Official Title of Project: Improving PACT Coordination across Settings and Services

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In lieu of a formal study protocol for this project, we are providing the original project proposal from 2015, with redaction of staff names from the proposal for privacy reasons. The original project proposal is excerpted from its parent VA Care Coordination QUERI Program proposal: "Improving Patient-Centered Care Coordination for High Risk Veterans in PACT" (QUE 15-276). In the attached proposal document, the Coordination Toolkit and Coaching project is referred to under its official title of "Improving PACT Coordination across Settings and Services."

Since the project proposal included here was written, changes have been made throughout the five-year project period. Accurate and updated documentation of the project has been entered and kept current in the ClinicalTrials.gov Protocol Registration. All trial conduct, amendments, and procedures were tracked in the Protocol Registration section of the study record. This project was determined to be non-research by the VA Greater Los Angeles Healthcare System's Institutional Review Board and therefore did not include a formal study protocol or statistical analysis plan document. We also did not have an informed consent document, as we did not have any human subjects.

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2.0 Implementation Project (IP) #1: Improving PACT Coordination across Settings and Services

2.1 IP#1 Specific Aims

1) Develop an evidence-based, user-friendly Care Coordination Toolkit and a Care Coordination Distance Coaching Manual to improve care for high-risk Veterans. The Manual will be used as the basis for training care coordination coaches. Both the Toolkit and Manual will be based primarily on previously tested tools.

2) Pilot the Care Coordination Toolkit and Distance Coaching Manual at one site and engage participating VISNs, medical centers, and clinics.

3) Use a cluster-randomized evaluation design across three VISNs, randomized at the PACT clinic level, to compare the effectiveness of the Care Coordination Toolkit alone to the combination of the Care Coordination Toolkit plus distance coaching for improving Veteran experience of care, communication and coordination between PACT providers and specialists, and utilization of acute care services.

2.2 IP #1 Background and Rationale

Failure to coordinate care well is a source of waste in health care ($25-$45 billion in 2011).[10] Excellent coordination of care remains a central tenet and expected benefit of a patient-centered medical home, and improvement in coordination of care was one of the motivations behind the introduction of VA's PACT model in 2010.[11] Care coordination is particularly critical for Veterans seeking care in VA, given that these Veterans have a high number of comorbid conditions and higher mental health burden.[12] While VA providers benefit from a shared electronic health record in an integrated health system, care coordination has been identified as a challenge for VA patients with multimorbidity[13] and for primary care providers.[14,15] Other recent work has identified primary care providers' communication with specialists, a major facilitator of care coordination, as a prevalent challenge.[16] The passage of the Veterans' Choice Act has further increased the need to focus on care coordination, given the increased involvement of non-VA providers in delivering care to Veterans.

VA Care Coordination Setting: In VA, most high-risk Veterans are managed in primary care rather than a specialty service.[17] PACT was expected to improve care coordination by creating the care manager role for the PACT teamlet nurse. However, there have been significant challenges in implementing the care manager role as intended. Many of the care coordination challenges involve the "medical neighborhood" outside of PACT.[9] Care coordination remains an inherently human endeavor, consisting of communication between a variety of different individuals who share responsibility for the patient, including the patient and caregivers. Technology can support human social systems, but those human systems need to be functioning well in order to make best use of technological supports. Care coordination challenges of various types have resulted in a wide variety of relevant tools. No integrated toolkit that organizes these tools around the overall concept of care coordination, however, has yet been developed. The Care Coordination Toolkit will thus consist primarily of previously tested tools, but will assemble the tools around key elements of coordination that support both interpersonal and technological aspects of care coordination improvement.

VA initiatives have implemented a number of technological supports with the aim of improving care coordination through bi-directional primary care provider-specialist communication.[18] A major facilitator of care coordination, for example, has been electronic consults that allow a primary care provider to query a specialist for guidance without necessitating the patient see the specialist in person. The Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) also allows providers and primary care providers to interact via videoteleconferencing. However, adoption of these innovations is dependent on specialist and PACT

team participation, and implementation rates have varied among different specialties and across sites.[19] In addition, these innovations have not been designed or tested specifically around the concept of care coordination as an outcome.

Conceptual Framework: The proposed work is guided by the Framework for Organizational Transformation, which identifies five key features of successful, sustained implementation of quality improvement activities in organizations: "(1) Impetus to transform; (2) Leadership commitment to quality; (3) Improvement initiatives that actively engage staff in meaningful problem solving; (4) Alignment to achieve consistency of organization goals with resource allocation and actions at all levels of the organization; and (5) Integration to bridge traditional intra-organizational boundaries among individual components."[20] Features 1, 2, and 3 are important determinants of success for quality improvement programs; features 4 and 5 (alignment and integration) are particularly relevant to PACT teams, which need to integrate themselves into the organizational landscape of their respective VA healthcare systems and with non-VA care. Later, the Framework for Organizational Transformation was distilled into a six-step process used in toolkits for the prevention of pressure ulcers[21] and falls[22] in hospitals: 1) leadership engagement, 2) change management, 3) selecting intervention components, 4) implementing the intervention, 5) measuring for improvement, and 6) sustainability. The toolkits were designed for interdisciplinary teams at all stages of organizational readiness. We will use the six-step approach to systematize our toolkit improvement strategies. The proposed project follows the later framework.

To address leadership engagement, the project will engage VISN, medical center, and local PACT leaders in an assessment and planning process using previously developed EBQI principles. The need to engage leadership is critical regardless of strategy, given the repeated finding of leadership involvement as a facilitator in implementing any initiative.[23] Our leadership engagement, toolkits and coaching strategies will each include a focus on change management and intervention component selection. One change management approach will be to provide intervention sites with feedback on their baseline organizational readiness for care coordination, using the tool developed by the Implementation Core. Given that specific gaps in care coordination are likely to vary locally, we do not propose a "one-size-fits-all" intervention here. Rather, each of our two implementation strategies will emphasize matching particular coordination solutions to the local coordination problems being experienced. To study the process of intervention implementation, we will compare toolkit to toolkit plus coaching strategies, and will measure improvement and sustainability based on patient and provider experience measures as well as patient utilization of acute care.

2.3 IP #1 Procedures

2.3.1 Proposed IP #1 Improvement Strategies

Toolkit and Coaching Implementation Strategies: Both toolkit and distance coaching strategies have been used in a wide variety of VA quality improvement initiatives, including by the National Center for Patient Safety, but, to our knowledge, have not formally been compared, although toolkits and distance coaching have been compared to other alternatives. Kilbourne and colleagues compared a standard package of technical assistance to reengage patients with serious mental illness in VA care to an individualized distance coaching strategy focused on sites not responsive to the standard package, using an adaptive design.[24] Distance coaching resulted in enhanced program uptake by sites, but no change in patient-level utilization of mental health services, for reasons that may have been related to the patient population under study and the statistically conservative nature of the study design. Speroff compared toolkit and collaborative approaches outside VA, and found that a collaborative was better at changing processes of care, but neither approach was successful in changing outcomes in the intensive care unit setting.[25] Both the Kilbourne and Speroff studies differ substantially from ours in terms of the problem being investigated and the patients involved, so results cannot be generalized to the PACT setting.

A toolkit strategy has many aspects in its favor – toolkit deployment is relatively inexpensive and makes tools nationally available and accessible over a relatively short time horizon. A potential limitation of this strategy, however, is the lack of interaction with an expert to tailor the tools provided to the needs and local organizational context of the user, potentially limiting the level of engagement with the tools. This limitation is suggested by preliminary PACT Toolkit data from Fiscal Years 2011-2014 (IP#1 staff member, unpublished data), showing variable uptake of the toolkit by VISN (mean number of unique users per VISN ± standard deviation, 731 ± 298; range 302-1386), despite aggressive marketing and a PACT Collaborative.[26,27] We hypothesize that toolkit uptake would be greater overall, and less variable, if individual PACT clinic champions had personal access to an expert coach to guide them through use of the tools, allowing these champions to become comfortable with the tools and share them with colleagues. Although the original PACT collaborative did include coaches, the amount and intensity of coaching was low (five industrial engineers and five coaches for the entire national collaborative, with coaching activities performed as a collateral duty[26]). This hypothesis will be tested by adding coaching to the Care Coordination Toolkit. Our distance coaching approach will be based on prior tested facilitation and coaching materials and use a variety of communication methods (videoconferencing, teleconferencing, instant messaging and other means) to provide personalized technical assistance to PACT teams for improving care coordination. A distance coaching strategy has the advantage of being easily scaled and sustained while making economical use of limited resources.

An additional principle that is implicit in implementation of successful care coordination improvement strategies is that of *creating routine systems for communication* and *organizational alignment* that connect units that frequently need to coordinate care. [6] The Care Coordination Toolkit will focus on creating effective routine systems. For example, in VA, studies have found that care coordination agreements were associated with better care coordination experiences for primary care providers (manuscript in preparation). However, it matters how these agreements are implemented; in interviews, some specialists indicated that these agreements are not treated as binding in everyday use (unpublished data). Any gap between appearances and reality suggests a potential implementation problem that needs to be tackled in order for care to improve.

In summary, we will compare the use of a novel Care Coordination Toolkit alone with Toolkit use plus facilitation by a remotely-based coaching team. For both strategies being compared, we will systematically engage VISN and facility leaders as partners in testing these approaches, using principles of EBQI and CPPR.[8,28]

2.3.2 IP #1 Study Design

Specific Aim 1: Develop a Care Coordination Toolkit and Distance Coaching Manual

Aim 1 will span October 2015 – September 2016. Development will begin with an environmental scan to collect and use relevant tested care coordination tools and coaching materials from existing sources. We will then conduct approximately twenty one-on-one interviews with potential users of the identified tools and coaching materials to assess their reactions to the tools. We will also assess the utility of harvested tools using the Agency for Healthcare Research and Quality (AHRQ) Toolkit Guidance,[29] which addresses tool content, usability, organization, design, and language. Finally, we will compare the set of promising tools against the six-step approach (leadership engagement, change management, selecting intervention components, implementing the intervention, measuring for improvement, and sustainability), to determine where voids in coverage exist. At this phase, new tools and coaching content will be created to fill these voids. All materials will then be adapted and formatted to create a common look and feel. The draft toolkit will then be deployed by VA-CASE.

VA *Care Coordination Toolkit:* An initial review shows several relevant tools in the PACT Toolkit. These include the readmission risk calculator (tool 5), PACT Teamlet checklist (tool 20), VA Geriatrics Resource Guide (tool 21), PACT Roll-out kit for providers (tool 24), huddle checklist (tool

68) and co-managed care toolkit (tool 75). Additionally, the Specialty Care Toolkit's care coordination agreement guide (tool 17) and E-consult guides (tool 28) are relevant. However, all of these tools need to be updated given new developments, including the CAN score, the Patient Care Assessment System (PCAS), and the Veteran's Choice Act. In addition, the currently available PACT and Specialty Care Toolkits do not include many tools on general management principles and approaches, which is a strength of the AHRQ toolkits, including the fall prevention toolkit created by Dr. Ganz. These general management tools include obtaining leadership buy-in, assessing available resources, team formation and management, audit and feedback, and sustainability. New tools to engage patients in improving ambulatory care also need to be added, and could be adapted from the Aligning Forces for Quality Initiative.[30] Finally, we will identify and adapt tested tools from successful projects that have included elements of care coordination, such as those focused on improving hospital discharge or care for specific chronic conditions.

Care Coordination Distance Coaching Manual: Candidate coaching materials include Mental Health QUERI's facilitation guide,[31] and the materials hosted on VA's Transformational Coach SharePoint Site. The coaching team that will help develop and then use the manual consists of individuals who have experience in working with PACT teamlets, are facile with data, and are expert at building relationships via non-face-to-face means. The coach will serve as an external facilitator, working closely with an internal facilitator or "champion" at each PACT clinic.[31] Two project advisors have special expertise in this area and will consult on manual development.

Specific Aim 2: Pilot Testing and Site Engagement

Aim 2 spans October 2016 – March 2017. During this period, the Care Coordination Toolkit and Coaching Manual will be pilot tested at the South Texas Veterans Affairs Healthcare System and three of its PACT clinics. VISNs, medical centers, and clinics for the cluster randomized evaluation will also be identified.

Pilot Testing: We will pilot test our engagement strategies, toolkits, and coaching approaches. Engaged clinics will identify care coordination improvement aims and tools, as well as QI measures. Assessment of pilot results will include a usability assessment of chosen tools based on a user focus group, and qualitative interviews of project participants from each site aimed at identifying what tools or coaching strategies were used and on obtaining feedback on how the approaches could be made more helpful. We will also test the coaching manual to see whether it is sufficiently prescriptive to actually result in a standardized coaching approach. Finally, we will conduct cognitive interviews to determine whether the implementation core's readiness assessment instrument can distinguish clinics in terms of their readiness to improve care coordination, specifically around whether the clinics' care coordination problems are more pervasive (e.g., insufficient staffing) versus more bounded (e.g., inability to get patients in to a particular specialty clinic). The readiness assessment will be refined based on the cognitive interviews. Findings from the readiness assessment will be used to update toolkit and coaching materials.

Site Engagement: The two evaluation strategies, once pilot tested, will be implemented and evaluated in PACT clinics within three VA VISNs. In parallel with pilot testing, therefore, the site engagement process will begin. The engagement process will take account of the VA VISN, medical center, and local site contexts, thus recognizing the critical role that network and facility leadership plays in facilitating any new VA endeavor aimed at changing routine care. As a first step, the Chief Consultant for the Office of Primary Care and the senior project PI, who are experienced in VISN engagement through EBQI,[7] will identify potential participating VISNs. As in other EBQI efforts, the project PI will then approach the VISN Director and Chief Medical Officer regarding their willingness to participate. Once a VISN agrees to participate, the project team will prepare VISN-specific feedback reports based on PACT Compass and Survey of Healthcare Experiences of Veterans (SHEP) Patient-Centered Medical Home data relevant to care coordination. Reports will focus on

showing clinic level data for each medium-sized (≥ 5000 patients) or larger non-contract PACT clinics, whether community based or medical center based, in each potentially participating VISN. At a videoconference meeting with VISN leaders, the two study PIs will present the data and consider with them which medical centers and clinics would be best to engage in care coordination improvement. The PIs will then work with medical center and PACT leaders from identified clinics on engaging the individual PACT sites, including provision for needed release time for those at each site who will be participating in a care coordination QI team. Physician, nurse, and administrative leaders from each clinic will then complete the implementation core's readiness assessment (organizational readiness for care coordination), to assess problems with care coordination and readiness to address those problems.

Specific Aim 3: Cluster Randomized Evaluation Comparing Two Implementation Strategies

Aim 3 spans April 2017-September 2018. During this period, we will conduct a cluster randomized evaluation of using prior evidence to improve care coordination via a toolkit alone (six clinics) versus the combination of the care coordination toolkit plus individualized distance coaching (six clinics). Implementation sites will be distributed across the three VISNs such that each VISN includes two clinics for each strategy for a total of four per VISN, or 12 altogether. The care coordination toolkit will be marketed to all sites, but only the six clinics randomly assigned to also receive distance coaching will receive this supplemental support.

Initiating the Implementation Strategies: We will introduce the Toolkit to QI teams at each of 12 PACT clinics using a variety of modalities including email and webinars. For the six clinics randomly assigned to receive coaching in addition to the toolkit, the coach will be available on demand, via videoconference, webinar, telephone, and instant messaging, depending on the communication preferences of the individual clinic champions. Scheduled coaching activities will include an introductory coaching call with teams from each of the six clinics, with subsequent meetings initially scheduled on a weekly basis. The introductory coaching call will include a presentation about high-risk patients' challenges and needs for care coordination and an overview of the toolkit. Subsequent meetings will include case reviews, where teams discuss how they would use the toolkit to address different types of patient needs. We have budgeted a limited number of site visits to the six coaching strategy clinics to augment the distance coaching model; site visits will occur at the discretion of site leaders and can be scheduled at any time during the implementation period as needed.

2.3.3 Key Outcomes and Analyses

Measuring and Analyzing Care Coordination Outcomes: We will assess each of our two evidence-based implementation strategies for care coordination (toolkit and toolkit plus coaching) through a patient survey, electronic data, historical document review, and key stakeholder interviews. Through these data sources, we will evaluate both processes and outcomes relevant to the two strategies. Our primary outcome is patient experience of care coordination, measured based on the Multimorbidity Hassles Scale (measured at baseline and follow-up).[33] Secondary outcomes include provider perceptions of the quality of coordination between primary and other services (measured six months in to the implementation via interviews), and electronic administrative data-based measures of acute care utilization (ED and hospital visits, and length of stay for hospitalized patients) and of patient care experiences. Due to the continuous nature of the administrative data, we will compare all PACT patients at each participating site based on study year one results (baseline) compared to study year three results (post-implementation).

Patient Survey on Experiences of Care Coordination: The primary outcome (Multimorbidity Hassles Scale) will be compared between the two groups (toolkit and combined toolkit/coaching), with a minimum of 564 patients per group. The Multimorbidity Hassles Scale was specifically designed and tested for VA patients with multiple chronic conditions.[33] This 16-item scale asks patients questions

such as whether they are getting their medications refilled on time, whether they had information about why they were referred to a specialist, whether there has been poor communication between different doctors or clinics, or disagreements between doctors about the patient's diagnosis or the best treatment for the patient. Prior work has shown that better scores were associated with better ratings of the usual care physician on communication and coordination of care, that patients with multimorbidity have higher hassles than patients with a single chronic illness, and that all items load onto a single factor when subjected to factor analysis, thus capturing a unified concept. The Multimorbidity Hassles Scale will be measured on all patients with CAN score > 90 in participating clinics. We will use VA administrative data from the Corporate Data Warehouse (CDW) to determine assignment to each clinic and the relevant CAN score for each patient. The scale will be administered via computer-assisted telephone interviews from a survey contractor.

Administrative Data on Patient Experiences of Care Coordination and on Acute Care Utilization: Secondary outcomes will include clinics' overall performance on items routinely collected by VA, including coordination of care items found in the SHEP Patient-Centered Medical Home survey, which derive from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Patient-Centered Medical Home survey, and PACT compass metrics related to care coordination. Although we will identify medium-sized or larger clinics, we may have a limited number of CAHPS surveys available. To mitigate this limitation, we will use control charts to plot change over time, because CAHPS is administered throughout the year. Our team has expertise in this approach using CAHPS (IP#1 data analyst, manuscript submitted for publication).

Key Stakeholder Interviews: Key stakeholder interviews will assess both user ratings of the utility and usability of the two strategies as a secondary outcome, and the process of implementation of each strategy. We will conduct semi-structured key stakeholder interviews across all 12 sites approximately 6 months after the toolkit is made available. For all sites, we will assess toolkit adoption and perceived usefulness, methods used to implement tools (e.g., PDSA cycles), resources needed, challenges and facilitators, and perceived impact of tool implementation. In addition, we will ask about other ongoing efforts to improve care coordination, outside of the Care Coordination Toolkit. For sites receiving coaching, the interviews will also assess the perceived quality of coaching and participation in the coaching calls/activities. All key informants will also be asked about their perceptions of the quality of care coordination at their site. Key stakeholders will include the site quality improvement teams and leads (up to 5 interviews per site). We will adapt the interview protocol used by the National PACT Toolkit team.

Document Review: In addition to key stakeholder interviews, we will abstract information from coaching call minutes to assess participation by the 6 coached sites receiving coaching. Specifically, we will collect information on who participated, frequency of coaching calls, and topics discussed. From this information we will construct variables to measure "dose" of coaching, such as number of calls each site participated in, and how many quality improvement team members participated (on average).

Power and sample size calculations: With participating clinics required to have a minimum of four teamlets, an average PACT teamlet panel of 1200, 10% of that panel defined as "high risk" by CAN score criteria (CAN score > 90), and a survey response rate of 40% (the most recently available response rate for SHEP's patient-centered medical home survey was 44.3%[35]), then we project at least 192 survey responders per clinic. For our primary outcome, the Multimorbidity Hassles Scale has a mean of 17.7 (standard deviation 14.4) in a sample of patients with multiple chronic illnesses (n=227).[33] In a design with six clinics assigned to the toolkit group and six clinics to the combined toolkit/coaching group, a sample size of 94 responders per clinic is needed to provide 80% power to detect a small to moderate effect size of 0.3 standard deviations, assuming an intracluster correlation coefficient of 0.01, a type I error rate of 5%, and an attrition rate of 40% at 18 months.

Thus, we have sufficient sample to survey a total of 1128 patients (94x6=564 in the toolkit group and 94x6=564 in the toolkit/coaching group) in the current evaluation.

Key Covariates. In our analyses of the Hassles Scale (patient survey) as an outcome we will control for clustering at the PACT site level and include VISN as a covariate. We will also include patient-level factors: gender, age, number of providers longitudinally involved in patients' care, use of non-VA care (e.g., fee-basis), and distance to travel for primary care based on the patient's address of record. In our secondary outcome analyses based on electronic data we will use a similar approach though only some of the above variables will be available electronically.

Limitations. Although the proposed design is cluster-randomized, the total number of clusters (six clinics per implementation strategy) is small. Thus, quantitative assessment of the effect of clinic-level factors, such as baseline organizational readiness to coordinate care, on the effectiveness of each implementation strategy will not be possible. Second, our PACT sites do not include very small clinics (with <5000 patients) and our results cannot be generalized to these. Our power calculations, however, indicate we will be able to rigorously assess our primary outcome.

2.4 IP #1 Impact

If successful, the project will improve care coordination in twelve sites in three VISNs, and will provide readily-applicable methods for spreading these results throughout VA. In addition, the project will indirectly inform VA regarding factors, including the availability of distance coaching, that may influence the utility of toolkits.

2.5 IP #1 Timeline

Year	FY16				FY17				FY18				FY19			
Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Aim 1: Develop online toolkit and coaching manual																
Develop readiness assessment	X	X														
Develop and post online toolkit		X	X	X												
Develop standardized coaching strategy/manual		X	X	X												
Aim 2: Pilot toolkit and coaching strategy and engage VISNs in site selection																
Pilot readiness assessment					X											
Pilot standardized coaching manual					X	X										
Tool usability focus groups with pilot sites					X	X										
Refine readiness assessment, coaching manual, and online toolkit per pilot tests					X	X										
Identify participating VISNs, facilities and clinics					X	X										
Aim 3: Deploy toolkit and combined toolkit/coaching strategies																
Conduct readiness assessments							X									
Launch toolkit marketing campaign							X	X	X							
Implement coaching strategy							X	X	X	X	X	X				
Analyses																

Field patient experience of care survey							X				X				
Conduct interim evaluation of implementation and provider perceptions of care coordination								X							
Analysis and final report												X	X	X	X

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