#### STATISTICAL ANALYSIS PLAN

# 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

#### SDR 16-195

#### NCT03280225

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# Preface

The VHA predictive model identifies the top 5% of VHA patients at the highest predicted risk for suicide. These Veterans identified by VHA 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. 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.

Using this predictive model, VHA's Office of Mental Health and Suicide Prevention implemented 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).

Implementation assistance in the form of virtual external facilitation, an evidence-based implementation strategy, was offered to sites having difficulty implementing REACH VET during the system-wide rollout of the program. The analysis plan for specific aim 1b is below.

# Scope and Analysis

Low performing VHA facilities were identified by leadership in seven Veteran Integrated Service Networks (VISN). Implementation assistance in the form of virtual external facilitation, an evidence-based implementation strategy, was offered to sites having using a stepped wedge design clustering sites at the VISN level. Two VISNs no longer needed facilitation by the time they reached the opportunity to receive it; these VISNs and facilities were excluded from any analyses. REACH VET Historic Summary Reports contain summary metrics used to evaluate facility performance on the four measures listed below.

# **REACH VET Outcome Measures**

- <u>Coordinator Assigned</u> the percentage of eligible Veterans who had a Coordinator assigned within a week of the monthly REACH VET scores 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.
- <u>Provider Assigned</u> the percentage of eligible Veterans who had a Provider assigned within a week of the monthly REACH VET scores 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.

- <u>Care Evaluation Performed</u> the percentage of eligible Veterans who had a care evaluation performed within a week of the monthly REACH VET scores 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.
- <u>Attempted Outreach</u> the percentage of eligible Veterans with a recorded attempted outreach within a week of the monthly REACH VET scores 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.

All outcomes data was collected from the Week 2 view of the REACH VET Historic Summary Report and encompasses days 1-14 after the release date.

### **Design Methods**

Initial analysis design prescribed a stepped-wedge model clustering sites at the VISN level as depicted in figure 1.

	Months																								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Cluster A - 5 Sites																									
Cluster B - 4 Sites																									
Cluster C - 4 Sites																									
Cluster D - 6 Sites																									
Cluster E - 4 Sites																									
Pre-Implementation							Post-Implementation																		

Figure 1. Study design assuming stepped wedge method at VISN level.

After initial sensitivity analysis (see section on Model fitting) it was determined that clustering at the VISN level lacked sufficient sample size compared to the quasi-experimental pre-post design as represented in figure 2.

		Months																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Site 1																								
Site 2																								
Site 3																								
Site 4																								
Site 5																								
Site 6																								
Site 7																								
Site 8																								
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*Figure 2. Study design timeline assuming clustering within site.* 

# **Model Fitting**

Pan (2001) proposed a quasilikelihood model-selection method for GEE under the independence model criterion (QIC). This criterion can also be used to select the best working correlation structure in GEE analyses (Cui, 2007).

Stepped wedge within CLUSTERS QIC Scores									
Outcome	Independent	Autoregressive	Compound	Unstructured					
			Symmetry						
Coordinator	59.0	60.0	69.2	NC					
Accepted									
Provider	86.0	86.3	92.6	36.6 *					
Assigned									
Care Evaluation	89.8	89.7	93.5	45.1					
Performed									
Outreach	95.3	95.5	126.8	NC					
Attempted									

# Stepped Wedge within CLUSTERS QIC Scores

NC – non-convergence, \* Unstructured matrix is predominately negative on the pairs

### Stepped Wedge within SITES QIC Scores

Outcome	Independent	Autoregressive	Compound	Unstructured
	-	_	Symmetry	
Coordinator	57.3	56.9	60.07	CE
Accepted				

Provider	97.1	92.0	109.2	CE
Assigned				
Care Evaluation	109.0	102.8	116.6	CE
Performed				
Outreach	116.9	107.8	119.8	CE
Attempted				

CE – converged with error

#### 6-month Pre-Post within SITES QIC Scores

Outcome	Independent	Autoregressive	Compound	Unstructured
			Symmetry	
Coordinator	38.2	38.6	37.5	NC
Accepted				
Provider	73.0	66.5	57.0	NC
Assigned				
Care	80.7	73.0	71.8	NC
Evaluation				
Performed				
Outreach	87.2	81.3	81.6	NC
Attempted				

Choose 6-month pre-post quasi-experimental model using compound symmetry correlation structure for observations within sites, time variable in months to account for secular trends, and a binary intervention variable (0,1) indicating study phase (pre-facilitation, post-facilitation).

Note, we do not model a transition period from pre-to-post Average number of implementation days = 175 (SD 49.3). Index date is based upon date of site visit.

# Analysis

Our quasi-experimental pre-post intervention analysis evaluated four outcome measures as tracked by the REACH VET program across 23 VAMCs, during 6-month periods prior to implementation and again after the onset of implementation. We used the REACH VET Historic Summary Report to collect metrics for Coordinator assignment, Provider assignment, Care evaluation, and Attempted outreach all within one week of each monthly report's release date. To compare statistical differences in outcomes between pre-and post-periods we used 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.

# References

Cui, J. (2007). QIC Program and Model Selection in GEE Analyses. The Stata Journal:

*Promoting Communications on Statistics and Stata*, 7(2), 209–220. <u>https://doi.org/10.1177/1536867X0700700205</u>

Pan, W. (2001). Akaike's information criterion in generalized estimating equations. *Biometrics*, *57*(1), 120–125. https://doi.org/10.1111/j.0006-341x.2001.00120.x