The Ontario Drug Policy Research Network: Bridging the gap between Research and Drug Policy

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ABSTRACT

Policymakers have cited several barriers to using evidence in policy decisions, including lack of research relevance and timeliness. In recent years, several reports have focused on the successes and challenges of researcher–policymaker collaborations, a form of policy engagement intended to help overcome barriers to the use of research evidence in policymaking. Although these reports often demonstrate an increase in research relevance, rarely do they provide concrete methods of enhancing research timeliness, which is surprising given policymakers’ expressed need to receive “rapid-response” research. Additionally, the impact of researcher–policymaker collaborations is not well-discussed. In this paper, we aim to describe the collaboration between the Ontario Drug Policy Research Network (ODPRN) and its policymaker partner, the Ontario Public Drug Program (OPDP), with a particular focus on the ODPRN’s research methodology and unique rapid-response approach for policy engagement. This approach is illustrated through a specific case example regarding drug funding policies for pulmonary arterial hypertension. Moreover, we discuss the impact of the ODPRN’s research on pharmaceutical policy and lessons learned throughout the ODPRN and OPDP’s five-year partnership. The described experiences will be valuable to those seeking to enhance evidence uptake in policymaking for immediate policy needs.

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1. Introduction

Evidence-informed policymaking is recognized as an important tool to improve health outcomes. For example, evidence-informed anti-tobacco policies partly contributed to a significant decrease in tobacco use [1], and the consequent decline in lung cancer-related deaths [2] and
hospital admissions for childhood asthma [3]. Although there is persistent advocacy for evidence-informed policymaking, the challenges of utilizing evidence in policy are well documented [4]. Policymakers regularly cite lack of timeliness and relevance of research as barriers to considering evidence in policy decisions [5–8]. The absence of ongoing communication between researchers and policymakers [5] poses an additional challenge to developing evidence-informed policy, as interaction among these groups is necessary to enhance research relevance.

Several established models of researcher–policymaker collaborations are designed to overcome these challenges [9]. Among the most successful is the interactive model [9–11], in which continuous researcher–policymaker interaction and collaboration facilitate the process of producing policy-relevant research findings [12]. As researcher–policymaker collaborations become more common, understanding existing interactive and collaborative methods is imperative to optimizing future endeavours. To date, most reports describe the potential successes and challenges of researcher–policymaker interactions [5,10] rather than specific methods of collaboration. Two examples of exceptions include a report on the partnership between a mental health research unit and the mental health reform branch of the Ontario government [13]; and an Australian researcher–policymaker collaboration focused on case-mix classification of subacute and acute patients in Australia [14]. Each of these collaborations focused on enhancing communication between policymakers and researchers through regular meetings and forums to inform research questions and potentially impact policy directions. These examples have demonstrated successful policy engagement, but there are a few notable limitations. First, reports on research–policy collaborations rarely provide a comprehensive description of the impact of the collaboration, with only a few examples of ongoing impact assessment evident in the available literature; for example, the integration of research into pharmaceutical policy systems in Stockholm, Sweden [15,16]. Second, many descriptions of partnerships focus on engaging with policymakers while conducting traditional research studies—therefore, the research typically spans two years or longer. Given that policymakers have expressed a desire for a “rapid-response” research program that could be consulted for these pressing policy concerns [17], describing the experiences of such a program is essential.

The Ontario Drug Policy Research Network (ODPRN), a collaboration between policymakers and researchers, reflects the principles of the interactive model while incorporating a rapid-response approach. Its goals are to provide timely, high-quality, policy-relevant research findings to policymakers, with the ultimate goal of safe and cost-effective use of pharmaceutical therapies. The current paper highlights the ODPRN as a case example of a researcher–policymaker collaboration using a rapid-response method that has not been reported elsewhere in the literature. We describe the ODPRN’s research processes, the impact of its research, and lessons learned throughout its five-year collaboration with its policymaker partner.

2. Methods: The ODPRN rapid-response research approach

2.1. Formation of the researcher–policymaker partnership

The ODPRN was initiated by researchers who had prior experience interacting with drug policymakers. Aware of the challenges drug policymakers often faced when seeking timely research to inform their policies, these researchers conceptualized a method of conducting rapid pharmacoepidemiological research in response to immediate policymaker needs. In 2008, the ODPRN was funded by the Ontario Ministry of Health and Long-Term Care (MOHLTC) to implement their model of rapid-response research in collaboration with policymakers. The funding opportunity was designed to facilitate interactive partnerships; thus, it enabled the ODPRN to secure policymaker collaborators at the Ontario Public Drug Program (OPDP), who had limited capacity to conduct analyses that were relevant to their policy needs. The OPDP is a division within the MOHLTC responsible for the province’s nearly $5 billion (CAD) publicly funded drug benefit programs such as the Ontario Drug Benefit (ODB) Program, which provides drug coverage to individuals receiving social assistance, the elderly (over 65 years of age), residents of homes for special and long-term care, and people receiving professional home care services. Through its expert advisory committee, the Committee to Evaluate Drugs (CED), the OPDP governs the approval process for drugs within program formulas. As such, the OPDP requires timely and evidence-based information on effectiveness, cost-effectiveness and budget impact to form decisions on funding schemes.

2.2. ODPRN structure

To conduct rapid-response research, a unique organizational structure was developed by ODPRN researchers (Fig. 1) consisting of three main units:

(1) The Rapid Response Unit (RRU) is comprised of epidemiologists, a project manager, and biostatisticians whose primary function is to work with policymakers to efficiently respond to research requests using linked population-level information from datasets housed at the Institute for Clinical Evaluative Sciences (ICES). These linked databases contain healthcare services data for the entire population of Ontario (approximately 13 million people) since 1988. This includes demographic, physician claims, emergency department utilization, hospitalization, and drug data for ODB program recipients (approximately 2.5 million people).

(2) The Core Academic Unit (CAU) is composed of researchers (both clinician–researchers and others) and trainees in the Student Training Program who collaborate with the RRU in fulfilling policymaker research requests, as well as addressing their own research questions through traditional academic research.

(3) The Knowledge Translation Unit (KTU) is comprised of knowledge translation (KT) specialists with experience and training in implementation and research.
dissemination. The KTU disseminates the ODPRN’s research findings to target knowledge users and stakeholders, including policymakers, researchers, clinicians and the public.

By design, policymaker requests account for up to 70% of the ODPRN’s research activities. Remaining activities are dedicated to academic research initiated by CAU members. The availability of methodological expertise and operational infrastructure to clinical researchers is an important driver of CAU member engagement.

2.3. The ODPRN research process

The ODPRN consulted with the OPDP to determine communication processes and to describe data availability and project scope. Given that ongoing communication is the gold standard of successful partnerships [12], the collaboration established a formal monthly meeting schedule and appointed a key OPDP contact to attend meetings and engage in informal communication (e.g. e-mail, phone) with the ODPRN. These processes frame the ODPRN’s rapid-response research methods (Fig. 2), including: (1) clarification and refinement of the research question; (2) streamlined data collection and analysis; and (3) effective communication of research findings.

2.3.1. Clarification and refinement of the research question

In determining which policies or policy changes are required, the OPDP considers various sources of information including clinical trial evidence, clinical expertise and opinions/experiences of stakeholders (e.g. patients, pharmacists). ODPRN evidence is requested when current population-level information on real-world drug safety and drug utilization patterns is required to inform policies.

The OPDP submits research requests, consisting of one or a series of questions relating to a particular policy under consideration, and required timelines to the RRU Lead (Box 1a, Fig. 2). The ODPRN and the OPDP collaborate to refine the objectives, confirm project feasibility given data availability and requested timelines, and ensure that the output will appropriately address the OPDP’s specific needs (Box 2a and 2b, Fig. 2). To facilitate this process, the ODPRN prepares project proposals that outline methods, potentially relevant outcomes, limitations of the proposed analyses, and mock tables and figures of the anticipated output.

2.3.2. Streamlined data collection and analysis

Rapid analyses are conducted with a typical completion time of 5–10 business days (Box 3, Fig. 2). The speed of the research response is facilitated by several factors. First, the ODPRN utilizes readily available data from linked administrative databases, which significantly shortens the time period for data collection. Second, a streamlined research ethics process is in place with the ODPRN’s home institution when only administrative data is used for research purposes, with research ethics approval feasible within 2 to 3 days. Third, the ODPRN has developed templates of analytic plans for frequently conducted study designs. This allows for the ODPRN’s epidemiologists to rapidly generate detailed documents that outline all necessary analytical parameters (e.g. cohort size, time frames, outcomes of interest) for the analyst. Finally, dedicated analysts who are familiar with standard approaches utilized in responding to policymaker requests enable rapid analyses.
2.3.3. Effective communication of research findings

Results are reported confidentially in a format based on the expressed preferences of the OPDP (Box 3, Fig. 2). The analyses are summarized in one to two pages, beginning with the key findings, followed by the scope of the issue and policy implications. This text is followed by supporting tables and figures, and finally the methodological details. These reports are written to facilitate understanding of methods and interpretation of results. In addition to producing reports, the OPDP may be invited to present their results at OPDP and CED meetings, which extends the dissemination of the findings to key decision makers (Box 4b, Fig. 2). Furthermore, the OPDP recognizes the value of reporting findings in peer-reviewed publications; therefore, OPDPN reports are not circulated publically and a majority of reports are formatted and submitted as academic publications (Box 4a, Fig. 2). The rapid-response research process is primarily driven by OPDPN requests and focuses on pharmacoepidemiology. However, an alternative approach to conducting research and disseminating results to the OPDP occurs through the CAU. Investigator-led research questions are proposed at bi-monthly OPDPN meetings (Box 1b, Fig. 2), and any completed projects that may be of interest to policymakers are reported to the OPDP, while also being published as peer-reviewed academic publications (Box 4c, Fig. 2). Other dissemination efforts include posting ‘Research Minutes’—one-page summaries of OPDPN publications targeting knowledge users such as policymakers, clinicians and the general public—on the OPDPN website (www.odprn.ca) (Box 5, Fig. 2).

3. Case example: Funding for pulmonary arterial hypertension (PAH) pharmacotherapy in Ontario

Pulmonary arterial hypertension (PAH) is a rare and potentially life-threatening condition. Prior to 2010, the OPDP only funded PAH monotherapy (i.e. one drug at one time) due to the lack of evidence at the time on the effectiveness and safety of PAH combination therapy (i.e. multiple drugs at one time). Clinicians and patients advocated to the MOHLTC that this was an impediment to optimal care.

A multi-disciplinary sub-committee of the CED was created to address PAH drug funding schemes for the OPDP. To help inform this policy revision process and gain insight on population-level patterns of PAH drug utilization, the OPDP submitted a research request to the OPDPN in November 2009, after which the OPDPN rapid-response approach was initiated.

3.1. Clarification and refinement of the research question

The OPDP key contact and two OPDPN scientific leads attended a series of CED sub-committee meetings to refine the research questions. The key analyses that were discussed focused on understanding current PAH utilization
patterns and costs, determining whether any combination therapy was currently being prescribed (despite funding restricted to monotherapy only), and to examine the potential impact of restricting the initiation of PAH drugs to prescribers at Ontario Centres of Excellence (i.e. PAH specialist centres).

3.2. Streamlined data collection and analysis

After determining the scope of the research request, data were retrieved from appropriate provincial databases. Analyses were conducted using the described rapid-response procedures.

3.3. Effective communication of research findings

By February 2010, the OPDPN had distributed three reports to the OPDP and CED PAH sub-committee, highlighting their key results (Table 1). Overall, it was found that the vast majority of initiation was occurring in or near Centres of Excellence, and that existing combination therapy was rare.

3.4. PAH funding policy implications

PAH drug funding changes were enacted in June 2010 (Table 1); funding was expanded to include combination therapy of selected PAH drugs, and PAH drug initiation was restricted to Ontario’s five Centres of Excellence. Various sources of information were used by the CED to inform these policies, including randomized controlled trials on the harms and benefits of combination therapy (of which there is limited evidence), and input from specialists, drug manufacturers and patient advocacy groups. In addition to this information, the CED considered the OPDPN’s findings on real-world prescribing patterns and utilization of PAH drugs, which was stated to have significantly contributed to the adjustment of funding criteria given that the OPDP was previously unaware of actual prescribing and usage patterns in Ontario (OPDP, personal communication, July 5, 2012). In particular, the finding that 84% of people initiated their PAH therapy within or close to a Centre of Excellence confirmed for the OPDP that the new restrictions would not introduce substantial hardship or disruption for newly diagnosed PAH patients.

3.5. Impact of OPDPN research

Between September 1, 2008 and June 1, 2013, the OPDPN has successfully completed 26 research requests and submitted a total of 59 reports to the OPDP (i.e. one research request may result in multiple reports and policy-relevant CAU research has also been provided to the OPDP as a report). Additionally, the OPDPN has published 57 manuscripts based on both policymaker research requests and CAU work, some of which received considerable attention at the clinical, public and policy levels [18–20].

In addition to producing policy-relevant research, the OPDPN measures the potential impact of OPDP policies that were informed by OPDPN evidence. For example, analyses were conducted by the OPDPN examining PAH drug prescribing and utilization patterns after the enactment of revised policies in June 2010 to evaluate the PAH funding changes. Preliminary findings show that 22% of individuals on PAH medications were prescribed combination therapy in the 30 months following the OPDP funding change relative to 5% of individuals on PAH medications prior to the OPDP funding change, demonstrating a fourfold increase in PAH combination therapy (Report on Pulmonary Arterial Hypertension Therapy in Ontario, OPDPN 2012). Recent studies show that for many individuals, increased access to combination therapy for PAH may improve clinical worsening (defined broadly as all-cause death, hospitalization or disease progression) and exercise capacity [21–23], thus potentially also improving quality of life [24]. This example demonstrates first that policy changes resulting in increased access to therapies deemed to be clinically beneficial for certain patients can be informed by OPDPN research, and second that researchers can continue to work policymakers following policy implementation to evaluate impact.

Perhaps one of the most unique aspects of the partnership is that the OPDPN is able to fulfill research requests on a broad range of topics in drug policy due to the diversity
of expertise in its membership (e.g. clinicians, pharmacists, content experts, health economic experts, biostatisticians, epidemiologists), and its ability to quickly seek the advice of external experts when needed. This collaboration is in contrast to most researcher–policymaker collaborations that often focus on providing research results for one topic. As a result, the ODPRN has produced important research results in various other policy areas, including diabetes treatment and monitoring, and opioid analgesics. For example, a series of ODPRN studies investigating the prescribing and safety of opioids informed the OPDP's decision to further restrict funding for long-acting oxycodone (OPDP, personal communication, July 5, 2012) and informed legislation around the use of opioid analgesics [25]. Thus, it is apparent that the ODPRN's research has impacted decision making in many areas of pharmaceutical drug policy through their partnership with the OPDP.

4. Discussion

4.1. Lessons learned about researcher–policymaker collaboration

The ODPRN's rapid-response research methods comprise a unique approach to addressing immediate policy concerns and fill a gap in reported researcher–policymaker collaborations. For example, Canadian pharmaceutical drug policymakers described a “firefighting” culture in which political and societal pressures created a pressing need for policy change, and desired a rapid-response research program that could be consulted for particular pharmaceutical policy concerns [17]. The ODPRN model of research addresses an expressed need for these particular policy questions. Designing methods that are at once responsive, relevant, and robust is an important element of the ODPRN’s success to date.

In this collaboration, various elements have streamlined the process of translating evidence into policy. First, the partners found it necessary to be responsive to each other's needs. Policymakers require analyses quickly to utilize current research results in policymaking. Researchers require clear study objectives and must ensure that scientific output is of high quality and rigor. At the outset of collaboration, the ODPRN and OPDP acknowledged one another's specific requirements and sought to create a process that would meet these needs. For example, the ODPRN learned how to work with the OPDP to clarify research objectives through intensive communication, the creation of documentation such as project proposals, and opportunities to increase policymaker knowledge on research methods (e.g. through “lunch and learn” sessions for OPDP members). This acknowledgement of needs and establishment of processes to address them characterizes mature, successful relationships between researchers and policymakers [12].

Moreover, the ODPRN and OPDP were required to understand the environments in which each partner works and operates. Perhaps one of the greater challenges for the ODPRN was realizing that evidence is not often the primary driver of policymaking [7], which can hinder the process of utilizing ODPRN research results in evidence-informed policymaking. One such example involved an analysis of blood glucose test strips (BGTS) for patients with diabetes in Ontario. BGTS are commonly prescribed to patients with diabetes, but have limited clinical benefit to certain groups [26,27], leading to potential overuse and significant costs to the healthcare system. The ODPRN analyzed potential cost avoidance related to hypothetical scenarios involving changes to prescribing of BGTS and reported these findings in 2009 [28]. The study identified up to $300 million CAD in potential cost savings over 5 years; however a policy designed to set maximum quantity limits for reimbursement of these products was not announced until the spring of 2013 [29]. The slow adoption of evidence was likely due to factors including MOHLTC’s concern about the acceptability of the proposed options and a failure to implement similar policy options in other Canadian jurisdictions. ODPRN researchers learned to recognize that policymaking may be delayed until the timing and political climate is optimal [30]. Acceptance of this policymaker culture was facilitated by the structure of the ODPRN, which enables researchers to engage in academic work independent of OPDP requests and ensures that the ODPRN can still produce impactful research without relying on the OPDP to initiate requests or implement policy actions.

Finally, as with other researchers who have engaged with policymakers in research processes [12], effective communication was perhaps one of the most important factors in overcoming barriers and developing a successful partnership. To address this challenge, ODPRN members established open, early and frequent communication with the OPDP. Both partners recognized that dedicated time was required on both ends to facilitate communication; therefore, ensuring the availability of key contacts for both groups was essential for the ODPRN and OPDP to strengthen their collaboration.

4.2. Limitations

Assessing the impact of ODPRN research is limited in part by the dearth of available and meaningful indicators for assessing policy impact. The ODPRN is currently assessing impact by tracking the number of citations of ODPRN research in policymaker documents, and obtaining policymaker feedback through personal communication and surveys. In the future, the ODPRN will expand its evaluation framework to better capture the policy impact of its research. Another limitation of this paper is that information on meaningful clinical and economic outcomes of policy decisions impacted by ODPRN research is not yet available for some ODPRN studies; however, the ODPRN is initiating an evaluation of policy decisions related to their research.

5. Conclusions

Collaborative research processes can produce mutually beneficial partnerships between researchers and policymakers. Researchers at the ODPRN have engaged OPDP policymakers in an innovative approach to conducting and utilizing research evidence in policymaking, starting with collaboratively defining research questions, and ending
with the dissemination of research results. Between these two key activities, the ODPRN conducts a rapid-research process that enhances the timeliness of dissemination. Overall, the ongoing ODPRN—OPDP collaboration depicts a partnership in which the information needs of policymakers – i.e., current, relevant, and scientifically rigorous research in a timely manner – are satisfied. The ODPRN’s scientific expertise and ownership of the research process ensures that the findings maintain a high level of quality and independence. The described research processes and lessons learned throughout five years of researcher–policymaker partnership will be valuable to those seeking to enhance evidence uptake in policymaking for immediate policy needs. Effective integration of research into policymaking will lead to informed decisions that profoundly affect the well-being of society at large.

Conflicts of interest statement

The opinions, results and conclusions reported in this paper are those of the authors and are independent from the funding sources. No endorsement by the Institute for Clinical Evaluative Sciences or the Ontario Ministry of Health and Long-Term Care is intended or should be inferred. Dr. Mohammad Mamdani has received honoraria from Boehringer Ingelheim, Pfizer, Bristol-Myers Squibb, and Bayer. All other authors report no conflicts of interest.

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