STATISTICAL ANALYSIS PLAN

FY19_Pilot3_Forester_Implementation Of The Care Ecosystem Training Model For Individuals With Dementia In A High-Risk, Integrated Care Management Program

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1 INTRODUCTION

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. 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. 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 this pragmatic clinical trial pilot, we developed and tested 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 PWD in a large health system.

The integrated care management program (iCMP) within Mass General Brigham is a nurse-led longitudinal care management program embedded in Primary Care practices across the Mass General Brigham 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 Mass General Brigham 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 STUDY OBJECTIVES AND OUTCOMES

2.1 Study objective

The primary objective of this study is to establish the feasibility of collecting emergency department (ED) visit data among the PWD cared for by the primary care practices. The secondary objective of this study is to measure short term impacts of the adapted Care Ecosystem training on PWD and their caregivers.

2.2 Primary outcome measure

The primary outcome is the change in ED visits per member per month from the 12 months prior the adapted Care Ecosystem training to the 6 months post training.

2.3 Secondary outcome measure

The secondary outcome is the change in caregiver distress between baseline and 6-month follow-up survey. Caregiver distress is measured by the Neuropsychiatric Inventory Questionnaire (NPI-Q), a brief proxy/caregiver-report of patient severity and caregiver distress across 12 neuropsychiatric symptom domains. Scores on the NPI-Q Distress scale can range from 0 to 60. The NPI-Q has demonstrated reliability and validity in dementia patients.

3 STUDY METHOD

This is a pragmatic randomized quality improvement pilot trail 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. 15 integrated care management program (iCMP) nurse care managers were randomly assigned to receive early Care Ecosystem training (intervention) and the remaining 15 assigned to received Care Ecosystem delayed training after the study period (control). The time period of interest for outcomes in intervention and control groups is the 6-month period between early and delayed training.
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4 STUDY POPULATION AND INCLUSION CRITERIA

The study population consists of all PWD who actively received care management services from the 30 selected nurse care managers at the time of early training.

4.1 Inclusion criteria

Nurse care managers had to meet all of the following inclusion criteria in order to be selected for the study:

- Actively providing care management services within the Mass General Brigham iCMP program

- Ability to understand study procedures and to comply with them for the entire length of the study.

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

- Medicare beneficiary aligned to the Mass General Brigham 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 iCMP 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

5 RANDOMIZATION

The study team collaborated with iCMP leadership to identify 30 nurse care managers, prioritizing nurses who served the most disadvantaged practices. The selected nurses were randomly assigned using a randomization process in SAS to either early (intervention group) or delayed training (control group). Persons with dementia and their caregivers who meet inclusion / exclusion criteria were included in the study.

6 SAMPLE SIZE

Preliminary estimates based on 2018 data suggested that on average FTE iCMP nurse care managers in our health system have 10 Medicare beneficiaries diagnosed with dementia on their panels. For this pragmatic quality improvement trial, we planned to engage 30 active iCMP nurse care managers (out of a total of approximately 65 nurse care managers) serving approximately 300 PWD and their caregivers (150 in each arm).

Among the 30 nurse care managers actually selected for the study, a total of 393 PWD met the inclusion criteria, 206 patients corresponding to the 15 intervention nurses and 187 patients corresponding to the 15 control nurses. The population was refined to exclude patients without a designated caregiver, deceased or moved to skilled nursing facility (for full list of exclusions see Figure 1 of cohort flowchart). This validated cohort included 143 PWD in the intervention group, and 113 PWD Controls.

7 GENERAL ANALYSIS CONSIDERATIONS

7.1 Analysis populations

7.1.1 Utilization Outcome Cohort

For ED visit outcome measurement, the validated cohort was then further restricted to those with at least 1 member month of Medicare FFS eligibility and alignment to our ACO in the pre and the post period (Intervention n=126, Control n=105), to allow for sufficient utilization data for measurement. (See Figure 1 of cohort flowchart)

7.1.2 Clinical Outcome Cohort

For the NPI-Q Distress outcome measurement, the validated cohort was restricted to baseline and follow-up survey respondents with completed NPI-Q Distress measures (Intervention n=35, Control n=28). (See Figure 1 of cohort flowchart)

7.2 General considerations for statistical analysis

Data are summarized by treatment group. Continuous variables are summarized using mean and standard deviations. Categorical variables are summarized using frequency and percentages. SAS Enterprise Guide 7.1 is used for analyses.

Demographic and other baseline characteristics are compared between groups. Race, ethnicity, age, gender, language, marital status, baseline primary care provider (PCP) utilization per member per month (PMPM), baseline inpatient utilization PMPM, baseline ED utilization PMPM, and baseline observation visits PMPM are summarized for the Utilization Outcome Cohort. For the Clinical Outcome Cohort, the same characteristics will be summarized, as well as NPI-Q Distress (caregiver distress), NPI-Q Severity (patient symptom severity), PHQ-8 (caregiver depression), and Quick Dementia Rating Scale (patient dementia severity) from the baseline survey.

A combination of t-tests (at $p<.05$), chi square tests (at $p<.05$) and standardized mean differences (cutoff of .15 or greater) were used to identify differences between cohorts and covariates for risk adjusted models. Based on these criteria, race, ethnicity, and age were identified as different between intervention and control in the Utilization Outcome Cohort, as were baseline PCP visits, inpatient hospitalizations, and Observation visits. For the Clinical Outcome Cohort, PHQ-8 (caregiver depression) was different across Intervention and Control. Risk adjusted models for clinical outcomes also adjusted for the demographic characteristics (race, ethnicity, and age) identified for the risk adjusted utilization models in order to maintain consistency across models.

7.3 Missing data

Missing data were not imputed for analyses.

8 STATISTICAL ANALYSES

8.1 Primary outcome analysis

The change in ED visits PMPM from 12 months prior to training to 6 months post-training for intervention and control cohorts are compared using a differences-in-differences model with a negative binomial distribution (to account for utilization count data) and log link. This model estimates a difference-in-differences rate ratio that provides an estimate of the relative rate reduction/increase in ED visits PMPM in the intervention group as compared to controls.

Models included a weight for the number of member months in the pre and post periods, allowing PWD with more member months (and therefore more stable estimates) to contribute more strongly to the intervention effect. The training ("enrollment") month was not included in either pre or post period. Models adjusted for baseline utilization and demographic characteristics (race, ethnicity, age) that differed across intervention and control cohorts. A sensitivity analysis removed PWD who died in the post period.

We hypothesized high feasibility in measuring ED visits for this population but had no specific hypothesis regarding whether the program would impact ED utilization in the relatively short 6 month-post period.

8.2 Secondary outcome analysis

The secondary outcome of change in NPI-Q distress score from baseline survey to 6-month follow-up survey for intervention and control cohorts is compared using a difference-in-differences model with a linear distribution and identity link. Models adjusted for differences in demographic characteristics (race, ethnicity, age) and PHQ-8 at baseline. A point difference of 2 or greater on the NIPQ-Distress scale is generally considered to be clinically meaningful; therefore a difference in differences estimate of 2 or more in this model (i.e., a relative difference of 2 points or more between Intervention and Controls) would suggest a meaningful impact of the Intervention.

We hypothesized a relative decrease in NPI-Q distress in the Intervention group as compared to Controls.

9 ADVERSE EVENTS

There were no adverse events, serious adverse events or significant protocol deviations.

Figure 1. Cohort Flowchart