Improving palliative care in the home and community: Building CAPACITI (Community Access to PAlliative Care via Interprofessional primary care Teams Improvement) Wave 2 Cluster Randomized Controlled Trial

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1. BACKGROUND: Palliative care (PC) is an approach to care that emphasizes quality-of-life rather than curative treatment for patients with advanced illness and their families.[1] Of the 250,000 Canadians and 100,000 Ontarians who die annually,[2] it is estimated that >80% could benefit from PC.[3] **This research focuses on the problem of improving access to PC, *in particular home-based PC*, in Canada.**[4,5] Home-based PC is defined in this study as receiving PC by a generalist primary care physician (non-specialist) in the home or community (non-institution). Systematic reviews, summarizing results from many randomized trials, showed *home-based* PC—delivered by physicians working in interprofessional teams—improved quality-of-life, reduced symptom burden (e.g. pain, dyspnea, etc.), and lowered caregiver distress.[6-11] Providing home-based PC is aligned with patient preferences as >80% of patients prefer to die at home,[12,13] yet 65% of Canadians die in hospital.[14] Despite the clear benefits of home-based PC, most dying Ontarians do not have access to it; and if they do, receive it very near death. An Ontario study of patients in their last year of life showed <10% received home-based PC by a primary care physician, mostly occurring in the month before death.[15] We focus on primary care physicians in this grant because evidence shows that home-based PC by a primary care physician reduces hospital deaths by half,[16,17] yet every year 40% of primary care physicians do not bill for any PC service.[18] Access to home-based PC is even less in rural, northern, and First Nations communities.[19]

Why do so few Ontarians have access to home-based PC? As PC evolved into a specialty in Canada, PC specialists began to be seen as the only providers of home-based PC, thereby reducing primary care providers' knowledge, confidence and role clarity in PC. But high-quality PC need not be exclusively delivered by specialists or in hospitals. Systematic reviews show home-based PC can be effectively delivered by primary care physicians working in primary care teams, when provided appropriate training and support.[20,21] This evidence defined efficacious primary care teams as: teams of interprofessional providers, with primary care physicians and nurse coordinators at a minimum, and often times social workers, psychospiritual counselors, and other allied health providers.[22] Research also shows many primary care providers are willing to provide home-based PC, but lack support to build their team's PC "capacity"[23,24]—defined in this proposed study as having enhanced knowledge, skills, tools, and practice supports for effective team collaboration and local system coordination.

There are compelling reasons to better integrate primary care and home-based PC. Research shows we have grossly insufficient numbers of specialist physicians to serve the growing need. Co-PI (HS) co-led a study that identified only 109 specialist PC physicians in Ontario, of which <30 worked in the home and community.[18] Moreover, nearly all Canadians have a primary care provider. Considering longitudinal relationships and continuity of care, primary care providers are ideally positioned to identify the need for PC and initiate it earlier themselves among their patients.[25] Besides better patient care, research also shows home-based PC reduces healthcare costs by avoiding hospitalizations.[8,17,22,26] The last year of life represents 10-25% of the total annual healthcare budget,[27] of which hospitalizations comprise 70% of costs.[28] Furthermore, the passing of the Bill C-14 in 2016, legislating Medical Assistance In Dying, underscores the urgent need to increase access to PC as an alternative to hastened death.[29] Thus to increase access to PC to more Ontarians, we need to develop capacity for primary care teams to deliver home-based PC, using a model adaptable to the local context and diverse communities.

2. CAPACITI PROGRAM: To address this gap, our study team proposes a quality improvement intervention called **CAPACITI**: **C**ommunity **A**ccess to **PA**lliative **C**are via **I**nterprofessional **T**eams **I**mprovement. CAPACITI is PC training and coaching program for primary care teams, comprised of three, two-month (4 session) modules. Each module addresses a critical component of implementing a PC approach into primary care practice: (1) Identify and Assess; (2) Enhance Communication Skills; (3) Enhance Skills for Ongoing Care (including involvement of family and specialists). Over bi-monthly (one hour) sessions, each CAPACITI module uniquely integrates 3 components: clinical education in the form of expert advice and tips; evidence-based tools; and high-facilitation and expert coaching for adaptation to local context. CAPACITI is different from many PC interventions as it does not add new human resources or automatically refer to specialists; instead it builds capacity within the existing primary care team so they themselves can work together differently and provide more access to home-based PC. Thus built-capacity is more likely to be sustained beyond the program.

International experience has demonstrated that a very similar training program, the Gold Standards Framework (GSF), was highly effective.[30] GSF is an intervention in the United Kingdom (UK) that has successfully built PC capacity in primary care, hospitals, and long-term care for over 15 years. GSF is a PC training program complete with education, materials, and tools (14 hours of training taught across 6-12 months). The GSF program has been extensively evaluated. A critical review of 15 publications evaluating GSF found that the "greatest benefits" of the GSF program was it facilitated teams to identify more patients on a PC registry and improve their coordination practices.[30] For instance, one study of 10 primary care teams showed that among the 1% expected annual deaths, teams provided home-based PC to 12% of patients before GSF which rose to 52% after GSF (range 31% to 107%).[31] Other GSF literature has corroborated this finding: after GSF, primary care teams were able to identify 65% (range 35% to 90%) of the 1% of expected deaths as requiring home-based PC.[32] The critical review also found consistent evidence that post-GSF, teams provide PC earlier before death, reduce hospital deaths by 50%; have more interprofessional teamwork and communication; and increase family caregiver satisfaction.[30] GSF has been implemented in literally thousands of primary care teams across the UK. However, GSF's success was in part due to 3 contextual factors that exist in the UK but not in Canada: an organized network of primary care trusts, end-of-life and PC patient registries via widespread electronic medical records, and financial incentives for reaching targets in the PC registry.

CAPACITI is an enhanced version of GSF, where our team maintained GSF's strengths but modified it for the Canadian context. In addition, what makes CAPACITI particularly novel is that our team emphasizes practice supports in each module on clinical education or tools and utilizes high-facilitation and expert coaching. Together these unique modifications to GSF help primary care teams better operationalize PC delivery in Canada. Context-relevant practice supports are critical because knowledge translation (KT) evidence has shown that education or tools alone do not change practice without context-relevant KT on system integration.[33-35] For instance, education programs teach clinicians drug dosages for optimal management of complex symptoms, but offer little guidance on ensuring timely delivery of drugs to patients at home day or night. High-facilitation and expert coaching are critical to manage change initiatives and overcome KT challenges unique to the local context.

The recently completed pilot study of CAPACITI (Wave 1) with 27 teams across Ontario, demonstrated the feasibility and efficacy of this intervention. This version of CAPACITI featured 10 shorter modules, provided in monthly sessions over one year. Similarly, this iteration offered monthly webinars, accompanied by assigned activities and active

facilitation. The intervention was evaluated using pre and post survey data reported by team members, session feedback, and focus groups with the teams. The program showed potential for helping primary care teams operationalize an early PC approach. The CAPACITI content and program structure were revised based on the findings of the pilot study. The 10 sessions in the pilot intervention were bundled into 3 independent modules, which will be each held over a period of 2 months, so that teams can select the module(s) relevant to them and complete this material in a shorter time. We conducted further literature reviews to integrate a comprehensive inventory of effective and relevant PC education programs, training materials, clinical and collaboration tools, and measurement surveys relevant to primary care. Based on the pilot work, both the CAPACITI intervention and the study measures have been refined and their potential effectiveness increased. In the current study, CAPACITI will be provided to teams using a learning management system and evaluated as a cluster randomized controlled trial.

In this project, we propose the optimal model for implementing the CAPACITI modules, with trained staff facilitators, local specialist mentors and expert coaches. We will evaluate this intervention in a cluster randomized controlled trial. We engaged KUs representing the provinces (e.g., OPCN) and primary care provider teams themselves to ensure participation, feasibility, and adequate sample size. We also engaged national, multi-provincial, and patient collaborators. The knowledge generated from this study will be high-quality, generalizable, and ready for spread across diverse regions in Canada.

3. GOALS AND OBJECTIVES: The main goal of the Second Wave of this study is to provide a revised version of CAPACITI to a new set of primary care teams in Ontario and to use a randomized controlled trial methodology to compare the effect of this program, delivered facilitated versus unfacilitated, on teams' abilities to increase patient access to, and team capacity for, home-based early palliative care. CAPACITI Wave 2 feature three distinct education modules, each which will be evaluated individually.

PRIMARY OBJECTIVES: To determine if teams differ in the below both between trial arms (facilitated versus unfacilitated) and within teams before versus after CAPACITI:

1. **PC access and timing**, measured as a) Percent of patients in the past 3 months identified as requiring a palliative care approach, and b) Typical timing of when to initiate a palliative care approach for cancer and non-cancer patients respectively.
2. **PC competency**, measured as team member competency in providing key tenets of palliative care using the validated EPCS.
3. **Assignment completion and perceived change in practice**, reported upon completion of the module using the Assignment completion and change survey.

SECONDARY OBJECTIVES: To determine if teams between study arms and pre/post CAPACITI differ in:

1. **CAPACITI confidence** in PC, where primary care team member's capacity is measured by confidence in palliative care skills specific to the CAPACITI modules using our own CAPACITI competencies survey.
2. **Team interprofessional collaboration**, measured by team member's perceptions how they work and act together in terms of partnership, cooperation, and coordination using the AITCS-II.
3. **Team satisfaction** with CAPACITI, measured by team member's assessments of module sessions (post module only).

4. **CAPACITI effectiveness by context**, measured by team's perceptions of program overall and using qualitative interviews or surveys (post module only).
5. **Program analytics,** measured through the Learning Management System, including module pages accessed by team members, time spend on platform, quizzes completed, etc.
6. **Effectiveness on above outcomes by co-variates**, factors impacting effectiveness of program (of other outcomes) according to team and individual member characteristics (e.g. profession, rurality, ORCA readiness, etc.).

4.0. METHODS

4.1. STUDY DESIGN: Our study design is a prospective cluster randomized controlled trial of interprofessional primary care teams who register for CAPACITI Wave 2 modules. CAPACITI offers three distinct educational modules, each which will be evaluated separately. The primary comparison will be between the trial arms upon completion of a module. Our study will also measure the change in outcomes within the same team, before and after completion of a module.

4.2. STUDY ARMS: Both the intervention and control groups will have access to all the CAPACITI module materials, provided on a learning management system. The intervention group will receive module facilitation, that is, coverage of module materials in four live webinars (bimonthly for the 2 month duration of the module = 4 webinars). The control group will not receive module facilitation (i.e., will entail self-directed learning).

4.3. RANDOMIZATION: Teams who register for a module will be randomized to either the intervention or control arm using a permuted block design to ensure groups of equal sizes.[36] The sequence of allocation will computer-generated and each assignment placed in a numbered sealed envelope, which will de consecutively opened for each team that registers for a module. For teams that register for multiple modules, randomization to either the intervention or control arm will occur independently for each module. That is, group allocation for a module does not predetermine that for future, different modules. Teams that wish to retake a module can select the group to which they are allocated – no further data will be collected from the team for that module. Teams will be stratified by province and team size.

4.4. STUDY POPULATION: Our study is expected to include 60 interprofessional primary care teams per module (10 teams per term, each offered for 6 terms [times]), who meet the below inclusion criteria and are willing to participate in at least one CAPACITI module. Each team will have between 3 and 10 members participating in the module for an expected total of 300 team members (60 teams x 5 members/team). The teams will come from across Canada and will be geographically diverse (e.g. rural, urban, and remote), which is critical to generating evidence on generalizability in diverse communities across the country.

4.5. INCLUSION CRITERIA: Each team must:

- Be an interprofessional "team", defined as having a minimum of a: family physician or nurse practitioner; and practice coordinator. They can have other team members (e.g. social worker, pharmacist, etc.).
- Be community-based and willing to provide PC in patient's homes, defined as managing symptoms, addressing psychosocial needs, educating patients and families, and coordinating care.

- Have a minimum of three team members who agreed to participate in a CAPACITI module and complete the course measures.

4.6. RECRUITMENT:
Study participants will be members of primary care teams that enroll in CAPACITI. Potential teams across Canada will be informed about CAPACITI through advertising by our partner stakeholders and organizations, including Pallium Canada, Hospice Palliative Care Ontario, Saint Elizabeth Health Care, Canadian Hospice Palliative Care Association, and provincial professional associations, e.g., Medical Association of Ontario. The 18 co-Is will also disseminate to their provincial partners, e.g., BC Centre for Palliative Care to promote the program (see CAPACITI Program Information sheet). CAPACITI will be offered across 6 terms, with rolling enrollment for the modules which are all repeated each term. The program will be offered free to teams, with the understanding that those participating will complete the educational and data collection components.

4.7. EVALUATIVE FRAMEWORK: We will use the Kirkpatrick Model, a globally recognized training evaluation framework, to frame the various program evaluation components. This model outlines 4 critical domains of an effective training program[1]:

- **Reaction:** The participant's reaction or satisfaction to the education program.
- **Learning:** The participant's acquired knowledge and skills from the education program.
- **Behaviour**: The participant's application of what they learned during the program to their practice.
- **Results**: The direct outcomes, e.g., patient outcomes, that occur as a result of the education program.

The Summary of Data Outcomes Table below summarizes how we will access each of the domains in the Kirkpatrick Model

4.8. OUTCOMES: We will use quantitative (validated survey tools) and qualitative (semi-structured focus groups) methods. Quantitative outcomes will be measured per module as the difference between the intervention and control arms, immediately following completion of the module. We will also measure change in the outcomes for each team member before versus after a module.

PRIMARY OUTCOMES:

1. **PC access and timing**, measured based on self-reported i) number of patients in caseload and number (calculated %) reported as Identified as requiring a palliative care approach, ii) Typical timing of when to initiate a palliative care approach for cancer and non-cancer patients respectively.
2. **PC competency**, measured by scores on the End-of-life Professional Caregiver Survey (EPCS)
3. **Assignment completion and perceived change in practice**, measured by number of module assignments attempted/completed (checklist) and reported change in thinking, behaviour, processes and patient/family experience (Assignment Completion & Change Survey)

SECONDARY OUTCOMES: To determine if teams between study arms and pre/post CAPACITI differ in:

1. **CAPACITI confidence** in PC, where primary care team member's capacity is measured by scores on the CAPACITI Competency Survey.
2. **Team interprofessional collaboration**, measured by scores on the Assessment of Interprofessional Team Collaboration Scale II (AITCS II).
3. **Satisfaction** with CAPACITI program measured by team members' Session evaluations (poll survey).
4. **CAPACITI effectiveness by context**, measured by team's Perceptions of program overall (team focus group).
5. **Program analytics, for each team member** measured through the Learning Management System (module pages accessed, time spend on platform, quizzes completed, session attendance).
6. **Effectiveness on above outcomes by co-variates**, contextual factors impacting effectiveness of program outcomes, specifically across self-reported: i) Team/member characteristics, ii) Individual's level of readiness, measured by scores on the Organizational Readiness to Change Assessment survey (ORCA), and iii) Individual's preferred learning style.

Summary of Data Outcomes and Measures by Framework Domain

Data Outcome	Kirkpatrick Model Domain Assessed	Outcome Measure/Instrument
Primary		
1. PC access and timing	**Results**	Access: Total case load, # identified PC, Timing: Typical timing of when first palliative care will be initiated for cancer and noncancer patients
2. PC competency	**Learning**	End-of-life Professional Caregiver Survey (EPCS) – 20 items
3. Assignment completion / Change in practice	**Learning** **Behavior** **Results**	Checklist of completion of module specific assignments (study created survey) Change survey – 4 items
Secondary		
1. CAPACITI confidence	**Behavior**	CAPACITI Competencies Survey – 20 items
2. Team interprofessional collaboration	**Behavior**	Assessment of Interprofessional Team Collaboration Scale II (AITCS II) – 23 items
3. Satisfaction with program	**Reaction**	Perception of webinar content Self-report poll – 4 items
4. CAPACITI effectiveness by context	**Reaction** **Learning** **Behavior**	Semi-structured focus groups to access team perceptions of the CAPACITI-FNIM program
5. Program analytics	**Reaction**	LMS metric tracking (# participants, module completion, time spent in session, downloads)
6. Effectiveness on above outcomes by co-variates	**Impact on all domains**	Team Registration Form (location, electronic medical record platform, etc.) Team Member Registration Member Form (profession, learning preference, PC training, years in role, etc.) Organizational Readiness to Change Assessment survey (ORCA) – 31 items

4.9. DATA SOURCES AND DATA COLLECTION:

All data will be collected online, self-reported through the Learning Management System.

Team Registration Form

Team characteristics and module registration. Includes team name, location, electronic medical record platform, team members.

Team Member Registration Form

Team member demographics. Includes profession, role, PC training, years working with team, remuneration model, preferred learning style (self-directed or group facilitated), team PC practice (total patients seen in last 3 months, # identified PC in last 3 months, timing of when to initiate PC for cancer patients, timing of when to initiate PC for non-cancer patients)

Organizational Readiness to Change Assessment survey (ORCA). We will use a modified version of the ORCA to ensure that the items are relevant to the CAPACITI modules.[37] The ORCA measures organizational readiness to implement evidence-based practices in clinical settings. The survey was developed from the Promoting Action on Research Implementation in Health Services (PARIHS) framework, a theoretical model to guide implementation of evidence-based interventions. The original version of the ORCA consists of 77 items, with subscales, grouped according to the main areas of the PARIHS framework, and organized by 3 major domains: Evidence, the nature and strength of the evidence and its potential for implementation (4 subscales); Context, the environment or setting in which the proposed change is to be implemented (6 subscales); Facilitation, capacity or types of support needed to help people change their attitudes, behaviours, skills and ways of thinking and working (9 subscales). Each item is scored on a 5-point Likert scale rating the strength of agreement with each statement, from 1 (strongly disagree) to 5 (strongly agree). Reliability tests indicate that most subscales of the ORCA tool meet standard requirements of internal consistency of alpha >0.80. The ORCA is intended to be modified to ensure applicability to the intervention being assessed – the modified version for out study contains a total of 31 items with 8 subscales.

Module Surveys

Module surveys will be completed by participants from all teams before (T1) and after the module (T2) and at 12 months following module completion (T3).

End-of-life Professional Caregiver Survey (EPCS). The EPCS is a 28-item scale developed to assess palliative care-specific educational needs within an interprofessional team related to three main subdomains: Effective Care Delivery (ECD 8-items); Patient and Family-Centered Communication (PFCC 12-items); and Cultural and Ethical Values (CEV 8-items) (Lazenby, 2012). Each item is scored on a 5-point Likert scale ranging from 1 (lowest level of skill) to 5 (greatest level of skill). Items represent care-provider comfort with a variety of situations related to palliative and EOL care. The EPCS covers all eight domains of the national palliative care guidelines and core lessons of physician-specific and nurse-specific end of life education curricula in the USA. The EPCS exhibits strong internal consistency (alpha = 0.96). For the purposes of this study we will exclude the CEV sub-domain items from the EPCS.

CAPACITI Competencies Survey. The CAPACITI Competencies Survey is a study created questionnaire based on the CanMEDS framework for improving patient care by enhancing

physician training and the topics covered in the CAPACITI program. CanMEDS, developed by the Royal College of Physicians, delineates critical competencies to effectively meeting the health care needs of patients, including communication, expertise, collaboration, advocacy, and commitment (cite https://www.royalcollege.ca/rcsite/canmeds/canmeds-framework-e). Each item is scored on a 7-point Likert scale ranging from 1 (lowest level of confidence) to 7 (greatest level of confidence). The Competencies Survey was developed and tested in Wave 1 of CAPACITI. The CAPACITI Competencies Survey exhibits strong internal consistency (alpha = 0.96).

Assessment of Interprofessional Team Collaboration Scale II (AITCS II). The AITCS is an instrument designed to measure interprofessional collaboration among team members. The AITCS consists of 23 items considered characteristic of interprofessional collaboration (how team works and acts). Scale items represent three elements considered to be key to collaborative practice. These subscales are: Partnership (8 items), Cooperation (8 items), and Coordination (7 items). Each item is scored on a 5-point Likert scale indicating the extent to which the team exhibits each, ranging from 1 (Never) to 5 (Always). Internal consistency estimates for reliability of each subscale range from 0.80 to 0.97, with an overall reliability of 0.98

Assignment Completion & Change Survey. This survey is a two-part, study created questionnaire based on the CAPACITI module activities. Part A is unique to each module, asking participants to indicate the extent to which they were able to complete each of the session assignments for the module. Response options are: Have not started (1), Started but not completed (2), Completed (3). Part B contains four items assessing changes in thinking, behaviour, processes, and patient/family experience, respectively. Each item is scored on a 5-point Likert scale, rating the strength of agreement with each element of change, from 1 (strongly disagree) to 5 (strongly agree).

Module Session Evaluation

Participants will be asked to complete an evaluation poll at the end of each module session, consisting of 4 items: 3 items scored on a 5-point Likert scale ranging from 1 (Not at all/ Poor/ Not successful) to 5 (Very likely/ Excellent / Extremely successful) and 1 dichotomous item assessing perceived bias (Yes/No).

1. How likely are you to adopt at least one idea or concept from this session in your practice or organization?
2. How would you rate this webinar overall?
3. How successful were we in meeting the objectives in providing tools, knowledge or tips?
4. Do you perceive any degree of bias in any part of this webinar?

Post Module Team Focus Groups

We will conduct virtual focus group with a purposive sample of teams who complete the CAPACITI modules both in the intervention and control groups: 6 to 10 teams in each arm PER MODULE (12 to 20 teams total, 60 to 100 team members total). The focus group discussion guide was developed and tested in Wave 1 of CAPACITI. In the focus group we will inquire if implementation was perceived as successful (If so, how? If not, why?) and what were the barriers and facilitators. The interview data will be supplemented by field notes maintained by staff during the study. (See appendix for focus group discussion guide)

Data Collection Schedule

Team Registration	Team Member Registration	Pre Module	Post Module	12 Months Post Module
Team Characteristics (e.g., region)	Individual Demographics and Characteristics (e.g., profession)	End-of-Life Professional Caregiver Survey (EPCS)	End-of-Life Professional Caregiver Survey (EPCS)	End-of-Life Professional Caregiver Survey (EPCS)
	ORCA (Organizational Readiness to Change Assessment) Survey	CAPACITI Competencies Survey	CAPACITI Competencies Survey	CAPACITI Competencies Survey
	Practice Characteristics [Total case load, # identified PC, Typical timing for first initiation of PC cancer and non-cancer]		Practice Characteristics [Total case load, # identified PC, Typical timing for first initiation of PC cancer and non-cancer]	Practice Characteristics [Total case load, # identified PC, Typical timing for first initiation of PC cancer and non-cancer]
			Module Session Evaluation (at each Session)	
			Assignment Completion & Change Survey	
		AITC-II survey – interprofessional team collaboration scale	AITC-II survey – interprofessional team collaboration scale	

4.10. STATISTICAL POWER/SAMPLE SIZE: Sample size calculation is based on the assessment of the primary outcomes of Effective Care Delivery (ECD 8-items) subdomain on the End-of-life Professional Caregiver Survey (EPCS) and the % of patients identified as requiring a palliative care approach.

Previous work using the EPCS with nurses, physicians, and social workers identified a mean score of 3.6 for the ECD subdomain and a standard deviation (SD) of 1.0 (scale from 1 to 5). We assumed that a difference of 0.5 in SD (i.e., a delta of 0.5 or a half point on the scale) between treatment groups at T2 would be important to detect. Accounting for the cluster design, we estimate that the correlation between providers within teams was 0.15 and that each team would have a minimum of 4 members participate. Given a two-sided alpha of 0.05, a power of 80%, 192 providers from 48 teams would be required. This will also allow for detection of a 1-point difference increase of the % of patients identified as requiring a palliative care approach (SD=2). We anticipate 60 teams with an average of 5 members per team.

4.11. ANALYSIS PLAN: The intervention is at both the team and individual level. The unit of analysis is at the individual and team level, depending on the outcome considered.

Quantitative analysis (registration and survey data): Treatment groups will be compared with respect to registration variables (potential covariates) by tabulation methods (means, standard deviations, frequencies). Both team level variables (e.g., region) and member level variables (e.g., PC training) will be tabulated. The primary analysis will be a between treatment comparison of intervention and control groups of post module scores on the primary outcomes

(EPCS and % identified for PC). Secondary analyses will include comparisons of all team outcomes. Mixed model ANOVA methods will be used, taking into account the increased variance due to cluster randomization, for the assessment of the primary outcomes [Donner, 1981]. Confidence intervals (CI) for the difference of means will be calculated and adjusted for data clustering. Multilevel mixed models with two levels, cluster and repeated measures will be used to investigate the effect of the intervention over time (baseline, post module, 6 months post module).

Qualitative Analysis (focus group data): We will conduct a thematic analysis using a constant comparison method along a 4-stage process based on Pope's Framework Approach,[38] as we have done previously:[39,40] 1) Focus groups will be audio taped and transcribed into a document, along with staff notes, for analysis. 2) The Focus group questions will be used to create a template for organizing each team's data and emerging ideas. 3) Emerging ideas from each template construct will be coded and compared within and across teams, first independently by two analysts and then conjointly. Emerging themes will be compared and discussed until consensus is obtained between the analysts. 4) Common themes for each construct will be identified. We will maintain an audit trail that documents and justifies decisions in the analysis to promote consistency.[41]

4.12. DATA ACCESS, PRIVACY, AND ETHICS: The confidentiality of all participants' identities will be strictly maintained. Only research team members will have access to the data. Informed consent will be obtained from all provider participants. All identifying information will be removed from both quantitative and qualitative data once collected, to ensure no breeches in confidentiality. Safeguards will be undertaken to ensure the confidentiality of virtual focus group responses. No individual responses will be identifiable in any results shared with those outside the research team. No personal information such as name and email address, used to arrange the focus groups, will be linked to responses. Personal information will be deleted once the focus groups are complete. The focus groups will be digitally audiotaped, with the permission of participants. This is to ensure accuracy in capturing the groups' responses. Audio recordings of the focus groups will only be heard by the study analyst(s) of the research team and the recordings will be destroyed once the study is finished (approximately after one year). These recordings will be transcribed, however, as mentioned, the transcript will not contain any identifiable information. The participant contact list and focus group responses will be securely stored as a password protected files on a private drive on the Juravinski Cancer Centre network. Ethical approval will be sought from the Hamilton Health Sciences, McMaster University Research Ethics Board prior to commencement of the study.

5. KNOWLEDGE TRANSLATION (KT): The CAPACITI intervention represents real-time integrated KT with local teams of primary care providers.[42] Specifically the intervention's emphasis on practice supports helps teams adapt knowledge to diverse local contexts. CAPACITI's high-facilitation and coaching allow for tailoring of evidence to address local barriers, which increases the likelihood of adopting and sustaining the intervention. We have 4 co-Is from other provinces and collaborations with the national organization to support KT spread. They will help us work with regional and provincial KUs to align our research program with their policy directives. Our key end-of-grant deliverables are:

- Deliver a series of KT meetings, presentations, reports, and policy briefs to share our results with KUs and policymakers across Canada.
- Publish our results in peer-reviewed journals and present at relevant academic conferences.

- Create a national implementation report on delivering PC by primary care teams, including details on lessons learned, implementation strategies, and considerations for further implementation of the intervention across Canada and geographic diversity.

6. TIMELINE: Study activities for this cRCT requires 3 years: Start-up (6 months), Intervention and data collection (18 months), final data analysis (6 months) and KT (6 months).

7. SIGNIFICANCE: This study will generate robust evidence on the CAPACITI intervention's effect on access to home-based palliative care and primary care team capacity on a large scale using a rigorous research methodology. In a program comprised of three distinct modules, CAPACITI offers clinical education and evidence-based tools, while integrating practice supports to improve team collaboration and system coordination, and providing high-facilitation and expert coaching to adapt to the local context. CAPACITI is unique because it builds capacity within the existing team, and does not add new front-line human resources; thus any built-capacity is more likely to be sustained beyond the grant. Ultimately, this study will generate evidence that will strengthen the primary care system, increase access to home-based PC, and improve satisfaction for dying patients and their families in diverse communities across Canada.

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