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

Statistical Analysis Plan 7/23/25 – Version 1

This statistical analysis plan (SAP) builds upon the ISCRTN protocol (ISCRTN18069367). The protocol was registered before outcome data were available and includes details on inclusion and exclusion criteria, as well as outcome measures and hypotheses. This SAP document was drafted after outcome data were available but before they were analyzed, although many of the details were previously outlined in a grant proposal written before the study began (November 2022).

Aims:

1. To evaluate the effects of Caring Letters on clinical outcomes and VA clinical utilization rates
2. To evaluate the impact of adding an implementation strategy of centralizing the work to the existing implementation strategy of mandating change

Background:

Beginning in March 2020, all Veterans with an inactivated High Risk for Suicide Patient Record Flag (HRS PRF) were mandated to receive caring letters, but the details of the program (e.g., intervention development) were left to each facility. All VA facilities were randomized at the facility level to start receiving centralized Caring Letters either in June, 2023 (Early Start group) or January, 2024 (Delayed Start group).

Assignment of Facilities to Early or Delayed Start:

Randomization occurred in March 2023. To account for the fact that the needed note templates in the federal Electronic Health Record (EHR) were not completely finalized at that time, sites that have already transitioned to the federal EHR or that were scheduled to potentially implement the federal EHR in summer of 2023 were assigned to the delayed start group. To assign the remaining sites to early or delayed start, we used permuted block randomization, stratified by geographic region (Northeast, South, Midwest, West).

Eligibility for Centralized Caring Letters Intervention

Participants were included in the Centralized Caring Letters intervention if they had an inactivated HRS PRF during the recruitment period (Phase 1: 6/30/23-6/29/24; Phase 2: 1/31/24-6/29/24). All Veteran age ranges were included.

Included participants in the centralized caring letters group:
1. Had a valid mailing address on file with the VHA
2. Were not removed or opted out by a local Suicide Prevention Coordinator prior to enrollment in the intervention
3. Had not died before upload of their name and address information for mail processing
4. Were not actively enrolled in and receiving Caring Letters from the Veterans Crisis Line Caring Letter

project at the time of eligibility for enrollment

Eligible Cohort for Aim 1 Veteran-Level Analyses (Centralized vs No Caring Letters):

Participants will be included in the study cohort if they have an inactivated HRS PRF between 6/30/2016 and 2/29/20 (no caring letters), or were enrolled in the Centralized Caring Letters intervention (for Phase 1 sites, enrollment occurred between 6/30/23-6/29/24, and for Phase 2 sites, enrollment occurred between 1/31/24– 6/29/2024).

Individuals will be excluded if they were actively enrolled in the Veterans Crisis Line Caring Letters or Veterans Crisis Line Caring Letters extension program at the time of eligibility for enrollment. Non-veterans who received Centralized Caring Letters will be excluded from the cohort.

Our primary analyses are intent to treat, but we will examine sensitivity of results to exclusion of individuals who were unlikely to receive centralized caring letters because they died within 14 days of eligibility or because there was evidence of a bad address within 30 days of eligibility. We will also examine sensitivity of results to exclusion of individuals who opted out of the intervention, did not have a valid mailing address on file with the VHA, or who were opted out of the intervention by a local Suicide Prevention Coordinator (SPC) before enrollment. We will examine sensitivity of results to the COVID pandemic by censoring outcome data at 3/1/2020 for the no caring letters group.

Eligible Cohort for Aim 2 Veteran-Level Analyses (Centralized vs Decentralized Letters):

Participants will be included in the decentralized caring letters group if they have an inactivated HRS PRF between 3/1/2022 and 6/29/2023 (Phase 1 sites) or between 3/1/2022 and 1/30/2024 (Phase 2 sites). Participants will be included in the Centralized Caring Letters intervention if they have an inactivated HRS PRF during the recruitment period (Phase 1: 6/30/23-6/29/24; Phase 2: 1/31/24-6/29/24).

Individuals will be excluded if they were actively enrolled in the Veterans Crisis Line Caring Letters program at the time of eligibility for enrollment. Non-veterans who received Centralized Caring Letters will be excluded from the cohort.

Our primary analyses are intent to treat, but we will examine sensitivity of results to exclusion of individuals who were unlikely to receive centralized caring letters because they died within 14 days of eligibility or because there was evidence of a bad address within 30 days of eligibility. We will also examine sensitivity of results to exclusion of individuals who opted out of the intervention, did not have a valid mailing address on file with the VHA, or who were opted out of the intervention by a local Suicide Prevention Coordinator (SPC) before enrollment.

Treatment/Exposure: The centralized caring letters intervention includes 8 cards mailed over the year after flag discontinuation (months 1, 2, 3, 4, 6, 8, 10, 12). Centralized Caring Letters were sent in two phases, according to the site of Veterans' care. Phase 1 site participants had a discontinued HRF between 6/30/2023 – 6/29/2024 and Phase 2 site participants had a discontinued HRF between 1/31/2024-6/29/2024.

Outcome Metrics:

Primary outcome measure

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

Secondary outcome measures

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.
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.

Data Sources and Analytic Plan:

Data Sources

Data sources for individual-level analyses will include the VA Corporate Data Warehouse (inpatient, outpatient, and purchased care; Vital Status File), OSP standard suicide overdose event table, and the National Death Index (through the VA/DoD Mortality Data Repository). Facility-level data on caring contact mailings from VA's Suicide Prevention Applications Network (SPAN) will also be used.

Analytic plan

Aim 1: Our primary analyses will be intent-to-treat. Primary analyses will compare the cohort of Veterans with an inactivated HRS PRF who receive centralized Caring Letters and the cohort of Veterans with an inactivated HRS PRF who were not mandated to receive any Caring Letters (no centralized or decentralized letters). We will analyze differences in proportions of Veterans with an inactivated HRS PRF who had each of our primary and secondary outcome measures with a chi-square test. Differences in frequency of psychiatric hospitalizations and mental health outpatient visits will be examined with Wilcoxon rank-sum tests. For frequency outcomes, we will conduct multivariable regression models (negative binomial and Poisson models) controlling for sociodemographics, past-year mental and physical comorbidities, past-year inpatient or outpatient mental health care, past-year suicide attempts, year, month, and facility. For incidence outcomes, we will model cause-specific hazard functions (using time of HRS PRF inactivation as time 0), controlling for the same covariates. We will explore the sensitivity of our results to the COVID pandemic by censoring outcome data at 3/1/2020. Our randomized phased roll-out will facilitate our ability to isolate the impact of Caring Letters from the impact of contemporaneous effects. We will explore the extent to which the effect of receipt of centralized Caring Letters differs for sites in the early and delayed start groups. If we find the effect of Caring Letters is similar in a comparison of the first half of VAMCs to the second set, that increases our confidence that observed effects are due to Caring Letters and not due to a co-occurring policy change or other national event. We will also conduct exploratory analyses of associations among Caring Letters and all-cause and suicide mortality, following the approaches described above.

Aim 2: To compare differences in reach in the centralized versus decentralized Caring Letters approaches, we will tabulate changes in the number of facilities and VISNs that reported that they complied and sent Caring Letters each month from 3/2022 to 6/2025. In addition, we will run multivariable linear regression analyses at the facility-month level to isolate the impact of the centralized intervention on reach from the impact of changes in eligible Veterans' sociodemographics, mental health staffing levels, and average health care utilization. We will also calculate the mean monthly percentage of centralized caring letters that were sent according to the mailing schedule.

Exploratory Aim 2: We will compare Veterans with an inactivated HRS PRF who received centralized Caring Letters to Veterans who received decentralized Caring Letters. Outcomes and models are the same as those outlined in Aim 1.