FY19_PILOT3_FORESTER_IMPLEMENTATION OF THE CARE ECOSYSTEM TRAINING MODEL FOR INDIVIDUALS WITH DEMENTIA IN A HIGH-RISK, INTEGRATED CARE MANAGEMENT PROGRAM

Study Chairman or Principal Investigator:

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Supported by:

The National Institute on Aging

Study Intervention Provided by:

Partners HealthCare

(Any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol, the date the modification was approved by the Executive Committee, and the date it became effective.)

Version 3
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PRÉCIS

Study Title

Implementation of the Care Ecosystem training model for individuals with dementia in a high-risk, integrated care management program.

Objectives

Our primary objective is to test the feasibility of collecting emergency department visit data among the PLWD cared for by the primary care practices.

Our secondary objective is to determine the short-term impacts of an adapted Care Ecosystem curriculum and workflow on care management processes, healthcare utilization, behavioral symptoms of dementia, caregiver burden, and caregiver depression.

Design and Outcomes

We propose a pragmatic randomized quality improvement pilot trial to assess the feasibility and effectiveness of an adapted Care Ecosystem dementia care training for pre-existing nurse care managers who provide care management to high risk patients. We will work with iCMP medical and operational leaders to engage 30 targeted nurse care managers who serve PCP practices with the highest proportions of minority / low SES patients. 15 iCMP nurse care managers will be randomly assigned to receive early Care Ecosystem training and the remaining 15 will be assigned to received delayed Care Ecosystem training. Persons with dementia (PWDs) and their caregivers will not be informed whether their nurse care manager has received Care Ecosystem training, and will therefore be masked to the assignment of their care manager.

Data and outcomes to be included in the QI study will include:
(1) iCMP key process measures to be extracted from Epic documentation system (patient status, number of contacts between nurse manager and patient and/or caregiver, community resource requests)
(2) Medicare claims data (health care utilization and costs)
(3) Epic clinical data (caregiver strain and depression, behavioral symptoms of dementia, medication reconciliation, documented serious illness conversations/advance care planning)
(4) Semi-structured interviews of nurse care managers
(5) Surveys of caregivers to augment data captured in Epic clinical data and allow for evaluation of short-term impacts of enhanced training (caregiver strain and burden, caregiver depression symptoms, patient behavioral symptoms of dementia and patient quality of life for PWD).

Interventions and Duration

The adapted Care Ecosystem intervention will include three distinct phases:

(1) Developing an adaptation of Care Ecosystem training and workflows through feedback from a workgroup consisting of recently retired highly experienced iCMP nurse care managers, an iCMP medical director, a dementia expert, pharmacist, and an active caregiver.
(2) Training of iCMP nurse care managers in the adapted version of Care Ecosystem (e-learning modules and workflows, 1-day in-person training).
(3) Implementing the adapted Care Ecosystem intervention with trained nurse care managers.
(4) Booster sessions and process audits to augment intervention fidelity

We will compare the outcomes detailed above between the early training nurse cohort and the delayed training nurse cohort.

We plan to spend the first 3 months of the project collecting feedback and adapting the training. Nurse care managers will be trained at the end of month three. Outcome measures will be collected at the end of month nine. The delayed training cohort will receive training in month ten.

Sample Size and Population

Preliminary estimates based on 2018 data suggest that on average FTE nurse care managers in our health system have 10 Medicare beneficiaries diagnosed with dementia on their panels. For this pragmatic quality improvement trial, we plan to engage 30 active iCMP nurse care managers serving approximately 300 PWD and their caregivers. These 30 nurses represent roughly half of all existing nurse care managers. Because of the pilot nature of this QI intervention and budget limitations we do not plan to engage all nurses, rather we will seek to engage nurse care managers serving the largest proportions of minority / low SES patients. This pilot will provide information that will guide future large-scale implementations of the adapted Care Ecosystem training inside and outside of Partners Healthcare.

While all patients receiving care from these nurse care managers may be impacted, we will measure process and outcomes only among the estimated 300 PWD and caregivers who have an indication of dementia within Medicare claims data and are actively receiving care management services from the nurse care manager at the time of early training (end of month 3).

STUDY TEAM ROSTER

List individuals who play key roles in the development and execution of the study, especially those who may need to be contacted by the sites during the course of the study. Include address, telephone, fax and e-mail address of each individual listed and include a brief summary of each individual's main responsibilities.

Principal Investigator: Brent P. Forester, MD, MSc

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Main responsibilities/Key roles: Dr. Forester will oversee all aspects of the study including trainings, implementation of the model, regular communication with all members of the research and clinical teams, regulatory materials, data collection and analysis and manuscript preparation.

Co-Investigators: Christine Vogeli, PhD

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Main responsibilities/Key roles: Dr. Vogeli will supervise the creation of the quantitative data files from Partners data assets (including EPIC, claims data, programmatic data) and lead the analysis of outcomes based on these data.

Christine Ritchie, MD, MSPH

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Main responsibilities/Key roles: Dr. Ritchie will lead the adaptation of CareEco training with the Taskforce and will oversee iCMP care manager training. She will advise on study implementation, assist in the interpretation of data analyses and engage in relevant manuscript preparation. She will work with the study team in planning for the next phase of work after the completion of the pilot.

Karen Donelan, ScD, EdM

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Main responsibilities/Key roles: Dr. Donelan will develop the semi structured interview guides and caregiver surveys. She will manage data collection based on these tools and will summarize findings from semi-structured interviews.

PARTICIPATING STUDY SITES

All Primary care practices, nurse care managers who work within those practices, and patients who receive care from these providers are within Partners Healthcare.

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1 STUDY OBJECTIVES

1.1 Primary Objective

The primary objective of this study is to establish the feasibility of collecting emergency department visit data among the PLWD cared for by the primary care practices.

1.2 Secondary Objectives

The secondary objective of this study is to measure short term impacts of the adapted Care Ecosystem training on PWD and their caregivers.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

The prevalence of Alzheimer's Disease (AD) and related dementias, currently affecting 5.8 million Americans, is expected to increase to 14 million by the year 2050, with annual costs escalating from $290 billion to $1.1 trillion. Nearly half the individuals with dementia in the US are not diagnosed, and amongst those who are, 50% are not informed of their diagnosis, while most are identified during the moderate stage of the illness[2]. Dementia adversely impacts caregivers, who provide 16 million hours of unpaid care per year for individuals with AD and related dementias, and suffer greatly from stress, depression, anxiety, and health problems, which often leads to poor outcomes for their loved ones with dementia. Furthermore, behavioral symptoms of dementia, including agitation and depression, are nearly universal over the course of the illness and substantially contribute to elevated risks for morbidity, mortality, utilization of costly acute health care services, caregiver stress and long- term care placement[3,4]. Primary care physicians report a lack of time, training and resources to systematically screen for, diagnose, and treat dementia, as well as to provide adequate psychosocial support to unpaid caregivers[5,6]. This may lead to inadequate advance care planning and contribute to avoidable ED visits, hospital admissions and medical interventions as the disease progresses. Prior studies have demonstrated that enrollment in a collaborative care program for dementia is associated with improved functioning and quality of life, reduction in behavioral symptoms of dementia and a decrease in caregiver burden with a net cost savings as high as $2800 annually per patient[7]. Many of these programs are, however, resource intensive, requiring the creation of new clinical teams embedded in primary care settings. Recently, a telephone-based collaborative dementia care intervention (Care Ecosystem), that provides personalized support and standardized education through care plan protocols[8] delivered by trained health care navigators, has demonstrated lower rates of ED utilization and reduced caregiver depression and burden[9].

The Care Ecosystem (CareEco) model uses a telephone-based intervention to support persons with dementia (PWDs) and their caregivers, screening for common dementia-related problems and providing modular standardized support protocols and caregiver education. Specially trained health care navigators systematically identify needs and address health status, advance care planning, medication management and management of challenging behaviors. Health care navigators receive backup support from a nurse,

social worker, dementia specialist, and pharmacist, and maintain close communication with the primary care provider of the PWD. CareEco was found to reduce ED utilization, improve PWD quality of life and improve caregiver outcomes[9]. While the healthcare navigators used in CareEco offer clear value, this model, if adopted in a system with established, robust care management teams and no preexisting health care navigators, could actually increase cost by adding personnel in the setting of limited space and resources. We hypothesize that adapting the CareEco model to augment the dementia care provided by a pre-existing care management team could improve care manager self-efficacy in supporting PWDs, improve outcomes for PWDs and their caregivers, and optimize sustainability by enhancing dementia care competency of existing clinicians. In the proposed pragmatic clinical trial pilot, we will develop and test an adapted form of the CareEco intervention with experienced Integrated Care Management Program (iCMP) nurse care managers engaged in the care of high-risk, high-cost patients in a large health system. The strategic priorities of our health system are aligned with this work, both as a tool to provide higher-quality care to a high-risk population and as an opportunity to reduce ED visits and avoidable costs.

The integrated care management program (iCMP) at Partners HealthCare is a nurse-led longitudinal care management program embedded in Primary Care practices across the Partners network that provides care management support to the most medically complex and seriously ill patients. iCMP care managers assess each patient to clarify problems, identify barriers to accessing clinical care and community-based services, including the social determinants of health, and create a patient-centric care plan. The iCMP program serves all payor populations and has cared for over 38,000 patients since 2012. Approximately 14,000 patients are presently enrolled in iCMP, 64% of whom are Medicare beneficiaries. An independent evaluation of Medicare patients in iCMP, relying on 18 months of claims data post-iCMP assessment, found an average savings in total medical expense (TME) of $101 per member per month[10]. iCMP teams care for many patients with dementia, but are not specifically trained in the care of persons with dementia (PWD) and their caregivers. iCMP care managers have described lower levels of self-efficacy in the care of PWD. An analysis of cognitive disorders within the Partners system identified a conservative estimate of dementia prevalence of 8.8% among iCMP Medicare patients based on ICD-10 diagnosis codes for dementia, as compared to a roughly 5.1% prevalence of dementia among all Medicare patients. Thus, the iCMP program provides an opportunity to train nurse care managers in an adapted CareEco model for dementia patients.

2.2 Study Rationale

The Care Ecosystem model is a telephone-based care program that provides standardized, proactive, personalized, and scalable support and education for caregivers, medication guidance, and promotion of proactive decision-making. It has demonstrated an improvement in patient quality of life and reduced unnecessary healthcare expenditures[9]. The CareEco intervention makes readily available an implementation protocol toolkit that that includes care protocols, educational materials, and online training.

In the original study, a Care Team Navigator (CTN) and the PWD-caregiver dyad were at

the center of the intervention. The CTN first conducted a structured needs assessment scripted for CTNs that covered immediate needs, responded to immediate concerns and then reached out proactively to work with the dyad on caregiver support and education; medications; planning ahead for medical, financial, and legal decisions; and managing behaviors. The needs assessment was either completed in the first call, or in several calls over the first few months. While the content of the care included structured components and evidence-based protocols, the focus of the care was always tailored to the needs of each dyad. Issues that exceeded the CTN's scope were triaged to a specialist team that included a dementia specialist, pharmacist, nurse and social worker. CTNs telephoned dyads at approximately monthly intervals for 12 months with phone frequency adjusted according to each dyad's needs and preferences. All follow-up calls included screening for significant incidents (that may or may not result in ED/hospital visits), as well as changes in medication, behavior, and function. They also followed-up on progress and/or adjustments to goals discussed previously as well as the caregiver's wellbeing. Participants who declined regular contact were offered a "light" version of the intervention and were sent personalized educational materials via mail or email. This study was conducted in both urban (San Francisco Bay Area) and rural (Nebraska) settings.

As noted in the background, PWD receiving CareEco had improved quality of life and reduced emergency department visits. Caregivers experienced decreased depression and caregiver burden within the first 6 months[9]. The evidence from the CareEco trial, therefore, supports a pragmatic trial as a next step. Since the conclusion of the CareEco study, an academic health system in Colorado, an integrated health system in Minnesota, and an academic integrated health system in New Orleans have all adopted CareEco as a care delivery model. They used the Open-access CareEco tools (toolkit, educational materials, data dictionary) to develop projects at each of their sites, demonstrating that it is feasible to adapt and implement CareEco in diverse settings. While CareEco has been adopted by 3 other health systems, none of these systems are formally evaluating its implementation in an embedded trial. In the original clinical trial, the intervention posed minimal risk, with no indication of adverse events or unintended consequences. Under value-based contracts, care management programs, and in particular care management embedded within primary care practices, have become a common strategy to address inappropriate utilization among complex patients[11]. We propose to build on this model and test an adaptation of Care Eco that involves uptraining existing primary care embedded nurse care managers rather than adding a new care navigator to address the needs of PWD and their caregivers. This adaption both improves the fit with our health system and would be applicable to many other accountable care organizations with existing high-risk care management programs. We anticipate that this adaptation will enhance scalability by using pre-existing staffing infrastructure, improve efficiency by weaving dementia care into an established care delivery model, and optimize sustainability by matching evidence-based workflow protocols with engaged clinicians (iCMP nurse care managers).

3 STUDY DESIGN

A description of the trial design should include:

- This is a pragmatic embedded randomized pilot trial of an adapted Care Ecosystem training model for nurse care managers. The primary outcomes will assess the feasibility of collecting emergency department visit data among the PLWD cared for by the primary care practices. Secondary outcomes will provide early indicators of program effectiveness.
- The setting for the intervention is the Partners HealthCare primary care-based integrated care management program (iCMP). The program is available in all 182 Partners primary care practices serving adult patients. Partners HealthCare is a non-profit integrated delivery system created by the merger of the Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH). Partners primary practices serve patients residing in New Hampshire, and central and eastern Massachusetts. iCMP has been a network-wide population health program since 2012, and has strong evidence of effectiveness [10, 12]. iCMP employs registered nurses, social workers and community health workers who manage care for approximately 14,000 adult patients.
- The original Care Ecosystem model that our intervention will be based on is a telephone-based intervention to support PWDs and their caregiver, screening for common dementia-related problems and providing modular standardized support protocols and caregiver education. Specially trained health care navigators identify needs and address health status, advance care planning, medication management and management of challenging behaviors. The intervention will occur via 1) development of an adaptation of the CareEco training through feedback from a task group; 2) training of iCMP nurse care managers in the adapted CareEco model; 3) implementing the adapted CareEco intervention with existing nurse care managers.
- We will train iCMP nurse care managers, already assigned to work with PWD and their caregivers, in the Care Ecosystem model. In collaboration with iCMP leadership we will identify 30 nurse care managers serving primary care practices with the highest proportions of minority / low SES patients. These nurse care managers will be randomly assigned to receive either early or delayed Care Ecosystem training.
- We anticipate that nurses who receive training will change the way they provide care to all their patients with dementia. However, measurement of patient-level process and outcome measures will be among patients who have an indication of dementia within their Medicare claims data and who are actively engaged with care management as of the date care managers in the early training cohort are trained. Preliminary estimates based on 2018 data suggest that on average nurse care managers have 10 Medicare beneficiaries diagnosed with dementia on their panels, yielding approximately 300 PWDs and their caregivers (150 patients in each arm).
- We will spend the first 3 months of the project collecting feedback and adapting the training. The nurse care managers who are assigned to receive

early training will be trained at the end of month three, while those assigned to receive delayed training will be trained at the end of month 9.

- Adapted Care Ecosystem training for the nurse care managers will occur via video-based learning as well as a 1-day in-person training held at the Assembly Row headquarters of Partners HealthCare.
- Study subjects include patients receiving care from 30 nurse care managers serving primary care practices with the highest proportions of minority / low SES patients. Nurse care managers will be randomly assigned to early vs. late training. Preliminary estimates based on 2018 data suggest that on average nurse care managers have 10 Medicare beneficiaries diagnosed with dementia on their panels, yielding approximately 300 PWDs and their caregivers overall; 150 receiving care management from nurses who receive early training, and 150 receiving care from nurses who receive delayed training. PWD and their caregivers will be blinded as to the timing of Adapted Care Ecosystem training of their iCMP care manager.
- All measurement and analysis will be performed by the study team using data housed within an existing Partners IRB approved Population Health Data Repository, or new quality improvement data collected by members of the study team.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

The study population will consist of all persons with dementia who receive care from 30 selected iCMP nurse care managers. Only nurses who have been completely trained and onboarded into iCMP and with existing patient panels (e.g. 6 or more months of experience) will be asked to participate in the Care Ecosystem Training during this pilot period. The training will be provided as part of on-going QA activities within the program, and similar to other training programs participation by individual nurse care managers will be optional. The study team will work with clinical and operational leaders of the program to reach out to the 30 identified nurse care managers and schedule them for early or delayed training. As the enhanced Care Ecosystem training will provide necessary skills for care managers, it will be implemented as a quality improvement trial.

All PWD who are actively receiving care management services from a selected nurse care manager at the time of early training (end of month 3) will be included in the study. PWD will be identified based on the presence of one or more diagnosis code consistent with dementia during the year ending July 31, 2020. Preliminary estimates based on 2018 claims data suggest that a total of 300 PWD will be included in the study. Caregivers of PWD will be identified using Epic documentation. This study will primarily leverage existing patient data collected within the Epic clinical record and medical claims. These data will be augmented with surveys of PWD caregivers to allow for preliminary evaluations of effectiveness. Both existing data and surveys pose minimal risks to patients. Surveys will include standard language informing caregivers that their decision to participate in the survey will not impact their care or Medicare

benefits, that their participation is voluntary and that the information gathered will only be used to improve care quality for PWD and their caregivers.

4.1 Inclusion Criteria

Nurse care managers must meet all of the following inclusion criteria in order to be enrolled in the study:

- Actively providing care management services within the Partners HealthCare iCMP program
- Ability to understand study procedures and to comply with them for the entire length of the study.
- Nurse care managers will be considered subjects for the structured interview component of the pilot, with a waiver of documentation of consent

PWD must meet all of the following inclusion criteria in order to be enrolled in the study:

- Medicare beneficiary aligned to the Partners Medicare ACO
- ICD-10 diagnosis code consistent with dementia in Medicare claims between August 1, 2019 and July 31, 2020 (excluding diagnoses for diagnostic testing services)
- Actively engaged in care management services with a nurse care manager enrolled in the study
- Must be at least 18 years old or older

Caregivers must be identified by the iCMP care manager or in the PWD health record as next of kin, health proxy, guardian or primary paid caregiver or by the PCP, must speak English or Spanish, and must be at least 18 years old or older.

4.2 Exclusion Criteria

Nurse care managers meeting any of the following criteria will be excluded from the study:

- Fewer than 6 months of employment as an iCMP nurse care manager

PWD meeting any of the following criteria will be excluded from the study:

- Permanent resident of long-term care or deceased at the start of the study

Caregivers of PWD meeting any of the following criteria will be excluded from the study:

- Preferred language other than Spanish or English

- lives out of the country
- unclear relationship with PWD

4.3 Study Enrollment Procedures

- The investigative team has presented this study to iCMP leadership prior to funding. The study team will attend an iCMP operations team meeting to discuss the Care Ecosystem training and expectations for participation in training. Calendar year 2019 data will be used to determine the percentage of minority / lowest SES patients within the practices each care manager serves. The study team will collaborate with iCMP leadership to identify 30 nurses, prioritizing nurses who serve the most disadvantaged practices. These nurses will be randomly assigned to either early or delayed training. An e-mail co-signed by the investigator leading the training and iCMP leadership will be sent to the selected nurses informing them of their training date. Limitations in funding do not allow for training of all 87 nurse care managers within this pilot.
- Nurses will be asked to complete an assessment of baseline dementia care knowledge and skills prior to their training.
- Patients who actively receive care management from the 30 identified nurses and who have a diagnosis of dementia within Medicare claims data will be identified as PWD for this study. We will leverage existing data within EPIC to identify caregivers for these PWD.
- Preliminary examination of the structured fields within Epic that are used to house information on caregivers suggests that we will likely need to develop alternative methods, including review of notes, for identifying caregivers.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Following IRB approval, the intervention will include three distinct phases:

(1) **Developing an adaptation of CareEco training through feedback from a task group**. The CareEco model will be adapted for iCMP teams with input from a taskforce consisting of recently retired highly experiences iCMP nurse care managers, an iCMP medical director, a dementia expert, a pharmacist, and an active caregiver. The taskforce will provide information on current care management practices for PWDs and their caregivers and guide the development of 1) the adapted CareEco training, and 2) the needs-based protocols provided by CareEco. We anticipate that adaptation of the training will involve elimination of clinical content already well known by care managers and enhancement/refinement of content (i.e., management of behavioral symptoms, strategies to reduce caregiver stress) identified by the workgroup as an observed need of iCMP nurse care managers. For example, nurse care managers currently receive training on serious illness conversations[13], and advance care planning and documentation; these modules in the CareEco training will therefore be truncated. The current training content includes 23 6-minute videos and

hands-on practical training. Based out our review of these videos, the number of these videos will be substantively reduced; a 1-day in-person training will be planned to address hands-on, practical skills-based training needs. Revision of the protocols will be informed by current iCMP workflows and EMR documentation strategies. This phase will occur during the first three months of the project.

(2) **Training iCMP nurse care managers in the adapted version of CareEco.** Prior to the 1-day in-person training, the care managers will engage in approximately 60 minutes of e-learning of the abbreviated video training. The virtual training through video technology (secure Zoom platform) will occur all in one day and will address communication skills, the use of the CareEco protocols, documentation expectations and workflow concerns. For their involvement, iCMP care managers will receive a stipend and CEU credits. On a weekly basis, the intervention team will offer an hourly check-in to address any questions that arise. The iCMP nurse care managers will also have access to a dementia care expert, in addition to their pre-exiting social work and pharmacy team. The intervention team will monitor for intervention fidelity and work with iCMP nurse care managers if deviation from the adapted assessment and protocols are observed. Nurses in the early training cohort will receive their training in month three or month four, while nurses in the delayed training cohort will receive their training at the beginning of month ten.

(3) **Implementing the adapted CareEco intervention with trained nurse care managers.** The adapted CareEco model will be delivered by the iCMP nurse managers within Partners HealthCare to patients on their panels as clinically appropriate. All care to PWD and their caregivers will be delivered over the phone. The care managers will always address immediate needs first, then screen for common problems and provide personalized support and standardized education using the adapted CareEco Care Plan Protocols; Medications, Safety, Referrals and Caregiver Education, Caregiver Well-being, Behavior Management, and Advance Care Planning[8]. Call frequency will be about monthly but personalized to each dyad's needs and preferences. The study team will offer booster sessions and coaching over the course of the study to iCMP nurse managers who either ask for assistance or who, through chart audits, do not appear to be integrating the training into the care of their PWD. Implementation will occur following completion of training for the nurse care managers randomized to the early training cohort.

5.2 Handling of Study Interventions

As described above, the adapted Care Ecosystem training model will consist of dementia care management delivered via phone by nurse care managers to support PWDs and their caregivers.

Due to the pragmatic and embedded nature of this pilot, iCMP nurse care managers will be informed that the intervention will include training on enhanced dementia care management. PWDs and their caregivers will not be informed when their nurse care manager has received CareEco training and will therefore be masked to CareEco training assignment of their care manager.

5.3 Concomitant Interventions

There will be no restrictions on the amount or nature of concomitant interventions for PWDs and their caregivers.

5.4 Adherence Assessment

iCMP nurse care managers will be expected to complete all e-learning modules and attend the entirety of the 1-day in-person training. The intervention team will monitor for intervention fidelity through iCMP data and work with iCMP nurse care managers if deviation from the adapted assessment and protocols are observed.

6 STUDY PROCEDURES

There will be five sources of data to be used in these analyses.

- iCMP Program Data: iCMP collects key process measures including patient status within the program, the number of nurse care manager contacts with the patient / caregiver and community resource requests. Nurses can document caregiver strain and PWD behavioral symptoms in structured fields or in iCMP visit notes. Caregiver depression can likewise be assessed and documented in iCMP visit notes. These data will be used to measure iCMP visit frequency and documentation of key patient and caregiver outcomes in order to assess CareEco implementation fidelity. iCMP program data is captured within Epic and flows directly into the Partners data warehouse, where it is co-housed with clinical and financial data from the Partners electronic health record (Epic) and linked claims data for patients in the Medicare MSSP contract.

- Medicare Claims data will be used to identify iCMP patients with dementia at baseline and over time, and to construct measures of health care utilization and costs.

- Epic clinical data will be used to identify patient caregivers, capture PWD and caregiver outcomes documented in the iCMP note, and identify whether medication reconciliation and serious illness conversations / advance care planning occurred related to the iCMP interaction. In addition, Epic contains structured assessments of caregiver strain and PWD behavioral symptoms. All Epic elements flow to tables within the Partners data warehouse.

  For some PWD, outcome measures of caregiver strain and PWD behavioral symptoms have already been integrated into Epic documentation (see data sources above). We will compare EMR-integrated measures with measures derived from the surveys of PWD caregivers to determine the relative completeness and quality of the two data sources with a goal of reducing more resource-intensive primary data collection in future studies.

- Caregiver Survey: All caregivers of PWD (among the eligible cohort) will be asked to participate in a survey at months three (prior to the launch of the CareEco intervention) and nine. A waiver of documentation of consent will be requested for the caregiver survey. The survey will assess caregiver strain and burden, caregiver depression symptoms and behavioral symptoms of dementia and quality of life for the PWD. To streamline identification of caregivers of PWD, study staff will provide nurse care managers with a list of identified PWD and we will review medical records of persons with dementia to identify their caregivers.. Study staff will request that nurse care managers verify the primary caregiver for each PWD. Caregivers of PWD will be sent an invitation letter by mail (caregivers). The invitation letter will be accompanied by a study Fact Sheet about the study and will inform caregivers of their right to refuse participation. The Fact Sheet will address the following points: the research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided

with additional pertinent information after participation. If eligible participants refuse, there will be no further contact. If there is no response, we will call to confirm receipt of the letter, re-sending and/or and reviewing content as needed. If participant agrees to be interviewed, the interview will be scheduled. At the time of the interview, the interviewer will again repeat study fact sheet details and proceed if the respondent consents.

- The survey of Caregivers will be administered by phone in both English and Spanish to ensure responses from diverse patient and caregiver populations. Spanish versions will be administered by an experienced native Spanish language health care surveyor with over four years of experience. Care-giver respondents will be offered a $25 bank gift card, via Forte, in appreciation of their time and effort. Based on our prior experience, we expect 50% to 60% of PWD caregivers will respond. We will assess the extent to which patients with less severe dementia would be able to self-report their symptoms, but for this pilot only caregivers will be surveyed.

- Semi-structured interviews of nurse care managers: All care managers selected for adapted CareEco will be invited to participate (via e-mail) in individual semi-structured quality assurance interviews to debrief on their experiences. The email will address include the following: the research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation. Nurses will be informed be informed of the potential benefits and risks of participation. Nurses have the right to refuse participation, and decisions to participate will not be linked to employment or be shared with iCMP leadership. This pilot seeks to understand barriers to implementing the CareEco training; information on barriers and challenges will be used for research purposes only and will not become part of personnel files or result in disciplinary actions. No identifiable data from nurse interviews will be shared outside of the study team. Nurses will be asked to approve recording to aid in transcription of the interviews; nurses can refuse recording, but still participate in the interviews. Nurses will receive a small stipend to compensate for their time. Interviews will be performed by phone; a waiver of documentation of consent will be requested for the nurse care manager interviews.

  Interviews will be scheduled two months after the launch of the CareEco training (month five). These interviews will be conducted in care manager offices or by telephone or a video technology platform at the convenience of the care manager. The interviews will last approximately 30 to 40 minutes. Research with the iCMP care management staff, conducted by our team in both 2017 and 2018 as part of a PCORI funded study of care management programs, achieved 75% participation rates. Interview domains will include 1) general experience in caring for PWD and their caregivers; 2) experience in direct outreach to caregivers and patients (including identifying the most knowledgeable or engaged caregivers); 3) perceptions of services most needed and most difficult to arrange for patients with dementia and their caregivers; 4) assessment of the adequacy of training as adapted to the iCMP context; 5) recommendations for further adaptation of the CareEco model, and 6) among care managers not participating in the training, implementation

barriers, including contextual factors, fit and overarching issues that impacted non-participation.

The following table summarizes the measures that will be used in this study.

Variable	Source	Primary or secondary outcome	Description
ED visits	Medicare Claims data	Primary	ED visits per member per month over 6 months; Feasibility of collection (Primary objective), difference between early and delayed cohorts (secondary objective)
Service utilization and costs	Medicare Claims data	Secondary	Hospitalizations, Observation stays, urgent visits, total medical expense; Feasibility of collection (Primary objective), difference between early and delayed cohorts (secondary objective)
Documentation of advance care planning	Epic	Secondary	
Documentation of medication review and reconciliation	Epic	Secondary	
Caregiver Depression *	Caregiver survey	Primary and Secondary	PHQ-8 (8 item)
Caregiver strain and burden *	Epic	Primary and Secondary	Caregiver Strain Index presence in Epic and magnitude
Caregiver strain and burden *	Caregiver survey	Primary and Secondary	Zarit Rating Scale (12-item)[15]
Behavioral Symptoms of Dementia *	Epic and Caregiver survey	Primary and Secondary	NPI-Q (Neuropsychiatric inventory Questionnaire)[16] presence in Epic and magnitude
PWD quality of life	Caregiver survey	Secondary	QOL-AD (13 items)[17]
Unmet need and caregiver challenges	Caregiver survey	Secondary	CAHPS[18] and scaled responses to caregiver self-assessment
iCMP Care in*tensity / quality	Epic	Secondary	Patient contacts, community resource request
Dementia, stage and severity	Caregiver survey	Control variables	Quick Dementia Rating Scale[19]
Patient and caregiver characteristics	Epic and Caregiver survey	Control variables	Age, race, ethnicity, primary language, area level income, Elixhauser score[20] caregiver relationship to patient, living proximity to patient

6.1 Schedule of Evaluations

CRESCENT Timeline	Project Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Execute subcontract	■											
IMPACT IRB approval		■										
Select and randomize iCMP Nurse Care Managers		■										
Identify PWD and caregivers among selected iCMP Nurse Care Managers		■										
Adapt Care Ecosystem training for iCMP nurse care managers		■										
Provide adapted Care Ecosystem training to Nurse Care Managers				■						■		
Conduct Initial Survey of PWD and Caregivers		■	■									
Semi-structured interview of nurse care managers					■							
Conduct follow-up Survey of PWD and Caregivers								■	■			
Construct clinical and claims based study variables								■	■			
Analyze data, Summarize Findings									■	■	■	
Disseminate findings internally											■	
Disseminate findings externally												■

6.2 Description of Evaluations

This section should include definitions of the row headings in the Schedule of Evaluations and any special instructions. All of the items listed on the Schedule of Evaluations should be described in this section.

6.2.1 Screening Evaluation

Consenting Procedure

Nurse care manager participation in the CareEco training is a quality improvement project and therefore consent is not applicable. Nurse care mangers will be recruited to participate in individual phone-based semi-structured interviews by the study team. We seek a waiver of documentation of consent as interviews are low risk and will not be performed in person.

We will recruit caregivers of PWD to participate in a telephone interview. PWD will not be contacted within this study. We seek a waiver of documentation of consent as surveys of caregivers of PWD are low risk and will not be performed in person. We will review medical records of persons with dementia to identify their caregivers. Caregivers will be informed that their responses to these surveys will be kept entirely confidential. They will be given the option to opt out of answering the survey questions; those who opt out will not have their data included in the final analysis.

Finally, we will use existing Medicare Claims data and Epic medical record data to measure outcomes for PWD. Outcomes, by source, are listed in Table 1 above. We seek a waiver of informed consent for the use of these data. All data will remain on

secure drives within the health care delivery organization (as all study staff are part of the organization). The use of this secondary data is low risk and be presented in aggregate consistent with HIPPA protections when shared with members of the CRESCENT prime team.

Screening

There will not be screening procedures for this study.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

Patients who actively receive care management from the 30 identified nurses and who have a diagnosis of dementia within Medicare claims data will be identified as PWD for this study. We will leverage existing data within EPIC to identify caregivers for these PWD. Both PWD and their caregivers will be considered study subjects.

Preliminary examination of the structured fields within Epic that are used to house information on caregivers suggests that we will likely need to develop alternative methods, including review of notes, for identifying caregivers.

Baseline Assessments

Caregiver survey: Caregivers will be sent an advance letter about the study, and then calls to caregivers will occur at month three (prior to the launch of the CareEco intervention) and again at month nine. The survey battery administered during these calls will include:

- Caregiver Strain Index
- Caregiver Patient Health Questionnaire (PHQ-8)
- Neuropsychiatric Inventory Questionnaire (NPI-Q) (includes caregiver distress)
- Quality of Life in Alzheimer's Disease (QOL-AD) (includes caregiver and patient measures)
- Quick Dementia Rating Scale (patient)
- Experience of Care and Unmet Needs (adapted from CAHPS)

The surveys will be administered by phone in both English and Spanish to ensure responses from diverse patient and caregiver populations. Spanish versions will be administered by a trained, experienced bilingual interviewer with over four years of experience. Based on prior experience, we expect 50-60% of PWD caregivers will respond. We will assess the extent to which patients with less severe dementia would be able to self-report their symptoms, but for this pilot only caregivers will be surveyed.

Nurse care manager interview: A semi-structured interview of nurse care managers will be conducted at month five (two months following the launch of the adapted CareEco intervention) for quality assessment purposes. Interviews will be conducted by telephone at the convenience of the care manager and will last approximately 30 to

40 minutes. Interview domains will include 1) General experience in caring for PWDs and their caregivers; 2) Experience in direct outreach to caregivers and patients (including identifying the most knowledgeable or engaged caregivers); 3) Perceptions of services most needed and most difficult to arrange for patients with dementia and their caregivers; 4) Assessment of the adequacy of training as adapted to the iCMP context; and 5) Recommendations for further adaptation of the CareEco model. These data will be used to identify implementation barriers, and improve care quality.

Randomization

Nurse care managers selected by for participation in training will be randomly assigned to early vs. delayed training. Preliminary estimates based on 2018 data suggest that on average nurse care managers have 10 Medicare beneficiaries diagnosed with dementia on their panels, yielding approximately 300 PWDs and their caregivers overall; 150 receiving care management from nurses who receive early training, and 150 receiving care from nurses who receive delayed training. PWD and their caregivers will be blinded as to the timing of Adapted Care Ecosystem training of their iCMP care manager.

6.2.3 Follow Up/Final Evaluation

Refer to "Baseline Assessments" for a description of the assessments that will be used to collect data from PWDs/caregivers at both baseline and follow-up.

Medicare claims data will be used to construct measures of health care utilization and costs. This data will be accessed in months eight and nine.

Epic clinical data will be used to capture PWD and caregiver outcomes documented in the iCMP note and to identify whether medication reconciliation and serious illness conversations/advance care planning occurred related to the iCMP interaction. In addition, Epic elements flow to tables within the Partners data warehouse.

7 SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

There are minimal safety concerns associated with this intervention. While nurse care managers who participate in the training may change the way they interact with patients and caregivers, all clinical and patient management decisions will remain in the RN, PCP and other care providers' hands. Our investigative team includes that medical director of the iCMP program. Although we do not anticipate safety issues, if nurses do identify issues that are prompted by the training, we will work with the iCMP team to update nurses or advise them of the issues.

The major risks to caregivers of PWD will be discomfort related to the survey questions. We will inform caregivers that they can refuse to answer any questions and can terminate their participation at any time. We will also inform caregivers that refusal to answer any questions will not have any impact on the care they are receiving.

8 INTERVENTION DISCONTINUATION

We will not specify criteria for discontinuation of the intervention for this pilot study.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

The primary purpose of this pilot is to assess feasibility of collecting the primary clinical outcome, defined as emergency department visits among the PWD. Secondary outcomes will assess the feasibility of implementation, number of contacts between nurse care managers and care partners, and documented advance care planning.

9.2 Sample Size

Given limitations to the trial duration, this study is considered a pilot to understand the feasibility of measurement and to provide data to support calculation of effect sizes for a subsequent full-scale study if the initial pilot results appear promising.

9.3 Outcomes

The primary outcome for the is pilot is emergency room visits within 6 months. We will rely on Epic and Medicare claims data for all measures of healthcare service utilization and costs, care intensity / quality, documentation of advance care planning, and documentation of medication review. These outcomes will be assessed for all PWD who are cared for by selected nurse care managers using retrospective analysis of existing health care data. We anticipate that this will include 150 PWD among care managers who receive early training and 150 PWD who receive delayed training. These data are housed in an existing data repository; we anticipate minimal missing data. Key secondary outcomes will assess the number of contacts between nurse care managers and care partners, and documented advance care planning; these measures likewise available from the existing data warehouse and we anticipate minimal missing data.

In order to ensure systematic capture of key clinical outcomes within this pilot, we will survey caregivers of PWD receiving care management from the 30 selected nurse care managers and meeting our inclusion and exclusion criteria at months 3 and 9. We expect that a minimum of 50% of caregivers will complete each survey, yielding an expected sample of 75 PWD caregiver respondents completing each survey and 37 PWD caregiver respondents completing both an initial and follow- up survey for nurses assigned to the early and the delayed training. We will assess the completeness and correlation of behavioral symptoms of dementia, caregiver depression, caregiver burden, and PWD quality of life captured via trained nurse care managers (and documented in Epic or iCMP data) with caregiver survey responses.

9.4 Data Analyses

Depending on the type of outcome, we will conduct either a linear, negative binomial, or logistic regression, with random effects for nurses, to account for multiple patients nested within the same nurse. The primary predictor will be intervention (iCMP nurse care manager assignment to early CareEco training versus delayed training). Models will be adjusted for a limited number of baseline covariates: dementia stage and severity; Elixhauser score; and patient characteristics. If there are many unbalanced patient or

nurse characteristics, we will use propensity score weighting to adjust for confounding in the face of the limited sample size. Secondary models will examine process measures as potential mediators of the intervention effect on reported outcomes, clinical outcomes, and utilization outcomes. Subgroup analyses will be explored, but given the limited sample size, we do not expect sufficient power to detect effect modification nor significant intervention effects within subgroups.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Primary data collection for PWD and caregivers will include multiple patient-level clinical and claims measures drawn from system records as well as telephone surveys conducted with caregivers of PWD at baseline and follow up. Survey interviewers will be supervised by Dr. Donelan and will not be aware of whether the PDW's nurse care manager has undergone CareEco trraining. Data for all patients and caregivers will be maintained in RedCAP; survey data will be entered directly into RedCAP using standard survey procedures. Interviewers will maintain a record of all attempted contacts (Call Log) and their outcomes; a final disposition for each attempted case will be determined when all efforts are exhausted.

10.2 Data Management

RedCAP tools for data management include a participant list, a PWD/Caregiver list, apatient/caregiver baseline and follow up survey tools

10.3 Quality Assurance

10.3.1 Training

Training of nurse care managers will be standardized and based on task force feedback gathered in the first two months of the study.

10.3.2 Quality Control Committee

If there is a study quality control committee, describe membership and list the reports that they review.

10.3.3 Metrics

Provide quality control metrics for outcome measures.

10.3.4 Protocol Deviations

The team will hold weekly meetings to discuss study progress, including any necessary adaptations that require IRB review. A LabArchives record will be created for the project and linked to RedCAP documents and workflows. Using this approach, protocol deviations can be identified and reported promptly.

10.3.5 Monitoring

PI, Co-PIs, and Project Manager will ensure proper monitoring and tracking of all pilot data, records, and forms. All identifiable data will be secured on password protected Partners Healthcare system computers or locked file cabinets. All data will be de-identified as soon as practically possible. Regularly scheduled meetings (2 times per month) will be used to track progress and ensure compliance with study protocols. The study team will have established protocol and workflow to communicate with clinical teams in real time if patient safety issues are identified that need immediate attention.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

11.2 Informed Consent Forms

Nurse care manager participation in training is a quality improvement project and therefore consent is not applicable.

For PWD and caregivers, completion of the survey does not generally require a consent form, rather the elements of consent are in the advance letter and are confirmed in the telephone interview. Completion of the survey implies consent, no additional consent forms will be signed by PWD or their caregivers.

11.3 Participant Confidentiality

Any data, forms, reports, video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. Recordings will be saved for the duration of the pilot, and transcripts will be saved for seven years. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NIA, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

Include in this section the guiding ethical principles being followed by the study. If the study is conducted at international sites, consider including reference to the Declaration of Helsinki, CIOMS, International Ethical Guidelines for Biomedical Research Involving

Human Subjects (2002), or another country's ethical policy statement, whichever provides the most protection to human subjects.

13 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed by the Steering Committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

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