Peer Support to Enhance Diabetes Shared Medical Appointments: Examining Comparative Effectiveness in VA Health Systems

Health Services Research and Development Service (HSR&D)

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Abstract

Objectives: Providers are often unable to communicate as frequently as needed with diabetes patients who have poor risk factor control and face significant self-management challenges. Moreover, many VA patients face barriers to attending frequent face-to-face visits. This project will evaluate the implementation of a novel program found in a recent VA randomized, controlled trial to significantly improve VA patients' diabetes-specific social support, insulin starts, and glycemic control compared to usual nurse care management. The program uses periodic group sessions in conjunction with calls between paired patients with diabetes to promote more effective care management as well as peer-to-peer (P2P) communication among diabetes patients who both have poor glycemic control and are working on similar care goals. Participants are matched with another patient of similar age and facing similar self-management challenges. "Peer buddies" are encouraged to talk by phone at least weekly to provide mutual support and share their progress on meeting their self-management goals. The goal of this service is to enhance the effect of shared medical appointments (SMAs), a service model demonstrated to be effective in improving outcomes among patients with diabetes and other chronic conditions and now being widely implemented in VA. Based on the success of the efficacy trial of this intervention, we now seek to evaluate a wider-scale implementation of this program.

Methods: During implementation of the P2P program in conjunction with shared medical appointments (SMAs) in five diverse VA facilities, we will evaluate the effectiveness of SMAs alone and SMAs+P2P compared to usual care, and study the implementation process in order to gather information required to disseminate the program more broadly in Veterans Health Administration (VHA).

List of Abbreviations

BP: blood pressure

CFIR: Consolidated Framework for Implementation

CCMR: Center for Clinical Management Research

HbA1c: hemoglobin A1c

HBC: Health Behavior Coordinator

HSR&D: Health Services Research and Development

IVR: interactive voice response

MI: motivational interviewing

NCPD: National Patient Care Database

OTS: Office of Telehealth Services

PACT: Patient Aligned Care Teams

P2P: Peer-to-Peer

QUERI: Quality Enhancement Research Initiative

QUICC: University of Michigan Quality Improvement for Complex Conditions

RC: Research Coordinator

RCT: randomized controlled trial

SBP: systolic blood pressure

SM: self-management

SMA: shared medical appointment

VHA: Veterans Health Administration

Contents

Protocol Title: Implementation Study of the Peer-to-Peer Program for Patients with Diabetes

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2.0 Introduction

2.1 The Challenge of Supporting Patients' Diabetes Self-Management

Twenty-five percent of VHA patients have type 2 diabetes, representing about 1.5 million Veterans. VA initiatives have improved diabetes care quality, but in FY14, 20-30% of VA diabetes patients still had poor glycemic control (A1c > 9%), poor blood pressure control (>140/90), or were not on a statin.[1] In light of strong evidence that complications from diabetes can be significantly reduced with glucose and blood pressure control and statin treatment, improving management of these is essential. While there are now effective treatments for diabetes, success of these therapies depends on how well patients self-manage over a sustained time: taking prescribed medications; following diet and exercise regimens; self-monitoring; and coping emotionally with the rigors of living with diabetes. Yet, many patients face multiple barriers to effective diabetes self-management (SM). These include lack of sufficient SM knowledge and skills; lack of self-confidence ('self-efficacy') and/or motivation; and problems from other co-morbidities and physical limitations. In addition, many adults with diabetes lack effective support from their families and friends to help them manage their diabetes, a lack that represents an often-neglected barrier to successful diabetes care.[2,]

2.2 The Effectiveness of Shared Medical Appointments

Group visits, including Shared Medical Appointments (SMAs), bring patients with the same chronic condition and facing similar SM challenges together with a team of providers and are a highly effective and efficient way to provide SM education and support. SMAs are defined by groups of patients meeting together over time for comprehensive care, usually involving a practitioner with prescribing privileges. They incorporate many of the core components of high-quality chronic disease care, such as planned, scheduled contact with a with an interdisciplinary team of providers; a targeted focus on improving SM skills; peer support from and interaction with other patients facing similar challenges; and regular review and adjustment of treatment plans.[6-9] Several recent meta-analyses of randomized controlled trials (RCTs) of diabetes SMAs, including a 2014 review led by co-investigator David Edelman for the VA, have found that SMAs are more effective than usual care in improving A1c levels and systolic blood pressure (SBP).[8-10] A recent RCT in VA found improvements in cholesterol levels among Veterans with poorly controlled diabetes and hypertension who participated in group medical clinics compared to usual care. [11] In the face of this evidence form efficacy trials, researchers noted the need now for large-scale trials and implementation studies that measure real-world impacts on patient-centered and staff-centered outcomes, costs, and utilization.

2.3 The Need for More Effective, Scalable Models to Maintain Achieved Gains

As with other evaluated programs, most studies of SMAs to date have examined outcomes during and immediately after participation in SMAs. There is growing evidence that no matter how effective a short-term, more intensive diabetes SM support program is in improving outcomes immediately after completion of the program, many patients do not succeed in maintaining SM and clinical improvements achieved through the program.[12-15] In the face of resource and staff constraints, novel approaches to help patients sustain SM improvements are needed that do not rely exclusively on face-to-face or professionally led programs. Sustaining gains may be especially difficult for the many VA patients who lack social support. Both receiving and providing social support is associated with improved SM and clinical outcomes.[16-19] Many VA patients not only lack an extensive social network, but also opportunities to be of service formerly available through jobs or military service.

2.4 Peer Support as a Means to Enhance and Maintain Gains from SM Programs

Peer support among patients with the same chronic health problem may be a particularly potent intervention, combining the benefits of both receiving and providing social support. "Peer support" is defined as "support from a person who has experiential knowledge of a specific behavior or stressor and similar characteristics as the target population."20 Because peers share similar characteristics, this approach is intrinsically culturally sensitive. A 2015 meta-analysis of 13 RCTs testing peer support interventions' effectiveness in improving glycemic control in adults with type 2 diabetes concluded that

peer support programs resulted in a significant reduction in A1c [pooled mean difference between arms: -0.57 (95% CI: -0.78 to -0.36)].21 Most of this effect was from programs with moderate (one or two contacts a month per patient) or high (more than two contacts in a month per patient) frequency of contact. Programs with low frequency of contact showed no significant reduction.

Other recent systematic reviews have found similar benefits of peer support in diabetes.[22-24] In response to the growth of evidence on peer support's effectiveness, the World Health Organization (WHO) has endorsed further development and evaluation of peer support programs for improving diabetes outcomes.[25] In VA, peer support is a strong and growing part of VA services for people with serious mental illness. Programs such as Vet-to-Vet for Veterans with psychiatric diagnoses are now implemented at many VA facilities,[26, 27] and one-on-one peer interventions target Veterans recently returned from combat.[28, 29] In the field of diabetes, efficacy trials have examined two models of predominantly telephone-delivered one-on-one peer support: 1) peer coach models in which one Veteran provides support to another; and 2) reciprocal, or mutual, peer support models in which both Veterans give and receive support. Both of these models have been found to be more effective than other comparison groups in improving glycemic control.[30-32] As described in Section 1.6, the reciprocal peer support model tested by M Heisler et al. was more effective than nurse care management in improving glycemic control and other diabetes outcomes.[30] This mutual peer support model may be a particularly effective complement to SMAs, as SMA participants have the chance to get to know each other over time and can continue to work together through telephone calls and periodic patient-directed group sessions with other SMA participants to improve SM behaviors and sustain gains achieved through the SMAs.

2.5 Examining the Effectiveness of Implementation of SMAs Combined with Reciprocal Peer Support in Diverse VA Facilities

In light of the evidence from efficacy trials that examined diabetes SMAs and reciprocal peer support models separately, important next steps are to: 1) evaluate these programs in a large-scale, multi-site pragmatic clinical trial to examine effectiveness in diverse real-life VA settings compared to usual care; 2) assess whether a reciprocal peer support program among Veterans participating in SMAs can sustain gains achieved through SMAs; and 3) rigorously evaluate the process and costs of implementation of these interventions as clinical programs in a diverse set of VA facilities.

2.6 Previous Work

This study builds on the work of Michele Heisler, MD, MPA (PI) and research team members David Edelman, Susan Kirsh, Michael Goldstein, Julie Lowery, Timothy Hofer, and site PIs Hank Wu, Donna Zulman, and Alexander Guirguis. Dr. Heisler has extensive experience running large-scale, multi-site health system and behavioral RCTs and implementation studies.[30, 33-35] She has developed and tested a range of peer support models in both VA and non-VA settings.[15, 30, 33, 35] Dr. Edelman has led some of the definitive RCTs showing the short-term effectiveness of SMAs and is a national leader in the development and evaluation of diabetes SMAs,[8, 9] as is Dr. Kirsh.[6, 9, 36-38] Drs. Jeffery and Wu have also led RCTs showing the effectiveness of SMAs in diabetes,[39, 40] and Dr. Zulman brings expertise in interventions targeting complex patients.[41, 42] Dr. Lowery brings in-depth expertise and experience in conducting mixed methods implementation studies.[41-46] Dr. Hofer has expertise in advanced statistical methods and research design.[47, 48] He has particular expertise in the design and analysis of cluster randomized trials, working with Dr. Heisler on the cluster RCT of the Adherence and Intensification of Medications (AIM) program funded by NIDDK and VA. [30, 34]

Prior P2P Efficacy Trial

The proposed pragmatic clinical trial will extend findings from Heisler et al.'s RCT comparing a reciprocal peer support program (P2P) with a nurse care management model (NCM) funded through an HSR&D IIR (04-239). Patients in the P2P group attended an initial group session to set diabetes-related behavioral goals, receive peer communication skills training, and be paired with another age-matched peer in the same cohort of study participants. Both peers had poor glycemic control and were encouraged both to give and receive support from each other in their joint efforts to improve glycemic control. Peers were encouraged to talk weekly using a telephone platform that recorded call occurrence

and provided reminders to promote peer contact. Optional group sessions were offered at 1, 3, and 6 months. NCM patients attended an initial educational session, were assigned to a nurse manager, and were helped to make follow-up appointments with that NCM.

The 244 participants were from 2 VA health care facilities and had A1c levels greater than 7.5% during the 6 months prior to enrollment. In the 216 patients (89%) who completed the A1c assessments at 6 months, mean A1c level decreased from 8.02% to 7.73% (-0.29%) in the P2P group and increased from 7.93% to 8.22% (+0.29%) in the NCM group (between-group difference 0.58%,P = 0.004). Among patients with a baseline A1c level >8.0%, those in the P2P group had a mean decrease of 0.88%, compared with a 0.07% decrease among those in the NCM group (between-group difference, 0.81%; P < 0.001). Eight patients in the P2P group started insulin therapy, compared with 1 patient in the NCM group (P = 0.020). Patients in the P2P program expressed high levels of satisfaction with their participation. While this RCT examined P2P as a stand-alone program, its design is well-suited to complement and extend formal professional-led programs such as diabetes SMAs, as is proposed in the current application.

Consolidated Framework for Implementation Research (CFIR)

We will use the Diabetes QUERI CFIR to guide the design of the qualitative phase of the study.[49] (The electronic version of this article can be found online at: http://www.implementationscience.com/content/4/1/50.) The CFIR comprises common constructs from across implementation frameworks and models already in the literature, including Greenhalgh, Rogers, and Kitson et al.[50-52] The CFIR's five major domains are the intervention, inner and outer setting, the individuals involved, and the process by which implementation is accomplished.
Pettigrew and Whipp, more than 20 years ago, emphasized the essential interactive dimensions of content of intervention, context (inner and outer settings), and the process of implementation.[53] This basic structure is also partially echoed by the PARiHS framework, which describes the three key domains of evidence, context, and facilitation.[52] The CFIR has an additional domain for the individuals involved to acknowledge their important role in implementation. Within each of these five major domains is a comprehensive list of constructs that have empirical or normative support for their influence on implementation effectiveness. We have already used the framework for the formative evaluation of three different national implementation projects in VA (*MOVE!*, digital screening for diabetic retinopathy, and *MOVE!* telehealth; reports and manuscripts in preparation). Based on this previous work, we have developed a methodology for coding and analyzing qualitative data using the framework, which is described below in section 3.0, Formative Evaluation, Aim 3.

2.7 Significance and Impact

The proposed project supports HSR&D research priorities to improve Veterans' health care by developing, testing, and disseminating effective, innovative interventions that: (1) increase access to high-quality care to vulnerable Veterans; and (2) provide ongoing equitable health care and support services that improve long-term outcomes among all Veterans. Interventions such as the ones proposed are designed to be feasible in the face of resource constraints and simple enough to be integrated into standard care processes. In addition, the intervention is designed to interface with and support efforts within VA to expand the use of SMAs as a strategy to improve outpatient care and access. Beginning in 2005, the VA has mandated shared or group medical appointments as a means to improve clinic efficiency and quality of care.[6] Both local and national Advanced Clinic Access meetings endorsed this methodology for decreasing waiting times, improving patient access and outcome measures, and minimizing costs. The PACT initiative has promoted SMAs or group visits as they promote team- based, patient centered access and quality of care components of PACT. The P2P program is consistent with—and builds on—this approach. Both SMAs and P2P emphasize the importance of peer support, active Veteran engagement with care, and SM. The P2P program takes SMAs a step further by providing an infrastructure for the peer support component to continue on a regular basis beyond the face-to-face meetings, something especially important to Veterans who face barriers to accessing VA-based care. In addition to studying the implementation of P2P in diverse sites, this study will evaluate whether the addition of P2P can improve patients' SM efforts and outcomes above and beyond the use of SMAs alone

over a longer period of time. Finally, the post-implementation evaluation will provide important information and specific tools to facilitate broader dissemination of the program, as well as contribute to the field of implementation science by identifying contextual factors associated with implementation success or failure.

2.8 Vulnerable Populations:

No children will be included in this study. Women and minorities will be included to the extent that they are enrolled to the SMA program at the participating sites. We will not take special efforts to focus our recruitment efforts on any particular sub-group of eligible patients. The research includes surveys, interviews, and medical record review.

VA Patients

As this study is an effectiveness trial conducted under real-world implementation conditions we will conduct the study in those who 1) are eligible to participate in SMAs, and 2) who can give informed consent. This excluded individuals with impaired decision making capacity, those who do not speak English proficiently, and prisoners. It includes all other groups. There are no medical interventions as part of this study, so we will not exclude pregnant women.

VA Employees

VA Employees will be asked to participate in interviews based on their role in the SMA and/or P2P programs. The director of primary care, clinicians participating in the SMAs, the P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists) will be asked to participate in semi-structured interviews. These employees could be pregnant. There are no medical interventions as part of this study.

3.0 Objectives

We propose to evaluate the implementation of a novel program found in a recent VA randomized, controlled trial to significantly improve VA patients' diabetes-specific social support, insulin starts, and glycemic control compared to usual nurse care management. In two prior randomized trials, we found that automated telephone assessment and self-care support calls increased use of guideline-concordant services, decreased symptoms, and improved glycemic control. However, providers are often unable to communicate as frequently as needed with diabetes patients facing self-management challenges. Moreover, many VA patients face barriers to attending frequent face-to-face visits. Accordingly, we developed and tested an intervention using group sessions in conjunction with phone calls between peers to promote more effective care management as well as peer-to-peer communication among pairs of diabetes patients who both had poor glycemic control and were working on similar care goals. Participants are matched with another patient of similar age and facing similar self-management challenges. These "peer buddies" are encouraged to talk by phone at least weekly to provide mutual support and share their progress on meeting their self-management goals. The goal of this service is to enhance and sustain the effect of shared medical appointments (SMAs), a service model demonstrated to be effective in improving outcomes among patients with diabetes and other chronic conditions and now being widely implemented in VA. Based on the success of the efficacy trial of this intervention, we now seek to evaluate a wider-scale implementation of this program.

In this study, as the Peer-to-Peer (P2P) program is implemented in conjunction with shared medical appointments (SMAs) in five diverse VA facilities. One of these facilities, Palo Alto, includes four distinct clinics in different cities. We will evaluate the effectiveness of SMAs alone and SMAs+P2P compared to usual care in these sites, and study the implementation process in order to gather information required to disseminate the program more broadly in VHA. The specific aims of the study are presented below.

Summative Evaluation of Program Effectiveness

Aim 1: Evaluate the effect of SMAs and SMAs+P2P on diabetes patients' glycemic control, systolic blood pressure, anti-hypertensive use, statin use, and insulin starts at 6 and 12 months post-enrollment.

Aim 2: Assess the impact of SMAs and SMAs+P2P on service utilization and patient-centered outcomes at 6 and 12 months post-enrollment.

Formative Evaluation of Implementation Process

Aim 3: Use constructs from the CFIR to conduct a post-implementation evaluation of the implementation process at the five participating sites (including 3 CBOCs at the Palo Alto site).

We will also obtain data throughout implementation on the staff effort to calculate the costs of the program (**Aim 4**).

In summary, the P2P program builds on the demonstrated strengths of group medical visits and peer support on self-care behaviors and health outcomes. This study will provide important information on its effectiveness and the barriers faced in different VA facilities when implemented as part of existing clinical processes.

4.0 Resources and Personnel

4.1 Where Research will be Conducted

The study will be based at the VA HSR&D Center for Clinical Management Research (Ann Arbor Health Care System). This site has extensive expertise conducting VA and other federally-funded research and has the resources necessary to carry out the proposed research project. The Ann Arbor study team will be responsible for hosting the servers where the study data are stored, and for granting permissions as required for the conduct of this study. All employee participants will be recruited for interviews by Ann Arbor study staff. Patient participants who have been selected for telephone interviews and who have given verbal consent when contacted by a RC from their site will be contacted and interviewed by Ann Arbor study staff by telephone.

Patient participants will be recruited from five VA Medical Centers: Ann Arbor, West Haven, Palo Alto, Sacramento, and Providence. The Palo Alto site will include four locations: Palo Alto, Monterey, San Jose, and Livermore clinics.

4.2 Project Team

The major components of the study, and the investigators responsible, are:

- Design and implementation of P2P (Heisler)
- Formative evaluation (Lowery)
- Summative analysis (Hofer, Wiitala, Heisler, Edelman)
- Integration of P2P with SMAs (Kirsh)
- Design, oversight, and assessment of motivational interviewing (MI) training for group facilitators and peers (Heisler, Goldstein)

The specific responsibilities of the project team are described below.

Michele Heisler, MD, Principal Investigator. Dr. Heisler will oversee implementation of P2P at the participating sites, including working with Drs. Lowery and Kirsh to interview key stake holders and adjust implementation of the program as needed to the context of each of the sites. She will work with Dr. Goldstein to develop and implement the training program for the group facilitators, and with Dr. Edelman to design a methodology for assessing the fidelity of the P2P program. She will be responsible for ensuring adherence to the project timeline, and directing the work of the project manager and data analyst.

Julie Lowery, PhD, Co-Investigator. Dr. Lowery is the Associate Director of the Ann Arbor HSR&D Center for Clinical Management and Research (CCMR) and Co-Implementation Research Coordinator for the Diabetes QUERI (with Laura Damschroder). Ms. Damschroder and Dr. Lowery developed the CFIR, which will be used in this project, and have used this framework for developing the interview guides, coding, and analyzing data for three VA implementation projects thus far. Dr. Lowery will be responsible for overseeing the conduct of the pre- and post-

implementation formative evaluation, including developing the interview guide, overseeing the conduct of the interviews, and assisting the qualitative analyst with coding and analyzing the interview data. During the pre-implementation period, she will use the findings from interviews with key stakeholders to assist the sites in implementing the P2P programs. As part of her work on the interviews, Dr. Lowery may have access to PHI, recruit participants (including obtaining informed consent), administer interviews, and conduct data analyses. During the post-implementation evaluation, she will use the findings from the interviews to assist Dr. Kirsh with development of the dissemination plan.

Tim Hofer, MD, Co-Investigator. Dr. Hofer is Associate Director for Measurement and Information Technology at CCMR, and a core faculty member of the Diabetes QUERI. Dr. Hofer has expertise in statistical methods related to patient profiling, quality measurement, and research design. Relevant to this study, he has particular expertise in the design of cluster randomized trials, serving in such a capacity for a recently completed cluster randomized trial funded by the VA and National Institute of Diabetes and Digestive and Kidney Diseases, for which Dr. Heisler was co-PI. Dr. Hofer worked with Dr. Heisler to devise the design and analysis for this resubmission in response to reviewers' concerns. Dr. Hofer will be responsible for overseeing the study design and analyses.

Wyndy Wiitala, PhD, Biostatistician. Dr. Wiitala supervises the data managers at CCMR, provides consultation on research design and statistical analysis, and serves as the primary data analyst on a variety of projects. She has expertise in the use of VA databases, as well as use of multi-level modeling and imputation for missing data. She will be responsible for conducting the analyses of the summative data in year 4. Dr. Wiitala will have access to PHI.

Susan Kirsh, MD, Consultant. Dr. Kirsh is Associate Professor of Medicine, Case Western Reserve University, School of Medicine, Cleveland, Ohio, and an attending physician at the Louis Stokes Cleveland VAMC, Ohio. She is also the National Director for Clinic Practice Management and Access. As part of this responsibility she has the opportunity to work with clinical teams across the country in support of the implementation of team models for diabetes care and, in particular, to facilitate implementation of shared medical appointments as a PACT priority. As a consultant on this study, she will serve as the SMA expert and will lead the dissemination effort, by working to identify opportunities and tools for implementation of the program as part of SMAs and PACT. Dr. Kirsh will also review patient materials and data collection instruments.

David Edelman, MD, Co-Investigator. Dr. Edelman is a research scientist at the Center for Health Services Research in Primary Care, Durham VA Medical Center, and Associate Professor, General Internal Medicine, Duke University Medical School. He has extensive research and clinical experience with group- based interventions in chronic illness. He will work with the participating sites to implement and evaluate P2P as part of their existing group visits, drawing on his previous experience in the evaluation of group medical clinics for patients with diabetes and hypertension. As part of this work he will assist the research team with designing the post-implementation interviews for the formative evaluation, designing a measure of fidelity assessment for the group visits, providing consultation on the analyses of the summative data, and assisting with interpretation of the analyses of the qualitative data.

Michael Goldstein, MD, Consultant. Dr. Goldstein is Associate Chief Consultant for Preventive Medicine, VA National Center for Health Promotion and Disease Prevention. He has significant experience and expertise in training providers and counselors in MI and health behavior counseling skills. For the proposed research, he will design a training program that the Health Behavior Coordinators (HBCs) at the SMA + P2P participating sites can use for training the P2P group facilitators, who will be teaching MI techniques to the P2P peers, as well as modeling the use of these techniques when they serve as facilitators for the group sessions. He will also work with the research team to design an instrument for assessing the fidelity of the P2P group visits,

including the initial visit when the facilitator trains the peers in MI techniques, and the subsequent visits when the facilitator enforces and models those techniques. He will assist with analysis of the fidelity data.

Jennifer Burges, MPH, Project Manager. Ms. Burgess will be responsible for preparing and submitting all IRB documents. She will assist the PI with hiring and training the site RCs and P2P facilitators, as well as monitoring study progress to ensure accomplishment of enrollment goals and adherence to protocol requirements. She will be responsible for overseeing the establishment and maintenance of the participant tracking database, overseeing the administration of the follow-up surveys, and monitoring the quality of the study data as it is collected. She will work with the site RCs to resolve problems with recruitment and data collection as they arise. Ms. Burgess with also work with the clinical teams conducting SMAs and P2P groups at the sites to document the similarities and differences in these programs between sites. She will have access to PHI.

Dana Horowitz and Caroline Clingan, Research Associates. The RAs will be responsible for assisting clinical personnel to recruit Veterans receiving care at the Ann Arbor VA into SMAs as needed to assure that the SMAs are operating to capacity. This includes conducting eligibility screens and scheduling patients for their initial SMA appointment. She will recruit for the study from all Veterans participating in SMAs. This includes obtaining HIPAA waivers, mailing/collecting study surveys, entering data into the enrollment and tracking database, and entering survey data into the study database. They may also assist the sites with their recruitment efforts. The RAs will provide assistance to the sites in creating calendars for the SMAs and P2P drop-in sessions, assuring rooms are reserved, SMA and P2P facilitators understand which SMAs will be providing P2P, and those who will be assessing fidelity know which visits to attend. They will make sure fidelity assessments and self-assessments of the SMAs and P2P drop-in sessions are done when required, and will conduct the assessments when the HBC (or other designated assessor) cannot attend. They will assist the Ann Arbor qualitative analyst in recruiting and obtaining consent for those Veterans selected for patient interviews, as well as staff selected for interviews and sustainment assessments. They may also assist with transcription of staff and patient interviews. The RAs will be responsible for the creation of P2P protocols and tools for participants (handbooks, calendars, etc.), and will maintain a SharePoint site as a central data repository including the most up-to-date study procedures and clinical tools. They will have access to PHI.

Christine Kowalski and Naomi Kane, Qualitative Analysts. Ms. Kowalski has significant experience with conducting semi-structured interviews of VA staff and with using the CFIR to code and analyze interview data. She will be responsible for conducting the staff and patient interviews for the proposed study, and for coding and analyzing the interview data using the CFIR, with assistance from Dr. Lowery. Ms. Kane will assist Ms. Kowalski with conducting the patient interviews and with coding analyzing all interview data. Ms. Kowalski and Ms. Kane may have access to PHI, recruit participants (including obtaining informed consent), administer interviews, and conduct data analyses.

Jennifer Burns, MHSA, Data Manager. Ms. Burns will be in charge of identification of eligible candidates for all sites using VA databases, the random selection of eligible candidates to be offered SMAs, extracting the secondary data (Aims 1 and 2) from centralized VA databases, preparing the data for analysis, and conducting preliminary analyses under the supervision of Dr. Wiitala. She will have access to PHI.

Cynthia Ellis, Transcriptionist. The transcriptionist will transcribe the recordings of the interviews with employee participants and patient participants. Any identifying data in the transcripts (e.g., names of other patients, providers, facilities) other than study ID will be removed during the transcription process. The transcriptionist may have access to PHI if it is discussed during an interview.

Leah Gillon, Database Manager. Ms. Gillon has immense experience in the administration of

Access databases. She will be responsible for the design and maintenance of all of the sites' databases and, as such, will have access to PHI.

Melanie Parent, Troo Tucker, Vera Gaetano, Kevin Chun, Cindie Slightam, Amy Gregory, Aaron Tierney, and Isabella Romero, Site Research Coordinators. The RCs will be responsible for inviting all patients who are joining an SMA group at their site if they are willing to participate in this study, obtaining signed HIPAA authorizations and study surveys for all study participants, providing incentives to participants, entering data into the enrollment and tracking database, and entering survey data into the study database. They will also help the clinical team mail letters of invitation to SMAs, recruit these patients by phone, conduct eligibility screens, and schedule patients for their initial SMA. They will conduct fidelity assessments of the SMA and P2P group meetings. The RCs are responsible for notifying the CIRB and the Ann Arbor project manager of any adverse events, complaints, or issues that arise at their study site. The RCs will have access to PHI only for the participants at their site.

Alexander Guirguis, Donna Zulman, Lorrie Strohecker, and Wen-Chih Wu, Site Principal Investigators. The Site PIs will be responsible for ensuring adherence to the project timeline and protocol, and directing the work of the site RCs. In addition, they may assist the site RCs with any of their study duties.

Megan Crete, Jeffrey Cass, Site Consultants. The site consultants will assist with the training of new SMA and P2P facilitators in MI. They also may assist with recruitment and SMA fidelity assessments.

4.3 Contractors/DUAs

None.

5.0 Study Procedures

5.1 Study Design

5.1.1 Overview

This study represents Steps 4 and 5/6 of the QUERI Process[55], which are also described under "Implementation Trial with Evaluation" in the new Research/Implementation Pipeline used for the most recent QUERI Annual Reports (Appendix 1 to this protocol). Specifically, this will be a hybrid 1 effectiveness trial conducted under real-world implementation conditions in multiple sites and regions. The focus is on assessing the impacts of the program on patient outcomes (research aims 1-2), as well as optimization of the implementation strategy (aim 3).

This project is being conducted at five VA facilities (including eight clinics) implementing SMAs as part of usual care. These sites have been selected because they are interested in implementing P2P groups as an add-on to the SMAs as part of usual care. As these programs are starting, resources at each site do not permit all eligible patients to receive these two new programs. Therefore there are three groups being studied, all receiving usual care for their facilities: (1) usual care without SMAs, (2) usual care with SMAs, and (3) usual care with SMAs and P2P.

The study design is a multi-site, modified cluster randomized controlled design. Our first analysis is a comparison of two active treatment arms, one involving SMA and the second involving SMA+P2P. Some sites may only conduct one group at a time depending on variability of their resources over time, but all sites will conduct a number of groups over the study period and the two

treatments will be offered in a random sequence within site, providing the clusterized random assignment required for comparability of the two treatment arms. In a modification of the classical cluster randomized design, patients are not assigned to groups prior to the group randomization to treatment but are recruited from a population of eligible patients when the site is ready to run a new group. If patients are then selected differentially into the groups we will lose all the advantages of the randomization step. Thus patients will be randomly sampled for invitation from eligible patients and recruited for each wave of the group treatment with a standard script that is identical whether the group is SMA only or whether P2P will be offered as an additional optional part of the intervention. All invited patients will be told that they are being invited to participate in SMAs, provided a brief description of what the SMAs involve, and informed that some groups will also be offered an additional (optional) opportunity to participate in P2P as a supplement to the SMAs. All invited patients will also be told that they are being offered an additional (optional) opportunity to participate in this research study. Participation in the research study is not required to participate in the SMAs or SMAs + P2P.

The study population will consist of diabetes patients who have poor glycemic control. Because not all eligible patients will be able to be invited to participate in one of the two programs during the study period, we will also have a pool of eligible patients whom we can use for untreated controls. We will randomly pull a sample of patients from each site to serve in this group. Thus, the trial will compare outcomes across three different treatment groups: (1) usual care without SMAs, (2) SMAs; and (3) SMAs + P2P.

We will use a mixed methods approach to our data collection and analyses. Summative data for Aims 1 and the service utilization outcomes in Aim 2 will be obtained from VA databases and will include data on clinical outcomes and service utilization, which will be measured at baseline, at 6 months, and over a period of 12-18 months post-enrollment. Because this is an implementation study, we intend to use clinical data wherever possible, rather than add to staff burden with the imposition of additional collection of data solely for research purposes—especially when data on the clinical measures of interest are already collected as part of patient care. For two of the arms (SMA, SMA+P2P), we expect labs to be drawn at baseline and 6 months through SMA staff as part of usual care. In usual care without SMAs, we may have more missing values for A1cs, although guidelines recommending checking A1cs at least every 6 months in patients with poor glycemic control.

Data on patient-centered outcomes (Aim 2) will be obtained from surveys of all participants who are scheduled to participate in SMAs and agree to participate in the study at the five sites to allow for comparisons across the SMA and SMA + P2P groups. We will collect laboratory and service utilization data on patients in all three treatment groups. Qualitative data on organizational factors likely to affect P2P program implementation will be obtained via semi-structured interviews prior to implementation, mid-implementation (7-10 months following program implementation at each site), and post-implementation (18-24 months following program implementation at each site) as part of Aim 3. To further look into the SMA sustainment efforts in Ann Arbor, additional staff interviews, staff meeting observations, and SMA observations will be conducted in Ann Arbor only. Data on staff time required for implementation of P2P will also be collected throughout the study to calculate the overall cost of program implementation (Aim 4).

Patient enrollment will take place for 18 months at the five sites. Patients receiving P2P can stay in the P2P program as long as they wish (while the program is being funded).

VA patient research procedures include completion of three surveys (baseline, 6 months post-enrollment, and 12 months post-enrollment) and collection of medical record data from VA databases. Additionally, a subset of participants will be asked to participate in interviews as part of the program evaluation.

As SMAs are being implemented as part of usual care, resources will not permit all patients

eligible for the program to be invited. Of those patients who are not invited to participate, a random sample will be identified from each site to serve as an untreated control (usual care without SMAs). We request a waiver of informed consent and HIPPA authorization for these patients in order to collect laboratory and service utilization data solely for research purposes.

Semi-structured interviews with five to eight key informants (VA staff) at the participating sites will be conducted to obtain information on CFIR constructs likely to influence implementation success. These interviews will include the director of primary care, clinicians participating in the SMAs, P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists).

5.1.2 Risks

VA Patients
Participants will be instructed to skip any survey or interview question they feel uncomfortable answering. Participants may also end an interview at any time. Participants will be told that they may withdraw from the study at any time without penalty. If a potential study participant does need support or wants further clarification of any issue, a study investigator will address the concern in a sensitive and professional manner (i.e., by calling the participant directly and/or recommending follow up with his primary care provider).

We believe that risk of a breach of confidentiality is low. Throughout the study, IRB and HIPAA guidelines will be followed to ensure the privacy and integrity of the information we collect. To minimize the risk of a breach of confidentiality, we will perform the following steps. First, as soon as the cohort is defined by the data manager, each patient in the cohort will be assigned a unique study ID. All electronic data, including audio recordings, will be stored in an access-restricted folder on the HSR&D drive, which resides behind the VA firewall. All identifying data (e.g., names of other patients, providers, facilities) will be removed from transcripts of the audiofiles during the transcription process. At the study's conclusion, all personally identifying information (PII) will be moved to an access restricted folder on the Ann Arbor VA OI&T network, accessible only to the HSR&D data manager. Members of the study team will no longer have access to these data. Data will be destroyed by the data manager 6 years following the end of the fiscal year after completion of the research project. All research data will be presented in aggregate form only. The data manager will also be responsible for creating analytic datasets for statisticians and investigators; these datasets will be de-identified per HIPAA guidelines. Furthermore, study staff members sign a pledge of confidentiality and understand that breach of confidentiality is grounds for dismissal. Study staff members are required to complete annual training on privacy and HIPAA, as well as biannual training on human subjects protection. All research findings will be presented in aggregate only.

Minimization of risk to usual care
A number of steps will be taken to ensure the safety and confidentiality of patients who participate in the P2P program. All patients participating in P2P will receive training for the peer support component of the study in order to prepare them for those interactions. Patients' confidentiality will be protected via several mechanisms. Patients who are comfortable doing so will be asked to provide their name and phone number to their partner. All patients will be advised to not give out their address or other personal information. This will be explained to the participants during the initial face-to-face group visit, and on the "Do's and Don'ts" card given to the participants to help guide the peer support calls. Finally, messages left on participants' answering machines will not reference any information about their diabetes or other health problems.

VA Employees
There are no physical or psychological risks to study participation. The social/legal: risk to these

participants is potential loss of confidentiality from their interview responses and observational data (Ann Arbor only). The interviews will include questions about various characteristics of the VA medical center where they work, and respondents may provide negative comments about the organization. Linking these responses to a particular employee could result in adverse actions against that employee by other members of the organization, including the employee's supervisor.

Ann Arbor study staff will recruit the employees for all participating sites to reduce the risk of a breach of confidentiality. The same precautions for protecting the audiofiles and transcripts of Veteran participants will be used for protecting these data, along with observation notes, from VA employees. Data will be stored behind the VA firewall at the VAAAHS and minimal Ann Arbor study staff members will have access.

VA Patients and VA employees
There is no direct benefit to patients or VA employees as a result of participation. Patients may benefit indirectly, as this study may result in improvement in diabetes care at the VA. Findings from the study should provide information that will help with implementation of the P2P program, to facilitate its integration into existing clinic structures and processes and reduce the effort required by employees to implement and maintain the program.

The study team will meet regularly during the recruitment period. These meetings will include discussion of the events of the week, particularly any problems/events that have come up. The PI and study team will work to address any problems/events to reduce the likelihood of occurrence in the future, to keep the risk to subjects as low as possible, and to maximize the potential study benefits. The research team will visit the sites in year 2 (approximately six months following implementation) to conduct an on-site assessment of program status, interview key staff members, and to problem-solve any issues that have come up.

5.1.3 Study Population

VA Patients
We will enroll up to 1,100 VA patients to the SMA and SMA+P2P groups and 1,100 VA patients to the control group. Inclusion criteria are reflective of the criteria to participate in SMAs and P2P, with the addition of criteria to insure informed consent. Please see section 5.4 for a complete list of these criteria.

VA Employees
We will enroll up to 56 VA employees for the pre-, mid-, and post-implementation interviews. VA Employees will be asked to participate based on their role in the SMA and/or P2P programs. The director of primary care, clinicians participating in the SMAs, the P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists) will be asked to participate in semi-structured interviews. These employees, who may play a role in the SMA or P2P program (as a referring provider, or as someone facilitating the SMA or P2P group visits), will be targeted to obtain information on CFIR (Consolidated Framework for Implementation Research) constructs likely to influence implementation success. Additionally, in Ann Arbor, we will enroll up to an additional 25 VA employees in the sustainment assessments (i.e., interviews, meeting observations, SMA observations). Employees will be asked to participate based on the teamlets who will be conducting upcoming SMAs. All members of the involved teamlets (e.g., MD, PharmD, RD, RN, LPN, MSA, etc.) will be asked to participate in the sustainment assessments.

5.1.4 Vulnerable Subjects

Note: this study includes surveys and interviews only, no clinical interventions.)

VA Patients
As this study is an effectiveness trial conducted under real-world implementation conditions, we will conduct the study in those who 1) are eligible to participate in SMAs, and 2) who can give informed consent. This excluded individuals with impaired decision-making capacity, those who do not speak English proficiently, and prisoners. It includes all other groups. There are no interventions as part of this study, so we will not exclude pregnant women.

VA Employees
Employees will be included for interviews and observations to gain knowledge regarding implementation of SMAs and the P2P program.

5.2 Recruitment Methods

At a minimum, we will require 560 VA patients in the SMA and SMA+P2P groups and 560 VA patients in the control group (see power calculation in Section 5.6.1 below). We will also enroll up to 56 VA employees.

VA Patients
SMA and SMA+P2P groups – As ***usual care***, some sites may only conduct one group at a time depending on variability of their resources over time, but all sites will conduct a number of groups over the study period and the two treatments will be offered in a random sequence within site. Patients are not assigned to groups, but are recruited from a population of eligible patients when the site is ready to run a new group. Thus patients will be randomly sampled for invitation from eligible patients and recruited for each wave of the group treatment with a standard script that is identical whether the group is SMA only or whether P2P will be offered as an additional optional part of the intervention. There will be two methods of recruitment: existing mechanisms and data pull.

Existing Mechanisms
During the start-up period of this project, many of the participating sites established a strong referral base and high participation rate in their SMAs. All patients referred to SMAs will be scheduled into the next available SMA; the scheduler will not be aware of which SMA groups will be offering P2P as an additional optional component. Once the patient is scheduled, the scheduler will communicate the patient's information to the RC through encrypted email, CPRS alert, or a phone call.

All patients scheduled for an SMA who meet our eligibility criteria will be mailed the Study Intro Letter, the Study Info Letter, a HIPAA authorization, and the baseline survey. Participants will be asked to return the baseline survey (with a waiver of written informed consent) prior to attending their first SMA, and the signed HIPAA authorization prior to the study team linking medical record data to the survey data. The RC may call participants who have not returned the baseline survey and/or HIPAA prior to the first SMA. Whenever possible, the RC will attend the first SMA in order to administer/collect any outstanding baseline surveys and/or HIPAAs for those interested in the study, and distribute incentives for completion. Depending upon what type of group is starting at the time the participants are starting SMAs, they will become part of the ***SMA group*** or the ***SMA + P2P group***.

Data Pull
Each quarter, the Data Manager will pull a list of all patients meeting the eligibility criteria outlined below. At our Ann Arbor site and Palo Alto site and subsites, the RC will provide

each newly eligible patient's assigned provider (PCP or RN) the opportunity to opt that patient out of SMA recruitment. Providers will be asked to respond within 1 week and at that point, any patients who were not opted-out will be recruited.

Eligible patients will be sent an SMA Info Letter explaining that they are being invited to participate in SMAs, provided a brief description of what the SMAs involve, and informed that some groups will also be offered an additional (optional) opportunity to participate in P2P as a supplement to the SMAs. This introductory letter will also explain that they will asked if they are interested in participating in a research study to evaluate this program, It will explain that they may participate in the SMAs regardless of their decision to participate in the research study. It will also include a phone number to call to opt-out of the invitation to participate in the research study, or to opt-out of both the invitation to participate in SMAs and the research study. Unless patients respond that they do not wish to participate, the letters will be followed with a phone call to further describe the program. If patients are interested in participating, they will also be asked a set of brief screening questions to screen out people with active substance abuse. Then the RC will schedule the patient to attend an upcoming SMA or SMA + P2P meeting. Veterans who do not wish to participate will be replaced with another Veteran randomly selected from the population of eligible Veterans, until the SMA group is filled. A full group will range from 10 – 14 patients depending upon the site resources.

The patients who elect to participate in the SMAs will be asked if they are interested in participating in the study. If they are interested in the study, they will be asked to sign a HIPAA authorization to collect their medical record data and link it to survey information collected as part of the study in order to evaluate the SMA program. Even if they decide not to participate in the evaluation, they can still participate in the programs. Those who are interested in the study will be sent a BL Packet Letter, the Study Info Letter, a HIPAA authorization, and the baseline survey. Participants will be asked to return the baseline survey (with a waiver of written informed consent) prior to attending their first SMA, and the signed HIPAA authorization prior to the study team linking medical record data to the survey data. The RC may call participants who have not returned the baseline survey and/or HIPAA prior to the first SMA. Whenever possible, the RC will attend the first SMA in order to administer/collect any outstanding baseline surveys and/or HIPAAs and distribute incentives for completion. Depending upon what type of group is starting at the time the participants are starting SMAs, they will become part of the ***SMA group*** or the ***SMA + P2P group***.

Follow-up surveys, along with a pre-stamped business reply envelope, will be mailed to participants at 6-months and 12-months after their first SMA. Participants who not return a completed survey will be mailed a second survey 2 weeks after the initial mailing. RAs may follow up by phone with participants who have outstanding surveys.

A random sample of the participants who participate in the P2P program, stratified by participation level, will be asked to participate in a semi-structured telephone interview to better understand their experiences with the program. At the end of the program, patients will be stratified by participation level: the ***low participation group*** (began the intervention but completed fewer than 25% of weekly phone calls/group sessions in 12 months of program participation); ***moderate participation group*** (completed approximately 50% of weekly phone calls/group sessions); and the ***significant participation group*** (completed greater than 75% of weekly phone calls/group sessions). Study staff will attempt to interview, by phone, an equal number of participants in each of these 3 groups.

The patients who are invited but decline participation in the P2P (***declined participation group***) will be asked if they are willing to answer a few questions with a study team member. The responses will be recorded but there will be no link between the responses and the participant.

Of the patients receiving usual care who were randomly not selected for invitation SMAs (since in all the sites too many patients will be eligible for invitation than there are resources to accommodate over the study period), a random sample will be selected from each wave to be part of the ***no intervention control group*** under a waiver of informed consent.

Patients will receive a $20 gift card upon completion of the baseline survey and a $10 gift card will be mailed with both the 6 and 12-month survey. Additionally, Patients who participate in an interview will receive a $10 gift card by mail.

VA Employees
Members of the Ann Arbor study team will send an introductory email with an attached information letter to these potential participants explaining the study. This email will give them an option to call to opt-out. Those who do not opt-out will be contacted by the RAs or Ms. Kowalski and will be asked if they are willing to participate. Employees who do not opt-out may also be approached in-person at the time of an observation. Verbal informed consent will be obtained from those willing to participate, and an appointment to complete the interview/observation will be scheduled. Verbal informed consent will also be captured at the beginning of recorded interviews.

5.3 Informed Consent Procedures

Informed Consent will not be sought for

- *Veterans randomly selected from those who have not been asked to participate in SMAs (inactive controls). There will be no contact with this group.*

- *Veterans who are invited to participate in SMA or P2P but elect not to (declined participation group). We would like to ask them a few questions at the time that they elect not to participate or soon after by telephone in order to better understand the barriers to participating in the program. (Appendix 3, Refuser Questions)*

Request Waiver of Documentation of informed consent

- *Veterans in the SMA and SMA+P2P groups.*
  Veterans who are interested in the research study will be asked for verbal informed consent. Those who provide verbal informed consent will be sent a study survey by mail, as well as an information letter about the study, a HIPAA authorization request, and a postage paid return envelope. This will allow participants to complete the baseline study survey at home, eliminating the inconvenience of needing to come in early to a clinical appointment to complete the consent process and paper survey just prior to their first SMA.

  Until a signed HIPAA authorization is returned, survey/interview data will not be linked to PHI collected from administrative/medical record data. The RC may call participants who have not returned a signed HIPAA prior to the first SMA. The RC may also attend the first SMA to administer/collect any outstanding HIPAAs. If a signed HIPAA has not been returned at the time that the follow-up surveys are mailed, an additional HIPAA will be included in the mailing.

- *Employees.*
  Employees will be e-mailed an introductory letter, including an information sheet about the study. Those who are interested in participating will be asked to provide verbal informed consent.

Training will be conducted with each study team member approved to obtain informed consent at each recruiting site. This training will be conducted by telephone by the Ann Arbor project manager. In addition to this structured training, informed consent procedures will be reviewed with all study staff at the regularly study meetings, which will include discussion of the events of

the week where we will answer questions and address any problems/events to reduce the likelihood of occurrence in the future.

5.4 Inclusion/Exclusion Criteria

VA Patients

Inclusion criteria are reflective of the criteria to participate in SMAs and P2P, with the addition of criteria to insure informed consent:

1. Meet at least one of the following criteria in the past 2 years:
   For data pull patients:
   a. At least one VA hospitalization with a type 2 diabetes-related ICD-9 or 10 code
   b. At least two VA outpatient visits with a type 2 diabetes-related ICD-9 or 10 code, or
   c. At least one VA prescription for a glucose control medication (insulin or oral agents) or monitoring supplies.
   For clinical referrals:
   a. Scheduled for diabetes SMA
2. Poor glycemic control, indicated by a HbA1c in the past six months of:
   a. at least 7.5% if age < 70, or
   b. at least 8% if age 70+
3. No active substance abuse disorder (smoking cigarettes is not an exclusion)
4. No serious psychiatric illness, including bipolar disorder, dementia, schizophrenia, or personality disorders (MDD and PTSD are not exclusions)
5. Has a current address and telephone number listed in VA databases
6. Is competent to provide informed consent
7. Can communicate in English and by telephone
8. Not terminally ill
9. Able to participate in an outpatient program
10. Not a prisoner

VA Employees

VA Employees will be asked to participate based on their role in the SMA and/or P2P programs. The director of primary care, clinicians participating in the SMAs, P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists) will be asked to participate in the pre-, mid-, and post-implementation semi-structured interviews. For the sustainment assessment, members of Ann Arbor teamlets who are involved in upcoming SMAs (e.g., MD, PharmD, RD, RN, LPN, MSA, etc.) will be asked to participate.

5.5 Study Evaluations

Patient Research Participants

VA patient research procedures include completion of three surveys (baseline, 6 months post enrollment, and 12 months post enrollment) and collection of medical record data from VA databases. Additionally, a subset of participants will be asked to participate in interviews as part of the program evaluation.

Patient Inactive Controls

Medical record information will be pulled from VA databases. The data will include A1c levels, blood pressures, insulin start dates, statin use, and number of admissions/bed days of care/outpatient visits.

Patient Refusers of SMAs and P2P
Patients in the declined participation group will be asked to answer a few questions by the RC at the time of refusal or soon after refusal by telephone.

Employee Research Participants
Semi-structured interviews with five to eight key informants (VA staff) at the participating sites will be conducted to obtain information on CFIR constructs likely to influence implementation success. These interviews will include the director of primary care, clinicians participating in the SMAs, the P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists). Additionally, in Ann Arbor, up to an additional 25 VA employees will participate in sustainment assessments (i.e., interviews, meeting observations, SMA observations). These employees will include all members of the teamlets involved in hosting upcoming SMAs.

5.6 Data Analysis

This will be an effectiveness trial conducted under real-world implementation conditions in multiple sites and regions. The focus is on assessing the impacts of the P2P program on patient outcomes as well as optimization of the implementation strategy.

5.6.1 Analysis Plans by Aim
Aim 1 (Evaluation of the effect of SMAs and SMAs+P2P compared to usual care on diabetes patients' glycemic control, blood pressure, statin use, and insulin starts at 6 and 12-18 months post-enrollment): The primary analysis will be an intention to treat analysis (ITT) comparing all participants scheduled for an SMA (regardless of whether an SMA was actually attended) and eligible patients randomized to usual care. We also will conduct analyses comparing outcomes between the usual care group and: 1) The SMA Attendee group, defined as a subset of those in the SMA ITT group who attended at least one SMA; and 2) the SMA Engagement group, defined as the subset of patients who attended at least half of the SMAs offered in the series.

We will conduct a "difference-in-differences" (DID) analysis on our primary A1c outcome using a multilevel linear mixed effect model. The model will include an indicator or treatment, an indicator for time, the treatment-time interaction (DID estimator), and variables to adjust for baseline A1c, age, gender, and race. Random intercepts to include will be for patients (level-1) nested within site (level-2). An identical analysis will be used for the secondary SBP outcome. In the secondary analyses of insulin and statin starts, we will implement a multilevel logistic regression model, and for anti-hypertensive medication class changes, we will implement a multilevel Poisson regression model. To analyze the 6- and 12-month differences in utilization measures between treatment groups, we will use a two-sample Mann-Whitney U test. Vargha and Delaney's A statistic will be used to describe the effect size of the Mann-Whitney test. As a robustness check, we will repeat the above analyses on a subset of patients who will be matched 1:1 based on propensity scores. The propensity score model will be developed using a logistic regression on the patient demographics. Although our initial analyses will use observed data, because we are relying on data available in the EHR, we anticipate more missing values than if this were an efficacy trial. Accordingly, we will use logistic regression to model patients' likelihood of having outcome data and defined strata within which outcome values were missing at random. We will then stratify patients according to these propensities and randomly sample from the observed outcome distribution and impute these values for missing data within each stratum. As a sensitivity analysis for the primary A1c outcome, we will impute the missing data such that any missing A1c measurements at 6 or 12 months will match the value at baseline.

Aim 2 (Assessment of the impact of SMAs and SMAs+P2P on service utilization and patient-centered outcomes, including patients' satisfaction with VA care, diabetes-specific quality of life and social support at 6 and 12 months post-enrollment). In our analysis of changes in patient-centered outcomes as reported on patient surveys, we will conduct a paired Wilcoxon signed rank test to determine if there are significant changes between baseline and the 6- and 12-month post-enrollment evaluation periods. We will use the Benjamini-Hochberg (BH) procedure to attempt to control the false discovery rate due to the multiple comparisons. There were very few participants in the SMA+P2P group chose to be formally matched with another participant in their SMA to give and receive peer support outside the SMA. If we do not have sufficient sample size of participants in P2P, we will be unable to compare outcomes between the SMA-only and SMA+P2P arms. In that case, will only conduct our primary analysis that combines the two SMA groups (SMA-only and SMA+P2P) into one active treatment group and compare clinical outcomes of participants participating in SMAs with those in usual care.

Fidelity of the P2P Program. To collect data on fidelity, checklists of key content areas to cover and communication skills that should be used will be completed and forwarded to Ann Arbor. A HBC or another qualified health behaviorist will attend the first P2P visit (immediately following the first SMA) and will complete a fidelity assessment checklist. Additionally, they will provide feedback to the P2P facilitator immediately following the session. This feedback will be documented and shared with the Ann Arbor study team. An assessor will continue to attend drop-in sessions, completing fidelity assessments and providing feedback, until he/she feels the P2P facilitator is ready to continue without assistance. Then the fidelity assessments will be completed approximately every 3rd drop-in session for the remainder of the study. Additionally, the P2P facilitators will be asked to complete self-assessment checklists after each session which will be forwarded to Ann Arbor.

Process and Content Assessments of SMAs. A fidelity checklist of key content areas to cover and communication skills that should be used will be completed and forwarded to Ann Arbor. The intention of this assessment is for us to keep track of what is being covered during the SMAs, but we will not provide feedback to the facilitators. The goal is for the local sites to maintain local control over the content of their SMAs. The HBC or RC will attend all sessions of first and last SMA cohorts during the study period (and one in the middle if possible) and any cohorts following a significant change in SMA curriculum/protocol. A SMA facilitator will be asked to conduct a self-assessment at all sessions, which are also to be forwarded to Ann Arbor.

Aim 3: Staff interviews will be used to identify recommendations and develop a tool-kit for facilitating widespread dissemination efforts, and to contribute to the implementation science literature. The evaluation will include semi-structured interviews with five to eight key informants at the participating sites, including the director of primary care, clinicians participating in the SMAs, P2P group facilitators, and other key staff involved in diabetes patient care (e.g., nurses, dieticians, pharmacists). During the start-up period of this project, key stakeholders helped identify a subset of CFIR constructs that are likely to play a role in the effectiveness of the P2P program, such as: relative advantage, adaptability, complexity, and cost (intervention characteristics); patient needs and resources, external policies and incentives (outer setting); networks and communications, relative priority, goals and feedback, leadership engagement, available resources (inner setting); knowledge and beliefs (characteristics of individuals); and planning and engaging (process). These relevant constructs will be used to develop the semi-structured interview guides and to deductively code the interview responses. Interviews will be audiotaped and transcribed. Seven to ten months and eighteen months to two years following implementation of the SMA + P2P program at the participating sites, we will use this data collection procedure for collecting data on CFIR constructs from staff at the participating sites.

Additionally, in Ann Arbor, semi-structured interviews, meeting observations, and SMA observations will be conducted to further evaluate clinical efforts to sustain SMAs. The evaluation will include all members of teamlets involved in upcoming SMAs. The interviews will be audiotaped and transcribed. Teamlet planning meetings and SMAs will be observed by two

members of the Ann Arbor study team, who will take detailed notes. The notes from the SMA observations will not include any patient data, but will rather focus on how the SMA is structured and how the facilitators run the session.

In addition, we will conduct semi-structured interviews with a random sample of patients invited to participate in SMAs or SMAs + P2P, to better understand their experiences with the program (above and beyond their satisfaction with the program, determined as part of Aim 4). We will purposefully sample up to 140 Veterans, approximately 15-20 at each site (including of the four clinics within the Palo Alto site), approximately 12 months after enrollment, stratified into three groups according to level of participation in the intervention: low participation (began the intervention but completed fewer than 25% of weekly phone calls/group sessions in 12 months of program participation); moderate participation (completed approximately 50% of weekly phone calls/group sessions); and significant participation (completed greater than 75% of weekly phone calls/group sessions). By stratifying according to level of participation, we hope to understand both the barriers and facilitators patients experience in participating in the program. For the declined participation group, the RC at each site will ask patients who are contacted but do not enroll if they are willing to answer a few questions. These questions will be asked by the RC by phone at the time the patient declines participation in the SMA program. These questions will also be asked of those who participate in SMAs and are offered P2P as an optional add on but decline. The RC will ask these in person whenever possible; otherwise the RC will do this by phone. Those who agree to this short (expected to take less than 5 minutes) questionnaire will be asked questions about demographics, diabetes management and service utilization. The responses will be entered into a database, but there will be no patient identifiers. Interviews for the remaining groups will be conducted by telephone by Ann Arbor study staff and will last about 20 minutes. These interviews will be audio-recorded for transcription and analysis. We will continue to sample and interview patients until additional interviews no longer identify new themes in the areas of inquiry.

Analysis of the qualitative data from the formative evaluations will begin with a deductive approach to coding interview data according to CFIR constructs. Once the data have been organized by constructs, an ordinal value (-2, -1, 0, 1, or 2) will be assigned to each construct at each site. These values represent the perceived magnitude and “role” of each construct in the implementation of the program—e.g., -2 for the construct of “relative priority” means there are a number of other high priority clinical programs competing for resources/attention, +2 means the proposed program has a high priority compared to other programs based on explicit facility goals related to improving the care of patients with diabetes. The data will also be coded inductively, to identify themes or issues not captured by the CFIR constructs that may deserve attention during the implementation process. In the post-implementation evaluation these data will then be used to construct a matrix for identifying potential correlations between each construct and program outcomes. Strong correlations will then form the basis of specific recommendations for program dissemination.

Table 4 provides an example of what the matrix might look like for analyzing the staff interview data. Constructs A and B do not appear to be correlated to program outcomes, in that there is no orderly progression from low to high magnitude of the construct, consistent with the progression from small to large decrease in HbA1c. In contrast, constructs C and D do show a correlation, suggesting that these constructs might be important factors affecting successful implementation of the program. Thus, these findings can be used to develop recommendations for future efforts to disseminate the program, depending on what these factors are, and how they are manifested in the individual sites. We have used this rating process successfully to identify those constructs that appear to be most closely correlated with intervention outcomes in four different VA QUERI implementation studies, including an evaluation of VHA’s specialty care initiatives (E-consults and SCAN-ECHO). The process provides a more systematic means of linking constructs to implementation success than simply organizing qualitative data according to themes.

Table 4: Example Findings from Qualitative Analyses of Staff Interviews

	Sites (in order from least to biggest decrease in HbA1c)			
Co	**1**	**2**	**3**	**4**
A	-2	+	0	+
B	+	+	0	+
C	-1	-2	0	+
D	-2	0	+	+

Aim 4 (Obtain data throughout implementation on the staff effort required, to be used for calculating the costs of the program): Costs will be assessed from the VA perspective and will focus on the direct costs of the P2P program itself. We will ask the facilitators to record the number of group visits and duration of each, and the time spent in training and pre-visit preparation.

5.6.2 Sample Size and Power Calculations

We chose five VA health systems (8 sites, as one healthy system will implement the program in 4 separate sites within the system) in which to implement SMAs + P2P based on our estimation of feasibility of implementation, given budget and time constraints. This number of health systems should also provide some variability in terms of the CFIR constructs (especially implementation context), which is important for investigating the role of these constructs in implementation success. We want to ensure that the study has a sample size sufficient to detect a clinically meaningful decline in A1c of 0.5% or a SBP decline of 5mm Hg between SMA and SMA+P2P. Based on discussions with clinical managers at a number of sites, both in relation to this project and others, they would be unlikely to undertake an addition of a new clinical management strategy unless it offered a benefit of this magnitude.

The clustering induced by the treatment in small groups requires that we account for the intra-class correlation within clusters in our sample size calculation. An increasing number of publications have started to provide estimates of ICCs from practice-based interventions.[82 83 84 85 86] However, there are not good sources for estimates of ICCs of clinical intermediate outcomes induced by shared medical appointments. In a previous RCT conducted by us of P2P alone, which given the intimate nature of the pairing may represent an upper limit of induced correlation that might be found in a larger SMA, we found that the ICC was estimated at 0.10 but it was not significantly different from 0. Thus we used a range of 0 to 0.10 for the estimate of ICC of the outcome a1c or SBP measurement.

We present sample size calculations using Satterthwaite's approximate F test using modified degrees of freedom rather than a t-test to calculate the power for trials and the number of clusters and cluster sizes required for the difference of means in the presence of clustering or differential clustering effects between study arms as described by Roberts (2005) and implemented by Batistatou and Roberts (2011). We estimate that we can conduct 10 to 16 SMA groups per site (equally distributed between SMA and SMA+P2P) with 8-14 people per group. At our low estimate of 10 SMA groups per site, we can detect an effect size of 0.5% decline in A1c with a power of 0.8 for all but the lowest number of participants per group (10) and highest ICC (0.1).

For the comparison of both SMA groups to inactive control we must take into account the differential ICC between groups as the inactive controls will have no clustering induced by the treatment and therefore will have an ICC of 0. We continue to assume a worst case scenario of an ICC of 0.10 in the intervention group. In this case we examine our ability to detect a difference of 5mm Hg in blood pressure between SMA groups and the inactive controls.

The standard deviation of a decline in A1c was estimated to be 1.45 from this same RCT mentioned in the paragraph above. The estimate of the standard error of the change in BP was estimated from a database of actual BPs obtained in routine clinical practice for 24,000 patients with diabetes and hypertension in one large service network in the VA over a 24 month period in FY 2004-2005. It depends on both the variation in BP change at the person level and variability within person between measurements. Increasing numbers of measurements in the 6 month window decreases the within person component of variance. Using the proposed 6 month pre- and post-intervention windows on either side of a 12-month intervention period we estimated the standard error for the change in blood pressure as 17 mmHg for the mean of 3 BP measurements that was observed in the sample for each of the pre and post periods.

Again, we assume that we can conduct 10 to 16 SMA groups per site (equally distributed between SMA and SMA+P2P) with 8-14 people per group. At the maximum, this would give us 1,568 people in active treatment and an equal number of inactive controls. At the minimum, this would give us 560 people in active treatment and an equal number of inactive controls. In this scenario, at our low estimate of 10 SMA groups per site, we can detect an effect size of 5mm decline in SBP with a power of 0.8 across all our ranges of group size and ICC. In this scenario, we also have a power at 0.8 at all estimated ICCs to detect a 0.5% difference in A1c between the active treatment groups and controls.

Table 5 shows a snapshot of the number of eligible patients per site. Across all sites, we will recruit between 560 and 1,568 active treatment patients and an equal number of inactive controls.

Table 5: Number of Patients with Diabetes* with qualifying A1c, and Number of These Patients with and without Serious Mental Illness (SMI) or Substance Use Disorder (SUD) and with SBP>140**

Site	No. of Diabetes Patients	No. of Diabetes Patients without SMI or SUD	No. of Diabetes Patients with Qualifying A1c**	No. with Mean SBP>140 in Past 6 months
West Haven (Firm A)	3,748	306	397	187
Providence	5,466	636	794	105
Palo Alto	3,877	404	534	110
Livermore	1,212	156	168	88
Monterey	3,736	298	381	160
Sacramento	5,847	858	1,045	210
Ann Arbor	11,020	2,064	2,576	955

*Source: VHA CWD (last updated 2015).

**Patients less than 70 years old with A1c>7.5, for patients age 70 or above Ac1>8.0

5.7 Withdrawal of Subjects

The interventions (SMAs and P2P) are usual care. Only the surveys, collection of medical record data, and interviews are research. Patients can elect to withdraw from the study and this does not change the usual care intervention in any way.

6.0 Privacy and Confidentiality

Throughout the study, IRB and HIPAA guidelines will be followed to ensure the privacy and integrity of the information we collect. To minimize the risk of a breach of confidentiality, we will perform the following steps. First, as soon as the cohort is defined by the data manager, each patient in the cohort will be assigned a unique study ID. All electronic data, including audio recordings, will be stored in an access-restricted folder on the HSR&D drive, which resides on the OI&T server behind the VA firewall. All identifying data (e.g., names of other patients, providers, facilities) will be removed from transcripts of the audiofiles during the transcription process.

In addition to transcription by study team members, audio files may also be transcribed by approved staff from the VA Salt Lake City (VASLC). The VASLC has a Centralized Transcription Service Center available to VA sites and monitored by their own IRB. The audio recordings to be transcribed by VASLC staff will be labeled by the subject's study ID number and saved behind the VA Firewall in the study's secure shared project folder on Ann Arbor VA research drive. The VASLC transcription staff will be given access to the SLC Transcription sub-folder within the secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview and save the completed transcript in the sub-folder using the same study ID number. No data (audio files, in process transcripts, or completed transcripts) will leave the Ann Arbor VA secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

At the study's conclusion, all personally identifying information (PII) will be moved to an access restricted folder on the Ann Arbor VA OI&T network, accessible only to the HSR&D data manager. Members of the study team will no longer have access to these data. Data will be destroyed by the data manager 6 years following the end of the fiscal year after completion of the research project. All research data will be presented in aggregate form only. The data manager will also be responsible for creating analytic datasets for statisticians and investigators; these datasets will be de-identified per HIPAA guidelines. Furthermore, study staff members sign a pledge of confidentiality and understand that breach of confidentiality is grounds for dismissal. Study staff members are required to complete annual training on privacy and HIPAA, as well as biannual training on human subjects protection. Patient HIPAA authorizations will be maintained in a locked filing cabinet at the patient's study site in a restricted access office. Paper surveys (identified by study ID only) will be mailed to Ann Arbor and be maintained in a locked filing cabinet in a restricted access office.

The research team will conduct patient recruitment and interviews in/from private offices. P2P and SMA visits will be held in conference rooms. Ground rules, specifically regarding confidentiality, will be discussed with the group at the first visit.

All research findings will be presented in aggregate only.

When study personnel are removed from the research team, their permissions to access the study files on the VA server will be removed.

In the event of a breach of confidentiality, the ISO and Privacy Officer will be notified within one hour of discovery of the improper use or disclosure.

7.0 Communication Plan

The project manager, Jennifer Burgess, will verify VA Central IRB approval and the local VA facility

approval before study recruitment can begin at that site. There are no facilities where the research is being conducted but the facility is not engaged in research. At the end of any individual site's participation in this research, the CIRB local facility director and LSI will be notified by an email from an Ann Arbor study investigator.

As P2P is being implemented, the research team will conduct regular conference calls (approximately biweekly) with the implementation team at each site, to track progress and address any questions that arise regarding implementation. These biweekly calls will continue for the first few months of patient enrollment and will decrease in frequency as appropriate, depending on the challenges (or lack thereof) associated with implementation. The research team will visit the sites in year 2 (approximately six months following implementation), to conduct an on-site assessment of program status and to problem-solve any issues that have arisen. These regular calls and site visits will be used as opportunities to ensure the study is conducted according to the IRB-approved protocol. These team calls will include discussion of any updates to the protocol, informed consent processes, and/or HIPAA authorizations. Minutes for these meetings, and any updated documentation, will be posted on the study SharePoint site, to which all study staff have access.

Because this study has no medical intervention, and researchers have no contact with the participants, we do not expect any reportable medical adverse events, and other reportable events are unlikely. However, in the event that there is a breach of confidentiality, protocol deviation, or another UAP, reports will be made by the study team member who discovers the event to the VA Central IRB (CIRB). If the report is not made by the Ann Arbor project manager, she should be notified at the same time a report is made. Any UAPs meeting the definitions of serious and related to the research will be reported within 5 business days of discovery to the CIRB secure SharePoint site dedicated to this purpose. UAPs that do not meet these definitions will be reported to the Ann Arbor project manager as they are discovered, and will be reported to the CIRB in summary at the time of continuing review/project closure. Protocol deviations/violations that are likely to substantially adversely affect 1) the rights, safety, or welfare of a participant; 2) a participant's willingness to continue participation; or 3) the integrity of the research data, including VA information security requirements will all be reported within 5 working days of being made aware of the occurrence. These will be reported through the secure SharePoint site dedicated to this purpose. Any UAPs and/or protocol deviations will be discussed at the regular study conference calls, and will be posted on the study SharePoint site.

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