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

Principal Investigators:
Sandra Simmons, PhD (sandra.simmons@vumc.org)
Amanda Mixon, MD (amanda.s.mixon@vumc.org)
Contents

Cover letter ................................................................................................................. Error! Bookmark not defined.
Study Abstract ................................................................................................................. 3
GANTT Chart .................................................................................................................... 4
  Discussion of Timeline .................................................................................................. 4
Chronology of Major Study Events .................................................................................. 5
  Table 1. Major Study Events ....................................................................................... 5
Study Enrollment .............................................................................................................. 6
  Figure 1. Eligibility Tracking ....................................................................................... 6
  Figure 2. Enrollment Tracking ..................................................................................... 7
  Discussion of Study Recruitment and Enrollment ......................................................... 8
Baseline Characteristics of Intervention and Control Participants .................................. 9
  Table 2. Baseline Characteristics .............................................................................. 10
  Discussion of Baseline Characteristics ...................................................................... 10
Patient Retention ............................................................................................................ 11
  Figure 3. Patient Retention ....................................................................................... 11
  Discussion of Patient Retention ................................................................................. 12
Patient Safety .................................................................................................................. 13
  Table 3. Death Summary Table .................................................................................. 13
  Table 4. Hospitalizations or Emergency Department Visits Deemed Unrelated to Study Activities .................................................................................................................. 13
  Table 5. All Hospital Admissions/ER Visits ................................................................ 13
  Discussion of Patient Safety ....................................................................................... 13
Reconsideration of Power/Sample Size ......................................................................... 15
Appendices ...................................................................................................................... 16
  A. Previous DSMB Feedback Reports ......................................................................... 16
  B. Original Work Proposed .......................................................................................... 17
  C. Informed Consent Forms ........................................................................................ 18
    Participant Consent Form .......................................................................................... 18
    Surrogate Consent Form .......................................................................................... 18
  D. Adverse Event Determination Letters .................................................................. 19
    Determination for Adverse Event ............................................................................. Error! Bookmark not defined.
    Determination for Adverse Event ............................................................................. Error! Bookmark not defined.
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

Discussion of Timeline
### Chronology of Major Study Events

**Table 1. Major Study Events**

<table>
<thead>
<tr>
<th>Event 1</th>
<th>Event 2</th>
<th>Event 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Study Enrollment

Figure 1. Eligibility Tracking

Veterans Screened

PT/OT/CC/GEC Consult pending

SNF Eligible

Non-SNF Recommendation

Eligible

Currently Monitoring Eligibility Status

Demographically Ineligible

Met ALL Inclusion Criteria

Later Deemed Ineligible**

Approached

Not Approached

Consented

Consent not obtained

Patient or Family refused

Patient unable to consent & no surrogate available

Patient undecided at time of discharge

D/C'd to SNF in < 48 hours

D/C'd home

D/C'd to IPR

D/C'd to LTC

D/C'd to OSH, Psych Hospital or LTAC

D/C'd to SNF in < 48 hours

D/C'd home

D/C'd to IPR

D/C'd to LTC

D/C'd to OSH, Psych Hospital or LTAC

Study Enrollment Figure 1. Eligibility Tracking

Table of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>Physical Therapy</td>
</tr>
<tr>
<td>OT</td>
<td>Occupational Therapy</td>
</tr>
<tr>
<td>CC</td>
<td>Community Care Consult</td>
</tr>
<tr>
<td>GEC</td>
<td>Geriatric Extended Care Consult</td>
</tr>
<tr>
<td>SNF</td>
<td>Skilled Nursing Facility</td>
</tr>
<tr>
<td>LTC</td>
<td>Long-term Care</td>
</tr>
<tr>
<td>IPR</td>
<td>In-patient Rehab</td>
</tr>
<tr>
<td>Psych Hospital</td>
<td>Psychiatric Hospital</td>
</tr>
<tr>
<td>LTAC</td>
<td>Long-term Acute Care</td>
</tr>
</tbody>
</table>

**Veterans met all demographic and clinical criteria for participation, but their final hospital discharge...
Figure 2. Enrollment Tracking

The graph illustrates the enrollment tracking from study enrollment months 1 to 27. It shows the actual and estimated enrollment numbers along with the enrollment prediction based on a 3-month enrollment. The data points are labeled as follows:

- Estimated Enrollment: Yellow line
- Actual Enrollment: Blue line

Key points:
- At 18 months, the estimated enrollment is 480, and the actual enrollment is 288.
- At 24 months, the predicted enrollment is 540, and the actual enrollment is 324.

The graph helps in understanding the enrollment progress over time and the accuracy of the predictions.
Discussion of Study Recruitment and Enrollment
### Baseline Characteristics of Intervention and Control Participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention N (%)</th>
<th>Control N (%)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Enrolled</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian (White)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Deviation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interquartile Range</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Enrollment Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 to 9 medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 9 medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DBI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Baseline Characteristics

Discussion of Baseline Characteristics
Patient Retention

Figure 3. Patient Retention

Abbreviation Table

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>D/C</td>
<td>Discharge</td>
</tr>
<tr>
<td>SNF</td>
<td>Skilled Nursing Facility</td>
</tr>
<tr>
<td>F/U</td>
<td>Follow-up</td>
</tr>
</tbody>
</table>

Discontinued from Study (Intervention) $N=$

- Reason
- Hospital D/C $N=$
  - x pending SNF Discharge
  - x pending 7-Day follow-up
  - x pending 90-Day follow-up
  - 7-Day F/U $N=$
  - x pending 7-Day follow-up
  - x pending 90-Day follow-up
  - 90-Day F/U $N=$

Discontinued from Study (Control) $N=$

- Reason
- Hospital D/C $N=$
  - x pending SNF Discharge
  - x pending 7-Day follow-up
  - 7-Day F/U $N=$
  - x pending 7-Day follow-up
  - x pending 90-Day follow-up
  - 90-Day F/U $N=$

Potentially Eligible $N=$

- Eligible $N=$
  - Did not approach $N=$ Reason
  - Approached $N=$
    - Consented $N=$
      - Randomized $N=$
        - Intervention $N=$
          - x pending Hospital Discharge
          - Hospital D/C $N=$
            - x pending 7-Day follow-up
            - x pending 90-Day follow-up
            - 7-Day F/U $N=$
            - x pending 90-Day follow-up
            - 90-Day F/U $N=$
        - Control $N=$
          - Hospital D/C $N=$
            - x pending 7-Day follow-up
            - x pending 90-Day follow-up
            - 7-Day F/U $N=$
            - x pending 90-Day follow-up
            - 90-Day F/U $N=$
Discussion of Patient Retention
Patient Safety

Table 3. Death Summary Table

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Date Enrolled in Study</th>
<th>Date exited Study</th>
<th>Study Group</th>
<th>Date of Death</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Enrollment Site</th>
<th>Intervention Patients</th>
<th>Control Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5. All Hospital Admissions/ED Visits

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Date Enrolled in Study</th>
<th>Date Exited Study</th>
<th>Study Group</th>
<th>Admission/Visit Date</th>
<th>Admission Type</th>
<th>Admission Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussion of Patient Safety
Reconsideration of Power/Sample Size
Appendices

A. Previous DSMB Feedback Reports
See Additional PDF attachments
B. Original Work Proposed
See Additional PDF attachments
C. Informed Consent Forms
Participant Consent Form
See Additional PDF attachments

Surrogate Consent Form
See Additional PDF Attachments
D. Adverse Event Determination Letters