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# Case management in primary care for frequent users of healthcare services with chronic diseases and complex care needs: an implementation and realist evaluation protocol

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## ABSTRACT

**Introduction:** Significant evidence in the literature supports case management (CM) as an effective intervention to improve care for patients with complex healthcare needs. However, there is still little evidence about the facilitators and barriers to CM implementation in primary care setting. The three specific objectives of this study are to: (O1) Identify the facilitators and barriers of CM implementation in primary care clinics across Canada; (O2) Explain and understand the relationships between the actors, contextual factors, mechanisms, and outcomes of the CM intervention; (O3) Identify the next steps towards CM spread in primary care across Canada.

**Methods and analysis**: We will conduct a multiple-case embedded mixed methods study. CM will be implemented in 10 primary care clinics in five Canadian provinces. Three different units of analysis will be embedded to obtain an in-depth understanding of each case: the healthcare system (macro level); the CM intervention in the clinics (meso level); and the individual/patient (micro level). For each objective, the following strategy will be performed: (O1) an implementation analysis, (O2) a realist evaluation, and (O3) consensus building among stakeholders using the TRIAGE method.

**Ethics and dissemination:** This study, which received ethic approval, will provide innovative knowledge about facilitators and barriers to implementation of CM in different primary care jurisdictions, and will explain how and why different mechanisms operate in different contexts to generate different outcomes among frequent users. Consensual and prioritized statements about next steps for spread of CM in primary care from the perspectives of all stakeholders will be provided. Our results will offer context-sensitive explanations that can better inform local practices and policies, and contribute to improve the health of patients with complex healthcare

needs who frequently use healthcare services. Ultimately, this will increase the performance of healthcare systems, and specifically mitigate ineffective use and costs.

**Registration details:** A realist evaluation does not need registration.

**Strengths and limitations of this study**

- This multiple-case embedded mixed methods study will provide new knowledge on the implementation of case management interventions to improve care integration for individuals/patients who frequently use healthcare services.

- The design of this study allows adapting the knowledge acquired on case management to local contexts, the first step to implementation.

- The multiprovincial nature of this study will allow to spread the new knowledge generated on CM in primary care settings in different Canadian jurisdictions and will increase generalizability.

- While some challenges are expected with this study, mitigated strategies are nevertheless proposed.

## INTRODUCTION

In Canada, as in many industrialized countries [1 2], close to 80% of healthcare costs are attributable to 10% of the population [3 4]. Data reveal that this 10% segment of the population comprises individuals/patients who frequently use hospital services for increasingly complex healthcare needs. Thus, albeit relatively small, this segment of the population uses a disproportionate amount of available healthcare and social services. Frequent use of emergency departments (ED) is a good proxy of high use of other healthcare services [5-7] as it is most commonly accepted in the literature [8-12], and provides a convenient and easy measure within a pragmatic context, as compared to cost for example. As such, five percent of ED's patients account for 30 to 50% of all visits [8 13]. As frequent use is not optimal for individuals/patients [14] or healthcare systems [15 16], better upstream care is a modifiable parameter that can effectively prevent it. Indeed, the majority of these individuals/patients who frequently use hospital services have a substantial burden of disease and would be best managed in primary care. [17].

In line with the Agency for Healthcare Research and Quality Multiple Chronic Conditions Research Network, complex healthcare needs can be defined as the gap between an individual's needs and the ability of health services to meet those needs [18]. Individuals/patients with complex healthcare needs often attempt to fulfill their unmet needs by using excessive health and social services in an uncoordinated way. Requiring a variety of services from various systems (e.g. health, social, education) and community networks, this often leads to difficulties with the integration of care[19]. This results in negative experiences for individuals/patients [14], poorer health outcomes, high mortality rates and considerable costs [19].

Case management (CM) was reported to be effective for individuals/patients who frequently used healthcare services [10 20 21]. By definition, CM is a collaborative approach used to assess, plan, facilitate, and coordinate care to meet individual/patient and family healthcare needs, through

communication and available resources including all sectors of health care (such as community, primary, secondary and tertiary care), as well as sectors outside of the health system (such as social services, housing, etc.) with the intent of improving individual and health system outcomes [22]. Three systematic reviews (including randomized controlled trials, non-randomized controlled trials, interrupted time series, and controlled and non-controlled before-and-after studies) concluded that CM was effective for individuals/patients who frequently used healthcare services, particularly on ED use and cost as well as on social and clinical outcomes [8 10 11]. A scoping review conducted by our team corroborated these findings by revealing that CM could reduce ED visits and hospitalisations as well as costs [9].

However, despite the evidence supporting CM as an effective intervention for individuals/patients that frequently use services, there is still a paucity of evidence about the facilitators and barriers to CM implementation [10 23]. Our literature review with thematic analysis of key factors of CM interventions among frequent users of healthcare services outlined that the case finding processes, the selection and training of the case manager, the intensity of the intervention, as well as care integration among all partners were important aspects to consider during CM implementation [23].

CM has rarely been implemented in primary care in Canada. Therefore, before spreading this intervention in primary care settings in different jurisdictions, stakeholders including individuals/patients/communities need to be engaged in adapting the intervention to their local context. Accordingly, further research is needed to better understand the facilitators and barriers (mechanisms) to CM implementation, as well as the influence of different primary care contexts on outcomes, e.g., self-management, quality of life, services integration, services use, and costs [9 24 25].

Therefore, the specific objectives of this study are threefold: (O1) identify the facilitators and barriers of CM implementation in primary care clinics across Canada; (O2) explain and

understand the relationships between the actors, contextual factors, mechanisms, and outcomes of the CM intervention; and (O3) identify the next steps towards CM spread in primary care across Canada.

## METHODS AND ANALYSIS

### Study design

To address these objectives, we will conduct, between September 2018 and August 2022, a multiple-case embedded mixed methods study, which constitutes a valuable design for performing research evaluation inquiries on complex systems in varied and dynamic contexts [26] [27]. In addition to allowing an in-depth analysis of each case, this design offers opportunities for comparison between cases. The inclusion of multiple cases capitalizes on organizational variation and allows for examination of how contextual factors influence implementation to develop a more informed understanding of change processes. It also allows for observation recursive or singular facilitators and barriers, and draws conclusions that could be transferable to other primary care contexts[28]. Furthermore, mixed methods involve combining qualitative and quantitative methods in complex program evaluation, primary research, and literature review; they are being increasingly used in health sciences; specifically, case studies can use qualitative, quantitative and mixed methods (multiple sources of evidence) to explain one or more cases [29].

### Study location and sampling

Five Canadian provinces are involved in the study: Saskatchewan (SK), Quebec (QC), Nova Scotia (NS), New Brunswick (NB) and Newfoundland and Labrador (NL). Considering that different primary care team models have been implemented throughout Canada [30 31], the primary care context of each jurisdiction will be taken into account when evaluating implementation and outcomes [31].

Two primary care clinics per province, where CM has not been previously implemented, will be recruited using a purposeful sampling strategy [32]. The recruitment of the clinics will be conditional to: the manager and team interest in implementing CM and engaging in the research project; availability and interest of a registered nurse or nurse practitioner to develop the role of the case manager. We will thus work with 10 cases (two per province), each case being the intervention implemented in each clinic. It is recommended that four to 10 cases be considered [33] in the multiple case study logic of theoretical replication, in which contrasting results are anticipated [26]. Two clinics per province will facilitate variability within each province. Cases will be selected in order to represent real-world differences [34] in terms of geographic location, model of practice, diversity of care teams, and size, based on the opinion of team members in each jurisdiction. Three different units of analysis will be explored to obtain an in-depth understanding of each case: (a) the healthcare system (macro level); (b) the CM intervention in the clinics (meso level); and, (c) the patient including their family and community (micro level).

**Objective 1: To identify facilitators and barriers of CM implementation in primary care clinics in Canada**

An implementation analysis will be conducted for identifying facilitators and barriers to, and informing implementation of, CM in primary care in different provinces [35]. Implementation analysis is very useful with complex interventions that can be influenced by the context within dynamic environments. The case study design is appropriate for implementation analysis of interventions [35].

*Conceptual framework*

Data collection and analysis will rely on the Consolidated Framework for Implementation Research (CFIR) of Damschroder *et al*. [36], which is aimed to foster implementation of findings

into practice. The CFIR is composed of five major domains: outer setting, inner setting, characteristics of the individuals involved, intervention characteristics, and, the process of implementation. Four constructs are related to the outer setting (e.g., external policies); 12 are related to the inner setting (e.g., culture and leadership engagement); five are related to individual characteristics (e.g., knowledge and beliefs); eight are related to the intervention (e.g., adaptability); and eight are related to process (e.g., planning). '*The CFIR provides a practical structure for approaching complex and transient states of constructs in the real world by embracing, consolidating, and unifying key constructs from published implementation theories*.'[36]

To properly address care integration, the CFIR will be linked to the Valentijn et al. framework [37] combining the concepts of primary care and integrated care. In this framework, person-focused care is the guiding principle for achieving integration across the care continuum, i.e. system integration (macro level), professional and organisational integration (meso level) as well as clinical integration (micro level).

*Pre-implementation*

A CM nurse mentor will facilitate 3-day training sessions for all CM nurses and will also lead monthly 1-hr community-of-practice meetings by teleconference, to assist with mentoring, collective learning and support [38]. As recommended by Damschroder et al. CFIR [36], team stakeholders will interact with the clinics in their province to co-design the adaptation of the CM intervention to their reality. According to the CFIR [36], the core components of the intervention, such as patient assessment, individualized care plan, care coordination and self-management support [39-42], will be maintained across all clinics, whereas more peripheral elements will be adaptable, e.g., as integration in the context. This adaptability will increase knowledge uptake [24] and promote integration with complementary programs outside of the clinics, while ensuring that

CM is being rigorously evaluated.

*Recruitment*

Each clinic will identify 30 patients with the most complex healthcare needs and who, according to their clinical experience of the existing gap between the individual's needs and the ability of health services to meet those needs [18] could benefit from CM. Inclusion criteria will be: living with at least one chronic condition; frequent ED users as defined by ≥4 ED visits in the previous year [43 44] (which have been recognized as a good proxy of frequent use of other healthcare services [5-7]); and, a score ≥ 17 on the INTERMED-Self-Assessment Questionnaire [45] evaluating complex healthcare needs. Exclusion criteria will be: frail elderly with loss of autonomy; individuals/patients without a chronic condition or with a prognosis of less than a year; or, patients already followed by a case manager in another program, e.g., mental health, senior care, addiction program. Case managers will offer the CM intervention to these individuals/patients over a 12-month period.

*Intervention*

The intervention will focus on four main recognized components of CM [39-42]: (C1) evaluation of patient needs and preferences; (C2) co-development and maintenance of a patient-centred individualized care plan, with the patient, family and other partners; (C3) coordination of health and social services among all partners; and (C4) education and self-management support for patients and families. This intervention is congruent with criteria from the *Case Management Society of America* [22] and the six standards of practice of the *National Case Management Network of Canada* [46]: (S1) determining and verifying patient eligibility; (S2) assessing patient needs; (S3) documenting patient goals and priorities; (S4) planning and adjusting services included in individualized service plans, including patient education and self-management support; (S5) monitoring patient needs and progress; and (S6) supporting transition processes. The intervention

also aligns with the six care integration characteristics proposed to consider a patient's experience[47]: (I1) consideration of patient and family needs; (I2) communication with the patient and between healthcare providers; (I3) access to information; (I4) involvement in decision-making; (I5) care planning; and, (I6) transitions between various professionals.

*Data collection*

The mixed method data collection will rely on the five following complementary strategies.

(1) Individual semi-structured interviews (qualitative data) will be conducted between six and nine months following initiation of CM intervention with all case managers, patients/families and clinic managers. Two focus groups per clinic will be also scheduled, enrolling eight primary care providers per group (including physicians, nurses, social workers, pharmacists and others) through purposive sampling [48]. All interviews and focus groups, conducted using a semi-structured interview guide composed of open-ended questions on facilitators and barriers of CM implementation and adapted to each category of stakeholders, will be digitally recorded and transcribed verbatim. Interview guides will address the domains and constructs of Damschroder's CFIR [36] and Valentijn Framework [37]. Data saturation will not necessarily be reached for each category of stakeholders, but their diversity will allow for a comprehensive representation of each case [49].

(2) Non-participant observation (qualitative data) of CM activities and meetings, e.g., patient-case manager, individualized service plan development, team discussions, at each clinic for thirty hours at 6 months will be conducted. Research assistants will collect data by means of an observation grid and field notes [48].

(3) Self-administered and validated questionnaires (quantitative data) with accepted psychometric properties will be administered to all individuals/patients in the presence of the research assistant. At baseline, the following characteristics will be assessed: age; gender; marital status; education; occupation; economic status with family income and patient perception of his or her economic situation; health literacy [50 51]; multimorbidity [52 53]; care integration [54]; self-management [55 56] and health related quality of life [57]. Care integration, self-management and health related quality of life, will be re-evaluated at 12 months.

(4) Clinical data on service use during the year of the intervention (quantitative data) will be collected through the patient's electronic medical record: ED visits; overnight stays; primary care and specialist visits. Costs will be measured from a healthcare system perspective, including costs of the CM intervention and of healthcare expenditures. Costs of the intervention will consider nurse training, mentoring, and CM implementation. Participant healthcare expenditures, such as ED visits, overnight stays, professional visits, will be calculated using predetermined fees, e.g., from the CIHI Patient Cost Database [58].

(5) Intervention fidelity evaluation (quantitative data) will be assessed to determine whether the intervention was delivered as intended [59]. For this purpose, research assistants will collect data relevant to the delivery of the main components of the CM intervention from the medical records of participants after six and 12 months using a fidelity grid. Similar data on CM intervention fidelity were collected successfully in our previous study [60].

*Data analysis*

Qualitative data analysis: Interview- and observation-based data will be analysed together using a deductive (themes based on the Damschroder et al. CFIR and Valentijn frameworks) and inductive (themes suggested by the data while not in frameworks) thematic analyses [61].

Qualitative data will be managed using multi-site NVivo 10 server software (QSR International Pty Ltd).

Quantitative data analysis: Descriptive statistics will be performed. Intervention fidelity will be represented by the proportion of delivery for each component of the CM intervention. Regression models will be developed to evaluate relationships between contextual elements, i.e. intervention fidelity, patients' characteristics and outcomes, using SPSS version 24. An incremental cost-effectiveness/utility ratio [62] will be calculated, using data collected on costs and QALY (i.e., SF-6D), at baseline, and 12 months after the CM implementation. Multivariate parametric analyses with bootstrap replications will be conducted along with cost-effectiveness acceptability curves[63].

Integration of qualitative and quantitative methods - Two types of integration will be performed: qualitative and quantitative results will be compared, and qualitative and quantitative data will be merged for each case [29]. Considering the inherent variety and changing contexts of the study, results of qualitative and quantitative data analyses will be compared, and the comparison interpreted using a side-by-side joint comparison table (rather than trying to calculate non-biased quantitative effects [64]). Then for each case, qualitative and quantitative data will be merged [26]. A case history will be reported (synthesizing merged data), and the 10 case histories will be used to compare cases by means of a descriptive and interpretative matrix (mixed methods matrix), allowing systematic comparisons among cases and analysis units (macro, meso and micro) [61]. Different analytical techniques for case study will be used among which pattern comparison, research of competing explanations and construction of explanations [26]. Management, data reduction and cross care comparisons will be conducted with NVivo 10 software using matrix queries. All categories of stakeholders will be invited to participate in key steps of the analysis to ensure meaningful interpretation.

**Objective 2: To explain and understand the relationships between actors, contextual factors, mechanisms and outcomes of CM intervention**

A realist evaluation will be conducted according to Pawson and Tilley [65]. Realist evaluation is a theory-driven approach for studying complex interventions to explain how and why they are effective, under what conditions and for which groups of patients. It is based on four concepts for explaining and understanding the complex relationships in a given intervention: context (C); mechanism (M); outcome (O); and, context–mechanism–outcome (CMO) configuration [65-67]. The multiple-case study is a recognised design for investigating CMO configurations in healthcare research [68-73]. The realist evaluation will use a multi-method (quantitative and qualitative), theory-driven approach to provide an explanation of why outcomes occur [67], and will follow three phases: stating an initial program theory; testing this program theory; and, refining this program theory.

*Stating an initial program theory*

A proposed initial middle-range program theory developed in our realist synthesis [74] of the literature on CM for individuals/patients that frequently use healthcare services in primary care will provide a rigorous basis for the next two phases of data collection (testing and refining the program theory).

*Data collection (testing and refining the program theory)*

In the next year, same participant sampling and data collection will be repeated in the same clinics identified in Objective 1, with a new cohort of patients. However, qualitative data will be used to identify and better understand CMOs. The same quantitative data will be used to measure outcomes, i.e. self-management, health related quality of life, care integration, services use and costs at baseline, 6- and 12-months for developing CMOs. For qualitative data collection,

interview guides and the observation grid will be informed by the initial theory and tailored to the participant groups. Interviews and focus groups will be performed using realist interview techniques [75]. The theory will be discussed with individuals/patients who will then provide their own experience and vision for collaborative conceptual refinement. The interviewer will play an active role in explaining the contexts and outcomes of interest, and in ensuring that participants understand the terminology of the realist evaluation. Participants will be asked to share how they think their experience relates to this theory and to reflect on what may explain the outcomes in their setting [76]. Data collection will be iterative until reaching saturation [65 75].

*Data analysis*

Quantitative data will be analyzed, as described above, to inform outcomes. Qualitative data, including interviews, focus groups and observation, will be analysed with NVivo using thematic analysis, guided by the initial program theory from the realist synthesis. Analysis will remain open to emergent themes that support further theory refinement. Similar to the above integration, quantitative and qualitative results will be compared (producing joint display table), and quantitative and qualitative data will be merged for each case (producing case histories and a mixed method matrix).

Research assistants from the various provinces will co-analyze quantitative, qualitative and mixed methods evidence. They will identify CMO configurations, first within each primary care clinic (case) and then across sites. All team members will be involved in certain steps of the analysis. A recap table [77] will be constructed using columns to separate components of the initial theory and rows representing different cases. This approach will facilitate within-case analysis, highlighting similarities or discrepancies between data sources. It will also facilitate cross-case analysis to identify patterns (demi-regularities or semi predictable patterns) across cases. Analysis of CMO configurations will help complete, confirm, or modify the components of our initial theory, and

ultimately produce a refined theory explaining how and why CM works, in specific contexts, and for specific categories of patients. Results will be reported in line with the RAMESES II reporting standards for realist evaluation [78].

**Objective 3: To identify the next steps towards CM spread in primary care across Canada**

The Technique for Research of Information by Animation of a Group of Experts (TRIAGE) method will be used to reach consensus among all stakeholders about the next steps forward with spread (expansion and extension), in light of our case study results. The process of developing a shared understanding from the different stakeholders' perspectives through discussion improves progress of an innovation towards spread [25]. TRIAGE is a research method based on the attainment of a group consensus to supply first-hand information for decision-making [79]. It is a structured and inductive method of data collection comprising three successive phases: preparation; individual production; and interactive production.

*Preparation*

A full-day meeting will be organized, gathering the tripartite structure (clinical, scientific and policymaker leads) of all pan-Canadian SPOR Networks in Primary and Integrated Health Care Innovations (PIHCI) and at least one individual/patient from each province in order to embody categories of stakeholders across Canada. PIHCI is a network building on regional and national achievements in community-based primary and integrated health care [80]. During this preparation phase, a brief executive summary of project results will be produced and tailored to inform each specific audience and category of stakeholders. The evaluation question that will be discussed and disseminated to the participants is as follows: Based on your own experience, what should be the next steps towards the spread of CM in primary care, in your area of expertise (patient engagement, clinical care, policy and research)?

*Individual production*

All stakeholders will receive the executive summary of the results, two months prior to the meeting, and will be asked to provide a maximum of five statements in response to the question stated above. Beyond five statements, information is expected to become redundant [79]. These statements will be kept confidential and sent back to the organisation team.

*Interactive production*

This phase will take place during the full-day meeting. The project and results will be presented to all participants. Each group of stakeholders will gather to identify, by consensus, the most important and relevant statements among those brought forth in their stakeholder category. An expert animator will act as a facilitator and lead interactions among group experts. The interactive step of TRIAGE relies on a prominent visual aid. A wall of the room will be used and divided into three main sections: memory, groupings and selection. The memory section is, in fact, a bank of all statements gathered in the previous step, which have been numbered and transcribed. As group interactions occur, the selection process will evolve, with cards moving from one section to another, from left (memory) to right (selection). It will also be possible to modify the statements. "Selected" statements will also be ranked and prioritized. At the end of the meeting, each group of stakeholders will present their selected statements in order of priority.

## ETHICS AND DISSEMINATION

This project received approval from the CIUSSS de l'Estrie - CHUS Research Ethic Board (project number MP-31-2019-2830). All participants will provide informed consent prior to engagement and recruitment. In addition, certificates of approval will be obtained in each of the provinces before data collection is commenced. If appropriate, adherence to Chapter 9 of the TCPS2 (2014) will be observed and upheld.

This four-year multiple-case, mixed-method study will result in the potential for great impact with stakeholders, but mostly for individuals/patients. New evidence-based knowledge will be provided on the implementation of CM interventions, which can contribute to improve care integration for individuals/patients who frequently use healthcare services, and ultimately reduce ineffective healthcare use and costs. The proposed design will allow adapting the knowledge acquired on CM to local contexts, the first essential step towards implementation [81]. Moreover, recognition of facilitators and barriers to implementation as well as, the influence that context exerts on outcomes will pave the way for the spread of CM in primary care settings in different Canadian jurisdictions.

This study built on various strengths, but mostly on the engagement of knowledge users who were and will be involved throughout the entire process to ensure that the new knowledge generated by CM in primary care will be refined and tailored to their own specific needs [81]. These stakeholders will then be best suited to further adapt CM knowledge to their own local context and to increase the chance of successfully implementing CM in their setting [81]. All of these steps will increase spread and positively influence the healthcare system as well as individuals/patients/communities and clinicians' experiences, and outcomes [24 25 36].

This study builds on many important aspects related to the rigour of the approach and methodology. As such, all stakeholders, including individuals/patients, from the five provinces (SK, QC, NB, NS, NL) already working together, have participated in the elaboration of research questions that were relevant from their perspectives. This partnership with stakeholders is strengthened by a solid engagement plan as well as a relevant knowledge transfer plan tailored for each stakeholder audience. The conceptual basis of this study is based on a rigorous research plan that unifies key constructs from published implementation theories (CFIR) [36] as well as a framework combining the concepts of primary care and integration of care (Valentijn) [37]. The

intervention is evidence-based and shaped for individuals/patients who frequently use healthcare services [8-12 82]. As for data collection, appropriate sampling strategies will be pursued, while data quality and reliability will be ensured through three main strategies [26]: the 10 case histories will integrate relevant qualitative and quantitative data in a Master database; the database will contain sufficient information about data collection; and, data collection will follow published methods. Validity of the study will be ensured by mixing qualitative and quantitative methods (comparison of results and data merging), multiple data sources and evaluators triangulation [26]. Transferability will be ensured by several strategies such as theoretical basis, observation replication across cases [26], and thorough description of the context [61].

While some challenges are expected with this study, mitigated strategies are nevertheless proposed. To ensure meaningful involvement of all provinces and team members in the project, relationships and team building will be nurtured and stakeholders will be encouraged to speak in their preferred language (English or French). Being engaged with our patient partners over the last four years, solutions have been developed to accommodate their needs, e.g., help with a wheelchair, being flexible regarding schedule if hospitalization or deterioration, training. Partnerships will also be monitored annually. The circumstances of this vulnerable clientele may also influence data collection as well as study validity. This challenge will be overcome by research assistants administrating the questionnaire to patients and assisting them as needed and by patient partners that will advise on ways to enhance feasibility and patient's acceptability. In a similar study conducted by our team, a 93% retention rate was achieved, demonstrating the efficacy of our strategies [60].

Based on popular conceptual frameworks and rigorous methodology, design, and methods, this pan-Canadian study holds promise to guide policy decision-making, and to ultimately and positively impact health services systems as well and most importantly, the health of Canadians.

This study will generate findings on the implementation of CM in primary care for individuals/patients with chronic conditions and complex healthcare needs who frequently use healthcare services, as well as to implement an evidence-based intervention that will not only improve the care experience and outcomes but will also mitigate ineffective use and costs.

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## LIST OF ABBREVIATIONS

CM: Case management; CFIR: Consolidated Framework for Implementation Research; CIHI: Canadian Institute for Health Information; CMO: Context-Mechanism-Outcome; ED: Emergency department; NB: New Brunswick; NL: Newfoundland and Labrador; NS: Nova Scotia; PIHCI: Primary and Integrated Health Care Innovations; QC: Quebec; SK: Saskatchewan; SPOR: Strategy in Patient Oriented Research; TRIAGE: Technique for Research of Information by Animation of a Group of Experts.

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## AUTHORS' CONTRIBUTION

CH, M-CC, KAB, FB, SD and VR are the principal investigators of the study. All authors contributed to the conception, the design of the study as well as to the editing and final approval of the protocol.


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## COMPETING INTERESTS

All authors declare that they have no competing interests.

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# Case management in primary care for frequent users of healthcare services with chronic diseases and complex care needs: an implementation and realist evaluation protocol

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| | |

# Case management in primary care for frequent users of healthcare services with chronic diseases and complex care needs: an implementation and realist evaluation protocol

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## ABSTRACT

**Introduction:** Significant evidence in the literature supports case management (CM) as an effective intervention to improve care for patients with complex healthcare needs. However, there is still little evidence about the facilitators and barriers to CM implementation in primary care setting. The three specific objectives of this study are to: (O1) Identify the facilitators and barriers of CM implementation in primary care clinics across Canada; (O2) Explain and understand the relationships between the actors, contextual factors, mechanisms, and outcomes of the CM intervention; (O3) Identify the next steps towards CM spread in primary care across Canada.

**Methods and analysis**: We will conduct a multiple-case embedded mixed methods study. CM will be implemented in 10 primary care clinics in five Canadian provinces. Three different units of analysis will be embedded to obtain an in-depth understanding of each case: the healthcare system (macro level); the CM intervention in the clinics (meso level); and the individual/patient (micro level). For each objective, the following strategy will be performed: (O1) an implementation analysis, (O2) a realist evaluation, and (O3) consensus building among stakeholders using the TRIAGE method.

**Ethics and dissemination:** This study, which received ethic approval, will provide innovative knowledge about facilitators and barriers to implementation of CM in different primary care jurisdictions, and will explain how and why different mechanisms operate in different contexts to generate different outcomes among frequent users. Consensual and prioritized statements about next steps for spread of CM in primary care from the perspectives of all stakeholders will be provided. Our results will offer context-sensitive explanations that can better inform local practices and policies, and contribute to improve the health of patients with complex healthcare

needs who frequently use healthcare services. Ultimately, this will increase the performance of healthcare systems, and specifically mitigate ineffective use and costs.

**Registration details:** A realist evaluation does not need registration.

**Strengths and limitations of this study**

- This multiple-case embedded mixed methods study will provide new knowledge on the implementation of case management interventions to improve care integration for individuals/patients who frequently use healthcare services.
- The design of this study allows adapting the knowledge acquired on case management to local contexts, the first step to implementation.
- The multiprovincial nature of this study will allow to spread the new knowledge generated on CM in primary care settings in different Canadian jurisdictions and will increase generalizability.
- While some challenges are expected with this study, mitigated strategies are nevertheless proposed.

## INTRODUCTION

In Canada, as in many industrialized countries [1 2], close to 80% of healthcare costs are attributable to 10% of the population [3 4]. Data reveal that this 10% segment of the population comprises individuals/patients who frequently use hospital services for increasingly complex healthcare needs. Thus, albeit relatively small, this segment of the population uses a disproportionate amount of available healthcare and social services. Frequent use of emergency departments (ED) is a good proxy of high use of other healthcare services [5-7] as it is most commonly accepted in the literature [8-12], and provides a convenient and easy measure within a pragmatic context, as compared to cost for example. As such, five percent of ED's patients account for 30 to 50% of all visits [8 13]. As frequent use is not optimal for individuals/patients [14] or healthcare systems [15 16], better upstream care is a modifiable parameter that can effectively prevent it. Indeed, the majority of these individuals/patients who frequently use hospital services have a substantial burden of disease and would be best managed in primary care. [17].

In line with the Agency for Healthcare Research and Quality Multiple Chronic Conditions Research Network, complex healthcare needs can be defined as the gap between an individual's needs and the ability of health services to meet those needs [18]. Individuals/patients with complex healthcare needs often attempt to fulfill their unmet needs by using excessive health and social services in an uncoordinated way. Requiring a variety of services from various systems (e.g. health, social, education) and community networks, this often leads to difficulties with the integration of care[19]. This results in negative experiences for individuals/patients [14], poorer health outcomes, high mortality rates and considerable costs [19].

Case management (CM) was reported to be effective for individuals/patients who frequently used healthcare services [10 20 21]. By definition, CM is a collaborative approach used to assess, plan, facilitate, and coordinate care to meet individual/patient and family healthcare needs, through

communication and available resources including all sectors of health care (such as community, primary, secondary and tertiary care), as well as sectors outside of the health system (such as social services, housing, etc.) with the intent of improving individual and health system outcomes [22]. Three systematic reviews (including randomized controlled trials, non-randomized controlled trials, interrupted time series, and controlled and non-controlled before-and-after studies) concluded that CM was effective for individuals/patients who frequently used healthcare services, particularly on ED use and cost as well as on social and clinical outcomes [8 10 11]. A scoping review conducted by our team corroborated these findings by revealing that CM could reduce ED visits and hospitalisations as well as costs [9].

However, despite the evidence supporting CM as an effective intervention for individuals/patients that frequently use services, there is still a paucity of evidence about the facilitators and barriers to CM implementation [10 23]. Our literature review with thematic analysis of key factors of CM interventions among frequent users of healthcare services outlined that the case finding processes, the selection and training of the case manager, the intensity of the intervention, as well as care integration among all partners were important aspects to consider during CM implementation [23].

CM has rarely been implemented in primary care in Canada. Therefore, before spreading this intervention in primary care settings in different jurisdictions, stakeholders including individuals/patients/communities need to be engaged in adapting the intervention to their local context. Accordingly, further research is needed to better understand the facilitators and barriers (mechanisms) to CM implementation, as well as the influence of different primary care contexts on outcomes, e.g., self-management, quality of life, services integration, services use, and costs [9 24 25].

Therefore, the specific objectives of this study are threefold: (O1) identify the facilitators and barriers of CM implementation in primary care clinics across Canada; (O2) explain and

understand the relationships between the actors, contextual factors, mechanisms, and outcomes of the CM intervention; and (O3) identify the next steps towards CM spread in primary care across Canada.

## METHODS AND ANALYSIS

### Study design

To address these objectives, we will conduct, between September 2018 and August 2022, a multiple-case embedded mixed methods study, which constitutes a valuable design for performing research evaluation inquiries on complex systems in varied and dynamic contexts [26] [27]. In addition to allowing an in-depth analysis of each case, this design offers opportunities for comparison between cases. The inclusion of multiple cases capitalizes on organizational variation and allows for examination of how contextual factors influence implementation to develop a more informed understanding of change processes. It also allows for observation recursive or singular facilitators and barriers, and draws conclusions that could be transferable to other primary care contexts[28]. Furthermore, mixed methods involve combining qualitative and quantitative methods in complex program evaluation, primary research, and literature review; they are being increasingly used in health sciences; specifically, case studies can use qualitative, quantitative and mixed methods (multiple sources of evidence) to explain one or more cases [29].

### Study location and sampling

Five Canadian provinces are involved in the study: Saskatchewan (SK), Quebec (QC), Nova Scotia (NS), New Brunswick (NB) and Newfoundland and Labrador (NL). Considering that different primary care team models have been implemented throughout Canada [30 31], the primary care context of each jurisdiction will be taken into account when evaluating implementation and outcomes [31].

Two primary care clinics per province, where CM has not been previously implemented, will be recruited using a purposeful sampling strategy [32]. The recruitment of the clinics will be conditional to: the manager and team interest in implementing CM and engaging in the research project; availability and interest of a registered nurse or nurse practitioner to develop the role of the case manager. We will thus work with 10 cases (two per province), each case being the intervention implemented in each clinic. It is recommended that four to 10 cases be considered [33] in the multiple case study logic of theoretical replication, in which contrasting results are anticipated [26]. Two clinics per province will facilitate variability within each province. Cases will be selected in order to represent real-world differences [34] in terms of geographic location, model of practice, diversity of care teams, and size, based on the opinion of team members in each jurisdiction. Three different units of analysis will be explored to obtain an in-depth understanding of each case: (a) the healthcare system (macro level); (b) the CM intervention in the clinics (meso level); and, (c) the patient including their family and community (micro level).

**Objective 1: To identify facilitators and barriers of CM implementation in primary care clinics in Canada**

An implementation analysis will be conducted for identifying facilitators and barriers to, and informing implementation of, CM in primary care in different provinces [35]. Implementation analysis is very useful with complex interventions that can be influenced by the context within dynamic environments. The case study design is appropriate for implementation analysis of interventions [35].

*Conceptual framework*

Data collection and analysis will rely on the Consolidated Framework for Implementation Research (CFIR) of Damschroder *et al*. [36], which is aimed to foster implementation of findings

into practice. The CFIR is composed of five major domains: outer setting, inner setting, characteristics of the individuals involved, intervention characteristics, and, the process of implementation. Four constructs are related to the outer setting (e.g., external policies); 12 are related to the inner setting (e.g., culture and leadership engagement); five are related to individual characteristics (e.g., knowledge and beliefs); eight are related to the intervention (e.g., adaptability); and eight are related to process (e.g., planning). '*The CFIR provides a practical structure for approaching complex and transient states of constructs in the real world by embracing, consolidating, and unifying key constructs from published implementation theories*.'[36]

To properly address care integration, the CFIR will be linked to the Valentijn et al. framework [37] combining the concepts of primary care and integrated care. In this framework, person-focused care is the guiding principle for achieving integration across the care continuum, i.e. system integration (macro level), professional and organisational integration (meso level) as well as clinical integration (micro level).

*Pre-implementation*

A CM nurse mentor will facilitate 3-day training sessions for all CM nurses and will also lead monthly 1-hr community-of-practice meetings by teleconference, to assist with mentoring, collective learning and support [38]. As recommended by Damschroder et al. CFIR [36], team stakeholders will interact with the clinics in their province to co-design the adaptation of the CM intervention to their reality. According to the CFIR [36], the core components of the intervention, such as patient assessment, individualized care plan, care coordination and self-management support [39-42], will be maintained across all clinics, whereas more peripheral elements will be adaptable, e.g., as integration in the context. This adaptability will increase knowledge uptake [24] and promote integration with complementary programs outside of the clinics, while ensuring that

CM is being rigorously evaluated.

*Recruitment*

Each clinic will identify 30 patients with the most complex healthcare needs and who, according to their clinical experience of the existing gap between the individual's needs and the ability of health services to meet those needs [18] could benefit from CM. Inclusion criteria will be: living with at least one chronic condition; frequent ED users as defined by ≥4 ED visits in the previous year [43 44] (which have been recognized as a good proxy of frequent use of other healthcare services [5-7]); and, a score ≥ 17 on the INTERMED-Self-Assessment Questionnaire [45] evaluating complex healthcare needs. Exclusion criteria will be: frail elderly with loss of autonomy; individuals/patients without a chronic condition or with a prognosis of less than a year; or, patients already followed by a case manager in another program, e.g., mental health, senior care, addiction program. Case managers will offer the CM intervention to these individuals/patients over a 12-month period.

*Intervention*

The intervention will focus on four main recognized components of CM [39-42]: (C1) evaluation of patient needs and preferences; (C2) co-development and maintenance of a patient-centred individualized care plan, with the patient, family and other partners; (C3) coordination of health and social services among all partners; and (C4) education and self-management support for patients and families. This intervention is congruent with criteria from the *Case Management Society of America* [22] and the six standards of practice of the *National Case Management Network of Canada* [46]: (S1) determining and verifying patient eligibility; (S2) assessing patient needs; (S3) documenting patient goals and priorities; (S4) planning and adjusting services included in individualized service plans, including patient education and self-management support; (S5) monitoring patient needs and progress; and (S6) supporting transition processes. The intervention

also aligns with the six care integration characteristics proposed to consider a patient's experience[47]: (I1) consideration of patient and family needs; (I2) communication with the patient and between healthcare providers; (I3) access to information; (I4) involvement in decision-making; (I5) care planning; and, (I6) transitions between various professionals.

*Data collection*

The mixed method data collection will rely on the five following complementary strategies.

(1) Individual semi-structured interviews (qualitative data) will be conducted between six and nine months following initiation of CM intervention with all case managers, patients/families and clinic managers. Two focus groups per clinic will be also scheduled, enrolling eight primary care providers per group (including physicians, nurses, social workers, pharmacists and others) through purposive sampling [48]. All interviews and focus groups, conducted using a semi-structured interview guide composed of open-ended questions on facilitators and barriers of CM implementation and adapted to each category of stakeholders, will be digitally recorded and transcribed verbatim. Interview guides will address the domains and constructs of Damschroder's CFIR [36] and Valentijn Framework [37]. Data saturation will not necessarily be reached for each category of stakeholders, but their diversity will allow for a comprehensive representation of each case [49].

(2) Non-participant observation (qualitative data) of CM activities and meetings, e.g., patient-case manager, individualized service plan development, team discussions, at each clinic for thirty hours at 6 months will be conducted. Research assistants will collect data by means of an observation grid and field notes [48].

(3) Self-administered and validated questionnaires (quantitative data) with accepted psychometric properties will be administered to all individuals/patients in the presence of the research assistant. At baseline, the following characteristics will be assessed: age; gender; marital status; education; occupation; economic status with family income and patient perception of his or her economic situation; health literacy [50 51]; multimorbidity [52 53]; care integration [54]; self-management [55 56] and health related quality of life [57]. Care integration, self-management and health related quality of life, will be re-evaluated at 12 months.

(4) Clinical data on service use during the year of the intervention (quantitative data) will be collected through the patient's electronic medical record: ED visits; overnight stays; primary care and specialist visits. Costs will be measured from a healthcare system perspective, including costs of the CM intervention and of healthcare expenditures. Costs of the intervention will consider nurse training, mentoring, and CM implementation. Participant healthcare expenditures, such as ED visits, overnight stays, professional visits, will be calculated using predetermined fees, e.g., from the CIHI Patient Cost Database [58].

(5) Intervention fidelity evaluation (quantitative data) will be assessed to determine whether the intervention was delivered as intended [59]. For this purpose, research assistants will collect data relevant to the delivery of the main components of the CM intervention from the medical records of participants after six and 12 months using a fidelity grid. Similar data on CM intervention fidelity were collected successfully in our previous study [60].

*Data analysis*

Qualitative data analysis: Interview- and observation-based data will be analysed together using a deductive (themes based on the Damschroder et al. CFIR and Valentijn frameworks) and inductive (themes suggested by the data while not in frameworks) thematic analyses [61].

Qualitative data will be managed using multi-site NVivo 10 server software (QSR International Pty Ltd).

Quantitative data analysis: Descriptive statistics will be performed. Intervention fidelity will be represented by the proportion of delivery for each component of the CM intervention. Regression models will be developed to evaluate relationships between contextual elements, i.e. intervention fidelity, patients' characteristics and outcomes, using SPSS version 24. An incremental cost-effectiveness/utility ratio [62] will be calculated, using data collected on costs and QALY (i.e., SF-6D), at baseline, and 12 months after the CM implementation. Multivariate parametric analyses with bootstrap replications will be conducted along with cost-effectiveness acceptability curves[63].

Integration of qualitative and quantitative methods - Two types of integration will be performed: qualitative and quantitative results will be compared, and qualitative and quantitative data will be merged for each case [29]. Considering the inherent variety and changing contexts of the study, results of qualitative and quantitative data analyses will be compared, and the comparison interpreted using a side-by-side joint comparison table (rather than trying to calculate non-biased quantitative effects [64]). Then for each case, qualitative and quantitative data will be merged [26]. A case history will be reported (synthesizing merged data), and the 10 case histories will be used to compare cases by means of a descriptive and interpretative matrix (mixed methods matrix), allowing systematic comparisons among cases and analysis units (macro, meso and micro) [61]. Different analytical techniques for case study will be used among which pattern comparison, research of competing explanations and construction of explanations [26]. Management, data reduction and cross care comparisons will be conducted with NVivo 10 software using matrix queries. All categories of stakeholders will be invited to participate in key steps of the analysis to ensure meaningful interpretation.

**Objective 2: To explain and understand the relationships between actors, contextual factors, mechanisms and outcomes of CM intervention**

A realist evaluation will be conducted according to Pawson and Tilley [65]. Realist evaluation is a theory-driven approach for studying complex interventions to explain how and why they are effective, under what conditions and for which groups of patients. It is based on four concepts for explaining and understanding the complex relationships in a given intervention: context (C); mechanism (M); outcome (O); and, context–mechanism–outcome (CMO) configuration [65-67]. The multiple-case study is a recognised design for investigating CMO configurations in healthcare research [68-73]. The realist evaluation will use a multi-method (quantitative and qualitative), theory-driven approach to provide an explanation of why outcomes occur [67], and will follow three phases: stating an initial program theory; testing this program theory; and, refining this program theory.

*Stating an initial program theory*

A proposed initial middle-range program theory developed in our realist synthesis [74] of the literature on CM for individuals/patients that frequently use healthcare services in primary care will provide a rigorous basis for the next two phases of data collection (testing and refining the program theory).

*Data collection (testing and refining the program theory)*

In the next year, same participant sampling and data collection will be repeated in the same clinics identified in Objective 1, with a new cohort of patients. However, qualitative data will be used to identify and better understand CMOs. The same quantitative data will be used to measure outcomes, i.e. self-management, health related quality of life, care integration, services use and costs at baseline, 6- and 12-months for developing CMOs. For qualitative data collection,

interview guides and the observation grid will be informed by the initial theory and tailored to the participant groups. Interviews and focus groups will be performed using realist interview techniques [75]. The theory will be discussed with individuals/patients who will then provide their own experience and vision for collaborative conceptual refinement. The interviewer will play an active role in explaining the contexts and outcomes of interest, and in ensuring that participants understand the terminology of the realist evaluation. Participants will be asked to share how they think their experience relates to this theory and to reflect on what may explain the outcomes in their setting [76]. Data collection will be iterative until reaching saturation [65 75].

*Data analysis*

Quantitative data will be analyzed, as described above, to inform outcomes. Qualitative data, including interviews, focus groups and observation, will be analysed with NVivo using thematic analysis, guided by the initial program theory from the realist synthesis. Analysis will remain open to emergent themes that support further theory refinement. Similar to the above integration, quantitative and qualitative results will be compared (producing joint display table), and quantitative and qualitative data will be merged for each case (producing case histories and a mixed method matrix).

Research assistants from the various provinces will co-analyze quantitative, qualitative and mixed methods evidence. They will identify CMO configurations, first within each primary care clinic (case) and then across sites. All team members will be involved in certain steps of the analysis. A recap table [77] will be constructed using columns to separate components of the initial theory and rows representing different cases. This approach will facilitate within-case analysis, highlighting similarities or discrepancies between data sources. It will also facilitate cross-case analysis to identify patterns (demi-regularities or semi predictable patterns) across cases. Analysis of CMO configurations will help complete, confirm, or modify the components of our initial theory, and

ultimately produce a refined theory explaining how and why CM works, in specific contexts, and for specific categories of patients. Results will be reported in line with the RAMESES II reporting standards for realist evaluation [78].

**Objective 3: To identify the next steps towards CM spread in primary care across Canada**

The Technique for Research of Information by Animation of a Group of Experts (TRIAGE) method will be used to reach consensus among all stakeholders about the next steps forward with spread (expansion and extension), in light of our case study results. The process of developing a shared understanding from the different stakeholders' perspectives through discussion improves progress of an innovation towards spread [25]. TRIAGE is a research method based on the attainment of a group consensus to supply first-hand information for decision-making [79]. It is a structured and inductive method of data collection comprising three successive phases: preparation; individual production; and interactive production.

*Preparation*

A full-day meeting will be organized, gathering the tripartite structure (clinical, scientific and policymaker leads) of all pan-Canadian SPOR Networks in Primary and Integrated Health Care Innovations (PIHCI) and at least one individual/patient from each province in order to embody categories of stakeholders across Canada. PIHCI is a network building on regional and national achievements in community-based primary and integrated health care [80]. During this preparation phase, a brief executive summary of project results will be produced and tailored to inform each specific audience and category of stakeholders. The evaluation question that will be discussed and disseminated to the participants is as follows: Based on your own experience, what should be the next steps towards the spread of CM in primary care, in your area of expertise (patient engagement, clinical care, policy and research)?

*Individual production*

All stakeholders will receive the executive summary of the results, two months prior to the meeting, and will be asked to provide a maximum of five statements in response to the question stated above. Beyond five statements, information is expected to become redundant [79]. These statements will be kept confidential and sent back to the organisation team.

*Interactive production*

This phase will take place during the full-day meeting. The project and results will be presented to all participants. Each group of stakeholders will gather to identify, by consensus, the most important and relevant statements among those brought forth in their stakeholder category. An expert animator will act as a facilitator and lead interactions among group experts. The interactive step of TRIAGE relies on a prominent visual aid. A wall of the room will be used and divided into three main sections: memory, groupings and selection. The memory section is, in fact, a bank of all statements gathered in the previous step, which have been numbered and transcribed. As group interactions occur, the selection process will evolve, with cards moving from one section to another, from left (memory) to right (selection). It will also be possible to modify the statements. "Selected" statements will also be ranked and prioritized. At the end of the meeting, each group of stakeholders will present their selected statements in order of priority.

## Patient and Public Involvement

This project was developed in close collaboration with patient-partners, with which we developed a trusty relationship and a collaborative approach. These partners are listed as co-authors (GG, CL, JR, AS, CS, VS, MW). These patient-partners were involved in the elaboration of the research questions that were relevant from their perspectives. Patient-partners will advise on ways to enhance study feasibility and patient's acceptability. They will be engaged in interpretation of data. Results will be disseminated to patients through lay language newsletters and local media.

## ETHICS AND DISSEMINATION

This project received approval from the CIUSSS de l'Estrie - CHUS Research Ethic Board (project number MP-31-2019-2830). All participants will provide informed consent prior to engagement and recruitment. In addition, certificates of approval will be obtained in each of the provinces before data collection is commenced. If appropriate, adherence to Chapter 9 of the TCPS2 (2014) will be observed and upheld.

This four-year multiple-case, mixed-method study will result in the potential for great impact with stakeholders, but mostly for individuals/patients. New evidence-based knowledge will be provided on the implementation of CM interventions, which can contribute to improve care integration for individuals/patients who frequently use healthcare services, and ultimately reduce ineffective healthcare use and costs. The proposed design will allow adapting the knowledge acquired on CM to local contexts, the first essential step towards implementation [81]. Moreover, recognition of facilitators and barriers to implementation as well as, the influence that context exerts on outcomes will pave the way for the spread of CM in primary care settings in different Canadian jurisdictions.

This study built on various strengths, but mostly on the engagement of knowledge users who were and will be involved throughout the entire process to ensure that the new knowledge generated by CM in primary care will be refined and tailored to their own specific needs [81]. These stakeholders will then be best suited to further adapt CM knowledge to their own local context and to increase the chance of successfully implementing CM in their setting [81]. All of these steps will increase spread and positively influence the healthcare system as well as individuals/patients/communities and clinicians' experiences, and outcomes [24 25 36].

This study builds on many important aspects related to the rigour of the approach and methodology. As such, all stakeholders, including individuals/patients, from the five provinces (SK, QC, NB, NS, NL) already working together, have participated in the elaboration of research questions that were relevant from their perspectives. This partnership with stakeholders is strengthened by a solid engagement plan as well as a relevant knowledge transfer plan tailored for each stakeholder audience. The conceptual basis of this study is based on a rigorous research plan that unifies key constructs from published implementation theories (CFIR) [36] as well as a framework combining the concepts of primary care and integration of care (Valentijn) [37]. The intervention is evidence-based and shaped for individuals/patients who frequently use healthcare services [8-12 82]. As for data collection, appropriate sampling strategies will be pursued, while data quality and reliability will be ensured through three main strategies [26]: the 10 case histories will integrate relevant qualitative and quantitative data in a Master database; the database will contain sufficient information about data collection; and, data collection will follow published methods. Validity of the study will be ensured by mixing qualitative and quantitative methods (comparison of results and data merging), multiple data sources and evaluators triangulation [26]. Transferability will be ensured by several strategies such as theoretical basis, observation replication across cases [26], and thorough description of the context [61].

While some challenges are expected with this study, mitigated strategies are nevertheless proposed. To ensure meaningful involvement of all provinces and team members in the project, relationships and team building will be nurtured and stakeholders will be encouraged to speak in their preferred language (English or French). Being engaged with our patient partners over the last four years, solutions have been developed to accommodate their needs, e.g., help with a wheelchair, being flexible regarding schedule if hospitalization or deterioration, training. Partnerships will also be monitored annually. The circumstances of this vulnerable clientele may also influence data collection as well as study validity. This challenge will be overcome by

research assistants administrating the questionnaire to patients and assisting them as needed. In a similar study conducted by our team, a 93% retention rate was achieved, demonstrating the efficacy of our strategies [60].

Based on popular conceptual frameworks and rigorous methodology, design, and methods, this pan-Canadian study holds promise to guide policy decision-making, and to ultimately and positively impact health services systems as well and most importantly, the health of Canadians. This study will generate findings on the implementation of CM in primary care for individuals/patients with chronic conditions and complex healthcare needs who frequently use healthcare services, as well as to implement an evidence-based intervention that will not only improve the care experience and outcomes but will also mitigate ineffective use and costs.

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## LIST OF ABBREVIATIONS

CM: Case management; CFIR: Consolidated Framework for Implementation Research; CIHI: Canadian Institute for Health Information; CMO: Context-Mechanism-Outcome; ED: Emergency department; NB: New Brunswick; NL: Newfoundland and Labrador; NS: Nova Scotia; PIHCI: Primary and Integrated Health Care Innovations; QC: Quebec; SK: Saskatchewan; SPOR: Strategy in Patient Oriented Research; TRIAGE: Technique for Research of Information by Animation of a Group of Experts.

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## AUTHORS' CONTRIBUTION

CH, M-CC, KAB, FB, SD and VR are the principal investigators of the study. CH, M-CC, KAB, FB, SD, VRR, MB, PLB, YC, MFD, LG, FL, PM, TGP, MEP, PR, RV, SB, CC, MC, BD, ÉD, LE, SG, GG, PG, RJG, JG, GL, CL, NR, DAR, JR, VS, TS, AS, CS, JS, MW, JY, PP contributed to the conception, the design of the study, editing and final approval of the protocol and will either be involved in data collection or interpretation.

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## COMPETING INTERESTS

All authors declare that they have no competing interests.

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