research question is straightforward and the results provide clear direction, uptake is supported. However, PDMs may refuse to act on evidence with which they disagree (e.g., conflicts with their experience; Wathen et al. 2011). Notwithstanding an initial agreement between researchers and PDMs on the shared value of the research, other values may conflict (e.g., scientific rigour needed for publication as opposed to the imperative to act within a timeline and available resources, respectively) (Estabrooks et al. 2012; McGrath et al. 2009). In this way, iKT may not be as useful for public health problems that require urgent action or are contentious; after all, research is a single input that decision makers must consider in their calculation for action.

Goals also need to be shared at the appropriate level of responsibility. The labels of "policy maker" or "decision-maker" may be somewhat misleading, as this group comprises different roles (e.g., analysts, advisors, decision-makers) and functions (e.g., evidence gathering, advising, decision-making), each of which may have differing needs and goals (Morestin 2017). Consider, for example, junior policy analysts and senior executive directors within a ministry of health. Each has different responsibilities (e.g., gathering evidence to inform a policy options paper as opposed to weighing the pros and cons of different options to make a decision they are accountable for) and likely differs in training and familiarity with accessing, appraising, synthesizing and applying research evidence. Thus, the ultimate goals of each, their role within the same iKT project and the best ways to nurture these relationships, are likely to be different.

These relationship considerations are integral to fostering strong communication and building a shared understanding. One of the benefits of iKT is that two groups – researchers and KUs – gain a better understanding of each others' "worlds" and thus are better able to accommodate and support each other (Kothari and Wathen 2013). Exposure to PDMs helps researchers understand the nuances that influence their decisions and better prepares them to contribute research to the policy process, including how to best communicate research, to whom and at what time (Cairney et al. 2016; Kothari and Wathen 2013). This

understanding and mutual respect also prepares the grounds from which future collaborations spring, and a number of authors spoke to how iKT helped sow these seeds (Bryant et al. 2011; Hayden et al. 2015; Henderson et al. 2014; Kothari et al. 2014b; Naqshbandi Hayward et al. 2016; Valaitis et al. 2012). In this way, while the iKT research itself may not yield desired results, the relationships built therein may be a fruitful consolation.

To determine to what extent iKT creates future collaborations and long-term health improvement, evaluating iKT strategies is critical to understanding its effects (Gagliardi et al. 2017). However, only one study evaluated the iKT process (Kothari et al. 2014b) with a concentration on the effects of partnerships between members of a research network, rather than specific research and health outcomes. Evaluating the effects of partnership beyond process measures has been a long-standing difficulty (Dowling et al. 2004; El Ansari et al. 2001; Winters et al. 2016), and research linking iKT to more intermediate and distal outcomes (e.g., research uptake) is considered an important next step (Gagliardi et al. 2017). Given how crucial relationships are to the success of iKT, qualitative data of the research process (e.g., reflective notes, observations, interviews) are needed for evaluating the processes inherent to partnership research (Sarkies et al. 2017; Waterman et al. 2001). Taking a time-series approach to evaluation in order to identify specific activities and key events that helped to develop the research–KU partnership has been recommended as a way to better evaluate the iKT process (Gagliardi et al. 2016). Regardless of the methods, our finding of a lack of iKT evaluation is shared by others (Camden et al. 2015; Gagliardi et al. 2016).

Finally, as has been noted in other reviews of iKT research (Gagliardi et al. 2016), poor reporting on KU engagement represented an important gap in the current research evidence, as it was difficult to determine what methods were used to involve KUs in the research and how they contributed across stages of the research process. Despite many articles providing overviews or descriptions of iKT activities, few related how KUs were engaged to outcomes of interest such as process outcomes (e.g., stakeholder satisfaction, future collaborations) or health outcomes (Kothari et al. 2014a; Wathen et al. 2011). Moreover, few reported on factors that have been identified as important to iKT, such as if there were existing relationships with KUs, whether they influenced methodology evolution, if they were familiar with iKT and saw value in it, whether trust and mutual learning developed and how arising issues were managed (Bhattacharyya et al. 2013; Bowen and Graham 2013; Sibbald et al. 2014). Additionally, despite the importance of both individual and organizational contextual factors in enabling iKT (Gagliardi et al. 2014), individual characteristics such as knowledge, attitude and motivation were not described. It is important for iKT researchers moving forward to share how they attempted to address these factors and what strategies were successful in order to build best practices (Gagliardi et al. 2014; 2017; Kothari and Wathen 2017).

While not all of the studies included in our review reported in detail on their iKT processes and activities, our findings align with recent work in this area. Extracting information on the iKT process was challenging, and it remains unclear to what extent the iKT process actually achieves its intended outcomes (Gagliardi et al. 2016). They also reported that

despite the assumption that a lack of funding impeded the iKT process, working with KU funders did not appear to reduce barriers or improve outcomes relative to study without this funding dynamic (Gagliardi et al. 2016). In one case we examined, this funding dynamic was a challenge, as the funder already had an idea of the research goals – a situation that might be a bit more collaborative if neither party held the metaphorical purse strings (Bullock et al. 2010). While only one of our studies noted the challenge of identifying the right stakeholder (Henderson et al. 2014), Camden et al. (2015) reports on both targeted and open strategies for recruiting stakeholders and that it was easier when they were formally affiliated with an organization and/or had a clear job description. The authors note power sharing within these relationships, and particularly researchers relinquishing power to make others feel more empowered to participate. Both our study and Camden et al. (2015) also stress the importance of an up-front negotiation process, such that a clear, shared understanding of the research is set; this includes rewriting scientific materials so they are more readily understood and that different KU groups might have different needs and understandings of others' needs. All of our studies noted that there is a lack of evaluation data on iKT (Camden et al. 2015; Gagliardi et al. 2016). Where our study adds to the literature is the observation that "overview" programs seemed to be better equipped to support iKT than one-off projects and, as a result, provided more detailed reports of plans for engagement and relationship structure, enabling factors as well as the long-term implications of these relationships (Bornstein et al. 2017; Bullock et al. 2010; Henderson et al. 2014; Naqshbandi Hayward et al. 2016; Wathen et al. 2011). Our review is also the only one to not just describe challenges, but also how teams overcame them.

Our work also aligns with broader iKT literature. For instance, the iKT facilitators noted that the studies we reviewed lend support for a recent conceptual framework to assess organizational capacity for iKT (Gagliardi and Dobrow 2016), including dedicated support resources for iKT, enabling opportunities for interaction between researchers and KUs and time for iKT activities and relationship-building. In particular, our findings highlight the importance of the process of conducting iKT: if capacity to develop, build and maintain relationships is absent, iKT initiatives will likely falter and eventually fizzle out. Future research could further explore how relationships that support iKT are developed, and how to enable knowledge systems where KUs can come to researchers with their questions as needed (Gagliardi et al. 2017; Kothari and Wathen 2017). A KU-initiated research is much more likely to result in benefits beyond research project objectives (e.g., sustained change) compared to researcher-driven, or even co-produced research questions (Bornstein et al. 2017; Bush et al. 2017).

There are some limitations to our work. While we decided to focus on iKT given its prevalence in the Canadian KT community, we did not capture studies employing similar approaches (e.g., community-based participatory research, Engaged Scholarship, T2 research). Thus, while we have tried to draw from this body of literature to help

contextualize our findings, we may have missed key insights on involving PDMs in public health research. Our intention with this work was to explore the operationalization of the concept of iKT within the Canadian context, particularly given the emphasis that CIHR has placed on iKT research and the variable quality of these relationships in Canada (Sibbald et al. 2014). While our low capture of international literature may limit the applicability of these findings in other jurisdictions, many of our findings are consistent with international literature on partnership in research, including the importance of partnership management (Greenhalgh et al. 2016) and the time required to develop these (Rycroft-Malone et al. 2016), and clarifying contributions from KUs (Kitson et al. 2013).

Second, given the small number of included studies, the minority of which provided rich descriptions of their iKT workings, our conclusions are largely based on a few richly described studies (notably Bullock et al. 2010; Henderson et al. 2014; McGrath et al. 2009; Wathen et al. 2011) from the perspective of researchers and research teams. It is unclear how much of PDMs' perspectives are reflected in these reports, particularly their perspectives on the engagement process. Nonetheless, the findings provide important foundational evidence regarding the current state of iKT in public health literature while drawing attention to the "black box" of researcher–policy maker partnerships. iKT is not a singular action, and given the centrality of partnerships within iKT, the mechanics of relationship-building and maintenance must be elucidated to enable critical appraisal and advance the state of the art.

Finally, we did not consult experts in the field with our findings after completing the scoping review. While consultation with research consumers can be an optional final step in scoping reviews (Arksey and O'Malley 2005), others believe it should be a requirement (Levac et al. 2010). This would have further strengthened our methodological rigour, as it would have enabled public health PDMs to reflect on their own experiences with iKT research and determine if our findings reflected their experience – and presumably similar experiences of other PDMs.

Conclusions

Our scoping review of PDM involvement in public health iKT research resulted in a few conclusions of note. First, overall vague reporting around the contributions of KUs in general, and the roles of PDMs in particular, made it impossible to determine the role of PDMs relative to other KUs involved with the research. Thus, it remains unclear what PDMs contribute to public health iKT research relative to other types of KUs, and how this particular relationship can be better supported. While the general principles we have synthesized are likely to strengthen the iKT process (e.g., meaningful engagement, flexible opportunities, developing trust), it is up to each team to determine the optimal engagement process. In this way, our work aligns with the broader partnership literature in that investing in the process of relationship-building and management is critical to developing and achieving shared goals.

Our findings also indicate that "overview" programs of research typically appear to have

more dedicated resources for supporting iKT development and are thus more successful at building meaningful relationships with KUs. The majority of challenges that iKT teams experience can be overcome through patience and creativity. Future research on this topic should include detailed descriptions of how partnerships are built and maintained, and how challenges such as identifying the "right" KUs and navigating conflicting priorities are addressed. For example, given that public health issues often have a variety of stakeholders at different levels, future iKT research should consider sharing how they dealt with the logistical and representational challenges of managing diverse groups of KUs. Not all partners have an equal stake in the research, and successfully managing the differences between stakeholders is important for aligning the strengths of each relationship towards shared goals.

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RAPPORT DE RECHERCHE

Entre dynamique d'amélioration de la qualité des soins et conformisme administratif : comportements des établissements de santé français face au paiement à la performance (P4P)

Between the Dynamics of Quality of Care Improvement and the Administrative Conformity: Behaviours of Participating Hospitals in the French Pay-for-Performance (P4P) Program

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Résumé

Le paiement à la performance (P4P) continue de se développer dans les systèmes de santé des pays industrialisés, malgré des preuves encore assez limitées de son efficacité. Cette étude propose de comprendre le comportement des établissements de santé face à ce nouveau mode de paiement en se basant sur l'expérimentation de P4P hospitalier conduite en France. Nous avons, pour cela, combiné une approche quantitative basée sur un questionnaire auprès des établissements participants et une analyse qualitative dans neuf établissements afin de mieux identifier les processus à l'œuvre. L'étude montre que des actions correctives ont été réalisées dans certains établissements mais que les effets du programme sur l'organisation restent en fait assez limités puisqu'ils s'opèrent davantage à la marge. Les comportements semblent être essentiellement le reflet d'une volonté de conformation des organisations aux attentes de la tutelle, sans transformations organisationnelles majeures. Il sera toutefois intéressant de voir comment des perceptions différentes structurent ces comportements sur le long terme.

Abstract

The pay-for-performance (P4P) model continues to develop in the health systems of the industrialised countries, despite the limited evidence of its effectiveness. The goal of this study is to understand the behaviours of hospitals in this new payment model, based on the pilot project conducted in France. To do this, we combined a questionnaire-based quantitative approach with participating institutions and a qualitative analysis of nine facilities to better identify the processes at work. The study shows that corrective actions have been taken in some institutions but the impacts of the program on the organization are, in fact, quite limited since they occur more in the margin. It seems that the behaviours essentially reflect a will of conformation to the authority from the part of the organizations, without major organizational changes. However, it will be interesting to see how the different perceptions will structure the behaviours in the long-term.

Introduction

Le paiement à la qualité, ou paiement à la performance (P4P), s'est largement diffusé ces 10 dernières années dans les systèmes de santé des pays développés (Cashin et al. 2014). Ce nouveau mode de financement consiste à inciter les fournisseurs de soins à améliorer la qualité des soins en distribuant des bonus ou des pénalités financières en fonction de leurs résultats à un certain nombre d'indicateurs de qualité. L'hypothèse, tirée de la théorie économique, est que les incitations financières permettraient d'encourager des comportements « vertueux » qui engendreraient une augmentation plus rapide de la qualité des soins (Glied et Miller 2015). En France, ce mécanisme incitatif a d'abord concerné les médecins généralistes puis s'est progressivement étendu à la sphère hospitalière. Seulement, l'efficacité de ce dispositif a rarement été démontrée dans la littérature (Busse 2016; Eijkenaar 2012; Mendelson et al.

2017; Ogundeji et al. 2016). Ainsi, pour mieux appréhender son impact, plusieurs auteurs préconisent d'étudier, plus précisément, les comportements des établissements de santé en réponse à cette instrumentation initiée par les tutelles (McDonald 2014; McDonald et al. 2015; McHugh et Joshi 2010).

Pour caractériser ces comportements, la théorie de l'agence, s'appuyant sur le principe d'une relation entre un principal (ici, le payeur) et un agent (l'hôpital), est un référentiel dominant (Claveranne et al. 2007). Cette théorie considère la question des comportements des établissements face à une incitation économique comme le résultat d'un arbitrage entre le gain espéré et le coût de l'effort pour l'obtenir (Blomqvist 1991; Eijkenaar 2013; Trybou et al. 2015). D'autres théories issues des théories des organisations précisent davantage l'influence qu'aurait l'environnement sur les stratégies des établissements (Burnett et al. 2015; Pfeffer et Salancik 1977). L'adaptation des organisations à l'environnement serait effectivement plus complexe à appréhender puisque cela ne se limiterait plus à satisfaire les demandes d'un « principal » unique mais plutôt à répondre à des pressions institutionnelles plus larges provenant notamment d'organes de régulation, mais aussi d'organisations en position de leadership ou bien encore de la société dans son ensemble. Cet éclairage permettrait de rendre compte de la richesse des comportements des agents, les dirigeants s'attachant à prendre les décisions les plus adaptées aux caractéristiques de l'environnement dans son ensemble. Fray (2009) considère, à ce titre, le comportement de l'hôpital comme la résultante de deux modes de gouvernance distincts : un mode de gouvernance externe et un mode de gouvernance interne (Fray 2009). Le mode de gouvernance externe correspond aux relations entre les tutelles (Ministère, ARS, agences gouvernementales) et l'hôpital. Ce mode permettrait de gérer la situation de dépendance très forte de l'organisation hospitalière vis-à-vis du régulateur qui contrôle ses activités (autorisations d'exercer, niveaux d'activité, décisions de fusions, …) ainsi que les ressources financières qui en découlent. Le mode de gouvernance interne consisterait, lui, en un partage des responsabilités entre la direction et les sphères médico-soignantes, dans la production des soins.

Ce cadrage nous servira ainsi de référence pour mieux comprendre comment les établissements de santé français ont répondu au P4P. Notre étude se base, en effet, sur l'expérience du P4P dans les établissements de santé français. Ce programme, nommé Incitation financière à l'amélioration de la qualité (IFAQ), prévoyait de verser un bonus aux établissements qui obtiendraient le meilleur score sur des indicateurs de processus préalablement sélectionnés (Tableau 1). Menée sous l'égide du ministère de la Santé et de la Haute Autorité de santé (HAS), la première expérimentation (IFAQ1) a vu le jour en 2012, suivie d'une seconde expérimentation (IFAQ2) en 2015. Ces deux expérimentations ont permis le développement d'un « paiement à la qualité » généralisé à l'ensemble des établissements de santé français à partir de 2016 (Ferrua et al. 2015).

TABLEAU 1. Programme IFAQ2

IFAQ2*	2015
	440 établissements de santé, tous statuts confondus
Type d'incitation	Uniquement des bonus, attribués en fonction du score obtenu
	176 hôpitaux récompensés
Taille de l'incitation	Entre 0,3 % et 0,5 % du budget annuel de l'établissement
	Primes allant de 50 k€ – 600 k€
Mesures	Indicateurs de processus uniquement • Pratiques cliniques (infarctus du myocarde, accident vasculaire cérébral, hémorragie du post partum, hémodialysés chroniques) • Informatisation du dossier patient • Certification des hôpitaux par la Haute Autorité de santé • Satisfaction du patient • Infections nosocomiales
	Score agrégé prenant en compte niveau atteint et évolution, si applicable

* Pour plus d'informations sur le modèle : http://www.has-sante.fr/portail/upload/docs/application/pdf/2016-02/ifaq2_doc_info_29_01_2016_vf.pdf

Ce programme a-t-il amené à une modification des modes d'organisation internes de l'établissement ou, au contraire, est-ce que les établissements se sont contentés de s'accommoder à cette nouvelle règle du jeu sans trop les modifier et ainsi « soigner » les relations avec les tutelles ? Cette étude propose une analyse du comportement des établissements ayant participé à IFAQ2. Cela permettra de voir si les établissements, une fois passée la première phase d'expérimentation (IFAQ1), initient réellement des actions correctives leur permettant d'améliorer la qualité des soins au sein de leur établissement.

Méthodes

Design de l'étude

Notre analyse, conduite en 2016, porte sur les établissements ayant participé à la deuxième phase de l'expérimentation IFAQ (IFAQ2) qui a eu lieu en 2015. Le design des programmes de P4P pouvant être très différent d'un pays à l'autre, nous présentons les caractéristiques principales du programme français (Tableau 1) (Werner et Dudley 2009).

Pour répondre à notre question de recherche, nous avons choisi de réaliser une méthode mixte combinant de manière séquentielle une approche quantitative puis une analyse qualitative permettant ainsi une triangulation des données (Royer et Zarlowski 2014). Cette méthode est d'ailleurs préconisée pour analyser les démarches d'amélioration de la qualité en santé (Portela et al. 2015). L'objectif était avant tout de décrire, dans sa globalité, les différents comportements adoptés par les établissements face au dispositif IFAQ et d'identifier différents profils d'établissements, plus ou moins sensibles aux programmes de P4P tels qu'IFAQ.

Recueil de données

Notre étude s'appuie, en premier lieu, sur les données d'une enquête par questionnaire, menée auprès des directions des établissements participant à IFAQ2, dont la finalité était de mieux comprendre l'expérience du P4P dans ces établissements. La direction générale, le président de la commission médicale d'établissement (CME), la direction qualité ainsi que la direction des soins devaient répondre au questionnaire collégialement. Ces acteurs ont été ciblés car ils étaient censés être en mesure de donner une vision d'ensemble de l'implantation du dispositif dans leur établissement. La structure du questionnaire s'est basée sur un instrument développé précédemment aux États-Unis (Meterko et al. 2006). L'administration du questionnaire s'est faite en ligne à l'aide du logiciel Eval&Go™. Pour cette étude, nous avons retenu 12 items sur les 42 que comportait le questionnaire car ils permettaient d'explorer spécifiquement la question du comportement des établissements face à IFAQ (Tableau A à www.longwoods.com/content/25791).

Dans un second temps, une étude qualitative auprès de neuf établissements ayant participé à IFAQ2 a été conduite (Tableau B à www.longwoods.com/content/25791). Les entretiens ont été réalisés auprès d'établissements de santé aux statuts différents (public/privé) et répartis sur le territoire français. Pour chaque hôpital, un binôme de chercheurs a été constitué. Des entretiens semi-directifs (individuels et collectifs) ont été conduits en suivant une grille (Tableau C à www.longwoods.com/content/25791). Celle-ci prévoyait des questions correspondant aux items du questionnaire et explorait également les raisons de ces comportements et les actions qui avaient été effectivement réalisées (Tableau D à www.longwoods.com/content/25791).

Traitement des données

DONNÉES QUANTITATIVES

La présentation descriptive des principales variables quantitatives recueillies dans l'enquête sera suivie d'une analyse des correspondances multiples (ACM), réalisée afin de mieux identifier et catégoriser les différents types de comportements des établissements face à IFAQ.

DONNÉES QUALITATIVES

Les entretiens ont donné lieu à une retranscription systématique. Nous avons réalisé un codage thématique à partir du logiciel NVivo 11® (Miles et Huberman 1994). Cette analyse s'est composée de deux étapes. La première étape de l'analyse correspond à la construction des codes, à partir de la lecture des premiers entretiens. Dans une deuxième étape, nous avons codé l'ensemble des entretiens à partir de ces codes. Nous avons remanié les codes au cours de l'analyse pour qu'ils rendent compte au plus près du contenu des entretiens.

Résultats

Étude par questionnaire

Le taux de réponse à l'enquête était de 66 %, correspondant à 289 observations. L'échantillon était représentatif de la population initiale (Tableau D à www.longwoods.com/content/25791). Pour les 12 items, le nombre de réponses fluctuait, allant d'un taux de réponse de 33 % à 100 % pour les questions obligatoires.

Description des variables quantitatives issues de l'enquête IFAQ2

Les résultats descriptifs semblent montrer que l'introduction d'IFAQ n'a pas engendré de réorganisations profondes en interne, les actions étant restées relativement limitées. On constate que le niveau de connaissance du dispositif à l'intérieur de l'établissement n'est pas très élevé parmi les établissements répondants (Tableau 2). Seuls 27 % d'entre eux estiment qu'une majorité de leurs cadres de santé sont au courant du dispositif contre 22 % pour les chefs de département. Concernant la stratégie de communication utilisée, quasiment la moitié des établissements s'est limitée à transmettre les informations aux instances dédiées, en interne, à la qualité et à la sécurité des soins (Comités de lutte pour la douleur, pour les infections nosocomiales …) plutôt que de communiquer uniformément à l'ensemble du personnel. En revanche, une grande majorité de répondants considère que le modèle IFAQ, basé sur des indicateurs de processus, est pertinent (86 %).

TABLEAU 2. Statistiques descriptives

Variables	(N[1])	(%)
La majorité de ces personnels connaissent les composantes du score IFAQ2		
… les infirmiers	289	2,42
… les secrétaires	289	1,04
… les aides-soignants	289	1,73
… les médecins	289	7,96
… les cadres de santé	289	26,64
… les chefs de département	289	22,15
L'établissement a communiqué en interne sur		
… sa participation à IFAQ	250	71,20
… le fait d'avoir été primé	96	77,08
La communication sur la participation à IFAQ a été réalisée auprès des instances dédiées uniquement	169	44,38
Les dirigeants trouvent pertinente la composition du score IFAQ	95	86,32
Établissements primés IFAQ2 (oui)	289	30,68
La prime a un effet de réputation		
… vis-à-vis de la Haute Autorité de santé (HAS)	193	54,40
… vis-à-vis de l'Agence régionale de santé (ARS)	193	53,37
… vis-à-vis des patients	193	24,87

TABLEAU 2. Statistiques descriptives

Variables	(N[1])	(%)
Les dirigeants savent quels indicateurs ont été inclus pour le calcul du score IFAQ2	264	86,36
… Processus cliniques pour quatre indications[2]	289	70,24
… Infections nosocomiales	289	83,04
… Satisfaction des patients	289	51,90
… Informatisation du dossier patient	289	62,98
… Certification des hôpitaux par la Haute Autorité de santé	289	79,58
Les dirigeants considèrent IFAQ2 comme un enjeu financier	289	67,94
La prime a été répartie sur le poste budgétaire		
… de la qualité	70	22,86
… du budget global	70	41,43
… pas encore répartie	70	35,71
Les établissements non primés ont mis en place des actions correctives suite aux résultats d'IFAQ	130	60,77
Les dirigeants considèrent qu'IFAQ a un impact positif sur la qualité des soins	208	51,44

1. Nombre de réponses obtenues à la question

2. Infarctus du myocarde, accident vasculaire cérébral, hémorragie du post partum, hémodialysés chroniques

Il est à noter que 30 % des établissements ayant répondu à l'étude ont finalement reçu une prime dans le cadre de l'expérimentation. Les effets de réputation de ces primes ne sont pas ressentis de manière uniforme par les établissements. Parmi les répondants, 54 % estiment que cela a un effet vis-à-vis de la Haute Autorité de santé (HAS) et 53 % pensent que c'est important vis-à-vis de l'Agence régionale de santé (ARS). En revanche, pour trois quarts des répondants, le fait d'être primé ne leur semble pas important aux yeux des patients.

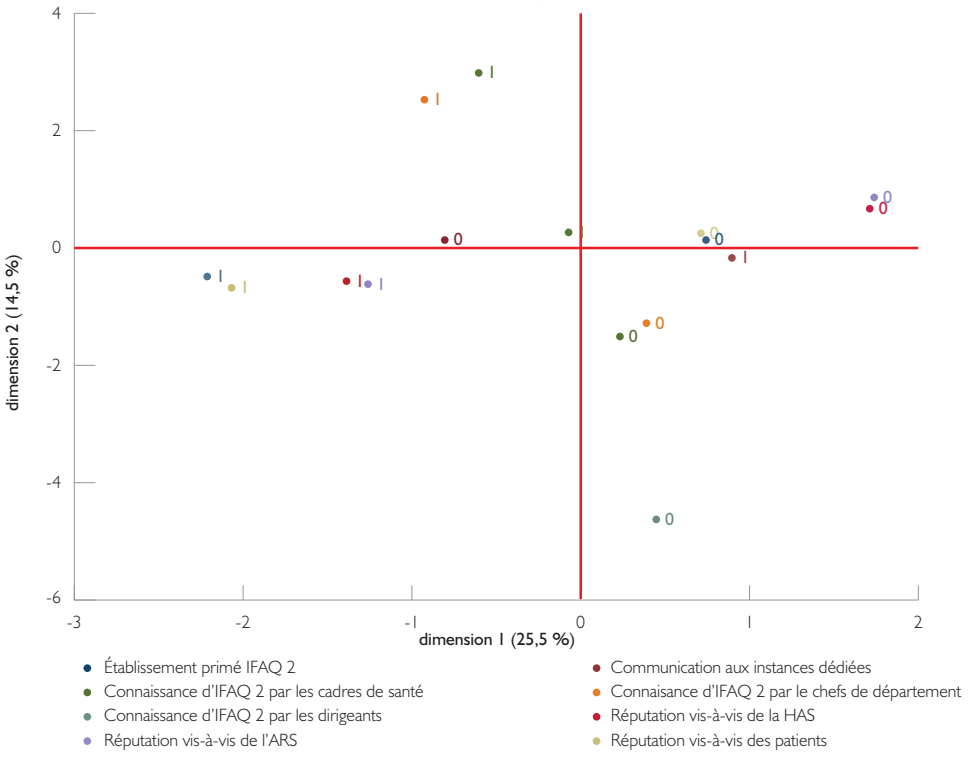
Enfin, il est intéressant de constater qu'une majorité de répondants considèrent d'une part, qu'IFAQ représente pour eux un enjeu financier (68 %) et que d'autre part, il aurait un impact positif sur la qualité des soins (51 %). Parmi les établissements non primés, 61 % d'entre eux déclarent qu'ils ont mis en place des actions correctives portant sur le recueil des données, suite aux résultats d'IFAQ, alors que parmi les établissements primés, l'attribution des bonus s'est répartie entre le service qualité (23 %) et le budget global (41 %) alors que 35 % ne les avaient pas encore distribués.

ANALYSE DU COMPORTEMENT DES ÉTABLISSEMENTS

Nous avons ensuite effectué une ACM sur les variables qui nous paraissaient être les plus révélatrices de ces comportements (Figure 1).

Comme le montre la figure 1, le plan identifié par les deux premiers axes factoriels explique 38 % de l'inertie totale des données. Les huit variables présentées sur la figure avaient à la fois une qualité de représentation des axes supérieure à 18 % et la meilleure contribution à la formation des axes. L'analyse factorielle des réponses données fait apparaître

FIGURE 1. Analyse des correspondances multiples



Note : ARS : Agence régionale de santé ; HAS : Haute Autorité de santé

deux dimensions permettant de caractériser les comportements des hôpitaux : une dimension que l'on nommera « niveau en matière de maîtrise de la politique qualité en interne » et une seconde que l'on appellera « niveau de prise en compte d'IFAQ comme un levier d'amélioration de la qualité ».

L'axe horizontal est principalement déterminé par la première dimension intitulée « niveau en matière de maîtrise de la politique qualité en interne ». Sur cet axe, s'opposent les hôpitaux qui ont été primés et ceux qui ne l'ont pas été, la prime se basant sur des résultats aux indicateurs sur plusieurs années. S'opposent également les hôpitaux qui ont fait une communication sur les résultats de leur établissement à IFAQ à l'ensemble du personnel, par rapport à ceux qui ont restreint cette communication aux instances dédiées. Enfin s'opposent les dirigeants qui ont l'impression qu'être primé peut avoir des répercussions positives sur leurs relations avec la HAS, l'ARS et les patients contre ceux qui ne le pensent pas. Pour synthétiser, on peut dire que sur cet axe, s'opposent les établissements qui ont perçu la qualité comme un élément stratégique et qui se sont engagés depuis longtemps dans les démarches d'amélioration de la qualité et ceux qui n'ont pas pris le « virage qualité » et qui ont donc du retard dans « l'acculturation » à cette démarche.

L'axe vertical est déterminé par « le niveau de prise en compte d'IFAQ comme un levier d'amélioration de la qualité », où s'opposent les établissements qui expliquent avoir récemment mis en place des actions d'amélioration de la qualité suite à leur participation à IFAQ et ceux pour qui cela n'a pas abouti à des modifications. S'opposent les hôpitaux dont une majorité de cadres de santé et de chefs de département connaissent le dispositif IFAQ et ceux pour lesquels ce n'est pas le cas. S'opposent également sur ce même axe, les dirigeants qui trouvent la composition du score IFAQ2 pertinente et ceux qui ne la trouvent pas. En résumé, ce deuxième axe oppose les établissements qui ont réagi au dispositif IFAQ, contre ceux qui ont été moins réactifs.

Étude qualitative

Dans un second temps, nous avons conduit 25 entretiens qui ont pu expliquer les mécanismes d'adoption du P4P dans les établissements. Les entretiens ont été menés auprès de la direction (direction qualité, direction des finances, direction générale), mais également avec des médecins, des infirmières, des responsables informatique ou qualité (Tableau B à www.longwoods.com/content/25791.

DEUX LOGIQUES COMPORTEMENTALES

Se distinguent deux logiques comportementales selon que l'on perçoit IFAQ sous l'angle de la gestion de la qualité ou selon celui de la gestion avec l'extérieur.

IFAQ VU SOUS L'ANGLE DE LA GESTION DE LA QUALITÉ

Cette étude a montré que les établissements ont accueilli avec attention le dispositif IFAQ. Pour certains, il se vit comme une nouvelle méthode pour mesurer le niveau de qualité des soins au sein de leur établissement. Alors que les résultats de l'enquête quantitative semblent attester d'une forte adhésion concernant le choix des indicateurs composant le score (86,32 %, n = 95), les entretiens montrent toutefois que certains professionnels les trouvent encore très insuffisants alors que, pour les autres, ce score agrégé, basé sur des indicateurs de processus, permettrait de donner des orientations sur la façon d'améliorer la qualité des soins. Pour beaucoup, le recours au levier financier reste un bon moyen de rendre les professionnels de santé plus concernés par la démarche.

« IFAQ, ça permet de donner des outils à l'établissement pour perpétuer une démarche d'amélioration continue de la qualité … »	Privé	Direction
« Les indicateurs de tenue du dossier patient ou du courrier de sortie de fin d'hospitalisation, pour moi, c'est le b.a.-ba. »	CLCC	Qualité
« Les médecins j'ai toujours l'impression que je les ennuie avec mes sujets, là, avec de l'argent en jeu, ils m'écoutent plus. »	CLCC	Qualité
« IFAQ, j'ai trouvé ça très positif en termes de management interne, mais le programme manque de visibilité, il est trop complexe. »	Public	Direction
« Le financement nous permettra de mettre en place une application pour la consultation anesthésique, ils voient concrètement l'utilité au quotidien. »	Privé	Qualité

« Voir que le travail permet d'avoir des retombées financières qui leur permettent d'améliorer leur quotidien, pour eux, c'est clé. En message, pour moi, c'est clé. C'est idiot, on est toujours dans le système de la carotte et du bâton, enfin là pour l'instant, il faut en profiter, il n'y a que la carotte. »	CLCC	Qualité
« Là, avec IFAQ, on a une carte supplémentaire, et vraiment on leur montre sous l'angle, « regardez IFAQ ça permet des investissements supplémentaires pour du matériel, etc. », ça devient concret. »	Privé	Qualité
« Grâce à IFAQ, on a identifié une fragilité ou un point d'amélioration potentiel et avec le financement on réinvestit dans cela, c'est typiquement ce que les tutelles attendent. »	Privé	Qualité

Le programme IFAQ a également suscité l'intérêt des directions pour sa capacité à comparer les établissements. Le score offre, en effet, selon eux, une occasion de les mettre en comparaison en proposant une méthode de classement même si chacun souligne les limites de ce « benchmarking », les directions sont tentées de comparer, entre eux, les primés et les non primés. Cet usage est renforcé par les ARS qui ont parfois fourni la liste exhaustive des établissements primés, indépendamment de leur statut (public/privé).

« Avoir un benchmark c'est très important. Je compare nos scores à la moyenne nationale et ensuite à nos concurrents sur le territoire … la gériatrie et les post-urgences gériatriques embolisent lourdement notre système … on est désavantagés, le fait qu'on ait des urgences exige beaucoup de flexibilité dans les services. »	Public	Direction
« Vis-à-vis de l'ARS c'est hyper important IFAQ. Quand on a été primé, on leur avait dit « vous voyez, on fait de la qualité nous ». Je ressens de la fierté d'avoir été primé deux fois. »	Public	Direction
« Avec IFAQ, on essaie de savoir si on est dans la course. »	Public	Direction
« Je vais regarder sur le site Scope santé au niveau régional les notes des établissements sur certains indicateurs, c'est intéressant de voir ce qu'ont donné les autres, ça stimule. »	Public	Qualité
« Le benchmarking c'est hyper important, on fait ça tout le temps, certes la valeur intrinsèque est dérisoire en comparaison de nos budgets, mais là on est plus au niveau du symbole. »	Privé	Direction
« C'est vraiment un plus vis-à-vis de l'ARS d'être dans IFAQ, c'est une façon de leur dire, vous pouvez compter sur nous, on est un établissement de référence. »	Privé	Qualité

IFAQ VU SOUS L'ANGLE DE LA GESTION AVEC L'EXTÉRIEUR

Certains directeurs semblent inscrire IFAQ dans un mouvement plus général. Ils assimilent ce dispositif à une contrainte institutionnelle comme une autre, les directions d'établissement ayant l'habitude de s'accommoder à ce genre de changement de règles émanant des tutelles. Des établissements regrettent, à ce titre, le manque de mise en cohérence des différentes mesures. Certaines demandes de la tutelle sont effectivement venues en contradiction du dispositif IFAQ. Par exemple, des décisions de certification ont amené à évincer certains établissements de la prime alors qu'ils avaient de bons résultats pour les indicateurs sélectionnés. Malgré cela, l'analyse qualitative, en cohérence avec les résultats de l'enquête quantitative (51,44 % des répondants au questionnaire considèrent que IFAQ a un impact sur la qualité des soins), montre que si tous les interviewés ne semblaient pas convaincus de l'impact réel du programme, ils prenaient, tout de même, très au sérieux cette nouvelle demande. Pour certains, la participation à l'expérimentation leur permettait de se placer aux premières loges alors que, selon eux, se jouaient les prémices d'une évolution du système de financement. En

effet, malgré les précautions prises par les promoteurs du programme, un nombre important d'établissements ont largement anticipé la généralisation d'IFAQ. Dans l'ensemble, il apparaît qu'une majorité de directeurs souhaitent se positionner très tôt sur ces questions. Pour certains, la participation à IFAQ semble même être un élément distinctif. Participer à un programme comme celui-ci serait habituellement réservé à une « élite » qui aurait l'habitude d'être mieux informée par les tutelles.

« Sur ce genre de projets, celui qui démarre en premier gagne, c'est important de faire partie de ce genre d'expérimentations. »	Privé	Direction
« Vous savez, certains établissements ont des liens contrairement à nous. Pour une fois, on a pu faire partie de l'expérimentation dès ses débuts, c'est important pour nous … et aussi au niveau des tutelles, le fait d'être primé valorise, l'argent c'est important … avec IFAQ pour une fois, ce n'est pas le statut qui paye, on est associés aux initiés. »	Privé	Direction
« On débloque symboliquement des crédits. Mais cela n'avait pas de rapport financier. 15 000 euros c'est anecdotique par rapport au montant de la dotation IFAQ, cela correspond à un signal managérial du comité qualité. »	Privé	Finances
« Ça nous semblait naturel de nous engager dans IFAQ, mais pas nécessairement de communiquer dessus. Nous préférions communiquer sur les indicateurs de qualité. On a demandé aux services et aux pôles de s'améliorer. »	Privé	Qualité
« Il y a un effet d'aubaine avec cette récompense. Mais après ? C'est vrai, nous n'avons aucune garantie. »	Public	Direction

Le calibrage de la communication à propos du programme est, à ce sujet, une bonne indication de la différenciation des deux logiques comportementales. Certains établissements ont souhaité que le programme reste confidentiel et ont sollicité uniquement les instances dédiées à la qualité des soins. Cela correspond à presque la moitié des répondants selon l'enquête quantitative (44,38 %). D'autres ont pensé que ce programme devait s'adresser à l'ensemble des professionnels et ont donc adopté une communication plus large afin de toucher l'ensemble du personnel. Des interviewés précisent que cette stratégie de communication dépend beaucoup de l'équipe de direction et de sa conviction dans l'efficacité de ce type de démarches d'amélioration de la qualité.

« C'est vrai que nous avons un appui fort de la direction de l'établissement sur IFAQ2 et bon, nous, on a communiqué en réunion de cadre, en CME. »	Privé	Qualité
« Pour nous IFAQ c'était vraiment un objectif stratégique. On avait sensibilisé tout l'encadrement. Puis on a communiqué sur notre prime via le journal interne et la réunion de CME. »	Public	Direction
« On n'en a pas parlé en équipe de direction, mais je ne souhaite pas me concentrer sur les composantes IFAQ. Je trouve que c'est un calcul un peu risqué. Je trouve que l'on est plutôt dans une démarche d'amélioration globale de la qualité donc je préfère tout travailler, on ne peut pas se permettre de délaisser certains indicateurs. »	Public	Qualité
« Quand on a vu qu'on pouvait avoir un retour financier qui n'était pas négligeable, nous avons fait largement de la communication au niveau du comité des directeurs, au niveau des réunions, au niveau de toutes les instances. »	CLCC	Qualité
« Si vous demandez aux professionnels de notre établissement s'ils connaissent IFAQ, ils vont se gratter la tête. Nous, on a communiqué aux instances et pendant les réunions de pôles. On leur parle indicateurs, chaque infirmière est membre d'un des comités. »	Privé	Qualité

COHABITATION DE LOGIQUES DE GOUVERNANCE INTERNE ET EXTERNE

Au cours des entretiens, la plupart des établissements ont tenu à replacer IFAQ dans son contexte historique en rappelant que les établissements primés étaient, en réalité, ceux qui avaient justement enclenché des démarches qualité depuis plusieurs années déjà, les résultats obtenus n'étant selon eux, en aucun cas, le résultat d'une réaction à une incitation, mais plutôt le fruit d'un travail de long terme auprès des équipes. Cette remarque laisse penser qu'ils remettent en question l'effet incitatif du dispositif, le percevant davantage comme une récompense pour le travail fourni.

« Dans notre établissement, IFAQ est très peu connu, ce n'est pas un terme qui parle. Je n'ai pas développé de politique ni de stratégie spécifique pour IFAQ … IFAQ, c'est la valorisation du travail réalisé il y a bien longtemps … »	Public	Direction
« Ici, la démarche qualité est ancienne, elle remonte à plus de 15 ans … Elle avait commencé par la maternité … pour moi, la prime ce n'est pas une incitation. C'est simplement une récompense. »	Public	Qualité
« Pour le moment, c'est une reconnaissance plus qu'une incitation … c'est comme un bon point à l'école. »	Public	Direction
« Selon moi, IFAQ c'est une conséquence heureuse d'une politique déjà en place. »	Privé	Direction
« Avec IFAQ, on reconnaît une démarche qui a été faite depuis plusieurs années. On est plutôt sur le travail des années précédentes, mais du coup on est sanctionnés positivement, on est reconnus par rapport à ça. Par rapport à la roue d'amélioration de la qualité, cela nous permet de continuer ce que l'on a fait avant, là on est remerciés et ça nous permet d'aller plus loin. »	Privé	Qualité
« Même non engagé dans IFAQ, nous aurions poursuivi cette démarche dans laquelle nous sommes engagés, nous n'aurions pas seulement ciblé nos efforts sur le seul établissement engagé dans IFAQ sur les 3 que compte notre groupement hospitalier. »	Public	Qualité
« Pour moi, IFAQ c'est le prolongement d'une démarche déjà initiée. IFAQ c'est une poire pour la soif, c'est un cadeau de consolation. »	Public	Direction
« C'est vrai, la prime IFAQ, ça habille un établissement. »	CLCC	Qualité
« Il faut vraiment un projet au niveau de l'établissement et ne pas juste être complaisant avec l'ARS pour faire des vrais projets qualité. Il faut une politique d'établissement et se reposer sur une forte culture qualité de l'établissement pour porter ces sujets. La qualité, ça ne s'improvise pas, il faut une cohérence en amont et des orientations stratégiques très fortes. »	Privé	Direction

Cette dynamique ne semble pas pour autant entrer en contradiction avec l'adaptation au dispositif IFAQ pour des raisons de gouvernance externe, décrite plus haut. Deux mouvements parallèles semblent coexister, de manière disjointe. Un premier mouvement correspondant à une dynamique d'amélioration continue de la qualité engagée sur le long terme et un second étant davantage de l'ordre d'une adaptation rapide et « tactique ».

Discussion

Cette étude permet de mieux caractériser les comportements des établissements de santé face à l'incitation IFAQ, en fonction de l'importance relative accordée aux deux modes de gouvernance interne et externe. Dans le cas d'IFAQ, il semble que la logique de gouvernance externe ait prévalu par rapport à la logique de gouvernance interne. Les réponses données par les établissements sont, avant tout, le reflet de leur volonté d'adaptation à leur environnement et de leur souhait de gérer cette relation d'interdépendance en se conformant aux attentes,

même exigeantes, des tutelles. Tout comme pour un certain nombre de réformes récentes, comme l'implantation du dossier patient informatisé au sein des hôpitaux, l'introduction du P4P n'aurait ainsi engendré que peu de transformations organisationnelles, la majorité des établissements s'accommodant à ce nouvel élément sans pour autant s'en saisir réellement comme d'un outil d'amélioration de la qualité (Béjean et al. 2016). Ceci n'exclut pas que des actions correctives aient pu être réalisées dans certains établissements, mais les effets du programme sur l'organisation restent en fait assez limités puisqu'ils s'opèrent davantage à la marge, et ne modifient pas les fonctionnements internes ni les relations entre les sphères soignantes et administratives.

Est-ce à cause de la structure de l'incitation et notamment de la définition de la qualité choisie pour le modèle IFAQ? On se limite effectivement à des évaluations du respect d'un certain nombre de processus, qui n'appellent pas en eux-mêmes des changements radicaux et qui peuvent être souvent améliorés par une rigueur accrue dans le recueil des informations (Moisdon 2014). De plus, le modèle ne permet pas un financement pérenne de la qualité du fait de sa distribution sous forme de primes ; donc il se peut que les établissements estiment que ce dispositif ne soit pas capable de soutenir une amélioration continue de la qualité des soins. On peut supposer que dans un environnement moins incertain, où les règles du jeu seraient plus stables et mieux connues à l'avance, les établissements auraient pu s'emparer de ce dispositif pour progresser réellement sur la qualité des soins.

Il est cependant important de considérer nos résultats en prenant en compte leurs limites. L'étude par questionnaire n'a permis d'interroger que les directions des établissements et ne révèle donc pas les ressentis des professionnels de « frontline », responsables de la prise en charge des patients au quotidien. De plus, le taux de non-réponses est relativement élevé pour certaines questions de l'étude. L'analyse qualitative explicative permettait de limiter au mieux le risque d'erreur d'interprétation en apportant des éléments permettant une compréhension plus fine des processus à l'œuvre (Pawson 2004). Enfin, cette étude se limite au cas français et certaines spécificités du système peuvent avoir joué un rôle dans la mise en œuvre du P4P. Enfin, il serait intéressant de conduire une analyse longitudinale pour savoir si des effets d'apprentissage peuvent s'observer sur le long terme, les démarches d'amélioration de la qualité s'initiant souvent sur des temps plus longs que ceux adoptés pour la présente étude.

Les résultats de cette étude permettent de réfléchir à la pertinence de recourir à ce levier de régulation. Nous avons montré que si la mise en place de cette incitation n'a pas perturbé les démarches d'amélioration de la qualité initiées précédemment, et les a même encouragées, nous n'avons pas pu montrer, pour autant, d'effets tangibles de ce dispositif sur l'amélioration de la qualité des soins. Ceci est cohérent avec la littérature internationale publiée sur le sujet (Bonfrer et al. 2018; Jha 2017). Davantage de recherches doivent ainsi être menées sur ces questions pour s'assurer que l'introduction d'un paiement à la qualité incite à l'amélioration de la qualité et n'introduise pas de rentes de situation où les meilleurs établissements seraient systématiquement récompensés et les « mauvais élèves » n'auraient alors plus d'incitation à changer leurs pratiques, tant les écarts se seraient creusés. Cette étude portant sur l'impact

d'un paiement à la qualité mis en œuvre au sein d'établissements de santé apporte des éléments de preuve qui peuvent intéresser les tutelles désireuses de poursuivre ou d'initier des programmes similaires au Canada, ou ailleurs (Milstein et Schreyoegg 2016).

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