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Implementation of a new clinical and organizational practice to improve access to primary care services: A protocol for an implementation evaluation

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Abstract

Introduction: In Canada, as in most Organisation for Economic Co-operation and Development (OECD) countries, health care systems face significant challenges in ensuring better access to primary care. A regional healthcare organization in Quebec (Canada) serving a population of approximately 755,459 citizens has implemented a standardized access approach to primary care services for this population. The objective of this new clinical and organizational 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 characterize the conditions of implementation of this practice.

Methods: This investigation uses an embedded single-case study, defined in this case as the process of implementing a clinical and organizational practice within a healthcare organization. Based on 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 pre- and post-implementation analysis based on performance indicators will be conducted. This study is ultimately situated within a participatory organizational 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).

Keywords: Access to primary care, interprofessional collaboration, shared decision, navigation between care and services, continuum of care and services, complex health innovation in the delivery and organization of care and services.

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Strengths and limitations of this study:

1. The collection of qualitative and quantitative data from a range of organizational stakeholders will contribute to a better understanding of the factors that promote or impede the implementation of the clinical and organizational practice.
2. As this practice mobilizes a multitude of intra- and inter-service actors, this study will make it possible to document the issues regarding inter-professional and inter-service collaboration related to its implementation.
3. Although the results of this study are based on a case study within one health and social services network, the lessons learned from this study may be transferable to other organizations.

Introduction

Context of the study

In most Organisation for Economic Co-operation and Development (OECD) countries, health systems are under considerable pressure to adapt their services to sociodemographic changes, such as an aging population, and high prevalence of chronic diseases and mental health problems[1]. 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 hospitalized [2 3]. In Canada, access to many health care and 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 [4 5]. Few studies have examined the factors that lead to improved access to primary care, with most focusing on access to specialty services [6].

One of the determining elements of access concerns the process of directing users to the right services according to their needs [7]. Studies have shown that certain methods of managing referrals to different services can reduce waiting times and have various positive effects [7 8]. Indeed, the quality of referrals is an important element [9]. Imison and Naylor's (2010) 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 [9]. Other studies emphasize the value of using guidelines and referral forms, which have the greatest potential for reducing costs and improving efficiency in the delivery of services [9 10]. Furthermore, the process of referral to the most relevant resources according to users' needs could be greatly improved using multidisciplinary teams [11]. Finally, the adoption of a patient-centred approach is one of important measures identified to reduce waiting times [10-12].

A pan-Canadian public consultation with users and health care professionals revealed major flaws in the referral process [13]. Many professionals complain that they must deal with multiple entry points that operate in different ways, that they refer users to programs that often have very long waiting lists, and that they are not informed about what happens to the user once they are referred [13]. 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 [13].

In the province of Quebec (Canada), a vast reform was undertaken in 2015 of the structure of the entire health and social services network with the intent of ensuring greater efficiency and effectiveness [14]. In this reform, 182 general and specialized institutions offering youth, community, hospital, long-term care and public health services were merged into 34 large organizations called Centres intégrés de santé et de services sociaux (CISSS) 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 [14].

This lack of standardization 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 [12]. 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 has conducted an in-depth review of its access mechanisms to standardize 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 (e.g., 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 [e.g., telephone centre, hospital emergency room, family medicine group (FMG)]. The objective of standardizing 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 specialized team at CIUSSS-CN, called the *Access Team*.

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

The referral orientation is based on a standardized 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 [15]. The priority needs analysis is carried out using a template that makes it possible to synthesize the essential data collected concerning the user's priority needs (e.g., parental support, anxiety, home service organizations), to analyze 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 professional expertise. These professionals can support the professional responsible for the orientation in identifying the user's priority needs and in choosing the appropriate orientation.

This standardized 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 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 organizations to ensure better fluidity in the continuum of care for the user. At another level, the deployment of this new practice relies on major organizational 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 programs to be able to respond to the more individualized needs of users, an important challenge in such complex and centralized organizations.

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 organizational 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 characterize the conditions for implementing this new practice in the FMGs. The specific objectives include:

1. Describe the organizational context in which the new practice is being deployed and specifically the challenges related to the adaptation of organizational 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

Real-world research-evaluation is proposed using a 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[16]. They are particularly appropriate when implementing innovative approaches [17]. They aim to collect the necessary quantitative and qualitative data required for evaluation [18]. Based on the *Strategic framework for useful and used evaluation* proposed by Fortin and colleagues [19], this approach consists of accompanying the main actors involved in the implementation of an organizational 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 [19]. It makes it possible to consider all the strategic and governance aspects as well as the socio-political, economic, organizational, 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 (e.g., perceived benefits for and by users and their families, professionals, and clinicians), while ensuring that the lessons learned 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 operationalized in our study as the implementation of a novel clinical and organizational practice in four medical clinics, that is, two family medicine groups (FMGs), one university family medicine group (U-FMG) and one network family medicine group (R-FMG)[2] in the CIUSSS-CN territory. As defined by Yin [20], 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 multi-level and multi-actor governance and organizational 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 [20 21].

With respect to evaluation, two approaches will be used: the comprehensive approach, to consider all the facts and challenges relating to the project [22 23]; and the participatory and pluralist approach, to include the perspectives of the various actors, partners and stakeholders concerned by the project [24 25]. 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 (e.g., a restricted working committee for the operationalization 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 co-construction, 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 [26].

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 organization.

[2] A family medicine group (FMG) is a group of primary care family physicians who work closely with other health professionals (social workers, nurses, etc.). An academic family medicine group (U-FMG) is an FMG that is distinguished by its academic recognition in teaching. A network family medicine group (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.

Based on the lessons learned from this evaluation, the new practice will be deployed in the four FMG clinics, which have distinct characteristics with respect to their organization and mission (e.g., 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[3], 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 programs providing the services to examine the fit between the referral made, the program 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 pre- and post-implementation analysis will be performed. Since pre-implementation data do not exist for the four participating clinics, the post-implementation data will be compared to pre-implementation 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 pre- and post-implementation 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 [27]. 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 organizational practice.

The qualitative data collected from users, professionals, administrative staff, and physicians will be analysed using a thematic analysis [28] (e.g., user experience, interprofessional collaboration, satisfaction with tools, work organization). A descriptive analysis [29] will be used to analyse the quantitative data.

Table 1: Study variables by phase of the evaluative study

APPROACH	Variables	Collection Methods
Qualitative	1. 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 6 variables: • The deployment and appropriation of the new practice;	**For each of the 4 settings, individual semi-structured interviews with:** • 10 users (n=40). • 3 professionals (n=12). • 3 physicians (n=12).

[3] For phase 2, the administrative officers will not be met since they are not involved in the referral process unlike the Access Team.

	• The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process; • Intra- and inter-professional, inter-service and inter-organizational collaboration; • Follow-up with the referent following the referral. 2. The issues for **users** will be documented based on their perceptions and satisfaction. They will be questioned on the following 4 variables: • The identification of their priority needs; • The shared decision-making process and comfort in making decisions; • Targeted referral; • The delay between the time of the request for services and the referral made. 3. 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 4 variables: • Management issues surrounding the implementation of this new practice; • The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process. 4. **Professionals and managers** will also be questioned on the following 2 variables: • The treatment of complex situations and the associated issues; • Analysis of the match between the referral made, the targeted program and the service offer available.	**For each of the 4 settings, focus groups with 3 supervisory staff (managers, coordinators) (n=12).** **Focus group regarding the treatment of complex situations with 4-5 managers and coordinators** **Focus groups in various programme service areas that receive referrals to CIUSSS-CN programs** • Group per service area (n=5) of 3-5 professionals and managers (n=15-25).
Quantitative	1. Performance indicators collected in the 4 clinics: • The type and number of requests processed by professionals; • The time between the request, the referral and the service received by the user; • The number of users taken in charge in each clinic; • The number of requests refused by the programs offering the service. 2. Analysis of the match between the referral made, the targeted program and the service offer available. 3. Pre and post implementation analysis to compare the trajectory of certain profiles.	**QUANTITATIVE:** • Performance indicator collection log (see variables section) deployed in the 4 clinics for a period of 3 months. • Data bank at CIUSSS-CN

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 (FRQS) and the CIUSSS de la Capitale-Nationale. It has received ethical approval from the regional health organization 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 (e.g., 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).

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 specialized services, which are very different contexts [6]. 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 [5-10]. 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 organizational 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 organizational changes required to support this new practice. Such a transformation requires attention to the capacity to adapt organizational structures so that the organization 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 mobilizing physicians in this change process, which is a well-documented challenge in the literature on health system transformations [30].

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 organizations 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 recognized as essential dimensions of better quality of care and services and greater efficiency of the health care systems [30-31].

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.

List of abbreviations

- CIUSSS: Centre intégré universitaire de santé et des services sociaux
- FQRS: Fonds de recherche en santé du Québec
- FMG: family medicine group
- U-FMG: university family medicine group
- R-FMG: family medicine network group

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4. Université de Sherbrooke
5. University of Ottawa
6. FRQS scholarship researcher

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Contributors

All authors reviewed and approved this manuscript.

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The principal investigator is a FRQS fellow.

Competing interests

None declared.

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Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale
Québec

Québec, le 10 juillet 2019

Madame Nancy Côté
Chercheure
Centre de recherche sur les soins et les services de première ligne de l'Université Laval

Objet : Approbation finale
Projet # 2020-1800, 2020-1800_SPPL, intitulé: «Orienter efficacement l'usager dans le continuum de soins et de services dans le cadre de l'accès intégré et harmonisé aux services de proximité. ».

Madame,

Le Comité d'éthique de la recherche sectoriel Santé des populations et première ligne du CIUSSS de la Capitale-Nationale a fait l'examen des corrections qui lui ont été soumises concernant le projet cité en titre, en comitéplénier, lors de sa réunion du 14 mai 2019.

Les documents suivants ont été présentés aux fins d'évaluation du dossier:

- F20 - **4330**, Réponses aux conditions du CER

- Ventilation du budget (Budget.pdf) [date : 17 avril 2019]
- Rapport d'évaluation CES (Rapport évaluation.pdf)
- Protocole de recherche (Protocole VF.pdf) [date : 18 décembre 2018]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Usagers VF.pdf) [date : 17 avril 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Professionnels VF.pdf) [date : 17 avril 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Médecins VF.pdf) [date : 17 avril 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Gestionnaires VF.pdf) [date : 17 avril 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS- Groupe de discussion VF.pdf) [date : 17 avril 2019]
- Outils d'évaluation et questionnaires (Schéma d'usagers VF.pdf) [date : 17 avril 2019]
- Outils d'évaluation et questionnaires (Schéma d'entrevue professionnels VF.pdf) [date : 17 avril 2019]
- Outils d'évaluation et questionnaires (Schéma d'entrevue médecins VF.pdf) [date : 17 avril 2019]
- Outils d'évaluation et questionnaires (Schéma d'entrevue gestionnaires VF.pdf) [date : 17 avril 2019]
- Outils d'évaluation et questionnaires (Schéma de groupe VF.pdf) [date : 17 avril 2019]
- Autres documents remis aux participants (Recrutement PATIENTS ACCÈS V1.pdf) [date : 17 avril 2019]

- Autres documents remis aux participants (Recrutement-Flyers PATIENTS ACCÈS V1.pdf) [date : 17 avril 2019]
- Autres documents (Formulaire d'engagement à la confidentialité VF.pdf)
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Usagers VF.docx) [date : 28 mai 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Professionnels VF.docx) [date : 28 mai 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Médecins VF.docx) [date : 28 mai 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS- Groupe de discussion VF.docx) [date : 28 mai 2019]
- Formulaire d'information et de consentement (Formulaire de consentement ACCÈS-Gestionnaires VF.docx) [date : 28 mai 2019]

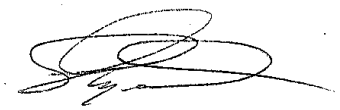
Ainsi, je vous informe que le résultat de l'examen éthique et scientifique de ce projet de recherche est positif et que le comité d'éthique approuve le projet #2020-1800, 2020-1800_SPPL jusqu'au 10 juillet 2020, ainsi que les documents ci-haut mentionnés.

Cependant, le comité d'éthique tient à s'entretenir avec vous lors de votre retour de l'Angleterre sur le conflit de rôle potentiel de l'usager-partenaire impliqué dans votre recherche.

Je vous rappelle qu'il est important de toujours utiliser la dernière version approuvée du formulaire d'information et de consentement. Le formulaire d'information et de consentement portant les signatures originales doit être conservé dans les dossiers du chercheur et une copie remise au participant.

Je vous souhaite un bon succès dans la réalisation de ce projet.

Je vous prie de recevoir, Madame, l'expression de mes sentiments les meilleurs.



Jean Maziade
Médecin
Président CÉR-S santé des populations et première ligne
CIUSSS de la Capitale-Nationale

Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale
Québec

Formulaire de demande de renouvellement de l'approbation d'un projet de recherche ou d'une banque

Titre du protocole : **Orienter efficacement l'usager dans le continuum de soins et de services par le soutien d'une pratique collaborative impliquant les usagers, les GMF/GMF-U/GMF-R et les professionnels dans le cadre de l'accès intégré et harmonisé aux services de proximité.**

Chercheur principal (au CER Éval) : **Nancy Cote**

Date de dépôt initial du formulaire : **2021-05-17 13:52**

Déposé par : **Chouinard, Rebecca**

Date d'approbation du projet par le CER : **2019-07-10**

Identifiant Nagano : **rchouinard**

Numéro(s) de projet : **MP-13-2020-1800, 2020-1800_SPPL**

Formulaire : **F9-8109**

Statut du formulaire : **Approuvé**

Suivi du BCER

1. **Statut de la demande**
   Demande approuvée

Renseignements généraux

1. **Votre demande concerne quel type de projet?**
   Un projet de recherche avec participants

2. **Indiquez le titre du projet en français.**

   Orienter efficacement l'usager dans le continuum de soins et de services par le soutien d'une pratique collaborative impliquant les usagers, les GMF/GMF-U/GMF-R et les professionnels dans le cadre de l'accès intégré et harmonisé aux services de proximité.

3. **Indiquez le nom du chercheur responsable au CIUSSS-CN**

   Cote, Nancy

4. **Ce projet est-il réalisé par un étudiant dans le cadre de ses études?**
   Non

5. **Veuillez indiquer le nom du superviseur ou directeur du projet de recherche étudiant.**

6. **Votre projet de recherche est-il relié à un fond SIRUL (Système d'information de la recherche de l'Université Laval) qui doit être renouvelé par le Comité d'éthique de la recherche du CIUSSS de la Capitale-Nationale ?**

Non

7. **Votre projet nécessite-t-il que l'autorisation d'accès aux dossiers émise par la direction des services professionnels (DSP) soit renouvelée ?**

Non

Projet de recherche avec participants

1. **Votre projet est-il multicentrique**

Oui

Nom de l'établissement et le nombre de participants recrutés depuis le début du projet

CIUSSS de la Capitale-Nationale et 36 participants

2. **Indiquez le statut actuel du projet de recherche:**

Projet interrompu ou en attente

Donnez-en la raison:

La crise sanitaire qui prévaut actuellement ne nous permet pas de démarrer la phase 2 du projet.

3. **Informations relatives aux participants:**

Nombre de participants prévus:

146

Nombre de participants recrutés depuis le début (si ce nombre est supérieur ou si vous prévoyez que le nombre soit plus élevé que ce qui est prévu dans le protocole, veuillez compléter une demande d'amendement):

36

Nombre de participants exclus ou ayant retiré leur consentement (après la signature du formulaire de consentement, avoir donné un consentement verbal ou en ligne) depuis le début du projet:

0

Raisons des exclusions ou des abandons:

- ☐ Retrait du consentement
- ☐ Critères d'inclusion/exclusion
- ☐ Effets secondaires
- ☐ Autres

4. **Au cours de la dernière année:**

Y a–t–il eu des modifications apportées au protocole qui n'ont pas été soumises au CÉR?

Non

Y a-t-il eu une situation de conflit d'intérêt (apparent, éventuel ou réel) touchant un ou plusieurs membres de l'équipe de recherche et non divulguée au moment du dépôt du projet?

Non

Le projet a–t–il posé des problèmes ou soulevé des difficultés sur le plan éthique qui n'ont pas été portés à la connaissance du CÉR?

Non

Les mesures prises pour garantir la confidentialité des informations ont-elles toujours été conformes au protocole approuvé par le CÉR?

Oui

Veuillez résumer les activités du projet au cours de la dernière année. (Le projet s'est-il déroulé comme prévu au protocole? Quel fut le nombre de dossiers consultés vs le nombre prévu initialement? Idem pour les échantillons ou les données de la banque.)

Selon le protocole, la phase 2 du projet aurait dû être amorcée en juillet 2020. En raison du contexte lié à la COVID-19, il fut impossible de procéder à sa réalisation. Les restrictions sanitaires et le délestage important des professionnels concernés par cette deuxième phase nous contraignent encore actuellement à l'incertitude quant au moment précis de sa réalisation. En fonction de l'évolution de la crise sanitaire, nous ferons le point avec les quatre GMF participants au mois de septembre prochain.

Dans l'intervalle, la phase 1 a pu être complétée. Nous avons terminé notre rapport préliminaire des résultats pour la phase 1 en janvier 2021.

Voulez–vous porter un autre élément à l'attention du CÉR?

Non

Dépôt de fichiers

1. **Veuillez joindre ici tout autre document jugé pertinent.**

Signature

1. **J'atteste que les renseignements fournis dans le présent formulaire sont exacts ou au meilleur de mes connaissances.**

Rebecca Chouinard

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	**As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.**
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	p.1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	p.1

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	p.2
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.2-3
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.4
6. Specific aims	Purpose of the project and of this report	p.4
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.4
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.5-7 b) p.5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	P. 5-6
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	p.5-7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	p.7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.8

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	Not appropriate; protocol article
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a) N/A b) p.2
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	N/A (protocol article)
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	p.2
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	Discussion, p.8-9
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.10

BMJ Open

Implementation of a new clinical and organizational practice to improve access to primary care services: A protocol for an effectiveness-implementation hybrid study

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Title page

Implementation of a new clinical and organizational practice to improve access to primary care services: A protocol for an effectiveness-implementation hybrid study

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Word count: 3929

Abstract

Introduction: In Canada, as in most Organisation for Economic Co-operation and Development (OECD) countries, health care systems face significant challenges in ensuring better access to primary care. A regional healthcare organization in Quebec (Canada) serving a population of approximately 755,459 citizens has implemented a standardized access approach to primary care services for this population. The objective of this new clinical and organizational 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 characterize 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 organizational practice within a healthcare organization. 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 pre- and post-implementation analysis based on performance indicators will be conducted. This study is ultimately situated within a participatory organizational 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).

Strengths and limitations of this study:

1. This study will document the issues associated with the complexity of organizational structures and work processes, given the mobilization of a multitude of intra- and inter-service actors, that are related to the practice's implementation.
2. The collection of qualitative and quantitative data from a range of organizational stakeholders will contribute to a better understanding of the factors that promote or impede the implementation of the clinical and organizational practice.
3. 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 limits of the Type 2 effectiveness-implementation hybrid study (e.g., poor adoption and fidelity of the implementation strategy).
4. 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 (OECD) countries, health systems are under considerable pressure to adapt their services to sociodemographic changes, such as an aging population, and high prevalence of chronic diseases and mental health problems[1]. 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 hospitalized [2 3]. In Canada, access to many health care 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 [4 5]. Few studies have examined the factors that lead to improved access to primary care, with most focusing on access to specialty services [6].

One of the determining elements of access concerns the process of directing users to the right services according to their needs [7]. Studies have shown that certain methods of managing referrals to different services can reduce waiting times and have various positive effects [7 8]. Indeed, the quality of referrals is an important element [9]. Imison and Naylor's (2010) 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 [9]. Other studies emphasize the value of using guidelines and referral forms, which have the greatest potential for reducing costs and improving efficiency in the delivery of services [9 10]. Furthermore, the process of referral to the most relevant resources according to users' needs could be greatly improved using multidisciplinary teams [11]. Finally, the adoption of a patient-centred approach is one of the important measures identified to reduce waiting times [10-12].

A pan-Canadian public consultation with users and health care professionals revealed major flaws in the referral process [13]. Many professionals complained that they must deal with multiple entry points that operate in different ways, that they refer users to programs that often have very long waiting lists, and that they are not informed about what happens to the user once they are referred [13]. 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 [13].

In the province of Quebec (Canada), a vast reform was undertaken in 2015 of the the entire health and social services network structure with the intent of ensuring greater efficiency and effectiveness [14]. In this reform, 182 general and specialized institutions offering youth, community, hospital, long-term care and public health services were merged into 34 large organizations called Centres intégrés de santé et de services sociaux (CISSS) 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 [14].

This lack of standardization 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 [12]. 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 standardize 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 (e.g., 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 [e.g., te 811 provincial non-urgent health problem call number, hospital emergency department, family medicine group (FMG)]. The objective of standardizing 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 specialized 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 programs (e.g., mental health assistance program, support program for the elderly). Its function is to process requests from physicians, particularly those practicing in the FMGs, and from various external partners (e.g., community organizations, schools, city).

The referral orientation is based on a standardized 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 [15]. The priority needs analysis is carried out using a template that makes it possible to synthesize the essential data collected concerning the user's priority needs (e.g., parental support, anxiety, home service organizations), to analyze 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.

This standardized 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 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 organizations to ensure better fluidity in the continuum of care for the user. Second, the deployment of this new practice relies on major organizational 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 programs to be able to respond to the more individualized needs of users, an important challenge in such complex and centralized organizations. 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 organizational practice in one of the network's major gateways, the FMGs.

Insert Figure 1 here

Figure 1: The referral process

Purpose of the study

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

1. Describe the organizational context in which the new practice is being deployed and specifically the challenges related to the adaptation of organizational 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 limits of this approach is the significant time lag between the development of the interventions and its implementation in the field [16]. 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[16]. 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 mobilizes 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[17]. They are particularly appropriate when implementing innovative approaches [18]. They aim to collect the necessary quantitative and qualitative data required for evaluation [19]. Based on the *Strategic framework for useful and used evaluation* proposed by Alami and colleagues [20], this approach consists of accompanying the main actors involved in the implementation of an organizational 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 [20]. It makes it possible to consider all the strategic and governance aspects as well as the socio-political, economic, organizational, 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 (e.g., perceived benefits for and by users and their families, professionals, and clinicians), while ensuring that the lessons learned 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 operationalized in our study as the implementation of a novel clinical and organizational practice in four medical clinics, that is, two family medicine groups (FMGs), one university family medicine group (U-FMG) and one network family medicine group (R-FMG)[1] in the CIUSSS-CN territory. As defined by Yin [21], 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 multi-level and multi-actor governance and organizational 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 [21 22].

With respect to evaluation, two approaches will be used: the comprehensive approach, to consider all the facts and challenges relating to the project [23 24]; and the participatory and pluralist approach, to include the perspectives of the various actors, partners and stakeholders concerned by the project [25 26]. 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 (e.g., a restricted working committee for the operationalization 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 co-construction, 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 [27].

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 organization. Based on the lessons learned from this evaluation, the new practice will be deployed in the four FMG clinics, which have distinct characteristics with respect to their organization and mission (e.g., teaching component, expanded drop-in appointment availability, interprofessional work model). An evaluation process will be carried out during implementation and will

[1] A family medicine group (FMG) is a group of primary care family physicians who work closely with other health professionals (social workers, nurses, etc.). An academic family medicine group (U-FMG) is an FMG that is distinguished by its academic recognition in teaching. A network family medicine group (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.

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[2], 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 programs providing the services to examine the fit between the referral made, the program 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 pre- and post-implementation analysis will be performed. Since pre-implementation data do not exist for the four participating clinics, the post-implementation data will be compared to pre-implementation 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 pre- and post-implementation 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 [28]. 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 organizational practice. The diversity of the participants will be sought in relation to these criteria, albeit 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 organization for their support.

The qualitative data collected from users, professionals, administrative staff, and physicians (e.g., user experience, interprofessional collaboration, satisfaction with tools, work organization) will be analysed using a thematic analysis [29]. The audio-taped individual and focus group interviews will be transcribed and anonymized. 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

[2] For phase 2, the administrative officers will not be met since they are not involved in the referral process unlike the Access Team.

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 (e.g., decision trail), audio taping/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 [30] 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 programs offering the service. The time between the request, the referral and the service received by the user will be captured using an average (standard deviation).

Table 1: Study variables by phase of the evaluative study

APPROACH	Variables	Collection Methods
Qualitative	1. 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 6 variables: • The deployment and appropriation of the new practice; • The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process; • Intra- and inter-professional, inter-service and inter-organizational collaboration; • Follow-up with the referent following the referral. 2. The issues for **users** will be documented based on their perceptions and satisfaction. They will be questioned on the following 4 variables: • The identification of their priority needs; • The shared decision-making process and comfort in making decisions; • Targeted referral; • The delay between the time of the request for services and the referral made. 3. 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 4 variables: • Management issues surrounding the implementation of this new practice; • The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process. 4. **Professionals and managers** will also be questioned on the following 2 variables: • The treatment of complex situations and the associated issues; • Analysis of the match between the referral made, the targeted program and the service offer available.	**For each of the 4 settings, individual semi-structured interviews with (data collection #1):** • 10 users (n=40). • 3 professionals (n=12). • 3 physicians (n=12). **For each of the 4 settings, focus groups with 3 supervisory staff (managers, coordinators) (n=12) (data collection #2):** **Focus group regarding the treatment of complex situations with 4-5 managers and coordinators (data collection 3#):** **Focus groups in various programme service areas that receive referrals to CIUSSS-CN programs (data collection #4):** • Group per service area (n=5) of 3-5 professionals and managers (n=15-25).

Quantitative	1. Performance indicators collected in the 4 clinics: • The type and number of requests processed by professionals; • The time between the request, the referral and the service received by the user; • The number of users taken in charge in each clinic; • The number of requests refused by the programs offering the service. 2. Pre and post implementation analysis to compare the trajectory of certain profiles.	**QUANTITATIVE:** • Performance indicator collection log (see variables section) deployed in the 4 clinics for a period of 3 months • Data bank at CIUSSS-CN

The realisation of the study across time is illustrated in Figure 2.

Insert Figure 2 here

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 (FRQS) and the CIUSSS de la Capitale-Nationale. It has received ethical approval from the regional health organization 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 (e.g., 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).

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 specialized services, which are very different contexts [6]. 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 [5-10]. 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 organizational 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 organizational changes required to support this new practice. Such a transformation requires attention to the capacity to adapt organizational structures so that the organization 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 mobilizing physicians in this change process, which is a well-documented challenge in the literature on health system transformations [31].

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 organizations 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 recognized as essential dimensions of better quality of care and services and greater efficiency of the health care systems [31-32].

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 limits 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 (e.g., 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 limit 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 [16]. In our study, the use of Alami and colleagues' 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 limit. A further potential limit concerns the absence of pre-implantation 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.

List of abbreviations

- CIUSSS: Centre intégré universitaire de santé et des services sociaux
- FQRS: Fonds de recherche en santé du Québec
- FMG: family medicine group
- U-FMG: university family medicine group
- R-FMG: family medicine network group

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Contributors

- Substantial contributions to the conception or design of the work (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault) or interpretation of data for the work (Nancy Côté, Rébecca Chouinard, Andrew Freeman)
- Drafting the work or revising it critically for important intellectual content (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault)
- Final approval of the version to be published (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault);
- 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 (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault).

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Competing interests

None declared.

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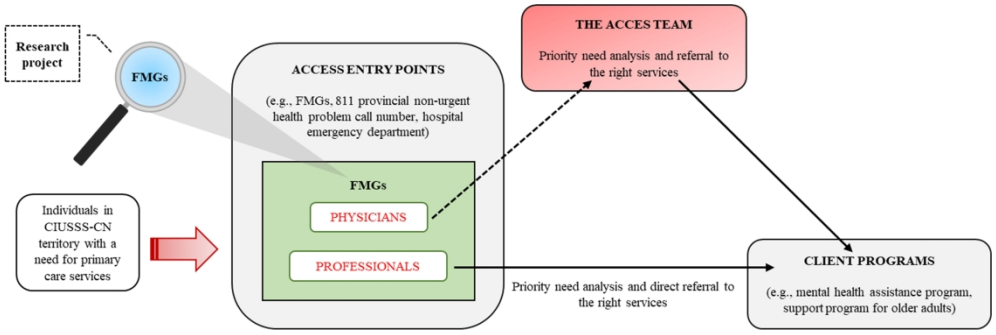

Figure 1: The referral process

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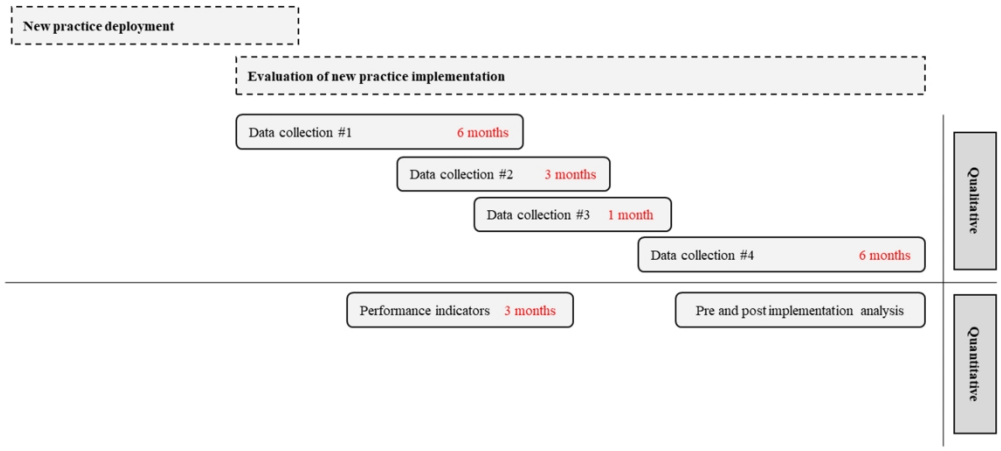

Figure 2: The realisation of the study across time

285x129mm (600 x 600 DPI)

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	**As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.**
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	p.1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	p.1

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	p.2
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.2-3
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.4
6. Specific aims	Purpose of the project and of this report	p.4
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.4
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.5-7 b) p.5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	P. 5-6
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	p.5-7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	p.7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.8

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	Not appropriate; protocol article
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a) N/A b) p.2
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	N/A (protocol article)
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	p.2
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	Discussion, p.8-9
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.10

BMJ Open

Implementation of a new clinical and organizational practice to improve access to primary care services: A protocol for an effectiveness-implementation hybrid study

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Title page

Implementation of a new clinical and organizational 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 (OECD) countries, health care systems face significant challenges in ensuring better access to primary care. A regional healthcare organization in Quebec (Canada) serving a population of approximately 755,459 citizens has implemented a standardized access approach to primary care services for this population. The objective of this new clinical and organizational 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 characterize 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 organizational practice within a healthcare organization. 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 pre- and post-implementation analysis based on performance indicators will be conducted. This study is ultimately situated within a participatory organizational 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:

1. This study will document the issues associated with the complexity of organizational structures and work processes, given the mobilization of a multitude of intra- and inter-service actors, that are related to the practice's implementation.
2. The collection of qualitative and quantitative data from a range of organizational stakeholders will contribute to a better understanding of the factors that promote or impede the implementation of the clinical and organizational practice.
3. 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 (e.g., poor adoption and fidelity of the implementation strategy).
4. 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 (OECD) countries, health systems are under considerable pressure to adapt their services to sociodemographic changes, such as an aging population, and high prevalence of chronic diseases and mental health problems[1]. 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 hospitalized [2 3]. In Canada, access to many health care 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 [4 5]. Few studies have examined the factors that lead to improved access to primary care, with most focusing on access to specialty services [6].

One of the determining elements of access concerns the process of directing users to the right services according to their needs [7]. Studies have shown that certain methods of managing referrals to different services can reduce waiting times and have various positive effects [7 8]. Indeed, the quality of referrals is an important element [9]. Imison and Naylor's (2010) 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 [9]. Other studies emphasize the value of using guidelines and referral forms, which have the greatest potential for reducing costs and improving efficiency in the delivery of services [9 10]. Furthermore, the process of referral to the most relevant resources according to users' needs could be greatly improved using multidisciplinary teams [11]. Finally, the adoption of a patient-centred approach is one of the important measures identified to reduce waiting times [10-12].

A pan-Canadian public consultation with users and health care professionals revealed major flaws in the referral process [13]. Many professionals complained that they must deal with multiple entry points that operate in different ways, that they refer users to programs that often have very long waiting lists, and that they are not informed about what happens to the user once they are referred [13]. 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 [13].

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 [14]. In this reform, 182 general and specialized institutions offering youth, community, hospital, long-term care and public health services were merged into 34 large organizations called Centres intégrés de santé et de services sociaux (CISSS) 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 [14].

This lack of standardization 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 [12]. 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 standardize 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 (e.g., 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 [e.g., te 811 provincial non-urgent health problem call number, hospital emergency department, family medicine group (FMG)]. The objective of standardizing 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 specialized 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 programs (e.g., mental health assistance program, support program for the elderly). Its function is to process requests from physicians, particularly those practicing in the FMGs, and from various external partners (e.g., community organizations, schools, city).

The referral orientation is based on a standardized 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 [15]. The priority needs analysis is carried out using a template that makes it possible to synthesize the essential data collected concerning the user's priority needs (e.g., parental support, anxiety, home service organizations), to analyze 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 standardized 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 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 organizations to ensure better fluidity in the continuum of care for the user. Second, the deployment of this new practice relies on major organizational 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 programs to be able to respond to the more individualized needs of users, an important challenge in such complex and centralized organizations. 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 organizational practice in one of the network's major gateways, the FMGs.

Insert Figure 1 here

Figure 1: The referral process

Purpose of the study

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

1. Describe the organizational context in which the new practice is being deployed and specifically the challenges related to the adaptation of organizational 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 [16]. 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[16]. 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 mobilizes 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[17]. They are particularly appropriate when implementing innovative approaches [18]. They aim to collect the necessary quantitative and qualitative data required for evaluation [19]. Based on the *Strategic framework for useful and used evaluation* proposed by Alami and colleagues [20], this approach consists of accompanying the main actors involved in the implementation of an organizational 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 [20]. It makes it possible to consider all the strategic and governance aspects as well as the socio-political, economic, organizational, 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 (e.g., perceived benefits for and by users and their families, professionals, and clinicians), while ensuring that the lessons learned 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 operationalized in our study as the implementation of a novel clinical and organizational practice in four medical clinics, that is, two family medicine groups (FMGs), one university family medicine group (U-FMG) and one network family medicine group (R-FMG)[1] in the CIUSSS-CN territory. As defined by Yin [21], 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 multi-level and multi-actor governance and organizational 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 [21 22].

With respect to evaluation, two approaches will be used: the comprehensive approach, to consider all the facts and challenges relating to the project [23 24]; and the participatory and pluralist approach, to include the perspectives of the various actors, partners and stakeholders concerned by the project [25 26]. 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 (e.g., a restricted working committee for the operationalization 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 co-construction, 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 [27].

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 organization. Based on the lessons learned from this evaluation, the new practice will be deployed in the four FMG clinics, which have distinct characteristics with respect to their organization and mission (e.g., teaching component, expanded drop-in appointment availability,

[1] A family medicine group (FMG) is a group of primary care family physicians who work closely with other health professionals (social workers, nurses, etc.). An academic family medicine group (U-FMG) is an FMG that is distinguished by its academic recognition in teaching. A network family medicine group (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.

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[2], 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 programs providing the services to examine the fit between the referral made, the program 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 pre- and post-implementation analysis will be performed. Since pre-implementation data do not exist for the four participating clinics, the post-implementation data will be compared to pre-implementation 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 pre- and post-implementation 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 [28]. 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 organizational practice. The diversity of the participants will be sought in relation to these criteria, albeit 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 organization for their support.

The qualitative data collected from users, professionals, administrative staff, and physicians (e.g., user experience, interprofessional collaboration, satisfaction with tools, work organization) will be analysed using a thematic analysis [29]. The audio-taped individual and focus group interviews will be transcribed and anonymized. 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

[2] For phase 2, the administrative officers will not be met since they are not involved in the referral process unlike the Access Team.

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 (e.g., decision trail), audio taping/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 [30] 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 programs offering the service. The time between the request, the referral and the service received by the user will be captured using an average (standard deviation).

Table 1: Study variables by phase of the evaluative study

APPROACH	Variables	Collection Methods
Qualitative	1. 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 6 variables: • The deployment and appropriation of the new practice; • The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process; • Intra- and inter-professional, inter-service and inter-organizational collaboration; • Follow-up with the referent following the referral. 2. The issues for **users** will be documented based on their perceptions and satisfaction. They will be questioned on the following 4 variables: • The identification of their priority needs; • The shared decision-making process and comfort in making decisions; • Targeted referral; • The delay between the time of the request for services and the referral made. 3. 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 4 variables: • Management issues surrounding the implementation of this new practice; • The impact of the new practice on the organization of work; • The shared decision-making process with the client; • Perceived support in the change process. 4. **Professionals and managers** will also be questioned on the following 2 variables: • The treatment of complex situations and the associated issues;	**For each of the 4 settings, individual semi-structured interviews with (data collection #1):** • 10 users (n=40). • 3 professionals (n=12). • 3 physicians (n=12). **For each of the 4 settings, focus groups with 3 supervisory staff (managers, coordinators) (n=12) (data collection #2):** **Focus group regarding the treatment of complex situations with 4-5 managers and coordinators (data collection 3#):** **Focus groups in various programme service areas that receive referrals to CIUSSS-CN programs (data collection #4):** • Group per service area (n=5) of 3-5 professionals and managers (n=15-25).

	• Analysis of the match between the referral made, the targeted program and the service offer available.	
Quantitative	1. Performance indicators collected in the 4 clinics: • The type and number of requests processed by professionals; • The time between the request, the referral and the service received by the user; • The number of users taken in charge in each clinic; • The number of requests refused by the programs offering the service. 2. Pre and post implementation analysis to compare the trajectory of certain profiles.	**QUANTITATIVE:** • Performance indicator collection log (see variables section) deployed in the 4 clinics for a period of 3 months • Data bank at CIUSSS-CN

The realisation of the study across time is illustrated in Figure 2.

Insert Figure 2 here

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 (FRQS) and the CIUSSS de la Capitale-Nationale. It has received ethical approval from the regional health organization 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 (e.g., 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 specialized services, which are very different contexts [6]. 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 [5-10]. 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 organizational 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 organizational changes required to support this new practice. Such a transformation requires attention to the capacity to adapt organizational structures so that the organization 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 mobilizing physicians in this change process, which is a well-documented challenge in the literature on health system transformations [31].

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 organizations 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 recognized as essential dimensions of better quality of care and services and greater efficiency of health care systems [31-32].

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 (e.g., 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 [16]. In our study, the use of Alami and colleagues' 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 pre-implantation 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.

List of abbreviations

- CIUSSS: Centre intégré universitaire de santé et des services sociaux
- FQRS: Fonds de recherche en santé du Québec
- FMG: family medicine group
- U-FMG: university family medicine group
- R-FMG: family medicine network group

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Contributors

- Substantial contributions to the conception or design of the work (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault) or interpretation of data for the work (Nancy Côté, Rébecca Chouinard, Andrew Freeman)
- Drafting the work or revising it critically for important intellectual content (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault)
- Final approval of the version to be published (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault);
- 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 (Nancy Côté, Rébecca Chouinard, Andrew Freeman, Marie-Pierre, Gagnon, Mylaine Breton, Arnaud Duhoux, El Kebir Ghandour, Maude Laberge, Elisabeth Martin, Jean-Paul Fortin, Ivy Bourgeault).

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Competing interests

None declared.

Open access

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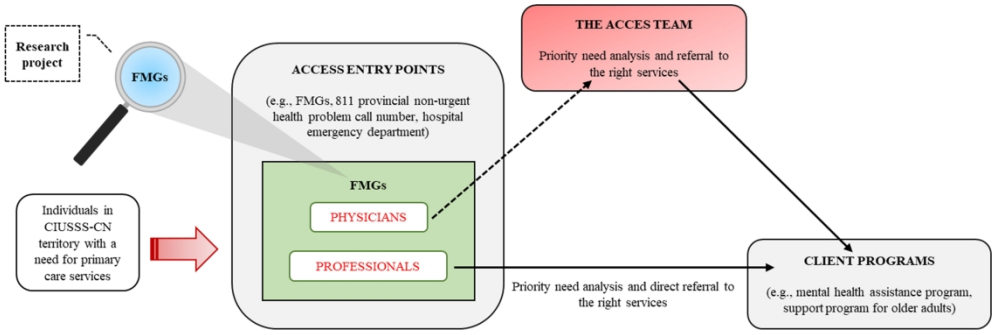

Figure 1: The referral process

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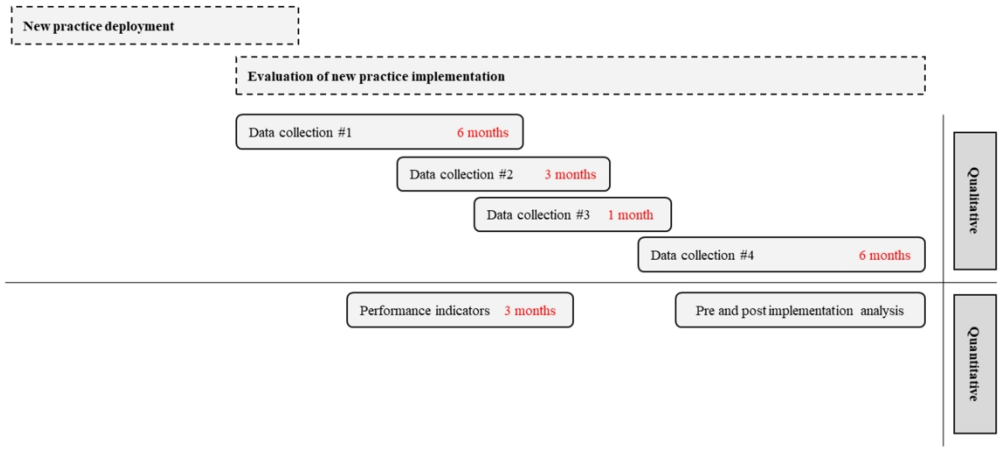

Figure 2: The realisation of the study across time

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September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	**As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.**
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	p.1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	p.1

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	p.2
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	p.2-3
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	p.4
6. Specific aims	Purpose of the project and of this report	p.4
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	p.4
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a) p.5-7 b) p.5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	P. 5-6
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	p.5-7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	p.7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	p.8

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	Not appropriate; protocol article
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a) N/A b) p.2
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	N/A (protocol article)
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	p.2
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	Discussion, p.8-9
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	p.10