RESEARCH PROTOCOL

Delivering Methadone Maintenance Treatment through Primary Care: A Qualitative Study of Physicians' Views

RESEARCH TEAM

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BACKGROUND AND RATIONALE

Opioid use disorder is a chronic, relapsing health condition (Amato et al., 2005). When left untreated, it can lead to serious social, economic, and physical harms for affected individuals and broader society. Different therapeutic options exist to treat heroin and related opioid use disorders, such as counselling and opioid substitution. Methadone maintenance treatment (MMT) is a comprehensive program that involves the long-term prescribing of an oral medication—methadone—as an alternative to the opioid on which the client was dependent (Erdelyan & Young, 2009). It is premised on the belief that substituting methadone for heroin and other opioids decreases the need for individuals to engage in risky behaviours and, consequently, reduces harms associated with illicit drug use (e.g., transmission of disease, crime, overdose) (Fischer et al., 2005). It also enables people who are dependent on opioids to re-establish their lives and address their substance use problems. The empirical literature supports the effectiveness of MMT, especially in combination with other supportive services (e.g., counselling), on a number of individual and social indicators, such as suppressing heroin use, reducing mortality, reducing HIV transmission, and reducing heroin-related crimes (Amato et al., 2005; Fullerton et al., 2014; Joseph, Stancliff, & Langrod, 2000; Lind, Chen, Weatherburn, & Mattick, 2005; Schilling, Dornig, & Lungren, 2006).

MMT in Nova Scotia is delivered in a variety of settings, including hospital and community primary care centers; specialized methadone clinics; specialized community clinics serving specific populations such as people with HIV/AIDS; and specialized hospitals, residential settings, and correctional facilities (College of Physicians & Surgeons of Nova Scotia, 2012). As methadone is a controlled substance in Canada, all physicians must receive specialized training and obtain an exception from Health Canada in order to prescribe methadone. There is a strong push locally, nationally, and internationally towards increasing the capacity of primary care physicians to treat and manage opioid use disorders; thereby, increasing access to

MMT—a priority articulated recently in the Mental Health and Addictions Strategy for Nova Scotia (Nova Scotia, 2012). In addition to increasing access, another advantage of delivering MMT in primary care settings is that it may contribute to normalizing an evidence-based treatment and destigmatizing those who use MMT (Greenwood, 1992; Nosyk et al., 2013); thereby, transforming MMT into a "medical response to a medical problem" (Latowsky & Kallen, 1997, p. 397), rather than an exiled response to a social problem. Evidence also suggests that MMT is just as effective when it is delivered in primary care settings compared to being provided in specialist addiction settings (Lewis & Bellis, 2001). Providing MMT in private doctors' offices also facilitates care of comorbid health conditions for people with opioid use disorders (Nosyk et al., 2013).

The success of a model that integrates MMT into primary care both depends on the willingness of opioid dependent individuals to receive MMT and the readiness of physicians to seek an exemption and prescribe MMT (Dooley, Asbridge, Fraser, & Kirkland, 2012). Research indicates that MMT is underutilized. In some jurisdictions, MMT programs have trouble attracting and retaining individuals who may benefit from such treatment (Fischer, Chin, Kuo, Kirst, & Vlahov, 2002; Schilling et al., 2006). Service users may refuse or disengage with MMT because they perceive such services to be controlling, inconvenient, punitive, disrespectful, and ineffective (Fischer et al., 2002; Smye, Browne, Varcoe, & Josewski, 2011). In other jurisdictions, there are long waitlists for MMT, indicating that underutilization is due principally to its inaccessibility (Chan, Charette, Kosior, & Lim, 2014; Luce & Strike, 2011). In such cases, it becomes important to identify and address structural barriers producing poor access to MMT. One important issue that has been identified in the literature is the reluctance of primary care physicians to integrate MMT into their practices. Understanding MMT from the perspectives of primary care physicians is vital to expanding it to primary care settings; thereby, increasing access to and uptake of services and treatment.

Physicians' decisions in relation to prescribing any medicine are influenced by a wide range of clinical, relational, social, contextual, and logistical factors (Bradley, 1992; Wun, Chan, & Dickinson, 2002; Zwolsman, te Pas, Hooft, Wieringa-de Waard, & van Dijk, 2012). This is certainly true in the context of integrating MMT with primary care (Herman & Gourevitch, 1997). Two quantitative studies have examined decision-making among Canadian primary care physicians regarding MMT. In 2008, primary care physicians in Nova Scotia were surveyed on the topic of MMT (Dooley et al., 2012). The study revealed important information about the physicians' attitudes towards prescribing methadone. For instance, the researchers found that, although the majority of survey respondents (57%) were willing to prescribe methadone, the primary care physicians demonstrated low levels of knowledge about MMT. Additionally, factors that significantly influenced their willingness to prescribe methadone included a preference for abstinence-based substance use treatment, a disapproval of illicit substance use, and issues related to training and support. A subsequent survey, conducted in 2013, examined reasons for which primary care physicians in Alberta were reluctant to obtain a methadone exemption (Chan et al., 2014). The key findings were that physicians' willingness to seek an exemption and provide MMT were influenced by their level of comfort providing MMT, whether MMT was an obligation imposed on primary care physicians, the degree to which MMT would change the demographics of their current patients, and their exposure to addiction training in medical school. Additional barriers included the current process for obtaining a methadone exemption, the perception of the MMT patient population as being difficult, discomfort managing opioid dependent patients, and lack of MMT experience or training.

Although these studies reveal important information regarding MMT decision-making among primary care physicians, they are limited by their low response rates as well as the rigidity of quantitative survey methods that prevent an in-depth exploration of physicians' views. A diverse range of issues are important

for primary care physicians as they contemplate incorporating MMT in their practices. The current qualitative study will build upon the aforementioned body of research by elaborating on the findings uncovered by quantitative surveys and by exploring new issues that may have been overlooked. Moreover, the study will elicit recommendations from the primary care physicians concerning how to support MMT being adopted and sustained in primary care settings.

OBJECTIVES

The purpose of this study is to gain an in-depth understanding of the factors that primary care physicians consider important when contemplating the delivery of MMT to treat opioid use disorders in primary care settings. The primary research question is: ***What do primary care physicians believe to be important factors affecting their decision to deliver methadone maintenance treatment to treat substance use disorders in community-based primary care settings?***

RESEARCH PLAN

DESIGN: The study will use a qualitative descriptive design, which is an established qualitative methodological approach. Qualitative description allows for a full account of experiences or events that are too complex to understand using quantitative methods (Neergaard, Olesen, Andersen, & Sondergaard, 2009; Sandelowski, 2010). Although qualitative description can have overtones or elements of other research approaches, such as ethnography, grounded theory, or phenomenology, the core of this approach is to provide "straight descriptive summary of the informational contents of data organized in a way that best fits the data" (Sandelowski, 2000, pp. 338-339) by presenting an insider's perspective (Milne & Oberle, 2005). Unlike ethnography which aims to provide a robust description, grounded theory which aims to develop theory, or phenomenology which creates interpretative meaning of the data, qualitative description aims to highlight participants' voices in describing their experiences in their own language (Neergaard et al., 2009). The aim of qualitative description is descriptive and interpretive validity, whereby researchers represent events or experiences in accordance with how those with lived experiences would make meaning of them (Sandelowski, 2000). Although not as interpretative as other qualitative research methods, qualitative description produces detailed and nuanced findings that closely align with the actual data (Sandelowski, 2000). Qualitative description is the least theoretical of qualitative research methods; however, it is not atheoritcal as it is influenced by theory and previous knowledge (Sandelowski, 2010).

PARTICIPANTS: Approximately 30 primary care physicians will be invited to participate in the study. Inclusion criteria for participation will include: (a) primary care physician; (b) currently provides medical services in the Halifax and surrounding area; (c) works in a community-based primary care setting; and (d) speaks English. Physicians who prescribe or do not prescribe methadone in their current primary care practice will be represented in the sample

RECRUITMENT: Study participants will be recruited using a purposive sampling strategy, which describes a process for deliberately involving individuals with requisite demographic or experiential characteristics in research. Recruitment strategies will include snowball sampling (asking participants to nominate others), advertising in relevant media (e.g., Doctors NS Magazine, various newsletters), and distributing recruitment advertisements to physicians via email, fax, and mail. Recruitment will end when theoretical saturation has been achieved; that is, responses to the interview questions become redundant, new themes stop emerging, and different insights into treatment planning are unlikely to be produced by conducting

additional interviews. Potential participants will be asked to contact the principal investigator via phone or email, at which point they will be screened for eligibility and, if appropriate, scheduled for an initial meeting.

CONSENT: At the initial meeting, the consent form will be verbally reviewed with the participants. At that time, the participants will be given the option to either: (a) sign the consent form and proceed with the interview, (b) take time to consider the consent form and book an interview at a later date, or (c) not participate in the study.

DATA COLLECTION: The primary data collection technique will be individual, semi-structured interviews. The interviews will consist of open-ended questions that query various dimensions of providing MMT in primary care settings. Interviews will be conducted in-person in a location that is convenient for the participants, such as the physicians' offices. All interviews will be audio-recorded and transcribed using a denaturalised approach that aims to capture verbatim statements but not speech errors, pauses or involuntary vocalizations (Oliver, Serovich, & Mason, 2005).

DATA ANALYSIS: The qualitative data will be analyzed using an inductive thematic analytic framework to identify predominant themes and recurring patterns (Braun & Clarke, 2006; Saldaña, 2009). Thematic analysis is a form of pattern recognition that involves identifying themes through careful reading and rereading of the transcripts (Fereday & Muir-Cochrane, 2006). The thematic analysis, led by the principal investigator, will be conducted in three coding cycles. In the first cycle, open coding and line-by-line analysis will performed by fracturing the qualitative data into discrete codes reflecting what participants had said within a particular line of text. Each code will be given an operational definition describing how it is to be applied during the coding process. In the second coding cycle, the initial codes will be reorganized and combined based on conceptual similarities, and will be collapsed into broader meta-codes through a recursive process of moving back and forth between the codes and the original text. The third cycle will consist of sorting, categorizing, and refining the broad codes into overarching themes. Each theme will represent the sentiments of several participants, and capture key ideas and patterns that were important and meaningful to the research questions. Qualitative software (NVivo 10) will be used to support the data analysis. Qualitative analysis does not proceed in a linear fashion nor does it wait for the completion of data collection (Saldaña, 2009). As such, during the data collection phase of the study, the principal investigator and research assistant transcribing the audio recordings will write reflexive journals about the interviews and discuss their insights with the team. This information will be documented and used during the first and second coding cycles to identify preliminary codes, patterns, and themes.

TIMEFRAME: Data collection for the study will begin in July 2015 and will be completed by March 2016. Data analysis will be completed by June 2016 and a write-up of the findings will be completed by August 2016.

DISSEMINATION PLAN

Visually appealing syntheses of the findings in user-friendly language will be developed. Electronic and hard copies of the summaries will be distributed to primary care physicians and healthcare planners. An academic article will be developed and published within high quality, reputable peer-review journals and will be emailed or mailed to the study participants. Additionally, presentations will be given at local meetings and conferences.

ETHICAL CONSIDERATIONS

Research ethics approval will be obtained from the Nova Scotia Health Authority Research Ethics Board, the Saint Mary's University Research Ethics Board, and other institutional review boards as required. Written, informed consent will be obtained from all study participants.

PERSONALLY IDENTIFIABLE DATA: Names and contact information (i.e., phone numbers, email addresses) will be collected for communicating with participants in relation to the recruitment and interview procedures. A master list containing personally identifying information (e.g., names, location) will be used to identify and communicate with the participants. The master list will be password protected and maintained on the secure computer network of Saint Mary's University. This list will be kept separate from the research data and will be destroyed upon completion of the study. Consent forms will be stored separately from the research data in a locked filing cabinet located in the office of the principal investigator (McNally South, Room 431) at Saint Mary's University. The participants will be assigned a study ID that will be used on any data collection forms and on the audio recordings. When reporting the study results, no information that may reveal the identity of any individual who participated in the study will be disclosed.

STORAGE OF DATA: Upon completion of each interview, the digital audio files will be transferred to the secure, password-protected computer network of Saint Mary's University. All other electronic records including participant lists and transcripts will also be saved on this secure network. Paper records, such as consent forms, will be locked in a filing cabinet located in the office of the principal investigator at Saint Mary's University. Only the principal investigator (J. Livingston), the supervising investigator (E. Brooks), and a designated, trained research assistant will have access to these electronic and paper records.

DESTRUCTION OF DATA: Personally identifying information (e.g., participant names and contact information) stored electronically will be kept on the secure, password-protected computer network of Saint Mary's University. This electronic personally identifying information will be erased upon completion of the study (i.e., August 1, 2016). De-identified data (audio-recordings and transcripts) will be stored electronically on the secure, password-protected network of Saint Mary's University. This information will be retained for seven years following the completion of the study (i.e., August 1, 2023). Consent forms will also be retained for seven years following study completion.

HARMS: This study involves gathering primary data by interviewing primary care physicians about their own practices and views. The most serious risk is the potential breach of privacy and confidentiality. Procedures have been established to mitigate this risk.

BENEFITS: The current study will provide valuable information to healthcare planners and decision-makers as they work towards expanding access to MMT for people with opioid use disorders across Nova Scotia.

LIABILITY: No statements have been made that attempt to limited liability to which the investigators, the institutions with which they are affiliated, or the sponsoring company or institution would ordinarily be subject.

FINANCIAL SUPPORT AND COMPENSATION: An honorarium of $170 will be offered to physicians to help defray the loss of patient income. The honorarium is based on the sessional rate for specialists in Nova Scotia. Funding for this project has been provided by the Nova Scotia Health Authority.

REFERENCES

Amato, L., Davoli, M., Perucci, C. A., Ferri, M., Faggiano, F., & Mattick, R. P. (2005). An overview of systematic reviews of the effectiveness of opiate maintenance therapies: Available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment, 28*(4), 321-329. doi: 10.1016/j.jsat.2005.02.007

Bradley, C. (1992). Factors which influence the decision whether or not to prescribe: The dilemma facing general practitioners. *British Journal of General Practice, 42*(364), 454-458.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*, 77-101.

Chan, N., Charette, J., Kosior, R., & Lim, R. (2014). Survey of physician willingness to provide methadone maintenance therapy among primary care physicians in Alberta. *Canadian Journal of Addiction, 5*(4), 8.

College of Physicians & Surgeons of Nova Scotia. (2012). Methadone maintenance treatment handbook. Retrieved April 27, 2015, from http://www.nspmp.ca/library/00000264-library.pdf

Dooley, J., Asbridge, M., Fraser, J., & Kirkland, S. (2012). Physicians' attitudes towards office-based delivery of methadone maintenance therapy: results from a cross-sectional survey of Nova Scotia primary-care physicians. *Harm Reduction Journal, 9*, 20. doi: 10.1186/1477-7517-9-20

Erdelyan, M., & Young, C. (2009). Methadone maintence treatment: A community planning guide. Toronto: Centre for Addiction and Mental Health.

Fereday, J., & Muir-Cochrane, E. (2006). Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. *International Journal of Qualitative Methods, 5*(1), 80-92.

Fischer, B., Chin, A., Kuo, I., Kirst, M., & Vlahov, D. (2002). Canadian illicit opiate users' views on methadone and other opiate prescription treatment: An exploratory qualitative study. *Substance Use and Misuse, 37*(4), 495-522.

Fullerton, C. A., Kim, M., Thomas, C. P., Lyman, D. R., Montejano, L. B., Dougherty, R. H., . . . Delphin-Rittmon, M. E. (2014). Medication-assisted treatment with methadone: Assessing the evidence. *Psychiatric Services, 65*(2), 146-157. doi: 10.1176/appi.ps.201300235

Greenwood, J. (1992). Persuading general practitioners to prescribe--Good husbandry or a recipe for chaos? *British Journal of Addiction, 87*(4), 567-575.

Herman, M., & Gourevitch, M. N. (1997). Integrating primary care and methadone maintenance treatment: Implementation issues. *Journal of Addictive Diseases, 16*(1), 91-102. doi: 10.1300/J069v16n01_06

Joseph, H., Stancliff, S., & Langrod, J. (2000). Methadone maintenance treatment (MMT): A review of historical and clinical issues. *Mount Sinai Journal of Medicine, 67*(5-6), 347-364.

Latowsky, M., & Kallen, E. (1997). Mainstreaming methadone maintenance treatment: The role of the family physician. *Canadian Medical Association Journal, 157*(4), 395-398.

Lewis, D., & Bellis, M. (2001). General practice or drug clinic for methadone maintenance? A controlled comparison of treatment outcomes. *International Journal of Drug Policy, 12*(1), 81-89. doi: 10.1016/S0955-3959(00)00077-3

Lind, B., Chen, S., Weatherburn, D., & Mattick, R. (2005). The effectiveness of methadone maintenance treatment in controlling crime. *British Journal of Criminology, 45*(2), 201-211. doi: 10.1093/bjc/azh085

Luce, J., & Strike, C. (2011). A cross-Canada scan of methadone maintenance treatment policy development: Canadian Executive Council on Addictions.

Milne, J., & Oberle, K. (2005). Enhancing rigor in qualitative description: a case study. *Journal of Wound, Ostomy, and Continence Nursing, 32*(6), 413-420.

Neergaard, M. A., Olesen, F., Andersen, R. S., & Sondergaard, J. (2009). Qualitative description - The poor cousin of health research? *BMC Medical Research Methodology, 9*(52). doi: 10.1186/1471-2288-9-52

Nosyk, B., Anglin, M. D., Brissette, S., Kerr, T., Marsh, D. C., Schackman, B. R., . . . Montaner, J. S. G. (2013). A call for evidence-based medical treatment of opioid dependence in the United States and Canada. *Health Affairs, 32*(8), 1462-1469.

Nova Scotia. (2012). Together we can: The plan to improve mental health and addictions care for Nova Scotians. Retrieved July 25, 2013, from http://www.gov.ns.ca/health/mhs/reports/together_we_can.pdf

Oliver, D. G., Serovich, J. M., & Mason, T. L. (2005). Constraints and opportunities with interview transcription: Towards reflection in qualitative research. *Social Forces, 84*(2), 1273-1289.

Saldaña, J. (2009). *Coding manual for qualitative researchers*. London: Sage.

Sandelowski, M. (2000). Whatever happened to qualitative description? *Research in Nursing & Health, 23*, 334-340.

Sandelowski, M. (2010). What's in a name? Qualitative description revisited. *Research in Nursing & Health, 33*(1), 77-84. doi: 10.1002/nur.20362

Schilling, R., Dornig, K., & Lungren, L. (2006). Treatment of heroin dependence: Effectiveness, costs, and benefits of methadone maintenance. *Research on Social Work Practice, 16*(1), 48-56. doi: 10.1177/1049731505277059

Smye, V., Browne, A. J., Varcoe, C., & Josewski, V. (2011). Harm reduction, methadone maintenance treatment and the root causes of health and social inequities: An intersectional lens in the Canadian context. *Harm Reduction Journal, 8*(1), 17. doi: 10.1186/1477-7517-8-17

Wun, Y. T., Chan, C. S. Y., & Dickinson, J. A. (2002). Determinants of physicians' attitude towards prescribing. *Journal of Clinical Pharmacy & Therapeutics, 27*(1), 57-65. doi: 10.1046/j.1365-2710.2002.00389.x

Zwolsman, S., te Pas, E., Hooft, L., Wieringa-de Waard, M., & van Dijk, N. (2012). Barriers to GPs' use of evidence-based medicine: A systematic review. *British Journal of General Practice, 62*(600), e511-e521. doi: 10.3399/bjgp12X652382