McMaster University | Family Medicine

Pilot Research Project Funding 2020-2021

Call for Applications

In 2020-2021, the Department of Family Medicine (DFM) at McMaster University will fund up to 9 pilot projects (maximum $5000 each) for research in primary care, including one grant in medical education. These one-year grants are intended to build research capacity in the DFM. Studies should address areas of research related to primary health care. The projects should produce findings that will support the development and submission of future research proposals to external funding agencies.

There are two sources of funding based on faculty affiliation. For faculty with a primary affiliation to DFM at McMaster University who are members of Family Medicine Associates (FMA), there is a total of $25,000 available. For faculty with primary affiliation to DFM at McMaster and are not FMA members (i.e. community physician or faculty researcher), there are four grants available for a total of $20,000.

This funding call encourages the use of the McMaster University Sentinel Information and Collaboration (MUSIC) by GFT physicians (members of the FMA) and for physicians working in the community.

Click below to access the application guidelines and forms:
http://fammedmcmaster.ca/research/research-resources/pilot-funding/

Completed pilot research project applications are due **October 26, 2020 by 8pm**
Submit to Amy Tatemichi, DFM Research Administrative Assistant:
tatemichi@mcmaster.ca (905) 525-9140 x 21685

Research Project Criteria

- The project needs to focus on areas of research that are directly relevant and of value to primary health care
- The project needs to have at least two DFM faculty members involved as core investigators. Allied health professionals are welcome to participate as co-investigators, as are students, residents, and fellows, but the project must be led by a faculty member with a primary affiliation to DFM at McMaster
- There is a limit of one application per principal investigator
- Preference will be given to principal investigators who have not received DFM pilot funding within the past two years.
- The grant may serve as the total support for a project, or supplement an existing research effort, as long as a specific portion of the research is identified as being made possible by this grant, and provided that the investigator states specifically how the balance will be funded, providing evidence of its guaranteed availability
- The funding is not for program development
- The grant must not duplicate funding for a research project
- Examples of pilot studies include: development and testing of a new survey instrument, a needs assessment, qualitative work to develop a survey instrument, a systematic review, or pilot/feasibility testing of an intervention
- Projects must meet the usual requirements for approval by a Research Ethics Board or seek a waiver from a Research Ethics board, once granted. If submitting to HIREB, certification may be required for principal investigator(s). See Appendix 1

About the Proposal

The proposal should be no more than four pages (excluding cover page and budget) and should address the areas listed below. Proposals will be reviewed according to the criteria listed in Appendix 2.

- Background / rationale: describe the purpose of the study and why it is important
- Objectives: identify what will be achieved by conducting this research
- Research question: The McMaster Health Sciences Library has a web page to assist with formulating a good qualitative or quantitative research question
- Study setting: describe where the research will take place and who will be involved
- Study design: describe the qualitative, quantitative, or mixed-method design of your study
- Study sample: describe the number and type of participants involved in the research and the rationale for inclusion
- Recruitment: describe the human subjects involved in the research (if applicable), how will you recruit them to participate, and the departments or organizations you will need to approach to allow participation

- Data collection: describe how you will collect qualitative or quantitative data in-person or virtually, and the types of data collection tools you will use (surveys, interviews, focus groups, etc.)
- Data analysis: describe the qualitative or quantitative methods you will use to analyze the data
- Measures/outcomes or findings: describe quantitative measures and outcomes, or qualitative findings, as applicable
- Ethical considerations: describe ethics required for human subjects or retrospective review (see www.hireb.ca). If the project could be considered quality assurance or quality improvement, you may be able to apply for a waiver from HiREB. Faculty may be required to attain certification for ethics applications (see Appendix 1) and follow the process for ethics approval at DFM (see Appendix 7)
- Knowledge Translation: describe intent to publish or present your results/findings. If a publication is produced, a DFM Knowledge Translation Specialist will contact the principal investigator to arrange the production of a short 45 second video. The principal investigator is also requested to present their research at a future DFM or GFT departmental meeting
- Budget table and justification (no more than 1 page): see Appendix 3 for Research Project Budget Information
- Timeline: create a chart outlining the key project activities by the12 months of the project. For an example, see Appendix 8, page 4
- List of References

Developing Your Proposal

The principal investigator and/or research team are strongly encouraged to attend "Moving your research from idea to action: a hands-on exercise to map out a pilot study" at the DFM Spring Retreat, September 22, 2020 at 8:00 am. Additional details are provided in Appendix 5. Here are more suggestions to assist with the design and development of your proposal:

- Attend a Medical Education or Clinical and Health Systems Research Group rounds, co-chaired by Drs. Lawrence Grierson and Michelle Howard respectively. These sessions take place monthly in September and October and are announced in the DFM Weekly Newsletter. Contact dfmresearch@mcmaster.ca if you would like to attend
- Visit our website to access our Research Knowledge and Skill Builder seminar series. Topics include "Basic and Advanced Research Designs for Primary Care Research" and "Pilot Studies: What We Need to Know". See Appendix 6 for a full list of topics
- Request a review of your proposal by members of our research staff. Please submit a draft of your proposal 4 weeks in advance of October 26 for feedback to dfmresearch@mcmaster.ca

- See Appendix 8 for an example of a successful pilot project proposal and budget
- DFM's Faculty Portal has a "Begin to do Research" page; you may access the faculty portal with your MACID and password. See also faculty research resources from UBC Department of Family Medicine

Project Timelines

Proposal due:	October 26, 2020
Funding announced:	January 4, 2021
HiREB approval or waiver due by:	February 28, 2021
Research account opening HIREB approval or waiver required):	March 31, 2021
Interim report due:	June 30, 2021
Project completed by:	December 31, 2021
Final report due:	January 31, 2022

Application Checklist

The application should consist of the following:

☐ Application cover sheet with email consent from each co-investigator (see Appendix 4)

☐ Research proposal (maximum 4 pages)

☐ Budget and budget justification (maximum 1 page)

☐ Curriculum vitae of the principal investigator, highlighting clinical and educational accomplishments, as well as research, relevant to the proposal. **Abbreviated CVs are preferred**, to focus on activity over the last 5 years.

☐ Appendices of no more than 2 pages related to the work proposed (optional)

Proposals are due by **October 26, 2020 at 8 pm** to Amy Tatemichi, DFM Research Administrative Assistant: tatemichi@mcmaster.ca

Appendices

Appendix 1: Required Certification for Faculty Research Participation at McMaster

Note: not all the items listed below are required for all ethics applications. There may also be other courses, questionnaires or certifications required. Always check the most up-do-date requirements when completing your HiREB application: www.hireb.ca

1. **Tri-council Policy Statement 2: Course on Research Ethics** (TCPS 2: CORE)

For non-clinical trials, the study PI must have completed TCPS 2:CORE or GCP (below) when obtaining ethical approval by the Hamilton Integrated Research Ethics Board (HiREB)
Completed through the Panel on Research Ethics website
TCPS 2:CORE User guide

2. **Good Clinical Practice** (GCP)

For clinical trials, the study PI must have completed GCP training when obtaining ethical approval by HiREB
Request access to the CITI GCP Training by emailing hsresadm@mcmaster.ca

3. **McMaster Tutorial for Researchers Conducting Retrospective Review of Health Records**

Required for studies involving chart reviews when obtaining ethical approval by HiREB
Completed through McMaster University

4. **Integrating Sex & Gender in Health Research core certification**

Required for all applicants to CIHR, not just the PI. However, collaborators are exempt. Three modules are required:

sex and gender in biomedical research
sex and gender in primary data collection with human participants
sex and gender in analysis of secondary data from human participants
Completed through the CIHR Institute of Gender and Health

5. **CIHR Equity and Diversity Questionnaire**

Required for all applicants to CIHR at the full application stage, not just the PI. However, collaborators are exempt.

Completed through ResearchNet

Directions for completing the questionnaire

Appendix 2: Review Criteria[1] for DFM Pilot Research Project Proposals

- BACKGROUND AND RATIONALE (10 points): Are the specific aims/hypothesis for the research project clearly stated? Does the proposal explain why this project should be undertaken? Does it reflect an adequate review of the literature?
- SIGNIFICANCE (10 points): Is the project relevant to primary care practice? Is the proposed project original or unique in any respect (new problem or question, new or unique study method or evaluation technique, etc.)? Will the outcome of the project likely help to advance primary care?
- METHODS (40 points): Do the proposed methods appropriately address the specific aims/hypotheses? Are the methods well described? Are methodological problems anticipated and alternative approaches proposed?
- INVESTIGATORS (10 points): Are the professional (including clinical, educational or research) competencies and previous research experiences of the principal investigator and co-investigators appropriate to carry out the project? Do the previous research experiences, availability of pilot data, or the clarity in presentation of the research methods indicate that the investigators are familiar with the research methods being employed?
- FEASIBILITY (10 points): Is the intervention or research activity feasible according to the proposed scope and timeline of the project? Will the target population be available for recruitment and participation in the project within the proposed timeline?
- BUDGET (10 points): Does the budget match the staffing resources required (i.e. staff, students) to complete the project? Is the probable outcome worth the time and money invested? Will the grant serve as the total sum for the project or supplement an existing research effort? If the grant will provide only partial support for the project's total budget or any personnel, has the investigator stated specifically how the balance will be funded and provided evidence of its guaranteed availability?
- LIKELIHOOD TO CONTRIBUTE TO FUTURE RESEARCH ENDEAVOURS (5 points): Will the project most likely generate findings that can support a future full-scale grant application?
- PRIORITY AREA (5 points): Does the project focus on the priority area of the call for proposals (i.e. research related to primary health care or medical education)?

[1] Review criteria adapted from the TIPPS call for pilot funding, Canadian College of Clinical Pharmacy Research Grant Call for proposals, and CFPC Janus Research Grants

Appendix 3: Research Project Budget Information

Please present your budget in a table with budget amounts and a description of the items, as in the example below.

Item and description	**Cost**
Personnel	
Research Staff *(see table below for wages)*	
Supplies and services	
Office supplies	
Equipment/Software *to a maximum cost of $750. Please note NVivo, SPSS, and Endnote software are available for faculty use at the DFM Research faculty workstations, 5th floor, DBHSC*	
Participant honoraria	
Knowledge Translation/Dissemination *(to a maximum of $750)*	
Other: transcription services, simulation lab fees, travel to and from research sites for data collection, meetings, etc.	
Total *(to a maximum of $5000)*	

Research Staffing	
Research Assistant, Data Manager	Hourly rate of $25 – $32; add 30% benefits
Research Coordinator, Knowledge Translation Specialist, Biostatistician	Hourly rate $29 - $37; add 30% benefits
Business Analyst for MUSIC (OSCAR) data requests	Hourly rate $32 - $42; add 30% benefits
Practicum Students	

Fall or Spring Term (10 hours per week for 16 weeks)	Recommended stipend of $500 per month ($2000)
Summer Term (40 hours per week for 16 weeks)	Recommended stipend of $500 per month ($2000)
Volunteers Undergraduate medical students and residents are interested in primary care research. Arrangements can be made to have a volunteer on your project. Volunteers must receive a concrete and desired outcome from their experience (e.g. role in a publication), and researchers must be aware that their time and availability is limited. Contact our Research Administration team at dfmresearch@mcmaster.ca	

Ineligible Expenses

· Institutional or administrative overhead

· Travel or other expenses related to presentation of findings at conferences

· Salary support is restricted to that of technical or support personnel, and is not to be used for salary support of the principal investigator or co-investigators

Appendix 4: Application Cover Sheet

The fillable form is located here:

https://fammedmcmaster.ca/research/research-resources/pilot-funding/

Appendix 5: Spring Retreat Pilot Project Session Description

Title: Moving your research from idea to action: a hands-on exercise to map out a pilot study.

Facilitators: Michelle Howard, Dee Mangin

Description: If you are considering applying for a pilot research grant or if you have a question and aren't sure where to start, this workshop will help you formulate a systematic approach to getting started.

Learning objectives:

- To understand what pilot studies are, and how they contribute to successful research
- To apply concepts learned about pilot studies to an example from literature.
- To create a draft outline of a pilot study you are interested in doing.

Appendix 6: Research Knowledge and Skill Builder Topics and Links

RKSB is a monthly in-service learning opportunity for faculty and staff. It occurs the last Tuesday of every month from September to June. Previous topics and slides are listed below.

Topic	Presenter(s)	Link
Project Management		
Creating and Managing a Research Budget	Laura Cleghorn, Julie Datta, Dawn Elston, Francine Marzanek-Lefebvre	Slides
Supports and Services at McMaster		
The Grant Process	Catherine Gill Pottruff	Slides
Research Methods and Design		
Vulnerable Populations	Fiona Kouyoumdjian	Video
Basic and Advanced Research Designs for Primary Care Research	Ric Angeles	Video | Slides
Accountability, Transparency, Rigour, and Reproducibility: How & Why to Use ClinicalTrials.gov and Research Reporting Guidelines	Jessica Gaber, Dee Mangin, Larkin Lamarche	Video | Slides
Pilot Studies: What We Need to Know	Sayem Borhan	Slides
Validating Tools	Matthew Kwan, Jeffrey Graham	Video | Slides
Scoping Reviews, Rapid Reviews, Systematic Reviews	Housne Begum	Video | Slides
Critically Appraising Literature	Jennifer Lawson	Video | Slides
Quantitative Design		
Frontend and Backend Database Development	Steve Dragos	Video | Slides

Qualitative Design		
Qualitative Research: Overview of Methods	Meredith Vanstone	Video | Slides
Grounded Theory, Phenomenology & Narrative Methodologies: Designing methodologically rigorous qualitative studies	Meredith Vanstone	Video | Slides
Data Coding and Analysis	Meredith Vanstone	Slides
Interviews and Focus Groups	Jessica Jurgurtis	Slides
Responding to Sensitive Health & Social Issues	Laura Cleghorn, Jessica Gaber	Slides
Writing		
Manuscript Preparation and Authorship	Lawrence Grierson	Slides
Collective Skill Building and Collegial Support	Cathy Risdon	Video | Slides
Editing	Casey Irvin	Video | Slides
Communication		
Presenting Data in Visually Engaging Ways	Casey Irvin	Video | Slides
Community Engagement	Casey Irvin, Jessica Gaber, Pam Forsyth, Dawn Elston, Neha Arora	Video | Slides

Productivity		
Organizing your Work	Casey Irvin, Laura Cleghorn, Larkin Lamarche	Video | Slides
Software		
REDCap	Ricardo Angeles, Steve Dragos	Part 1: Video | Slides Part 2: Video | Slides
Just the basics: Learning about the essential steps to do some simple things in SPSS	Larkin Lamarche, Melissa Pirrie	Video | Slides Video | Slides
How To Build a Survey using the McMaster LimeSurvey Service	Michael Wilson	Video | How-to Guide
EndNote for Research	Steve Dragos,	Video | Slides
What to Know About NVivo A Qualitative Primer	Laura Cleghorn, Jessica Gaber	Part 1: Video | Slides Part 2: Video | Slides
Knowledge Translation		
Knowledge Translation	Casey Irvin and Erin Beaulieu	Part 1: Video | Slides Part 2: Video | Slides

Appendix 7: Information about the Research Ethics Process at DFM

At the request of the DFM Chair, all HiREB applications are to be reviewed by our research staff prior to requesting the Chair's signature. Additional approvals for research participation and recruitment may be required by DFM Leadership and/or other committees prior to submission to HiREB.

Steps	Timeline
1. Additional approvals may be required if: a. You wish to recruit research participants from the McMaster Family Health Team (patients, clinicians, and/or residents). Approval by DFM Leadership is required. b. You are using OSCAR or MUSIC data, or your participants are from the McMaster Family Health Team. Approval by DFM Leadership is required. c. You wish to recruit medical students as participants. Approval is required from the Undergraduate Medical Education Program (UGME) Protocol Review Committee (PRC). d. You wish to recruit participants (patients, clinicians, and/or residents from a department other than DFM, approval from the respective department may be required. If you require any approvals listed above, our Clinic Research Coordinator can assist you with this process: dfmresearch@mcmaster.ca	Approval from DFM Leadership may take up to a one month. Approval from the UGME PRC may take up to 6-10 weeks. Approval timelines from other medical departments are variable.
2. Complete the online HiREB application: https://www.hireb.ca/ Helpdesk: 905-521-2100 x70014; erebhelpdesk@hhsc.ca. Applications that involve human subjects must use the General Application Form. Retrospective chart reviews can use the Chart Review Application Form.	See HiREB website for submission instructions and deadlines: https://hireb.ca/meetings-news/
3. Before you request the Chair's signatures: • Send Amy Tatemichi, Research Administrative Assistant, (tatemichi@mcmaster.ca 905-525-9140 x21685) a PDF of the HiREB application, the protocol, consent form(s), and data collection forms. • Research Staff will review your application and correspond with you about any recommended changes.	Research staff may take up to seven business days to review your application; please allow enough time before the HiREB submission deadline.
4. Once staff have reviewed your HIREB application, you will be notified to request Dr. Price's signature. After all signatures are obtained, the online application is submitted for HiREB review.	HiREB reviews can take 4-6 weeks.

Appendix 8: Example of a Successful Pilot Project Proposal and Budget

(see over)

McMaster University | Family Medicine

Department of Family Medicine
Pilot Research Project Funding - General Stream
Application Cover Sheet

Title of Project: Interpretation services in primary care research trial (INTERPRT): A feasibility study of the use of phone interpretation services in hypertension and diabetes care for patients with limited English proficiency at McMaster Family Practice

Principal Investigator Name:	Gabrielle Inglis
Email:	gabrielle.inglis@medportal.ca
Title:	MD, MMSc, CCFP
Primary academic affiliation (list one only):	Department of Family Medicine
Physician group membership (select one):	■ I am a physician member of Family Medicine Associates ☐ I am a community physician or faculty researcher
Research focus (select one):	■ Primary care research ☐ Medical education research
Are you a new investigator? (i.e. held a research appointment for a period of 0 to 5 years)	■ Yes ☐ No
Have you received DFM Pilot funding in the past 2 years?	☐ Yes ■ No
Signature:	
Date:	Oct 27, 2019

Co-investigators:

Note: Along with your application package, please attach email confirmation from each co-investigator that they agree to be listed on the application.

Co-investigator # 1	Name: Morgan Black
	Email: morgan.black@medportal.ca
	Title: MD, CCFP
	Academic Affiliation: DFM
Co-investigator #2	Name: Shayna Henry
	Email: shayna.henry@medportal.ca
	Title: MB BCh BAO, MSc
	Academic Affiliation: PGY-1, DFM
Co-investigator #3	Name: Rhythm Shah
	Email: rhythm.shah@medportal.ca
	Title: MD, CCFP
	Academic Affiliation: DFM
Co-investigator #4	Name:
	Email:
	Title:
	Academic Affiliation:
Co-investigator #5	Name:
	Email:
	Title:
	Academic Affiliation:
Co-investigator #6	Name:
	Email:
	Title:
	Academic Affiliation:
Co-investigator #7	Name:
	Email:
	Title:
	Academic Affiliation:
Co-investigator #8	Name:
	Email:
	Title:
	Academic Affiliation:

Intro/Background
Effective communication is a necessity for any successful physician-patient encounter. Language barriers can hinder communication between physician and patient, creating difficulties in accessing primary care (Laher et al, 2018). In particular, for chronic disease management and treatment, failures in communication can result in inadequate longitudinal followup, suboptimal care, and the development of complications. Access and care over time are two of the 5 key functions through which primary care achieves better health outcomes for populations. For diabetes and hypertension, language barriers have been identified as a contributor to health disparities (Fernandez et al, 2010; Eamranond et al, 2008). This is not surprising as these conditions require careful and regular monitoring for complications, and important messages about management and followup may well can get lost in translation, impacting the quality of patient care.

Studies have shown that interpretation services can increase patient understanding of disease (Wilson et al, 2005), access to health care (Jacobs et al, 2004), and adherence to follow up, ultimately improving patient outcomes. Studies have also demonstrated the importance of trained interpreters in these roles, as opposed to family members or friends (Flores et al, 2012). Language Line ™ is a professional telephone-interpretation service available to Canadian health care practitioners for a per unit charge. Despite the presence of this service, and other similar services in Canada, patients in the primary care setting do not always have access to professional interpretation services. As a result, usual care in many primary care settings - including McMaster Family Practice (MFP)- involves ad hoc translation by available staff members, family, rare in-person professional interpreters provided by local agencies, or no translation at all, compromising our ability to deliver patient-centered care. As a result, there is limited data available from the Canadian context on the consistent use of professional interpretation services and its impact on patient care.

Objective
The purpose of this study is to evaluate the feasibility of conducting a full-scale randomized-control trial comparing the use of phone interpretation services with usual care for limited English proficiency (LEP) patients in primary care living with diabetes and hypertension. The study will generate the pilot data, and more precise budget information needed to support a larger grant application.

Research Questions
The following questions will be addressed in this pilot study. The category of consideration based on recommendations for feasibility study outcomes (Thabane et at, 2010) is noted in parenthesis.

1. To what extent is the implementation of this study feasible in the primary care setting, specifically at MFP?
    a. What is the rate of recruitment, consent, and drop out for eligible participants? **(Process)**
    b. What is the nature of any challenges with the randomization process? **(Process)**
    c. What is the nature of any data collection challenges pertaining to the clinical outcome measures that we have selected, including diabetic and hypertension visit endpoints outlined below? **(Resources/management)**
    d. What is the percentage of missing data for each outcome collected? **(Resources/management)**
    e. What is the nature of the data collection challenges pertaining to two measures of primary care engagement (frequency of appointments and attendance at follow-up visits) for LEP patients with diabetes or hypertension in primary care? **(Resources)**
    f. What is the nature of any data entry problems? **(Management)**

2. What is the variance, and are there any potential floor and ceiling effects, for the clinical outcomes listed below? **(Scientific)**
    a. Diabetic visit endpoints: HbA1C recorded, rate of self-reported eye exams, blood pressure (BP) recorded, BP control, ACR recorded, renoprotection with ACEI if necessary based on ACR, use of Metformin when indicated, number of intended and missed diabetes visits
    b. Hypertension visit endpoints: BP recorded, BP control, measure of creatinine in the last year
3. What is the level of patient and provider satisfaction and acceptability of phone interpretation services? **(Scientific)**
4. What is the length of time of visits using Language Line ™ compared to usual care? **(Resources)**
5. What is the cost per patient recruited of Language Line™ service and research staff? **(Resources)**

Methodology

Setting

The setting of this study is McMaster Family Practice (MFP) in Hamilton, Ontario, Canada.

Sample

Patients of McMaster Family Practice who are 16 years of age or more and identified by clinicians to have limited English proficiency and a diagnosis of either hypertension or diabetes will be invited to participate. The definition of "limited English proficiency" will remain intentionally imprecise to more closely reflect real practice settings where no standardized measure is used to determine those individuals who would benefit from interpretation services. MFP has four clinician teams comprised of five physicians each, caring for a total of approximately 5000 patients per team. Participants (N=30) will be randomized to intervention or control group after consent and baseline data collection.

Recruitment

Those physicians at MFP who agree to participate will be shown a list of their patients on the diabetic and hypertension disease registries and asked to identify those with limited English proficiency. These patients will be contacted by the research team and their primary language recorded, to identify the top 4 most common languages spoken. Patients speaking these languages will then be booked in for their regular diabetic or hypertension follow-up appointments, matching these with half days that the administrative assistant will be present to explain the study and consent prior to the appointment. Patients will be invited to attend fifteen minutes early to discuss a research study. A brief explanation of the study written in their first language will be mailed to their home in advance. Upon check-in for their appointment, the administrative assistant will bring the patient into a clinic room and provide information about the study, written in their first language. Upon review of the information, using Language Line ™, the administrative assistant will ask if they have any questions and if they are interested in participating. If interested, participants will be asked to provide informed consent, using consent forms written in their first language. This recruitment flow has been successfully trialed in the MUSIC in IUD RCT at MFP.

Procedures

Physicians, Nurse Practitioners, and Pharmacists who agree to participate will be given an in-service training on the use of Language Line ™. After providing informed consent, participants will be assigned into either the control or intervention (Language Line ™) group. Patients will then proceed with their visit with the clinician accordingly, with either standard of care (control group), or Language Line ™ support (intervention group). Participants will be followed for a period of six months or a maximum of three visits, during which time those in the intervention group will continue to have Language Line ™ support during each visit. To ensure ongoing Language Line ™ support, charts will be flagged with a reminder, booking alerts will be used, and the research assistant will do a weekly screen for appointments and add a reminder to "reason for visit". At the end of their first visit, patients in both intervention and control group

will be asked to complete a brief written survey (in primary language) regarding their satisfaction with the visit. Those patients randomized to the intervention group, will be asked to answer an additional two to three questions pertaining to the acceptability of the intervention. Response options for each of the questions will be on a Likert-type scale. A survey to understand health care professionals' perceptions of the intervention will be completed once, after the study is complete.

Outcomes & Measures
Basic demographic information will be collected and include age, gender, ethnicity, first language, and level of education. To capture some information about socioeconomic status, we will map participant postal codes to deprivation indices.

Clinical data collected from chart audits will include:

a. Diabetes data: Hba1c recorded, change over time, rate of self-reported eye exams, blood pressure control (measured as binary at target/not at target, and as a continuous variable to measure change over time), renoprotection with ACEI if necessary based on ACR (measured as binary on ACEi/not on ACEi), use of Metformin when indicated.
b. Hypertension data: blood pressure control (measured as binary at target/not at target, and as a continuous variable to measure change over time), Creatinine measured within the past year

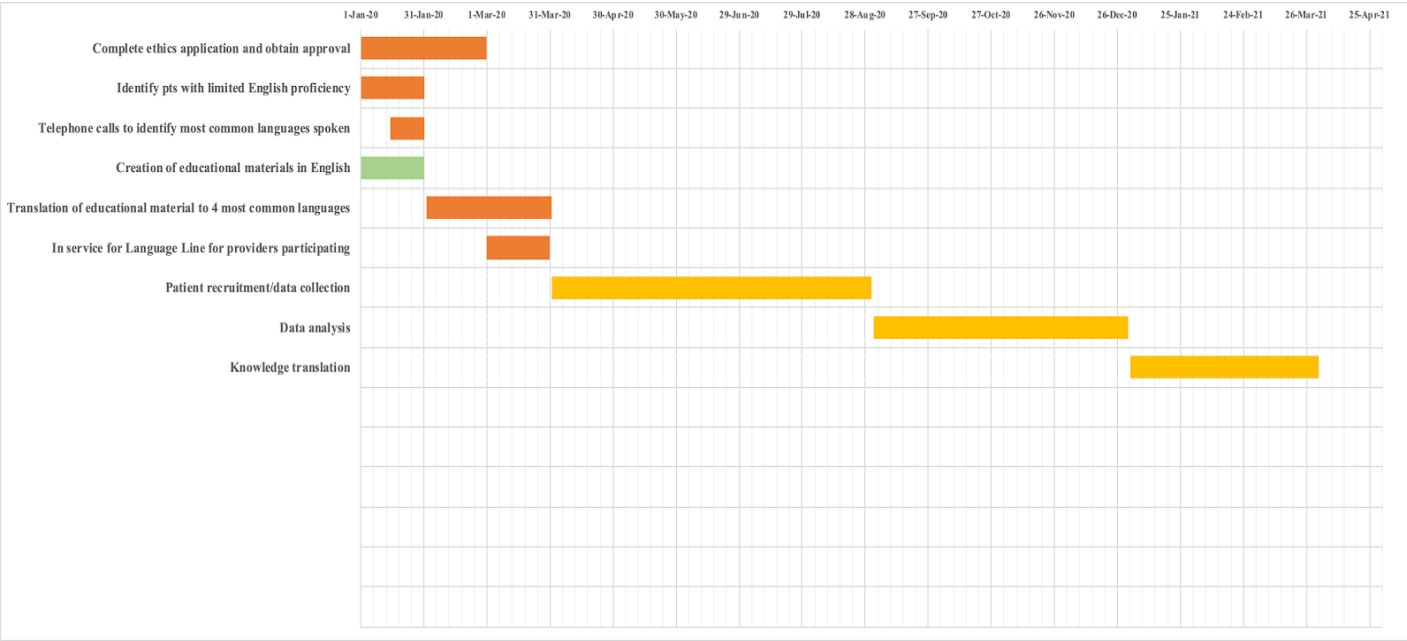
Although the above demographic and clinical data will be extracted from the chart, the aim of this data extraction in this study is to assess the feasibility of collecting and evaluating these data in a larger randomized-control trial. Feasibility outcomes are outlined in detail in Table 2 of the Appendices. Predetermined criteria for success are outlined in Table 2 of the Appendices.

Data management
All data will be entered and stored into REDCap, a secure, online data management tool, by a research assistant. This will include data extracted from charts such as Hba1c, notification of Emergency room visits, etc. which will be identified only by Study ID number. Consent forms and paper surveys will be stored in a locked filing cabinet in a locked office at DBHSC (5thfloor). Consent forms (containing names) and surveys (only ID numbers) will be kept separate so as not to link names to data. A Masterfile linking Study ID number to name will be kept, to allow for ongoing chart audits by the Research Assistant as participants are followed throughout the study.

Data Analysis
Means (and standard deviations) and proportions will be calculated for continuous and categorical clinical outcomes respectively (total sample and by group). The data will be inspected for floor and ceiling effects. Open-ended responses will be descriptively analyzed.

Ethical Issues
This study will be submitted to the Hamilton Integrated Research Ethics Board for review and approval.

Timeline



Summary

The purpose of this study is to generate the pilot data necessary to support application for a larger grant, in order to implement a full randomized-control-trial. We intend to submit results of this feasibility study to the journal "Pilot and feasibility studies", and intend to publish a scoping review of the existing literature in this area. We intend to present results locally and at relevant primary care research conferences.

References:

Eamranond, P. P., Legedza, A. T., Diez-Roux, A. V., Kandula, N. R., Palmas, W., Siscovick, D. S., & Mukamal, K. J. (2009). Association between language and risk factor levels among Hispanic adults with hypertension, hypercholesterolemia, or diabetes. American heart journal, 157(1), 53-59.

Fernandez, A., Schillinger, D., Warton, E. M., Adler, N., Moffet, H. H., Schenker, Y., ... & Karter, A. J. (2011). Language barriers, physician-patient language concordance, and glycemic control among insured Latinos with diabetes: the Diabetes Study of Northern California (DISTANCE). Journal of general internal medicine, 26(2), 170-176.

Flores, G., Abreu, M., Barone, C. P., Bachur, R., & Lin, H. (2012). Errors of medical interpretation and their potential clinical consequences: a comparison of professional versus ad hoc versus no interpreters. Annals of emergency medicine, 60(5), 545-553.

Jacobs, E. A., Shepard, D. S., Suaya, J. A., & Stone, E. L. (2004). Overcoming language barriers in health care: costs and benefits of interpreter services. American journal of public health, 94(5), 866-869.

Laher, N., Sultana, A., Aery, A., Kumar, N. (2018). Access to Language Interpretation Services and its Impact on Clinical and Patient Outcomes: Scoping Review. Wellesley Institute, Toronto, ON, Canada.

Wilson, E., Chen, A. H., Grumbach, K., Wang, F., & Fernandez, A. (2005). Effects of limited English proficiency and physician language on health care comprehension. Journal of general internal medicine, 20(9), 800-806.

Appendices

Table 1: Research Questions & Outcome Measures

Categories	**Question**	**Outcome Measure (method of collection)**
Process	What is the rate of recruitment, consent, and drop-out for eligible participants?	Number of participants enrolled, not interested, and dropped out of study before 6-month period (master file)
Process	What is the nature of the challenges with the randomization process?	Description (recruitment file, research team notes)
Resources	What is the nature of the data collection challenges pertaining to the clinical outcome measures that we have selected, including diabetic and hypertension visit endpoints?	Description (research team notes)
Resources	What is the percentage of missing data for each outcome collected?	Data completeness quantified (number of missing data points)
Resources	What is the nature of the data collection challenges pertaining to two measures of primary care engagement (frequency of appointments and attendance at follow-up visits) for LEP patients with diabetes or hypertension in primary care?	Description (research team notes)
Resources	What is the length of time of visits using Language Line ™ compared to those visits with usual care?	Timed by Research Assistant
Management	What is the nature of data entry problems?	Description (research team notes)
Scientific	What is the variance, potential floor and ceiling effects, for the clinical outcomes?	Inspection of data. Simple statistics.
Scientific	What is the level of patient and provider satisfaction and acceptability of phone interpretation services?	Range of scores (Likert-type scale survey)

Table 2: Criteria for Success

Research Question	**Target**
Feasibility	
Recruitment, consent, participant retention	30% (20 staff identify 5 patients, recruit 100 patients, consent and retain 30, goal n=30) Retention will be considered successful if participants in the intervention group consent to using Language Line™ throughout entire study period.
Randomization	Successful randomization into control and intervention groups with appropriate use of interpretation services by intervention group
Data completeness for clinical outcome measures	75%
Length of appointment time	Acceptable length of appointment time when using Language Line™ based on provider feedback
Cost	As there is no existing standard for acceptable cost of using interpretation services in the primary care setting, assessment of cost per patient will largely be used to guide budget estimates for future larger RCT
Clinical Outcomes	
• HbA1C • Rate of self-reported eye exams • Blood pressure control • Renoprotection with ACEI if necessary based on ACR • Use of Metformin when indicated • Number of intended diabetes visits • Number of missed diabetes visits • Creatinine measured in the last year • Patient and provider satisfaction	For these clinical outcomes, the study would continue without modification in the following circumstances: • Inspecting the data for floor and ceiling effects to ensure sufficient variation between control and intervention group with respect to these measures • Signal of direction of effect that interpretation services improve HbA1C levels, blood pressure, quality of care (metformin use, renoprotection), access to care (intended visits) and adherence to care (decreased number of missed visits) • Signal of direction of effect that both patient and provider are more satisfied by clinical encounters using Language Line™

Budget

Interpretation Costs	**Amount (time/quantity)**	**Cost/per unit**	**Total Cost**
Language Line 3 visits x 30 minutes x 15 participants (intervention group)	**22.5 hours**	**$1.70/minute**	**$2295**
Materials translation Consent forms (4 pages x 4 languages) Mailouts (1/2 page x 4 languages) Surveys (1/2 page x 4 languages)	**20 pages**	**$75/page**	**$1500**
General Supplies (paper, ink cartridges, printing, postage)			**$200.00**
Human Resources Costs	**Amount (time/quantity)**	**Cost/per unit**	**Total Cost**
Medical Student Research Assistant duties including phone calls, consenting of patients and administration of surveys	**50 hours**	**Volunteer**	**$0.00**
Research Assistant (Data Manager) To assist research team with collation and cleaning of dataset	**25 hours**	**$29/hr + 30% for benefits**	**$942**
Total			**$4937.00**