Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Grant Title: Effect of Patient Priorities Care Implementation in Older Veterans with Multiple Chronic Conditions (VA HSR IIR 20-079)

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Status: Approved

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Section Aa: Title & PI

A1. Main Title

IMPROVING CLINICAL OUTCOMES IN VA PRIMARY CARE THROUGH ADAPTATION OF THE PATIENT PRIORITIES CARE PROGRAM

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

None

A5. Funding Source:

Organization: VA HSR&D

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?

Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?

The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:

NCT04922320

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

As Veterans age, they must confront an increasing number and complexity of chronic conditions and disabilities. Nearly two-thirds (64.9%) of adults over age 65 live with multiple chronic conditions (MCC), and an estimated 171 million Americans will have MCC by 2030. The current approach to managing MCC, based on adherence to single-disease clinical practice guidelines (CPG) fails to provide optimal care for three key reasons. First, patients with MCCs are at increased risk of adverse outcomes from the application of multiple CPG, including drug-drug and drug-disease interactions and the harms of polypharmacy, and these outcomes may be of greater importance than the disease-specific outcomes that CPG often target. Second, CPG fail to focus on outcomes most important to older adults, including living independently in one's home, increasing physical function, and engaging in meaningful social relationships. Third, patients, caregivers and clinicians are burdened by the workload of multiple disease-specific interventions, and may wish to decrease this burden, particularly when the workload is not aligned with patients' goals. The situation demands a paradigm shift in decision-making that results in the provision of the appropriate amount of care to achieve what matters most for patients and their families.

Consistent with the priorities of VACO Geriatrics and Extended Care and VA Whole Health, this research aims to transform VA primary care into personalized patient-centered care whereby clinicians recommend primarily the care that achieves the priorities of older Veterans with MCC. To meet this need, we developed Patient Priorities Care (PPC), a process that aligns treatment decisions with patient priorities rather than disease guidelines. We initiated PPC outside VA as a transformative innovation for routine outpatient visits, and conducted a pilot study within VA. PPC is a structured process whereby a facilitator first guides patients to identify their priorities: a) their health outcome goals (what matters most and what they want to achieve from their care) and b) care preferences (what they are willing and able to do or receive). Second, patient priorities are communicated to clinicians by electronic health records (EHR). In the third step, clinicians collaborate with patients to align healthcare to meet patient priorities rather than disease endpoints. We have demonstrated feasibility and effectiveness of the PPC approach in a nonacademic private practice with 366 older adults with MCC, 10 primary care providers and 5 cardiologists. Compared to usual care (UC), patients reported greater reductions in treatment burden (β=-5.0; p=.01) and more deprescribing (Odds Ratio= 2.05 [1.43-2.95]). A subsequent VA geriatrics clinic pilot found that Veterans who received PPC (N=35) compared to UC (N=35) had fewer medications added (P=.05) and more home and community services aligned with

priorities (P=.03). These results suggest PPC is effective at reducing burdensome care (e.g., inappropriate meds) and innovative by focusing on care that achieves patient priorities rather than CPG.

Section D: Purpose and Objectives

Achieving patient priorities-aligned care for a larger population of older Veterans will require consistent implementation of the Patient Priorities Care program across a range of primary care clinics with variable baseline resources for and potential barriers to adopting this program. Implementation requires understanding of the policy, procedures, and structures needed to sustain PPC within VA. Therefore, we will conduct a hybrid design study of PPC in two VA primary care centers (Houston and West Haven) to 1) identify strategies to optimize implementation using a primary care-research partnership (formative assessment); 2) determine outcomes associated with PPC (effectiveness); and 3) measure the adoption, reach, and costs of the implementation (summative assessment).

Aim 1. Conduct a formative assessment of PPC implementation for Veterans with MCC. We will conduct semi-structured qualitative interviews with stakeholders, including leadership, clinician, and staff partners. We will use i-PARIHS formative evaluation framework to identify barriers and promoters of implementation of PPC within VA primary care, strategies for overcoming barriers and building on strengths, and modification of existing PPC tools to embed PPC into existing structures and workflow. Expected outcomes include recruitment of clinical champions, VA-specific modes of training primary care providers, PPC note templates for the EHR, and processes for PPC facilitator and clinician interactions.

Aim 2: Evaluate the effectiveness of PPC in a randomized controlled study at two VA primary care centers. Conduct a randomized clinical trial at the Houston, Texas, and West Haven, Connecticut primary care practices to determine if PPC results in care that reduces treatment burden and unnecessary medications, increases home and community services use, and aligns care with patient priorities compared with usual care.

Aim 3. Conduct a summative assessment of implementation outcomes of PPC in VA primary care Evaluate PPC implementation in primary care using Proctor's

implementation outcomes framework (i.e., acceptability, adoption, appropriateness, feasibility, fidelity, penetration, and activity cost accounting).

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:

Both

Age:

Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:

All Ethnicities

Primary Language:

English

Groups to be recruited will include:

Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Employees or lab personnel

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Aim 1: Employees within primary care will be specifically targeted for participation because the intent of Aim 1 is to understand the professional culture and community in which Aim 2 will be conducted. The participation of employees is necessary for the

conduct of Aim 1. To guard against any undue influence or coercion by the study on the administrating institutions employees, the informed consent process will emphasize the voluntary nature of the research. No potential subjects will be punished for non-participation and there will be no coercion or benefit for participation. The use of providers¿ descriptions of their workflow and experiences involves no more than minimal risk to the individuals in this study because it involves only a one-time interview. This activity does not involve procedures for which written consent is normally required outside of the research context. The interview asks non-invasive questions about routine workflow and communication. All providers will be assured that their participation is strictly voluntary. We will only identify individuals in the study by study number. Records linking the study number to the provider names will be kept in double locked storage.

Aim 2: To administer the intervention, we will recruit and consent VA primary care providers with panels of >10% older Veterans with MCC. For primary care providers willing to consent as study clinicians, they must have approval from local primary care leadership, and be willing to participate in PPC training activities and all PPC procedures. To guard against any undue influence or coercion by the study on the administrating institutions employees, all potential participants will be explicitly informed that participation in this study is entirely voluntary. At any time, healthcare providers can choose not to participate in the study. Healthcare providers may refuse to participate or withdraw at any time without jeopardy to their employment. Individuals will be given ample time to consider whether or not they would like to participate in the study.

Aim 3: For the vulnerable class of employee participants, all potential participants will be explicitly informed that participation in this study is entirely voluntary. At any time, healthcare providers can choose not to participate in the study. Healthcare providers may refuse to participate or withdraw at any time without jeopardy to their employment. Individuals will be given ample time to consider whether or not they would like to participate in the study.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

d) Questionnaire/survey/interview

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This is a multiple methods study that will use quantitative and qualitative methods to collect data needed to assess the effectiveness and implementation of Patient Priorities Care intervention at two VA primary care sites, MEDVAMC in Houston, Texas and VACT in West Haven, Connecticut. The West Haven site has obtained their own IRB approval from their local site.

Aim 1: We will perform a formative evaluation of implementation with telephone-based qualitative interviews with clinicians and stakeholders.

Aim 2: We will conduct a randomized clinical trial with older Veterans with multiple morbid conditions who will be assigned to either the Patient Priorities Care intervention or usual care.

Aim 3: We will perform a summative evaluation of implementation which will include

stakeholder interviews with clinicians, clinical staff, and patients following the conclusion of the study.

Inclusion Criteria:

Aim 1 Inclusion criteria: 1) Defined role in primary care at MEDVAMC or VACT (hospital and community-based) clinics (physicians, physician assistants, nurse practitioners, pharmacists, psychologists, nurses, case managers, social workers, clerks, dieticians, Whole Health staff, primary care leadership, primary care team leads, etc).

Aim 2 Inclusion criteria: 1) Veteran patients who have MCC from 2 VA facilities: a. MEDVAMC in Houston, TX b. VACT in West Haven, CT 2) age ≥ 65 years, 3) ≥2 encounters in prior 18 months, 4) ≥ 3 active health problems on active problem list or prescribed ≥10 medications.

Aim 3 Inclusion criteria: Consent in Aim 1 or Aim 2 and participation in the PPC intervention arm.

Exclusion Criteria:

Aim 1 Exclusion criteria: Non-VA clinicians

Aim 2 Exclusion criteria: 1) Non-Veteran patients, 2) nursing home resident, 3) end stage renal disease on dialysis 4) Documented current substance abuse 5) Currently in Hospice Care/palliative care 6) Active bipolar or psychotic disorder

Aim 3 Exclusion criteria: Non-VA clinicians, and patient participants enrolled in usual care.

F2. Procedure

Aim 1: Recruitment. We will conduct interviews with targeted VACT and MEDVAMC personnel. After receiving approval from the Primary Care Chief at the clinics of interest, we will contact potential participants via email. The email will specify the goals of the study, and will invite providers to participate in a one-time interview. In the email, we will provide an option to opt out of participation by replying to the email. If we do not receive an opt out return email within 10 days, we will contact the potential participants to invite their participation and schedule a telephone interview. Prior to a scheduled interview, participants will receive verbal description of the purpose, procedures, and

risks involved in this study. They will be told that interviews will be digitally recorded. Participants will be asked to verbally consent prior to the interview. The interviewer will obtain verbal consent prior to conducting interviews.

We will also purposively sample across the two targeted facilities to ensure representation of each facility in each category. We estimate that 12-18 stakeholder interviews will be conducted to achieve thematic saturation. Interview topics will vary by informant category. Given the focus on integration of PPC into VA primary care sites (and significant preliminary work engaging with patients to develop PPC), we will not enroll patients in Aim 1.

Interview Process. We will conduct all interviews by phone or videoconference. During the verbal consent process, we will request permission from participants to record and transcribe each interview. Using established VA processes, we will digitally record, transcribe and securely store interviews behind the VA firewall on the M Drive in a project subfolder. We will conduct 30-45 minute interviews at a time convenient to participants. The interview guide will be based on our interpretation of the i-PARIHS framework for implementing PPC in VA primary care.

Aim 2: We will recruit PCPs during Aim 1 activities as described above. We will approach interested PCPs to enroll them in the study. We will then identify eligible Veterans from participating PCP panels. We will use the local data warehouses to identify Veterans meeting eligibility criteria and then confirm eligibility by manual chart review and PCP assent. We will use the chart review tool (attached in Section S) to exclude for Veteran deceased status, living outside catchment area, hearing impairment, active substance abuse disorder, serious mental illness (bipolar, schizophrenia, schizoaffective disorder, psychotic spectrum disorder), active dementia, end stage renal disease on dialysis, nursing home or hospice care, and non-English speaker/use of translator. We will target recruitment to Veterans with scheduled PCP visits within the upcoming 2-3 months to ensure timely scheduling of facilitator visits if randomized to PPC group. We will recruit eligible Veterans via an opt-out letter sent on behalf of the PCP mailed to their home address. Letters written at a sixth-grade reading level will indicate that research personnel will contact the patient after ten days unless the patient requests that he/she not be contacted. A local or toll-free telephone number answered by voicemail will be available for those with questions or who want to leave an opt-out message. We will then call eligible Veterans to introduce the study objectives and procedures and to obtain verbal consent to administer a screening

protocol consisting of interest and mild cognitive impairment via the Blessed Orientation Memory Concentration Test (BOMC), For all potential participants who express interest in the study and who do not meet the exclusion criteria, study personnel will review the consent document in detail and ask the participant to provide verbal consent if they affirm participation. All consented participants will be mailed a copy of the informed consent documents and a blank copy of the baseline assessment surveys to assist with the baseline administration. After consent, study personnel will schedule a baseline assessment call with the participant. During baseline assessment, we will collect sociodemographic characteristics, treatment burden, collaboration with the healthcare team, social activity, health measures, and chronic illnesss care (all included in the attached baseline interview in Section S). . A validated screen assessment for home and community services use pulled from VINCI. During baseline assessment, we will also ask if the participant is willing to have their PCP visit audio recorded. All consented participants who complete baseline assessment will be randomized into the PPC or UC groups. Randomization will be blocked and stratified by PCP to assure balance in the number of patients assigned to two study arms by enrolled PCP. Within each clinician, we will use random blocks of 4 and 6. Blocking ensures half will be randomized to PPC and half to UC. Varying block size makes the sequence of assignments more difficult to predict. The random numbers will be generated in SAS PROC PLAN. The research assistant (RA) conducting baseline evaluations will not access any randomization procedures, leaving that RA blinded during the evaluation.

Intervention Procedures. PPC arm. Once a participant is randomized to the PPC arm, research staff will notify the facilitator, who will schedule a PPC facilitation encounter (20-30 minutes, by phone or videoconference at Veteran preference) 2-3 weeks before the upcoming PCP visit. The facilitator conducts a structured assessment using a written conversation guide that begins with general questions establishing what is most important to Veterans about their health and moves toward establishing specific goals, defined as actionable outcomes, and what patients are willing/not willing to do to achieve these goals (care preferences). The result of this assessment is a structured patient priorities report delivered to PCPs. This report is designed to facilitate changes in the patient's care plan to align it with his/her priorities. During the visit, the PCP will use one or more of the established PPC decisional strategies to align care with patients' priorities. An established education for PCPs about the facilitation process, training on how to understand the patient priorities report, and the decisional strategies training occurs prior to the PCP seeing any intervention patients. The PCP will document

changes in care made to achieve the identified priorities in the EHR note. In Aim 1, we will tailor each of these procedures, including methods for facilitator communication about priorities, creating EHR templates for documenting priorities-aligned changes in care, how training will be delivered, and determining whether the facilitator visits will be delivered in-person or by video. UC arm. PCPs will not be alerted when an encounter involves a UC group participant. UC participant visits will appear the same as all other unenrolled patient encounters. PCPs will be trained in Aim 1 to address the needs of UC participants based on their typical approach without the use of a facilitator or explicit process for identifying patient priorities. UC participants will not receive any additional preparation. Within 2 weeks after the primary care encounter, both PPC and UC participants will be contacted by a member of the research team to complete a phone survey of their experience of the PCP encounter (attached in Section S). At 4 months after baseline assessment, all participants (PPC and UC) will be contacted by phone to complete follow up assessment, including addendum (20 minutes, follow up assessment and addendum each attached in Section S). A blinded research coordinator will review all patient charts (via the chart review tool, attached in Section S) to assess clinical care changes documented in the medical record that could be attributed to study participation. If the research team is unable to reach the participant by phone, they will mail a Brief Final Survey along with a pre-addressed and stamped return envelope to the participant as a final attempt to collect followup assessment data. The Brief Final Survey takes no more than 5 minutes to complete (see attachment in Section S) and will be labeled with the participant's Study ID only. At the conclusion of their participation, all participants (PPC and UC) will be mailed a Thank You Letter (attached in Section S).

Aim 3: Implementation survey of appropriateness, feasibility, and acceptability: PCPs and facilitator-clinicians will complete interviews to assess appropriateness, feasibility, and acceptability. We will conduct interviews with participating facilitators and clinicians. PPC facilitators will be interviewed for 45-60 minutes. Clinicians from the same practice may be interviewed together for 30-45 minutes. The interview guide (attached in Section S) for facilitators and clinicians will solicit perspectives on the initial training and audit-feedback sessions, time required to complete tasks in the PPC process, and successes and challenges of implementing PPC within routine VA primary care. Summative evaluation of patients: Patients will be interviewed individually by phone within 2 weeks after their PCP appointment to solicit their perspectives on the benefits and challenges of articulating and communicating their health priorities and on the extent to which their priorities drove clinical decision-making.

Cost effectiveness analysis: We will pull financial data from CDW to analyze cost of PPC processes.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 290 Worldwide: 448

Please indicate why you chose the sample size proposed:

Aim 1: A recent study found that researchers can reach 95% saturation in 12 interviews. The estimate of 12-18 interviews will be sufficient to reach 95%-100% saturation on themes of interest.

Our analyses also show that at the higher end of the range for this option (95th%ile) 11¿12 interviews might be needed, tracking with existing literature indicating 12 interviews are typically needed to reach higher degrees of saturation. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0232076

Aim 2: We calculated a sample size to detect a between-group difference in the primary outcome with 80% power at a 2-sided significance level of 5%. Our prior PPC demonstration study and VA geriatrics pilot revealed small to medium effect sizes (Cohen¿s d = .20) for between-group (PPC vs. UC) differences in change in treatment burden questionnaire scores (TBQ) and the number of home and community services recommended and used from baseline to post-intervention. Based on these findings, we used Optimal Design software to estimate the sample size required to detect small effects in multilevel work for delta = 0.25 (accounting for the random error associated with each person [i] treated by provider [j]) for between-group differences in pre-post change in these primary outcomes. Based on TBQ estimates from our prior study, we assumed minimal effect size variability (fixed effects model), 2% variance by provider (blocking variable), and a 0.6 pre-post covariate correlation (rsq=0.36). These estimates indicate that a total sample of 16 PCPs with an average of 25 patients per provider will allow for 80% power (2-tailed at alpha = 0.05) to detect a small multilevel delta = 0.25

between-group effect on change in TBQ. Our prior PPC results with use of home and community services (see preliminary work 5.E. above) reveals minimal effect size variability, 9% variance by provider, and a 0.35 pre-post covariate correlation (rsq = 0.12). A sample size of 336 (16 PCPs total for both sites - 8 PCPs from Houston - with an average of 25 patients per PCP) will allow for 80% power to detect a small to medium effect (delta = 0.29) for between-group improvement in use of home and community-based services. Adjusting these numbers for up to 15% Veteran attrition results in 396 total Veteran subjects total for both sites, with 264 of those Veteran subjects in Houston.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Aim 1: Interviews will be transcribed and analyzed for themes. Qualitative data will be managed using Atlas-ti qualitative analysis software. We will use domains of the i-PARIHS framework to conduct a framework analysis of interview data. Analysis will involve charting themes across participant subgroups to identify saliency and compare and contrast participants' interview accounts to identify meaningful associations and patterns in the data. From this analysis, we anticipate the development of pragmatic implementation tools.

Aim 2: We will compare baseline demographic and clinical characteristics for the PPC and UC participants using independent samples t tests (for interval variables) and $\chi 2$ tests (for categorical variables). We will then use similar tests to examine differences in demographic and clinical characteristics between those who completed the post assessment and those who did not. Primary and secondary outcome analyses at post-intervention will be intention-to-treat and will use multiple imputation procedures PROC MI and MI ANALYZE in SAS Version 9.4 under the conditionally missing-at-random assumption.91 If intraclass correlation coefficients (ICCs) for primary outcomes reveal that the degree of total variance explained by variance between providers is low (i.e., ICCs < 0.05), Analysis of Covariance will be employed to examine treatment differences in outcomes immediately post-intervention (at 6 months). However, if ICCs reveal an adequate degree of between-provider variance in primary outcomes (i.e., ICCs greater than 0.05), we will employ multilevel modeling using PROC

MIXED in SAS to account for the dependency of observations in the data. An unstructured covariance structure type will be specified. For the secondary outcome of ambulatory health care utilization, we will perform either multiple logistic regression or use generalized linear mixed effects models (using PROC GLIMMIX), depending on the level of dependency that exists within the data. If multilevel models are warranted, participants will be the level 1 unit, which will be nested within providers (level 2). With either approach (multilevel or not), a separate model will be conducted for each primary and secondary outcome post-intervention. Models will include treatment group (i.e., PPC vs. UC) as a predictor and respective baseline scores for the outcome, age, Deyo comorbidity score, and any demographic or clinical variables that differed between the study arms at baseline as covariates. We will calculate treatment group effect sizes with 95% confidence intervals post-intervention. To account for the multiple secondary outcomes, we will use a Bonferroni-adjusted alpha of 0.025. Sensitivity analyses for contamination: For each outcome, multilevel models (patients nested within providers) will examine whether treatment group differences vary if participants were seen in the first vs. second half of a PCP¿s participant allocation. Non-significant time (1st vs 2nd half) by treatment group interactions will indicate similar treatment effective for earlier versus later participants. Furthermore, among the subset of audio-recorded encounters, the signed rank test will be used to examine differences in the number of PPC steps used by PCPs (based on analyses of coded transcripts) for PPC vs. UC encounters.

Aim 3: Using descriptive statistics, we will examine frequency distributions and proportions for all quantitative variables. Interviews with practice-based implementation team members will be performed and analyzed using directed content analysis. Based on our study questions and relevant literature, analysts will develop an initial codebook to answer questions about the implementation outcomes above. Research team will then review the data to develop themes. Quantitative and qualitative findings will be triangulated using standard content analysis methods. This triangulation protocol will allow us to create meta-themes that synthesize the quantitative and qualitative findings. We have used similar methods in prior analyses of implementation of health services interventions in VA primary care.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Aim 1 and Aim 3: Since no medical procedures or interventions are planned for these aims of the study, there will be minimal research risk and no therapeutic risk (physical, social, legal, or other) to participants. There may be a small psychological risk that participants may become sad or upset when talking about their experiences. As with any research study, there may also be a minimal risk of loss of confidentiality through the unintended release of PHI, which is a minimal risk for this study.

Aim 2 The potential risks of the intervention are minimal and patients in the care of these VA practices may benefit by having more involvement in their care. There is no therapeutic risk; any changes made are to the therapeutic benefit of the patient. We will collect survey and chart review information from study participants. Because we will be collecting patient-reported data through surveys and clinical data via chart review, potential research risks in this phase of the study include loss of time related to completing surveys, apprehension about disclosing information related to health care, and breach of confidentiality. For participants in the audio-recorded group, there may be a small psychological risk that participants may self-conscious, suspicious or upset when talking about their condition and treatments. There is a small risk of breach of confidentiality. Procedures will be taken to minimize the possibility of a breach in confidentiality. No participants will be identified in any publication or report of this study.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

The proposed research provides no direct benefits to the study subjects. It is anticipated that VA patients with multiple chronic conditions, primary care clinicians, and VA administrators as well as policy decision-makers will benefit from the knowledge gained through this research.

Describe potential benefit(s) to society of the planned work.

This study targets aspects of the VA HSR&D Priority Area: Long-Term Care and Caregiving. The VHA has set a high priority on developing systems that incorporate Veteran preferences to enhance management of chronic illness. Our study addresses this need. This study will provide valuable information regarding the use of patient-reported measures and the integration of the PPC intervention into routine care to guide the identification of patient priorities and the alignment of care to meet these priorities in higher risk patients. Further, although the PPC intervention that will be adapted for this study has some evidence from a non-VA clinical trial setting, it has not been assessed when incorporated into routine VA care. We anticipate that the information garnered from this work will not only improve outcomes but will also inform more patient-centered approaches to chronic illness care. The study will also generate important data on the readiness, process, and success of implementation of the PPC intervention and its impact on the outcomes of older Veterans with multiple morbid conditions. In addition to facilitating the local implementation of study protocols, we believe important generalizable knowledge will be generated from this work that can be applied to future PPC dissemination and implementation. As this is a minimal risk study, the importance of the knowledge to be gained in this study far outweighs the risk.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Since risks to the subjects are minimal, the proposed research is reasonable in relation to the anticipated benefits.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

For chart review to determine subject eligibility, a waiver of consent and HIPAA authorization is requested for the entire study to access CPRS. No written authorization from participants will be collected.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The main risk to study subjects will be the compromise of protected health information (PHI). However, there is an adequate plan to protect the data involved in this study from improper use and disclosure.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

The waiver of consent/HIPAA authorization will not adversely affect the rights and welfare of study subjects as it will not affect the care and treatment provided to patients. The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research. The main risk to study subjects will be the compromise of protected health information (PHI). However, there is an adequate plan to protect the data involved in this study from improper use and disclosure.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Since the proposed study will involves patients meeting certain clinical criteria, eligible patients could not be identified without accessing their chart information.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

N/A

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

A plan exists such that only the PI and relevant clinical staff will have access to these password-protected identifiers, which are subsequently removed when sharing data with co-investigators, and reporting or disseminating results. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. PHI is not disclosed to any other person or entity except for the authorized oversight of the research study by the PI and clinical staff. The Division uniformly adheres to all patients and patient data security and confidentiality rules and regulations set forth by the VA.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

Yes

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

Yes

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

Yes

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

Will additional pertinent information be provided to subjects after participation?

No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.

Contacting subjects after study participation increases the risk of breach of confidentiality.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

The actual care delivered is standardized and evidence-based, rather we are evaluating differences in workflow and patient centered techniques. Therapeutic risk to patients is minimal. The changes in care would not normally require written consent. We are obtaining consent for permission to collect pre- and post-assessment data.

To reduce the risk of exposure to COVID for patients and staff, we request verbal consent to participate in the project. We will inform participants that the risks of loss of confidentiality is low and we will take all measures to ensure PHI is protected. Verbal consent for Aim 1 will be kept in an Excel sheet maintained on a VA server behind the VA firewall. Verbal consent status for Aims 2 and 3, will be recorded in the study database to be maintained on a VA server behind the VA firewall.

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Aim 1: Approval will be obtained from the Primary Care Chiefs of each clinic. Using the list of clinic leadership, providers, and staff, email notification of the study and intent to follow up will be sent to all eligible clinic personnel, with instructions for opting out of further communication. All clinic personnel currently receive electronic communication from the facility. The email will emphasize the voluntary and confidential nature of the study. Research staff will follow up after 10 days to all potential participants who did not respond either with interest or to opt out. Participants who respond with interest will be scheduled for an interview at a time of their convenience. Verbal consent will be obtained before recording begins on the day of the interview and again after recording begins. A copy of the verbal consent cover letter was provided if requested. The verbal consent cover letter is attached in Section S.

Aims 2 and 3: We will recruit PCPs from among those who were contacted or identified during Aim 1 activities. We will approach interested PCPs to enroll them in the study for Aim 2 and Aim 3 (see attached flyer in Section S). Study staff will contact potential PCP participants, review and discuss the PCP assent form (attached in Section S) and obtain assent. A blank copy of the PCP assent form will be made available to them for their reference. We will then identify eligible Veterans from participating PCP panels. We will use the local data warehouses to identify Veterans meeting eligibility criteria (1) Veteran patients who have MCC from 2 VA facilities: a. MEDVAMC in Houston, TX b. VACT in West Haven, CT 2) age ≥ 65 years, 3) ≥2 encounters in prior 18 months, 4) ≥ 3 active health problems on active problem list or prescribed ≥10 medications) and then confirm eligibility by manual chart review and PCP assent. We will use the chart review tool (attached in Section S) to exclude for Veteran deceased status, living outside catchment area, hearing impairment, active substance abuse disorder, serious mental illness (bipolar, schizophrenia, schizoaffective disorder, psychotic spectrum disorder), active dementia, end stage renal disease on dialysis, nursing home or hospice care, and non-English speaker/use of translator. We will target recruitment to Veterans with scheduled PCP visits within the upcoming 2-3 months to ensure timely scheduling of

facilitator visits if randomized to PPC group. We will recruit eligible Veterans via an opt-out letter sent on behalf of the PCP mailed to their home address. Letters written at a sixth-grade reading level will indicate that research personnel will contact the patient in approximately a week unless the patient requests that he/she not be contacted. Letters will specify that participation is voluntary. A local or toll-free telephone number answered by voicemail will be available for those with questions or who want to leave an opt-out message. We will then call eligible Veterans to introduce the study objectives and procedures and to obtain verbal consent to administer a screening protocol. For all potential participants who express interest in the study and who do not meet the exclusion criteria, study personnel will review the consent document in detail and ask the participant to provide verbal consent if they affirm participation in activities of Aim 2 and 3. All consented participants will be mailed a blank copy of the informed consent documents for their reference.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

Yes

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

Yes

Photographs, videotapes, and/or audiotapes of you:

Yes

Identifiable biospecimens

No

Will identifiable biospecimens be stored for future research?

NA

If yes, is the storage of biospecimens optional for subjects?

NA

Will identifiable private information be stored for future research?

No

If yes, is the storage of information optional for subjects?

NA

Questionnaire, Survey, and/or subject diary

Yes

Other:

No

At what institution will the physical research data be kept?

All data will be under the direct supervision of Dr. Dindo, Principal Investigator. Research data in paper form will be stored in a locked file cabinet of the MEDVAMC HSR&D COIN (Bldg 152), 2002 Holcombe Blvd. Houston, TX.

How will such physical research data be secured?

All physical data will be secured in a locked cabinet in a locked office of the MEDVAMC HSR&D COIN (Bldg 152), 2002 Holcombe Blvd. Houston, TX.

At what institution will the electronic research data be kept?

All electronic data will reside on a VA server on the VA domain. Data, including all data collected through the West Haven site, will be stored on the M Drive in the folder titled: M:\Research. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):
The electronic research data will be stored on a secure VA server in the folder M:\Research\Dindo_L_VAPPC_H-48932. This folder will be password protected with access granted only to those members of the research team who require access. This protocol for data management will protect data from improper use and disclosure. No thumbdrives, flashdrives, or portable hard drives, will be used for this protocol. It is understood by the PI that data will not be used or shared with others outside the scope of the research study as documented in the protocol approved by the IRB and MEDVAMC R&D Committee. Removal of access to research study data will be accomplished for all study personnel when they are no longer part of the research team.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Coded data sets of a subset of the data produced by this protocol, specifically the text from the chart reviews and patient notes, will be shared between the Principal Investigator of the study and the UTHealth Science Center at Houston, per the approved Data Use Agreement. The data sets will be scrubbed of identifiers and reviewed by the Privacy Officer prior to sharing. The study ID codebook will remain behind the VA firewall; no study ID codebook or other form of patient identifiers will be transmitted. Appropriate institutional approvals will be obtained prior to transmitting and/or receiving these data.

Will you obtain a Certificate of Confidentiality (COC) for this study?

No

Please further discuss any potential confidentiality issues related to this study.

The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

VACT is a second site obtaining their own IRB approval for the clinical implementation of the research activities. All patient data for both sites will be pulled by members of the MEDVAMC research team and stored behind the VA firewall. The VACT research team will have access to the study database; therefore no data will be transferred.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there

is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance(other than food) that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

None