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Protocol for a mixed-method analysis of implementation of case management in primary care for frequent users of health care services with chronic diseases and complex care needs

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Abstract

Introduction: Case management (CM) in a primary care setting is a promising approach to integrating and improving health care services and outcomes for patients with chronic conditions and complex care needs who frequently use healthcare services. Despite evidence supporting CM and interest in implementing it in Canada, little is known about how to do this. This research aims to identify the barriers and facilitators to the implementation of a CM intervention in different primary care contexts (objective 1) and to explain the influence of the clinical context on the degree of implementation (objective 2) and on the outcomes of the intervention (objective 3).

Methods and analysis: A multiple-case embedded mixed methods study will be conducted on CM implemented in ten primary care clinics across five Canadian provinces. Each clinic will represent a sub-unit of analysis, detailed through a case history. Cases will be compared and contrasted using multiple analytical approaches. Qualitative data (objectives 1 and 2) from individual semi-structured interviews (N=130), focus group discussions (N=20) and participant observation of each clinic (36 hours) will be compared and integrated with quantitative (objective 3) clinical data on services use (N=300) and patient questionnaires (N=300). An evaluation of intervention fidelity will be integrated into the data analysis.

Ethics and dissemination: This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number MP-31-2019-2830). To our knowledge, this is the first study to analyze the implementation of CM in Canadian primary care settings. Results will provide the opportunity to refine the CM intervention and to facilitate effective evaluation, replication and scale-up. This research provides knowledge on how to respond to the needs of individuals with chronic conditions and complex

care needs in a cost-effective way that improves patient reported outcomes and health care use, while ensuring care team well-being.

Keywords

Primary health care; case management; chronic illness; complex care needs; frequent users; implementation; evaluation; context, intervention fidelity.

Article Summary

Strength and limitations of this study

- This protocol details the steps for the implementation of a case management (CM) intervention for frequent users of health services with chronic conditions and complex care needs.
- A novel conceptual model for CM implementation is proposed based on the integrative functions of primary care and the effective implementation of health care interventions.
- The barriers and facilitators to implementing CM will be detailed and the influence of the clinical context on the degree of implementation and on the outcomes of the intervention will be evaluated.
- While the proposed conceptual model does not cover every possible construct for effective implementation, an inductive approach to data analysis will be used to allow for emergent themes and all stakeholders will participate in data analysis in order to ensure validity.

Introduction

A priority for primary care research and the Canadian health care system is to address the complex needs of patients who frequently use health care services (1, 2). These patients may suffer from a combination of chronic illnesses, mental illness and/or socioeconomic vulnerabilities (3-5). Patients with chronic illnesses typically have a wide range of needs that require them to adopt new behaviours, such as meeting with care providers on a regular basis, adhering to treatment plans, monitoring their symptoms and making important decisions while also changing aspects of their lifestyle to preserve their physical, psychological and social well-being (6-8). Far from "misusing" the health care system, studies show that frequent users do so in an attempt to address unmet needs for health care and social services (3, 9). Studies suggest that these attempts are often unsuccessful and result in repetitive use of services in an uncoordinated way through frequent hospitalizations or visits to the emergency department (10, 11). This leads to negative experiences for both the care providers and for the patients, poor health indicators and high mortality rates for the patients and considerable costs to the health care system (11-13). Several countries have therefore experimented with new models of health care delivery that can achieve better coordination and integration of services, some of which have been found to reduce fragmentation and improve care continuity (14). Early examples of such models include the Chronic Care Model (CCM) (15) and the Innovative Care for Chronic Conditions framework (16). These models emphasize the importance of providing support to patients for self-management and decision-making, seeking innovative approaches within available clinical information systems and proposing ways to redesign the delivery of health care (14).

Individuals with chronic illnesses require organized care and close follow-up delivered over an extended period of time (17). The primary care setting is the most suitable for supporting individuals with chronic illnesses due to its defining features of patient-centered first contact, continuous, comprehensive, and coordinated care (17, 18). Health systems built on the principles of primary care achieve better health

outcomes and greater equity, at a lower cost (19) than systems with a specialty care orientation (18). Integrated care may be achieved in a primary care setting through the creation of inter-sectorial linkages between health and social policies, i.e. the linking of health care to other human service systems (eg. long-term care, education, vocational and housing services) in order to improve clinical outcomes, patient and provider satisfaction and efficiency (14, 18, 20).

Case management

Case management (CM) in a primary care setting is one approach that has been shown to increase the integration of health services (21, 22) and to improve care and outcomes for patients with chronic conditions and complex needs who frequently use health care services (23, 24). Defined as "a collaborative, client-driven process for the provision of quality health and support services through the effective and efficient use of resources" (25), CM is among the best models available to mitigate the high utilization of the health care system and associated costs (23, 26). An adaptive randomized trial of CM interventions targeting frequent users of health services demonstrated that appropriate patient identification, staff training and centralized intervention delivery are components of CM that can be successfully implemented on a large scale and lead to a decrease in health consumption (27). A recent systematic review (10) identified the most common components of CM interventions for chronically ill patients including the integration of services between hospitals and home or other facilities, regular home visits, regular telephone calls, individual assessment and care planning, education and self-management support, psychosocial support, and ongoing supervision and assessment. The same study found that a reduction in hospital admission rates was reported after implementation of CM interventions (10). A systematic review of literature on the characteristics of CM interventions in primary care reporting positive outcomes for frequent users of health care revealed three essential requisites for success. First, the intervention must identify and target patients with the greatest needs,

and who are therefore most likely to benefit from the intervention. Second, the intervention must be delivered with sufficient intensity (i.e. frequently enough or with a high enough dose) to produce the desired effect. Third, an interdisciplinary approach to care planning is preferred, where a variety of professionals from both care and cure sectors actively participate in the intervention (28).

Despite the evidence base supporting CM as an intervention for frequent users, little evidence exists about the facilitators and barriers to CM implementation (29). Although there is a strong interest in implementing CM in the Canadian primary care setting, little information is available on how to do this. CM has rarely been implemented and documented systematically in order to identify and replicate best practices. This protocol is part of a larger research program on CM in primary care for frequent users of healthcare services with chronic diseases and complex care needs (2) and details the steps for the implementation analysis that was not described in the original protocol of the whole program.

Objectives

1) To identify the barriers and the facilitators to implementation of the CM intervention in different primary care contexts.

2) To explain the influence of the clinical context on the degree of implementation.

3) To evaluate the influence of the context of implementation on the outcomes of the intervention.

Methods/Design

Conceptual model

The conceptual model developed to guide this research protocol was informed by two multi-level conceptual frameworks in order to analyze the effective implementation of an integrative primary care intervention. Multi-level frameworks represent the interacting layers of phenomena inherent to

organizations and are commonly used to develop theories, measure and analyze phenomena while accounting for the complexity inherent to these systems (30, 31). Multi-level interventions mobilize resources and facilitate linkages across organizations "to solve coordination problems and adapt to change" (31).

The first framework used to guide this research protocol is the Valentijn et al. framework for integrated care based on the integrative functions of primary care (18). The concept of integration originates from organizational theory and refers to "the quality of the state of collaboration" that may exist among the multiple levels of service delivery with the purpose of achieving a required mutual effort and agreement (14). Integrated health care interventions are a means to improve access, quality and continuity of services in a more efficient way, especially for people with complex needs (18) . This framework describes the central role of primary care in integrating the multiple levels of health care: system integration at the macro level; organizational and professional integration at the meso level; clinical integration at the micro level; and functional and normative integration to link the macro, meso and micro levels (18). Valentijn et al.'s framework is intended for analyzing and testing the causal relationships within and between the integration levels, which interact to varying degrees depending on the specific context of health care delivery (18). This framework is therefore suitable for studying the different primary care contexts of the CM intervention from the perspective of integrated care and is the unifying thread to the implementation and evaluation of the CM intervention.

The second framework used to guide this research protocol is the Consolidated Framework for Implementation Research (CFIR), intended to promote effective implementation and formative evaluation of complex, multi-level interventions in health care (32). The CFIR provides a taxonomy of constructs that can be used to understand, measure and assess implementation across a variety of

contexts. The constructs are categorized into five major domains that similar to the Valentijn et al. (2013) framework, reflect a multilevel perspective. The *outer setting* refers to the economic, political and social context in which the implementing organization is situated and corresponds to the macro level. The *inner setting* corresponds to the meso level of the organizational context and includes constructs such as the structure and culture of the implementing organization. At the micro level, the *individuals* involved in the intervention are described. The CFIR includes two additional domains: the *characteristics of the intervention*, a description of its core components, and the *implementation process*, considered a dynamic, non-sequential and non-linear domain that can stem from any level, macro, meso or micro (32). When understood, process provides insight that links the various levels of analysis and shed light on the causal or generative mechanisms underlying the intervention being studied (32, 33). Barriers and facilitators may arise at multiple levels of intervention delivery, as external influencers, organizational or professional components or during the process by which an intervention is adopted within an organization (32).

The conceptual model developed to guide this research protocol is presented in Figure 1. On the left side of the figure are the core components of the CM intervention, described in the proceeding section. During implementation, the intervention takes on unique properties and characteristics related to the local context in which it is introduced (referred to in Figure 1 as the *context of implementation*) (32). The context of implementation includes macro, meso and micro level determinants, depicted by the concentric circles in the middle of the figure. The process of implementation is represented by the arrow at the bottom of the figure, which represents the dynamic and continuous nature of intervention implementation. Finally, to the right, are the final expected outcomes of the intervention, based on the quadruple aims to optimize health system performance: improved patient outcomes, health care use, care team well-being and cost effectiveness (34).

Constructs were selected from both Valentijn et al. (2013) and Damschroder et al. (2009) to reflect the objectives of this research. The characteristics of the intervention after implementation in a particular local context will be analyzed based on the intervention's *adaptability* to meet local needs, its *relative advantage* to the context, and its *complexity* or difficulty of implementation. At the macro level, how the intervention contributes to *system integration* will be examined, including vertical integration and collaboration across care sectors and horizontal integration through a holistic view of the patient (18). This construct reflects the implementing organization's knowledge of the needs of its patient population and its ability to respond with appropriate structures, techniques and resources (*patient needs and resources*) (32). The organization's degree of networking with external services and structures (*cosmopolitanism*) will be examined, as well as its formal strategies and policies supporting external linkages (*external policies and incentives*).

At the meso level, *organizational* and *professional integration* will be examined, which refer to the partnerships between services and professionals within the implementing organization. The *structural characteristics* of the organization and the *implementation climate* will be described. At the micro level, interest will shift to *clinical integration*, which reflects the level of coordination and coherence of the primary care delivery process (18). The *knowledge and beliefs* of the various professionals involved in the intervention will be examined, as well as their perceived *self-efficacy* to implement CM, and their *individual stage of change*, which refers to their progress towards full adoption and sustained use of the intervention (32).

Finally, the process of implementation will be analyzed by examining how the CM intervention was planned and executed at the local level, how professionals were mobilized and engaged for participation

in the intervention, and by examining the mechanisms put in place to discuss and provide feedback about the experience, progress and quality of implementation (*planning/executing*; *engaging*; *reflecting/evaluating*). These constructs reflect the level of *functional* and *normative integration* resulting from the implementation of the intervention: how the implementing organization mobilized management functions in support of the intervention, as well as the degree of development of a shared goal or mission among participating individuals and partner organizations for the implementation of the intervention (18).

The intervention

An intervention was designed to reflect the standards of practice of the National Case Management of Canada as well as the Case management society of America (25, 35). The activities of the intervention follow the Canadian Institutes for Health Research (CIHR) Strategy for Patient Oriented research and incorporate the integration characteristics of the National Collaboration for Integrated Care and Support (36, 37). Patients with chronic conditions most often seek and receive comprehensive care in a primary care setting (38) and the leadership of a case manager who is experienced in primary care has been shown to facilitate the successful implementation of chronic care models (39). The CM intervention is therefore designed to be delivered by a primary care health professional in a primary care clinical setting over a period of 12 months.

In consideration of these guidelines and of the results of previously cited studies (10, 11, 23, 27, 28), an intervention was designed comprised of four main components: 1) evaluation of patient needs and preferences; 2) co-development and maintenance of a patient-centered individualized services plan; 3) coordination of services among all partners; and 4) education and self-management support for patients and families.

1. Evaluation of patient needs and preferences

The identification of patients who are in need of intervention and who stand to benefit the most from CM is an essential first step (27, 28), ideally executed by an interdisciplinary team (5, 40). Patients are identified by searching administrative data or clinical records in addition to their referral for the CM intervention by primary care professionals. This approach combines clinician judgement with objective data from electronic medical record (EMR) or administrative databases (2, 41). The CM intervention targets patients who present with at least one chronic illness, including mental illness, who frequently use health services as determined by 4 or more emergency department visits or hospitalizations in the previous 12 months, and who have complex needs as determined by the care team. Once a patient has been identified for inclusion in the CM intervention, the case manager examines the patient's medical records going back 12 months in order to understand the reasons for the frequent use of services. The case manager identifies the patient's physical and/or mental illnesses as well as social challenges such as insecure housing or employment, poverty, violence, substance use disorders, etc. The case manager also documents the health and social services previously provided to the patient, as well as the names, roles and contact information of professionals currently involved with the patient or who may eventually be called upon to participate in the care of the patient.

The case manager validates with the patient the information collected from the medical records and determines the patient's personal needs and preferences for future services and resources. This step constitutes the first in-depth interaction between the case manager and the patient, and is essential for building mutual trust and respect (21), for establishing a patient-centered care process, and for encouraging the commitment of the patient as a partner in the care process (42, 43). The patient may prefer to be accompanied by a caregiver or advocate with lived experience of the patient's health

situation who can assist in navigating the health and social services system (44). When referring to "the patient" in this article, we also refer to an individual who may stand in for the patient at any point during the intervention. Finally, the case manager seeks the patient's consent to communicate with potential care professionals throughout the intervention and ensures that the patient understands and agrees to the next step of the intervention: the creation of an Individualized Services Plan (ISP). The ISP is a tool for planning and coordinating tailored services intended to give meaning and direction to the patient in consideration of his or her life goals (45), personal environment, resources and culture, in collaboration with a multidisciplinary team of professionals (46) and health and social services organizations.

2. Co-development and maintenance of a patient-centered ISP

The ISP for patients with chronic conditions may lead to improvements in physical and psychological health, as well as in their ability to self-manage their condition (46-48). It is among the most commonly used strategies in CM interventions (10, 11). The case manager identifies resources available in the local health and social services network and within the community that may be appropriate for the patient. This involves a holistic analysis of the patient's situation and the identification of clinical-administrative issues and a final list of care professionals that will be invited to examine the patient's situation. These may be health care and social services professionals, managers or representatives of community organizations. The case manager communicates directly with targeted care professionals to request their involvement, to ensure that the reason for the intervention is understood and to agree upon a mutually convenient date, time and place for an ISP meeting with the patient. The case manager prepares the agenda for the ISP meeting and communicates with the patient to reconfirm consent regarding the professionals who will participate in the meeting and to maintain a relationship of trust

and transparency with the patient. The ISP meeting is ideally held in-person, but may be done by phone or online.

At the beginning of the ISP meeting, the care team reviews the potential resources and services that may be proposed to the patient prior to the patient's arrival. This allows the care team to collaboratively examine the patient's situation, needs and preferences and to mobilize their multidisciplinary perspectives (46). The ISP is then developed with the patient and their advocate upon their arrival. The ISP includes a maximum of 3 or 4 objectives in line with the patient's overall expectations and life project (49). The group proposes preferred methods of communication and strategies for exchanging information for the duration of the intervention. The case manager writes up the ISP in plain language and validates that the patient understands and agrees to it.

3. Coordination of services among all partners

Patients with chronic illnesses and complex care needs are often cared for by multiple providers in various locations and experience difficulty navigating the health system and other ressources resulting in unmet needs, a lower quality of life and higher mortality rates (48). A coordinated response by care providers that promotes patient empowerment over an extended period of time is recommended (14). In this intervention, the case manager transmits a copy of the written ISP to the patient and the care team and follows-up regularly with the patient's primary care providers in the clinical setting, ensuring active engagement and direct communication. As the principal contact-person and advocate for the patient, the case manager establishes contact with the services or resources identified in the ISP, providing a personalized reference for the patient, explaining the case and informing care professionals of past and potential challenges facing the patient.

Regular communication and follow-up encourages the patient's active engagement in the intervention, a strategy that has been shown to reduce future use of emergency services (26, 50, 51). The case manager talks to the patient about their preferred method for reaching the case manager and other relevant services. Adherence to the ISP throughout the intervention is ensured by maintaining contact with the care professionals involved with each patient, and by verifying if the patient's goals have been attained. The ISP should be reviewed at least once every 3 months. If the patient desires a change in their ISP, or if a care professional identifies any issues throughout the intervention, the case manager reassesses the situation with the patient and adjusts the ISP as necessary.

4. Education and self-management support for patients and families

Self-management support was found to be the strategy most frequently associated with health improvements in patients with chronic diseases in a primary care setting (17). Education and self-management support activities aim to increase the patient's skills, confidence and motivation to control and manage their symptoms and to follow their ISP with structured support for problem solving and continuous assessment of the patient's objectives and progress (52). This component of the intervention is considered an ongoing and transversal process to be performed as needed throughout the intervention.

Case managers aim to develop the patient's ability to monitor their condition, take appropriate action and identify when and how to ask for professional help by assessing the patient's knowledge and learning needs and suggesting beneficial activities, such as journaling symptoms and vitals, and informational resources based on the patient's unique situation. Case managers are trained in motivational interviewing, a "client-centered, directive communication method aimed at changing behavior" (53). The case manager supports the patient to set realistic goals through a "smart" action

plan that includes specific behavioral goals that are measurable and attractive to the patient, that may be accomplished in a realistic time frame and that build on previous positive experiences. The case manager helps the patient prepare for meetings with the various care professionals to ensure that the patient is empowered to communicate his or her goals and to receive the desired care. Patients are coached on how to effectively communicate with their relatives, to establish expectations, and to ensure a successful care partnership.

Study setting

The CM intervention will be implemented in ten primary care clinics, each representing a unique case. Two clinics were selected from each of the five participating Canadian provinces of Newfoundland, Nova Scotia, New Brunswick, Québec and Saskatchewan using a purposeful sampling strategy (54). Clinics were selected that had not previously implemented CM and that were interested in implementing the CM intervention and participating in the research project. The interest of a health care professional, a nurse or a social worker, to develop the role of the case manager and to be available to dedicate approximately 1 day per week to the study was essential. The case manager was required to have primary care experience and was offered training in the intervention and continuous support and follow-up through the establishment of a community of practice.

Patient and public involvement

Patient partners were involved in this research since its inception, including the design of the research questions and the development of this protocol of which they are coauthors (VS and MW). They continue to provide their expertise regarding study feasibility and acceptability. They will be involved in the interpretation of data and in the dissemination of results.

Timeline

The implementation of the CM intervention will take place over a period of one year. A cohort of patients will be recruited at each clinic and will be administered the intervention over the course of 12 months.

Patient recruitment

Each clinic will identify 30 patients for enrolment in the CM intervention, for a total of 300 patients across the 5 participating provinces. Patients are selected who are most likely to benefit from CM, based on the clinical judgement of the case manager and the family physician. Criteria for inclusion in the study are as follows: 1) living with at least one chronic physical or mental illness; 2) frequent user of health care services ie. having 4 or more hospitalizations or visits to the emergency department in the previous year; 3) having complex care needs as determined by the care team. Patients who are ineligible for participation in the study include individuals whose prognosis is less than one year or who are exhibiting a loss of autonomy.

Study design

The implementation analysis is designed as a multiple-case embedded study, where each of the ten clinics will represent one sub-unit of analysis. This design is best-suited to analyzing complex interventions implemented in variable and dynamic settings, and where the underlying context is difficult to isolate from the intervention itself (55). This design allows several levels of analysis, the observation of various organizational processes or behaviours, the examination of the context and process of implementation, and the interaction among involved stakeholders (56). It also favors the use of mixed methods of data collection and analysis (57).

Data collection

To accomplish the objectives of this research, a mixed methods data collection is planned. Multiple sources of information will be used to collect both qualitative and quantitative data.

Individual semi-structured interviews will be administered to all case managers (1-2 per clinic) and clinic managers (1 per clinic) at each study site at the start of the intervention (T0), and at the end of the intervention (T12 months). At the end of the intervention (T12 months), 10 patients and/or their representative will also be interviewed. Patients will be purposefully selected to achieve maximum variation (54). A total of 130 individual semi-structured interviews will be administered across the 10 participating clinical sites. An interview guide was developed composed of 18 open-ended questions based on the constructs of the conceptual model (Figure 1). The first part of the interview will address the clinical context of the CM intervention, the services offered at each clinical site to patients with chronic conditions and complex care needs, and the way in which the clinic works with other health and social services organizations. In the second part of the interview, questions will be asked about the implementation of the four components CM intervention, the context of implementation, the barriers and facilitators to intervention, and about individual perceptions and attitudes towards the intervention.

Focus groups

A focus group discussion will be held at each participating clinic, once at the beginning of the intervention (T0) and once at T9-12 months, for a total of 20 focus groups throughout the CM intervention. Primary care providers, including physicians, nurses, social workers, pharmacists and any health and social services professionals involved in the intervention will be invited to take part in a discussion facilitated by a member of the PriCare research team. The interview guide described above for the semi-structured interviews will be adapted and used to guide the focus group discussion.

Non-participant observation

The activities of the intervention at each of the ten clinical sites will be observed for thirty-six hours during the implementation year. A member of the PriCare research team will observe the CM activities including the meetings between the patient and the case manager, the development of the ISP, meetings between the primary care professionals, and any other activities adopted by the clinic under observation. Data collection will be guided by means of an observation grid developed to reflect the four components of the CM intervention and the constructs of the conceptual framework.

Clinical data on services use

Quantitative data from patient medical records will be collected at the beginning (T0) of the intervention for a period of 12 months, before the patient's first visit with the case manager, and at the end of the intervention 12 months) (N=300). The purpose of this data collection is to compare the utilization of services in the year before the intervention with utilization during the intervention. Data will include the number of emergency department visits, overnight stays in the hospital and primary care professional visits. Patient expenditures from these activities will be calculated using an established fee schedule from the Canadian Institute of Health Information (CIHI) patient cost estimator (58). The cost of the intervention will be measured by tracking expenditures related to the CM activities.

Patient self-administered questionnaires

Participating patients (N=300) will be asked to complete a 30-minute questionnaire at baseline (T0), at the halfway point (T6 months) and at the end of the intervention (T12 months) under the guidance of a member of the PriCare research team. Questionnaires are available in both English and French and have been validated. Data collected will include age, gender, marital status, education, occupation, economic status with family income and patient perception of his or her economic situation, health literacy,

multimorbidity, care integration, self-management and quality of life. Health literacy will be measured using Chew's 3 questions for screening patients with inadequate or marginal health literacy (59, 60), multimorbidity with the Disease Burden Morbidity Assessment (21 items) (61, 62), care integration with the Picker Institute Questionnaire (13 items) (63), self-management with the Partners in Health Scale (12 items) (64, 65), quality of life with the SF-12v2 (12 items) (66) , quality-adjusted life years (QALY) derived from the SF-12v2 (67) and psychological distress with Kesslers' 6 questions regarding a person's emotional state (68).

Intervention fidelity evaluation

The degree to which an intervention is delivered as intended is critical to the attainment of expected outcomes (69, 70). Referred to as intervention fidelity, the delivery and the degree of adherence to the four main components of the intervention will be assessed based on the qualitative and quantitative data collected by a member of the PriCare research team during the intervention year. A fidelity grid was developed using the Carroll et al. (2007) conceptual framework for implementation fidelity (71). In addition to identifying the essential components of the intervention as described previously, adherence to the content, frequency, duration and coverage of the intervention as described in this protocol, as well as the moderating factors that may influence implementation such as intervention complexity, the facilitation strategies used, the quality of intervention delivery, and the responsiveness of participants will be documented (71). The fidelity grid guides the data collection via a series of general questions referring to each element of (71) conceptual framework, identifies primary and secondary sources of data and specifies the data collection method for each element of the conceptual framework.

Outcome variables

As described in the conceptual model (Figure 1), the main outcomes of the intervention that will be examined are based on the quadruple aims to optimize health system performance: *improved patient-reported outcomes*, *health care use*, *cost effectiveness* and *care team well-being* (34). Self-management and quality of life are the main patient-reported outcomes collected from the patient-administered questionnaire at baseline and at the end of the intervention (T12 months). Health care use will be based on the clinical data collected on services use including the number of emergency department visits, overnight hospital stays and primary care professional visits. It will also be based on health services integration, assessed within the patient-administered questionnaire. Care team well-being will be evaluated from the data collected from the individual semi-structured interviews and focus group discussions with health care professionals. Finally, cost effectiveness will be based on the CIHI cost estimator, as previously described.

Analysis

A combination of analytical strategies will be used to reflect the variability and dynamic nature of context analysis and the mixed methods approach as used in this research (55, 57, 72). First, qualitative and quantitative data collected will be integrated through a comparison of results for similarities and differences throughout the analysis phase (72). Second, qualitative and quantitative data will be compared for variables measured in several ways such as health services utilization, self-management, quality of life and care integration (73). Third, qualitative and quantitative data will be merged for each of the 10 cases (the participating clinical sites). A case history will be reported for each clinical site that will constitute the synthesis of the merged data. Fourth, a comparison of the cases will be completed using a mixed methods matrix (54). All categories of stakeholders involved in this research including the principal investigators, research assistants, patient partners, clinical experts, technical and scientific experts and policy makers, will be called upon to participate in the data analysis to ensure valid and

meaningful interpretations. Additional analytical techniques for case study research (55) will be used as detailed below.

Objective 1

To identify the barriers and the facilitators to implementation of the CM intervention in different primary care contexts, the qualitative data collected using individual semi-structured interviews, focus groups and non-participant observation will be analyzed. Responses to questions regarding the perceived barriers and facilitators to responding to the needs of patients with chronic conditions and complex care needs, to working with internal clinic partners and external health and social services partners to care for this patient population, and to the process of implementing the four main components of the CM intervention will be extracted and analyzed. Information regarding the perceived complexity of the intervention, ease of implementation, care professional engagement and satisfaction with the intervention, and available support strategies to facilitate implementation will be extracted from the data collection grid used for the non-participant observation and for the fidelity evaluation.

Objective 2

A similar approach will be taken to explain the influence of the context of implementation on the degree of implementation. Interviewees and participants in the focus group discussions will be asked specific questions regarding the local clinical context, the workplace environment, relationships with external health and social services partners, individual attitudes and perceptions to the intervention and the overall process of implementation of the CM intervention. This information will be extracted and compared to the results of the fidelity evaluation to assess the degree of implementation of the intervention.

A mixed thematic analysis approach will be used (54). Each of the ten clinical sites will be analyzed separately as an individual case study using a deductive approach based on the conceptual model (Figure 1), as well as an inductive approach based on emergent constructs. A case history will be reported, guided by the constructs of the conceptual model (Figure 1). Subsequent to individual analysis of the ten cases, a comparison between the cases will be performed using a descriptive and interpretative matrix (54). This approach allows systematic comparison among cases and among units of analysis. Analytical techniques specific to case study research will be used as described in (55) including pattern comparison, research of competing explanations and construction of explanations. Qualitative data will be managed using multisite NVivo 12 server software (QSR International Pty Ltd).

Objective 3

To evaluate the influence of the context of implementation on the outcomes of the intervention, clinical data on services use and quantitative data extracted from the patient self-administered questionnaires will be analyzed using descriptive statistics. Quantitative data will be analyzed first and then interpreted in integration with qualitative data and the intervention fidelity evaluation described above, rather than trying to calculate non-biased quantitative effects (73). Regression models will be developed to evaluate the relationships between intervention fidelity, patient characteristics, the constructs of the conceptual model reflecting the contextual elements of the intervention, and the outcomes of the intervention. This will be done using SPSS version 26. An incremental cost-effectiveness/utility ratio (ICER or ICUR) (74) will be calculated using data collected on costs and quality-adjusted life years (QALY) before and after implementation of the CM intervention. Multivariate parametric analyses with bootstrap replications will be conducted together with cost-effectiveness acceptability curves (CEAC) (75).

Discussion

CM is a promising approach to delivering care to patients with chronic illnesses and complex care needs, but little is known about its implementation in a primary care setting (21). As an intervention composed of multiple components and steps that will be implemented in multiple sites, CM is an example of a complex, context-dependent intervention (76). Identifying and analyzing the contextual determinants across a variety of sites is necessary to understand how the intervention can produce its intended outcomes (77). An implementation analysis achieves a deeper understanding of the conditions that are most likely to lead to the successful implementation of the core components of the intervention (56). It serves to identify variation in outcomes associated with different contexts and to identify implementation problems (73). An implementation analysis can reveal how an intervention causes change in a particular context and highlights an intervention's strengths and weaknesses in relation to intended outcomes (56).

This research will detail the steps involved in implementing the four main components of the CM intervention at different clinical sites and will identify barriers and facilitators to implementation, providing the opportunity to address potential problems and to refine the intervention. This context of implementation which will be further understood through a detailed, theoretically-based approach to the identification and analysis of the macro, meso and micro level determinants of implementation (18, 32). The implementation process will be studied, highlighting the development and change across time of the steps required to implement the intervention in various contexts. This research will respond to some of the most important issues raised in recent publications on CM for frequent users of health care services with chronic illnesses and complex care needs (21, 23, 24, 26) , by contributing to the understanding of how to implement this intervention in different primary care contexts in a cost-effective way that improves patient reported outcomes and health care use, while ensuring the well-being of the care team.

The multi-level conceptual framework proposed in this study may be helpful for future research because it combines the approach to analyzing the effective implementation of health care interventions, with the principles of the integrative functions of primary care. The resulting framework supports the analysis of effective implementation not only of CM, but also of primary care interventions aiming to achieve care integration. The framework reflects the importance of intersectorial linkages and ensures the incorporation of constructs aimed to improve access, quality and continuity of services for patients with complex needs (18), regardless of the intervention being implemented. It is also particularly suited to the analysis and formative evaluation of complex, multi-level interventions in health care, verifying what works where and why across multiple contexts (32). The conceptual framework represents how patient, organizational and systems-level elements of implementation, the dynamic, time-dependent process of implementation, and the defining features of primary care, can translate into meaningful intervention outcomes, based on the quadruple aims to optimize health system performance. The framework can inform the effective implementation of complex primary care interventions that seek to facilitate the continuous, comprehensive and coordinated delivery of services to individuals or populations, and that necessitate the engagement of multiple stakeholders across various sectors.

The use of “multi-strategy” or “multi-faceted” frameworks to describe and analyze the implementation of complex interventions increases the precision and specificity of reporting, which facilitates effective evaluation and replication (78, 79). The proposed research fulfills an essential step towards replication and scalability of CM by identifying the implementation strategies that support the adoption, scale-up and replication of best practices in CM (78, 80). Given the complex nature of the CM intervention, practitioners report challenges to implementation, especially considering the lack of guidelines or a blueprint on how to operationalize its core components across different settings (81). Implementation is

often poorly reported in published literature, which presents a challenge to both research and practice and impedes replication and immediate adoption in a clinical setting (79, 82). To achieve wide-scale adoption and replication, the CM intervention must be tailored to the local context in an approach that considers the individual, the team of professionals, the organizational setting and the greater system (81). Few studies have described, categorized and analyzed intervention implementation in a contextually tailored approach (82). This research will thus provide this information for both researchers and practitioners, which according to our knowledge, has not yet been done.

Study validity

Construct validity is ensured through a detailed conceptual model and consistency in the application of its constructs in the data collection and analysis. Internal validity is ensured through a systematic coding and rigorous organization of collected data and the triangulation of several sources of qualitative data acquired from different participating stakeholders including patients, case managers, clinic managers, researchers, clinicians and informal caregivers (55). Analysis and comparison of different case studies in various implementation contexts will reinforce external validity and transferability. The observation and analysis of multiple levels, and their replication across several cases enhances both internal and external validity (55).

Figure Legend

Figure 1: Conceptual model for the implementation analysis of a case management intervention

List of Abbreviations

CEAC: Cost-effectiveness acceptability curves

CFIR: Consolidated framework for implementation research

CIHI: Canadian Institute of Health Information

CIHR: Canadian Institutes for Health Research

CCM: Chronic care model

CM: Case management

EMR: Electronic medial record

ICER: Incremental cost-effectiveness ratio

ICUR: Incremental cost-utility ratio

ISP: Individualized services plan

QALY: Quality-adjusted life years

Declarations

The funders played no role in designing the study, neither did they in data collection, analysis and interpretation or in the writing of the manuscript.

Ethics approval

This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number MP-31-2019-2830).

Consent for publication

This manuscript does not contain any individual person's data in any form.

Availability of data and materials

Not applicable.

Competing interests

None declared.

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Author Contributions

AD drafted the manuscript under the supervision of CH and MCC. All authors contributed to the development of the protocol and read and approved the final manuscript.

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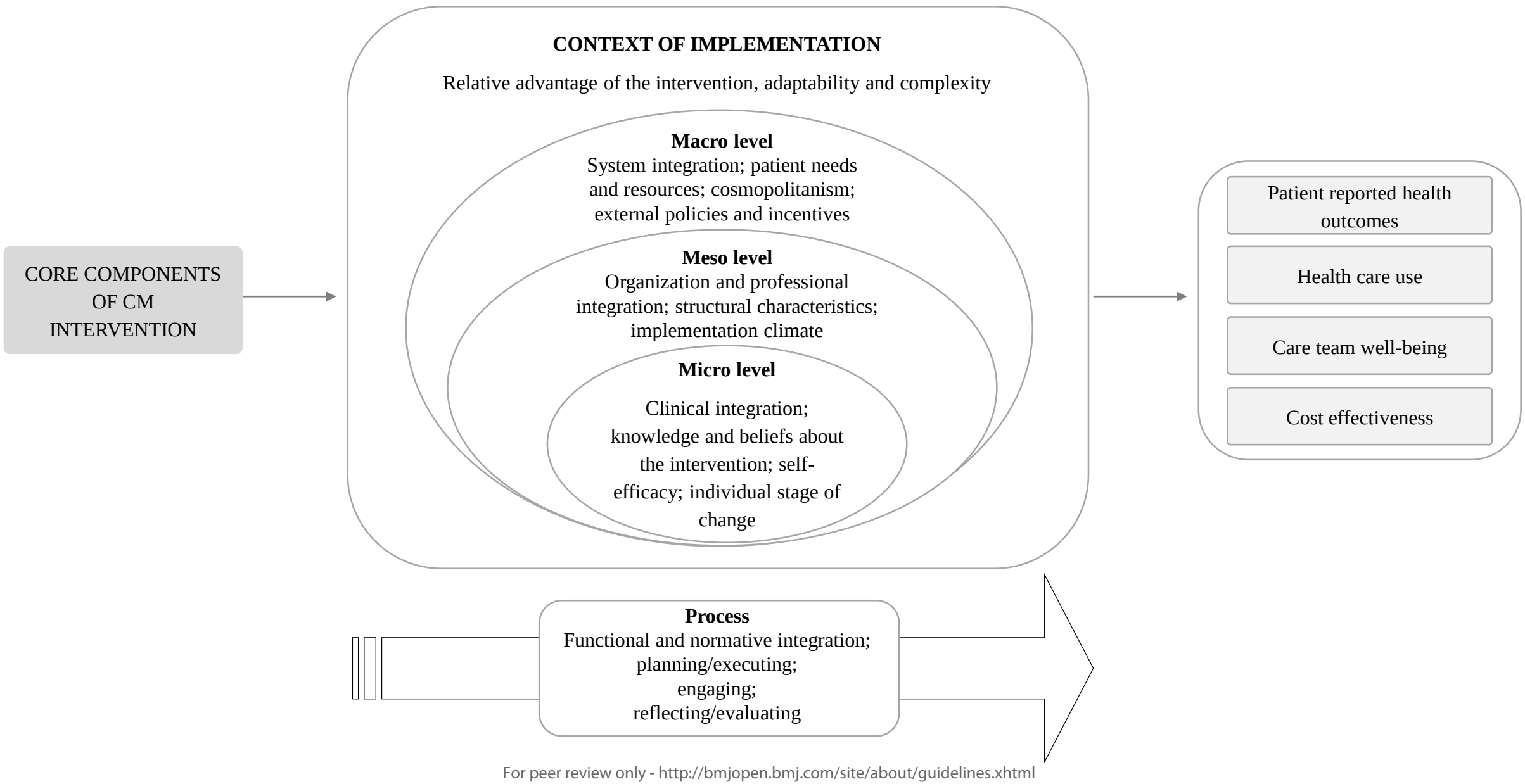
Figure 1. Conceptual model for the implementation analysis of a case management intervention



Source: Damschroder 2013 & Valentijn 2013

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Protocol for a mixed-method analysis of implementation of case management in primary care for frequent users of health care services with chronic diseases and complex care needs

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Secondary Subject Heading:	General practice / Family practice, Research methods
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Protocol for a mixed-method analysis of implementation of case management in primary care for frequent users of health care services with chronic diseases and complex care needs

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Abstract

Introduction: Case management (CM) in a primary care setting is a promising approach to integrating and improving health care services and outcomes for patients with chronic conditions and complex care needs who frequently use healthcare services. Despite evidence supporting CM and interest in implementing it in Canada, little is known about how to do this. This research aims to identify the barriers and facilitators to the implementation of a CM intervention in different primary care contexts (objective 1) and to explain the influence of the clinical context on the degree of implementation (objective 2) and on the outcomes of the intervention (objective 3).

Methods and analysis: A multiple-case embedded mixed methods study will be conducted on CM implemented in ten primary care clinics across five Canadian provinces. Each clinic will represent a sub-unit of analysis, detailed through a case history. Cases will be compared and contrasted using multiple analytical approaches. Qualitative data (objectives 1 and 2) from individual semi-structured interviews (N=130), focus group discussions (N=20) and participant observation of each clinic (36 hours) will be compared and integrated with quantitative (objective 3) clinical data on services use (N=300) and patient questionnaires (N=300). An evaluation of intervention fidelity will be integrated into the data analysis.

Ethics and dissemination: This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number MP-31-2019-2830). Results will provide the opportunity to refine the CM intervention and to facilitate effective evaluation, replication and scale-up. This research provides knowledge on how to respond to the needs of individuals with chronic conditions and complex care needs in a cost-effective way that improves patient reported outcomes and health care use, while

ensuring care team well-being. Dissemination of results is planned and executed based on the needs of various stakeholders involved in the research.

Keywords

Primary health care; case management; chronic illness; complex care needs; frequent users; implementation; evaluation; context, intervention fidelity.

Article Summary

Strength and limitations of this study

- This protocol details the steps for the implementation of a case management (CM) intervention for frequent users of health services with chronic conditions and complex care needs.
- A novel conceptual model for CM implementation is proposed based on the integrative functions of primary care and the effective implementation of health care interventions.
- The barriers and facilitators to implementing CM will be detailed and the influence of the clinical context on the degree of implementation and on the outcomes of the intervention will be evaluated.
- While the proposed conceptual model does not cover every possible construct for effective implementation, an inductive approach to data analysis will be used to allow for emergent themes and all stakeholders will participate in data analysis in order to ensure validity.

Introduction

A priority for primary care research and the Canadian health care system is to address the complex needs of patients who frequently use health care services (1, 2). These patients may suffer from a

combination of chronic illnesses, mental illness and/or socioeconomic vulnerabilities (3-5). Patients with chronic illnesses typically have a wide range of needs that require them to adopt new behaviours, such as meeting with care providers on a regular basis, adhering to treatment plans, monitoring their symptoms and making important decisions while also changing aspects of their lifestyle to preserve their physical, psychological and social well-being (6-8). Far from "misusing" the health care system, studies show that frequent users do so in an attempt to address unmet needs for health care and social services (3, 9). Studies suggest that these attempts are often unsuccessful and result in repetitive use of services in an uncoordinated way through frequent hospitalizations or visits to the emergency department (10, 11). This leads to negative experiences for both the care providers and for the patients, poor health indicators and high mortality rates for the patients and considerable costs to the health care system (11-13). Several countries have therefore experimented with new models of health care delivery that can achieve better coordination and integration of services, some of which have been found to reduce fragmentation and improve care continuity (14). Early examples of such models include the Chronic Care Model (CCM) (15) and the Innovative Care for Chronic Conditions framework (16). These models emphasize the importance of providing support to patients for self-management and decision-making, seeking innovative approaches within available clinical information systems and proposing ways to redesign the delivery of health care (14).

Individuals with chronic illnesses require organized care and close follow-up delivered over an extended period of time (17). The primary care setting is the most suitable for supporting individuals with chronic illnesses due to its defining features of patient-centered first contact, continuous, comprehensive, and coordinated care (17, 18). Health systems built on the principles of primary care achieve better health outcomes and greater equity, at a lower cost (19) than systems with a specialty care orientation (18). Integrated care may be achieved in a primary care setting through the creation of inter-sectorial linkages

between health and social policies, i.e. the linking of health care to other human service systems (eg. long-term care, education, vocational and housing services) in order to improve clinical outcomes, patient and provider satisfaction and efficiency (14, 18, 20).

Case management

Case management (CM) in a primary care setting is one approach that has been shown to increase the integration of health services (21, 22) and to improve care and outcomes for patients with chronic conditions and complex needs who frequently use health care services (23, 24). Defined as "a collaborative, client-driven process for the provision of quality health and support services through the effective and efficient use of resources" (25), CM is among the best models available to mitigate the high utilization of the health care system and associated costs (23, 26). An adaptive randomized trial of CM interventions targeting frequent users of health services demonstrated that appropriate patient identification, staff training and centralized intervention delivery are components of CM that can be successfully implemented on a large scale and lead to a decrease in health consumption (27). A recent systematic review (10) identified the most common components of CM interventions for chronically ill patients including the integration of services between hospitals and home or other facilities, regular home visits, regular telephone calls, individual assessment and care planning, education and self-management support, psychosocial support, and ongoing supervision and assessment. The same study found that a reduction in hospital admission rates was reported after implementation of CM interventions (10). A systematic review of literature on the characteristics of CM interventions in primary care reporting positive outcomes for frequent users of health care revealed three essential requisites for success. First, the intervention must identify and target patients with the greatest needs, and who are therefore most likely to benefit from the intervention. Second, the intervention must be delivered with sufficient intensity (i.e. frequently enough or with a high enough dose) to produce the

desired effect. Third, an interdisciplinary approach to care planning is preferred, where a variety of professionals from both care and cure sectors actively participate in the intervention (28).

Despite the evidence base supporting CM as an intervention for frequent users, little evidence exists about the facilitators and barriers to CM implementation (29). Although there is a strong interest in implementing CM in the Canadian primary care setting, little information is available on how to do this. CM has rarely been implemented and documented systematically in order to identify and replicate best practices. This protocol is part of a larger research program on CM in primary care for frequent users of healthcare services with chronic diseases and complex care needs (2) and details the steps for the implementation analysis that was not described in the original protocol of the whole program.

Objectives

1) To identify the barriers and the facilitators to implementation of the CM intervention in different primary care contexts.

2) To explain the influence of the clinical context on the degree of implementation.

3) To evaluate the influence of the context of implementation on the outcomes of the intervention.

Methods/Design

Conceptual model

The conceptual model developed to guide this research protocol was informed by two multi-level conceptual frameworks in order to analyze the effective implementation of an integrative primary care intervention. Multi-level frameworks represent the interacting layers of phenomena inherent to organizations and are commonly used to develop theories, measure and analyze phenomena while accounting for the complexity inherent to these systems (30, 31). Multi-level interventions mobilize

resources and facilitate linkages across organizations “to solve coordination problems and adapt to change” (31).

The first framework used to guide this research protocol is the Valentijn et al. framework for integrated care based on the integrative functions of primary care (18). The concept of integration originates from organizational theory and refers to “the quality of the state of collaboration” that may exist among the multiple levels of service delivery with the purpose of achieving a required mutual effort and agreement (14). Integrated health care interventions are a means to improve access, quality and continuity of services in a more efficient way, especially for people with complex needs (18) . This framework describes the central role of primary care in integrating the multiple levels of health care: system integration at the macro level; organizational and professional integration at the meso level; clinical integration at the micro level; and functional and normative integration to link the macro, meso and micro levels (18). Valentijn et al.’s framework is intended for analyzing and testing the causal relationships within and between the integration levels, which interact to varying degrees depending on the specific context of health care delivery (18). This framework is therefore suitable for studying the different primary care contexts of the CM intervention from the perspective of integrated care and is the unifying thread to the implementation and evaluation of the CM intervention.

The second framework used to guide this research protocol is the Consolidated Framework for Implementation Research (CFIR), intended to promote effective implementation and formative evaluation of complex, multi-level interventions in health care (32). The CFIR provides a taxonomy of constructs that can be used to understand, measure and assess implementation across a variety of contexts. The constructs are categorized into five major domains that similar to the Valentijn et al. (2013) framework, reflect a multilevel perspective. The *outer setting* refers to the economic, political

and social context in which the implementing organization is situated and corresponds to the macro level. The *inner setting* corresponds to the meso level of the organizational context and includes constructs such as the structure and culture of the implementing organization. At the micro level, the *individuals* involved in the intervention are described. The CFIR includes two additional domains: the *characteristics of the intervention*, a description of its core components, and the *implementation process*, considered a dynamic, non-sequential and non-linear domain that can stem from any level, macro, meso or micro (32). When understood, process provides insight that links the various levels of analysis and shed light on the causal or generative mechanisms underlying the intervention being studied (32, 33). Barriers and facilitators may arise at multiple levels of intervention delivery, as external influencers, organizational or professional components or during the process by which an intervention is adopted within an organization (32).

The conceptual model developed to guide this research protocol is presented in Figure 1. On the left side of the figure are the core components of the CM intervention, described in the proceeding section. During implementation, the intervention takes on unique properties and characteristics related to the local context in which it is introduced (referred to in Figure 1 as the *context of implementation*) (32). The context of implementation includes macro, meso and micro level determinants, depicted by the concentric circles in the middle of the figure. The process of implementation is represented by the arrow at the bottom of the figure, which represents the dynamic and continuous nature of intervention implementation. Finally, to the right, are the final expected outcomes of the intervention, based on the quadruple aims to optimize health system performance: improved patient outcomes, health care use, care team well-being and cost effectiveness (34).

Constructs were selected from both Valentijn et al. (2013) and Damschroder et al. (2009) to reflect the objectives of this research. The characteristics of the intervention after implementation in a particular local context will be analyzed based on the intervention's *adaptability* to meet local needs, its *relative advantage* to the context, and its *complexity* or difficulty of implementation. At the macro level, how the intervention contributes to *system integration* will be examined, including vertical integration and collaboration across care sectors and horizontal integration through a holistic view of the patient (18). This construct reflects the implementing organization's knowledge of the needs of its patient population and its ability to respond with appropriate structures, techniques and resources (*patient needs and resources*) (32). The organization's degree of networking with external services and structures (*cosmopolitanism*) will be examined, as well as its formal strategies and policies supporting external linkages (*external policies and incentives*).

At the meso level, *organizational* and *professional integration* will be examined, which refer to the partnerships between services and professionals within the implementing organization. The *structural characteristics* of the organization and the *implementation climate* will be described. At the micro level, interest will shift to *clinical integration*, which reflects the level of coordination and coherence of the primary care delivery process (18). The *knowledge and beliefs* of the various professionals involved in the intervention will be examined, as well as their perceived *self-efficacy* to implement CM, and their *individual stage of change*, which refers to their progress towards full adoption and sustained use of the intervention (32).

Finally, the process of implementation will be analyzed by examining how the CM intervention was planned and executed at the local level, how professionals were mobilized and engaged for participation in the intervention, and by examining the mechanisms put in place to discuss and provide feedback

about the experience, progress and quality of implementation (*planning/executing*; *engaging*; *reflecting/evaluating*). These constructs reflect the level of *functional* and *normative integration* resulting from the implementation of the intervention: how the implementing organization mobilized management functions in support of the intervention, as well as the degree of development of a shared goal or mission among participating individuals and partner organizations for the implementation of the intervention (18).

The intervention

An intervention was designed to reflect the standards of practice of the National Case Management of Canada as well as the Case management society of America (25, 35). The activities of the intervention follow the Canadian Institutes for Health Research (CIHR) Strategy for Patient Oriented research and incorporate the integration characteristics of the National Collaboration for Integrated Care and Support (36, 37). Patients with chronic conditions most often seek and receive comprehensive care in a primary care setting (38) and the leadership of a case manager who is experienced in primary care has been shown to facilitate the successful implementation of chronic care models (39). The CM intervention is therefore designed to be delivered by a primary care health professional in a primary care clinical setting over a period of 12 months.

In consideration of these guidelines and of the results of previously cited studies (10, 11, 23, 27, 28), an intervention was designed comprised of four main components: 1) evaluation of patient needs and preferences; 2) co-development and maintenance of a patient-centered individualized services plan; 3) coordination of services among all partners; and 4) education and self-management support for patients and families.

1. Evaluation of patient needs and preferences

The identification of patients who are in need of intervention and who stand to benefit the most from CM is an essential first step (27, 28), ideally executed by an interdisciplinary team (5, 40). Patients are identified by searching administrative data or clinical records in addition to their referral for the CM intervention by primary care professionals. This approach combines clinician judgement with objective data from electronic medical record (EMR) or administrative databases (2, 41). The CM intervention targets patients who present with at least one chronic illness, including mental illness, who frequently use health services as determined by 4 or more emergency department visits or hospitalizations in the previous 12 months, and who have complex needs as determined by the care team. Once a patient has been identified for inclusion in the CM intervention, the case manager examines the patient's medical records going back 12 months in order to understand the reasons for the frequent use of services. The case manager identifies the patient's physical and/or mental illnesses as well as social challenges such as insecure housing or employment, poverty, violence, substance use disorders, etc. The case manager also documents the health and social services previously provided to the patient, as well as the names, roles and contact information of professionals currently involved with the patient or who may eventually be called upon to participate in the care of the patient.

The case manager validates with the patient the information collected from the medical records and determines the patient's personal needs and preferences for future services and resources. This step constitutes the first in-depth interaction between the case manager and the patient, and is essential for building mutual trust and respect (21), for establishing a patient-centered care process, and for encouraging the commitment of the patient as a partner in the care process (42, 43). The patient may prefer to be accompanied by a caregiver or advocate with lived experience of the patient's health situation who can assist in navigating the health and social services system (44). When referring to "the

patient" in this article, we also refer to an individual who may stand in for the patient at any point during the intervention. Finally, the case manager seeks the patient's consent to communicate with potential care professionals throughout the intervention and ensures that the patient understands and agrees to the next step of the intervention: the creation of an Individualized Services Plan (ISP). The ISP is a tool for planning and coordinating tailored services intended to give meaning and direction to the patient in consideration of his or her life goals (45), personal environment, resources and culture, in collaboration with a multidisciplinary team of professionals (46) and health and social services organizations.

2. Co-development and maintenance of a patient-centered ISP

The ISP for patients with chronic conditions may lead to improvements in physical and psychological health, as well as in their ability to self-manage their condition (46-48). It is among the most commonly used strategies in CM interventions (10, 11). The case manager identifies resources available in the local health and social services network and within the community that may be appropriate for the patient. This involves a holistic analysis of the patient's situation and the identification of clinical-administrative issues and a final list of care professionals that will be invited to examine the patient's situation. These may be health care and social services professionals, managers or representatives of community organizations. The case manager communicates directly with targeted care professionals to request their involvement, to ensure that the reason for the intervention is understood and to agree upon a mutually convenient date, time and place for an ISP meeting with the patient. The case manager prepares the agenda for the ISP meeting and communicates with the patient to reconfirm consent regarding the professionals who will participate in the meeting and to maintain a relationship of trust and transparency with the patient. The ISP meeting is ideally held in-person, but may be done by phone or online.

At the beginning of the ISP meeting, the care team reviews the potential resources and services that may be proposed to the patient prior to the patient's arrival. This allows the care team to collaboratively examine the patient's situation, needs and preferences and to mobilize their multidisciplinary perspectives (46). The ISP is then developed with the patient and their advocate upon their arrival. The ISP includes a maximum of 3 or 4 objectives in line with the patient's overall expectations and life project (49). The group proposes preferred methods of communication and strategies for exchanging information for the duration of the intervention. The case manager writes up the ISP in plain language and validates that the patient understands and agrees to it.

3. Coordination of services among all partners

Patients with chronic illnesses and complex care needs are often cared for by multiple providers in various locations and experience difficulty navigating the health system and other ressources resulting in unmet needs, a lower quality of life and higher mortality rates (48). A coordinated response by care providers that promotes patient empowerment over an extended period of time is recommended (14). In this intervention, the case manager transmits a copy of the written ISP to the patient and the care team and follows-up regularly with the patient's primary care providers in the clinical setting, ensuring active engagement and direct communication. As the principal contact-person and advocate for the patient, the case manager establishes contact with the services or resources identified in the ISP, providing a personalized reference for the patient, explaining the case and informing care professionals of past and potential challenges facing the patient.

Regular communication and follow-up encourages the patient's active engagement in the intervention, a strategy that has been shown to reduce future use of emergency services (26, 50, 51). The case

manager talks to the patient about their preferred method for reaching the case manager and other relevant services. Adherence to the ISP throughout the intervention is ensured by maintaining contact with the care professionals involved with each patient, and by verifying if the patient's goals have been attained. The ISP should be reviewed at least once every 3 months. If the patient desires a change in their ISP, or if a care professional identifies any issues throughout the intervention, the case manager reassesses the situation with the patient and adjusts the ISP as necessary.

4. Education and self-management support for patients and families

Self-management support was found to be the strategy most frequently associated with health improvements in patients with chronic diseases in a primary care setting (17). Education and self-management support activities aim to increase the patient's skills, confidence and motivation to control and manage their symptoms and to follow their ISP with structured support for problem solving and continuous assessment of the patient's objectives and progress (52). This component of the intervention is considered an ongoing and transversal process to be performed as needed throughout the intervention.

Case managers aim to develop the patient's ability to monitor their condition, take appropriate action and identify when and how to ask for professional help by assessing the patient's knowledge and learning needs and suggesting beneficial activities, such as journaling symptoms and vitals, and informational resources based on the patient's unique situation. Case managers are trained in motivational interviewing, a "client-centered, directive communication method aimed at changing behavior" (53). The case manager supports the patient to set realistic goals through a "smart" action plan that includes specific behavioral goals that are measurable and attractive to the patient, that may be accomplished in a realistic time frame and that build on previous positive experiences. The case

manager helps the patient prepare for meetings with the various care professionals to ensure that the patient is empowered to communicate his or her goals and to receive the desired care. Patients are coached on how to effectively communicate with their relatives, to establish expectations, and to ensure a successful care partnership.

Study setting

The CM intervention will be implemented in ten primary care clinics, each representing a unique case. Two clinics were selected from each of the five participating Canadian provinces of Newfoundland, Nova Scotia, New Brunswick, Québec and Saskatchewan using a purposeful sampling strategy (54). Clinics were selected that had not previously implemented CM and that were interested in implementing the CM intervention and participating in the research project. The interest of a health care professional, a nurse or a social worker, to develop the role of the case manager and to be available to dedicate approximately 1 day per week to the study was essential. The case manager was required to have primary care experience and was offered training in the intervention and continuous support and follow-up through the establishment of a community of practice.

Patient and public involvement

Patient partners were involved in this research since its inception, including the design of the research questions and the development of this protocol of which they are coauthors (VS and MW). They continue to provide their expertise regarding study feasibility and acceptability. They will be involved in the interpretation of data and in the dissemination of results.

Timeline

The implementation of the CM intervention will take place over a period of one year. A cohort of patients will be recruited at each clinic and will be administered the intervention over the course of 12 months.

Patient recruitment

Each clinic will identify 30 patients for enrolment in the CM intervention, for a total of 300 patients across the 5 participating provinces. Patients are selected who are most likely to benefit from CM, based on the clinical judgement of the case manager and the family physician. Criteria for inclusion in the study are as follows: 1) living with at least one chronic physical or mental illness; 2) frequent user of health care services ie. having 4 or more hospitalizations or visits to the emergency department in the previous year; 3) having complex care needs as determined by the care team. Patients who are ineligible for participation in the study include individuals whose prognosis is less than one year or who are exhibiting a loss of autonomy.

Study design

The implementation analysis is designed as a multiple-case embedded study, where each of the ten clinics will represent one sub-unit of analysis. This design is best-suited to analyzing complex interventions implemented in variable and dynamic settings, and where the underlying context is difficult to isolate from the intervention itself (55). This design allows several levels of analysis, the observation of various organizational processes or behaviours, the examination of the context and process of implementation, and the interaction among involved stakeholders (56). It also favors the use of mixed methods of data collection and analysis (57).

Data collection

To accomplish the objectives of this research, a mixed methods data collection is planned. Multiple sources of information will be used to collect both qualitative and quantitative data.

Individual semi-structured interviews will be administered to all case managers (1-2 per clinic) and clinic managers (1 per clinic) at each study site at the start of the intervention (T0), and at the end of the intervention (T12 months). At the end of the intervention (T12 months), 10 patients and/or their representative will also be interviewed. Patients will be purposefully selected to achieve maximum variation (54). A total of 130 individual semi-structured interviews will be administered across the 10 participating clinical sites. An interview guide was developed composed of 18 open-ended questions based on the constructs of the conceptual model (Figure 1). The first part of the interview will address the clinical context of the CM intervention, the services offered at each clinical site to patients with chronic conditions and complex care needs, and the way in which the clinic works with other health and social services organizations. In the second part of the interview, questions will be asked about the implementation of the four components CM intervention, the context of implementation, the barriers and facilitators to intervention, and about individual perceptions and attitudes towards the intervention.

Focus groups

A focus group discussion will be held at each participating clinic, once at the beginning of the intervention (T0) and once at T9-12 months, for a total of 20 focus groups throughout the CM intervention. Primary care providers, including physicians, nurses, social workers, pharmacists and any health and social services professionals involved in the intervention will be invited to take part in a discussion facilitated by a member of the PriCare research team. The interview guide described above for the semi-structured interviews will be adapted and used to guide the focus group discussion.

Non-participant observation

The activities of the intervention at each of the ten clinical sites will be observed for thirty-six hours during the implementation year. A member of the PriCare research team will observe the CM activities including the meetings between the patient and the case manager, the development of the ISP, meetings between the primary care professionals, and any other activities adopted by the clinic under observation. Data collection will be guided by means of an observation grid developed to reflect the four components of the CM intervention and the constructs of the conceptual framework.

Clinical data on services use

Quantitative data from patient medical records will be collected at the beginning (T0) of the intervention for a period of 12 months, before the patient's first visit with the case manager, and at the end of the intervention 12 months) (N=300). The purpose of this data collection is to compare the utilization of services in the year before the intervention with utilization during the intervention. Data will include the number of emergency department visits, overnight stays in the hospital and primary care professional visits. Patient expenditures from these activities will be calculated using an established fee schedule from the Canadian Institute of Health Information (CIHI) patient cost estimator (58). The cost of the intervention will be measured by tracking expenditures related to the CM activities.

Patient self-administered questionnaires

Participating patients (N=300) will be asked to complete a 30-minute questionnaire at baseline (T0), at the halfway point (T6 months) and at the end of the intervention (T12 months) under the guidance of a member of the PriCare research team. Questionnaires are available in both English and French and have been validated. Data collected will include age, gender, marital status, education, occupation, economic status with family income and patient perception of his or her economic situation, health literacy,

multimorbidity, care integration, self-management and quality of life. Health literacy will be measured using Chew's 3 questions for screening patients with inadequate or marginal health literacy (59, 60), multimorbidity with the Disease Burden Morbidity Assessment (21 items) (61, 62), care integration with the Picker Institute Questionnaire (13 items) (63), self-management with the Partners in Health Scale (12 items) (64, 65), quality of life with the SF-12v2 (12 items) (66) , quality-adjusted life years (QALY) derived from the SF-12v2 (67) and psychological distress with Kesslers' 6 questions regarding a person's emotional state (68).

Intervention fidelity evaluation

The degree to which an intervention is delivered as intended is critical to the attainment of expected outcomes (69, 70). Referred to as intervention fidelity, the delivery and the degree of adherence to the four main components of the intervention will be assessed based on the qualitative and quantitative data collected by a member of the PriCare research team during the intervention year. A fidelity grid was developed using the Carroll et al. (2007) conceptual framework for implementation fidelity (71). In addition to identifying the essential components of the intervention as described previously, adherence to the content, frequency, duration and coverage of the intervention as described in this protocol, as well as the moderating factors that may influence implementation such as intervention complexity, the facilitation strategies used, the quality of intervention delivery, and the responsiveness of participants will be documented (71). The fidelity grid guides the data collection via a series of general questions referring to each element of (71) conceptual framework, identifies primary and secondary sources of data and specifies the data collection method for each element of the conceptual framework.

Outcome variables

As described in the conceptual model (Figure 1), the main outcomes of the intervention that will be examined are based on the quadruple aims to optimize health system performance: *improved patient-reported outcomes*, *health care use*, *cost effectiveness* and *care team well-being* (34). Self-management and quality of life are the main patient-reported outcomes collected from the patient-administered questionnaire at baseline and at the end of the intervention (T12 months). Health care use will be based on the clinical data collected on services use including the number of emergency department visits, overnight hospital stays and primary care professional visits. It will also be based on health services integration, assessed within the patient-administered questionnaire. Care team well-being will be evaluated from the data collected from the individual semi-structured interviews and focus group discussions with health care professionals. Finally, cost effectiveness will be based on the CIHI cost estimator, as previously described.

Analysis

A combination of analytical strategies will be used to reflect the variability and dynamic nature of context analysis and the mixed methods approach as used in this research (55, 57, 72). First, qualitative and quantitative data collected will be integrated through a comparison of results for similarities and differences throughout the analysis phase (72). Second, qualitative and quantitative data will be compared for variables measured in several ways such as health services utilization, self-management, quality of life and care integration (73). Third, qualitative and quantitative data will be merged for each of the 10 cases (the participating clinical sites). A case history will be reported for each clinical site that will constitute the synthesis of the merged data. Fourth, a comparison of the cases will be completed using a mixed methods matrix (54). All categories of stakeholders involved in this research including the principal investigators, research assistants, patient partners, clinical experts, technical and scientific experts and policy makers, will be called upon to participate in the data analysis to ensure valid and

meaningful interpretations. Additional analytical techniques for case study research (55) will be used as detailed below.

Objective 1

To identify the barriers and the facilitators to implementation of the CM intervention in different primary care contexts, the qualitative data collected using individual semi-structured interviews, focus groups and non-participant observation will be analyzed. Responses to questions regarding the perceived barriers and facilitators to responding to the needs of patients with chronic conditions and complex care needs, to working with internal clinic partners and external health and social services partners to care for this patient population, and to the process of implementing the four main components of the CM intervention will be extracted and analyzed. Information regarding the perceived complexity of the intervention, ease of implementation, care professional engagement and satisfaction with the intervention, and available support strategies to facilitate implementation will be extracted from the data collection grid used for the non-participant observation and for the fidelity evaluation.

Objective 2

A similar approach will be taken to explain the influence of the context of implementation on the degree of implementation. Interviewees and participants in the focus group discussions will be asked specific questions regarding the local clinical context, the workplace environment, relationships with external health and social services partners, individual attitudes and perceptions to the intervention and the overall process of implementation of the CM intervention. This information will be extracted and compared to the results of the fidelity evaluation to assess the degree of implementation of the intervention.

A mixed thematic analysis approach will be used (54). Each of the ten clinical sites will be analyzed separately as an individual case study using a deductive approach based on the conceptual model (Figure 1), as well as an inductive approach based on emergent constructs. A case history will be reported, guided by the constructs of the conceptual model (Figure 1). Subsequent to individual analysis of the ten cases, a comparison between the cases will be performed using a descriptive and interpretative matrix (54). This approach allows systematic comparison among cases and among units of analysis. Analytical techniques specific to case study research will be used as described in (55) including pattern comparison, research of competing explanations and construction of explanations. Qualitative data will be managed using multisite NVivo 12 server software (QSR International Pty Ltd).

Objective 3

To evaluate the influence of the context of implementation on the outcomes of the intervention, clinical data on services use and quantitative data extracted from the patient self-administered questionnaires will be analyzed using descriptive statistics. Quantitative data will be analyzed first and then interpreted in integration with qualitative data and the intervention fidelity evaluation described above, rather than trying to calculate non-biased quantitative effects (73). Regression models will be developed to evaluate the relationships between intervention fidelity, patient characteristics, the constructs of the conceptual model reflecting the contextual elements of the intervention, and the outcomes of the intervention. This will be done using SPSS version 26. An incremental cost-effectiveness/utility ratio (ICER or ICUR) (74) will be calculated using data collected on costs and quality-adjusted life years (QALY) before and after implementation of the CM intervention. Multivariate parametric analyses with bootstrap replications will be conducted together with cost-effectiveness acceptability curves (CEAC) (75).

Discussion

CM is a promising approach to delivering care to patients with chronic illnesses and complex care needs, but little is known about its implementation in a primary care setting (21). As an intervention composed of multiple components and steps that will be implemented in multiple sites, CM is an example of a complex, context-dependent intervention (76). Identifying and analyzing the contextual determinants across a variety of sites is necessary to understand how the intervention can produce its intended outcomes (77). An implementation analysis achieves a deeper understanding of the conditions that are most likely to lead to the successful implementation of the core components of the intervention (56). It serves to identify variation in outcomes associated with different contexts and to identify implementation problems (73). An implementation analysis can reveal how an intervention causes change in a particular context and highlights an intervention's strengths and weaknesses in relation to intended outcomes (56).

This research will detail the steps involved in implementing the four main components of the CM intervention at different clinical sites and will identify barriers and facilitators to implementation, providing the opportunity to address potential problems and to refine the intervention. This context of implementation which will be further understood through a detailed, theoretically-based approach to the identification and analysis of the macro, meso and micro level determinants of implementation (18, 32). The implementation process will be studied, highlighting the development and change across time of the steps required to implement the intervention in various contexts. This research will respond to some of the most important issues raised in recent publications on CM for frequent users of health care services with chronic illnesses and complex care needs (21, 23, 24, 26) , by contributing to the understanding of how to implement this intervention in different primary care contexts in a cost-effective way that improves patient reported outcomes and health care use, while ensuring the well-being of the care team.

The multi-level conceptual framework proposed in this study may be helpful for future research because it combines the approach to analyzing the effective implementation of health care interventions, with the principles of the integrative functions of primary care. The resulting framework supports the analysis of effective implementation not only of CM, but also of primary care interventions aiming to achieve care integration. The framework reflects the importance of intersectorial linkages and ensures the incorporation of constructs aimed to improve access, quality and continuity of services for patients with complex needs (18), regardless of the intervention being implemented. It is also particularly suited to the analysis and formative evaluation of complex, multi-level interventions in health care, verifying what works where and why across multiple contexts (32). The conceptual framework represents how patient, organizational and systems-level elements of implementation, the dynamic, time-dependent process of implementation, and the defining features of primary care, can translate into meaningful intervention outcomes, based on the quadruple aims to optimize health system performance. The framework can inform the effective implementation of complex primary care interventions that seek to facilitate the continuous, comprehensive and coordinated delivery of services to individuals or populations, and that necessitate the engagement of multiple stakeholders across various sectors.

The use of “multi-strategy” or “multi-faceted” frameworks to describe and analyze the implementation of complex interventions increases the precision and specificity of reporting, which facilitates effective evaluation and replication (78, 79). The proposed research fulfills an essential step towards replication and scalability of CM by identifying the implementation strategies that support the adoption, scale-up and replication of best practices in CM (78, 80). Given the complex nature of the CM intervention, practitioners report challenges to implementation, especially considering the lack of guidelines or a blueprint on how to operationalize its core components across different settings (81). Implementation is

often poorly reported in published literature, which presents a challenge to both research and practice and impedes replication and immediate adoption in a clinical setting (79, 82). To achieve wide-scale adoption and replication, the CM intervention must be tailored to the local context in an approach that considers the individual, the team of professionals, the organizational setting and the greater system (81). Few studies have described, categorized and analyzed intervention implementation in a contextually tailored approach (82). This research will thus provide this information for both researchers and practitioners, which according to our knowledge, has not yet been done.

Study validity

Construct validity is ensured through a detailed conceptual model and consistency in the application of its constructs in the data collection and analysis. Internal validity is ensured through a systematic coding and rigorous organization of collected data and the triangulation of several sources of qualitative data acquired from different participating stakeholders including patients, case managers, clinic managers, researchers, clinicians and informal caregivers (55). Analysis and comparison of different case studies in various implementation contexts will reinforce external validity and transferability. The observation and analysis of multiple levels, and their replication across several cases enhances both internal and external validity (55).

Figure Legend

Figure 1: Conceptual model for the implementation analysis of a case management intervention

List of Abbreviations

CEAC: Cost-effectiveness acceptability curves

CFIR: Consolidated framework for implementation research

CIHI: Canadian Institute of Health Information

CIHR: Canadian Institutes for Health Research

CCM: Chronic care model

CM: Case management

EMR: Electronic medial record

ICER: Incremental cost-effectiveness ratio

ICUR: Incremental cost-utility ratio

ISP: Individualized services plan

QALY: Quality-adjusted life years

Declarations

The funders played no role in designing the study, neither did they in data collection, analysis and interpretation or in the writing of the manuscript.

Ethics approval

This project received approval from the CIUSSS de l'Estrie – CHUS Research Ethic Board (project number MP-31-2019-2830).

Dissemination plan

Patients and family partners, clinicians, policy makers and researchers have formed a steering committee to collaborate in planning and executing this research process. A knowledge translation plan has been developed with the goals of increasing awareness and bringing change to practice, policy and future research. Dissemination goals are determined by each stakeholder group and executed by a group representative. Dissemination methods include news releases in social media and local/provincial media outlets, executive-summary reports to clinician audiences, presentations at meetings of Canadian

professional associations (for family physicians, nurses and social workers), conference presentations at annual international meetings of the NAPCRG and the CAHSPR, and articles in peer-reviewed journals.

Consent for publication

This manuscript does not contain any individual person's data in any form.

Availability of data and materials

Not applicable.

Competing interests

None declared.

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Author Contributions

AD: conception and design of the work; acquisition, analysis and interpretation of data; drafting and substantial revisions to the manuscript; MCC: conception of work; analysis and interpretation of data; substantial revision to the manuscript; KAB: conception of work; analysis and interpretation of data; substantial revision to the manuscript; FB: conception of work; analysis and interpretation of data;

substantial revision to the manuscript; SD: conception of work; analysis and interpretation of data; substantial revision to the manuscript; VR: conception of work; analysis and interpretation of data; substantial revision to the manuscript; MB: analysis and interpretation of data; substantial revision to the manuscript; MC: analysis and interpretation of data; substantial revision to the manuscript; BC: analysis and interpretation of data; substantial revision to the manuscript; ML: analysis and interpretation of data; substantial revision to the manuscript; CP: analysis and interpretation of data; substantial revision to the manuscript; VS: analysis and interpretation of data; substantial revision to the manuscript; MW: analysis and interpretation of data; substantial revision to the manuscript; CH: conception and design of the work; acquisition, analysis and interpretation of data; substantial revisions to the manuscript; guarantor of the manuscript. All authors approved the final manuscript and agree to be responsible for all aspects of the work.

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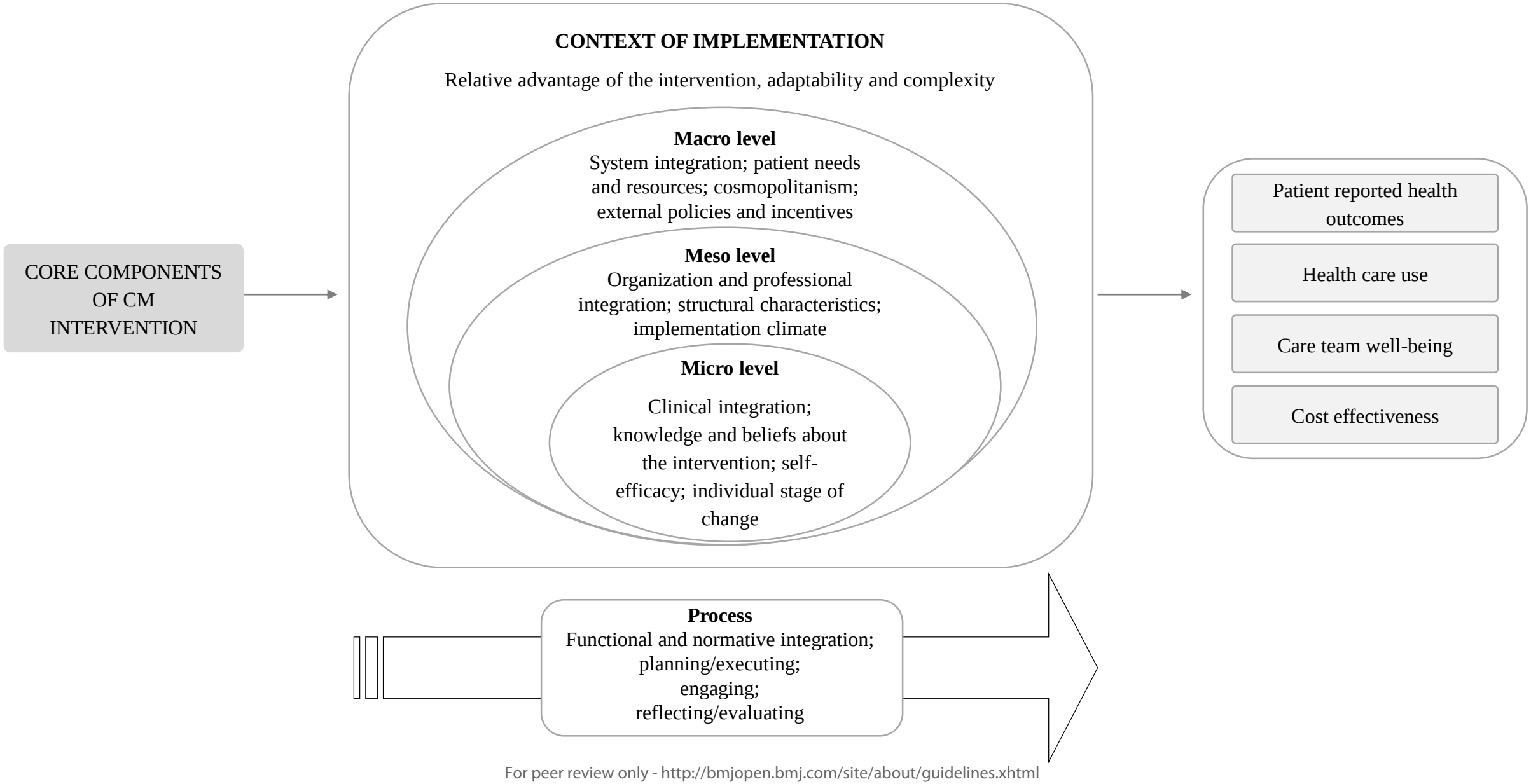
Figure 1. Conceptual model for the implementation analysis of a case management intervention



Source: Damschroder 2013 & Valentijn 2013