PEPReC

Partnered Evidence-based Policy Resource Center
A VA QUERI Center

Evaluation of the Extension of the VCL Caring Letters Suicide Prevention Campaign: Plan for Quantitative Analysis

Date: May 30, 2024

Evaluation Overview | Quantitative Analysis Overview

Evaluation Overview

Goal: To assess if the extension of the Veterans Crisis Line (VCL) Caring Letters meaningfully impacts utilization of health services or health outcomes among Veterans.

Eligible Cohort: Previous Caring Letters recipients who contact the VCL in the 395 days following the date of their last mailed letter. Veterans are eligible for enrollment in the extension if 1) they enrolled in the original Caring Letters trial and 2) they contact VCL on behalf of themselves in the 395 days following the date of their last mailing. Veterans who enroll in the extension (referred to hereafter as repeat callers) will maintain the same signatory condition (i.e., letters signed by a peer or a provider) that they were assigned in the original trial. Utilization and health outcomes will be assessed from the 12-months following the VCL contact that qualified enrollment in the extension.

Treatment/Exposures: Repeat callers are randomized to either receive no additional Caring Letters (control condition) or three additional Caring Letters (treatment condition). For repeat callers enrolled in the treatment condition, letters will be mailed starting in the first month after the repeat call and then mailed every other month thereafter. These letters augment the Caring Letters sent during the original Caring Letters trial. In the original Caring Letters trial, a total of nine letters were sent over the course of the intervention.

Randomization: To ensure adequate gender representation across conditions, randomization will be conducted using permuted block randomization, stratified by gender. After callers are successfully matched to CDW data, they are stratified by gender. Using a random number generator, randomization will occur weekly using blocks of four callers with two conditions (A=treatment condition, B=control condition), allowing for six permutations ((1-AABB, 2-ABAB, 3-ABBA, 4-BAAB, 5-BABA, 6-BBAA)).

Data: The analytic file will be compiled from the following data below. Specific variables are detailed in the sections that follow.

- VCL Medora data
- Corporate Data Warehouse (CDW) database
- Office of Mental Health and Suicide Prevention (OMHSP) Standard Suicide Overdose Event Table (encompassing both SPAN and its replacement – the Suicide Behavior and Overdose Report [SBOR])
- VA/DoD Mortality Data Repository (MDR) incorporates National Death Index (NDI) and data from VA and DoD administrative records

Outcomes: The outcomes for the study are listed below, along with data source, in Table 1. We will measure all outcomes as binary variables, taking the value of '0' if the outcome did not occur and '1' if it did.

Table 1. Study Outcomes & Data Sources	
Study Outcome	**Data Sources**
Clinical Outcomes	
All-Cause Mortality	CDW Vital Status File, CDWWork Spatient.Spatient, CDWWork.SVeteran.SMVIPerson
Suicide-Related Events	OMHSP Suicide Attempt Surveillance Data
Suicide Mortality	VA/DOD Mortality Data Repository
Utilization Outcomes	
All-Cause Inpatient	CDW Data
All-Cause Outpatient	CDW Data
Mental Health Inpatient	CDW Data
Mental Health Outpatient	CDW Data
Emergency Department	CDW Data

Additional Variables (covariates): We will collect data on Veteran sociodemographic characteristics including age, gender, race/ethnicity, marital status, branch of military service, discharge status, years of service, age at separation, and active or reserve status. We will also collect data on Veterans health status including past-year mental illness diagnoses, as well as past-year incidence of suicide-related events, past-year inpatient mental health care use, past-year outpatient mental health care use, and incidence of Elixhauser comorbidities.

Quantitative Analysis Overview

The primary analyses will be performed after the final letters are sent, and after monitoring and cleaning of data. Enrollment in the extension started on 03/19/2022 and ended on 03/17/2023. Outcome data collection ended on 03/17/2024, with the exception of suicide mortality data, which will not be available until FY2026. Analyses will be conducted at the patient-month level.

Primary Analysis: Comparison of Additional Caring Letters vs. No Additional Caring Letters

We will compare the incidence of outcomes between repeat callers enrolled in the control (i.e., no additional Caring Letters) and treatment (i.e., three additional Caring Letters) conditions. We will test the following hypothesis:

- H1: Veterans who contact the VCL again and receive additional Caring Letters will have a higher proportion of VA mental health outpatient visits compared to Veterans who contact the VCL again and do not receive the additional Caring Letters.

We will examine differences in the use of VHA health services (all-cause inpatient and outpatient services, inpatient and outpatient mental health services, and emergency department services) and health outcomes (suicide-related events, all-cause mortality, and suicide-related mortality) between repeat callers enrolled in the control (i.e., no additional Caring Letters) and treatment (i.e., three additional Caring Letters) conditions using chi-square tests.

We will use time-to-event analyses (i.e., Cox regression models) to examine the adjusted association of receiving additional Caring Letters with the aforementioned outcomes if we observe imbalance in patient characteristics between treatment and control groups. If conducted, adjusted analyses will include individual-level characteristics (i.e., age, gender, race, etc.) in addition to time fixed effects to control for temporal trends. To evaluate if results are sensitive to binary outcome measurement, we will also assess if incidence of outcomes differs between groups. We will use t-tests to measure unadjusted differences and if indicated, Ordinary Least Squares or Poisson regression models adjusted for the aforementioned characteristics to measure adjusted differences.

Subgroup Analyses

1. Repeat callers may differ from those who do not contact the VCL again (i.e., the analytic cohort for the extension may differ from the analytic cohort for the original trial). To assess this, we will examine the characteristics of callers enrolled in the original trial and those enrolled in the extension using standardized differences. If characteristics meaningfully differ, we will conduct subgroup analyses to assess if the extension disproportionately affects certain groups of callers. This will help us assess if any differences in findings between the main trial and the extension may be driven by differences in the analytic cohorts, and provide additional context to interpret results.

Secondary Analysis: Comparison of No Caring Letters, Original Caring Letters Intervention, and both the Original Caring Letters Intervention and the Extension

We will also compare frequencies of the aforementioned outcomes between callers who did not enroll in the Caring Letters intervention (control group, received no Caring Letters), enrolled in only the original Caring Letters intervention (treatment group 1, received 8 or 9 Caring Letters), and enrolled in both the original Caring Letters intervention and the extension (treatment group 2, received 12 Caring Letters).

The control and treatment groups will be constructed as follows:

- The control group will be comprised of two groups of callers. The first group of callers are those who contacted the VCL between 2/1/2018-2/1/2020, prior to the start of the original Caring Letters intervention, and would have been eligible for the intervention had it been available (i.e., a historical control). The second group of callers are those who contacted the VCL after the intervention began, between 9/1/2020-3/17/2023, but did not provide enough identifying information to receive mailings (i.e., no mailing address), and thus could not be enrolled in the

Caring Letters intervention. These time periods were selected to avoid the first six months of the COVID-19 pandemic.

- Treatment group 1 will be constructed of callers who enrolled in the original Caring Letters intervention between 3/19/2022-3/17/2023, and did not receive the extension owing to the timing of their enrollment in the original intervention (i.e., enrollment in the extension for these callers would have began after the conclusion of the extension intervention).
- Treatment group 2 will be constructed of callers who enrolled in the original Caring Letters intervention (contacted the VCL between 6/11/2020-6/10/2021) and in the extension (contacted the VCL in the year following receipt of their final mailing from the original Caring Letters intervention, between 3/19/2022-3/17/2023).

We will examine differences in the use of VHA health services (all-cause inpatient and outpatient services, inpatient and outpatient mental health services, and emergency department services) and health outcomes (suicide-related events, all-cause mortality, and suicide-related mortality) between callers in these three groups. We will use Chi-Square tests to compare the frequencies of outcomes between the control group, treatment group 1, and treatment group 2.

Next, we will use time-to-event models (i.e., Cox regression) to examine the association between treatment status (i.e., enrollment in the original Caring Letters intervention only or original Caring Letters intervention and the extension) and each outcome. Owing to measurement changes of suicide-related events in the VA that overlap with the time periods for the control group and treatment group 1, frequency of suicide-related events will be considered an exploratory outcome for this analysis. The control group will be used as the reference group. We will report results in terms of marginal effects (vs. hazard ratios), which can be interpreted as the incremental change in the likelihood of experiencing each outcome for callers in treatment group 1 and treatment group 2, relative to those in the control group. Survival models will include caller characteristics (age, sex, race, ethnicity, marital status, age at separation from service, discharge status, military branch, incidence of past-year suicide attempt, incidence of past-year inpatient or outpatient mental health visit, Elixhauser comorbidities). Owing to the removal of the Veterans Day Mailing in 2023, callers in treatment group 1 received either 8 or 9 Caring Letters. As such, we will include a variable to indicate receipt of the Veterans Day Mailing to control for this change. To control for temporal trends, models will also include year and month of call.

Potential Internal Threats and Solutions to Internal Validity

1. *Selection bias.* Callers who do not contact the VCL in the year after receipt of their final mailing might differ from those who do. Those who contact the VCL again may have more severe mental illness or be less engaged with health services, and thus use the VCL more intensely. Thus, those callers who enroll in the extension (treatment group 2) may be at greater risk for adverse events than those who do not enroll in the extension (treatment group 1)—this could lead to underestimation of the intervention's effectiveness. To assess this, we will first compare the characteristics of callers in treatment groups 1 and 2 using standardized differences. If there are significant differences between callers in treatment groups 1 and 2, we will use inverse probability weighting to adjust for the probability of enrolling in the extension. This method assigns higher weights to individuals who are less likely to enroll in the extension, thereby reducing the influence of selection bias in the analysis. We will then re-run models described above with the inverse probability weights. We might also perform subgroup analyses based on

characteristics that significantly differed between treatment groups 1 and 2, which would tell us if the effects of the intervention are concentrated among certain types of callers.

2. *Survival bias.* Callers who do not enroll in the extension (treatment group 1) may have experienced mortality before enrollment in the extension began. This could lead to an overestimation of the effect of the extension on adverse health outcomes (i.e., mortality and suicide-related events) if individuals at higher risk of mortality are systematically excluded from treatment group 2. To assess if results might be sensitive to survival bias, we will exclude callers from treatment group 1 and 2 who experience mortality prior to the end of the follow-up period for the extension (3/17/2023).