Primary Care Practice and Provider Information Sheet and Consent Form

Title of Study: ARC – Access to Resources in the Community / Accès aux Ressources Communautaires

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Funding Agencies:
Canadian Institutes of Health Research SPOR initiative

Participation in this study is entirely voluntary. Please read this Information Sheet and Informed Consent Form carefully and feel free to ask the study team as many questions as you like to help inform your decision about participating in the study.

Why is my primary care practice being given this form?

This study is recruiting primary care practices in Ottawa (central and eastern regions of Champlain Local Health Integration Network (LHIN)) and in Sudbury (within the North East LHIN). Your practice is situated in one of these regions.

Why is this study being done?

Primary care providers deliver essential services that can help prevent the onset of disease and the deterioration of existing ones. There are numerous health and social services available to patients residing in this community that can help complement the services provided in primary care, and further support patients to achieve good health and wellbeing.

Some of these resources include health promotion services such as:

Falls prevention *Smoking cessation* *Chronic disease education programs*
Mental health counseling *Exercise programs* *Dietary counseling*

Others services address the social barriers that patients may face, which can contribute to poor health. These services include:

Caregiving support *Translation* *Advocacy* *Accompaniment (e.g. to appointments)*
Transportation (e.g. to access required services)

Many of these services are underutilized. Consultations with local primary care physicians and nurses have revealed that they are largely unaware of the extent of services available and do not know where to find such information consistently. When shown where that information can be readily obtained, they were encouraged by the breadth of services available and the ease with which the information can be accessed. There is therefore an opportunity to increase patient access to these resources by **enhancing primary care patients and providers' knowledge** of these resources and of the navigation tools that can support them to identify the appropriate resource **(Enhancing knowledge of resources).**

In addition, patients with social barriers (e.g. a lack of transportation or social support, and language or literacy barriers) face additional challenges in reaching these resources despite having received a recommendation from their provider and knowing their availability. There is considerable evidence that a lay navigator can help individuals with social barriers that limit their ability to access these services overcome these barriers and make use of these services **(Lay Navigator support)**.

What is the objective of the study?

The objective of the study is to determine whether a lay patient navigator helps patients access community resources that can benefit their health and wellbeing.

How is the study designed?

This study will be conducted in 12-15 family medicine practices in the Ottawa and Sudbury regions. Primary Health Care Providers that that can refer patients to community resources are invited to participate in the study.

The study will compare the effect of a lay patient navigator to that of existing navigation services (211 services) on the patients' ability to access community services.

All practices/providers agreeing to participate will receive the following:

1. An orientation on the breadth of available community based health and social resources available in their region (offered to all members of the practice)
2. Waiting room promotional material (e.g., posters, flyers, videos) demonstrating the breadth of existing community based health and social resources, and advertising the ARC study.
3. A standardized referral form to facilitate and streamline the process of referring patients to community resources.

Providers identifying the need for a patient to access one or more community resource will invite these patients to take part in the ARC study.

Patients having agreed to participate in the ARC study will be randomized to the Intervention arm or the Control arm.

Arm #1: Control: Enhancing knowledge of resources

Patients randomized to the control arm will be given information to access Ontario 211, a telephone and online navigation service available to all Ontarians.

These patients will be informed that Ontario 211 provides services to help people identify the resource they need.Patients will be instructed to dial 2-1-1 to obtain more information on the nature of this service from a 211 representative.

Arm #2: Intervention: Enhancing knowledge of resources + Lay Navigator support
Patients randomized to the intervention arm will have access to the services of a lay Patient Navigator to support them in accessing the community resource to address the identified need.

The Patient Navigator will help the patient identify the appropriate program in their community that can address a need identified by their provider on the referral form, or additional needs identified by the patient during their encounter with the Navigator, unless the needs identified by the patient are of a medical nature. In that case, the provider will be notified of the patient's request, and asked for

approval to proceed. The navigator does not provide support to accessing specialized medical care. The Navigator will help patients assess and address potential social barriers that would prevent them from accessing the program (e.g., obtain transportation or translation services), and provide other support to enhance utilization as needed. The Patient Navigator will also facilitate information continuity between the community resources and the patient's provider. To empower patients and to improve their self-efficacy for future needs, the navigator will also orient the patient to the Ontario 211 navigation services.

What is expected from my practice?

All primary care practices participating in the study will be expected to:

- Complete a practice baseline survey that allows the research team to understand their practice context (one per practice);
- Provide space in the waiting room to display promotional material relating to community resources and the ARC study (if feasible);
- Identify a practice "Champion" (practice clinical or administrative staff) as the main person responsible for the communication between the research team and practice members and to oversee the study in the practice;
- Where feasible: Provide space in the practice for meetings to take place between the Patient and Practice Navigator (approximately one half day a week);

What is expected from providers?

All primary care providers participating in the study will be expected to:

- Attend an orientation session about available community resources;
- Participate in a baseline and follow-up survey to assess their experience with the study (one per provider);
- Provide their practice identification number that would allow the study team to link their data to health administrative data for the purpose of analyses (Optional).
- Collaborate with the Patient Navigator to the extent they deem appropriate in the exchange of information relating to their patients' access to the community resources;
- Complete a brief standardized referral form for each patient for whom they identify a need that can be addressed through access to a community resource;
- Provide all referred patients with a sealed study information package, and request their permission (verbal) to be contacted by phone by a research team member for participation in the study.

  Note that some providers may be contacted to participate in an interview to assess their experience with the study. Consent for that aspect of the study will be obtained separately at that time for those invited.

What is expected from my patients?

Patients having agreed to take part in the study will be asked to complete a survey at the time of the referral and another similar survey three months later to understand their expectations and experience accessing the community resource to address their need. The surveys should take approximately 30 minutes to complete and will be administered by telephone. Patients will also be asked to provide their Ontario Health Plan Number to allow the researchers to link their study information to health administrative data for the purpose of analyses (optional). These analyses are conducted to allow the researchers to obtain information about the types of health services used by patients in the study.

Some patients may be invited to take part in an interview following the second survey at the end of the study to better understand their experience with the study. Consent for that interview will be obtained separately at that time.

How long will I be involved in the study?

The entire study will last approximately 18 months. Patient recruitment in the study will take place over 12 months. Your patients' participation in the study will be approximately three months. Allowing for that follow up period, the total study period during which there is patient involvement will be 15 months. Allowing for some preparatory work in the practice before the process is established, your involvement in the study will be approximately 18 months.

What are the potential risks I may experience?

This study has minimal risks to your practice and patients. We will take all reasonable steps to avoid disruption to your practice. Some study related requirements, such as working with the ARC Research Coordinator, completing the survey or referral form, may cost the practice time.

We will minimize the risk that any confidential and sensitive patient information be accessed by unknown parties. All electronic communication between you and the study personnel (including Patient Navigator) that relate to patients will take place through secure communication channels. All data collected will be securely stored in the study database using all reasonable protection steps (encryption, secure network, limited access, password protection).

Will I or my practice be paid for our participation?

To offset the opportunity costs associated with your practices' participation in this study we offer $400 per practice, plus $200 per primary care provider (up to $800) for their participation in the study for a total practice payment up to $1,200.

Can I expect to benefit from participating in this research study?

Your practice, primary care providers and patients may or may not directly benefit from participation in this study**.** The facilitation services offered to your practice to help incorporate referrals to community resources into the usual practice routine may make it easier for providers to make referrals to community resources, and thereby enhance patients' access to health promoting community resources.

All practices participating in this study may benefit from learning about available community resources that are available to help meet their patients' needs.

The study team can provide you with summary information collected in the patients' study surveys, and this may be helpful to understand the needs of your patients. For example, the research team may provide your practice with the results of an analysis comparing the profile of patients you have referred to a community resource and who have used the recommended resource those who haven't. A list of barriers they face, and their self-reported ability to address their health needs could be provided.

Patients randomized to Arm #1: Enhancing knowledge of resources may benefit from the navigation services offered by Ontario 211; potentially raising awareness of existing health and social services available in their community.

Patients randomized to the *Arm #2: Enhancing knowledge of resources + Lay Navigator support* may benefit from the support the Patient Navigator is providing them; potentially overcoming the social barriers they face in accessing the services and become more likely to utilize the recommended service.

Do I have to participate? What are my options? If I agree now, can I change my mind and withdraw later?

Both you and your practice's participation in this study is entirely voluntary. Even if your practice chooses to participate, you do not have to. The alternative to this study is for you to continue providing the usual standard of care.

You can refuse to answer any question during the surveys and/or the interview.

You may at any time after agreeing to participate withdraw from the study. You may request to remove all of your data that had been collected to date. If your entire practice withdraws, all data relating to your practice that had been collected to date can be removed. For practices randomized to the arm that provides the Patient Navigator, this would include the discontinuation of the services provided by the Patient Navigator and the study team will no longer collect your or your patients' personal information for research purposes.

Your decision to participate in this study or not will not impact your practice's status within your region or your employment status within your practice.

How is my practice and my personal and my patient information being protected?

- If you decide to participate in this study, the investigator(s) and study staff will collect your and your practice's identifying information.
- Information that identifies you and your practice will be released only if it is required by law.
- All information collected during your and your practice's participation in this study will be identified with a unique study number (for example participant # AB01), and will not contain information that identifies you or your practice.
- All information and data collected during your and your practice's participation in this study will be securely stored at the Bruyère Research Institute and Laurentian University.
- Documents leaving the Bruyère Research Institute and Laurentian University will only contain the coded study number.
- A Master List provides the link between your and your practice's identifying information and the coded study number. This list will only be available to Drs. Dahrouge and Gauthier and their staff and will not leave their respective sites.

- The Master List and coded study records will be stored securely.
- For audit purposes only, all original study records may be reviewed under the supervision of Dr. Dahrouge's and Dr. Gauthier's staff by representatives from:
    - the Ottawa Health Science Network Research Ethics Board (OHSN-REB),
    - the Ottawa Hospital Research Institute
    - the Bruyère Continuing Care Research Ethics Board
    - the University of Ottawa Research Ethics Board
    - the Hôpital Montfort Research Ethics Board
    - Laurentian University Research Ethics Board
    - the University of Ontario Institute of Technology Research Ethics Board
- Neither you or your practice will be identified in any publications or presentations resulting from this study.
- Research records will be kept for 10 years, as required by the OHSN-REB.
- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research study can be found on the above listed website by using the clinical trial registration number *[pending approval]*.

Providers having consented to allow their data to be linked to health administrative data held at the Institute for Clinical Evaluative Sciences (ICES) will provide their CPSO billing number that would allow the study access to ICES (e.g. data such as health services information related to their patients) to be included in the analyses. ICES is an independent, not-for-profit research institute that is a prescribed entity under Ontario's Personal Health Information Privacy Act. ICES deploys a variety of measures to protect the information entrusted to it. ICES holds all health care services covered by OHIP and delivered in the province of Ontario.

The purpose of linking the study data to ICES is to evaluate the effect of the intervention on health service utilization. Physical security measures, technological safeguards like encryption and a robust framework of policies and procedures work together to protect information. These data are securely held in encoded form and analyzed at the ICES (www.ices.on.ca). All relevant datasets will be linked using unique, encoded identifiers and analyzed at ICES. You may find this brief video intended to inform the population about the work being done at ICES useful "The power of data to improve health" at **https://www.youtube.com/watch?v=5pZhRSM1cyk&feature=youtu.be**

Will I be informed about any new information that might affect my decision to continue participating?

You will be told immediately of any new findings during the study that could affect your willingness to continue in the study.

Who can I contact if I have questions?

If you have any questions or should you no longer wish to remain a part of the ARC study, please call Andrea Perna (613) 562-6262 ext.2920 or email arc@bruyere.org. In Sudbury, please call Patrick Timony (705) 675-1151 ext. 4298 or email Pe_Timony@laurentian.ca

You can also contact the study principal investigator, Simone Dahrouge at (613) 562-6262 ext. 2913 or sdahrouge@bruyere.org. In Sudbury, please contact Alain Gauthier at (705) 675-1151 ext: 4301 or email agauthier@laurentian.ca

The Ottawa Health Science Network Research Ethics Board (OHSN-REB), Bruyère Research Ethics Board, Montfort Research Institute and the ethics boards of our research partners have reviewed this protocol. These Boards consider the ethical aspects of all research studies involving human participants at participating hospitals, institutes and universities.

If you have any questions about your rights as a study participant, you may contact:

- Chairperson, OHSN-REB at 613-798-5555, ext. 16719
- Research Ethics Coordinator, Bruyère Research Ethics Board at reb@bruyere.org or 613-562-6262 ext. 4003
- Montfort Hospital Research Ethics Board, 745A suite 102 Montreal road, Ottawa, Ontario at 613-746-4621, ext. 2221 or via email at ethique@montfort.on.ca
- Protocol Officer for Ethics in Research, University of Ottawa, at ethics@uottawa.ca or 613-562-5387
- Research Ethics Officer, Laurentian University at 705-675-1151 ext 3213, 2436 or toll free at 1-800-461-4030 or email ethics@laurentian.ca.
- Ethics and Compliance Officer, University of Ontario Institute of Technology, researchethics@uoit.ca or 905-721-8668 X 3693

ARC – Access to Resources in the Community/ Accès aux ressources communautaires

Consent for Practice Participation

I am being invited to participate in this RANDOMIZED CONTROL study.
I therefore understand that the patients I refer to community resources using the ARC referral form and that consent to participate in the ARC study will be randomly assigned to the Arm #1: Enhancing knowledge of resources OR Arm #2: Enhancing knowledge of resources + Lay Navigator support to patients through a chance process at the start of patients' enrollment in the study

- ☑ This study was explained to me by _____.
- ☑ I have read each page of this Practice and Provider Information and Consent Form.
- ☑ All of my questions have been answered to my satisfaction.
- ☑ If I decide later that I would like to withdraw my or the practice's participation from the study, I can do so at any time.
- ☑ I voluntarily agree on behalf of _____ (practice name) to participate in this study.
- ☑ I will be given a copy of this signed Practice Informed Consent Form.

_____ _____ _____

Practice Delegate Printed Name Practice Delegate Signature Date

On behalf of: _____
Practice Name

<u>Investigator or Delegate Statement</u>

I have carefully explained the study to the Practice Delegate. To the best of my knowledge, the Practice Delegate understands the nature, demands, risks and benefits involved in taking part in this study.

_____ _____ _____

Investigator/Delegate's Printed Name Investigator/Delegate's Signature Date

ARC – Access to Resources in the Community/ Accès aux ressources communautaires

Consent for Provider Participation (one copy per provider)

- ☑ This study was explained to me by _____.
- ☑ I have read each page of this Practice and Provider Information and Consent Form.
- ☑ All of my questions have been answered to my satisfaction.
- ☑ If I decide later that I would like to withdraw my participation from the study, I can do so at any time.
- ☑ I voluntarily agree to participate in this study.
- ☑ I will be given a copy of this signed Provider Consent Form.
- ☑ I agree that the ARC Patient Navigator can support my patients to access resources that I did not recommend (only resources that do not require a physician referral)

_____ _____ _____ _____

Provider Printed Name Provider Signature CPSO Date

Investigator or Delegate Statement

I have carefully explained the study to the Provider. To the best of my knowledge, the Provider understands the nature, demands, risks and benefits involved in taking part in this study.

_____ _____ _____

Investigator/Delegate's Printed Name Investigator/Delegate's Signature Date