Statistical Analysis Plan

Table of Contents

Overview

This statistical analysis plan (SAP) builds upon the details included in the ISCRTN protocol (ISRCTN27551361). Initial analysis details were documented before outcome data was available for the study (version 1: November 6, 2020). The SAP includes plans to analyze both the randomized signatory component as well as the observational data on outcomes associated with receipt of letters (regardless of signatory).

The analysis plans for the observational component have evolved over time. In our original (11/6/20) SAP, we documented potential strategies to assess threats to internal validity, including the beginning of the COVID-19 pandemic, in our analysis of the association between receipt of caring letters and our primary and secondary outcomes. These strategies included identification of a viable instrumental variable that would be associated with timing of initial letter receipt but not outcome. We were unable to identify a strong, valid instrument and instead designed a difference in difference-in-differences (triple differences) approach that would compare changes from before to after a Veterans Crisis Line (VCL) call among a) Veterans who received letters (called between 6/20 and 6/21), b) Veterans who did not receive letters but called during the beginning of COVID lockdowns (called between 3/20 and 5/20), and c) Veterans who did not receive letters and called a year before COVID lockdowns (allowing us to observe outcomes in a pre-pandemic period; called between 6/18 and 3/19). This is documented in version 2 of the SAP (4/2/22) and was also published in the appendix of our paper describing the development and initial stages of the caring letters evaluation.[1]

When we implemented the triple differences approach after data collection was complete in June 2022, we learned that the assumptions behind a difference-in-differences approach were not supported in our data. Trends in outcomes were not parallel before the index call across our different treatment groups. Therefore, in January 2023, we pivoted to using time-to-event analyses and cause-specific hazard functions that include controls for year, month, and onset of the COVID pandemic. The cohort was reframed to include index calls between 6/11/2018 and 6/10/2021. This is the approach reported in the manuscript.

Further adjustments to the analytic sample, measures, and analyses are summarized below and documented in version 3 of the SAP, 6/22/23.

Analytic Sample

During the course of the study, we identified elements of the VCL Medora dataset that would allow us to more accurately verify our sample matched the goals of our inclusion criteria (Veterans who contacted VCL on behalf of themselves and communicated with a VCL responder). Therefore, from the sample of individuals presumed to receive at least one letter, we additionally excluded third party contacts (a variable that was not available at the beginning of the study, when the code to identify letter recipients was created), as well as calls in which a responder made an outgoing call to a Veteran and was unable to make contact, and calls in which the source of the VCL contact was an email referral, compassionate care, caregiver, Facebook, or assigned callback from our treatment group. This was an analytic refinement and not a change in the goals of the study.

Measures

We dropped both subsequent VCL call and calls to VA411 (help line included in the Caring Letters) as secondary outcomes. Subsequent VCL calls were dropped because a substantial proportion of VCL callers contact the VCL frequently — sometimes multiple times a day. Without knowing the timing of letter receipt, analyzing the association between multiple VCL calls and receipt of letters is unlikely to be informative. Calls to VA411 were dropped because data on call volume were unavailable. We also did not pursue suicidal ideation as an outcome, as it is unreliably documented in the medical record. We focus on suicide attempt incidence rather than frequency, because of concerns about the reliability of event frequency data. Suicide mortality remains an outcome of interest, but cause of death data are not yet available for the entire sample.

One covariate – rank – was not readily available and was not included in our final analyses. Data on active vs reserve status was missing for 41% of our sample and was thus not included. We also considered using years of service, but it was highly correlated with age at separation from service (Pearson correlation coefficient = 0.6) and was not included. Marital status was added as a covariate. We extended the lookback period for Elixhauser comorbidities from one year to two years to account for fewer opportunities for comorbidity ascertainment during the height of the COVID-19 pandemic.

Analyses

In the randomized signatory analyses, we did not observe any significant relationship between signatory and any of our primary or secondary outcomes in unadjusted analyses, so we refrained from running adjusted regression models for numbers of visits or Cox regressions to explore associations between caring letters and all-cause mortality. Details of our final analyses are documented in version 3 of the SAP (6/22/23).

1. Reger MA, Lauver MG, Manchester C, Abraham TH, Landes SJ, Garrido MM, Griffin C, Woods JA, Strombotne KL, Hughes G. Development of the Veterans Crisis Line caring letters suicide prevention intervention. Health Services Research 2022; 57(S1): 42-52. doi: 10.1111/1475-6773.13985

Randomized Evaluation of the VCL Caring Letters Suicide Prevention Campaign:
Plan for Quantitative Analysis
VERSION 1

Last Updated: November 6, 2020

Evaluation Overview | Quantitative Analysis Overview | Data Flow

Evaluation Overview

Goal: To test the effectiveness of a Caring Letters campaign on clinical outcomes and utilization rates in order to identify an effective and sustainable evidence-based practice to reduce suicide behaviors among veterans.

Eligible Cohort: All VCL callers with an identifiable address in VHA databases. The following callers will be excluded: (1) friends and family calling on behalf of a veteran, (2) civilians, and (3) callers who have died prior to being randomized. Furthermore, individuals who call the hotline after enrollment in the study will be flagged so as not to be re-randomized. Individuals who die after enrollment in the study will be flagged so as not to continue receiving letters.

Treatment/Exposures: A control group will be constructed from VCL callers two years prior to the trial start date. A total of nine (9) letters will be sent to the callers over the course of the intervention. One (1) letter will be sent to all callers on Veteran's Day, and an additional eight (8) letters will be mailed to each caller, each spaced approximately one month apart beginning from the initial call date.[1] Eligible veterans who call the VCL after the trial start date will be randomized to one of two interventions, detailed below.

Arm 1: Peer signatory letter
Arm 2: Provider signatory letter

Randomization: To ensure adequate gender representation in the peer signatory conditions, randomization will be conducted using permuted block randomization, stratified by gender. New callers will be identified monthly; randomization will occur monthly using blocks of 4 patients with 2 conditions (A=peer signatory, B=provider signatory). This set up allows for 6 permutations ((1-AABB, 2-ABAB, 3-ABBA, 4-BAAB, 5-BABA, 6-BBAA)).

After callers are successfully matched to CDW data, they are stratified by gender. Within each stratum, a uniform random number will be generated in SQL (range 0-1) that corresponds to each block of 4 patients. If the random number, R, is >= 0 and < 1/6, the block of 4 callers is assigned to permutation 1 (order of assignment to letter type is AABB). If 1/6 <= R < 2/6, the

[1] The specific months will be 1,2,3,4,6,8,10,12 + Veteran's Day card

block of 4 callers is assigned to permutation 2 (order of assignment to letter type is ABAB). The same pattern follows for permutations 3-6.

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

- VCL Medora data
- CDW database
- SSA Vital Status file
- Mortality Data Repository
- OMHSP Standard Suicide Overdose Event Table (encompassing both SPAN and its replacement – the Suicide Behavior and Overdose Report [SBOR])
- 311 data

Outcomes: The outcomes for the study are listed below, along with data source, in Table 1.

Table 1. Study Outcomes

Clinical Outcomes	VHA Utilization (Incidence & Frequency)	VCL Utilization (Incidence & Frequency)	Others
• All-cause mortality (*CDW Spatient Table*, *Vital Status file*) • Suicide mortality (*Mortality data repository*) • Non-fatal suicide event (incidence & frequency) (*ICD-10 codes and OMHSP_Standard_SuicideOverdoseEvent Table*) • Suicidal ideation (*OMHSP_Standard_SuicideOverdoseEvent Table*)	• Any VA healthcare services (*CDW*) • Psychiatric hospitalization (*CDW*) • Outpatient mental health services (*CDW*) • ED visits (*CDW*)	• Subsequent VCL call (*Medora data*)	• 311 aggregate monthly call volume (external 311 partner data)

Additional variables (covariates):

- Sociodemographics
  - Age
  - Gender
  - Race/ethnicity
  - Branch of military
  - Discharge status
  - Years of service
  - Age at separation
  - Active or reserve component
  - Rank

    - VAMC
- Comorbidities in past year
    - Mental illness diagnoses
    - Elixhauser comorbidities
- Past SAEs
- Past mental health utilization
- Exploratory: Other covariates in the VCL caller data; REACH-VET risk score

Quantitative Analysis Overview

The primary analyses will be performed after the final letters are sent, and after monitoring and cleaning of data collected from all callers. Main analyses will be performed according to the intention-to-treat (ITT) principle, in which all callers are analyzed according to their initially assigned study arm at baseline, regardless of whether letters were received.

Data structure: Patient-month level.

Analysis 1: Pre-Post Comparison: The pre-post analysis will compare outcomes between callers who receive Caring Letters compared to callers in the previous two years. We will test the following three hypotheses:

- H1: lower incidence of VA documented suicide attempts in the post period.
- H2: lower incidence and frequency of VA psychiatric hospitalization in the post period.
- H3: higher rates of engagement in VA healthcare (in general) and higher outpatient mental health utilization rates in the post period.

We will analyze differences in proportions of VCL callers who engaged with any outpatient VA health care before and after the Caring Letters campaign with a chi-square test. Similarly, chi-square tests will be used to examine differences in incidence of suicide attempts, incidence of psychiatric hospitalization, and incidence of mental health outpatient visits. Differences in frequency of hospitalizations and mental health outpatient visits will be examined with Wilcoxon rank-sum tests. Pre-post analyses of associations among outcomes and Caring Letters will not be able to rule out the possibility that observed differences in outcomes are due to unmeasured temporal changes coinciding with Caring Letters.

<u>Potential threats to internal validity may include the following scenarios</u>:

1. Historical differences in outcomes pre- and post-trial start date. These may include overall trends or Covid-19 specific differences (especially in March 2020 and beyond).

2. Historical differences in caller composition (and thus likelihood of experiencing an outcome). These may include overall trends in callers, or Covid-19 specific trends in callers.
3. Policy changes that coincide with the intervention.

Potential strategies to assess and address threats to internal validity:

1. Examining monthly trends in outcomes over time.
2. Examining overall differences and monthly trends in caller characteristics. We will pull three years of VCL caller history and explore whether patterns of repeat calls and caller sociodemographic and clinical characteristics evolve over time.
3. Identification of alternate contemporaneous comparison groups
4. Identify a potential instrumental variable (variable associated with letter receipt but not with health care utilization or mortality). One potential instrument may be delays in mail delivery that lead to variation in timing of initial letter receipt? We can look at the date between call and bad-address notification from print vendor as a proxy.

Analysis 2: Comparison of Letter Signatories

Our Aim 2 analyses (cross-arm analyses among individuals engaged in VA care) will not be subject to the history threats to internal validity that exist in Aim 1. We can further isolate the impact of caring letter signatory on outcomes by controlling for the potential confounders noted above, in addition to confounders with potential prognostic value, such as mental health diagnoses (Kahan 2014). Dichotomous outcomes will be examined with logistic regression, and counts of hospitalizations and visits will be examined with zero-inflated Poisson or negative binomial models. Exploratory analyses of associations among Caring Letters and all-cause and suicide mortality will be conducted with Cox regression (using time of VCL call as time 0).

Budget Impact Analysis (BIA):

We will examine the budget impact of Caring Letters among all VCL callers over a 12-month period. We will compare costs related to inpatient and outpatient mental health care use and medications before the Caring Letters campaign with costs related to health care use and medications, as well as costs of mailing the letters during the Caring Letters campaign. We expect inpatient costs to decrease and outpatient costs to increase due to the intervention. We do not expect Caring Letters to serve as a substitute for any existing mental health outreach program. Costs of both VA-provided and purchased care will be captured. In all analyses, we will use the Gross Domestic Product Deflator to adjust costs to 2020 dollars. The budget impact of each version of Caring Letters will be assessed. Mean costs per patient-month alive will be reported.

Data Flow

VCL Data is downloaded from backups on a weekly basis. The data is downloaded from the Saturday two weeks prior through the end of the Friday of the previous week. That data is then uploaded to the Caring Letters data system that resided on CDWA01. A SQL script is then run to parse the new data, identify callers who can be matched to the CDW and enroll them into the program, then generates a list of all letters due to go out this week.

This includes letters for newly enrolled patients as well as patients enrolled previously who are getting subsequent letters. Once the letter file has been generated it is sent to the print vendor using encrypted email. The print vendor then sends back information on any patients with a change of address, any addresses that are undeliverable and the mail receipt of when each batch of letters was sent out.

Randomized Evaluation of the VCL Caring Letters Suicide Prevention Campaign:
Plan for Quantitative Analysis
VERSION 2

Last Updated: April 1, 2022

Evaluation Overview | Quantitative Analysis Overview | Data Flow

Evaluation Overview

Goal: To test the effectiveness of a Caring Letters campaign on clinical outcomes and utilization rates in order to identify an effective and sustainable evidence-based practice to reduce suicide behaviors among veterans.

Eligible Cohort: All VCL callers with an identifiable address in VHA databases. The following callers will be excluded: (1) friends and family calling on behalf of a veteran, (2) civilians, and (3) callers who have died prior to being randomized. Furthermore, individuals who call the hotline after enrollment in the study will be flagged so as not to be re-randomized. Individuals who die after enrollment in the study will be flagged so as not to continue receiving letters.

Treatment/Exposures: A control group will be constructed from VCL callers two years prior to the trial start date. A total of nine (9) letters will be sent to the callers over the course of the intervention. One (1) letter will be sent to all callers on Veteran's Day, and an additional eight (8) letters will be mailed to each caller, each spaced approximately one month apart beginning from the initial call date.[2] Eligible veterans who call the VCL after the trial start date will be randomized to one of two interventions, detailed below.

Arm 1: Peer signatory letter
Arm 2: Provider signatory letter

Randomization: To ensure adequate gender representation in the peer signatory conditions, randomization will be conducted using permuted block randomization, stratified by gender. New callers will be identified monthly; randomization will occur monthly using blocks of 4 patients with 2 conditions (A=peer signatory, B=provider signatory). This set up allows for 6 permutations ((1-AABB, 2-ABAB, 3-ABBA, 4-BAAB, 5-BABA, 6-BBAA)).

After callers are successfully matched to CDW data, they are stratified by gender. Within each stratum, a uniform random number will be generated in SQL (range 0-1) that corresponds to each block of 4 patients. If the random number, *R*, is >= 0 and < 1/6, the block of 4 callers is assigned to permutation 1 (order of assignment to letter type is AABB). If 1/6 <= *R* < 2/6, the

[2] The specific months will be 1,2,3,4,6,8,10,12 + Veteran's Day card

block of 4 callers is assigned to permutation 2 (order of assignment to letter type is ABAB). The same pattern follows for permutations 3-6.

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

- VCL Medora data
- CDW database
- SSA Vital Status file
- Mortality Data Repository
- OMHSP Standard Suicide Overdose Event Table (encompassing both SPAN and its replacement – the Suicide Behavior and Overdose Report [SBOR])
- 311 data

Outcomes: The outcomes for the study are listed below, along with data source, in Table 1.

Table 1. Study Outcomes

Clinical Outcomes	VHA Utilization (Incidence & Frequency)	VCL Utilization (Incidence & Frequency)	Others
• All-cause mortality (*CDW Spatient Table*, *Vital Status file*) • Suicide mortality (*Mortality data repository*) • Non-fatal suicide event (incidence & frequency) (*ICD-10 codes and OMHSP_Standard_SuicideOverdoseEvent Table*) • Suicidal ideation (*OMHSP_Standard_SuicideOverdoseEvent Table*)	• Any VA healthcare services (*CDW*) • Psychiatric hospitalization (*CDW*) • Outpatient mental health services (*CDW*) • ED visits (*CDW*)	• Subsequent VCL call (*Medora data*)	• 311 aggregate monthly call volume (external 311 partner data)

Additional variables (covariates):

- Sociodemographics
  - Age
  - Gender
  - Race/ethnicity
  - Branch of military
  - Discharge status
  - Years of service
  - Age at separation
  - Active or reserve component
  - Rank

    - VAMC
- Comorbidities in past year
    - Mental illness diagnoses
    - Elixhauser comorbidities
- Past SAEs
- Past mental health utilization
- Exploratory: Other covariates in the VCL caller data; REACH-VET risk score

Quantitative Analysis Overview

The primary analyses will be performed after the final letters are sent, and after monitoring and cleaning of data collected from all callers. Main analyses will be performed according to the intention-to-treat (ITT) principle, in which all callers are analyzed according to their initially assigned study arm at baseline, regardless of whether letters were received.

Data structure: Patient-month level.

Analysis 1: Pre-Post Comparison: The pre-post analysis will compare outcomes between callers who receive Caring Letters compared to callers in the previous two years. We will test the following three hypotheses:

- H1: lower incidence of VA documented suicide attempts in the post period.
- H2: lower incidence and frequency of VA psychiatric hospitalization in the post period.
- H3: higher rates of engagement in VA healthcare (in general) and higher outpatient mental health utilization rates in the post period.

We will analyze differences in proportions of VCL callers who engaged with any outpatient VA health care before and after the Caring Letters campaign with a chi-square test. Similarly, chi-square tests will be used to examine differences in incidence of suicide attempts, incidence of psychiatric hospitalization, and incidence of mental health outpatient visits. Differences in frequency of hospitalizations and mental health outpatient visits will be examined with Wilcoxon rank-sum tests. Pre-post analyses of associations among outcomes and Caring Letters will not be able to rule out the possibility that observed differences in outcomes are due to unmeasured temporal changes coinciding with Caring Letters.

<u>Potential threats to internal validity may include the following scenarios</u>:

4. Historical differences in outcomes pre- and post-trial start date. These may include overall trends or Covid-19 specific differences (especially in March 2020 and beyond).

5. Historical differences in caller composition (and thus likelihood of experiencing an outcome). These may include overall trends in callers, or Covid-19 specific trends in callers.
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Potential strategies to assess and address threats to internal validity:

5. Examining monthly trends in outcomes over time.
6. Examining overall differences and monthly trends in caller characteristics. We will pull three years of VCL caller history and explore whether patterns of repeat calls and caller sociodemographic and clinical characteristics evolve over time.
7. Identification of alternate contemporaneous comparison groups
8. Identify a potential instrumental variable (variable associated with letter receipt but not with health care utilization or mortality). One potential instrument may be delays in mail delivery that lead to variation in timing of initial letter receipt? We can look at the date between call and bad-address notification from print vendor as a proxy.

Analysis 2: Comparison of Letter Signatories

Our Aim 2 analyses (cross-arm analyses among individuals engaged in VA care) will not be subject to the history threats to internal validity that exist in Aim 1. We can further isolate the impact of caring letter signatory on outcomes by controlling for the potential confounders noted above, in addition to confounders with potential prognostic value, such as mental health diagnoses (Kahan 2014). Dichotomous outcomes will be examined with logistic regression, and counts of hospitalizations and visits will be examined with zero-inflated Poisson or negative binomial models. Exploratory analyses of associations among Caring Letters and all-cause and suicide mortality will be conducted with Cox regression (using time of VCL call as time 0).

Budget Impact Analysis (BIA):

We will examine the budget impact of Caring Letters among all VCL callers over a 12-month period. We will compare costs related to inpatient and outpatient mental health care use and medications before the Caring Letters campaign with costs related to health care use and medications, as well as costs of mailing the letters during the Caring Letters campaign. We expect inpatient costs to decrease and outpatient costs to increase due to the intervention. We do not expect Caring Letters to serve as a substitute for any existing mental health outreach program. Costs of both VA-provided and purchased care will be captured. In all analyses, we will use the Gross Domestic Product Deflator to adjust costs to 2020 dollars. The budget impact of each version of Caring Letters will be assessed. Mean costs per patient-month alive will be reported.

Addendum (Covid threats)

Letters began to be mailed out to VCL callers in June 2020, only 3 months after the start of COVID-19-related lockdowns. Therefore, it will be necessary to separate out changes in outcomes that are due to calls during the pandemic from changes in outcomes that are due to receipt of the letters. To isolate the effect of the letters from the effect of the pandemic, we will use a differences in differences-in-differences (or 'triple differences') approach: we will compare changes from before to after a VCL call among a) Veterans who received letters (called between 6/20 and 6/21), b) Veterans who did not receive letters but called during the beginning of COVID lockdowns (called between 3/20 and 5/20), and c) Veterans who did not receive letters and called a year before COVID lockdowns (allowing us to observe outcomes in a pre-pandemic period; called between 6/18 and 3/19). Sensitivity of results to inclusion of a fourth group (those who called between 4/19 and 2/20 – who had part of their post-call period during the beginning of COVID) will be evaluated.

The treatment group studied for this evaluation will have received letters during the COVID-19 pandemic. If the reasons for calling the VCL differ systematically during the pandemic compared to pre-pandemic times, and if these reasons are associated with either baseline risks of outcomes or interact with the caring letters program to change the treatment effect of the program our results may not generalize to a post-pandemic period. To understand the degree to which this is likely to be an issue, we will re-run our analyses, restricting our treatment group to include individuals who received letters but who may have been less adversely affected by the COVID-19 pandemic (e.g., callers from counties with relatively low COVID burden at the time of their call). We can also incorporate measures of COVID burden to the triple differences analyses described above. An additional sensitivity analysis will match callers during the letters campaign to earlier (pre-2020) callers who called from locations experiencing other high-stress events, including wildfires, flooding, and hurricane damage.

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This includes letters for newly enrolled patients as well as patients enrolled previously who are getting subsequent letters. Once the letter file has been generated it is sent to the print vendor using encrypted email. The print vendor then sends back information on any patients with a change of address, any addresses that are undeliverable and the mail receipt of when each batch of letters was sent out.

Randomized Evaluation of the VCL Caring Letters Suicide Prevention Campaign:
Plan for Quantitative Analysis
VERSION 3
Last Updated: June 22, 2023

Evaluation Overview | Quantitative Analysis Overview | Data Flow

Evaluation Overview

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Table 1. Study Outcomes

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• All-cause mortality (*CDW Spatient Table*, *Vital Status file*) • Suicide mortality (*Mortality data repository*) – left for future analyses • Suicide attempt (incidence (*ICD-10 codes and OMHSP_Standard_SuicideOverdoseEvent Table*)	• Any VA healthcare services (*CDW*) • Psychiatric hospitalization (*CDW*) • Outpatient mental health services (*CDW*) • ED visits (*CDW*)

Additional variables (covariates):

- Sociodemographics
  - Age
  - Gender
  - Race/ethnicity
  - Marital status
  - Branch of military
  - Age at separation
  - Discharge status
  - VAMC
- Comorbidities in past two years
  - Mental illness diagnoses

    - Elixhauser comorbidities
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Quantitative Analysis Overview

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We will analyze differences in proportions of VCL callers who engaged with any outpatient VA health care before and after the Caring Letters campaign with a chi-square test. Similarly, chi-square tests will be used to examine differences in incidence of suicide attempts, incidence of psychiatric hospitalization, and incidence of mental health outpatient visits. Differences in frequency of hospitalizations and mental health outpatient visits will be examined with Wilcoxon rank-sum tests.

Pre-post analyses of associations among outcomes and Caring Letters will not be able to rule out the possibility that observed differences in outcomes are due to unmeasured temporal changes coinciding with Caring Letters. One strategy to account for this is a difference in difference-in-differences (triple differences approach). To isolate the effect of the letters from the effect of the pandemic, we attempted to compare changes from before to after a VCL call among a) Veterans who received letters (called between 6/20 and 6/21), b) Veterans who did not receive letters but called during the beginning of COVID lockdowns (called between 3/20 and 5/20), and c) Veterans who did not receive letters and called a year before COVID lockdowns (allowing us to observe outcomes in a pre-pandemic period; called between 6/18 and 3/19). Sensitivity of results to inclusion of a fourth group (those who called between 4/19 and 2/20 – who had part of their post-call period during the beginning of COVID) will be evaluated. A triple differences approach requires an assumption that, absent treatment, trends

in outcomes would evolve in parallel in the post-treatment period. In our sample, trends were not parallel in the pre-treatment period, so the parallel trends assumption was not supported.

An alternate approach models time to event while controlling for time and historic events. In this approach, the cohort was reframed to include index calls between 6/11/2018 and 6/10/2021. Because many VCL callers have more than a single contact with the VCL during their lifetime, we allowed individuals to appear in both the treatment and comparison group. We included all eligible treatment individuals in our cohort who had at least one VA inpatient or outpatient encounter in the 24 months prior to their call. To create the pool of eligible calls for the comparison group, we generated a list of all calls from 6/11/2018 to 6/10/2021 and dropped comparison calls after the index caring letters date for Veterans who are in the treatment group. From the remaining comparison calls that met treatment group eligibility criteria and had at least one VA inpatient or outpatient encounter in the 24 months prior to their call but who did not receive caring letters, we randomly selected one call per Veteran.

We used individual-level survival models for each outcome, modeling time to event. We used cause-specific hazard functions for modeling utilization and suicide attempts, where death was a competing risk. We controlled for COVID (1 = called in March 2020 or later), receipt of caring letters, month, year, as well as the other covariates listed above.

Analysis 2: Comparison of Letter Signatories

Our Aim 2 analyses (cross-arm analyses among individuals engaged in VA care) will not be subject to the history threats to internal validity that exist in Aim 1. We can further isolate the impact of caring letter signatory on outcomes by controlling for the potential confounders noted above, in addition to confounders with potential prognostic value, such as mental health diagnoses (Kahan 2014). Dichotomous outcomes were examined with logistic regression.

Budget Impact Analysis (BIA):

We will examine the budget impact of Caring Letters among all VCL callers over a 12-month period. We will compare costs related to inpatient and outpatient mental health care use and medications before the Caring Letters campaign with costs related to health care use and medications, as well as costs of mailing the letters during the Caring Letters campaign. We expect inpatient costs to decrease and outpatient costs to increase due to the intervention. We do not expect Caring Letters to serve as a substitute for any existing mental health outreach program. Costs of both VA-provided and purchased care will be captured. In all analyses, we will use the Gross Domestic Product Deflator to adjust costs to 2020 dollars. The budget impact of each version of Caring Letters will be assessed. Mean costs per patient-month alive will be reported. This analysis will be completed at a later date.

Data Flow

VCL Data is downloaded from backups on a weekly basis. The data is downloaded from the Saturday two weeks prior through the end of the Friday of the previous week. That data is then uploaded to the Caring Letters data system that resided on CDWA01. A SQL script is then run to parse the new data, identify callers who can be matched to the CDW and enroll them into the program, then generates a list of all letters due to go out this week.

This includes letters for newly enrolled patients as well as patients enrolled previously who are getting subsequent letters. Once the letter file has been generated it is sent to the print vendor using encrypted email. The print vendor then sends back information on any patients with a change of address, any addresses that are undeliverable and the mail receipt of when each batch of letters was sent out.