SAMEPAGE Study Protocol

Study title: Involving Family to Improve Communication in Primary Care (SAMEPAGE)

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Background

Dementia is among the most profoundly disabling and costly of all health conditions.(1) With devastating impacts and no known cure, health care is nevertheless pivotal to detection and treatment of behavioral symptoms and co-occurring medical conditions, initiation of social service referrals, and planning for future needs. Dementia poses special communication challenges in primary care(2-5) where most persons are initially treated.(6, 7) As persons with dementia have a high burden of co-occurring medical conditions,(1, 8, 9) communication challenges affect not only dementia diagnosis and treatment,(10, 11) but the care of other conditions, resulting in costly and burdensome treatments, inappropriate medication use, and potentially avoidable hospitalization.(12-17) Family caregivers play a vital role in dementia care, and are typically present and actively involved in medical visits.(18, 19) However, knowledge of how to optimize family caregiver involvement in medical visits is lacking.

This study will refine a brief intervention to effectively and purposely involve family caregivers ("companions") who accompany persons with cognitive impairment to primary care visits. Existing evidence suggests that this focus is appropriate and potentially powerful. Nearly 4 in 10 patients attend primary care visits with a companion.(20, 21) These patients are older, in worse health, and more likely to have cognitive impairment than those who attend visits alone.(20-22) Companions are most often family members who not only attend visits,(20, 21) but actively participate in medical dialogue in varied ways that both help and hinder care.(21, 23, 24) Patients(25-27) and clinicians(28) strongly endorse involving family to meet the communication needs of patients who lack the capacity to obtain, process, and understand basic health information to make appropriate health decisions. However, *evidence-based strategies that specify **how** to involve family companions do not now exist*. Agenda-setting strategies (e.g., symptom checklists, question prompts) are a pragmatic approach to structure pre-visit preparations and increase patient involvement in care.(29, 30) However, few strategies target older adults,(31, 32) and ***none*** address the needs of persons with cognitive impairment and their accompanying family companions.

The study team has established proof of concept for a brief checklist to be used by older patients and their companions in the waiting room prior to medical visits. The checklist is designed to elicit and align patient and companion perspectives regarding patient health issues to discuss with the doctor, and to stimulate discussion about the companion's role in the visit. The premise for the checklist is that companions are typically motivated to support patients during medical visits, but that they often lack knowledge of the patient's health concerns and preferences for communication assistance. In a proof of concept randomized study of 32 patient-companion dyads, we found that the checklist was highly endorsed by patients, companions, and doctors. Analyses of audiotaped medical visits indicated that communication was significantly more patient-centered among patient-companion dyads who completed the checklist as compared with those who received usual care, and did not receive the checklist.(33) In post-visit surveys, doctors were 34% more likely to agree that intervention versus usual care companions "helped them provide good care to the patient" (94.1% vs. 60.0%; p=0.02). Intervention patients were more likely than usual care patients to agree that because their companion was present they "better understood their doctor's advice and explanations" (82.4% vs. 46.7%; p=0.03). However, *older adults with moderate and severe cognitive impairment were excluded in this early phase study*. Therefore, building on our preliminary work, this study seeks to refine and test the checklist to address the communication needs of older adults across a range of mild, moderate, and severe cognitive impairment.

Study Aims

This study includes two specific Aims. The work associated with Specific Aim 1 was previously undertaken through a complementary study which was separately approved under IRB protocol 6194 ((34)). Although we restate the two specific Aims of this project for the sake of comprehensiveness, this proposal seeks approval for the work that pertains to Specific Aim 2.

Aim 1. To refine a patient-companion checklist to address the communication needs of cognitively impaired older adults during primary care visits. We will undertake an iterative user-centered design process to incorporate patient and companion feedback regarding checklist content and alternative delivery characteristics (optimal timing of delivery prior to the medical visit; whether the checklist is self-administered versus delivered by a facilitator) by undertaking in-depth interviews with older patients with mild, moderate, or severe cognitive impairment (n=20) and their companions (n=20; 20 dyads in total).

Aim 2. To evaluate the feasibility of delivering the refined checklist to patients with cognitive impairment and their companions and to compare the checklist and control protocol with respect to patient centered communication (from visit audiotapes). We will conduct a two-group pilot randomized trial to examine feasibility of the protocol and to compare medical communication during visits of patient-companion dyads who complete the checklist (n=50) with patient-companion dyads who receive usual care (n=50).

Study Design

We will conduct a two group pilot randomized trial of up to 100 (50 per group) patients ages 65+ with cognitive impairment and their unpaid companion to test the effects of the refined checklist for medical communication. Each patient-companion dyad will be randomized to the intervention (to receive the checklist) or to a control protocol. Aim 2 has been designed as a pilot trial to evaluate the feasibility of delivering the study protocol to patients with cognitive impairment and their companions in primary care, and to generate preliminary evidence regarding the effect of the checklist on medical communication. For these reasons, the control group protocol will comprise usual care which is in this case existing clinical practice.(35, 36) Patients (when feasible), companions, and doctors in both intervention and control groups will complete in-person post-visit surveys immediately after the visit. Patients (when feasible) and companions will separately complete follow-up surveys by telephone two weeks after the doctor visit conducted by a research staff member. Because of high (100%) retention in our proof-of-concept study, we expect low dropout.

Participants

We propose to enroll as many as 100 patient-companion dyads to provide us with information about the feasibility and acceptability of our study protocol, and preliminary insight regarding the effects of the intervention on medical

communication. We estimate that we will screen as many as 2,000 patients ages 65 and older to reach our target enrollment. In our proof of concept study 263 patients were screened and 32 (12.1%) patient-companion dyads were enrolled. As the Aim 2 pilot study will impose eligibility criteria pertaining to cognitive impairment, we have conservatively estimated that we will need to screen a larger number of older patients to attain recruitment goals than in our proof-of-concept study. However, we note that prevalence of mild cognitive impairment is not uncommon, and may be as high as 42% among older adults (37). The sample size of this study is based on practical factors related to available funding and duration of the R21 mechanism that is supporting this project.

Participants of this study will include three groups: (1) Older adult primary care patients with cognitive impairment, (2) Companions of older adult primary care patient study participants, and (3) primary care clinicians. Inclusion/exclusion criteria for each of these groups are as follows:

A. Older adult primary care patients. Inclusion criteria: 65 years or older, established patient of participating primary care clinician, regularly attend medical visits with one or more family member or unpaid friend "companion(s)", agree to allow companion to be contacted and participate in the study, authorize disclosure of PHI in their electronic health record, able to provide informed consent or have a legally authorized representative. Exclusion criteria: younger than 65 years, no evidence of cognitive impairment, do not attend medical visits with family member or unpaid friend.
B. Family companion. Inclusion criteria: Family member (spouse, adult child, parent, adult sibling) or unpaid friend who accompanies older adult participant to medical visits. Exclusion criteria: paid non-family member who accompanies patient to visits.
C. Primary care clinicians. Inclusion criteria: practicing physician, nurse practitioner or physician assistant at a participating primary care practice.

Recruitment

Primary care clinicians: Once IRB approval has been received, we will discuss the study with primary care clinicians who have an established practice at 3 primary care practices and we will invite them to participate. If a primary care clinician would like to participate they will be asked to provide written informed consent. We will track the number of primary care clinicians who are invited to participate and the number who agree to participate.

Older adult primary care patients and their companions: Patients will be recruited to the study in a phased process. Patients who are scheduled for an upcoming visit with a participating primary care clinician will be identified from the clinic schedule via electronic scheduling software by our research team. Patients will be mailed a letter informing them of the study. The letter will state that patients will receive a call in about 10 days to explain the study in greater detail. The letter will include a postcard that patients may return by mail if they would like to "opt-out" from learning more about the study. Patients who do not "opt-out" will be called by phone to inquire about their interest in learning more about the study. We will attempt no more than six calls to potentially eligible participants – but will leave no more than two voice messages at their place of residence. Patients who at the time of the phone call express an interest in participating will be asked questions to determine eligibility**.** *Companions* of eligible patients will be contacted by research staff to introduce the study, answer questions, and state that participation is voluntary. Companions who express interest in participating will be asked questions to determine eligibility**.** For patients with significant cognitive impairment who are unable to interact with study staff by telephone, eligibility will be assessed by completing the screening survey with a knowledgeable informant.

Consent Process

We will enroll practicing clinicians 3 primary care clinics, established patients of participating clinicians, and patients' companions. Informed consent of clinicians, patients, and companions will be obtained by research staff who are trained in human subject research and the study protocol. Written consent will be obtained from clinicians at the inception of the study prior to recruitment of patients. Oral consent of potential patient participants and potential companion participants will be obtained prior to completing telephone screening interviews to determine eligibility for the study. Patient eligibility will not be contingent on the availability of a legally authorized representative (LAR)

for those who are able to complete the telephone screening interview and who are identified as having very mild cognitive impairment on the basis of making 1 error on the six-item cognitive screen. For patients who make 2 or more errors on the six-item cognitive screen during telephone screening call or who are unable to complete the telephone screening call, we will obtain written consent from their LAR prior to the enrollment visit if the LAR is not the companion. Written consent from patients in conjunction with an evaluation of their capacity to consent and written consent from their companions will be obtained immediately prior to a scheduled clinician visit. Study staff will ask patients about the purpose of the study, the risks involved in participating in the study, and the study procedures that are to be followed. For patients who are unable to provide acceptable answers, study staff will seek to obtain oral assent from the patient and written proxy consent from their LAR when the companion is the LAR (for those whose consent had not yet been obtained). For all patient participants, research staff will complete a form that specifies how informed consent was obtained.

Study Implementation

We will partner with practicing primary care clinicians, established patients of participating clinicians, and patients' companions. Patient and companion eligibility will be ascertained by telephone by research staff. Written consent from patients and companions will be obtained immediately prior to a scheduled visit. After providing consent, enrolled patient-companion dyads will be randomly assigned to intervention or control group.

Patient-companion dyads who are assigned to the intervention group will be asked to complete a paper/pencil communication checklist to elicit topics they would like to discuss with their clinician during their visit and to discuss the patient/companion roles to be assumed. Patient-companion dyads assigned to the control group will receive usual care. Research staff will place two audio-recording devices in the exam room of all participating patient-companion dyads. The research staff will show patients, companions, and clinicians how to operate the audio-recording device and will state that the devices may be paused or stopped by the patient, companion, or clinician at any point during the visit. Upon completion of the visit research staff will retrieve the devices, collect the completed checklist from intervention group participants, and provide brief (10-15 minute) post-visit questionnaires to the patient and the companion to complete (separately) in the waiting room prior to leaving the office. Research staff will offer to assist reading and/or completing the questionnaires to patients or companions who request assistance. Clinicians will be asked to complete a brief survey of questions relating to patient health and patient/companion behavior during the visit. Two weeks after the visit, research staff will telephone patients and companions separately to complete a brief (20 minute) telephone survey. Patients and companions will each be compensated with a $25 gift card for the in-person interview and with a $25 gift card for the telephone interview (up to $50 total) for their time.

Clinician participation in the study will occur throughout the duration of recruitment. Immediately after providing informed consent, clinicians will be asked to complete a one-page survey of socio-demographic characteristics, training, and experiences in the care of persons with dementia. Clinicians will subsequently complete a brief one-page survey immediately after the visit of participating patients. Patient and companion participation in this study will occur over no longer than one month of time, and will involve a screening telephone call to determine eligibility, one in-person encounter at the time of a regularly scheduled office visit, and one follow-up telephone call of approximately 30 minutes duration. The in-person encounter is not expected to require more than 45 minutes time beyond the regularly scheduled primary care visit. Participants will provide written consent to participate in the study (10 minutes) complete a pre-visit communication tool (10 minutes), agree to the audiotaping of their clinician visit, and complete a brief post-visit survey (10-15 minutes).

Participant Assignment

Each patient-companion dyad will be randomized to treatment or control group in a 1:1 ratio using stratified, blocked randomization by doctor with alternating block sizes of 4 and 6 for each clinician. A statistical program, developed by the project statistician and unknown to study staff will be used to prospectively generate random treatment group assignment of study participants for each participating clinician. A set of opaque envelopes will be prepared for each clinician following the results of the statistical program. Upon providing informed consent, research staff will open the next sequentially ordered envelope specifying treatment group by clinician. Patient-companion dyads assigned to

the treatment group will receive a copy of the pre-visit checklist and a clipboard and pen. Patient-companion dyads assigned to the control group will receive care as usual. Participants and research staff responsible for the randomization protocol at the enrollment visit will be aware of participant assignment status after it occurs. The PI, project statistician, and research staff responsible for coding study outcomes will be blinded throughout the study. As randomization occurs at the level of the patient-family dyad, clinicians will care for patients in both groups. Clinicians will be blinded to group assignment.

Measurement

Trial measures will be derived from baseline surveys administered to primary care clinicians at the time of informed consent, patients' electronic health records, audio-recordings of doctor visits, post-visit survey responses provided by older adults, companions, and doctors immediately after the visit, and follow-up telephone surveys administered to patients and companions (Table 1). Audio-recordings of visit communication will be coded using the Roter Interaction Analysis System (RIAS), a validated system for empirically describing medical communication with high levels of reliability and predictive validity.(38) The RIAS assigns each speaker statement (doctor, patient, and companion) to one of 38 mutually exclusive and exhaustive communication categories that may be further collapsed to summary categories.(23, 39) Trained staff, blinded to group assignment, will code visit recordings. Reliability will be assessed by a random sample of double-coded tapes drawn throughout the coding period.

Table 1. Study Outcomes, Source of Information, Timing of Administration	**BL**	**Visit**	**FU**
Clinician: age, gender, training, geriatric specialization, years in practice, % panel age 65+	D		
Visit processes: duration (in minutes); patient and companion verbal activity(38), patient-centered communication(23, 40), discussion of memory in visit		T	
Acceptability of checklist: perceptions of utility, burden, helpfulness (33)		P,C, D	
Cognitive function: Mini-mental state examination(41, 42); received diagnosis		P; EMR	
Demographic factors: age, gender, race/ethnicity, living arrangement, relationship (e.g., spouse, child), geographic proximity			P,C
Health: self-rated(43), physical limitations, numbers of prescribed medications			P,C
T=audiotaped enrollment visit; P=patient; C=companion; E=electronic medical record; D=primary care clinician; FU=2-week telephone interview			

The primary outcome of the Aim 2 trial is an objective composite measure of visit medical communication that will be constructed from RIAS-coded categories. This outcome, *patient-centered communication,* is a ratio of statements that encompass psychosocial and socio-emotional elements of medical dialogue that reflect the lived experience of patients (in the numerator), in relation to statements that are more biomedical and disease-focused (in the denominator).(23, 40) Higher values (>1) indicate more patient-centered encounters and lower values (<1) indicate more doctor-centered encounters. Prior work indicates the measure has predictive and concurrent validity in relation to consequential patient and doctor outcomes.(23, 40, 44, 45) We will additionally examine several secondary outcomes of *visit processes* (e.g., visit duration and verbal activity of patients, companions, and doctors, from audiotapes) and *discussion of memory* from audiotapes. Acceptability will be evaluated from responses to the agenda setting checklist by intervention dyads. Measures of patient-companion concordance will be constructed to indicate whether each health issue was selected as a priority by the patient only, companion only, neither, or both. From companion responses to post-visit surveys we will assess how the checklist was completed (patient only, companion only, together) and how long it took to complete the checklist. The utility, burden, and helpfulness of the checklist will be assessed in written post-visit surveys using questions from our formative work. (33) Additional measures. From patients' electronic health record we will assess age, gender, and diagnosis of cognitive impairment or dementia at the time of the enrollment visit. Cognitive function will be measured using the Mini-Mental State Examination (MMSE)(41) which will be administered to patients by research staff immediately after the enrollment visit. From telephone interviews we will assess patient race/ethnicity, living arrangement, educational attainment, receipt of help with self-care and household activities, and numbers of daily prescribed medications. Measures of companion characteristics will include relationship to the patient, gender, self-rated health, and educational attainment, from

follow-up telephone interviews. We will assess clinician characteristics (age, gender, specialty training, and years in practice) from baseline surveys administered at the time of informed consent.

Analysis

Analyses will be performed in SAS statistical software, with each patient-companion dyad and their recorded visit as the unit of analysis. In this two-group randomized pilot trial, we will compare the effects of the refined checklist on medical communication among up to 100 (50 per group) patients ages 65+ with cognitive impairment and their companion. Simple statistics (frequency distributions, group means) will be used to assess potential differences between eligible patients willing and unwilling to participate, between enrolled participants assigned to intervention and control groups, and process measures relating to completion of the agenda setting intervention. We will rely on established cut-points and approaches to constructing primary and secondary outcome measures, as well as measures of patient and companion attributes that will serve as control variables (socio-demographic characteristics, health status, aspects of the patient and companion relationship). We will rely on established cut-points of the Mini-Mental State Examination test to categorize patient participants as having mild (scores of 20-25), moderate (scores of 10-20) or severe (scores of less than 10) cognitive impairment.(41, 42) We will primarily evaluate the consistency, direction, and magnitude of differences in study outcomes by undertaking analyses that are stratified by intervention group (checklist versus usual care) and for the subgroups of patient cognitive function (mild, moderate, or severe, based on the Mini-Mental State Examination cut-points). Intervention effects on primary and secondary outcomes will be examined using regression models in which the main independent variable is treatment assignment. We will use generalized estimating equations (PROC GENMOD in SAS, version 9.4 (SAS Institute, Cary North Carolina)) to assess the direction, magnitude, and statistical significance of between-group differences in outcomes. The generalized estimating equations method will be used because it accounts for within-clinician clustering of patients and the different numbers of enrolled patient-companion dyads per clinician.(46) An exchangeable correlation structure will be assumed. Regression models will include treatment assignment (agenda setting versus usual care) and patient-level covariates that are postulated as affecting communication, such as age, gender, and cognitive function. We will evaluate recruitment, retention, and the timeliness and completeness of collected data,(47) as well as checklist acceptability (utility, burden, helpfulness) using questions from our formative work. (33) The statistical significance of patient-companion concordance/discordance on priorities for the visit agenda will be assessed with McNemar's test. We recognize the need for caution in interpreting pilot trial results. We will evaluate recruitment and dropout rate as well as effect size of primary and secondary outcomes to help inform the design and sample size calculations for a larger trial. We will examine similarities and differences in pilot trial results and our initial proof-of-concept study. The ultimate goal of the Aim 2 pilot trial is to demonstrate the feasibility of implementing the study protocol among primary care patients with a range of cognitive impairment and their companion and to glean insight regarding effects of the refined checklist for medical communication.

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