

# VA DROP Data Safety Monitoring Board Report

**A randomized controlled trial to evaluate the effects of an intervention to reduce exposure to medications among hospitalized older Veterans discharged to skilled nursing facilities (SNFS)**

**VA Merit Award Number IIR 17-033**

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## Study Abstract

There is a dearth of evidence related to the management of multiple co-existing geriatric syndromes, and few interventions have been implemented to reduce medications while also monitoring health outcomes. The relationship between polypharmacy, adverse drug events, and geriatric syndromes in the VA population supports the rationale for an intervention focused on deprescribing medications before hospital discharge. We have pilot-tested a multifaceted intervention (**Drug Reduction in Older Patients, DROP**) to engage patients and providers to reduce the number and/or dose of medications prior to hospital discharge. The proposed randomized, controlled trial is powered to evaluate the effect of this intervention on a reduction in medications as defined by the total number of prescribed medications, the number of potentially inappropriate medications (PIMs), anticholinergic and sedative drug burden and the number of medications associated with geriatric syndromes. In addition, we will collect relevant data on the prevalence and severity of geriatric syndromes and other clinical outcomes. We also will use a hybrid research design to evaluate both effectiveness and implementation issues to better inform future adoption and sustainability. Our *overarching hypothesis is that a hospital-based intervention to safely reduce the total number of medications represents the most feasible way to impact multiple health-related outcomes among older Veterans*. Our Specific Aims reflect the primary outcomes that are the focus of the analyses, although we also will measure secondary outcomes related to VA healthcare utilization and patient safety:

**Specific Aim 1: Implement a patient-centered deprescribing intervention (DROP) in the hospital to reduce the total number of medications Veterans are prescribed at hospital discharge.**

*Hypothesis 1a:* DROP will result in a significant reduction in total medication exposure due to discontinuations and dose reductions at hospital discharge, Skilled Nursing Facility (SNF) discharge and 90-days after SNF discharge.

*Hypothesis 1b:* DROP will result in a significant reduction in the number of potentially inappropriate medications (PIMs) at hospital discharge, SNF discharge and 90-days after SNF discharge.

*Hypothesis 1c:* DROP will result in a significant reduction in the anticholinergic and sedative drug burden at hospital discharge, SNF discharge and 90-days after SNF discharge.

*Hypothesis 1d:* DROP will result in significantly fewer medications associated with geriatric syndromes at hospital discharge, SNF discharge and 90-days after SNF discharge.

**Specific Aim 2: Document the effects of a Veteran-centered deprescribing intervention (DROP) on medication adherence, health status, and geriatric syndromes.**

*Hypothesis 2a:* DROP will result in a significant improvement in medication adherence and self-rated health status at 7 and 90 days after SNF discharge.

*Hypothesis 2b:* DROP will result in a lower prevalence and severity of geriatric syndromes at 7 and 90 days after SNF discharge.

**Specific Aim 3: Evaluate intervention implementation to inform future adoption and sustainability.**

*Aim 3a:* Identify patient-level barriers and facilitators of DROP.

*Aim 3b:* Identify VA and Non-VA provider-level barriers and facilitators of DROP.

*Aim 3c:* Identify system-level factors that influence sustainability after hospital discharge.

## GANTT Chart

enrollment.

Discussion of Timeline

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## Chronology of Major Study Events

Table 1. Major Study Events


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Study Enrollment  
 Figure 1. Eligibility Tracking

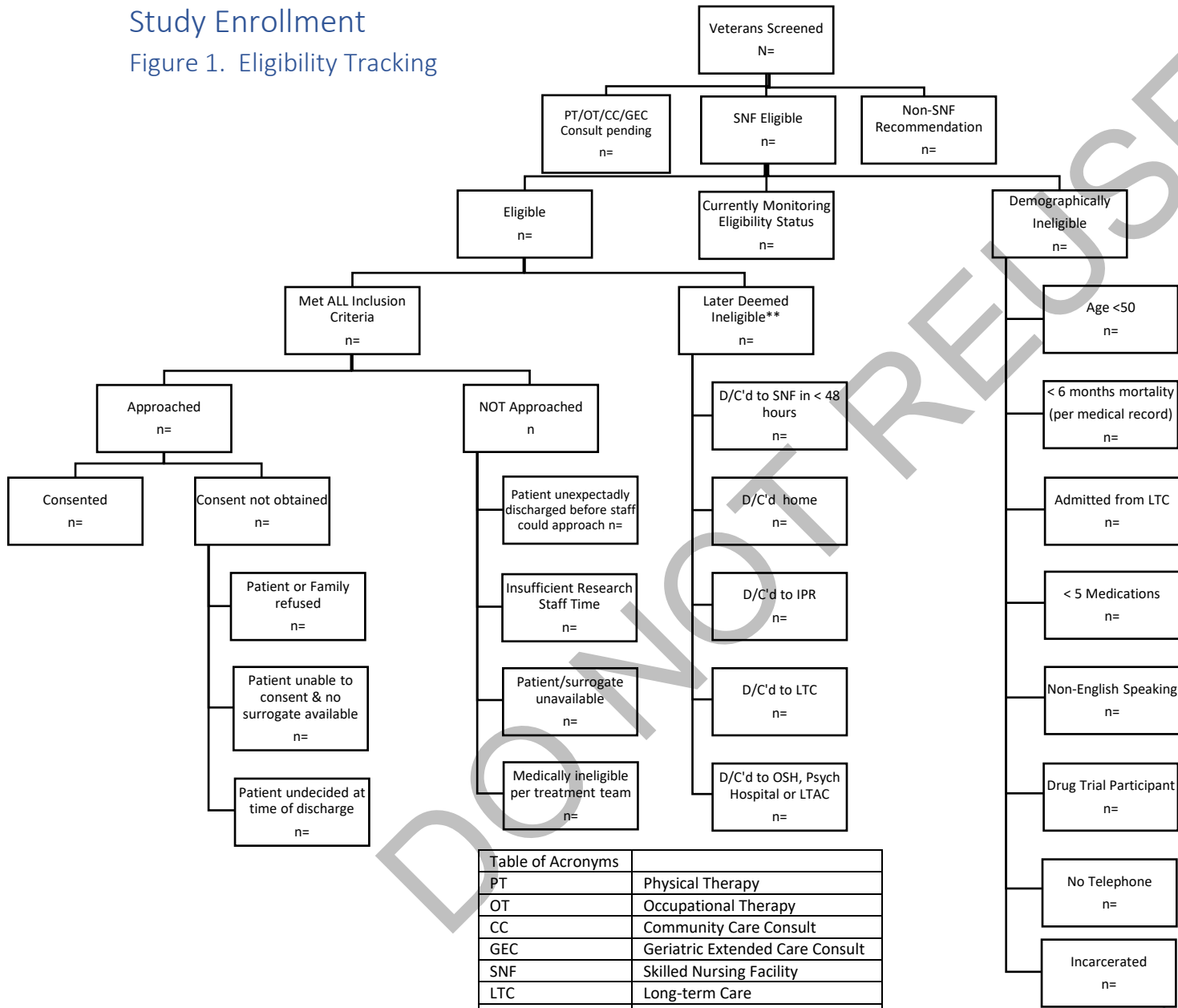
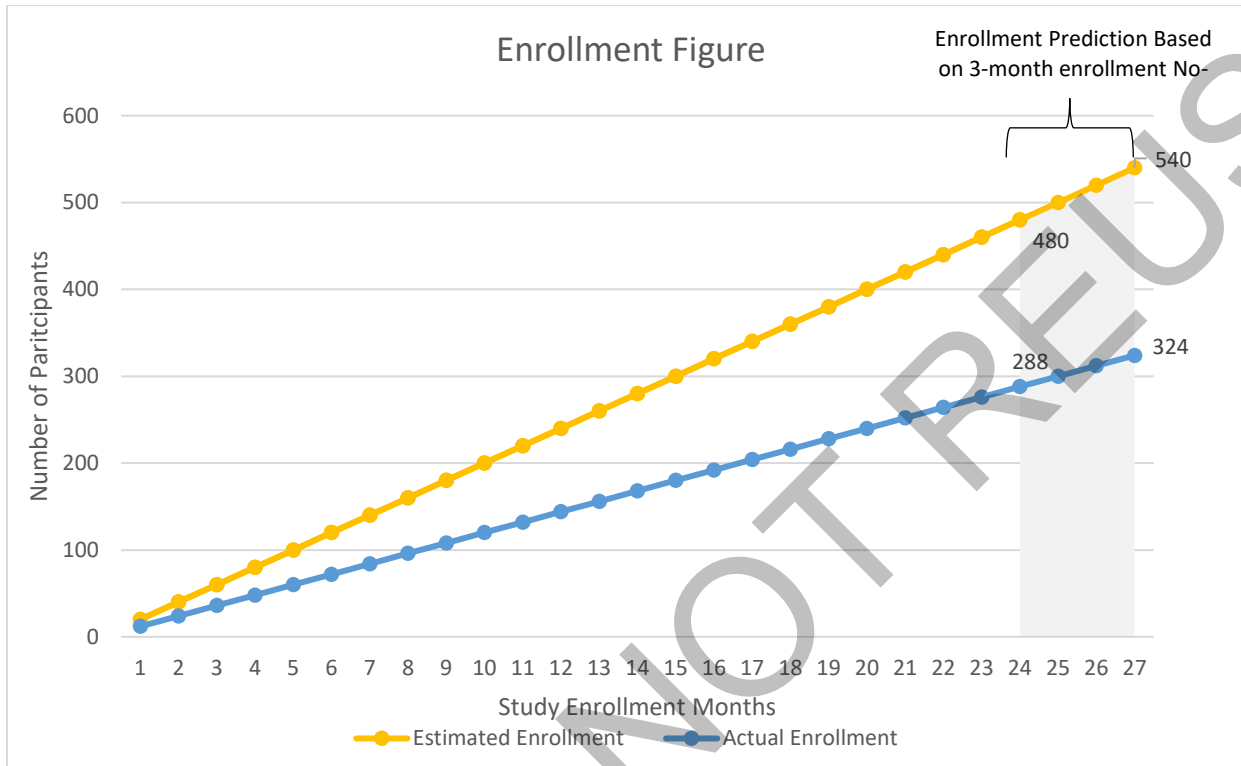


Table of Acronyms	
PT	Physical Therapy
OT	Occupational Therapy
CC	Community Care Consult
GEC	Geriatric Extended Care Consult
SNF	Skilled Nursing Facility
LTC	Long-term Care
IPR	In-patient Rehab
Psych Hospital	Psychiatric Hospital
LTAC	Long-term Acute Care

\*\* Veterans met all demographic and clinical criteria for participation, but their final hospital discharge

Figure 2. Enrollment Tracking



Discussion of Study Recruitment and Enrollment

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Baseline Characteristics of Intervention and Control Participants

Characteristics	Intervention N (%)	Control N (%)	Total N (%)
<b>Total Enrolled</b>			
<b>Gender</b>			
Male			
Female			
Unknown or Not Reported			
<b>Ethnicity</b>			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
<b>Race</b>			
Asian			
Black or African American			
Caucasian (White)			
Other			
Unknown or Not Reported			
<b>Age</b>			
Mean			
Standard Deviation			
Median			
Minimum			
Maximum			
Interquartile Range			
<b>Enrollment Medications</b>			
5 to 9 medication			
More than 9 medications			
<b>DBI</b>			
Mean			

Standard Deviation			
Median			
Interquartile Range			
<b>Geriatric Syndrome Endorsement<sup>a</sup></b>			
Delirium			
Cognitive Impairment <sup>b</sup>			
Depression <sup>b</sup>			
Incontinence			
Weight Loss			
Pain <sup>b</sup>			
Falls			
Pressure Ulcers			

Table 2. Baseline Characteristics

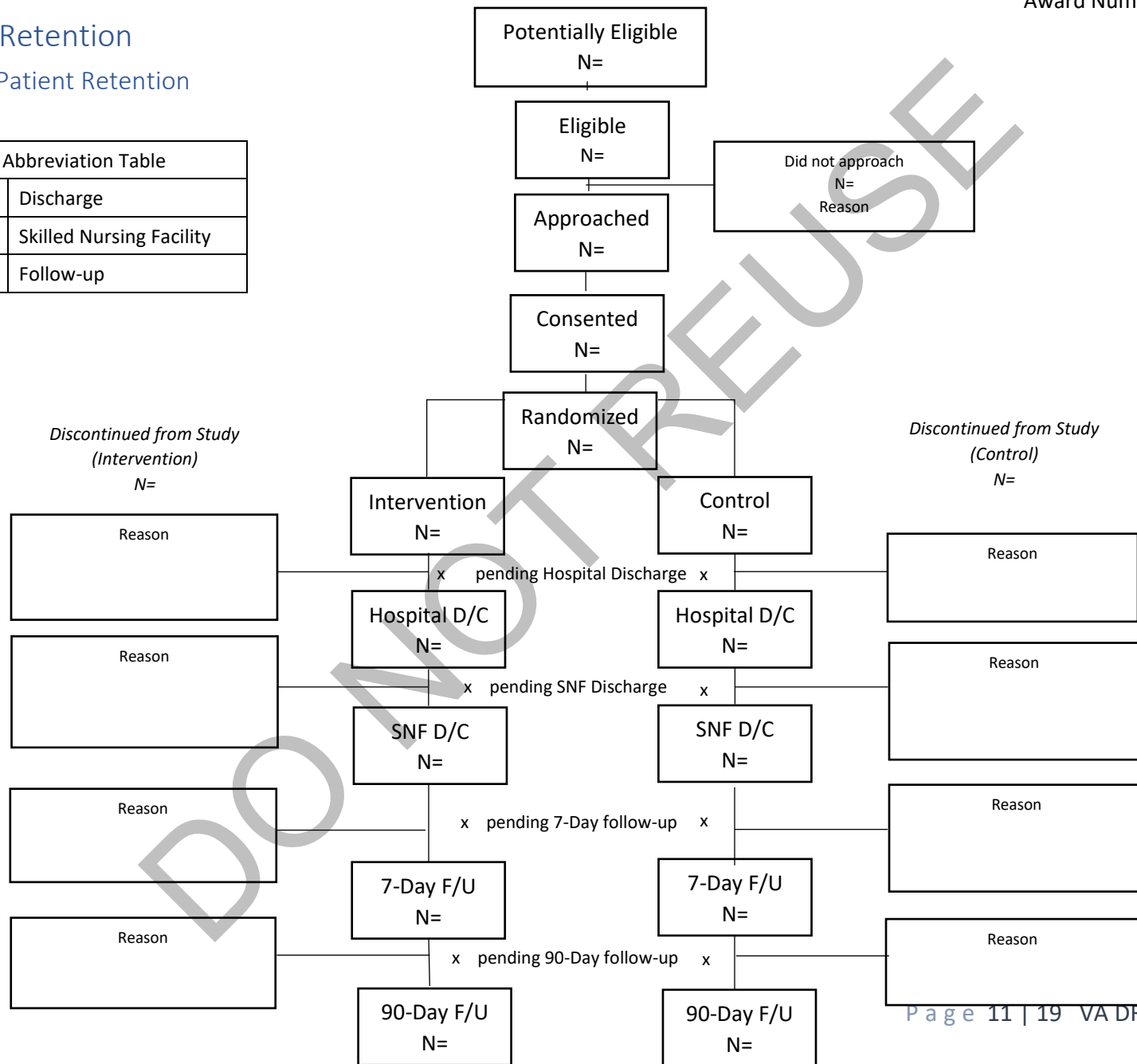
Discussion of Baseline Characteristics

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## Patient Retention

Figure 3. Patient Retention

Abbreviation Table	
D/C	Discharge
SNF	Skilled Nursing Facility
F/U	Follow-up



Discussion of Patient Retention

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## Patient Safety

Table 3. Death Summary Table

Study ID	Date Enrolled in Study	Date Exited Study	Study Group	Date of Death	Notes

Table 4. Hospitalizations or Emergency Department (ED) Visits Deemed Unrelated to Study Activities

Enrollment Site	Intervention Patients	Control Patients

Table 5. All Hospital Admissions/ED Visits

Study ID	Date Enrolled in Study	Date Exited Study	Study Group	Admission/Visit Date	Admission Type	Admission Reason

## Discussion of Patient Safety

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## Reconsideration of Power/Sample Size

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## Appendices

### A. Previous DSMB Feedback Reports

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B. Original Work Proposed  
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C. Informed Consent Forms

Participant Consent Form

**See Additional PDF attachments**

Surrogate Consent Form

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D. Adverse Event Determination Letters

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