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Evaluation of a centralized caring letters suicide prevention intervention for Veterans Health Administration patients with inactivated high risk for suicide patient record flags

Submission date
08/08/2023

Recruitment status
No longer recruiting

Registration date
12/09/2023

Overall study status
Completed

Last Edited
26/03/2026

Condition category
Other

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The Veterans Health Administration (VHA) uses High Risk for Suicide Patient Record Flags (HRS PRF) in a patient's electronic health record (EHR) during times of possible higher risk for suicide. These flags alert clinicians and improve suicide prevention services. Even after the acute risk has decreased and the flags are inactivated, the Veterans represent a high-risk cohort who may benefit from additional suicide prevention resources. To help address this challenge VHA created a policy in 2020 that required facilities to start using the Caring Letters suicide prevention intervention for patients after high risk flags are inactivated. Caring Letters (sometimes called Caring Contacts) is one intervention that has lowered rates of suicide in prior studies. With this approach, someone sends patients letters about once a month for a year to let them know that others are thinking of them and wishing them well. Although this approach is a promising practice, review of the policy requirement to provide Caring Letters for patients after high risk flag inactivation showed that many sites had not started using Caring Letters, and places that have a program in place did not always deliver the intervention with fidelity (or as intended).

With a goal of improving the delivery of the Caring Letters intervention, the VHA Suicide Prevention Program (SPP) is working with a program evaluation team to design and examine a new Centralized approach to Caring Letters. With this new approach a single national team will deliver the intervention rather than relying on the individual facilities to do it. The evaluation will randomly assign half of the VA sites to start the Centralized Caring Letters approach in June 2023 and the other half of sites will keep using the local site delivered approach to Caring Letters with usual procedures (also known as "Decentralized" Caring Letters). By the end of January 2024 all the sites will use the Centralized approach. The delayed start will help the evaluation team look at the differences in the two approaches to help determine whether the new Centralized approach is better. The evaluation will also look at the impact of Centralized Caring Letters on emergency department use and hospitalizations for mental health reasons and patients' use of resources like mental health care. The evaluation will also look at aspects of the program delivery to help understand program implementation. Interviews with a small group of

patients receiving the Caring Letters and with some VHA staff will help inform the evaluation. The results will help guide how the High Risk Flag Caring Letters program will continue.

Who can participate?
All Veterans Health Administration (VHA) patients will be included in the program evaluation if they have an Electronic Health Record (EHR) High Risk Flag that is inactivated between June 30th, 2023 – June 29th, 2024 for the first half of sites, and they will be included if they have (EHR) High Risk Flag inactivated between January 31, 2024 – June 29, 2024 for the second half of sites. Patients will not be included if they do not have a valid mailing address or if they are removed or opted out of receiving Caring Letters by their local VA Suicide Prevention Coordinator prior to starting the program . Individuals will not be included if they are deceased prior to their information being uploaded for mail processing. Patients will also not be enrolled if they are already enrolled in and receiving Veterans Crisis Line (VCL) Caring Letters, which is a similar Caring Letters project managed by the Department of Veterans Affairs (VA) Office of Mental Health and Suicide Prevention. Individuals who are enrolled will include all genders and all ages represented by Veterans who meet these criteria.

What does the study involve?
All individuals will receive a series of cards, sent in envelopes, wishing them well and letting them know that there are resources and people available to help them if they need anything. The Veterans will receive a total of 8 cards in one year. The cards will start to be mailed a few weeks after the patient's Electronic Health Record High Risk Flag is inactivated. For the first 4 months, the letters will be sent every month. Then they will be sent every other month. After the first 6 months of the program, we will reach out to some VHA patient participants (about 30) to collect information in interviews about what it was like to receive the letters and whether they found them to be helpful or caring. This information will be used to help guide program continuation.

What are the possible benefits and risks of participating?
The benefits are unknown. Prior research has shown that receiving Caring Letters can reduce rates of suicide behaviors. There are few risks. If someone had a negative experience with their military service or with their healthcare at the VA, they may have negative feelings about receiving letters from a provider from the VA. However, if they want to opt out of receiving the letters they can request to do so. It is illegal for someone to open mail that is not addressed to them, but it is possible this could happen; therefore, it is possible an unintended person could read the Caring Letters.

Where is the study run from?
The evaluation of the Centralized High Risk Flag Caring Letters program is a partnership between investigators at the VA Puget Sound Health Care System in Seattle, WA, USA, the U.S. Department of Veterans Affairs (VA) Office of Mental Health and Suicide Prevention, and VA QUERI (Quality Enhancement Research Initiative) based in Washington D.C., USA. Other partner sites for the evaluation of this program include the Central Arkansas Veterans Health Care System in Little Rock, AR, USA and the VA Partnered Evidence-based Policy Resource Center (PEPReC) in Boston, MA, USA.

When is the study starting and how long is it expected to run for?
April 2023 to March 2026

Who is funding the study?
This study is funded by two groups from the United States Department of Veterans Affairs (VA): The VA Quality Enhancement Research Initiative (QUERI) and the VA Office of Mental Health and Suicide Prevention.

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
PEC 23-073

Study information

Scientific Title
Evaluation of a centralized caring letters suicide prevention intervention after inactivation of an electronic health record (EHR) high risk flag: an effectiveness-implementation hybrid type 2 trial

Study objectives
Aim 1: To evaluate the effects of Caring Letters on clinical outcomes and VA clinical utilization rates.
Among Veterans with High Risk Flag inactivation, Veterans who receive nationally Centralized Caring Letters will have:
1.1. A higher incidence of VA emergency department (ED) visits compared to Veterans who had an inactivated HRF and never received Caring Letters (i.e., Veterans with HRF inactivation prior to the policy requiring Caring Letters).
1.2. Higher incidence of VA psychiatric hospitalization compared to Veterans who had an inactivated HRF and never received Caring Letters (i.e., Veterans with HRF inactivation prior to the policy requiring Caring Letters).

1.3. Veterans who receive centralized Caring Letters will have higher incidence of outpatient mental health care, any outpatient care, and any inpatient care utilization compared to Veterans who had an inactivated HRF and never received Caring Letters (i.e., Veterans with HRF inactivation prior to the policy requiring Caring Letters).
Exploratory Aim 1: To examine rates of suicide attempts , all-cause mortality and suicide for Veterans who receive centralized Caring Letters compared to Veterans who had an inactivated HRF and never received Caring Letters (i.e., Veterans with HRF inactivation prior to the policy requiring Caring Letters).

Aim 2: To evaluate the impact of adding an implementation strategy of centralizing the work to the existing implementation strategy of mandating change.
2.1 Using pre-post comparisons, Centralized Caring Letters will be: Sent to a higher percentage of eligible Veterans with High Risk Flag inactivation (increased reach) and
2.2. Centralized Caring Letters will adhere to the mailing schedule at least 90% of the time.
Exploratory Aim 2: To examine the incidence of outpatient mental health visits, ED visits, psychiatric hospitalizations, any outpatient care and any inpatient care among Veterans with HRF inactivation who receive centralized Caring Letters vs decentralized Caring Letters. We will also examine rates of suicide attempts, all-cause mortality, and suicide for Veterans who receive centralized Caring Letters among Veterans with HRF inactivation who receive centralized Caring Letters vs decentralized Caring Letters.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This project has been reviewed and meets the criteria for classification as non-research. The purpose of this project is to support internal implementation and evaluation efforts to evaluate the effects of the Centralized High Risk Flag Caring Letters suicide prevention intervention on VA clinical utilization rates. The project will involve use of secondary VA data that are collected as a part of routine care and/or clinical management. This project will be collecting information that is designed for quality improvement initiatives, as described in the Department of Veterans Affairs, Office of Research and Development Program Guide (1200.21), "VHA Operations Activities That May Constitute Research."
These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This project is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation. This determination was confirmed by Matthew Miller, PhD, MPH, Director for the Suicide Prevention Program, VHA Office of Mental Health and Suicide Prevention on November 29, 2022. Therefore, consistent with VA policy, no other review is required.

Primary study design
Interventional

Study design
Randomized hybrid effectiveness-implementation Type 2 Trial, combined with pre-post comparison of treatment vs no treatment

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Suicide prevention in US Veterans

Interventions
Caring Letters is a suicide prevention intervention that is well-suited for a high-risk population. Caring Letters consist of simple expressions of care and support sent through the mail. Caring Letters directly work at the level of social support to enhance feelings of belongingness, but this model also has the potential to impact other factors by promoting links to medical and mental health care. This approach continues to be one of few interventions that has reduced rates of suicide in a randomized controlled trial. The Centralized High Risk Flag Caring Letters are based on templates with unique messages for each mailing. Letters will be mailed out on a schedule that has been used in other successful trials, with letters mailed monthly for the first 4 months and then bi-monthly (Months 1, 2, 3, 4, 6, 8, 10, 12). Eligible Veterans will be identified weekly. Letters will be mailed according to the pre-determined schedule and corresponding templates will be sent out. The letters and envelopes will be designed as personalized cards (colorful envelopes distinguishable from other VA correspondence or bills). Contact information for the Veterans Crisis Line is included with each letter. The VA Suicide Prevention Program policy requires this outreach to Veterans following High Risk Flag inactivation, and the planned evaluation will provide actionable program guidance related to the effectiveness of this approach and of centralizing delivery of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Incidence and frequency of VA psychiatric hospitalization from analysis of VA health care records data obtained from the VA's Corporate data Warehouse (CDW) assessed for 1 year of Centralized Caring Letters delivery and in a pre-intervention comparison cohort
2. Incidence and frequency of VA emergency department visits obtained from analysis of VA health care record data from the CDW assessed for 1 year of Centralized Caring Letters and in a pre-intervention comparison cohort
3. Rates of outpatient VA mental health care utilization from analysis of VA health care record data from the CDW assessed for 1 year of Caring Letters and in a pre-intervention comparison cohort

Key secondary outcome(s)
1. Incidence of any outpatient care, and any inpatient care obtained from analyses of VA health care record data from the CDW assessed for 1 year of Caring Letters and in a pre-intervention comparison cohort.
2. Suicide attempts, as measured by a record of a suicide-related event in VA suicide behavior surveillance data (reports submitted by VA providers) or ICD-10 codes during the 1-year receipt of Caring Letters. A record of a suicide attempt in either data source will indicate that the case is positive for a suicide attempt. ICD-10 codes that will be considered a suicide attempt include those associated with intentional poisoning and other intentional self-harm assessed for 1 year during Centralized Caring Letters delivery and in a pre-intervention comparison cohort.
3. All-cause mortality, i.e., death rate from all causes of death obtained from VA health care record data from the CDW assessed for 1 year during Centralized Caring Letters delivery and in a pre-intervention comparison cohort of.
4. Rates of suicide: Suicide mortality rates will be obtained from the VA/DoD Mortality Data Repository which contains the National Death Index (state death records data) for all Veterans assessed for 1 year during Centralized Caring Letters and in a pre-intervention comparison

cohort. Since these data are not available until about 2 years after the year of death, these results will be delayed compared to other analyses.
5. A secondary goal for this study is to collect data on the delivery of the intervention and the role of the implementation strategy of centralizing the program delivery. Differences in reach in the centralized versus decentralized Caring Letters approaches will be assessed using administrative data. Fidelity to the centralized Caring Letters approach will be assessed using administrative data. The RE-AIM analytic framework will be used to examine implementation and impact of the intervention. Data from qualitative interviews with Veteran participants (N=30) and VA Staff including Suicide Prevention Coordinators (N=6) and Office of Mental Health & Suicide Prevention (OMHSP) leadership (N=4) will also be collected and analyzed.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Participants will be included in the Centralized Caring Letters intervention if they have an inactivated High Risk for Suicide Patient Record Flag (HRS PRF) during the recruitment period which is 30/6/2023 – 29/06/2024 for phase 1 sites and 31/1/2024 – 29/06/2024 for phase 2 sites and:
1. Have a valid mailing address on file with the VHA
2. Are not removed or opted out by a local Suicide Prevention Coordinator prior to enrollment in the intervention.
3. Have not died before upload of their name and address information for mail processing
4. Are not actively enrolled in and receiving Caring Letters from the Veterans Crisis Line Caring Letter project at the time of eligibility for enrollment
All Veteran age ranges and genders will be included.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
14283

Key exclusion criteria
1. No fixed valid mailing address available in VHA records
2. Death prior to upload of name and address information for mail processing
3. Actively enrolled in and receiving Caring Letters from the Veterans Crisis Line Caring Letter project at the time of eligibility for enrollment

Date of first enrolment
30/06/2023

Date of final enrolment
29/06/2024

Locations

Countries of recruitment
Puerto Rico

United States of America

Study participating centre
VA Puget Sound Healthcare System
1660 S Columbian Way
Seattle
United States of America
98108

Study participating centre
Partnered Evidence-Based Policy Resource Center (PEPReC) / VA Boston Healthcare System Research & Development
150 South Huntington Avenue
Boston
United States of America
02130

Study participating centre
Central Arkansas Veterans Healthcare System
2200 Fort Roots Drive
Little Rock
United States of America
72114

Study participating centre

Veterans Crisis Line
400 Fort Hill Avenue
Canandaigua
United States of America
14424

Sponsor information

Organisation
Veterans Crisis Line

Organisation
Quality Enhancement Research Initiative

ROR
https://ror.org/03cdz5d08

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Veterans Affairs

Alternative Name(s)
Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, Veterans' Administration, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1	23/07/2025	01/08/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes