






# BMJ Open Implementation of a new clinical and organisational practice to improve access to primary care services: a protocol for an effectiveness-implementation hybrid study

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## ABSTRACT

**Introduction** In Canada, as in most Organisation for Economic Co-operation and Development countries, healthcare systems face significant challenges in ensuring better access to primary care. A regional healthcare organisation in Quebec (Canada) serving a population of approximately 755 459 citizens has implemented a standardised access approach to primary care services for this population. The objective of this new clinical and organisational practice is to ensure that users benefit from the same referral process, regardless of the entry point, in order to be directed to the right services. This new practice integrates a shared decision-making process between the user and the professional, and a collaborative process between different health professionals within and between services. The objective of our research is to identify and characterise the conditions of implementation of this practice.

**Methods** This effectiveness-implementation hybrid investigation will use an embedded single-case study, defined in this case as the process of implementing a clinical and organisational practice within a healthcare organisation. Further to an evaluation conducted during a preliminary phase of the project, this study consists of evaluating the implementation of this new practice in four medical clinics (family medicine groups). A qualitative analysis of the data and a quantitative preimplementation and postimplementation analysis based on performance indicators will be conducted. This study is ultimately situated within a participatory organisational approach that involves various stakeholders and users at each step of the implementation and evaluation process.

**Ethics and dissemination** This study was approved by the Ethics Committee of the Sectoral Research in Population Health and Primary Care of the Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (#2020-1800). The results of the investigation will be presented to the stakeholders involved in the advisory committees and at several scientific conferences. Manuscripts will be submitted to peer-reviewed journals.

## Strengths and limitations of this study

- This study will document the issues associated with the complexity of organisational structures and work processes, given the mobilisation of a multitude of intraservice and interservice actors, that are related to the practice's implementation.
- The collection of qualitative and quantitative data from a range of organisational stakeholders will contribute to a better understanding of the factors that promote or impede the implementation of the clinical and organisational practice.
- The use of the strategic framework approach as well as the involvement of multiple actors both in the data collection and on the advisory committees should help to mitigate the potential limitations of the type 2 effectiveness-implementation hybrid study (eg, poor adoption and fidelity of the implementation strategy).
- The diversity in the profiles of the Family Medical Group clinics should help to mitigate the potential risk of selection bias.

## INTRODUCTION

### Context of the study

In most Organisation for Economic Co-operation and Development countries, health systems are under considerable pressure to adapt their services to sociodemographic changes, such as an ageing population, and high prevalence of chronic diseases and mental health problems.<sup>1</sup> One of the solutions to these challenges is to strengthen access to primary care, which allows more users to obtain care without having to go to the emergency room or be hospitalised.<sup>2 3</sup> In Canada, access to many healthcare services is universal through publicly funded health insurance.



Currently, the access difficulties being experienced in many Canadian provinces pose significant challenges regarding equity in obtaining timely care and coordinated access to different professional services.<sup>4 5</sup> Few studies have examined the factors that lead to improved access to primary care, with most focusing on access to specialty services.<sup>6</sup>

One of the determining elements of access concerns the process of directing users to the right services according to their needs.<sup>7</sup> Studies have shown that certain methods of managing referrals to different services can reduce waiting times and have various positive effects.<sup>7 8</sup> Indeed, the quality of referrals is an important element.<sup>9</sup> Imison and Naylor's study identifies major problems among family physicians, who often do not make referrals to the right resource and do not provide enough, or the right, information to allow for adequate referral.<sup>9</sup> Other studies emphasise the value of using guidelines and referral forms, which have the greatest potential for reducing costs and improving efficiency in the delivery of services.<sup>9 10</sup> Furthermore, the process of referral to the most relevant resources according to users' needs could be greatly improved using multidisciplinary teams.<sup>11</sup> Finally, the adoption of a patient-centred approach is one of the important measures identified to reduce waiting times.<sup>10 12</sup>

A pan-Canadian public consultation with users and healthcare professionals revealed major flaws in the referral process.<sup>13</sup> Many professionals complained that they must deal with multiple entry points that operate in different ways, that they refer users to programmes that often have very long waiting lists, and that they are not informed about what happens to the user once they are referred.<sup>13</sup> Users also expressed dissatisfaction with the referral process; they would like to be more involved in the decisions that concern them, and that the navigation process between the different services be simplified.<sup>13</sup>

In the province of Quebec (Canada), a vast reform was undertaken in 2015 of the entire health and social services network structure with the intent of ensuring greater efficiency and effectiveness.<sup>14</sup> In this reform, 182 general and specialised institutions offering youth, community, hospital, long-term care and public health services were merged into 34 large organisations called Centres intégrés de santé et de services sociaux and Centres intégrés universitaires de santé et de services sociaux (CIUSSS), the sole exception being certain hospitals that remained independent. Paradoxically, although this reform was specifically intended to improve access and navigation between the various services, it generated new challenges, including the coexistence of several access points, numerous referral forms, disparate intervention tools, and significant and highly variable waiting times depending on the sector.<sup>14</sup>

This lack of standardisation and equity in access processes is at the root of various difficulties experienced by users in their care process, including errors in referral to the right service, the need to frequently

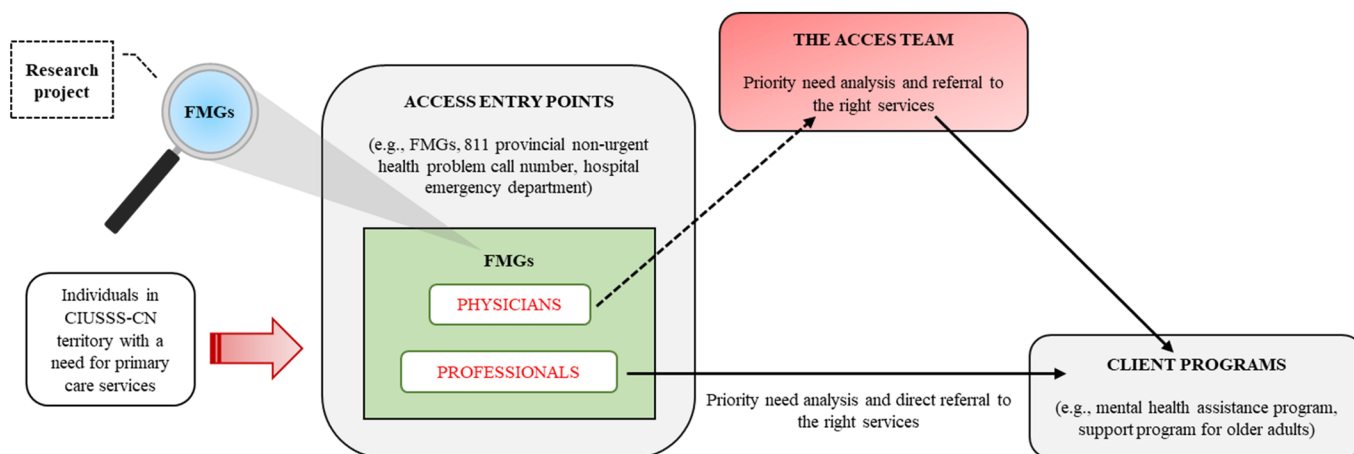
repeat their story, disparities in the information provided and complex navigation through the various services.<sup>12</sup> In Quebec, all regions are reviewing their primary care access mechanisms.

To address these challenges, the CIUSSS de la Capitale-Nationale (CIUSSS-CN) in the Quebec City region conducted an in-depth review of its access mechanisms to standardise the processes at all the entry points to primary care services on its territory. The creation of the CIUSSS-CN is the result of the merger of 11 health and social services institutions. One of the central elements of this transformation is the abolition of the multiple access points to services that were previously attached to the various service areas (eg, mental health access point, youth access point). Referrals will now be made directly to the appropriate services through the multiple entry points located on the CIUSSS-CN territory (eg, te 811 provincial non-urgent health problem call number, hospital emergency department, family medicine group (FMG)). The objective of standardising access is to allow users to benefit from the same referral process, regardless of the entry point. Specifically, the professionals working at these entry points are now able to refer users to the right services themselves, except for physicians, who will instead refer requests to a specialised team at CIUSSS-CN, called the Access Team.

The Access Team plays a central role in this referral process. It comprises social workers and nurses dedicated exclusively to the referral of requests to services in the various client programmes (eg, mental health assistance programme, support programme for the elderly). Its function is to process requests from physicians, particularly those practicing in the FMGs, and from various external partners (eg, community organisations, schools, city).

The referral orientation is based on a standardised process that relies on the analysis of the user's priority needs, that is, the needs on which it is most necessary to intervene. These needs are determined through a process of shared decision-making between the professional, the user and his or her family. The process of identifying priority needs is carried out jointly with the clinical team, considering the user's values and the various service options available.<sup>15</sup> The priority needs analysis is carried out using a template that makes it possible to synthesise the essential data collected concerning the user's priority needs (eg, parental support, anxiety, home service organisations), to analyse them and to formulate a professional opinion for referral. For complex situations, the professional may call on other professionals from the various CIUSSS-CN service divisions to contribute their expertise. These professionals can support the professional responsible for the orientation in identifying the user's priority needs and in choosing the appropriate orientation. The referral process is illustrated in [figure 1](#).

This standardised access to primary care and services implies important changes at two levels. First, at the clinical level, the new practice is based on the analysis of



**Figure 1** The referral process. CIUSSS-CN, Centres intégrés universitaires de santé et de services sociaux de la Capitale-Nationale; FMGs, family medicine groups.

priority needs, rather than solely the diagnosis, to make a referral. The new practice also relies on sustained collaboration between professionals, service managers and the network of community organisations to ensure better fluidity in the continuum of care for the user. Second, the deployment of this new practice relies on major organisational changes, notably through the implementation of the Access Team, which is a completely new entity. This practice also implies a significant capacity to adapt the service offer within the client programmes to be able to respond to the more individualised needs of users, an important challenge in such complex and centralised organisations. In the context of this transformation of access to primary care services within the CIUSSS-CN, a research project was funded to evaluate the implementation of this new clinical and organisational practice in one of the network's major gateways, the FMGs.

### Purpose of the study

The overall objective of this study is to identify and characterise the conditions for implementing this new practice in the FMGs. The specific objectives include:

1. Describe the organisational context in which the new practice is being deployed and specifically the challenges related to the adaptation of organisational structures and work processes
2. Evaluate the effects of the new practice based on performance indicators.
3. Understand the experience of professionals, physicians, managers and users in relation to the new practice and identify the challenges.

### METHODS AND ANALYSIS

The research on evidence-based interventions frequently favours a stepwise approach; one of the limitations of this approach is the significant time lag between the development of the interventions and its implementation in the field.<sup>16</sup> To address this issue, hybrid designs have been developed to promote the examination of effectiveness

and implementation outcomes within a single study. Our research will use a hybrid implementation approach, and specifically the type 2 model, that incorporates a dual focus on effectiveness and implementation outcomes.<sup>16</sup> This model permits simultaneous testing or piloting of implementation strategies during an effectiveness trial.

Our study is based on a real-world research-evaluation that mobilises participatory, pragmatic, descriptive and exploratory approach based on a mixed methodology. Pragmatic studies make it possible to obtain evidence that reflects the characteristics of the context in which a practice is carried out.<sup>17</sup> They are particularly appropriate when implementing innovative approaches.<sup>18</sup> They aim to collect the necessary quantitative and qualitative data required for evaluation.<sup>19</sup> Based on the *Strategic framework for useful and used evaluation* proposed by Alami *et al.*,<sup>20</sup> this approach consists of accompanying the main actors involved in the implementation of an organisational project to highlight, at each phase of the project, the factors or conditions that facilitate or constrain the introduction of change in the intended direction.<sup>20</sup> It makes it possible to consider all the strategic and governance aspects as well as the sociopolitical, economic, organisational, professional, human, legal, ethical and technological elements likely to influence its implementation. This approach consists of focusing on the results and the factors that influence them (eg, perceived benefits for and by users and their families, professionals and clinicians), while ensuring that the lessons learnt from the evaluation can be useful for clinical and management decision-making. The use of this strategic framework will thus make it possible to consider the characteristics and different stages of the project, the actors, the environment, the challenges and the different levels of intervention. It also facilitates the choice of evaluation methods and knowledge-sharing strategies to be adopted and adapted to the innovative nature of the project. In this sense, knowledge sharing and its translation into action throughout the project are at the heart of the approach.

More specifically, we are proposing an embedded single-case study, which is operationalised in our study as the implementation of a novel clinical and organisational practice in four medical clinics, that is, two FMGs, one university FMG (U-FMG) and one network FMG (R-FMG) (A FMG is a group of primary care family physicians who work closely with other health professionals (social workers, nurses, etc). An academic FMG (U-FMG) is an FMG that is distinguished by its academic recognition in teaching. A network FMG (R-FMG) is an FMG that intervenes with users to complement the service offer of the FMGs and with the objective of responding primarily to the needs of those who are not registered or who are unable to see their own family physician. This type of FMG provides an increased service offer to all clients, registered or not.) in the CIUSSS-CN territory. As defined by Yin,<sup>21</sup> embedded single-case studies refer to case studies that involve units of analysis at more than one level, which is the case with our medical clinics, that are included in the new practice deployment plan led by CIUSSS-CN. The study includes a comparative analysis based on quantitative performance indicators. This methodological choice will make it possible to consider the complex characteristics of the project, which involve multilevel and multi-actor governance and organisational dynamics. The case study will also be relevant for understanding the needs of managers to monitor and integrate the lessons of the evaluation into their decision-making processes. This approach is particularly appropriate when the object of study cannot be separated from its context.<sup>21 22</sup>

With respect to evaluation, two approaches will be used: the comprehensive approach, to consider all the facts and challenges relating to the project<sup>19 23</sup>; and the participatory and pluralist approach, to include the perspectives of the various actors, partners and stakeholders concerned by the project.<sup>24 25</sup> To this end, several committees, which bring together managers, direct service providers, researchers and user-partners have been established to participate at different levels in the implementation of the practice and the research process (eg, a restricted working committee for the operationalisation of the orientations; an expanded committee for strategic decisions; a community of practice that brings together other similar institutions in the province of Quebec interested in knowledge transfer). The purposes of the evaluation are also twofold: an evolutionary (developmental) and formative purpose, to respond to the concerns of coconstruction, support and translation of knowledge into action with all the actors, considering the different stages of the project and a certain summative purpose, to assess the achievement of the initial objectives.<sup>18</sup>

### Data collection

An evaluation has been conducted of the implementation of the practice in the Access Team, the role of which is to receive referrals from the entire primary care services network of the CIUSSS-CN. This evaluation consisted of identifying the factors that promoted or hindered the

implementation of the new practice in this particular organisation. Based on the lessons learnt from this evaluation, the new practice will be deployed in the four FMG clinics, which have distinct characteristics with respect to their organisation and mission (eg, teaching component, expanded drop-in appointment availability, interprofessional work model). An evaluation process will be carried out during implementation and will aim to identify the favourable and unfavourable conditions for implementation in this specific sector with a view to its potential transferability to other similar clinical organisations. The same variables that were used in the evaluation of the Access Team will be used in the data collection in the four participating clinics. In addition to users and professionals (For phase 2, the administrative officers will not be met since they are not involved in the referral process unlike the Access Team.), physicians will also be interviewed since they are generally the first point of entry for users in these clinics and work closely with professionals. Focus groups will be conducted in the programmes providing the services to examine the fit between the referral made, the programme targeted and the services available. See [table 1](#) for specific details.

In addition, clinical and administrative data will be collected in the clinics using a data entry tool developed as part of the project, which will make it possible to document various performance indicators for medical clinic professionals (see [table 1](#)). Based on this data, a preimplementation and postimplementation analysis will be performed. Since preimplementation data do not exist for the four participating clinics, the postimplementation data will be compared with preimplementation data taken from a database that compiles information on the care trajectories of users who have obtained services from the CIUSSS-CN. It will thus be possible to identify certain trajectory profiles and make a preimplementation and postimplementation comparison based on the performance indicators selected (see [table 1](#)) for users in the same territory. This method of analysis will make it possible to evaluate the effects of the new practice, particularly on the volume of requests processed, the time it takes to be referred and the relevance of the targeted referral.

The participation of all respondents in this study is voluntary. The selection of participants will be based on different criteria to ensure internal diversification for each group.<sup>26</sup> For the service users, we will apply the following criteria: age, gender, nature of priority needs, choice of orientation regarding services. For the other groups, we will apply the following criteria: age, gender, number of years of experience in their respective profession and their level of experience with the new clinical and organisational practice. The diversity of the participants will be sought in relation to these criteria, although without necessarily identifying these criteria in advance. If we have difficulty recruiting participants, we will explore other strategies that will rely on the involvement of, and existing relationships with, key stakeholders in the organisation for their support.



**Table 1** Study variables by phase of the evaluative study

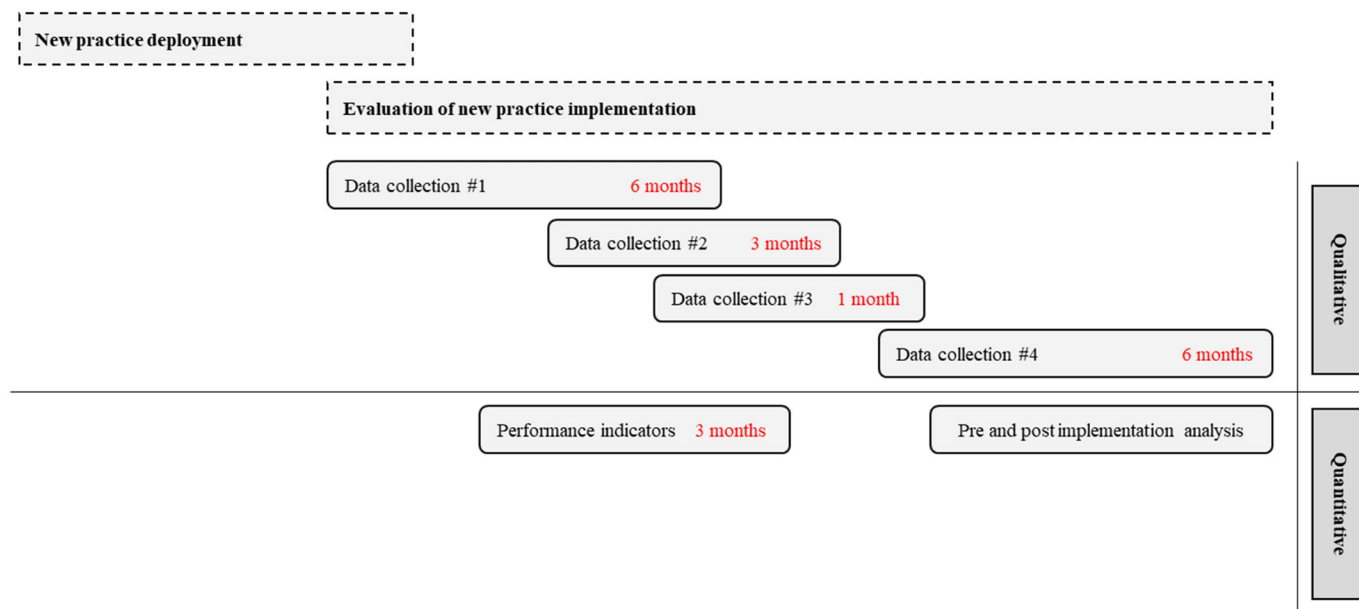
Approach	Variables	Collection methods
Qualitative	<ul style="list-style-type: none"> <li>▶ Practice issues for physicians and professionals will be documented based on their professional experience and their interprofessional collaborative work. Data will be collected regarding the following six variables:               <ul style="list-style-type: none"> <li>– The deployment and appropriation of the new practice.</li> <li>– The impact of the new practice on the organisation of work.</li> <li>– The shared decision-making process with the client.</li> <li>– Perceived support in the change process.</li> <li>– Intraprofessional and interprofessional, interservice and interorganisational collaboration.</li> <li>– Follow-up with the referent following the referral.</li> </ul> </li> <li>▶ The issues for users will be documented based on their perceptions and satisfaction. They will be questioned on the following four variables:               <ul style="list-style-type: none"> <li>– The identification of their priority needs.</li> <li>– The shared decision-making process and comfort in making decisions.</li> <li>– Targeted referral.</li> <li>– The delay between the time of the request for services and the referral made.</li> </ul> </li> <li>▶ The issues for supervisory staff (managers, coordinators) will be documented based on their role and their needs for support. They will be questioned on the following four variables:               <ul style="list-style-type: none"> <li>– Management issues surrounding the implementation of this new practice.</li> <li>– The impact of the new practice on the organisation of work.</li> <li>– The shared decision-making process with the client.</li> <li>– Perceived support in the change process.</li> </ul> </li> <li>▶ Professionals and managers will also be questioned on the following two variables:               <ul style="list-style-type: none"> <li>– The treatment of complex situations and the associated issues.</li> <li>– Analysis of the match between the referral made, the targeted programme and the service offer available.</li> </ul> </li> </ul>	<p>For each of the four settings, individual semistructured interviews with (data collection #1):</p> <ul style="list-style-type: none"> <li>▶ 10 users (n=40).</li> <li>▶ 3 professionals (n=12).</li> <li>▶ 3 physicians (n=12).</li> </ul> <p>For each of the four settings, focus groups with three supervisory staff (managers, coordinators) (n=12) (data collection #2):</p> <p>Focus group regarding the treatment of complex situations with 4–5 managers and coordinators (data collection #3):</p> <p>Focus groups in various programme service areas that receive referrals to CIUSSS-CN programmes (data collection #4):</p> <ul style="list-style-type: none"> <li>▶ Group per service area (n=5) of 3–5 professionals and managers (n=15–25).</li> </ul>
Quantitative	<ul style="list-style-type: none"> <li>▶ Performance indicators collected in the four clinics:               <ul style="list-style-type: none"> <li>– The type and no of requests processed by professionals.</li> <li>– The time between the request, the referral and the service received by the user.</li> <li>– The no of users taken in charge in each clinic.</li> <li>– The no of requests refused by the programmes offering the service.</li> </ul> </li> <li>▶ Preimplementation and postimplementation analysis to compare the trajectory of certain profiles.</li> </ul>	<p>Quantitative</p> <ul style="list-style-type: none"> <li>▶ Performance indicator collection log (see variables section) deployed in the four clinics for a period of 3 months.</li> <li>▶ Data bank at CIUSSS-CN.</li> </ul>

The realisation of the study across time is illustrated in figure 2.  
 CIUSSS-CN, Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale.

The qualitative data collected from users, professionals, administrative staff and physicians (eg, user experience, interprofessional collaboration, satisfaction with tools, work organisation) will be analysed using a thematic analysis.<sup>18</sup> The audiotaped individual and focus group interviews will be transcribed and anonymised. A comprehensive summary of each individual and group interview will be prepared; these summaries will be structured according to the interview guide elements and the themes that emerge. The coding will be carried out by the first and the second authors, using the NVivo software, to permit greater interrater reliability. Subsequently, a matrix will be constructed to organise the themes as they emerge; this information will constitute the first level of analysis. Over the course of the investigation, the analysis of the interview data will be regularly discussed with the other researchers. As well, the emerging findings will be presented to the members of the advisory committees. These members' questions and reflections will be used to clarify the analysis of the data. Consistent with the inductive and iterative data analysis process to be used, the data

collection and analysis steps will occur simultaneously; this approach also corresponds with the goal of achieving data saturation. Consistent with qualitative inquiry, we will adhere to several criteria to create authenticity in our investigation, including: inductive data analysis, analysis records (eg, decision trail), audiotaping/verbatim transcription for content, data saturation, peer audit to confirm coherence (using the range of disciplines of the research team: sociology, nursing, rehabilitation, policy analysis), ongoing discussions with the members of the committees, and participants actual quotations to provide thick description of their experience.

A descriptive analysis<sup>27</sup> will be used to analyse the quantitative data. Frequencies (percentages) will be used to summarise the type and number of requests processed by professionals, the number of users taken in charge in each clinic, and the number of requests refused by the programmes offering the service. The time between the request, the referral and the service received by the user will be captured using an average (SD).



**Figure 2** The realisation of the study across time.

### Patient and public involvement

The user-partners played a key role from the very beginning of the project. Their involvement was significant in the preparation and writing of the grant application, which included their participation in several team meetings and participation in the writing of certain sections. The governance of the project has been designed to ensure that user-partners are involved in the decision-making processes, which will allow the project committee to remain responsive to user concerns throughout the implementation of the project.

### ETHICS AND DISSEMINATION

This project respects the ethics, integrity and responsible conduct research standards defined by the Fonds de recherche du Québec and the CIUSSS-CN. It has received ethical approval from the regional health organisation with which the researchers are affiliated (# 2020-1800). Regarding ethical considerations specific to the participants in the individual interviews and focus groups, we specified all their rights in accordance with the rules of the sectoral research ethics committee (CER-S) in population health and primary care (eg, the right of participants to withdraw from the study at any time and to refuse to answer certain questions; the confidentiality obligations of the researchers; the confidentiality obligations of the focus group participants). The results of the investigation will be presented to the stakeholders involved in the advisory committees and at several scientific conferences. Manuscripts will be submitted to peer-reviewed journals.

### DISCUSSION

Few studies have focused on practices to improve access to primary care services, referral mechanisms and

coordination of these services to meet the frequently complex needs of users. Most of them deal with access to specialised services, which are very different contexts.<sup>6</sup> Referral management has been identified as an important element in the process of accessing primary care, and some practices may be more appropriate than others to reduce waiting time, better direct users to appropriate services and simplify navigation between different services.<sup>5 10</sup> This study will make an important contribution to the understanding of the elements involved in transforming access in the specific area of primary care by generating knowledge about both the efficiency of the new practice implemented and the factors that facilitate or hinder clinical and organisational change on this scale. The originality of the approach lies in the attention paid not only to the issues related to the implementation of the clinical practice, but also to the organisational changes required to support this new practice. Such a transformation requires attention to the capacity to adapt organisational structures so that the organisation can offer services that truly meet the priority needs of users. It requires attention to the support mechanisms for professionals and managers, as well as to the conditions for mobilising physicians in this change process, which is a well-documented challenge in the literature on health system transformations<sup>28</sup>.

The implementation of this new practice also calls for greater participation by users in identifying their needs, increased collaboration between different professionals and different departments, as well as greater cooperation with the network of community organisations and other public bodies. The findings generated by this research will help to shed light on the factors that promote or hinder these collaborations, which are recognised as essential dimensions of better quality of care and services and greater efficiency of healthcare systems.<sup>28 29</sup>

Given the difficulties of access to primary care, policy-makers are very interested in evaluating this model and its potential for dissemination in similar settings. The results generated could thus be very important in transforming access to primary care in Quebec and generate learning for other contexts nationally and internationally.

Regarding the potential limitations of our investigation, there is a potential risk of selection bias in choosing the FMGs. We will endeavour to diversify the profile of the clinics as much as possible (eg, the number of physicians, the types of professionals and the client profiles) to maximise the representativeness of the settings chosen. Similarly, these measures could also mitigate the potentially limited transferability of the findings given that the study takes place in a single health and social services network. A potential limitation of the type 2 effectiveness-implementation hybrid study approach concerns the difficulties that can arise if the implementation strategy leads to poor adoption and fidelity, as it can compromise the effectiveness trial field.<sup>16</sup> In our study, the use of Alami *et al's* strategic framework approach, as well as the involvement of multiple actors both in the data collection and the advisory committees, should help to mitigate this limitation. A further potential limitation concerns the absence of preimplantation quantitative data for the four participating clinics; however, the use of data from a database that compiles information on the care trajectories of users who have obtained services from the CIUSSS-C should enable comparable trajectory profiles.

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**Contributors** Substantial contributions to the conception or design of the work (NC, RC, AF, M-PG, MB, AD, EKG, ML, EM, J-PF and IB) or interpretation of data for the work (NC, RC and AF) Drafting the work or revising it critically for important

intellectual content (NC, RC, AF, M-PG, MB, AD, EKG, ML, EM, J-PF and IB) Final approval of the version to be published (NC, RC, AF, M-PG, MB, AD, EKG, ML, EM, J-PF and IB); Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (NC, RC, AF, M-PG, MB, AD, EKG, ML, EM, J-PF and IB).

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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