QUX 16-004, Learn, Engage, Act, Process (LEAP) for Personalized Weight Management Support (QUE 15-286)

NCT02825680

Study Protocol and Statistical Analysis Plan

September 15, 2020

This study was conducted as a pragmatic stepped-wedge clustered randomized controlled trial designed as a non-research quality improvement initiative primarily to improve the quality of preventive services in the VA as part of an ongoing partnership with the VA National Center for Health Promotion and Disease Prevention (see letter from Linda Kinsinger, MD, MPH; Chief Consultant for Preventive Medicine). Given the non-research quality improvement designation, this study did not have a protocol reviewed by an Institutional Review Board, but the following is an excerpt from the study proposal which was peer reviewed and approved for funding in June 2015 as part of a VA Quality Enhancement Research Initiative field program at the VA Ann Arbor Healthcare System (aka PROVE QUERI). This document provides an excerpt from the nationally reviewed proposal that describes the study aims, procedures, design, and analysis plan for this trial.

For more details on study design and analysis, please visit:
https://bookdown.org/revans_evans/leap_reach_analysis/

Excerpt from PROVE QUERI Program Proposal:

Project #2:
Learn. Engage. Act. Program (LEAP) for Personalized Weight Management Support

1.0 Specific Aims

Obesity and associated health conditions cause significant burden for Veterans, 78% of whom are overweight or obese. Treatment of overweight/obesity is a high priority for VHA as part of personalized, proactive, Veteran-driven care, outlined in the Blueprint for Excellence (BPE). The VA/DoD clinical practice guidelines (CPGs) for weight management recommend comprehensive lifestyle intervention (at least 12 sessions in 12 months) as the foundation of treatment for overweight/obesity.[139]

The MOVE!® weight management program was first disseminated in January 2006 through VHA's National Center for Health Promotion and Disease Prevention (NCP)[140] and is one of the largest scale integrated weight management programs in the world. Several evaluations of the MOVE! program have shown significant, though modest, weight loss for participants[141-143] and reduced incidence of diabetes.[144] This is laudable, given the challenges in losing weight that face this population.[141,142,145-147] Personalized coaching combined with high group cohesion among participants appear to consistently result in significantly longer engagement and higher weight loss.[141,148] NCP recently disseminated revised guidelines for in-person group delivery of MOVE! (hereafter, referred to as ***New MOVE!***), which is the cornerstone of the family of MOVE! weight management programs available to Veterans. *New MOVE!* has been redesigned to align with the new CPGs and formative findings from the VA Diabetes Prevention Program (DPP) Clinical Demonstration Project.[148] Implementation of *New MOVE!* is expected to increase Veteran engagement and outcomes through greater treatment intensity, stronger group cohesion, and a single consistent coach transitioning to a more personalized style of delivery using patient-centered coaching skills.

NCP has a long history of providing program support to local MOVE! teams tasked with delivering MOVE!, and now with implementing *New MOVE!*, through monthly phone calls, quarterly education sessions and *ad hoc* technical assistance. Despite this, local programs often do not align with CPGs; they vary widely in the number of sessions offered and other key characteristics,[101,149] often because of local organizational barriers.[100,101,150] Providing more intensive systems redesign and implementation support to help local teams mitigate these barriers will help increase fidelity to *New MOVE!*. Higher fidelity to *New MOVE!* will improve weight outcomes,[151,152] and a more effective program will help increase Veteran participation and continued engagement. This project will compare an enhanced form of NCP support plus the "Learn. Engage. Act. Program" (LEAP) versus enhanced NCP support alone.

Aim 1: To develop three core products to enhance NCP support to VAMCs and to pilot LEAP in three VAMCs.
H1: Dissemination of products to enhance NCP support will improve MOVE! outcomes.

Aim 2: To determine effectiveness of LEAP plus enhanced NCP support (LEAP+NCP) versus enhanced NCP support alone.
H2: VAMCs with LEAP+NCP will have better MOVE! group outcomes than VAMCs with enhanced NCP support alone.

Aim 3: To conduct formative and cost evaluations to refine design of LEAP and inform future scaling-up of LEAP.

2.0 Rationale

Since its inception in 2006, MOVE! has enjoyed relative success. However, the high burden of overweight/obesity in VHA creates an urgency to strive for greater improvements in MOVE! effectiveness with respect to system-wide outcomes and to decrease the high variation in MOVE! program characteristics and outcomes across VAMCs. VAMCs report high annual rates (95%)[143,153] of obesity screening and brief counseling,[153] which presents a key opportunity to engage Veteran who are candidates for MOVE!. Although VHA compares quite favorably in rates of individuals who initiate participation in a weight loss program – less than 6% initiate participation in weight loss programs in the general population,[154] while 10-12%[143] of MOVE! candidate Veterans do so – there is room for improvement.

Figure 4: Aggregate FY2014 MOVE! Group Visits per 100 Overweight/Obese Veterans Enrolled in Primary Care by VAMC

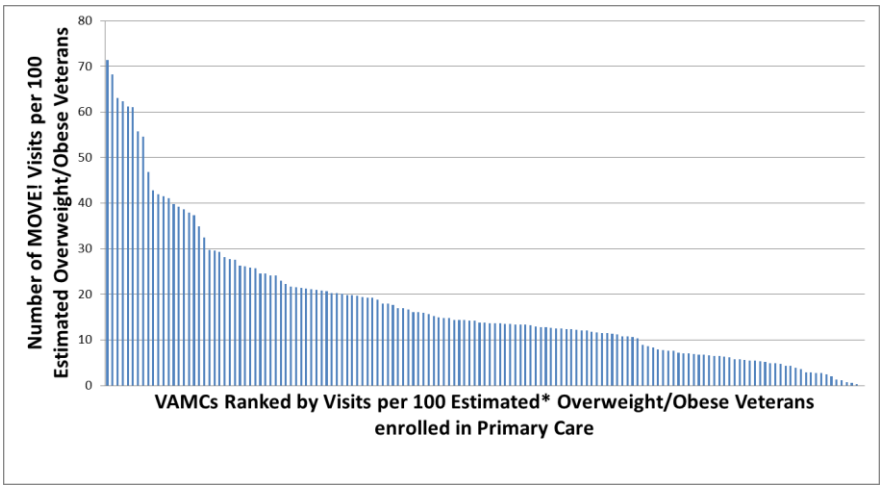


Figure 4 shows the wide variation in MOVE! group visit rates across VAMCs in FY2014. The highest-ranked VAMC reported more than 70 MOVE! group visits per 100 candidate Veterans. However, several VAMCs appear not to have a viable MOVE! group program, reporting fewer than 10 visits. One reason for high variation in aggregate visits may be variation in local organizational barriers. Our earlier work with three different lifestyle programs (MOVE!, TeleMOVE, and the Telephone Lifestyle Coaching (TLC) program) consistently revealed high variation in the presence of key organizational barriers, which affects viability of MOVE! group programming. In a recent NCP call with 79 MOVE! Coordinators, **99% expressed willingness to participate in a program aimed at providing more intensive support to implement *New MOVE!*. This dramatically high level of interest speaks to the strong need for additional support to assist with implementation.**

Our primary outcome of interest is the aggregate number of visits for MOVE! candidates who live within 40 miles of their VAMC. This outcome can be improved by increasing the number of participants who complete at least one session and/or increasing the number of sessions completed by each participant. Improved group cohesion, a stronger relationship with a consistent coach, more personalized coaching, and opportunities to attend more sessions should increase these numbers, which will lead to better weight outcomes.[155] Furthermore, engaging more Veterans in MOVE! will help VHA "transition from sick care to health care in the broadest sense" through more "personalized, proactive and patient-driven care that inspires Veterans to their highest possible level of health and well-being" (BPE Strategy 6).

3.0 Procedures

As described in our Implementation Core*, three core products will be developed in Year 1: 1) a Construct Assessment Tool; 2) a Barrier Busters Tool; and 3) a Program Intelligence Portal (Portal). These products will be made available online for use by MOVE! teams in all VHA facilities. Much of the work has already been done on the Construct Assessment and Barrier Busters Tools. Most of our tool development effort in the first year will be devoted to developing the Portal, which will draw on advanced methods for visually displaying data in a way that has meaning for local teams. For example, users might be interested in seeing geographic displays (e.g., choropleth maps) to visually display where MOVE! participants are coming from compared to non-participants, or longitudinal graphs of engagement and weight outcomes over time. In partnership with OABI, our team will develop a Portal for MOVE! that utilizes next-generation analytic and data visualization tools (e.g., Pyramid Analytics)[156] available through the VA eQuality Measures (eQM) platform. The Portal will be developed using principles of user-centered design that will help to ensure it truly meets the needs of local teams.[157-159] Each of the three products developed in the first year have been specifically chosen to address high-priority gaps. ***In fact, NCP is so eager to embrace these tools we are making them available online to all sites in Year 2*** and will evaluate their effectiveness via interrupted time-series analyses (described below).

Posting products online is likely to achieve only incremental benefits, because local or individual constraints will preclude accessing and using them effectively. Thus, LEAP will be employed to provide intensive support using methods that make it feasible for scaling up to all sites; in fact, we plan to randomize 48 sites (plus three pilot sites) through the course of the project (see Figure 5 below), with the remaining sites acting as controls.

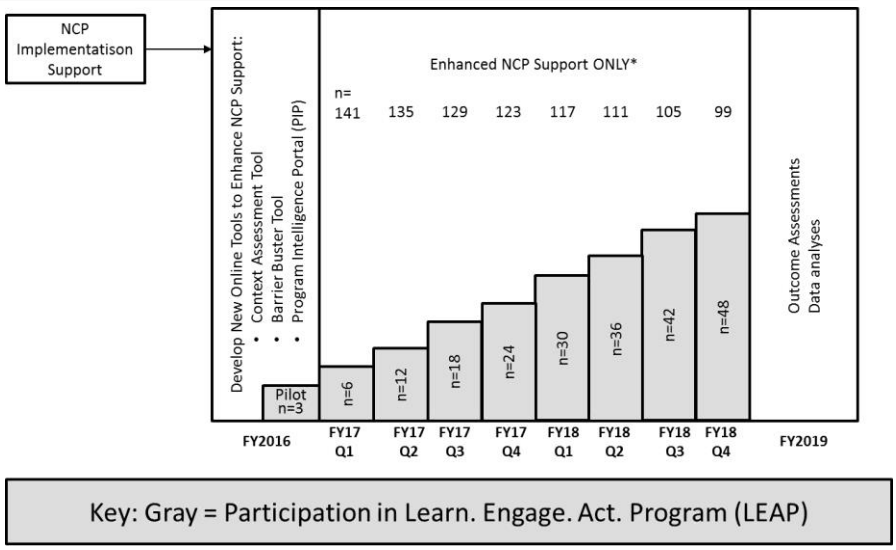
LEAP, as described in the Implementation Core, will be adapted to work with VAMC teams to implement *New MOVE!*. Findings from prior work with a quality collaborative revealed the importance of open communication, relationship building, methods training, monitoring performance, and facilitating team-

based problem-solving.[92] Three VAMCs, one from each performance tertile, will participate in a pilot of LEAP in Y1Q4. In Years 2-3, teams from six VAMCs will participate in LEAP each quarter as described below. When LEAP was described (including the level of commitment require) in a national call, hosted by NCP in May 2015 with all MOVE! coordinators, ***99% of 79 participants said "Yes" they would be willing to participate.***

3.1 Study Design

Our goal is to evaluate outcomes for all VAMCs nationwide. For Aim 1, because our NCP partners want to quickly disseminate the core products by posting them online and providing short orientations on national calls, we will use an interrupted time series analysis to assess primary, secondary, and tertiary outcomes before and after dissemination of the products among sites who do not participate in LEAP. Outcome assessments will rely on administrative data available through the Corporate Data Warehouse (CDW). Our team has extensive experience working with MOVE! program data and linking to other utilization and diagnosis data.[141,142,145-147]

Figure 5: Project Activities and Stepped-wedge Trial Design



For Aim 2, in years 2-3 we will randomly assign sites to LEAP, six sites at a time. At the beginning of each quarter, sites not included in the pilot and not randomized in previous quarters will be characterized by tertile of performance with respect to aggregate visits (our primary implementation outcome). Two sites will be randomly selected from each tertile of performance to initiate LEAP. Thus, each cohort of sites will comprise two high performing sites (a key "ingredient" for the LEAP sessions), two "learner sites" and two sites that have moderate performance. This will provide a forum where the more successful sites can "mentor" sites who are further behind. By the end of FY18, 48 sites will have participated in LEAP, plus three pilot sites in FY16. The final three months of follow-up for the last cohort will occur in FY19Q1.

3.2 Key Variables & Analyses

The primary outcome will be VAMC-level aggregated number of MOVE! visits accrued within a six-month analysis period among candidates for MOVE! who live within 40 miles of the VAMC: an implementation outcome with respect to reach.[160] The secondary outcome will be average percentage weight loss by patients at each VAMC at six months after a baseline MOVE! visit. Tertiary outcomes will include: 1) the proportion of patients who have at least 12 MOVE! visits within 12 months (a specified goal in the new CPGs); and 2) the proportion of patients who achieved at least 5% weight loss at six months.

For Aim 1, in addition to developing the three core products, we will evaluate their impact after they are disseminated to VAMCs in FY17 through interrupted time series analyses using administrative program data. Data prior to launch of these products (FY17 Q1) will provide "before" data. "After" data will come from sites not randomized to receive the more intensive intervention (see Aim 2) and up to the randomization time for sites randomized to LEAP. Analytic models will be similar to that of Aim 2, except the primary exposure variable will be an indicator for the period after dissemination of the three core products .

To determine effectiveness of LEAP (Aim 2), we will use a generalized linear mixed-effects model with visit counts and log link for primary outcome, percent weight loss for secondary outcome, and whether at least 12 visits in 12 months were made (1/0) and logit link for tertiary outcomes. Each model will include site as random intercepts and two indicators for tertiles as fixed effects. The primary exposure variable will be the binary time-dependent exposure variable indicating the intervention quarter for the site, i.e., a variable indicating the quarter at or beyond when the site is randomized to initiate LEAP. For each outcome, the

parameter estimate of this exposure variable will allow testing for the effectiveness of LEAP and summarize the LEAP effect expressed as rate ratio for primary outcome, difference in percent weight change for secondary outcome, and odds ratio for tertiary outcome. The model can include other variables (e.g., quarter and participant covariates).

Power considerations. Across all sites, there will be about 22,080 MOVE! participants (20 participants per closed MOVE! cohort X 1 cohort per quarter X 8 quarters X 147 sites, with 48 sites randomized in steps to LEAP and 99 not randomized). Our previous work showed an average of 4 visits during the 6 months of follow-up and 6% completing at least 8 visits.[142] We assume the minimum detectable and meaningful difference in rates during LEAP in comparison to the control period to be 7 vs. 5 visits (corresponding to a rate ratio of 1.4 and assuming a bit higher rate in control group than the number observed in the preliminary data due to implementation of tools across all sites) and percent of patients with at least 12 visits in 12 months as 10% vs. 7% (corresponding to an odds ratio of 1.48). For power considerations, the design assumes randomization of 6 sites (2 sites per tertile) to LEAP every quarter over 8 quarters starting at Q1 of FY17, and one unexposed quarter, while 3 sites are piloted (Q4 of FY16), no differential effect of LEAP across the tertiles, that 48 sites will be randomized to LEAP (rather than all VAMCs), and a within-site correlation of 0.1. The proposed design will have 99% power to detect the odds ratio of 1.4 or higher and 91% power to detect an odds ratio of 1.48 or higher with a two-sided 0.05 test.

For Aim 3, qualitative data from multiple sources will be collected, coded, and analyzed by our experienced team using documented rigorous approaches. An implementation-focused evaluation[161] will be conducted to understand implementation processes at local facilities and to refine the content and style of the LEAP sessions. Sessions will be audio recorded (with permission from the group) and transcribed. Information related to the ERIC strategies[83,91] used, CFIR constructs[75] mentioned as barriers or facilitators, and adaptations to *New MOVE!* will be coded and tracked along with themes related to processes and stories of implementation efforts – especially as they intersect with support through LEAP. A post-implementation interpretive evaluation[161] will be conducted based on qualitative data collected through telephone interviews with 5-10 stakeholders (including MOVE! coordinators, Health Promotion and Disease Prevention Manager, Health Behavior Coordinator, MOVE! physician champion, Director of Primary Care, possibly a Computer Applications Coordinator, and/or quality manager) at 12 sites, half of whom participated in LEAP and half of whom did not, in FY2018-19. We will also conduct site visits to 12 other sites during this same time period. Micro costing analyses will be conducted using time logs kept by LEAP workshop facilitators and estimates of time spent by local teams. We will use approaches documented in our cost evaluation of the VA DPP program.[162]

Key covariates. NCP will administer surveys at least twice (annually if allowed by VACO policy) to facility MOVE! coordinators that will include measures of context based on CFIR constructs, adaptations of *New MOVE!*, and program fidelity by eliciting key program characteristics (e.g., length). Additional covariates will include facility complexity, urban versus rural, participation in another concurrent study related to MOVE!, and proportions of Veterans in populations of interest, including but not limited to racial minorities, OEF/OIF Veterans, and women. Additionally, we will track VAMC team "engagement," e.g., through website metrics that will track use of the core products by user account, attendance at the LEAN workshops, etc.

4.0 Impact

Published evidence highlights that more sessions attended in evidence-based weight loss programs are strongly associated with more weight loss. By the end of the project, through incremental improvements expected by making the user-designed Portal available with the other enhancements to NCP support and even more significantly, through improvements expected in the 51 facilities participating in LEAP, we anticipate a 20% improvement in the aggregate visit rates for MOVE! group and a 10% improvement in weight outcomes. In addition, specifications for reporting data through the Portal will be given to OABI. Our methods for developing program metrics (user-based design) and the highly scalable LEAP approach to program implementation can be applied to programs other than MOVE!.

5.0 Partnerships/Management

Expertise and specific responsibilities of the team are detailed in the budget justification.

PI: Laura Damschroder, MS, MPH, Core Investigator, VA CCMR; Co-Implementation Research Coordinator, Diabetes QUERI.

Co-Investigator: David Goodrich, EdD, MA, MS, Implementation Facilitator, VA CCMR.

Co-Investigator: Teresa Damush, PhD, Core Investigator, Indianapolis HSR&D COIN; Implementation Research Coordinator, Stroke QUERI.

Co-Investigator: Tannaz Moin, MD, MSHS, Core Investigator, VA Greater Los Angeles HSR&D COIN.

Co-Investigator: Robin Masheb, PhD, Research Psychologist, VA CT Healthcare System.

Partnerships. We have worked closely with several leaders in **NCP** to develop this proposal and they have committed to supporting this project in many tangible ways as described in their Letter of Support. Likewise **OABI** is enthusiastic about this work because this project will provide an exemplar approach for utilizing user-centered design approaches to integrate the power of big datasets into local settings in a way that initiates action to improve care for Veterans; these are hallmarks of system learning, which is a high priority within the BPE. They have committed to orienting our team to newer and more sophisticated data analytics and visualization tools, to link additional data that may not already be available through eQM, and will provide expert feedback as the Portal develops. Our affiliated HSR&D COIN has a long partnership with **Primary Care** leaders, including Gordon Schectman, who has committed to encouraging primary care leaders in LEAP VAMCs to support members of the MOVE! implementation teams who may be members of the primary care clinic. Dr. Schectman will also help disseminate MOVE! outcomes in a way that encourages PACTs to more effectively motivate patients to initiate participation in MOVE!; a recent single-site study found that patients were more likely to initiate MOVE! when they felt heard by their providers and options were discussed.[163]

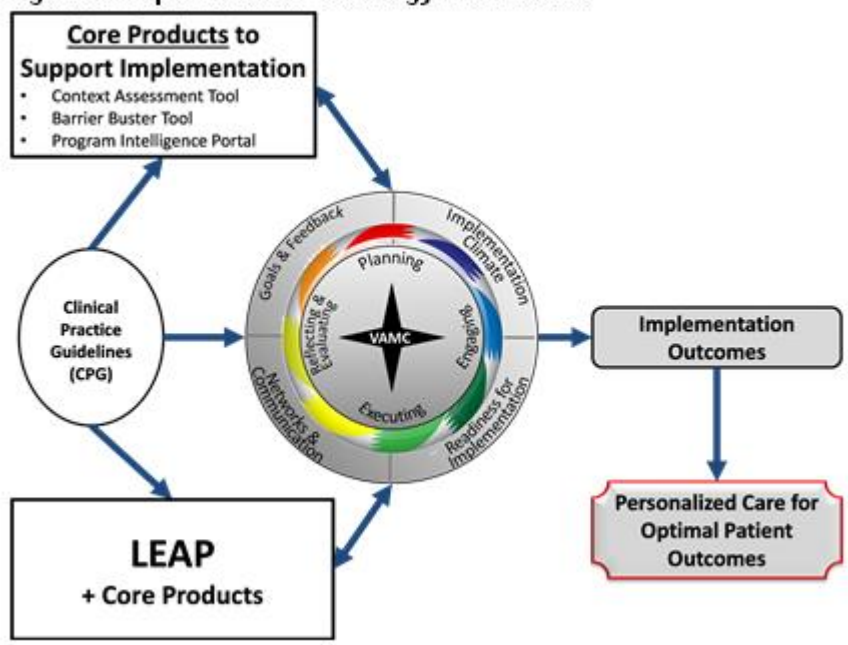
Support for project management, data management, and data analysis will come from QUERI core staff.

*Excerpt from proposal describing Implementation Core:

2.0 Implementation Strategy: LEAP (Learn. Engage. Act. Program) + Core Products

LEAP (Learn. Engage. Act. Program.) is the primary implementation strategy we are proposing to develop and use for the projects included in this proposal (with an abbreviated version being proposed for our QI project). LEAP, plus additional products we plant to develop, is depicted in Figure 2. Our implementation strategy begins with change triggered by new clinical practice guidelines (CPGs). We propose to support implementation of CPGs in local VAMC settings with our Core Products and LEAP. The embedded "wheels" at the center of the figure depict the interacting and mutually reinforcing role of high-priority CFIR constructs. The four key Process constructs (inner wheel) interact to overcome barriers related to constructs in the Inner Setting (outer wheel). LEAP will employ the "micro" strategies listed in Table 1 (next page) in a way that is tailored to the local Inner Setting. Teams at local sites will employ these strategies, guided by the Barrier Busters Tool (described below) and integrated with systems redesign approaches. We hypothesize that use of these strategies will lead to successful implementation of CPGs in VAMCs as reflected by improved implementation outcomes. Improved implementation will in turn lead to optimal patient outcomes – in the case of our PrOVE QUERI projects, these outcomes will be the more personalized care encapsulated by the CPGs.

Figure 2: Implementation Strategy Framework



2.1 LEAP

Quality collaboratives are often successful in helping local implementation teams identify and address barriers through systems redesign approaches. For example, the Stroke QUERI-led evaluation of a quality collaborative resulted in significant improvements in stroke care by improving fidelity of the care provided with CPGs.[92,93] However, the challenge with traditional collaboratives is that they are relatively resource-intensive, e.g., travel and time off for week-long kick-off meetings, site visits by expert facilitators, etc.[94] It is often infeasible to scale these resource-intensive programs within VHA with 150 VAMCs and 819 outlying clinics.

We have designed LEAP to overcome these issues by leveraging best practices in distance-learning, which has long wrestled with how to effectively engage participants in learning and hands-on program activities.[95] LEAP was conceived to provide intensive support using methods that make it feasible for scaling up to involve many sites. It is a multi-faceted implementation strategy that will involve an intensive distance learning series of workshops designed to engage local teams. LEAP will draw on the best of quality collaboratives[92,96] and meld these components with distance learning technologies to create a scalable yet intensive support system. LEAP will help teams navigate their local settings and mitigate barriers to implementing new initiatives (i.e., New MOVE! and shared decision making for lung cancer screening in projects 1 and 2) by building skills in open communication, developing productive working relationships, providing methods training and program monitoring, and building team-based problem-solving skills.

Table 1: LEAP Program Components & Strategies

Sessions	CFIR Construct Addressed[75]	Discrete Strategies & Tools
Pre- and overall	Planning Engaging	Capture and share local knowledge[91] TAMMCS: SIPOC Mapping Create a learning collaborative[91] Make training dynamic[91] Recruit, designate, and train for leadership[91] TAMMCS: Charter[97] Provide ongoing consultation[91]
1-5	Planning Engaging Self-efficacy	System Redesign (SR) improvement model[97] Develop a formal implementation blueprint[91] TAMMCS: SMART Aims, Charter[97] Assess for readiness; identify barriers and facilitators[91] ***Context Assessment Tool*** Audit and provide feedback[91] ***Program Intelligence Portal*** Promote adaptability[91] Tailor strategies[91] ***Barrier Busters Tool*** Promote network weaving[91]
6-10	Executing Reflecting & Evaluating	Conduct cyclical small tests of change[91] TAMMCS: Plan-Do-Study-Act (PDSA)[97] Capture and share local knowledge[91] Audit and provide feedback[91] Train the trainer strategies[91]

Table 1 shows a high-level overview of the LEAP series of workshops (Appendix A provides more detail): there will be 10 initial sessions followed by 2 follow-up sessions for technical assistance and problem-solving and one additional session of celebration when each site will present their accomplishments. Eight of the initial sessions will be preceded by a short interactive video (about 15 minutes) posted online and up to ½ hour of pre-work to complete. LEAP is unique in blending systems redesign approaches, through collaboration with VA's Center for Applied Systems Engineering (VA-CASE) and Dr. Teresa Damush from the Stroke QUERI, with implementation strategies as guided by the ERIC-CFIR mapping. For example, we would propose to use a PDSA approach (as part of the ERIC strategy to "Develop a formal implementation blueprint") to address the CFIR's "Planning" construct.

The initial sessions and pre-work will allow sites to incrementally implement changes while getting support and feedback from our team and from peer VAMC teams. In a systematic review of quality improvement (QI) curricula for clinicians, tailored coaching and time for experiential learning combined with audit and feedback were associated with more positive QI process outcomes.[98] A content expert (co-investigator from the respective projects), a facilitator from the Implementation Core, plus a VA-CASE systems redesign expert will participate in the sessions and serve as coaches. The content experts will provide training and answer questions on the clinical guidelines/interventions to be implemented; the VA-CASE coach will provide training in systems redesign and will offer process improvement support; and our implementation facilitator will help the teams with problem-solving and goal-setting.

LEAP aligns closely with VA's Blueprint for Excellence (BPE). Specifically, it will help promote a "positive culture of service" by providing tools and strategies to promote "an environment of continuous learning…" (BPE 5.2.b) and provide support and "training of front-line supervisors and managers" (5.2.c). In addition, as foundational developers of key scientific frameworks (CFIR and ERIC) and through our exceptionally productive, close working relationship with NCP and OABI, we will use this approach to "rapidly translate research findings and evidence-based treatment into clinical practice" (7.2.h, QUERI Strategic Plan). Finally, our collaboration with VA Center for Applied Systems Engineering (VA-CASE, described below) will help ensure effective skill-building and use of Lean system redesign techniques (BPE 2.2.e).

2.2 Core Products

In addition to LEAP, we will design certain core products to support implementation. The selection, development, and design of these core products will be guided by the CFIR and ERIC as well as "micro-theories" that underlie the broader implementation strategies (e.g., theories underpinning effective audit and feedback strategies[99]). Each of the three core products to be developed in the first year have been chosen to address high-priority gaps identified in our research. Specifically, members of our team have led seven implementation studies that all used the CFIR to assess contextual factors and their influence on implementation outcomes.[100] These studies revealed that the constructs depicted in the outer "wheel" shown in Figure 2 were associated with successful implementation.[100,101]

The first core product to be developed in Year 1 is a Context Assessment Tool, which can be administered multiple ways (e.g., self-administered, periodic survey) to identify the salient and high priority constructs at local sites. This information will be used to guide selection of ERIC strategies via the second product, the Barrier Busters Tool. This tool relies on a mapping of ERIC strategies to the CFIR constructs. This work is

currently underway by our team. An international panel of experts will complete the mapping this summer. A mock-up of the tool to be developed based on this mapping is posted on the CFIR website.

Our third tool, the Program Intelligence Portal (Portal), will use audit and feedback (A&F) to support the CFIR constructs, Reflecting and Evaluating (R&E) and Goals & Feedback. Using A&F to support R&E is particularly important in light of our unpublished Qualitative Comparative Analyses (QCA) of contextual factors across three lifestyle programs in VA (including MOVE!) that consistently point to R&E as necessary for successful implementation. Yet many sites do not have a process for R&E, primarily due to lack of access to program data provided in an understandable way, and lack of skills in using program information strategically for successful implementation. A&F strategies can help mitigate this gap.[102]

We plan to employ principles of user-centered design to develop the Portal, which are based on the desire to understand users' needs. Our goal in the Implementation Core is to develop products that are intuitive and meet the specific needs of users by incorporating user feedback into every step of development process. We will obtain feedback from the users we seek to engage regarding their needs, preferences, and abilities. Once the potential users in the proposed projects have been interviewed regarding their information requirements, the appropriate visual structures can be selected for mapping the data to meet these needs. For example, are data needed to identify clusters, a hierarchy, or a network of relationships? After the appropriate visual structures for this information have been determined, alternative data visualization techniques will be considered and reviewed with users for consideration,[103] along with design elements such as content, color, and layout.

Letter of Support from Linda S. Kinsinger, MD, MPH, Chief Consultant for Preventive Medicine, VA National Center for Health Promotion and Disease Prevention, dated May 26, 2015 describing that this project is quality improvement and not research:

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Office of Patient Care Services (10P4)
National Center for Health Promotion and Disease Prevention (10P4N)
3022 Croasdaile Dr. Suite 200
Durham, NC 27705

In Reply Refer To: 10P4N

May 26, 2015

Amy Kilbourne
Director, QUERI Program
VA Health Services Research and Development
Washington, DC 20002

Dear Dr. Kilbourne:

As the Chief Consultant for Preventive Medicine, I am writing to express my enthusiastic support for the proposed QUERI program, PeRsonalizing Options for Veteran Engagement (PrOVE). The aims of this QUERI are very closely aligned with the goals of VA's National Center for Health Promotion and Disease Prevention (NCP).

NCP has been a primary partner of the Diabetes QUERI for the nearly 10 years. Diabetes QUERI researchers helped us to evaluate and enhance our efforts to implement and improve MOVE!® and TeleMOVE!. One of the largest Diabetes QUERI projects conducted, the VA Diabetes Prevention Program Clinical Demonstration Project and Implementation Evaluation (VA DPP), was initiated at the request of NCP. We funded the clinical demonstration, and the evaluation was funded by a QUERI RRP and SDP. Furthermore, during the past year, we disseminated a redesigned MOVE! program (http://www.move.va.gov/GrpSessions.asp), which includes several features informed by work conducted by Diabetes QUERI investigators.

Given our productive track record partnering together already, I am especially excited about the opportunity to continue working with this enthusiastic and talented group of investigators and staff. We hope to continue to advance our efforts to further improve MOVE!, and we look forward to working with them on new initiatives. One of those new initiatives is the lung cancer screening shared decision making (SDM) project (Angie Fagerlin, PI) that is being proposed. NCP has been responsible for overseeing the lung cancer screening demonstration project across 8 different VAMCs. A requirement of offering lung cancer screening to patients in VAMCs is that there be a discussion with patients to help them make the decision about whether they wish to be screened. Currently each site participating in the demonstration project determines its own process for how to conduct this discussion.

Dr. Tanner Caverly approached us over a year and a half ago about developing a decision aid to help personalize lung cancer screening decisions and enhance shared decision making. Since then I have been in regular contact with Dr. Caverly as he developed and tested his decision support tool, and more recently as we have discussed how best to implement it in the eight screening demonstration sites. This tool has the potential to be of tremendous benefit to providers as they discuss lung cancer screening options with their patients. Nevertheless, I realize it may be challenging to implement, given various organizational barriers. I am very much looking forward to seeing if the implementation strategy proposed by the PrOVE QUERI can facilitate implementation and use of the tool as part of the screening guidelines. As the office responsible for overseeing the lung cancer screening demonstration project, we have already informed the sites that we support the use of this tool and encourage their

participation in this project. If the tool proves to be successful, we will include it as part of the lung cancer screening guidelines to be disseminated throughout VHA.

And of course I am very interested in the MOVE! project (Laura Damschroder, PI) that is proposed. My staff and I have been meeting frequently (monthly or more often) with Ms. Damschroder and her team this year to discuss how the Diabetes QUERI (and now the PrOVE QUERI) can best support us in our efforts to improve MOVE!, and then more recently to figure out the specific design of the project included in this proposal. We are very excited with the proposed project and intend to continue to be closely engaged in this effort. In particular, we will:

1) Provide feedback and input as the PrOVE team develops the three core products that will be integrated into "enhanced NCP support:" a context assessment tool, a barrier busters tool, and a program intelligence portal.
2) Provide "enhanced NCP support" to the field (as described in the proposal) by leveraging the three core products to be available online – in fact we were so enthusiastic about these products, we strongly encouraged the team to make them available to everyone.
3) Administer a survey to VAMCs at least twice and possibly annually to collect information about local MOVE! programs and high-priority contextual factors. We understand this data is important for the insights needed to evaluate our implementation strategies and to understand the factors associated with successful MOVE! outcomes. We will work with the PrOVE team to design the survey to ensure it includes the measures needed while ensuring it is as streamlined as possible.
4) Encourage sites randomized to LEAP to engage fully in the program.

For both the lung cancer screening SDM project and the MOVE! project, we will randomize the sites as proposed in the respective projects. This letter also confirms that the primary purpose of both projects is to conduct operations evaluations designed to inform quality improvement efforts as part of the ongoing collaboration between NCP and the previous Diabetes QUERI (now the PrOVE QUERI). The projects support internal evaluation efforts to understand and assess the implementation of lung cancer screening guidelines and the updated MOVE! guidelines. Both projects will involve use of secondary and primary VA data collected for evaluation purposes using assessments that are part of routine care. These projects are designed and will be implemented for internal VA purposes, to better inform NCP in our efforts to improve the quality of preventive services in VA. Thus, these efforts are deemed as quality improvement and not research. Any proposed data collection that is not needed for the purposes of this internal evaluation will be submitted for IRB review and approval.

For the past several years, Dr. Michael Goldstein, Associate Chief Consultant for Preventive Medicine, and I have been active members of the Diabetes QUERI Executive Committee. We're very committed to the QUERI model and strongly believe it provides great value to VHA and to the country's healthcare systems overall. We look forward to continuing our productive partnership with the PrOVE QUERI. Dr. Goldstein will serve as a member of the Advisory Committee of the new QUERI. We heartily endorse this application and encourage the selection committee to give it its highest consideration.

Sincerely,

Linda S. Kinsinger

Linda S. Kinsinger, MD, MPH
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