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# Optimizing outreach for performance on diabetes lab monitoring

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 02/06/2026 | Not yet recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [X] Statistical analysis plan |
| 09/06/2026 | Ongoing | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 16/07/2026 | Nutritional, Metabolic, Endocrine | [X] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

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# Additional identifiers

# Study information

### Scientific Title
Optimizing veteran outreach for performance on diabetes lab monitoring

### Study objectives
To determine the optimal outreach communication modality (aka "dynamic treatment regimen") to prompt diabetes laboratory monitoring among Veterans with diabetes overdue for lab monitoring and/or retinal screening, using a Multiple Comparisons with the Best (MCB) framework.

### Ethics approval required
Ethics approval not required

### Ethics approval(s)

### Primary study design
Interventional

### Allocation
Randomized controlled trial

### Masking
Blinded (masking used)

### Control
Active

### Assignment
Sequential

### Purpose
Health services research

### Study type(s)

### Health condition(s) or problem(s) studied
Diabetes laboratory monitoring among Veterans with diabetes overdue for lab monitoring and /or retinal screening

### Interventions
This 2-stage SMART trial is a prospective, adaptive, individually randomized trial consisting of two randomization rounds. Randomization is computer-generated using the R package blockrand.

Stage 1: Randomization:
*Population: Veterans empaneled in primary care at site 663 (Puget Sound), identified on a rolling monthly basis as meeting criteria for diabetes lab monitoring or retinal eye health outreach. Specifically, eligible patients are those who appear in the denominator of at least one component eQM (dmg23h_ec subgroup, dmg31h_ec, or ked01_ec) and simultaneously fail to meet the numerator criterion for that measure (that is, they are actively due for the associated monitoring activity) at the time of monthly eligibility assessment.

*Randomization: Patients are randomized 1:1 to receive either:
Vet-Text: Automated SMS health system alert
Letter: Automated printed letter

*Stratification: By status of lab 'not done' for eQM dmg23h_ec in month prior to randomization (binary: done/not done), applied only among patients eligible for the dmg23h_ec subgroup at enrollment. Patients enrolled exclusively via ked01_ec or dmg31h_ec eligibility (and therefore not in the dmg23h_ec subgroup denominator) are not stratified on this variable.

*Outcome: The primary outcome is a patient-level binary: whether the patient met the numerator criterion for at least one component eQM for which they were eligible at enrollment, by the conclusion of the trial observation window. The Weighted and Replicated Estimator (WRE) will be used for embedded dynamic treatment regimen (EDTR) means.

Stage 2: Adaptive Re-Randomization
*Eligibility: Patients who do not respond or complete any eligible metric numerator after a 12-week period from entry (remain as 'metric not met' in all components for which they were enrolled, and remain in the denominator of those eQMs), post-Round 1 randomization.

*Randomization: Patients are randomized 1:1 to low-effort or high-effort arms:
Arm 1: Vet-Text + Letter (simultaneous, "Low-effort" arm)
Arm 2: Nurse phone call ("High-effort" arm)

*Re-randomization Ratio: 1:1

*Timing of Second Randomization: Onset of the 4th month eQM reporting cycle (rolling), after entry into Round 1 cohort.

## Intervention Type
Other

## Primary outcome(s)
1. Any eligible numerator met (patient-level binary) measured using data collected on the component(s) of the electronic quality measure (eQM) for which the Veterans were eligible at enrollment (DM: HbA1c Missing, DM: Retinal Exam, Timely by Disease, and/or Kidney Health Evaluation for Patients with Diabetes) at the conclusion of the trial observation window

## Key secondary outcome(s)
1. eQM component dmg31h_ec completion measured using data collected on the proportion of patients eligible for dmg31h_ec at enrollment who met the retinal exam numerator at trial conclusion

2. eQM component ked01_ec completion measured using data collected on the proportion of patients eligible for ked01_ec at enrollment who met the kidney health evaluation numerator (eGFR + uACR) at trial conclusion

3. eQM component dmg23h_ec subgroup completion measured using data collected on the proportion of patients eligible for dmg23h_ec subgroup at enrollment who met the HbA1c monitoring numerator at trial conclusion

### Completion date
20/03/2027

# Eligibility

### Key inclusion criteria
1. Veterans appearing in the denominator of at least one component electronic quality measure (eQM) (dmg23h_ec subgroup, dmg31h_ec, or ked01_ec) who are not yet meeting the numerator criterion for that component at the time of monthly eligibility assessment (i.e., they are actively due for the associated monitoring activity)
2. Valid contact information
3. Assigned to participating VA site (663)
4. Ages 18-85 (note: dmg23h_ec and dmg31h_ec eligibility is restricted to ages 18-75 per eQM specification; ked01_ec eligibility extends to age 85; patients ages 76-85 may be enrolled via ked01_ec eligibility alone)
5. Have assigned primary care provider in PCMM
6. Have had at least one inpatient or outpatient encounter anywhere in VHA within the three years prior to the eQM reporting period end date

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
85 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Assigned to H-PACT, GERI, SCI, or HBPC
2. Receiving hospice services in prior year (not included in eQM denominator)

3. 65 years with frailty and advanced illness (dementia medication, advanced illness definition set, or 2 instances of frailty; not included in eQM denominator)
4. Invalid/bad mailing address and invalid/non-working phone number (no valid outreach contact)

### Date of first enrolment
01/08/2026

### Date of final enrolment
30/09/2026

## Locations

### Countries of recruitment
United States of America

## Sponsor information

### Organisation
VA Puget Sound Health Care System

### ROR
https://ror.org/00ky3az31

## Funder(s)

### Funder type

### Funder Name
Veterans Health Administration (VHA) Office of Primary Care

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Statistical Analysis Plan | | 08/06/2026 | 09/06/2026 | No | No |