# Institutional Review Board

# Intervention/Interaction Detailed Protocol

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Project Title: Caring for Caregivers and People Living with Dementia under Home-Based Primary Care

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## 1. Background and Significance

**The Homebound**

Approximately two million older adults in the United States are homebound, defined as leaving home once a week or less. Another 5.5 million are unable to leave home without difficulty or assistance from another person. These persons have multiple chronic conditions, functional impairments, and often, limited social capital. Most receive formal and informal caregiving in the home. They have unmet care needs and high mortality. Since the COVID-19 pandemic, the prevalence of homebound older adults has doubled, with significant racial inequities. Among adults 70 and older, we found that in 2020, the prevalence of homebound status increased from approximately 5.0% from 2011-2019 to13.0% in 2020. The estimated population of completely homebound older adults in 2020 increased to 4.2 million. This increase was most evident among Black non-Hispanic (from 9.0% to 22.6%) and Hispanic/Latino (from 16.7% to 34.5%) older adults. Because of difficulty leaving home, frail homebound older adults are commonly unable to access traditional office-based primary care. Provision of HBPC is critical to assuring equitable access of primary care to this diverse, vulnerable population.

**Dementia Prevalence Among Homebound Older Adults**

Between 40-80% of homebound adults are living with dementia. In a large epidemiologic study of homebound Medicare beneficiaries, 80% of completely homebound beneficiaries had dementia.

**Home-Based Primary Care (HBPC)**

HBPC provides medical care by physicians, advanced practice providers, and, often, interprofessional care teams at home over time. This care addresses complex medical issues, as well as patients' functional status, cognitive and behavioral concerns, and social determinants of health.6HBPC has been studied extensively and has demonstrated reductions in hospital admission, emergency department visits, hospital length of stay, and admissions to long-term care. The ongoing Center for Medicare and Medicaid Innovation Center Independence at Home demonstration, which tests the provision of HBPC in the context of a shared-saving payment mechanism, produced 10-times the per year savings of Accountable Care Organizations among Medicare fee-for-service beneficiaries. HBPC has been growing in the context of lessons learned during the COVID-19 pandemic and the expansion of value-based care initiatives. There has been growing interest among payers, payviders (entities such as Humana and CVS / Aetna that are both payers and providers of healthcare delivery services), health systems and investors in HBPC. As a result, HBPC has been growing to meet the vast gap in care between those needing services and those receiving them (only 12% of homebound Medicare beneficiaries receive HBPC). While growth in HBPC services increases, there is an accompanying need for the demonstration for consistent, high-quality care. Based on our work with LN practices, it is clear that many gaps in care quality exist in HBPC. One of these gaps is the provision of evidence-based care to PLWD.

**Dementia Prevalence among People Receiving HBPC**

As previously stated, approximately 50% of patients cared for by HBPC practices in the US have dementia. As more Americans choose to receive long-term care in the home and as HBPC practices expand to meet growing demand, it is critical that HBPC practices provide high quality care for PLWD and their caregivers. The high prevalence of dementia among HBPC patients creates incentives and economies to implement dementia-focused care innovations not available in typical ambulatory-based practice, where the prevalence of dementia is much lower. Dementia care is challenging for HBPC practices. Unfortunately, most HBPC practices are not equipped to provide optimal care to PLWD or their caregivers. In a recent survey of LN members, we asked them to identify the one thing they wanted to address to provide better care. The top choice was better dementia care. LN practices stated they lacked the knowledge and skills to meet the needs of their PLWD and their caregivers. They indicated a strong desire to acquire additional skills and knowledge in the care of PLWD and to be able to better support the caregivers of PLWD.

**Caregiver Burden Experienced in the Support of HBPC Patient with Dementia**

Caregiver stress, depression, anxiety, and reduced well-being are common among caregivers of PLWD, exacerbated by care recipient behavioral symptoms, and negatively impact morbidity and mortality for both themselves and the person for whom they care. Although some caregivers adjust well to their role of caring for a PLWD, approximately 40% report stress that negatively impacts their health and well-being. Caregiver stress is a strong predictor of negative outcomes for both the caregivers themselves and for those they care for. Caregivers describe a variety of sources of stress that include challenging behavioral symptoms of the PLWD, concerns about whether they are doing their caregiving job well, uncertainty about disease progression, worries about the direct impact of caregiving on their own

health, complexities navigating their own life in addition to caregiving responsibilities, and social isolation. These caregiving stressors can lead to an array of negative health outcomes, including worsened immune function, declines in mental and physical health and increased mortality. Collaborative care interventions have been shown to improve caregiver outcomes; in our work, clinicians have noted that training in caregiver support alerts them to issues they have not previously recognized and gives them the skills to address them. Given the high prevalence of PLWD and their related caregivers in HBPC practices, training HBPC practices in better caregiving has the potential to significantly improve outcomes for PLWD and those caring for them.

**Existing Dementia Care Models Should be Adapted Specifically for HBPC**

There is substantial need to develop dementia care interventions for HBPC. First, as noted above, no evidence-based dementia care models for HBPC patients living with dementia and their caregivers exists. Because HBPC patients have significant functional limitations contributing to their homebound status, caregiver burden in this population is even greater than among PLWD who are not homebound due to functional impairments experienced by homebound, which adds to caregiver burden. Further, homebound PLWD and their caregivers commonly lack access to office-based dementia care specialists (geriatricians, psychiatrists, neurologists) or office-based health system dementia care resources because of their inability to leave their homes. The development of the proposed Dementia Care Quality at Home intervention can serve to address this important gap in care delivery.

**Dementia Care Models**

Several dementia collaborative care models have been developed to improve care delivery and support PLWD. These include the Healthy Aging Brain Center, the Alzheimer's and Dementia Care program, and MIND at Home. None of these programs have been translated to or tested systematically in HBPC practices.

We participated in the development of Care Ecosystem, a model that uses health care navigator training, patient/caregiver assessment, and modular interventions focused on the caregiver to support PLWD and those caring for them. Care Ecosystem coalesced the key core components from several other effective dementia care models and translated them into three core components: 1) a standardized assessment tool to assess PLWD and caregiver needs; 2) seven modules created to optimize the well-being of the PLWD and their caregiver; and3) regular team-based review of persons participating in the program to address care challenges and a team-based case conference approach to solve these challenges. In a randomized controlled trial of Care Ecosystem focused on patients receiving care in office-based primary care practices, PLWD receiving the intervention had improved quality of life and reduced emergency department visits. Caregivers experienced decreased depression and caregiver burden, as well. After the original Care Ecosystem trial, we adapted Care Ecosystem into the CaRe EcoSystem iCmp dEmeNTia(CRESCENT) intervention so that it could be better integrated into traditional office-based primary care. Rather than using health care navigators as the primary effector arm of dementia assessment and support, we modified the training and the intervention so that it can be easily integrated into routine healthcare workflow in primary care or health system dementia initiatives. In a pilot trial, we adapted the Care Ecosystem dementia care intervention to be used by clinicians (i.e., nurse care managers) while maintaining its three core components (assessment, modules, and case-based team meetings). Office-based clinicians reported that the intervention Caring for Caregivers and

People Living with Dementia under Home-Based Primary Care improved their knowledge base and offered a thoughtful structured approach for identifying unmet needs in PLWD and their caregivers.

## 2. **Specific Aims and Objectives**

In our proposal, *"Caring for Caregivers and People Living with Dementia under Home-Based Primary Care"* we propose to combine features of the two previously proven models of dementia care, Care Ecosystem and CRESCENT into the HBPC setting, and thereby bring expert dementia care to the frontlines of healthcare delivery in an intervention we call Dementia Care Quality at Home intervention. The overarching goal of this project is to develop a dementia care intervention for PLWD and their caregivers, Dementia Care Quality at Home, and test the feasibility of implementing the intervention in HBPC practices to ultimately improve outcomes of PLWD and their caregivers. The two practices include Queens Geriatric Services Home Based Primary Care Program based in Honolulu, Hawaii and Virginia Commonwealth University Health Home-Based Primary Care Program (VCU) in Richmond, Virginia

Objectives: Over the course of the 24-month project, we will:

1. Develop and refine HBPC Dementia Care Quality at Home. We will:

- Conduct qualitative focus groups with relevant stakeholders (caregivers of PLWD, and HBPC clinicians and staff) to learn how to refine and adapt the intervention for HBPC.
- Adapt existing dementia care models (Care Ecosystem and CRESCENT) into the Dementia Care Quality at Home intervention using feedback from stakeholder focus groups

2. Establish feasibility (primary outcome), acceptability, and fidelity of HBPC Dementia Care Quality at Home through an open-pilot trial involving two HBPC practices by:

- Training clinicians and staff at two HBPC practices and implementing the adapted Dementia Care Quality at Home intervention.
- Determining the feasibility, acceptability, and fidelity in implementing Dementia Quality Care at Home for PLWD and their caregivers.
- Identifying barriers and facilitators to implementation of the adapted intervention (Dementia Care Quality at Home) in HBPC practices.

The project will be conducted through two main aims:

For Aim 1, we will develop and refine HBPC Dementia Care Quality at Home. We will conduct a user-centered intervention adaptation process via qualitative focus groups (n=4 focus groups). Two groups per HBPC practice-one each for practice clinicians/staff and for caregivers of PLWD, up to 48 persons total or until theme saturation) to explore perceptions of the proposed intervention and ensure both caregiver-centered and practice-centered approaches to delivery modality, structure, skills, and format. In this process, we will employ the DART framework to define stakeholder needs and motives, understand the potential value of intervention, identify stakeholder preferences, and engage

stakeholders in a user-centered design process to refine the intervention. There are no hypotheses for this qualitative aim.

For Aim 2, we will evaluate the feasibility, acceptability, and fidelity in implementing HBPC Dementia Care Quality at Home in two practices for the practices and for caregivers of PLWD. We will conduct a live open-pilot of HBPC Dementia Care Quality at Home. Hypothesis 1: HBPC Dementia Care Quality at Home will meet benchmarks of feasibility, acceptability, and fidelity by the HBPC practices implementing it and by caregivers of PLWD who experience the intervention. Hypothesis 2: HBPC Dementia Care Quality at Home intervention will be acceptable to caregivers of PLWD and will be feasible to implement at the practice level. We will assess feasibility of caregivers of PLWD to engage with the intervention, the acceptability of the intervention to caregivers, and the impact of the intervention on caregiver well-being by surveying caregivers at the conclusion of the pilot. In addition, we will assess multiple dimensions of feasibility, acceptability, and fidelity of the intervention for the practices. The two participating HBPC practices, as noted, are members of the LN, have been trained in quality improvement methods and use a quality improvement information platform for their quality improvement processes. We will leverage the resources of the practices and incorporate a quality improvement approach during the open-pilot to iterate and improve the intervention.

In Aim 1, we will conduct qualitative 4 focus groups with up to 48 HBPC clinicians and staff and caregivers of PLWD to adapt a Dementia Care Quality at Home manual and to identify barriers and facilitators to implementation

In Aim 2, we will conduct a feasibility, open-pilot study of Dementia Care Quality at Home developed in Aim 1, among caregivers of PLWD cared for by HBPC practices and practice clinicians and staff with n=2 groups; up to 50 patients. We aim to establish feasibility, acceptability, and fidelity of the intervention.

## 3. General Description of Study Design

This study will be conducted through four qualitative focus groups. The four focus groups will be separated into a group of up to 12 HPBC clinicians, staff and caregivers of PLWD per group. There will be 2 practices and 2 focus groups per practice. MGB will be the sIRB of record and Johns Hopkins Medicine, the Queens HBPC program, and the VCU HBPC program will all serve as relying sites.

The study will be tested for its feasibility, acceptability, and fidelity in an open trial with pre-post assessments with up to 25 patients per practice (n = 2; up to 50 patients).

## 4. Subject Selection

Caregiver participants will be a) adults (18 years or older) b) have English fluency and literacy and live in the United States c) live with and care for an individual with ADRD d) anticipates providing care for the next 6 months e) provide an average 4 hours of supervision or direct assistance per day for the care recipient and f) have been identified by the practice as experiencing caregiver stress.

Staff participants will be a) 18 years or older b) have English fluency and literacy and live in the United States and c) a part of a HBPC primary care program or closely connected to the practice.

Participants will be informal caregivers recruited from Virginia Commonwealth University or Queens HBPC practices.

All recruitment efforts will be documented in a RedCap database.

## 5. **Subject Enrollment**

Aim 1: Participants will be informal caregivers recruited from VCU or Queens HBPC practices. After enrollment the Clinical Research Coordinator (CRC) will schedule the focus group for either HBPC staff or for HBPC PWD caregivers at a time that is convenient. All participants will also undergo a zoom session with the CRC to ensure that they are comfortable with the platform.

Aim 2: Eligible caregivers identified by their clinicians will be told about Dementia Care Quality at Home and invited to participate. Caregivers who agree to participate will be contacted by the CRC, who will introduce the study and obtain informed consent. After informed consent, the caregiver will complete the enrollment interview. Once the enrollment interview has been completed, the practice dementia champions will be notified and instructed to reach out to the caregiver to enroll them into the Dementia Care Quality at Home program.

As part of enrollment, we will obtain basic demographic information via telephone or through a RedCap questionnaire. Review of the baseline informed consent information on the questionnaire and completion of the demographic questionnaire will imply consent.

After the completion of the baseline questionnaire, the research assistant will complete the UBACC with the study participant. The UBACC is a 10-item scale that assesses decision-making capacity by confirming an individual's comprehension of the study procedures outlined by the research assistant in the verbal informed consent. This tool will assure that PWD have the capacity to consent for themselves. If they lack capacity, their caregiver will be required to provide verbal consent and they will be asked to provide verbal assent. Research indicates the UBACC tool is both reliable and valid and appropriate for use by trained research assistants. Specific areas assessed include understanding, appreciation, and reasoning. Responses to questions are scored as 0, 1, or 2. A "2" indicates an acceptable response. For responses that are not scored as 2, the research assistant may review those sections of the consent form and re-ask those specific questions. Persons who pass the UBACC will be eligible to participate in the study,

regardless of dementia status. If the person with dementia (PWD) does not pass the UBACC, the caregiver of the PWD will be invited to participate and PWD may still assent to participation.

## 6. **STUDY PROCEDURES**

There will be four focus groups that will be separated into a group of up to 12 HPBC clinicians, staff and caregivers of PLWD per group. There will be 2 practices and 2 focus groups per practice. Each person in a group will meet over Zoom for approximately 60 minutes. Within the focus group, individuals will be talking about their lived experience with dementia in the context of home-based primary care practices. They may also examine and provide feedback on the draft intervention that aims to improve the outcomes of persons with dementia and their caregivers. A moderator will ask several questions while facilitating the discussion. Participants will also be asked a few background questions.

Information about the results of the research study or the results of your individual participation in the research study are not expected to be returned. However, at the conclusion of the study, if a participant asks for the findings of the study, this can be sent to their preferred mode of contact.

The project outcomes we plan to achieve:

1) Develop and refine HBPC Dementia Care Quality at Home.

2) Conduct N=4 qualitative focus groups with up to 12 HPBC clinicians, staff and caregivers of PLWD per group. There will be 2 practices and 2 focus groups per practice

3) Adapt existing dementia care models (Care Ecosystem and CRESCENT) into the Dementia Care Quality at Home intervention using feedback from stakeholder focus groups

4) Establish feasibility (primary outcome), acceptability, and fidelity of HBPC Dementia Care Quality at Home through an open-pilot trial involving two HBPC practices by:

Clinicians and staff will be paid $50 for their participation in the focus groups. Caregiver groups will be paid $50 for their participation in the focus group in Aim 1 and $50 for completing follow-up surveys in Aim 2.

## 7. **Risks and Discomforts**

It is unlikely that participants will incur any risk of physical harm because of study participation. Participants may find some questionnaire items to be emotionally upsetting or may experience psychological discomfort while discussing their experiences during intervention sessions. The study PIs are geriatricians with expertise in the care of PLWD and issues related to caregiver stress and will triage and refer individual participants to an appropriate level of clinical care, as needed.

## 8. **Benefits**

Caregivers may benefit from the improved care and support from their home-based primary care practice.

## 9. **Statistical Analysis**

Power analyses are not appropriate for our qualitative analyses from our focus groups (4 focus groups; up to 12 HPBC clinicians, staff and caregivers of PLWD per group. There will be 2 practices and 2 focus groups per practice

Power analyses are also not appropriate for intervention refinement where the goal is to "explore" feasibility and opportunities to refine the intervention.

Project Analyses: Focus group data will be analyzed using Nvivo12. We will assess reliability (kappa) of coding for themes and patterns of responses. The postdoctoral fellow, with supervision of the MPIs, will code qualitative data into superordinate themes and subthemes. The research assistant will complete reliability coding. Discrepancies will be resolved through discussions until reliability is obtained (kappa >.80). We will use qualitative thematic analyses with a hybrid deductive-inductive analyses plan. Inductive analyses will be guided by the Framework method. For quality assurance, we will follow the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (https://pubmed.ncbi.nlm.nih.gov/17872937/) for study conduct and reporting.

## 10. **Monitoring and Quality Assurance**

Dr. Ritchie is responsible for the data and safety monitoring. The interviews will be recorded on MGB Zoom and uploaded directly to MGB Shared File Area (SFA) and/or MGB Cloud Storage. All investigators and research staff have completed the research conduct certifications and trainings required by MGB. All investigators and research staff use laptops encrypted per MGB policy.

Recordings will be transcribed by an online service that contracts with MGB and de-identified by the research study team. Demographic data will be de-identified and formatted on a clean document.

The transcripts will be stripped of identifiers. All participants will be assigned an identification number and pseudonym. All transcripts from the audio recordings will be reviewed for accuracy. During this review, participants' names – and other identifiable names (e.g., spouses or partners, hospitals, doctors) will be replaced by a pseudonym (interviewee) or capitalized generic indication of the relationship (e.g., HUSBAND, WIFE, DAUGHTER, DOCTOR). Only these revised transcripts will be reviewed during the qualitative analyses. The interview recordings will be deleted at the end of this study.

Only the research study team will have access to the correspondence table with concatenated IDs and names. Interview data and correspondence table with concatenated IDs will be kept in password-protected files on a MGB Shared File Area or MGB Cloud Storage only accessible to research staff through direct invite. Dr. Ritchie is responsible for data storage.

We will assess reliability (kappa) of coding for themes and patterns of responses. Study personnel with supervision from MPIs, will code qualitative data into superordinate themes and subthemes. The research assistants will complete reliability coding. Discrepancies will be resolved through discussions until reliability is obtained (kappa >.80). We will use qualitative thematic analyses with a hybrid deductive-inductive analyses plan. Inductive analyses will be guided by the Framework method. We will follow the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines for study conduct and reporting.

The MPIs have ample expertise with recruitment and retention, as well as proposed data analyses methods.

## 11. **Privacy and Confidentiality**

☒Study procedures will be conducted in a private setting

☒Only data and/or specimens necessary for the conduct of the study will be collected

☒Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)

☐Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)

☒Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol

☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)

☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies

☒Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research

☒All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens

☒The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research

☐Additional privacy and/or confidentiality protections