Statistical Analysis Plan (SAP)

Patient Priority Care for Older Adults With Multiple Chronic Conditions (PPC-CCF): Reducing unwanted care and improving outcomes by aligning care with the health priorities of older adults with multiple chronic conditions

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Introduction

Much healthcare for older adults with multiple chronic conditions (MCCs) is burdensome and of uncertain benefit, resulting in unwanted and unhelpful care [1]. Patient Priorities Care (PPC) aligns care with patients' health priorities (i.e. the health outcomes most desired given the healthcare each is willing and able to receive) [2]. The primary aim of this project is to test, using a parallel group design involving 2 matched primary care sites, whether PPC increases achievement of participants' desired activities (goals) and decreases patient treatment burden and unwanted health care. The overarching aim and focus of secondary analyses is to assess the value of this program as described below.

Study Design

Setting and Population

Cleveland Clinic has 84 primary care sites across northeast Ohio with approximately 400 primary care providers (PCPs). 125 participants will be recruited from each of 2 primary care practices. The intervention practice was selected based upon Medicare payer mix, patient characteristics, and care team composition. A usual care site was selected though a matching procedure examining multivariate difference based on age, race, and dual enrollment in Medicare-Medicaid [3], [4].

Potentially eligible participants include patients 65 years or older who are patients of participating clinicians. Criteria for identifying eligible persons from administrative or electronic health record (EHR) data include combinations of ≥ 3 chronic conditions; ≥10 medications; >1 hospitalization (or>10 days in the hospital); >2 ED visits over the past year; seen by ≥2 specialists over past year; receive any care coordination services. Exclusion criteria include hospice eligibility, advanced dementia or moderate to profound intellectual disabilities, not English speaking or nursing home residence. A list of patients meeting above criteria will be generated and provided to PCPs to obtain their permission to invite patients. PCPs may suggest removing any patients who may not be appropriate for the intervention.

Aims and objectives

Primary aim: Determine whether, post-intervention, patients enrolled in PPC report a greater improvement in achievement of desired activities, shared decision making and value and a greater reduction in levels of treatment burden from baseline than do those in the usual care cohort.

Secondary aim: Determine whether, post-intervention, patients enrolled in PPC achieve better alignment of care per Cleveland Clinic's ACO Survey Item

Outcomes

Outcome	Operationalization
Primary	
Treatment burden	Patient score on 'Treatment Burden Questionnaire' (TBQ, score range 0-150, Cronbach's alpha=0.90) [5]
Achievement of desired activities	Patient score on PROMIS Ability to Participate in Social Roles and Activities Short Form 6a (score range 6-30; Cronbach's alpha = 0.98) [6]
Nonhealthy days	Number of days in which patients dead or in hospital, emergency department, nursing home or undergoing ambulatory procedure requiring several hours for completion and recovery within 12 months following baseline interview [7], [8].
Shared decision making	Patient score on CollaboRATE tool (score 0-100, Cronbach $\alpha = 0.89$; score range, 0-100 with higher score denoting greater perceived shared decision-making; dichotomized as 100 vs <100, with 100 representing a participant who reported the top score on all 3 items) [9]
Secondary	
Shared prescribing decision making	Response to Cleveland Clinic ACO survey item *"When starting a new medication, did your provider ask what you thought was best for you?"*

Populations and subgroups to be analyzed

None planned

Analyses

Propensity Weights

We will estimate propensity score models with the PSMATCH procedure (SAS, version 9.4; SAS Institute INC). Balance on baseline characteristics between the two groups will be achieved by using inverse probability of treatment weights [10]. Balance will be evaluated by comparing the (weighted) distribution of the covariates using absolute standardized mean differences of .25 or less and side-by-side plots of the distribution of each covariate [11]–[13].

Missing data will be handled by using multiple imputation using the fully conditional specification procedure in SAS statistical software. Rubin's formulas will be used to combine estimates from multiply imputed full datasets into a single set of results using the MIANALYZE procedure in SAS [14]

Multivariate models

Multivariate linear models will be used to examine the strength and significance of the association between treatment group and 1.) patient reported outcomes (TBQ, PROMIS Ability to Participate in Social Roles and Activities Short Form) at follow-up and 2.) number of nonhealthy days defined as days dead or in contact with the healthcare system within 12 months of baseline interview. Shared decision making as reflected in the Cleveland Clinic shared decision-making item and the dichotomized CollaboRATE scale will be analyzed with multivariate logistic regression models. All outcomes will be adjusted for the corresponding baseline value, demographic and clinical characteristics of patients. All models will propensity weighted and run with imputed data. Regression diagnostics, such as residual plots, will be run to test all model assumptions.

Power Calculation

As sample sizes were limited due to the COVID pandemic, our research was exploratory in nature and power calculations for the reduced sample were not performed. Post-hoc power calculations based on the observed effect size are also generally discouraged so we will not perform these analyses [15-16]

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