STUDY PROTOCOL

Risk Stratified Enhancements to Clinical Care: Targeting Care for Patients Identified Through Predictive Modeling as Being at High Risk for Suicide, with the Office of Mental Health Operations

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List of Abbreviations

CDW:	Corporate Data Warehouse
CeMHOR:	Center for Mental Healthcare and Outcomes Research
EBP:	Evidence-based practices
FY:	Fiscal year
i-PARIHS:	Integrated Promoting Action on Research Implementation in Health Services
MAX:	Medicaid Analytic eXtract
MIRECC:	Mental Illness Recovery Education Clinical Center
NDI:	National Death Index
OMHO:	Office of Mental Health Operations
OSP:	Office of Suicide Prevention
PEPReC:	Partnered Evidence-Based Policy Resource Center
PERC:	Program Evaluation Resource Center
QUERI:	Quality Enhancement Research Initiative
RCT:	Randomized controlled trial
REACH VET:	Recovery Engagement and Coordination for Health – Veterans Enhanced treatment
RE-AIM:	Reach, effectiveness, adoption, implementation, and maintenance
RQA:	Rapid Qualitative Analysis
SDR:	Service directed research
SMITREC:	Serious Mental Illness Treatment Resource and Evaluation Center
SPAN:	Suicide Prevention Applications Network
SPC:	Suicide Prevention Coordinator
VA:	Department of Veterans Affairs
VHA:	Veterans Health Administration
VISN:	Veteran Integrated Service Network

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EVALUATION OBJECTIVES

Suicide prevention is a top priority for the Department of Veterans Affairs (VA) and the Veterans Health Administration (VHA). To improve suicide prevention, it is important to identify people as early as possible. One innovative approach recently validated in VHA is the use of predictive modeling and electronic medical record data that identifies Veterans at risk and thus facilitates implementation of targeted prevention[1]. The VHA predictive model has identified the top 5% of VHA patients who were at the highest predicted risk for suicide. These Veterans accounted for approximately 24% of all the suicide deaths, 37% of all reported suicide attempts, and 31% of inpatient psychiatric hospitalizations observed in VHA over the course of one year[1,2]. The model also allowed examination of different risk strata (e.g., the top 0.1%, 1%, or 2%).

Veterans in the highest 0.01% of the risk stratum had suicide rates 82 times greater than the rest of the sample in a development model. The benefits of the model were retained in a validation sample; Veterans in the same risk stratum had suicide rates that were 60 times higher than the population. This model provides new information about who is at risk; fewer than 2% of the 5% of patients identified as high risk received clinical flags for being at risk in the previous 12 months.

For those identified as high risk, VHA's Office of Mental Health and Suicide Prevention developed a national suicide prevention outreach program entitled Recovery Engagement and Coordination for Health – Veterans Enhanced Treatment (REACH VET). REACH VET utilizes a dashboard to provide the names of patients identified by the model monthly to coordinators at each VA medical facility. REACH VET coordinators are responsible for notifying providers of the patient's status and prompting providers to re-evaluate care and take appropriate clinical steps if they are not already occurring (e.g., contacting the patient to re-engage in care, discussing potential changes in care with the patient).

To further strengthen REACH VET, treatment recommendations and/or augmentations are suggested. One recommendation is Caring Letters, an effective, low-cost suicide prevention intervention. Caring Letters involves the sending of recurring brief notes to patients at high risk expressing care and concern. It is one of the only psychosocial suicide prevention interventions that have reduced suicide mortality rates in a randomized controlled trial[3–7]. Despite positive results, Caring Letters have yet to become routine care – primarily because it requires considerable tracking to send letters. If these issues can be addressed, it is an ideal intervention to scale up for a large empirically defined high risk group.

REACH VET is currently being implemented in VHA. Additional implementation assistance in the form of virtual external facilitation, an evidence-based implementation strategy, will be offered to sites having difficulty implementing. VISNs will have the opportunity to receive facilitation for at least 4 of their facilities having difficulty implementing REACH VET; the REACH VET Program Manager will discuss this with VISN leadership, who will decide if they want to participate in facilitation. Participating VISNs will be randomized to when their VISN will receive facilitation.

The VA Serious Mental Illness Treatment, Resource, and Evaluation Center (SMITREC) and Partnered Evidence-Based Policy Resource Center (PEPReC) are conducting a summative evaluation of REACH VET's impact on Veteran outcomes using VHA databases. The current study extends the breadth and depth of their evaluation with these specific aims.

Specific Aim 1: Evaluate the impact of virtual external facilitation versus standard implementation.

> **Specific Aim 1a:** Conduct a formative evaluation to identify barriers and facilitators to implementation to define and refine the virtual external facilitation strategy.
>
> **Specific Aim 1b:** Conduct a summative evaluation of virtual external facilitation versus standard implementation.

Specific Aim 1c: Collect the costs of the REACH VET and Caring Letter interventions and of the virtual external facilitation strategy for subsequent analysis of potential cost effectiveness.

Specific Aim 2: Develop and evaluate the augmentation of REACH VET using Caring Letters, an evidence-based suicide prevention intervention.

Specific Aim 2a: Conduct a formative evaluation of the augmentation of REACH VET with Caring Letters.

Specific Aim 2b: Refine the Caring Letter intervention for scale up to the VHA-wide REACH VET program.

BACKGROUND/CONTEXT

Veteran suicide rates remain high despite improvements to mental health services and suicide prevention programs.

Despite work done to strengthen VHA mental health services and suicide prevention, suicide rates in VHA have been stable[8]. These rates stand in contrast to increasing rates in other Americans, especially middle-aged men[9,10] and in Veterans who do not utilize VHA services[11,12], suggesting that VHA programs may have mitigated expected increases. Nevertheless, the finding that suicide rates in VHA remain high represents a strong call for action. Novel approaches that reduce the incidence of suicide-related events are needed earlier, ideally before suicide-related behaviors occur.

Predictive models improve identification of patients at risk for suicide.

While there is agreement about the risk and protective factors for suicide that should be assessed[13], research that has examined clinicians' ability to predict suicide has consistently reported poor results[14–16]. Despite the difficulty in predicting risk, there is little information about multivariable models that clinicians can use to aid in decision-making[17]. To improve identification of those at risk, a number of big data initiatives have been developed to create predictive models that use information from medical and administrative records to identify patients at risk for suicide. Reports from these initiatives have shown that predictive modeling can identify patients at risk[18], and that predictive modeling may be more accurate than clinical evaluation[19].

The VHA recently developed and validated a strong predictive model[2]. The model utilized clinical data from an archival VHA data set that contains comprehensive patient-by-patient, encounter-by-encounter clinical and administrative data derived from VA's electronic medical record. Data regarding vital status and cause of death were obtained from the National Death Index, a centralized national database of death record information on file in state vital statistics offices[2]. The model allowed for identification of the top 5% of VHA patients who were at the highest predicted risk for suicide and who accounted for approximately 24% of all the suicide deaths, 37% of all reported suicide attempts, and 31% of the inpatient psychiatric hospitalizations observed in VHA over the course of one year[1,2]. The model also allowed examination of different risk strata (e.g., the top 0.1%, 1%, or 2%).

Veterans in the highest 0.01% of the risk stratum had suicide rates 82 times greater than the rest of the sample in a development model. The benefits of the model were retained in a validation sample; Veterans in the same risk stratum had suicide rates that were 60 times higher than the population. When the risk stratum was adjusted to focus slightly more broadly on the highest 0.10% of the risk, Veteran suicide rates were 30 times higher than the population in a validation sample. These models provide new information about VHA patients at risk; fewer than 2% of the 5% of patients at high risk for suicide had received clinical flags for being at risk in the previous 12 months.

Additional work is needed to move predictive modeling into the field to inform care.

While predictive models allow for identification of those at risk for suicide, additional tools are needed to provide this information to the appropriate providers along with recommendations for how to use this information about patient risk. Developers of the VA predictive model noted that if development of a model "proved feasible, the next steps would be for the health care system to develop methods for informing providers about which of their patients are at high risk and for enhancing care[2]."

VHA developed REACH VET to provide risk information and suggest care enhancements to providers.

VHA developed a suicide prevention outreach program that utilizes the predictive model, entitled Recovery Engagement and Coordination for Health – Veterans Enhanced Treatment or REACH VET. REACH VET coordinators at each facility are responsible for monitoring the REACH VET dashboard that both identifies those at high risk and identifies and tracks next steps for coordinators and providers. Following identification of patients at risk, coordinators notify each patient's provider of their high-risk status and orient the provider to the dashboard. Providers are required to re-evaluate the patient's care, determine if care enhancements are needed (e.g., re-engaging the patient in care, creating a safety plan), and contact the patient. REACH VET includes use of the predictive model to identify high-risk patients, use of the dashboard by coordinators and providers, re-evaluation of care, and outreach.

Caring Letters is an efficacious suicide prevention approach that is extremely well suited for a targeted, empirically defined, high-risk population.

While REACH VET is directly tied to the predictive model and brings needed information to the provider so they can reach out to the right patients before they harm themselves, it involves standard VHA services which are not all specifically for suicide prevention. Thus, it is critical to augment REACH VET with a scalable suicide-specific evidence-based practice. Caring Letters is one of the only suicide prevention interventions that have reduced suicide mortality rates in a randomized controlled trial (RCT). It is a psychosocial intervention that involves sending recurring brief notes of care and concern to high-risk patients. The concept was developed over 40 years ago and has been tested through a variety of delivery modalities (e.g., standard mail, email, SMS texting). Caring Letters were sent to patients 1, 2, 3, 4, 6, 8, 10, and 12 months after contact with services in the model that was used successfully in previous research studies[3]. Eight original studies, two follow-up studies, and one secondary analysis have been conducted on a variety of Caring Letter models[3–7,20–22]. Two RCTs demonstrated decreased suicide rates after Caring Letters were sent by mail or telephone. Three studies showed a statistically significant reduction in repeat suicide attempts. An additional six studies, including a follow-up study and a study reporting secondary analyses, showed mixed or non-conclusive results but also showed trends toward a preventative effect. Two studies did not show preventative effects for the follow-up interventions; however one [23] did not using an intent to treat analysis because they could not reach a lot of people and the other[21] ended the study early and were then underpowered.

Caring Letters are effective, non-invasive, low risk, and inexpensive. Despite positive results in multiple clinical trials, Caring Letters have yet to become routine care – primarily because it requires considerable tracking to send letters. However, if these issues are addressed, it is an ideal intervention to scale up for a large empirically defined high risk group. It is the ideal intervention to test with a large-scale empirically defined high-risk group, such as those identified by the predictive model.

VHA is now implementing REACH VET nationally.

Two memoranda were sent to VA Network Directors and VISN Mental Health Leads to first inform them about the REACH VET program and direct them to identify a REACH VET coordinator and then to provide additional information and dates of the implementation. OMHSP is funding the staffing and

resources for intervention development and implementation of REACH VET. The evaluation team was included during the planning grant to develop an evaluation plan that matched the intervention and implementation plan, as well as to offer input on the type of implementation plan that would facilitate randomized program evaluation.

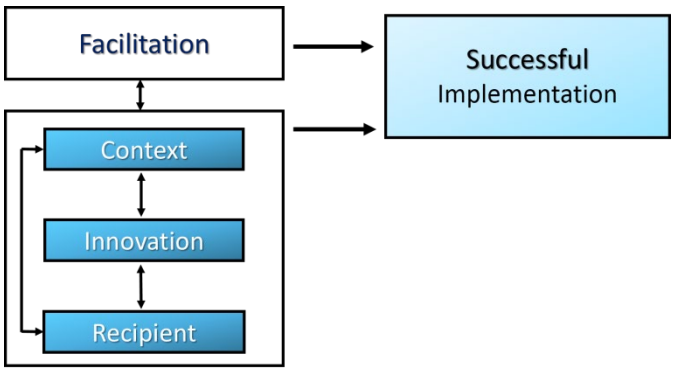
Facilitation is an evidence-based implementation strategy to support sites that have difficulty implementing innovative programs.

Implementation facilitation is a multi-faceted "process of interactive problem solving and support that occurs in the context of a recognized need for improvement and a supportive interpersonal relationship[24]." Facilitation has been used nationally across VHA to implement a number of different clinical interventions. In fact, facilitation has been further developed as a strategy through partnerships between VHA researchers and VHA operational partners[25]. Virtual external facilitation has been used nationally in VA to implement a low complexity intervention where a provider utilized a patient registry to contact patients lost to care[26]. The current project will examine this minimally intensive version of implementation facilitation, virtual external facilitation, with a moderately complex innovation targeting a high-risk clinical population.

Conceptual Models

The implementation approach has been guided by the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS)[27] framework. The i-PARIHS framework proposes that successful implementation of evidence-based practices (EBPs) is the result of the facilitation of an innovation with recipients in the inner and outer context. Facilitation is the active ingredient with designated facilitators activating implementation by assessing and responding to the characteristics of the recipients of the innovation within their own settings. See Figure 1.

Figure 1. Graphical representation of iPARIHS framework.



According to i-PARIHS, the innovation is the focus of implementation (e.g., REACH VET). The construct of innovation includes characteristics of the innovation (e.g., relative advantage, usability, and trialability[28–30]) and the evidence related to the innovation. Evidence includes more than research evidence; it includes information obtained from clinical experience and patient preferences or experience[27,31].

The construct of recipients focuses on the targets for implementation, which may be individual providers or medical facilities. Key characteristics of recipients include: motivation, values and beliefs, goals, skills and knowledge, time, resources and support, local opinion leaders, collaboration and teamwork, existing networks, learning environment, power and authority, and presence of boundaries[27].

According to i-PARIHS, factors within the inner and outer context of the recipients affect implementation. Inner context includes the immediate setting for implementation (e.g., mental health clinic) and the organization in which that clinic is located (e.g., medical center). Outer context refers to the wider health system in which the organization is based and the policies, regulatory frameworks, and political environment that govern the way the health system functions (e.g., VHA). Examples of inner context constructs include: leadership support, culture, organizational priorities, evaluation and feedback processes, learning networks, and structure. Examples of outer context constructs include: policy drivers

and priorities, incentives and mandates.

Facilitation is an evidence-based strategy for achieving practice change[24,32–36]. The i-PARIHS framework identifies facilitation as the ingredient that activates the other constructs to produce successful implementation[32,37,38]. Facilitation bundles an integrated set of implementation strategies. These include identifying and engaging key stakeholders at all organizational levels, problem identification and resolution, providing assistance with technical issues, developing information exchange networks, academic detailing, marketing, staff training, formative evaluation, auditing and feedback, evidence-based quality improvement, engagement of opinion leaders and clinical champions, and role modeling. Facilitators' actions are dependent on a facility's needs and the timing of the implementation process. An external facilitator is an expert in implementation and the relevant clinical areas[38].

METHODS

Overview of Evaluation Methods

This evaluation will utilize a mixed methods approach. To evaluate our aims, the project will utilize a stepped wedge controlled trial design. This design staggers the timing of providing implementation support and allows every participating VISN to receive the implementation support. The unit of intervention in this study is the site and randomization will occur at the VISN level for virtual external facilitation. Using a balancing algorithm for facility size, suicide admissions, and rural vs. urban status, sites will be randomized to when virtual facilitation will occur. Below we describe the conceptual models, national implementation plan, clinical interventions, and implementation strategy, followed by the design, outcomes, and analysis for each specific aim.

Project Management

- **Sara J. Landes, PhD (PI, CAVHS)** serves as the principal investigator for this evaluation project and is an Investigator at the Central Arkansas Veterans Healthcare System, VISN 16 Mental Illness Research Education and Clinical Center (MIRECC) and Assistant Professor of Psychiatry at University of Arkansas for Medical Sciences. Dr. Landes specializes in testing implementation strategies across a wide range of service contexts, and has received implementation science research funding from QUERI, NIMH, and the DOD. She is also a co-investigator on the Military Suicide Research Consortium's new dissemination and implementation core. She has a history of partnering with the Office of Mental Health and Suicide Prevention on implementation research projects. Dr. Landes will head an evaluation team consisting of a qualitative investigator, cost evaluation investigator, project coordinator, research assistants, and a qualitative interviewer/coder. **Karen Drummond, PhD (Co-I, CAVHS)** is a Research Health Scientist at HSR&D Center for Mental Healthcare and Outcomes Research (CeMHOR). Dr. Drummond is a medical anthropologist and health services researcher with training and expertise in qualitative methods, rapid data analysis techniques, and formative evaluation. Dr. Drummond will help with qualitative data collection, analysis and dissemination of results for the evaluation. **Jacob Painter, PhD, PharmD (Co-I, CAVHS)** is an Assistant Professor at the University of Arkansas for Medical Sciences (UAMS) in the Division of Pharmaceutical Evaluation and Policy; and an investigator at the Center for Mental Healthcare & Outcomes Research (CeMHOR). His research focuses on economic analysis of mental health approaches for Veterans. Dr. Painter will assist in the development, collection, and analysis for the evaluation of costs associated with the intervention. **Susan Jegley, MSW (Project Coordinator, CAVHS)** is a Health Science Specialist at CeMHOR who has considerable experience as a project coordinator. For this project she will have primary responsibility for regulatory compliance and budget management. She will assist in preparation of and coordinate all IRB/R&D submissions and maintain IRB regulatory files. She will

develop and maintain administrative tracking systems to ensure regulatory compliance and fiscal responsibility. She will also assist with data collection, data entry, and dissemination of results. **Rebecca Raciborski, PhD, (Research Staff, CAVHS)** has experience in economic analysis of mental health approaches. She will assist Dr. Painter in the data collection for evaluation of costs. **Jeffery Pitcock, MPH (Program Analyst, CAVHS)** has experience in data collection, cleaning, and analysis, especially using data from VA's CDW. He will be responsible for the data analysis of REACH VET dashboard data. **Jack Woods, MSW (Research Assistant, CAVHS)** has experience working on a number of qualitative research studies. Mr. Woods is an experienced research assistant who will coordinate data management, maintain the project's regulatory binder, and correspond with staff. He will coordinate evaluation activities with study personnel and assist in data entry and dissemination of the results. **Nyssa Curtis, MA (Research Assistant, CAVHS)** has experience working on a number of qualitative research studies. She will be responsible for transcription of qualitative interviews.

- **John McCarthy, PhD, MPH (Co-I, SMITREC)** is Director of the Serious Mental Illness Treatment Resource and Evaluation Center (SMITREC) and Director of the National Primary Care – Mental Health Integration Evaluation in VHA. He has over 100 peer-reviewed publications, including first authorship on the manuscript that developed the predictive model that provided the foundation for this project. Dr. McCarthy will coordinate patient data management and analysis for the predictive model as well as the evaluation, working closely with PEPReC on the latter. **Claire Hannemann, MPH (Programmer Analyst, SMITREC)** is an Epidemiologist and Population Health Analyst at the Serious Mental Illness Treatment Resource and Evaluation Center. She received an MPH in Epidemiology from the University of Michigan School of Public Health, in Ann Arbor, Michigan, and she conducted core data management and analysis for the VA's groundbreaking predictive modeling for suicide risk. Ms. Hannemann will assist Dr. McCarthy with patient data management and analysis for the predictive model as well as the evaluation of REACH VET implementation in close collaboration with the Partnered Evidence-based Policy Resource Center (PEPReC).
- **Craig Rosen, PhD (Co-I, VAPA)** is the Deputy Director for the Dissemination and Training Division of the VA's National Center for PTSD. He has expertise in implementing practices to enhance VA care and evaluating large scale rollouts in VA. He will serve as the site PI and oversee all aspects of project execution at the Palo Alto VAMC. He will supervise all study personnel at this site. **Brandy Smith, BA (Interviewer, VAPA)** is a Research Assistant at the Palo Alto VAMC. She has experience working on numerous VA studies conducting qualitative data collection and analysis. She will be involved in recruiting subjects; obtaining informed consent; administering survey/interview procedures; and assisting with data analysis.
- **Mark Reger, PhD (Co-I, VAPSHCS)** is Chief of Psychology at the VA Puget Sound Health Care System and Associate Professor of Psychiatry at the University of Washington School of Medicine. He previously worked for 10 years in the Department of Defense leading military suicide prevention, surveillance, and research initiatives. Dr. Reger will lead the intervention team with Dr. Bridget Matarazzo. He will also lead the development and refinement of the Caring Letters component of the intervention.
- **Bridget Matarazzo, PsyD (Co-I, Rocky Mountain MIRECC)** is Co-Director of the VA National Suicide Risk Management Consultation Program and Co-Director of the Rocky Mountain MIRECC Suicide Prevention Consultation Service. She also is an Assistant Professor in the Department of Psychiatry at the University of Colorado, School of Medicine. She is also the

national clinic lead of the REACH VET program and will lead the intervention team with Dr. Mark Reger.

Table 1: Members of the Evaluation Team who will consent participants and their access to PII and PHI.

Study Staff Member	Access to Coordinator PII	Obtain consent from Coordinator	Access to Provider PII	Obtain consent from providers	Access to Leadership PII	Obtain consent from leadership	Access to patient PHI
Sara Landes	Yes	No	Yes	No	Yes	No	Yes
Karen Drummond	Yes	No	Yes	No	Yes	No	No
Jacob Painter	Yes	No	Yes	No	Yes	No	No
Susan Jegley	Yes	No	Yes	No	Yes	No	Yes
Jeffery Pitcock	Yes	No	Yes	No	Yes	No	Yes
Rebecca Raciborski	Yes	No	Yes	No	Yes	No	Yes
Jack Woods	Yes	Yes	Yes	Yes	Yes	Yes	No
Nyssa Curtis	Yes	No	Yes	No	Yes	No	No
Craig Rosen	No	No	No	No	No	No	No
Brandy Smith	Yes	Yes	Yes	Yes	Yes	Yes	No
John McCarthy	No	No	No	No	No	No	Yes
Claire Hannemann	No	No	No	No	No	No	Yes
Ira Katz	No	No	No	No	No	No	No
Mark Reger	No	No	No	No	No	No	No
Bridget Matarazzo	Yes	No	Yes	No	Yes	No	No

Data Use Agreements (DUAs)

A data use agreement was finalized with the Office of Mental Health Operations (OMHO). This DUA covers the REACH VET dashboard data being sent to the evaluation team. This data includes: names of patients identified by REACH VET and their information as displayed in the dashboard and actions taken by the REACH VET coordinator and providers.

Table 2: REACH VET Dashboard Variables for Data Collection

Patient Level Variables:
First Name
Last Name
Last 4 of SSN
Facility (location)
Date First Showed up on Dashboard
Coordinator Level Variables:
First Name

Last Name
Is there a High Risk Suicide Flag documented in CPRS?
Dates - Coordinator:
- Received name of patient
- Identified a primary patient provider
- Notified provider of the specific patient and program requirements
- Asked provider to re-evaluate patient's care

Provider Level Variables:

First Name
Last Name
Dates - Provider:
- Received notification from REACH VET coordinator about the patient
- Reviewed current diagnoses and treatment plan
- Indicated enhanced care options:
  - Caring Communications
  - Safety Planning
  - Increased monitoring of stressful life events
  - Improve coping skills
  - Other
- Care was reviewed and no changes are clinically indicated at this time
- Informed Veteran that they have been identified as being at risk
- Discussed care enhancement options with the Veteran
- Discussed treatment plan changes with the Veteran
- Indicated that outreach attempts have been made but provider unable to get in touch with the Veteran
- Indicated that no outreach to Veteran is clinically indicated at this time

NATIONAL IMPLEMENTATION PLAN

Clinical Intervention: REACH VET

The intervention will be provided through coordinated activities of REACH VET coordinators and providers at facilities. The REACH VET dashboard provides the names of patients who are identified as high risk by the predictive model to REACH VET coordinators at each facility. The dashboard provides names, contact information, risk stratum (e.g., 0.1%), and the clinical characteristics that contributed to a patient's risk (e.g., inpatient psychiatric discharge, chronic non-cancer pain). It also provides prompts for next steps for coordinators and providers and a record of actions that have been completed. REACH VET coordinators are responsible for monitoring the dashboard, identifying the primary provider for each patient (and if none exists, working with leadership to assign one), notifying providers of the patient's status on the dashboard, and ensuring the provider understands the REACH VET program and their responsibilities.

The provider's responsibilities include acknowledging notification of their patient's high risk status in the REACH VET dashboard; contacting the patient; re-evaluating diagnoses, treatment plans, and care provided for diagnosed conditions; ensuring patients have access to care when they need it; ensuring patients are receiving evidence-based care; considering additional enhancement strategies; and when changes to the treatment plan or enhanced care is clinically indicated, discussing these changes with the patient. Providers are instructed to document all actions taken to support the patient in the REACH VET dashboard and the electronic medical record. REACH VET electronic medical record templates will allow consistent reporting and evaluation of provider behavior.

The plan for national roll out of REACH VET was developed by OSP, with input from the evaluation team and other partners. National implementation of REACH VET began in November 2016 and included identification of a REACH VET coordinator at each facility, REACH VET dashboard training for coordinators and interested providers, and rollout of the dashboard. Each facility initially received the top eight names of patients identified as being in the top 0.1% of risk for suicide at that facility. Over the following three months, facilities will receive additional names via the dashboard until all patients in the top 0.1% have been identified; facilities can opt to receive the full list at any time. Standard implementation strategies will include training and education, chart note templates to support documentation, an intranet site of resources for coordinators and providers, technical assistance as requested, and clinical consultation as requested. Barriers and facilitators will be assessed during this time by the evaluation team.

Figure 2. Trial design.

		Study Month							
Network	**Sites**	**1-3**	**3 – 6**	**6 - 9**	**9 - 12**	**12 - 15**	**15 - 18**	**18 - 21**	**21 - 24**
A	1-4	Facilitation							
B	5-8	Awaiting Facilitation		Facilitation					
C	9-12	Awaiting Facilitation		Facilitation					
D	13-16	Awaiting Facilitation			Facilitation				
E	17-20	Awaiting Facilitation				Facilitation			
F	21-24	Awaiting Facilitation					Facilitation		
G	25-28	Awaiting Facilitation						Facilitation	

Virtual

External Facilitation Implementation Strategy

Additional implementation support will begin in April 2017. We will target 7 networks and 4 sites in each network not meeting the criterion for timely notification. The participating VISNs will be randomized to when the sites in their network will receive facilitation.

The facilitators will be two master's level and one doctoral level clinicians with clinical expertise in suicide prevention and REACH VET; the facilitators are funded through OSP and are not part of the evaluation team. They attended facilitation training February 1-2, 2017. The training included how to conduct virtual facilitation and utilized a virtual external facilitation manual developed by a workgroup of the Behavioral Health QUERI's Implementation Facilitation Learning Collaborative.

External facilitators will use a variety of strategies to facilitate implementation, including provider education, performance monitoring and feedback, and formative evaluation. To adapt to each facilities' particular circumstances, facilitators will select from a broad range of strategies (e.g., facilitate stakeholder engagement, conduct provider education, facilitate performance monitoring and feedback, and conduct formative evaluation) based upon an assessment of each facility's needs, barriers, and facilitators.

Clinical Intervention: Caring Letters

This project will evaluate methods and feasibility for the use of a Centralized Caring Letters program in conjunction with REACH VET.

REACH VET Participants

Veterans who have been flagged as high risk through REACH VET will be recruited from two VA facilities, including VA Puget Sound and Central Arkansas Veterans Healthcare System.

A local Caring Letters Coordinator will contact the local REACH VET Provider who will determine whether Caring Letters is clinically appropriate for the patient identified by REACH VET. REACH VET Providers will exclude patients from the program if they had no mailing address to receive Caring Letters, psychosis that indicates Caring Letters could be counterproductive, adverse behavioral problems (e.g., patient threats towards the provider, boundary problems with a provider), or similar concerns.

Centralized Caring Letters Intervention
For patients appropriate for Centralized Caring Letters, a centralized administrator will track, print, and mail the Caring Letters on behalf of the providers at pilot sites. The provider will be notified before each Caring Letter is sent to avoid any potential misunderstandings with patients (e.g., the patient thanks the provider for the card, but the provider does not recall sending anything), and to ensure that providers have the chance to withdraw a patient from the program when clinically indicated (e.g., changes in clinical status).

The standard VA model for REACH VET Caring Letters will be used. Detailed procedures have been developed for sending Caring Letters, including a template for the cards. The model was based on a systematic review of evidence-based approaches from the literature. The cards were tested in focus groups with several Veteran groups, and with high risk Veterans on a psychiatric inpatient unit. A total of eight Caring Letters will be sent over the course of one year (monthly for four months, and then every two months for the remaining period). Similar to previous studies, the letters will be printed on a flat card and will be sent in a sealed envelope. The envelopes will be colored like a greeting card to increase the likelihood they will be noticed and opened. Protocols have been developed to address patient responses to letters (e.g., expression of thanks, indications of risk).

The goals will be to develop a centralized Caring Letter protocol in a way that remains meaningful to the patient, establish criteria for patient selection, adapt existing processes for sending letters, and automate the process for scale up. The evaluation team will document feasibility and acceptability to providers and patients, and resources needed.

Outcomes

This project focuses on evaluation of implementation outcomes and development and formative evaluation of a centralized protocol for Caring Letters. Outcomes assessed are described here by specific aim.

Specific Aim 1: Evaluate the impact of virtual external facilitation versus standard implementation.

Specific Aim 1a: Conduct a formative evaluation to identify barriers and facilitators to implementation to define and refine the virtual external facilitation strategy.

Design: We will conduct formative evaluation of the implementation process, with a focus on barriers and facilitators related to i-PARIHS constructs (e.g., characteristics of the innovation, context, and recipient), with 28 facilities in 7 VISNs.

Measures: Data sources will include qualitative interviews with site staff, including REACH VET coordinators, SPCs, mental health and primary care providers, and facility or VISN leadership. We will aim to conduct at least three interviews per facility, with a maximum of five interviews per facility. Interviews will be conducted by phone and be audio-recorded and transcribed. Interviews will be conducted to refine the virtual external facilitation strategies to be used. During virtual external facilitation, we will conduct monthly debriefings with the facilitators.

Analysis*:* Rapid Qualitative Analysis (RQA)[39] strategies will be used to ensure timely communication of findings to our OSP partners and to allow us to refine our virtual external facilitation strategies as needed. Each interview transcription will be read by two members of the qualitative team, who will then distill information pertaining to previously identified domains of interest based on iPARIHS (context, innovation, recipient), as well as emergent themes, into an episode profile. Episode profiles will be compared and any discrepancies resolved by referring back to the original transcript and/or presenting the profile to the larger team for discussion. Completed episode profiles will be entered into tables to create a composite matrix of data for each site, in order to be able to compare across participant responses. We will then share these episode profiles and site matrices with the qualitative coding team, REACH VET Program Manager, and external facilitators via a Lync meeting to discuss potential refinements to facilitation strategies.

Specific Aim 1b: Conduct a summative evaluation of virtual external facilitation versus standard implementation.

Design*:* All VA sites (N = 144) within VA's 18 regional networks that were directed to implement REACH VET will receive standard implementation. Network directors will be asked if they would like to receive additional implementation help for sites in their VISN having difficulty implementing REACH VET (e.g., not meeting the criterion of completing at least 80% of provider notifications of patient high-risk status within 7 days during the last month). VISNs participating will be randomized to when the VISN receives virtual external facilitation at 4 of their sites having difficulty implementing.

Measures: We will assess the impact of facilitation on REACH VET implementation using the four outcome measures as tracked by the REACH VET program. We will use the REACH VET Historic Summary Report to collect data for Coordinator assignment, Provider assignment, Care evaluation, and Attempted outreach all within one week of each monthly report's release date. These metrics are those tracked to determine a facility's implementation of REACH VET. They are defined as:

- Coordinator Assigned – the percentage of eligible Veterans who had a Coordinator assigned within a week of the monthly REACH VET report being released. The denominator is the number of eligible Veterans within that week. The numerator is the number of Veterans with a record of a Coordinator assigned within or prior to that week.
- Provider Assigned – the percentage of eligible Veterans who had a Provider assigned within a week of the monthly REACH VET report being released. The denominator is the number of eligible Veterans within that week. The numerator is the number of Veterans with a record of a Provider assigned within or prior to that week.
- Care Evaluation Performed – the percentage of eligible Veterans who had a care evaluation performed within a week of the monthly REACH VET report being released. The denominator is the number of eligible Veterans within that week. The numerator is the number of Veterans with a record of a care evaluation performed within or prior to that week.
- Attempted Outreach – the percentage of eligible Veterans with a recorded attempted outreach within a week of the monthly REACH VET report being released. The denominator is the number of eligible Veterans within that week. The numerator is the number of Veterans with a recorded attempted outreach within or prior to that week.

Analysis: To compare statistical differences in outcomes between pre- and post-facilitation periods we will use generalized estimating equations (GEE) to control for clustering of observations within VAMCs. Fixed effects included a time-dependent variable identifying change in intervention

status (pre-post) as well an independent variable of time to account for the possibility of improvement due to secular trends.

Specific Aim 1c: Collect the costs of the REACH VET and Caring Letter interventions and of the virtual external facilitation strategy for subsequent analysis of potential cost effectiveness.

Design: In order to quantify the amount of effort and time needed to offer virtual external facilitation, the facilitators will maintain weekly logs of activities engaged in (and time spent) related to the implementation. This information, along with data regarding the activities and time of staff at sites implementing REACH VET, will allow for preliminary data collection related to the cost of implementation and the cost of the intervention.

Measures: Intervention and implementation strategy costs will include fixed and variable costs. Intervention and implementation strategy costs will be collected in real time using the "accountant perspective." Variable intervention costs include time spent by clinical staff delivering the intervention (e.g., time spent using the dashboard, entering progress notes into the medical record, and contacting providers). Variable implementation strategy costs will be calculated based on time spent delivering implementation strategies. Costs will be calculated separately for each team member based on their respective VA salaries and fringe costs. Time spent on intervention and implementation strategy activities will be estimated using computerized log books to record the time spent on specific activities during the evaluation. Fixed intervention and implementation strategy costs include the cost of provider education materials, intervention training, and other materials needed for implementation strategies. Fixed training costs will be calculated from the duration of the trainings and salaries of trainers and trainees and material costs will be estimated based on project acquisition costs.

Analyses: This data will be analyzed in a subsequent proposal.

Specific Aim 2: Develop and evaluate the augmentation of REACH VET using Caring Letters, an evidence-based suicide prevention intervention.

Specific Aim 2a: Conduct a formative evaluation of the augmentation of REACH VET with Caring Letters.

Specific Aim 2b: Refine the Caring Letter intervention for scale up to the VHA-wide REACH VET program.

Design. To develop the centralized Caring Letters protocol, we will implement centralized Caring Letters in two sites that demonstrate early success at implementing REACH VET and who have sufficient numbers of patients to allow for sending letters. We will conduct formative evaluation to adapt and refine the Caring Letters protocol and intervention.

Qualitative Interviews. Qualitative interviews will be conducted with REACH VET coordinators and Caring Letters Coordinators at each of the sites. These interviews will focus on the feasibility and acceptability of the intervention, as well as determine the resources needed for a centralized letter program.

Analysis. We will use the Rapid Qualitative Analysis (RQA)[39] strategies described in Specific Aim 1 to analyze this data.

HUMAN SUBJECTS PROTECTION ISSUES AND DATA MONITORING PLAN

This evaluation will involve collection of both primary and secondary data:

1. Primary data will be collected for Aims 1a, 1c, & 2a, and will consist of data collected from qualitative interviews with site staff, including REACH VET coordinators, Suicide Prevention

Coordinators, mental health and primary care providers, and facility or VISN leadership (e.g., VISN Mental Health Lead). During virtual external facilitation, we will also conduct monthly debriefings with the facilitators.

2. Secondary data will be collected for Aims 1b & 2a from:
    a. *REACH VET Dashboard Data*: The Office of Mental Health Operations (see DUA).
    b. *CPRS chart reviews:* CAPRI National CPRS access.

Potential Risk/Benefit Analysis

Risks. Potential risks for this evaluation are minimal. For primary data collection, though VA staff members will be interviewed solely as agents of the organization, there is still a risk of breach of confidentiality. No data will be collected directly from VA patients. Secondary data will be collected from VA administrative databases by the Office of Mental Health Operations and provided to the evaluation team in a secure manner (e.g., via upload to VINCI). Precautions will be taken to minimize these risks.

Benefits. There are no direct benefits to subjects participating in this study. However, this evaluation will help enable VA to evaluate the extent of implementation of the REACH VET program (e.g., the reach, adoption, and implementation fidelity), as well as determine how virtual external facilitation can support facilities having difficulty implementing the program. This evaluation will also collect initial data on the cost of the REACH VET program and cost of the virtual external facilitation strategy.

Adverse & Serious Adverse Events

Adverse events. Following guidelines put forth by NIH and VA, we define an adverse event as an unexpected reaction, side effect, or untoward event that occurs during the study. We also consider unanticipated problems or events that place participants at a greater risk of harm or discomfort than was previously known or recognized as adverse events. Stable, chronic conditions that are present prior to the study and do not worsen will not be considered. Given the nature of the study, the following adverse events are possible: discomfort or distress during primary data collection and breaches of confidentiality for data collected from participants and from databases.

Serious adverse events. Serious adverse events are defined as death, any life-threatening experience, prolonged hospitalization, persistent or significant disability or incapacity, congenital anomaly, or the need for surgical, behavioral, social, or other intervention to prevent any of the above. Given the minimal risk nature of the study, and that no experimental treatment is being tested, we expect no serious adverse events for those participating directly in the evaluation (e.g., VA staff).

Reporting of adverse and serious adverse events. The PI or designee will be responsible for evaluating any adverse events and serious adverse events and submitting the appropriate reports to the CAVHS Research Service within 5 working days after being made aware of the occurrence. The PI will evaluate whether a participant in the study should be discontinued from further participation in the study, for safety reasons. The PI and study staff will respond immediately to all directives from the CAVHS Research Service or VA concerning the protocol and the continuation of the evaluation.

Participants/Subjects

Planned/targeted enrollment. Primary data collection: There will be a maximum of 157 participants (all VA staff) from whom data will be collected. Since participants will be selected based on their roles and some participants may serve duplicate roles within their clinics (e.g., a SPC may also serve as a REACH VET Coordinator), the total number of actual subjects will likely be less than 157. The table below illustrates the types and approximate number of VA staff from whom we will collect data in each group across all sites.

Table 3: Site participants

Setting	Stakeholder Group	Participants
VISN	MH Director	7
	PC Director	7
	External Facilitators	3
VAMC	REACH VET Coordinators	28
	SPCs	28
Primary Care Clinic	MH Providers	28
	PC Providers	28
MH Specialty Clinic	MH Providers	28
Total		157

Secondary data collection: The study population for all administrative data analyses will include a maximum of 4,200 patients and 900 providers. These numbers are estimates based on large facilities (e.g., the top 0.1% of patients at a large facility is approximately 150 patients and we are including 28 facilities) and therefore are likely overestimates. We plan to sample 10% of patients and their associated providers.

Inclusion/exclusion criteria. Inclusion criteria includes VA site staff, including REACH VET coordinators, Suicide Prevention Coordinators, mental health providers, and facility or VISN leadership who are: (a) at least 18 years of age, (b) have access to a telephone, (c) English speaking, and (d) mentally and physically able to complete the interview.

We will take special steps to insure that VA employees do not feel coerced to participate. VA employees generally need the permission of their supervisors to take time away from routine duties. Additionally, in order to meet with providers, appointments must be scheduled through designated clinic staff. Once staff members have been scheduled, they will be sent a letter with the elements of informed consent explaining that they have the right to decline participation. Potential subjects can contact study staff in advance to decline participation. At the time of each contact with study staff, they will be given the opportunity to decline participation in the study. The employee's supervisor will not be informed of the employee's decision and no negative employment consequences will result if an employee chooses not to participate.

This study will not enroll or involve any of the special classes of research subjects, such as pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations per IRB regulations.

Participant Recruitment Methods

Sites will be recruited via REACH VET Coordinator monthly calls and email communications. Within each site, staff participants will be recruited by identifying the local REACH VET Coordinator, Suicide Prevention Coordinator, providers identified in the REACH VET dashboard, and by contacting local or regional mental health leadership.

Compensation. No compensation will be offered to participants for participating in this evaluation.

Withdrawal of Subjects

Participants may withdraw from the evaluation at any time by verbal or written request, which will be documented in the case file by the investigator. Withdrawal will not be communicated to any site staff in order to maintain confidentiality and avoid the potential for coercion.

Privacy and Confidentiality (Data Management and Monitoring)

Investigators will not disclose participants' PII. All investigators and staff will have complied with all VA research training requirements prior to beginning participation in this evaluation.

All information on individual subjects will be kept confidential on restricted-access server files behind the VA firewall. Study staff will obtain a list of the names and addresses of REACH VET staff from mental health leadership at each site in order to recruit providers to complete telephone interviews. The study PI and Qualitative Lead will maintain an electronic file linking identification numbers to the names of the provider interview participants (participant "crosswalk"). These files will be in a folder that is separate from other evaluation data. Access to the analytic files within VA will be limited to the principal investigator and those team members involved in the analyses. Individually unique user identification codes and passwords are necessary to access the network. Accounts and passwords comply with existing VA policy and procedures.

Hard copies of participant responses will be kept in a locked area of CeMHOR space at CAVHS. Hard copies will be maintained in accordance with the VA Record retention schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Only project staff with credentials and permission to use the data will have access to the data.

Data Security and Sharing

How Data Will Be Stored. Contact and consent information will be stored in a restricted-access folder on the password-protected HSR&D server at the Central Arkansas Veterans Healthcare System (CAVHS), North Little Rock, AR campus (\\R02LITHSMDC101.V16.MED.VA.GOV\SERVICES$\HSR). The information will remain stored and maintained per VA policies and procedures. Participants will be given a non-identifying code linking them to the audio recording of the interviews. The paper data will be kept in the study PI's Office in Building 58, North Little Rock, AR. Qualitative interviews will be stored temporarily on VA approved digital audio recorders (Phillips DPM 8000). These temporary electronic files will be purged from the recorder upon upload to a password protected file on the secure network server on the CAVHS campus. Audio data will not include identifying information. Instead each participant will be given a corresponding number.

Who Will Have Access. Dr. Landes and Ms. Jegley will have access to the REACH VET dashboard and CPRS records for screening, medical chart reviews and to conduct periodic reviews for AEs and SAEs. Mr. Woods will have access to the REACH VET dashboard and CPRS records for the Caring Letters component of this evaluation. Mr. Pitcock will have access to the REACH VET dashboard to analyze data related to the dashboard. Dr. Landes, Ms. Jegley, Dr. Painter, Dr. Raciborski, and Mr. Pitcock will have access to time tracking logs for cost evaluations. Dr. Landes, Ms. Jegley, Ms. Smith, Mr. Woods, and Ms. Curtis will have access to contact information of the site staff, REACH VET coordinators, and facilitators for interviewing purposes. Dr. Landes, Ms. Jegley, Ms. Smith, Mr. Woods, and Ms. Curtis will have access to the list that correlates the identifying number to the participant. This crosswalk file will be maintained in a separate password protected file on the secure network server on the CAVHS campus. All records will be accessible for inspections and copying by authorized representatives of VA, OHRP, and other authorized entities. If any member of the evaluation team leaves the study, his/her access to study data will be removed immediately. If, in spite of the implemented precautions, participant data is lost, stolen, or compromised, it will be reported immediately to the PI. The PI or designee will report the event to the IRB, the ISO, the PO, and the ACOS/R&D immediately upon discovery, but no longer than 1 hour after learning of the breach of confidentiality.

How Long It Will Be Stored. VA Records Control Schedule DAA-0015-2015-0004, disposition authority number-0032 requires that records be maintained for 6 years following the end of the fiscal year after completion of the project. Audio recordings of interviews and other electronic records will be

retained on a VA server for this period of time. All hard copies of records will be stored in locked filing cabinets on VA property until the close of the study, at which time they will be surrendered to Research Administration for storage for six years following the end of the fiscal year after completion of the project.

Communication Plan

All site approvals (CAVHS and VAPAHCS) will be obtained in compliance with local IRB and R&D procedures. For each site participating but not engaged in research (in this study, the 28 sites receiving virtual implementation facilitation), we will notify the Director prior to conducting evaluation activities at his/her facility (see Director's Letter). Also, we will process any changes in the protocol, consent processes, or cessation of engagement in research for any sites in concordance with local IRB and site procedures.

The PI will meet regularly with the evaluation team, which includes the Local Site Investigator from Palo Alto (Dr. Rosen), and through this mechanism we will facilitate all above communications.

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