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Inpatient safer aging through geriatrics-informed evidence-based practices quality enhancement research initiative

Submission date
09/10/2025

Recruitment status
Not yet recruiting

Registration date
28/10/2025

Overall study status
Ongoing

Last Edited
10/10/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Safer Aging through Geriatrics-Informed Evidence-Based Practices (SAGE) QUERI was established to support the VA's commitment to be the largest Age-Friendly Health System (AFHS) in the U.S. More than 4 million Veterans are aged 65+. Many experience inappropriate care and unmet care needs, leading to increased harms, worse quality of life, more health care utilization, and increased costs. SAGE 1.0 sought to reduce these negative outcomes by rigorously testing implementation strategies for 4 evidence-based practices (EBPs) focused on the AFHS's 4 "Ms" (what Matters, Mentation, Medication, and Mobility), focusing on outpatient and home-based settings. After reaching more than 8,000 Veterans in VISN 4, in Inpatient SAGE ("iSAGE"), this research now turns its attention to the hospital setting. The preliminary analysis found nearly 700,000 Veterans received "4Ms" care in 2024, but only 58,000 (8%) were from inpatient hospital settings, and 3 VA sites accounted for 90% of these episodes. This proposed renewal seeks to address this gap by bringing 3 of the tested EBPs to the hospital setting for the first time. The impact goal of iSAGE is to build on and expand SAGE QUERI 1.0's work by implementing and spreading 3 AFHS-aligned EBPs from SAGE 1.0 to VA hospital settings within VISNs 4, 5, 6, and 8, to improve older Veteran outcomes at scale. The Eliminating Medications through Patient OWnership of End Results (EMPOWER) deprescribing intervention engages older adults in their own medication management to stop potentially harmful medications. This holds substantial promise, as it was found that more than 24,000 older Veterans who are admitted to VISN 4 and VISN 8 hospitals annually are receiving high-risk medications. The Surgical Pause (SP) intervention, supported by the National Surgery Office, screened thousands of older Veterans for frailty and addressed goals in preoperative outpatient clinics, and this research proposes to extend it to the more than 26,000 frail older Veterans who are admitted to the hospital and face urgent and emergent surgeries each year. In SAGE 1.0, the Tailored Activity Program (TAP-VA) intervention reduced caregiver burden, improved quality of life for Veterans with dementia, and filled a gap in care that frontline clinicians perceived as critically important. More than 100,000 Veterans with dementia were hospitalized in 2023, and extending implementation to the hospital (TAP-H) will allow us to reach more caregivers and address uncontrolled dementia behaviors that often lead to hospitalization. For each EBP, a hybrid type 2 effectiveness-implementation randomized trial will be conducted to test standard versus

enhanced implementation strategy bundles across VA medical centers in VISNs 4, 5, 6, and 8, randomizing at the VAMC level.

Who can participate?
Veterans age 65 or older who are enrolled in a VA Medical Center or within participating VA medical centers in Veterans Integrated System Networks (VISN) 4, 5, 6, and 8 can participate. Additional project-specific requirements apply.

What does the study involve?
The trial will occur in three phases: (1) Pre-Implementation (6 months), (2) Implementation (9 months), and (3) Maintenance by clinical partners (12 months). Our primary effectiveness outcomes are: 1) EMPOWER: cessation of targeted medications after discharge; 2) Surgical Pause: reduction in observed to expected mortality among high-risk patients (with expected mortality >2.5%); and 3) TAP-H: unplanned hospital readmissions; and our primary implementation outcome is reach. Using the QUERI Implementation Roadmap and support from 4 Cores (Operations, led by MPI Burke; Implementation and Data, led by MPI Hall; Partnership, led by MPI Brown; Mentoring, led by MPI Werner) and a Rapid Response Team, our Specific Aims are to: (1) Rigorously compare Standard vs. Enhanced Implementation Bundles to: (a) reduce days spent elsewhere than home in the 90 days after discharge and (b) expand the reach of AFHS-aligned evidence-based practices; (2) Train the next generation of leaders in the principles and practices of implementation science and Age-Friendly Health Systems; and (3) Build capacity to respond to the needs and priorities of operational partners.This work represents some of the first efforts to rigorously implement AFHS-aligned EBPs in the inpatient hospital setting. It aligns directly with QUERI priorities to optimize the quality and efficiency of inpatient care, ensure aging Veterans receive interventions to prevent harm, and drive a culture of innovation.

Depending on project eligibility, participation might include consultation of goals before an elective surgery (The Surgical Pause), receiving a mailed pamphlet on reducing medication harms (EMPOWER), or engaging in a program that provides dementia education and instruction on engagement in meaningful activities for a Veteran and their caregiver.

What are the possible benefits and risks of participating?
There are no direct benefits of participating. Possible risks are dependent on specific study participation but could include withdrawal symptoms from reducing medication. Consultation with your primary care physician prior to reducing or stopping medication is recommended.

Where is the study run from?
iSAGE QUERI staff are based out of the Corporal Michael J. Crescenz VAMC and the Pittsburgh VA Medical Center. iSAGE programs are being implemented in self-electing clinics and medical centers within the VISNs 4, 5, 6, and 8.

When is the study starting and how long is it expected to run for?
May 2025 to September 2030

Who is funding the study?
The Department of Veterans Affairs (USA)

Who is the main contact?
Robert Burke, MD, MS, robert.burke5@va.gov

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
eRA#1I50HX004156; QUE 25-037

Study information

Scientific Title
Implementing the Age-Friendly Health System in the VHA inpatient setting: using evidence-based practices to improve outcomes in older adults

Acronym
iSAGE QUERI

Study objectives
iSAGE's impact goal is to build on and expand SAGE QUERI 1.0's work by implementing and spreading 3 AFHS-aligned evidence-based practices (EBPs) from SAGE 1.0 to VA hospital settings in VISNs 4, 5, 6, and 8, to improve older Veteran outcomes at scale. More than 4 million Veterans are aged 65+. Many experience inappropriate care and unmet care needs, leading to increased medical harms, more frequent health care utilization, and increased costs. The VA has committed to being the largest Age-Friendly Health System (AFHS) in the U.S. through addressing 4Ms (what Matters, Medication, Mentation, and Mobility) in clinical encounters with older adults, but a national dashboard focused on 4Ms care delivery shows that only 8% of the VA 4Ms assessments occurred in hospitals. iSAGE addresses this gap by expanding on our prior work in outpatient and home-based settings in SAGE 1.0 and bringing 3 EBPs to the inpatient hospital setting. Our Specific Aims are to: (1) Rigorously compare Standard vs. Enhanced Implementation Bundles to: (a) reduce days spent elsewhere than home in the 90 days after discharge and (b) expand the reach of AFHS-aligned evidence-based practices; (2) Train the next generation of leaders in the principles and practices of implementation science and Age-Friendly Health Systems; and (3) Build capacity to respond to the needs and priorities of operational partners.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This project has been approved as non-research, 15/05/2025, by Scotte R. Hartronft, MD, MBA, FACP, Executive Director, VA Office of Geriatrics & Extended Care, Veterans Health Administration.

Study design
Cluster-randomized parallel-arm hybrid type 2 effectiveness-implementation trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improve inpatient, age-friendly care by implementing age-friendly EBPs within the inpatient hospital setting at VAMCs in VISNs 4, 5, 6, and 8 with Veterans 65+years old.

Interventions
iSAGE will be implementing 3 age-friendly, evidence-based practices in VAMC hospital settings:

1. Eliminating Medications through Patient OWnership of End Results (EMPOWER) is a deprescribing intervention supported by GEC and pharmacy leadership. It has been a powerful tool to help older adults stop potentially harmful medications: for every 3 brochures mailed in SAGE QUERI 1.0, 1 older adult stopped their high-risk medication. In assessing the need for inpatient implementation of the program, we found that more than 24,000 of the older Veterans admitted to VISN 4 and VISN 8 hospitals annually are receiving high-risk medications,

and that existing medication reconciliation processes in the hospital offer exceptional opportunities to engage Veterans in deprescribing.

2. The Surgical Pause (SP), supported by the National Surgery Office, screens older Veterans for frailty and assesses what matters to align surgical decision-making with patient goals. Of the thousands of older Veterans screened for frailty in outpatient clinics during SAGE 1.0, more than 500 had robust goals-of-care conversations to ensure their treatment was aligned with "what Matters." We propose to extend SP to the more than 26,000 frail older Veterans who are admitted to the hospital and face urgent and emergent surgeries each year.

3. Tailored Activity Program-Hospital (TAP-H) will extend a successful intervention for Veterans with dementia (TAP-VA) to the hospital setting and pair it with an app called Plans4Care that extends help beyond the initial inpatient program session. In SAGE 1.0, TAP-VA, which is supported by GEC, reduced caregiver burden, improved quality of life for Veterans in the community, and filled a gap in care that frontline clinicians perceived as critically important. More than 100,000 Veterans with dementia are hospitalized annually in VA, and extending implementation to the hospital (TAP-H) will allow us to reach more caregivers and address uncontrolled dementia behaviors that often lead to hospitalization.

We also anticipate synergistic improvements in care. For example, EMPOWER may be particularly helpful when used in conjunction with Surgical Pause (SP) and Tailored Activity Program (TAP-H), through proactive engagement about any new high-risk medications (e.g., pain medication after a procedure) and offering an alternative to medications through behavioral and environmental interventions to treat disruptive behaviors in Veterans with dementia.

To help understand the how and why of implementation, we will pay particular attention to representativeness across our secondary implementation outcomes and EBPs. For example, for reach, adoption, and maintenance, we will compare characteristics of those who do and do not receive, implement, and sustain the EBP, respectively, at either the Veteran, staff, surgical line, and/or VAMC level, as appropriate. This will also help us identify areas for targeted focus in enhanced implementation during the crossover period.

Intervention Type
Behavioural

Primary outcome(s)
1. Implementation Outcome – Reach: Reach will be measured as the number and proportion of eligible Veterans enrolled in each evidence-based program (EBP) over time
2. Process Outcome – 4Ms Template Completion: Completion of the 4Ms note template will be measured for Veterans receiving each intervention at the time of care delivery
3. Effectiveness Outcomes – EBP-Specific:
3.1. EMPOWER: Cessation of targeted medications will be measured after hospital discharge
3.2. Surgical Pause: Reduction in observed-to-expected mortality will be measured among high-risk patients with expected mortality greater than 2.5% at the time of surgical outcome assessment
3.3. TAP-H: Unplanned hospital readmissions will be measured within the post-discharge period

Key secondary outcome(s))
1. Cross-EBP Secondary Effectiveness Outcome: Days elsewhere than home (DEH) will be measured for Veterans receiving each EBP during the follow-up period
2. EBP-Specific Secondary Effectiveness Outcomes:

2.1. EMPOWER:
2.1.1. Medication dose reduction will be measured following discharge
2.1.2. Reduced falls will be measured during the post-intervention monitoring period
2.2. Surgical Pause:
2.2.1. Quality of goal clarification documents ("What Matters" conversations) will be assessed at the time of documentation
2.2.2. Hospital and ICU lengths of stay will be measured post-consultation
2.2.3. Perioperative complications will be measured during the surgical recovery period
2.3. TAP-H:
2.3.1. Caregiver burden, including "time on duty," will be measured during the caregiving period
2.3.2. Veteran readmission rates and skilled nursing facility utilization will be measured during the post-discharge period

Completion date
30/09/2030

Eligibility

Key inclusion criteria
Veterans are eligible for inclusion if they are:
1. Inpatients admitted to one of the VAMCs in VISNs 4, 5, 6, and 8* participating in iSAGE implementation
2. Aged 65+ years
3. Meet EBP-specific inclusion criteria
3.1. EMPOWER: 1) Receiving one or more medication classes targeted by EMPOWER brochures prior to or during inpatient admission prescribed by VA or non-VA provider; and 2) not enrolled in hospice
3.2. TAP-H: 1) Diagnosis of dementia (using ICD-10 codes and dementia-specific medications); and 2) caregiver aged 18+ willing to participate (in-person or virtually), identified by CPRS facesheet
3.3. SP: 1) Admitted to an inpatient general, vascular, or orthopedic surgical service *or* to a non-surgical service with new surgery consult for general, vascular, or orthopedic surgery; AND 2) RAI≥37 *or* one of 6 Preoperative Acute Serious Conditions (PASC) *or* admission to hospital from a non-home environment (e.g., SNF)

*EBPs being implemented at participating VAMCs:
VISN 4: Altoona (EM, TAP), Butler (EM, TAP), Coatesville (EM, TAP), Erie (EM, TAP), Lebanon (EM, TAP), Philadelphia (EM, TAP, SP), Pittsburgh (EM, TAP, SP), & Wilkes-Barre (EM, TAP), PA; Wilmington, DE (EM, TAP)
VISN 5: Baltimore, MD (EM, TAP); Martinsburg, WV (EM, TAP); Washington, DC (EM, TAP)
VISN 6: Richmond, VA (SP)
VISN 8: Miami (EM, TAP, SP), Bay Pines (EM, TAP, SP), Gainesville (EM, TAP, SP), Tampa (EM, TAP, SP), West Palm Beach (EM, TAP), & Orlando, FL (EM, TAP, SP)

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group

Senior

Lower age limit
65 years

Sex
All

Key exclusion criteria
1. Receipt of hospice care or being in long-term nursing home care
2. Veterans with severe mental illness will be excluded from EMPOWER
3. Veterans without a caregiver will be excluded from TAP-H

Date of first enrolment
01/10/2026

Date of final enrolment
30/09/2030

Locations

Countries of recruitment
United States of America

Study participating centre
James E. Van Zandt Veterans Administration Medical Center
2907 Pleasant Valley Boulevard
Altoona
United States of America
16602

Study participating centre
Butler VA Medical Center
325 New Castle Road
Butler
United States of America
196001

Study participating centre
Coatesville VA Medical Center
1400 Black Horse Hill Road
Coatesville
United States of America
19320

Study participating centre
Erie VA Medical Center
135 East 38th Street
Erie
United States of America
16504

Study participating centre
Lebanon VA Medical Center
1700 South Lincoln Avenue
Lebanon
United States of America
17042

Study participating centre
Corporal Michael J. Crescenz Department of Veterans Affairs Medical Center
3900 Woodland Avenue
Philadelphia
United States of America
19104

Study participating centre
Pittsburgh VA Medical Center-University Drive
University Drive C
Pittsburgh
United States of America
15240

Study participating centre
H. John Heinz III Department of Veterans Affairs Medical Center
1010 Delafield Road
Pittsburgh
United States of America
15240

Study participating centre
Wilkes-Barre VA Medical Center
1111 East End Boulevard
Wilkes-Barre

United States of America
18711

Study participating centre
Wilmington VA Medical Center
1601 Kirkwood Highway
Wilmington
United States of America
19805

Study participating centre
Richmond VA Medical Center
1201 Broad Rock Boulevard
Richmond
United States of America
23249

Study participating centre
Baltimore VA Medical Center
10 North Greene Street
Baltimore
United States of America
21201

Study participating centre
Martinsburg VA Medical Center
510 Butler Avenue
Martinsburg
United States of America
25405

Study participating centre
Washington VA Medical Center
50 Irving Street, Northwest
Washington
United States of America
20422

Study participating centre

C.W. Bill Young Department of Veterans Affairs Medical Center
10000 Bay Pines Boulevard
Bay Pines
United States of America
33744

Study participating centre
Bruce W. Carter Department of Veterans Affairs Medical Center
1201 Northwest 16th Street
Miami
United States of America
33125

Study participating centre
Malcom Randall Department of Veterans Affairs Medical Center
1601 Southwest Archer Road
Gainesville
United States of America
32608

Study participating centre
James A. Haley Veterans' Hospital
13000 Bruce B. Downs Boulevard
Tampa
United States of America
33612

Study participating centre
Thomas H. Corey VA Medical Center
7305 North Military Trail
West Palm Beach
United States of America
33410

Study participating centre
Orlando VA Medical Center
13800 Veterans Way
Orlando
United States of America
32827

Sponsor information

Organisation
United States Department of Veterans Affairs

ROR
https://ror.org/05rsv9s98

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Veterans Affairs

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Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available