FULL PROTOCOL TITLE

Pragmatic Trial: Improving Communication for Primary Care Patients

NCT04819191

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SHARING Choices

Supported by:

The National Institute on Aging
R33AG061882

Version 10 *(Please change version number with each amendment)*

August 31, 2023

PRÉCIS

Alzheimer's Disease and Related Dementias (ADRD) are among the most profoundly disabling and costly of all health conditions(1) and the 5th leading cause of death.(2) Family and friends (hereafter referred to as family) are at the forefront of managing ADRD across the continuum of care. Family are also key for helping making decisions at the end of life.(3-5) However, family members are not routinely engaged in discussions about prognosis(6, 7) and are often poorly prepared for surrogate decision-making.(5, 8, 9) Compared to persons without ADRD, persons living with ADRD are less likely to complete an advance directive or formally designate a surrogate decision-maker,(10) placing them at heightened risk for unnecessary suffering and high utilization of burdensome and costly end-of-life care.(7, 11, 12) Advance care planning (ACP) is a communication process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care.(13) Early initiation of ACP is an imperative in ADRD care due to the long course of illness and its progressive and devastating effects. Little attention has been directed at identifying strategies that improve ACP for persons with ADRD and their family in primary care, which is the most common setting of initial diagnosis(14, 15) and ongoing medical management.(16, 17)

This protocol is to examine the effectiveness of the pragmatic implementation of SHARING CHOICES in primary care practices (Aims 3 and 4 of the overall grant). The goal of SHARING CHOICES is to proactively engage family in ongoing interactions with primary care and stimulate and support ACP and attention to ADRD in all primary care patients and particularly for those with ADRD, throughout the disease trajectory. The design is a cluster randomized trial with pragmatic implementation of SHARING CHOICES into routine clinical care to examine the effectiveness for all older patients and persons with ADRD diagnoses. The components of SHARING CHOICES, which are all available in routine primary clinical care but have not been systematically implemented, include: 1) an electronic message or letter from the primary care practice introducing the components of SHARING CHOICES available to patients in their practices, including ACP, 2) a person-family agenda-setting checklist to align patient and family perspectives regarding the role of the family member in primary care interactions, 3) ongoing access to a trained and certified ACP facilitator to lead ACP conversations with patient and family, in collaboration with the patient's primary care clinician, 4) facilitated registration for the patient portal (including family) to enable and extend electronic interactions and information access to family members, when this is consistent with patient preferences, and 5) implementation support, education and resources about ADRD for practice staff, tailored to SHARING CHOICES practices. This work is informed by the outcomes of stakeholder and patient interviews and focus groups and a pilot study in which we refined SHARING CHOICES to optimize implementation for primary care patients aged 65 and over and their families, including patients with ADRD.

Study Title

Pragmatic Trial: Improving Communication for Primary Care Patients

Objectives

This study is a pragmatic trial to evaluate the effectiveness of SHARING CHOICES included in routine clinical care with primary care patients age 65 years and over

including those with mild to severe ADRD. We will evaluate uptake of the SHARING CHOICES components by patients and family and study outcomes through secondary analysis of information collected in routine clinical care.

Design and Outcomes

This will be a pragmatic randomized, controlled trial of SHARING CHOICES included in routine clinical care in primary care practices. Randomization will be at the practice level. All components of SHARING CHOICES are currently available in primary care but have not been routinized in these practices. Sites randomized to control will continue with usual care, while sites randomized to SHARING CHOICES will have the SHARING CHOICES components included in routine clinical care, including outreach on the components and availability of certified ACP facilitators. Facilitator staff will participate in two fidelity simulations with standardized patients (SPs). Facilitators will be assessed according to a pre-designed checklist developed to determine fidelity of ACP conversations occurring as part of the pragmatic trial. Results of the fidelity assessment will be used to evaluate the effectiveness of ACP training protocols central to the implementation of SHARING Choices in usual care. Simulation activities for this trial will pose minimal risk to facilitators, offer opportunities for debriefing with expert faculty to support management and emotional response to encounters including just-in-time coaching to reinforce exemplary skills.

The study outcomes will be collected through secondary analysis of data collected for non-research purposes. Primary outcomes will be extracted from the electronic health record (EHR) and Maryland-District of Columbia health information exchange (CRISP) and analyzed at the practice level, including rates of advanced care planning documentation, advance directive documentation and potentially burdensome care within 6 months of death for patients who have died. Data extracted by CRISP and delivered to the study team will only be for patients who died during the observation time period during the trial. Death data will be collected from the Vital Statistics Agency by CRISP.

Trial Procedures and Duration

The control group will receive usual care, comprising standard primary care at participating practices. Patients at implementation practices will receive usual care in addition to SHARING CHOICES components. The SHARING CHOICES components include: 1) an invitation letter from the primary care practice introducing SHARING CHOICES initiatives, 2) access to a facilitator trained in the protocol and leading ACP for persons age 65 and older including those with a diagnosis of ADRD and family members who are interested in engaging, 3) a person-family agenda-setting checklist to align perspectives about the role of family and stimulate discussion about health care issues and ACP, 4) facilitated registration for the electronic health record portal to enable and extend electronic interactions and information access to patients and family, and 5) implementation support, education and resources about ADRD for practice staff.

Patients and families at SHARING CHOICES practices interested in ACP will have

access to a practice ACP facilitator to schedule a discussion. SHARING CHOICES will be available to all patients 65 or older in these practices. Trained and certified ACP facilitators will lead ACP. All facilitators will be trained in all elements of the SHARING CHOICES protocol, with supplemental training for ADRD.

ACP discussions will include an initial meeting of up to 45 minutes, with a process for scheduling future contacts as needed. We expect meetings will most often occur at the primary care practice, but may also occur by phone or through telehealth, in the community or at the individual or family residence. In the initial meeting the facilitator will follow a conversation guide and employ motivational interviewing techniques to evaluate readiness and facilitate uptake and adoption of SHARING CHOICES components. Patients will be offered all components, with the duration and nature of the conversations and resulting decisions tailored to individual preferences.

To evaluate ACP facilitator implementation skill and competency to perform ACP conversations, each facilitator will do two case-based simulations with standardized patients (SPs) via teleconference (**D2**, **D3**). The first case is an SP with mild cognitive impairment and the second case involves an SP with dementia and their caregiver. Each simulation will include a 10-minute pre-brief session (**D1**) to orient the facilitator to the simulation and a 30-minute simulation with the SPs followed by a 15-minute debrief to identify adherence to the intervention, quality of delivery, and areas for further improvement. Adherence will be measured using the Advance Care Planning (ACP) Facilitator Evaluation Checklist, a short fidelity instrument adapted from SHARE (IRB00242431) and Respecting Choices® to evaluate communication skills and the key elements in an ACP conversation (**E1**, **E2**). The results will also be used to inform additional booster training for facilitator staff.

The overall duration of patient follow-up will be 12 months as measured from the most recent primary care appointment date when the patient is sent the SHARING CHOICES materials. The overall study duration is expected to be 18 months.

Sample Size and Population

We will engage a diverse mix of practices by geographic region (urban, suburban, rural) and size. The unit of randomization for this study is the primary care practice. Study participants will include all primary care patients age 65 and over, including those with ADRD and their family at up to 100 primary care practices. We anticipate that 9,200 of 87,000 of older patients will have a diagnosis of ADRD, and 7,000 will die within 12 months of study entry and be eligible for the potentially burdensome end-of-life care outcomes.

STUDY TEAM ROSTER

Principal Investigator: **Jennifer Wolff**

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The PIs will have primary responsibility for all scientific and regulatory aspects of the study, but will closely coordinate study activities with co-investigators and staff. The PIs of the study, Wolff and Dy, and study staff are based in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health and have joint appointments in the School of Medicine.

Study Staff:

Research Program Manager (JHU): **Diane Echavarria**
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Diane Echavarria and Danny Scerpella will have day-to-day responsibility for coordinating the efforts of all the investigators and collaborating organizations in implementing the study

protocols. Mr. Scerpella and Dr. Giovannetti will oversee data management and security for the trial. Kimberly Cockey will assist in study procedures following Medstar system requirements.

Co-Investigators:

Name	Organization
Cynthia Boyd	JHU School of Medicine
Jessica Colburn	JHU School of Medicine
Valerie Cotter	JHU School of Nursing
Danetta Sloan	JHU School of Public Health
David Roth	JHU School of Medicine
Kelly Smith	MedStar
David Weisman	MedStar
Stephen Fernandez	MedStar
Erin Giovannetti	MedStar

PARTICIPATING STUDY SITES:

We will conduct the study in partnership with primary care practice health systems operated by Johns Hopkins Community Physicians (JHCP) and Medstar Health.

Study objectives

1.1 **Primary Objective**

This study (Aims 3 and 4 of the overall grant) aims to evaluate the implementation effectiveness of SHARING CHOICES in primary care practices. Effectiveness will be evaluated in a pragmatic, cluster randomized trial of primary care practices to examine the impact of SHARING CHOICES on the rates of ACP, AD documentation, and end of life outcomes in patients aged 65 years and older, including those with mild to severe ADRD.

2 BACKGROUND AND RATIONALE

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

Engaging family in primary care is particularly important in ADRD because of the important role assumed in medical decision-making,(18-21) especially at the end of life.(22-24) Our study seeks to improve communication for persons with ADRD by establishing a structured protocol to proactively engage family in ongoing interactions with primary care and stimulate and support ACP and attention to ADRD in primary care throughout the disease trajectory. Our premise is that individuals and families expect primary care practices to initiate ACP(25) and provide information and referrals for ADRD needs, (26, 27) but that individual, family, and system factors including time, knowledge, and resources inhibit these conversations from occurring.(12) This protocol aims to inform decision-making regarding routine implementation of SHARING CHOICES, which seeks to better equip patients and family with the knowledge, skills, and support to engage in more effective communication and ACP.

2.2 **Study Rationale**

Almost all (98%) community-living older adults with ADRD rely on the help of family caregivers.(28, 29) The societal cost of ADRD is exceedingly high due to heavy reliance on family, particularly at the end of life.(1, 30) Family caregivers of persons with ADRD provide hands-on care, coordinate information and care, and serve as surrogate decision-makers when persons with ADRD can no longer make decisions themselves.(28, 29) Family caregivers of persons with ADRD actively participate in primary care visits,(31-33) and may inhibit or facilitate ACP.(24, 34, 35) Barriers related to lack of knowledge, fear, and reluctance are remediable with support and education.(12, 36) A meta-analysis of 12 ACP interventions in community settings reported a statistically significant pooled effect size of 1.92 for advance directive completion at 1-18 months follow-up.(36) Caregiving burden, stigma, and illness characteristics amplify the difficulty and importance of ACP discussions for older adults with ADRD.(24, 37) The few ACP interventions that specifically address the needs of persons with ADRD have been undertaken in nursing homes.(36, 38, 39) The lack of accuracy of advance directive documentation in the electronic health record is well-recognized. The level of accuracy at our two health system partners is not now well understood. Both JHCP and MedStar Health seek to conduct an audit of data quality relating to the primary outcome to assess data accuracy prior to the launch of the trial. Simulations using standardized patients are a high-fidelity, low-stake opportunity to evaluate knowledge, skills, and competencies for behavioral attributes (e.g., communication skills) associated with high-quality healthcare delivery. Simulation trainings have been used to assess caregivers' and clinicians' confidence, empathy, and knowledge of topics related to dementia care. Simulation trainings have also been used to routinely assess how well members of a care team adhere to elements of an intervention and serve as an extension of training role plays to ensure that skill decay is minimized for staff with direct interaction with patients. The goal of simulation is not only to assess skills and competency, but also to aid staff in identifying opportunities for improvement to ensure patient safety. Utilization of simulated patients in SHARING Choices adds to the literature on how simulation training can be used to evaluate readiness and aptitude of staff engaging in methodologically rigorous ACP conversations with patients with ADRD and their caregivers. Katwa et al. used a simulation training for care home staff to increase knowledge about advance care planning, noting that simulation training could be used "to test the strength of implementation of policies and standard operating procedures" and to "check for compliance" (30). The study will evaluate adherence to the Respecting Choices ACP framework (*see section 4.1 below*), quality of delivery, and areas for further improvement that may impact study outcomes. Simulation activities for this trial will pose minimal risk to facilitators, offer opportunities for debriefing with expert faculty to support management and emotional response to encounters including just-in-time coaching to reinforce exemplary skills.

3 **STUDY DESIGN**

This study will evaluate the implementation effectiveness of SHARING CHOICES to increase the rate of advance directive documentation and improve end-of-life outcomes using a pragmatic, cluster randomized trial design. Outcomes from data collected in routine clinical care will be aggregated at the practice level in up to 100 diverse primary care practices from 2 health systems. Practices randomized to SHARING CHOICES will have information electronically sent or mailed to their patients. SHARING CHOICES practices will have access to a trained ACP facilitator who will be available to engage the patients and their healthcare agent in ACP discussions when desired. We will evaluate effectiveness of SHARING CHOICES by analyzing data collected for non-research purposes from the electronic health record (EHR). To facilitate understanding of how to operationalize the primary endpoint of advance directive documentation and with support from JHCP and MedStar Health leadership, we will perform an advance directive audit within the EHR to characterize the quality of data existing in the electronic health record across 19 JHCP and 35 MedStar clinics prior to the launch of the intervention. To ensure ACP facilitator implementation fidelity to the methodological training components of the ACP conversation, facilitation staff will be evaluated via supervised interactions with simulated patients (**D1**, **D2**, **D3**).

4 IDENTIFICATION OF PRIMARY CARE PRACTICES

(1) Practice Identification: Practices will be included from two health systems: Johns Hopkins Community Physicians (JHCP) and MedStar Health. For the purposes of this study, primary care is defined as adult internal medicine, family medicine, and geriatric medicine. Practices will be randomized to SHARING CHOICES or usual care, stratified by health system and balanced on clinical characteristics.

4.1 Facilitator Identification:

Facilitators will be social workers or trained lay facilitators who will be employees of the Johns Hopkins School of Medicine or JHCP. Facilitators will be provided 15 hours of initial training, and biweekly, one hour training sessions prior to the start of the trial. Training will include all components of SHARING CHOICES, including: certification in the Respecting Choices ACP curriculum, with specific attention to working with patients with ADRD and families; documenting and uploading advance directives; patient and family portal registration and use; ADRD resources; and facilitating family communication with the agenda-setting checklist. Training will be delivered and reinforced using traditional didactics, case scenarios and video conversations, and modeling and mentored role play (see Attachment A4 for the training agenda). ACP facilitator staff will participate in two 55-minute simulation sessions to assess training fidelity, communication skills and the key elements of an ACP conversation.

5 STUDY INTERVENTIONS

Components of SHARING CHOICES that will be implemented as part of routine primary care in implementation practices include:

1) an electronic notice or letter from the primary care practice introducing SHARING CHOICES, including ACP (attachment A1 and B1),

2) a person-family agenda-setting checklist to align patient and family perspectives regarding the role of the family member in primary care interactions and stimulate interest in ACP (attachment A3 and B2),

3) access to a trained and certified facilitator to lead ACP conversations within the practice, and distribution of AD forms (attachment A2 and A5),

4) information on registration for the patient portal (for patient *and* family) to enable and extend electronic interactions and information access to patients and their family (A6, B3), and

5) implementation support, education and resources about ADRD for practice staff, tailored to SHARING CHOICES practices.

6 STUDY PROCEDURES

Audit

Preparatory to the detailed audit, an exploratory analysis will be performed using Natural Language Processing (NLP) to determine the number of existing patient records with a textual reference to advance care planning processes and documentation. This analysis will not include patient identifiers. NLP will be used to identify the proportion of patients whose charts do and do not have official documentation of an advance directive (e.g., documentation of a named health care agent or completion of a living will) and/or MOLST/MOST who also have a textual reference to advance care planning-related conversations or documentation in the clinicians' note. Results will be examined in the aggregate by clinic site. We seek to understand the percentage of patients at each clinic who have engaged in an ACP-related encounter by whether they do or do not have documentation of their wishes.

For each of the 19 JHCP and 35 MedStar Health clinics that are part of this trial, we will randomly select 30 - 40 electronic health records of patients age 65 and older under the care of a clinician at the clinic for whom an advance directive has been documented in the electronic health record. Trained study staff at JHCP and MedStar Health will manually review the documented advance directive to confirm that the uploaded document is an advance directive, and, if so, whether the advance directive includes the naming of a health care agent only, the completion of a living will only, or both. The goal of the advance directive audit will be to identify the percentage of advance directives that are documented as being completed that are in fact an advance directive. We will additionally identify variability in the accuracy of advance directive completion by clinic, by patient age group, and for patients with and without a diagnosis of dementia.

Mailings

PHI from EPIC will be requested and disclosed to School of Public Health team members to access data on patients who may be eligible for the advance care planning services – this data will include name, age, primary care physician, upcoming appointments, and address. The team members will use this to identify patients who can receive the SHARING CHOICES intervention (over 65 and with an upcoming appointment in primary care clinics randomized to SHARING CHOICES) and will use patient names and addresses in order to mail the information about the SHARING CHOICES components available in their clinic.

Facilitator Processes and Procedures

For ensuring fidelity of skills and competency, adherence to the SHARING Choices protocol, communication skills, and key elements in an ACP conversation will be assessed via evaluation of interactions with standardized patients (SPs) (**D1**, **D2**, **D3**). The Facilitator Lead (Valerie Cotter) and a Facilitator Evaluator will utilize the Advance Care Planning (ACP) Facilitator Evaluation Checklist (**E1**, **E2**), a short fidelity instrument adapted from SHARE (IRB00242431) and Respecting Choices®. This is a 35-item checklist instrument to evaluate how well the ACP meeting is organized, which ACP topics were addressed, how the ACP conversation will be documented, and effectiveness of communication between the facilitator and SP. Data from the ACP Facilitator Evaluation Checklist will be used to provide feedback to each facilitator and inform additional booster training for the facilitators.

Individuals trained to guide ACP conversations will be invited to provide oral consent (**C1, C2**) to have the results of their assessment used for research purposes. Prior to the simulated patient evaluation, oral consent will be collected remotely. The objectives, procedures, and a clear statement explaining risks and benefits of the study will be presented during this review. All consenting will be completed by research staff trained in human subject research and the study protocol. Research staff will be required to read the entirety of the oral consent scripts, allowing for any questions, comments, or concerns of prospective participants.

ACP discussions will include an initial meeting of up to 45 minutes with scheduling future contacts as needed. We expect meetings will most often occur at the primary care practice, but may also occur by phone or through telehealth, in the community, or at the individual or family residence. In the initial meeting the facilitator will follow a conversation guide and employ motivational interviewing techniques to evaluate readiness and facilitate uptake and adoption of SHARING CHOICES components. Subsequent meetings can occur through ad-hoc requests (by patients, family, clinicians, or staff), or triggers such as hospitalizations.

Outcomes

Outcomes from practices randomized to SHARING CHOICES will be compared to practices within the same system who are randomized to usual care. Outcomes will be assessed at the level of the practice. Control practices will continue to deliver their usual care practices with respect to ACP and agenda setting.

7 SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

Refer to section 7.4, DSMB.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Refer to section 7.4, DSMB.

7.3 Adverse Events and Serious Adverse Events

The risks of participating in this study involve the potential for becoming upset, psychologically stressed or fatigued, and potential loss of confidentiality. Subjects may experience discomfort when discussing health or worries. A trained facilitator will be available to discuss any questions or concerns about ACP. If concerns that are distressing come up in the course of facilitation discussions or any adverse events occur, facilitators will provide this information to primary care providers and provide contact information for participants to discuss any distressing issues. As with all standard care, patients and families may decide to stop ACP facilitation at any time.

It is possible that some persons and family members who choose to have an ACP conversation with the ACP facilitator may become upset or experience discomfort by responding to questions about wishes for future medical care, by participating in agenda setting or ACP discussions. ACP is an accepted standard in clinical care where benefits outweigh risks, and we will institute several accepted mechanisms to reduce the potential for psychological discomfort. SHARING CHOICES facilitators will receive training in techniques for approaching persons, including those with ADRD and family members, about ACP. Additional training in sensitivity to discussing topics related to ACP and cultural competency for working with diverse populations where there may be specific needs for these discussions will be required.

- As with all standard care, ACP is voluntary for patients, and ACP sessions will only be initiated or terminated at the direction of the patient.
- While it is possible that agenda setting or ACP may introduce tension in the person-family relationship by acknowledging the distinct perspective of each individual, extensive research has also found significant benefits with these discussions, and facilitators will be trained to anticipate concerns and mediate difficult discussions.
- Family of older persons with significant health conditions, including those with Alzheimer's Disease and Related Dementias, are at heightened risk of depression and anxiety. Should this come up as in issue, the facilitator will ask the family if they would like an educational brochure about depression or anxiety (as

appropriate), and encourage them to follow up to discuss this with their clinician.

- In the event of extreme psychological discomfort among patients or families in ACP discussions, facilitators will be trained in procedures for ensuring necessary medical or professional referrals. We will identify appropriate referral resource(s) for distressed family members. Primary care patients will be referred to their primary care clinician. Family will be referred to the health system referral resource or to medical or psychological care (e.g., counseling, support, advocacy) as appropriate.

7.4 Safety Monitoring

The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to the National Institute of Aging (NIA) Director to monitor participant safety, data quality and evaluate the progress of the study. The DSMB will be responsible for reviewing the safety of study participants during the conduct of this study and provide recommendations to the research team on specific aspects of the research protocol as it pertains to safety, potential study alerts and adverse events.

The DSMB includes experts in or representatives with familiarity in the conduct of clinical trials with older adults from the fields of:

- Relevant clinical expertise,
- Clinical trial and research methodology, and
- Biostatistics.

The DSMB responsibilities are to:

- Review the research protocol, informed consent documents and plans for data safety and monitoring;
- Provide periodic and independent review of study procedures including enrollment progress;
- Evaluate the progress of the trial and appropriateness of trial procedures, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome;
- Review adverse events (AEs) including serious events and offer recommendations regarding the trial based on such observed events;
- Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator;
- Protect the safety of the study participants;
- Report to NIA on the safety and progress of the trial;
- make recommendations to the NIA, the Principal Investigator, and, if required, to the Food and Drug Administration (FDA) concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
- If appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis and have the approval of the DSMB;
- Ensure the confidentiality of the study data and the results of monitoring; and,

- Assist the NIA by commenting on any problems with study conduct, enrollment, sample size and/or data collection.

Any DSMB member who develops a conflict of interest during the course of the trial will be asked to resign from the DSMB and another person with similar areas of expertise will be sought. Otherwise, DSMB membership is to be for the duration of the trial. The DSMB will discharge itself from its duties when the last participant completes the study.

8 INTERVENTION DISCONTINUATION

As with usual clinical care, the facilitator will stop ACP discussions whenever the patient or family chooses not to participate.

9 STATISTICAL CONSIDERATIONS

9.1 **General Design Issues:** N/A.

9.2 **Sample Size and Randomization**

The unit of randomization for this study is the primary care practice. Practices will be stratified by health system and balanced on practice characteristics, including practice size, geographic location (urban, rural, suburban), and patient mix by race.

Practices randomized to control will continue to provide usual care. Practices randomized to SHARING CHOICES will provide usual care as well as the components of SHARING CHOICES. SHARING CHOICES will be available to all patients ages 65 and older who receive care at up to 33 practice sites.

9.3 **Interim analyses and Stopping Rules:** N/A.

9.4 **Outcomes** will include the rates of advance directive documents uploaded to the EHR (primary outcome), advance care planning documentation, and potentially burdensome care within the last six months of life.

9.5 **Data Analyses**

We will compare SHARING CHOICES and control practices by analyzing the distribution of practice-level characteristics at baseline using appropriate graphical procedures, summary statistics, and multivariate methods. We will examine consistency of effects stratified by patient age group, gender, race, ADRD diagnosis, and primary care practice. We will compute the effect size of outcomes to assess SHARING CHOICES effects relative to published treatment effect estimates for ACP.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection

No data will be collected; all data will be secondary analyses of data collected for routine clinical care. Health information technology staff will extract outcome measures of ACP documentation, advance directive documentation, portal registration, and potentially burdensome end-of-life care from the patient electronic health record. Data extracted will also include demographics, insurance type, diagnoses, potentially burdensome end-of-life care (e.g. hospitalizations, emergency department visits), deaths, advance directive documentation, advance care planning documentation, and uptake of patient and family portal registration and use. All data are routinely recorded as part of routine clinical care and available in the EHR and from the Maryland-DC CRISP health information exchange.

10.2 Data Management

Information extracted from electronic health records will be stored in a database on a secure server (SAFE Desktop). The data will be analyzed and presented only in aggregate at the practice level and individual practices will not be identified. All demographic information will remain confidential. No personal identifiers will be included in the database. The electronic database will be managed by Senior Statistician on the study, David Roth who will track and log issuance of analytic datasets, and return/removal when approved use ends. Access to analytic datasets will be subject to conditions established by the PIs and Dr. Roth. Electronic analytic datasets will be provided to authorized study personnel with the same data protection requirements established for the study database and can only be used on the secure SafeDesktop (JHCP). Only the PIs, Co-Investigators and research staff will have access to the SafeDesktop that contains study data. The PIs and the research staff are listed in eIRB and have completed the Human Subjects Training.

Patient protected health information (PHI) will be obtained by the Chesapeake Regional Information System for our Patients (CRISP). Death data from the Vital Statistics Agency will be collected by CRISP and used to deliver a de-identified data set for patients who died during the study.

Data will be stored and managed by Johns Hopkins personnel on data storage servers housed at the secure Mt. Washington site. Data will be transferred only to devices accessible to those with credentialed Johns Hopkins University log-in information. Transfer or storage of data will be on encrypted devices with specific user access. Access to patient data will be restricted to authorized study personnel at Johns Hopkins as determined by study PIs, and will include the PIs, Co-Investigators, and select research staff members. All credentialed users will be listed in the eIRB and have completed patient privacy, electronic information security and data management, and health privacy for researchers training. If a patient revokes permission for PHI access, data will be destroyed in accordance with Johns Hopkins University data management policies.

Connection to the data will be completed on SAFE Desktop. If the performance of analytical software is not adequate on the virtual workspace, limited datasets from CRISP will be downloaded from SAFE Desktop and analyzed on the personal workstation of lead

statistician, David Roth, which is managed by IT@JH (EB-CO-8TTQ2W2 – Note: Dr. Roth is in the process of updating his workstation to an IT@JH managed laptop: EB-CO-257ZKS3). Datasets are limited and patients are assigned a unique identifier by CRISP which obfuscates identification by Johns Hopkins or MedStar Health personnel. Downloaded data on the personal workstation will be managed by David Roth and accessible only to Dr. Roth and Vishal Sekhon. Immediately upon completion of analysis, downloaded data will be deleted. Upon request, a Certificate of Destruction can be made available to memorialize this action.

10.2.1 **Data Sharing for Analysis**

Data Sharing will be brokered with involvement of the Maryland-DC CRISP health information exchange, and supported by a Data Use Agreement between Johns Hopkins and MedStar Health to share an integrated limited data set that combines de-identified patient-level information from both organizations.

As graphically depicted in Figure 1, Johns Hopkins and MedStar Health will first upload patient-level information regarding candidate patient participants from each respective health systems to CRISP using a secure link that was successfully piloted in the R61 planning phase period. CRISP will assign CRISP IDs that are unique to the health information exchange only. These CRISP IDs, ID mapping instructions, and data extracted from the information exchange for patients who have died will be returned to each respective organization. Hopkins and MedStar will then integrate CRISP IDs with information extracted from their electronic health records that is pertinent to proposed data analyses, such as treatment group, age, gender, race/ethnicity, having a documented advance directive, and for those under the care of a clinician from intervention clinics, date of SHARING Choice mailing(s), and completion of an advance care planning conversation.

Johns Hopkins and MedStar Health data staff will independently create limited data sets using CRISP IDs as identifiers, working with guidance and support of the Johns Hopkins Core for Clinical Research Data Acquisition (CCDA) staff. A CCDA staff member will review and certify each limited data set to ensure that it adheres to standards.

MedStar Health will share a limited dataset with CRISP IDs with Johns Hopkins. Limited datasets for both organizations will be stored and analyzed on SAFE Desktop, following the data safety standards detailed in Section 10.2. David Roth will combine the two limited datasets and remove duplicate patients (identified by CRISP IDs, matching across Johns Hopkins and MedStar Health).

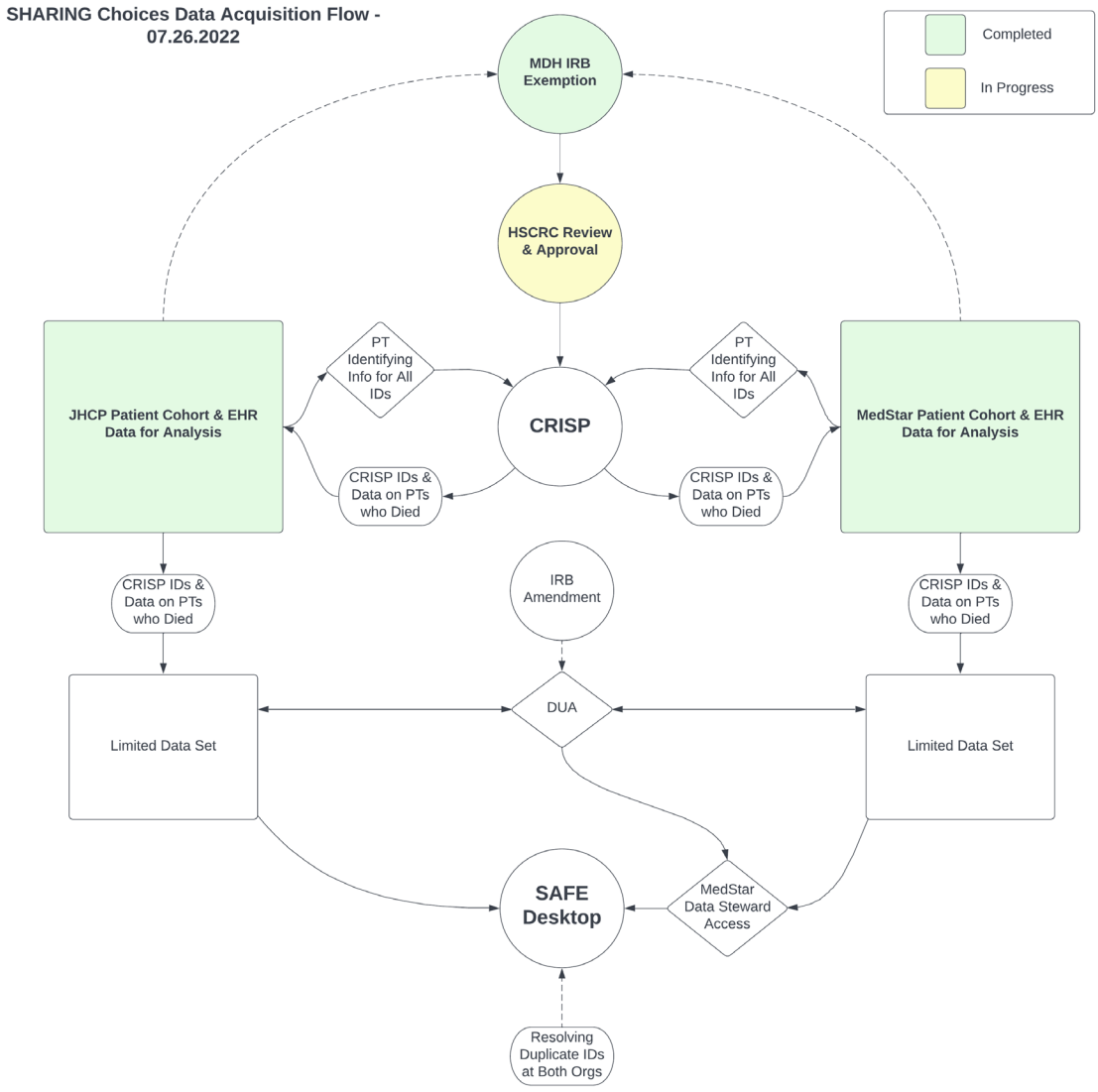

Figure 1. Data Acquisition, Storage, and Flow for Analysis

10.3 **Quality Assurance**

10.3.1 Training

All ACP facilitators will be trained in Respecting Choices First Steps ACP Facilitator Training with additional elements for working with patients with ADRD and their families. Respecting Choices is a validated curriculum for training clinicians and laypersons to facilitate advance care planning conversations. In addition to being certified in Respecting Choices, the facilitator will be trained to be knowledgeable of the other aspects of the SHARING CHOICES components. Facilitators will be required to successfully facilitate at least one ACP conversation prior to facilitating ACP conversations and will receive regular mentoring, monitoring and feedback. To

ensure skills and competency for ACP conversations, facilitation staff will be evaluated via supervised interactions with simulated patients. Evaluation results will be used to determine the necessity for additional booster training sessions.

Our clinical partners and co-investigators at JHCP and MedStar Health will guide the training for the advance directive audit to be completed prior to the launch of the trial to assure quality of clinical data in the advance directives fields in the electronic health record at all clinics.

10.3.2 Quality Control Committee N/A

10.3.3 Metrics

Detailed instructions will be followed to ensure metrics related to advance directive completion as noted in the electronic health record. Patient records that are reviewed will be marked with a chart note by the reviewer indicating the Quality Improvement work.

10.3.4 Protocol Deviations

All protocol deviations will be reported to the IRB in a timely manner.

10.3.5 Monitoring

Study co-investigators skilled in ACP discussions and working with patients with ADRD and their families will regularly meet with ACP facilitators to review discussions, troubleshoot issues and answer questions.

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

There will be no consent forms for the portions of this study relating to the practice-level pragmatic trial. All components of the implemented intervention will be available to all patients over 65 years of age at implementation practices as part of usual care.

We are requesting a waiver of the documentation of informed consent for the collection of data resulting from the ACP Facilitator Simulation Evaluation activity. The request for a waiver of documentation of consent is requested as an individual's signature, name, and other identifiable information in connection with their evaluation results puts the respondent/participant at greater risk of loss of privacy and loss of confidentiality than if they completed this anonymously. Research staff will verbally read the entirety of the oral consent script (**C1**, **C2**), provide information about the use of their evaluation data, and obtain assent to participate. This document will be in compliance with the IRBs of JHU and

MedStar. Verbal assent following the oral consent script and questions implies consent.

11.3 Participant Confidentiality

Any data that is electronically extracted will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept only on an encrypted database (ICTR Safe Desktop), which will also be used for data analyses. Information will not be released, except as necessary for monitoring by IRB, the FDA, the NIA, and the OHRP.

We will institute multiple procedures for protecting against and minimizing risks to privacy and confidentiality. Staff will be trained regarding HIPAA and human subjects protections regulations and procedures. No data will be stored or analyzed on portable devices such as laptops, flash drives, smart phones, or personal digital assistants. No personal identifiers will be included in the analytic database.

Data will be stored in a password protected secure database on an encrypted server. No identifying information will be used in any publications. All data transfers (including database, text, and audio files) will be accomplished using a secure and encrypted data management program or using encrypted Johns Hopkins password-protected servers.

11.4 Study Discontinuation

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

12 ETHICAL CONSIDERATIONS

This study is guided by the prevailing ethical considerations that are outlined in the 1974 Belmont report that include: respect for persons, justice, and beneficence. These principles are outlined in Good Clinical Practice training criteria that have been completed by the study team and are supported by this protocol and our study team's standard operating procedures which ensure fidelity to the protocol.

Benefits: This is a minimal risk study. Given the evidence supporting the components of SHARING CHOICES, we anticipate that older persons, including those with ADRD, and family will experience more benefit than risk from being in a practice that has SHARING CHOICES and that risks associated with participation are reasonable in comparison to knowledge that may be gained. Benefits for patients in SHARING CHOICES practices may include greater clarity regarding the patient's health and treatment preferences and the communication roles to be assumed by family during face-to-face medical visits, in electronic interactions with primary care providers, and in future medical decision-making. Societal benefits will result from this study. We will evaluate SHARING CHOICES to improve the quality of communication about end of life care in primary care, extending knowledge of regarding the implementation and effects of advance care planning for persons, including those with ADRD, outside of institutional settings. If this trial has a positive effect on communication, the methodology has broad potential application to

improve advance care planning and end of life care in primary care. Participants in control practices will not directly benefit from participation.

Payment: Facilitators will be reimbursed for their time as part of the study.

Costs: There will be no costs for participants.

13 COMMITTEES N/A

14 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will include the required acknowledgement about NIA funding.

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16 SUPPLEMENTS/APPENDICES

- A1 Patient Hopkins SHARING CHOICES Letter
- A2 Patient Maryland-DC-Virginia Advance Directive
- A3 Hopkins Agenda-Setting Checklist
- A4 Facilitator Training Agenda