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Title

Improving access for vulnerable populations in Australia and Canada: Protocol for a Mixed-Method Evaluation of six complex interventions

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Abstract

Introduction: Access to primary health care (PHC) has a fundamental influence on health outcomes, particularly for members of vulnerable populations. Innovative Models Promoting Access-to-Care Transformation (IMPACT) is a five-year research program built on community – academic partnerships to design, implement and evaluate organisational innovations to improve access to appropriate PHC for vulnerable populations. Six Local Innovation Partnerships (LIPs) in three Australian states and three Canadian provinces used a common approach to implement six different interventions. This paper describes the protocol to evaluate the processes, outcomes and scalability of these innovations.

Methods and analysis: The evaluation used a convergent mixed-methods design involving longitudinal (pre and post) analysis of the implementation of six interventions in regions associated with each LIPs. Study participants vary according to relevance at each site, and include vulnerable populations, PHC practices, their clinicians and administrative staff, service providers in other health or community and social service organizations, intervention staff and members of the LIP teams. To generate an understanding of the set-up and implementation processes, we have been using data from: interviews with key informants; non-participant observation; routine organizational process data; document analysis; and economic evaluations collection tools. To examine the impact on participating individuals and organizations, we used patient, provider practice and organisational surveys, semi-structured interviews, direct observation, and semi-structured interviews administered in most of the settings before and three-to-six months after the interventions.

Ethics and dissemination: The IMPACT research program received ethics approval from St Mary's Hospital Montreal SMHC # 13-30. The varied interventions received a range of other ethics approvals across the six jurisdictions. The findings will be shared through a range of activities including publications in scientific journals, presentations at conferences, plain language press releases targeted at decision makers and public, communications via social media and project newsletters. Outcomes should help inform the work of others grappling with similar access problems.

Strengths and Limitations of this Study

- International research program designed to improve access to primary health care for vulnerable populations
- Community – academic partnerships in six regions in Australia and Canada.
- Each intervention required mobilisation of local resources to match regional access needs and implement an intervention tailored to local context
- Interventions evaluated using a common methodology oriented to Levesque et al's Access to Care Framework and an overarching logic model.

Background

Recent and widespread reforms in primary health care (PHC) in western countries reflect a growing concern that health systems should become more affordable, inclusive and fair [1, 2]. In Australia and Canada, PHC reforms prioritise access to effective and high-quality health services, with equity being at the heart of that system [3, 4]. Despite these reforms, meaningful gaps in equitable access to PHC remain [5-7]. These gaps particularly affect vulnerable populations, such as poor, refugee and indigenous communities [7-13] and translate into unmet needs for care, delayed or inappropriate treatments, avoidable emergency department consultations and hospitalisations [5, 14]. Few PHC innovations directed at these needs have generated transformative change throughout health care systems [5].

The Canadian Institutes of Health Research's (CIHR) Community-Based Primary Health Care (CBPHC) Signature Initiative was designed to identify innovative approaches to improving the delivery of appropriate, high-quality community-based PHC [15]. The Initiative, launched in 2013, aimed to develop and compare innovative models for CBPHC delivery within Canada and/or internationally; build research capacity; and foster effective knowledge translation to improve the delivery of CBPHC. The Initiative's most significant investment involved funding 12 teams to conduct five-year intervention studies to improve access to CBPHC and/or chronic disease prevention and management for vulnerable populations. One of the 12 teams had an additional focus on Australian PHC through collaboration with the Australian Primary Health Care Research Institute's Centre of Research Excellence program. The successful applicant to the Canada/Australia funding opportunity was a consortium of researchers, clinicians and policy makers from three Australian states (New South Wales, Victoria, South Australia) and three Canadian provinces (Alberta, Ontario, Quebec).

The resulting program, Innovative Models Promoting Access-to-Care Transformation (IMPACT), [16] involved a five-year research program built upon a network of Local Innovation Partnerships (LIPs) bringing together decision makers, researchers, clinicians and members of vulnerable communities. In each of the six regions, LIPs worked to design, implement and evaluate unique organisational interventions to address a priority gap in access to appropriate PHC for vulnerable populations [17]. The CBPHC funding underwrote evaluation of these interventions, but not their implementation costs.

This paper describes the approach used to evaluate the effectiveness and further scalability of the interventions generated by the IMPACT program. Figure 1 depicts the overall design of the program, and Box 1 details the design of the IMPACT program. Specific evaluation questions are outlined in Box 2.

Methods

DESIGN

Our evaluation used a convergent mixed-methods design [18] involving longitudinal (pre and post) evaluation of the implementation of interventions in regions associated with the six LIPs. Qualitative and quantitative data relevant to each intervention were collected in parallel, organised separately, then brought together to provide complementary evidence to answer the study's research questions. Data were collected by common tools administered before and three to six months after each intervention.

The overall project was oriented to Levesque et al.'s Access to Care Framework [19] and was informed by a logic model (Figure 2) that represented the potential consequences of the interventions. The Levesque framework views access to PHC as a dynamic process, the interface between five dimensions of client abilities (ability to initiate, seek, reach, pay or engage) and five dimensions of service accessibility (approachability, acceptability, availability/accommodation, affordability and appropriateness). The scientific work of the study was informed by an International Expert Forum comprising leading primary care health services researchers from Europe, North America and New Zealand who critically appraised the design, evaluation tools and approaches and participates in the interpretation of key findings.

SETTING

Table 1 outlines the characteristics of the six settings and vulnerable populations targeted by the interventions. Regions corresponding to the six sites are characterized by low socio-economic status (SES) and diverse cultures.

Table 1 Characteristics of the IMPACT interventions

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
Targeted population	Individuals and groups of vulnerable populations living in North Lethbridge that have limited access to PHC. Includes immigrant, low income, Aboriginal, senior and homeless populations.	Orphaned patients (no PHC provider), particularly those in high deprivation neighborhoods (low income, low social support, etc.) and those with complex needs	PHC patients, with strategies to ensure equitable access to community resources for socially vulnerable patients	Vulnerable populations with at least one of these characteristics: low socioeconomic status, underemployed, socially isolated due to geographic distance/public transport inaccessibility, mental health issues. Specific subgroups: aged (65+) or those living with a disability or mental health condition	Patients with poorly controlled diabetes attending practices in low socioeconomic localities. Specific subgroups in these localities included: low socioeconomic status, Indigenous community, culturally and linguistically diverse communities, refugee and humanitarian entrants.	Aged and frail residents with complex/chronic health problems and high medical needs from 3 RACF across the Adelaide metropolitan area. This population cohort characterises by social isolation and reliance on others for the provision of care and thus can be extremely vulnerable.
Primary research question	What are the components of outreach and co-location as identified by vulnerable populations that contribute to making PHC services more approachable and engaging (e.g., welcoming and unintimidating) for vulnerable populations in other contexts?	What are the benefits of having a community health worker (CHW) in a clinic? What does the CHW have to do to achieve those benefits (tasks, activities, roles)?	Can organizational changes be implemented within PHC practices to increase providers and staff members' awareness of community-based primary health care, support them to make appropriate referrals to community resources and address patients' social	Can a health service brokerage process involving PHC liaison workers and social service providers in the community a) identify vulnerable individuals who are likely to benefit from better access to quality PHC?	For a vulnerable population with chronic disease, 1. What is the impact of supported access through PHC to web based information and education tools that support self-management, navigation and/or self-monitoring of health service use, risk	Can a PHC provider-led, multidisciplinary team approach to the management of chronic/complex conditions with a focus on fall prevention and end-of-life care result in improved access and provision of high quality, safe and effective PHC for Residential Aged Care Facilities (RACF)?

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
			barriers to reaching these resources?	b) successfully link these individuals with PHC practices?	behaviours and health outcomes? 2. What factors enable use of web based information and education tools that support self-management by different patients attending practices in low socioeconomic areas?	Can this type of program improve outcomes for vulnerable aged care residents, including a reduction in hospital transfers, readmissions or relapse rates?
Intervention type	A pop-up service (a type of outreach) with a focus on cross team collaboration). Addressing access dimensions approachability, ability to engage and ability to reach.	A community health worker connects vulnerable patients to services, assists primary care practices to provide appropriate care and helps patients develop navigation skills to overcome barriers to access.	Lay Navigators support PHC patients to reach community resources. PHC practice staff training and facilitation to increase providers' awareness of community resources.	A health service brokerage process implemented in 3 health care services.	Supported access through PHC to a diabetes self-management website that provided information and referral options to support self-management, facilitated by practice nurses at a health check visit in the PHC practice	Participating Residential Aged Care facilities implemented a process of redesign of policies and procedures to improve consistency of primary care in particular afterhours care.
Key elements of the intervention	• Bringing together a variety of service providers in one location that is easily accessible to residents of North Lethbridge at one time (4–5 hours).	• Following assessment, a community health worker connects vulnerable patients to new family physicians and needed social and	• A non-clinical, bilingual, Patient Navigator is established in practices to assist patients to reach the health and social services available in	• Identification of vulnerable patients who are likely to benefit from improved access to an appropriate PHC provider.	• Identifying clients who have poor self-management of type 2 diabetes from an audit of medical records. • Providing training to general practitioners and practice nurses	• Implementation of protocols to improve consistency of care, including afterhours care provision (redesign of policies and procedures).

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
	• Providing training to the service providers about creating a warm and welcoming environment. • Attendees directly accessing services such as a physician, dental care, immunizations, recreation services, food bank, etc. in one place at one time.	community services, assists primary care practices to provide appropriate care and helps patients develop navigation skills to overcome barriers to access.	the community to which they have been referred.	• Identification of PHC providers able to provide care according to the patients' needs and preferences. • Linkage to an appropriate PHC provider and follow up with each patient to ascertain whether they are likely to seek care from the PHC provider in the future (with repeat process if patient reports lack of fit).	about improving diabetes self-management and health literacy. • Developing a web-based diabetes portal designed to improve self-management and referrals to appropriate providers for self- management support. • Recalling clients for a health check involving assessment, brief advice, demonstration of the web portal and discussion of several pages relevant to the patient, arranging a follow up visit with the GP and another health check at 12 months.	• Peer-led PHC provider and other clinic RACF training in the protocols. • PHC provider assigned to all residents of RACF. • Each resident has a care plan. • Awareness and education for families and carers.

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
Recruitment	*Patients* Principally by distribution of posters and postcards through existing service providers and at community businesses (e.g., grocery store, etc.); media release, radio advertisement and social media (Twitter, Facebook, *via* our team and also through participating service provider organizations)	*Patients* Patients registered on a centralized waiting list who were attributed to a family physician at one of four participating clinics were selected on a territorial basis using the material and social deprivation index. If the patients' neighbourhood scored high for material and/or social deprivation, they were eligible to receive the intervention. *Practices* This LIP targeted possible clinics located in their local territory. These clinics were subsequently contacted by a member of the research team (if there was an existing relationship) or by one of the local partners.	*Patients* The study does not recruit patients directly. Eligible study patient participants are identified by their primary care provider and are patients who are referred to a community resource by their primary care provider. *Practices* Practices with whom our research group has had a working relationship will form the potential pool of potential participants.	*Patients* New and existing HACC, ICH-T and dental clients who cannot identify a personal FP or have not made contact with their FP for 12 months or more. *Practices* Accredited primary care practices operating in the Greater Dandenong area willing to provide care for new patients with access vulnerability. Practices needed to provide general primary care services. Practices will need to be willing to take on clients with a disability or mental health condition. FPs/practices will be briefed by the academic team and provided with training materials.	*Patients* Eligible participants are patients attending the practice in the previous 2 years with type 2 diabetes aged 40-74 years with HbA1c>7 or BP>130/80 or BMI > or =30. They will be invited by a mail invitation sent from the practice. *Practices* Family practices will receive a written invitation from the Primary Health Network to participate in the study. The invitation will be provided to practices providing care for the target groups (socioeconomically diverse and Arabic-speaking practices). Those practices who agree to participate will be asked to complete the practice survey and their staff	*Patients* The residential aged care facility staff will assist with identifying appropriate and interested residents. Residents must have the cognitive capacity to understand what is being asked of them and be able to give informed consent either verbally and/or by signing the consent form. *Practitioners* Clinical staff (physicians, nurse practitioners, nurses) who are employed by the residential aged care facility implementing the Dandelion intervention or, in the case of some FPs, have visiting arrangements to the relevant residential aged care facility.

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
					complete the baseline practitioner survey.	Practitioners will be invited to complete an on-line questionnaire and also participate in a qualitative interview.

INTERVENTIONS

Patient and Public Involvement

The development of the interventions was informed by regional assessments of access related need, formal community consultations and a series of research studies completed by the IMPACT team (see Figure 1). In each region, formal community consultation comprised two deliberative forums with local decision makers, health and human service providers and community representatives to prioritise access needs for their vulnerable populations and develop a solution specific to local needs. Deliberative forums provided opportunities for members of the community to listen and negotiate through dialogue, creating mutual understanding and developing social capital [20]. The first forum in each region identified priority primary care access gaps; the second focussed on possible approaches to address these gaps.

The research studies comprised: a scoping review of organisational interventions to improve access for vulnerable populations (Project 1a) [21]; an email and social media search to identify unpublished PHC access innovations (Project 1b) [22]; a series of systematic reviews of components of each intervention (Project 2); and several access-oriented reanalyses of data generated by the Commonwealth Fund (Project 3)[23, 24] (See Figure 1).

Intervention Design

The interventions ranged in focus and mechanism. The Alberta LIP held a series of pop-up events where a range of service health and social welfare providers met with members of the local community. Quebec and Victoria LIPs developed interventions linking consumers with a source of ongoing primary care. South Australia worked with partners to evaluate an aged care intervention to improve after-hours access to quality primary care. Finally, New South Wales implemented an intervention to improve diabetes care, including development of a website and health checks.

STUDY POPULATION

The interventions involved a range of participants, including: vulnerable populations, PHC practices, their clinicians and administrative staff, other service providers, intervention staff and LIP teams members.

Study participants: vulnerable populations

All interventions were targeted at vulnerable populations, defined for this study as community members whose demographic, geographic, economic, and/or cultural characteristics compromised their access to PHC. The specific social vulnerability of the study population varied based on regional priorities. They included residents of aged care facilities, diabetics from immigrant populations, people living with chronic disease and community members in regions with limited supply of primary care professionals.

Study Participants: health care providers

Most of the interventions involved family physicians, non-physician clinicians (i.e. nurses, social workers), managers and other executives, as well as administrative staff in family practices or community organizations.

Study participants: intervention staff

The composition and nature of intervention staff varied between LIP interventions. Different sites used lay and health professional navigators, family practice nurses, allied health professionals, health care managers, community service providers, residential aged care nurses, trainers and intake/screening staff.

Study participants: members of Local Innovation Partnerships

Each LIP had a research team (study investigators and research associates) and a broader advisory group ("LIP core team"). The LIP Core team comprised an IMPACT Principal Investigator, a LIP Lead, a LIP coordinator (a field worker responsible for coordinating, documenting and managing the work of the LIP) and decision makers, other researchers, clinicians, and members of the community.

MEASURES

The study measures are grouped in terms of their focus on patients and health care providers; intervention staff; and members of LIPs.

1) MEASURES GATHERING DATA FROM CONSUMERS AND HEALTH CARE PROVIDERS

a) Quantitative data measures

We developed four different **survey instruments** (questionnaires) for patients, health care providers (family practitioners and nurses), family practices, and staff within community services. Since the impact of the intervention on the participants will be determined by comparing responses before and after the intervention, the questions in the post-intervention questionnaires duplicated many of the pre-intervention questions plus additional questions about the respondents' intervention experiences.

As with other projects funded by the CBPHC initiative, the patient, provider and practice surveys were adapted from previously-used instruments, including surveys originating from an initiative of the Canadian Institute for Health Information [25], and supplemented by additional questions developed for this study (Table 2). Each questionnaire was piloted prior to finalisation. All surveys were available in English and French (for Canadian administration to English speaking and Francophone populations).

Table 2: Survey measures

Survey	Informed by or adapted from existing instruments or studies
Patient survey	Primary Care Assessment Tool [26]; Primary Care Assessment Survey [27]; EQ-5D-5L [28]; Veterans RAND 12-item Health Survey [29]; Canadian Survey of Experiences with Primary Health Care [30]; Perceived Need for Care Questionnaire [31]; Canadian Community Health Survey [32]; Patient Perception of Patient-Centeredness [33]; GP Patient Survey [34]; Interpersonal Processes of Care Survey [35]; Health Literacy Questionnaire [36] The patient survey was translated into French, Arabic and Easy English where required.
Provider survey	Comparison of Models of Primary Care in Ontario study [37]; Preventive Evidence into Practice study [38]; National Pain Strategy [39]; Community-Based Primary Health Care Common Indicator Project [40]
Practice survey	Community-Based Primary Health Care Common Indicator Project [40]

Organizational survey	Evaluation of the Primary Care Partnership Strategy. Victoria, Australia.[41]

The patient survey provided data on patients' ability to access PHC (including ability to perceive, seek, reach, pay and engage), experiences with and utilisation of healthcare services (appropriate care and referrals), relationships with PHC providers, links with community and other health services, engagement with primary medical care, and the appropriateness of healthcare received. It included information on general health and demographics. One site translated the patient survey into Arabic and another prepared plain language versions for participants with developmental disability or other cognitive problems. The survey was administered face-to-face or by telephone, as appropriate for vulnerable populations.

The PHC provider survey was completed by primary care clinicians responsible for direct patient care (family practitioners or nurses/nurse practitioners). Questions included demographic information and explored their experience, confidence and clinical activities used in managing vulnerable populations in general and the population targeted by the LIP.

The PHC practice survey was designed to ascertain the structural and organisational characteristics of PHC clinics. The survey captured details on the patient population, services, procedures and policies, especially as related to vulnerable patients. It also sought information on staffing, funding sources, collaborative arrangements and communication infrastructure. It was completed by the lead physician or, where available, practice manager.

The health and community services practitioner survey was used where applicable and included items from the PHC surveys where relevant, with additional questions used in previous evaluations of state-wide partnership-based health system reform strategies. The survey focused on internal policies, procedures, practices and relations with external service providers and PHC providers. It was completed by health and community service workers and/or managers. Individual LIPs supplemented these tools, as required.

b) Qualitative data measures

In-depth qualitative, semi-structured interviews with patients and PHC providers were conducted before and three-to-six months after the completion of the intervention. Interview guides were aligned to components of the Access Framework (1) and local logic models. Guides were tailored at each site to reflect features of the local intervention. Question sequencing was flexible, allowing participant responses to guide the course of the interview. Contact Summary Sheets documented interviewer reflections after each interview [42].

Patient interviews. Most sites limited pre-intervention qualitative data collection from patients to two open-ended questions that described patient prior experiences of seeking and reaching primary care. These questions were administered in conjunction with the patient survey. Post-intervention interviews investigated patients' experience and perceived acceptability of the intervention and its perceived impact on their ability to access primary care.

PHC provider interviews. Pre-intervention provider interviews explored existing organizational and individual approaches relating to the provision of accessible primary care to vulnerable populations. Post-intervention interviews explored how the intervention influenced usual routines (organizational and individual) relating to vulnerable patients the impact of the intervention on their own and the practice's work, and on the perceived feasibility of its broader implementation.

Non-participant observation in PHC settings: Canadian sites compiled a comprehensive profile of the contextual, organisational and physical structure of a sample of PHC practice settings. The profile was based on a modified tool previously used in the collection of observational data from family practices [43, 44]. Observers documented the physical space of the practice, front desk and administrative staff scheduling procedures and routines, staff interactions, practice flow and other waiting room/reception desk activities. These observations were focused on activities relevant to vulnerable patients' access and were recorded as field notes.

2) MEASURES GATHERING DATA FROM INTERVENTION STAFF

Interviews with intervention staff and/or members of health and community services were conducted in some LIPs to explore their involvement in the delivery of the intervention and perceptions concerning the sustainability of intervention activities.

Expense diaries: Intervention staff gathered data on the cost of all non-research activities that incur a cost or opportunity cost (e.g., use of existing resources), including staff time (hourly salary), consumables/operating costs (e.g., telephone calls, printing), travel, and one-off costs (e.g., web site development).

Navigator records: Several of the interventions used health navigators to assist with access needs. Navigators kept field diaries, minutes of team meetings and materials and evaluation reports from the educational events associated with the intervention.

3) MEASURES GATHERING DATA FROM MEMBERS OF LOCAL INNOVATION PARTNERSHIPS

The study's process evaluation relied on data from interviews with LIP Core Team and Research Team members. These were conducted in four cycles (2014, 2016, 2017, 2018) by independent research assistants not associated with the LIPs. Each site's LIP lead, LIP coordinator and other research staff participated in interviews at these time points assessing their perceptions of how the program was organised, including governance (international/national executive committees, project organisation, etc.), approaches to researcher and stakeholder collaboration (LIPs), organisation of staff and communication. Non-researcher members of the LIP Core Teams were also interviewed at several time points at most sites.

LIP coordinators documented the development and characteristics of their region's intervention. All coordinators kept a diary that recorded key events during the development and implementation of the intervention.

DATA COLLECTION

Surveys: We used the software program Qualtrics™ *[45]* for collecting and organising survey data. Trained members of the research team working in each region administered surveys in-person or over the telephone. PHC professionals and practice staff also had access to paper versions which were then imported into *Qualtrics*™.

Interviews: In-depth semi-structured interviews were conducted by trained interviewers face-to-face or over the phone. Interviews were audio-recorded. In the three Australian LIPs, the recorded interviews were transcribed verbatim. In Canada, narrative summaries (i.e. purposeful transcription) of the interviews were created by researchers who conducted the interview. All qualitative interview data were managed using the QSR International's server-based software NVivo for Teams [46]. Non-participant observations were recorded as field notes by research staff attending participating PHC practices during the intervention. The number of observations varied by LIP and depended on the interventions' method and mechanism of implementation. Each observation session lasted approximately one hour.

DATA MANAGEMENT

All qualitative and quantitative data associated with the interventions were collected locally and labelled with a unique participant number. Common rules were followed for naming variables and coding data to facilitate merging and mixed-methods analysis. For the analysis, both the qualitative and the quantitative data sets were stored in a central data repository. Separate qualitative and quantitative analytic teams were established for analysis.

DATA ANALYSIS

Evaluation questions were formulated to guide the analysis of the set-up, implementation and impact of the organizational interventions (Box 1).

Evaluation question 1: The research program's support for the intervention.

The first evaluation question uses a developmental evaluation approach to explore how the overall program's approach to governance, relationships and processes influenced the design, development, implementation and sustainability of the interventions.

We collected data about how the programs were planned, implemented and evaluated [47]. This process evaluation focused on all aspects of the development and implementation of the IMPACT program, with a particular focus on the evolution of work within each LIP. The process contributes to ongoing reflection by the IMPACT team about the way the research program has been conducted through reports and discussions after each round of data collection.

Data sources include semi-structured interviews with LIP Core Team and Research Team members, routinely collected documents (including minutes of meetings) and, in some LIPs, interviews with partners and stakeholders. The analysis of the first evaluation question involved a hybrid deductive-inductive content thematic analysis [48]. The initial round of analysis included identification of themes, codes and key words based on analysis of notes and interview transcripts. The process was iterative and members of the research team reviewed the initial codes. To ensure coding reliability between the intervention sites, one qualitative researcher separately and independently coded two Australian and two Canadian interviews. All issues identified were discussed by the team and then further analysis was undertaken.

Evaluation question 2: the implementation of the intervention

The second evaluation question seeks to identify whether the interventions were implemented as planned, and to ascertain the contextual factors influencing the intensity and fidelity of the interventions. Here, the unit of analysis is the intervention implemented at each of the six sites: each intervention is a case. Overall, we used an embedded qualitative design where the majority of the analyses depended on qualitative data routinely collected during the interventions.

Data sources included the measures used to gather data from intervention staff and from members of the LIPs (see above). Sites used additional processes to track implementation fidelity. Some measured the degree to which patients attended health checks or practices to which they had been linked. Others captured detail of patient assessments, use of intervention components (ie websites) and referral destination.

LIP coordinators in each site used their diaries, along with minutes of meetings of the LIP partnerships to help generate two summary documents: a) the Template for Intervention Description and Reporting

(TIDieR), a template for describing the characteristics of each intervention [49] and b) perceived contextual influences on the implementation and fidelity of each intervention arranged within a self-designed template, based on Stange and Glasgow's approach to reporting contextual influences on the patient-centred medical home [50]. Both documents were further informed by each region's demographic data and access needs assessments conducted early in each LIP's development. A central analysis team combined this data with documentation of outputs from the deliberative forums as well as summarised data from the Developmental Evaluation.

The validity of the data was checked using a member checking approach [51] where summaries were shared with and corroborated by LIP coordinators, LIP leads and core team members.

Finally, the analysis team will use a cross-case synthesis analytic technique incorporating constant comparative analysis where resulting data can be compared. Summaries will be coded then node extracts reviewed and matrices developed, comparing the interventions across thematic domains. We will use May's ecological model of the ways that context interacts with participants and interventions as a lens to explore the data [52].

Evaluation question 3 and 4. Evaluation of the impact of the intervention on patients, providers, practices and on health care utilisation

Question three considers, how did the interventions influence i) patient participants' abilities to access appropriate primary health care ii) providers' knowledge and confidence to support the care of vulnerable patients and iii) practice processes and policies to support vulnerable patients' access to appropriate primary care. Evaluation question 4 seeks to ascertain the effect of the interventions on i) enduring relationships with PHC; ii) appropriateness of referrals iii) use of comprehensive primary care iv) continuity and vi) use of emergency departments and hospitals for ambulatory care sensitive conditions.

This component of the evaluation will be addressed with a convergent mixed-methods design, informed by the Levesque et al Access to Care Framework [19] and the project's logic model. Analysis will first take place at the level of the LIP intervention by local analysts who will identify the dimensions of access within the logic model that would be influenced by the intervention.

Quantitative analysis began with data cleaning and, dependent upon sample sizes, exploratory factor analysis so that items with high communality can be combined, thus reducing problems associated with running multiple statistical tests [53]. In each LIP, the distribution of test variables were checked to ensure they met the assumptions of the statistical test for which they were used. For example, variables for which a ceiling or floor effect was evident will be excluded.

First, we sought to identify change between variables measured in pre- and post-intervention surveys, at the level of each LIP intervention by creating change scores (post-intervention minus baseline responses). We then assessed predictors of change (where sample size was sufficient) through beginning with bivariate tests for relationships between predictors (i.e. patient: age or gender; practitioner type; practice size) and change scores, prior to conducting multivariate analyses of predictors of change scores based upon statistically significant univariate analyses. Where sample size is not sufficient, a case study or qualitative approach will be used to consider factors that might have influenced the results.

Qualitative analysis: Conceptual phrases from the Levesque *et al.*'s Access to Care Framework [19] will be attributed to segments of data from pre-intervention interviews of patients and providers using structural coding techniques. The similarly coded segments will then be collated for more detailed coding and analysis using an inductive approach. A similar process will be applied for post-intervention patient and provider interview data. The coding for pre- and post-intervention data will then be compared for each domain of the Access to Care Framework [19], noting changes that can be attributed to the intervention.

Each LIP then will develop case studies generated from the analytic plans and designed around the components of the questions that fitted the logic of each intervention.

Cross case analysis The analysis between the LIPs will be informed by Crabtree et al.'s approach to meta-synthesising results where investigators who conducted the original projects are part of the analysis team [54]. This approach incorporates tacit knowledge from investigators and other products of the research program into the overall analysis. We will begin by identifying aspects of the evaluation questions where data exists to be able to generate valuable insights for policy makers, clinicians, vulnerable communities and researchers. The analysis will be performed by a team comprising at least one member of each of the LIPs.

ETHICS AND DISSEMINATION

The IMPACT research program received ethics approval from St Mary's Hospital Montreal SMHC # 13-30. The varied interventions received other ethics approvals across the six jurisdictions. The findings will be shared through a range of activities.

During the course of the study, a quarterly newsletter has been made available to study participants, collaboration partners and the interested public to inform them about the progress of the study and its results. This newsletter is disseminated via the mailing list and remains available for download on the project website. Updates on the study are also communicated via IMPACT's Twitter account. Policy and practice summaries will be developed and made available to the decision makers through collaboration partners and plain language press releases. The results will be disseminated in scientific journals and will be presented at relevant international and national conferences. To ensure high accessibility, we aim to publish our work in open access journals. Outcomes should help inform the work of others grappling with similar access problems.

Discussion

The protocol outlines the approach for the evaluation of a large-scale, multi-site program, built on community-academic partnerships and designed to address important challenges or barriers in the delivery of PHC. The program of work is complex and requires cooperation and collaboration between diverse teams at a local, national and international level. The diversity of targeted vulnerable populations and differences in the interventions trialled has challenged planning, data management and measurement.

Nevertheless, as the multiple facets of the evaluation are addressed over the next 12 months, we anticipate rich insights into the evolving field of primary care health services research that is built on community-academic partnership.

The program of work within the IMPACT initiative has already identified the promise of formal integration of services to improve access to primary care services for vulnerable populations [21], the prevalence of effective but unpublished PHC access interventions [22], and the factors associated with multiple barriers to primary care [23]. Our systematic reviews provide rigorous information on the effectiveness of several innovations, as well as on their scalability in different contexts and anticipated economic impact.

For the broader PHC community, the results of evaluations of the evolution of the partnerships and the impact of the interventions will provide a better understanding of the influence of context in the implementation of community focussed access interventions and significant new data on mechanisms supporting the implementation of community academic partnerships. The work should generate a deeper understanding of the ways in which system-level organisational innovations can improve access to PHC for vulnerable populations and new knowledge concerning improvements in primary health care delivery in health service utilization.

This work will be uniquely relevant to real world implementation of new policy and program options for improving access to PHC care by vulnerable populations in a range of contexts and systems. The findings will contain rich source of practical experience and examples of applications of innovations to inform the work of others grappling with similar complex access problems.

List of abbreviations

CBPHC = Community-Based Primary Health Care

CHW = community health worker

FP = Family Physician

IMPACT = Innovative Models Promoting Access-to-Care Transformation

LIP = Local Innovation Partnership

PHC = primary health care

PI = Principal Investigator

PN = practice nurse

RACG = Residential Aged Care Facilities

SES = socio-economic status

TIDieR = Template for Intervention Description and Reporting

Declarations

Statement on ethics approval & consent

This study has been approved by the relevant Human Research Ethics Committees at each study site in Australia and Canada.

Consent for publication

Availability of data and material

Can be given upon request to the corresponding author.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

GR, JFL, MH, CSc, SDa, VL, SDe, NS, and JH designed the study. MH, CSp, JA and ED provided further design input following funding. GR, SDe and MK led the writing of this manuscript and all authors approved the final version.

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Box 1 Overall design of the IMPACT program

- **Work of the Local Innovation Partnerships (LIPs) (inner circle in figure 1)**
    - IMPACT began by *building Local Innovation Partnerships* in each of 6 regional jurisdictions – 3 in Canada and 3 in Australia. These learning networks of decision makers, researchers, clinicians and members of the community were, in most regions, built on pre-existing relationships between researchers, decision makers and clinicians.
    - Each LIP identified PHC access-related needs in their regions by conducting PHC access needs evaluations (incorporating data from regional service providers and primary care organisations to develop a profile of the demographic, economic and geographic characteristics of each LIP). Findings were then presented to deliberative, consultative community forums that aimed to identify and prioritise each region's PHC access related needs.
    - Work within the partnerships was informed by a LIP Implementation Guide providing an overview of current thinking about implementation, core principles and specific checklists for helping the LIPs implement, improve, and sustain their locally designed interventions for improving access to care for vulnerable populations.
    - Further forums then identified potential organisational innovations suitable and able to be implemented in each region. The potential innovations were reviewed by the LIP and informed by realist reviews conducted for each potential intervention. Finally, the most appropriate innovations were trialled and evaluated in the regions corresponding to each LIP.
    - IMPACT's funding did not cover the implementation of the intervention – financial support for each intervention needed to come from LIP
- **Work supporting the contribution of the Local Innovation Partnerships (outer circle in Figure 1)**
    - We used two different approaches to **scope organisational access related primary care innovations** (Project 1). Deliberative forums were informed by a scoping review [21] and an environmental scan [22] that identified organisational interventions with a potential to improve access to community-based PHC for vulnerable populations.
    - A **realist review** of the priority intervention (Project 2) was conducted by the research team for each LIP. The overall design of the interventions was informed by key contextual factors and mechanisms relevant for each regional intervention identified by these reviews [55]
    - Further information on access in primary care was generated by a series of mixed methods analyses of results and interpretations of several Commonwealth Fund Surveys (2014 International Health Policy Survey of Older Adults and the 2013 survey of all adults) (Project 3) [23, 56]
- **The evaluation of the innovations (Project 4)**
    - This paper outlines the process used for the evaluation of the innovations.

Box 2. Evaluation Questions (Project 4)

1) IMPACT support for the intervention
   a) To what degree and how did the IMPACT approach to governance, relationships and processes actively influence the design and development of the intervention?
   b) To what degree and how did the IMPACT approach to governance, relationships and processes actively influence the implementation and sustainability of the intervention?

2) Implementation of the intervention
   a) Were the interventions implemented as planned?
   b) What contextual factors influenced the intensity and fidelity of the interventions?

3) Impact of the intervention on patients, providers and practices
   a) How has the intervention influenced patient participants' ability to access appropriate primary health care?
   b) How has the intervention influenced the provider's knowledge and confidence to support the care of vulnerable patients?
   c) How has the intervention influenced practice processes and policies to support vulnerable patients' access to appropriate primary care?

4) Has the intervention a) influenced the degree to which patients form and strengthen enduring relationships with primary (health) care; b) led to changes in health service utilization such as i) more appropriate referrals? ii) use of more comprehensive primary care? iii) continuity of care? and iv) reduced use of emergency departments and hospitals for ambulatory care sensitive conditions?

5) Sustainability and transferability of the intervention
   a) To what degree are the interventions i) sustainable? ii) transferrable to other settings? iii) cost-effective?
   b) What contextual factors influenced the sustainability and transferability of the interventions? What other contextual changes have emerged as a result of the intervention?

Figure 1. Overall design of the IMPACT program

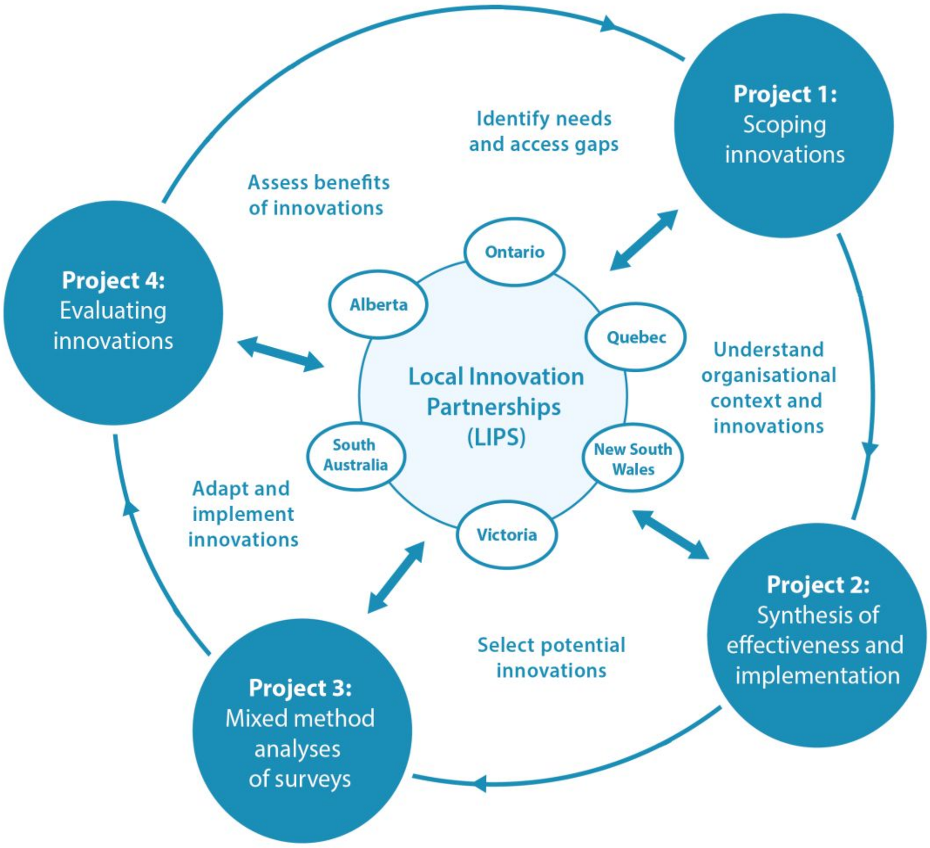
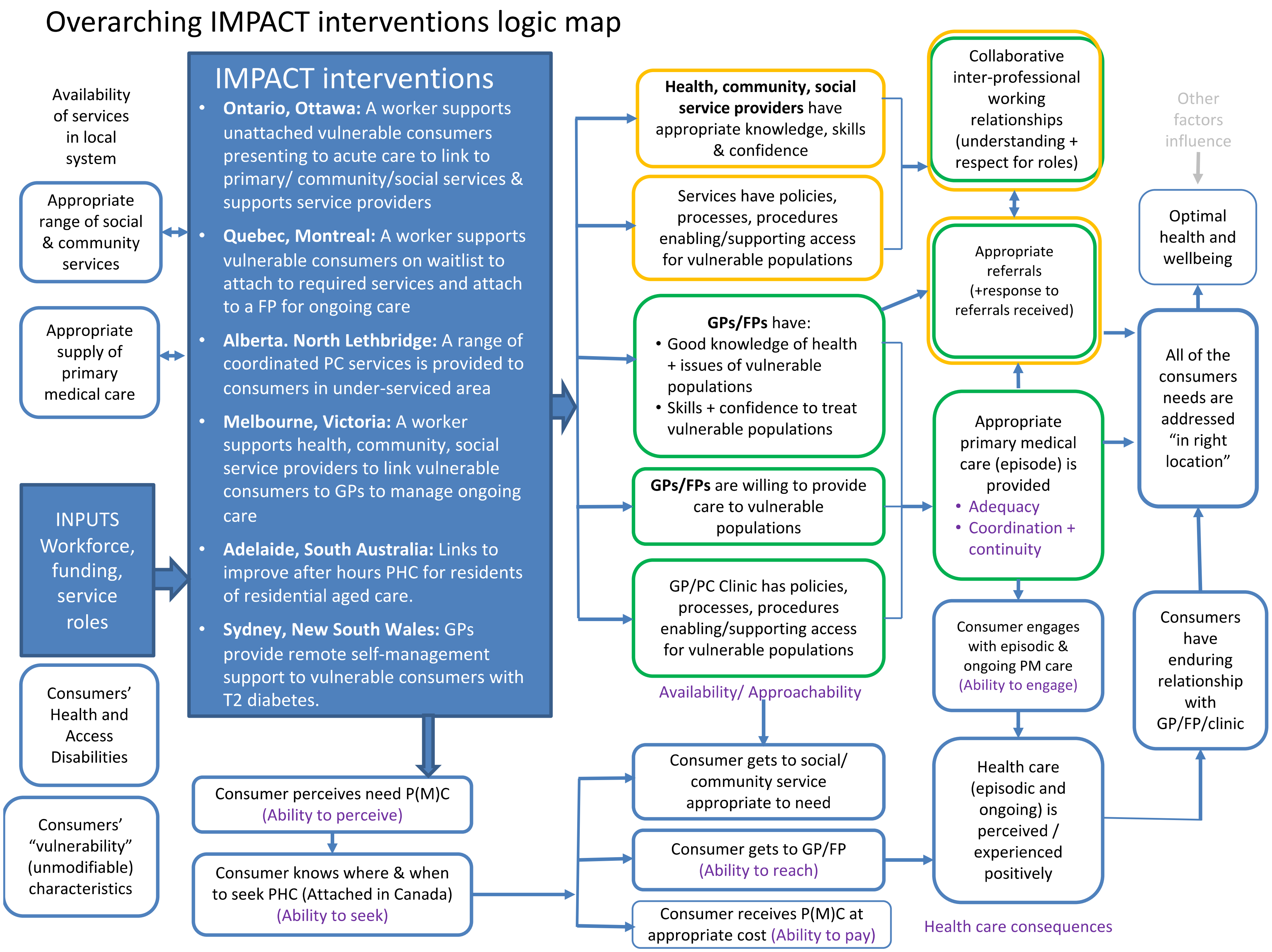


Figure 2 Overall Logic Map for the IMPACT study



Footnote: Each box in the Logic Map expresses a domain at a general level on the pathway to enhance PHC access for vulnerable populations. There is a general underlying temporal/causal flow from left to right. The dark blue box represents inputs and activities from all the interventions. Arrows have been included to provide a guide to the kind of causal pathways that have been expressed. Domains relevant to key stakeholders are arranged in vertical layers, with colour used systematically: a) Orange boxes relate to health, community and social service providers other than FPs; b) Green boxes relate to FPs and their organizations (clinics); c) Blue boxes relate to consumers/patients; d) There are references to the Access to Care Framework [1] in purple text.

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Improving access to primary health care for vulnerable populations in Australia and Canada: Protocol for a Mixed-Method Evaluation of six complex interventions

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Title

Improving access to primary health care for vulnerable populations in Australia and Canada: Protocol for a Mixed-Method Evaluation of six complex interventions

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Abstract

Introduction: Access to primary health care (PHC) has a fundamental influence on health outcomes, particularly for members of vulnerable populations. Innovative Models Promoting Access-to-Care Transformation (IMPACT) is a five-year research program built on community-academic partnerships. IMPACT aims to design, implement and evaluate organisational innovations to improve access to appropriate PHC for vulnerable populations. Six Local Innovation Partnerships (LIPs) in three Australian states (New South Wales, Victoria, South Australia) and three Canadian provinces (Ontario, Quebec, Alberta) used a common approach to implement six different interventions. This paper describes the protocol to evaluate the processes, outcomes and scalability of these organizational innovations.

Methods and analysis: The evaluation will use a convergent mixed-methods design involving longitudinal (pre and post) analysis of the six interventions. Study participants include vulnerable populations, PHC practices, their clinicians and administrative staff, service providers in other health or social service organizations, intervention staff and members of the LIP teams.

Data were collected prior to and 3–6 months after the interventions and included interviews with members of the LIPs, organizational process data, document analysis and tools collecting the cost of components of the intervention. Assessment of impacts on individuals and organizations will rely on surveys and semi-structured interviews (and, in some settings direct observation) of participating patients, providers and PHC practice surveys.

Ethics and dissemination: The IMPACT research program received initial ethics approval from St Mary's Hospital (Montreal) SMHC # 13-30. The interventions received a range of other ethics approvals across the six jurisdictions. Dissemination of the findings should generate a deeper understanding of the ways in which system-level organisational innovations can improve access to PHC for vulnerable populations and new knowledge concerning improvements in primary health care delivery in health service utilization.

Strengths and Limitations of this Study

- International research program designed to improve access to primary health care for vulnerable populations
- Community-academic partnerships in six regions in Australia and Canada
- Each intervention required mobilisation of local resources to match regional access needs and implement an intervention tailored to local context
- Interventions will be evaluated using a common methodology oriented to Levesque et al.'s Access to Care Framework and an overarching logic model
- The study evaluation is limited by it being confined to six jurisdictions within two affluent Western nations. No rural communities were involved. Instruments were only available in English, French (in Canada) and Arabic (in New South Wales). The Victorian team worked with an accessible language service to develop Easy English versions of consent documents and questions within the Patient Survey.

Background

Recent and widespread reforms in primary health care (PHC) in Western countries reflect a growing concern that health systems should become more affordable, inclusive and fair (1, 2). In Australia and Canada, PHC reforms prioritise access to effective and high-quality health services, with equity being at the heart of that system (3, 4). Despite these reforms, meaningful gaps in equitable access to PHC remain (5-7). These gaps particularly affect vulnerable populations, such as poor, refugee and Indigenous communities (7-13) and translate into unmet needs for care, delayed or inappropriate treatments, avoidable emergency department consultations and hospitalisations (5, 14). Few PHC innovations directed at these needs have generated transformative change throughout health care systems (5).

The Canadian Institutes of Health Research's (CIHR) Community-Based Primary Health Care (CBPHC) Signature Initiative was designed to identify innovative approaches to improving the delivery of appropriate, high-quality community-based PHC (15). The Initiative, launched in 2013, promoted the development and comparison of innovative models for CBPHC delivery in Canada and/or internationally; build research capacity; and foster effective knowledge translation to improve the delivery of CBPHC. The Initiative's most significant investment involved funding 12 teams to conduct long term intervention studies designed to improve access to CBPHC and/or chronic disease prevention and management for vulnerable populations. One of the 12 teams had an additional focus on Australian PHC through collaboration with the Australian Primary Health Care Research Institute's Centre of Research Excellence program. The successful applicant to the Canada/Australia funding opportunity was a consortium of researchers, clinicians and policy makers from three Australian states (New South Wales, Victoria, South Australia) and three Canadian provinces (Alberta, Ontario, Quebec).

The resulting program, Innovative Models Promoting Access-to-Care Transformation (IMPACT) (16), is a 5-year research program built upon a network of Local Innovation Partnerships (LIPs) bringing together decision makers, researchers, clinicians and, in some cases, members of vulnerable communities in each of the six regions. The LIPs collaborated in the design, implementation and evaluation of unique organisational interventions.

Figure 1 contains a schematic of the program, descriptions of its overall design and details of three companion projects that informed the work of the LIPs.

Work of the Local Innovation Partnerships (LIPs) (inner circle in figure 1)

The program began with *the formulation of Local Innovation Partnerships* in each of six regional jurisdictions – three in Canada and three in Australia. The networks were set in communities where partnerships could be developed to address a priority gap in access to appropriate PHC for vulnerable populations (17). These learning networks of decision makers, researchers, clinicians and members of the community were, in most regions, built on pre-existing relationships between researchers, decision makers and clinicians.

Each LIP identified PHC access-related needs in their regions by conducting PHC access needs evaluations (incorporating data from regional service providers and primary care organisations) to develop a profile of the demographic, economic and geographic characteristics of each LIP's region. Findings were then presented to deliberative, consultative community forums that aimed to identify and prioritise each region's PHC access related needs.

Further forums then identified potential organisational innovations suitable and able to be implemented in each region. The potential innovations were reviewed by the LIP and informed by realist reviews (18) conducted for each potential intervention. Finally, the most appropriate innovations were trialled and evaluated in the regions corresponding to each LIP. The CBPHC funding underwrote evaluation of the interventions but did not cover their implementation costs. Hence teams in each region were charged with identifying resources to enable one of the priority needs to be addressed by an intervention.

Work within the partnerships was informed by a *LIP Implementation Guide* providing an overview of current thinking about implementation, core principles and specific checklists for helping the LIPs implement, improve and sustain their locally designed interventions.

Interventions were implemented between June 2016 and June 2018. At the time of submission, data are still being gathered to inform components of the evaluation. Figure 2 shows a timeline of the research program, including interventions, data collection and evaluation.

This paper describes the approach that will be used to evaluate the effectiveness and further scalability of the interventions generated by the IMPACT program. Evaluation used a common approach and a common set of tools; however, local and national modifications to the core methodology were encouraged.

Methods

STUDY AIMS AND OBJECTIVES

The objectives of the overarching IMPACT project are as follows:

1. To develop a network of partnerships between decision makers, researchers and community members to support the improvement of access to PHC for vulnerable populations;
2. To identify organisational, system level CBPHC innovations designed to improve access to appropriate care for vulnerable populations and establish the effectiveness and scalability of the most promising innovations;
3. To support the selection, adaptation and implementation of innovations that align with regional partners local populations' needs and priorities; and
4. To evaluate the effectiveness, efficiency and further scalability of these innovations.

This paper describes the evaluation approach to address the fourth program objective and aims to explore:

- The research program's support for the intervention.
- The implementation of the intervention
- The impact of the intervention on patients, providers and practices and on health care utilisation.

These evaluation aims are expanded in the data analysis section. Our detailed, formal evaluation questions are listed in online Supplementary appendix 1.

DESIGN

Our evaluation will use a convergent mixed-methods design (19) involving longitudinal (pre and post) evaluation of the implementation of interventions in regions associated with the six LIPs. Qualitative and quantitative data relevant to each intervention were collected in parallel, organised separately, then brought together to provide complementary evidence to answer the study's research questions. Data collection for the evaluation used common tools administered before and 3–6 months after each intervention. This paper describes the strategy that will be employed to evaluate the collected data.

The evaluation (as with the larger program) will be oriented to Levesque et al.'s Access to Care Framework (online Supplementary appendix 2) (20) and informed by a logic model (online Supplementary appendix 3) representing the mechanisms and potential consequences of the interventions. The Levesque framework views access to PHC as a dynamic process representing the interface between five dimensions of client abilities (ability to initiate, seek, reach, pay or engage) and five dimensions of service accessibility (approachability, acceptability, availability/accommodation, affordability and appropriateness). The scientific work of the study was informed by an International Expert Committee comprising leading primary care health services researchers from Europe, North America and New Zealand. The Committee was a committee of review, reflecting upon and critically appraising the projects' design, evaluation tools and approach to interpretation of key findings.

SETTING

Table 1 outlines the characteristics of the six settings and vulnerable populations targeted by the interventions. Regions corresponding to the six participating sites are characterized by low socio-economic status (SES) and diverse cultures (including high proportions of refugees and newly arrived migrants). Several regions contain substantial Indigenous communities.

Table 1 – Details of interventions in the six local innovation partnerships

	CANADIAN LIPS			AUSTRALIAN LIPS		
	ALBERTA LIP	QUEBEC LIP	ONTARIO LIP	VICTORIA LIP	NSW LIP	SOUTH AUSTRALIA LIP
Targeted population	Individuals and groups of vulnerable populations living in North Lethbridge that have limited access to PHC. Includes immigrant, low income, Aboriginal, senior and homeless populations.	Orphaned patients (no PHC provider), particularly those in high deprivation neighbourhoods newly assigned to family physicians through a centralised wait list.	Primary care patients, with strategies to ensure equitable access to community resources for socially vulnerable patients	Vulnerable individuals who are clients of one of three community based chronic disease services. Clients had at least one of these characteristics: low socioeconomic status, socially isolated due to geographic distance/public transport inaccessibility, chronic illness, developmental disability	Patients with poorly controlled diabetes attending practices in low socioeconomic localities Specific subgroups: low socioeconomic status, culturally and linguistically diverse communities, refugee and humanitarian entrants	Aged and frail residents with complex/chronic health problems and high medical needs from three Residential Aged Care Facilities across the Adelaide metropolitan area This population cohort is characterised by social isolation and reliance on others for the provision of care and thus can be extremely vulnerable

Primary research question	What are the components of outreach and co-location as identified by vulnerable populations that contribute to making PHC services more approachable and engaging (e.g., welcoming and unintimidating) for vulnerable populations in other contexts?	Can telephone contact from lay workers to vulnerable patients newly assigned to family practice clinics increase: 1. Patients' ability to seek and engage with care 2. The quality of the patient / provider relationship. And 3. Can the intervention decrease the likelihood of using an emergency department for minor care	Can organizational changes be implemented within primary care practices to increase providers and staff members' awareness of community-based primary health care, support them to make appropriate referrals to community resources and address patients' social barriers to reaching these resources?	Can a health service brokerage process involving PHC liaison workers and social service providers in the community a) identify vulnerable individuals who are likely to benefit from better access to quality PHC? b) successfully link these individuals with PHC practices?	For a vulnerable PHC population with chronic disease 1. What is the impact of supported access to web based information and education tools that support self-management, navigation and/or self-monitoring of health service use, risk behaviours and health outcomes? 2. What factors enable use of web based tools that support self-management by different patients attending practices in low socioeconomic areas?	Can a PHC provider-led, multidisciplinary team approach to the management of chronic/complex conditions with a focus on fall prevention and end-of-life care result in improved access and provision of high quality, safe and effective PHC for Residential Aged Care Facilities (RACF)? Can this type of program improve achieve reductions in hospital transfers, readmissions or relapse rates?

Intervention type	A pop-up service (a type of outreach) with a focus on cross team collaboration (e.g., going to existing community events for hard to reach populations)	A telephone outreach service by lay volunteers to patients in deprived neighbourhoods newly assigned to family physicians to help them prepare for the first visit and explain important access-related issues.	A lay patient navigator supports primary care patients to reach community resources. Primary care practice providers and staff receive training and facilitation to increase their awareness of community resources and support them to identify patient needs that can be addressed by community resources, and refer and support their patients' access to these resources	Community based chronic disease services identified patient without an identifiable primary care provider. A broker then linked identified patients to one of a panel of volunteer family practitioners.	Support access through PHC to a diabetes self-management website that provides information and referral options to support self-management, facilitated by practice nurses at a health check visit in the PHC practice	Participating Residential Aged Care facilities (RACF) implement a process of redesign of policies and procedures to improve consistency of primary care, in particular afterhours care.

Recruitment	*Patients* Principally by distribution of posters and postcards through existing service providers and at community businesses (e.g., grocery store, etc.), media release, radio advertisement and social media (Twitter, Facebook, *via* our team and also through participating service provider organizations)	*Patients* The vulnerable population are residents from neighbourhoods with highest level of material and/or social deprivation based on postal code newly assigned by a centralised waiting list to family practices. *Practices* This LIP targeted possible clinics located in the LIP's local territory.	*Patients* Eligible study participants are identified by their primary care provider and are those who are referred to a community resource by their primary care provider. *Practices* Practices with whom the research group has had a working relationship with form the pool of potential practices enrolled in the study.	*Patients* New and existing services clients who cannot identify a personal FP or have not made contact with their FP for 12 months or more. *Practices* Accredited primary care practices operating in the study region willing to provide care for new patients with access vulnerability. Practices needed to provide general primary care services and be willing to take on clients access vulnerability.	*Patients* Eligible participants are patients aged 40–74 years attending the practice in the previous 2 years with type 2 diabetes with HbA1c>7 or BP>130/80 or BMI ≥ 30. Participants are invited by a mail invitation sent from the practice. *Practices* Family practices providing care for the target groups (socioeconomically diverse and Arabic-speaking practices) will receive a written invitation from a Primary Health Network to participate.	*Patients* The RACF staff will assist with identifying eligible residents. Residents must have the cognitive capacity to understand what is being asked of them and be able to give informed consent. *Providers* Clinical staff (physicians, nurse practitioners, nurses) who are employed by the residential aged care facility implementing the intervention or, in the case of some FPs, have visiting arrangements to the relevant residential aged care facility.
Modifications to the core evaluation	Pre intervention patient survey not used Narrative summaries of qualitative interviews Conduct of non-participant observations	Narrative summaries of qualitative interviews Conduct of non-participant observations	Narrative summaries of qualitative interviews Conduct of non-participant observation	Plain language materials for low literacy clients Interviews with intervention staff and additional LIP team members Qualitative interviews transcribed	Patient survey available in Arabic Qualitative interviews transcribed	Pre intervention patient survey not used Qualitative interviews transcribed

INTERVENTIONS

Patient and Public Involvement

The development of the interventions was informed by regional assessments of access related need, formal community consultations and a series of research studies completed by the IMPACT team (see Figure 1). In each region, formal community consultation comprised two deliberative forums with local decision makers, health and human service providers and community representatives to prioritise access needs for their vulnerable populations and develop a solution specific to local needs. Deliberative forums provided opportunities for members of the community to listen and negotiate through dialogue, creating mutual understanding and developing social capital (21). The first forum in each region identified priority primary care access gaps and the second focussed on possible approaches to address these gaps. The research studies comprised: a scoping review of organisational interventions to improve access for vulnerable populations (Project 1a) (22); a search using email and social media to identify unpublished PHC access innovations (Project 1b) (23); a series of systematic reviews of the components of each intervention (Project 2); and several access-oriented reanalyses of data generated by the Commonwealth Fund (Project 3) (24, 25, 26) (See Figure 1).

Intervention Design

The interventions ranged considerably in focus and mechanism. The Alberta LIP held a series of pop-up events where a range of health service and social welfare providers provided needed care in collaboration with members of a local, vulnerable community. Both Quebec and Victoria LIPs developed interventions to link consumers with a source of ongoing primary care. The Ontario intervention involved a lay, bilingual navigator integrated in primary care practices supporting patients to reach community resources to which they had been referred. South Australia worked with local service providers and decision makers to evaluate an aged care intervention to improve after-hours access to quality primary care. Finally, the New South Wales LIP implemented an intervention to improve diabetes care, including development of a website and health checks.

STUDY POPULATION

The interventions involved a range of participants, including vulnerable populations, PHC practices, their clinicians and administrative staff, service providers in other health or community and social service organizations, intervention staff and members of the LIP teams.

Study participants: vulnerable populations

All interventions were targeted at vulnerable populations, defined for this study as community members whose demographic, geographic, economic, and/or cultural characteristics impeded or compromised their access to PHC. The specific social vulnerability of the study population varied based on the priority established in each of the six regions. They included residents of aged care facilities, diabetics within immigrant populations, people living with chronic disease and community members in regions with limited supply of primary care professionals.

Study Participants: health care providers

Most of the interventions involved the participation of family physicians, non-physician clinicians (i.e., nurses, social workers) and administrative staff working within family practices. Several sites included participants from members of health, social service or community organizations. Here, participants included administrative staff, clinicians, managers and, in some sites, directors or executives of these organisations.

Study participants: intervention staff

The composition and nature of intervention staff varied between LIP interventions. Different sites used lay and health professional navigators, family practice nurses, allied health professionals, health care managers, community service providers, residential aged care nurses, trainers and intake/screening staff.

Study participants: members of Local Innovation Partnerships

Each LIP had a research team and a broader advisory/reference group (“LIP Core team”). The research team comprised study investigators and research associates. The LIP Core team in each region comprised, in general, an IMPACT Principal Investigator, a LIP Lead (responsible for the function of the LIP), a LIP coordinator (a field worker responsible for coordinating, documenting and managing the work of the LIP) and decision makers, other researchers, clinicians, and members of the community.

MEASURES

The study evaluation will rely on data collected during the implementation and follow up of the interventions. The study measures are grouped in terms of their focus on patients and health care providers; intervention staff; and members of LIPs.

1) MEASURES GATHERING DATA FROM CONSUMERS AND HEALTH CARE PROVIDERS

a) Quantitative data measures

We developed four different **survey instruments** (questionnaires) for patients, health care providers (family practitioners and nurses), family practices, and staff within health and community services. Since the impact of the intervention on the participants will be determined by comparing responses before and after the intervention, the questions in the post-intervention questionnaires duplicated many of the pre-intervention questions. These were combined with additional questions about the respondents’ intervention experiences.

As with other projects funded by the CBPHC initiative, the patient, provider and practice surveys were adapted from a number of previously-used instruments, including surveys originating from an initiative of the Canadian Institute for Health Information (27), and supplemented by additional questions developed for this study (Table 2). Each questionnaire was piloted prior to finalisation. All surveys were available in English and French (for Canadian administration to English speaking and Francophone populations). The New South Wales LIP developed an Arabic version of the patient survey and the Victorian team worked with an accessible language service to develop Easy English versions of the patient survey and associated consent documents.

Table 2: Survey measures

Survey	Informed by or adapted from existing instruments or studies
Patient survey	Primary Care Assessment Tool (28); Primary Care Assessment Survey (29); EQ-5D-5L (30); Veterans RAND 12-item Health Survey (31); Canadian Survey of Experiences with Primary Health Care (32); Perceived Need for Care Questionnaire (33); Canadian Community Health Survey (34); Patient Perception of Patient-Centeredness (35); GP Patient Survey (36); Interpersonal Processes of Care Survey (37); Health Literacy Questionnaire (38) The patient survey was translated into French, Arabic and Easy English where required.

Provider survey	Comparison of Models of Primary Care in Ontario study (39); Preventive Evidence into Practice study (40); National Pain Strategy (41); Community-Based Primary Health Care Common Indicator Project (42)
Practice survey	Community-Based Primary Health Care Common Indicator Project (42)
Organizational survey	Evaluation of the Primary Care Partnership Strategy. Victoria, Australia (43)

The patient survey provides data on participating patients' ability to access PHC (including ability to perceive, seek, reach, pay and engage), experiences with and utilisation of health care services, relationships with PHC providers, links with community and other health care services, engagement with primary medical care, and the appropriateness of health care received. It includes measures of the patient's experience of PHC (appropriate care and referrals) and information on general health and demographics. The survey was administered either face-to-face or by telephone.

The provider survey was completed by primary care clinicians responsible for direct patient care (either family practitioners or nurses/nurse practitioners). Questions explore the range of vulnerable patients cared for and their experience, confidence and clinical activities used in managing the specific vulnerable population targeted by the LIP. Demographic information includes questions about age, gender, site of professional training, professional experience and hours of work.

The practice survey ascertains the structural and organisational characteristics of PHC clinics (usually general/family practices). The survey captures details on the participating clinic's patient population, services, procedures and policies, especially as related to vulnerable patients. It also seeks information on staffing, funding sources, collaborative arrangements and communication infrastructure. It was completed by the most relevant individual at each practice site (generally either the lead physician or, where available, practice manager).

The organisational (health and community services provider) survey was administered in sites where these organisations were involved in the intervention. The survey includes items from the PHC surveys where relevant, with the addition of questions used in previous evaluations of state-wide partnership-based health system reform strategies. The survey focusses on each organisation's internal policies, procedures, practices and relations with external service providers and PHC providers. It was completed by health and community service workers and/or managers participating in the interventions. Individual LIPs supplemented these tools, as needed, to address the informational needs specific to their context.

b) Qualitative data measures

In-depth qualitative data were collected using semi-structured interviews with patients and PHC providers. In general, interviews with patients and PHC providers were conducted before and 3–6 months after the completion of the intervention. All interviews were aided by interview guides aligned to components of the Access to Care Framework and the local logic models. The guides were tailored at each site to reflect features of the local intervention. Question sequencing was flexible, allowing participant responses to guide the course of the interview. Contact Summary Sheets have been used to document interviewer reflections after each interview and their developing understanding of emerging answers to the research questions (44).

Patient interviews. Most sites limited pre-intervention qualitative data collection from patients to two open-ended questions that, in conjunction with a series of prompts, asked patients to describe their prior experiences with seeking and reaching primary care. These questions were administered in conjunction with the patient survey. Post-intervention interviews investigated patients' experience with the intervention, the intervention's perceived acceptability and the impact on the patient's ability to access primary care.

PHC provider interviews. Pre-intervention provider interviews explored existing organizational and individual approaches relating to the provision of accessible primary care to vulnerable populations. Post-intervention interviews explored how the intervention influenced usual routines (organizational and individual) relating to access of vulnerable patients (frequency of actions such as information giving, referrals, etc.) and adoption by providers. Providers were asked about the impact of the intervention on their own and the practice's work, and on the perceived feasibility of its broader implementation.

Non-participant observation in PHC settings: The Canadian sites compiled a comprehensive profile of the contextual, organisational and physical structure of a sample of PHC practice settings involved in the interventions. The profile was based on a modified tool previously used in the collection of observational data from family practices (45, 46). Observers documented the physical space of the practice, front desk and administrative staff scheduling procedures and routines, staff interactions, practice flow and other waiting room/reception desk activities. These observations were focused on activities relevant to vulnerable patients' access and were recorded as field notes.

2) MEASURES GATHERING DATA FROM INTERVENTION STAFF

Interviews with intervention staff and/or members of health and community services were conducted in some LIPs. These interviews explored their involvement in the delivery of the intervention and their perceptions concerning the sustainability of the intervention's activities.

Expense diaries: Intervention staff gathered data on the cost of all non-research activities undertaken as part of the interventions that incur a cost or opportunity cost (e.g., use of existing resources), including staff time (hourly salary), consumables/operating costs (e.g., telephone calls, printing), travel, one-off costs (e.g., web site development) and rental of accommodation.

Navigator records: Several of the interventions used health navigators to assist with patient access to care. For these interventions we collected navigator field diaries, minutes of meetings between navigators and the study teams and materials and evaluation reports from the educational events associated with the intervention.

3) MEASURES GATHERING DATA FROM MEMBERS OF LOCAL INNOVATION PARTNERSHIPS

The study's process evaluation will rely on data from interviews with LIP Core Team and Research Team members. These were conducted in four cycles (2014, 2016, 2017, 2018) by independent research assistants not associated with any of the LIPs. Each site's LIP lead, LIP coordinator and other research staff participated in interviews at these time points assessing their perceptions of how the program was organised, including governance (international/national executive committees, project organisation, etc.), approaches to researcher and stakeholder collaboration (LIPs), organisation of staff and communication. Non-researcher members of the LIP Core Teams were also interviewed at several time points at most sites.

LIP coordinators documented the development and characteristics of their region's intervention. All coordinators kept a diary that recorded key events during the development and implementation of the intervention.

DATA COLLECTION

Surveys: We used the software program *Qualtrics*™ (47) to organise survey data. Trained members of the research team working in each region administered surveys either in-person or over the telephone. PHC professionals and practice staff were also able to self-complete their questionnaires using a paper version. Self-completed questionnaires were then imported into *Qualtrics*™.

Interviews: In-depth semi-structured interviews were conducted by trained interviewers face-to-face or over the phone, depending on participants' availability. In each case, interviews were audio-recorded. In the three Australian LIPs, the recorded interviews were transcribed verbatim. In Canada, narrative summaries (i.e., purposeful transcription) of the interviews were created by researchers who conducted the interview. All qualitative interview data were managed using the QSR International's server-based software NVivo for Teams (48).

Non-participant observations were recorded as field notes by research staff attending participating PHC practices during the intervention. The number of observations varied by LIP and depended on the interventions' method and mechanism of implementation. Each observation session lasted approximately one hour and was recorded as a field note.

DATA MANAGEMENT

All qualitative and quantitative data associated with the interventions were collected locally and labelled with a unique participant number. Common rules were followed for naming variables and coding data to facilitate merging and mixed-methods analysis. For the analysis, both the qualitative and the quantitative data sets are stored in a central data repository. Separate qualitative and quantitative analytic teams have been established to assist in the implementation of the evaluation plan. These will evolve into teams focussed on additional analyses generating manuscripts and other outputs.

DATA ANALYSIS

Evaluation questions have been formulated to guide the analysis of the set-up, implementation and impact of the organizational interventions. The formal questions are included in online Supplementary appendix 1.

Evaluation question 1: The research program's support for the intervention.

The first evaluation question uses a developmental evaluation approach to explore how the overall program's approach to governance, relationships and processes influenced the design, development, implementation and sustainability of the interventions.

We collected data about how the programs were planned, implemented and evaluated (49). The process evaluation focuses on all aspects of the development and implementation of the IMPACT program, with a particular focus on the evolution of work within each LIP. The process, conducted through reports and discussions after each round of data collection, has contributed to ongoing reflection by the IMPACT team about the way the research program has evolved.

Data sources include semi-structured interviews with LIP Core Team and Research Team members, routinely collected documents (including minutes of meetings) and, in some LIPs, interviews with partners and stakeholders. The analysis of the first evaluation question will involve a hybrid deductive-inductive content thematic analysis (50). The initial round of analysis will include identification of themes, codes and key words based on analysis of notes and interview transcripts. The process will be iterative and members of the research team will review the initial codes. To ensure coding reliability between the intervention sites, one qualitative researcher will separately and independently code two Australian and two Canadian interviews. All issues identified will be discussed by the team and further analysis then undertaken.

Evaluation question 2: the implementation of the intervention.

The second evaluation question seeks to identify whether the interventions were implemented as planned and to ascertain the contextual factors influencing the intensity and fidelity of the interventions. Here, the unit of analysis will be the intervention implemented at each of the six sites: each intervention is a case. Overall, we will use an embedded qualitative design where the majority of the analyses will depend on qualitative data routinely collected during the interventions.

Data sources include the measures used to gather data from intervention staff and from members of the LIPs (see above). Sites used additional processes to track implementation fidelity. Some measured the degree to which patients attended health checks or practices to which they had been linked. Others captured detail of patient assessments, use of intervention components (i.e., websites) and referral destination.

LIP coordinators in each site will use their diaries, along with minutes of meetings of the LIP partnerships to help generate two summary documents: a) the Template for Intervention Description and Reporting (TIDieR), a template for describing the characteristics of each intervention (51) and b) perceived contextual influences on the implementation and fidelity of each intervention arranged within a self-designed template, based on Stange and Glasgow's approach to reporting contextual influences on the patient-centred medical home (52). Both documents are further informed by each region's demographic data and access needs assessments conducted early in each LIP's development. A central analysis team will combine this data with documentation of outputs from the deliberative forums as well as summarised data from the Developmental Evaluation.

The validity of the data will be checked using a member checking approach (53) where summaries are shared with and corroborated by LIP coordinators, LIP leads and core team members.

Finally, the analysis team will use a cross-case synthesis analytic technique incorporating constant comparative analysis where resulting data can be compared. Summaries will be coded then node extracts reviewed and matrices developed, comparing the interventions across thematic domains. We will use May's ecological model of the ways that context interacts with participants and interventions as a lens to explore the data (54).

Evaluation question 3 and 4. Evaluation of the impact of the intervention on patients, providers, practices and on health care utilisation

Evaluation question 3 considers how the interventions influenced i) patient participants' abilities to access appropriate primary health care, ii) providers' knowledge and confidence to support the care of vulnerable patients and iii) practice processes and policies to support vulnerable patients' access to appropriate primary care.

Evaluation question 4 seeks to ascertain the effect of the interventions on i) enduring relationships with PHC; ii) appropriateness of referrals; iii) use of comprehensive primary care; iv) continuity; and vi) use of emergency departments and hospitals for ambulatory care sensitive conditions.

This component of the evaluation will be addressed with a convergent mixed-methods design, informed by the Levesque et al. Access to Care Framework (20) and the project's logic model (see online Supplementary appendix 3). Analysis will first take place at the level of the LIP intervention by local analysts who will identify the dimensions of access within the logic model that would be influenced by the intervention.

Quantitative analysis will begin with data cleaning and, dependent upon sample sizes, exploratory factor analysis so that items with high communality can be combined, thus reducing problems associated with running multiple statistical tests (55). In each LIP, the distribution of test variables will be checked to ensure they meet the assumptions of the statistical test for which they were used. For example, variables for which a ceiling or floor effect is evident will be excluded.

First, we will seek to identify change between variables measured in pre- and post-intervention surveys at the level of each LIP intervention by creating change scores (post-intervention minus baseline responses). We will then assess predictors of change (where sample size is sufficient) through beginning with bivariate tests for relationships between predictors (i.e., patient age or gender; practitioner type; practice size) and change scores prior to conducting multivariate analyses of predictors of change scores based upon statistically significant univariate analyses. Where sample size is not sufficient, a case study or qualitative approach will be used to consider factors that might have influenced the results.

Sample size varied across interventions. In terms of patient level data we require interventions being included in the quantitative components of the final evaluation to have at least 25 patients with data available for analysis

Qualitative analysis: Conceptual phrases from the Access to Care Framework (20) will be attributed to segments of data from pre-intervention interviews of patients and providers using structural coding techniques (56). The similarly coded segments will then be collated for more detailed coding and analysis using an inductive approach. A similar process will be applied for post-intervention patient and provider interview data. The coding for pre- and post-intervention data will then be compared for each domain of the framework noting changes that can be attributed to the intervention. Each LIP will then develop case studies generated from the analytic plans and designed around the components of the questions that fitted the logic of each intervention.

Cross case analysis: The analysis between the LIPs will be informed by Crabtree et al.'s approach to meta-synthesising results where investigators who conducted the original projects are part of the analysis team (57). This approach incorporates tacit knowledge from investigators and other products of the research program into the overall analysis. We will begin by identifying aspects of the evaluation questions where data exists to be able to generate valuable insights for policy makers, clinicians, vulnerable communities and researchers. The analysis will be performed by a team comprising at least one member of each of the LIPs.

ETHICS AND DISSEMINATION

The IMPACT research program received ethics approval from St Mary's Hospital Montreal SMHC # 13-30. The varied interventions received other ethics approvals across the six jurisdictions. Ethics applications were tailored to the needs of the vulnerable populations included in the study and to the sometimes complex requirements of health services implementing components of the study. At times this required additional tailoring of the survey tools, in particular the patient questionnaires. The findings will be shared through a range of activities.

During the course of the study, a quarterly newsletter has been made available to study participants, collaboration partners and the interested public to inform them about the progress of the study and its results. This newsletter is disseminated via a mailing list and remains available for download on the project website. Updates on the study are also communicated via IMPACT's Twitter account. Policy and practice summaries will be developed and made available to the decision makers through collaboration partners and plain language press releases. The results will be disseminated in scientific journals and will be presented at relevant international and national conferences. To ensure high accessibility, we aim to publish our work in open access journals. Outcomes should help inform the work of others grappling with similar access problems.

Discussion

The protocol outlines the approach for the evaluation of a large-scale, multi-site program, built on community-academic partnerships and designed to address important challenges or barriers in the delivery of accessible, high quality PHC to vulnerable communities. The program of work is complex and requires cooperation and collaboration between diverse teams at a local, national and international level. The diversity of targeted vulnerable populations and differences in the interventions trialled has challenged planning, data management and measurement.

Nevertheless, as the multiple facets of the evaluation are addressed, we anticipate rich insights into the evolving field of primary care health services research, and primary care oriented community-academic partnerships. Lessons from this evaluation will inform governments and communities who wish to improve access to CBPHC about the conditions necessary to ensure that innovations such as these can be adapted and scaled up. The strong partnerships between communities, providers, policy-makers and researchers will ensure that these innovations are most relevant and have the best chance of being implemented broadly in the respective systems.

The program of work within the IMPACT has already identified the promise of formal integration of services to improve access to primary care services for vulnerable populations (22), the prevalence of effective but unpublished PHC access interventions (23), and the factors associated with multiple barriers to primary care (24). Our systematic reviews provide rigorous information on the effectiveness of several innovations, as well as on their scalability in different contexts and anticipated economic impact.

For the broader PHC community, the results of evaluations of the evolution of the partnerships and the impact of the interventions will provide a better understanding of the influence of context in the implementation of community focussed access interventions and significant new data on mechanisms supporting the implementation of community-academic partnerships. The evaluation will provide unique insights into how innovations work in different contexts and both their direct, indirect and unanticipated impacts. Resorting to a clear logic conceptualisation of PHC systems will enable us to identify relevant organisational levers and contextual influences that can be harnessed to create sustainable and scalable changes in CBPHC to favour access for the vulnerable.

The work should generate a deeper understanding of the ways in which system-level organisational innovations can improve access to PHC for vulnerable populations and new knowledge concerning improvements in primary health care delivery in health service utilization.

This work will be uniquely relevant to real world implementation of new policy and program options for improving access to PHC care by vulnerable populations in a range of contexts and systems. The findings will contain a rich source of practical experience and examples of applications of innovations to inform the work of others grappling with similar complex access problems.

List of abbreviations

CBPHC = Community-Based Primary Health Care

CHW = community health worker

FP = Family Physician

IMPACT = Innovative Models Promoting Access-to-Care Transformation

LIP = Local Innovation Partnership

PHC = primary health care

PI = Principal Investigator

PN = practice nurse

RACG = Residential Aged Care Facilities

SES = socio-economic status

TIDieR = Template for Intervention Description and Reporting

Supplementary Appendices

Appendix 1: Evaluation Questions (Project 4)

Appendix 2: Levesque et al.'s conceptual framework of access to health care

Appendix 3: Overall logic map

Declarations

Statement on ethics approval & consent

This study has been approved by the relevant Human Research Ethics Committees at each study site in Australia and Canada.

Consent for publication

Not required.

Availability of data and material

Can be given upon request to the corresponding author.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

GR, JFL, MH, CSc, SDa, VL, SDe, NS and JH designed the study. MK, CSp, JA and ED provided further design input following funding. GR, SDe and MK led the writing of this manuscript and all authors approved the final version.

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Registration

Given that the IMPACT study was an exploratory evaluation of six health service innovations using a mixed methods approach and a before-after design and that the assignment of the medical intervention was not at the discretion of the investigators, we followed the guidelines of the International Committee of Medical Journal Editors (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/) in not registering the overall study. The Ottawa intervention secured funding to subsequently incorporate a clinical trial. This study (recently described in JMIR Research Protocols available at https://www.researchprotocols.org/2019/1/e11022/) has a trial registration number at ClinicalTrials.gov of NCT03105635 (https://clinicaltrials.gov/ct2/show/NCT03105635/).

Figure Legends

Figure 1. Overall design of the IMPACT program. The work within the LIPs was informed by the findings of three separate inter-related initiatives (Projects 1–3). We used two different approaches to **identify effective and/or innovative organisational interventions** designed to improve PHC access for vulnerable populations (Project 1). The first was a scoping review mapping the existing evidence on PHC organizational access interventions that reported outcomes related to avoidable hospitalization, emergency department admission, or unmet health care needs (22). The second used a social media approach to conduct an environmental scan seeking innovative organisational interventions with a potential to improve access to community-based PHC for vulnerable populations (23). We conducted a series of **realist reviews** of the priority intervention chosen by each LIP (Project 2). The reviews were coordinated by members of the international research teams in collaboration with members of each LIP. The findings from the reviews informed the overall design of the interventions and helped LIPs helped identify key contextual factors and mechanisms relevant for each regional intervention. Further information on access in primary care was generated by a series of **mixed methods analyses** of several Commonwealth Fund Surveys (2014 International Health Policy Survey of Older Adults and the 2013 survey of all adults) (24, 25, 26) (Project 3). This paper outlines the process that will be used for the evaluation of the innovations (Project 4).

Figure 2. Timeline of IMPACT activities. DE, developmental evaluation interviews.

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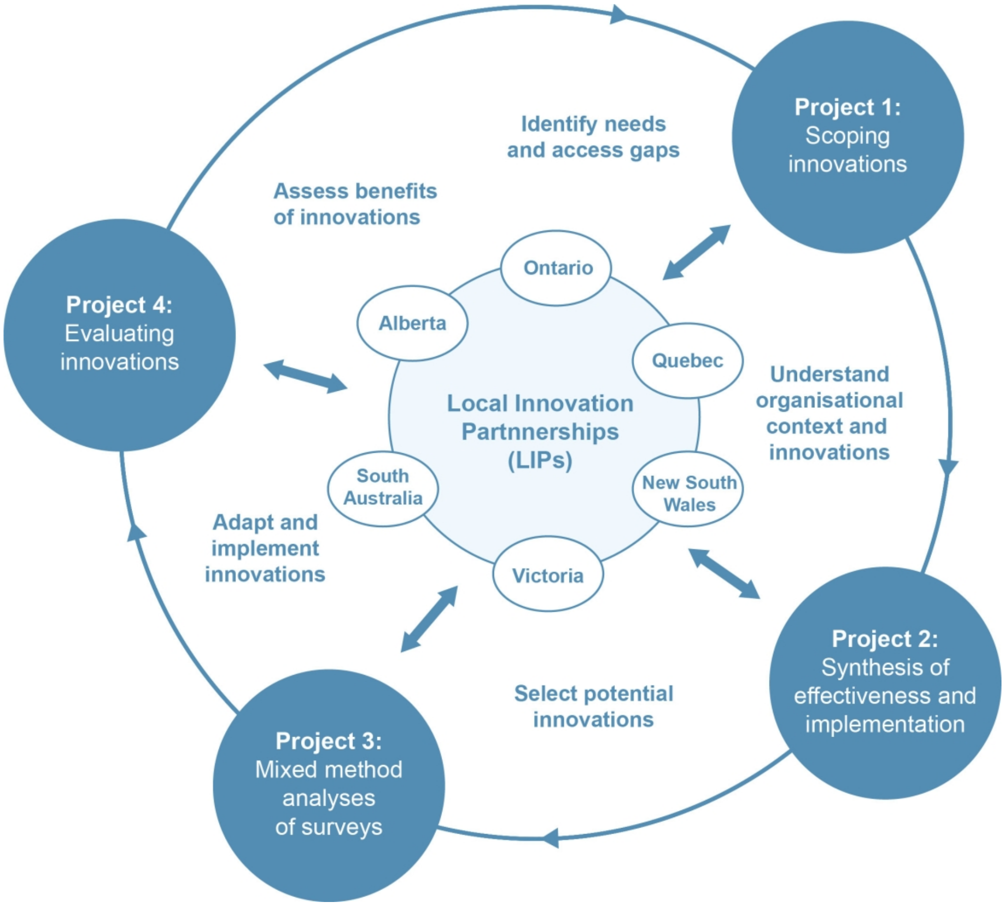

Figure 1. Overall design of the IMPACT program. The work within the LIPs was informed by the findings of three separate inter-related initiatives (Projects 1–3). We used two different approaches to identify effective and/or innovative organisational interventions designed to improve PHC access for vulnerable populations (Project 1). The first was a scoping review mapping the existing evidence on PHC organizational access interventions that reported outcomes related to avoidable hospitalization, emergency department admission, or unmet health care needs (22). The second used a social media approach to conduct an environmental scan seeking innovative organisational interventions with a potential to improve access to community-based PHC for vulnerable populations (23). We conducted a series of realist reviews of the priority intervention chosen by each LIP (Project 2). The reviews were coordinated by members of the international research teams in collaboration with members of each LIP. The findings from the reviews informed the overall design of the interventions and helped LIPs helped identify key contextual factors and mechanisms relevant for each regional intervention. Further information on access in primary care was generated by a series of mixed methods analyses of several Commonwealth Fund Surveys (2014 International Health Policy Survey of Older Adults and the 2013 survey of all adults) (24, 25, 26) (Project 3). This paper outlines the process that will be used for the evaluation of the innovations (Project 4).

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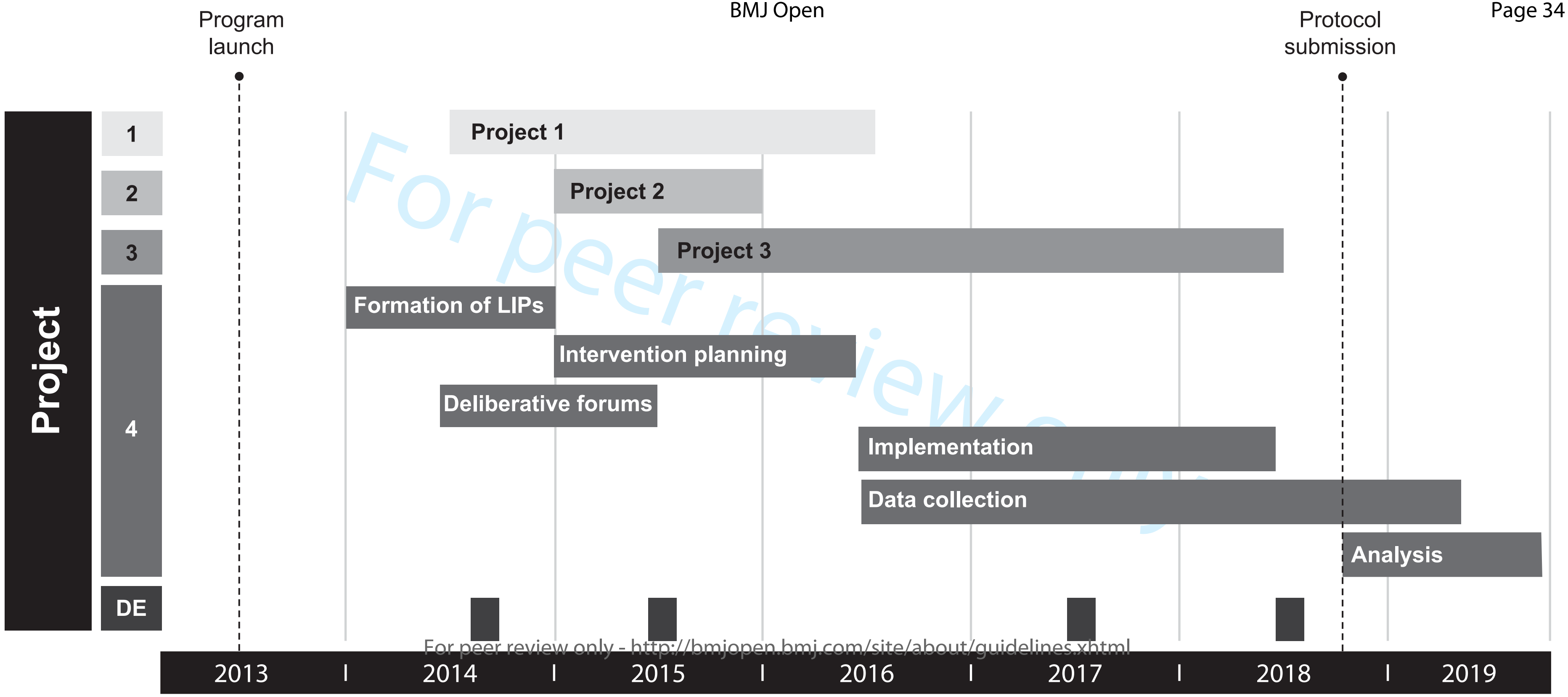
Program launch
Protocol submission
Project
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Project 1
Project 2
Project 3
Formation of LIPs
Intervention planning
Deliberative forums
Implementation
Data collection
Analysis
2013
2014
2015
2016
2017
2018
2019

Appendix 1. Evaluation Questions (Project 4)

1) IMPACT support for the intervention
   a) To what degree and how did the IMPACT approach to governance, relationships and processes actively influence the design and development of the intervention?
   b) To what degree and how did the IMPACT approach to governance, relationships and processes actively influence the implementation and sustainability of the intervention?

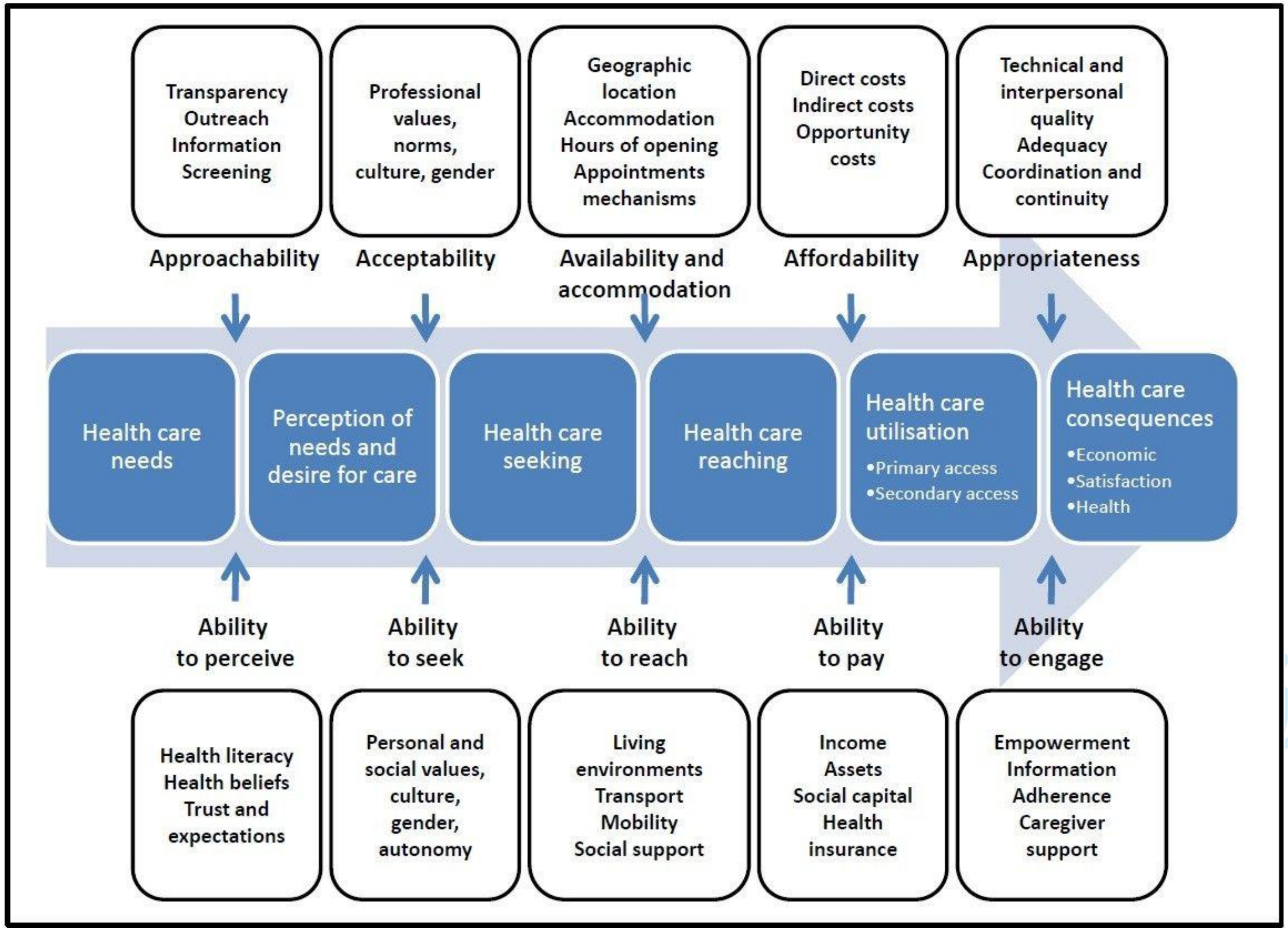
2) Implementation of the intervention
   a) Were the interventions implemented as planned?
   b) What contextual factors influenced the intensity and fidelity of the interventions?

3) Impact of the intervention on patients, providers and practices
   a) How has the intervention influenced patient participants' ability to access appropriate primary health care?
   b) How has the intervention influenced the provider's knowledge and confidence to support the care of vulnerable patients?
   c) How has the intervention influenced practice processes and policies to support vulnerable patients' access to appropriate primary care?

4) Has the intervention a) influenced the degree to which patients form and strengthen enduring relationships with primary (health) care; b) led to changes in health service utilization such as i) more appropriate referrals? ii) use of more comprehensive primary care? iii) continuity of care? and iv) reduced use of emergency departments and hospitals for ambulatory care sensitive conditions?

5) Sustainability and transferability of the intervention
   a) To what degree are the interventions i) sustainable? ii) transferrable to other settings? iii) cost-effective?
   b) What contextual factors influenced the sustainability and transferability of the interventions? What other contextual changes have emerged as a result of the intervention?

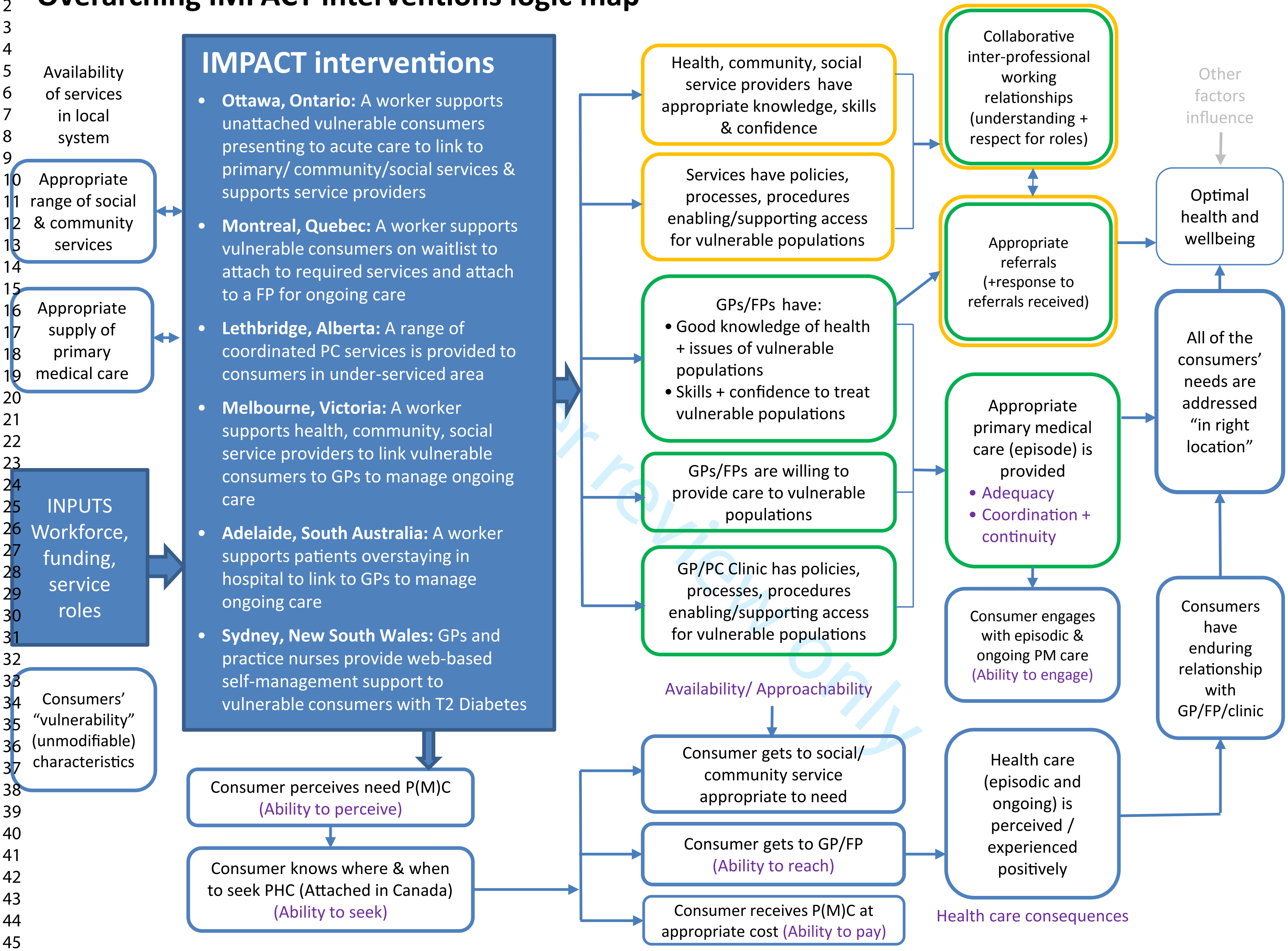
Appendix 2. Levesque et al.'s conceptual framework of access to health care



Adapted from: Levesque JF, Harris MF, Russell G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. *Int J Equity Health* 2013;**12**:18.

Appendix 3. Overall logic map

Overarching IMPACT interventions logic map



Availability of services in local system

Appropriate range of social & community services

Appropriate supply of primary medical care

INPUTS Workforce, funding, service roles

Consumers' "vulnerability" (unmodifiable) characteristics

IMPACT interventions

- **Ottawa, Ontario:** A worker supports unattached vulnerable consumers presenting to acute care to link to primary/ community/social services & supports service providers
- **Montreal, Quebec:** A worker supports vulnerable consumers on waitlist to attach to required services and attach to a FP for ongoing care
- **Lethbridge, Alberta:** A range of coordinated PC services is provided to consumers in under-serviced area
- **Melbourne, Victoria:** A worker supports health, community, social service providers to link vulnerable consumers to GPs to manage ongoing care
- **Adelaide, South Australia:** A worker supports patients overstaying in hospital to link to GPs to manage ongoing care
- **Sydney, New South Wales:** GPs and practice nurses provide web-based self-management support to vulnerable consumers with T2 Diabetes

Consumer perceives need P(M)C (Ability to perceive)

Consumer knows where & when to seek PHC (Attached in Canada) (Ability to seek)

Health, community, social service providers have appropriate knowledge, skills & confidence

Services have policies, processes, procedures enabling/supporting access for vulnerable populations

GPs/FPs have:
- Good knowledge of health + issues of vulnerable populations
- Skills + confidence to treat vulnerable populations

GPs/FPs are willing to provide care to vulnerable populations

GP/PC Clinic has policies, processes, procedures enabling/supporting access for vulnerable populations

Availability/ Approachability

Consumer gets to social/ community service appropriate to need

Consumer gets to GP/FP (Ability to reach)

Consumer receives P(M)C at appropriate cost (Ability to pay)

Collaborative inter-professional working relationships (understanding + respect for roles)

Appropriate referrals (+response to referrals received)

Appropriate primary medical care (episode) is provided
- Adequacy
- Coordination + continuity

Consumer engages with episodic & ongoing PM care (Ability to engage)

Health care (episodic and ongoing) is perceived / experienced positively

Health care consequences

Other factors influence

Optimal health and wellbeing

All of the consumers' needs are addressed "in right location"

Consumers have enduring relationship with GP/FP/clinic

Footnote: Each box in the Logic Map expresses a domain at a general level on the pathway to enhance PHC access for vulnerable populations. There is a general underlying temporal/causal flow from left to right. The dark blue box represents inputs and activities from all the interventions. Arrows have been included to provide a guide to the kind of causal pathways that have been expressed. Domains relevant to key stakeholders are arranged in vertical layers, with colour used systematically: a) Orange boxes relate to health, community and social service providers other than FPs; b) Green boxes relate to FPs and their organizations (clinics); c) Blue boxes relate to consumers/patients; d) References to Levesque et al.'s Access to Care Framework (20) are in purple.