Community **P**aramedic **C**oaching **P**rogram for **C**aregivers and **P**eople with **D**ementia **(CP3D)**

PI: Manish Shah
Co-I: Gwen Costa Jacobsohn
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PURPOSE OF THE STUDY AND BACKGROUND

Purpose & Aims

The purpose of this program of research is to proactively reduce the need for acute care services by community-dwelling persons with dementia and their informal caregivers, using community paramedics to deliver an evidence-based coaching intervention in coordination with their primary care providers. Intervention sessions, delivered at home over the course of a year, will help the patient-caregiver dyad better navigate dementia-related medical, behavioral, and social issues, improving both psycho-social and medical outcomes.

The aims of this pilot study are to (1) assess the applicability, appropriateness, and feasibility of the intervention delivery model, as applied to persons with dementia and caregivers receiving primary care in a rural community, (2) iteratively re-design and adapt the program to incorporate ongoing stakeholder feedback, (3) pilot test data collection instruments used in measuring pre-post changes in outcomes of interest, including survey items and chart review forms.

Primary outcomes of interest include:

- Healthcare utilization of person with dementia and caregiver: ED use
- Intervention / Implementation metrics: Proportion of coaching home visits completed, proportion of coaching phone calls completed

Secondary outcomes of interest include:

- Psycho-social outcomes: Caregiver burnout (Zarit), caregiver anxiety (GAD-7), caregiver depression (CESD-10), satisfaction (Caregiving Satisfaction Scale), resilience (Caregiving Self-Efficacy, Work-Family Conflict), caregiver quality of life (C-DEMQOL)
- Healthcare utilization of person with dementia and caregiver: Communication/visits with clinic providers (CAPACITY Measure also)
- Knowledge: Knowledge of dementia (DKAS)

Other exploratory variables of interest:

- Psycho-social outcomes: Work performance (WHO HPQ), memory and behavioral problem burden (RMBPC), impact on finances, community resources and engagement,
- Healthcare utilization of person with dementia and caregiver: Hospitalization, use of case management services, desire to institutionalize
- Intervention/Implementation metrics: home safety measures, advanced care planning
- Knowledge: caregiving skills

Background

Persons with dementia (PwD) have complex medical and social needs that are often unpredictable due to disease heterogeneity and changing symptom presentation as dementia progresses. Community-dwelling PwD and their caregivers rely extensively on emergency care services to address medical and behavioral needs, particularly during periods when primary care clinics are closed, appointment times are unavailable, or they are faced with new / challenging symptoms they feel ill-equipped to manage at home[1]. The ED, however, is often not optimally

suited to meeting the acute care needs of PwD / caregivers. ED use can even contribute to deleterious outcomes (e.g., increased risk of agitation, delirium, falls, and hospitalizations).[2-5] Frequently the issues that bring PwD to the ED are ones that could have been prevented through upstream caregiver education / support, anticipatory guidance about symptomatic changes and disease progression, and improved communication channels between the patient-caregiver dyad and the primary healthcare team.[1, 6] Alternatively, the issues could have been addressed through real-time assessment in a clinic setting or virtually through telemedicine.[7-9]

Community paramedicine is a community-based health care model in which paramedics function outside their traditional emergency response and transport roles to support residents and facilitate more appropriate use of emergency care resources.[10] Depending on the goal of the specific program, community paramedics can screen for specific conditions (e.g., depression), reconcile prescribed medications, conduct home safety evaluations, provide psychosocial support, coaching, or education (e.g., how to access appropriate care, medication reconciliation), and recommend referrals to community/social service programs.[11, 12] Through these programs, community paramedics can address problems as they occur within patients' homes— possibly preventing the development of acute medical problems, reducing the need for unnecessary transport and improving patients' quality of life.[13, 14] Community paramedicine programs have shown tremendous promise, leading to reductions in 911 calls, ambulance transports, ED utilization, hospital readmissions, and overall health care costs.[15]

Community paramedicine programs have gained traction across the state of Wisconsin. As more local EMS agencies implement these programs (e.g. Madison Fire, Fitchrona EMS, Ryan Brothers), it is advantageous for us examine ways to utilize this resource as a way of delivering home-based interventions, particularly for underserved populations and patients with complex needs (such as rural patients with dementia).[16-18] Based on our current program of research (see IRB ID #2015-1197), we believe that community paramedics can effectively use coaching techniques to build the knowledge and skills of patients and their caregivers, as well as effectively facilitate communication with other health care providers (e.g., primary care) and social services to improve healthcare outcomes. We specifically believe that this coaching model can be beneficial in supporting community-dwelling persons with dementia and their primary caregivers as they navigate disease-related medical and social issues.

2. STUDY DESIGN

Overview

This pilot study is designed to evaluate the potential effectiveness of the implementation strategy and intervention delivery model of a community paramedic coaching program for caregivers of persons with dementia, in direct coordination with the patient and caregiver's primary health care team. Specifically, ***we will assess the acceptability, appropriateness, and feasibility of the program***[19], collecting data from all implementation stakeholders at multiple time points throughout the study period using quantitative survey instruments and qualitative interviews.

The study will employ a stepped design using a rapid-cycle evaluation approach.[20, 21] Three cohorts of 4-5 dyads each will start the intervention at staggered intervals. Within each cohort, a new dyad will begin the program approximately every two weeks, with an approximate four week gap between each cohort for feedback collection and program iteration. Real-time feedback obtained from multiple intervention stakeholders (caregivers, persons with dementia, coaches, clinical staff/providers) will be used to iteratively improve intervention delivery and program implementation for the next, all while the first group continues the pilot. In this way, problems can be identified and solutions generated, with enough time to adapt the program and evaluate revisions. Staggering participant start dates allows for multiple rapid-cycle iterations within a single

pilot study.

Formal outcome measures will be collected via caregiver surveys and chart reviews (both caregiver and patient) at four points in the pilot timeline: baseline, 13 weeks, 25 weeks, and post-intervention.

Intervention Description
The intervention is an adaptation of the evidence-based REACH program (Resources Enhancing Alzheimer's Caregiver Health), designed for and validated in multiple settings to give education, tools, and support to informal caregivers of people with dementia, delivered through a series of at-home visits (minimum of 9 in-person and 3 phone sessions) conducted by trained and certified coaches over 6-12 months.[22-27] The content of the coaching visits will follow the REACH program protocol, with materials customized with information about local community resources (e.g., Dane County). Coach/administrator training for delivery of the REACH intervention will be conducted by master trainers from the Rosalynn Carter Institute for Caregiving, a department of Georgia Southwestern State University, who administers, certifies, and provides oversight for REACH sites nationally (https://www.rosalynncarter.org/programs/rci-reach/). An overview of the REACH content delivered by a coach across a normative 6-9 month delivery period is uploaded as a separate document. For the purposes of this pilot study, we have coordinated with RCI to extend delivery of the same content over a 12-month period, with home visits occurring more frequently at the beginning and spreading further apart towards the end, and additional phone "REVIEW" sessions between home-visits.

Each home visit covers specific coaching content, building on strategies and behaviors covered in prior sessions. The program includes flexibility to allow coaches to adapt the timing/delivery of content to attend to the needs of the caregiver (e.g., answering questions about previously-covered topics, covering topics from a future visit to help coach a caregiver through an emergent dementia-related issue). Sessions typically last 1-2 hours. Following each visit, the coach completes a fidelity checklist and writes client progress notes as per the REACH protocol.

This pilot adapts prior REACH implementations in two main ways: (1) intervention coaches will be community paramedics with advanced medical training, rather than social workers (or other non-medical social service personnel), and (2) the program will be formally coordinated with the patient and caregiver's primary care practice, allowing for care coordination and information sharing between participants, coaches, and clinic staff/providers. Participants will also have the ability to share information about their use of community dementia care resources (e.g., social services, transportation, senior center case management, dementia caregiver support groups, dementia-related educational programming, respite) with coaches so they can communicate necessary information to the clinic for possible inclusion in the participant's EHR (as per the clinic's determination), facilitate care coordination, and help keep the patient's care plan up to date. Paramedic coaches will be utilizing their medical knowledge, but not providing any direct medical care.

This pilot study also differs from prior REACH trials in that outcome measures include health care and emergency services utilization, particularly related to the occurrence of acute medical and behavioral problems, as well as perceptions of health care quality, in addition to caregiver psycho-socio-emotional measures (already included in the standard REACH assessment package).

3. CHARACTERISTICS OF THE RESEARCH POPULATION

3.1. Subject Characteristics

a) **Number of Subjects:** We aim to enroll 15 patient-caregiver dyads (30 participants total), and interview 5-10 stakeholders for feedback on intervention processes. We will enroll all eligible stakeholder participants, anticipated not to exceed 10 individuals.

b) **Gender and Age of Subjects:** All patient subjects will be age 60 and older. Caregiver subjects will be adults at least 18 years of age. No limitations will exist regarding the gender of patient or caregiver subjects. No age or gender restrictions for stakeholder participants.

c) **Racial and Ethnic Origin:** There are no restrictions based on race or ethnicity for patient/caregiver subjects or stakeholder subjects.

d) **Vulnerable Subjects:** Patients must have a confirmed diagnosis of early or mid-stage dementia made by the patients' primary care provider and confirmed by testing, and are therefore considered a vulnerable population. All patients with dementia will be enrolled with their primary informal caregiver (with whom they live). Both must agree to participate in this study and complete the consent process in order to be enrolled. If the patient lacks capacity their legally authorized representative (LAR) can provide consent on their behalf. Stakeholders employed by the Department of Emergency Medicine (coaches) are potentially vulnerable as they are employees.

3.2. **Inclusion and Exclusion Criteria**

a) **Patient Inclusion Criteria:**
- ≥60 years old
- Diagnosis or indication in medical record of mild to moderate dementia (any subtype)
- English speaking
- Community-dwelling (independent and assisted living acceptable)
- Living with their primary informal caregiver
- Patient of a UW Health primary care provider affiliated with and participating in the study

b) Patient Exclusion Criteria
- Receiving intensive care management services
- Receiving aggressive care for another condition (e.g., chemotherapy for cancer, surgery planned for problem)
- In isolation due to contagious illness
- Enrolled in home hospice
- Currently incarcerated, in police custody, or ward of the state
- Legally blind or deaf (unable to hear or see even with assistive devices)
- Lacks decisional capacity and no available legally authorized representative (LAR) to provide consent
- Patient refuses enrollment

c) Caregiver Inclusion Criteria:
- Adult informal caregiver (≥18 years old) of a person eligible for this study (determination based upon caregiver self-identification).
- Lives in the same household (primary residence) as the patient with dementia.
- Has a working telephone
- English speaking

- UW Health primary care provider

d) Caregiver Exclusion Criteria:

- Unable to participate in the program as defined below
- Employed by a professional/private agency to provide care to the care recipient (i.e., professional caregiver, not an informal caregiver)
- Has a diagnosis of dementia or cognitive impairment causing functional impairment
- In isolation due to contagious illness
- Legally blind or deaf (unable to hear or see even with assistive devices)
- Refuses enrollment

e) Stakeholder Inclusion Criteria (No Exclusion Criteria):

- Involved in the implementation study activities in related to the intervention, either as a clinician, member of the clinical staff, paramedic coach, social service provider, or member of an affiliated UW Health IT department.

4. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

4.1. **Method of Subject Identification and Recruitment—Patients and Caregivers:** Potentially eligible patient/caregiver participants will be identified by the patient's primary care provider prior to a clinic visit in which the patient and informal caregiver will be present. During the clinic visit, the provider will briefly describe the study and pilot intervention and ask if both the patient and caregiver would be interested in hearing more about the study. The provider will make it clear that there are no repercussions for choosing not to hear about or participate in the study. If both agree, the clinic team member will obtain phone contact information from the caregiver, as well as the time(s) at which they would like to receive a call from a member of the research team. They will also be asked if they would like to provide an email address so that the research team can email a copy of the consent form in advance of the phone call. All interested potential participants will be sent a hard copy of the consent document in the mail prior to the phone call, regardless of whether or not they provide an email address.

If the participants do not answer the phone at the specified time, the researcher will leave a short voice message containing no PHI or information about the details of the study--containing only the name of the researcher, that the caller is from the University of Wisconsin, a call back number, and a time when the researcher will try to call them again. If the researcher is unable to reach the potential participants after 3 attempts, they will let the referring primary care team know (for reference).

4.2. Method of Subject Identification and Recruitment—Stakeholders: Potential stakeholder qualiparticipants will be identified based upon their role in implementing the intervention, e.g., primary care providers, members of the clinic staff (nurses, care coordinators), paramedic coaches delivering the REACH intervention, or a person affiliated with the UWHealth Health Information Exchange team. All identified stakeholders have the option of choosing whether or not they wish to participate in the feedback interviews.

4.3. **Process of Consent—Patient and Caregiver Participants:** If both the patient and caregiver are interested hearing about the study, a member of the research team will call potential participants at the predetermined time. During the phone call, the researcher

will describe the study and review all consent documentation content (sent previously via mail, and email if address is voluntarily provided), including a detailed explanation of the study, its potential benefits, and the potential risks of participation. Both patient and caregiver participants will be asked if they have any questions. Once all questions have been answered, each participant will be asked separately to give oral consent to participating in the study (via waiver of signed consent).
For those patients interested in participating, the researcher will formally assess the decisional capacity of the patient (per UW IRB policy, there is no reason to believe that the caregiver would not have decisional capacity, and so no evaluation will take place of the caregiver). The decisional capacity evaluation assesses the potential subject's understanding of the study, and will be assessed using the following checklist, which has been used in previous UW IRB approved studies with similar populations of participants:

- □ Participant was able to convey the purpose of the study.
- □ Participant was able to convey the potential risks of the study.
- □ Participant was able to convey the potential benefits of the study.
- □ Participant recognized the voluntary nature of the study.
- □ Questions were answered to the participant's satisfaction.

If the patient agrees to participate, though lacks decisional capacity, the researcher will discuss the study further with a LAR (likely the caregiver), if present. If the patient subject does not have one, or have one activated, then the next of kin will be approached (if present), including spouse, adult child, adult sibling, or close friend. If the LAR orally agrees to study participation on behalf of the patient, the consent process will continue. If an LAR is required but not present, the dyad will be excluded (but could be enrolled during another clinic visit). If the patient declines participation, even if the LAR agrees, the dyad will be excluded.

Once the patient participant consents, the researcher will obtain oral consent from the caregiver participant. If the caregiver declines to participate, then the entire dyad will not be enrolled.

4.4. **Process of Consent—Stakeholder Participants:** Stakeholders (e.g., clinic staff, providers, coaches, IT professionals) will be asked to provide feedback to the research team regarding intervention implementation processes. This feedback will be collected in a series of short qualitative interviews at various points in the study timeline. As these interviews involve minimal risk, will occur over the phone or secure videoconference, and involve only the gathering of targeted feedback about implementation processes (with secure handling/storage of all data collected), we request a waiver of signed consent. All potential stakeholder participants will instead be provided a study information sheet describing the study and their participation in it. This can be delivered electronically to the participant(s), and reviewed verbally at the start of each interview session. Consent will not be obtained by the supervisor of the potential participant.

5. METHODS AND STUDY PROCEDURES

Study duration: Study duration will be one year for each enrolled patient-caregiver dyad, starting at the time of the first coach home visit (intervention delivery). Delivery of the study intervention overall will last approximately 18 months, based upon the study timeline. Data will be abstracted from participants' EHR for an additional 1 year post intervention delivery to monitor long-term effectiveness.

Study visits/calls: Following the completion of all enrollment and consent processes,

participants will be asked if they would like to complete the baseline surveys (caregiver and patient versions) that day, or if they would prefer to schedule another time to complete them, preferably within the next 2-3 days). All surveys will be administered orally by a research associate using a paper form. Answers will be entered directly into REDCap (ICTR iteration).

Once the survey is complete, the study team will schedule a time for the paramedic coach to call the dyad to introduce themselves, as well as a time for the first in-home visit.

The content the REACH intervention is defined by the NIH-funded, validated program and we will faithfully follow the intervention, with tailoring to the individual participants as per the REACH training guidelines. ***Fundamentally, these are coaching visits, not care delivery or service delivery visits.*** The first session will focus on relationship development, along with conducting the standard REACH initial assessments (surveys), a home safety walkthrough, and medication reconciliation. This visit will likely last longer than the following sessions. At the end of the first visit, the second visit will be scheduled. Second, third, and fourth visits will each be one week apart. The fifth visit will occur two weeks after the fourth (intervention week 6), and the sixth two weeks after that (intervention week 8). Coaching phone calls will take place on intervention weeks 5 and 7, when no home visit occurs.

Following the first 6 home visits, in-person coaching sessions will be scheduled once per month for the remainder of the program, unless the coach and caregiver feel more frequent home visits are necessary (at the coach's discretion). Coaching phone calls can be scheduled for every two weeks (alternating with home visits), or as needed as per coach's discretion.

Post-visit Documentation: Immediately following a home visit or phone call, the coach will complete the required REACH online post-visit form (on RCI's secure HIPAA compliant web portal). Information entered includes: logistics of the visit (e.g., when, where, and visit duration, time/date of the next scheduled coach visit/call), topics covered, materials handed out, activities performed (e.g., home safety check, medication review), questions/concerns/needs mentioned by the caregiver or patient, and any community resources discussed that require follow-up at the next visit.

Coach-clinic coordination: Coaches will also write a brief summary of the home/phone visit to be sent via HealthLink/CareLink in-basket to the RN Care Coordinator at the primary care clinic (our designated clinical point of contact for the coaches). The purpose of this message is to provide relevant information about the visit to primary health care team, highlighting basic logistics (when the visit occurred, time for the next visit), general topics covered, any concerns they have for either the patient or caregiver, and any specific issues for which someone at the clinic should follow up with the caregiver/patient directly (if needed). As per clinic practice, the RN Care Coordinator will relay any information to the appropriate care team members, and/or enter information into the patient or caregiver's medical record (consistent with her existing role coordinating care for complex case management). Coaches and research staff will not enter information directly into a participant's electronic medical record.

Should there be an issue the coach feels requires more attention from a member of the clinic staff (including care coordination or social work), the in-basket message will be followed by a phone call to the RN Care Coordinator. After discussing the issue with the coach (with each person located in a private/secure location), the Care Coordinator will document and route communication about the problem to the appropriate clinic team member, who will address it as per standard clinic practice.

Should a member of the primary care team want the coach to observe or mention any particular issue at the next coaching visit, the primary health care provider or Care Coordinator will communicate that securely via HealthLink/CareLink in-basket or phone.

Survey data collection: In addition to the baseline survey, two mid-intervention surveys will be administered by phone by a member of the DEM research team at (approximately) intervention week 13 and week 25. A post-intervention survey will be administered at the completion of the study period (approximately 50 weeks).

As a formal part of the RCI REACH intervention, coaches will also be conducting a survey (containing validated instruments required for all sites using the REACH intervention) at the first home visit, and again at the final visit. These will be administered separately from the researcher-administered surveys. Data obtained from these survey instruments will be used by RCI for program monitoring and evaluation purposes, and as part of pilot data collection by the UW study team.

Feedback interviews: Stakeholders and caregiver participants will be asked for their feedback about the intervention and the structure/processes of program implementation in qualitative interviews distributed across the duration of the pilot study period. These will be conducted in person, by phone, or via secure web-based video conferencing application by a member of the DEM research team who does not supervise any of the potential participants. Interviews will be recorded, transcribed, and de-identified in order to identify areas in need of immediate improvement. Using a rapid-cycle evaluative approach, potential solutions to these problems will be addressed by members of the study team, with additional input from stakeholders gathered as necessary. Program improvements will be implemented on an ongoing basis, with continued evaluation to ensure intended solutions have had the desired effects (without unintended consequences).

Any informal feedback provided to the coaches by participants or clinic staff during intervention sessions will be recorded in the coaches' notes for that visit/call, and communicated to the study team for program improvement purposes.

Involvement of Study Personnel: The consent process and survey/interview data collection will be conducted by a trained member of the DEM research team. Intervention sessions (i.e., home visits) will be conducted by paramedic coaches trained and certified to the REACH standards who will provide these services. Primary care providers at the clinic will be involved in the initial screening for participation. The clinic's RN Care Coordinator will receive information from the paramedic coaches after each home/phone visit via HealthLink/CareLink in-basket message (information sharing between the clinic and coach authorized by both patient and caregiver as part of the consent process). Adding of information from these messages to the participant's electronic medical record is at the discretion of that individual's clinical care team, as per standard clinic protocol.

Length of Study Activities: We anticipate the consent process to last approximately 30 minutes. Baseline survey administration should take approximately 60 minutes. Mid-point and post-study surveys/interviews should each take less than one hour. Each coach visit session will take approximately one to two hours. Coach phone calls should take 30 minutes or less, based upon participant need. Feedback interviews (with participants, coaches, clinic staff/providers, and IT team members) will be designed to take 45 minutes or less.

Location of Study Activities: Initial screening and contact with potential participants take

place at the primary care clinic (in either a clinic examination room or other private location such as a conference room). The consent process and initial survey will occur over the phone. Coach visits (intervention) will take place in the participants' home and over the phone. If requested by the participants, intervention sessions could be scheduled at a mutually-agreed upon location (e.g., local senior center, café') in a private or semi-private area. Other caregiver surveys/interviews administered by members of the DEM research team will be conducted over the phone. Stakeholder interviews will be conducted either over the phone or secure videoconferencing system (e.g. WebEx).

Costs to the Subject: No costs will be incurred by research subjects.

Payment for Participation: Participating dyads will receive $50 (cash) for each data collection event (surveys, interviews) in which they participate. Over the duration of the study, each dyad will have the opportunity to receive $200 for data collection participation. Dyads who remain in the study until completion will also receive an additional $50, for a total of $250 per dyad. Clinic staff or other stakeholders participating in qualitative feedback interviews will receive $25 for each session (estimating 3-4 interviews across 18 months) throughout the duration of the study.

Return of Individual Research Results: Results from the longitudinal analysis of an individual patient or caregiver's survey data (measuring changes between pre and post-intervention metrics) will not be made available to research participants. Some individual-level assessment tools (e.g., caregiver burnout inventory) may be provided to the coaches to tailor content and aid in the delivery of the intervention, but no scores will be provided back to the participants or healthcare providers. No measures will be scored in real-time. All measures are for research purposes only, not diagnostic. At the completion of the pilot study period, participants will have the option of receiving an aggregated summary of study findings.

6. SUBJECT WITHDRAWALS

Subjects will be advised during the consent process, both verbally and in the written consent forms, that they have the right to withdraw from the study at any time without repercussions or changes in the quality of care they receive from their primary health care providers. Participants may be involuntarily withdrawn from the study by the research team if the other member of the dyad chooses to withdraw, or is otherwise unable to complete the study (e.g., death, is permanently moved to a long term care facility).

7. SAFETY AND REPORTABLE EVENTS

This study is a coaching study without delivery of medical care. As such, it is a minimal risk study (no greater than day to day activities). Furthermore, no published literature regarding this intervention has reported any problems. Despite this presumed safety, it is incumbent upon research staff to maximally protect participants and will do so through a Data and Safety Monitoring Plan.

This plan will be overseen by the PI (Dr. Shah), with external review from an Independent Safety Officer approved by the NIH. In this plan, all research team members will be involved in safety monitoring. During the study follow up calls, research staff will assess if any adverse events, serious adverse events, or unanticipated problems have occurred. All events or unanticipated problems whether observed by the staff, elicited from or volunteered by the subject, will be documented, including the date of onset, brief description of the experience, the relationship to REACH intervention and any action taken with respect to the REACH. Any negative reactions that arise during the course of this study will be discussed in the weekly

research team meetings. All events will be reviewed to determine if a change in protocol is necessary. If a serious adverse event related to study activities occurs that is unanticipated, it will be reported to the NIH and the University of Wisconsin IRB per posted guidance and associated timelines.

8. RISK/BENEFIT ASSESSMENT

8.1. **Potential Risks**:

a) Risks involved with participating in this research are minimal. The primary risks to caregiver and patient participants are loss of confidentiality, potential discomfort for the caregiver in answering survey instrument questions (e.g., stress, depression, anxiety, resilience, or burnout), and potential emotional distress that could arise while discussing topics relating to care for a loved one with dementia with trained paramedic coaches, health care providers, or members of the research team.

b) The primary risks to stakeholder participants are loss of confidentiality privacy, particularly for the coaches as they will be employees of the Department of Emergency Medicine.

8.2. **Protection Against Risks:**

a) To minimize the risk of loss of confidentiality, all members of the research team, health care providers, and paramedic coaches will have completed the required HIPAA training, and processes for sharing information between these individuals will be tightly controlled. We have instituted strict measures to ensure protection of patient information. This includes restricting communicating about participants through HealthLink/CareLink in-basket, and storage of all electronic data containing PHI on HIPAA-compliant approved servers (either firewall-protected servers in the UW Department of Medicine or ICTR-administered REDCap servers). All completed paper forms containing identifiable information will be destroyed or stored in locked offices accessible to only the research team.

b) As caring for someone with dementia often involves difficult decisions and stressful or emotional situations, all paramedic coaches and members of the research staff will receive training not only in the basics of dementia caregiving, but also in best practices for communicating with dementia caregivers. Coaches will also need to pass a “certification test” (administered by a master trainer) prior to communicating with any patient or caregiver enrolled in the study. As part of the intervention delivery, coaches will be providing caregivers with information about accessing support services, including psychological/emotional and social support, and can provide coaching support to caregivers in obtaining these services.

c) To further minimize the risk of discomfort, patients and caregivers will be clearly informed that they can stop participating at any time without any repercussions or changes in the quality of care they receive from their primary health care providers. Throughout the study, they will be reminded that they can take a break during any of the coaching home visits. During surveys or qualitative interviews, participants be instructed that they can decline to answer any questions that make them uncomfortable.

d) This study involves patients diagnosed with dementia, who by nature of their illness are vulnerable. We have built in specific procedures during the informed consent process to ensure that each participant has the decisional capacity to provide consent, and will seek consent from a LAR for all patients who do not demonstrate capacity. In addition, even after the patient consents to participation, if the caregiver (or LAR, if different) has any objection to the patient participating in the study, we will withdraw the dyad from any further study activities.

e) In addition, all individuals interested in participating will be provided ample

opportunity to consider participation and will be aware that participation is voluntary. Participants will also be aware that they may withdraw at any time without adverse effect to their care.

f) For the stakeholder participants, protection will be enhanced by excluding staff supervisors (really only applicable for the coaches and IT professionals) from obtaining consent and moderating the discussions regarding the REACH program processes. Furthermore, the supervisors will not be able to listen to recordings of the discussions, or review the transcripts until they have been de-identified.

8.4. **Potential Benefits to Subjects:** As the intervention being given to all participants has been tested and demonstrated in multiple NIA-funded trials to improve some psycho-social, knowledge acquisition, and physical health outcomes for caregivers of people with dementia, we expect caregiver participants to receive some measure of direct benefit from full participation. As this is a pilot study to examine the delivery of the intervention in a different context (in order to adapt and improve its delivery), we cannot guarantee that they will experience any particular benefits. There are, however, indirect benefits of participation, in that study findings have the potential to improve care delivery for patients with dementia and their caregivers. It will allow us to better understand how to meet caregivers' needs using an upstream preventative approach, in order to reduce occurrences of acute health/behavioral problems resulting in ED use. There are no direct benefits to stakeholder participants.

9. CONFIDENTIALITY OF DATA AND INFORMATION STORAGE

All participant enrollment activities, coach visits, survey administration, and feedback interviews will be conducted in (or from, if via phone or videoconference) semi-private or private settings by trained study personnel. Copies of consent forms, along with any other hard copies of survey materials, coach notes, or any other documentation/records pertaining to the subjects' participation in the study will be kept in a locked research office in the DEM, where only approved study team members will have access.

Electronic survey data, along with internal participant tracking data, will be entered into a HIPAA-compliant REDCap database stored on secure ICTR servers. Only authorized research team members (not including health care providers) will have access to this database. As part of RCI's oversight, monitoring, and program evaluation of the REACH intervention (to be formally contracted following approval of this human subjects protocol), the UW research site will be required to submit the data from specific assessments conducted as part of the routine intervention, as well as logistical information regarding the process of intervention delivery (e.g., number of visits, topics covered at each visit, number of phone calls, topics covered in each phone call) and caregiver demographics. Data will be transmitted by direct entry into the proprietary HIPAA-compliant database system at RCI, via secure encrypted online data-entry portal. Only authorized personnel at RCI and UW-Madison can view and download data entered/stored in the system, encrypted for download onto secure firewall-protected servers in either location. Authorized study personnel at UW Dept. of Emergency Medicine will have the ability to download any data stored in the RCI database for use in our analyses and evaluations of intervention delivery.

Qualitative feedback interviews (with caregivers or stakeholders), conducted for QI, study process documentation, and adaptation purposes, will be recorded on a digital audio recorder (if in person or by phone) or via built-in recording function of the UW-approved web-based video conferencing platform. Immediately following each interview, the file will be uploaded and stored on a HIPAA-compliant firewall-protected DEM server (administered by the Dept. of

Medicine), and then deleted from the original location. Only approved study personnel will have access to the project files on the server. Recordings will be transcribed by study personnel, de-identified during the transcription process, and transcription files saved in the same secure location. Participant supervisors will only be given access to de-identified transcripts.

No communication including participant information will occur over email. Instead, communication about participants will bpe limited to HealthLink/CareLink In-Basket

Documentation from coach home visits, created by the paramedic coaches, will be electronically delivered by study personnel to clinic staff via HealthLink/CareLink. Those notes will be included in the patient's health record and routed to the appropriate providers as per standard clinical practice. Hard copies of the coach notes, along with completed surveys, will remain in the possession of the paramedic coach (kept in a locked office) until physically handed-off to a member of the DEM study team, who will store them with the other study records mentioned above. All participants will be made aware of how/what information will be shared between coaches and primary health care providers during the consent process and during the first home visit. If the coach believes any other kind of information discussed during a home visit should be communicated to the subject's health care provider, beyond what has previously been described, the coach will explicitly ask for participant permission to include the information in the notes.

At the completion of data collection, all paper documentation will be scanned and stored on a HIPAA-compliant firewall-protected DEM server (administered by the Dept. of Medicine). At that point, all electronic forms of data will be de-identified.

10. RESEARCH INFORMATION IN MEDICAL RECORDS

As part of the study design, notes from home visits will be securely delivered to the RN Care Coordinator at the primary care clinic via HealthLink/CareLink in-basket message. The Care Coordinator will integrate it into the patient's electronic medical record and route to other members of the care team at her discretion as per standard clinical practice. All methods of information sharing between study team and clinic staff members will be HIPAA-compliant and approved by the UW Health Sciences IRB.

11. DATA ANALYSIS AND MONITORING

Sample Size Determination: There is no power analysis for this study, as it is a pilot to determine the feasibility/appropriateness of administering the intervention using paramedic coaches, as well as for determining the logistical processes necessary for integrating the intervention with existing clinical operations of a UW Health family medicine clinic. Questions of feasibility and acceptability are not suitable to a power calculation. The data gathered in this study will provide vital information to inform the design of future large-scale studies to determine effectiveness.

Statistical Analysis: The data gathered from this study will be summarized using descriptive statistics (mean, median, range, etc.) to understand the feasibility and acceptability of administering the intervention using paramedic coaches, as well as for determining the logistical processes necessary for integrating the intervention with existing clinical operations of a UW Health family medicine clinic.

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