Evaluating a Patient-Centered Tool to Help Medicare Beneficiaries Choose Prescription Drug Plans (CHOICE)

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1. Protocol

A. Abstract

To obtain publicly subsidized insurance coverage for prescription drugs, Medicare beneficiaries must choose among the private plans offering coverage in their geographic area. While Part D has reduced beneficiary spending on and lowered prices for prescription drugs, Medicare beneficiaries consistently report that choosing a plan is difficult, time consuming and unpleasant.

In this project, we test the effects of a patient-centered Medicare Part D prescription drug decision tool that is scalable and patient-centered and builds on research indicating that many people would like expert assistance in making this choice. Our main objectives are to determine whether providing Medicare beneficiaries with a patient-centered decision tool and whether providing an expert recommendation of a particular plan improve decision outcomes relative to providing them with access to publicly available tools.

B. Specific Aims

Aim 1: To determine whether providing Medicare beneficiaries with a patient-centered decision tool to help them choose among plans improves outcomes for patients including a greater likelihood of changing a plan, better coverage for prescribed drugs, lower decisional conflict when choosing plans, and greater satisfaction with the choice process relative to current practice.

Aim 2: To determine whether providing people with personalized expert plan recommendations improves outcomes for patients including a greater likelihood of changing a plan, better coverage for prescribed drugs, lower decisional conflict when choosing plans, and greater satisfaction with the choice process relative to current practice and relative to a similar tool without such recommendations.

Aim 3: To determine what types of older adults are likely to use an internet-based tool for health plan choice.

C. Study Overview

In this study, we will test the effectiveness of two versions of a web-based tool to help people choose among Part D plans (Treatments A and B) relative to each other and relative to standard care (Control). Both treatment arms will incorporate simplified design and automated importation of an individual's drugs relative to standard care. The treatment arms will vary based on whether they provide expert guidance on recommended plans. In the control arm, study participants will be directed to the existing, publicly available Medicare.gov website and will receive instructions on how to download their drugs from the Palo Alto Medical Foundation (PAMF) patient-facing EMR (myhealthonline). Our study sample will include PAMF patients who were enrolled in Part D plans during the 2016 enrollment period. Prior to the 2017 open enrollment period (October 15 to December 7, 2016), we will invite a subset of PAMF patients enrolled in Part D plan to participate in a study examining the effectiveness of decision tools that provide personalized information on the financial implications of enrolling in different Part D plans.

For aims 1 and 2, the *primary study outcomes* will be:

1) Plan switching
2) Change in generosity of coverage of prescription drugs

3) Satisfaction with the choice process
4) Decisional conflict

Secondary study outcomes for aims 1 and 2

5) Enrollment in an expert-recommended plan
6) Difficulty choosing a plan
7) Confidence in choosing a plan
8) How much do you like the plan you chose
9) Satisfaction with chosen plan (people found this difficult)
10) Knowledge of the Medicare Part D prescription drug benefit?

For aim 3, we will analyze how the following patient characteristics influence enrollment in the trial and take-up of the treatment among those randomized to the treatment arm:

1) Prescription drug profile
2) Age
3) Use of myhealthonline

We will measure the primary study outcomes using a combination of administrative data and a post open enrollment survey administered to all study participants. We will also collect information on individual characteristics at the time of enrollment in the study and implement a survey examining use of the intervention tool to assess patient experience at the time of use.

D. Background

Medicare beneficiaries consistently report that choosing a plan is difficult, time consuming and unpleasant. In our preliminary qualitative work, older adults said that these difficulties cause them to seek assistance from trusted authorities like brokers and counselors and sometimes even to avoid changing their plan altogether.

Research on plan choice is consistent with these observations. People are often not enrolled in the plan that would cover their drugs at the lowest price and rarely change plans even when there are alternatives that provide coverage at a lower cost. In addition, brands have strong effects on individual choices, and it is not clear whether particular brands provide real value for consumers or simply serve as a decision short-cut.

Research has also shown, however, that personalized information on the financial implications of enrolling in different plans can influence plan choice. Using a relatively simple, paper-based intervention, Kling et al. demonstrate that, when people received a letter with personalized information about the cost of enrolling in different plans, they were more likely to switch plans than those who received information about the availability of this type of information on the Centers for Medicaid and Medicare Services (CMS) website. While this trial shows potential for decision tools to improve outcomes in this area, many questions remain on how best to provide this type of information to consumers. Although publicly available tools are available to Medicare beneficiaries to help them make these types of decisions, evidence suggests that they rarely use this source of information.

One potential barrier is that the currently available tools are difficult for beneficiaries to use. In our ethnographic research observing Medicare beneficiaries using the Medicare.gov website, we identified two limitations of the existing tool: 1) it is difficult for beneficiaries to customize the information with their personal drug histories, and 2) the most commonly used tool (Medicare.gov plan calculator) is difficult for people to navigate and use. We have developed a tool that addresses these barriers by importing beneficiaries' information about drug use directly into the tool and by creating a patient interface that incorporates modern design concepts and patient input to make the tool accessible and effective for beneficiary decision making.

In our ethnographic study, older adults also expressed interest in having additional support, often indicating they would like the help of an expert, such as an insurance broker or other type of knowledgeable individuals.

Our study is based on the hypothesis that these barriers create switching costs for beneficiaries and that removing these barriers would lower switching costs making beneficiaries more likely to evaluate their alternatives and to enroll in plans that provide better coverage for the drugs they are likely to use. We also hypothesize that reducing switching costs, particularly by providing expert recommendations, will reduce decisional conflict and create greater satisfaction with the choice process.

While the tool we have designed in partnership with patient stakeholders is easier to use than the Medicare.gov website, it provides less detail on how the different plans cover particular types of drugs. In our qualitative work examining the use of the first version of our tool, we found that its simplicity was more attractive to some people than others. Thus, we will examine particular characteristics of individuals including numeracy, "do-it-yourselfness", and satisficer/maximizer behavior influence how people evaluate the decision process in the different tools.

A final issue in this context is whether simply providing access to web-based decision support tools is likely to assist the types of people who experience the greatest difficulty in decision-making. We will examine the take-up of decision support in this setting to determine how well targeted it is by analyzing who chooses to enroll in our trial and among those who enroll, who uses the study intervention.

E. Participants

Our study population will include PAMF patients aged 66 to 85 who were enrolled in Part D coverage during 2016. We plan to have a final study sample of at least 915 people with complete data on study outcomes.

F. Screening

We will prescreen patients using administrative to identify potential study participants based on whether they are enrolled in Medicare, their age (66-85), whether they live in the primary PAMF service area (county=Santa Clara, San Mateo, Santa Cruz, and Alameda), and whether they have active medication orders in the PAMF EMR. We will also exclude patients enrolled in MediCal or a Medicare Advantage plan in 2016. In preliminary analyses, we have identified 46,525 PAMF patients who meet these criteria.

An important sampling issue for our study is whether people are married or cohabitating. Randomizing people who are cohabitating to different treatment arms could lead to cross-arm contamination, potentially diluting the treatment effects. We will prescreen patients for cohabitation/marital status based on patient residence and phone number. We will then randomly choose one member of each household to participate in the intervention. In our preliminary analysis, we excluded an additional 7,659 people using this method. Because this represents fewer people than we would have expected based on national rates of marriage among older adults, we will also screen for cohabitation when recruiting. Again, based on our preliminary analysis, there will be 38,866 remaining patients eligible for recruitment.

G. Recruitment

We will recruit a subset of those patients eligible for recruitment with a goal of obtaining complete study data from 915 patients. We will identify a set of patients for recruitment by randomly choosing a subset of approximately 10,500 patients from those who are eligible for recruitment. For the patients targeted for recruited (recruitment sample), we will send them a letter in August introducing the study and inviting them to participate. The letter will inform the respondent that they have been selected to participate in a study of the effects of providing personalized information on Medicare Part D prescription drug plans and that they will be randomized to different arms representing different ways of providing that information, that participation in the intervention will allow them to easily access information from PAMF on the prescription drugs they are currently using. The e-mail will also inform the patients that they will receive a $50 electronic Target gift certificate at the end of the open enrollment period for participating in the study following the completion of a questionnaire. The letter will direct participants to a website (enrollment portal) where they can check if they meet the eligibility criteria and, if so, enroll in the study and provide informed consent.

The initial invitation will include a study ID that the participant will use to enter the enrollment portal. This ID will be used as their study ID throughout the study and will be used to link data from their medical records to data gathered as part of the study. The enrollment portal will have 4 functions:

1. Eligibility verification - When patients log into the application, they will verify their name and address as well as their eligibility to participate in the study based on age, part d enrollment, and single representative from their household. (We will not exclude people from accessing the tool based on the single representative but will exclude them from data analysis). They will also identify the Part D plan in which they are currently enrolled.
2. Informed consent
3. Collect contact information - Consented participants will provide their e-mail address, using double-entry verification, and will be informed that further communication regarding the study will be by e-mail rather than by mail.
4. Pre-enrollment survey (Survey 1) - We will ask a few questions intended to provide information on individual characteristics of interest for the purpose of data analysis.

We will consider people who consent through the enrollment app as the “enrolled” population. The enrolled population will be randomly assigned to one of three arms (Treatment A, Treatment B or Control). Within 2 days after subjects enroll, we will send them by e-mail a letter that includes their study ID and information on how to access the tool, including the location of the website, when it will be available and log-in instructions. They will use the study ID to log into the website when open

enrollment begins. Shortly before and close to the end of open enrollment, we will send them another reminder with the same information.

We will provide support to study participants in the form of an e-mail address and a phone number they can call. This information will be available in our study tool, the control arm screen and the consent form. We will indicate that they will receive a response within 48 business hours.

Table 1: Recruitment Objectives

Sample Name	Category	Assumptions	Number of Study Subjects
Eligible for Recruitment	Eligible for recruitment		38,866
Recruited Sample	Chosen for mail recruitment	Derived from assumptions below	10,417
	Check for Eligibility	20% of those who contacted by mail check their eligibility	2,083
Enrolled Population	Enroll in Study	Assume 40% attrition among those who access enrollment app	1,250
Study Sample	Complete final survey	Assume 80% of those enrolling complete final survey	1,000
Objective based on sample size calculation		based on 3 arms of 305 each	915

Source: trial protocol tables google sheet – recruitment objectives

We will identify a set of patients for recruitment by randomly choosing a subset of approximately 10,500 patients from those who are eligible for recruitment. We estimate that 20% of those contacted will choose to access the enrollment portal. Among those who access the enrollment portal, we estimate 30% attrition based on ineligibility or lack of consent. Finally, we estimate that 60% of those who enroll will complete the final survey in January. The table above identifies the effects of each these assumptions on our final sample size.

We estimate the size of the final study sample will be 1,000 people with 333 assigned to each arm. Our sample size calculations indicate that we need 305 people per arm to have adequate sample size (see detail under section “assessments”).

H. Randomization

We will randomize those who enroll in the study into two treatment arms and one control arm in which they will be directed to different on-line tools. Participants will be randomized at the time they enroll by simply assigning them sequentially to the three arms as they consent.

I. Retention

While our study period is relatively short, only lasting throughout the open enrollment period, a key issue in retention in encouraging people to participate in a survey at the end of the open enrollment

period. Study participants will receive their $50 gift certificate from Target after completing the post open enrollment survey in January.

J. Intervention

The study has two types of interventions. The primary intervention is access to a decision tool (Aim 1) and the second is access to a decision tool with expert recommendations (Aim 2). People who enroll in the study will be randomized to one of three arms – two treatment and one control arm. People randomized to the treatment arms will receive a one of two versions of an on-line decision tool that automatically imports information on their prescription drug use from an electronic medical record into a decision tool developed as part of the study. In Treatment Arm A (expert recommendations), the tool will provide people with a score for each plan using an algorithm for generating expert recommendations based on the individual's prescription drug usage and the characteristics of the different plans. In Treatment Arm B (individual analysis), we will provide information on each of the characteristics underlying the expert recommendation but not the recommendation itself. In the control arm, people will receive information on how to download their prescription drug information from the electronic medical record and how to access the Medicare.gov Plan Finder tool.

The calculations underlying the calculator as well as the expert recommendations will be powered by software we have purchased from a private third party, [redacted]. [redacted] produces software that allows a user to enter electronically a set of prescription drugs and returns information on associated out-of-pocket spending and the premium for each Part D plan available to the beneficiary. [redacted] also provides a "score" which represents a weighted average of the person's estimated out-of-pocket spending and premium and the plan's consumer satisfaction rating. Our user interface will, in turn, present this information to study participants in a patient-centered way and will manipulate the information in the two study arms as described above.

Participants will not actually enroll through our calculator. Instead we will direct participants to the appropriate company website or to the Medicare website where they can enroll.

The decision tool will be available throughout the open enrollment period.

K. Assessments

The study outcomes will be based on both primary data collection and administrative data sources. The sample size was chosen to adequately power the primary study outcomes.

Table 2: Summary of Outcome Measures for Comparative Effectiveness Evaluation

Note: Primary study outcomes are italicized and bold.

Outcome Type		Measures	Data Source
Patient Satisfaction	Aims 1 and 2	• ***Satisfaction with choice process***	Post-enrollment survey (primary)
Plan Choice	Aims 1 and 2	• ***Change in Part D plan chosen***	2016 plan from enrollment app and 2017 plan from post

			open enrollment survey. Also question in post enrollment survey about "did they change their plan?"
	Aims 1, and 2	• Indicator of enrollment in lowest cost plan* • Indicator of enrollment in expert chosen plan*	2017 plan from post open enrollment survey and information on OOP cost from [redacted] collected in admin panel.
Spending on prescription drugs	Aims 1, and 2.	• ***Difference in spending between lowest cost plan and chosen plan****	[redacted] information for all plans and indicator of which plan was chosen from post open enrollment survey.
	Aims 1 and 2	• Difference in spending between 2016 plan and 2017 plan based on initial drug list.* Note: this address whether they switched to a lower cost plan	[redacted] information for all plans and indicator of which plan was chosen from post open enrollment survey and which plan they were initially enrolled in from enrollment app.
Choice Experience	Aims 1 and 2	• ***Decisional Conflict*** • Knowledge about Part D program • Sources of information used • Time spent making decision	Post-enrollment survey
		• How satisfied were you with the process of choosing a plan? • Decision confidence • Decision conflict • Choice knowledge – understanding of features of chosen plan • Right amount of information • Define user monitoring outcomes	Intervention survey

* Note that calculating these variables requires a drug list for each person. For all people, we can construct an initial drug list based on the data in the EMR. For a subset of people who we observe using the tool, we can construct a revised drug list based on their activity in the tool. All these outcomes are based on the initial drug list.

L. Data Management

See data flow chart document.

M. Study Timeline

May 31 – Large dataset of test data

June 30 – UI changes implemented

July 15 – refreshed study data available to developer

July 31 – administrative console implemented

August 1 – Invitations mailed to participant

August 1 – October 14 – recruitment and enrollment

August 1 – website available with “coming soon” information

August 1-August 30 – complete testing and list of changes to developer

September 30 – all changes implemented

October 1 – generate dataset of all [redacted] information for everyone chosen for recruitment.

October 1 – October 12 – final verification of functionality

October 15 – e-mail reminder (exact date depends on when tool is refreshed with 2016 open enrollment information

October 15 – December 7 – Open enrollment – tool available

December 8 – e-mail follow up survey

January 4 – e-mail reminder about survey

December 8 – January 15 – follow up survey open

January 16 – e-mail gift cards

2. Statistical Plan

Sample size calculations:

	Hypothesis						
Outcome	Relative to control, treatment groups will have:	Baseline rate	SD	Change	Power	N per group	Notes:

Plan switching	Higher rates of plan switching	13.6		8.704	80%	305	Kling et al find 28% of people in treatment group relative to 17% in control. Ketcham et al 2013 find relative high rates of switching among new enrollees - 33% between 2009 and 2010 and that switching rates increased over time. KFF (2103) finds 13.6 among all ages in PDP plans. Change is Kling effect of 65% change applied to KFF baseline rate.
Satisfaction with choice process	Greater satisfaction with the choice process	2.6	1.03	0.6	80%	50	Scale of 1-4 in preliminary study with 1 as very satisfied. Data represent means of medicare versus all vendus arms where medicare is the baseline.
Decisional conflict	Less decisional conflict						
Coverage	enrollment in plans that coverage current drugs more generously	368	286	74	80%	236	Based on Kling et al
Coverage (alternative)	Increase in coverage generosity from last years to this years plan	-129	588.42	-543	80%	20	Based on Fall 2015 Results

Analyses:

For aims 1 and 2, we will compare outcomes between each treatment group and the control group, defining the study population as those who enroll in the study through the enrollment portal and are randomly assigned to a study arm. The main focus of our analyses will be the comparison of the Expert arm relative to the control arm. We will calculate differences in means and proportions using t-tests and chi-squared tests based on the type of study outcome. We will also test the expert arm relative to the treatment arm without expert recommendations to identify the independent effect of expert recommendations. We will develop unadjusted estimates of the treatment effect as well as estimates adjusting for individual characteristics from survey and administrative data.

For aim 3, we will analyze how individual characteristics affect whether people choose to participate in the trial (take up of our invitation to participate). The key study variables will include age, use of myhealthonline, and prescription drug profile.