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Evaluation of the implementation and effects of management through care and services pathways: A protocol study

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Abstract

Background: In 2015, the Government of Quebec undertook a vast reorganization of its health and social services network. This reform mainly aimed to promote and simplify access to services for the population, contributing to the improvement of the quality and safety of care, and increasing the efficiency and effectiveness of the network. Since 2016, several health care organizations (HCOs) have pushed reform even further by developing management through care and service pathways (MCSP). This study aims to identify, in a processual manner, the different factors involved in implementing MCSP in different HCOs, in the turbulent context of the COVID-19 pandemic.

Method: The methodology of this research project is based on developmental evaluation. The objective of developmental evaluation is to guide organizations and actors in the adaptation and development of innovations in complex and turbulent environments. Data will be collected over a three-year period using five strategies: i) organizational questionnaires; ii) analysis of clinical-administrative databases; iii) documentary analysis (grey and scientific literatures); iv) participant observations and v) semi-structured interviews with key actors involved in the implementation of MCSP.

Discussion: In addition to the operationalization of pathways, the implementation of MCSP i) involves transforming the governance of the health care organization both at the strategic and operational levels and ii) is a demanding process that requires changes in practices, modifications in the allocation and configuration of resources and the development of new collaborations between the different actors in the organization, the partners and the users involved in this transformation. Several studies claim that governance innovations can create conditions that are favourable to the emergence of innovations in terms of available services and responding to the needs of populations. This research will develop knowledge of the factors involved in implementing MCSP in complex and turbulent contexts and propose scale-up across the province.

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Introduction

Background

Ensuring the enhanced organization of services in order to promote access appears to be a priority for many health care systems, both in Canada and at the international level (1, 2). To that end, many have developed methods of management through care and service pathways (MCSP) (3, 4), which address the complexity of the issues faced by health care systems: accessibility, equity, performance, and allocation of resources, among others. Indeed, MCSP represents a form of governance innovation that aims to increase the capacities of health and social services organizations to adapt to the needs of the population, notably through the improvement of accessibility and the continuity of services (5). MCSP therefore aims to improve the performance of HCOs on an ongoing basis, through greater integration of services and practices, by following four guiding principles: ongoing improvement, partnerships, measurement of performance by choosing appropriate monitoring indicators, and the establishment of a matrix governance model based on a bottom-up approach (6).

This research project is based on a pilot study carried out in 2017-2019 (6) and aims to monitor the development and implementation of the MCSP to enrich the body of knowledge and feed the teams in charge of this implementation. However, several researchers raise the difficulties to implement pathways which represents a major organizational change, requiring significant technological and administrative means and resources (7). In addition to the operationalization of pathways, 1) implementation of MCSP involves transforming the governance of the HCO both at the strategic and operational levels, and 2) is a demanding process that requires changes in practices; modifications in the allocation and configuration of resources; and the development of new collaborations between the different actors in the organization, the partners and the users involved in this transformation. This is why considering the contexts for implementation and allowing for the adaptation of processes are some of the challenges revealed by past pandemic experiences (8, 9) and the current COVID-19 pandemic, which poses a major and unprecedented challenge to health care system (10).

In this regard, there are four major gaps between the field of MCSP and the scientific literature in this domain. First, enhanced understanding is needed of how MCSP, as a new method of matrix management, influences HCOs both in terms of clinical and managerial practices and governance. Second, what are the facilitators and barriers to the implementation of MCSP, both at the micro level (organization and territory) and at the macro level (scaling to other contexts)? Third, what are the most appropriate indicators to take MCSP into account at the clinical, managerial, and financial levels, as well as in terms of equity and co-evolutionary links with partners that are external to the organization? Fourth, there is a real need to better theorize the implementation of MCSP, considering the interdependence with the context (partners external to the organization) and the role of adaptation in the large-scale implementation of an innovation such as MCSP.

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What do we mean by management through care and service pathways in health care organizations? Several definitions and names are used in relation to pathways: care pathways; care process effectiveness; clinical pathways; critical pathways; integrated care pathways; case management plans; clinical care pathways; care maps (11). Notably, we can refer to the definition adopted by the European Pathway Association (EPA):

> "A complex intervention for the mutual decision making and organization of predictable care for a well-defined group of patients during a well-defined period. Defining characteristics of pathways include: an explicit statement of the goals and the key elements of care based on evidence, best practice and patient expectations; the facilitations of the communication and coordination roles and sequencing the activities of the multidisciplinary care team, patients and their relatives, the documentation, monitoring and evaluation of variances and outcomes; and the identification of relevant resources." p.3, (12).

The scientific literature indicates that the pathways can take different forms, from the description of actual practices and tools to improve them (e.g. a document that describes or supports the coordination of services throughout the care process) to more prescriptive strategies (e.g. a care plan, a procedure/process, a guide to best practices) that are very detailed, even complex (11-13). They can cover different themes (e.g. a population suffering from a pathology, or an action/process), but must be based on clearly identified inclusion/exclusion criteria (14). For example, the following inclusion criteria are often cited: reach a significant number of users; target the critical mass (60 to 80% of a targeted group); choose a pathway with a high level of predictability that requires a certain level of consistency in its practices; choose a pathway with a high cost of care; prioritize a pathway requiring multidisciplinary care (14-16).

Certain pathways can be based on the actual situation and developed through a continuous improvement loop, or on a revised version considered as a best practice. All require the establishment of a clinical and organizational integration process at all levels of the organization (14) allowing support of the ongoing improvement, quality and efficiency of care (11). Based on multidisciplinary work both in terms of its design and operations (9, 13), the pathways could be described as:

- Supporting the formalization of the sequencing of care processes and actions and, in some cases, their standardization (13, 16);
- Supporting shared decision making (9);
- Reducing variations in care, both in terms of the route towards accessing care and in practices (or interventions);
- Increasing the quality of care in terms of relevance, competent implementation, and security (9, 11, 13).

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With regard to coordination, Vanhaecht, De Witte and Sermeus (2007) propose three models which they position based on lines of predictability as well as consensus between the members of a multidisciplinary team (12). These models are:

- the Chain model: adapted to high levels of predictability and consensus, where there is a very high degree of precision for each stage and the time between the stages is relatively short (e.g. planned surgery, chemotherapy treatment);
- the Hub model: structured around a case manager for a moderately high level of predictability and consensus, where flexibility or a long monitoring period is necessary in certain cases (e.g. internal medicine, rehabilitation, psychiatry);
- the Web model: adapted to a high level of unpredictability, where the regular (i.e. daily) adjustment of a professional network linked together by an information system and coordination mechanisms is necessary (e.g. crises, emergencies, intensive care of users with multiple comorbidities) (13).

Study context

In 2015 the Government of Quebec undertook extensive reorganization of its health and social services network by establishing merged large health care organizations (HCOs) with more than 10,000 employees that bring together several HCOs with different missions on several sites and covering large geographical territories. Since 2016, several of these large HCO have pushed reform even further through development of MCSP. The latter is a *"operating method based on structural foundations and criteria allowing the optimization of care and services pathways to ensure they adhere to the needs of users"* p.13, (17). In turn, care and services pathways are *"the part of the process followed (care interventions and episodes) by a group of users with a clinical condition or a similar profile [...], they integrate, in a cross-cutting manner, the access mechanisms, interventions for the promotion of health, evaluations/research/guidance, follow-up/support treatment by way of preventative treatment"* p.15, (17).

Since 2017, the research team has been following the implementation of the MCSP in one and then three HCOs that have developed the MCSP in their own way, depending on their geographic, socioeconomic, populational and epidemiological context since the reform in 2015. In 2018, the Ministry of Health and Social Services (MSSS) mobilized these 3 HCOs to form a provincial committee to conceptualize and implement an integrated model of MCSP fed by the experiences of each of these establishments. This new ministerial model has been implemented in these three "developer" HCOs as well as in three other establishments "experimenter". These three HCOs are identified as "experimenter" because they did not participate in the initial implementation process. Since, the research team has documented and evaluated the implementation of MCSP in Quebec, initially in these three "developer" HCOs. This research project aims to continue the evaluation of the three "developer" HCOs as well as the scaling up of the three "experimenter" HCOs. The main

lessons learned from the pilot study show that in Quebec, MCSP innovation is characterized by two main elements and two main consequences (6).

Firstly, an activity phase based on the strategic communities approach (18, 19). Strategic communities are interorganizational collaborative structures composed of professionals, frontline managers, general practitioners, medical specialists and representatives of community organizations (whose mandate is to create, implement and evaluate new ideas relating to the organization of intersectoral work (18, 19). This means that MCSP is based on the collaboration and cooperation of all the actors involved in health care and service pathways and in which both users and community partners (e.g., community organizations, municipalities, schools) are closely involved. With this perspective, the operating methods are no longer hierarchical, but rather cooperative, with a significant part left to the emergence and joint creation of diagnoses and solutions (10). Involving users and community partners from a systemic perspective is part of this theoretical reflection surrounding the MCSP.

Secondly, this innovation needs to introduce a matrix structure into the organization to link the facilitation structure and the management structure. The individuals in charge of MCSP are functional specialists who are responsible for the implementation, functioning and improvement of care and services pathways through the creation of new organizational methods for services (20). Horizontal coordination across the matrix (the pathways) and between the horizontal and vertical lines (the directions) is done through mutual adjustment between the administrative and clinical professionals at all levels of governance (20). This type of structure aims to profile the service offer and increase the flexibility and cross-cutting nature of the organization to adapt it in a way that is relevant to contextual needs (of the users, the partners, the population of the territory, etc.).
Thirdly, MCSP involved the change of vision from traditional management to a large-scale matrix management model, while respecting the specific context of each organization, which was a significant challenge to overcome.

Finally, implementing MCSP means the development of new roles. Dual collaboration and the sharing of power and leadership (between health professionals, including doctors) are some of the additional challenges faced.

These findings lead us to define MCSP as a governance innovation based on a cross-sectional, non-hierarchical approach to the operation of health organizations, where collaboration with external partners and users is central to ensuring the integration of services aimed at improving the health of the population in a given territory (6).

Conceptual framework

The implementtation of MCSP will be analyzed as a governance innovation whose objective is to improve the integration of health care and services with the involvement of partners in the territory,

with a view to improving access for the entire population being served to improve access to the entire population served. Such implementation requires a systemic and territorial vision. The proposed framework constitutes a theoretical contribution in the field of implementation. In addition to integrating the five characteristics influencing the implementation of an innovation, it incorporates the notion of multilevel governance as well as a model for assessing the effects of the pandemic on the governance of MCSP. Although a conceptual model such as the Consolidated Framework for Implementation Research (CFIR) (21) could have been used, the present theoretical construct better fits the context of the study and the governance adopted by the MSPC in HCOs. Nonetheless, the CFIR was used in the construction of the Performance Analysis Model on which we rely for the development of our questionnaires.

Fig 1: Conceptual framework

Fig 1 shows the interlinking of these innovation characteristics and the interrelated dimensions for integration through MCSP implementation process in each context. The pandemic context is also one of the elements considered. This framework that builds on previous studies (21), is composed by four theoretical main elements:

1) Based on the Complex Adaptive System (CAS), which involves a high number of actors or components that are different, autonomous, and above all interdependent (22-24). Their interdependence is what interlinks the influence of an actor or a component with the presence and the intensity of the presence of other actors or components. From this CAS perspective, the use of multilevel governance can be encouraged through the combination of operational autonomy and interdependence between the organizations and systems (21). This multilevel governance is envisaged in a pluralist context, in which it is impossible to conceive of an absolute authority because of shared leadership and distributed powers (25, 26). This leads us to think of health care organizations in terms of interactions and co-evolution between the actors, going beyond a vision that is merely hierarchical (27).

2) There are five characteristics influencing the implementation of innovation as defined by Greenhalgh et al. (2004) (28) and Klein et al. (1996, 2001) (29, 30): (i) the characteristics of the actors (perceptions, values); (ii) the attributes of the innovation (ease of use, correspondence with practical needs); (iii) the internal characteristics of the organization in which the innovation is being implemented (the availability of resources, the adaptation of structures); (iv) the characteristics of the external environment (implication and effects on the partners, co-evolutionary principles); (v) the characteristics related to the piloting of an innovation (strategy and implementation process). Together, these elements will enable focus on the factors that are key to success in the implementation of pathways and identification of the essential elements to ensure their transferability. In doing so, it is crucial to take the interaction between these different elements into consideration using the CAS framework.

3) The conceptual framework includes the dimensions of the integration process that aim to establish coherence between the clinical system, multilevel governance and the collective system for the interpretation and values that form the space in which the actors interact (31, 32). These

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dimensions are clinical integration; integration of the clinical team; functional integration; normative integration and systemic integration.

4) The framework for robust governance strategies in the turbulent context of the COVID-19 pandemic. Because of the COVID-19 health crisis, we have decided to add the model for robust governance strategies in a turbulent context developed by Ansell, Sorensen and Torfing (33). This framework will be used to gain a detailed understanding of the effects of COVID-19 on the governance of MCSP in the HCOs being studied, as well as on their network of partners. The implementation of the MCSP is the implementation of a particular modality of process management. The governance innovation in the case of this implementation is the implementation of a matrix governance within the HCOs (34). This matrix governance allows to manage in a transversal and therefore processual way: it is the type of governance allowing a process management such as the MCSP.

To analyze the organizations being studied, we will use the typology of the six strategies proposed to formulate robust governance solutions. Robust governance strategies aim to maintain or achieve a public program, function, or purpose through the flexible adaptation, agile modification, and pragmatic redirection of governance solutions. Table 1 presents the strategies proposed for the formulation of robust governance solutions (33).

Table 1: Strategies proposed for the formulation of robust governance solutions

Terms	Definitions
Scalability	"Aims to flexibly mobilize and de-mobilize resources across organizations, levels and sectors to scale the provision of particular solutions to meet changing needs and demands (35)."
Prototyping	"Aims to create new, adaptative solutions through iterative rounds of prototyping, testing, and revision based on prompt feedback (36)."
Modularization	"Aims to create solutions that are divided into a series of modules that can be used flexibly in response to changes in the different aspects of the problem at hand (37)."
Bounded autonomy	"Aims to create a broad-based ownership and strategic commitment to an overall strategy by involving regional and local actors in the implementation of key tasks and regulations and encouraging them to adapt the overall governance strategy to the changing conditions on the ground (38)".
Bricolage	"Aims to flexibly use and combine available ideas, tools, and resources to fashion a workable solution in the face of turbulence (39, 40)."
Strategic polyvalence	"Aims to deliberately design solutions that can be taken in new directions and serve new purposes depending on situational analyses of demands, barriers, and emerging opportunities (41)."

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The inclusion of a COVID-19 component as part of our research will allow us to understand *in situ* the robust governance strategies implemented in the current turbulent context of the COVID-19 pandemic, which has had a major impact on public services such as the health care system in terms of adaptation and change (33). The pandemic has caused pathways to be altered, transformed or mature enough to continue "unsupervised" (self-organized). This study will document and analyze these phenomena.

5) In order to meet objectives 2 (conditions for implementing MCSP), 3 (measurement of the impacts of the pandemic on the MCSP as well as the possible effects of the MCSP), 4 (analysis of the performance of the MCSP) and 5 (influence context and partnership networks), the team will rely on the Performance Analysis Model (PAM) co-developed by Thiebaut, Maillet and the provincial committee (42). This analytical framework includes 11 dimensions (see table 2).

**Figure 2: Integrated care pathway performance
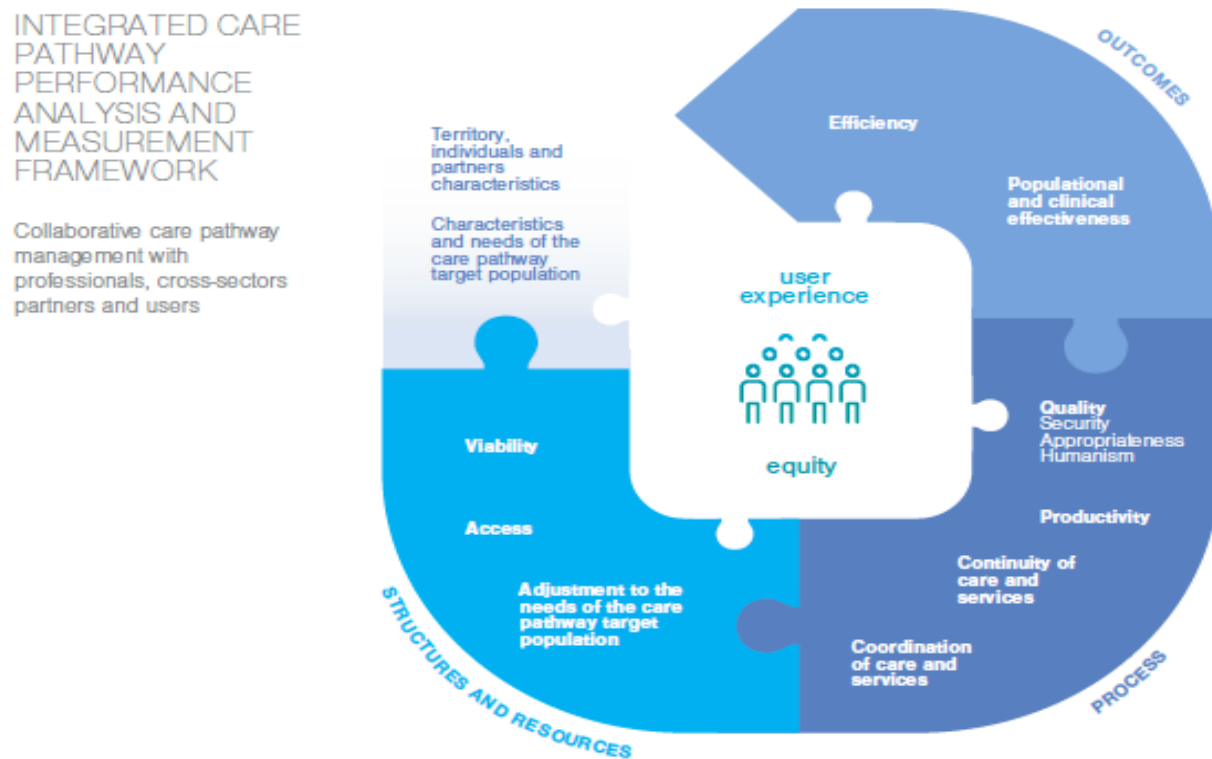analysis and measurement framework (41)**

Table 2: Performance Dimensions and Indicators

	Performance Dimensions	Possible indicators
Structure and resources	**Viability**	• Number of nurses per 1,000 inhabitants (or according to the total number of people targeted by the trajectory) [11] for the Territorial and local service networks (RTS) where the trajectory is implemented
	Accessibility	• Rate of use of services by specific populations (defined according to language, age, origin, etc.) over a given period • Number of days before the 3rd available appointment
	Adjustment to the needs of the target population	• Age-standardized rate of mental health hospitalizations per 100,000 inhabitants • Adjusted rate of hospitalizations for ambulatory care sensitive conditions per 100,000 inhabitants under age 75 • Proportion of people aged 65 and over with loss of autonomy reached through home support services and having benefited from an intervention for the prevention of falls
Process	**Coordination and continuity**	• Percentage of clients followed in oncology by a designated pivot nurse in oncology (PNO), regardless of the place of intervention • Rate of emergency hospital admissions of patients due to acute exacerbations of their chronic disease
	Relevance	• Proportion of family physicians who report that they consistently provide written instructions on how to manage their home care to their patients with chronic conditions [10] • Proportion of clinicians using clinical practice guidelines for certain pathologies [10]
	Security	•

	Performance Dimensions	Possible indicators
	Humanism	• Time spent with patients in terms of average duration of a regular consultation [11] • Proportion of workers met by a user and who clearly communicated their role
	Productivity	• Rate of use of operating rooms • Average length of stay for the eight main causes of high-volume hospitalizations (according to the trajectories chosen and the references for each of these trajectories)
Outcomes	**Clinical and population efficacy**	CLINICAL: • In-hospital death rate within 30 days of major surgery • Adjusted rate of hospitalizations for ambulatory care sensitive conditions per 10,000 population (e.g., COPD, diabetes) POPULATION: • Rates of regular and occasional smokers by age and gender [27] • Proportion of the population with obesity [27]
	Efficiency	• Average cost per screened case of breast cancer [12] • Percentage of public drug program spending on generic drugs

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Materials and Methods

Study aims

This project represents an opportunity to follow and support the implementation of a scale-up of a governance innovation from its point of departure, within four HCOs in real time. More specifically, the project aims to:

1. Document the clinical, organizational and partnership practices established by MCSP in each participating HCO (developers and experimenter), based on the four principles of MCSP (ongoing improvement, partnership, measurement of performance, and the establishment of a matrix governance model);
2. Describe and analyze the implementation conditions over time (facilitators and barriers) of the structure and the process of MCSP for each of the HCOs ("developer" and "experimenter" HCOs);
3. Measure the effects of the implementation of MCSP on the degree of integration of care and services for the users, the partners, and the HCOs;
4. Analyze and measure the effects of the COVID-19 pandemic on MCSP and, in turn, how MCSP has been able to contribute in terms of the adaptation of "developer" and "experimenter" HCOs in light of the pandemic;
5. Understand the influence of the context, including the management of the pandemic, on the implementation of MCSP and on its effects.

Design study

The methodology of this research project is based on developmental evaluation. The objective of developmental evaluation is to generate ongoing knowledge to guide organizations and actors in the adaptation and development of innovations in complex environments (43). The evaluation allows for analysis of the implementation and its effects, conducted through the implementation of projects while taking into consideration the needs of the users of the innovation, at the operational, tactical, and strategic levels as well as at the contextual level (partners). We will conduct a multilevel and multiple case study using process analysis (44-46). This method consists of synthetic research by multiple cases study (30) with nested levels of analysis to describe, measure and analyze the implementation of the MCSP in different contexts (47, 48) As part of our study, we propose a longitudinal study of interlinked cases (49, 50) to understand and to compare intra- and inter-organizational variations at a given moment and over time (50).

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Case study

The three "developer" HCOs were selected in 2018 by the MSSS to participate in the provincial committee and in the development of a scaling-up of MCSP through their own experiences (Table 3).

Table 3: Characteristics of the three "developer" HCOs

HCO	Geographical region	Population and territory	Number of employees	Number of pathways to follow	Pathways/ continuum followed (tracer cases)
A	Semi-urban and rural	476,000 (2015) 12,820 km^2	17,000	2	Chronic diseases Alternate level of care (ALC)
B	Very urban	445,600 (2018) 88 km^2	12,369	2	Chronic diseases Healthy weight management
C	Rural	516,281 (2018) 47,000 km^2	17,211	2	Chronic diseases Autism spectrum disorder (ASD)

The "experimenter" HCO will be selected by our research team in accordance with their interest in experimenting with MCSP, the level of integration of MCSP already achieved (variability of the initial conditions for implementation) and the diversity of contexts between cases (Table4).

Table 4: Characteristics of the "experimenter" HCO

HCO	Geographical region	Number of trajectories to follow	Pathways/ continuum followed (tracer cases)
D	Urban	2	Chronic diseases Alternate level of care (ALC)

In each of the HCOs we will follow two tracer cases, specifically two pathways (care and service continuums), to study the implementation of MCSP (Objectives 1 and 2); that of the Performance

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Analysis Model for MCSP (Objectives 3 and 4) and the effects of this implementation (Objectives 4 and 5).

Data collection

We will use five sources of data: documentary analysis, participant observation, semi-structured individual interviews, organizational questionnaires, and analysis of clinical-administrative databases. The data collected as part of this research will not be made available for replication because it is confidential and restricted by ethical considerations.

Qualitative data

We will carry out documentary analysis of the available written records on the structure and process of MCSP for each case under study. These documents will come from the gray literature collected during the three years of implementation of the pilot project for the implementation of the MCSP in the three "developer" HCOs and with the provincial committee. In addition, we will conduct participant observations during the meetings that will take place at the different levels. For example, participant observations will be made during meetings of operational visual stations (working group, and pathway coordination body). They will be undertaken by the members of the research team and recorded in the form of field notes, taking descriptive account of the development of the different situations observed. We plan to conduct 44 participant observations (12 per "developer" HCO and 8 per "experimenter" HCO).

We will also carry out individual semi-structured interviews. The interviews will focus on the implementation of MCSPs and their effects on the operation and degree of integration of care and services. These will be undertaken by at least one researcher and one student, in person, by videoconference or by telephone, with the key actors involved in the implementation of MCSP, until data saturation is achieved (see Table 5; N anticipated: 78 to 81). The selection of key participants will be based on the methodology of reasoned and selective choices (51) and will reflect the diversity of the actors involved in the pathway coordination bodies or in decision making, including users, community partners, practitioners, managers, senior executives and ministerial actors. As part of the institutional convenience committee request, a gatekeeper per HCO has been identified to support the research team in carrying out the project. Institutional convenience consists, among other things, in verifying the adequacy between the clientele targeted in the research project and the clientele of the establishment, the availability of the facilities, equipment and human resources of the establishment. The gatekeeper will connect potential participants with the research team. Initial contact and recruitment will be made by the principal investigators or research professionals via email or telephone.

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Participants and recruitment

According to the governance structure currently envisaged (Fig 3), the following participants were anticipated for the individual interviews (Table 5).

Fig 3: Generic matrix governance structure for MCSP (from working draft)

Table 5: Type and estimated number of participants

Type of participants	Number of interviews (estimated)
Users who are members of pathway coordination bodies	N = 2 x 2 x 4 = 16 users
Community partners who are members of pathway coordination bodies	N = 1*2*4 = 8 partners
Local practitioners/managers who are members of pathway coordination bodies and operational visual sites	N= 2*2*4 = 16 practitioners
Managers responsible for tactical and strategic pilot projects	N = 2*2*4 = 16 managers
Senior executives present in the strategic pilot project room	N= (2*4) + (2*4) = 16 decision makers
Ministerial actors connected to MCSP and its implementation	N = 3 individuals from the MSSS
Pan-Canadian actors involved in a similar process	+/- 3 to 6
Estimated total interviews	**78 to 81**

Survey and database

The quantitative component includes two parts for data collection and analysis: i) an organizational questionnaire, and ii) the consultation of clinical-administrative databases.

We will develop an organizational questionnaire to measure the effects of MCSP on matrix governance processes and operations, as well as the effects of MCSP on accessibility, continuity and equity of the care and services provided by each of the HCOs under study. This survey is based on the Performance Analysis Model (PAM) for MCSP, co-developed by Thiebaut, Maillet and the provincial committee (42) (see fig. 2 and table 2). It will be sent to the four HCOs on four separate occasions between 2023 and 2025. These four rounds of data collection will allow us to gain an organizational picture of MCSP both during and after the pandemic context. A purposeful sampling will be carried out to identify the participants who will answer the questionnaire (Table 6).

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Table 6: Type and estimated number of participants

Type of participants	Number (approximative)
Organsizational survey: managers, senior executive, clinicians, intervenants	N= 40*4=160
Partners (community) survey	N= 4*10=40
User survey (healthcare users)	N= 4*10= 40
Total	N=240

To analyze the profiles of use by targeted pathways, we will refer to two clinical-administrative databases: iCLSC and InfoCentre in the HCOs that are relevant to this study. Insofar as possible, we will use data that has already been collected and monitored by the pathway management bodies.

The variables requested per pathway will be (non-exhaustive list): age; gender; place of birth; place of residence; diagnosis; type of treatment; type of services accessed; professionals consulted; referencing and other data allowing the establishment of the profile types for each pathway studied as well as the monitoring of the performance indicators of the PAM (accessibility, continuity, and equity). All relevant data collected by the MCSP bodies will also be assembled. Being in a co-construction process (developmental evaluation), we have access to anonymized and aggregated clinic-administrative data as soon as we are involved in the field.

Data analysis

Analysis of the multiple data sources will require a combination of qualitative and quantitative approaches.

Qualitative data analysis

The qualitative data will be collected through a documentary analysis, participant observations and semi-structured individual interviews. The individual interviews will be recorded and transcribed. The analysis of all these qualitative data will be led using an iterative approach in a team and will involve the subsequent reading of the verbatim records, the coding, and the thematic analysis in connection with the framework, followed by validation by the participants and the monitoring committee. One professional and one research assistant will code the interviews according to a mixed strategy that is both deductive (conceptual framework) and inductive (emergence). A summary list of initial codes based on our conceptual framework will serve as an *a priori* coding grid. It will be modified and enriched over the course of the coding and preliminary analyses. The coding will be monitored using a double coding technique carried out by research professional and the main researchers (LM, GCT and NT). Parallel independent coding will be done for the first five interviews, followed by a comparison of results. This process will be repeated until a consensus

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list of initial codes has been made and once a level of intercoder reliability of over 90% has been reached (52). Data from the semi-structured interviews and the observations will be analyzed thematically. The analytical phases will be interspersed with research team meetings and will involve the input of the monitoring committee. The analyses will be conducted using the software QDA Miner 6 (53).

Survey and database analysis

A priori, our dependent variables are the effects of MCSP, meaning respect for user needs, user pathways and the performance of HCOs (see fig. 2 and table 2). The independent and intermediary variables are the characteristics of MCSP, for example: access mechanisms, interventions for health promotion/evaluation/research/guidance. These variables will be validated by conducting interviews with participants.

We plan to use reliability scores for the implementation of MCSP, ANOVA tests to compare the contexts for implementation, and multiple and logistical linear regressions to model the effects according to the tracer cases (the monitored pathways in each of the HCO (N = 8) and the contexts for implementation). The variables adjusted following the interviews will be used to carry out the analysis. The questionnaire will be sent online via the LimeSurvey[1] platform. The software that will be used for the treatment and analysis of the data collected by questionnaire and the data collected through the clinical-administrative databases is SPSS 26.0 (54).

Lastly, to go beyond a "universal" definition of management and organizational theories, differentiated analysis according to gender will be included both in terms of the description of the implementation of MCSP (Objectives 1 and 2) but also in terms of the effects and impact (Objectives 3 and 4) as well as the comparison of the contexts for implementation (Objective 5). Differentiated analysis according to gender provides a more representative vision of the population (here: users, community actors, clinicians, professional, decision-makers and managers), considering the differentiated realities and needs of women and men (55, 56). For example, the questionnaire will be formulated in a way that allows differentiation between responses according to gender (accompanied by other variables such as leadership, management and collaboration models, the composition of operational, tactical, and strategic committees, etc.). Similarly, during the qualitative analysis, the corpus of texts will be coded and worked on while taking into consideration this major variable, including in the field of management in HCOs.

Ethical considerations and declarations

The research protocol was reviewed and approved by Ethics Committee of the institution of health and social services on 28th January 2021 (2021-Projet #MP-31-2021-3799).

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[1] https://www.limesurvey.org/

Consent for publication: As part of the written informed consent, all participants will be asked to give permission for information they provide in interviews to be published in an anonymized form.

Status and timeline of the study

Step 1 of the study is under way. Surveys (organizational, partners and users) were developed by the research team on Lime Survey software and tested with a panel of 5 key respondents in December 2022. The time 1 for the survey will be scheduled at the end of February 2023. Next one will be in December 2023 (Time 2), September 2024 (Time 3) and February 2025 (Time 4).

In parallel, we finish to organise the qualitative data collect with 16 individuals from each territory (4) and 6 to 9 individuals from provincial administration and other Canadian provinces. All these persons will be recruited and interviewed between October 2022 and Mars 2025.

Since 2022, we have obtained permission to use the anonymized clinical-administrative database of HCOs in the study. In partnership, we will use these databases and support the implementation of CMHP in each territory through tailored feedback workshops.

Discussion

What contribution can we make to MCSP?
Although several studies have demonstrated the impact of the context at the local level (57, 58) and at the national level (59, 60), it is necessary to bring these two research areas together to gain a detailed understanding of the co-evolution between MCSP, the policies and the local actors in terms of a multilevel, adaptive governance system (61).

The call for more collaborative and participatory research, notably involving users and community partners (e.g., community organizations, municipalities, schools) from a systemic perspective in healthcare system, forms part of our theoretical considerations surrounding MCSP. This is particularly relevant (but not only) to the development of knowledge about the adaptation of the MCSP within HCOs in the turbulent environment we are experiencing with the COVID-19 pandemic. The pandemic has had several impacts on the health system (e.g., on resources, service delivery, management, and governance).

In this context, this study could help to increase knowledge of MCSP implementation in different HCOs and their networks, as well as transferability at the provincial level, an aspect that has not been addressed in previous studies. Work on scaling up innovation is gaining momentum (62-65). However, the implementation of governance innovations such as GTSS appears to be promising but less explored. This is exactly the challenge we wish to take up with our partners in order to find the adapted and adaptive formula for each of the territories and trajectories targeted by this study. This study could help to demonstrate how, through MCSP implementation, the health care system can enable health and social service organizations to better adapt to the needs of the population and may has contributed to the ability of HCOs to adapt to the COVID-19 pandemic;

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Finally, this study could help to generate practical knowledge by creating theory-based implementation suggestions through the Complex Adaptive System developed together with key stakeholders like HCOs, users, community organisation, municipalities, education sector.

In brief, the implementation of MCSP and its evaluation can be challenging (time, human resources, collaboration), but also generate unprecedented and as yet unknown outcomes from a theoretical (reconciling the local and the political within coherent multi-level adaptive governance), practical (managing uncertainty by collaborating intra- and inter-organizational to meet the needs of populations adaptively), and finally political (building a robust and adaptive health system at the same time is a dream for many governments and societies) perspective.

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Abbreviation

ALC: Alternate level of care
CAS: Complex Adaptive System
CFIR: Consolidated Framework for Implementation Research
ENAP: National School of Public Administration
EPA: European Pathway Association
HCOs: Healthcare Organization(s)
i-CLSC: Data base used in part of HCO (Local Community Service Centers)
IUPLSSS: University Institute on primary health care and social services
MCSP: Management through Care and Services Pathways
MSSS: Ministère de la Santé et des Services sociaux (Ministry of Heath and Social Services)
PAM: Performance Analysis Model
RTS: Réseaux territoriaux et locaux de santé (Territorial and local service networks)

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References

1.   Baker G, Denis J-L. Étude comparative de trois systèmes de santé porteurs de changement : leçons pour le Canada. 2011.

2.   Noseworthy T, Wasylak T, O'Neill B. Strategic clinical networks in Alberta:Structures, processes, and early outcomes. Healthcare Management Forum. 2015;28(6):262-4.

3.   Ellis Brian W. The care pathway: a tool to enhance clinical governance. British Journal of Clinical Governance. 1999;4(2):61-72.

4.   Bragato L, Jacobs K. Care pathways: the road to better health services? Journal of Health Organization and Management. 2003;17(3):164-80.

5.   Moore M, Hartley J. Innovations in governance. Public Management Review. 2008;10(1):3-20.

6.   Maillet L, Thiebaut G-C, Touati N, Champagne G. L'expérience des trajectoires de soins et des services de santé au Québec : l'animation comme levier de gouvernance collaborative et intersectorielle. In: Bazinet A, Boudreau, Christian,, Charbonneau M, editors. La collaboration interorganisationnelle : conditions, retombées et perspectives en contexte public. Québec: Presses de l'Université du Québec; 2021. p. 131-57.

7.   Vanhaecht K, Ovretveit J, Elliott MJ, Sermeus W, Ellershaw J, Panella M. Have We Drawn the Wrong Conclusions About the Value of Care Pathways? Is a Cochrane Review Appropriate? Evaluation & the Health Professions. 2012;35(1):28-42.

8.   Vanhaecht K, De Witte K, Panella M, Sermeus W. Do pathways lead to better organized care processes? Journal of Evaluation in Clinical Practice. 2009;15(5):782-8.

9.   Allen D, Gillen E, Rixson L. Systematic review of the effectiveness of integrated care pathways: what works, for whom, in which circumstances? International Journal of Evidence-Based Healthcare. 2009;7(2):61-74.

10.   Turner S, Botero-Tovar N, Herrera MA, Borda Kuhlmann JP, Ortiz F, Ramírez JC, et al. Systematic review of experiences and perceptions of key actors and organisations at multiple levels within health systems internationally in responding to COVID-19. Implementation Science. 2021;16(1):50.

11.   De Bleser L, Depreitiere R, De Waele K, Vanhaecht K, Vlayen J, Sermeus W. Defining pathways. Journal of Nursing Management. 2006;14(7):553-63.

12.   Vanhaecht K, De Witte K, Sermeus W. The impact of clinical pathways on the organisation of care processes. 2007.

13.   Vanhaecht K, Panella M, van Zelm R, Sermeus W. An overview on the history and concept of care pathways as complex interventions. International Journal of Care Pathways. 2010;14(3):117-23.

14.   Europe. WHO-. Primary health care 2016 [Available from: https://www.who.int/health-topics/primary-health-care#tab=tab_1.

15.   Zander K. Integrated Care Pathways: Eleven International Trends. Journal of integrated Care Pathways. 2002;6(3):101-7.

16.   Haute autorité de santé. Chemin clinique – une méthode d'amélioration de la qualité. 2004.

17.   Guide de la gestion par trajectoires de soins et de services - Un modèle de gestion favorisant l'intégration des soins et services en partenariat avec les usagers, les proches et les partenaires. Version du 12 juin 2019 [press release]. En cours.

18.   Lane J, Lortie PB, Gohier C, Massuard M, Marengo S, Bazinet J, et al. Guide pour accompagner l'implantation de bonnes pratiques. In: Sherbrooke CiudsessdlEChud, editor. Sherbrooke. Québec2015.

19.   Roy M, Audet M, Archambault J, St-Louis D. Créer une communauté stratégique pour favoriser le changement. Gestion. 2010;34(4):48-54.

20.   Mintzberg H. Le Management : Voyage au centre des organisations. D'Organisations é, editor. Paris1989.

Study Protocol

21.   Maillet L, Lamarche P, Roy B, Lemire M. At the heart of adapting healthcare organizations: Developing a multilevel governance framework. Emergence: Complexity and Organiztion E:CO. 2015;17(3):1-11.

22.   Begun JW, Zimmerman B, Dooley K. Health Care Organizations as Complex Adaptive Systems. In: Mick SM, Wyttenbach M, editors. Advances in Health Care Organization Theory. San Francisco: Jossey-Bass; 2003. p. 253-88.

23.   Palmberg K. Complex adaptive systems as metaphors for organizational management. The Learning Organization. 2009;16(6):483-98.

24.   Farazmand A. Chaos and Transformation Theories: A Theoretical Analysis with Implications for Organization Theory and Public Management. Public Organization Review. 2003;3(4):339-72.

25.   Denis J-L, Lamothe L, Langley A. The dynamic of collective leadership and strategic change in pluralistic organizations. The Academy of Management Journal. 2001;44(4):809-37.

26.   Rhodes RAW. Understanding Governance: Ten Years On. Organization Studies. 2007;28(8):1243-64.

27.   Tenbensel T. Multiple modes of governance. Public Management Review. 2005;7(2):267-88.

28.   Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

29.   Klein KJ, Conn AB, Smith DB, Sorra JS. Is everyone in agreement? An exploration of within-group agreement in employee perceptions of the work environment. Journal of Applied Psychology. 2001;86(1):3-16.

30.   Klein KJ, Sorra JS. The Challenge of Innovation Implementation. The Academy of Management Review. 1996;21(4):1055-80.

31.   Couturier Y, Bonin L, Belzile L. L'intégration des services en santé : une approche populationnelle. Montréal: Les Presses de l'Université de Montréal; 2016.

32.   Contandriopoulos, Denis J-L, Touati N, Rodriguez R. Intégration des soins : dimensions et mise en œuvre. Ruptures, revue transdisciplinaire en santé. 2001;8(2):38-52.

33.   Ansell C, Sørensen E, Torfing J. The COVID-19 pandemic as a game changer for public administration and leadership? The need for robust governance responses to turbulent problems. Public Management Review. 2020:1-12.

34.   Maillet L, Thiebaut G-C, Duranceau M-F, Breton M, Marchand J-S, Manceau L-M, et al. Integrated Care Pathways and Networks: Implementing Governance Innovations in Quebec's Health and Social Services System. International Journal of Integrated Care (IJIC). 2019;19(S1):1-2.

35.   Ansell C, Jacob T. How Does Collaborative Governance Scale? . Bristol: Policy Press; 2018.

36.   Brown T, Wyatt J. Design Thinking for Social Innovation. Development Outreach. 2010;12(1):29-43.

37.   Ansell C, Gash A. Collaborative Platforms as a Governance Strategy. Journal of Public Administration Research and Theory. 2018;28:16-32.

38.   Ferraro F, Etzioni D, Gehman J. Tackling Grand Challenges Pragmatically: Robust Action Revisited. Organization Studies. 2015;36(3):363-90.

39.   Phillips N, Tracey P. Opportunity recognition, entrepreneurial capabilities and bricolage: connecting institutional theory and entrepreneurship in strategic organization. Strategic Organization. 2007;5(3):313-20.

40.   Chandra Y, Paras A. Social Entrepreneurship in the Context of Disaster Recovery: Organizing for Public Value Creation. Public Management Review. 2020:1-22.

41.   Padgett JF, Ansell C. Robust Action and the Rise of the Medici, 1400–1434. American Journal of Sociology. 1993;98(6):1259–319.

Study Protocol

42.   Thiebaut G-C, Lavoie C, Labrecque-Pégoraro S, Maillet L. Pour de trajectoires de soins et services performantes : Un outillage pour l'analyse et la mesure. . Sherbrooke, Québec.: Institut Universitaire de Première Ligne en Santé et Services Sociaux du CIUSSS de l'Estrie - CHUS.; 2020.

43.   Patton MQ. Developmental evaluation: Applying complexity concepts to enhance innovation and use. New York, NY: Guilford Press; 2011.

44.   Langley A. Strategies for Theorizing from Process Data. Academy of Management Review. 1999;24(4):691-710.

45.   Langley A, Abdallah C. Templates and Turns in Qualitative Studies of Strategy and Management. In: Donald DB, David JK, editors. Building Methodological Bridges. Research Methodology in Strategy and Management. 6: Emerald Group Publishing Limited; 2011. p. 201-35.

46.   Langley A, Smallman C, Tsoukas H, Van de Ven AH. Process Studies of Change in Organization and Management: Unveiling Temporality, Activity, and Flow. Academy of Management Journal. 2013;56(1):1-13.

47.   Yin RK. Case Study Rechearch : Design and Methods Fourth Edition. Londres: Sage (1994); 2009.

48.   Contandriopoulos, Champagne F, Potvin L, Denis J-L, Boyle P. Savoir préparer une recherche: La définir, la structurer, la financer. Morin G, editor. Montréal: Presses de l'Université de Montréal (1990); 2005. 197 p.

49.   Musca G. Une stratégie de recherche processuelle : l'étude longitudinale de cas enchâssés. M@n@gement. 2006;9(3):153-76.

50.   Yin RK. Case study research: design and methods. Thousand Oaks: Sage Publications; 2003.

51.   Poupart J, Deslauriers J-P, Groulx LH, Laperrière A, Mayer R, Pires AP. La recherche qualitative: enjeux épistémologiques et méthodologiques. 1 ed. Boucherville, QC: Gaetan Morin; 1997.

52.   Miles MB, Huberman AM. Qualitative data analysis : an expanded sourcebook. Thousand Oaks, California: Sage Publications; 1994. 338 p.

53.   QDA Miner 6. Qualitative date analysis software for mix methods - Provalis Research. 2020.

54.   SPSS. IBM SPSS Statistics 26.0. 2019.

55.   Horstmann S, Schmechel C, Palm K, Oertelt-Prigione S, Bolte G. The Operationalisation of Sex and Gender in Quantitative Health-Related Research: A Scoping Review. Int J Environ Res Public Health. 2022;19(12).

56.   Francoeur C, Labelle R, Sinclair-Desgagné B. Gender diversity in corporate governance and top management. Journal of business ethics. 2008;81:83-95.

57.   Lamarche P, Lamothe L, Bégin C, Léger M, Vallière-Joly M. L'intégration des services : enjeux structurels et organisationnels ou humains et cliniques ? Ruptures, revue transdisciplinaire en santé. 2001;8(2):71-92.

58.   Fleury M-J, 2000;15(2):117-48 DJ-L. Proposition d'un modèle d'évaluation de la mise-en-oeuvre et des effets de la planification des programmes régionaux d'organisation des services de santé mentale au Québec. . The Canadian Journal of Program Evaluation 2000;15(2):117-48.

59.   Ridde V, Robert E, Guichard A, Blaise P, van Olmen J. L'approche realist à l'épreuve du réel de l'évaluation des programmes. Canadian Journal of Program Evaluation. 2012;26(3):37-59.

60.   Contandriopoulos AP, F. C, Denis JL, Pineault R. L'évaluation dans le domaine de la santé - Concepts et méthodes. Bulletin canadien d'histoire de la médecine. 1993;33(1):12-7.

61.   Reypens C, Lievens A, V. B. Hybrid Orchestration in Multi-stakeholder Innovation Networks: Practices of mobilizing multiple, diverse stakeholders across organizational boundaries. . Organization Studies 2021;42(1):61-83.

62.   Wodchis WP, Dixon A, Anderson GM, Goodwin N. Integrating care for older people with complex needs: key insights and lessons from a seven-country cross-case analysis. 2015. 2015.

63.   Ashton T. Implementing integrated models of care: the importance of the macro-level context. 2015. 2015.

Study Protocol

64.	Paina L, Peters DH. Understanding pathways for scaling up health services through the lens of complex adaptive systems. Health Policy and Planning. 2011.

65.	Pfotenhauer S, Laurent B, Papageorgiou K, Stilgoe, Jack. The politics of scaling. Social Studies of Science. 2022;52(1):3-34.