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Whole Health in VA Health Care:

Insights on Implementation, Research, and Future Evaluations

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DISCLAIMER

All statements in this report, including its findings, conclusions, and views expressed, and any errors of omission for the information assembled are those of the authors, and do not necessarily reflect the views of the US Department of Veterans Affairs or the US government.

ABSTRACT

This paper was commissioned by the National Academy of Science Engineering and Medicine (NASEM) Subcommittee on Whole Health. The aims for this commissioned paper are to (1) describe VA's efforts to implement, scale, and maintain whole health approaches (including, but not limited to the VA Whole Health Initiative) and the factors that support or undermine those efforts and their spread; (2) describe efforts outside of the VA to promote whole health, with particular interest are systems that serve large veteran populations who may or may not also use the VA, and (3) describe needs and opportunities, especially regarding measurement issues that could be used to evaluate whole health.

INTRODUCTION

As has been described by the National Academy of Sciences, Engineering and Medicine (NASEM), whole health systems are different than our current systems of healthcare. Whole health systems are multi-sectoral ranging from health behavior promotion to environmental. In each sector, care coordination is present and relates back to addressing what matters to the individual. Whole health systems go beyond providing care for the individuals and have identified aspects related to health and social factors that help people achieve whole health. Whole health is viewed as an approach to health care that empowers and equips people to take charge of their health and well-being and live their life to the fullest. Whole health is a transformative paradigm motivated by a traditional health care system that is inefficient and under resourced to meet individuals' health and wellness needs. The Institute of Medicine characterized these short comings in their 2009 report (Institute of Medicine, 2009), as did the NASEM report on Integrating Social Needs Care into the Delivery of Health Care: Moving Medicine Upstream to Improve the Nation's Health in 2019, that highlighted the disjointedness of health care and social services. And witnessed most recently in the COVID-19 pandemic, it has been apparent that our public health system is reactive and even further fragmented. Whole health systems are thus expected to address these inefficiencies and gaps, and ultimately lead to improved individual well-being. The VA has taken on this challenge to ..radically change and enhance both the experience and practice of health care" (Krejci et al., 2014, p. S5).

In this paper we offer out insights about the implementation of whole health in the VA, research addressing whole health and implications for future evaluations. In the first section a review the VA implementation of whole health is presented, including related legislative, programmatic and research initiatives that have supported these efforts since the early 2000's. Special emphasis is on the collaborative efforts applying whole health to improve pain care in

the VA. In the second section, selected whole health initiatives developed and emerging outside the VA healthcare system are described. In the third section potential opportunities for evaluation and research regarding measures that could be used to evaluate elements of whole health.

1. VA WHOLE HEALTH VISION AND IMPLEMENTATION

The VA Journey

In the US Department of Veterans Affairs (VA) Healthcare System, whole health approach to care has been a focus for nearly two decades. In the early 2000's VA focused on providing personalized, proactive, and patient driven healthcare with efforts to connect patients with regular primary care through the VA patient aligned care teams (PACTs) Attention to the value of integrative health was of keen interest (Bell et al., 2002). While these efforts proved valuable to engage patients in primary care and to facilitate a point of contact for their VA care, some populations of high-risk patients such as those with chronic pain conditions, complex health related social needs and or serious mental health issues still had challenges, despite being in a PACT. Subsequent studies began to explore strategies to address these issues. For example the randomized trial of enhancement of care coordination services in the VA Patient Aligned Care Team (PACT) Intensive Management (PIM) at five facilities demonstrated that by adding care coordination to the established PACT model (Nelson et al., 2014; Rosland et al., 2013), patients had an increase in primary care and social work services and outpatient costs, a decrease in inpatient costs resulting in similar total costs (Yoon et al., 2018) and had modest improvements in patient experience of care. Still, barriers for specialty care, including under fee basis care, and limited availability of alternative therapies remained.

By 2011, the VA was shifting to an integrated care approach (Krejci et al., 2014). This shift was evidenced by the establishment of the Office of Patient Centered Care and Cultural Transformation (OPCC&CT), which was charged with catalyzing and sustaining cultural transformation for and with Veterans from a primarily reactive, disease focused, physician centered care model to a personalized, proactive, patient driven approach. The expectation was that by prioritizing Veterans and their values, and by partnering with them to create a personalized strategy to optimize their health, healing, and well-being, patient satisfaction and outcomes would be improved (Kligler, 2022; Krejci et al., 2014). OPCC&CT defined the whole health system (WHS) as an "approach to healthcare that empowers and equips people to take charge of their health and well-being and live their life to the fullest." The goal is to transform the organization *and culture* of care to a system which starts with the individual and the care planned is with their personal preferences at the center.

This concept of individualizing care and empowering people to take charge initially focused on VA patients, i.e. Veterans, and their actions, and has evolved to include not only what providers and employees in the health system can do to support Veterans, but to also adopt these principles in their own lives. This broader framework of the VA WHS is depicted in the graphic (Figure 1) and exemplifies a circle of health intended to acknowledge each person's uniqueness, with patients at the center. The OPCC&CT the website notes that, "From there, they are empowered through mindful awareness and self-care. They are supported and guided by a team of professionals, who may draw from both conventional and complementary approaches. They are embraced by their community. Using the circle of health framework, patients and other individuals identify what matters most to them, and then they work with their Whole Health team to create a personal health plan that will move them closer to what is important to them" (U.S. Department of Veterans Affairs, 2022). This framework includes three main components for supporting an individual personal health plan: 1) The "Pathway", which

introduces Veterans to concepts of WHS and facilitates identification of personal health goals and a personal health plan, through whole health Facilitated Groups or one-on-one peer interaction. 2) "Well-Being Programs", which includes complementary and integrative care (CIH) such as yoga, and tai chi groups, health coaching, and other self-care/skill building groups.

3)"Whole Health Clinical Care", which uses a whole health paradigm for providing care in both traditional and CIH settings.

It has been expected that by implementing a culture of WHS of care, that is an overall organizational system that includes engaged leadership, incentive alignment, infrastructure support, trained providers supported employees and employee whole health, there would be associated improvements in organizational, health practice, employee outcomes and patient outcomes. For example, expected organizational improvements include increased system level value of WHS care delivery, allocation of WHS resources, and alignment of system level incentives. Regarding healthcare practices it is expected that there would be improved use of WHS tools to guide care, use of WHS messaging, WHS integration within clinical teams, and belief in WHS care delivery. Regarding employee impacts, it is expected that employee health and well-being and satisfaction would improve, and burnout would decrease. Regarding patient outcomes, it is expected that there would be an increase in personal health plans, patient engagement aligned with personal health goals, patient satisfaction and health and well-being, functional and clinical outcomes. It is also expected there would be changes in health care utilization, although it remains uncertain which areas are projected to be affected.

In 2014 the OPCC&CT was charged by the VHA National Leadership Council to create the Integrative Health Coordinating Center (IHCC) to fill an infrastructure gap that would (1) to identify and remove barriers to providing integrative health across the system; and (2) be a resource for clinical practices and education for both Veterans and for clinicians. The NLC recognized that "a proactive approach to optimize health and healing addresses all aspects of

life that can influence outcomes. Many of the strategies that may be of benefit extend beyond what is conventionally addressed or provided by the health system". To facilitate this system wide transformation, the OPCC&T undertook a range of activities to develop and enhance the existing resources to support implementation of the WHS. The overall strategy to drive the change needed included clinical innovation, enhanced professional education, and research partnerships to build evidence.

With the creation of the IHCC, the OPCC&CT established several clinical innovation hub sites at VA medical centers across the VHA. These innovations hubs were intended to have strong leadership and a commitment to a cultural transformation to the new model of care. To begin to address the gap in professional education, the OPCC&CT also launched an educational program for VHA clinicians "Whole health: change the conversation—advancing skills in the delivery of personalized, proactive and patient-driven care" which prioritized transformative and experiential learning. Together the education and the clinical hubs sought to train clinicians in effective integrative health therapies while expanding the whole health services of interest to patients. It was viewed that by expanding the integrative health services offerings, the VA would be more responsive to patients needs and preferences.

Regarding research partnerships, in the early days the focus was on specific integrative health practices, which was needed to also complement the training and clinical expansion of services. The OPCC&CT partnered with the VA Office of Research and Development Evidence Synthesis Program to conduct evidence reviews of various specific integrative health practices (Hempel et al., 2014; Peterson et al., 2016). The OPCC&CT also partnered with external collaborators in the Bravewell Collaborative (Abrams et al., 2013) to pilot *PRIMIER2* (Patients Receiving Integrative Medicine Interventions Effectiveness Registry) in the integrative medicine practice-based research network, known as *BraveNet*.

In 2016, additional legislative initiatives spurred on the VA WHS implementation, at least for the focus on integrative health practices for pain management. Notably the legislation known as the Comprehensive Addictions and Recovery Act (CARA) ("Public Law 114-198: Comprehensive Addiction and Recovery Act of 2016," July 22, 2016; U.S. Government, 2016), mandated VHA to implement alternative approaches to pain management to decrease the use of opioids. The legislation's focus on increasing the use of complementary and integrative health approaches dovetailed well with the VA's development of the WHS paradigm. The CARA legislation also included specific funding for research and evaluation of the effectiveness of complementary and alternative health approaches for pain management. This additional research funding added to the OPCC&CT partnership with the Office of Research and Development, led by the Health Services Research and Development Service (HSRD), Quality Enhancement Research Initiative (QUERI) and launched in two research programs--the Center for Evaluating Patient-Centered Care (EPCC) and the Complementary and Integrative Health Evaluation Center (CIHEC)-focused on complementary and integrative health components of WHS. Further the CARA supported a demonstration and evaluation of implementing WHS focused on outcomes for improving care for pain management. The two new QUERI Centers were tapped to support and evaluate the WHS Demonstration program. The WHS demonstration included funding for 18 VA medical centers to implement WHS. Each of the 18 VISNs identified and funded a Flagship site to implement the WHS.

The WHS Demonstration project focused on the implementation of evidence-based complementary and integrative health therapies in WHS. The implementation included dissemination of evidence for CIH therapies to clinicians, researchers, and other stakeholders. The evaluation led by the EPCC-CIHEC used a rapid assessment method (Trotter et al., 2001) to assess each flagship site's stage of WHS implementation at multiple time points. The report by Bokhour and colleagues (2020) presented early findings from the evaluation of the WHS

implementation, utilization of WHS services, and the impact on the health and well-being of Veterans receiving services at the flagship sites. Using an observational study design, they compared outcomes of Veterans who received WHS services and those did not receive WHS but received conventional care. They relied on data from patients VA electronic health records and a longitudinal survey. They reported that use of WHS services at the sites increased, and there was a positive association of WHS use with many areas of Veterans' health and well-being. They demonstrated that Veterans with chronic pain who used whole health had a three-fold reduction in opioid use and reported better perceptions of the care received as being more patient-centered, greater engagement in healthcare and self-care, and better perceived stress indicating improvements in overall well-being. Employees with more involvement in the WHS also had lower turnover, lower burnout, and greater motivation.

The work of EPCC and CIHEC in partnership with the OPCC&CT formed the foundation for VA's Congressional report on the impact of implementing the WHS and provided data and research to the *Congressional Commission on Creating Options for Veterans' Expedited Recovery (COVER)*(Creating Options for Veterans' Expedited Recovery (COVER)

Commission, 2020). Completed over a two-year long process, the landmark COVER

Commission engaged multiple stakeholders within and external to VA. The Commission concluded that "...a cross-cutting range of improvements are needed, but most importantly that the VA must transform its delivery model to one that is person centered, relationship-based, and focused on veterans' whole health" (p. 3). The COVER Commission specifically recommended that the VA "establish an ongoing research program focused on testing and implementation of promising adjunctive CIH modalities associated with positive mental health, functional outcomes, and wellness that support whole health and the VA Health Care Transformation Model."

Together, the activities and recommendations of the COVER Commission, and the progressive work of the OPCC&CT and partnerships with VA research over nearly two decades have supported the expansion of CIH and WHS across VA. These efforts culminated in VA leadership's approval in February 2020 of VHA modernization efforts to engage Veterans in Lifelong Health, Well-Being, and Resilience, which mandated the integration of Whole Health into mental health and primary care across VHA and have continued to the present.

Expansion in VA Research Addressing Whole Health and Related Components

Answering the call for ongoing research to address integrative health care options and whole health, the HSRD and QUERI revised its strategic priorities to include whole health explicitly and went on to fund additional health services research initiatives and implementation studies focused on WHS and evaluation of its components. (See Table 1). Among HSRD research completed by 2009, projects included those focused on whole health (N=17), coaching (N=51), and care coordination (N=97).

Among those HSRD studies focused on whole health (N= 17) HSRD funded awards include one CDA, 11 investigator-initiated research or nursing research initiative awards, and three HSRD QUERI-funded (PPO or CRE) center awards. Eight studies are completed, and nine studies are ongoing.

The completed studies include one focused on COVID (C19-20-393; PI D Blonigen) and peer support impacts and one (SDR-20-031; PI: J Thompson-Hollands) focused on generating pilot data for the role of family members in PTSD treatment. Notably among the completed studies (CRE 12-426-PI L. Woodard, Houston, TX) was a VISN and research partnership focused on evaluating the process of implementing a collaborative goal-setting intervention personalized to patient activation and health literacy levels. Known as Empowering Patients in

Chronic Care [EPIC], the study sought to implement the goal setting into routine PACT care in five VA facilities across two VISNs to evaluate the effectiveness and patient-centeredness of this intervention relative to usual care. Completed in 2018, the project resulted in creation of a toolkit to ensure sustainability of the program beyond the life of the research study. The toolkit includes: 1) a sustainable process map for Veteran identification and scheduling; 2) a decision tree for EPIC coach identification; 3) EES-accredited E-learning platform for EPIC coach training; 4) a clinic profile request form to ensure creation of an EPIC clinic; 5) revised and updated EPIC manuals; 6) Frequently Asked Question guide for facilitators; and 7) a SharePoint site to house EPIC materials and instructions. The toolkit was applied in Crown Point, IN without support from any research staff (Arney et al., 2020; Arney et al., 2018; Woodard et al., 2018; Woodard et al., 2020).

Among the 51 funded studies that address coaching, 42 studies completed in 2021, and nine studies are listed as active. Among completed studies, noteworthy is the evaluation of A Coaching by Telephone Intervention for Veterans and Care Team Engagement (ACTIVATE) trial (Oddone et al., 2017; Oddone et al., 2018). In ACTIVATE, researchers assessed rates of enrollment in prevention programs and changes in behavioral activation in Veterans participating in a telephone coaching intervention. The coaching intervention tested in ACTIVATE included Using motivational interviewing techniques, coaches reviewed the HRA results, determined patient preferences regarding their modifiable risk factors, discussed strategies for addressing these risk factors, and advised patients on the prevention programs that would be most helpful for achieving their goals. Coaches were instructed to assess patient

readiness to enroll in prevention programs and to help patients develop SMART (small, measurable, attainable, relevant, timely) goals. The second telephone call, with the same coach, occurred 1 month later. During this call, coaches determined whether patients had

enrolled in one or more prevention programs. If they had not yet enrolled, coaches used motivational interviewing to problem-solve and set new SMART goals (Oddone et al., 2018).

The ACTIVATE Coaching intervention resulted in resulted in a greater than twofold rate of enrollment in prevention services compared to controls. In secondary analyses Nouri et al (2019) examined whether the intervention effect would be stronger among Veterans with low health literacy (specifically, reading and numeric literacy) as compared to those with high health literacy. They found that among the 417 Veterans studied, those with low numeracy enrolled in prevention programs at a slightly higher, but not statistically significant, rate compared to those with high numeracy; and among those with high numeracy, those in the intervention group performed better on patient activation measures. Their results suggest that health literacy and numeracy skills of patients is important to consider when designing whole health coaching and that coaching strategies that are more tailored to those with low health literacy and numeracy may result in greater patient activation.

The ACTIVATE study is the only study to date that examined costs (Sloan et al., 2020). They found that short term (6 months) costs were similar among those who received the whole health coaching compared to those who completed a health risk assessment with no coaching (\$8665-\$9900 in 2016 dollars), although among some unemployed Veterans with fair or poor perceived health, costs in the intervention group were higher (\$12,814 vs \$7971). Indeed, the authors concluded that cost evaluation of health risk assessment and coaching programs warrant longer observation period and further that such programs should specifically target patients with high rates of health care utilization, with the goal of improving their health and, over the long term, reducing their utilization and costs.

Studies on care coordination include those examining the effectiveness of intensive primary care interventions for high-risk high need patients have also employed elements of

whole health (Edwards et al., 2017; Hsu et al., 2019). Hsu and colleagues (2019) used Whole Health Coaching (VHA Office of Patient Centered Care and Cultural Transformation, 2017) as part of an intensive outpatient care coordination program for high-risk VA patients, known as ImPACT (PPO13-117; PI-D Zulman) They focused on VA patients with high risk for hospitalization and mortality (based on the upper 5% CAN score to assess and describe patient's goal setting behaviors and to identify factors associated with patients' goal progress. They used Whole Health Coaching to enhance staff skills. Although a small study at a single site, they found that high risk patients participating in the intensive outpatient program patient goal setting was evident and included medical behavioral and social domains. They reported that 88% of the 113 patients studied set at least one goal and the majority (n = 72, 64%) of patients attained goal progress. Patient's goals covered different domains, from medical, behavioral and social. During subsequent encounters, the team regularly assessed patients' readiness for change and followed up on their goal progress using motivational interviewing and health coaching techniques. When patients reached program completion, the team used a discharge note template to indicate whether they had progressed toward their goals during program enrollment. The ImPACT study concluded that future care coordination interventions might incorporate strategies to have a broader integration of behavioral and social service components within PACT programs.

Among the nine newer and ongoing studies focused on whole health, they target a range of specific populations (e.g. women Veterans homeless Veterans, patients with diabetes, PTSD and chronic pain) and interventions (e.g., patient training in communication, provider training in deprescribing, and patient coaching). All the ongoing studies are using study designs that include randomization, comparison groups, and longitudinal outcome measurements.

Notably, among the newest studies in this list is a randomized controlled trial focused on empowering patients with diabetes to engage actively in decision making (IIR19-442-PI: H

Gordon, Chicago, IL). The study is building on pilot work that tested SpeakUp! Video communication training for patients (Gordon et al., 2020a&b). The study is using a Hybrid Type 2 design to 1) partner with key clinical staff to develop a strategy for delivering the Speak Up! video in VA outpatient primary care clinics using a facilitated Plan Do Study Act (PDSA) process and 2) examine the effectiveness of the Speak Up! video using the RE-AIM framework to evaluate Reach into the patient population, Effectiveness to improve outcomes (Hemoglobin A1c, communication self-efficacy, diabetes distress), Adoption by providers and clinics, Implementation (completion, fidelity, and intensity), and Maintenance after the end of external facilitation. If successful by the end of the study (2025) the investigators will have generated the evidence to justify widespread dissemination of the video training.

Additional details about the full list of these completed and ongoing studies are included in their abstracts provided in the Appendix.

The HSRD QUERI program has also supported specific initiatives focused on whole health. Notably, one of the QUERI strategic objectives focuses on Veteran's life journey and tailoring care to Veterans through the different seasons of their lives, and has supported establishment of at least five programs focused on different aspects of Veterans life journey (See website here: Tailoring Care to Veterans' Life Journey (va.gov) (See Table 2) These five QUERI funded programs partner with multi-level stakeholders, to deploy and evaluate implementation and quality improvement strategies to optimize effective care for Veterans as they age.

Yet another research initiative that has furthered the partnership of the WHS and integrative health and the focus on pain management is the ongoing VA and Department of Defense (DOD) and National Institutes of Health/National Center on Complementary and Integrated Health (NCCIH) joint sponsorship and funding of the Pain Management Collaboratory

(Kerns et al., 2019). Begun in 2017, the PMC and its related studies are building evidence on the effectiveness of non-pharmacological pain management approaches and specific integrative health therapies that are central to the WHS core services being offered for veterans and military service personnel (Kerns & Brandt, 2020). These studies are underway, and several were described in a journal supplement in 2020.

Review of Research Evidence on Whole Health and Pain Management

These VA research efforts focused on WHS programs, and its components have contributed to the peer reviewed literature. To gauge the contributions to new knowledge, we considered a broad review of literature on whole health. To keep the search within a scope aligned with the VA focus of whole on improving care for Veterans dealing with pain conditions, we limited our search to those focused on whole health and pain management. We identified articles listed on the HSRD website list and PUBMED (Figure 1). An initial search of the citations of HSRD funded VA research that were catalogued with key words for "whole health", yielded eight (8) journal publications. A broader search of published works in PUBMED in the last ten years with key word search terms of "whole health" and "pain" and/or "whole health models". After eliminating duplicates, and applying exclusions, we profiled the final set of 32 articles using a PICOTS (population, intervention, comparators, outcomes, timing, and setting) format (Table 3).

Of the 32 articles profiled, 22 are based on studies conducted in VA healthcare settings and seven in non-VA settings. Five of these publications related to the evaluation of the WHS demonstration program. Results of selected articles are highlighted below.

In their 2022 follow-up report on the WHS demonstration project evaluation, Bokhour and colleagues (2022) showed that among the 18 flagship sites implementing WHS, Veterans'

use of opioids decreased 23% (31.5–6.5) to 38% (60.3–14.4) among WHS users depending on level of WHS use compared to a secular 11% (12.0–9.9) decrease among Veterans using conventional care. Compared to those using conventional care users, they also found that WHS users had greater improvements in care experiences, care engagement, and well-being. In a March 2022 commentary, Kligler and colleagues (2022) who lead the WHS Demonstration and evaluation noted, that "Evaluation of the flagship outcome data is ongoing, and we expect future results to continue to inform the system's decisions about deployment priorities." (Kligler et al., 2022).

Reed and colleagues (2022) examined data from the WHS demonstration project. focused on assessing whether Veterans with comorbid chronic pain and PTSD utilized Whole Health services, including Core Whole Health Services and CIH therapies, to the same extent as Veterans without PTSD. Their survey of regular VA PACT patients (Goulet et al., 2016; Mayhew et al., 2019; U.S. Department of Veterans Affairs, 2020), who utilized up to ten different types of whole health services (acupuncture traditional, acupuncture BFA, massage, chiropractic guided imagery, meditation, tai chi, yoga, biofeedback and hypnosis), showed that Veterans with co-occurring chronic pain and PTSD consistently utilized more whole health services and CIH therapies compared to Veterans with chronic pain but without PTSD. The authors note that overall, their findings were consistent with prior research by Taylor and colleagues (2019) indicating about half of surveyed Veterans CIH therapies in the prior year. Yet Reed and colleagues found a lower use rate (about 40%) among Veterans in the chronic pain group, which they attribute to sampling a broader set of Veterans and using less detailed self-report. Interest in the WHS varied across services. Since there was higher use of WHS among Veterans in the Comorbid group, the authors contend that their results suggest that WHS may be an efficient way to reach complex Veteran populations, and that access and use of WHS provides patients with opportunities to set their personal health goals and choose

treatments aligned with those goals, thereby increasing engagement with healthcare and selfcare.

Among the other studies applying WHS features in pain management is the study by Seal and colleagues (2020). Designed as a multisite pragmatic clinical trial, the wHOPE is comparing a Whole Health Team (WHT) approach to Primary Care Group Education (PC-GE); with usual VA primary care. The intervention includes a medical provider, a complementary and integrative health (CIH) provider, and a Whole Health coach, who collaborate with VA patients to create a Personalized Health Plan emphasizing CIH approaches to chronic pain management. The active comparator intervention, PC-GE, is adapted group cognitive behavioral therapy for chronic pain. The study will test whether the WHT approach is superior to PC-GE and whether both are superior to decreasing pain interference in functioning among 750 veterans with moderate to severe chronic pain. Secondary outcomes include changes in pain severity, quality of life, mental health symptoms, and use of nonpharmacological and pharmacological therapies for pain. Data sources include a combination of extant clinical data from the VA electronic health records and patient-reported information over 12 months of followup. The study also aims to evaluate implementation processes and budget impacts (See also Tong et al., 2022). This study is ongoing and expected completion is in 2023 (Project Number: NCT04330365; PI: Seal).

Among ongoing studies whole health coaching is being explored for management of PTSD among Veterans (Johnson, 2018). Johnson and colleagues (2021) reported on piloting of whole health coaching for PTSD. Fifteen primary care Veterans with PTSD participated in peer-delivered whole health Coaching. This pilot work focused on the process of peer-delivered Whole Health Coaching including patient engagement, patient experience, fidelity to the coaching and peer roles, and patient satisfaction. Retention was 11 of 15 participants, and factors facilitating engagement included peers as providers and flexibility in scheduling/modality

of sessions. They reported that peers demonstrated high fidelity to coaching skills and participants expressed high satisfaction with the peer support. Although a small study, it suggests that having peer coaches may be feasible and worthy of further testing in similar primary care clinical settings.

Organizational aspects of WHS are also being evaluated. Including the organizational alignment of the overall WHS and the local organization of the programs within medical centers. One study focused on the local leadership of WHS, emphasizing the role of the WHS champion and how that role is developed and supported. Hyde and colleagues (2021) applied the Shea conceptual framework (2021) in examining the 18 flagship sites to gauge characteristics of successful clinical champions. They reported that key characteristics of strong clinical champions included belief in and enthusiasm for whole health approaches. Five additional characteristics include: 1) Personal use of whole health-aligned approaches; 2) Institutional knowledge; 3) Organizational change or QI experience; 4) Credibility with colleagues; and 5) Decision-making authority. They also identified key factors in the selection process, such that the characteristics align with the intention and purpose of the role, whether it is to lead a new way or change the approach to care, one or more champions may be needed. Hye and colleagues reported two important themes regarding how clinical champions were prepared and trained, and how they were supported over time. They noted that training could build over time and be tiered as programs mature. The also noted the importance of creating a structure for ongoing support and mentorship such as through regular Community of Practice calls, to provide opportunities for on-going education, information sharing, and skill building.

Several studies highlight potential opportunities for future practice and research. For example, a recent study by Jones and colleagues (2022) highlight the opportunities that exist for future innovations and evaluation. They reported on their single site observational study of

health care use among a cohort of Veterans enrolled in an integrated primary care program where SDOH and SUD prevention, assessment and treatment were central components of service design. They found improved primary care engagement and reductions in acute care and specialty mental health and SUD services following clinic enrollment. The largest changes were observed for patients with historically high levels of ED use. And yet, for other patients with histories of homelessness or SUDs, increasing trends in ED visits and hospitalizations prior to IPC were attenuated upon IPC enrollment. While these findings suggest that increasing primary care capacity to address addiction and SDOH may benefit health systems striving to reduce acute care overuse, the authors noted that referrals to other specialty services like whole health, were not addressed in the study. This study points to the challenge in disentangling potential effects of WHS from other ongoing initiatives and innovations, which while important, is difficult to pinpoint and measure.

In another study, focused on an important tenet of WHS that emphasizes the importance of planning and goal setting clinician perceptions about patient engagement, Katz and colleagues (2020) conducted an analysis of data from the 2016 PACT national survey, which included 2,478 direct care clinicians direct care clinicians (primary care clinicians, registered nurses, and clinical associates) from 609 clinics. For all 3 subscales of patient engagement (planning and goal setting; motivational interviewing; and organizational strategies to promote self-management) they found that respondents at high-performing clinics were more likely to report having regular team meetings to discuss performance improvement and having leadership responsible for implementing PACT. They concluded that several desirable organizational and contextual factors were associated with high performance of patient engagement care practices. Strategies to improve the organizational functioning of primary care teams may enhance patient engagement in care.

Two VA system-wide care coordination Initiatives that have been happening alongside the WHS may enhance the opportunities to address other aspects of whole health. These initiatives include the Care Coordination and Integrative Case Management (CC/ICM) initiative led by the Office of Nursing Services and the National Social Work program Office, and the Community Care Transformation Model led by the Office of Community Care . Both initiatives are informed by the Care Management Society of America (CMSA) model and standards, and deeply rooted in the Collaborative Chronic Care Model (CCM) (Bodenheimer et al., 2002a, 2002b; Coleman et al., 2009; Von Korff et al., 1997), which has proven effective in improving patient health outcomes including for mental health outcomes, in a wide range of settings. As with the CCM, components are flexibly implemented according to local needs. In the case of the CC/ICM early phases sites began in 2018, slowed during the peak of the pandemic and has been reinvigorated in 2022. The Office of Community Care approach has evolved with legislated requirements to expand access to community care providers for VA enrolled Veterans. The Office of Community care is primarily focused on ensuring coordination of services for Veterans who need or require services from VA community care network providers. These ongoing VA efforts focused on care coordination for Veterans within VA-facility based providers and between VA and VA Community care providers includes more complex patient population and expanded care settings that could also be considered in future implementation of whole health programs.

The CC/ICM and OCC leaders have worked to find a common approach for enhancing care coordination, focused on identifying those patients who are high need/high risk and high cost relying on prior measures validated for predicting hospitalization and mortality (Fihn et al., 2014; Wang et al., 2013) to align resources to meet the health system planning and subsequent care processes (Greenstone et al., 2019). Care coordination was the focus of a VA HSRD State-of-the-Art conference and journal supplement and highlighted several studies underway

addressing aspects of care coordination in VA care (Cordasco et al., 2019). At least two ongoing studies focused on measurement issues, including validating measures used for patient needs assessment (Project Number: 1I50HX003275-01; PI: C Battaglia) and examining if and how specific care processes are associated with patient's health care use, mortality and patient and provider perceptions of care integration (Project Number: 1I01HX003261-01A2; PI: D. Hynes). These ongoing studies may shed light on some of the measurement gaps regarding coordination and care planning with direct links to patient centered outcomes, which may be useful in evaluation of WHS (Kligler, 2022).

2. Efforts Outside the VA to Promote Whole Health Serving Veterans

Veterans also seek care outside VA, including in the private sector when they become eligible for Medicare coverage or through state Medicaid programs. Veterans may use a combination of services under these public and private healthcare systems and providers.

Only one study identified in our literature search focused on Medicare beneficiaries. Bouchery and colleagues implemented and evaluated a whole health program, known as *Race to Health!*, in a community mental health center focused on Medicare services and expenditures (Bouchery et al., 2018). In this whole health model conducted in 2009-2015, the monitoring of overall health and wellness education within the center's outpatient mental and substance use disorder treatment services was embedded. During the first two and one-half years of the program implementation, patients who participated in *Race to Health!* compared with matched patients at other mental health clinics with no whole health program, had a significant decrease in Medicare expenditures by \$266 per beneficiary per month. *Race to Health!* patients had fewer hospitalizations, emergency department (ED) visits, and office visits per month relative to the comparison group. Their results translated into about one less hospitalization for every two patients served, five fewer ED visits for every six patients served, and four fewer office visits for

every patient served. Although limited to fee-for service Medicare beneficiaries at one mental health clinic and lacking patient centered outcomes such as satisfaction, quality of life and out of pocket costs, it is among the earliest studies of whole health that provides evidence that whole health care models can affect expenditures and service utilization.

Another study revealed potential for integrated peer support programs to combat loneliness among people with serious mental illness. Researchers surveyed a national sample of adults with serious mental illness and found that loneliness was associated with pain, functioning, and hospitalizations. Their findings suggest a broader whole health approach that considers addressing maladaptive cognition and social skills training, such as through partnering clinical components with trained peer support. We did not find evidence about any active programs combining these whole health program components in non-VA settings.

Our literature search and reviews were limited to those focused on whole health and pain, due in part by the timeline for this report, and therefore studies focused on other aspects of whole health or whole health applied to other conditions were not identified in our search. Further refinement is also needed to consider specific populations or conditions of interest. An evidence review that considers a search with broader terms used outside the VA setting (e.g., care coordination, accountable care, coaching, peer support, self-efficacy, patient activation, integrative care, etc) and likely combinations of terms would be needed to identify articles that address other applications of whole health and/or key components of whole health in non-VA settings.

For example, in Medicare, the CMS Innovation Center has led the transformation to create accountable care models, advance health equity and reduce costs, "...through high quality, affordable person-centered care", over the last ten years (Centers for Medicare & Medicaid Services, 2022). Indeed, there have been more than 50 models initiated and evaluated during this time. Among these care models, some (e.g., Accountable Health

Communities Model; Maternal Opioid Misuse Model) (Brooks-LaSure et al., 2021; Centers for Medicare & Medicaid Services, 2020) have focused on addressing the health-related social needs of beneficiaries and examining if health outcomes and costs improve. Yet none of these models have the whole health vision that the VA espouses. We are also aware of related studies focused on the impact of care coordination services in Medicare (e.g., Bindman, et al., 2018) and those focused on health-related social needs (e.g., Sadowski, et al., 2009;). For example, Bindman and colleagues showed how the addition of care coordination services in Medicare was associated with reduced mortality and costs after hospitalization (Bindman & Cox, 2018). Enhanced care coordination across providers, including health care and social service providers has been emerging over several years under Medicare and Medicaid programs, and with increasing evidence regarding association with positive health effects (Sadowski et al., 2009; Sandberg et al., 2014). A growing number of health systems are screening for healthrelated social needs, yet there do not appear to be programs on scale with what the VA offers (Sandberg et al., 2014; Shah et al., 2016). Medicare accountable care models have focused on identifying needs in standard ways so that clinicians and staff can identify people at risk (Billioux et al., 2017). While identifying people with unmet health related social needs is an important first step to connect people with resources within a health system and/or in their communities, scaling resources to meet the needs, or to combine the screening with other whole health components, such as self-activation, coaching, wellness counseling, mindfulness training, etc., is not yet evident on a large scale, and was not identified in our search.

There has been evidence in non-VA settings about other components of whole health such as goal setting and peer support, and which has informed VA research and program implementation strategies (Kersten et al., 2015; Lorig et al., 2014). Notably, Lorig and colleagues (2014) and others have demonstrated that setting specific, measurable, achievable, relevant, and time-bound goals through action planning is one method that has been associated

with improved health and self-efficacy outcomes. Goal setting has become a cornerstone of the VA whole health care planning process for individual patients. And there are likely other examples of studies conducted in non-VA settings that have informed VA practice. An expanded search that includes different search terms should be further explored to identify additional relevant research on specific aspects of whole health models and outcomes of interest that have potential for informing VA whole health efforts and programs.

3. Needs and Opportunities for Evaluating Whole Health

It is apparent that the activity and accomplishments of the VA whole healthcare journey has reached across the entire VA healthcare system. In addition, the breadth of interventions evaluated has included both the Veteran experience and the practice of whole health. From reviewing this chronology and the range of evaluation activities that have emerged over two decades, there are at least three factors that may have contributed to this progress and spread.

First there has been a strong and sustained organizational commitment to whole health. Not only has there been a vision at the highest levels in the VA organization, the OPCC&CT developed and implemented the plans across the VA clinical settings. The stepped approach, beginning with innovation hubs and flagship sites within the VISNs fostered the expertise and innovative thinking needed and helped to establish communities of practice in whole health. Once established, research and clinical partners were able to leverage the clinical innovation hubs for evaluation and research studies. The VA has sustained the whole health vision, even while facing leadership transitions, as well as other political and organizational challenges.

A second factor is the opportunity created by legislative mandates to channel this vision, notably with the CARA legislation. With the attention of Congress on improving pain care options in the VA and focused on enhancement of complementary and integrative health

options came together with the objectives of whole health. This mandate created opportunities for stronger partnerships on specific aspects of the whole health vision. In addition, this legislation came with additional funding, which supported novel resources for training, services, and new research partnerships. The legislation and its companion funding supported the initiatives needed to build evidence on whole health components focused on pain care.

The research partnerships are a critical third area that supported the growth and spread of whole health. The long standing and embedded nature of research in the VA to be ready and willing to partner to build evidence and effect change catapulted the evidence on whole health. Clinical and research leaders in the VA have worked closely from the early days to develop the vision and to build the partnerships needed to move the plan along. Evidence also grew and strengthened over time, beginning with observational studies and later, leveraging the innovation hubs and clinical expertise to conduct more rigorous and controlled study designs now underway.

In considering factors that have undermined progress on whole health, it is difficult to single out any one aspect for a large national public health care system. According to the VA website the Veterans Healthcare Administration provides care at 1,293 healthcare facilities including 171 medical centers and 1,112 outpatient sites and serves more than 9 million Veterans per year (U.S. Department of Veterans Affairs). As the founding and current leaders of the OPCC&CT have said, "As should be evident by now, this is not a quick fix or a small or even programmatic change. It is an effort to transform the culture of the VA system and to totally rewire what healthcare is and how it works" (Gaudet & Kligler, 2019).

Transforming a healthcare system to reinvent itself is not done quickly, and it is not done in isolation. The culture of health and healthcare in general is a factor that affects how any single system works. Veterans relying on the VA for care also rely on other health systems and

services for the health and wellness they seek. As we have witnessed how the COVID-19 pandemic impacted the vital functioning of healthcare systems around the globe, and impacted most every sector of the world economy, the pandemic caused some shifts in the whole health from in-person to reliance on tele-health delivery of services. According to some (e.g., Kligler, 2022; Heyworth, et al., 2020) the pivot to tele-whole health was well received by Veterans and providers. Research on the effectiveness of tele-whole during the pandemic is still underway, however. The pandemic indeed has demonstrated how what happens outside the VA healthcare system also affects what happens inside VA healthcare.

There are opportunities for enhancing further progress on whole health in the VA. One area is to expand the partnerships with other VA clinical offices. New partnerships with specific VA clinical services may help to include other populations in testing and evaluating whole health components. More evidence on how well whole health works for Veterans with diabetes, cardiovascular disease, kidney disease and multiple morbidities would be useful. Working more closely with social work and nursing services may also offer opportunities to include population subgroups who have complex needs. How whole health works for Veterans from different cultural and socioeconomic backgrounds could inform how well whole health components can address health related social needs for those with the most complex needs and any adaptations that might be required.

Regarding research on whole health, focus on additional outcomes especially considering economic and functional domains. In our search we found only one study that examined costs of whole health coaching (Sloan et al., 2020). A better understanding of the investment and benefits of whole health are needed. Other research gaps to address include stronger evidence on the causal effects of whole health components. It is encouraging to that there are several ongoing studies that are using experimental and pragmatic clinical trial designs (i.e. controlled trials), and implementation and effectiveness study designs (i.e., hybrid

type 1 and 2 designs). Research that addresses patients with multimorbidity and over time is also needed to enhance our understanding of the longitudinal effects of whole health. Continued development of tools derived from research evaluation that can be applied in clinical settings would help spread effective whole health practices.

Outreach that includes both scientific and practice audiences may also help to critically evaluate whole health progress and its potential over the long term. The OPCC&CT might consider a conference or series of conferences to focus on measurement issues. Bringing together those conducting the research and implementation studies, as well as patients, to discuss practical measures and timing of measurement, is needed. Kligler recently noted some areas such as how best to measure well-being, as well as whether or not Whole Health leads to cost avoidance, and whether tele-Whole Health is as effective as in person (Kligler, 2022). Taking these ideas further, the VA should also explore if and how whole shifts the cost burden between patients and the health system. Additional measurement issues that warrant attention include when to measure patient well-being and other outcomes as well as the frequency of measurement.

Outreach that addresses the practice and spread of whole health is also important. The VA should consider whether there is potential to involve providers in the VA Community Care Networks in whole health to avoid fragmentation of care. The extent to which Veteran Service Organizations and other agencies, including Medicare and other health systems that support Veterans can and should be involved in the shift to a whole health system should also be considered. Ongoing outreach efforts with key stakeholders would help to inform the VA if the outcomes measured are aligned with the practices being delivered and with stakeholders' expectations.

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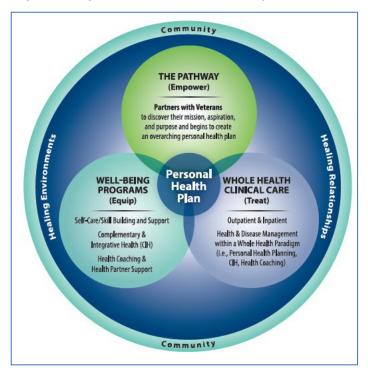
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Figure 1. Figure 1. VA Whole Health System Circle of Health



Source: VA Whole Health Library Whole Health Library Home (va.gov) Accessed April 8, 2022.

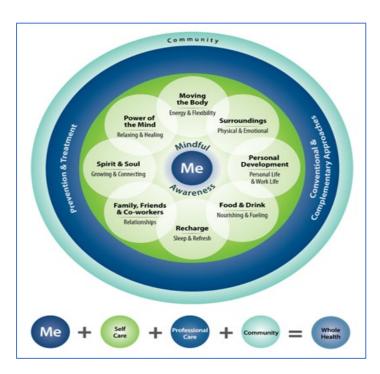
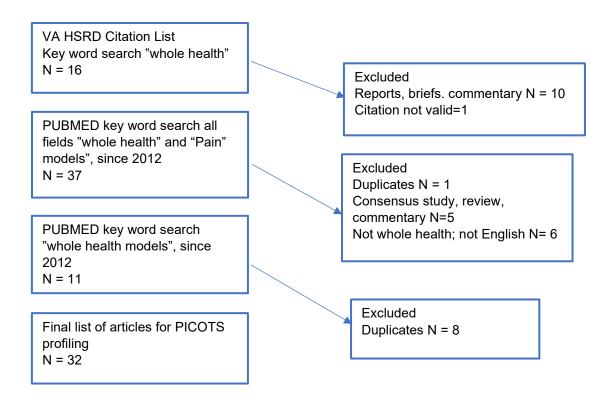


Figure 2: Literature Search Results of Peer Reviewed Articles Focused on Whole Health and Pain and Whole Health Models



APPENDIX A

HSRD FUNDED STUDIES AS OF MARCH 5, 2022 WHOLE HEALTH

IIR 19-187:

Using Data Analytics and Targeted Whole Health Coaching to Reduce Frequent Utilization of Acute Care Among Homeless Veterans

Abstract:

Background: Ten percent of patients account for up to 70% of acute care costs. Among these "super-utilizer" patients, homelessness is a robust social determinant of acute care utilization. Through a field-based dashboard and clinical aids, the Hot Spotter Analytic program assists Patient Aligned Care Teams (PACT) with targeting and tailoring care for the highest-need homeless Veterans. However, many Veterans identified by the Analytics do not engage in supportive services that reduce risk for acute care utilization. Peer Specialists (PS) are a high-value workforce that can facilitate Veterans' engagement in care. Yet, there is a need to enhance the PS role with a structured approach that can capitalize on known facilitators of care engagement among homeless Veterans. Whole Health Coaching (WHC) is one such approach. By focusing on patients' values and goals rather than treatment of specific conditions, WHC reduces patients' stigma regarding their care needs and increases patient activation and well-being, which can increase engagement in supportive services.

Significance: By training a high-value workforce in a patient-centered approach to care that facilitates engagement in supportive services, our proposed research can reduce homeless Veterans' reliance on acute care services, thereby minimizing the financial burden these patients exert on the care system. This proposal responds to several VA HSR&D Research Priorities including Mental Health, Healthcare Value, Primary Care Practice, Healthcare Informatics, and Whole Health, as well as VA-related Legislative Priorities (MISSION Act).

Innovation and Impact: A critical innovation of this research is use of data-driven processes (Hot Spotter Analytics) to better target and tailor care for high-need, homeless Veterans in VHA. Our proposed research is also innovative in that it seeks to integrate the Analytics with a workforce (PS) and approach to care (WHC) that are rapidly expanding in primary care services VA-wide. These features of our target intervention are consistent with the National Academy of Medicine's recommendations for high-quality care for high-need patients. Finally, by focusing on the development of personal health goals that are aligned with patients' priorities and values, WHC is a key innovation to be added to existing VHA services for homeless Veterans.

Specific Aims: The goal of this project is to integrate use of Hot Spotter Analytics with Peer Specialists trained in Whole Health Coaching (PS-WHC) and evaluate whether this approach reduces homeless Veterans' frequent use of acute care. Aim 1: Conduct an RCT to test whether receipt of PS-WHC (vs. Enhanced Usual Care; EUC) predicts (1a) lower acute care utilization, (1b) better health-related outcomes, and whether (1c) the effects of PS-WHC on 1a and 1b are mediated by increased (i) patient activation and well-being, and (ii) access to supportive services. Aim 2: Conduct a process evaluation to inform VA's potential widespread

implementation of Hot Spotter Analytics + PS-WHC on PACTs. Aim 3: Conduct a Budget Impact Analysis (BIA) to determine the impact on total costs of VA care due to implementing PS-WHC.

Methodology: Using a Hybrid Type 1 design at the Palo Alto and Bedford VAs, 220 Veterans on PACT panels who are (i) on the VA Homeless Registry, and (ii) persistent super-utilizers of acute care will complete a baseline interview, be randomized to either EUC (usual PACT care + Hot Spotter Analytics and text reminders of appointments) or EUC plus 12 sessions of PS-WHC over 12 weeks, and be re-interviewed at 3, 6, and 9 months. For Aim 2, the CFIR framework will guide key informant interviews with 7 PACT staff/leaders and 12 patients from each site. For the BIA, we will include only VA costs from VA, Fee Basis care, and Choice care. Costs will be estimated per patient for all treatment beginning with randomization and continuing for 9 months.

Next Steps/Implementation: Depending on the results, we will work with our VACO partners in the National Center for Homelessness Among Veterans, the Office of Patient Centered Care & Cultural Transformation, and the Office of Mental Health & Suicide Prevention to conduct a large multisite implementation trial.

IIR 19-442:

Empowering Veterans to Actively Communicate and Engage in Shared Decision Making in Medical Visits, A Randomized Controlled Trial

Abstract:

Background: Type 2 diabetes mellitus (T2D) affects almost one in five VA patients overall and almost one in four VA patients who are racial and ethnic minorities. Adherence to medication regimens and lifestyle factors (such as diet and exercise) is important to improve outcomes in T2D. Adherence to these factors and subsequent achievement of outcomes is related, at least in part, to effective communication in medical encounters. Empowering and activating patients to use more effective communication behaviors with their providers leads to better adherence to treatment and better biomedical outcomes. However, interventions to improve communication have not been adopted in practice largely due to the cost of trained personnel to deliver the training. Thus, there is a gap in effective interventions that can improve communication related outcomes. In a recent VA HSR&D funded trial we showed efficacy of the Speak Up! video. Veterans watching the video had significantly higher self-efficacy to communicate and lower hemoglobin A1c at follow-up. Significance: Type 2 diabetes (T2D) is common, expensive, and chronic. Estimates put the prevalence of T2D at almost 20 percent. The proposed study is highly significant because the condition under study, T2D, is highly prevalent and has negative impacts for Veterans with the symptoms and sequalae of T2D. Our objective to activate patients' communication to achieve goals of care and to improve outcomes of T2D is responsive to VA priorities to improve customer service, primary care practice, and care of complex chronic diseases.

Innovation: Our proposal to engage patients in communication in medical visits is innovative because addressing patients' communication as contrasted with providers' communication is unique in the VA. It is also innovative because activating patients facilitates patient-centered care and shared decision making which are key goals in the VA/DOD guideline for the

management of T2D and contributes to VA's commitment to the Whole Health model. Also, our intervention could be a paradigm for encouraging patients with other conditions to use active participatory communication. Specifically, the design and communication content of Speak Up! could serve as a model for the development of activation interventions for Veterans with other conditions.

Specific Aims: Our proposed Hybrid Type 2 study has two specific aims: Aim 1. Implementation aim – In partnership with key clinical staff develop a strategy to deliver the Speak Up! video in VA outpatient primary care clinics using a facilitated Plan Do Study Act (PDSA) process. Aim 2. Effectiveness aim – Examine the effectiveness of the Speak Up! video using the RE-AIM framework to evaluate Reach into the patient population, Effectiveness to improve outcomes (Hemoglobin A1c, communication self-efficacy, diabetes distress), Adoption by providers and clinics, Implementation (completion, fidelity, and intensity), and Maintenance after the end of external facilitation. Hypothesis 1. Patients will have improvements in outcomes (A1c, diabetes distress, communication self-efficacy) from before to after watching the video. Exploratory Hypothesis 2. Patients that are at higher risk of having challenges communicating with physicians (patients with low health literacy, African- American patients, patients with depression) will also have improvements in outcomes.

Methodology: The proposed study is a Hybrid Type 2 effectiveness – implementation trial of the intervention using a cluster-randomized stepped-wedge design in six clinics. We will test our implementation strategies using a formative evaluation guided by the Promoting Action on Research Implementation in Health Services (PARIHS) framework, and we will use the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework: to examine effectiveness of the Speak Up! Video; to supplement the formative evaluation from PARIHS; and to conduct a summative evaluation to evaluate success of the implementation strategies.

Implementation/Next Steps: This proposal will test the feasibility of implementing the Speak Up! video in primary care and if successful will generate the evidence to justify widespread dissemination of the video.

IIR 20-079:

Effect of Patient Priorities Care Implementation in Older Veterans with Multiple Chronic Conditions

Abstract:

Background: As Veterans age, they face an increasing number of chronic conditions and functional limitations. Multiple chronic conditions (MCC) in this population are inadequately treated by current approaches to healthcare, based on single-disease guidelines. These guidelines do not provide optimum care for patients with MCC for three key reasons: 1) single disease treatments in cases of MCC can often be conflicting and lead to adverse events because they do not take into account disease or drug interactions; 2) they do not take into account the priorities of older adult patients (what matters most) when offering treatment recommendations; 3) Guideline in this older population often lead to care that is burdensome.

Significance/Impact: Patient Priorities Care (PPC) was designed with input from patients, caregivers, and clinicians to address these concerns by promoting a shift in decision-making for

MCC which will result in less burdensome care, fewer adverse events, and care which is focused on what matters most for patients (including increased use of long-term home and community-based services and support) for Veterans with MCC and their families.

Innovation: The PPC approach elaborates specific patient priorities (i.e., values-based patient outcome goals and care preferences) and trains clinicians to recommend care that aligns with patient priorities rather than single-disease guidelines alone.

Specific Aim 1: Using our primary care-research partnership, we will conduct a formative assessment of PPC implementation for Veterans with MCC and develop implementation tools. Aim 1 Methods: We will perform stakeholder interviews with leadership, clinician, and staff partners structured by a formative evaluation framework. The assessment will identify barriers to implementation of PPC within VA primary care, and inform our enablers of implementation (e.g., recruitment of clinical champions, training of interested primary care providers, note templates, and processes for identifying care that aligns with patient priorities within routine care). Specific Aim 2: Evaluate the effectiveness of PPC in a randomized controlled study at two VA primary care centers. Aim 2 Methods: We will conduct a randomized clinical trial with 366 Veterans at Houston DeBakey VA and West Haven, Connecticut VA primary care practices to determine if PPC results in care that reduces treatment burden and unnecessary medications, increases use of home and community services, and aligns care with patient priorities compared with usual care. We will determine if Veterans randomized to PPC have lower ratings on the treatment burden questionnaire, and increased number of home and community-based services used compared to usual care at six months post intervention. Specific Aim 3: Conduct a summative assessment of implementation outcomes of PPC in VA primary care. Aim 3 Methods: Evaluate PPC implementation in primary care using Proctor's implementation outcomes framework (i.e., acceptability, adoption, appropriateness, feasibility, fidelity, penetration, and activity cost accounting). Participants will complete pre and post surveys and post-implementation interviews to assess these implementation outcomes of the PPC intervention. Cost analysis will be performed to determine costs associated with PPC.

Implementation/Next Step: Working with the VA Whole Health program and VA Office of Geriatrics and Extended Care, we to evaluate our effectiveness and implementation outcomes and develop an implementation toolkit and strategies for dissemination across VA.

IIR 18-230:

MOVE!+UP: Testing a Tailored Weight Management Program for Veterans with PTSD

Abstract:

Project Summary/Background: Post-traumatic stress disorder (PTSD), prevalent among Veterans, puts Veterans at increased risk for obesity and related conditions. Veterans with PTSD lose less weight in VA's MOVE! weight management program, due to PTSD symptoms that interfere with activity and healthy diet. In addition, many Veterans who receive evidence-based PTSD treatment remain symptomatic. A behavioral weight loss program that augments standard PTSD care and targets PTSD-related weight loss barriers called MOVE!+UP was piloted and iteratively refined among 44 overweight Veterans with PTSD. The fully developed MOVE!+UP is led by a psychologist and a Veteran peer support counselor, who provide complementary expertise. It includes 16 in-person group sessions with 90 minutes of general weight loss support, coupled with Cognitive Behavior Therapy skills to address PTSD-specific

barriers. Each session also includes a 30-minute community walk to address hypervigilance-based activity barriers and enhance classroom-based learning. Veterans receive two individual dietician visits, and counseling calls as needed. The cohort receiving the final MOVE!+UP package reported high satisfaction and had better weight loss outcomes than Veterans with PTSD in the general MOVE! program. They also reported substantial PTSD symptom reduction. Treatment targets like eating behaviors, activity, and insomnia also improved. MOVE!+UP effectiveness must be tested in a randomized trial.

Significance/Impact: MOVE!+UP is timely and efficient, simultaneously addressing physical and mental health of a priority Veteran group. MOVE!+UP is positioned to address HSR&D priorities by promoting mental health and improving PTSD symptoms, access to care, and whole health. This study is aligned with HSR&D and ORD methodological priorities by using a hybrid type 1 trial. This study's cost and utilization analyses, and systematic identification of implementation barriers and facilitators, would place effectiveness findings in context and facilitate rapid translation to the field if MOVE!+UP is effective. This study will also provide insights about ways that general MOVE! and PTSD care can be enhanced to improve reach and effectiveness. Innovation: MOVE!+UP is the first weight loss program designed to address obesity in Veterans with PTSD.

Specific Aims: This study proposes to randomize overweight/obese Veterans with PTSD enrolled in PTSD care to usual care enhanced with enrollment in MOVE! (control) or usual care enhanced with MOVE!+UP (intervention), and is guided by three aims: 1) Test whether intervention participants have greater 6-month weight loss (primary outcome), and 6-month PTSD symptom reduction and 12-month weight loss (secondary exploratory outcomes), relative to controls; 2) Assess whether compared to control, intervention participants have greater improvements on 6-month treatment targets: physical activity, eating behavior, insomnia, depression, and social support; 3) Estimate intervention and control condition costs and utilization, and identify MOVE!+UP implementation barriers and facilitators, to contextualize Aim 1 and inform future implementation.

Methodology: Hybrid type 1 trial with 164 overweight/obese Veterans with PTSD enrolled in PTSD care.

Implementation/Next Steps: This hybrid type 1 trial will provide data needed to prepare a MOVE!+UP implementation package for broader VA implementation if MOVE!+UP is effective. If it is not effective, Aims 2 and 3 will help understand how overweight Veterans with PTSD could be better supported in the future. Implementation activities would be coordinated with existing local, VISN, and national operational partners.

IIR 19-265:

Enhancing Geriatric Pain Care with Contextual Patient Generated Data Profiles

Abstract:

Background: Pain is not an inevitable or normal part of aging. However, chronic pain for geriatric patients is widespread, occurring in approximately 50% of community dwelling adults age 65 or over. Ineffectively treated chronic pain patients are at risk for poorer quality of life and functional decline. Risk for addiction to opioids prescribed for pain are increasingly recognized for geriatric pain patients. Evidence suggests that pain in geriatrics patients is common,

challenging to assess, and requires a whole-person approach to diagnosis, treatment and monitoring. The goal of this study is to refine and test an approach to create contextual Patient Generated Data (PGD) profiles to guide geriatric pain care.

Significance/Impact: Our proposed work will contribute to effective pain management and delivery of patient centered care. The proposed work aligns with many areas of high priority for VA including aging Veterans, pain management, informatics, and whole health and has implications for the redesign of the Electronic Health Record. Innovation: This study includes an innovative approach to patient centered care by examining contextual PGD contribution in depth in a vulnerable Veteran population with chronic pain.

Specific Aims: Aim 1: Prioritize content for contextual PGD profiles to support patient centered care for geriatric Veterans with chronic pain. Aim 2: Develop a prototype contextual PGD display and evaluate its usability. Aim 3: Examine the impact of contextual PGD profile displays on patient adherence, pain function, satisfaction, and shared decision making in a randomized trial.

Methodology: The study population is Veterans with chronic pain, caregivers involved in their daily lives, and the primary care clinicians who treat these Veterans in primary care or geriatrics clinics in both urban and rural settings. Clinicians will include physicians, nurse practitioners, nurses, social workers, psychologists, and other relevant primary care team members. This is a mixed methods study incorporating focus groups with clinicians and with Veteran patients and caregivers and systematic evaluation of iterative contributions of contextual PGD to develop and optimize methods for Veterans to contribute contextual PGD An additional group of Patient-Aligned Care Team members will engage in a card sort exercise, reporting in more detail on the relevance of particular contextual PGD elements for clinical care. There will be a randomized comparison at the patient level comparing patient visits that include contextual PGD and those that do not. The primary outcome is adherence to the pain management regimen. Secondary outcomes include pain function, patient satisfaction, and shared decision making in the visit.

Next Steps/Implementation: Our project includes multiple assessments designed to improve collection of contextual PGD to inform future implementation, working closely with our operational partners the Offices of Healthcare Informatics, Connected Care, Connected Health and Patient Centered Care and Cultural Transformation.

IIR 19-387:

MyPath: A Patient-Centered Web-Based Intervention to Improve Reproductive Planning for Women Veterans

Abstract:

Background: High rates of medical and mental health comorbidities result in elevated risks of poor maternal and neonatal outcomes among women Veterans compared to their civilian counterparts. Proactive planning and optimization of physical and mental health prior to pregnancy can mitigate these risks; however, nearly 40% of pregnancies among Veterans are unintended. National guidelines recommend routine delivery of patient-centered reproductive planning services in primary care, including assessment of reproductive goals followed by tailored contraceptive and/or preconception counseling, to reduce unintended pregnancy and improve pregnancy outcomes. Only 38% of women Veterans at risk of pregnancy, however, report having contraceptive or preconception health discussions with their primary care provider

in the past year. We developed "MyPath," a novel patient-facing web-based decision support tool, to address gaps in reproductive planning services in VA primary care. MyPath's objectives are to help women Veterans consider their reproductive goals, increase their knowledge, align contraceptive and pregnancy timing decisions with their goals and health needs, and engage in shared decision making with providers. In pilot testing among 58 Veterans, use of MyPath prior to clinic visits was highly acceptable to Veterans and increased reproductive planning discussions compared to usual care without increasing providers' perceived workload. MyPath use was also associated with increased decision quality and effective contraceptive use. Additional evaluation of MyPath in a pragmatic randomized trial is needed to assess effectiveness and collect implementation data.

Significance/Impact: Patient-centered, scalable interventions that can enhance delivery of VA reproductive planning services without creating burden on primary care providers are urgently needed. The MyPath intervention leverages interactive patient-facing technology to empower women to make high-quality informed decisions and engage with providers about their reproductive health needs. If found to be successful, MyPath will lead to increased access to patient-centered reproductive planning services in VA primary care, addressing key HSR&D priorities, including access, primary care practice, women's health, and whole health. Innovation: MyPath is the first online decision support tool designed to promote patient-centered reproductive planning services in primary care settings and to facilitate high-quality decisions aligned with reproductive goals. We will deliver the tool using the innovative strategy of partnering with the national VEText program to send the MyPath link to Veterans before appointments in an automated text message appointment reminder.

Specific Aims: 1) Aim 1 will test the effect of the MyPath tool used before primary care visits on occurrence of reproductive planning discussions with shared decision making (primary outcome), patient-provider communication self-efficacy, and contraceptive decision quality, compared to usual care; 2) Aim 2 will test the longer-term effect of MyPath on contraceptive utilization, unintended pregnancy, and preconception health behaviors, compared to usual care; 3) Aim 3 is an implementation process evaluation, including quantitative and qualitative data collection to identify implementation barriers and facilitators and intervention costs.

Methodology: This study is a 3-site hybrid type 1 pragmatic randomized controlled trial clustered at the provider level among 24 women's health primary care providers and their reproductive-aged Veteran patients. We will assess outcomes among a minimum of 342 women Veterans by telephone surveys post-visit and at 3- and 6-month follow up. We will collect information on barriers and facilitators to implementation using quantitative and qualitative methods, including interviews with Veterans, providers, and clinic leaders.

Next Steps/Implementation: The pragmatic design, in combination with strong operational partnerships, will enable rapid translation of research findings into practice if MyPath is found to be effective, with the ultimate objective of improving reproductive health outcomes and well-being among women Veterans nationally.

NRI 18-234:

Tailored Approaches to Reduce Distress and Improve Self-Management for Veterans with Diabetes (TARDIS)

Abstract:

Background: Diabetes self-management is critical to sustaining optimal health following diagnosis. Diabetes distress (DD) is a crucial factor that influences a Veteran's engagement in diabetes self- management. DD is distinct from depression, and includes four domains (i.e., regimen, emotional, interpersonal, healthcare provider). The presence of DD negatively impacts engagement in self-management and HbA1c. Despite interventions aimed at decreasing DD, these interventions have shown minimal lasting effects. One reason may be because interventions do not tailor information to an individual's DD.

Significance/Impact: This proposal will be the first to examine the impact of correlating factors on DD, and then design and test a self-management intervention tailored upon a Veteran's DD type. This proposal addresses the [VHA Strategic Plan Priority areas of utilizing resources more efficiently and improving the timeliness of services, and the HSR&D Research Priorities of Population Health/Whole Health and Primary Care Practice. This proposal's findings can improve both care delivery and health outcomes of Veterans, as we will help facilitate the Veteran's linkage to ubiquitous, existing VHA and community services]. Innovation: This proposal will develop an intervention that targets sub-optimal T2D self-management by providing tailored self-management information in conjunction with connections to supportive services. We will identify how, and to what extent, DD and its factors, influence a Veteran's self-management behaviors.

Specific Aims: Aim 1 will examine the association of [psychosocial factors (depression, PTSD), environmental factors (finances, support), self-management behaviors, and HbA1c with DD. These Aim 1 data will inform the identification of modifiable factors and selection of the population] for a diabetes self- management intervention for Veterans with T2D. Aim 2 will describe self-management challenges and preferred learning strategies [to inform the intervention components and delivery approach for Veterans with T2D. Obtaining in-depth perceptions of DD type, self-management strategies and challenges, and learning preferences is essential to tailoring intervention components]. The purpose of Aim 3 is to design & pilot test an innovative, tailored T2D self-management information and supportive services intervention for Veterans with T2D, to promote engagement in self-management behaviors. In Aim 3 we will determine the feasibility and acceptability of the intervention for Veterans with T2D.

Methodology: This proposal uses an explanatory, sequential mixed-methods design to describe DD in a sample of Veterans who receive care at Durham. In Aim 1 we will survey Veterans (n = 200), and balance enrollment by HbA1C ($< 9 \text{ or } \ge 9$) and medication use (insulin, no insulin). In Aim 2 we will conduct semi- structured interviews with a sub-sample (n = \sim 36) of Veterans surveyed in Aim 1. We will balance enrollment by HbA1C, medication use, and DD level as operationalized by the Diabetes Distress Scale (low, moderate, high). In Aim 3 we will develop and refine the intervention using findings from Aims 1 & 2 and strategies successfully used by co-mentors. To develop the intervention, we will conduct semi-structured interviews with stakeholders (n = \sim 20: physicians, nurses, administrators) to review components (e.g., learning approaches, relevant VA/community resources) to ensure relevancy. We will modify components and the delivery strategy as needed. Then, we will test the intervention with 30 Veterans to evaluate [feasibility and acceptability], and utilization of recommended supportive services, using quantitative and qualitative approaches.

Implementation/Next Steps: The next steps include dissemination of findings about DD, and its correlates, and the development of an IIR. This IIR will be a Phase III efficacy trial and will be

sufficiently powered to test the effects of providing self-management information and connections to supportive services tailored to a Veteran's DD to improve HbA1c.

IIR 18-228:

Engaging Patients to Promote Deprescribing

Abstract:

Background - Despite multiple provider- and system-level interventions to reduce potentially inappropriate medications (PIMs), many Veterans are still prescribed drugs that provide little benefit, placing them at unnecessary risk of adverse drug events (ADEs). One mechanism to reduce PIMs is through deprescribing, a de-implementation-based approach to thoughtfully discontinue a medication a patient is currently prescribed. Many Choosing Wisely recommendations address PIMs. Specifically, proton pump inhibitors (PPIs), a medicine used to reduce gastric acid, should be de-escalated to the lowest dose necessary to provide relief. Many older patients with diabetes are over-controlled, with blood sugar levels lower than recommended, yet remain on multiple diabetes medicines and may be able to use fewer medicines. These patients are also at higher risk of low blood sugar from insulin and sulfonylureas and should have limited use of these agents. Finally, gabapentin is often used offlabel to treat pain, with greatly increased use over the past several years. There are many barriers to deprescribing PIMs. Many interventions solely target the prescribing provider. Although some believe providers have primary responsibility for deprescribing, patient initiation of discontinuation conversations can effectively facilitate deprescribing. In a single-site pilot study, we successfully reduced PIMs by engaging VA Primary Care patients by providing them with Veteran-centric EMPOWER ("Eliminating Medications through Patient Ownership of End Results") brochures. However, it is not known if this approach will be as successful for Veterans with other chronic conditions or at non-pilot sites.

Aims – We propose three aims. 1) Examine the impact of a patient-centered intervention to change provider prescribing (the primary outcome), as determined by the frequency with which medications are either deprescribed or de-escalated. 2) Examine the effect of a patient-centered intervention on engaging patients, via post-visit surveys of Veterans' interaction with the brochures and their influence on deprescribing discussions and deprescribing. 3) Using qualitative methods, identify key organizational contextual factors related to intervention fidelity, feasibility, acceptability, and appropriateness to support future implementation.

Methods and Innovation – We propose a multisite quasi-experimental trial using a Hybrid Type I Effectiveness-Implementation design of providing EMPOWER brochures directly to Veterans who may be deprescribing candidates for three cohorts of PIMs (PPIs, diabetes medications, and gabapentin). We will mail brochures in advance of scheduled primary care visits, unlike distribution methods used in other studies. Our primary outcome will be the composite of deprescribing and de-escalation of target medications, identified in pharmacy dispensing records of the Corporate Data Warehouse (Aim 1). Mail-based surveys sent after the scheduled primary care visit will assess patient engagement with the brochure and its impact on patient- provider communication (Aim 2). Finally, qualitative data from clinicians and staff addressing Proctor's Implementation Outcomes will provide the foundation for future implementation strategies (Aim 3).

Significance and Next Steps – Our study directly addresses multiple Veteran Care Priorities, including health care value, primary care practice, quality/safety, and Whole Health, and is aligned with current VA initiatives to prioritize patient preferences via individually-tailored, proactive care plans. The proposed work is strongly supported by Pharmacy Benefits Management and Office of Patient Centered Care and Cultural Transformation, which will facilitate the dissemination of findings to improve the quality and safety of medication use within VA. By study end, we will have established the effectiveness of an innovative, low-tech, patient-focused intervention to promote deprescribing of commonly used medications for three populations, thereby directly improving quality, safety, and value of VA care while also setting the stage for wider implementation and generalization of this approach to other potentially inappropriate medications.

IIR 19-384:

Preventing Loss of Independence through Exercise in Community Living Centers (PLIE-CLC)

Background: Dementia is a neurodegenerative disorder that is associated with a progressive decline in cognitive function that slowly robs people of the ability to function independently. Community Living Centers (CLCs) provide care for approximately 20,000 Veterans with dementia annually, many of whom have comorbid conditions such as posttraumatic stress disorder and traumatic brain injury that can complicate their care. CLC staff receive limited training in strategies for engaging residents with dementia in meaningful activities and managing dementia-related behaviors, and this training gap can result in low quality of life for residents and suboptimal care. We have developed an innovative group movement program for Veterans with dementia called Preventing Loss of Independence through Exercise (PLIÉ). The goal of this study is to refine PLIÉ for CLCs and develop and pilot-test remote staff training procedures so that PLIÉ can be widely implemented.

Significance/Impact. Our proposal is directly responsive to the following 2019 HSR&D Priority Areas: Long-Term Care/Aging and Population Health/Whole Health. In addition, it employs rigorous implementation science methods and is designed to address the ORD-wide research priority of increasing the real-world impact of VA research. Innovation, PLIÉ capitalizes on recent discoveries in neuroscience, behavioral psychology and integrative health and shifts the paradigm of care by targeting abilities and neural mechanisms that are maintained, rather than lost, in the setting of dementia. This includes the ability to learn new movement sequences through procedural or 'muscle' memory; the ability to calm the mind and increase attention through mindful body awareness and breathing; and the ability to connect in meaningful ways with others. PLIÉ was originally designed for and tested in adult day programs that contract with VHA, and results to date suggest that participants are experiencing clinically meaningful improvements in quality of life and mobility (standardized effect sizes >0.4) and high levels of caregiver satisfaction. In 2017, we received a VA Innovators Award that enabled us to pilot PLIÉ at the San Francisco VA CLC (PLIÉ-CLC). Participants gave the program high satisfaction ratings (mean: 4.75 on 5-point Likert scale) and reported noticeable physical and emotional benefits in themselves and others. SFVA CLC staff are continuing to implement the program with positive results. Dr. Barnes was nominated for a Federal Executive Board Employee of the Year Award in 2018 for her ground-breaking work on the PLIÉ program.

Specific Aims. 1) To identify barriers and facilitators to implementation of PLIÉ-CLC by conducting semi-structured interviews with VHA leaders, CLC directors and CLC staff. 2) To

refine PLIÉ-CLC to maximize its scalability and potential for implementation and develop remote training procedures through iterative Plan- Do-Study-Act (PDSA) cycles at two local CLCs. 3) To assess feasibility and provide proof-of-concept for PLIÉ- CLC implementation by piloting remote training procedures at 4 CLCs sequentially.

Methodology and Expected Results. This mixed-methods pre-implementation study will include key informants (Aim 1) and CLC residents, clinical champions and instructor trainees (Aims 2 and 3). The expected result is that PLIÉ will be successfully adapted for CLCs, that remote training materials and procedures will be fully developed by the end of the 3-year study, and that pilot data will support the feasibility and potential clinical benefits of implementation.

Next Steps/Implementation: We will seek funding to perform a type II hybrid effectiveness-implementation study and will work with VHA operational partners (see letter of support from Office of Geriatrics and Extended Care) to disseminate PLIÉ-CLC nationally, including working with community-based organizations that provide care to Veterans with dementia and caregivers as part of the MISSION Act.

SDR 20-031:

Reaping the Wisdom of Positive Deviants to Increase the Reach of Family Involvement in PTSD Treatment

Abstract:

BACKGROUND: Post-traumatic stress disorder (PTSD) is a devastating illness that has substantial costs to Veterans, their families, and the Veterans Health Administration (VA). Although effective treatments for PTSD exist, high rates of treatment dropout and generally suboptimal response rates remain common. Incorporating family members in treatment represents one avenue for improving outcomes and providing Veteran-centered care, and surveys of Veterans in outpatient VA PTSD care indicate that 80% are interested in family involvement. However, despite this strong interest and potential for benefit, national administrative data show that <1% of Veterans in VA PTSD treatment have even a single family-involved session. To understand the factors contributing to the use of family involvement in PTSD treatment, the project team proposes a study using qualitative methods to assess relevant contextual factors.

SIGNIFICANCE/IMPACT: The project is highly responsive to HSR&D's Research Priorities, particularly the Whole Health approach to care which emphasizes the salience of Veterans' broader context as a cornerstone of health and wellness. The project also has the potential to advance PTSD treatment for Veterans by distilling wisdom from facilities that have had relatively greater success in implementing family-inclusive care. Given the substantial disease burden of PTSD among VA patients, enhancing our treatment of this disorder would meaningfully improve the lives of millions of Veterans.

INNOVATION: Despite research documenting the important bidirectional impacts between PTSD symptoms and social support, and the ways that family functioning and behaviors can impact PTSD treatment (in both positive and negative directions), to our knowledge there has been no systematic research to understand how family involvement is implemented in practice in VA.

SPECIFIC AIMS: (1) To identify current practices, attitudes, and facilitators and barriers to family involvement through key stakeholder interviews (total $n \ge 30$) at 5 "positive deviant" and 5

"lower-involvement" VA facilities. (2) To identify best clinical practices and recommendations for enhancing the implementation of family involvement through input from a Stakeholder Advisory Board.

METHODOLOGY: The project is guided by the i-PARIHS framework. A Stakeholder Advisory Board (SAB) composed of operational partners, Veterans and family members, and other individuals with key knowledge will provide guidance and feedback throughout all phases of the project. Regarding methods, interviews will be conducted with clinicians and administrators at "positive deviant" VA facilities (those in the 90th percentile nationally with respect to incorporating family members into Veterans' PTSD treatment), as well as at "lower-involvement" facilities (those in the 10th percentile). The premise of the positive deviant approach is that some members of a community have already discovered innovative solutions to problems which face that community, and these strategies or changes may be applied to improve the performance of others. Interview transcripts will be coded using a rapid analytic approach, allowing for efficient data reduction and identification of key themes. Results will then be transformed into matrices to allow for comparisons across facilities. Following the identification of factors that promote or inhibit the implementation of family involvement, tailored strategies will be selected that are likely to address each context-specific variable.

IMPLEMENTATION: Recommendations for clinical/administrative best practices with regard to enhancing family involvement in PTSD treatment will be compiled into a provider-facing tip sheet, to be distributed by our operational partners as well as through the National Center for PTSD website. Findings will lead directly to a subsequent IIR proposal in which we will test the use of the identified implementation strategies to increase the uptake of family involvement in PTSD treatment, ultimately enhancing recovery from PTSD for Veterans.

PPO 18-223:

Implementation of Mobile Health for Veterans in Primary Care: Using Peers to Enhance Access to mental Health Care

Abstract:

Background: One in four Veterans presenting to VA primary care suffers from mental health conditions, most commonly depression. However, due to barriers such as time constraints on providers, Veterans' stigma about seeking mental health care, and costs associated with traveling to VA for care, most of these Veterans do not receive any treatment for their mental health problems. Mobile health ("mHealth") is an innovative and low-cost means of expanding access to mental health care for Veterans. The effectiveness of mobile applications (apps) and other mHealth tools is emerging. Nevertheless, poor patient engagement and poor sustainability remain the Achilles' heel of these tools. These implementation challenges greatly limit the routine use of these otherwise promising innovations. Peer Specialists (PS) can enhance patients' engagement with apps that are intended for self-care of mental health problems by helping to orient patients to these apps and by providing technical support and accountability. Consistent with this, recent studies indicate strong support among PSs and primary care providers for using PSs to facilitate patients' engagement with mobile apps. In combination with the recent expansion of PSs into primary care, these studies suggest that PSs may be the ideal workforce and primary care the ideal setting in which to facilitate the implementation of mHealth into routine care in VA.

Significance/Impact: By capitalizing on a high-value workforce shown to improve Veteran's engagement in mental health care (i.e., PSs), this research stands to accelerate the implementation of mHealth in VA, and, in turn, improve access to mental health care for Veterans. Our proposed research responds to VHA and HSR&D priorities of Access to Care, Mental Health, Population and Whole Health, and Virtual Care, as well major VA- related Legislative Priorities (MISSION Act).

Innovation: PSs hold substantial promise for maximizing routine implementation of mHealth in VA, but no protocols have been designed to guide this process. In this study, we will rapidly design and then conduct a proof-of-concept test of the deployment of PSs in the implementation of mHealth in VA primary care. The protocol for PS support of mHealth will be grounded in the Whole Health model being disseminated in primary care settings VA-wide. Although we expect our PS protocol design will be easily adaptable and generalizable to multiple apps, in this study we focus on one expert-endorsed VA app – Mood Coach.

Specific Aims: (1) Conduct a formative evaluation to identify barriers and facilitators to using PSs to support implementation of mHealth in primary care. (2) Integrate the findings from the formative evaluation to design the protocol for PS' support of mHealth in VA primary care. (3) Evaluate the feasibility, acceptability, and safety of the protocol among Veteran patients and PSs.

Methodology: For Aim 1, we will hold qualitative interviews with three PSs and three primary care providers each from five sites participating in a VA national evaluation of Peers in primary care. For Aim 2, to guide protocol design, we will convene two meetings of a Steering Committee comprising VA and DoD stakeholders and incorporating the Veteran perspective. For Aim 3 at each of two sites that are participating in the national evaluation of Peers in primary care (Palo Alto and Syracuse), PSs will use the protocol to introduce Mood Coach to 12 primary care patients who screen positive for depression but subsequently did not meet the VA SAIL metric for continuity of care for depression. Four weeks later, objective app usage data will be extracted, and patients will be interviewed to assess satisfaction with the mHealth support received from the PS, feedback regarding barriers and facilitators to this process, and changes in depression symptoms.

Next Steps: By completing these pilot aims; we will be well positioned to submit a subsequent HSR&D IIR – a Hybrid Type 1 RCT at the Palo Alto and Syracuse VAs to evaluate the effectiveness and implementation potential of using PSs to support mHealth implementation.

C19 20-393:

Expanding VA Peer Support Workforce Capacity to Facilitate Increased Access to VHA Mental Health Services and Continuity of Care for Veterans with Mental Illness During The COVID-19 Pandemic

Abstract:

BACKGROUND/RATIONALE: Emerging data indicate that the COVID-19 pandemic and its associated effects, such as mass unemployment and social isolation, are contributing to emotional distress in the general population and exacerbating mental health conditions for those with existing mental health and substance use disorders. Veterans are particularly at high risk of

negative mental health sequelae associated with the COVID-19 pandemic due to existing high rates of mental illnesses, social isolation, and other social risk factors.

With a potential influx of new and existing Veterans presenting with emotional distress due to COVID-19, the VHA mental health care system will face additional pressure to increase access to mental health services. These increased demands will potentially make access to VHA mental health services, which is already difficult, even more limited, particularly for racial and gender minority Veterans (i.e., African American, women, and LGBTQ Veterans) who often struggle with engagement in VHA services. Alternative strategies are urgently needed to expand services and increase access during the COVID-19 outbreak and thereafter.

Peer support is a promising, but largely untapped resource that could increase VA mental health care systems' capacity to attend to Veterans' mental health care needs. In VHA mental health care settings, peers are Veterans with a history of mental illness or substance use disorder who receive specialized training to use their recovery experiences to instill hope, engage patients, and support their recovery. Several studies have shown that, in mental health care settings, peers are effective at engaging Veterans, reducing inpatient admissions, and delivering short-term mental health interventions focusing on depression, anxiety, and substance use disorders.

Despite growing evidence demonstrating the effectiveness of peer services and the increasing number of peers in VHA mental health care settings, peers remain grossly underutilized, and are not given opportunities to perform higher-level duties that are within their scope of practice. The ramifications of underutilization and inadequate utilization of peer support services are far reaching. Most importantly, underutilization negatively affects Veterans who would otherwise benefit from peer services. Moreover, peers may become disengaged employees, adding to potential loss of financial revenue for the VHA due to reduced billable hours. The unique circumstances of COVID-19 also could dilute the peer role even further if administrators, desperate for staff coverage, are tempted to reassign peers to menial tasks as opposed to carrying out their specialty role.

Given the healthcare changes and related challenges created by COVID-19, we seek to develop better understanding of how peer programs have reconfigured or shifted peer support services to maintain and potentially expand delivery of peer support services such as Veterans' outreach and engagement that traditionally require in-person contact, and to respond to new and potentially increasing mental health needs of Veterans.

OBJECTIVE(S): This study seeks to explore how to maximize existing peer support services to provide mental health support to Veterans seeking mental health treatment during and after the COVID-19 outbreak. The study's specific aims are:

Aim 1: Describe changes in peer programs' structures, peers' roles and activities in mental health settings during the COVID-19 pandemic, and characterize programmatic adaptations made to maintain and/or enhance mental health care services delivery to Veterans.

Aim 2: Identify and describe successful strategies for enhancing peer support capacity in mental health care during the COVID-19 pandemic.

METHODS: The setting for this study was VHA medical centers and community-based clinics (CBOCs) from Indiana, Ohio, and Michigan. Study Participants were 19 peers and 10 peer supervisors from 13 VHA facilities. Participants were recruited using direct outreach by email,

through presentation at regional peer support meetings, and snow-ball methods, asking enrolled participants to refer other potential participants.

We conducted semi-structured interviews with participants over the phone or through VA Microsoft Teams. Interviews lasted 30-60 minutes and focused on peer support services utilization before and during the COVID-19 pandemic, as well as challenges experienced, and adaptations made to peer programs to maintain service delivery and/or to meet new Veterans' mental health care needs. The interviews were guided by the Consolidated Framework for Implementation Research (CFIR). In addition, we collected demographic data (e.g., age, gender, education, length of work tenure). We inquired about their experiences of burnout using the three items from the VA All Employee Survey (AES): a) I feel burnout from my work; b) I worry that this job is hardening me emotionally; and c) I have accomplished many worthwhile things in this job. We also administered self-report measures that assessed the impact of COVID-19 on participants using a modified version of the Pain Management Collaboratory Coronavirus Pandemic Measures (PMC), the PROMIS Global health Scale, and the Fear of Illness and Virus Evaluation (FIVE) - Adult Report Form.

Qualitative Data Analysis: A team of 6 analysts analyzed the data, which included two of the study investigators and 4 research assistants trained in qualitative data analysis. We used an inductive/deductive thematic analysis approach, which involves identifying and comparing common emergent themes across transcripts. The qualitative team met early in the project to read the transcripts, gain a general understanding of the data and variations across participants, and develop a working set of codes. Once we had a defined set of codes, we coded the documents independently (focused coding), including the initial coded transcripts, with approximately 20% of the documents coded in common to maintain consistency and consensus in our coding practice. We compared our codes periodically to avoid coding drift and resolved discrepancies through consensus discussions. Throughout this process, we refined the coding scheme as new or inconsistent data emerged. Then, we conducted axial coding, analyzing excerpts from coded sections, identifying themes, and making connections in the data, and summarizing our findings.

IMPACT: Study participants discussed the negative impact of COVID-19 on the delivery of services to Veterans. For some programs, the pandemic made bare some of the underlying issues that impede peers' utilization, success, and full integration into interdisciplinary teams. However, many programs capitalized on opportunities offered during the pandemic to reconfigure their programs and innovate. We identified several strategies that helped some peer programs to maximize peer support services to meet Veterans' mental health and social needs during the pandemic. We also reinforced the value of peer support programs to support Veterans during times of crisis and highlight their potential contributions to continue to improve Veterans' health.

CDA 12-276:

Implementation Research for Evidence-Based Care for Alcohol Dependence

Abstract:

BACKGROUND/RATIONALE: Alcohol use disorders (AUD) are common and chronic, affecting 6.5% of VA patients. While standard care is to refer patients with AUD to specialty addictions treatment, most do not go. Experts agree that care for AUD should be expanded to primary care settings. While many behavioral treatments that are offered in specialty settings cannot reasonably be delivered in primary care, three medications are FDA-approved for treating AUD, can be prescribed in primary care, and are recommended by VA guidelines. However, most Veterans with AUD (~95%) do not receive them, and there are likely many barriers to primary care providers' prescribing them. This CDA focused on addressing this gap in care for Veterans with AUD.

OBJECTIVE(S): The specific aims were to: 1) Describe barriers and facilitators to VA primary care providers' treating AUD; 2) Develop and pre-test an intervention to prepare primary care providers to treat AUD in VA primary care; and 3) Test whether the intervention - disseminated in the context of other systems level supports for management of AUD - is effective for increasing prescriptions for AUD medications at a single VA facility.

METHODS: Planned methods included using 1:1 qualitative interviews (Aims 1 and 2), focus groups (Aim 2), electronic surveys (Aims 2 and 3), and advanced interrupted time series design (Aim 3) applied to secondary VA clinical and administrative data and developing the intervention based on state-of-the-art social marketing methods and other behavior change theories.

FINDINGS/RESULTS: Not yet available.

IMPACT: Dr. Williams's CDA research resulted in greater understanding of: 1) barriers to provision of pharmacotherapy for AUD in primary care and specialty clinics, 2) disparities in receipt of high-quality care for AUD and HIV across key patient- and community-level characteristics, and 3) patterns of alcohol use and care among transgender Veterans. Further, two implementation interventions are being developed and tested to increase access to care for addictive disorders for key populations of Veterans at risk. This research addresses key HSR&D priority areas (e.g., opioid use), is aligned with the Office of Equity and the Whole Health Initiative, and ultimately holds enormous potential to increase access to and quality of care, as well as health outcomes, for the substantial number of Veterans with substance use disorders.

CRE 12-083:

Motivational Coaching to Enhance Mental Health Engagement in Rural Veterans

Abstract:

BACKGROUND/RATIONALE: There is a substantial burden of mental health (MH) problems in rural OEF/OIF/OND veterans. After a decade of war, over 51% of OIF, OEF, and OND veterans in VA healthcare have received MH diagnoses; the majority (27%) have received diagnoses of posttraumatic stress disorder (PTSD). Studies show that veterans residing in rural areas experience significantly greater MH severity and poorer outcomes than their urban counterparts. Surprisingly, there are no published studies on the differential MH burden among OEF/OIF/OND veterans in VA healthcare based on rurality. To begin to address this knowledge gap, using rural-urban commuting area (RUCA) zip code data to define rurality and national VA administrative data to obtain ICD-9 MH diagnoses codes, our group found that increasing rurality was associated with a higher prevalence of MH disorders in OEF/OIF/OND veterans nation-wide and in VISNs 16 and 21. (Seal, preliminary data) For instance, compared to the

prevalence of MH diagnoses among urban OEF/OIF/OND veterans in VISN 21 (44.7%), the MH burden was higher in rural veterans(47.4%) and even greater in "isolated rural" veterans (54.6%),(Relative Risk=1.22, 95% CI=1.11-1.34 for MH diagnoses in isolated rural vs. urban veterans) (Seal, preliminary data).

The majority of OEF/OIF/OND veterans with MH problems do not receive an adequate course of MH treatment. The VA Uniform Mental Health Services Handbook mandates that all veterans, including those receiving care at CBOCs serving rural veterans, have access to evidence-based MH treatments. Minimally adequate MH treatment has been defined as 8 MH treatment sessions or receiving 2 months of psychiatric medication plus > 4 visits within 1 year. Unfortunately, the majority of OEF/OIF/OND veterans have not received an adequate course of MH treatment as found in a nationally representative sample of veterans, and veterans enrolled in VA healthcare. Indeed, at the San Francisco VA Medical Center (SFVAMC), our group demonstrated significantly improved MH treatment initiation in OEF/OIF/OND veterans who presented to our new co-located primary care-mental health clinic compared to usual primary care, but sustained engagement in specialty MH services remained poor with drop-out after 1-2 sessions.

OBJECTIVE(S): In a randomized multi-site pragmatic effectiveness trial, compare the effectiveness of MH Referral alone with MH Referral plus MI-based coaching to improve MH services engagement in veterans receiving care at CBOCs. Compared to MH Referral alone, MI coaching will significantly:

H2a. Increase MH services initiation and retention (number of MH visits) (Primary Hypothesis).

H2b. Increase the use of e-health "self-help" MH treatment options, such as afterdeployment.org.

H2c. Increase perceived need and readiness for MH treatment and decrease barriers to MH services.

Secondarily, we will evaluate change in mental health symptoms, high-risk behaviors (e.g., driving under the influence, etc.), functioning, quality of life, perceived access to MH care, and satisfaction with VA healthcare.

METHODS: We will conduct a pragmatic effectiveness RCT of MH Referral plus the MI-based MH treatment engagement intervention vs. MH Referral only (Control) in veterans who receive care in VA CBOCs serving rural veterans (months 10-44, 34-month RCT). All participants will be enrolled and followed for 8 months. Enrollment will begin at study month 15 and will conclude at study month 46. The last wave of enrollment will begin at month 39 to allow a full 8-month follow-up period until month 46 (25-month enrollment period). This leaves 4 months for data analysis and manuscript preparation.

IMPACT: This study evaluated the impact of rural culture on MH referral and engagement processes at rural CBOCs in VISN 16 & 21 and used this information to adapt and implement a Motivational Interviewing coaching intervention to improve access to mental healthcare for rural veterans. This research also helped illuminate barriers to care and preferences for mental health services among rural veterans with mental health symptoms. Information from this project can be used to develop implementation toolkits for MH treatment engagement interventions for rural veterans. This project also filled a gap in the scientific literature about the effectiveness of

peer motivational coaching for mental health treatment engagement among rural veterans with mental health symptoms who were not in treatment at baseline. We found that mental health treatment engagement was not superior among participants randomized to the peer motivational coaching intervention arm compared to controls. Nevertheless, we found that mental health treatment engagement after baseline assessment (by veteran peers) was higher than expected (~45%) in both groups. Importantly, we found greater mental health symptom improvement among participants in the peer motivational coaching intervention compared to controls and that in most cases these improvements were statistically significant. We also found that participants randomized to the peer motivational coaching intervention reported significant improvements in several quality-of-life domains compared to controls. Qualitative data collected from trial participants during the intervention revelled that veterans found the calls themselves to have therapeutic value, perhaps obviating the need for mental health treatment, thereby explaining these findings.

The study has already resulted in additional operational work in this area. The team has a one-year VA operations grant from the Office of Patient-Centered Care and Cultural Transformation (OPCC-CT) which extends the scope of our VA HSR&D CREATE-supported COACH study. Specifically, the OPCC-CT pilot funding allows us to test the VA Whole Health coaching model delivered by a mix of veteran peers and research staff for both urban and rural veterans to support self-management approaches to chronic disease. We have adapted the VA Whole Health coaching model to include the motivational coaching intervention currently being tested by veteran peer coaches for rural veterans to support engagement in mental health services through our CREATE study. We also have a one-year grant from the VA Office of Mental Health services (OMHS) to pilot the use of the COACH motivational interviewing intervention by veteran peer specialists for veterans seen in primary care needing assistance with various behavioral interventions to support health and wellness.

IIR 14-435:

The Cost Effectiveness of Complementary and Alternative Treatments to Reduce Pain

Abstract:

BACKGROUND/RATIONALE: Chronic musculoskeletal pain and some common co-morbid conditions are costly to treat and highly prevalent among OEF/OIF/OND Veterans. Provision of complementary and integrative health therapies (CIH, a main component of "whole health", or CAM) are a VHA-wide priority, are available throughout the VA and appear to be effective at treating some types of chronic musculoskeletal pain. Little is known about what CIH approaches Veterans with chronic musculoskeletal pain use and whether CIH use results in reductions in pain, opioid use, or healthcare costs.

OBJECTIVE(S): We examined the cost effectiveness of CIH therapies in improving chronic musculoskeletal pain and six comorbid conditions among Veterans of OEF/OIF/OND wars. Aims: (1) determine the extent of CIH use; (2) determine costs associated with CIH use; (3) determine the cost effectiveness of adjunctive CIH use compared to usual care alone as well as the healthcare cost impact of CIH use with both pain and pain-comorbid conditions; and (4) obtain feedback on CIH use, CIH costs and study results using an advisory board of key VA stakeholders with expertise in CIH and pain.

METHODS: We created a cohort of Veterans of OEF/OIF/OND wars with chronic musculoskeletal pain who used the VHA between 2010-2013 (n=530,216) and retrospectively examined veterans' use of nine CIH therapies. The cohort and its data on CIH use took over two years to assemble, given the complexity of the sample and using natural language processing to derive CIH use data.

Pain Outcome: We defined chronic musculoskeletal pain as either: 1) having 2+ visits with musculoskeletal diagnosis codes likely to represent chronic pain separated by 30-365 days or 2) 2+ visits with musculoskeletal diagnosis codes within 90 days and with 2+ numeric rating scale pain scores >4 at 2+ visits within 90 days. Applying either of our two chronic musculoskeletal diagnosis criteria would have produced similar results: 99% of our cohort met the first criterion and 91% met the second.

Pain Comorbid Outcomes: Traumatic brain injury (TBI), PTSD, substance abuse disorder, sleep disturbance, symptoms of anxiety, and symptoms of depression.

CIH Use: Our advisory group recommended we examine nine CIH therapies because of the evidence base and relevance to pain: acupuncture, biofeedback, guided imagery, therapeutic massage, meditation, Tai Chi, yoga, hypnosis, and chiropractic visits. To identify CIH therapy use, we conducted electronic medical record searches for 1) structured data (i.e., clinic procedure [CPT4] codes, VA administrative ["CHAR"] codes used to note CIH use in medical records, or chiropractic provider codes and 2) unstructured narrative clinical notes of CIH use. For unstructured narrative notes, we used natural language processing (NLP) text mining techniques. We defined "CIH use" as having either a structured code signifying CIH or being in an NLP "definite" or "probable" CIH use category. We defined "no CIH use" as having no structured code signifying CIH and being in the NLP "no" CIH use category.

Analysis: To examine predictors of CIH use, we excluded those with unclear use of CIH therapies based on NLP findings, reducing the analytic sample to 468,806. To examine the cost effectiveness, we used combination of multi-level regression modeling and propensity score analysis, and double robust estimation methods for comparisons. We examined the effects on pain and opioid use over a year. Costs were VHA healthcare costs. We also performed sensitivity analyses.

FINDINGS/RESULTS: [From Taylor et al., 2018] Over a quarter (27%) of younger veterans with chronic musculoskeletal pain used any CIH therapy, 15% used meditation, 7% yoga, 6% acupuncture, 5% chiropractic, 4% guided imagery, 3% biofeedback, 2% tai chi, and used 2% massage. Use of any CIH therapy was more likely among females, single patients, patients with three of six pain conditions, or patients with any of six comorbid conditions. [From Evans et al., 2018]. Within gender, additional age and race/ethnicity disparities in CIH use existed. Among women, patients under age 44 or Hispanic, White, or patients of other race/ethnicities were similarly likely to use CIH; in contrast, Black women, regardless of age, were least likely to use CIH. Among men, White and Black patients, and especially Black men under age 44, were less likely to use CIH than other men. [From Herman et al., 2019] CIH users differed from nonusers across all baseline covariates except the Charlson comorbidity index. They also differed on annual pre-CIH-start healthcare costs (\$989 versus \$637 for inpatient, \$8,551 versus \$4,370 for outpatient, and \$1,161 versus \$787 for pharmacy)), pain (4.33 versus 3.76), and opioid use (66.6% versus 54.0%). The multi-level regression modeling results indicated lower annual healthcare costs (-\$637; 95% CI: \$1,023, \$247), lower pain (-0.34; -0.40, -0.27), and slightly

higher (< a percentage point) opioid use (0.76; 0.59, 0.93) for CIH users in the year after CIH start. Sensitivity analyses indicated similar results for three most-used CIH approaches (acupuncture, chiropractic, and massage), but a cost increase for Veterans with 8+ CIH visits. Also, our use of an Advisory Board guided us on which CIH to assess; how to define musculoskeletal pain; what CIH code words to use in natural language process searches, to examine only VA healthcare costs (which included CIH provision costs and excluded non-VA costs); and the implications of our findings for the VA (that CIH approaches hold promise for pain reduction and, as such, potentially opioid prevention, providing further evidence of the need to support their implementation).

IMPACT: This was the first VA widespread study of individual-level CIH use among Veterans with musculoskeletal pain and the impact of CIH use on pain, healthcare utilization and costs. Patients appear willing to use CIH therapies, given 27% used them. However, low rates of use for some specific CIH suggest the potential to increase CIH use. Furthermore, given that gender, race/ethnicity and age disparities in CIH use existed, it seems important to tailor CIH engagement efforts to reduce that differential CIH use. Finally, given that CIH use appears associated with subsequent lower healthcare costs and pain and slightly higher opioid use and given the VA's growing interest in CIH use, more detailed analyses of CIH's impacts are warranted.

CRE 12-426:

Point-of-Care Health Literacy and Activation Information to Improve Diabetes Care

Abstract:

BACKGROUND/RATIONALE: Diabetes mellitus is a highly prevalent chronic condition, affecting one in four Veterans who use the Veterans Affairs (VA) health care system. Patient self-management is critical for controlling diabetes and reducing its cardiovascular sequela. Providing diabetic patients with effective whole health training and self-management support can be challenging due to time constraints at primary care encounters and limited clinician training with behavior change. We have previously demonstrated that a group-based, VA primary care intervention can help patients set highly effective, evidence-based diabetes goals resulting in improved diabetes self-efficacy and hemoglobin (Hb) A1c levels. This study aims to evaluate the process of implementing a collaborative goal-setting intervention personalized to patient activation and health literacy levels (i.e., Empowering Patients in Chronic Care [EPIC]) into routine PACT care in five VA facilities across two VISNs and to evaluate the effectiveness and patient-centeredness of this intervention relative to usual care.

OBJECTIVE(S):

Specific Aim 1: Assess effective processes for and costs associated with implementing a collaborative diabetes goal-setting intervention personalized to patient activation and FHL (i.e., EPIC) into the routine workflows of VISN 12 PACTs.

H1: Formative measures within the PARIHS framework (evidence, context, facilitation) will be associated with implementation of EPIC (defined by reach, adoption, cost effectiveness, and fidelity measures) into routine PACT care.

Specific Aim 2: Evaluate the effectiveness of delivering collaborative goal-setting personalized to patient activation and functional health literacy (FHL) on clinical (HbA1c) and patient-centered (Diabetes Distress Scale) outcomes among eligible patients in enrolled PACTs.

H2: Patients receiving collaborative goal-setting personalized to activation and FHL levels will have significant improvements in a) HbA1c and b) Diabetes Distress Scale levels, respectively, at 6-months (post-intervention) compared with patients receiving enhanced usual care.

H3: Patients receiving collaborative goal-setting personalized to activation and FHL levels will maintain significant improvements in a) HbA1c and b) Diabetes Distress Scale levels at 1-year follow-up, respectively, compared with patients receiving enhanced usual care.

METHODS: In Phase 1 of the study, we implemented EPIC into routine PACT care. We conducted a mixed-methods formative evaluation that included 35 key informant interviews with VISN 12 leadership, clinicians, and staff and an assessment of organizational readiness for change. This evaluation identified how group and one-on-one sessions of EPIC can best be implemented into routine PACT workflows.

In Phase 2, we conducted a randomized clinical trial enrolling 280 Veterans, from a projected sample of 284, with poorly controlled diabetes (defined by average hemoglobin A1c of >= 8%). Veterans were randomized at the patient level to receive EPIC or enhanced usual care (EUC). Consented subjects were allocated evenly between EPIC and EUC. EPIC consisted of six 1-hour group sessions focusing on 1) Your Health, Your Values, 2) Diabetes ABCs, 3) Setting Goals and Making Action Plans, 4) Communication with Your Health Care Provider, 5) Staying Committed to Your Goals, and 6) Reviewing and Planning for the Future. After each group session, a one-on-one goal-coaching session between an EPIC clinician, drawn from the local PACT staff, and Veteran participants focused on collaborative goal-setting. EPIC coaches were trained to personalize goal-setting using patient-reported activation and health literacy data.

We collected laboratory and survey data at baseline, post-intervention, and post-maintenance phase. We evaluated the effectiveness of personalized goal-setting compared to enhanced usual care on clinical (e.g., hemoglobin A1c) and patient-centered (e.g., Diabetes Distress Scale) outcomes.

IMPACT: Integration of patient-reported measures into routine care should aid PACT providers in personalizing goals and action plans for Veterans with treated but uncontrolled diabetes. Having PACT members conduct the personalized goal-setting will improve clinical and patient-centered outcomes because patient goals/action plans can better align with the PACT treatment plan. PACT personnel will gain a greater understanding of patients' challenges and problems related to diabetes self-care, and patients will likely gain a deeper appreciation of diabetes self-management through collaborative goal-setting. Information gained from this work will provide greater understanding of the role of collaborative goal-setting in targeting high-risk patient populations within the PACT setting and could be extended to other chronic conditions. The profile of clinicians delivering the intervention varies by clinical site. Nation-wide adoption of this intervention is possible because of widespread implementation of PACT in the VA and the flexibility in the staffing patterns of delivery. Furthermore, deliberate efforts to engage PACT personnel in the planning and implementation of the effectiveness study will enhance the potential impact and feasibility of adoption across VA PACTs. We have concluded the interventional phase of the project and are conducting data analysis currently that will further

elucidate the project impact. Given that our findings support EPIC's effectiveness, we are currently exploring different potential funding opportunities that will enable us to implement and disseminate the program more broadly. To date, we have secured funding from our partners in VISN 12 to disseminate the project more broadly throughout the VISN. This funding has enabled us to create an EPIC toolkit to ensure the program is embedded long-term, accounting for products and processes traditionally accomplished by members of the research staff. These elements include: 1) A sustainable process map for Veteran identification and scheduling; 2) A decision tree for EPIC coach identification; 3) EES-accredited E-learning platform for EPIC coach training; 4) A clinic profile request form to ensure creation of an EPIC clinic; 5) Revised and updated EPIC manuals; 6) Frequently Asked Question guide for facilitators; and 7) a SharePoint site to house EPIC materials and instructions. Our partners in Crown Point, IN have utilized the EPIC toolkit and are currently running a cohort of Veterans without support from any research staff.

IIR 07-140:

Effects of Performance Measurement on Healthcare Systems

Abstract:

BACKGROUND/RATIONALE: There may be a number of unintended consequences of current approaches to defining, measuring, and reporting quality in primary care. Yet there is little empirical research documenting the existence of such effects, especially at the level of the patient-clinician encounter.

OBJECTIVE(S): This research examined how the VA's clinical performance measurement (PM) system affects the practice of healthcare from the perspective of primary care staff. The specific objective of this exploratory study was to develop an in-depth understanding of positive and negative unintended effects of primary care clinical performance measurement on care delivery processes, on healthcare providers, and on patients.

METHODS: We conducted a series of semi-structured in-person individual interviews of staff members at four VA facilities between February and July 2009. Facilities were selected to assure variability in the number of veterans served and facility scores on national VA performance measures. A total of 60 interviews were conducted including 44 with primary care staff (14 physicians, 10 physician assistants/nurse practitioners, 14 intake nurses, 6 clinic nurse/physician managers) and 16 interviews with facility administrators (4 facility directors/chiefs of staff, 5 primary care service line leaders, 7 PM/quality improvement specialists). Interviews were recorded, transcribed and content coded to identify thematic categories, subtopics, and relationships.

FINDINGS/RESULTS: The VA's national performance measurement system is implemented at the local level primarily through electronic clinical reminders, the allocation of primary care staff task responsibilities, and feedback systems. These implementation strategies play an important role in determining how PMs affect staff care decisions. Much of the burden to address PMs in clinic practice falls upon intake nurses. These nurses do not feel there is leeway for them to use their discretion in addressing PM related clinical reminders. Both nurses and physicians describe ways the PM system can make it difficult to adapt care to patients who are inappropriate for or refuse specific preventive health interventions. In many cases the clinical reminder cannot be "turned off" for these patients and therefore the same issues resurface on

each patient visit. Several instances of "gaming" were described to achieve higher scores without actually improving care. Participants also indicated that pressure to meet performance measures can lead to care decisions that are inappropriate for the individual patient, such as polypharmacy. Participants also noted positive "halo" effects of PMs. For example, performance scores can be a source of pride and positive competition and incorporating preventive health PMs into the clinical encounter can send the message to patients that the VA cares about their whole health.

IMPACT: Results of this study will be shared with VA Office of Quality and Performance and other VA leadership groups. This work is expected to influence how future generations of PMs are implemented into VA primary care settings.

APPENDIX B

HSRD FUNDED STUDIES AS OF MARCH 5, 2022 WHOLE HEALTH COACHING

IIR 19-187:

Using Data Analytics and Targeted Whole Health Coaching to Reduce Frequent Utilization of Acute Care Among Homeless Veterans

Abstract:

Background: Ten percent of patients account for up to 70% of acute care costs. Among these "super-utilizer" patients, homelessness is a robust social determinant of acute care utilization. Through a field-based dashboard and clinical aids, the Hot Spotter Analytic program assists Patient Aligned Care Teams (PACT) with targeting and tailoring care for the highest-need homeless Veterans. However, many Veterans identified by the Analytics do not engage in supportive services that reduce risk for acute care utilization. Peer Specialists (PS) are a high-value workforce that can facilitate Veterans' engagement in care. Yet, there is a need to enhance the PS role with a structured approach that can capitalize on known facilitators of care engagement among homeless Veterans. Whole Health Coaching (WHC) is one such approach. By focusing on patients' values and goals rather than treatment of specific conditions, WHC reduces patients' stigma regarding their care needs and increases patient activation and well-being, which can increase engagement in supportive services.

Significance: By training a high-value workforce in a patient-centered approach to care that facilitates engagement in supportive services, our proposed research can reduce homeless Veterans' reliance on acute care services, thereby minimizing the financial burden these patients exert on the care system. This proposal responds to several VA HSR&D Research Priorities including Mental Health, Healthcare Value, Primary Care Practice, Healthcare Informatics, and Whole Health, as well as VA-related Legislative Priorities (MISSION Act). Innovation and Impact: A critical innovation of this research is use of data-driven processes (Hot Spotter Analytics) to better target and tailor care for high-need, homeless Veterans in VHA. Our proposed research is also innovative in that it seeks to integrate the Analytics with a workforce (PS) and approach to care (WHC) that are rapidly expanding in primary care services VA-wide. These features of our target intervention are consistent with the National Academy of Medicine's recommendations for high-quality care for high-need patients. Finally, by focusing on the development of personal health goals that are aligned with patients' priorities and values, WHC is a key innovation to be added to existing VHA services for homeless Veterans.

Specific Aims: The goal of this project is to integrate use of Hot Spotter Analytics with Peer Specialists trained in Whole Health Coaching (PS-WHC) and evaluate whether this approach reduces homeless Veterans' frequent use of acute care. Aim 1: Conduct an RCT to test whether receipt of PS-WHC (vs. Enhanced Usual Care; EUC) predicts (1a) lower acute care utilization, (1b) better health-related outcomes, and whether (1c) the effects of PS-WHC on 1a and 1b are mediated by increased (i) patient activation and well-being, and (ii) access to supportive services. Aim 2: Conduct a process evaluation to inform VA's potential widespread implementation of Hot Spotter Analytics + PS-WHC on PACTs. Aim 3: Conduct a Budget Impact Analysis (BIA) to determine the impact on total costs of VA care due to implementing PS-WHC.

Methodology: Using a Hybrid Type 1 design at the Palo Alto and Bedford VAs, 220 Veterans on PACT panels who are (i) on the VA Homeless Registry, and (ii) persistent super-utilizers of acute care will complete a baseline interview, be randomized to either EUC (usual PACT care + Hot Spotter Analytics and text reminders of appointments) or EUC plus 12 sessions of PS-WHC over 12 weeks, and be re-interviewed at 3, 6, and 9 months. For Aim 2, the CFIR framework will guide key informant interviews with 7 PACT staff/leaders and 12 patients from each site. For the BIA, we will include only VA costs from VA, Fee Basis care, and Choice care. Costs will be estimated per patient for all treatment beginning with randomization and continuing for 9 months.

Next Steps/Implementation: Depending on the results, we will work with our VACO partners in the National Center for Homelessness Among Veterans, the Office of Patient Centered Care & Cultural Transformation, and the Office of Mental Health & Suicide Prevention to conduct a large multisite implementation trial.

IIR 20-240:

Pragmatic Obstructive Sleep Apnea Weight Loss Trial Assessing Effectiveness and Reach (POWER)

Abstract:

Background: Prevalent obesity related conditions like obstructive sleep apnea (OSA) represent an important opportunity for the VA to improve population health. OSA markedly reduces quality of life and is associated with 3-fold greater risk for cardiovascular disease. Although obesity is the single greatest reversible risk factor for OSA, the 1 million Veterans with OSA and obesity rarely receive weight loss care to reverse OSA and other serious comorbidities. Efficacy trials reinforce that time and resource intensive lifestyle-based weight loss programs improve weight and physiologic measures of OSA severity (apnea hypopnea index, AHI). However, there are barriers to translating these findings into meaningful gains for population health. First, VA has limited capacity to counsel patients around lifestyle change. Less than one-third of Veterans with OSA and obesity are counseled about weight loss and even fewer are referred to weight loss services. Second, VA's current weight loss offerings are difficult to access. Only 12% of Veterans with OSA and obesity utilize MOVE!, and those referred to MOVE! achieve minimal weight loss—1.2 kg at 1 year. Third, prior weight loss trials focused on intermediate measures (e.g., AHI), limiting understanding of effectiveness for meaningful outcomes. To meet these challenges, we propose a pragmatic trial of proactively offering a remote video-based and selfdirected weight loss intervention with telephone-based coaching to Veterans with newly diagnosed OSA. Our weight loss intervention (D-ELITE) is adapted from a program known to be effective in a non-VA population, with 44% of participants achieving ≥5% weight loss at 24 months. Further optimizing reach, our remote intervention includes low-technology options (e.g., DVD videos) to accommodate those with low technology literacy.

Significance: Our research tests a program of proactively providing Veterans with OSA the tools to manage weight loss in a way that is independent of local provider time and resources. Our research addresses a key gap in Veteran's health in a way that aligns with important VA priorities including population health, virtual care, access, and health care value. We anticipate our intervention can efficiently achieve improvements in quality of life while reducing the burden and risk of serious comorbidities. Innovation and Impact: Our research directly challenges the

traditional provider-driven model of healthcare delivery where providers direct care and provide necessary services aimed at managing a single disease. Instead, we propose to proactively deliver weight loss services to a high-risk group using a population health approach. In doing so, we will conduct the first trial of remote and self-directed weight loss care in OSA and will test whether weight loss care can improve meaningful outcomes such as quality of life and cardiovascular risk.

Specific Aims: Our primary aim is to test the effectiveness of a proactively delivered and pragmatic weight loss intervention to improve co-primary endpoints of sleep-related quality of life and weight among Veterans with OSA and obesity. Secondarily, we will compare additional outcomes between groups: cardiovascular risk scores, sleep symptoms, and AHI. Finally, we will also conduct an implementation process evaluation informed by the RE-AIM framework to identify barriers and facilitators to widespread implementation.

Methodology: We plan a hybrid type 1 pragmatic randomized controlled trial. We will proactively identify Veterans with OSA and obesity nationwide using data from the CDW (n=696), randomizing 1:1 to usual care plus the D-ELITE weight loss intervention or usual care alone. We will collect primary outcomes at 12 months, but we will also collect outcomes at 3 and 24 months to assess trends over time. We will use quantitative and qualitative methods to assess barriers to implementation, including a comprehensive budget impact analysis.

Next Steps/Implementation: If effective, we will work with our operational partner, the National Center for Health Promotion and Prevention (NCP), to integrate D-ELITE into NCPs suite of weight loss offerings. The National Program Office for Pulmonary/Sleep also agrees to promote policies supporting nationwide adoption.

IIR 19-153:

CoachToFit: Adapted Weight Loss Intervention for Individuals with Serious Mental Illness

Abstract:

Background: Between 40% to 60% of individuals with serious mental illness (SMI) are obese. Obesity and physical inactivity result in increased rates of chronic diseases, increased risk of death, and substantial health care costs. Treatment guidelines recommend that individuals with SMI who are overweight should be offered evidence-based weight loss interventions, including psychosocial interventions. The VA's weight management program, MOVE!, is attended by less than 5% of the overweight population and is not adapted to the cognitive needs and patient preferences for the population with SMI. Effective adapted weight management programs are not offered in VA because they are time-intensive and require the skills of trained providers who are often in short-supply. CoachToFit can address this gap in care. CoachToFit is a weight management program, adapted for the population with SMI, that includes a smartphone app delivering evidence-based weight management services with weekly telephonic support from a VA peer specialist who acts as a wellness coach. Peer specialists are individuals who draw upon lived experiences with SMI to provide services to others with SMI in clinical settings. CoachToFit was shown to have high rates of acceptability and usability and was efficacious for weight loss in a small sample. VA has an opportunity to address obesity in the population with serious mental illness, currently a substantial gap in care.

Significance/Impact: This project addresses obesity in the population with SMI by evaluating a weight management program that is not only evidence-based, it is sustainable, transportable, appealing to patients, easy to use, and minimally burdensome to the healthcare system. This effort addresses two HSR&D priority areas: 1) Mental Health: Testing new models of care to improve access, cost, and/or outcomes, and 2) Health Care Informatics: Building the evidence base for ehealth/mhealth tools. Innovation: CoachToFit's use of mobile technology is an important innovation in VA service delivery and its user-centered design involving individuals with SMI was the first of its kind. CoachToFit is enhanced by data visualization in real-time via a web-based dashboard used by VA peer specialists and their supervisor. We are aware of no other evidence-based mobile platforms to help people with SMI reduce their weight.

Specific Aims: The project aims to 1) Test the efficacy of CoachToFit, compared to usual care, in decreasing weight among Veterans with SMI who are obese; 2) Assess the hypothesized mechanisms of action for CoachToFit, including self-efficacy, motivation, and readiness to change; and 3) Characterize factors that will inform future implementation and maintenance of CoachToFit using a multi-stakeholder qualitative post- intervention evaluation guided by the RE-AIM framework.

Methodology: The study design includes a randomized controlled trial to test the efficacy of CoachToFit and assess the hypothesized mechanisms of action. This will include enrollment of obese Veterans with SMI from the mental health clinics at one VA medical center (n=256). Individuals will be randomized to CoachToFit or usual care. Those in CoachToFit will have access to the app and coaching for 6 months. Outcomes are assessed at 6- and 12-months. Efficacy outcomes utilize objective measures. The design also includes a multi- stakeholder qualitative post-intervention evaluation guided by the RE-AIM framework to characterize factors that will inform future implementation and maintenance of CoachToFit. This will include interviews with Veterans randomized to CoachToFit (n=30); interviews with staff stakeholders (n=18); a discussion with Veterans in local Veteran groups (n=2 groups; n=11 Veterans), and interviews with national leadership (n=3).

Next Steps/Implementation: If CoachToFit is found to be efficacious, the VA National Center for Health Promotion and Disease Prevention, along with input from national leadership in Peer Support Services and Mental Health Informatics, will assist in integration into the VA context.

IIR 19-031:

A Randomized Controlled Trial of Coaching into Care with VA-CRAFT to Promote Veteran Engagement in PTSD Care

Abstract:

Impact: Family members are primary sources of support for Veterans struggling with PTSD. While family support and encouragement are powerful facilitators of Veterans' mental health care engagement, few interventions have been developed that capitalize on this support. To address this gap, VA created Coaching Into Care (CIC) – a national telephone-based coaching service intended to educate, support, and empower family members and friends who are seeking services for a Veteran. While program evaluation data show that CIC is highly valued by callers, only about 25% of callers with Veterans not already in care, report that their Veteran sought care over the next six months. The proposed study tests an innovative approach to improve the effectiveness of CIC by integrating a web program called VA Community

Reinforcement and Family Training (VA-CRAFT), which is based on an empirically-validated intervention. The long-term goal is to establish an efficacious, efficient, scalable, and satisfying family outreach intervention that will significantly increase mental health service initiation among a high priority Veteran population while addressing the needs of their primary supporters, their family members.

Background: PTSD is a highly prevalent psychiatric disorder among combat Veterans that often results in significant individual impairment and distress for family members. Although evidence-based treatments are available, most Veterans with PTSD do not receive any mental health care. Preliminary work suggests that VA's Coaching Into Care services could be improved by integrating VA-CRAFT. In a prior HSR&D-funded pilot, our team found that family members who completed the relatively brief VA-CRAFT course alone (without coaching) had greater decreases in caregiver burden than wait-list controls. However, qualitative interviews also suggested that participants often did not raise the issue of treatment with their Veteran due to not believing such a conversation would be successful. Therefore, we developed CIC+VA-CRAFT to leverage the strengths of both approaches to increase family members' motivation, perceived ability to have treatment-seeking conversations with their Veteran, and success at engaging their Veterans in care. Initial findings from an NC- PTSD-funded pilot of CIC+VA-CRAFT suggest that this brief, blended intervention is feasible, acceptable, and potentially more effective than CIC alone in enhancing Veteran mental health treatment initiation.

Objectives: This project will employ a two-group randomized controlled trial (RCT) to compare CIC+VA- CRAFT to CIC only (treatment as usual). Specific aims are to: 1) Determine the effectiveness of CIC+VA- CRAFT in enhancing Veterans' mental health service initiation compared to CIC only; 2) Determine if CIC+VA- CRAFT is non-inferior to CIC only on caller satisfaction, and 3) Conduct a process evaluation to inform potential future implementation of CIC+VA-CRAFT. The project will also explore potential 1) treatment effects on other important family-related outcomes, and 2) mediators and moderators of treatment. This proposal was developed as a collaboration between the VA CIC and VA-CRAFT programs and their leadership, which will facilitate the intervention's rapid dissemination should the trial prove successful.

Methods: This is a four-year RCT that will recruit spouses or intimate partners of Veterans with PTSD using social media advertisements and referrals from CIC. Participating partners will be randomized to the CIC+VA- CRAFT (n = 115) or CIC only (n = 115) condition for up to three months. CIC+VA-CRAFT will include four manualized CIC phone-coaching calls and access to the VA-CRAFT website. CIC participants will receive only CIC services as usual. Assessments will be at baseline, post-intervention (3 months after randomization), and six-month follow-up and will include partner reports of Veteran service utilization, caregiver burden, wellbeing, and relationship functioning. The feasibility and acceptability of implementing CIC+VA-CRAFT will be assessed with interviews of CIC+VA-CRAFT participants, Veterans of participants, and study and CIC phone coaches.

IIR 19-469:

Collaborative Specialty Care for Gulf War Illness

Abstract:

There is a quality chasm between the care Gulf War Veterans (GWVs) should receive and the care they do receive. Our data show 70% of GWVs with Gulf War Illness (GWI) do not receive treatment recommendations for their GWI and 78% are NOT very satisfied with their care. Reducing this quality chasm is essential. The VA and DoD have invested hundreds of millions of dollars to develop new treatments, including the second largest clinical trial for GWVs which is finding health coaching and problem-solving treatment both reduce the disability of GWI. Without effective models of healthcare to implement these treatments, GWVs will not benefit. In the current model of care, GWVs receive care locally through VA's primary care patient aligned care teams (PACTs). The VA War Related Illness and Injury Study Center (WRIISC) supports the current model of care by increasing local knowledge of the skills and treatments needed to manage GWI through national education efforts and electronic consultation (e-consultation) on difficult cases. The WRIISC and other stakeholders are currently questioning whether improving local knowledge of skills and treatments for GWI is enough to address the quality chasm, or if GWI is too complex to be treated in primary care without additional support from specialists in GWI. A potentially useful model of care for GWI is collaborative specialty care where specialists work with PACTs to synergistically treat patients. The local PACT is the lead of the team with the specialist providing some direct care to the patient (through tele-health) and also consulting with the PACT about other aspects of care. Collaborative specialty care is effective for other complex conditions (e.g., depression) with over 40 studies documenting its efficacy. The goal of this proposal is to conduct a hybrid type 1 randomized effectiveness/implementation trial for GWVs with GWI (n=220). Our primary aim is to determine the effectiveness of tele-CSC as compared to e-consultation. In tele-CSC, our specialty provider team will deliver health coaching and problem-solving treatment to GWVs and recommend the PACT make monthly optimization of analgesics. In e-consultation the specialty provider team will make a onetime recommendation to the PACT that the GWV locally receive health coaching and problemsolving treatment and analgesic optimization. Our secondary aim is to understand implementation outcomes. This information will be used to guide a future randomized (by VISN) multi-site implementation study. Throughout, an advisory committee of operations partners will be convened to ensure that the results of the study are able to directly and immediately improve care. Determining the best model of care to translate research into practice for GWVs with GWI is a key goal of the VA Gulf War Strategic Plan and a specific aim of this Request for Applications.

IIR 17-221:

Using Peer Navigators to Increase Access to VA and Community Resources for Veterans with Diabetes-Related Distress

Abstract:

Diabetes-related distress, the negative emotional impact of living with diabetes (DM), is a powerful predictor of psychosocial functioning, treatment adherence, and glycemic control. Practice guidelines and consensus statements call for innovative approaches to address DM-related distress. Despite availability of self- management and psychosocial interventions to reduce DM related distress, these interventions are underutilized due to constraints in time, finances, motivation, and resource-awareness. Interventions that leverage traditional medical care and community-based health promotion programs (e.g., DM self- management education

(DSME) programs) may enhance the ability of Veterans with DM to engage with a broad and accessible range of resources. Ensuring that Veterans with DM receive adequate self-care support requires interventions that (1) attend to both medical care and diabetes-related distress and (2) improve Veterans' access and engagement with DSME and traditional medical/mental care. Integrating VA and community health services and DSME resources is innovative and affords great opportunities to enhance Veteran outcomes and build VA community partnerships. Engagement of Veterans and community organizations in developing and delivering care responds to the 2016 HSR&D high-priority domain of Health Care Systems Change and aligns with the 2017 VA Under Secretary's priorities of Greater Choice (offering community and VA resources), Efficiency (community and VA coordination), and Timeliness (telephone delivery). This community-VA partnership and three-month Veteran peer coaching intervention (iNSPiRED) aims to enhance psychological well-being and diabetes self-management behavior in Veterans with DM by facilitating access to and use of healthcare and health promotion resources. The intervention focuses on reducing cognitive and practical barriers to use of services by engaging Veteran peers as coaches and navigators, and by encouraging engagement in health promotion and healthcare services in the VA and the greater community. A secondary goal, integral to the main goal, is to strengthen and integrate VHA partnerships with community- based organizations and Veteran Support Organizations (VSO's). This is a single-blind, parallel group randomized trial of a 3-month peer navigation intervention for Veterans with DM and elevated levels of DM-related distress. We will recruit Veterans with DMrelated distress through existing help-seeking channels within and outside of the VA in partnership with community agencies, VSO's, and the Houston VAMC. Eligible Veterans will be assigned at random to the iNSPiRED intervention (peer navigation and coaching) versus usual care (written resource materials and encouragement to continue follow- up with healthcare providers). Consistent with the focus on the overall emotional impact of DM, the PRIMARY OUTCOME is DM-related distress (DM Distress Scale). In previous studies the DDS has shown strong relationships with psychological symptoms, self-management behaviors, and objective measures of glycemic control. SECONDARY OUTCOMES include anxiety symptoms (Generalized Anxiety Disorder Scale), depression symptoms (Patient Health Questionnaire-8), DM self-management behaviors (DM Self- Management Scale), and self-reported use and new use of VA or community resources. In addition to participant-level outcomes, we will also assess STAKEHOLDER OUTCOMES through a mixed methods process evaluation. Our objective will be to measure the impact of stakeholder engagement activities on development and sustainability of VA-community partnerships, trust and communication, and capacity building. Assessment of primary and secondary endpoints will occur at baseline, post-intervention, and at 6 months. If this project meets intended goals, we will partner with VHA Office of Community Engagement and VHA Specialty Care to implement the intervention for DM and other chronic diseases.

IIR 14-063:

Vet COACH (Veteran peer Coaches Optimizing and Advancing Cardiac Health)

Abstract:

BACKGROUND/RATIONALE: Cardiovascular disease (CVD) is the leading cause of mortality among Veterans, and sub-optimal risk factor control is an important mechanism for the continued prevalence of CVD. Despite clinic-based programming that includes nurse care management, pharmacy support, telephone care programs, and intensive quality improvement

efforts, CVD risk factors remain sub-optimally controlled among Veterans. Given the high prevalence and cost within VHA, cost-effective mechanisms are needed to manage prevalent CVD risk factors. Veteran peer health coaches may be one such mechanism; however, previous work has provided limited data of this model with VHA primary care. Previous studies of peer support in non-VHA populations report significant improvement in hypertension control and CVD risk reduction.

OBJECTIVE(S): To test the effectiveness of a peer health coaching intervention to reduce CVD risk and promote health behavior change among Veterans with multiple CVD risk factors. To target a high-risk population, Veterans with poorly controlled hypertension and at least one other CVD risk factor are being recruited.

METHODS: A randomized controlled trial of n=400 Veterans is being conducted to compare a peer health coach intervention consisting of home visits, telephone support, and linkages to community-based and clinic resources as compared to usual VHA care. The primary outcome is reduction in systolic blood pressure from baseline to follow-up at 1-year. Secondary outcomes include a reduction in Framingham Cardiovascular risk score, individual cardiovascular risks, health related quality of life, and health care use. Effects of the intervention on intermediate outcomes will be assessed including social support, patient activation, patient/provider communication and health behaviors. We will identify Veteran and staff satisfaction with the intervention, and barriers and facilitators to adoption by conducting qualitative interviews with a subsection of Veteran participants, peer health coaches, and PACT primary care staff. The intervention cost will be assessed to inform feasibility for future studies.

FINDINGS/RESULTS: Trial results are pending; however, preliminary findings indicate data from VA Corporate Data Warehouse (CDW) can be effectively used in conjunction with census tract data to target geographic clustering of high-risk areas. Veterans from these areas can be successfully recruited as peer health coaches. Role play sessions conducted by the health coaches with a standardized patient actor increased observed behavior change in hypertension, smoking cessation and medication adherence counseling by 18 points on the Behavior Change Counseling Index. Results of this trial will inform peer support programs using geographic clustering of health risks to provide community-based delivery of prevention services to high-risk areas.

IMPACT: Integrating peer health coaches into PACT primary care teams may improve VHA's ability to provide community outreach to Veterans. CVD risk reduction provides an ideal target for intervention given the prevalence of modifiable risks among Veterans. The study will increase understanding of the utilization of peer support within PACT teams. If this study proves the main hypothesis, this evidence-based support model could be tested more widely among Veterans with other chronic conditions to improve health outcomes.

IIR 16-089:

Improving Access to Supported Employment for Veterans with Polytrauma/Traumatic Brain Injury

Abstract:

BACKGROUND/RATIONALE: Many Post-9/11 Veterans have experienced polytrauma/traumatic brain injury (TBI), which can result in functional limitations and challenges

to employment. Pogoda et al. (2016) found that among Veterans evaluated in Veterans Health Administration (VHA) polytrauma/TBI clinics, approximately 20% reported that they were unemployed and looking for work, and of these, 71.6% had a TBI diagnosis and were in their prime working years. Supported Employment (SE) is an evidence-based practice that helps individuals with disabilities find and maintain competitive employment through job coaching and unlimited support. Carlson et al. (2018) reported that Veterans with polytrauma/TBI have an interest in receiving supported employment (SE) services yet are not routinely informed of vocational rehabilitation programs. Though SE is targeted to Veterans with serious mental illness (SMI), up to 25% of the SE caseload may be used for non-SMI clinical populations. However, a recent VHA administrative review found that more than one-half of VA SE programs were working below their caseload capacity and were able to serve more Veterans. Moreover, very few polytrauma/TBI clinics were referring Veterans to SE.

OBJECTIVE(S): This research aims to increase access to SE for Veterans with polytrauma/TBI. This will be achieved by (1) identifying actionable barriers and facilitators to referring Veterans to SE, providing SE services to and retaining these clients, and integrating the SE and polytrauma/TBI clinic teams, (2) developing and refining an intervention package/toolkit for an SE-TBI program, and (3) implementing the intervention and conducting qualitative and quantitative assessment of its effectiveness at local VA Medical Centers (VAMCs) that are below SE caseload capacity.

METHODS: This longitudinal mixed methods study will be guided by the integrated-Promoting Action Research on Implementation in Health Services (i-PARIHS) framework. For Aim 1, we will identify barriers and facilitators to SE-TBI by interviewing SE vocational rehabilitation specialists and polytrauma/TBI providers at (a) 4 VAMCs that have a successful SE-TBI program, and (b) 12 VAMCs that are below SE caseload capacity. Based on findings from Aim 1, for Aim 2 we will adapt and refine current toolkit materials to develop a customizable intervention package that includes menu-based choices (e.g., educational materials, marketing practices to facilitate integration between the SE and polytrauma/TBI clinic teams) to maximize success in SE referral and implementation. Finally, for Aim 3, at the 12 VAMCs from Aim 1 that are below SE caseload capacity, through external and internal facilitation, we will implement an intervention package to enhance polytrauma/TBI participation in SE and document: (a) its effectiveness for change in number of Veterans with polytrauma/TBI referrals and SE caseload size from pre- to post-intervention, (b) stakeholder (SE vocational rehabilitation specialists, polytrauma/TBI providers, Veterans with polytrauma/TBI) perceptions of implementation and SE program progress, (c) Veteran vocational and nonvocational outcomes, and (d) SE program fidelity. We will follow each site's progress over an 18-month implementation and evaluation period.

FINDINGS/RESULTS: None.

IMPACT: Ensuring that Veterans with polytrauma/TBI can access effective vocational rehabilitation services may help prevent numerous downstream health and functional problems.

IIR 15-362:

Implementation Trial of a Coaching Intervention to Increase the Use of Transradial PCI

Abstract:

BACKGROUND/RATIONALE: Of the two approaches to performing cardiac catheterization, overwhelmingly cardiologists in the VA and US use the approach that is known to be less comfortable and safe for patients, more difficult for staff to monitor, and more costly to the health care system.

In cardiac catheterization, a long thin tube is threaded up to the coronary arteries via the radial artery in the wrist (trans-radial approach, or TRA) or via the femoral artery in the groin (transfemoral approach, or TFA). Then the catheter is used to obtain real-time images of the arteries that deliver blood to the heart (coronary angiography) and/or alleviate blockages that obstruct delivery of blood to the heart (percutaneous coronary intervention). Both TRA and TFA are considered standards of care; however, major bleeding (the primary complication from coronary catheterization) is 78% lower for TRA cases relative to TFA. Lack of awareness of those benefits is not what accounts for the slow rate of adoption of TRA. Rather, TRA is technically more challenging, and cardiologists and their teams have to sustain using TRA through a steep learning curve where TRA cases take longer and have a higher crossover rate (i.e., they cannot complete the case using TRA and have to switch to TFA). However, if they persist, after performing approximately 50 TRA cases they become as proficient with TRA as TFA.

OBJECTIVE(S): Our primary goal is to improve the VA's ability to implement new technically-challenging, evidence-based clinical procedures, such as TRA. We will test a previously-piloted, team-based coaching intervention to support adoption and implementation of TRA that is designed to help shorten the learning curve and sustain teams until they become proficient. Toward that goal, we want to build on, and contribute to conceptual models of innovation implementation and the cognition of development of expert skills that can help us understand why clinical procedures that have so many apparent advantages are implemented so slowly. Our specific aims are:

Aim 1: Test the effectiveness of a successfully-piloted, team-based coaching intervention in increasing implementation of radial-artery access cardiac catheterization

Aim 2: Adapt and refine a conceptual model of team-based coaching for implementation of new clinical procedures based on the Promoting Action on Research Implementation in Health Services framework.

Aim 3: Perform a cost analysis of the coaching intervention and effects on costs per episode of care.

METHODS: We will conduct a stepped wedge trial design, with a mixed-methods formative evaluation. In the stepped wedge trial, all participating sites ultimately receive the intervention, but are randomized to receive it at different time points or "steps." Sites serve as internal controls to account for site-specific confounders before and after the intervention. Because they are randomized to receive the intervention at different times, they also serve as controls for each other to account for secular time trends.

Some might also characterize this study as a hybrid implementation trial because we are assessing both implementation (i.e., practice) outcomes and clinical outcomes. The primary outcome is implementation of TRA, assessed as the proportion of radial catheterization

performed at the cath lab; and secondary outcomes include bleeding complications, employee job satisfaction and organizational commitment.

FINDINGS/RESULTS: We have no preliminary results at this time.

IMPACT: VA seeks to become a learning organization, and one of the central tenants of learning organization theory is that the organization invests in how to learn better (i.e., learns to learn better). That means identifying ways to more systematically integrate new practices or knowledge.

IIR 15-378:

Testing the Efficacy of a Technology-Assisted Intervention to Improve Weight Management of Obese Patients within Patient Aligned Care Teams at the VA

Abstract:

BACKGROUND/RATIONALE: Veterans shoulder a disproportionate burden of obesity and its co-morbidities, and modest weight loss improves health outcomes. The Veterans Affairs (VA) New York Harbor Healthcare System offers the MOVE! program, but only 8% of eligible patients attend. However, Veterans see their primary care providers (PCPs) 3.6 times per year supporting the importance of developing primary care-based interventions. The United States Preventive Services Task force (USPSTF) recommends the use of the 5As framework (Assess, Advise, Agree, Assist, Arrange) for counseling patients about weight. Interactive behavior change technologies can facilitate delivery of the 5As in primary care.

We developed a primary care-based intervention called Move Towards Your Goals (MTG) Peer-Assisted Lifestyle intervention (referred to as Peer-Assisted Lifestyle (PAL) Study to avoid confusion with the VA MOVE! Program) to facilitate delivery of 5As weight management counseling and increased adoption of intensive VA programs such as MOVE!. The intervention uses a novel software tool delivered on tablets to facilitate 5As-based weight management counseling with a health coach and the VA PACT healthcare team to promote goal-setting, behavior change, and weight loss in primary care. The intervention includes 15 health-coaching calls delivered by trained Veteran Peer Coaches to the patient over 12 months.

As part of a cluster-randomized controlled study, we will randomize 10 PACT teams at the Brooklyn VA to receive either the MTG Intervention or an Enhanced Usual Care control. The primary aim of the study is to explore differences in feasibility, acceptability, and intermediate, behavioral, and weight loss outcomes at 6 and 12 months of 520 patients recruited from the randomized PACTs

OBJECTIVE(S):

- 1) Test the impact of the MTG intervention on weight change, clinical and behavioral outcomes
- 2) Identify predictors of weight loss in Veterans participating in the intervention arm related to intervention components and goal-setting processes
- 3) Determine the impact of the MTG Intervention on provider and nurse obesity-related counseling practices and attitudes

METHODS: We will recruit up to 520 overweight/obese primary care patients from the 10 PACTs to participate. Patient participants within PACT teams randomized to PAL will use the goal-setting tool and meet with a peer coach to create weight management and lifestyle behavior change goals. They will also receive brief counseling by their PCPs and PACTs at their next regularly scheduled visit. This will be followed by 15 health coaching calls over the next 12 months. The Enhanced Usual Care arm will receive weight management handouts and information about MOVE! programs. Baseline data will be collected via surveys, chart review, and blood tests. All participants will come to 6 and 12-month study visits to evaluate intermediate, behavioral, and weight outcomes.

FINDINGS/RESULTS: We have trained PACT teams and started recruiting patients.

IMPACT: If the MTG intervention is shown to be effective, then it will inform improvement of weight management in VA primary care settings with peer coaches.

IIR 14-074:

Engaging Veterans and Family Supporters in PACT to Improve Diabetes Management

Abstract:

BACKGROUND/RATIONALE: Veterans with diabetes must control cardiovascular risk factors in order to prevent disabling and life-threatening complications. However, despite system wide advances in diabetes quality of care, over 30% of VHA patients with diabetes continue to have uncontrolled blood pressure, hyperglycemia, or hyperlipidemia. The nationwide VA PACT (Patient-Aligned Care Teams) initiative seeks to provide patients comprehensive, team-based support for following diabetes care regimens. PACT's success, however, hinges on its ability to effectively engage patients in care. One relatively untapped resource for supporting engagement in PACT is patients' family and friends. Three out of four adults with diabetes reach out to an unpaid family member or friend (a 'Care Partner') for ongoing help with diabetes management. These supporters help patients with medication adherence, tracking home glucose measurements, maintaining a healthy eating plan, and often accompany patients to their medical visits. However, while PACT emphasizes the importance of family members as part of the care team, PACT does not have formal mechanisms to involve health supporters in PACT care. Health supporters report that, in order to be more effective, they need more information on patient's medical care plans, clear channels for communicating with PACT team members, and information on navigating PACT resources.

OBJECTIVE(S): The overall objective of this randomized trial is to test a strategy to strengthen the capacity of supporters to help patients with high-risk diabetes engage in PACT care and successfully enact care plans. The central hypothesis is that providing health care engagement tools to both Care Partners and patients will increase patient activation and improve management of diabetes complication risks.

METHODS: This is a randomized controlled trial evaluating an intervention (Caring Others Increasing EngageMent in PACT, or CO-IMPACT) designed to structure and facilitate health supporter involvement in PACT so that patients can become more actively engaged in PACT care. 240 patients with diabetes receiving PACT primary care who: 1) are at high risk for diabetes complications due to hyperglycemia OR high blood pressure and 2) have a health supporter involved in their care will be recruited along with their health supporter. Patient-

supporter dyads are randomized to the CO-IMPACT intervention or usual PACT care for high-risk diabetes, for 12 months.

The intervention provides patient-supporter dyads: one coaching session on action planning, communicating with providers, navigation skills and support skills; preparation by phone before patients' primary care visits; after-visit summaries by mail; and biweekly automated phone calls to prompt action on new patient health concerns. CO-IMPACT builds on medical recordintegrated patient activation tools in the PACT toolkit and is designed to be implementable within existing PACT nurse encounters.

Primary outcomes for this study include a validated measure of patient activation (Patient Activation Measure-13) and a cardiac event 5-year risk score designed for patients with diabetes (UKPDS Risk Engine). Secondary outcomes include patients' self-efficacy for diabetes self-care; diabetes self-management behaviors including medication adherence; diabetes distress; and glycemic and blood pressure control. Measures among supporters include supporter activation, use of effective support techniques, distress about patient's diabetes care, and caregiver burden. We are also measuring patient-supporter and patient-provider relationship quality, patient safety (e.g., hypoglycemia), utilization, potential moderators of intervention effect such as patient health literacy level, and facilitators and barriers to wider implementation.

FINDINGS/RESULTS: This study began recruitment in November 2016. Recruitment is expected to be complete mid-year of 2018. Outcomes data currently are being collected.

IMPACT: If successful, the study will establish a new approach for involving patients' supporters in VA care, in ways that could avert devastating consequences of uncontrolled diabetes. Similar methods could be used by the VA and others to better support Veterans' family caregivers, and to improve health management for Veterans with other high-risk conditions.

IIR 15-364:

DVD Lifestyle Intervention (D-ELITE)

Abstract:

BACKGROUND/RATIONALE: More than a third of US Veterans who receive care through the VHA are obese, putting them at higher risk for multiple serious chronic health conditions. Developing evidence-based programs that are scalable, cost-efficient, and serve a diverse Veteran population is a priority for the VA National Center for Health Promotion and Disease Prevention (NCP). While the VA's MOVE! program is an effective lifestyle intervention for obesity, its reach has been limited. Some Veterans may best achieve weight loss with in-person group visits or by internet and mobile technology-intensive programs, while others may do better with a population-based, self-directed program that uses minimal technology. This trial is examining the effectiveness of a proven 12-month pragmatic self-directed, low technology, and low resource video-based lifestyle intervention targeting modest, clinically meaningful weight loss and increased physical activity among obese Veterans. If successful, this trial may help ease the burden that obesity places on Veterans and the health care system.

OBJECTIVE(S): We will test whether the intervention will yield better outcomes for obese Veterans compared with usual care (UC) controls, including:

Primary: Greater weight loss and improved physical function after 12 months.

Secondary: Improvements in sustained weight loss, physical function and activity, diet quality and self-efficacy, sleep disturbance and impairment, and blood pressure after 24 months.

METHODS: Using the VA Corporate Data Warehouse (CDW), we will identify Veterans in the Western US who are obese and likely free of major exclusionary conditions. We will mail an invitation to participate. For those who reply with interest, or do not respond, research staff will call the Veteran to explain the study and obtain verbal consent, as appropriate. We will assess change in weight via CDW. For co-morbidities and other outcomes, participants will complete questionnaires at baseline, and 12- and 24-months after randomization.

The lifestyle intervention is designed to achieve and maintain a weight loss of 5-10% of baseline body weight in a gradual stepwise fashion, and to gradually achieve at least 150 minutes per week of moderate-intensity physical activity, such as brisk walking. The intervention structure consists of watching one video each week for 12 weeks, focused on healthy eating, physical activity, and behavior change. Participants track their food intake and physical activity, work through a series of supplementary handouts, and have access to a lifestyle coach as desired for the first 12 months.

The study is powered on two continuous-scale endpoints, weight and SF-12. The two-sided type I error rate, =2.5%, was chosen to account for multiple comparisons using the Bonferroni adjustment. For weight, a sample of 464 total patients will be able to detect a difference in slope of 0.175kg/month between the intervention and UC groups with 90% power, two-sided alpha =2.5%, a 0.85 ICC and 2 repeated measures, while assuming 20% attrition at 12 months. For SF-12, a sample of 507 total patients will allow a standardized mean difference (Cohen's d) of 0.35 between the intervention and UC groups with power 90%, two-sided alpha =2.5%, while assuming 20% attrition at 12 months. To power our primary aim, we will enroll 500 Veterans. We will conduct a budget impact analyses to establish a business case for future implementation if the intervention is successful.

FINDINGS/RESULTS: None as of 9/4/2018.

IMPACT: The DELITE trial has potential to provide the evidence needed for deciding whether a low-cost, low-technology, self-directed program can be used to expand the treatment of obesity to a population-based level by improving access to obesity treatment regardless of Veteran place of residence.

CRE 12-289:

Building an Optimal Hand Hygiene Bundle: A Mixed Methods Approach

Abstract:

BACKGROUND/RATIONALE: "Hand hygiene is the single most important measure to prevent transmission of infectious organisms" (VHA Directive 2010-006, MRSA Prevention Initiative). Despite its fundamental place in infection prevention, compliance rates with hand hygiene protocols remain substantially below target levels. For example, prior studies in acute care hospitals have reported rates of compliance that average only 40%, while in a recent VHA study led by Dr. Perencevich (IIR 09-099), compliance rates across 11 hospital units in 3 VISNs ranged from 53% to 71% and averaged 61%.

Hospital-associated infections (HAI) are a major threat to patient safety. The most significant cause of HAI is methicillin-resistant Staphylococcus aureus (MRSA), which accounts for an estimated 94,000 invasive infections and 19,000 deaths annually in the US. In response to concerns about MRSA, VHA implemented an MRSA Prevention Bundle in October 2007 that included promotion of hand hygiene. Yet, low hand hygiene compliance highlights the considerable potential for hospital staff to serve as vectors for the transmission of MRSA and other HAIs and suggest that significant room for improvement exists.

A sustained, multifaceted approach is recognized as key to improving hand hygiene practices. However, little is known regarding which components of these multipronged or "bundled" approaches are essential. Identifying the most effective elements of hand hygiene intervention strategies will substantially advance the science in this area and greatly aid the implementation of more focused and efficient approaches for optimizing hand hygiene and reducing MRSA and other HAIs in VHA.

In an effort to establish VHA best practices for hand hygiene, a Working Group, comprised of our research team and several programs in the Office of Public Health and Office of Patient Care Services, is developing a national hand hygiene initiative. For this Working Group, Dr. Reisinger has led a VHA-wide survey of facility-level hand hygiene practices and completed a systematic literature review of hand hygiene interventions. This CREATE proposal builds on the pilot findings from the survey and literature review and is an essential next step in advancing understanding of practices to promote hand hygiene. Based on the systematic review, survey, and our pilot data, we have selected three interventions that are most likely to improve hand hygiene compliance; however, they are not yet evaluated sufficiently in the literature-individually or combined as a bundle-to recommend wide adoption. These interventions are 1) hand hygiene point-of-use reminder signs to serve as an environmental cue to action; 2) individual hand sanitizers, and 3) health care worker hand cultures. Additionally, significant barriers may exist to the adoption of these interventions and wider implementation would benefit from a qualitative process evaluation to examine possible barriers.

The proposal fills an important gap in identifying optimal hand hygiene bundles for acute care facilities and provides guidance to the VHA hand hygiene Working Group. Additionally, this mixed-methods approach has the potential to significantly impact the science of hand hygiene and improve patient safety both in and outside VHA by reducing the number of HAIs, while also improving the existing VHA MRSA prevention bundle.

OBJECTIVE(S): The proposed study will use a parallel, mixed-methods design that will integrate qualitative research (Aim 2) with a cluster-randomized controlled trial (Aim 1).

Specific Aims: The two specific aims and associated hypotheses of the project include:

1) Identify combinations of hand hygiene intervention strategies that optimize hand hygiene compliance and that could form an evidence-based hand hygiene bundle for VHA implementation. Hypothesis 1: Combinations of interventions will increase compliance rates more than single interventions. Aim 1 will entail a 30-month cluster-randomized controlled trial that will sequentially test three individual hand hygiene interventions to identify an optimal combination of interventions to increase hand hygiene compliance. The trial will be conducted in 59 hospital units in 10 VA hospitals in order to test the efficacy of individual and then sequentially added interventions to determine their incremental impact on hand hygiene compliance.

2) Identify institutional, organizational, ward/ICU, and individual level facilitators and barriers to implementing hand hygiene interventions. Hypothesis 2: Facilitators and barriers will pattern around contextual factors such as level of leadership support and organization of infection control programs. Aim 2 will entail a qualitative process evaluation that includes site visits to purposefully selected sites, semi-structured interviews, and observations to examine barriers and facilitators to the interventions and develop contextual insight for implementing and scaling-up the intervention at additional sites as a national initiative.

METHODS:

AIM I: The hand hygiene behavior of all facility staff working on the wards/ICUs during the periods of hand hygiene observation will be recorded.

All veterans admitted to acute care at the 10 VA medical centers during the study period will be included in this retrospective data analysis. Approximately 135,852 veterans will be included regardless of age, race, gender, or underlying health status. Additionally, women and minorities will be included in this study.

AIM 2: VA Infection Control (IC) Teams: Approximately 18 hospital epidemiologists, Infection Control Professionals, and MRSA/MDRO Coordinators will be asked to participate in the study through in-person and phone semi-structured interviews (3 members of the IC team from 6 sites). Hospital epidemiologists, Infection Control Professionals, and MRSA/MDRO Coordinators from 4 additional sites will be asked to participate in the study through phone interviews (approximately 12 study participants, 3 members of the IC team from 4 sites). The hospital epidemiologist is a Site PI on the study and will facilitate introductions to the IC team. The IC team will be asked to participate because of the unique knowledge they have regarding how hand hygiene is currently monitored and promoted at each VA facility and may have unique insights into the barriers and facilitators of implementation. The participants may not be veterans but are important to the study due to role as VA practitioners.

VA Healthcare Workers (HCWs): Approximately 140-150 healthcare workers (facility, leadership, nurses, physicians, respiratory therapists, dieticians, etc.) will be asked to participate in the study through in-person individual and group interviews. Approximately 24 will be from facility leadership. We anticipate approximately 6 participants per focus group. Two focus groups will be conducted on different units within each of 6 VA facilities. Healthcare workers may or may not be veterans; however, their participation in the study is important as they will provide crucial insight into how hand hygiene is practiced at their facility and barriers and facilitators to the interventions being implemented in the study.

FINDINGS/RESULTS: Pre-and post- intervention qualitative data collection for Aim 2 was conducted FY15-FY17. We conducted semi-structured interviews with 47 infection control staff and hospital leadership. We conducted 20 focus groups with 102 frontline staff at the 6 hospitals. We also collected local hand hygiene policies and data collection forms from the 10 participating hospitals. Despite being part of a single healthcare system, hand hygiene programs varied considerably across the ten facilities, including approaches to monitoring hand hygiene and interventions to improve compliance. Auditing hand hygiene compliance within these acute-care hospitals was problematic, because audit results were not seen as accurate, and the feedback process typically did not encourage positive change (paper under review at BMJ Quality and Safety). In addition, hand hygiene "champions" are tasked with contradictory

tasks including monitoring hand hygiene compliance and coaching staff to conduct hand hygiene at appropriate times (paper under development).

We have conducted 87,026 entry and exit hand hygiene observations. Baseline and hygiene compliance rates ranged from 15% to 75% at the different sites (paper near submission). We did not see an improvement in hand hygiene compliance when the frequency of changing hand hygiene signs changed (paper near submission). We have completed an initial analysis of the HH compliance trends; however, analysis testing for differences between interventions is ongoing.

IMPACT: The effort to improve hand hygiene practices continues to expand in VHA. Multiple VHA offices are coordinating efforts to establish a national hand hygiene initiative. Our study team is collaborating with several programs including Infection: Don't Pass It On (IDPIO) and Patient Care Services (NIDS) to reach this objective. The efforts include participation on the National Hand Hygiene Workgroup, chaired by Dr. Perencevich with Dr. Reisinger as a committee member, Dr. Reisinger chairing the Workgroup's Hand Hygiene Intervention Subgroup, and a serving on the planning committee and presenting at the VA-wide Summit promoting hand hygiene practices. Our research team and the studies we are conducting are poised to shape VHA policy on improving hand hygiene compliance and decreasing MRSA and other HAIs among our veterans.

CRE 12-288:

Will Veterans Engage in Prevention After HRA-Guided Shared Decision Making?

Abstract:

BACKGROUND/RATIONALE: Over half of all deaths, and many illnesses, can be attributed to three modifiable risk factors: tobacco use, overweight/obesity, and physical inactivity. There are clear links between these modifiable factors and heart disease, cancer, chronic lung disease, and stroke which continue to be the leading causes of death in the United States. VHA has made significant improvements in controlling conditions that lead to heart disease, cancer and stroke (e.g., hypertension and hyperlipidemia). We have not, however, done as well in addressing the underlying behavioral factors (e.g., obesity, tobacco use, and physical inactivity).

OBJECTIVE(S): The objective of this study was to determine if a telephone-based Shared Decision Making (SDM) intervention, using VHA's web-based HealtheLiving Assessment and a Prevention Coach would increase patient activation and enrollment in prevention programs compared to usual care. The Specific Aims include: to determine whether the intervention improved activation and participation of patients in prevention programs; to determine whether patients participating in the intervention had greater reduction in cardiovascular risk; and to conduct process evaluations of the intervention and its implementation to inform future dissemination and implementation.

METHODS: Two-site, two-arm effectiveness-implementation Hybrid Type 1 Intervention-Implementation trial. The study was performed at the Durham and Ann Arbor VA Medical Centers. Eligible Veterans had at least one modifiable risk factor (obese, inactive, or tobacco user) but were not currently enrolled in a prevention service. The brief telephone intervention was conducted by a prevention coach and used the output from VHA's HealtheLiving Assessment to engage Veterans in a conversation where individual preferences were matched

to behaviors and choices for specific prevention services (either in the VA or community) were offered. The resulting prevention action plan was documented in the medical record. Outcomes were obtained at 1 month and 6 months after enrollment. The co-primary outcomes were change in the Patient Activation Measure (PAM) and proportion enrolled in effective prevention services. The secondary outcome is 10-year risk of coronary events, as measured by Framingham Risk Score.

FINDINGS/RESULTS: Recruitment started in November 2014 and ended in May 2016. Of patients who screened eligible by phone, 79% consented (n=436) of whom 96% (n=417) were randomly assigned to one of the two arms.

On average, participants were 56 years old (SD=12.2). A large percentage of participants were African American (40%), most were male (85%), and over 25% of our participants reported inadequate income to cover bills at the end of the month reflecting a high proportion of financial vulnerability. In terms of health status, 69% of patients reported their general health as excellent, very good, or good. Eighty percent of participants met enrollment criteria because of weight (BMI 30), 50% for being moderately/vigorously active for less than 150 minutes/week, and 39% were active smokers. Approximately half of the participants had more than one eligible risk factor. The mean Health Risk Assessment (HRA)-generated health age was 60 years while the participants' average chronological age was 56 primarily reflecting their excess cardiovascular risk.

Adherence to the Intervention: Of the 208 participants randomized to the intervention, 194 participants (93%) completed the first coaching call, and 182 participants (88%) completed the second; 14 participants (7%) of intervention participants did not complete either call. The mean duration of the first coaching call was 34 minutes (SD 14 minutes), and the mean duration of the second coaching call was 12 minutes (SD 10 minutes).

Outcomes: At six months, intervention participants reported higher enrollment in a prevention program, 51% vs 29% (OR=2.5; 95% CI: 1.7, 3.9, p <0.0001) and higher participation in a prevention program, 40% vs. 23% (OR=2.3; 95% CI: 1.5, 3.6; p<.001) compared to usual care participants. There was no difference in PAM scores between groups at the one month assessment. However, at six months after baseline, intervention participants showed greater improvement in PAM scores than usual care participants (mean difference=2.5; 95% CI: 0.2,4.7; p=0.03). The FRS showed almost no change over time from baseline to six months for both groups (mean difference=0.7; 95% CI: -0.7,2.2; p=0.33).

Results were robust to missing data assumptions; in our sensitivity analyses for the primary outcome of enrollment, the OR with 95% CI ranged from 2.1 (1.4, 3.2) with all missing assumed to be not enrolled to 2.7 (1.8, 3.9) for all missing assumed to be enrolled.

Prevention Programs Chosen by Intervention Participants: We categorized prevention programs chosen by participants by type (diet/weight loss, exercise, or smoking cessation), and as VA-sponsored, or community-based. Among the 51% (n=91 of 177) of intervention patients who endorsed enrolling in a prevention program by 6 months, 52% selected diet or weight loss programs, 26% selected exercise programs, and 19% selected smoking cessation (3% remained uncharacterized). Overall, 55% of these participants selected VA programs and 45% selected non-VA programs.

IMPACT: This is the first trial to test an intervention that coupled results from an HRA with a telephone-delivered health coaching intervention designed to help participants enroll in a structured prevention program. Health coaches were successful in engaging participants in a discussion about prevention, guiding them to a program that matched their goals, which resulted in intervention participants enrolling and participating in programs to a significantly greater degree than participants not receiving coaching. Intervention participants also showed significant improvement in PAM scores, a measure that captures patients' knowledge, skills, and confidence in management of their health

The degree of prevention program enrollment observed in this study (over half enrolled, and 40% participating by six months) is much higher than reported in other studies that seek to engage primary care patients in prevention programs. In part this may be explained by integrating results from an HRA with health coaching. The health coaches guided patients to first understand their risk, the portion of it that was modifiable, and what they could do to improve their risk. They emphasized the difference between their current health state and their ideal health state and linked that concept to participants' values and hopes for the future. Rather than coaching to change a specific health behavior selected by the participant, coaches helped participants set a specific goal to enroll in a structured program that best matched their circumstances and preferences. In this way, the intervention was able to address a wide array of risky behaviors (e.g., weight, tobacco use) with a focus on helping to motivate patients to engage in effective, structured prevention programs. This approach leverages already-available prevention programs and requires less time than would be necessary to address changing the behavior itself. Additionally, the intervention has great potential for adoption within clinical settings because it is a relatively low-resource approach. Lastly, this approach may increase reach because many patients prefer telephone coaching for its convenience and personal approach.

A strength of our study is that we designed and conducted the intervention using elements that are widely available in VA and other large healthcare systems (e.g., online HRA, telehealth coaches). VA and other health systems are working to understand how to best incorporate health risk assessment into routine primary care as well as encouraging effective prevention programs for their patients. Our current study shows that when coupled with brief health coaching, patients are more likely to enroll and participate in prevention programs compared to using an HRA alone, thereby taking patients beyond goal setting to action.

Next steps should concentrate on how best to incorporate this relatively low-resource intensive intervention into routine primary care practice which we are doing in the implementation extension.

CRE 12-305:

Stay Strong: A Physical Activity Program for Afghanistan and Irag Veterans

Abstract:

BACKGROUND/RATIONALE: Veterans from Afghanistan and Iraq (OEF/OIF) are at high risk for becoming overweight and obese; 86% were overweight or obese at their first visit to the VA as reported in one recent study. However, existing VA programs are not designed for younger Veterans who are more comfortable with technology-mediated interventions than older Veterans and who may not yet have developed obesity-related chronic diseases. Additionally, OEF/OIF

Veterans include a relatively high percentage of women compared to previous Veteran cohorts. These differences should be addressed in lifestyle interventions customized to OEF/OIF Veterans.

Technology-mediated lifestyle interventions that include continuous, objective home monitoring of physical activity, automated internet-mediated feedback, and e-coaching increase physical activity and improve weight loss in non-Veteran populations. When delivered on a large scale, such interventions represent low cost but effective alternatives to face-to-face lifestyle change interventions. The VA health care system is in a strong position to implement such interventions on a national scale because of existing structures such as a national electronic medical records system. Such interventions can be centrally administered and marketed directly to Veterans, capitalizing on economies of scale, expanding intervention reach, and reducing the burdening of recruitment on the existing health care team. However, with the exception of one pilot study, prevention focused technology-mediated physical activity programs that include continuous, objective home monitoring of physical activity, automated internet or cell-phone mediated feedback, and e-coaching have not been customized and tested for OEF/IOF Veterans.

OBJECTIVE(S): This project will test the feasibility and effectiveness of the prevention-focused, internet-mediated healthy lifestyle Stay Strong program tailored to the needs, preferences, and demographics of OEF/OIF Veterans. The specific aims of this project are to: 1) evaluate the impact of an automated, centrally administered, smartphone app-mediated, physical activity intervention, Stay Strong, on physical activity among OEF/OIF Veterans; 2) evaluate the impact of Stay Strong on the secondary outcomes of weight loss, depression and pain among OEF/OIF Veterans; and 3) test for moderation of the intervention effect of the Stay Strong intervention by gender with respect to the primary outcome of physical activity per day, as well as secondary outcomes of weight loss, depression and pain.

METHODS: In this randomized controlled study, OEF/OIF Veterans randomly selected from clinical warehouse data (CDW) using a flag indicating OEF/OIF/OND status and younger than 65. Veterans will be randomized into either an active control arm (basic Stay Strong) or the Stay Strong app plus personalized exercise goals, tailored push notifications, and three phone-based health coaching calls in the first 6-8 weeks. Programs will last for one year for both arms. The primary outcome is change in physical activity per day averaged over 7 days. Weight loss, pain and depression are secondary outcomes. Because gender moderates the impact of physical activity interventions, we will and over-sample women. The trial is innovative in that study staff will have no face-to-face contact with participants. All participant recruitment, eligibility screening, informed consent, baseline assessment, randomization, intervention delivery and outcome assessment will be internet or smartphone app mediated. A constrained longitudinal data model in which baseline physical activity is modeled as a dependent variable in conjunction with the constraint of a common baseline mean across the treatment group will test for a between-group comparison in physical activity from baseline to 12 months in the intervention and control groups.

FINDINGS/RESULTS: Recruitment on this project has begun however, no findings to date.

IMPACT: If successful, the Stay Strong program could be implemented as a national program to augment the VA's current panel of options for OEF/OIF Veterans who need support to maintain a healthy lifestyle and prevent future disease.

IIR 14-070:

Evaluation of a peer Coach-Led Intervention to Improve Pain Symptoms (ECLIPSE)

Abstract:

BACKGROUND/RATIONALE: Chronic pain affects 40-70% of Veterans and is a leading cause of disability, resulting in substantial negative impact on millions of Veterans' lives. Pain reduces quality of life and is associated with emotional distress when it interferes with work, social and recreational activities, and family life. Pain self-management, which involves treatment adherence, behavioral change, and coping skills, is an effective, evidence-based treatment for chronic pain that has been advocated by both the Institute of Medicine and the VHA 2009 Pain Directive. However, implementation of a pain self-management model in VA is challenging because of limited time and resources in primary care, where most chronic pain is managed. As a result, pharmacological treatments, including opioid analgesics, are frequently the first line of treatment, and pain self-management is under-utilized.

OBJECTIVE(S): Evaluation of a Peer Coach-Led Intervention for the Improvement of Pain Symptoms (ECLIPSE) is a randomized controlled trial designed to test the effectiveness of a peer coach-delivered pain self-management intervention versus controls receiving a 2-hour class on pain and pain self-management. ECLIPSE has the following specific aims:

Aim 1: To compare 6-month (primary end point) and 9-month (sustained effect) effects of peer-supported chronic pain self-management versus control on overall pain (intensity and function), measured by the Brief Pain Inventory (BPI).

Aim 2: To compare 6- and 9-month effects of peer-supported chronic pain management versus control on self-efficacy, social support, pain coping, patient activation, health-related quality of life, and health service utilization.

Aim 3 (pre-implementation aim): To explore facilitators and barriers to the implementation of peer support for chronic pain, intervention costs, and fidelity to the model.

METHODS: ECLIPSE will enroll Veterans from primary care clinics who have chronic musculoskeletal pain. ECLIPSE is a Hybrid Type 1 study designed to test effectiveness, while also examining implementation barriers and facilitators. We will enroll 215 Veteran patients and 40 Veteran peer coaches. The 215 Veterans will be randomly assigned to the peer-coaching arm (n=120) or the control arm (n=95). Peer coaches will be assigned 3 Veterans each. The peer-coaching intervention will last 6 months and coaches and Veterans will be encouraged to meet (in person or by phone) at least bi-weekly. Peer coaches will be provided with a detailed manual and will be trained and supervised by the study nurse, who has delivered pain self-management interventions to Veterans in several previous studies.

The primary study outcome is overall pain, measured by the Brief Pain Inventory (BPI) which assesses both pain intensity and interference with activities. Secondary outcomes are self-efficacy, social support, pain coping, patient activation, health-related quality of life, and health care utilization. Outcomes will be assessed at baseline, 6 months (primary effect) and 9 months (sustained endpoint).

We are also conducting interviews with peer coaches, Veteran participants, and VA Patient-Aligned Care Team (PACT) staff to determine facilitators and barriers to implementing a peer coach-led self-management program in primary care in the VA.

FINDINGS/RESULTS: We are still in the process of recruitment, interviewing and collecting data; there are no main findings to date. However, we have results from part of Aim 3, interviews with clinicians about facilitators and barriers to implementation of the peer coach intervention. These findings indicate that clinicians 1) had an overall positive perception of the intervention; had specific intervention outcomes they thought were important; 3) anticipated the intervention could positively influence their role; 4) anticipated barriers to intervention participation and maintenance; and 5) had concerns regarding peer coach selection. These findings are interpreted in the context of the CFIR framework.

IMPACT: To maximize implementation potential of pain self-management in VA, alternative delivery methods are needed to provide Veterans with education and support needed to self-manage their pain, without requiring additional resources from healthcare teams. A novel and promising approach is a peer coaching model, in which Veterans with chronic pain who are successfully managing their pain offer information, support, and mentorship to other Veterans with pain. Peer support models have been found to be effective in the management of a variety of chronic conditions in VA and non-VA settings.

PPO 16-323:

Pilot Study of Standalone and Peer Supported Online Problem-Solving Program in Veterans with Untreated Mental Health Problems

Abstract:

BACKGROUND/RATIONALE: Veterans have high rates of psychological symptoms and adjustment problems that trouble them, but many go without professional mental health care due to stigma, logistical challenges, and a high value on self-sufficiency. The number of such Veterans is expected to increase in the next two decades as the proportion of Veterans who served in recent wars increases. To meet Veterans' mental health needs, VHA has invested resources in developing evidence-based, computerized self-help tools. Such online tools can be effective if people use them, but many of the tools do not have strong strategies for engaging Veterans to use them. VHA has also funded a peer support (PS) program aimed at improving engagement in MH care, yet there is little empirical data on how peer support can improve Veterans' psychological health. Combining online tools with peer coaching could leverage the unique strengths of these complementary resources to improve VHA mental health care and improve the overall health of the Veteran population. Use of a VHA-DOD developed online problem-solving training called Moving Forward (MF) has been found to improve problemsolving skills and improve mental health in Veterans preliminary studies, but its use has not yet been studied in VHA primary care patients with clinically significant symptoms. Similarly, preliminary research on PS for an online mental health program has shown an impact on use of the program, but no RCT has been conducted.

OBJECTIVE(S): The overall goal of this research program is to improve mental health care in Veterans by increasing the availability of mental health care that is non-stigmatizing and easily available to Veterans who have untreated mental health problems but choose not to seek or accept face-to-face VHA mental health care services. The specific aims of this pilot study are

preparatory to a large-scale RCT to test the effects of MF with and without peer support on two populations of Veterans who have untreated mental health problems.

Aim 1: Test feasibility and acceptability of recruitment and data collection strategies to study MF + PS in two populations of Veterans with unmet mental health needs.

Aim 2: Obtain preliminary efficacy results on the impact of MF and MF+PS on problem-solving skills and psychological health in Veterans with unmet mental health needs.

METHODS: This pilot study aims to investigate the feasibility and acceptability of methods to study the impact of the online problem-solving training, Moving Forward, with and without peer support, in Veterans with untreated mental health problems. We will study 60 VHA primary care patients who are referred for mental health treatment but decline or do not attend a mental health intake session and 60 Veterans living in the community who have untreated mental health problems. We will adapt an existing guide for peer support for an online mental health program for use with MF, train a PS to support use of MF, and monitor fidelity to the guide throughout the study. All who agree to enroll will be referred to a study website, where they will be screened, provide informed consent, and complete baseline assessments of problem-solving skills and psychological health, which will include measures of quality of life, depression, anxiety, and PTSD. Participants will then be randomized to one of 3 conditions: a no-treatment control group, MF, or MF+PS. Participants in the two active intervention groups will be asked to complete the 8 MF modules over 4 weeks and spend an additional 4 weeks using MF. Mid-point and end-of-program assessments of problem-solving and psychological health will be completed and use of the MF intervention will be objectively measured through the web site. Several indicators of feasibility and acceptability will be assessed to inform a large-scale RCT. User satisfaction, qualitative data on barriers and facilitators to use of MF and PS, and perceptions of usefulness of MF and PS will also be assessed. If results are encouraging, they will be disseminated and a Merit grant application for a large-scale RCT will be developed.

FINDINGS/RESULTS: TBA

IMPACT: In progress

CRE 12-306:

Risk Stratification and Tailoring of Prevention Programs

Abstract:

BACKGROUND/RATIONALE: Among the range of prevention programs in VHA, patients are likely to vary in their response to any given program. This variation is known as heterogeneity of treatment effects. To improve the effectiveness of new VA investments in prevention programs, it will be necessary to identify which Veterans have a better response to each program and which characteristics identify Veterans who might require alternative prevention programs. The purpose of this CREATE proposal is to systematically evaluate the heterogeneity of treatment effects (HTE) across the three prevention trials conducted as part of the Prevention CREATE Lab.

OBJECTIVE(S): The purpose of the study was to determine the participant characteristics associated with response to treatment in the 3 interventions in this CREATE proposal (Aim 1) and to determine the relationship between VA expenditures and participant characteristics associated with response to treatment (Aim 2). We also proposed a secondary aim to determine the participant characteristics associated with increased per-protocol adherence in the 3 interventions. To date, no studies have applied multiple HTE approaches to the same trial and only recently have these methods been applied to behavioral intervention trials.

METHODS: We obtained all data collected during the ACTIVATE trial (CRE 12-288) to examine HTE in the primary outcome of self-reported participation in a prevention program 6 months after enrollment via predictive risk modeling and via a data-driven approach. We also estimated 6-month VA total expenditures. In predictive risk modeling, patients are first grouped together within strata based on their risk from a pre-specified risk score (e.g., Framingham Risk Score [FRS] or an internally derived score constructed from a priori patient factors that have a plausible clinical relationship with the outcome). Treatment effects are then assessed within risk strata. This approach for describing treatment heterogeneity was first introduced in a landmark study showing that the clinical benefits accrued to patients randomized to receive carotid endarterectomy were entirely driven by 16% of the treatment group that was at highest risk for stroke. Data-driven methods identify subgroups with similar responses to treatment whose treatment effects vary from other subgroups. These methods generally consider all available baseline covariates to classify patients into discrete, intuitive subgroups (e.g., men age >57, men 57, women age >57, women 57). Many data-driven methods are derived using statistical classification methods8 (recursive partitioning or decision trees) that are well suited to situations with many predictors with potentially complex interactions and little a priori knowledge concerning which subgroups may benefit most. The underlying search, optimization, and modeling algorithms vary by method, and, consequently, answer subtly different questions, often yielding varying results even when applied to the same dataset. For example, the simultaneous threshold interaction modeling algorithm searches for the subgroups of patients that yield the largest differential treatment effect upon the outcome; model-based recursive partitioning (MoB) searches for subgroups (defined by treatment by covariate interactions) that yield a better fitting model than the overall treatment effect model.

FINDINGS/RESULTS: In the HTE analysis of prevention program participation, the PRM had discrimination (c-statistic) of 0.63 with 12 a priori chosen covariates, and the greatest treatment effect was in the second quartile, in which 54% (22 of 41) of intervention patients and 10% (5 of 50) of control patients reported prevention program enrollment. MoB identified 4 subgroups based on three of 28 covariates, with the greatest treatment effect among patients with lower mean numeracy, education less than a bachelor's degree, and diabetes, in which 54% (15 of 28) of intervention patients reported prevention program enrollment versus 7% (3 of 41) of control patients. The smallest effect was among those with high numeracy, with 38% (18 of 47) of intervention patients compared to 43% (23 of 53) of control patients.

In regression analysis of 6-month total VA expenditures, estimated mean expenditures were similar (\$8,664 for HRA+coaching vs \$9,900 for HRA-alone, p=0.25). In exploratory subgroup analysis, expenditures in the HRA+coaching group were higher than for HRA-alone among unemployed veterans with good sleep habits and fair or poor perceived health (\$12,814 vs \$17,318) but were lower among unemployed veterans with good sleep habits and good general health (\$5,082 vs \$11,612).

IMPACT: Both preventive risk modeling and data-driven methods imply a potential decision rule for prioritizing who may benefit the most from HRA+coaching. In a setting of constrained resources, the data-driven method suggests priority should be given to patients with low numeracy, low education, and diabetes. The predictive risk model showed that those with lower overall risk of enrollment would have greater benefit from the intervention, so coaching resources should be directed to these patients. However, because risk was defined by an internally developed prediction model, identifying these patients would be more difficult to operationalize. Data-driven and predictive risk methods approach subgroup identification differently, answer related but slightly different questions, and differ in the heterogeneity observed in the effect of an intervention that combined an HRA with health coaching.

Randomized trials provide the strongest evidence about intervention effectiveness, but there is growing recognition that the average treatment effect (ATE) generated from a trial does not generalize to most patients eligible for the intervention. A principled approach to identifying heterogeneity of treatment effects (HTE) is needed. Historically, HTE was assessed by identifying subgroups stratified by one variable (e.g., male vs. female), which are easy to implement and intuitive to understand. However, this approach often does not fully characterize the multivariable risk and/or benefit of treatment; additionally, there is a risk of false negatives due to lack of statistical power in small samples and a risk of false positives as the number of stratified analyses grows. To avoid some of these pitfalls, multivariable (predictive risk, data-driven) approaches have been developed to more systematically discover and describe HTEs.

CRE 12-285:

Randomized Controlled Trial of Group Prevention Coaching

Abstract:

BACKGROUND/RATIONALE: Primary prevention of cardiovascular disease (CVD) has been challenging to achieve; evaluation of new strategies for CVD primary prevention is the focus of this project, which is part of a CREATE (Collaborative Research to Enhance and Advance Transformation and Excellence) Program addressing prevention.

Multifactorial behavioral interventions are interventions that, instead of attempting to change a single health behavior among patients in a population (e.g., increased physical activity, smoking cessation), allow individual patients to choose one or more among a number of behaviors, any of which may get them to a common clinical objective (e.g., lowering blood pressure). These interventions often use some of a set of common approaches, such as goal-setting and improving self-efficacy, to assist patients in behavior modification. A recent systematic review suggests multifactorial behavioral interventions are likely efficacious in secondary prevention of CVD, and these interventions are also efficacious in a number of chronic illnesses (e.g., hypertension, diabetes). While there are studies that assess the performance of these interventions in patients without a common illness, there is little literature directly measuring risk reduction in a primary prevention population by means of multiple modest behavior changes; our group has performed such a study, but in a population very unlike VA (mostly white, mostly female, all insured).

Problem solving (PS) is an approach to behavior change that has a long history in the mental health literature, but is much less used, and less well tested, in the prevention arena. PS is an evolution of cognitive-behavioral therapy that addresses internal barriers to changing behavior,

urging patients to use specific techniques designed to prime them for success in any behavior change they propose to attempt. PS is well-tested in mental health, and there are small studies suggesting its utility in changing behaviors associated with improved physical health. It is traditionally done in an individual setting, but recent literature indicates promise in use in group settings. However, PS has unproven effectiveness both in group settings and among primary prevention patients.

Group visits have been shown to be an effective means of improving outcomes in a number of settings. Group visits can either involve medication management or be entirely focused on behavior change; self-management groups (SMGs) are behavior intervention groups that are conducted by a trained facilitator and focus on having patients teach each other how to adopt healthful behaviors (usually in chronic illness). Because there is no requirement for medication management, SMGs can be used efficiently in patients without medication-requiring chronic illness, as there is no attendant cost of employing a prescribing provider. SMGs can be used as a strategy to deliver a multifactorial behavior intervention in patients with a common illness. However, our study above is the only RCT we can find of SMGs in primary prevention.

OBJECTIVE(S): Our primary objective was to determine the effectiveness of group prevention coaching (GPC), compared to VA usual care, in reducing CVD risk in a primary prevention population. Our primary hypothesis was that, among patients with >5% 10-year risk for a cardiovascular event, there will be at least a 2.0% difference between GPC and usual care in reduction of predicted rate of fatal or non-fatal myocardial infarction (MI), as estimated by the Framingham Risk Score (FRS). We sought to determine the effectiveness of GPC (compared to VA usual care) in: (a) increasing physical activity, and (b) making dietary improvements. We also sought to determine the role of group cohesion in predicting the success (or lack thereof) of GPC among intervention patients.

METHODS: We performed a randomized, controlled trial (RCT) of our GPC intervention. Outcomes were be measured at baseline, 6 months, and 12 months after enrollment. The control group received usual care. We performed the study among patients at the Durham and Buffalo VAMCs. The patients were 401 VA users without prior history of cardiovascular event, but with at least 5% risk of such an event, with at least 2% of that risk potentially reversible. Risk was calculated by Framingham Risk Score (see primary outcome). We excluded patients with known significant atherosclerotic disease (coronary artery disease, stroke, peripheral arterial disease). To meet these criteria, all patients in the study had hypertension with less-thanoptimal control, OR elevated total cholesterol, OR were current smokers. We also excluded patients with other severe intercurrent illness or poor life expectancy, or who were currently engaged in formal efforts to improve a CV risk behavior, or who were cognitively impaired or unable to use a telephone.

Subjects provided written informed consent and completed a measurement battery. They were randomized, 1:1 and stratified by site, to receive or not receive the GPC intervention. Patients were assessed 6 and 12 months after baseline by a blinded research assistant.

The GPC intervention was delivered to patients in the active arm. The basic structure was that of a group problem-solving intervention, with interval phone calls delivered between each group session to check in on goal progress and reinforce group learning. Groups met at weeks zero, 3, 6, 10, 14, and 18; a focus group convened at 24 weeks without any intervention content. Each patient was to be called once between each group session. Groups had 5-15 patients, but

all but 2 groups had 8-12 patients. Problem-solving principles represented the content of the group sessions. Problem solving intends to teach patients to overcome internal barriers to healthful behaviors. The groups will be coordinated by a clinical psychologist hired for the research enterprise but trained and credentialed identically to a facility's Health Behavior Coordinator (HBC). The phone calls associated with the intervention were performed by a healthcare coach.

Our primary outcome variable was Framingham Risk Score. FRS is calculated using age, gender, blood pressure, total and HDL cholesterol, smoking status, diabetes status, and status of taking blood pressure medication. All components of the FRS were measured at each scientific assessment. We also measured physical activity by International Physical Activity Questionnaire, caloric intake by Block Brief 2000 Food Frequency Questionnaire, weight, self-efficacy by Patient Activation Measure (range, 0-100), group cohesion by the Group Cohesion Scale, and Problem Solving skill by the Social Problem Solving Inventory (range, 0-139). We also measured a number of socio-demographic covariates at baseline. Analysis was intent-to-treat, and performed by linear mixed modeling, adjusting for group clustering in the GPC arm.

FINDINGS/RESULTS: We randomized 202 patients to GPC and 199 to usual care. Mean age was 62.4 years, 10% were women, and 32% were black. Mean 10-year risk of cardiovascular event was 29.2% by Framingham Risk Score (FRS); baseline mean Patient Activation Measure (PAM) and Social Problem Solving Inventory (SPSI) scores were 60 and 105, respectively. Follow-up rate at 6-months was 62% in GPC and 64% in usual care. GPC patients attended a mean of 3.4 (of 6) group sessions; 43.6% attended 5 or 6 groups, and 14.9% did not attend any. Patients completed a mean of 3.9 (of 6 calls); 57.4% completed 5 or 6 calls, and 14.4% completed no calls. Among GPC patients, 47.7% chose to work on improved eating or weight loss, 17.9% chose to increase physical activity, 27.8% chose to quit smoking, and 6.6% chose another strategy for improving risk (medication adherence or cessation of non-tobacco substance). In the LMM analyses, there was no difference at 6 months between GPC and UC patients in FRS (mean difference 0.7%, 95% CI, -1.4%, 2.8%), PAM score (mean differences 1.3 points, 95% CI -1.3, 3.9), or SPSI (mean difference 1.6 points, 95% CI -0.8, 4.0).

Other outcome analyses (especially physical activity and diet content) are pending, as is a completers analysis.

IMPACT: Our intervention was not better than usual care in its impact on cardiovascular risk or patient activation. Patients only attended a moderate number of sessions.

CRE 12-083:

Motivational Coaching to Enhance Mental Health Engagement in Rural Veterans

Abstract:

BACKGROUND/RATIONALE: There is a substantial burden of mental health (MH) problems in rural OEF/OIF/OND veterans. After a decade of war, over 51% of OIF, OEF, and OND veterans in VA healthcare have received MH diagnoses; the majority (27%) have received diagnoses of posttraumatic stress disorder (PTSD). Studies show that veterans residing in rural areas experience significantly greater MH severity and poorer outcomes than their urban counterparts. Surprisingly, there are no published studies on the differential MH burden among OEF/OIF/OND veterans in VA healthcare based on rurality. To begin to address this knowledge gap, using

rural-urban commuting area (RUCA) zip code data to define rurality and national VA administrative data to obtain ICD-9 MH diagnoses codes, our group found that increasing rurality was associated with a higher prevalence of MH disorders in OEF/OIF/OND veterans nation-wide and in VISNs 16 and 21. (Seal, preliminary data) For instance, compared to the prevalence of MH diagnoses among urban OEF/OIF/OND veterans in VISN 21 (44.7%), the MH burden was higher in rural veterans(47.4%) and even greater in "isolated rural" veterans (54.6%),(Relative Risk=1.22, 95% CI=1.11-1.34 for MH diagnoses in isolated rural vs. urban veterans) (Seal, preliminary data).

The majority of OEF/OIF/OND veterans with MH problems do not receive an adequate course of MH treatment. The VA Uniform Mental Health Services Handbook mandates that all veterans, including those receiving care at CBOCs serving rural veterans, have access to evidence-based MH treatments. Minimally adequate MH treatment has been defined as 8 MH treatment sessions or receiving 2 months of psychiatric medication plus > 4 visits within 1 year. Unfortunately, the majority of OEF/OIF/OND veterans have not received an adequate course of MH treatment as found in a nationally representative sample of veterans, and veterans enrolled in VA healthcare. Indeed, at the San Francisco VA Medical Center (SFVAMC), our group demonstrated significantly improved MH treatment initiation in OEF/OIF/OND veterans who presented to our new co-located primary care-mental health clinic compared to usual primary care, but sustained engagement in specialty MH services remained poor with drop-out after 1-2 sessions.

OBJECTIVE(S): In a randomized multi-site pragmatic effectiveness trial, compare the effectiveness of MH Referral alone with MH Referral plus MI-based coaching to improve MH services engagement in veterans receiving care at CBOCs. Compared to MH Referral alone, MI coaching will significantly:

H2a. Increase MH services initiation and retention (number of MH visits) (Primary Hypothesis).

H2b. Increase the use of e-health "self-help" MH treatment options, such as afterdeployment.org.

H2c. Increase perceived need and readiness for MH treatment and decrease barriers to MH services.

Secondarily, we will evaluate change in mental health symptoms, high-risk behaviors (e.g., driving under the influence, etc.), functioning, quality of life, perceived access to MH care, and satisfaction with VA healthcare.

METHODS: We will conduct a pragmatic effectiveness RCT of MH Referral plus the MI-based MH treatment engagement intervention vs. MH Referral only (Control) in veterans who receive care in VA CBOCs serving rural veterans (months 10-44, 34-month RCT). All participants will be enrolled and followed for 8 months. Enrollment will begin at study month 15 and will conclude at study month 46. The last wave of enrollment will begin at month 39 to allow a full 8-month follow-up period until month 46 (25-month enrollment period). This leaves 4 months for data analysis and manuscript preparation.

IMPACT: This study evaluated the impact of rural culture on MH referral and engagement processes at rural CBOCs in VISN 16 & 21 and used this information to adapt and implement a Motivational Interviewing coaching intervention to improve access to mental healthcare for rural

veterans. This research also helped illuminate barriers to care and preferences for mental health services among rural veterans with mental health symptoms. Information from this project can be used to develop implementation toolkits for MH treatment engagement interventions for rural veterans. This project also filled a gap in the scientific literature about the effectiveness of peer motivational coaching for mental health treatment engagement among rural veterans with mental health symptoms who were not in treatment at baseline. We found that mental health treatment engagement was not superior among participants randomized to the peer motivational coaching intervention arm compared to controls. Nevertheless, we found that mental health treatment engagement after baseline assessment (by veteran peers) was higher than expected (~45%) in both groups. Importantly, we found greater mental health symptom improvement among participants in the peer motivational coaching intervention compared to controls and that in most cases these improvements were statistically significant. We also found that participants randomized to the peer motivational coaching intervention reported significant improvements in several quality-of-life domains compared to controls. Qualitative data collected from trial participants during the intervention reveled that veterans found the calls themselves to have therapeutic value, perhaps obviating the need for mental health treatment, thereby explaining these findings.

The study has already resulted in additional operational work in this area. The team has a one-year VA operations grant from the Office of Patient-Centered Care and Cultural Transformation (OPCC-CT) which extends the scope of our VA HSR&D CREATE-supported COACH study. Specifically, the OPCC-CT pilot funding allows us to test the VA Whole Health coaching model delivered by a mix of veteran peers and research staff for both urban and rural veterans to support self-management approaches to chronic disease. We have adapted the VA Whole Health coaching model to include the motivational coaching intervention currently being tested by veteran peer coaches for rural veterans to support engagement in mental health services through our CREATE study. We also have a one-year grant from the VA Office of Mental Health services (OMHS) to pilot the use of the COACH motivational interviewing intervention by veteran peer specialists for veterans seen in primary care needing assistance with various behavioral interventions to support health and wellness.

IIR 12-412:

Technologically Enhanced Coaching (TEC): A Program for Improving Diabetes Outcomes

Abstract:

BACKGROUND/RATIONALE: Peer support among patients with diabetes has been found to be an effective intervention to address barriers to diabetes self-management, however, one potential limitation of peer support programs is that peer supporters by definition lack substantial medical and other content knowledge. To increase the potential impact of peer support programs, a key next step is to test whether providing peer supporters with evidence-based educational tools enhances the effectiveness of such programs. We thus developed a personally tailored, interactive diabetes medication and self-management e-health decision aid (iDecide). In a prior study, we found that low-income, urban Latino and African American adults with diabetes who worked with Community Health Workers (CHWs) using iDecide had greater improvements with satisfaction and decreased diabetes distress. Since many health care systems in low-resource settings do not have trained CHWs or other outreach workers, it is important to investigate whether programs such as iDecide are helpful in assisting peer

coaches. Accordingly, in the current study we conducted a trial in a low-resource health care system (Detroit VA Medical Center) testing the effectiveness of a peer coach-delivered iDecide intervention for patients with poor glycemic control.

OBJECTIVE(S): The three main objectives of this randomized controlled trial were to: 1) Test the effectiveness of a technology-enhanced peer coaching program (iDecide arm) in improving glucose control relative to peer coaching without technology enhancement (Peer Support-Alone arm); 2) Assess the impact of the intervention on key patient-centered outcomes, including patients' satisfaction and involvement with care, perceived social support, diabetes-specific quality of life, and medication adherence; and 3) Identify patient characteristics associated with engagement in the intervention and mediators and moderators of the intervention's impact on patient outcomes.

METHODS: From September 2014 to September 2016, Veterans with A1c>8.0% were enrolled in a 6-month peer coaching intervention. Participants were randomized to either the iDecide arm or Peer Support-Alone arm, both consisting of an initial face-to-face coaching session followed by weekly phone calls to discuss behavioral goals. Veterans who had poor glycemic control in the past (A1c>8.0%) but whose most recent A1c in the prior 6 months was <8.0% were recruited as peer coaches. For peer coaches in both arms, we held a 2-hour initial training session that focused on key Motivational Interviewing-based communication skills and helping participants define a longer-term behavioral goal and specific short-term steps to reach that goal ('action planning'). Peer coaches in the iDecide arm participated in an additional 1-hour training session on how to navigate the iDecide tool that was delivered on iPads.

The iDecide program consisted of four main sections: 1) information and illustrative animations on how diabetes affects how glucose is processed in the body and how different medication classes, foods, and physical activity act to affect blood sugar; 2) participants viewed their own risk of diabetes complications (tailored based upon their baseline A1c) and could interactively change their A1c levels and see in pictographs how this changed their risk of different complications; 3) participants reviewed their current diabetes medications and barriers to taking medications that they had identified on the baseline survey and engaged with an interactive "issue card" to help elicit their preferences and priorities in terms of different medication characteristics; and 4) participants were prompted to set goals, develop a specific action plan to address identified barriers or other concerns, and generate specific questions and concerns to discuss with their doctor. Participants were given the link to the iDecide program with their personal information for them to access at their convenience throughout the intervention period and encouraged to continue to access the program as needed.

FINDINGS/RESULTS: Of the 260 Veterans enrolled, 255 participants (88%) completed 6-month assessments and 237 (82%) completed 12-month assessments. 98% were men, and 63% were African American. In the Peer Support-Alone group, mean baseline A1cs of 9.07% improved to 8.39% (-0.68%, p<0.001) at 6 months and remained 8.55% (-0.54, p=0.004) at 12 months. Mean baseline A1c in the iDecide group was 9.08% at baseline and improved to 8.38% (-0.70, p<0.001) at 6 months and remained 8.52% (-0.55, p=0.002) at 12 months. There were no significant between-group differences at 6-month or 12-month follow-up. There were no significant changes in systolic blood pressure at any time point in either group. Significant within-group improvements were observed in self-reported diabetes-specific social support in both groups between baseline and 6 months and between baseline and 12 months.

Conclusion: Clinical gains achieved through a volunteer peer coach program were not increased by the addition of a tailored e-Health educational tool.

IMPACT: This study is among the first efforts to respond to the call for the testing of e-health consumer health applications for use by nontraditional caregivers such as volunteer peer coaches with racial and ethnic minority and low-literate populations. Our study found that both peer support models were effective in improving A1c levels right after the interventions, and importantly, these gains were sustained 6 months after the programs' conclusion. The A1c improvements of >0.5% achieved at both 6- and 12-months in both intervention arms in this study are both statistically and clinically significant. A mean difference in A1c level of 0.5% translates into an absolute 2.8% risk reduction in diabetes events over 10 years.

Of note, these clinically significant and sustained gains were not further improved through use of an e-health educational tool in the initial face-to-face visit and its availability to participants throughout the intervention period. This suggests that the ongoing supportive relationships between peer coaches and their assigned patients in both peer support arms were the most important active ingredient in the intervention's success. This is good news for resource-constrained health systems that may lack the capacity to develop, continually update, and manage tailored e-health programs. Volunteer peer support programs can be important complements to over-burdened formal health care providers to improve the frequency and intensity of ongoing support between face-to-face clinic visits. Unlike most other tested diabetes management support programs, gains achieved over the 6-month intervention period were sustained 6 months after the end of the program. Moreover, such programs that mobilize patients to help other patients could realistically be provided over sustained periods of time.

PPO 16-335:

Pilot Testing Prehabilitation Services Aimed at Improving Outcomes of Frail Veterans Following Major Abdominal Surgery

Abstract:

BACKGROUND/RATIONALE: Frail Veterans are at increased risk for poor surgical outcomes. Although surgeons operate safely on even the oldest old, if the elder is also frail, the stress of surgery can result in significant mortality, morbidity, and institutionalization. Frailty is a clinical syndrome marked by muscle atrophy, diminished strength, decreased physical activity, and exhaustion. It is independent of any specific disease, but it increases with age, and is a more powerful predictor of increased perioperative mortality, morbidity, length of stay, and cost than predictions based on age or comorbidity alone. As the Veteran and US populations grow older and more frail, it is critically important to identify effective strategies for improving the surgical outcomes of these patients.

"Prehabilitation" has the potential to improve surgical outcomes among the frail. Prior research demonstrates that inter-disciplinary rehabilitation strategies deployed after surgery enhance recovery and improve outcomes by building strength, improving nutrition, and optimizing home supports. Based on this success, there is growing interest in deploying similar interventions before surgery in what some call "prehabilitation." By modifying physiological and environmental risks, prehabilitation aims to augment patients' capacity to compensate for the stress of both surgery and recovery. Frail patients will likely benefit disproportionately from prehabilitation

because they have the most diminished capacity to adapt to the stress of surgery. However, prehabilitation has not yet been studied in either Veteran or specifically frail populations.

OBJECTIVE(S): We examined the feasibility of a novel, multifaceted pre-habilitation intervention aimed at improving postoperative outcomes for frail Veterans undergoing major abdominal surgery. Specific aims were to:

- (1) Estimate rates of recruitment, randomization, retention, and compliance with the prehabilitation intervention.
- (2) Measure (a) physical performance, (b) pulmonary function, and (c) nutrition at baseline and 2-week intervals to estimate changes over time and explore the optimal duration of prehabilitation (2 vs. 4 vs. 6 weeks); and
- (3) Estimate overall and treatment-specific summary statistics for postoperative outcomes in terms of 30- and 90-day (a) mortality, (b) major complications, (c) length of hospital stay, (d) health-related quality of life, (e) quality of surgical care, and (f) change in level of independent living.

METHODS: This randomized pilot study will enroll a consecutive cohort of up to 50 Veterans identified as frail using a standardized frailty assessment and scheduled for major abdominal surgery on the general or urological surgery services at the VA Pittsburgh Healthcare System. We will randomize participants 1:1 to receive either: (1) standard preoperative optimization by the Interdisciplinary Medical Preoperative Assessment Consultation & Treatment Clinic (IMPACT), or (2) prehabilitation + standard IMPACT optimization. The 6-week long prehabilitation intervention will include (1) strength and balance training; (2) inspiratory muscle training; and (3) nutritional coaching and supplementation. Compliance with the prehabilitation regimen will be assessed through patient logs and pedometers.

Assessments will be made at baseline, every other week during prehabilitation, the week/day before surgery, and then again at 30 and 90 days after surgery. Inclusion criteria hinge on frailty as measured by the Risk Analysis Index (RAI), but frailty will be further assessed at multiple time points based on the RAI, Clinical Frail Scale, Edmonton Frail Scale and Fried Frail Scale. Physical performance will be assessed with the timed up and go, walking speed, grip strength, 6-minute walk test (6MWT) and the Short Physical Performance Battery (SPPB) to measure physical performance. Pulmonary function will be assessed with Maximal Inspiratory and Expiratory Pressures (MIP & MEP). Nutrition will be assessed with prealbumin and the 7-point Subjective Global Assessment. Standard postoperative outcomes (morbidity, mortality, length of stay) will be assessed by chart review. Survey instruments will be used to assess health-related quality of life, quality of surgical care, decision regret, preference for operative management, patient centeredness of care and satisfaction with the decision-making process. Analyses will inform the development of a larger randomized controlled trial testing the prehabilitation intervention.

FINDINGS/RESULTS:

Aim 1 Findings: 54 eligible patients were approached to enroll 18 (recruitment rate: 33%). Of the 36 who declined participation, the most common reason was the excessive burden of travel (9/36 or 25%) or desire not to delay surgery (3/36 or 8%). Enrolled participants were equally

randomized to prehabilitation or standard of care (9 in each group), but 3 crossed from prehabili to standard care and 5 crossed from standard care to prehab (chi-square 0.9, p=.34), leaving 11 patients in the prehab arm and 7 in the control arm. Overall retention rates were 83% and 61% at 30- and 90-days after surgery, respectively.

Duration of prehabilitation ranged from 3-10 weeks with a median of 4 weeks and a mean (standard deviation) of 5.7 (2.5). Compliance with the prescribed, on-site, hospital prehabilitation sessions was 94% overall and ranged from 82-100% among the prehabilitation patients. All patients were referred to physical therapy and nutrition as per protocol, and consults lasted approximately 15 minutes each. In-hospital training sessions lasted 90-120 minutes with 60-75 minutes of exercise and 30-40 minutes of instruction or assessment. Compliance with at-home exercise and nutrition logs was mixed: 3 of 10 (30%) returned their exercise logs demonstrating 90-100% compliance with exercise, but only 66% compliance with nutrition; the remaining participants did not return log books, but based on conversations, compliance was estimated between 0% and 80%. Nursing homes did not facilitate exercise, and overall, out-of-hospital compliance was estimated at 55%.

Aim 1 Conclusions: Recruitment and retention procedures were proven feasible. However, burdens of participation limit enrollment and compliance with prescribed interventions, potentially limiting the effect of the intervention. Home-based prehabilitation is a potential solution to these barriers.

Aim 2 Findings: Measurement of frailty, physical performance, pulmonary function and nutrition was proven feasible at every time point. The prehabilitation group demonstrated clinically significant improvements in grip strength from 27 to 29 kg (p=0.006), MEP from 90 to 109 centimeters of water (p=0.02), and 6-minute walk test from 909 to 1070 meters (p=0.015). Other measures demonstrated changes in line with what would be expected but were insufficiently powered for statistical significance. Overall, the prehabilitation group appeared more frail than the control group, and although they made modest improvements during prehabilitation, those improvements did not persist at 90-days after surgery, many deteriorating below baseline levels. By contrast, the control group deteriorated between baseline and surgery with regard to MEP (120 to 112, p=0.023), walking speed (1.54 to 1.07, p=0.024), and RAI score (25 to 29 (0.086), but largely recovered to baseline by 90-days after surgery. This may be due to more robust baseline performance among the control group as well as comparatively less invasive procedures.

Aim 2 Conclusions: Methods for assessing physical performance were proven feasible with clinically significant changes observed in both the prehabilitation and control groups in as few as 4 weeks. The added value of longer prehabilitation is uncertain.

Aim 3 Findings: There were no detectable differences in mortality, major complication or length of stay, though power was limited. Independent living at baseline and 90-days after surgery was unchanged, though as expected, several patients required increased levels of care at 30-days after surgery. There was no difference in health-related quality of life over time in the prehabilitation group, but among the control arm, quality of life improved from baseline to 90-days post op (0.67 to 0.8, p<.0001). The global rating of surgical care was identical in prehabilitation and control groups [8.4 on a scale from 1 (poor) to 10 (best)], indicating very good quality of care. Ratings for preoperative communication, operative recovery, and postoperative communication were all very good, ranging from 1.13-1.33 on a scale from 1

(good) to 3 (poor); the prehabilitation group had slightly higher scores, but the difference was not statistically significant.

There was no significant difference in decision regret between prehabilitation or control groups, or within groups over time. Patient centeredness of care trended to improve among prehabilitation patients from 1.78 to 1.42 (p=.086) but remained unchanged among the control group (1.46 to 1.56, p=.824). There was no difference between prehabilitation and control groups with respect to satisfaction with the decision-making process (2.19 vs 2.9, p=.252) or satisfaction with the decision (2.33 vs. 2.47, p=.346), though point estimates were better in the prehabilitation group (lower scores are better). Overall satisfaction with the diagnosis of frailty was equivocal in both groups (3.00 vs. 2.83, with 5 being perfect satisfaction and 3 being unsure). The prehabilitation patients were similarly equivocal about their overall satisfaction with their palliative care consultation (3.00). Both groups, however, were quite satisfied with the IMPACT clinic (4.46 and 4.63, respectively).

Aim 3 Conclusions: Methods for assessing postoperative outcomes were proven feasible, though as expected, this small pilot is insufficiently powered to detect significant change. Survey measures appear more sensitive to change and difference between groups and should be included in subsequent studies as secondary outcomes. Patient ambivalence about the "bad news" of their frailty diagnosis is understandable and may indicate a target for quality improvement.

IMPACT: Analyses will inform the development of a larger randomized controlled trial testing the prehabilitation intervention. Findings will be relevant for the as many as 42,000 frail Veterans scheduled for major elective surgery each year.

CDP 12-252:

Improving Weight Management at VA: Enhancing the MOVE!23 for Primary Care (CDA 10-206)

Abstract:

BACKGROUND/RATIONALE: Veterans shoulder a disproportionate burden of obesity and its co-morbidities, and modest weight loss in obese patients through diet and exercise improves health outcomes. The VA currently offers the MOVE! program to treat obesity, but only 9% of eligible patients utilize this consultation service. At the same time, Veterans on average see their Primary Care Providers (PCPs) 3.6 times per year, supporting the importance of developing primary care-based interventions. Interactive behavior change technologies utilizing expert system software programs can facilitate behavior change in primary care. The MOVE!23 software is an expert system program for patients referred to MOVE! but is not currently used in primary care by PACT. For my CDP, I will use qualitative methods to better understand the optimal use of goal-setting for weight management in an urban VA patient population and use state-of-the-art software evaluation methods to identify ways to enhance the MOVE!23 software to better facilitate goal-setting. I will then use this information to develop a brief intervention to treat obesity in Veterans that utilizes the enhanced MOVE!23 software and PACT to promote goal-setting, behavior change, and weight loss.

OBJECTIVE(S): The three main objectives of my CDA are to: 1) using qualitative methods, enhance the MOVE!23 software and determine optimal goal setting processes to develop a brief, computer-assisted intervention to treat obesity; 2) determine the feasibility and

acceptability of this brief intervention for urban, obese, VA patients within PACT; 3) explore the impact of this brief intervention on intermediate, behavioral, and weight loss outcomes at 3, 6, and 12 months post-intervention.

METHODS: Based on focus groups (n=56), key informant interviews (n=25), and usability testing of the MOVE!23 questionnaire, we developed the MOVE Towards Your Goals Intervention (MTG).

Pilot test of intervention: Veterans with overweight/obesity and upcoming primary care visits are recruited to participate in MTG through mailings and phone calls. The first 11 Veterans were recruited into a non-randomized pilot test and received the MTG (MOVE Towards Your Goals Intervention) intervention. The pilot test (n=11) informed the development of a pilot randomized controlled trial (RCT).

Pilot RCT: Veterans with a Body Mass Index 30 or 25-29.99 kg/m2 with existing comorbidities were recruited by phone in two phases approximately six months apart and randomized to MTG or "Enhanced Usual Care (EUC)," a control group. Participants in MTG meet with a health coach to set lifestyle and weight-loss goals and use a tablet-delivered goal-setting tool to facilitate in-person and phone coaching. In Phase 1, patients received baseline counseling immediately prior to their PC visit in order to activate discussion with their doctor. In Phase 2, we changed the protocol so that patient met with the health coach independent of the PC visit in order to facilitate scheduling and recruitment. In both phases, patients in the control met briefly with a coach to receive patient education materials. At baseline, 3, 6, and 12 months, participants were weighed and completed surveys. We assessed differences in outcomes between phase one and two

FINDINGS/RESULTS: Non-Randomized Pilot Test of MTG Intervention: We recruited 11 Veterans to participate in the non-randomized pilot study (91% male, 46% Black, 27% White, 27% Hispanic, mean age= 55.36 years (SD=15.10), mean BMI=30.1 kg/m2 (SD=4.47)). Immediately after the baseline health coaching session, 11/11 participants had set lifestyle goals, 8/11 increased or maintained motivation to lose weight, and 11/11 increased or maintained confidence in ability to lose weight. Two participants dropped out of the study and 1 was lost to follow up. At 3 months, a per-protocol analysis found that 8/8 participants engaged in phone coaching (range 2-6 calls, mean of 4 calls). Furthermore, 7/8 participants expressed interest in involvement in intensive weight loss programs at the VA and of those, 1 participant enrolled in and showed continued involvement. Four (50%) participants lost more than 1 kg, 3 of whom (37.5%) had 5% weight loss. Two (25%) stayed within 1 kg of their original weight, and 2 (25%) gained more than 1 kg. The mean weight change was -1.33 kg (SD 5.5).

Pilot RCT of MTG Intervention: 31 Veterans enrolled in phase 1 (mean age 53.48, 63% male, mean BMI 31.71, 54.84% African American, 22.58% White) and 14 enrolled in phase 2 (mean age 56.57, 79% male, mean BMI 30.27, 50% African American, 23.08% Hispanic). Overall, participants in the MTG intervention arm (phase 1 and phase 2 combined, N=21) tended to lose more weight at three-months, six-months and 12-months as compared to EUC (-0.80 \pm 1.95 vs. 0.07 \pm 2.40; p= 0.07, -1.52 \pm 3.05 vs. 0.23 \pm 3.64; p=0.08 and-1.02 \pm 4.16 vs. 0.74 \pm 4.90; p=0.40 for three-, six-, and twelve- months, respectively). There were no statistically significant differences in dietary or physical activity changes between the two groups. Intervention participants also reported higher dietary self-efficacy (4.89 \pm 9.02) than control (0.30 \pm 13.69) p=0.22.

Conclusion: The MTG intervention was shown to be feasible and acceptable to patients within the patient-centered medical home model of care at the Veterans Affairs and led to small amounts of weight loss at 12 months A major limitation of this study was that we were underpowered to see statistically significant change in weight loss and other clinically-important outcomes. Future research is needed to test the efficacy and cost-effectiveness.

IMPACT: This study provided pilot data for two funded randomized controlled trials to test the efficacy of interventions based on the MTG intervention. More specifically, these results led to improvements in the training of both health coaches and primary care physicians at the Veterans Health Administration.

PPO 16-126:

A Pilot Intervention to Help Homeless and At-Risk Veterans Manage Their Money

Abstract:

BACKGROUND/RATIONALE: Preventing and ending homelessness among Veterans is a national VA priority. While considerable efforts have been made towards providing housing for Veterans, more work is needed on helping Veterans gain skills for independent living to sustain and keep their housing. Research has shown that money mismanagement is a significant risk factor for Veteran homelessness. This pilot project evaluated a money management program designed for homeless Veterans in the VA's largest supported housing program.

OBJECTIVE(S): The objective of the proposed project was to pilot a new money management intervention for homeless and at-risk homeless Veterans called the Recovery Oriented Money Management Program (ROMMP). ROMMP is a new eight-week intervention developed for homeless and at-risk Veterans to help them manage money. ROMMP consists of three components: financial education groups, computerized budget assistance, and individual coaching. The three aims of the project were 1) to test feasibility of ROMMP; 2) assess money management and clinical outcomes from ROMMP; and 3) refine and further develop ROMMP.

METHODS: Feasibility of ROMMP will be assessed by tracking group attendance, utilization of computerized budget assistance, and engagement in individual coaching. Money management, housing, substance use, and quality of life will be assessed at baseline, 3 weeks, 8 weeks, and 12 weeks. Qualitative interviews will be conducted with Veterans in each cohort to obtain Veteran input in the development of ROMMP.

FINDINGS/RESULTS: A total of sixty-three Veterans across five cohorts of Veterans were enrolled in ROMMP. Veterans attended a mean of 2.8 group sessions and a mean of 3.0 individual financial coaching sessions. Thirty-nine Veterans (61.9%) agreed to participate in the research portion of ROMMP. Participants had a mean age of 54.2 years (sd= 13.2), mean of 13.0 years of education (sd= 1.5), 86% male, 56% non-white, 89% with history of homelessness with a total income of \$1,831.7 (sd= 1689.8). In addition, 45% of participants reported serious mental health symptoms and 62% reported problems with substance abuse. Mixed linear regression showed a trend towards decrease in the Conrad M3 mismanagement score from 9.8 (sd= 1.1) at baseline to 7.0 (3.1) at 12 weeks, F(3,22)= 2.41, p= .09. On average, Veterans "mostly agree" they were satisfied with the ROMMP program (mean= 5.0 out of 6-point scale, sd= .6) and they "slightly agree" the program made an impact of their money management (mean= 4.2 out of 6-point scale, sd= .6). Qualitative data was collected after every cohort to

continuously refine ROMMP to be more accessible and Veteran-centric. Qualitative findings indicated that Veterans viewed ROMMP as "fresh and new" and helped Veterans gain a "better understanding of what was going in and coming out" in terms of their savings and spending.

IMPACT: These pilot results demonstrate ROMMP to be an acceptable and feasible money management intervention that could be scaled and potentially replicated at other VAs. Through this project, the ROMMP intervention has been refined to be more Veteran-centric with the ultimate goal of implementing the program at other VA facilities to prevent and end Veteran homelessness. A larger controlled study of ROMMP would allow rigorous testing of the model and would be helpful in establishing program effectiveness.

CRE 12-010:

TeleMonitoring to Improve Substance Use Disorder Treatment After Detoxification

Abstract:

BACKGROUND/RATIONALE: Every year, approximately 30,000 Veterans receive inpatient detoxification (detox) for substance use disorders (SUDs). Detoxification is not SUD treatment; it is the medical management of withdrawal to prevent complications, which may be fatal. Detoxification inpatients who enter SUD treatment and peer-based mutual-help groups (e.g., Alcoholics Anonymous) have much better outcomes (less substance use, HIV/HCV risk behaviors, homelessness, rehospitalizations, Emergency Department visits) than those who do not. However, because of their unique characteristics (severe and chronic addictions, comorbidities, lack of resources, self- and provider-perceptions as unsuitable for treatment), most Veterans discharged from inpatient detoxification do not enter SUD treatment. For many Veterans, a pattern of repeated inpatient detoxification, with each episode incurring higher risk of overdose, occurs. Therefore, in its Uniform Services Handbook, Mental Health Operations places major emphasis on increasing the rate of SUD treatment initiation and engagement following detoxification, to benefit Veterans' outcomes and prevent more use of costly health care.

OBJECTIVE(S): The project's primary objective was to implement and evaluate Enhanced Telephone Monitoring (ETM) as a new and innovative telehealth intervention to facilitate the transition from inpatient detoxification to SUD specialty treatment (residential, outpatient, pharmacotherapy), thereby improving Veterans' outcomes and decreasing VA health care costs. In a randomized trial at two sites (VA Palo Alto and Boston), we hypothesized that patients receiving ETM, compared to patients in usual care (UC), would be more likely to enter and engage in SUD treatment and mutual-help, have better SUD and related outcomes, and have fewer and delayed acute care episodes. This project also conducted a process evaluation of how to implement ETM VA-wide, focusing on diverse subgroups of Veterans. Further, it is conducting a Budget Impact Analysis (BIA) to determine the impact of ETM on total costs of VA care. We hypothesize that the higher costs associated with ETM (because patients will engage in SUD treatment) will be more than offset by its lower costs of acute care.

METHODS: Patients in the ETM condition received an in-person session while in the detoxification program, followed by coaching over the telephone for 3 months after discharge. The intervention incorporated Motivational Interviewing, and Contracting, Prompting, and Reinforcing, to provide support while waiting for treatment, and facilitate entry into treatment and mutual-help, and improve responses to crises. Patients were assessed at baseline and 3 and 6

months post-discharge for outcomes and non-VA health care. Analyses of covariance were conducted to compare the UC and ETM groups on outcomes at follow-ups. The process evaluation to inform the implementation of ETM used the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework. Semi-structured interviews were conducted with inpatient detoxification staff and patients to yield facilitators of ETM implementation and modifiable barriers with associated action plans. For the BIA, costs of ETM are being measured through micro-costing methods. For patients in both the ETM and UC groups, all inpatient, residential, outpatient, and pharmacy care are being measured from VA utilization and cost files.

FINDINGS/RESULTS: Baseline demographic and clinical characteristics did not differ between Veterans randomly assigned to usual care (UC; n=150) or the intervention, Enhanced Telephone Monitoring (ETM; n=148). At the 3-month follow-up (i.e., at the end of the ETM intervention), compared to UC patients, ETM patients were significantly less likely to have received additional inpatient detoxification, but no more likely to have participated in 12-step groups or received outpatient addiction treatment. Even so, ETM patients had better alcohol, drug, and mental health outcomes. In contrast, at the 6-month follow-up, patients in ETM and UC generally did not differ on primary or secondary outcomes. Findings suggest that ETM deters additional detoxification episodes while the intervention is ongoing, but not after the intervention ends. Because telephone monitoring is low-intensity and low-cost, its extension over time may help reduce repeated detoxifications. In addition, qualitative analyses of detoxification and addiction treatment provider interviews found providers viewed the intervention as compatible with ongoing clinical practices.

IMPACT: VHA's Office of Mental Health and Suicide Prevention (OMHSP) is strongly committed to eradicating the dangerous, costly pattern of Veterans obtaining inpatient detoxification services but not receiving the substance use disorder (SUD) treatment they need. Telehealth interventions, a promising way to improve treatment access and outcomes by SUD patients, have not been utilized with the challenging population of detoxification inpatients before. In accordance with others in this CREATE, this project is helping to accomplish OMHSP's goal of implementing the Uniform Handbook by increasing Veterans' access to, engagement in, and benefit from, SUD treatment services, particularly among Veterans who are using VA medical services and need SUD services but are not receiving them.

IIR 13-319:

Motivationally Enhanced Mobile Delivery of MOVE! to Veterans with Mental Illness

Abstract:

BACKGROUND/RATIONALE: Obesity is a considerable problem in populations with serious mental illness (SMI), in part due to medication-induced weight gain and social disadvantage. Individuals with SMI often have cognitive deficits that need to be considered when delivering interventions. In-person interventions for weight management that are tailored for these cognitive deficits have been developed and found in multiple trials to result in lower weight. Unfortunately, the impact of these interventions is limited by low rates of utilization. Similar to the general population, underserved populations increasingly use smartphones for communication and internet access, which allows for more convenient engagement and retention in a weight management program. Evidence-based interventions have been delivered

via mobile technologies for the general population, yet there has been almost no effort to do the same for the population with SMI.

OBJECTIVE(S): 1) Develop CoachToFit, a weight management system that is tailored to meet the needs of individuals with SMI and delivers MOVE! via a smartphone app with support from peer wellness coaches; 2) Study the acceptability and usability of CoachToFit in Veterans with SMI; and 3) Evaluate changes in self-efficacy, motivation, and readiness among CoachToFit users. Although evaluating acceptability and usability is the primary goal for this study, we will also explore preliminary evidence for the efficacy of CoachToFit.

METHODS: App development utilized user-centered and agile development processes. Participants contributed to the design and evaluation of CoachToFit through participation in focus groups, in-lab usability trials, and a 30-day experiential usability trial. Participants ("users") were Veterans with SMI who were overweight who owned a phone running Android OS or iOS (iPhone). Data were collected from patient assessments and the smartphone app.

FINDINGS/RESULTS: Focus groups of overweight Veterans with SMI (n=6) were presented with the CoachToFit screen mockups for feedback. Feedback was used to design and name the CoachToFit app. A peer coach was hired who provided input on the coaching dashboard where CoachToFit user data was visualized to guide coaching. Additional functionality was added to the app to benefit users; including integrating the app with an external Bluetooth activity tracker watch and Bluetooth scale for weight monitoring.

With a working version of CoachToFit, in-lab usability testing with overweight Veterans with SMI (n=10) was completed. Cohort demographics were 10 males; aged 61.7+8.6; 5 diagnosed with schizoaffective disorder, 4 with bipolar disorder, and 1 with schizophrenia; 9 had Android phones and 1 had an iPhone. In-lab usability indicated that more explicit directional aids were necessary, and the graphing of data (weight and steps) needed further simplification, and there were particular problems with Bluetooth scale usability. There were very positive reactions to the activity tracker watch, and the educational modules and goal choices within the modules. Further refinement was made to CoachToFit. In sum, CoachToFit has 30 modules providing education on nutrition (n=15 modules) and exercise (n=15 modules). CoachToFit allows tracking of efforts to meet the personalized nutrition and exercise goals set at the end of each module, tracking and visualization of weight and step counts over time, and review of completed modules. A dashboard allows a peer coach to see an individual's progress for weekly supportive coaching by phone.

With a revised version of CoachToFit and the coaching dashboard, we enrolled 18 Veterans with SMI to carry the app for 30 days. Cohort demographics were 16 males, 2 females; aged 57.8+10.7; 5 diagnosed with schizoaffective disorder, 7 with bipolar disorder, 5 with schizophrenia, and 1 with recurrent major depressive disorder; 13 had Android phones, 5 had iPhones. The mean body mass index of the sample was 32.2+3.7 (obese). This cohort had an average PROMIS Global Physical Health T-score of 41.8 and average PROMIS Global Mental Health T-score of 42, meaning this cohort at baseline was one standard deviation worse (less physically, less mentally healthy) than the general population.

Overall, early results indicate strong acceptability and usability of CoachToFit in Veterans with SMI. The majority of the sample agreed that they would like to use CoachToFit often, thought CoachToFit was easy to use, felt the app and the watch and scale worked well together, felt confident using CoachToFit, found it not complicated, not cumbersome, and would not need

technical assistance to use it. The majority reported being satisfied with how easy it was to use, found the education modules easy to understand and informative. There was strong agreement across the cohort that they would recommend CoachToFit to a friend, would like to keep using it themselves, and felt it was made for people like them. Additionally, the majority felt comfortable that their information was collected by the app and would be happy for their clinical team to know of their progress with CoachToFit, although a few had concerns about the privacy of their data. There was consistent agreement that the weekly peer coaching was valuable.

Early results provided information about self-efficacy, motivation, and readiness among CoachToFit users. Self-efficacy and motivation for making changes around diet and exercise was high at baseline, so much so that there was little room for change. This indicates that a different measurement of self-efficacy and motivation should be explored for a future larger test of CoachToFit. Readiness to make a change in nutrition was improved in half of the sample, but there was limited movement in readiness to make a change in exercise. Given this was only a 30 day trial, users only received a maximum of 8 (4 nutrition; 4 exercise) of 30 modules; in a full trial allowing time for all 30 modules, we expect change in readiness for both nutrition and exercise.

Although not powered for examination of the efficacy of the program in 30 days, we explored weight changes. Several of the early users lost weight in 30 days; a range of 2-16 pounds lost.

IMPACT: CoachToFit can deliver an evidence-based weight management treatment that is specifically designed for the population with SMI, who report it has high acceptability and usability. Early results also indicate it is efficacious and a larger trial is warranted.

CDA 10-206:

Improving Weight Management at the VA: Enhancing the MOVE!23 for Primary Care

Abstract:

BACKGROUND/RATIONALE: Veterans shoulder a disproportionate burden of obesity and its co-morbidities. Modest weight loss in obese patients improves health outcomes. The Veterans Affairs (VA) New York Harbor Healthcare System offers the MOVE! program, but only 8% of eligible patients attend. However, Veterans see their primary care providers (PCPs) 3.6 times per year supporting the importance of developing primary care-based interventions. Interactive behavior change technologies utilizing expert system software programs can facilitate behavior change in primary care.

Using rigorous formative methods, we developed the MOVE Towards Your Goals (MTG) intervention. This intervention uses 4 components to deliver 5As counseling within the primary care setting-the MTG online tool, health coach counseling, brief PACT team counseling, and follow-up telephone coaching. The MTG tool is a mobile-friendly software program that can be readily delivered via tablet computers in the clinic setting to facilitate counseling by a health coach and PACT staff. This intervention was developed during the first 2 years of the CDA award by using qualitative data collected from focus groups of Veterans, Key informant interviews of PACT team staff, and Usability testing of the MTG tool (see abstracts 1-12 below, publications 2,3,5,10 below). To determine the feasibility of conducting an RCT of the MTG weight management intervention compared to Enhanced Usual Care (EUC), we conducted a pilot study.

OBJECTIVE(S):

- 1) Using qualitative methods, determine optimal goal-setting processes to develop a brief, technology-assisted intervention to treat obesity
- 2) Determine the feasibility and acceptability of this intervention for urban, obese, VA patients within PACT
- 3) Explore the impact of this intervention on intermediate, behavioral, and weight loss outcomes at 6 and 12 months post-intervention

METHODS: Veterans with Body Mass Index 30kg/m2 or 25-29.9kg/m2 with comorbidities (N=45) were recruited in two phases and randomized to MTG (n=22) or EUC (n=23). We collected process measures (e.g., number of coaching calls completed, number and types of lifestyle goals, counseling documentation) and written qualitative feedback. Secondary aims included weight and behavioral outcomes.

FINDINGS/RESULTS: Not yet available.

IMPACT: We developed and conducted a pilot RCT of a technology-assisted health coaching intervention for weight management. This led to VA and NIH funding to do 2 cluster randomized trials of different versions of the MTG Intervention. The Goals for Eating and Moving Study: Will test this intervention using student health coaches. The Peer Assisted Lifestyle Weight Management study will test this intervention with Veterans as peer health coaches. If this intervention later proves to be cost-effective, it could potentially improve obesity care within patient centered medical homes at the VA and other health systems.

IIR 11-353:

Training and Coaching to Promote High Performance in VA Community Living Centers

Abstract:

BACKGROUND/RATIONALE: VA is committed to providing high quality care in its Community Living Centers (CLCs). One way in which care quality is being improved is through a cultural transformation aimed at making CLCs more person-centered and less institutional by providing CLC residents with more choice and autonomy. A cultural transformation of this type necessitates changes to staff roles and responsibilities and has implications for direct-care workers. Previous research has shown that the ability of direct-care workers to perform in these new and more person-centered ways may be dependent on changes to the supervisory styles of nurse managers and other supervisors (Tyler & Parker, 2011; Lopez, 2006). Thus, while the cultural transformation taking place in VA CLCs will require direct-care workers to acquire new skills and knowledge, their ability to apply these new skills and knowledge may be reliant on the management practices of their supervisors.

OBJECTIVE(S): This study utilized a multi-level approach to test training interventions for direct-care workers and their supervisors in VA CLCs. Our specific aims and hypotheses are as follows:

Aim 1: Determine the effectiveness of an education intervention for DCWs designed to improve the response to challenging resident behaviors, communication skills, and clinical problemsolving skills of CLC direct-care workers.

Aim 2: Determine the effectiveness of a multi-level education intervention to both increase DCW knowledge and skills and improve supervisor management and communication skills.

Aim 3: Describe the link between CLC resident health outcomes (i.e., quality indicators) and both direct-care worker knowledge, skills, and communication and management practices.

Aim 4: Determine what factors are implicated in the effectiveness of the intervention implementation and what differentiates CLCs that achieve better results from those that do not.

METHODS: Twenty CLCs participated in this study: Five served as a control group; five received training for nurse managers only; five received training for DCWs only; and five received both training interventions. Using a pre-test and post-test design with a control group, our analyses examine the extent to which the combinations of interventions led changes in practice and resident outcomes. We measured changes in practice using the Care Coordination Survey. We also utilized the Resident Assessment Instrument Minimum Data Set (MDS) data to examine health outcomes for residents. Finally, telephone interviews were conducted with staff at six select CLCs to explain differences in intervention implementation and success.

FINDINGS/RESULTS:

Aim 1: Effectiveness of DCW Training:

DCWs at intervention sites received two trainings. The first focused on improving staff communication and the second on improving skills related to the care of residents with dementia and/or problem behaviors. After collection of our pre-intervention surveys, our consultants in VACO requested a change to our planned dementia training. This necessitated a change in our survey questions related to dementia knowledge and skills and resulted in our being unable to measure change in these skills using pre-test post-test methods. Instead, we could only analyze cross-sectional (post-survey) differences among the participating CLCs. Our ability to do this was further inhibited by VACOs requirement, issued during our intervention phase, that all VA CLC staff be educated using the same dementia training that was utilized in our study. This resulted in staff at several control sites receiving this part of the intervention. Not surprisingly, we detected no significant differences between our intervention and control sites on our measures of dementia skills and knowledge.

We did find statistically significant differences between intervention sites on our measures of supervisory support and relational coordination. Three of the intervention sites showed significant improvements on one or both of these scores while three showed significant declines on these measures.

Aim 2: Effectiveness of Multi-Level Intervention:

We used hierarchical linear modeling (HLM) to examine the effect of our DCW and nurse supervisor (coaching) training interventions on our survey based measures of communication, decision making, staffing, human resource management, supervisor support and relational coordination. We found no significant differences between intervention groups in communication, decision making, staffing or human resource management. We found that the coaching only group had significantly higher supervisory support scores, but significantly and unexpectedly lower relational coordination scores than the other groups.

Aim 3:

The purpose of Aim 3 was to describe the link between CLC resident health outcomes (e.g., antipsychotic use, pressure ulcers, urinary tract infections, behavioral symptoms, and functional decline) and direct-care worker knowledge, skills, and communication and management practices. We used hierarchical linear modeling (HLM) to examine the effect of our survey based measures on our 5 resident outcomes including random effects for facility and resident identification number in the model. We found no statistically significant effects of the interventions, in part because due to low variation on some of these outcomes and in part due to the mixed results of the interventions overall.

The most promising model was for the behavioral symptoms outcome where there were marginally significant findings for supervisory support (p=0.060) and supportive organizational context scales (p=0.083) when models were run separately. These findings suggest that behavioral symptoms could be improved by changing supervisory support and supportive organizational context, as the interventions had been intended to do.

Aim 4:

In order to determine what factors are implicated in the effectiveness of the intervention implementation and what differentiates CLCs that achieve better results from those that do not we conducted telephone interviews with staff at six CLCs. We used our measures of supervisory support and relational coordination to identify the six CLCs. Three of the intervention sites were found to have significant improvements on one or both of these scores (high performers) and three sites were found to have significant declines on these measures (low performers). Twenty-four interviews were conducted across the six CLCs, including at least three interviews at each CLC. A mix of staff including nurses, nursing assistants and CLC leadership were interviewed.

One challenge reported by all six CLCs was leadership turnover. Key leaders at all six of the CLCs had left the CLC during the course of this two year project. The primary difference between the high performers and low performers was the timing of this leadership turnover. In the high performer sites, leaders did not leave the facility until after the training intervention had been implemented, while in the low performer sites leaders left the CLC before the training was implemented.

Among the low performers, the intervention was not fully implemented, and few if any staff received the training. Among the high performers, nearly all targeted staff received the training intervention. This was often accomplished by securing support of middle managers, especially nurse supervisors, who as a result were more willing to release their staff from duties on their unit in order to receive the training.

IMPACT: The interventions did not have the hoped for effect on care. However, the study findings suggest that the impetus-to target supervisory support and organizational support in bolstering the effects of DCW training-focused in the right direction. Key findings about the importance of leadership consistency to see through an intervention and buy in from middle management may be helpful in other interventions.

IIR 10-135:

Behavioral Activation Therapy for Rural Veterans with Diabetes and Depression

Abstract:

BACKGROUND/RATIONALE: The co-occurrence of diabetes and depressive symptoms is highly prevalent and has dramatic consequences on the quality of life and health of affected patients. Due to the complex interrelation between these conditions, patients often experience both psychological and physiological difficulties. Furthermore, veterans with diabetes and depressive symptoms in rural settings have limited access to care. Interventions that reach veterans in rural / community-based primary care are needed, especially those that blend treatment strategies for physical and emotional health.

OBJECTIVE(S): The specific objective of this study was to compare the effectiveness of the Healthy Outcomes through Patient Empowerment (HOPE) intervention to enhanced usual care (EUC) on diabetes (HbA1c) and depression (PHQ-9) outcomes at 6 and 12 month follow-up. The exploratory aims of the project included: 1) The examination of the role of moderators and mediators on intervention effectiveness; 2) the evaluation of factors that mediate or moderate effectiveness at 6 and 12 months for patients enrolled in the HOPE intervention arm; and 3) The evaluation of the potential for embedding the HOPE intervention processes within a VA CBOC using the RE-AIM framework for evaluating effectiveness of behavioral interventions.

METHODS: The HOPE study is a randomized controlled trial. We enrolled 225 Veterans from the Michael E. DeBakey VA Medical Center and surrounding community-based outpatient clinics with uncontrolled diabetes and clinically-significant depressive symptoms. One hundred thirty-six Veterans were randomized to the HOPE Intervention and 89 to Enhanced Usual Care (EUC). Eligible, veterans lived 20 miles or more from the tertiary center where they are treated or receive their primary care through one of the surrounding VA community-based clinics. Veterans had an HbA1c level above 7.5 in the last 12 months and achieved a score of 10 or greater on the PHQ-9 scale administered by the study staff. Veterans randomized to both groups received screening, education, and notification of clinical findings along with follow-up in usual primary care. Participants randomized to HOPE also received behavioral coaching telephone sessions over a six month period. Coaches used a standardized, theory-based process for conducting the sessions with the aim of creating patient-centered and articulated goals and behavioral action plans. Hemoglobin A1c and PHQ-9 measurements along with self-report questionnaires were collected at baseline, 6 and 12 months follow-up. Changes in measurements from baseline were compared between groups.

FINDINGS/RESULTS: The proposed hypotheses for the study were: 1. that after 6 months (active treatment phase), HOPE will produce greater improvements in diabetes control (measured by hemoglobin A1c levels) and depression (measured by PHQ-9 scores) than will EUC. 2. that at 12 months (6-month active phase plus 6-month maintenance phase), HOPE participants will continue to evidence significantly greater improvements in HbA1c, and PHQ-9 compared with EUC participants.

Preliminary Analyses for the primary outcomes demonstrated small intervention effect sizes for change in depression (PHQ-9) of d=0.34 and diabetes-related QoL (PAID) of d=0.32; and no intervention effect for change in glycemic control (HbA1c) with d=0.06. PHQ-9 and HbA1c values did reach levels of minimally clinically significant change in the intervention group at 12-month follow-up (PHQ-9: from 15.8 +/- 4.2 to 10.1 +/- 6.9; HbA1c: 9.2 +/-1.4 to 8.7 +/-1.6); but these changes were not statistically significant compared to the usual care group in a time by treatment analyses: PHQ-9 (p=.10) and HbA1c (p=.74).

In each main area assessed, Veterans in the HOPE group had improvements in their depression symptoms (PHQ-9 change 5.7), glycemic control (A1c change 0.5), and diabetes distress (PAID change 17.4) but these changes were not statistically significant compared with the enhanced usual care group in our Intent to Treat Analyses. We are proceeding with additional analyses to explore treatment dose effects and other "treatment as received" analyses to determine if certain patients experience greater treatment related effects than others.

IMPACT: The HOPE Project demonstrated modest benefits on depression symptoms and diabetes related QoL for Veteran participants one-year after enrollment. There was no treatment benefits at one-year follow-up for glycemic control (HbA1c). Furthermore, the changes from 6 to 12 months were stable or even improved in the intervention group compared to some regression among usual care participants for the main outcomes.

The results of the study were not as robust as anticipated overall when comparing the HOPE intervention to enhanced usual care. Additional analyses are planned to identify characteristics of patients and potential dose-response effects that may be associated with higher likelihood of benefit from enrollment in the HOPE intervention. If present, the HOPE intervention could be targeted to this more selective at-risk population.

PPO 15-190:

Development of a Brief Measure of Patient Activation for Veterans

Abstract:

BACKGROUND/RATIONALE: Enhancing Veteran engagement with health care is the foundation for VHA's strategic goal to "advance health care that is personalized, proactive, and patient-driven." Evidence shows that patients differ in the aptitude and motivation to engage with health care. This is often conceptualized as the degree of patient activation, describing an active role orientation to health care. High patient activation characterizes individuals who seek health information, self-manage chronic conditions, and express preferences in health care encounters. Effective interventions have increased activation levels and improved health outcomes among individuals with chronic conditions and with mental health conditions. Such interventions are promising approaches to promoting health equity among Veterans Health Administration (VHA) users. However, a critical barrier to implementing such interventions is the absence of a reliable and valid measure of activation that reflects the needs of Veterans and is sufficiently brief for integration into routine clinical practice.

OBJECTIVE(S): The broad objectives of this program of research are to develop a brief measure of patient activation for use in VHA. Specific aims of this pilot project were to: a) Refine the operational definition of patient activation based on Veteran input; and b) Conduct cognitive testing of items that correspond to the construct definition. Completed objectives will result in an item pool to measure of patient activation that is suitable for quantitative psychometric analysis in a subsequent study.

METHODS: The study methods were guided by the National Institutes of Health Patient-Reported Outcome Measurement Information System (PROMIS) instrument maturity model. Stage 1 of the PROMIS model provides guidelines for defining a construct and deriving a corresponding pool of items using qualitative methods. First, a preliminary operational definition

was created based on a review of the literature, and a theoretical framework was identified. This definition was reviewed by a panel of experts. To refine the definition, individual, semi-structured interviews were conducted with 26 Veterans receiving treatment for mental health conditions or chronic medical conditions. Themes from qualitative data were coded using framework analysis. Next, psychometric measures of related constructs were reviewed, and relevant items were mapped to the construct definition. New items were developed to address gaps in construct coverage. Items were reviewed by investigators or content experts. Items were evaluated by cognitive testing interviews with 34 Veterans and revised for relevance and comprehension.

FINDINGS/RESULTS: Qualitative results mapped well to the theoretical framework for patient engagement. Based on these results, the construct name and definition were refined to focus on the propensity to engage with care. Descriptions of an active role orientation were common, but inconsistently included content referring to engagement behaviors, suggesting that the patient activation construct may not be a useful proxy for patient engagement among Veterans. The definition for engagement was comprised of the following categories of behaviors: selfmanagement; shared decision-making; health literacy behaviors; and healthcare navigation. Emergent themes of barriers and facilitators were also integrated into the construct definition. Individuals with a high propensity to engage are better able to both overcome personal and systems barriers and to make use of social and instrumental resources that facilitate engagement. Veteran identity was referenced in descriptions of several barriers and facilitators. New items were added to the item pool to address engagement behaviors not represented on other scales and to incorporate barriers and facilitators. Cognitive testing led to several important modifications in item wording and response options. After the successful completion of study objectives, a total of 75 items that map to the construct definition of Veteran engagement are ready for quantitative psychometric evaluation in the next stage of this research.

IMPACT: This study established a construct definition of Veteran engagement and drafted an item pool that will lead to a brief patient-reported measure of the propensity to engage with health care. The anticipated impact of this measure is to help Veterans achieve maximum benefit from health care services. The VHA population has a high burden of chronic illness. The demands of treatment for chronic conditions can be substantial for Veterans, and account for disproportionate amounts of VHA health care costs. A patient-reported measure of the propensity to engage has potential to enhance population health management. This information can be used to target and tailor coaching, decision support, and patient-facing messaging. This work will catalyze efforts to promote engagement with care by developing flexible and practical assessment tools that are applicable to Veterans with a range of chronic conditions.

CRE 12-021:

Promoting Effective, Routine, and Sustained Implementation of Stress Treatments (PERSIST)

Abstract:

BACKGROUND/RATIONALE: In 2006, VHA began national training initiatives for two evidence-based psychotherapies (EBPs) for PTSD, Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE). Since that time, VHA issued a policy requiring that its medical centers make CPT and PE available to all veterans with PTSD and over 4,000 mental health clinicians have completed competency based training to become approved CPT and PE

providers. Despite efforts to increase capacity to delivery CPT and PE, only a small proportion of veterans with PTSD receive CPT or PE. An understanding of factors that lead to successful implementation of CPT and PE in specialized outpatient PTSD clinics could set the stage for policy and programs to increase the penetration of evidence-based treatments within and possibly outside of VHA.

OBJECTIVE(S): The primary objective of this study was to identify organizational and clinic level factors that promote high levels of use of CPT and PE in specialized outpatient PTSD programs.

Secondary Objectives:

- (2) Explore the relationship between patient, facility and PTSD team characteristics and the likelihood of sustainability of EBPs for PTSD.
- (3) Explore the relationship between patient, facility and PTSD team characteristics and reach of EBPs for PTSD.
- (4) Describe variation in CPT and PE delivery in terms of patient selection, reach and dose.

METHODS: This was a mixed method study. Objective 1 involved Rapid Assessment Process methodology. We used VHA administrative data to select 10 PTSD teams from 9 VA medical centers that reflected a range of geographic regions, patient volume, and high, medium, and lower reach of CPT and PE. Over a 14 month period roughly corresponding to FY 2015, we conducted 100 individual interviews with 7 to 15 staff from each of the 9 medical centers, 3 staff with roles in overseeing national CPT and PE training initiatives and 1 staff involved in an EBP change initiative at an additional site. The study's interview guide was based on the National Health Service Sustainability Model. We used constant comparison to compare and contrast high, medium and low-use sites in terms of identified themes. Objective 2 through 4 data sources included an anonymous online survey of PTSD team clinicians to assess team processes and sustainability of CPT and PE using standardized measures as well as FY 2015 VHA administrative data. We used chart note templates and Natural Language Processing to determine whether or not a patient had received CPT or PE and to calculate EBP reach among therapy patients. We used factor analysis to create one overall team processes measure with higher scores indicating better team functioning. Because CPT and PE sustainability scores were highly correlated (r=.95, p < 0.0001), we combined CPT and PE into one sustainability score. Objective 2 analyses involved descriptive statistics and linear mixed models, with providers clustered within teams. Adjusted models used all independent variables with p < 0.2 from simpler models. Objective 3 analyses involved descriptive statistics and generalized linear mixed models with patients clustered within teams. Objective 4 analyses involved descriptive statistics and logistic and negative binomial regression models for dichotomous or count outcomes, respectively.

FINDINGS/RESULTS: Primary Objective: Reach was associated with how the clinic defined its "mission", clinic operations (e.g., patient selection and monitoring), staff beliefs about the benefits of CPT and PE, and the broader practice environment (medical center culture and priorities). Team mission was central to CPT and PE implementation as it influenced clinic operations, was reflected in staff beliefs, and tailored for fit with the broader practice environment. High reach teams described a unifying mission to deliver evidence-based psychotherapies for PTSD, which are by definition time-limited. This mission was embraced by

a credible team leader, enacted through EBP specific clinic procedures, reflected in the belief that CPT and PE benefited both patients and the clinic, and required collaboration with teams and programs outside of the PTSD team. Thus, implementation of a high reach PTSD team required team structures and processes developed to optimize use of CPT and PE, but also support from facility-level mental health leadership and agreement with other teams regarding flow of patients between programs. Lower reach teams had a broader mission, less specialized operations and were situated in mental health ecosystems with less movement of patients between teams.

Objective 2: Seventy eight out of 140 (56%) PTSD clinicians completed the staff survey. About two-thirds of responders were female and the majority (81%) identified as White. About two thirds had been working at the VA for at least six years. The difference between teams in CPT and PE sustainability was significant. Better team functioning was associated with greater sustainability; greater patient volume per provider was associated with lower sustainability. Team functioning and patient volume remained significant predictors of EBP sustainability in the multivariable adjusted model.

Objective 3: The 10 PTSD teams provided psychotherapy to 6,251 patients with PTSD during FY 2015. The majority of these patients (81.5%) were male; there was variation in terms of race, marital status and period of service. Across teams, 2174 (35%) of therapy patients received an EBP for PTSD, with more patients receiving CPT than PE. In the final model, patient but not team characteristics were associated with EBP reach. Patient variables associated with reduced odds of receiving an EBP included Hispanic ethnicity, Vietnam service era, service connected for PTSD, living more than 50 miles from a VA, past year psychiatric hospitalization and psychiatric co-morbidities.

Objective 4: EBP reach, characteristics of patients who receive an EBP, and the average number of EBP sessions varied by team. Patients seen in low reach teams received fewer EBP sessions than those in medium and high reach teams, but patients seen in medium reach teams received the most EBP sessions.

IMPACT: Efforts to expand reach and ensure sustainability of CPT and PE should focus on local contextual factors. Research is needed to determine whether there is an optimal level of reach to facilitate delivery of an adequate EBP dose.

PPO 13-395:

Mental Health Disparities and Communication Among African-American Veterans

Abstract:

BACKGROUND/RATIONALE: Despite guaranteed access to services and recent gains in narrowing gaps in service utilization and health outcomes, racial healthcare disparities persist in the VA healthcare system, including mental healthcare. Patient-provider communication has been identified as a significant contributor to racial healthcare disparities. Yet, the views and experiences of racial and ethnic minority Veterans regarding health communication, particularly shared decision-making (SDM) processes in mental healthcare, remain understudied. Lack of understanding of minority groups' experiences and views of patient-provider communication processes limit the VA's efforts to provide equitable, evidence-based, and person-centered care to all Veterans, especially racial minority Veterans, a fast- growing Veteran population. To begin

to address these issues, this project focused on African-American Veterans, and aimed to identify the factors and processes that influence minority Veterans' mental health communication, with the long-term goal to reduce racial healthcare disparities in the VA mental healthcare system.

OBJECTIVE(S): This project included several objectives. First, we assessed how African-American Veterans with mental illness view treatment decision-making in psychiatric encounters. Second, we examined barriers and facilitators to SDM. Third, we compared views and factors affecting SDM between African-American Veterans from this study and White Veterans from a historical control group.

METHODS: Participants in the study were 36 African-American Veterans with a diagnosis of mental illness receiving psychiatric outpatient medication management. We conducted semi-structured qualitative interviews and analyzed the data using an inductive approach informed by grounded theory. We also administered self-report measures that assessed patient-provider working alliance, attitudes towards medication, patient activation, and preferences for treatment decision-making. We examined the relationship between race and participants' characteristics on all measures and compared African-American and White Veterans using t-tests, chi squares, and step-wise linear regression.

FINDINGS/RESULTS: Participants in the study understood the concept of SDM and described it in terms that are consistent with definitions of SDM in the literature. They emphasized inclusion, collaboration, and agreement with providers as key components of SDM. For many participants, inclusion was particularly important; they want to be included in the treatment decision-making process and informed of treatment choices as well as providers' rationale for their treatment decisions. Most participants, 83% preferred to have a collaborative treatment decision making process with their mental health providers. However, only 40% reported that they actually experienced their preferred method of treatment decision making.

Participants identified several Veterans, providers, and system-level barriers to their participation in SDM. Veteran-focused barriers include Veterans' lack of knowledge about how to initiate and participate in SDM, Veterans' low level of self-efficacy, ambivalence about treatment, and fear - fear of making poor decisions, of being judged, and of being retaliated against. Examples of provider-focused barriers are providers' openness to SDM and negative patient-provider relationship. System-level barriers include shortage of providers, providers' burnout, and lack of time.

Study findings also indicated that attention to the broader context of patient engagement as well as to Veterans' social contexts, such as their racial identity and lived experiences, are necessary for successful SDM. Participants viewed providers' lack of understanding of their socioeconomic conditions, which include their experiences as African-Americans, as a key barrier to engagement in services and participation in SDM. In contrast, active patient engagement, which involves patient activation, and strong patient-provider relationships appear to be prerequisites for SDM.

Comparisons between African-American and White Veterans (N=141) on two key aspects of patient engagement - patient activation and working alliance, showed significant differences. After adjusting for demographics, race was significantly associated with patient activation, working alliance, and medication adherence scores. African-American Veterans had significantly lower levels of patient activation and working alliance than White Veterans. Patient

activation was also associated with working alliance, even after adjusting for sociodemographic factors and participants' length of time with their providers. Further, item-by-item examination of the Patient Activation Measure-MH indicated that African-American Veterans scored lower on items related to self-efficacy and patient-provider communication (e.g., "I am confident that I can tell my mental health clinician concerns I have even when he or she does not ask.").

Participants provided several suggestions for improving patient-provider communication among African-American and other minority Veterans. They involved 1) the use of peer support specialists to reach out to minority Veterans and to facilitate engagement in mental health services, 2) organizational support and resources to assist providers in their efforts to engage Veterans in SDM, which may include addressing issues such as staff burnout, providers' high caseloads, provider shortage, and time needed for providers to build relationships with Veterans, 3) stronger working alliance and relationships between Veterans and providers, and 4) providers' positive modeling and coaching in SDM.

IMPACT: Improving patient-provider communication among minority groups may potentially lead to better Veterans' health outcomes and reduced healthcare disparities. In this study, we identified several barriers to African-American Veterans' participation in SDM and engagement in mental health services. African-American Veterans experienced lower levels of self-efficacy compared to their White counterparts, which influence their participation in SDM and engagement in mental health services. Our findings suggest that interventions to promote SDM for minority Veterans should incorporate aspects of patient engagement, such as patient activation, and patients' social contexts. Our findings also indicate that organizations have an important role to play to support providers and Veterans in increasing their participation in SDM.

RRP 12-504:

Integrated Dual Disorders Treatment: Implementation During Early Adoption

Abstract:

BACKGROUND/RATIONALE: Substance use disorder (SUD) in people with severe mental illness (SMI) has been associated with psychiatric relapse, hospitalizations, homelessness, serious infectious disease, unemployment, violence, and incarceration. Integrated dual disorders treatment (IDDT) is an evidence-based practice for people with SMI and co-occurring SUD that can help reduce these negative outcomes. IDDT combines mental health and substance abuse services on a single treatment team, with strong emphases on stagewise treatment, comprehensive services that address a range of important needs, outreach, and motivational approaches. Unfortunately, IDDT is not routinely implemented in VA facilities.

OBJECTIVE(S): This project sought to inform future implementation efforts for IDDT in the VA by addressing two specific aims: 1) identify barriers and facilitators to VA implementation via a qualitative evaluation in four pilot sites, varying on both implementation duration and program type, 2) document costs associated with IDDT implementation to inform future efforts. The project used the Consolidated Framework for Implementation Research (CFIR) model as conceptual framework for the evaluation.

METHODS: Two sites, a Psychiatric Rehabilitation and Recovery Center (PRRC) team and Mental Health Intensive Case Management (MHICM) team had been receiving technical assistance and training on IDDT for two years. Two other sites, a HUD VA Supported Housing

(HUDVASH) team and MHICM team, started implementation with this project. External facilitation included a baseline and 12-month fidelity assessment with report and recommendations, intensive onsite clinical training for staff, and ongoing monthly consultation.

Members of the research team observed implementation efforts in the two new teams and conducted individual interviews with key stakeholders (team and service line leaders, clinicians, the external facilitator, and Veterans) at all four programs. Key stakeholders included IDDT The study team held intensive coding sessions early in the project code interviews and observations and refine the CFIR codebook. Coders then synthesized barrier and facilitator themes by CFIR element for each site to form preliminary site profiles. Midway through the project, study investigators convened an expert panel of both local and VA Central Office leaders to reflect on preliminary site profiles. Follow-up interviews and event observations were collected and coded, with updated site profiles and overall synthesis of the data by CFIR element.

For costs, we aggregated staff hours spent in fidelity assessment, training, coaching, planning, and shadowing efforts and multiplied by individuals' published salary, plus 30% fringe. We used annualized data for ease of interpretation.

FINDINGS/RESULTS: For outer context, all team leaders expressed a strong sense that IDDT was a good approach that fit the clinical population. Other outer context themes serving as facilitators included: addressing gaps in VA services for coordinated care, hearing about the success of other IDDT programs, proximity to national experts in IDDT, and support from service line and facility leaders. The PRRC program also cited improvements to unique encounters performance metric, as the program began successfully engaging some consumers. Outer context barriers included: lack of support from facility and service, detailing, and existing staffing or procedures inconsistent with the model.

For inner context, team cultures more strongly aligned with recovery-oriented care seemed to serve as ideal starting ground for implementing IDDT. Leadership and communication about IDDT implementation efforts and timelines were also important. Staff turnover was a noted barrier.

In general, experience with motivational interviewing, stage of change, and/or IDDT itself were considered strong facilitators as individual characteristics. In addition, even without this experience, team members with a willingness to learn new approaches and tendency to embrace Veteran-centered care were considered more "ready" to implement IDDT. Team members with a stronger background in 12-step models or those less familiar with the recovery model were noted as resisting the change to IDDT

All four teams specifically noted that the implementation process for IDDT is long and requires ongoing focused attention, leadership and coaching, with initial start-up probably taking more than one year. The larger HUDVASH team decided to implement with a small "teamlet" midway through the year. The two new programs eventually decided to pursue a service agreement to coordinate to complement the strengths and weaknesses of each. The older PRRC and MHICM teams attempted to coordinate similarly but struggled to do so effectively when experiencing philosophical or staging disagreements. Facilitation for both programs could have also been improved with more knowledge about the VA service system (a possible disadvantage for external facilitation), better engagement of service leadership at the facility, and faster movement from abstract model concepts to coaching and shadowing in actual IDDT casework. These sentiments were echoed, albeit less strongly, in the themes of barriers and facilitators

with the two more mature teams. A strong facilitator endorsed by both new and older teams in the implementation process was shadowing a more mature team in a VA setting to see how the model really looks after it "goes live."

IDDT intervention characteristics found to be advantageous included using MI, staging, and harm reduction with this population. Older team leaders liked the fact that the model is packaged with its own fidelity scale and that facilitators used well-developed materials to help staff learn the model. The flexibility of the model was endorsed as a positive by some. Conversely, a common refrain on all teams was a desire for more concrete, clarifications about what IDDT dictated clinically with a particular Veteran. Staff were inconsistent in their depiction of IDDT's complexity. HUDVASH spent 377 staff hours (\$14,634) in implementation efforts. MHICM spent 191 hours (\$8,739) in implementation efforts. External facilitation annualized hours were fairly constant for HUDVASH and MHICM: 69 hours (\$2,424) and 63 hours (\$2,222).

IMPACT: The project will inform future efforts to implement IDDT in the VA and improve services for veterans struggling with severe mental illness and substance use disorders. IDDT addresses a critical gap in services provided to veterans with both mental health and substance use disorders but remains difficult to implement for even mature teams. In some ways, coordinating across team lines is a common strategy in VA efforts but is antithetical to the IDDT model ideal: a single, cohesive team to provide comprehensive services to Veterans with dual disorders.

IIR 09-083:

Web-Based Delivery of MOVE! to Veterans With Serious Mental Illness

Abstract:

BACKGROUND/RATIONALE: People with serious mental illness (SMI) are at high risk for obesity and related medical problems, and die 10 to 20 years prematurely, most commonly from cardiovascular disease. The VA has deployed a "MOVE! Weight Management Program" nationally. Since individuals with SMI usually have cognitive deficits, specialized psychoeducational interventions are needed. Specialized, in-person weight management interventions have been developed and are recommended in treatment guidelines for individuals with SMI. These programs result in weight loss when delivered in efficacy trials done with motivated patients who are paid to receive the intervention. In usual practice, these interventions are rarely provided, patient enrollment and retention are low, and effectiveness has been inconsistent. Interventions require substantial clinician time and frequent clinic visits for patients. We studied whether these barriers could be addressed using computerized provision of diet and exercise education and decision support, combined with motivation and support from peer coaches.

OBJECTIVE(S): This project had three key objectives: 1) develop a comprehensive web-based system that delivers MOVE! using design features that meet the needs of individuals with SMI; 2) complete a randomized, controlled trial to evaluate the effectiveness, in veterans with SMI, of web-based MOVE! compared with in-person MOVE! and a control group; and 3) characterize, from the patient's perspective, the strengths, weaknesses, and barriers to the use of in-person and web-based MOVE!.

METHODS: This was a randomized, controlled, comparative effectiveness study. Inclusion criteria included a DSM-IV diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, recurrent major depressive disorder with psychosis, or post-traumatic stress disorder; age 18 and over; receipt of an antipsychotic medication for at least 3 months; a BMI of 30 or higher (obese) or a BMI of 28 and self-reported weight gain of at least 10 pounds in the last 3 months; medical clearance to participate by a VA physician; and some control over diet. Exclusion criteria included a history of bariatric surgery; pregnant and nursing mothers; a diagnosis of dementia; current participation in weight loss groups; or psychiatric hospitalization during the month prior to enrollment.

Patients were randomized to 1) web-based weight management with peer coaching, 2) in-person clinician-led weight services, or 3) treatment as usual. Web-based weight management included 30 modules plus weekly telephonic peer coaching. The web-based system could be accessed from clinic kiosks, or anywhere there was internet access. It provided simultaneous audio and text-based education, video, pedometer tracking, goal setting, homework, diet plans, and quizzes. Coaching was delivered by individuals with lived experience with mental illness, was phone-based, and utilized motivational interviewing principles. In-person weight management included 24 sessions and had the same curriculum as the online program. These two active interventions were available for six months following enrollment. Research assessments occurred at 0, 3, 6, 9, and 12 months. The efficacy of the intervention was assessed at 6 months, when all the main outcomes were assessed, and semi-structured interviews were conducted to understand barriers and facilitators to those outcomes. The maintenance of outcomes from the intervention was assessed at the 9- and 12-month brief assessments.

FINDINGS/RESULTS: 276 patients with SMI and who were overweight or obese were enrolled from a Veterans Affairs medical center. Enrolled participants included 94% males (n=259). The average age of participants was 54 years (SD=9.4) with a range of 23 to 77. The participants were 48% Black (n=131), 37% Caucasian (n=103) and other races. 65% (n=180) had a high school diploma and/or some college education, and the remainder had less education. At baseline, 232 participants (84%) were obese (BMI > 30). The 6 month retention rate was 84% (232/276) and the 12 month retention rate was 81% (223/276).

Between baseline and 6 months (intervention period), for those participants who were obese and, if randomized to an intervention, started at least one session/module, there was a time by group effect (F = 4.3, p = .01). The web-based with peer coaching group had weight loss averaging 6 pounds (t = 3.3; p < .01). No change was seen in care as usual (p = .91) or inperson services (p = .77). No effect was seen in non-obese patients (BMI < 30).

Between 6 and 12 months (maintenance period), for those participants who were obese and, if randomized to an intervention , started at least one session/module, there was an effect of time with all three groups losing a significant amount of weight (F = 23.2, p < .01), but no time by group effect. The web-based with peer coaching group had weight loss averaging 2 pounds (p < .01). The in-person group had weight loss averaging 2 pounds (p < .05). The care as usual group had weight loss averaging 4 pounds (p < .01). No effect was seen in non-obese patients (BMI < 30).

In terms of retention in the intervention, there was no difference in the percent of patients (33-34%) who completed 50% of the sessions/modules, but there was a significant difference in

how many completed 100% of the intervention. 22% of patients completed the web-based program compared to 0% completing all in-person groups (chi-sq = 20; p < .001). The web-based system was well-received by patients. Patients reacted very positively to the peers, who provided motivation and social connection. Patients who failed to engage with either the web-based or in-person program did not feel losing weight was a priority.

IMPACT: On-line weight management with peer supports can provide educational content and decision support that is tailored to individuals, convenient, and patient-centered. In those individuals who are obese, this on-line program was shown to be superior to both in-person clinician-led groups and usual care. Integration of peers and technology into care was well received. An internet-based system that helps Veterans lose weight in combination with phone-based peer support could be feasible to disseminate broadly at VA sites, including medical centers and community-based outpatient clinics serving rural and urban areas. The informatics system could be disseminated nationally for use by kiosk or internet. Web-based delivery can substantially enhance access to services that help veterans improve their diet and activity, lead to lower weight, and thereby reduce morbidity and premature death due to obesity. While this system is designed for a population with mental illness, it is quite possible that this system could also be effective in other populations that can have cognitive deficits, low literacy, or limited computer experience.

RRP 12-532:

Formative Evaluation of Veteran-Centered Post-Surgical Discharge Intervention

Abstract:

BACKGROUND/RATIONALE: Unplanned readmissions following surgery are associated with increased morbidity and mortality. Health systems are focusing more heavily on readmissions as some Affordable Care Act provisions withhold reimbursement for unplanned readmissions. Given that these provisions will begin to impact surgery reimbursements by 2015, this provides a critical window to identify and address factors influencing unplanned surgery readmissions. In this study, we focus on colorectal surgery as it occurs frequently within the VA, is associated with high readmission rates (13-16%) and has significant cost implications (\$18,000 per readmission). No interventions specifically target this population at or immediately following discharge to reduce unplanned readmissions. Evidence-based interventions have demonstrated reductions in readmissions, e.g., Project Re-Engineered Discharge (RED), by standardizing the hospital discharge process to improve care transitions for patients with medical illnesses. In addition to standardization, we have adapted this evidence based intervention to the context of a VA surgical service (RED-S) using empiric evidence and expert consensus.

OBJECTIVE(S): The specific objective of this study is to evaluate the feasibility and formative implementation of the Re-Engineered Discharge-Surgery (RED-S) intervention. The specific aims of this Rapid Response Proposal include, aim 1: to assess acceptability and feasibility of RED-S components using cognitive interviews with Veterans, their caregivers and clinicians in a high-volume VA surgical service; and aim 2: to conduct a formative evaluation of the implementation of RED-S with a pilot sample of Veterans and their clinicians following colorectal surgery.

METHODS: To achieve these objectives, we conducted a mixed-methods formative evaluation, culminating in the adaptation and pilot testing of acceptability and feasibility of RED-S among

Veterans being discharged following colorectal surgery. Our prior work refined the evidence-based Project RED intervention for the context of VA operative care line services, including adaptations for patient-reported symptoms and experts' recommendations for health-coaching instructions to avoid unplanned readmissions following colorectal surgery. In aim 1, we completed adaptation and elicited acceptability of this adapted RED-S intervention using cognitive interviews with Veterans following colorectal surgery and their caregivers and clinicians. 11 Clinicians and staff completed the formative evaluation interviews including the Organizational Readiness for Change Assessment (ORCA) to provide perceptions of evidence, context and facilitation of the intervention. 12 Patients and their caregivers completed cognitive interviews about the After Hospital Care Plan that was given to patients at discharge.

In aim 2, we conducted a feasibility pilot of Project RED-S using implementation-focused formative evaluation consisting of surveys and interviews with a sample of Veterans following colorectal surgery. Of the 44 patients we consented for Aim 2, 26 completed surgery and 21 (81%) of those completed our 30 day follow-up surveys. The results of this study will inform larger implementation studies of RED-S.

FINDINGS/RESULTS: In aim 1, cognitive interviews with Veterans revealed that the After Hospital Care Plan has positive features such as its layout, color, personalization, assistance in self-care, readability/ understanding of content, and provider contact information. Suggested areas for improvement include clarity, layout, and providing additional information in certain content areas. Formative evaluation interviews with staff and providers revealed potential barriers and facilitators to RED-S acceptance and implementation. The results of the ORCA survey demonstrated that frontline staff and clinical administrators are in agreement regarding strength of evidence and feasibility of the program. Front line staff and administrators deviated in perceptions of organizational context to support implementation, scoring lower than administrators in several subscales of context, including senior leadership culture (p=0.001), leadership feedback and data transparency (p=0.002), and resources to support change (p=<0.001). Qualitative themes suggested implementation barriers such as lack of communication and lack of clear expectations from administrators and added workload on frontline staff were barriers to implementation. Themes also suggested positive organizational characteristics that are likely to improve effectiveness of implementation, including shared focus on patient-centered care and commitment to patient care innovation. In aim 2, post-discharge interviews with veterans highlighted improvements in the discharge processes and improved clinical quality of care using the Care Transitions Measure (CTM3).

Compared with Veterans discharge prior to RED-S implementation, Veterans in the pilot were more likely to endorse the statements, "Staff took my preferences and those of my family or caregiver into account" (94.4% vs 48%; p<.05); "I had a good understanding of the purposes for my medications" (100% vs 58.2%; p<.05) "at discharge I had a good understanding of things I am responsible for in managing my health" (89.5% vs 69.2%; p=.10).

Preliminary data indicates that four out of the 26 patients that consented were readmitted to the hospital within 30 days of their discharge. This rate is consistent with the hospital average and not a reduction from pre-implementation rates. However, our formative evaluation indicated barriers to implementation with moderate uptake of intervention components during the pilot (only 47% of Veterans received RED-S after hospital care plans and only 18% received pharmacist-directed medication reconciliation). As RED-S is more consistently implemented and used by hospital staff, we anticipate better overall readmission outcomes.

IMPACT: The anticipated impact of a fully implemented RED-S includes improved discharge processes with greater reliability of intervention components (medication reconciliation, patient education with teach-back of warning signs, following appointment set, and follow-up call made), which result in reductions in unplanned hospital readmissions for colorectal surgery patients and improved long-term health outcomes.

RRP 12-200:

Aligning Transitions of Care for Post-Stroke Patients with Hypertension

Abstract:

BACKGROUND/RATIONALE: Stroke is the leading cause of death worldwide and the fourth leading cause of death in the United States. In North America, approximately 5 million people have had a stroke and 550,000 new cases occur each year. For Veterans admitted to the hospital, approximately 6,000 are diagnosed yearly as having had a stroke and another 5,000 with TIA (OQP and STROKE QUERI National Report 2009). For those who survive a stroke or a TIA 1 in 5 will suffer another stroke within 5 years.

Hypertension is a known modifiable risk factor for the development of a primary stroke or TIA and continues to be a risk factor for secondary prevention of stroke/TIA. For every 20 mm Hg increase in systolic blood pressure or 10 mm Hg increase in diastolic blood pressure, stroke mortality doubles. The recommended elements of care for patients with TIA and stroke have been well described in the American Heart Association/American Stroke Association guideline and endorsed by the American Academy of Neurology. One major component of care is intensive hypertension treatment and ongoing management with antihypertensive medications. While guidelines and recommendations for the control of blood pressure (BP) in patients after TIA/stroke are readily available, strategies to facilitate prescriber and patient adherence to recommended treatments are needed.

OBJECTIVE(S): This RRP will give us key insights into the various communication challenges posed during transitions of care for post-stroke patients with continuing hypertension. It will also give us pilot data about the feasibility of academic detailing as an intervention approach. If we find, for example, that the length and intensity of exposure to academic detailing raises awareness but does not translate into behavior change we will experiment with other types of coaching models such as the longitudinal model that was successfully implemented using the Four Habits intervention. Likewise, if we find that the majority of challenges are at the organizational rather than the individual level, we will explore the use of policies, practices and incentives in addition to person to person efforts to implement PACT. In a subsequent SDP or IIR we anticipate being able to study the effect of the academic detailing intervention on actual hypertension outcomes. We plan to study clinicians' orientations toward patients and toward one another to better understand the underlying dynamics of the PACT model and how they might be modified to improve care. Since this is largely a hypothesis generating study we anticipate that our next step will be to test our results in an experimental or quasi-experimental design.

METHODS: In Aim 1, we will use semi-structured "voice of the customer" interviews with key stakeholders to identify communication barriers in the transitions from hospital to home and home to primary care visits for inpatient and primary care clinicians, post TIA/stroke patients

with continuing hypertension and their caregivers. Interviews will be conducted with patients/caregivers 7-14 days post discharge and then again after the first follow-up primary care visit to determine their understanding of hypertension control after discharge and whether they are following discharge instructions for their hypertension medication.

In Aim 2, we will use a brief (15-30 minute) academic detailing session for inpatient and primary care clinicians. We will then test the feasibility of using academic detailing to deliver these materials to clinicians. We will follow up with a brief questionnaire to the clinicians who received the academic detailing to determine the perceived usefulness and effectiveness of the approach.

FINDINGS/RESULTS: We have completed enrolling Providers and Patients into the study and analyzing the Voice of the Customer Interviews. We are now set to meet with the Inpatient Residents (November 19, 2014) and will use a brief (15-30 minute) academic detailing session to deliver a mnemonic, ATTUNED, that is based on our voice of the customer interviews and is designed to facilitate the inpatient to outpatient transfer of care. We will follow up with a brief questionnaire to the clinicians who received the academic detailing to determine the perceived usefulness and effectiveness of the approach. We will modify as appropriate for the receiving outpatient physicians in their clinics. Data analysis is completed, and a manuscript based on our findings is under review at BMJ Quality and Safety.

IMPACT: Results from this study indicate that additional training targeting discharge communication for patients with stroke/TIA is needed and can be improved using the mnemonic ATTUNED.

IBB 09-034:

ASPIRE: Coaching Veterans to Healthy Weights and Wellness

Abstract:

BACKGROUND/RATIONALE: Nearly 78% of Veterans are overweight or obese, imposing a tremendous burden on the Veterans Health Administration (VHA) healthcare system for the treatment of obesity-related chronic disease and disability. While weight management treatment has been implemented in VHA, program data shows low enrollment, participation, and weight loss. Traditional behavioral weight loss trials frequently exclude individuals with multiple chronic health conditions. Additionally, men are less likely than women to participate in these trials. New weight loss approaches may be needed to treat these populations.

OBJECTIVE(S): To test whether a small-changes intervention (The Aspiring to Lifelong Health Program; aka ASPIRE), delivered in groups or individually via telephone, promotes greater weight loss than standard obesity treatment in a predominantly male, high-risk Veteran population. Data were collected in 2010-13.

METHODS: A three-arm, 12-month randomized pragmatic effectiveness trial was conducted. Participants were recruited from MOVE! referrals and randomly assigned to one of three programs: the 12-month ASPIRE weight loss program delivered 1) individually over the phone (ASPIRE-Phone) or 2) in-person group sessions (ASPIRE-Group); compared to 3) Veteran

Health Administration's VHA standard weight loss program, MOVE!. Participants in the ASPIRE arms met with health coaches weekly in months 1-3, bi-weekly in months 4-9, and monthly in months 10-12. Usual care participants met weekly for 12 weeks with limited options for follow-up care. The ASPIRE program had distinct characteristics: 1) the opportunity for most participants to work with one lifestyle coach throughout treatment, 2) an emphasis on behavior change through a "small steps" approach; 3) the prominence of self-monitoring both physical activity and food intake as a weight loss tool; and 4) the addition of a purely phone based option. Assessments that included the collection of weight, waist circumference and lab values, along with questionnaires, were conducted at baseline, 3-months and 12-months. ASPIRE also added a follow-up component to the study, which was offered to patients at their 12-month assessment. For phone and group patients, it consisted of sessions every other month and an assessment at 18 and 24 months. Usual care patients participated in the assessments only.

Phone-based Interviews were conducted shortly after the 3-month assessment with 19 patients in the ASPIRE phone arm and with 16 in the ASPIRE group arm. These interviews were recorded, transcribed and analyzed using NVivo qualitative software to identify themes associated with successful weight loss at 3-month.

Approximately 5% of all phone and group intervention sessions were audio-recorded. An expert rater used a checklist to rate session fidelity. A second rater independently assessed 30% of the recorded sessions to establish inter-rater reliability. The checklist was psychometrically validated. It was hypothesized that greater adherence to core behavioral change processes and patient-centered communication strategies by the interventionists would be associated with higher levels of weight loss.

Using intention-to-treat principles guide all analyses. The primary outcome was weight change and secondary outcomes included changes in anthropometric (e.g., waist circumference), behavioral, fitness, psychosocial, and physiological measures. The primary analytic approach relied on a linear mixed-effects model with baseline, 3- and 12-month outcomes (e.g., weight) as dependent variables, with each subject as a random intercept to adjust for within-patient correlation of the repeated measures, fixed predictors of study arm indicators, 3- and 12-month time indicators, and time-by-study arm interactions.

FINDINGS/RESULTS: 481 Veterans were enrolled in this study: 162 patients in the ASPIRE-phone arm, 160 in the ASPIRE-group arm and 159 in usual care MOVE. Participants were predominantly male (85%) with a mean age of 55 years old, low socioeconomic status (22% college graduate, 41% with annual income below \$20,000) and nearly balanced between minority and non-minority racial status (42% non-minority). Participants had a high burden of physical co-morbidities (mean 2.16) and mental health illness (57% with at least one diagnosis) burden. 84% of participants had pre-diabetes or diabetes. Baseline characteristics of participants were similar across the arms except for depression, substance abuse disorder and income. Seventy-eight percent and 75% of participants completed the 3- and 12-month assessments, respectively. Sixty-nine percent of patients enrolled in the second year of the program. Of these, 87% and 86% completed the 18- and 24-month assessments, respectively.

At 3 months, participants in the two ASPIRE programs lost significant weight (p's<.01)

compared to baseline. At 12 months, participants in all three arms lost significant weight compared to baseline (p's<.01); weight loss was comparable for ASPIRE-Phone and MOVE! participants (p = 0.91). However, ASPIRE-Group participants lost significantly more weight (-2.8 kg) than those in ASPIRE-Phone (-1.4 kg; p = .04) and MOVE! (-1.4 kg, p = .04). Secondary measures generally improved at 3 months. Significant improvements were more likely with the ASPIRE programs, but there were no differences between programs for any measure other than EuroQol utility, which increased more for ASPIRE-Phone participants compared to ASPIRE-Group (p=.03). At 12 months, participants in all three programs had significant improvement in life satisfaction, HDL, and functional exercise capacity (i.e., 6-minute walk distance; Table 3). At 3 and 12 months, the two ASPIRE programs resulted in lower fat intake compared to baseline, with this reduction significantly lower for ASPIRE-Group than for MOVE!. There were no other differences between arms at 12 months.

Program participation rates differed between arms. During the first three months, when the 3 programs had a comparable number (11-12) of scheduled sessions, participants completed 7.9 (7.3-8.5), 6.6 (5.9-7.3), and 3.2 (2.7-3.7) sessions in the ASPIRE-Phone, ASPIRE-Group, and MOVE! arms, respectively. Notably, fidelity checklist factors associated with high adherence to intervention content and high quality of coaching delivery were shown to have a significant association (all p's <.01) with weight outcomes at three months for participants in ASPIRE-group but not for ASPIRE phone participants. The qualitative data demonstrates that Veterans in the ASPIRE trial experienced many barriers to weight loss, including physical and mental health comorbidities, chronic pain, limited mobility, and low socio-economic status. However, despite these barriers, many Veterans exhibited high levels of resiliency and were able to make healthy lifestyle changes.

IMPACT: The incremental benefits of group-based ASPIRE over the current MOVE! program could yield significant population-level benefits if implemented on a large-scale in VA. The program is being implemented at one VA in North Carolina so far. We provided training and materials and will continue to serve as consultants. This experience will be used to develop recommendations for future implementations. NCP, our operational partner, is in the process of revamping MOVE! program guidelines based, in part, on results from this trial.

RRP 11-438:

Pilot to Implement Radical PCI in VA Catheterization Laboratories

Abstract:

BACKGROUND/RATIONALE: Percutaneous coronary intervention (PCI) is part of the comprehensive treatment of coronary heart disease, used as a life-saving treatment for a subgroup of high-risk heart attack patients (ST-segment-elevation myocardial infarctions) and to control chest pain in angina patients whose symptoms cannot be managed medically. Approximately 14,000 PCI procedures are performed in the VA system annually. PCI is generally safe, but the most common modifiable adverse events in patients undergoing PCI are bleeding complications, approximately two-thirds of which are related to the location of the vascular access site. PCI is typically performed by accessing the femoral artery (groin) though it can also be performed via the radial artery (wrist). While both access sites are standards of care, bleeding is easier to control in the radial artery, and both randomized trials and registry analyses have demonstrated the safety, efficacy, and improved outcomes associated with

routine use of radial-access PCI (rPCI) compared to femoral-access PCI (fPCI). While rPCI has been widely adopted in other countries, it is technically more challenging and most interventionalists are trained primarily in femoral access. As a result, radial PCI accounts for approximately 16% of PCIs in the US. Editorial literature identifies possible barriers to adoption and implementation of rPCI in VA. While training opportunities are limited, some interventionalists still successfully implement radial programs. Currently, there is limited research on determinants and evidence-based implementation strategies to increase the use of rPCI in appropriate cases.

OBJECTIVE(S): The specific research aims were: 1) to determine current use and barriers to use of rPCI in VA cardiac catheterization labs (cath labs) and 2) to adapt and pilot a coaching intervention in preparation for a larger randomized trial to increase the proportion of rPCI done in VA cardiac catheterization labs.

METHODS: This mixed-method study included semi-structured interviews and a national survey with VA interventional cardiologists and cath lab staff (e.g., nurse manager, cath lab technician) to understand factors influencing rPCI use and identify potential refinements or additions to the rPCI training program (Aim 1). We also adapted and pilot tested the effectiveness of a current private sector rPCI educational training program that used a reverse-site visit (i.e., trainees visiting an experienced lab where they participated in a full day training session including handson training) followed by a coaching visit (i.e., trainees visited at their lab by coaches) (Aim 2). Five VA cath labs sites were recruited with at least one interventional cardiologist accompanied by a cath lab nurse and/or radiology technician attending the educational training program (reverse site visit). One site dropped out of the study, and four sites completed the training (held in July 2012). Two additional VA cath labs were recruited to serve as control sites; staff from the control sites did not attend the training program. Staff from the intervention sites attended a daylong educational training program in Chicago, IL. It included education on the benefits of radial PCI, safety procedures, practice using a radial simulator, and opportunity to observe a live rPCI case. The intervention site participants also received a coaching visit for assistance with overcoming any material and technical challenges to implementing rPCI and in order for the research team to gather feedback from the participants about the training program.

Telephone interviews on barriers and facilitators to rPCI implementation were conducted with intervention site staff before and after the pilot rPCI training program, and once with staff at the control sites. Interview findings were used to create a structured survey that was fielded nationally to VA interventionalists identified in the VA Cardiac Assessment, Reporting and Tracking - Cath Lab (CART-CL) database. The survey assessed extent of experience with rPCI, perceptions of rPCI, prevalence of barriers to rPCI use, and interest in training for rPCI use. The CART-CL database was used to assess proportion of rPCI performed at intervention and control sites and a bleeding complication composite. We are also performing qualitative comparative analysis (QCA) and assessed cost data. QCA is a technique to identify associations among many variables based on Boolean logic, to determine if there are combinations of barriers or perceptions of rPCI strongly associated with cath lab rPCI rates. We assessed cost data in anticipation of a cost-effectiveness component of a larger future intervention study.

FINDINGS/RESULTS: The baseline telephone interviews were conducted with participating

cath lab staff members (n=8). Staff from four VA cath labs participated in the day-long rPCI educational training program (intervention) in July and received follow-up coaching visits from study staff. The survey was refined based on the preliminary findings from the interviews and the intervention and fielded to VA interventionalists nationally in February 2013 (n=78 out of 235 survey recipients [33% response rate] from 48 of the 65 cath labs surveyed [73% of sites]). Results from the interviews and survey showed that the most prevalent barriers interventional cardiologists cited were concerns about increased radiation exposure to the interventional cardiologist (63% of respondents cited as major or minor barrier) and to other cath team members (51% of respondents), and the steep learning curve (44%). However, even among these, most respondents rated them as minor rather than major barriers. Other barriers such as difficulty obtaining necessary equipment (25%), lack of support from cath lab staff (23%), and lack of training opportunities (18%), were cited less frequently by our survey respondents.

Respondents were asked to choose whether rPCI or fPCI was "much better," "better," or "somewhat better" for several patient care and procedure variables ("no difference" option given as well). Majorities of interventionalists rated rPCI as superior for ease of monitoring patients following the procedure (52%), comfort for patients (60%), allowing patients to go home sooner (65%), fewer vascular access complications (69%), and fewer bleeding complications (72%). However, majorities rated fPCI superior for technical results (i.e., procedure success rate) and faster procedure time. Favorable perceptions of rPCI, though not rPCI barriers, were correlated with higher rPCI rates per site. In multivariate analyses, perceptions of rPCI as equal to or better than fPCI for procedure time, and the proportion of diagnostic cases performed radially were positively associated with site-level rPCI volume. This is consistent with the supposition that once interventionalists become proficient with rPCI, procedure times cease to present a barrier. Any efforts to support greater rPCI implementation may benefit from acknowledging that procedure times for rPCI are initially longer, but ultimately decrease to as fast as or faster than fPCI procedure times. The fact that no reported barriers were associated with site-level radial rates suggests that no single barrier is a sufficient obstacle to preclude rPCI implementation.

In post-coaching intervention interviews, participants reported favorably on the coaching intervention. Cath lab nurses and radiology technicians reported that the training helped identify specific material or technique changes that addressed barriers or concerns, such as better placement of arm boards to reduce radiation exposure, use of hydrophilic catheters (to reduce arterial spasms, increasing patient comfort and reducing procedure delays), and changes to discharge policies to take advantage of the ability to discharge patients sooner. There were not significant changes in rPCI rates at pilot sites in the 3 month period after the coaching intervention, though the pilot was not powered to detect a change.

IMPACT: Discovering which barriers to implementing rPCI are the most prevalent in combination with piloting and refining an intervention to increase the uptake of rPCI has greatly informed our larger, VA-wide proposal. We are using the results of this pilot to launch a larger dissemination and implementation trial to test the reach, safety, effectiveness and cost-effectiveness of our piloted intervention. We hope to improve patient satisfaction and outcomes and decrease VA costs by increasing rPCI uptake nationally.

Patient and Provider Outcomes of E-Learning Training in Collaborative Assessment and Management of Suicidality

Abstract:

BACKGROUND/RATIONALE: Suicide prevention among military Veterans has become a national priority; yet there is a gap in suicide-specific intervention training for mental health students and professionals. The need for training in this area has become even more acute with the recent hiring by the Veterans Health Affairs (VHA) of thousands of clinicians to address the mental health needs of Veterans from all war eras. Since e-learning (online) education is more effective than traditional in-person (face-to-face) education for adult learners when methods, such as blended learning, are used, this mode of delivery may more easily meet the training and continuing education needs of busy medical professionals who may find it easier to fit online education into their daily schedules. A well developed in-person training approach known as the Collaborative Assessment and Management of Suicidality (or CAMS) has been recommended in systematic reviews as an effective tool for assessing and managing suicidality, as well as decreasing providers' fears, improving their attitudes, increasing their knowledge, confidence, and competence, and dispelling myths.

OBJECTIVE(S): There are four specific aims:

- 1. Refine a CAMS e-learning course that covers the same material and meets the same learning objectives of CAMS in-person training.
- 2. Test the effectiveness of the CAMS e-learning modality compared to the CAMS in-person modality and a concurrent non-intervention control in terms of provider evaluation and behavior.
- HO: Providers in each of the two CAMS arms will demonstrate higher levels of content mastery and confidence in acquired skills than providers in the no CAMS arm.
- H2: In the 12 months post-training, suicidal patients of providers in each of the two CAMS arms will receive higher rates of CAMS guideline concordant treatment, compared with providers in the no CAMS arm.
- 3. Test the effectiveness of the CAMS e-Learning delivery compared to the CAMS in-person delivery and a concurrent non-intervention control in terms of patient outcomes.
- H3, 4, 5: In the 12 months post-training, suicidal patients of CAMS e-learning providers and CAMS in-person providers will be similar for health services use patterns, duration of high risk episodes, and number of high risk episodes per patient.
- H6: In the 12 months post training, suicidal patients of providers in the no CAMS arm will have higher rates of emergency room use and inpatient mental health admissions, have a longer average duration of high risk episodes, and have more high risk episodes per patient.
- 4. Assess factors that facilitate or inhibit adoption of CAMS through e-Learning or In-person.

METHODS:

Design: A trial of CAMS e-learning in comparison to CAMS in-person was conducted, using a multicenter, randomized, cluster, three group design. Outpatient mental health providers without previous CAMS training were recruited from five VA hospitals in the southeastern VA region. Following informed consent, providers who completed a CAMS Pre-Survey were randomized to one of three conditions. Those randomized to either of the CAMS training conditions were granted 6.5 hours of clinic release time, 6.5 CEUs, and the CAMS text, following successful completion of training. Those randomized to the control condition received an emergency psychiatry text. Clinics were blocked 6-8 weeks in advance of training for providers in both training conditions. Delivery of training was then conducted over a four month period. At each site, in-person CAMS was delivered one-day and e-learning was implemented over a three week period following the in-person training.

Intervention: The Collaborative Assessment and Management of Suicidality (CAMS) is a structured clinical framework for assessing, monitoring, and intervening with a patient at risk for suicide. CAMS includes the use of problem-focused interventions of patient-defined "drivers" of suicide that is guided by a multi-purposed clinical tool called the Suicide Status Form (SSF). The final e-CAMS product was an asynchronous learning course. The e-CAMS modules included: 1) Introduction to Suicidality and CAMS Approach, 2) Collaborative Suicide Risk Assessment, 3) CAMS Status Tracking and Problem-Focused Treatment (PFT), and 4) Fusion of CAMS within the VA. A CAMS Coaching Component was provided to both CAMS training conditions to encourage adoption, recognize successes, and address barriers. The coaching component was six bimonthly, lunch hour, teleconferences with the developer of CAMS.

Study Population, Sample, Response: A total of 230 (out of an eligible 309, recruitment rate 72%) providers consented. Of these, 212 providers completed the pre-survey and were randomized: 69 to the e-learning condition, 70 to the in-person condition, and 73 to the control condition. The 139 providers randomized to e-learning, or in-person training were primarily female, Caucasian (67.7%) or African-American (25.6%), midlife, mid-level providers.

Settings: The study was conducted at five VA medical centers from 2009-2013 and was approved by the IRBs of all sites.

Study variables: Provider variables include satisfaction with training, confidence in managing suicidal crises, use of SSF forms, adoption of CAMS, adherence to CAMS. Patient variables include health services use patterns, duration of high risk episodes, number of high risk episodes, emergency room use, inpatient mental health admissions, and suicidality. Intervention variables included training completion and coaching attendance.

Methods of analyses: The VA Evaluation of Training was used to evaluate satisfaction and descriptive statistics were used to analyze frequencies. Pairwise comparisons of intervention means (ANOVA-type simple-effect comparisons) at each time point were carried out based on a priori specified hypotheses. Descriptive statistics were calculated for the total and individual item scores, including means, standard deviations, and frequency distributions. A generalized linear mixed models (GLMM) approach was used to model the longitudinal CAMS Survey provider outcome data.

FINDINGS/RESULTS:

Aim #1: We developed the CAMS-e, conducted a pilot, revised the e-CAMS, delivered the training in the first site, and again revised it. There is little difference in satisfaction ratings between the two types of training deliveries on the VA Evaluation of Training. The e-learning development, provider satisfaction, completion of training, coaching call attendance, and adoption is described in a manuscript published in Academic Psychiatry (Marshall, York, Magruder et al, 2014). This is the first evaluation of a suicide-specific e-learning training within the VA.

Aim #2: A second manuscript is in the final stages of preparation and describes the provider survey component. This will be submitted this Spring. Findings show that there were some modest immediate improvements due to the two training conditions; however, the effects were only sustainable at three months for one question related to hospitalization beliefs. There were only two items where the e-learning and in-person conditions were different, one (hospitalization) favoring in-person, and the other (practices related to liability) favoring e-learning; thus, there were no clear differences between the e-learning and in-person modalities, suggesting that either method could be used, but both need enhancements to boost and sustain knowledge.

Aim #3: We completed the development of a CAMS Chart Abstraction Protocol to assess provider adherence and patient outcomes. We have conducted chart reviews on 261 patients on the patient High Risk Flag who were followed by study providers in the 12 months following the training. Additional patients were eliminated because the provider did not have the minimum number of contacts post training.

Aim#4: Formative evaluation was conducted. Two focus groups were conducted in Site 1 divided by training modality. The protocol addressed the following areas: impression of training experience; experience in delivery; organizational incentives, rewards, and related organizational goals; facilitating factors or barriers; implementation success; compatibility with professional beliefs, values, and practices; and fit with workflow and program. There were no discernible qualitative differences between the reports of the two training groups. Attendance at coaching goals was poor. We have identified the facilitating and inhibiting factors in the trial.

IMPACT: To date, the project has had the following impacts:

- 1) success in obtaining 6.5 CEUs for the e-learning version
- 2) invitations to place e-CAMS on the Department of Defense learning platforms
- 3) VA Central Office has purchased a license to use the SSF as a clinical tool and template in the computerized electronic patient record system throughout the national VA. The template is in the developmental process.
- 4) Efforts are underway to move the CAMS e-learning on to the VA TMS which will facilitate system wide dissemination and has the potential to increase adoption in VAMC's or by providers.

IIR 09-366:

Effectiveness of an Automated Walking Program Targeting Veterans with COPD

Abstract:

BACKGROUND/RATIONALE: Low levels of physical activity are common in patients with chronic obstructive pulmonary disease (COPD), and a sedentary lifestyle is associated with poor outcomes including increased mortality, frequent hospitalizations, and poor health-related quality of life. Individuals with COPD who undergo a facility-based, exercise-focused pulmonary rehabilitation program experience significant improvements in health related quality of life, dyspnea, and exercise tolerance as well as reduced rates of hospitalization. Unfortunately, only a small percent of individuals with COPD who could benefit from pulmonary rehabilitation have access to and participate in such programs. Moreover, the benefits of short-term pulmonary rehabilitation programs tend to diminish rapidly after the program ends. Rural veterans are less likely to have access to facility-based pulmonary rehabilitation than urban veterans. Health related quality of life in rural veterans with COPD is significantly worse than for veterans with COPD who live in urban areas.

OBJECTIVE(S): The primary objective of this study was to assess the efficacy of an Internet-mediated, pedometer-based intervention designed to increase walking and health related quality of life for Veterans with COPD. The specific aims of this randomized controlled trial (RCT) with a wait list control were: 1) To test the effectiveness of an automated internet-mediated walking program for veterans with COPD with a primary outcome of improvement in health related quality of life at four months and at one year; 2) to estimate the effect of the internet-mediated walking program for veterans with COPD on all cause days of hospitalization over one year following randomization; and 3) to compare intervention reach, participation and satisfaction outcomes between rural and urban veterans among those randomized to the intervention arm.

METHODS: Participants were followed for 12 months to investigate the efficacy of the intervention in assisting patients with initiating and maintaining a regular walking program and improving health related quality of life. Eligible and consented patients wore a pedometer to obtain one week of baseline data and then were randomized on a 2:1 ratio to Taking Healthy Steps or to a wait list control. The intervention arm received iterative step-count feedback; individualized step-count goals, motivational and informational messages, and access to an online community. Wait list controls were notified that they were enrolled, but that their intervention would start in one year; however, they kept the pedometer and had access to a static webpage. Both groups completed on-line survey assessments at baseline, 4, and 12 months, and were asked to report adverse events on a regular basis. The primary outcome was changes in health related quality of life, as measured using the St George's Respiratory Questionnaire (SGRQ), a disease-specific instrument in patients with COPD. Secondary outcomes included days of hospitalization during the one-year intervention period, changes in average daily steps as measured using the study pedometer, self-reported dyspnea, intervention reach, and adverse event rates. The analysis was conducted based [on the original randomized treatment assignment regardless of participation (an intent-to-treat analysis) and included both a complete case analysis as well as an all case analysis using a linear mixedeffects model. Between-group differences in change scores (4 months or 12 months) were estimated after adjusting for baseline values of the outcome variables.

FINDINGS/RESULTS: Participants included 239 randomized Veterans (mean age 66.7 years, 93.7% male) with 155 randomized to Taking Healthy Steps and 84 to the wait list control arm; rural-living (45.2%); ever-smokers (93.3%); and current smokers (25.1%). Baseline mean SGRQ Total Score was 30.5% reported severe dyspnea; and the average number of comorbid

conditions was 4.9. Mean baseline daily step counts was 3497 (+/- 2220). There were no significant differences in baseline characteristics between study arms. One patient was dropped due to being an extreme outlier at 4 months on both step counts and SGRQ change.

For the 4 month data, we used a complete case analysis. Two hundred and twenty-one participants had complete SGRQ data at 4 months; 5 additional patients had responses that allowed calculation of at least one domain score. Those within the intervention group showed significant improvement in SGRQ-TS by 3.2 units (P<0.001). There was no significant difference in SGRQ-TS (2.3 units, P=0.1) between the two groups. A greater proportion of persons in the intervention than in the control group had at least a 4-unit improvement in SGRQ-TS (53% vs 39%, P=0.05). For domain scores, Symptoms improved by 7.2 units (P<0.001) and Impacts by 2.8 units (P<0.05) among those in the intervention group. Those within the control group showed no significant changes. Compared to control, those in the intervention had an improvement of 4.6 units (P=0.046) for Symptoms and 3.3 units (P=0.049) for Impacts scores. There was no significant difference in Activities score (0.6 unit, P=0.78) between the two groups.

Two hundred and ten out of the 238 study participants had step-count data at 4 months, with 201 meeting the study criteria for valid 4-month daily step counts. Those in the intervention group showed significant increase in their daily step count on average by 447 steps while those in the control group had a decrease in their daily step count of 346 steps. The difference in step counts at four months between the two groups was significant (779 per day; P=0.005) adjusting for baseline rural/urban status, and MMRC dyspnea score.

For the 12 month data, we used an all case analysis. At 12 months, 209 study participants had complete SGRQ data at 12 months, and 4 additional patients had responses that allowed calculation of at least one domain. Those within the intervention group showed significant improvement in SGRQ-TS by 2.5 units (P=0.01). For domain scores, Symptoms improved by 3.2 units (P=0.02) and Impacts by 3.4 units (P<0.01) among those in the intervention group from baseline. Those within the control group showed no significant changes. Compared to control, those in the intervention no longer showed significant improvement at 12 months on any domain scores and continued to show no improvement on TS.

At 12 months, there was no difference between or within arms from baseline for step counts. Surprisingly, the control group significantly increased daily step counts by 673 (P<.05) between 4 and 12 months. Self-reported hospitalizations are not significantly different between arms at one year post randomization.

IMPACT: Chronic Obstructive Pulmonary Disease (COPD) is a common disabling chronic condition that is more prevalent in veterans than in the general population. Limitations in daily activities due to reduced exercise tolerance along with frequent hospitalizations for COPD exacerbations contribute to poor quality of life and increased health care costs. Veterans on the Internet-mediated intervention, compared with the control group, reported improvement in two out of three subscales of the SGRQ health related quality of life and increased their step counts at 4 months. However, these results were not sustained at 12 months. Further work is needed to understand how to sustain improvements in the long term in this population. Nonetheless,

automated Internet-mediated interventions can be used to deliver care with to underserved rural Veterans or those who do not have access to facility-based pulmonary rehabilitation programs.

SDP 08-316:

Blended Facilitation to Enhance PCMH Program Implementation

Abstract:

BACKGROUND/RATIONALE: Implementation of evidence based practices and programs (EBPs) is complex, challenging, and rarely sustained. There is evidence that ongoing facilitation can foster EBP implementation. We previously developed an external/internal facilitation strategy that combines an external facilitator, an expert in implementation methods and specific EBPs, with a network-level internal facilitator who is familiar with clinic-level structures, climates, and practices and who, with mentoring, develops expertise in implementation facilitation. The Blended Facilitation study implemented and rigorously evaluated this strategy within the context of VA's Uniform Mental Health Services Handbook requirements for primary care-mental health integration (PC-MHI). Using external/internal facilitation can enable VA to foster the sustainable organizational change that new policy and associated implementation of system wide QI initiatives require.

OBJECTIVE(S): This project sought to 1) test effectiveness of the facilitation strategy versus standard national support on extent of clinic-level outcomes, provider behavior change, and changes in Veterans' service utilization; 2) assess organizational context, perceptions and attitudes regarding evidence for PC-MHI programs, and the facilitation process within the context of those findings; 3) collect data on facilitation time/activities for use in a future cost proposal; and 4) document activities and time required to transfer external/internal facilitation to VA Operations personnel.

METHODS: We used a multi-site, quasi-experimental design with non-equivalent comparison groups. Eight PC clinics from two VA networks received external/internal facilitation. We compared clinics to eight matched clinics in two matched networks. We excluded one matched clinic pair from administrative data analysis due to the facilitation site's failure to complete the program design phase. Using quantitative and qualitative methods we evaluated the facilitation strategy on RE-AIM framework dimensions of reach, effectiveness, adoption, implementation, and maintenance. We collected data during late phase PC-MHI implementation and one year later. We compared clinics on percentage of PC patients with a PC-MHI encounter, a first MH specialty care visit, and PC-MHI referral/same day encounter; percentage of PC providers referring at least one patient and providers' patients that were referred to PC-MHI. We also assessed PC-MHI program components and obtained expert ratings of clinics' program quality. We conducted 83 interviews with study facilitators to document their activities and collected time data for facilitation activities. We also conducted organizational context surveys early in the implementation process. At four selected facilitation sites, we assessed key stakeholder perceptions about facilitation and its value. To document efforts to transfer this strategy to VA Operations, we conducted 45 interviews with facilitators and collected time data for their activities.

FINDINGS/RESULTS:

Aim 1: In assessing late phase implementation, compared to non-facilitation sites, facilitation sites achieved statistically significant (p<0.05) higher rates of PC-MHI engagement (4.1%, 1.7%), providers referring at least one patient (86.8%, 72.9%), providers' patients referred to PC-MHI (1.72%, 0.25%), and patients receiving same day access to PC-MHI compared to nonfacilitation sites (32.0%, 9.2%). In assessing implementation maintenance phase, facilitation sites maintained statistically significant higher rates of engagement (4.8%, 2.3%), provider median referral rate (2.69%, 1.48%) and same day access (29.1%, 22.6%). Facilitation sites also maintained a greater proportion of providers referring to PC-MHI (94.4%, 87.0%) however; the difference was not statistically significant. Although the median rate for initial MHSC encounters at facilitation sites was lower than that of non-facilitation sites at both study periods (42% - 54%, 40% - 49% respectively) the differences were not significant. Upon examination of qualitative data, it was discovered that two non-facilitation sites were recording PC-MHI encounters without a PC-MHI program. An additional analysis excluding these encounters strengthened our original findings. In addition, the proportion of providers referring to PC-MHI in facilitation sites during the maintenance phase was statistically significant (94.4%, 69.8% respectively). These findings suggest that sites receiving facilitation implement PC-MHI more robustly and maintain their gains over time. Supporting these findings, our qualitative assessment of late phase implementation revealed that seven facilitation but only five comparison sites had implemented PC-MHI programs. During the maintenance phase, all facilitation but still only five comparison sites had programs. Experts rated all but one of the facilitation site programs higher than their matched comparison sites.

Aim 2: We examined the interplay between facilitation and organizational context and found that facilitation helps overcome organizational barriers. We also conducted a detail analysis of the facilitation process. Concordant with the literature, we found that facilitators both "do" things for stakeholders and "enable" stakeholders to do things for themselves. One particular activity type (e.g., education), however, can involve both "doing" (e.g., providing education) and enabling (e.g., fostering attendance). We also assessed change over time. Although certain activities cluster during particular implementation periods, we found organizational context and stakeholders' needs play a substantial role in what facilitators do and when they do it. We also observed systematic regional differences in the process, possibly due to organizational or facilitator characteristics. Finally, stakeholders and facilitators believed that facilitators ideally possess certain characteristics and skills. It is possible that coaching and mentoring may help those who do not possess these to obtain them.

Aim 3: Analysis of time data revealed that during the study, 3 facilitators spent 3,955 person hours helping clinics implement PC-MHI. Facilitators' top three activities in terms of person hours were preparation and planning, stakeholder engagement, and education. VHA stakeholders (n=399) from all levels participated in facilitation activities for 3,042 person hours. Aim 4: In transferring the facilitation strategy to OMHO, it was important to be flexible and respond to their changing agenda and balance quality improvement and scientific rigor. Consultants provided 590 person hours, during half of which they conducted preparation/planning and mentoring.

IMPACT: This project has cemented partnerships with operational leaders, continues to have significant impacts on VA's efforts to implement the Uniform Mental Health Services Handbook

to ensure that all Veterans have access to needed mental health services, has informed national policy and planning task forces and other research studies and has contributed to implementation of two PC-MHI 'best practices."

IIR 07-196:

Patient Centered Evaluation of Computerized Patient Records System

Abstract:

BACKGROUND/RATIONALE: Electronic Medical Records (EMR) can potentially improve quality and safety of ambulatory care. However, little research systematically documents the effect of EMRs on patient-centered care. Studies of the EMR's effect on patient-provider communication have been observational and had small sample sizes. Overall, these studies reported varied success regarding providers integrating the EMR into office visits, and suggest that further research is needed to evaluate the effectiveness of training providers in patient-centered communication and EMR use.

OBJECTIVE(S): The PACE aims were to study how EMR use affects patient-provider communication behaviors, and patient-centered care and related health outcomes; to develop a unique provider training program tailored to patient-centered EMR use; and to evaluate the effect of the training intervention on patient-provider communication, patient-centered care, and provider EMR use.

METHODS: The study used a quasi-experimental (pre-post intervention design) carried out in three phases:

- (1) **Pre-intervention:** Twenty-three primary care providers and 126 patients were enrolled. A pre-intervention patient-provider visit was conducted for each patient-provider pair. Visits were video recorded and reviewed for verbal and nonverbal patient-provider communication. MORAE software was used to record provider-EMR interaction data, including page views, navigation, and mouse clicks. Data were collected for related outcomes (patient and provider satisfaction).
- **(2) Training:** Findings from pre-intervention data guided development of a multifaceted provider training intervention promoting patient-centered EMR appropriation. The training intervention was delivered via a full day training workshop and individual feedback sessions.
- (3) Post-intervention: A second round of visits (n=77) was conducted with the same patient-provider pairs. Data collection (described in the pre-intervention phase) was performed per protocol. Within group analyses (pre-post) were used to test whether the training intervention resulted in significant improvements in (a) patient-centered EMR use and (b) related outcomes (patient and provider satisfaction).

FINDINGS/RESULTS: Of the 23 primary care providers enrolled in the pre-phase, 20 completed the post-phase (3 left the VA). The study enrolled 126 patients in the pre-phase, and 77 completed the post-phase. Reasons for patient drop out were as follows: 9 not interested; 3 passed away; 14 providers dropped out; 9 cancelled appointment/no show; 3 relocated; 3 changed PCP; and 8 we were unable to contact.

EMR Usage vs. Patient Engagement: The average time each provider spent during the visit performing EMR activity was 38.6% pre-intervention (sd=17.5%, median=33.5%, range=(0,

81.2%), as compared to 38.5% (sd=16.4%, median=39.2%, range=(8.8%, 69.3%) in post-intervention. The average time spent on patient engagement was 36% pre-intervention (sd=16%, median=35%, range=(5%, 76%), n=125), and improved to 38.9% (sd=17%, median=35.5%, range=(6%, 81%) post-intervention. Essentially, providers spent as much time engaged with the EMR as they did with patients. In interviews, providers expressed great concern regarding the need for multitasking between the EMR and patient. Providers recognized that existing EMRs are inefficient, which takes time away from patient-provider communication. Patients reported similar concerns but felt that technology use was inevitable and a good thing.

EMR Usage - Total Mouse Clicks: The average total mouse clicks per visit was 192 (sd=151, median=156, range=(0, 685), n=119) pre-intervention compared to 189 (sd=136, median=158, range=(31, 645), n=63) post-intervention. Providers shared the EMR screen with patients in 24.8% of pre-intervention visits. This improved to 28.9% in post-intervention visits. Mouse clicks are a quantifiable measure of EMR usage, and in both pre and post visits, the high volume of mouse clicks are evidence of poor usability and high task burden imposed by EMRs.

Patient-Centered Communication: Despite the heavy EMR burden on providers, 86.5% (pre) and 89% (post) of patients reported high satisfaction with provider's patient-centered communication. Pre-visit average score is 4.71 (sd=0.56, median=5, range=(1.67, 5); post-visit average score is 4.75 (sd=0.54, median=5, range=(2.17, 5). Similarly, 97.6% (pre) and 96% patients (post) were satisfied with provider's interpersonal skills. Pre-visit average score is 4.86 (sd=0.32, median=5, range=(3, 5), n=126); post-visit average score is 4.87 (sd=0.36, median=5, range=(3, 5).

Quality of Patient-provider Relationship: Providers, as a group, reported less satisfaction with visits than did patients. Only 70.6% (pre) and 74.3% (post) reported satisfaction with the quality of patient-provider relationships. Pre-intervention average score is 4.17 (sd=0.70, median=4.25, range=(1.75, 5); post-intervention average score is 4.23 (sd=0.64, median=4.25, range=(2, 5). Similarly, only 58.3% (pre) and 61.8% (post) of providers were satisfied with their ability to collect required data during visit. Pre-intervention average score is 3.95 (sd=0.86, median=4, range=(1.67, 5); post-intervention average score is 4.08 (sd=0.84, median=4, range=(1.33, 5).

In this study, a provider-coaching intervention was unable to significantly improve provider ability to incorporate the EMR in ways that facilitated patient-centered care. Contributing factors include EMR usability issues and inefficient workflows that shift the provider's focus from patient to computer. Pressed for time, providers multitask between patient interview and complex and inefficient EMR tasks. To populate notes, clinicians used various laborious mechanism, including direct typing, copy-paste from other parts of the EMR, and formatting the note. Providers use menu-driven interfaces for order entry of medications, lab tests, consults, and imaging. Such interfaces have multiple nested menus, long lists, and numerous data fields that require input. If EMRs are to support patient-centered care, they need to be redesigned to ease providers' EMR workload burden, thus increasing time spent in face-to-face communication with patients.

IMPACT: PACE findings emphasize the need to address EMR usability in next generation of

EMR technologies being developed by the VHA hi2 (Health Informatics Initiative) and iEHR team. Drs. Agha and Calvitti have served as subject matter experts for hi2 HMP (Health Management Platform) User Centered Design team since 2011. A concrete impact from PACE is the hi2's \$1 million commitment to fund usability research to support HMP and to develop software requirements for a usability analytics platform. PACE findings are also driving EHR redesign within the VA. Based on PACE data, Dr. Agha is leading a team of engineers, cognitive scientist, and clinicians at San Diego to prototype novel EHR user interfaces for hi2 HMP.

IAB 05-303:

Proactive Tobacco Treatment for Diverse Veteran Smokers

Abstract:

BACKGROUND/RATIONALE: Tobacco use is the leading cause of premature death in the United States and disproportionately affects Veterans and certain racial/ethnic minority groups. Most smokers are interested in quitting; however, current tobacco use treatment approaches are reactive and require smokers to initiate treatment or depend on the provider to initiate smoking cessation care. As a result, most smokers do not receive comprehensive, evidence-based treatment for tobacco use that includes intensive behavioral counseling along with pharmacotherapy. Proactive tobacco treatment integrates population-based treatment (i.e., proactive outreach) and individual-level treatment (i.e., smoking cessation counseling and pharmacotherapy) to address both patient and provider barriers to comprehensive care.

OBJECTIVE(S): The primary objectives of this study were to (1) Assess the effect of a proactive care intervention on population-level smoking abstinence rates (i.e., abstinence among all smokers including those who use and do not use treatment) and on use of evidence-based tobacco treatments compared to reactive/usual care among a diverse population of Veteran smokers, (2) Compare the effect of proactive care on population-level smoking abstinence rates and use of tobacco treatments between African American and White smokers, and (3) Determine the cost-effectiveness of the proactive care intervention.

METHODS: In this prospective randomized controlled trial, we identified a population-based registry of current smokers (N=6400) from four Department of Veterans Affairs (VA) Medical Centers facilities using the VA electronic medical record, who were randomized to proactive care or usual care. The proactive care intervention combines: (1) proactive outreach and (2) offer of choice of smoking cessation services (telephone or face-to-face). Proactive outreach included mailed invitations followed by telephone outreach with motivational enhancement (up to 6 call attempts) to encourage smokers to seek treatment with choice of services. Proactive care participants who chose telephone care received VA telephone counseling and access to pharmacotherapy. Proactive care participants who chose face-to-face care were referred to their VA facility's smoking cessation clinic. Usual care group participants had access to standard smoking cessation services provided by their VA facility and their VA primary care provider. Usual care participants could also call their local state telephone quitline. Because this study was testing proactive outreach, smokers were randomized prior to contact and a baseline survey was administered after randomization using a multiple-wave mailed questionnaire protocol. Additional baseline data were extracted from VA administrative databases. Outcomes

from both groups were collected 12 months post-randomization from participant surveys and from VA administrative databases. The primary outcome was population-level cessation at one year using a self-reported, 6-month prolonged smoking abstinence measure.

FINDINGS/RESULTS:

- **A)** Across the four VA Medical Centers, nearly all Veterans in primary care had their tobacco use status documented in the VA electronic medical record.
- **B)** Current smokers (N=6400, 1600 per site) as identified by the electronic medical record were randomly assigned to proactive care or usual care with an allocation ratio of 1:1 within each site and mailed a baseline survey. The sample was diverse; 28% African American, 62% Caucasian, 4% other race, and 4% unknown race. Seven percent were of Hispanic ethnicity.
- **C)** The baseline survey response rate was 66%. In the year prior to the start of the study, 57% had made a quit attempt, 1.7% had used telephone smoking cessation counseling, 11% had received in-person smoking cessation counseling and 37% had used smoking cessation medications.
- **D)** In the proactive care intervention group, 2519 were mailed outreach invitation materials. During telephone outreach, 1556 (62%) were successfully contacted. Of the participants mailed an outreach invitation packet, 392 (16%) elected VA telephone coaching and 77 (3%) elected in-person smoking cessation services at their VA Medical Center.
- **E)** The follow-up survey response rate was 67%. During the one year intervention period, current smokers in the proactive care group (57%) were more likely to make at least one quit attempt compared to usual care (53%, p=0.035). In addition, proactive care participants were significantly more likely to use telephone smoking cessation counseling than usual care participants (13.0% versus 1.9%, p<0.001). Proactive care participants were also more likely to have used smoking cessation medications (37.2% proactive care and 32.8% usual care, p=0.010). There were no significant differences in use of in-person smoking cessation counseling between the two groups, 6.3% proactive care and 5.7% usual care.
- **F)** We observed a significant increase in the population-level cessation rate of 2.6%. The population-level cessation rate at one year was 13.4% for proactive care compared to 10.8% for usual care (p=0.025). In generalized linear mixed model analysis, proactive care resulted in increased odds of population-level cessation, OR=1.274 (1.033, 1.571). Additional analyses incorporating multiple imputation methods to estimate missing outcome and independent covariate measures, which adjusted for baseline group differences in age of smoking initiation, and length of prior quit attempts, found that the effect of proactive care on population-level cessation persisted, OR=1.220 (1.002, 1.484).
- **IMPACT:** In this study, we tested a proactive care intervention that harnesses the power of the electronic medical record to identify populations of smokers in a health care system and capitalizes on the availability of validated telephone care protocols to efficiently deliver intensive behavioral counseling and facilitate access to pharmacotherapy. For vulnerable priority populations including racial/ethnic minorities and Veterans, telephone-based smoking cessation services are acceptable and effective for increasing engagement in evidence-based smoking

cessation treatments. Moreover, population-based proactive tobacco treatment using proactive outreach to connect smokers to evidence-based telephone or in-person smoking cessation services is effective for increasing long-term population-level cessation rates.

RRP 09-143:

Motivational Interview Training in Weight Management for SCI Providers

Abstract:

BACKGROUND/RATIONALE: Obesity is linked with major health implications in the general population and people with spinal cord injuries and disorders (SCI/D). Implementing provider training and education in patient counseling is important for the prevention and treatment of weight-related problems and to lessen the health risks associated with obesity. This project examined the effectiveness of a training method on the use and acceptance of motivational interviewing (MI) skills, an evidence-based counseling technique that is applicable among a wide range of Spinal Cord Injury Quality Enhancement Research Initiative projects

OBJECTIVE(S): This project was a pilot study which evaluated provider: (a) MI knowledge; (b) MI competency; (c) satisfaction with training; and (d) perceptions of barriers and facilitators to MI adoption and implementation into practice for Veterans with SCI/D.

METHODS: Interdisciplinary teams of clinicians from two VA Spinal Cord Injury (SCI) centers participated in sixteen-hour workshops on MI, and then received additional instruction through mock counseling sessions with expert feedback. The mock counseling sessions with simulated patients were audio-recorded and scored using the Motivational Interview Treatment Integrity (MITI) Scale. Individual feedback and tailored coaching to improve MI skills was provided for each of these sessions via telephone by a Motivational Interviewing Network of Trainers trainer. Mock counseling sessions and coaching continued until participants reached basic MI proficiency per MITI thresholds, or until five total sessions were reached. Data was collected from participants at baseline, after the training session, and after the mock counseling sessions to assess MI knowledge and reflective listening skills using the Helpful Response Questionnaire. Post-training, participants also responded to a series of questions, on their satisfaction with five aspects of their MI training experience: training format, its applicability to their work, trainer characteristics, overall experience, and practicing with the simulated patients. Participants were also asked to describe ways to improve each aspect of their training experience. Additionally, semi-structured telephone interviews were conducted to collect information on their training experience, their use of MI in their clinical setting, and to gain insight into perceived barriers and facilitators to adoption of MI in their clinical setting. Interviews were audio-recorded and transcribed verbatim. Interview data were analyzed using constant comparative analysis to assess provider satisfaction with the training and identify common barriers and strategies for overcoming them. The analysis of the qualitative data was conducted to elicit themes, patterns and inconsistencies. Descriptive statistics were computed for all quantitative variables.

FINDINGS/RESULTS: Nine SCI/D providers (88.9% females) completed the two-day training and all other study procedures. Average scores on the MI knowledge test and reflective listening skills measure were higher after the training session, compared to baseline. MI proficiency, as

measured by MITI summary measures, also increased from baseline. At the first counseling session after training, the average values for global therapist rating (M=3.8), reflections to question ratio (M=1.4:1) and percent open questions (M=64%) met MITI thresholds for beginning proficiency. Other MITI categories increased with practice and feedback afforded by the mock counseling sessions. On average, beginning proficiency in percent complex reflections and percent MI adherent giving information were met at the third mock counseling session. No participants met the MITI beginning proficiency thresholds on all measures before the MI training. Two met or exceeded the MITI beginning proficiency thresholds on all measures after the MI workshop. All participants met the MITI beginning proficiency goal after the workshop plus three mock counseling and coaching sessions. Results from the satisfaction survey showed that a majority of providers were moderately or very satisfied with their training experience. On a 1-to7 point scale (1=very dissatisfied, 7=very satisfied) participants reported high satisfaction with the training format, M (SD)=6.7 (0.5); its applicability to their work M (SD)=6.2 (0.3); trainer characteristics M (SD)=6.6 (0.3); overall experience M (SD)=6.5 (0.4); and mock practice sessions M (SD)=6.4 (0.1). Analysis of qualitative interview data showed that the training and its components were well received. Participants viewed MI as a useful tool to draw on in their practice to promote behavior change; some participants also wanted more support as they used it in clinical care. Suggestions for improving the current training format included providing time at the two-day training to talk about MI implementation and incorporation into clinical care as well as adding more follow-up sessions with the trainer to refresh, reinforce and practice MI skills. After completing the training, participants wanted more time to discuss clinical situations and problem solve specific clinical issues and patients with the trainer and their colleagues. Barriers cited include time constraints during in-patient visits, conflicting demands in care, insufficient number of MI trained staff, and lack of an organized approach and tools to assist with obesity management. Perceived facilitators included having more staff from multiple disciplines trained in MI, more consistent use of MI, agreement about what setting is most effective, having more time with patients to use MI, and opportunities to practice and to follow-up and ascertain whether MI counseling is working.

IMPACT: This pilot study was undertaken to help guide decision making regarding the use of MI as an adjunct to behavioral modification techniques in the VA SCI/D system of care. MI training was well received by the SCI/D providers, and they provided valuable feedback on how to facilitate their use of MI. Factors that would impede or facilitate MI adoption in clinical care identified in this study need to be addressed for successful implementation. Results from this study suggest many opportunities for future work in weight management in general, as well as in MI training and delivery for other health conditions. The generalizability of our findings is limited due to the small number of providers who participated. A larger study is needed to confirm the results; this pilot study will form the foundation for the development of a larger-scale study in the SCI/D system of care to assess the efficacy of MI in improving obesity-related outcomes in individuals with SCI/D.

RRP 09-190:

Controlling Hypertension Outcomes by Improved Communication & Engagement (CHOICE)

Abstract:

BACKGROUND/RATIONALE: Veterans often experience difficulties in self-management of chronic conditions, resulting in poor health outcomes. In the setting of stroke, self-management of hypertension is a major concern. Data from VISN 11 indicated that only 26% of Veterans with stroke met the established VA performance criteria for hypertension management of having at least 75% of blood pressure measurements at or below goal. Veteran self-management of hypertension is a critical component in the secondary prevention of stroke. Provider-patient relationship quality and communication have been identified as inhibiting or facilitating care processes and outcomes such as self-management. Patient-centered communication skills are associated with improved adherence, self-care, and health outcomes. Prior research shows that physicians and patients exert reciprocal influences on one another's communication. Models of successful self-management require physicians with excellent communication skills and patients who are active and knowledgeable about their conditions.

One model of communication enhancement - the Four Habits Approach - was developed by VA investigator and PI Richard Frankel more than a decade ago. The approach has been empirically validated and adopted broadly. In our randomized-controlled study, Controlling Hypertension Outcomes by Improved Communication & Engagement (CHOICE) (RRP 09-190), we tested the feasibility of two communication interventions: one with Veterans who have had a stroke and now demonstrate poorly controlled hypertension; the other with their treating VA primary care physicians.

OBJECTIVE(S): The communication intervention had two goals: (a) coaching to enhance Veterans' abilities to communicate their questions and concerns about self-management for hypertension to their physician; and (b) improving physicians' communication skills for enhancing and encouraging self-management of hypertension.

METHODS: This study was conducted in the Richard L. Roudebush VA Medical Center's primary care clinics, where 75 clinicians provide care to over 20,000 Veterans during 66,000 annual visits. This study enrolled 10 VA primary care physicians to participate in the randomized-controlled trial and 30 Veterans (up to 3 Veterans from the panel of each of the 10 participating physicians) who had a prior stroke event and had evidence of hypertension within the last 12 months.

An initial set of baseline visits in the outpatient clinic were videotaped and transcribed. A few weeks after the baseline visit, providers assigned to the intervention group reviewed their videotaped clinical encounters with PI Richard Frankel and received "executive coaching" in the Four Habits model, with a special focus on agenda-setting. Around the same time, Veterans in the intervention group likewise received one-on-one coaching after the baseline visit with a patient educator about strategies they could use to discuss hypertension management with their providers during their next clinical visit. A second set of outpatient visits in the outpatient setting were then videotaped and transcribed for all providers and Veterans enrolled in the CHOICE study. For each provider-patient dyad, CHOICE investigators conducted qualitative data analysis by viewing the videotapes and transcripts of the visits to evaluate how discussions of hypertension management by providers and Veterans during the 2nd set of visits compared with their baseline visits. CHOICE staff also administered and compared results of the Patient Activation Measure to Veterans in the intervention and control groups.

FINDINGS/RESULTS: Inviting providers to watch themselves on videotape proved to be a powerful method for learning and professional development. None of the five providers in the intervention group said they had ever seen themselves on videotape before nor were they defensive when reviewing their individual videotapes during the coaching sessions. Providers consistently recognized opportunities for growth and improvement in agenda-setting on their own without prompting. All five providers were MDs with extremely busy schedules in the outpatient clinics yet, three of the five enthusiastically asked for extended and/or additional coaching sessions with PI Frankel.

To obtain the video recordings, multiple challenges needed to be met in addition to the traditional IRB, R&D committee, and informed consent requirements to protect human subjects. Providers were not always comfortable with the idea of being videotaped, and the CHOICE team had to respond to their concerns. The video recordings were made with a small, unattended videorecorder attached to a tripod propped in an inconspicuous corner of the room. CHOICE study staff had to coordinate closely with clinical staff to get access to the correct room just minutes before the start of the visit and then return to the room just minutes after the visit had concluded to retrieve the equipment. In successfully recording 33 separate clinic visits, the CHOICE study demonstrated the viability of this method within the busy outpatient clinical setting of the Roudebush VA.

The video recordings also led to the discovery of an emergent finding. In viewing them, CHOICE investigators unexpectedly noted specific, recurring patterns in the ways that providers and patients interacted that persisted across visits. CHOICE investigators now refer to this set of patterns as the "internal logic of the outpatient visit" because it transcended individual providers and patients and was often remarkably consistent across visits. Limited agenda setting by physicians turned out to be a particular challenge driven by this internal logic. Given the private nature of provider-patient encounters, CHOICE investigators realized how few people would ever be in a comparable position to note patterns across visits and providers. The CHOICE team plans to study this phenomenon in greater depth and report out on it in a separate analysis. The CHOICE study indicates that individual coaching with busy primary care physicians at the VA is feasible and can lead to discernible changes in physician communication in general and agenda-setting in particular. These findings come at a time when there is renewed interest in coaching for experts and professionals, including physicians.

IMPACT: Improved physician patient communication has been linked with positive functional and clinical outcomes. A one-hour professional coaching intervention based on the "Four Habits" Model produced measurable change in communication. The approach may have applicability to other aspects of communication between patients who have had a stroke and their primary care physicians. Conversations about quality of life, functional ability, and lifestyle change are three areas that could benefit from further coaching and training in the Four Habits Approach.

EDU 08-427:

Training and Coaching to Promote High Performance in VA Nursing Home Care

Abstract:

BACKGROUND/RATIONALE: The study explored the feasibility of an educational intervention to strengthen workplace-learning systems in four VA Community Living Centers (CLCs).

OBJECTIVE(S): Specific aims were to 1) conduct a feasibility study to assess whether the educational intervention is practical to implement as designed and 2) conduct a pilot study to validate the methodology proposed for assessing outcomes of this educational intervention.

METHODS: A multi-level intervention targeting the translation of workplace learning into practice was implemented. The Direct Care Worker (DCW) intervention targeted both clinical knowledge and effective communication. The Coaching Supervision training addressed management and supervision practices for nurses, combined with effective communication. Four CLCs received both interventions, administered by the Paraprofessional Health Institute (PHI), using a train-the-trainer approach over the course of four 3-day sessions. Quantitative and qualitative data were collected to assess factors influencing effectiveness of implementation and to understand the impact of the trainings on participants.

FINDINGS/RESULTS: Seven of eight trainers successfully completed the PHI training sessions. Trainers reported the PHI sessions were well run, informative, and valuable to their work. They also reported feeling confident in their abilities to deliver the training at their CLCs. Three sites implemented the Coaching Supervision training, and two sites implemented the DCW training. One site was unable to implement any of the trainings in their facility due to turnover in staff. Trainers reported receiving positive feedback about the training sessions from their CLC colleagues and the two facilities that implemented both trainings planned to spread the trainings outside of the CLC. Barriers to implementation included lack of appropriate buy-in from leadership, initial confusion about the content of the trainings, and lack of staff and time to complete the trainings. The modified Care Coordination Survey, which had a response rate of 12.5% and had been previously used in hospital settings, had Cronbach's alphas scale reliabilities between 0.65 to 0.93. This survey shows promise for use in the Long Term Care setting.

IMPACT: The project generated knowledge about the feasibility and effectiveness of a multilevel, contextualized training approach that has led to the submission of a larger grant proposal and has potential applicability to other settings in which DCWs provide care to veterans.

RRP 09-161:

Measuring and Improving Sustainability in Mental Health System Redesign

Abstract:

BACKGROUND/RATIONALE: Change that is not sustained is a direct waste of resources expended in the change process and also has important indirect costs related to missed opportunities and damage to an organization's ability to implement change in the future. In 2008, VA Mental Health Service Lines at the clinic, facility, and VISN levels embarked on an ambitious effort of system redesign (SR). With the help of special, centrally-directed funding for the support of IHI-based, state-of-the-art change implementation techniques, well over one hundred SR projects aimed at a variety of worthy MH goals have been implemented. However, it was less clear how the sustainability of these SR ventures was being measured or supported

over time. The project directly addressed a number of related implementation and clinical goals of the MH QUERI Strategic Plan.

OBJECTIVE(S): Our research project was designed to examine the issue of sustainability as it relates to the VA Mental Health Systems Redesign initiative. The project had three specific objectives:

- **1)** Describe the array of SR projects and their outcome measures that had been started in the first phase of the MHSR Project.
- **2)** Use the 10 item British National Health Service Sustainability Index (SI) of Maher, Gustafson, and Evans (Maher et al, 2004) to:
- (a) describe the variability in sustainability factors across VISNs and facilities;
- (b) describe the predictors of sustainability index scores for the various projects; and
- (c) predict outcome measures and their sustainability for individual projects. The model posits that sustained change is related to ten metrics that can be group as Process, Organization, and Staff factors, which are included in the sustainability index (SI); and
- **3)** Interview a random sample of SR team members, including VISN 2 and 12 leadership, facility-level leadership, and clinical and administrative staff to better understand the factors that facilitate and impede change and sustainability.

METHODS: This mixed methods approach using: (1) project and systems data, (2) survey data of the Sustainability Index, and (3) qualitative data from interviews of VISN 2 and 12 staff, identified facilitators and barriers to sustaining change in VA. This work tested the use of the SI to indicate need for interventions to improve sustainability that can provide a foundation for studies in both MH and non-MH VA change projects.

FINDINGS/RESULTS:

- 1)The MH SR Project resulted in a wide variety of efforts. Many were aimed at access, but others addressed additional topics including inpatient and residential flow, and implementing evidence based practices.
- 2)While the MHSR Project aimed at a homogeneous model for change, the participation of leadership and team members in learning collaboratives and coaching was variable. Also highly variable was the sustainability index outcomes signaling significant heterogeneity across VISNs and facilities in their approach to implementation and sustainability of change.
- 3)The differences across types of employees and their response to the SI reflects the possibility that different approaches are needed for supporting change in different employee groups.
- 4)Larger studies are needed to show that the sustainability index will predict outcomes in VA.
- 5)The variance across VISNs and facilities in the total score and sub-scores of the SI suggests an opportunity for intervention and improvement. The British National Health Service uses the index to select appropriate interventions tailored to the problems faced by a given facility or VISN. A study of this approach to helping facilities having problems with change is warranted.

IMPACT: This mixed methods approach using: (1) project and systems data, (2) survey data of the Sustainability Index, and (3) qualitative data from interviews of VISN 2 and 12 staff, identified facilitators and barriers to sustaining change in VA. This work tested the use of the SI to indicate need for interventions to improve sustainability that can provide a foundation for studies in both MH and non-MH VA change projects.

The degree of heterogeneity found in projects mostly aimed at relatively "simple" (albeit important) measures like access makes the study of sustainability in a more complex project such as mental health integration or the PACT program necessary and inviting. It seems likely that the variables measured by the sustainability index will be even more critical in these situations and we are embarking on a pilot study of that at this time after consulting with Dr. Kirchner.

VA leadership should consider use of sustainability measures in all future VA projects involving performance improvement-including but not limited to the Sustainability Index tested in this study. Sustainability is the last "S" in the VATAMMCS change model, but more efforts are necessary to define how the VA will measure and define sustainability. This study, as well as including measures in future studies could make progress in this direction. This work could also contribute to the design of a model of sustainability to be used in future teaching of the VATAMMCS model.

SHP 08-152:

Improving Self-Management Through Facilitated Patient Physician Communication

Abstract:

BACKGROUND/RATIONALE: Low health literacy and variable communication skills of physicians are serious barriers to self-management in adults with chronic illness. Our pilot study was designed to test the feasibility of two interventions: one focused on improving the ability of veterans with poor health literacy and/or self-management skills to communicate their questions and concerns about chronic disease to their physician; the other to help physicians communicate more effectively with veterans who have difficulty in self-management. This proposal is aligned with continuing efforts in the VA to increase patients' level of involvement in their care and overcome barriers to self-management. This is the first study of its kind in the VA to intervene with both members of the physician-patient dyad in an attempt to improve care processes and outcomes related to self-management.

OBJECTIVE(S): This project has four specific aims:

- 1.Test the feasibility of assessing and enrolling veterans with poor health literacy and/or challenges in self-management and physicians with variable communication skills to participate in the study;
- 2.Test the feasibility of a one-on-one consultation between study veterans and a health educator focusing on improved communication about self-management;
- 3. Simultaneously, test the feasibility of a physician-based communication enhancement intervention:
- 4.Use the pilot data to develop an IIR that will test the effectiveness of the interventions in a randomized clinical trial.

METHODS: This is a pre-implementation study of two separate interventions that have been shown to be effective but have not been studied in combination. The study will be conducted in the primary care clinics of the Richard L. Roudebush VA Medical Center. The participants are five physicians with varying communication skills and 15 patients with chronic disease who have low health literacy or evidence of difficulties in self-management. Study methods include health

literacy screening, self-management screening, video-taping of patient-physician interaction before and after the interventions, follow-up interviews regarding the barriers and facilitators of the interventions, and analysis of Time 1 and Time 2 differences in veterans' expression, and physicians' encouragement, of communication about self-management.

FINDINGS/RESULTS: The study has undergone several changes since its inception including: a shift in entry criteria to include challenges in self-management as well as low literacy, recruiting of study physicians with variable, rather than just poor communication skills, and adjustments to the interventions based on our experience. Approximately 200 patients were approached using a variety of recruitment methods and 9 were recruited and videotaped at least once (2 Time 2 visits are pending). We found that coaching physicians and patients in parallel skills, especially agenda setting (Habit 1), and comprehension of medical instructions (Habit 4) resulted in measurable time 2 changes. We conclude that a larger trial is both feasible and desirable.

IMPACT: The proposed study directly addresses a stated need to enhance self-management skills of veterans with chronic diseases. The interventions we tested could have a direct effect on veterans by reducing communication barriers associated with poor self-management. The results from this pilot study will lead to the development of a 3 arm randomized controlled trial (physician intervention only, patient intervention only, and both interventions together) to improve self-management through facilitated communication.

NRI 97-026:

Improving Cancer Pain Management Using AHCPR Cancer Pain Guidelines

Abstract:

BACKGROUND/RATIONALE: Cancer pain is a pervasive problem for the person with cancer. Despite advances in knowledge, effective cancer management is infrequently achieved. While this problem is multi-factorial, the patient may have attitudinal barriers to effective pain management that can be ameliorated with novel interventions.

OBJECTIVE(S): The primary objective of this study is to determine the effects of two nursing interventions on the improvement of pain management (PM), functional status (FS) and quality of life (QOL) in veterans receiving cancer care in VA ambulatory care clinics. The two interventions will utilize selected cancer pain management strategies developed as Clinical Practice Guidelines by the Agency for Health Care Policy and Research (AHCPR). This study will test the hypothesis that those veterans in the intervention arms will have lower pain intensity scores, greater pain relief and satisfaction with PM, and will have higher QOL and FS scores specifically in the areas of physical and social functioning. A secondary aim is to measure the extent that cancer PM is affected by the intervening variables of age, affect, attitudinal barriers, veteran culture, type/stage of disease, and type of cancer treatment.

METHODS: The design of this randomized trial has one between-subjects factor, GROUP, with three levels (usual care, structured education, individualized coaching), and one within-subjects factor, TIME, with two measures, pre-test and post-test. Patients with cancer pain (n=320) are randomly assigned to one of three groups after stratifications to control for the confounding

variables of pain intensity and effects of cancer treatment. Those in the structured education arm view a video on cancer pain management and receive the AHCPR patient pamphlet on cancer pain management. Those subjects in the individualized coaching arm receive the same structured education as above, but also partake in four telephone coaching sessions focusing on the individual's specific pain management problems. The primary outcome variables measured after 12 weeks are: satisfaction with pain management, quality of life and functional status.

FINDINGS/RESULTS: A convenience sample of 289 adults with pain related to cancer and/or its/treatment participated The sample was predominantly male (88%), veteran, middle-aged (mn=60.8 +/- 11.5 years), with a variety of cancer types; over 30% were receiving cancer therapy. Analysis of variance was used to assess the difference within the three groups in the amount of change in the dependent variables. Patients in the Coaching group demonstrated significantly less interference with function from pain than those in the other groups and improved more in vitality than the Education group participants. They also had less pain, and improved pain relief and emotional well-being, although these were not statistically significant.

IMPACT: Our study evaluated two interventions aimed at reducing the pain related to cancer. These interventions will improve the quality of life and functional ability of cancer patients experiencing pain from their disease. Our findings will provide guidelines and strategies for both advanced practice and staff nurses caring for veterans experiencing pain from their cancer.

Table 1: Funded HSR&D Research on Whole Health Coaching

| PROJECT NO: | TITLE: | PI: | FUNDING END: |
|------------------------------|--|-------------------------|-----------------|
| Pre- Funded | Path To Better Sleep + Virtual Coaching: The Effectiveness and Implementation of Internet-Based Self-Management Program for Insomnia in a Regional Healthcare System | Hermes, Eric | Pre-Funded |
| IIR 19-187 | Using Data Analytics and Targeted Whole Health Coaching to Reduce Frequent Utilization of Acute Care Among Homeless Veterans | Blonigen, Daniel | 12/31/2025 |
| IIR 20-240 | Pragmatic Obstructive Sleep Apnea Weight Loss Trial Assessing Effectiveness and Reach (POWER) | Donovan, Lucas | 9/30/2025 |
| <u>IIR 19-153</u> | CoachToFit: Adapted Weight Loss Intervention for Individuals with Serious Mental Illness | Chinman, Matthew | 9/30/2024 |
| IIR 19-031 | A Randomized Controlled Trial of Coaching into Care with VA-CRAFT to Promote Veteran Engagement in PTSD Care | Kuhn, Eric | 8/31/2024 |
| IIR 19-469 | Collaborative Specialty Care for Gulf War Illness | McAndrew, Lisa | 5/31/2024 |
| IIR 17-221 | Using Peer Navigators to Increase Access to VA and Community Resources for Veterans with Diabetes-Related Distress | Kunik, Mark | 10/31/2023 |
| IIR 14-063 | Vet COACH (Veteran peer Coaches Optimizing and Advancing Cardiac Health) | Nelson, Karin | 2/28/2023 |
| IIR 16-089 | Improving Access to Supported Employment for Veterans with Polytrauma/Traumatic Brain Injury | Pogoda, Terri | 9/30/2022 |
| IIR 15-362 | Implementation Trial of a Coaching Intervention to Increase the Use of Transradial PCI | Helfrich, Christian | 12/31/2021 |
| IIR 15-378 | Testing the Efficacy of a Technology-Assisted Intervention to Improve Weight Management of Obese Patients within Patient Aligned Care Teams at the VA | Jay, Melanie | 12/31/2021 |
| IIR 14-074 | Engaging Veterans and Family Supporters in PACT to Improve Diabetes Management | Rosland, Ann- Marie | 9/30/2021 |
| IIR 15-364 | DVD Lifestyle Intervention (D-ELITE) | Hoerster, Katherine | 6/30/2021 |
| CRE 12- 289 | Building an Optimal Hand Hygiene Bundle: A Mixed Methods Approach | Reisinger, Heather | 1/31/2021 |
| <u>CRE 12-</u> <u>288</u> | Will Veterans Engage in Prevention After HRA-Guided Shared Decision Making? | Oddone, Eugene | 12/31/2019 |
| CRE 12- 305 | Stay Strong: A Physical Activity Program for Afghanistan and Iraq Veterans | Damschroder, Laura | 9/30/2019 |
| IIR 14-070 | Evaluation of a Peer Coach-Led Intervention to Improve Pain Symptoms (ECLIPSE) | Matthias, Marianne | 9/30/2019 |
| PPO 16- 323 | Pilot Study of Standalone and Peer Supported Online Problem Solving Program in Veterans with Untreated Mental Health Problems | Carlson, Eve | 9/30/2019 |
| <u>CRE 12-</u> <u>306</u> | Risk Stratification and Tailoring of Prevention Programs | Maciejewski, Matthew | 3/31/2019 |

| IAB 05-303 | Proactive Tobacco Treatment for Diverse Veteran | Fu, Steven | 6/30/2012 |
|------------|--|------------------|-----------|
| | Smokers | | |
| RRP 09- | Motivational Interview Training in Weight Management | Rajan, Suparna | 1/31/2012 |
| <u>143</u> | for SCI Providers | | |
| RRP 09- | Controlling Hypertension Outcomes by Improved | Frankel, Richard | 9/30/2011 |
| <u>190</u> | Communication & Engagement (CHOICE) | | |
| EDU 08- | Training and Coaching to Promote High Performance | VanDeusen- | 3/31/2011 |
| <u>427</u> | in VA Nursing Home Care | Lukas, Carol | |
| RRP 09- | Measuring and Improving Sustainability in Mental | Krahn, Dean | 9/30/2010 |
| <u>161</u> | Health System Redesign | | |
| SHP 08- | Improving Self-Management Through Facilitated | Frankel, Richard | 5/31/2009 |
| <u>152</u> | Patient Physician Communication | | |
| NRI 97-026 | Improving Cancer Pain Management Using AHCPR | Douglas, | 9/30/2004 |
| | Cancer Pain Guidelines | Marilyn | |

Table 2. HSRD Funded QUERI Centers Focused on Veterans' Life Journey

| Center | Principal Investigators & Clinical Partners |
|--|--|
| Center for Evaluating Patient-Centered Care (EPCC-VA) | Principal Investigator: Barbara Bokhour, PhD Partner: VA's Office of Patient-Centered Care & Cultural Transformation |
| Complementary and Integrative Health Evaluation Center (CIHEC) | Principal Investigators: Stephanie Taylor, PhD; A. Rani Elwy, PhD; and Steve Zeliadt, PhD Partner: VA's Office of Patient-Centered Care & Cultural Transformation |
| Caregiver Support Partnered Evaluation Center (VA CARES) | Principal Investigator: Courtney Van Houtven, PhD Partners: VA Caregiver Support Program and the Office of Care Management and Social Work |
| Advance Care Planning via Group Visits (ACP-GV) QUERI | Principal Investigator: Monica Matthieu, PhD, LCSW Partner: VA's Diffusion of Excellence |
| Function QUERI | Principal Investigators: Susan Hastings, MD; Kelli Allen, PhD; Courtney Van Houtven, PhD; and Virginia Wang, PhD Partners: VA Physical Medicine and Rehabilitation Service, VA Office of Geriatrics and Extended Care, VA Caregiver Support Program, VA Office of Voluntary Services, VA Diffusion of Excellence, and VISN 6 (Mid-Atlantic Healthcare Network) |
| Implementing the Age-Friendly Health System in VHA QUERI | Principal Investigators: Robert Burke, MD, MS; Judith Long, MD; Rachel Werner, MD, PhD; and Daniel Hall, MD, MDiv, MHSc Partners: VA's Geriatrics and Extended Care National Office, National Surgical Program Office, and VISN 4 |
| Preferences Elicited and Respected for Seriously Ill Veterans through Enhanced Decision- Making (PERSIVED) QUERI | Principal Investigators: Cari Levy, MD, PhD; and Mary Ersek, PhD, RN Partners: VA National Center for Ethics in Healthcare, VA Office of Geriatrics and Extended Care, and VISNs 2, 4, 8, 10, and 19 |

Source: VA HSRD QUERI News. QUERI Highlights Implementation and Evaluation Science. March, 2021 Online. <u>Tailoring Care to Veterans' Life Journey (va.gov)</u>. Accessed March 5, 2022

Table 3. Peer Reviewed Publications Profiled According to PICOTS N=32

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|---|---|--|---|-----------------------------|---|
| Dusek JA, Kallenberg GA, Hughes RM, Storrow AB, Coyne CJ, Vago DR, Nielsen A, Karasz A, Kim RS, Surdam J, Segall T, McKee MD. Acupuncture in the emergency department for pain management: A BraveNet multi-center feasibility study. <i>Medicine</i> (Baltimore). 2022 Mar 4;101(9):e28961. doi: 10.1097/MD.00000000000028961. | Adults Presenting to a Recruiting Emergency Department (ED) with Acute Non-Emergent Pain (e.g., Musculoskeletal, Back, Pelvic, Noncardiac Chest, Abdominal, Flank or Head) of ≥4 on a 0-10- point Numeric Rating Scale. | Acupuncture for Pain Management | RCT Acupuncture vs Usual Care N=165 | Self-Assessed Pain and Anxiety Using the Numeric Rating Scale; Pain, Anxiety, Post-ED Opioid Use and Adverse Events at 1 and 4 Weeks. ED Providers and Staff Perspectives Related to Acupuncture in ED | May 2021- Ongoing | 3 BraveNet PBRN Site University Hospitals: Case Western Reserve University; Vanderbilt University Medical Center; University of California-San Diego. |
| Bokhour BG, Hyde J, Kligler B, et al. From patient outcomes to system change: Evaluating the impact of VHA's implementation of the Whole Health System of Care [published online ahead of print, 2022 Mar 4]. Health Serv Res. 2022;10.1111/1475-6773.13938. doi:10.1111/1475-6773.13938 | Veteran Patients at One of 18 Demonstration Site VA Facilities. | Whole Health System of Care | Observational Survey & EHR data No Comparators N=1712 | Use of Opioids Extracted From Electronic Health Record (EHR) Survey: Care Experiences, Care Engagement, Well- Being (PROMIS-10 and PSS Scale); Pain (PEG & DVPRS Scales) | Oct 2017- Mar 2019 | EHR- Based Cohort of 1,368,413 Patients; Longitudinal Survey of Veterans Receiving Care at 18 Whole Health Pilot Medical Centers. |
| Garland EL, Hanley AW, Nakamura Y, et al. Mindfulness-Oriented Recovery Enhancement vs Supportive Group Therapy for Cooccurring Opioid Misuse and Chronic Pain in Primary Care: A Randomized Clinical Trial [published online ahead of print, 2022 Feb 28]. <i>JAMA Intern Med.</i> 2022;e220033. doi:10.1001/jamainternmed.2022.0033 | Adults with Chronic Pain Receiving Long-Term Opioid Therapy Who Were Misusing Opioid Medications From Primary Care Clinics in Utah. | Mindfulness- Oriented Recovery Enhancement (MORE) Supportive Group (SG) Psychotherapy (Comparators) | RCT MORE vs SG N=121 | Opioid Misuse Assessed by the Drug Misuse Index (Self-Report, Interview, and Urine Screen); Pain Severity and Pain-Related Functional Interference (Brief Pain Inventory) Through 9 Months of Follow-Up; Secondary Outcomes: Opioid Dose, Emotional Distress, Ecological Momentary Assessments of Opioid Craving | Jan 2016- Oct 2020 | 6 University of Utah Primary Care Clinics Across the Salt Lake Valley. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|---|---|---|---|-------------------------------|--|
| Reed DE 2nd, Bokhour BG, Gaj L, et al. Whole Health Use and Interest Across Veterans With Co-Occurring Chronic Pain and PTSD: An Examination of the 18 VA Medical Center Flagship Sites. <i>Glob Adv Health Med</i> .2022;11: 21649561211065374. Published 2022 Feb 11. doi: 10.1177/21649561211065374 | Veterans with Co- Occurring Chronic Pain and PTSD Versus Those With Chronic Musculoskeletal Pain Only at One of 18 Demonstration Site VA Facilities. | Whole Health System of Care | Observational Co-Occurring Chronic Pain and PTSD Versus Those With Chronic Musculoskeleta I Pain Only No Comparators N=4170 | Use of Core Whole Health Services: Whole Health Coaching, Education; Use of CIH Services: Acupuncture, Massage, Yoga | 2017- 2019 | 18 VA Flagship Sites for Whole Health Implementation. |
| Parikh A, Moeller SJ, Garland EL. Simulated opioid choice linked to opioid use disorder severity among veterans with chronic pain: initial validation of a novel paradigm [published online ahead of print, 2022 Jan 31]. <i>Am J Drug Alcohol Abuse</i> . 2022;1-10. doi:10.1080/00952990.2021.2007258 | Veterans on Long Term Opioid Therapy (LTOT) for Chronic Pain. | Picture Viewing Choice Task of Opioid-Related Images | Viewing Standardized Peasant, Unpleasant, Neutral and Blank Images | Opioid Related Choice (Vigor of Button Pressing During Picture Viewing Task); OUD Severity (Number of DSM-5 Measured OUD Symptoms); Craving; Anhedonia | Sep 2016- Ongoing | A Veterans Affairs Hospital in Utah. |
| Kuruvilla DE, Lindsey H, Grinberg AS, et al. Complementary and integrative medicine perspectives among veteran patients and VHA healthcare providers for the treatment of headache disorders: a qualitative study. <i>BMC Complement Med Ther.</i> 2022;22(1):22. Published 2022 Jan 25. doi:10.1186/s12906-022-03511-6 | Veteran Patients Diagnosed with Headache. VA Clinical Providers Across 12 VHA Headache Centers of Excellence (HCoE). | Semi-Structured Interviews with Veteran Patients and Clinical Providers | Observational Interviews No Comparators | Veteran Patient Perceptions of Complementary and Integrative Medicine for Headache Management; Provider Perceptions of Complementary and Integrative Medicine for Headache Management | Jan 2019- March 2020 | 12 VHA HCoEs located within a Veterans Affairs Medical Center: Cleveland; Minneapolis; Palo Alto; Richmond; San Antonio; Tampa; West Haven; Birmingham; Orlando; Pittsburgh; Salt Lake City; Greater West LA. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|---|---|---|--|-----------------------------|---|
| Rodgers-Melnick SN, Lin L, Gam K, et al. Effects of Music Therapy on Quality of Life in Adults with Sickle Cell Disease (MUSIQOLS): A Mixed Methods Feasibility Study. <i>J Pain Res. 2022</i> ;15:71-91. Published 2022 Jan 11. doi:10.2147/JPR.S337390 | Adults with Sickle Cell Disease (SCD) who Fit the Criteria for SCD Chronic Pain. | 6-Sessions of Music Therapy (MT) Waitlist Control (WLC) | Mixed Methods MT vs WLC N=12 | Feasibility and Acceptability of Music Therapy; Self-Efficacy (SCSES); Quality of Life (PROMIS-29, ASCQ-Me); Coping Skills (CSQ-SCD) | Jun 2018- Jan 2019 | Large Hospital in the Midwestern United States. |
| Roberts RL, Ledermann K, Garland EL. Mindfulness-oriented recovery enhancement improves negative emotion regulation among opioid-treated chronic pain patients by increasing interoceptive awareness [published online ahead of print, 2021 Nov 14]. <i>J Psychosom Res.</i> 2021;152:110677.doi:10.1016/j.jpsychores.2021.110677 | Patients with Opioid- Treated Chronic (Non- Cancer) Pain who were Prescribed Long-Term Opioid Therapy (LTOT). | 8 Weeks of Mindfulness Oriented Recovery Enhancement (MORE) Support Group (SG) Therapy (Comparators). | RCT MORE vs SG N= 45 | Reappraisal; Self- Regulation; Emotional Distress; Interoceptive Awareness | Sep 2017- Oct 2020 | Primary Care and Pain Clinics in Salt Lake City, Utah, USA; Secondary Data Analysis of Stage 2 of MORE RCT. |
| Kutz A, Martinson A, Stratton K, et al. Examining the relationship between pain interference, pain intensity, and mental health symptoms among veterans receiving long-term opioid therapy for chronic noncancer pain in primary care. <i>J Opioid Manag.</i> 2021;17(4):289-299. doi:10.5055/jom.2021.0661 | Veterans with Chronic Non-Cancer Pain Receiving Opioid Therapy Being Managed in Primary Care and Enrolled in PC-POP. | Retrospective Cohort Study | Retrospective Cohort No Comparators | Self-Reported Symptoms of: Pain Intensity; Pain Interference; Anxiety; Depression; Substance Use; Quality of Life | Aug 2018- Apr 2019 | VA Salt Lake City Health Care System. |
| Dannecker EA, Royse LA, Vilceanu D, et al. Perspectives of patients with chronic pain about a pain science education video [published online ahead of print, 2021 Jun 7]. Physiother Theory Pract. 2021;1-12. doi:10.1080/09593 985.2021.1934920 | Adult Patients who Recently Attended a First Visit to a Chronic Pain Clinic. | Qualitative Interviews | Observational Interviews No Comparators N=15 | Patient Perceptions of Pain Science Education; Patient Responses to Pain Science Education | May 2018- Feb 2019 | Academic Health Center's Pain Management Clinic in Missouri. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|--|--|---|---|--|-----------------------------------|---|
| Pebole MM, VanVoorhees EE, Chaudhry N, et al. Patient-centered behavioral services for women veterans with mental health conditions. <i>Transl Behav Med</i> . 2021;11(9):1676-1681. doi:10.1093/tbm/ibab057 | Female Veterans using VA Mental Healthcare Services within a Comprehensive Women's Health Clinic. | Needs Assessment Survey | Cross- Sectional survey No Comparators N=107 | Patients' Needs and Preferences for Behavioral Health/ Whole Health- Focused Services | Nov 2018- Mar 2019 | Women's Health Clinic in Durham, North Carolina |
| Johnson RA, Albright DL, Marzolf JR, et al. Experiences of Military Veterans in a Therapeutic Horseback Riding Program. <i>Clin Nurs Res.</i> 2021;30(7):923-933. doi:10.1177/10547738211003580 | Veterans with a Confirmed Diagnosis of Post-Traumatic Stress Disorder, Traumatic Brain Injury or Both. | 6- Week Therapeutic Horseback Riding Program | Before/After No Comparators N=20 | Perceived Benefits, Drawbacks and Views of the Therapeutic Horseback Riding Intervention | 2017 | Two Midwestern Therapeutic Horseback Riding Centers. |
| Farmer MM, McGowan M, Yuan AH, Whitehead AM, Osawe U, Taylor SL. Complementary and Integrative Health Approaches Offered in the Veterans Health Administration: Results of a National Organizational Survey. <i>J Altern Complement Med</i> . 2021;27(S1):S124-S130. doi:10.1089/acm.2020.0395 | Complementary and Integrative Health (CIH) Program Leads at VA Medical Centers and Community-Based Outpatient Clinics. | Organizational Survey | Cross- Sectional Survey No Comparators N=289 | Aspects of Complementary Integrative Health Approach Implementation | Aug 2017 to Jul 2018 | National VA Organizational Study; Complementary Integrative Health Leads from 289 VA (Medical Centers and Community Outpatient Clinic) Sites. |
| Hudak J, Hanley AW, Marchand WR, Nakamura Y, Yabko B, Garland EL. Endogenous theta stimulation during meditation predicts reduced opioid dosing following treatment with Mindfulness-Oriented Recovery Enhancement Dec16;. <i>Neuropsychopharmacology</i> . 2021;46(4):836-843. doi:10.1038/s41386-020-00831-4 | Veteran Patients at VA Medical Centers Receiving Long Term Opioid Therapy (LTOT) with Chronic Non-Cancer Pain. | Mindfulness- Oriented Recovery Enhancement (MORE) Supportive Group (SG) Treatment (Psychotherapy Sessions) | Ancillary Mechanistic Sub-study Overlaid on a Clinical Ttrial MORE vs SG N=62 | Opioid Dose (Timeline Follow-Back); Self- Reported Changes in Self- Referential Processing (NADA-State and PBBS); Alpha and Theta Power and FMT Coherence. | Septem ber 2016- Ongoing | Salt Lake City VA Medical Center |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|---|---|--|--|---|--|
| Seal KH, Becker WC Murphy JL, et al. Whole Health Options and Pain Education (wHOPE): A Pragmatic Trial Comparing Whole Health Team vs Primary Care Group Education to Promote Nonpharmacological Strategies to Improve Pain, Functioning, and Quality of Life in Veterans-Rationale, Methods, and Implementation. <i>Pain Med</i> . 2020;21(Suppl 2):S91-S99. doi:10.1093/pm/pnaa366 | Veteran Patients at VA Medical Centers with Moderate to Severe Chronic Pain. | Whole Health (WH) Team Approach/ Primary Care Group Education (PC-GE) Usual VA Primary Care (UPC) (Comparators) | Pragmatic Explanatory Continuum Indicator Summary (PRECIS)-2 RCT WH/PC-GE vs UPC N=750 | Pain Severity/Interference; Quality of Life; Pain Catastrophizing; Pain Self- Efficacy; Changes in Pain. Sleep; Mental Health Measures: (Depression; Stress; Psychosocial Impacts; Anxiety; PTSD); Alcohol Use; Illicit Use of Substances; Treatment Satisfaction | Ongoing (Expect ed to be Complet ed in 2023) | San Francisco VA Health Care System (Data Coordinating Center); VA Connecticut Healthcare System; VA Portland Health Care System; James A. Haley Veterans Hospital (Florida); VA St. Louis Health Care System. |
| Fortuna KL, Brusilovskiy E, Snethen G, Brooks JM, Townley G, Salzer MS. Loneliness and its association with physical health conditions and psychiatric hospitalizations in people with serious mental illness. Soc Work Ment Health. 2020;18(5):571-585. doi:10.1080/15332985.2020.181019 7 | Adults with Serious Mental Illnesses Aged 18+ Years. | N/A Cross-Sectional Survey | Cross- Sectional Survey No Comparators | Loneliness; Psychiatric Hospitalizations; Physical Health Functioning; Mental Health Functioning; Bodily Pain (SF-12); Self- Reported Physical Health Conditions (Health Status Questionnaire) | 2013- 2018 | National Study (N=232); Regional Sample (from Philadelphia Area) (N=117). |
| Elwy AR, Taylor SL, Zhao S, et al. Participating in Complementary and Integrative Health Approaches Is Associated With Veterans' Patient-reported Outcomes Over Time. <i>Med Care</i> . 2020;58 Suppl 2 9S:S125-S132. doi:10.1097/MLR.0000000000000135 | Veteran Patients Participating in Any Type of CIH Approach at 2 VA Medical Centers. | Longitudinal Survey Study Assessing Impact of Complementary and Integrative Health (CIH) Services on Veteran Health Outcomes | No Comparators | Veterans' Overall Physical/Mental Health (PROMIS 28); Pain Intensity Perceived Stress (Perceived Stress Scale- 4); Care Engagement (Patient Activation Measure-13). | 2017- 2019 | 2 VA Medical Facilities in Geographically Distinct Areas of the United States. Both Facilities are Considered to be Early Adopters of CIH Treatment Approaches, and Both Serve Suburban and Urban Veterans. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|--|--|-----------------------------------|--|-------------------------|--|
| Purcell N, Becker WC, Zamora KA, et al. Tailored to Fit: How an Implementation Framework Can Support Pragmatic Pain Care Trial Adaptation for Diverse Veterans Affairs Clinical Settings. <i>Med Care</i> . 2020;58 Suppl 2 9S(Suppl 2 9 Suppl):S80-S87. | VA Leadership and Frontline Clinicians. Veteran Patients with Chronic Pain at Five VA wHOPE Enrollment Sites. | Formative Evaluation Study of Whole Health Roll-Out (via Telephone Interviews) | No Comparators | Feasibility and Acceptability of the Study Interventions; Facilitators of and Barriers to Implementing and Staffing Each Clinical Study Arm and Recruiting and Enrolling Veterans into the Study | 2018 | VA Health Care Systems in: Portland; San Francisco; St. Louis; Tampa; Connecticut; Little Rock (Back-Up Site). |
| Hudak J, Prince KC, Marchand WR, et al. The temporal dynamics of emotion dysregulation in prescription opioid misuse. Prog Neuropsychopharmacol Biol Psychiatry. 2021;104:110024. doi:10.1016/j.pnpbp.2020.110024 | Veterans with a Self- Reported Chronic Pain Condition on Long-Term Opioid Therapy (Opioid Analgesics). | Event-Related Emotion Regulation Task While ECG and GSR are Recorded | Observational No Comparators | Opioid Use (Self-Report Morphine Equivalent Daily Dose); Prescription Opioid Misuse Status; Pain Severity; Emotional Distress; Autonomic Responses | Sep 2016- Ongoing | Veterans' Health Care Administration Medical Center in the Intermountain West. |
| Marszalek D, Martinson A, Smith A, et al. Examining the Effect of a Whole Health Primary Care Pain Education and Opioid Monitoring Program on Implementation of VA/DoD-Recommended Guidelines for Long-term Opioid Therapy in a Primary Care Chronic Pain Population. <i>Pain Med</i> . 2020;21(10):2146-2153. doi:10.1093/pm/pnaa155 | Veterans with Chronic Non-Cancer Pain Receiving Opioid Therapy Consecutively for the Past Three Months in Primary Care. | Whole Health Primary Care Pain Education and Opioid Monitoring Program (PC- POP) | Observational No Comparators N=25 | UDS; Prescription Drug Monitoring Program Queries; Naloxone Education/Prescriptions; Number of Whole Health Consults; Completion of Informed Consent; Morphine Equivalent Daily Dose | 2018- 2019 | VHASLCHCS (Salt Lake City VA Health Care Center). |
| Martinson A, Kutz A, Marchand W, Carney J, Clinton-Lont J. Factors associated with participation and nonparticipation in a VA Whole Health Primary Care Pain Education and Opioid Monitoring Program (PC-POP). <i>J Opioid Manag</i> . 2020; 16(3):179-188. doi:10.5055/jom.2020.0566 | Veteran Patients at a VA Medical Center. | Whole Health Primary Care Pain Education and Opioid Monitoring Program (PC- POP) | Observational N= 325 | Participation in Whole Health Primary Care Pain Education and Opioid Management Monitoring Program (PC-POP); Physical/Mental Health Characteristics | 2018 (Est.) | VA Salt Lake City Health Care System. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|--|--|--|--|-----------------------------|---|
| Montgomery AD, Ottenbacher R. Battlefield Acupuncture for Chronic Pain Management in Patients on Long-Term Opioid Therapy. <i>Med Acupunct</i> . 2020;32(1):38-44. doi:10.1089/acu.2019.1382 | Veteran Patients at a VA Medical Center on Long Term Opioid Therapy for Chronic Pain. | Battle-Field Acupuncture | Before/After Treatment Study No Comparators N=23 | Pain Before and After Treatment (Numeric Rating Scale); Pain 3 Months Prior to Treatment (Numeric Rating Scale); Pain 6 Months Post- Treatment (Numeric Rating Scale); Average Opioid mg Equivalents 3 Months Prior and 6 Months Post- Treatment | 2017- 2018 | Veterans Who Had Attended the Fargo VA BFA Group Clinic. |
| Haun JN, Ballistrea LM, Melillo C, et al. A Mobile and Web-Based Self-Directed Complementary and Integrative Health Program for Veterans and Their Partners (Mission Reconnect): Protocol for a Mixed-Methods Randomized Controlled Trial. <i>JMIR Res Protoc</i> . 2019;8(5):e13666.doi:10.2196/1366 | Veteran and Partner Dyads. Veterans with Co-Morbid Pain and PTSD. | Behavioral Intervention "Mission Reconnect" | Mixed Methods RCT N=38 Dyads Waitlist Control | Intensity of Pain; Self-Report PTSD Symptoms; Self-Report Psychological Symptoms; Stress Levels; Social Outcomes for Veterans and Their Partners | Sep 2019- Ongoing | Ann Arbor, Puget Sound, and Tampa VA Facilities. |
| Boyd, Hallie BSN, RN, CRRN, BCTMB The Integrative Therapy Nurse: A Valuable Player in Symptom Management, AJN, American Journal of Nursing: November 2018 - Volume 118 - Issue 11 - p 64-69 doi:10.1097/01.NAJ.0000547679.76 699.49 | Veteran Patients at VA Medical Center with Chronic Pain and Spinal Cord Injuries or Disorders. | Massage Therapy (MT) Sessions | Before/After Treatment Study No Comparators | Pain Levels Before and After Each Massage Therapy (MT) Session (0- 10 Scale) | Feb 2014- Feb 2017 | Minneapolis VA Medical Center. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|--|--|---|---|-----------------------------|---|
| Barnhill JL, Roth IJ, Faurot KR, Honvoh GD, Lynch CE, Thompson KL, Gaylord SA. Cultural Transformation in Healthcare: How Well Does the Veterans Health Administration Vision for Whole Person Care Fit the Needs of Patients at an Academic Rehabilitation Center? Glob Adv Health Med. 2022 Mar 17;11:2164957X221082994. doi:10.1177/2164957X221082994. | Veteran Patients at VA Medical Center Seen by Physiatrists and Allied Health Staff. | Veterans' Health Administration's Personal Health Inventory (PHI) (N=30), AND "Taking Charge of My Life and Health" Whole Health Course (N=6) | Observational No Comparators | Responses to the PHI; Post-PHI Questionnaire; Course Evaluation; Post- Participation Focus Group; Group Attendance | 2020 (Est.) | A Large Public University Rehabilitation Clinic in North Carolina (UNC Chapel Hill). |
| Purcell N, Zamora K, Bertenthal D, Abadjian L, Tighe J, Seal KH. How VA Whole Health Coaching Can Impact Veterans' Health and Quality of Life: A Mixed-Methods Pilot Program Evaluation. <i>Glob Adv Health Med</i> . 2021 Mar 5;10:2164956 121998283. doi: 10.1177/2164 956121998283. | Veteran Participants in San Francisco VA's Whole Health Coaching Pilot Program. | Whole Health Coaching Program | Pilot Study Mixed- Methods Quality Improvement (QI) Study (Survey and Qualitative Interviews No Comparators | Veterans' Physical Health (PROMIS- 10, PHCS-2); Veterans' Mental Health (PROMIS-10, PSS-4, PHCS-2); Veterans' Quality of Life; Participants' Satisfaction with the Coaching Program | Before 2020 | A Large VA Healthcare System (San Francisco) Encompassing a: Medical Center, and Six Community- Based Clinics in Northern California. |
| Marchand WR, Beckstrom J, Nazarenko E, Sweeny RU, Herrmann T, Yocus MR, Romesser J, Roper J, Yabko B, Parker A. The Veterans Health Administration Whole Health Model of Care: Early Implementation and Utilization at a Large Healthcare System. <i>Mil Med.</i> 2020 Dec 30; 185(11-12):e2150-e2157. doi: 10.1093/milmed/usaa198. | Veteran Patients at One of 18 Demonstration Site VA Facilities who Received WH Services During the First 20 Months of WH Implementation. | Whole Health Model of Care | Retrospective Study No Comparators | Referrals to Whole Health Services (WHS); Initial Treatment Engagement; Continuity of Treatment Engagement | Mar 2018- Oct 2019 | A Large VA Healthcare System; Retrospective Medical Record Review. |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|--|---|---|---|--|-------------------------|--|
| Bouchery EE, Siegwarth AW, Natzke B, Lyons J, Miller R, Ireys HT, Brown JD, Argomaniz E, Doan R. Implementing a Whole Health Model in a Community Mental Health Center: Impact on Service Utilization and Expenditures. <i>Psychiatr Serv.</i> 2018 Oct 1;69(10):1075-1080. doi: 10.1176/appi.ps.201700450. | Medicare Clients at Kitsap Mental Health Services (KMHS) who Participated in the Race to Health! Program. | Race to Health! Program (Whole Health Intervention) | Matched Clients from Other Mental Health Facilities N= 2643 | Acute Care Services Use: Hospitalization Rates; Utilization of Emergency Department (ED) Services; Office Visits; Total Medicare Expenditures for Medicare Clients | Jun 2009-Jul 2015 | A Community Mental Health Center in Kitsap County, Washington; Medicare Claims and Enrollment Data. |
| Dryden EM, Bolton RE, Bokhour BG, Wu J, Dvorin K, Phillips L, Hyde JK. Leaning Into Whole Health: Sustaining System Transformation While Supporting Patients and Employees During COVID-19. Global advances in health and medicine. 2021 May 26; 10(21649561211021047):21649561 211021047. | VA Employees (Clinical and Non-Clinical); Whole Health System Leaders at 18 VA Medical Centers. | Qualitative Interviews with Whole Health Leaders | No Comparators N=61 | Whole Health Transformation and Use During the COVID-19 Pandemic | Ongoing | Eighteen Veterans Administration Medical Center (VAMCs) Whole Health Flagship Sites. |
| Abadi M, Richard B, Shamblen S, Drake C, Schweinhart A, Bokhour B, Bauer R, Rychener D. Achieving Whole Health: A Preliminary Study of TCMLH, a Group-Based Program Promoting Self-Care and Empowerment Among Veterans. Health Educ Behav. 2022 Apr;49(2):347-357. doi: 10.1177/10901981211011043. Epub 2021 May 21. PMID: 34018443. | Veteran Participants in the Taking Charge of My Life and Health Program. | Taking Charge of My Life and Health Whole Health Program | No Comparators N= 77 | Self-Care Attitudes and Behaviors; Patient Motivation; Meaning and Purpose; Mental Health; Perceived Stress; Goal Progress; Goal Specific Hope | 2018 (Est) | Four VA sites Implementing Taking Charge of My Life and Health Program from both the Midwest and East Coast. |
| Johnson EM, Possemato K, Khan S, Chinman M, Maisto SA. Engagement, experience, and satisfaction with peer-delivered whole health coaching for veterans with PTSD: A mixed methods process evaluation. <i>Psychological Services</i> . 2021 Feb 25. | Primary Care Veterans with PTSD. | Peer-Delivered Whole Health Coaching | Mixed Methods Concurrent Equal Status Design; Pilot study No Comparators N=15 | Retention in Peer- Delivered Whole Health Coaching, Factors Facilitating Engagement in Coaching Program, Peers Fidelity to Coaching Skills, Participant Satisfaction | 2018- 2019 | Syracuse VA Medical Center |

| Citation | Population | Intervention | Comparators | Outcomes | Time | Setting |
|---|---|--|--------------------------|--|-----------------------------|--|
| Wolfe HL, Fix GM, Bolton RE, Ruben MA, Bokhour BG. Development of observational rating scales for evaluating patient-centered communication within a whole health approach to care. Explore (New York, N.Y.). 2021 Nov | Primary Care Providers in the Veterans Health Administration. | 2.5 Day Whole Health Clinical Education Program | No Comparators N=8 | Quality Scores (0–4) used to Measure Number of Instances and Extent to Which Providers Explored What Matters Most to Patients; Dimensions of Whole Health; | Oct 2017- Mar 2020 | Geographically Diverse VA Medical Centers in Different Regions (Northeast, Mid- Atlantic, South, and Midwest) of the |
| 1; 17(6):491-497. | | | | Development of a Whole Health Plan Tailored to Patient's Goals | | United States. |