Official Title: Concept Mapping as a Scalable Method for Identifying Patient-Important Outcomes

NCT #: NCT02792777

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Study Procedures Manual

I. Overview

A. Project aims

The VOICe project, funded by the Patient-Centered Outcomes Research Institute, will determine if group concept mapping (GCM), a structured brainstorming process, is a comprehensive and efficient method of identifying outcomes that are important to patients by comparing it to one-on-one interviews (the "gold standard"). The overarching objective of this methodology study is to provide high quality evidence to researchers, clinicians and policy makers about two methods used to elicit patient preferences for outcomes in order to inform best-practices for designing patient-centered research studies.

Aim 1: To engage patients to identify their own patient-important outcomes for managing their chronic conditions through 1) one-on-one interviews and 2) concept mapping groups.

Aim 2: To compare the comprehensiveness of concept mapping to one-on-one interviews for identifying patient-important outcomes for managing their chronic conditions.

Aim 3: To compare the efficiency of concept mapping to one-on-one interviews for identifying patient important outcomes for managing their chronic conditions.

B. Primary Outcomes

Primary outcomes:

1. Comprehensiveness of interviews as compared to one concept mapping group
2. Comprehensiveness of interviews as compared to three concept mapping groups
3. Comprehensiveness of concept mapping

Secondary outcomes: Efficiency of interviews compared to GCM

C. Timeline and key milestones

Project timeline: January 1, 2016- December 31, 2018.

Year 1: All training and interview activities will occur during the first year of the project.
Year 2: Final interview analysis and concept mapping sessions will occur during the second year.
Year 3: Abstract preparation will and dissemination of the results will occur in the final year of the project.

The full project timeline may be found on the project's Sharepoint site (https://tjuv.sharepoint.com/sites/PCORI/_layouts/15/start.aspx#/SitePages/Home.aspx)

Project milestones:

	Milestone Name	Description	Projected Completion Date
A	**Contract Start Date**	**-**	**1/1/2016**
B1	PAKSAB: Interview material preparation	• Develop updated protocol • Develop study procedure manuals • Develop recruitment materials • Develop interview guide	3/31/2016

B2	IRB approval	• Receive initial IRB approval for awarded study	3/31/2016
B3	Pilot interviews	• Train study personnel • Conduct pilot interviews (n= 9-12)	6/30/2016
B4	PAKSAB: Interview pilot and guide review	• Review pilot results • Refine interview guide • Submit to PCORI	6/30/2016
B5	Completion of 25% of interview recruitment and participation	• Recruit interview participants • Complete open-ended, semi-structured qualitative interviews (total goal n=90-120, 25% goal n=22-30) • Generate interim progress report for PCORI	6/30/2016
B	**Report Submission**	**Submit Progress Report, Using Interim Progress Report template**	**6/30/2016**
C1	Completion of 50% of interview recruitment and participation	• Recruit interview participants • Complete open-ended, semi-structured qualitative interviews (total goal n=90-120, 50% goal n=45-60)	9/30/2016
C2	PAKSAB: Initial interview transcripts and codebook generation	• Review initial interview transcripts • Generate codebook	9/30/2016
C3	Dissemination	• Publish initial project-specific website with detail including project goals, team members, and contact information	9/30/2016
C4	Completion of 25% of interview analysis	• Complete coding and initial analysis of 25% participant interviews (total goal n=90-120, 25% goal n=22-30)	12/31/2016
C5	PAKSAB: Interview coding results and interim report	• Review initial interview coding results • Generate interim report	12/31/2016
C6	Completion of 75% of interview recruitment and participation	• Recruit interview participants • Complete open-ended, semi-structured qualitative interviews (total goal n=90-120, 75% goal n=67-90)	12/31/2016
C	**Report Submission**	**Submit Progress Report, Using Interim Progress Report template**	**12/31/2016**
D1	PAKSAB: Concept Mapping material preparation	• Develop Concept Mapping prompt • Plan recruitment process	3/31/2017
D2	Completion of 100% of interview recruitment and participation	• Recruit interview participants • Complete open-ended, semi-structured qualitative interviews (total goal n=90-120)	3/31/2017
D3	Completion of 75% of one-on-one interview analysis	• Complete coding and initial analysis of 75% participant interviews (total goal n=90-120, 75% goal n=67-90)	3/31/2017
F6	Dissemination of results	• Submit CM manuscript • Present interview abstract in at least 1 national conference (pending acceptance from submissions with target date 9/30/17)) • Update project-specific website within Jefferson domain	6/30/2018

D4	Completion of 100% of interview analysis	• Complete coding and initial analysis of 100% participant interviews (total goal n=90-120)	6/30/2017
D5	PAKSAB: Interim Report	• Generate interim progress report for PCORI	6/30/2017
D	Report Submission	Submit Progress Report, Using Interim Progress Report template	6/30/2017
E1	Interview abstract submission and manuscript preparation	• Prepare and submit abstract from interview data • Begin preparation of manuscript from interview	9/30/2017
E2	PAKSAB: Interview analysis and abstract	• Complete final interview analysis • Submit interview abstract to PCORI	9/30/2017
E3	Concept Mapping preparation	• Complete recruitment of 25 participants per group (n=75) • Schedule CM groups • Train study personnel in CM methods	9/30/2017
E4	Concept Mapping data collection	• Conduct 3 sessions for each CM group (n= 3CM groups, n= 60 participants)	12/31/2017
E5	PAKSAB: CM result discussion	• Discuss initial CM results	12/31/2017
E6	Dissemination of results	• Update project-specific website within Jefferson domain – include members of team, overall project goals, links to any publications (once available)	12/31/2017
E	**Report Submission**	**Submit Progress Report, Using Interim Progress Report template**	**12/31/2017**
F1	Analysis Aims 2 & 3: Start	• Begin assessments for Aims 2 & 3 (comprehensiveness and efficiency)	3/31/2018
F2	PAKSAB Y3 Q1: Synthesis and reporting	Convene PAKSAB to complete the following: • Discuss final CM results • Prepare/submit CM abstract • Begin preparation of CM manuscript • Begin development of dissemination plan with DAT	3/31/2018
F3	Analysis Aims 2 & 3: Finalize	• Complete assessments for Aims 2 & 3 (comprehensiveness and efficiency)	6/30/2018
F4	CM manuscript completion	• Complete draft of CM manuscript	6/30/2018
F5	PAKSAB Y3 Q2: Synthesis and reporting	Convene PAKSAB to complete the following: • Review CM manuscript and decide on journal for submission • Refine results for Aims 2 & 3 • Develop dissemination plan with DAT • Plan next steps planning	6/30/2018

F7	PAKSAB: Results delivery	• Deliver CM results to PCORI • Deliver results from Aims 2& 3 to PCORI • Generate interim progress report for PCORI	6/30/2018
F	**Report Submission**	**Submit Progress Report, Using Interim Progress Report template**	**6/30/2018**
G1	Abstract and manuscript for Aims 1,2 & 3	• Prepare and submit abstract for Aims 1,2 & 3 • Prepare and submit manuscript for Aims 1,2 & 3	9/30/2018
G2	PAKSAB Y3 Q3: Synthesis and reporting	Convene PAKSAB to complete the following: • Review CM manuscript • Refine results for Aims 2 & 3 • Develop dissemination plan with DAT • Plan next steps • Review manuscript for Aims 2 & 3	9/30/2018
G3	PAKSAB Y3 Q4: Synthesis and reporting	Convene PAKSAB to complete the following: • Refine results for Aims 2 & 3 • Review manuscript for Aims 2 & 3 • Develop dissemination plan with DAT • Plan next steps	12/31/2018
G4	PAKSAB: Generation of final research and progress reports	• Generate final progress report • Initiate final research report	12/31/2018
G5	Dissemination of results	• Submit manuscript from Aims 2 and 3 • Revise/resubmit any other manuscripts as applicable (depending on prior results of peer review) • Present CM abstract in at least 1 national conference (pending acceptance based on submissions with target date 6/30/18) • Updating of project website with final results	12/31/2018
G	**Final Progress Report**	**Submit Final Progress Report, Using Final Progress Report Template**	**12/31/2018**
H	**Research Project Period End Date**		**12/31/2018**
I	**Draft Final Research Report Submission**	Submit Draft Final Research Report according to instructions found here: http://pcori.org/awardee-resources	**6/30/2019**
J	**Final Research Report**	Upon receipt of written summary, and as applicable, PI will make revisions and submit Draft Final Research Report for acceptance in accordance to PCORI policy and process.	**12/31/2019**
K	**Approval / sign off of the Lay Abstract**	Sign off must be no later than 90 days beyond the date PCORI accepts the final research report	**See Description**
L	**Contract Term Date**	-	**12/31/2019**
M	**Final Expenditure Report**	**Submit Final Expenditure Report (See Contract for Instructions)**	**90 days from Contract Term Date**
N	**Notification of Public Acceptance**	**See Contract for Instructions**	**Within 30 Days of Acceptance**

D. Team member roles, responsibilities and contact information

Patient Advocates And Key Stakeholder Advisory Board (PAKSAB): The PAKSAB includes patient advocates who are experienced with helping chronically disabled and disadvantaged populations negotiate various healthcare settings as well as key representatives from diverse domains of the care pathway. Members of the PAKSAB have been involved with the proposal from inception. Staff will provide updates at PAKSAB meetings, which are held quarterly.

Research Team: The research team includes all of the personnel listed below, who will work to complete the project objectives. Some PAKSAB members will also participate as part of the research team by conducting interviews and concept mapping sessions, assisting with analysis and data interpretation, and disseminating the results.

Name	Role	Department
Kristin Rising, MD, MS	Principal Investigator	Emergency Medicine
Marianna LaNoue, PhD	Principal Investigator	Family Medicine
Judd Hollander, MD	Co-Investigator	Emergency Medicine
Brendan Carr, MD, MA, MS	Co-Investigator	Emergency Medicine
Geoffrey Mills, MD, PhD	Co-Investigator	Family Medicine
Amy Cunningham PhD, MPH	Project Manager	Family Medicine
Alexzandra Gentsch, LSW	Project Coordinator	Emergency Medicine
Amanda Doty, MS	Research Assistant	Emergency Medicine
Lori Latimer, LSW	Research Assistant	Emergency Medicine

Contact info for Dr. Kristin Rising:
Phone: 215-503-5507
Email: Kristin.Rising@jefferson.edu

Additionally, Jefferson students may participate in the project through the Emergency Department's Academic Associates Program, the Dean's Summer Research Program, and the Jefferson College of Population Health MPH clerkship/capstone program.

Research team meetings are typically held on Fridays 10 AM-11:30 AM, in the Thomas Jefferson University Department of Emergency Medicine conference room.

More information about the PAKSAB members and research team may be found on the VOICe website: http://www.jefferson.edu/university/skmc/research/voice.html

***Administrative Roles*:** Administrative roles for the grant are below:

Role	Department
Financial Analyst/Grants Administrator	Emergency Medicine
Administrator	Emergency Medicine
Administrator	Family Medicine
Grants Administrator	Research Administration Center of Excellence (RACE)

II. Training

A. Research Staff

All research members will complete the following trainings:

- CITI training (basic human subjects protection, good clinical practice, responsible conduct of research-- must be taken prior to an individual starting research, and re-taken every two years): https://www.citiprogram.org/
- Conflict of interest disclosure (must be completed annually): http://www.jefferson.edu/university/counsel/coi.html
- Healthstream training (required modules vary by role): http://healthstream.tjuh.net/index.cfm

Members involved in coding for interviews

- NVivo (qualitative analysis software): The PIs will train research staff in NVivo. Additional NVivo resources are available here: http://www.qsrinternational.com/learning

Project Coordinator and Research Assistants

- EPIC (Needed for patient screening)
- Concept mapping method: The PIs will train research staff in concept mapping.
- Concept Systems Inc.: The PIs will train research staff how to use software needed for conducting analysis of concept mapping sessions. Concept mapping resources are available here: http://www.conceptsystems.com/trainings/

Additionally, the Jefferson Clinical Research Institute (JCRI) offers a full-day clinical research coordinator training and other periodic trainings on topics relevant to research staff. Updates are sent via the Office of Research Administration's listserv: https://lists.jefferson.edu/mailman/listinfo/ora.clinical

B. PAKSAB members

i. General: All PAKSAB members will receive an orientation to the project, including its objectives, methods and key milestones involving the PAKSAB.

ii. Members serving as researchers will complete basic training as identified above, depending on role.

C. Data management plan

i. Data types, storage and person(s) responsible:

Data	Storage	Person(s) Responsible
Research team documents (agendas, minutes, draft materials for discussion, timeline, presentations, manuscripts)	Sharepoint (Web based secure file sharing system)	Research team
PAKSAB materials	Sharepoint; also disseminated by email	Project Coordinator, RA
Eligible participant lists	Selectrus (Imported from Epic)	IT, Project Coordinator, RA
Patient medical record	Epic	Project Coordinator, RA
Patient Tracker (name, MRN, date approached, date enrolled, interview/concept mapping date, study ID, type of data)	REDCap	Project Coordinator, RA
Ineligible/Refusal lists	One Drive (Web based secure file	Research team

	sharing system)	
Consent forms	Locked cabinet	Project Coordinator
Demographic forms	Locked cabinet	Project Coordinator
Interview audio recordings	One Drive	Project Coordinator
Interview transcripts	One Drive	Research team
Concept mapping data (statements, sorting, rating, maps)	Concept Systems Inc. software, web based platform	Research team
Time tracking	Excel spreadsheet on Sharepoint	Research team
IRB documents (application, renewals)	Sharepoint	RA
PCORI progress reports, research report	Sharepoint	Co-I's, Project Manager
Grant financial records	RACE, PCORI	RACE
Project website	Thomas Jefferson University website	Project Manager, Marketing

ii. Metadata
Metadata are documentation for your data set. The VOICe project metadata includes the Patient Tracker in REDCap.

iii. Access
The research team—including PAKSAB members, students and others added as key personnel, will have access to study data as outlined in the IRB-approved protocol (15G.667). All research personnel must follow the data security steps outlined in section v. New research team members must be added to the study IRB via a new personnel amendment (http://www.jefferson.edu/university/human_research/forms.html) prior to viewing or collecting any study data.

iv. Data sharing
Research team members should discuss any data sharing requests with the PIs prior to sharing any procedural documents, data, or analytic study materials. Any data sharing must comply with the data security procedures below.

v. Data security and IRB compliance
Research personnel will follow the data entry, storage and security procedures outlined in the interview and concept mapping protocols, as well as the general guidance provided by the IRB.

According to the IRB, the following steps must be taken to ensure identifiable data remains confidential and secure:

a. If an individual is a Jefferson patient and research subject, a separate medical record must be maintained apart from any records required for the research.
b. There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
c. When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
d. Access to the data should be limited. Only the individuals who need the data should have access.
e. If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
f. If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.

g. If research data is stored on your Jefferson computer, encryption software must be installed on the computer. Contact IT if you are not sure if the encryption software is installed.
h. PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
i. Research data should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IT. Please see Jefferson University Policy 122.35 for complete information.
j. External monitors must not view the eMR.

vi. Backup, archiving

All documents on Sharepoint and One Drive are automatically backed up by IT. The Project Coordinator will also periodically back up all Sharepoint and One Drive documents on a secure Jefferson computer.

PCORI requires that "financial records, supporting documents, statistical records, and other records relevant to this Contract and performance under it must be retained by the Recipient for a period of five (5) years from the a) Contract Term Date, b) date of the final payment under this Contract, or c) conclusion of any audit or litigation related to this Contract, whichever is later."

III. Interview Protocols

Interviews and screening will take place in three different settings, with individual protocols listed separately below. Financial remuneration, interview time tracking and data entry and storage will be similar in all settings and outlined in Section D (page 15).

A. Jefferson Emergency Department Interview Protocol

A i. ED overview, triage process and patient flow

Patients can enter the Emergency Department in several ways:

1. Patients can come into the emergency department though the main entrance into the waiting room.
    - First they are "intaked", which is a mini-registration process.
    - Then they are triaged by the triage clinician.
    - Then they are registered.
    - Patients wait until they are called into a room or hallway bed in the ED.
2. Patients can come into the ED through "Fire Rescue" and are taken directly to the center desk.
    - First they are evaluated by the Senior Resident or Triage Nurse.
    - Then they are taken into a room or brought to a hallway bed.
    - A nurse registers them.
    - Then they receive formal triage
3. Patients can come into the emergency department and go straight into the Trauma Bay where they are actively worked on by the hospital staff.
4. After patients are in rooms (or hallway beds) and have been seen by the doctor it is determined which of several places they will go next:
    - Discharged home.
    - Placed in the Observation Unit.
    - Admitted to the hospital.
    - Transferred to another hospital or facility.

A ii. Screening process

Screening will take place during a random selection of days and times of day to ensure that we capture the full range of ED patients. Staff interviewers will sign up for three-hour shifts scattered on different days and at different times of day: morning, afternoon, evening, and night. Each PAKSAB interviewer will complete a minimum of two ED interviews. The research team will screen for eligible patients through the electronic medical record system. The research team uses a random generator to determine which patient to approach for enrollment, and will consult with the attending physician and nurse to determine the best time to approach the patient for enrollment.

Inclusion criteria

- Adult patient (age 18 and older)
- English speaking
- Capable of providing informed consent
- In the Jefferson Emergency Department (ED) for a type 1 or type 2 diabetes-related problem determined to require medical treatment: diabetic ketoacidosis, hypo/hyperglycemia, soft-tissue infections/cellulitis, neuropathy, retinopathy, acute renal failure, chest pain, and receiving diabetes medication refills.
- Patient has a less than fifty percent chance of being admitted to the hospital.

Exclusion criteria

- Patient is newly-diagnosed with diabetes
- Pregnancy
- Patient has had a significant permanent complication related to diabetes mellitus (DM) including:
    - End stage renal disease/on dialysis/history of kidney transplant
    - History of amputation
    - Blindness related to diabetes complication
- Patient undergoing medical clearance for a detox center or any involuntary court or magistrate order
- Patient in police custody or currently incarcerated individual
- Patient who has, in their clinician's best judgment, major communication barriers such as visual or hearing impairment or dementia that would compromise their ability to give written informed consent

After initial explanation of what the study is about, the research team will review an additional screening form to ensure exclusion criteria will not prevent them from participating in the study. The interviewer should document in the One Drive Excel sheet when patients a) initially appear eligible but are then found to be ineligible or b) decline participation, and list the reason for ineligibility/refusal. The interviewer will also document the reason for ineligibility/refusal along with demographic information (gender, age, race, and ethnicity) to assess for selection bias.

A iii. Scheduling process

Interviews of patients in the acute care setting will be performed in-person in a private space within the ED at a time that is convenient for the patient and least disruptive to their care. This may be the patient room, the family room, or an ED doctor's office. Interviewers will assign a study ID to each participant (ED participant ID numbers are in the 200's).

A iv. Consent process

Prior to the interview, the research team member will conduct an informed consent discussion. By speaking to the patient (and when appropriate, to the patient's clinician), the research team member will confirm that the patient has the current mental status and capacity to provide informed consent for this study.

Obtaining consent will occur in a private setting. The research team member will inform the patient of the nature of the study, the study purpose, the study procedures, the risks, and the alternatives to participation, including the alternative to not participate. Potential participants will be given time to read the consent form and ask questions before making their decision. The research team member will verbally confirm that each interested patient understands the risks, purpose, procedure, and nature of the study before asking for consent.

Patients who are interested will complete the informed consent discussion and may then decline or consent to participation in writing on an IRB-approved Informed Consent with HIPAA Authorization Form, prior to any further data collection. Participants will be given a copy of the informed consent form; the original will be kept on file in the research office.

Patients who are unable or prefer not to provide informed consent cannot be enrolled in this study.

A v. Interview process

Researchers will conduct the interview following the interview guide. Interviews will generally last about 30 minutes and will be recorded using two recording devices simultaneously.

Interviews should be done towards the end of an ED visit or after being discharged. Interviewer will check in with both attending doctor AND nurse to see when is an appropriate time to do the interview during patient's ED visit (can it be done during the visit without interfering or prolonging the visit?).

After the interview is completed, researchers will ask the participants to complete the demographic form. Interviewers will then log the assigned study ID number and interview date in the study log.

vi. Financial Remuneration, Time Tracking, and Data Entry and Storage
See section D (page 15) for details.

B. Jefferson Family Medicine Associates Interview Protocol

B i. Jefferson Family Medicine Associates (JFMA) overview and patient flow
Jefferson Family Medicine Associates (JFMA)'s main practice is located at 833 Chestnut Street, 3rd floor. The practice has nearly 80 family medicine faculty members and residents, 4 geriatric fellows, 2 sports medicine fellows, 7 nurse practitioners, and nearly 100 staff. JFMA is a Level III patient-centered medical home and has participated in the Southeastern Pennsylvania Chronic Care Initiative and other quality efforts.

JFMA has approximately 35,000 patients making more than 80,000 visits each year. Although the population is remarkably diverse with patients from every socioeconomic group, JFMA maintains a special interest in the healthcare needs of marginalized communities. More than half of JFMA patients are from minority groups, the majority of which are African Americans. Most of the visits to the practice are from individuals from medically underserved communities in Philadelphia.

B ii. Screening process
Research staff members will complete JFMA interviews each week; PAKSAB interviewers will complete a minimum of two JFMA interviews over the course of the study. The research team will screen the schedule of upcoming appointments at JFMA, available through Selectrus, on Monday and Wednesday of each week and will identify potentially eligible patients for enrollment who have visits that week. Research team members will verify each patient's eligibility via EPIC, and may contact the patient's provider if any questions arise regarding the patient's eligibility for the study.

To identify potential JFMA interview participants

- Log in to Selectrus with your campus key and password
- The following are the data elements of this report:
    - Patient's MRN (EPIC)
    - Patient name
    - Patient's date of birth
    - Patient's age as of today (confirmed date calculation is correct)
    - Patient's phone number (only one available in the data)
    - ICD9 codes from list provided that are active in patient's record
    - ICD10 codes form list provided that are active in patient's record
    - Most recent A1c result
    - Date of most recent A1c result
    - Second most recent A1c result
    - Date of second most recent A1c result
    - Yes/no for two or more A1c results greater than 7.5 within the past year
    - Patient's next appointment date
    - Patient's next appointment time
    - Provider scheduled for patient's next appointment

- The following are the finalized specifications/inclusion criteria of this report:
    - Patients 18 years or older (as of today) who have an active diagnosis of diabetes on their problem list (ICD9 diagnosis of 250.XX OR ICD10 diagnosis of E11.XX or E10.XX), who have a HbA1c result >= 7.5 at least once within the past year and who have an appointment scheduled at the JFMA (833 Chestnut) location

Inclusion criteria

- Adult patient (age 18 and older) at JFMA (833 Chestnut)
- Active diagnosis of type 1 or type 2 diabetes on problem list (ICD9 diagnosis of 250.XX OR ICD10 diagnosis of E11.XX or E10.XX)
- English speaking
- Capable of providing informed consent
- Scheduled for a routine follow-up visit at JFMA and has at least 1 measurement of HgbA1C > 7.5 in the prior year (with preference given to patients with 2 measurements of HgbA1C>7.5 in the past year).

Exclusion criteria

- Pregnancy
- Patient has had a significant permanent complication related to DM including:
    - End stage renal disease/on dialysis/history of kidney transplant
    - History of amputation
    - Blindness related to diabetes complication
- Patient undergoing medical clearance for a detox center or any involuntary court or magistrate order
- Patient in police custody or currently incarcerated individual
- Patient who has, in their clinician's best judgment, major communication barriers such as visual or hearing impairment or dementia that would compromise their ability to give written informed consent
- Newly diagnosed with diabetes at last doctor visit

After initial explanation of what the study is about, the research team will review an additional screening form to ensure exclusion criteria will not prevent them from participating in the study. The interviewer will document in the One Drive Excel sheet when patients a) initially appear eligible but are then found to be ineligible or b) decline participation. The interviewer will also document the reason for ineligibility/refusal along with demographic information (gender, age, race, and ethnicity) to assess for selection bias.

B iii Scheduling process

The research team uses a random generator to determine which eligible patients to approach for enrollment, The project coordinator will call eligible patients 1-2 days before their appointment to explain the study and determine the patient's eligibility and interest in enrolling. On the day of the visit, a research team member will be scheduled by the project coordinator to approach the eligible patient either before or after their doctor's visit to obtain consent and conduct the interview. Interviewers will assign a study ID to each participant (JFMA participant ID numbers are in the 100's) at the time interviews are done.

B iv. Consent process

When the research team member meets with a scheduled patient, he/she will obtain informed consent. The research team member will confirm that the patient has the mental capacity to provide informed consent for this study by speaking to the patient (and when appropriate, to the patient's clinician).

Obtaining consent will occur in either the JFMA small or large conference room. The research team member will inform the patient of the nature of the study, the study purpose, the study procedures, the risks, and the alternatives to participation, including the alternative to not participate. Potential participants will be given time to read the consent form and ask questions before making their decision. The research team member will verbally confirm that each interested patient understands the risks, purpose, procedure, and nature of the study before asking for consent.

Patients who are interested will consent to participation in writing prior to any further data collection. Participants will be given a copy of the informed consent form; the original will be kept on file in the research office.

Patients who are unable or prefer not to provide informed consent cannot be enrolled in this study.

B v. Interview process
Interviews will take place in a private setting within Jefferson Family Medicine Associates.
Researchers will conduct the interview following the interview guide. The interview will be taped using a digital recording device. Interviews will generally last about 30 minutes and will be recorded using two recording devices simultaneously.

After the interview is completed, researchers will ask the participants to complete the demographic form. Interviewers will then log the assigned study ID number and interview date in the study log.

B vi. Financial Remuneration, Time Tracking, and Data Entry and Storage
See section D (page 15) for details.

C. Post-Hospital Discharge Interview Protocol

C i. Hospital discharge overview
Jefferson Family Medicine Associates patients admitted to Thomas Jefferson University Hospital are admitted to JFMA's inpatient service. After their discharge, if they are discharged to home they are contacted by a JFMA transition of care coordinator to schedule a follow-up appointment at JFMA. The processes are the same for Jefferson Internal Medicine Associates (JIMA) patients.

C ii. Screening process
Patients enrolled for the post-acute period will be contacted by phone within one week after discharge from the Thomas Jefferson University Hospital. The research team will screen the list of JFMA/JIMA patients recently discharged from JFMA/JIMA's inpatient services, available through Selectrus, on Monday and Thursday of each week to identify potentially eligible patients.

To identify potential post-hospital discharge interview participants

- Log in to Selectrus with your campus key and password: http://reports.tjh.tju.edu/rs/login/auth
- Next to "Patient Centered Outcomes Research Institute - Diabetes Inpatients JFMA Service" report, select "Run Now" and select a "START DATE" and "END DATE" based on your discharge dates of interest
- The following are the data elements of this report:
    - Patient's account number
    - Patient's MRN (EPIC)
    - Patient name
    - Patient's date of birth
    - Patient's age as of today (calculation corrected)

    - All available phone numbers for patient
    - Patient's admit date/time
    - Patient's discharge date/time
        - If the patient has not yet been discharged, field will be blank
    - Discharge disposition description
        - If the patient has not yet been discharged, field will be blank
    - Discharge Diagnoses
        - If the patient's admit has not yet been coded, field will be blank
    - Name of where patient is discharged to
- The following are the finalized specifications/inclusion criteria of this report:
    - Patients aged 18 years or older (as of today) who have been admitted to the JFMA service
- ***Note: the list will include all admitted JFMA and JIMA patients, only some of whom have diabetes—staff will need to confirm the patient's diabetes diagnosis using the patient's active problem list or past medical history in EPIC.***

Inclusion criteria

- Adult patient (age 18 and older)
- Active diagnosis of type 1 or type 2 diabetes on problem list/in past medical history (ICD9 diagnosis of 250.XX OR ICD10 diagnosis of E11.XX or E10.XX)
- English speaking
- Capable of providing informed consent
- Diagnosis of moderately to poorly controlled diabetes mellitus (DM) defined as follows (for interview groups):
- Patient was discharged from either the Jefferson Family Medicine Associates (JFMA) or Jefferson Internal Medicine Associates (JIMA) hospital services within the past 7 days after admission for a diabetes-related problem including: Stroke/transient ischemic attack (TIA), gastroparesis, hyperglycemia/diabetic ketoacidosis, hypoglycemia, renal failure, chest pain/cardiac problem, neuropathy, retinopathy, infections (of any kind) - including but not limited to: urinary tract infection/pyelonephritis, osteomyelitis, cellulitis, colitis, gastroenteritis)
- Discharged in the last 7 days

Exclusion Criteria

- Pregnancy
- Patient has had a significant permanent complication related to DM including:
    - End stage renal disease/on dialysis/history of kidney transplants
    - History of amputation
    - Blindness related to diabetes complication
- Patient undergoing medical clearance for a detox center or any involuntary court or magistrate order
- Patient in police custody or currently incarcerated individual
- Patient who has, in their clinician's best judgment, major communication barriers such as visual or hearing impairment or dementia that would compromise their ability to give written informed consent
- Newly diagnosed with diabetes at last hospital visit
- Disposition to hospice
- Primary reason for admit is due to trauma or non-diabetes related health problem
- Admitted anywhere other than center city hospital

The project coordinator will consult with one of the PIs regarding the eligibility of post-hospital discharge individuals for the study. After initial explanation of what the study is about, the research team will review an additional screening form with patients to ensure exclusion criteria will not prevent them from participating in the study. The project coordinator or interviewer will document in the One Drive Excel sheet when patients a) initially appear eligible but are then found to be ineligible or b) decline participation. The interviewer will also document the reason for ineligibility/refusal along with demographic information (gender, age, race, and ethnicity) to assess for selection bias.

C iii. Scheduling process
The research team will contact eligible patients once they are discharged from the hospital, within 7 days of discharge, to inquire about interest in study participation, using the IRB-approved email and phone scripts. Interviewers will assign a study ID to each participant (post-discharge participant ID numbers are in the 300's).

C iv. Consent process
At the time of the phone call, the research team member will seek informed consent. The research team member will assess that the patient has the mental capacity to provide informed consent for this study by speaking to the patient (and when appropriate, to the patient's clinician).

The research team member will inform the patient of the nature of the study, the study purpose, the study procedures, the risks, and the alternatives to participation, including the alternative to not participate. The research team member will verbally confirm that each interested patient understands the risks, purpose, procedure, and nature of the study before asking for verbal consent.

Participants will be mailed a copy of the informed consent form; the original will be kept on file in the research office. Subjects who are interested in participating but prefer to come in for the interview will be consented at the time of their interview with an in-person interview consent form.

Participants who are unable to or do not provide informed consent cannot be enrolled in this study.

C v. Interview process
Researchers will conduct the interview using an interview guide developed by the research team. The interview will be taped using a digital recording device. Interviews will generally last about 30 minutes.

Interviews can be conducted in specified PI's offices during normal business hours and at the research assistant's desk after normal business hours. Phone interviews will be recorded using one recording device and in person interviews will be recorded using two recording devices simultaneously.

After the interview is completed, study staff will ask the participants to complete the demographic form. Interviewers will then log the assigned study ID number and interview date in the study log.

C_vi. Financial Remuneration, Time Tracking, and Data Entry and Storage
See page 15—note that for phone interview participants, remuneration is via gift card.

D. Financial Remuneration, Time Tracking, and Data Entry and Storage for all Interviews

D i. Financial remuneration for participants
There is payment remuneration for time and effort spent participating in this study. Interview participants will be compensated with $25 at the end of the interview. In-person study participants will be remunerated using cash or clincards (see "Participant payment" in Financial Policies and Procedures section). Participants receiving payment must complete a W-9 and receipt. If the interview is done by phone, patients will be asked

if they would like a CVS, Wawa, or Walgreens gift card. Gift cards will be mailed to patients when done over the phone. (see page 26 for more details)

D ii. Interview time tracking procedure
Interviewers will track the time needed to complete each step of the interview process in an Excel spreadsheet on One Drive.
This will include at a minimum:

- How much time you spend calling patients to set up interviews
- Time spent traveling to Jefferson to do interviews
- Time spent reviewing consent forms with patients
- Time spent doing actual interviews

D iii. Data entry and storage
In addition to demographic data collected at the end of each interview, patient records will be reviewed by trained research personnel with use of the medical record number (MRN) to determine:

- Date of birth
- Information on hospital and outpatient utilization in the prior 12 months, including date of visit, location of visit (i.e primary care office, ED, inpatient), date of discharge if applicable, reason for visit, and discharge diagnosis
- Information on the visit associated with this study, including location of the visit, time and day of arrival, reason for visit, treatments provided, discharge diagnosis and instructions, and discharge disposition and time
- Insurance status (and provider, if applicable)
- Chronic medical conditions

All paper documents will be secured in locked cabinets in the Project Coordinator's office. Research team members will assign a Study ID to each participant and enter the Study ID, participant's medical record number and demographic information in the Patient Tracker, which is stored in REDCap. Interview transcripts will be labeled with the study ID number and sent to ADA Transcriptions. Once data analysis is complete, audio recordings of the interview files will be destroyed. The research team will import the transcripts into the analytic database (NVivo 11.0 software) for coding.

IV. Concept Mapping Session Protocol

i. Screening process

Individuals for the concept mapping groups will be screened from a list of potentially eligible patients made available through Selectrus. Patients will be called by a research team member two weeks before the first GCM session takes place. Up to three phone attempts may be made leading up to the GCM session to ask a patient if they are interested in participating. An equal distribution of patients from each care setting will be recruited.

To identify potential concept mapping participants

Acute care setting:

- The following are the data elements of the Selectrus report:
    - Patient's account number
    - Patient's MRN (EPIC)
    - Patient name
    - Patient's date of birth
    - Patient's age as of today (calculation corrected)
    - All available phone numbers for patient
    - Patient's ED admit date/time
    - Patient's ED discharge date/time
        - If the patient has not yet been discharged, field will be blank
    - Discharge disposition description
        - If the patient has not yet been discharged, field will be blank
    - Discharge Diagnoses
        - If the patient's admit has not yet been coded, field will be blank
    - Name of where patient is discharged to
- The following are the finalized specifications/inclusion criteria of this report:
    - Patients aged 18 years or older (as of today) who have been admitted to the Jefferson ED

Note: the list will include patient who has had a visit to the Jefferson ED over the past 6 who has diabetes (with preference for those discharged in the last 3 months)

Post-acute care setting: Use Selectrus report procedure for post hospital discharge interviews with a filter for patients discharged from the JFMA/JIMA hospital service within the past 6 months. (page 11).

Primary care setting: Use Selectrus report procedure for JFMA interviews with a filter for patients who have had a routine scheduled office visit within the past 6 months (page 13)

Inclusion criteria

- Adult patient (age 18 and older)
- Active type 1 or type 2 diagnosis of diabetes on problem list (ICD9 diagnosis of 250.XX OR ICD10 diagnosis of E11.XX or E10.XX)
- English speaking
- Capable of providing informed consent
- *Acute care setting*: patient who has had a visit to the Jefferson ED over the past 6 months for a diabetes-related problem (with preference for those discharged in the last 3 months).
- *Post-acute care setting*: patient was discharged from the JFMA/JIMA hospital service within the past 6 months for a diabetes-related problem (with preference for those discharged in the last 3 months).
- *Primary care setting*: patient has had routine scheduled office visit within the past 6

months to the JFMA practice and has at least 1 measurement of HgbA1C > 7.5 in the prior year (with preference given for 2 measurements of HgbA1C>7.5 in the past year).

Exclusion Criteria

- Pregnancy
- Patient has had a significant permanent complication related to DM including:
    - End stage renal disease/on dialysis/history of kidney transplants
    - History of amputation
    - Blindness related to diabetes complication
- Patient undergoing medical clearance for a detox center or any involuntary court or magistrate order
- Patient in police custody or currently incarcerated individual
- Patient who has, in their clinician's best judgment, major communication barriers such as visual or hearing impairment or dementia that would compromise their ability to give written informed consent
- *Acute care and post-acute care settings*: Primary reason for admit is due to trauma or non-diabetes related health problem

After initial explanation of what the study is about, the research team will review an additional screening form to ensure exclusion criteria will not prevent them from participating in the study. The research team members will document in the One Drive Excel sheet when patients a) initially appear eligible but are then found to be ineligible or b) decline participation. The interviewer will also document the reason for ineligibility/refusal along with demographic information (gender, age, race, and ethnicity) to assess for selection bias.

ii. Scheduling process

Dr. LaNoue, in collaboration with participating PAKSAB members and study staff determined the dates and times for the concept mapping sessions:

a. 9/23 & 9/25
b. 11/11 &11/13
c. 12/2 & 12/4

- Patients will be contacted by phone in a random order and will be recruited for participation in one of the three concept mapping groups using the IRB-approved phone scripts. Each group will have a mix of patients from the three care settings (acute, post-acute and primary care). The research team will schedule up to 30 patients per group for an end target of 16-20 total patient-participants in each group. Research team members will assign a study ID to each participant (Method is denoted with a "C"; Sessions are denoted by A, B, C; Participant setting numbers stay the same: 100's, 200's, 300's (Examples: CA101, CB201, CC301)).

iii. Concept mapping process

The concept mapping process will consist of three steps that will take place over three sessions led by Dr. LaNoue and selected PAKSAB members. For each round of concept mapping, sessions 1 and 2 will take place at 833 Chestnut St on the 10th floor; session 3 will take place in the Department of Family & Community Medicine offices at 1015 Walnut Street, Suite 401. Before each session, the research team should make the preparations described below.

Months Before

- ☐ Contact the facilities manager to reserve training rooms in the computer lounge with enough computers for each participant
- ☐ Fill out a Project Activation Form (PAF) and email Jon Littlefield to set up a new project with the CS Global Max annual license (as well as one test project, if a practice run is needed)
- ☐ If a new person will be responsible for the data analysis, designate them as the Project Administrator on the PAF and follow up to make sure they are set up with a log-on user name and password
- ☐ Reserve a room for 3rd session, where participants can view the concept map, and have room for food
- ☐ Submit EPIC request to generate reports containing patient contact info for recruitment
- ☐ Create phone script for recruiting patients
- ☐ Make a plan for how to randomize list of potential participants
- ☐ Set up Patient Remuneration
    - Email greenphire contact with the following information: study title, JeffTrial #, Jefferson account number that is paying for the study, the payment schedule, and the number of cards that you need
    - Pick up the remuneration cards
    - Create a log to identify which numbered ClinCard was given to each participant
- ☐ Recruit patients (schedule up to 30 patients per group for an end target of 16-20 total in each group)

Week before

- ☐ Order food for all 3 sessions (Breakfast: fruit, yogurt, granola, oatmeal; Lunch for session 2 and dinner for session 3: 1/2 salad, ½ wraps, sugar free cookies, fruit)
    - Make sure that tax will not be applied to the delivery if using a p-card to pay for the order
    - Keep the receipts to turn in to the p-card administrator
- ☐ Mail letter with date, time, address, entrance to use, project coordinator and PI cell, agenda (doors open at x, you must arrive by x to participate, we will be done by x), breakfast and lunch will be provided, sign in at security desk and say you are here for the Concept Mapping Session
- ☐ Double check that you have enough ClinCards

Three days before

- ☐ Let security know about the group session a week in advance and give a list of names "Here is a list of individuals who will be attending a Concept Mapping Session scheduled to be done on the x floor. Any questions or concerns can be directed to Dr. Kristin Rising (cell: xxx-xxx-xxxx)"
- ☐ Print signs for outside doors
- ☐ Assign numbers to participant names
    - Method is denoted with a "C"; Sessions are denoted by A, B, C; Participant setting stays the same: 100's, 200's, 300's (Example: CA101)

Session 1 preparation

PREPARATION:

Software Set Up

1. Fill out a Project Activation Form and email Jon Littlefield to set up a new project with the CS Global Max annual license (as well as one test project, if a practice run is needed)
2. If a new person will be responsible for the data analysis, designate them as the Project Administrator on the PAF and follow up to make sure they are set up with a log-on and password

Food Delivery

1. Arrange to have an appropriate amount of food delivered,
2. Make sure that tax will not be applied to the delivery if using a p-card to pay for the order
3. Keep the receipts and turn them in to the p-card administrator

Patient Remuneration

1. Reach out to your Greenphire contact to get Greenphire training and your login id/password for the ClinCard system (this is NOT your Jeff sign-in info)
2. Email Greenphire contact with the following information: study title, JeffTrial #, Jefferson account number that is paying for the study, the payment schedule, and the number of cards that you need
3. Pick up the remuneration cards from Greenphire contact

Setting up the space:

1. Talk to the security desk. Have 2-3 people waiting in the lobby of the building to greet and direct participants to the meeting room
2. Set up refreshment table. Have 3+ people in room (with refreshments) to check participants in with sign in sheet, then to obtain informed consent, and finally to distribute demographic forms and W9s. Have the person who is collecting the forms check for completeness
3. To set up the brainstorming room, make sure that the projector and computer are working, and pull up a blank word document to record all of the responses – immediately save the document

SESSION 1:

Materials:

- Sign at the security desk ("Check in here", project coordinator and PI cell)
- Signs at both entrances of the building ("CM sessions inside", project coordinator and PI cell" "Use the 9th st entrance around the corner")
- Sign-in sheet
- Breakfast
- Recorders
- Schedule of events for team members (Roles to be assigned: 2 people as greeters, 3+ people to obtain informed consent, 1 research team member and 1 PAKSAB member to moderate the discussion, 1 person to record the brainstorming list, 1 person to accept/set up food order while brainstorming is in progress, 3-4 people to set up computers and explain sorting, and 2 people to distribute remuneration cards)
- 3 Folders, labelled as follows: Demographic Forms, W-9s + receipts, Informed Consent
- Patient packets (2 copies of informed consent, demographic form, ClinCards/ informational brochures, receipt template for each card, W9)
- ClinCard tracking log
- pens + notecards for optional written brainstorming
- pens for consenting
- Printed prompt for each participant
- Printed sorting instructions for each participant.
- Example sorting sheet

Steps:

1. **Check in process**
   - Check in person to mark that patient is present and give name tag with assigned participant number
   - **Consent process:** Prior to the concept mapping sessions, the research team will obtain informed consent, either individually or in small groups. The research team member will inform the patient of the nature of the study, the study purpose, the study procedures, the risks, and the alternatives to participation, including the alternative to not participate. Potential participants will be given time to read the consent form and ask questions before making their decision. The research team member will verbally confirm that each interested patient understands the risks, purpose, procedure, and nature of the study before completing the consent discussion. Patients who are interested will consent to participation in writing on an IRB-approved informed consent

with HIPAA Authorization Form, prior to any further data collection. Participants will be given a copy of the informed consent form; the original will be kept on file in the research office.
The study team should collect demographic and W-9 forms, and check them for completion.

2. **Introduction:** Start the session with PowerPoint introduction, then give the prompt. Optional: Allow for 5-10 minutes of written brainstorming:

   Concept Mapping Introduction
   "Thank you for agreeing to participate in this research study. As we explained in the consent form, there are two parts to this study, which will happen on two separate days. This morning we'll be doing the first activity, and then this afternoon we will do the second part. For this morning we are going to be brainstorming - Brainstorming is a way we can get variety of ideas from a group of people – you! In a few moments, I will state the question we will use for this brainstorming session. Then, I will give you a few minutes to write your ideas, your answers to the question, on paper. Then I will ask you to share out loud any and all ideas that you think of. Don't worry about repeating something that has already been said or saying something similar to what has already been said. There are no right answers or wrong answers.

   Two of my colleagues have joined us today and they will be writing down all of the responses that are said out loud.

   Are there any questions before we start?

   In the past, medical research has often focused on asking doctors what they think is most important in improving health care for their patients, but we have realized that patients may have different priorities and objectives when they seek health care. Today we would like to know what things patients think about when deciding whether their diabetes treatment has been successful. It can be anything patients consider important, including little things that matter on a day to day basis or things that patients might want to happen in the long term. We hope to use this information to improve the delivery of health care and prioritize the concerns patients tell us are important them.
   So with this in mind, the question I'd like to ask is: *You are here as a person with diabetes; when people with diabetes seek care, what are they hoping to change or improve?"*

   The moderator begins the discussion. As the responses are listed, the moderator dictates responses to the recorder, and the recorder types them into a list that is projected in front of all of the participants. Responses are collected until the session reaches theme saturation.
3. After the session, the team members clarify all of the items on the list to ensure that they are written in a consistent format. In the GCM software, make sure that brainstorming is active (under project settings) and upload the list as a text (txt) file into the software.
4. The Excel spreadsheet will then be uploaded to the Concept Systems Global Software and "sort cards" will be generated. These cards each contain one statement generated from the brainstorming session, and will be loaded into the Concept Systems Global Software for the second session.
5. Two individuals should set up lunch towards the end of Session 1.

SESSION 2:

Materials:

1. Sign-in sheet
2. Food
3. Meeting space with a computer for each participant
4. Sorting example sheet for each participant

Prep Steps:

1. Add participant ID into the software
2. Set up a participant ids (these must be unique for each project that is put on the same license) in the system for each participant within the CS software
3. Input rating question(s) into the software
4. Print out sorting example sheet for each participant
5. Print out of rules for each participant
6. Before the second session begins, de-select brainstorming and select the rating and sorting sections (on the project settings tab) within the GCM software.
7. Make a note of anyone who left during the break on the sign-in sheet

Steps:

1. Bring the participants into the computer room after team members have logged them into the system with the guest information. Explain the sorting process to the group using the example sheet/slides then explain the rules and hand them a set of the rules to keep with them. After everything has been sorted, show them how to name the piles.
2. Explain the rating system. Participants will rate items in response to these questions:
    - *How important is this goal to you personally when thinking about your diabetes care?*
    - *How achievable is this goal for you personally?*
3. 3-4 team members should walk around the room to answer questions and to assist participants who have conceptual questions, questions about computer use, or software use.
4. Before the patients leave, distribute the ClinCards by having each participant sign the receipt and record the participant name or study # next to the number of the ClinCard that they were given. If the DOB was not collected on the demographics form, make sure it is collected here. Make sure to specify when the card will be activated to the participant.
5. After the second session, uncheck the sorting and rating options and check the analysis options in the software (on the project settings screen) to start the data analysis phase. ** ONCE YOU ENTER DATA ANALYSIS, YOU WILL NOT BE ABLE TO CHANGE THE BRAINSTORMING/SORTING INFORMATION WITHIN THE SOFTWARE **

SESSION 3:

Materials:

1. Sign-in sheet
2. Food
3. Recorders
4. Meeting space with projection/computer system
5. Copy of final clustering solution and list of items for each of the participants, sorted numerically and by cluster

Prep Steps:

1. Talk to security to inform them of the research event

Steps:

1. Have the participants check in with the sign-in sheet.
2. Start with an introduction of the GCM process and explain what a point map is (with examples)
3. Read each statement that is contained within each cluster and ask the participants to come up with names that generally fit the majority of the cluster statements. Explain that statements that don't seem to fit can be moved into a different cluster.
4. After the names have been assigned, get consensus (by group majority) about which statements should be moved

After all sessions have been completed, submit receipts to the p-card administrator.

v. Financial remuneration for participants
Patients who complete all three sessions of the concept mapping will be compensated with $125, which will be allocated as follows: $50 upon completion of session 1 (brainstorming), $25 upon completion of session 2; $50 upon completion of session 3 (see below for session details). Study participants will be remunerated using Greenphire ClinCards (see "Participant payment" in Financial Policies and Procedures section).

vi. Concept mapping time tracking procedure
Research team members will track the time needed to complete each step of the concept mapping process in an Excel spreadsheet on Sharepoint.
This will include at a minimum:

- How much time you spend calling patients to set up concept mapping groups
- Time spent traveling to Jefferson to do concept mapping
- Time spent prepping for concept mapping groups
- Time spent doing actual concept mapping group meetings (brainstorming, structuring of statements, and interpretation)

vii. Data entry and storage
In addition to demographic data collected at the end of each interview, patient records will be reviewed by trained research personnel with use of the medical record number (MRN) to determine:

- Date of birth
- Information on hospital and outpatient utilization in the prior 12 months, including date of visit, location of visit (i.e office, ED, inpatient), date of discharge if applicable, reason for visit, and discharge diagnosis
- Information on the visit associated with this study, including location of the visit, time and day of arrival, reason for visit, treatments provided, discharge diagnosis and instructions, and discharge disposition and time
- Insurance status (and provider, if applicable)
- Chronic medical conditions

All paper documents will be secured in locked cabinets in the Project Coordinator's office. Research team members will assign a Study ID to each participant and enter the Study ID, participant's medical information, and demographic information into the Patient Tracker stored in REDCap. Concept mapping data will all be entered into the Concept Systems Global Software.

V. Data Analysis and Dissemination

A. Overview

Data analysis will be done in consultation with the VOICe Research Advisory Council (RAC). The RAC will be composed of three PhD-trained researchers and two PAKSAB members who have already agreed to be representatives on this council.

B. Interview analysis

We will use a conventional content analysis approach for the analysis of the semi-structured interviews with the purpose of classifying the interview text into distinct categories that represent similar meanings and allowing themes to emerge from the data. Dr. Rising will oversee this analysis, and work with a coding team of four others (Project Coordinator, Research Assistant, and 2 PAKSAB members) to train them for coding interviews. The coding team will meet regularly during this process with the co-PIs to discuss codes and ideas that arise during coding.

Each transcript will be labeled with the participant's demographic and illness characteristics as well as the location along the care continuum at which the data were collected (acute, post-acute, primary care) and the mode of data collection (phone, in person). Transcripts from the same care continuum location will be analyzed together. Transcripts will be coded by members of the research team with a content analysis approach to identify thematic clusters within each set of care continuum location. Once data are coded, we will use the query function in NVivo to sort the data by various patient characteristics to examine patterns.

C. Concept mapping analysis

Data from each of the three CM groups will be entered into Concept Systems Global Software separately, with initial thematic clusters generated by the software and final clusters determined by the CM participants within each group. Each CM group will include participants from all three locations on the care continuum (acute, post-acute, primary care), thus generating three final sets of location-agnostic themes.

D. Aims 2 & 3 analysis

For Aims 2 & 3, we are comparing the comprehensiveness and efficiency of interviews and concept mapping.

Our comparative analysis will start out with overall comparisons in which final thematic clusters from each of the three location-specific interview groups will be compared to the thematic clusters generated by the first CM group. This comparison will be a descriptive assessment of the presence/absence of each interview theme in the CM list. We will report proportions of the themes from each interview setting that were contained in the CM list as well as a detailed listing of each theme and in which lists it was present. Upon completion of this analysis, outputs from all three concept mapping groups will be aggregated and the same comparisons will be performed between the interview outcomes and the aggregated CM list.

We will then work with the RAC to study patterns in our data that emerge by setting, participant characteristics, mode of data collection, and any other categories as identified by the PAKSAB or RAC as potentially important. These analyses will be operationalized with the use of matrices and other data display techniques to study the potential contributions of these various characteristics to the outcomes identified within the proposed study. For example, a matrix of thematic clusters in columns and features of individuals (acute, post-acute, and primary care) in rows will allow us to explore consistencies and divergences in the data which are associated with these non-method based descriptors.

The efficiency of each method will be assessed by measuring overall resource utilization for conducting that method. We will determine the resource intensiveness for completion of a single concept mapping iteration through to completion, and for one set of interviews performed to saturation. The efficiency will be calculated based on the time required of research team and cost to conduct method.

We will also assess potential selection bias in who enrolled in interviews versus concept mapping using the data collected about who declines enrollment (gender, race, ethnicity, and age), and will assess on an on-going basis and at the end of the study how the enrolled patients compare to those who declined enrollment between the two groups. If we identify any systematic differences between the two groups, we will assess with our PAKSAB and our RAC how the difference(s) could have affected the thematic results obtained relative to the thematic results that we would have obtained.

E. Presentation and manuscript preparation

Staff will maintain lists of upcoming conferences for presentation submissions. We anticipate presenting study findings annually. We plan to submit at least one manuscript based on interview findings (target date 12/31/17) and one based on concept mapping (target date 6/30/18).

Publications/Presentations – Research Awardees must acknowledge PCORI funding in scientific publications (e.g., peer-reviewed journal articles), scientific posters, slide presentations, study newsletters or brochures, study websites, reports and other non-commercial publications that relate to the PCORI-funded research project by including the following acknowledgement statement and disclaimer statement (as applicable). These statements will appear in legible size font in either introductory text or a footer and bracketed terms will be used only as applicable.

Acknowledgement.
Research reported in this [work, publication, article, report, presentation, etc.] was [partially] funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (ME-1503-28476).

Disclaimer. The following disclaimer must accompany the acknowledgement statement in any substantive works that present research findings, conclusions or other editorial content (e.g., journal publication, scientific poster).
The [views, statements, opinions] presented in this [work, publication, article, report, etc.] are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

Any discussion of PCORI beyond these required statements in publications/presentations must be limited to the following factual reference.
The Patient-Centered Outcomes Research Institute (PCORI) is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that will provide patients, their caregivers, and clinicians with the evidence-based information needed to make better-informed healthcare decisions. PCORI is committed to continually seeking input from a broad range of stakeholders to guide its work.

F. Project website

The VOICe website is designed to inform patients, researchers and other stakeholders about the project purpose, project team, and findings: http://www.jefferson.edu/university/skmc/research/voice.html

G. Public Announcements

Any public announcement intended to be distributed to media outlets (i.e., press release) announcing receipt of a PCORI award or any research findings that relate to a PCORI award by a Research Awardee requires coordination with PCORI. Awardees must provide notice to PCORI by sharing the public announcement and intended distribution date(s) via email to fundedpfa@pcori.org with a copy to the assigned Program Officer to enable proper coordination.

VI. Financial Policies and Procedures

A. General Financial Management
The Research Administration Center of Excellence (RACE) Grants Administrator reviews the project expenses on a monthly basis and meets with the PIs quarterly to review the grant's financial status.

B. Purchasing
Contact Research Assistant regarding grant purchases.

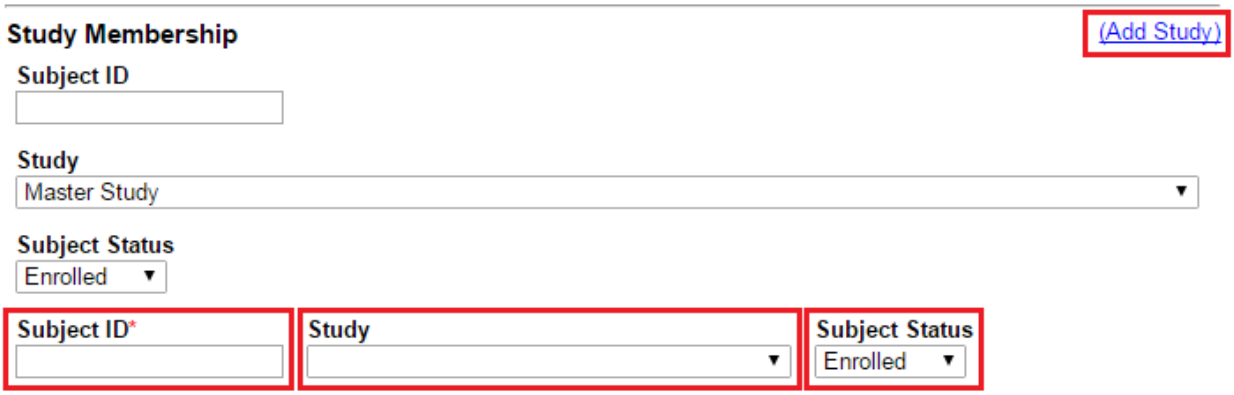
C. Subcontractor Invoicing
The RACE Grants Administrator reviews subcontractor invoices, forwards them to the PIs for approval, and then sends to Accounts Payable for payment.

D. Participant Payment
There is payment remuneration for time and effort of participating in this study. Interview participants will be compensated with a total of $25 at the end of the interview. Patients who complete all three sessions of the concept mapping will be compensated with $125, which will be allocated as follows: $50 upon completion of session 1 (brainstorming), $25 upon completion of session 2, and an additional $50 upon completion of session 3.

In-person study participants will be remunerated with cash (interviews before1/1/17) or Greenphire ClinCards (interviews conducted after 1/1/17 and all CM group participants). They must complete a W-9 and receipt to receive either payment. If the interview is done over the phone, patient's will be asked if they want a gift card from Wawa, CVS, or Walgreens and the gift card will be mailed to the patient.

Greenphire ClinCard Steps:

1. Log on to https://www.ClinCard.com/login/ Select "Register Subject" at the left of the navigation bar
2. From the drop down menu under study, select "Master Study" and then fill in the subject's name and select "search" to see if they are already in the ClinCard system. If not, proceed to add the participant to the master study. In Subject Registration, complete the following steps:
    a. Ignore the study ID box for now
    b. From the drop-down menu, select "Master Study"
    c. Make sure "Enrolled" is selected under study status
    d. Make sure "Thomas Jefferson (MAIN)" study status
    e. Enter their first and last name
    f. Select "Register"
3. Next, add the participant to your specific study through the following steps:
    a. Select "Edit Subject" button from the list of options on the right
    b. Don't change the first "Study" dropdown list. Instead, add the specific study information below starting with their Study ID, then select your specific study from the dropdown menu under this second "Study" option, and last make sure that "enrolled" is selected under "Subject Status." When all of the relevant information is added, make sure that you select the blue "Add Study" option in the top, right corner.



4. Once the participant is added to the study, first assign the participant a ClinCard (you will need to enter the full 16-digit ClinCard number) and then assign payments to that ClinCard with the following steps:
    a. Select "Assign ClinCard" from the list of options on the right
    b. Enter the 16-digit card number into the pop-up box
    c. Select "Assign"
    d. Select "Make Site Visit Payment" from the list of options on the right
    e. Select your specific study title from the drop-down list
    f. Use the sign-in sheets to determine which sessions the participant attended. For each session of the study, select the appropriate session from the "Milestone" drop-down list
        - If the participant attended the session, select "Pay"
        - If the participant attended the session, select "Missed"

VII. Reporting Requirements

A. PCORI reporting

PCORI requires progress reports on June 30 and December 31 of each grant year.
PCORI also requires a final research report. Templates are available here: http://www.pcori.org/funding-opportunities/awardee-resources

The Project Manager will collaborate with the PIs to complete these reports.

B. Institutional reporting

Jefferson's Office of Human Research requires an annual continuing review for expedited/full studies to maintain their approved status. Additionally, the PIs must submit amendments for protocol or study personnel changes. More information and forms can be found here:
http://www.jefferson.edu/university/human_research/forms.html

C. Risk Management and Adverse Event Reporting

Psychological risk and/or risk to privacy is expected to be minimal, if any, and limited to the risk of discomfort in interviews or concept mapping sessions when asked to share their opinions and personal information. Risks will be mitigated by ensuring a private location to conduct interviews and concept mapping sessions. It will also be mitigated by communicating frequently with enrolled patients to ensure that their continued participation is voluntary and informing them that they may opt to decline to answer any or all of the interview or questions. There is the possible risk of loss of confidentiality. All participants will be asked to keep the contents of the concept mapping discussions confidential, and all data will be de-identified. All electronic data are password-protected on network-level-access-secured computers. All paper documents are secured in locked cabinets in a locked office accessible only to research personnel. PHI is only collected to the extent required by our study protocol, and records are de-identified as soon as possible.

If a protocol deviation or adverse event occurs, the research team will document the incident in the protocol deviation or adverse event log and follow the procedures outlined in Thomas Jefferson University's Office of Human Research Policy & Procedures Manual, Policy GA 120: Reporting and Reviewing Unanticipated Problems Involving Risks to Subjects or Others:
http://www.jefferson.edu/content/dam/tju/human_research/irb/documents/PolicyandProceduresManual/20151201%20DO%20NOT%20MODIFY%20Policy%20and%20Procedure%20Manual%20COMPLETE%20CLEAN%20fixed.pdf

D. Research and Financial Misconduct

"Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Financial misconduct refers to any act to acquire financial gain for oneself or for those of relatives, friends, or associates from or through activities and transactions related to the conduct of any PCORI-funded research.

Recipient is required to report any findings of research or financial misconduct to PCORI within thirty (30) days of the conclusion of an investigation into research or financial misconduct related to any PCORI-funded research. Will research or financial misconduct occur with respect to any PCORI-funded research, the Recipient must notify PCORI, in writing, of the nature of the violation, the corrective actions that will be taken to correct the violation, and a timeline within which those corrective actions will be executed."

E. Study completion and closeout procedures

i. PCORI

To close the study with PCORI, the research team must submit a draft final research report, sign off on the lay abstract no later than 90 days after PCORI accepts the final research report, and submit the final expenditure report 90 days from contract term date.

ii. Thomas Jefferson University IRB
Upon completion of the study, the research team will notify the IRB of study completion using an OHR-9 final report: http://www.jefferson.edu/university/human_research/forms.html