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Participatory design of electronic health record tools for problem solving therapy

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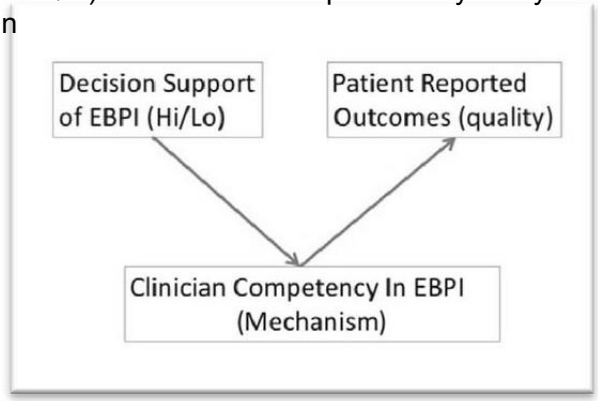
SPECIFIC AIMS. Although evidence-based psychosocial interventions (EBPIs) are a preferred treatment option by vulnerable populations, they are rarely available in community primary care settings and when available, are often delivered with poor fidelity.[1] High quality delivery of evidence-based psychosocial interventions (EBPIs) in primary care medicine is a function of many variables, including clinician training (UWAC Study 1) and usability of the intervention. Several studies find that for EBPIs to be delivered with sustained quality, on-going supervision and guidance is critical (this study's focus).[2-5] While the availability of clinicians trained in EBPIs is scarce, the availability to supervisors trained in EBPIs is even more limited. Given the ubiquity of electronic health records, automated decision support tools and feedback systems[6] have been found to be effective in supporting sustained quality EBPIs[7], but in practice have had mixed success on outcomes[8,9] such that they may actually hinder clinical care[10,11] and are often ignored by clinicians.[12] In a report by the Agency for Healthcare Research and Quality, a significant barrier to the use of decision support tools is that these tools have not been developed with input from the clinician or in consideration of their work environment. Using the Center's Discover, Design, Build, Test (DDBT) framework, we will work with clinicians from 13 BHIP sites to create a clinical decision tool that addresses the common decisional dilemmas clinicians face when implementing EBPIs. We hypothesize that creating tools to support EBPIs will result in improved clinician competency and sustained skill (target) to EBPIs, compared to clinicians without these supports, resulting in better patient outcomes (mediation, Fig. 1). The specific aims of this study are:

Aim 1: Discover Phase (6 months). Using PAR informed user-centered design methods we will interview clinicians in primary care about challenges they face in the delivery of two EBPIs, Behavioral Activation and Problem Solving Treatment, observe them delivering these EBPIs, and receiving feedback on cases from experts in these EBPIs. This process will help us to identify the common decisional dilemma's clinician's face in delivering EBPIs, their preferences for expert guidance strategies, and how decision support tools could be embedded into clinic workflow to *reduce obstacles* and *enhance the delivery* of EBPIs. Contribution to Center: Data from this phase will be used to inform the Typology of EBPI Targets.

Aim 2: Design/Build Phase (6 months). Based on information obtained in the discover phase, we will engage in a rapid cycle iterative prototype development and testing of decision support tools to support PST-PC will be carried out using user-centered design (UCD). The build of these tools will include the development of prototypes for user testing and refinement with input from care managers across the 13 BHIP sites. Contribution to the Center. Data from this phase will be used to inform the Matrix of EBPI Modifications.

Aim 3: **Test Phase (18 months)** In the second to third year of the proposed project we will test the decision-support tools in a small pilot trial with six providers and thirty patients randomized to the use of the decision support tools. **H1**: Clinicians with access to decision tools will report better acceptability, usability, and less burden when using PST-PC than clinicians without the tools (Acceptability of Intervention Measure, Intervention Appropriateness Measure, Feasibility Of Intervention Measure, System Usability, Modified Self-Efficacy Scale, and User Burden Scales). **H2:** Clinicians randomized to decision support tools will more competently deliver EBPI elements (fewer number of sessions rated below standard by experts and more time to first session rated below standard after certification) than clinicians randomized to unsupported EBPI. **H3:** Patients treated by clinicians with access to decision tools will have better patient-reported outcomes than patients treated by clinicians without access to these tools as assessed with functional disability (Sheehan Disability Scale) and change in depression symptoms over time (PHQ-9). We will conduct preliminary analysis to determine if change in clinical outcomes is mediated by clinician adherence to protocol.



Exploratory Aim: Use the data collected during Aims 1-3 to demonstrate proof-of-concept work on using machine learning and natural language processing to automate and potentially personalize decision support tools.

This study addresses IOM Recommendation 6-3: Conduct research to design and evaluate strategies that can influence the quality of psychosocial interventions, and NIMH SP 4.3 Develop innovative service delivery models to improve dramatically the outcomes of mental health services received in diverse communities and populations

SIGNIFICANCE

1Evidence-Based Depression Care is Lacking Among Vulnerable Populations. Depressive disorders are among the leading causes of disability, for which many effective treatments exist. Patients from low income and/or racial/ethnic minority populations are less likely to receive care for this prevalent and debilitating disorder.[13,14] Our research group has shown that, in contrast to patients with private insurance, patients with Medicaid insurance have poor quality of depression care, which highlights a wide disparity in care delivery related to income and insurance source.[15,16] Low-income populations with Medicaid insurance also have a higher rate of mood disorders.[17] Up to half of patients with depression receive no evaluation or treatment for mental health issues and fewer than one-quarter who are evaluated and found to be depressed receive any mental health care.[18] The increase in delivery of evidence-based depression care to vulnerable populations is a public health priority as described by the Healthy People 2020 objective for the mental health topic (MDMH 9 and 9.2 – increasing the proportion of adults with major depressive disorder who receive treatment). Delivery of effective depression treatments to vulnerable populations is a major opportunity to reduce the burden of depression among the US population.[19]

2Collaborative Care has demonstrated efficacy, but the sustained delivery of EBPIs is low. Collaborative Care (CC) is an effective integrated care model with a strong evidence base for vulnerable populations.[20,21] CC includes the use of EBPIs such as Problem Solving Treatment for primary care (PST-PC)[22]. Because of its evidence base, the CC model is now the subject of substantial dissemination and implementation support through state, regional and national efforts, including the implementation of CC-specific billing codes for Medicare insurance recipients. Central to the CC model is the "care manager," who provides many of the core features of CC, including patient assessment, education, medication management, and psychosocial interventions (BA and PST-PC).[23-25] Although many organizations elect to train care managers in PST-PC, the use of antidepressant medications is the predominant mode of treatment in settings using this model of care, despite patient preferences for EBPIs.[25,26] Part of the challenge in the limited availability of EBPIs in CC is the lack of on-going decision support to care managers in the use of EBPIs. An integral part of the CC model is on-going decision support by psychiatrists or other prescribing professionals, who are typically not trained in EBPIs. Thus, care managers who are trained by experts in EBPIs, loose access to critical support in treatments that patients prefer.

3Clinical Decision Support Systems: Application to EBPIs. Although access to expert opinion when delivering EBPIs results in sustained delivery of high quality care[3,27], the availability of this expertise is limited and costly. To mitigate this problem, recent efforts have turned out the use of Clinical Decision Support Systems (CDSS), data analytic tools embedded in electronic health records that compile patient information, synthesize and visualizes the information to support clinicians in making treatment decisions. Preliminary evidence suggests that these tools can be effective in supporting the use of EBPIs[6,7] in clinical practices, however, clinician uptake of these tools is low, owing to perceived burden and poor clinical utility.[9,11,12]. According to AHRQ's 2010 report on Clinical Decision Supports[28], poor uptake is due to developers lack of familiarity with clinician work flows and limited clinician involvement in their creation. Many CDSSs are tied to treatment algorithms and are largely alert sed systems, meaning the decision support tool is activated with a patient is not responding to care. Few incorporate complex decision rules, and in our experience, do not provide the type of support care managers seek when implementing EBPIs. As was discussed in UWAC Study 2, clinicians face many challenges in the implementation of EBPIs. Challenges relevant to sustained competency are memorability of the EBPI elements and ability to apply them with minimal guidance, ease of recovery from misapplications of EBPI content, amount of cognitive load the EBPI places on the clinician, in the form of task structure and number of steps required to implement it in a given session and across sessions, and flexibility of the EBPI to be implemented in different contexts.[29] For CDSS tools to be usable and effective for care managers delivering EBPIs in busy primary care clinics, they must address the decisional dilemma's that care managers feel they need the most support.

#Participant Action Research informed User-centered design (UCD) as a solution to creating a usable CDSS for EBPIs. Working from the AHRQ recommendations, we will employ our Discover, Design/Build and Teat (DDBT) Framework to create a CDSS to support sustained competency in the delivery of EBPIs (see **Methods Core** for more detailed explanation of the framework). Working with care managers from 13 primary care clinics that uses CC as their integrated care model, we will determine from care managers when they feel the need the most support in providing EBPIs, how that support should look, and how support tools would be integrated into the Care Management Tracking System (CMTS) a shared electronic health record that supports CC. Our intention is to develop a CDSS that is user friendly and effective, and is more than an alert system, but provides guidance on common decisional dilemma's care managers face.

The purpose of this study is to test whether an EBPI CDSS created with UCD-based clinician input throughout the process will result in a usable decision support tool, whether this tool will be (1) used by care managers, (2) improves the sustained EBPI competency, and (3) results in better patient outcomes through enhanced clinician ability to adhere to, and competently deliver, treatment (target mechanism of action; Fig. 1).

Impact. Decision support and access to expert opinion on the delivery of EBPIs is limited and significantly impacts the quality of care[3]. This problem is recognized by many large health care systems who want to support the use of EBPIs, for instance, the Veteran's Hospital Administration has invested in EBPIs, and have developed cost–efficient on-going support systems called communities of practice[30], these communities are hard to create and sustain[31], and do not guarantee against drift in clinician competencies. CDSS embedded in electronic health records appears the be the most efficient and sustainable method, but they are limited in the type of guidance they can provide and in their usability. The results from this pilot has the potential to make an impact on implementation and intervention science. By creating a decision support system that is informed by clinician input, we have the potential to impact the quality of EBPI care. This study is also part of the larger Center mission to begin creating a Typology of EBPI Targets for future intervention modification and potentially novel psychosocial interventions. It will also serve to inform the Center mission of identifying best methodology for EBPI modification (Matrix of EBPI Modifications).

INNOVATION

The main innovation from this project will be the implementation of UCD methods to create a clinical decision support system for sustained EBPI quality. The development of CDSS that clinicians will find useful (rather than burdensome), would be an innovation in the field; however, given the use of PAR and UCD in the development of this system, we may discover that the electronic health record is not the best way to provide the support clinicians want or need. Although we have planned this project to create a CDSS for an existing electronic health record, we may find that clinicians will uncover a unique process for clinical decision support.

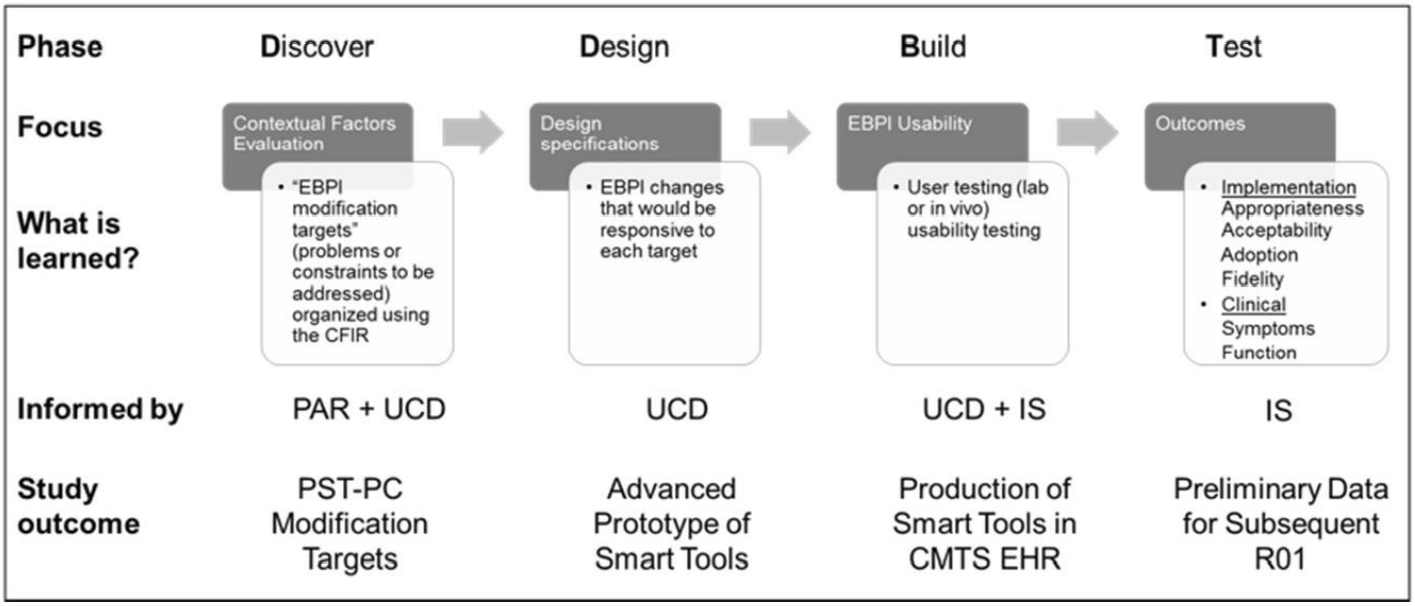
APPROACH

Team Expertise. The proposed research project brings together a novel team of investigators with complementary skills including primary care mental health integration and PAR (Bennett), and EBPIs for Collaborative Care (Raue). Dr. Munson (UCD expert) will provide our design/build incubator expertise from the Center Methods Core. Dr. Bennett's decades-long work in the implementation of mental health services in real-life primary care settings serving vulnerable populations informs the view that building EHR tools focusing on the support of EBPI delivery will result in greater uptake and resulting improved patient outcomes.[32-34] Dr. Raue is the lead trainer of EBPIs for the UW Aims Center and brings >10 years of experience working with clinicians in primary care on this EBPI.[5]

Problem-Solving Therapy for Primary Care (PST-PC). We will focus on developing support tools for PST-PC because it is a common and evidence based depression intervention in primary care. Currently, no decision support tools for PST-PC post certification have been created, and thus, we have the unique opportunity to build on the existing decision support literature to tools informed by clinician input. Commonly, PST-PC support and access to experts ends once the clinician has been certified. Although certified clinicians may seek support as needed from the AIMS Center, we have yet to have anyone do so post-certification.

Conceptual Frameworks. We drew upon several conceptual frameworks to structure the planned research project. First, The "Dynamic Systems Framework" for implementation and sustainability of interventions into real life contexts is a key model for the current study and underlies our proposed mechanism of action (Figure1).[38] This implementation science (IS) framework emphasizes the need for interventions, including EBPIs, to adapt to particular clinical contexts in order to be effective and sustained. Central to this model is the view that the better matched to the needs of the setting, the better the implementation, and the greater the effectiveness of the intervention will be.

Figure 2. DBBT Model for Research Study.



Study Setting. The study will be carried out within the Behavioral Health Integration Program (BHIP) of the primary care network of the University of Washington Health System. This network provides care to approximately 250,000 unique patients annually across 13 sites with a majority from vulnerable populations, including 60% Medicare or Medicaid insured, and a high proportion of patients from racial/ethnic minority populations. This is a high-need and high-cost population, with 38,000 visits annually associated with a diagnosis of depression. These multi-disciplinary sites deliver general primary care and utilize an evidence-based model of the team-based collaborative care system for the BHIP program. [22,39-43] BHIP has been in place since 2011 with over three thousand patients participating in treatment.

Study Overview. To accomplish the aims of the study, this project will be broken down into 3 phases that are tied to each aim of the study: The Discover Phase, (Aim 1), The Design and Build Phase (Aim 2), and the Test Phase (Aim 3; see Fig.1). For phases 1 and 2, we will identify 15 representative clinicians working in BHIP clinics partnering. For phase 3, we will work with 6 care managers and 30 patient participants, ≥18 years old with a PHQ9 of 10-20. The study will be conducted over a 2.5-year period during Y02 through Y04. Steps 1 and 2 will be conducted in the first 12 months of the study and Step 3 in the last 18 months (See timeline).

Phase 1 / Aim 1: Discover (6 months). The purpose of this phase is to uncover common decisional dilemmas and challenges in the sustained use of PST-PC. We will have the advantage of Study 2's *Discover* phase data that will have already identified modification targets of key components of PST-PC, including identification of user needs and user testing of PST-PC. We will replicate the user needs assessment and user testing process as is described in Study 2, with 15 representative clinicians to confirm that the information collected in rural FQHCs generalizes to BHIP clinics. We will need to conduct a new contextual evaluation and create an As-Is work-flow diagram focused on how clinicians interact with CMTS. This data will be useful in informing how CMTS can be used to support quality implementation of PST-PC elements.

Usability testing. Usability testing will be carried out using a "discounted usability engineering" approach.[44] Observation of PST-PC from UWAC Study 2 will be used for PST-PC usability, but we will conduct usability

testing with the current CMTS care management system. This will be carried out using a range of typical case scenarios. The design team will monitor clinician interaction with CMTS while using a Think-Aloud protocol to describe their experiences. Patient use testing will involve reviews of current patient care materials and workflows. These sessions typically will last one hour each. These usability testing sessions will be recorded for later reference.

Data synthesis and confirmation of findings. The Methods Core will conduct this analysis, through the creation of a **matrix of decisional dilemmas and expert advice**. The cells of this matrix will be populated with common decisional dilemma's clinicians face in implementing PST-PC, and accompanying expert advice. This matrix will be shared with the CPB, EAB, (see **Admin Core**) and the EBPI experts in the **Methods Core** (Aisenberg, Areán and Kaysen). For the CMTS based tool, an **as-Is workflow diagram** of challenges and opportunities for use of CMTS will be created to allow for a pictorial representation of CMTS use in the context of the care managers' day. As an example, we will need to determine whether care mangers use the CMTS before each patient, after each patient, or at different times of day (morning or at the end of day). This will determine if a CDSS embedded into the electronic health records would provide timely information. The generated matrix and diagrams will be reviewed by the 15 clinicians for confirmation of accuracy. Finally, data collected on the implementation challenges of PST-PC through these sources will be given to the Methods Core directors for use in the development of the Typology of EBPI Targets**.**

Phase 2 / Aim 2: Design and Build (6 months). The next step in the process will be to create initial prototypes of decision support tools, based on the findings in the *Discover* phase. The Methods Core designer, working in consultation with Drs. Munson, will create 3-5 initial prototypes. The process, described in the **Methods Core**, involves the same clinicians who participated in the *Discover* phase and has them work with the designer to create initial prototypes. If the clinicians recommend the creation of CDSS for the electronic health record, prototypes will be embedded in a mockup of the CMTS, which will then be uploaded into the remote prototyping portal for care managers to interact with and give further feedback for additional modification. As they interact with the prototype, they will engage in a think-aloud process and will assess each prototype based on the System Usability Scale (SUS; see **Methods Core** for description). This rapid iteration will end when we create a prototype with a SUS score of 80 or greater. Information from the think-aloud practice will be used to inform the prototype modifications.[44,45] Periodically there will be meetings with the CMTS developer group to ensure that aspects of the prototypes under development are technically feasible within the CMTS system and alternative approaches will be elicited to ensure that the prototypes are headed in a direction that can realistically be built into the EHR. Should the Discover phase reveal that a CDSS embedded in electronic health records is not the optimal method for decision support, prototypes of potential solutions will follow a similar process as described above.

Once a set of sufficiently advanced prototypes have been developed, we will move to the *Build* phase of the project. If the solution is a CDSS, at this point the CMTS developer team will be brought into the design process and the tools and desired functionalities will be described until it is clear to all parties. Feedback on the capacity of the CMTS system to accommodate specific designs will be reviewed. When an adequate agreement on the nature of the designs is achieved, the CMTS development team will build the proposed tools in a development environment. Whatever the solution is, a final prototype will undergo initial feasibility evaluation in pilot field deployments with Dr. Raue. He will test the system with one or two clinicians in the BHIP program using the prototype with test patient scenarios. Once we have completed the design of PST-PC support system so that it (1) meets needs of its clinicians (i.e., is useful), and (2) is easy to use and understand (i.e., is usable), we will move to the *Test* phase of this study. Data from this process will be used to inform the Matrix of EBPI Modifications.

Phase 3 / Aim 3: Test Phase (18 months). We will conduct a pilot study comparing clinicians randomized to decision support to clinicians randomized to no support. Six care managers who will each see 30 patients will be identified and complete informed consent. Clinicians at all 13 BHIP sites will be offered the opportunity to participate in the trial.

Patient eligibility. Patient participants will be identified through clinic electronic health records. Participants must be 18 years old or older and suffering from depression (score between 10 and 20 on the PHQ-9). Methods Core research assistants will contact potentially eligible patients to conduct a preliminary screening for eligibility, provide a brief description of the study, and obtain informed consent.

Clinician recruitment and training. Clinicians will be incentivized to participate in the trial by receiving free training in the PST-PC EBPI, culminating in a certification that can be used for career advancement for these clinical social workers. The training in this EBPI is under consideration to be delivered by the AIMS Center to all clinicians at the BHIP sites within the next several years. The results of the trial will be used to guide the remaining trainings. Six care managers in the BHIP program will be randomized to usual training or training with the use of the smart tools within the CMTS system. We will follow the PST-PC training protocol developed by the AIMS Center, which includes training in basic brief treatment skills, therapeutic elements of the intervention and therapy process. This is followed by simulated case training. Clinicians must pass an introductory session, middle and last session before deploying the intervention with patients. In PST-PC this is determined by obtaining a score of 3 ("satisfactory") or greater on the PST Adherence Scales, which utilizes a Likert-type rating scale (0 = *very poor*, 5 = *very good*). Dr. Raue will provide clinician training in PST-PC to all clinicians. Clinicians randomized to the decision support condition will also receive a training manual and in-person training in the use of these tools prior to the initiation of PST-PC training. Once a care manager in either arm of the study is certified to provide PST-PC, they will proceed to the four-month fidelity phase of the trial. Five active patients identified from the existing site registry of each care manager will receive treatment during the trial (30 total).

Clinician Data Collection. Three types of data will be collected from clinicians: clinician assessment of appropriateness and acceptability, intervention usability, and clinician ability to learn the intervention and maintain competency. To measure **decision support usability**, clinicians will complete the Acceptability of Intervention Measure, Intervention Appropriateness Measure, Feasibility Of Intervention Measure, System Usability, Modified Self-Efficacy Scale, and User Burden Scales), which are core measures for this Center. These scales will be collected through the UWAC data portal after clinicians have completed their intervention with 5 patients. To measure **sustained competency,** clinicians will collect audio recordings of patient sessions for review by experts. Dr. Raue will conduct these reviews using the PST Therapist Adherence Scales. Sustained competency will be defined by (1) time to first session rated below average after certification in PST-PC and (2) number of sessions rated as <3 ("satisfactory"). Clinicians will not be given feedback on session performance.

Patient data collection. We will use the UWAC data portal[49] designed specifically for research on mobile depression interventions to confirm eligibility, complete the consent process, and conduct baseline and outcomes assessment. Patient data will be collect before treatment initiation and after treatment ends. Patients will complete a demographic survey to determine gender, age, ethnicity, income categories, and educational level. Patients will complete a series of brief clinical measures to determine the presence of a depressive disorder and if there are any important comorbidities. The *Sheehan Disability Scale(SDS)* [50,51] is a brief analog too assess functioning in work, social, and health domains, using visual-spatial, numeric and verbal anchors. The scale has been validated in medical and psychiatric populations with a variety of psychiatric diagnoses.[50,51]**.** The *9-item Patient Health Questionnaire*[52] *(*PHQ-9) consists of 9 DSM depression symptoms and one disability item. It has been found to have excellent sensitivity to change over time (sensitivity = .88, sensitivity = .80).[53]

Data Analysis. Aim 3 focuses on pilot feasibility data to inform a larger (future) clinical trial comparing decision support of PST-PC to no decision support. Thus, analyses do not focus on hypothesis-driven inferential statistics but on descriptive statistics, graphical summaries, and basic effect sizes. **H1: Usability.** Differences in clinician reported usability between the two clinician groups will be plotted using a dotplot and tested using a *t*-test using the SUS and UBS as dependent variables. **H2: Fidelity/Competence.** We will compare groups on the proportion of clinicians who reach certification (i.e. score of 3 or greater on treatment competence on at least two sessions). Between treatment differences will be tested with a 2-sample proportion test. (Future analyses with larger sample size will use a generalized linear mixed model approach to account for the nested data.)[54,55] **H3: Patient Reported Outcomes.** Histograms and kernel density estimates will be plotted by treatment condition to explore differences on depression outcomes (PHQ-9 total score) and overall daily functioning (SDS). Descriptive statistics (*M* and *SD*) of these outcomes will also be examined by clinician group, using Cohen's *d* as an effect size summary. A *t*-test will be used to examine treatment differences in these patient outcomes. Of ultimate interest is whether the modified treatment (i.e., decision-supported PST-PC vs. unsupported PST-PC) effects patient outcomes through enhanced usability and clinician fidelity. We will use graphical summaries of the data to explore the relationships that are consistent with mediation (e.g., correlation of usability with patient outcomes [b pathway], and treatment differences on patient outcomes with fidelity

partialed out [c' pathway']). The primary focus here is whether the data and relationships appear consistent with mediation, as opposed to a formal test, which will be dramatically under-powered.

The **Exploratory Aim** will use data collected from Aims 1-3 to inform hypotheses about how modern computational tools for written text and spoken language might further extend tools to support PST-PC. Conducting such analyses are beyond the scope of the current project, given the anticipated data quantities, but rather would be the focus of future research. Potential targets for machine learning and NLP could include: a) understanding mechanisms of decision-supported PST-PC via predicting change in PHQ9 from content of written notes, and b) using NLP to evaluate the quality of PST-PC from CMTS-based notes.

Power and Sample Size. Sample sizes for Aims 1 and 2 were based on estimates from the UCD literature on necessary number of participants to capture critical design information, where the recommendation is 5-10 end users. Aim 3 is focused on gathering information (feasibility, recruitment and retention rates, response and attrition rates, etc.) for a future R01 application. As such, the sample size was set primarily for practical reasons; rather, it used estimated effect sizes and was not driven by power to test hypotheses.