

BMJ Open Primary care for individuals with serious mental illness (PriSMI): protocol for a convergent mixed methods study

Agnes Grudniewicz ,¹ Allie Peckham,² David Rudoler ,^{3,4} M Ruth Lavergne,⁵ Rachele Ashcroft ,⁶ Kimberly Corace,^{7,8} Mark Kaluziński,^{8,9} Ridhwana Kaoser,¹⁰ Lucie Langford,¹¹ Rita McCracken ,¹² W Craig Norris,¹³ Anne O'Riordan,¹⁴ Kevin Patrick,¹⁵ Sandra Peterson,¹⁶ Ellen Randall,¹⁷ Jennifer Rayner,^{18,19} Christian G Schütz ,^{20,21} Nadiya Sunderji,^{22,23} Helen Thai,²⁴ Paul Kurdyak ^{23,25,26}

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ABSTRACT

Introduction People with serious mental illness (SMI) have poor health outcomes, in part because of inequitable access to quality health services. Primary care is well suited to coordinate and manage care for this population; however, providers may feel ill-equipped to do so and patients may not have the support and resources required to coordinate their care. We lack a strong understanding of prevention and management of chronic disease in primary care among people with SMI as well as the context-specific barriers that exist at the patient, provider and system levels. This mixed methods study will answer three research questions: (1) How do primary care services received by people living with SMI differ from those received by the general population? (2) What are the experiences of people with SMI in accessing and receiving chronic disease prevention and management in primary care? (3) What are the experiences of primary care providers in caring for individuals with SMI?

Methods and analysis We will conduct a concurrent mixed methods study in Ontario and British Columbia, Canada, including quantitative analyses of linked administrative data and in-depth qualitative interviews with people living with SMI and primary care providers. By comparing across two provinces, each with varying degrees of mental health service investment and different primary care models, results will shed light on individual and system-level factors that facilitate or impede quality preventive and chronic disease care for people with SMI in the primary care setting.

Ethics and dissemination This study was approved by the University of Ottawa Research Ethics Board and partner institutions. An integrated knowledge translation approach brings together researchers, providers, policymakers, decision-makers, patient and caregiver partners and knowledge users. Working with this team, we will develop policy-relevant recommendations for improvements to primary care systems that will better support providers and reduce health inequities.

INTRODUCTION

People with serious mental illness (SMI), including schizophrenia, bipolar disorder

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study combines qualitative interviews and secondary analysis of population-based administrative data and thus will benefit from the detailed and contextualised insights of qualitative data and generalisability of quantitative data.
- ⇒ The study does not include individuals without access to a family physician or other primary care providers but does set the stage for further research with that population.
- ⇒ The study is limited to two Canadian provinces; however, it addresses health inequities that are common internationally and may inform research and policy beyond the Canadian context.

and severe major depressive disorder, tend to have higher rates of comorbid physical disease compared with the general population.¹⁻⁷ For example, people living with schizophrenia, when compared with the general population, have higher rates of cardiovascular disease, hyperthyroidism, chronic obstructive pulmonary disease, tuberculosis and obesity.^{5,8}

Medical needs and health service disparities for people with SMI

People with SMI tend to have shorter life expectancy (by at least 30%) with worse physical health than the general population, but receive fewer services and lower quality care than patients without SMI.^{1-4 6 8 9} Studies have found higher rates of death from cancer among people living with SMI than the general population (despite similar incidence rates), likely due to delayed detection, cancer screening disparities and contributing intrinsic and system challenges to maintaining optimal adherence to follow-up and treatment.^{3 4 10} Moreover, growing evidence suggests genetic susceptibility to developing



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For numbered affiliations see end of article.

Correspondence to

Dr Agnes Grudniewicz; grudniewicz@telfer.uottawa.ca

diabetes and metabolic abnormalities among people with SMI.^{11–13} Despite having higher risk for medical conditions, people with SMI may receive far fewer health services than the general population; for example, outpatient physician visits for people with SMI mostly consist of psychiatric medication check-ups and mental health and symptom management.^{3 14} The health vulnerability arising from this inequality in services received is compounded by a high prevalence of risk factors among people with SMI, such as smoking, drug and alcohol use and unhealthy diet.⁸ Compounding this, many of the common treatments for mental disorders have well-documented risks of weight gain and metabolic side effects that can increase the risk of heart disease, diabetes and other preventable and/or treatable health conditions.¹⁰ For example, antipsychotic medication use is associated with metabolic disturbances and syndromes which raise concerns about increased risks for cardiovascular disease and mortality.^{15–17}

There is strong evidence that comprehensive integrated medical care, including preventive healthcare and management of comorbid chronic disease, is critical for people living with SMI, and that access to this care has to be improved.^{1 3 8 10 14} Primary care seems to be best positioned for this role.^{14 18}

Access to primary care for people with SMI

By design, comprehensive primary care includes a spectrum of services over the lifecourse, from prevention to chronic disease management, and plays an important role in coordinating specialist and ancillary care, medical, social and psychiatric, for patients with complex health, mental health and social needs.¹⁹ A study of randomly selected primary care physicians in the USA found that their patients with SMI had higher levels of medical complexity compared with patients without SMI. Patients with SMI were more likely to need longer consultations, require support for chronic conditions rather than more routine care and have a follow-up scheduled.²⁰ Thus, people living with SMI can require more comprehensive services and care coordination than the general population; yet, this need is rarely met.^{3 21}

People living with SMI face challenges accessing primary care services for reasons ranging from cognitive barriers to provider bias,²¹ and primary care providers often feel ill-equipped to care for their patients with SMI.^{21 22} Further, mental healthcare is poorly integrated both within primary care and with the rest of the healthcare system, which can result in fragmentation and large gaps in care.^{23–25} Many primary care providers feel that they lack the knowledge and skills to manage care for patients living with SMI, often focusing on the mental illness over concurrent physical health needs.^{26–28} In addition, stigmatisation by healthcare providers can affect timely access to and the quality of health services that people living with SMI receive.^{26 29} For example, there is evidence of diagnostic overshadowing, when physical concerns of patients are misattributed to their mental

health condition.²⁶ People living with SMI can also struggle with a variety of barriers ranging from poverty and stigma to challenges with appointment scheduling, transportation, waiting in busy clinic waiting rooms, communicating and advocating for their health.^{1 14 21 30} Strengthening and supporting primary care services for people living with SMI is likely to have immense benefits for the health of this population, reducing suffering, pain, avoidable hospitalisations and mortality.

Improving quality of care for people with SMI

Researchers have examined the effects of interventions to increase access to and quality of physical health services for people with SMI. Improved quality was found with colocation of physical health and mental illness clinics, care management, increased role of nurses, structured physical assessments and organised models linking patients from emergency care to outpatient follow-up.^{1 21 30} While these studies demonstrate the ability to improve care through targeted interventions in specific contexts, we know little about existing barriers to accessing general physical healthcare for people with SMI in Canada, how different primary care models influence provision of physical health services or how to identify solutions that will work for people with SMI. Improving primary care systems is a large and expensive undertaking that needs to be based on a strong understanding of the true, context-specific barriers faced by patients and providers. Such an understanding is critical to developing or adapting effective interventions.

Study purpose and research questions

The purpose of this study is to describe the role that primary care plays in the prevention and management of chronic disease among people living with SMI by answering the following questions:

1. How do primary care services received by people living with SMI differ from the general population?
2. What are the experiences of people with SMI in accessing and receiving primary care services?
3. What are the experiences of primary care providers in caring for individuals with SMI?

An understanding of *how* primary care services are provided and *why* people living with SMI face such disparities in the quality and quantity of the health services they receive may help support efforts to reduce avoidable hospitalisations and mortality. We have chosen to focus on prevention and management of chronic disease for patients' co-occurring medical problems because of the urgent and unacceptable gap in access to and quality of care in these services.

METHODS AND ANALYSIS

In the quantitative strand, we will use secondary analyses of administrative data from both provinces to answer research question 1. In the qualitative strand, research questions 2 and 3 will be answered with semistructured interviews with

people living with SMI and with primary care providers, respectively.

This convergent mixed methods study was designed so that the quantitative and qualitative strands, considered equally important, are undertaken in parallel.³¹ However, we will use an *interactive* approach to the two strands where data collection and analysis in one strand can inform changes in the other. Integration of the methods at the analysis level will be done through *merging*, a mixed methods approach where the two sets of data are brought together for analysis and comparison. At the reporting level, we will integrate results through narrative and joint display tables that visually bring together quantitative and qualitative data.^{31 32}

This multisite mixed methods study will be conducted in Ontario and British Columbia, Canada to enable a context-based analysis of the care experience and ensure broader applicability of our findings to primary care.³³ Prevalence of SMI is similar in the two provinces: schizophrenia prevalence in Ontario is 1.0% vs 1.1% in British Columbia,³⁴ prevalence of major depressive disorder is 6.8% in Ontario vs 6.0% in British Columbia.³⁵ Prevalence of bipolar disorder, on the other hand, was found to be lower in Ontario (1.9%) than in British Columbia (2.9%).³⁶ By comparing across two provinces, each with varying degrees of mental health service reform and investment and different primary care models, results will shed light on system and organisational factors that facilitate or impede primary care for people living with SMI.

Patient and public involvement

This study protocol has benefited from the input and guidance of individuals with lived experience with mental illness (patients and caregivers) from its inception. As part of the larger research team, the Lived Experience Team (LET) includes four patient-partners and one caregiver-partner, all with experience engaging in research or as part of a hospital's client advisory committee. The purpose of the LET team is to improve both research quality and relevance and, within the context of this study, for the members to contribute their first-hand knowledge, unique perspectives and personal experiences with mental illness. The LET members supported the development of the proposed study, contributed to the development of the grant application and are active study team members. They meet as part of the broader research team on an ad-hoc basis and monthly as a LET advisory committee with two principal investigators. The study budget includes patient compensation and resources for sustainable engagement, per The Change Foundation's recommended practice.³⁷

Quantitative strand: administrative health data

The quantitative strand will use linked administrative health databases accessed through Population Data BC (PopDataBC) in British Columbia and ICES in Ontario to answer research question 1. We will request data for the period 2013/2014 through 2021/2022. Within each province, non-identifying data will be obtained with unique patient and provider IDs that will enable us to connect

records across datasets and over time. It is neither possible nor necessary to combine record-level data across provinces, but parallel analysis using comparable variable definitions and identical analytic procedures will permit us to explore and compare patterns across the provinces. The following databases will be accessed in each province:

- ▶ Patient registration file for provincial insurer: A record for all provincial residents who receive or are eligible to receive publicly funded healthcare services, including information about age, gender as reported at the time of registration and regional health authority of residence.
- ▶ Provider payment information and encounter records: Data on all fee-for-service and shadow-billed encounter records that describe services used and diagnosis codes assigned through British Columbia's Medical Services Plan and the Ontario Health Insurance Program.
- ▶ Hospital separations files: Records of all inpatient discharges and deaths for provincial residents through the Canadian Institute for Health Information Discharge Abstract Database.
- ▶ National ambulatory care reporting system: Database that collects data for hospital-based and community-based ambulatory care, including emergency department visits.
- ▶ Mental health services: Administrative and clinical data on all adults admitted to designated mental health hospitals, accessed through the Ontario Mental Health Reporting System in Ontario and the BC Mental Health and Substance Use Service in British Columbia.
- ▶ Prescription drugs: Records of prescriptions dispensed (all ages in British Columbia, ages 65+ or based on financial need or disability in Ontario).
- ▶ Citizenship and immigration: Administrative data on citizenship and immigration status provided by the Citizenship and Immigration Canada (CIC) Research and Evaluation Branch.

Study population

We will construct two different but overlapping cross-sectional cohorts (from 2015/2016 to 2019/2020) drawn from all adults 19 years of age and older to address research question 1.

Chronic conditions cohort

The first part of our analysis will focus on adults who have a diagnosis of one or more select chronic conditions: diabetes,³⁸ hypertension,³⁹ congestive heart failure,⁴⁰ chronic obstructive pulmonary disease,⁴¹ and asthma.⁴¹ We will divide the study populations into four comparison groups: people hospitalised for SMI (hospitalised for bipolar disorder, schizophrenia spectrum disorder and other psychotic disorders and major depressive disorder); people treated for SMI in the community but not hospitalised; people treated for other mental illnesses (in inpatient or outpatient settings) and people not treated for mental illness.⁴²

Hospitalisation cohort

The second part of our analysis will focus on a cross-section of adults with a hospital admission either for SMI or related to the chronic conditions listed above, with a length of stay of at least 72 hours. We will focus on hospitalisations between 2015/2016 and 2019/2020, to allow examination of service use up to 2 years prior to and following hospitalisation (2013/2014 through 2021/2022). For adults with multiple hospitalisations during the study period, we will randomly select an index hospitalisation. Where people have transfers to other institutions within 30 days, these will be examined as a single hospitalisation event. We will censor those who are deceased or move to long-term care.⁴³ We will create two comparison groups: people with psychiatric hospitalisations and people with hospitalisations for chronic conditions.

Measures

We will construct the following outcome measures of primary care service use within the chronic conditions cohort:

- ▶ **Primary care contacts:** A count of annual primary care contacts (combination of unique provider, patient and day).
- ▶ **Primary care contacts with a usual provider of care (UPC):** UPC will be assigned based on the plurality of primary care provider contacts in the previous 2 years. In case of a tie, UPC will be assigned to the provider with the highest total billings within the last 2 years. We will count the annual number of contacts and the proportion of contacts with the UPC physician.
- ▶ **Chronic disease management:** Management of diabetes, congestive heart failure, chronic obstructive pulmonary disease, hypertension and asthma. Among people with a diagnosis of diabetes, we will examine diabetes management including A1C testing, lipids and statins dispensed (limited to people aged 65+ in Ontario). Among people with an asthma diagnosis, we will examine if they received spirometry and controller medication prescriptions.^{44 45} We will also examine the proportion of patients with diabetes, hypertension, congestive heart failure and chronic obstructive pulmonary disease for whom premiums indicating longitudinal responsibility for chronic disease management were billed.^{46 47}
- ▶ **Screening:** Using submitted claims and lab data, we will determine if people have received screening for cervical cancer, breast cancer and colon cancer. For each test and each month, we will classify people as (1) ineligible for screening tests, (2) screened or (3) unscreened.⁴⁸ Annual values will reflect the proportion of screened months within the year.

We will also examine primary care use prehospitalisation and posthospitalisation with the following outcome measures within the hospitalisation cohort:

- ▶ **Primary care contacts:** A count of primary care contacts in the 2 years prior to and following hospitalisation.
- ▶ **Primary care contacts with a UPC:** We will count primary care contacts with a UPC in the 2 years prior to and following hospitalisation.

- ▶ **Screening:** Using submitted claims and lab data, we will determine if people have received screening for cervical cancer, breast cancer and colon cancer in the 2 years preceding and following hospitalisation. For each test and each month we will classify people as (1) ineligible for screening tests, (2) screened or (3) unscreened.⁴⁸ Annual values will reflect the proportion of screened months within the year.
- ▶ **Postdischarge follow-up:** Time to physician follow-up in days and the proportion of people who saw a family physician (or psychiatrist for SMI cohort) within 7 and 30 days of discharge.
- ▶ **Readmission:** Time to readmission in days and proportion of people admitted within 30 days.

The following variables describing patient characteristics will be used in descriptive analysis and to construct propensity scores: age, sex, neighbourhood income quintile, pharmaceutical coverage under programmes for people on income assistance, immigration status and rurality of residence.

Analysis

Analysis is largely descriptive, with comparison across the identified cohorts with respect to the outcomes identified above. To ensure greater comparability, we will use propensity scores based on age,⁴⁹ sex, neighbourhood income quintile and rurality to match the comparison groups.

Qualitative strand: in-depth semistructured interviews

We will use qualitative inquiry to answer our research questions about the lived experiences of people with SMI receiving and accessing primary care as well as those of primary care providers taking care of this population. The two sets of interviews will be conducted sequentially, starting with people with lived experience (phase I), followed by primary care providers (phase II). Below we describe recruitment and analysis for both studies together.

Participant recruitment

People living with SMI (phase I)

We will recruit up to 40 participants per province from a mix of tertiary mental health, academic and community hospitals. Eligible participants will be 19 years or older, have seen a primary care provider at least once in the last year and have been discharged from a psychiatric hospitalisation in the previous 3–24 months. We have chosen to use hospitalisation as a proxy for SMI to align with the quantitative data approach. In addition, in our consultation with the LET members, they shared that people would feel more comfortable participating in a study that defined its target population by a psychiatric hospitalisation rather than by an SMI diagnosis or label. Our sample size of up to 40 participants per province will allow us to seek maximum variation^{50 51} and stratify by type of hospital where the patient was admitted (tertiary, academic, community), gender and age group (eg, young adult, middle age, senior). The sample size is approximate as this will be an iterative process that overlaps with

data analysis, and interviews will continue until there is a sense that no new themes are being identified.^{52 53}

Prospective participants will be identified by hospital and clinical staff either during their hospital stay or through a hospital's outpatient follow-up programme (depending on each hospital's programmes and recruitment capacity). Patients who are currently hospitalised will be informed about the study and asked at discharge if they are interested in learning more about participation in the study and willing to provide consent to be contacted. Patients who are already discharged will be given information about the study during follow-up appointments, and similarly asked to provide consent to be contacted. In order to ensure that patients have time to adjust following hospitalisation, participants will not be contacted by the study team for a minimum of 3 months following discharge. Once that time period has elapsed, the study's research coordinator will reach out directly to prospective participants and enrol those who meet the study criteria and are interested in participating.

Interviews will be conducted by trained qualitative interviewers who are experienced with this population. They will be held either by telephone or by video conference, based on the participant's preference, and will be audio-recorded. The interview session will begin with verbal consent and participants will then be offered a choice of gift card as a thank you for participation. Following consent, short demographic questions will be asked. The interviewers will then ask a series of open-ended questions. The interview guide was developed in collaboration with our LET members and asks participants a variety of questions about their experiences with primary care, in particular prevention and management of chronic disease. Interviewees will be asked to share stories about times when primary care providers met their medical needs as well as to describe instances when they felt their medical needs were not met. We anticipate interviews will last between 60 and 90 min, but they may run shorter and/or be conducted over multiple sessions if preferred by the participant.

Primary care providers (phase II)

After we complete the interviews with people with lived experience, we intend to recruit 30 provider participants per province for interviews. We expect a sample size of 60 participants will allow us to reach saturation in each province and provide enough data to investigate potential differences by subgroups and regions.⁵⁴ We anticipate needing fewer interviews to reach saturation with provider participants due to the potential for less heterogeneity in provider experiences relative to patient experiences.

We will recruit providers by drawing on the support of a variety of primary care membership organisations. These partnering organisations will send recruitment emails to primary care providers via their listservs on our behalf. Interested providers will be asked to

contact members of the research team directly. We will also identify participants through partnering hospitals who will send recruitment emails on our behalf to referring primary care physicians. We will include primary care providers that care for people with SMI (eg, family physicians, nurse practitioners) from different primary care models (eg, solo practice, team-based practice).

Provider interviews will be conducted remotely, using either telephone or video conference, will last no longer than 60 min and will be audio-recorded. The same verbal consent process used with the patient participants will be followed, and an interview guide will be developed that covers various dimensions of providers' experience delivering care to people with SMI. This guide will be informed by preliminary results of interviews with people living with SMI (phase I). Provider participants will be asked to share: their experiences caring for patients with SMI, including chronic disease management and preventive services; challenges in providing care at the individual, organisational and systems levels; success stories and factors that enable them to provide quality primary care to people living with SMI. Interviews will conclude with a question about how participants think they can be better supported when caring for patients with SMI. An honorarium will be offered as a thank you for participation.

Analysis of qualitative data

The audio recordings of the interviews from phases I and II will be transcribed verbatim, and the transcripts will be analysed using NVivo software. We will conduct an inductive exploratory thematic analysis of the interview data,⁵⁵ starting with phase I data. Thematic analysis will occur concurrently with data collection in order to identify any emerging themes that could be added to subsequent interviews. This approach will also help to assess saturation.

We will follow thematic analysis as described by Braun and Clark.⁵⁵ A group of researchers will independently inductively code a sample of transcripts, then meet to discuss and develop a codebook. Once a codebook is finalised, all transcripts from that participant set will be coded. The qualitative team will then meet to group data into broad common themes. This stage requires active interpretation to inform theme development. Last, we will review extracts within themes to ensure they have been appropriately classified and determine if there are any contradictory elements.⁵⁵⁻⁵⁷ Constant comparison will be used to compare and contrast themes from our data with concepts already in the literature.⁵² A cross-case comparison between the two provinces will allow us to observe any similarities and differences between the experiences of both people with lived experience and providers in Ontario and British Columbia. The analysis will help identify individual, organisational and system-level opportunities for improvement.

ETHICS AND DISSEMINATION

This mixed methods study has received research ethics board approval from the University of Ottawa as well as institutions affiliated with the study team, as required. The quantitative strand of the study draws on fully deidentified data, which is not linked in any way to the qualitative data. Informed consent will be secured from all qualitative participants prior to their interviews and all qualitative data will be deidentified to protect the identity of study participants.

This project will generate traditional academic outputs crossing multiple disciplines, including peer-reviewed publications and conference presentations. We have engaged with knowledge users from provincial governments, tertiary facilities, academic and community hospitals and primary care settings for this study. During protocol development, these individuals provided critical insights into the gaps in adequate medical care faced by people with SMI. They will continue to engage as members of the study's working groups or as part of an advisory committee to (1) support the integration of the results using a contextual analysis³³ to derive understanding of how system and organisational factors contribute to supportive primary care; (2) enable stakeholders to contextualise the results using their real-world experience and (3) use the results of the study to create an action plan for implementing change⁵⁸. This engagement will inform interventions that aim to improve primary care by creating a more complete picture of the primary care and mental health context in Canada. Knowledge users will work with the research team to develop policy and organisational recommendations to support better primary care for patients with SMI.

Author affiliations

- ¹Telfer School of Management, University of Ottawa, Ottawa, Ontario, Canada
- ²Edson College of Nursing and Health Innovation, Arizona State University, Tempe, Arizona, USA
- ³Faculty of Health Sciences, Ontario Tech University, Oshawa, Ontario, Canada
- ⁴Ontario Shores Centre for Mental Health Sciences, Whitby, Ontario, Canada
- ⁵Department of Family Medicine, Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada
- ⁶Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, Ontario, Canada
- ⁷Substance Use and Concurrent Disorders Program, The Royal, Ottawa, Ontario, Canada
- ⁸Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada
- ⁹Department of Mental Health, The Ottawa Hospital, Ottawa, Ontario, Canada
- ¹⁰Faculty of Health Sciences, Simon Fraser University, Vancouver, British Columbia, Canada
- ¹¹Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ¹²Department of Family Practice, The University of British Columbia, Vancouver, British Columbia, Canada
- ¹³N/A, Victoria, British Columbia, Canada
- ¹⁴Patient and Family Centred Care, Kingston Health Sciences Centre, Kingston, Ontario, Canada
- ¹⁵Client and Family Relations, The Royal, Ottawa, Ontario, Canada
- ¹⁶Centre for Health Services and Policy Research, The University of British Columbia, Vancouver, British Columbia, Canada
- ¹⁷School of Population and Public Health, The University of British Columbia, Vancouver, British Columbia, Canada
- ¹⁸Research and Evaluation Department, Alliance for Healthier Communities, Toronto, Ontario, Canada
- ¹⁹Department of Family and Community Medicine, University of Toronto, Toronto, Ontario, Canada

- ²⁰Department of Psychiatry, The University of British Columbia, Vancouver, British Columbia, Canada
- ²¹BC Mental Health and Substance Use Service, Provincial Health Services Authority, Vancouver, British Columbia, Canada
- ²²Waypoint Research Institute, Penetanguishene, Ontario, Canada
- ²³Department of Psychiatry, University of Toronto, Toronto, Ontario, Canada
- ²⁴Department of Psychology, McGill University, Montreal, Québec, Canada
- ²⁵Centre for Addiction and Mental Health, Toronto, Ontario, Canada
- ²⁶ICES, Toronto, Ontario, Canada

Twitter Agnes Grudniewicz @agrudniewicz, Allie Peckham @PeckhamA, Rita McCracken @DrRitaMc and Jennifer Rayner @RaynerJen

Contributors AG, AP, DR and MRL conceptualised the study. AP and AG developed the qualitative research methods. AG wrote the introduction, qualitative strand methods and ethics and dissemination. DR and MRL developed and wrote the quantitative strand methods. ER substantially revised the protocol manuscript. LL, CN, AO, KP, NS, HT and PK advised on study design throughout protocol development. All authors provided substantial feedback on the manuscript and approved the final version.

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Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study.

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ORCID iDs

- Agnes Grudniewicz <http://orcid.org/0000-0003-2960-8178>
 David Rudoler <http://orcid.org/0000-0002-7564-5829>
 Rachelle Ashcroft <http://orcid.org/0000-0002-5666-1946>
 Rita McCracken <http://orcid.org/0000-0002-2962-0364>
 Christian G Schütz <http://orcid.org/0000-0002-5445-8290>
 Paul Kurdyak <http://orcid.org/0000-0001-8115-7437>

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