**PCAT STATISTICAL ANALYSIS PLAN (SAP)**

**Version:** 06086

**Project Title:** Optimizing Outreach for Performance on Diabetes Lab Monitoring

**Protocol ID:** PCIL-EQM-DM
**Brief Title:** Outreach for Diabetes
**Project Team:** Linnaea Schuttner, MD MS; John Geyer, MD; Chelle Wheat, PhD; Leslie Taylor, PhD; Ashok Reddy, MD; Brinn Jones; Anders Chen
**Lead Author:** *TBD*
**Senior Author:** Linnaea Schuttner, MD, MS
**Principal Investigator(s):** Linnaea Schuttner, MD, MS; John Geyer, MD
**Central Contact Backup:** Brinn Jones
**Sponsor:** VA Puget Sound Health Care System
**Collaborator:** VHA Office of Primary Care

**Conditions or Focus of Study:** Diabetes care; quality metrics; patient outreach
**Keywords:** diabetes, laboratory monitoring, outreach, adaptive randomization, quality improvement
**Study Type:** Interventional
**Primary Purpose:** Health services optimization
**Study Phase:** N/A
**Interventional Study Model:** Sequential multiple assignment randomized trial with a single adaptation point
**Number of Arms:** See below (adaptive, round-based)
**Masking:** PI (Schuttner)
**Allocation:** Randomized, adaptive
**Enrollment:** 2500
**Plan to Share IDP:** No

## 1. STUDY SUMMARY AND AIMS

### Study Purpose

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.

### Study Design

This 2-stage SMART trial is a prospective, adaptive, individually randomized trial consisting of two randomization rounds:

**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.
- Exclusion for Randomization: Invalid/bad mailing address, invalid/non-working phone number, not enrolled in PCMM, assignment to H-PACT, SCI, HBPC, or Geri-PACT.
- Outcome: See Section 5. 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.

**Adaptive Re-Randomization (Stage 2):**

- 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.

**Primary Outcome**

The primary outcome is a patient-level binary indicator: whether an enrolled 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.

Component eQMs contributing to eligibility and outcome:

| Component | Measure Name | Score Direction |
|---|---|---|
| SUBGROUP of dmg23h_ec | DM: HbA1c Missing | Lower is Better |
| dmg31h_ec | DM: Retinal Exam, Timely by Disease | Higher is Better |
| ked01_ec | Kidney Health Evaluation for Patients with Diabetes | Higher is Better |

Because ked01_ec represents the largest eligible population and because completion of kidney health evaluation (eGFR + uACR) is expected to co-occur with HbA1c monitoring (dmg23h_ec) within the same laboratory encounter, these two component outcomes are anticipated to be correlated at the patient level. Treating "any eligible numerator met" as the primary estimand correctly captures the patient action prompted by outreach (scheduling and completing a monitoring encounter) without inflating the composite numerator count for co-resolved lab measures. Retinal examination completion (dmg31h_ec) requires a distinct clinical encounter and is therefore analyzed as an independent secondary outcome.

**Secondary Outcomes**

- dmg31h_ec: Proportion meeting interval-recommended diabetes retinal exam, timely (binary, independent secondary outcome; analyzed separately given distinct care pathway)
- dmg23h_ec (subgroup): Proportion with HbA1c missing (lower is better; analyzed independently to decompose the lab-driven outcome pathway)
- ked01_ec: Proportion up-to-date with annual kidney health testing (eGFR + uACR; analyzed independently to decompose the lab-driven outcome pathway)
- Diabetes aggregate composite (tertiary/descriptive): Calculated as the SAIL-consistent denominator-weighted proportion across all three components (see formula below) for operational comparability with VHA performance reporting. This is not the primary analytic estimand.

**Tertiary composite formula (descriptive only):**

Composite = (N_dmg23h(sub) + N_dmg31h + N_ked01) / (D_dmg23h(sub) + D_dmg31h + D_ked01)

Where N denotes the passing numerator count and D denotes the eligible denominator count for each component. For dmg23h_ec subgroup, the raw passing numerator is used directly without inversion, consistent with dmg91_ec composite arithmetic. Note that individual patients may contribute to more than one component denominator and numerator in this formula; the enrollment N of 2,500 refers to unique patients, not patient-measure observations.

**Research Question**

What is the optimal outreach modality to improve diabetes monitoring completion (defined as meeting at least one eligible component eQM numerator) for patients with diabetes who are actively due for overdue retinal health and/or laboratory monitoring?

## 2. DATA SOURCES

| Table/Source | Time Period | Description | Analytic Variables of Interest |
|---|---|---|---|
| eQM interactive algorithm | Baseline, Outcome post R-1, Outcome post R-2 | eQMs | Numerator for: dmg23h_ec (missing a1c), ked01_ec, dmg31h_ec |
| Baseline: most recent in month prior to randomization | Dmg23h_ec: A1C (reports most recent hgba1c from CDW.Chem.LabChem within 12 months) | EvidenceSummary | |
| [CDWWork].[STIUNotes].[TIUDocument_8925] | During trial | Documentation of outreach | Modality, VisitDateTime |
| SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary] | Baseline | Descriptives & covariates | Age, sex, Priority |

| Table/Source | Time Period | Description | Analytic Variables of Interest |
|---|---|---|---|
| | | | group, marital status |
| SQL13.OABI_SHREC.[Demog].[SHREC_v3] | Baseline | Descriptives & covariates | Race |
| RB03.VINCI_CAN.[DOEx].[can_weekly_report_V2_5_history] | Baseline | Descriptives & covariates | CAN score |
| RB03.VINCI_PSSG.VINC_PSSG | Baseline | Descriptives & covariates | Drive distance |
| SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary] | Baseline | Descriptives & covariates | Primary care visit count >2 / <2 in past 12 months |
| cdwwork.RPCMM.CurrentProviderTeamMembership; cdwwork.ndim.RPCMMTeam | Baseline | Provider/team info | TeamSta6a, StaffSID, StaffName, RPCMMTeam |
| Operational data reports and eQM interactive algorithm | Baseline, after phase 1, after phase 2 | Cohort identification/outcome determination | Numerator, Denominator, Measure ID |

## 3. STUDY POPULATION AND ELIGIBILITY

### Inclusion Criteria

- Veterans appearing in the denominator of at least one component 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)
- Valid contact information
- Assigned to participating VA site (663)

- 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)
- Have assigned primary care provider in PCMM
- Have had at least one inpatient or outpatient encounter anywhere in VHA within the three years prior to the eQM reporting period end date

**Exclusion Criteria**

- Assigned to H-PACT, GERI, SCI, or HBPC
- Receiving hospice services in prior year (not included in eQM denominator)
- 65 years with frailty and advanced illness (dementia medication, advanced illness definition set, or 2 instances of frailty; not included in eQM denominator)
- Invalid/bad mailing address and invalid/non-working phone number (no valid outreach contact)

**Rolling Enrollment into Round 1**

Eligible patients are identified on a monthly basis using the eQM interactive algorithm. A patient becomes eligible for Round 1 enrollment in the month in which they first appear in the denominator of at least one component eQM and simultaneously fail to meet the numerator criterion for that measure. Eligibility is assessed at the start of each monthly eQM reporting cycle. Patients are enrolled and randomized upon first meeting these criteria; they are not re-enrolled in subsequent months if previously randomized. Rolling enrollment continues until the cumulative Round 1 cohort reaches the target of 2,500 unique patients, or until enrollment extension provisions (Section 7) are triggered.

Component eligibility pathway at enrollment (which component(s) a patient is due for) will be recorded at baseline for use in secondary and sensitivity analyses. Patients eligible for more than one component at enrollment will be counted once toward the enrollment total of 2,500.

**Sex:** All

**Age limits:** 18-85

**Accepts Healthy Volunteers:** No

## 4. STUDY TIME PERIOD

- Planned enrollment (start, rolling): June 15, 2026

- Trial start date: July 1, 2026
- Interventions: Outreach begins after randomization; re-randomization for non-responders at pre-specified intervals
- Data collection: Through 4 months after completion of enrollment milestone

## 5. STUDY OUTCOMES

### Primary Outcome: Any Eligible Numerator Met (Patient-Level Binary)

The primary outcome is a patient-level binary indicator (Y = 1 / 0): whether an enrolled patient met the numerator criterion for at least one component eQM for which they were eligible at the time of enrollment, at any point through the conclusion of the trial observation window.

- Denominator (trial): All unique patients enrolled in Round 1 (closed cohort; N target = 2,500). Each patient contributes exactly one observation to the primary analysis regardless of the number of component eQMs for which they were eligible.
- Numerator (trial): Patients in the enrolled cohort who meet the numerator criterion for at least one of their eligible component eQMs by trial conclusion.
- Observation window: From date of Round 1 randomization through end of trial data collection period (4 months post-enrollment completion).
- Baseline outcome state: All enrolled patients are confirmed as not meeting the numerator for any eligible component at the time of enrollment. This "due for" status is the eligibility trigger and defines the baseline outcome state (Y = 0 at enrollment for all patients).

Rationale for patient-level binary estimand: ked01_ec represents the largest eligible population (age range 18-85) and is the component for which most enrolled patients will be due. Completion of kidney health evaluation (eGFR + uACR) is expected to co-occur with HbA1c monitoring (dmg23h_ec) within the same laboratory encounter, producing correlated numerator completion across these two components at the patient level. A measure-level composite that sums numerators and denominators across components would count co-resolved lab outcomes multiple times for a single outreach-prompted patient action, inflating the apparent composite numerator without reflecting additional clinical benefit. The patient-level binary estimand correctly attributes outcome to the unit of randomization, avoids double-counting of correlated lab completions, and aligns the outcome directly with the clinical mechanism of the intervention (prompting the patient to attend a monitoring encounter).

Component eQMs (establishing eligibility and outcome pathway):

| Component | Measure Name | Score Direction | Notes |
|---|---|---|---|
| SUBGROUP of dmg23h_ec | DM: HbA1c Missing | Lower is Better | Lab-driven; expected to co-resolve with ked01_ec |
| dmg31h_ec | DM: Retinal Exam, Timely by Disease | Higher is Better | Distinct care pathway; requires separate eye care encounter |
| ked01_ec | Kidney Health Evaluation for Patients with Diabetes | Higher is Better | Lab-driven; largest eligible population; expected to co-resolve with dmg23h_ec subgroup |

A variant of dmg91_ec will be used for the trial. Dmg91_ec is used in the VHA Strategic Analytics for Improvement and Learning (SAIL) performance reporting system and has been a national accountability indicator since FY2023.

**Secondary Outcomes**

1. dmg31h_ec completion (primary secondary): Proportion of patients eligible for dmg31h_ec at enrollment who met the retinal exam numerator by trial conclusion. Analyzed as an independent binary outcome given the distinct clinical encounter required. This is the most operationally independent secondary outcome and is powered to detect meaningful differences in the retinal care pathway separately from the lab-driven pathway.
2. ked01_ec completion: Proportion of patients eligible for ked01_ec at enrollment who met the kidney health evaluation numerator (eGFR + uACR) by trial conclusion.
3. dmg23h_ec subgroup completion: Proportion of patients eligible for dmg23h_ec subgroup at enrollment who met the HbA1c monitoring numerator by trial conclusion.
4. Diabetes aggregate composite (tertiary/descriptive): Denominator-weighted proportion across all three component eQMs, consistent with SAIL dmg91_ec composite reporting (see formula in Section 1). Reported for operational comparability; not the primary analytic estimand. Individual patients may contribute to more than one component numerator and denominator in this calculation.

All secondary outcomes will be calculated using the same closed cohort approach, with denominator restricted to patients eligible for each respective component at enrollment.

## 6. STUDY COVARIATES

- Patient-level (a priori adjusted): Age, sex, race/ethnicity, pre-randomization baseline A1c (within 12 months prior), site, drive distance, prior PC utilization, time (month) of enrollment, component eligibility pathway at enrollment (which eQM(s) patient was due for at inclusion)
- Intervention-level: Outreach modality arm (Vet-Text vs. Letter; high effort vs. low effort)
- Stratification: dmg23h_ec status ('not done' in reporting period) in month prior to randomization (binary); applied only to patients eligible for the dmg23h_ec subgroup at enrollment. Patients enrolled exclusively via ked01_ec or dmg31h_ec eligibility are not stratified on this variable.

## 7. STATISTICAL ANALYSES AND MAIN TABLES

Sample Size and Power (See Appendix C for Methods)

- Target enrollment: 2,500 unique patients
- Alpha: 0.05, two-sided
- Power: 80%
- Primary outcome assumed completion rate: 73.4% (mean across three outcome measures and as of March 1, 2026.
- Cluster adjustment: N/A; unit of randomization and analysis is the patient
- Multiplicity: None for primary outcome

### Descriptive Analyses

Baseline comparability between arms on demographics, baseline A1c, component eligibility pathway, and other covariates, using chi-square/ANOVA as appropriate. Enrollment volume by month will be reported to characterize the rolling entry process.

### Primary Analysis

- Estimand: Patient-level binary outcome (any eligible numerator met) under intention-to-treat.
- Intention-to-treat (ITT): All randomized participants analyzed according to the EDTR they are consistent with, under WRE replication and IPW.

- Justification: WRE with inverse probability of treatment weights provides unbiased EDTR mean estimates under randomization, handling replication of responders and single-path consistency for non-responders. The binary patient-level outcome is well-suited to the WRE framework as originally specified.
- Responder definition for Stage 2 eligibility: A patient is defined as a non-responder (eligible for re-randomization) if they have not met the numerator criterion for any component eQM for which they were eligible at enrollment, as of the 12-week assessment. Patients who meet any eligible numerator by 12 weeks are classified as responders and are not re-randomized.

**Data construction:**

For each participant i:

- Stage 1 weight: w_1i = 1/0.5 = 2 (1:1 randomization)
- Responder replication: If Stage 1 response R_i = 1, create two replicated rows (one for each second-stage option on their initial arm) with weights w_i = 2 each; outcome Y_i = 1 by design
- Non-responder single path: If R_i = 0, include one row consistent with observed Stage 2 assignment, with weight w_i = 1/(0.5 x 0.5) = 4 (probability of Stage 1 arm x Stage 2 arm)
- EDTR-specific means: For each EDTR k, estimate mu_k = sum_i w_i Y_i 1{i contributes to k} / sum_i w_i 1{i contributes to k}

For variance estimation, nonparametric bootstrapping over participants will be used to obtain SE and 95% confidence intervals. Robust (sandwich) SEs from WRE logistic regression will be evaluated as an alternative.

**ITT Primary Analysis:**

- Compute mu_k for all EDTRs via WRE/IPW and their covariance matrix of mu
- Convert to per-subject covariance V using the large-sample relation Var(mu_k) approximately V_kk/N; estimate V by Monte Carlo/Bootstrap at anchor N and rescale
- Apply MCB to test H_k: mu_best minus mu_k >= delta_min across all k not equal to best, with multiplicity control; report the set of best EDTRs and the selected best if unique. Implementation via smartsizer package.

All outcomes reported as risk differences with 95% CI; final selected set reported under MCB at alpha = 0.05.

**Secondary Analyses**

1. Stage 1 comparison (Letter vs. Vet-Text): Two-proportion test for primary binary outcome completion (ignoring Stage 2). Risk differences with 95% CI.
2. Stage 2 comparison (Letter + Vet-Text vs. Nurse navigation): Limited to non-responders randomized in Stage 2. Two-proportion test for primary binary outcome completion (ignoring Stage 1). Risk differences with 95% CI.
3. Covariate-adjusted WRE: Weighted logistic regression including baseline covariates and component eligibility pathway to assess robustness. Adjusted marginal means reported.
4. Component pathway subgroup analyses: Primary binary outcome estimated separately within the subgroup of patients eligible only for lab-driven components (ked01_ec and/or dmg23h_ec) and within those eligible for dmg31h_ec, to characterize differential outreach effects by care pathway.

**Interim Analysis & Stopping**

- If the minimum enrollment goal of 2,500 unique patients is not reached within 12 weeks of trial start (July 1, 2026), the enrollment window will be extended in 4-week increments using the same monthly rolling eligibility assessment, until the target is met or a stopping decision is made by the study team.

8. TIMELINE

| Activity | Q2 '26 | Q3 '26 | Q4 '26 | Q1 '27 | Q2 '27 |
|---|---|---|---|---|---|
| DNRA/SAP | x | | | | |
| Develop/review workflow | x | x | | | |
| Data process prep | x | x | | | |
| Programming/Randomization | x | x | | | |
| Round 1 Enrollment/Intervention | | x | x | | |
| Data review/Interim Analysis | | | x | | |
| Round 2 Randomization/Intervention | | | | x | |
| Final analysis | | | | x | x |

| Activity | Q2 '26 | Q3 '26 | Q4 '26 | Q1 '27 | Q2 '27 |
|---|---|---|---|---|---|
| Manuscript/evidence brief | | | | | x |

## 9. PROJECT LINKS

- Project Proposal:
- Readme/Project Description:
- Data Summary Document:

## 10. APPENDICES

### APPENDIX A: Workflows

### APPENDIX B: Shell Tables and Figures

- Table 1. Baseline Demographics and Component Eligibility Pathway by Randomization Arm
- Table 2. Primary Outcome (Any Eligible Numerator Met) and Secondary Outcomes by Randomization Arm(s) -- ITT and by Round
- Table 3. Tertiary Aggregate Composite (SAIL-consistent) -- Descriptive
- CONSORT Diagram: Flowchart of participant progress through randomization rounds, including component eligibility pathway at enrollment

### APPENDIX C: Sample Size Simulations

- Assumptions:
    - Letter completion before Stage 2 trigger- Kiran et al. (2018) reported 24.8% completion for mailed reminder letters among males. Note that the female rate was considerably higher (33.0%), but given our population of primarily older white males, the male-specific estimate is used.

      pR_L = 0.25, letter completion before Stage-2 trigger
    - VetText completion before Stage 2 trigger - 29% completion among non-completers. Kiran et al. (2018) reported 28.8% completion for phone call reminders among males (vs. 41.2% among females). The male difference between letter and phone call arms was only 4.1 pp and non-significant (p = 0.073), suggesting a more modest benefit of active reminders over

letters in men. Updated from 0.35 to 0.29 to reflect the male-specific data. VetText is treated as analogous to a phone/automated reminder for this purpose.

pR_V = 0.29, VetText completion before Stage-2 trigger

- Conditional completion probabilities among Stage-1 non-responders: Nurse navigation for CRC screening non-responders: 27% (Percac-Lima et al., 2009) to 33.6% (Lasser et al., 2011) in the overall study populations. The higher rates observed by Lasser et al. (39.7-39.8%) were specific to Black and non-English-speaking subgroups, which are not representative of our population. Given that our population is primarily older white males, we adopt a conservative estimate of 30%, midway between the two overall study rates.

  p2_L_N  = 0.30, if Stage1=Letter, NR -> Nurse

- Stage1 = Letter, Stage2 = Letter + VetText (combined reminder): No direct literature was identified that evaluated the effect of a combined mailed letter + automated text reminder specifically among screening non-responders in a population of older white males or Veterans. This assumption (24%) represents a conservative expert-informed estimatebased on the following reasoning:

  - Stage 1 non-responders to a mailed letter are a self-selected group unlikely to respond strongly to a repeat mailed letter alone.
  - Adding an automated text reminder (VetText) may provide a modest incremental nudge via a different modality, but diminishing returns are expected among persistent non-responders.
  - 24% is set deliberately below the nurse navigation assumption (30%)  to reflect the lower intensity of this intervention combination.

  p2_L_LV = 0.24, if Stage1=Letter, NR -> Letter+VetText

- Stage1 = VetText, Stage2 = Nurse Navigation: Same nurse navigation assumption as above (30%), applied to non-responders from the VetText arm. Effect assumed equivalent regardless of Stage 1 arm, and adjusted downward from the literature range to reflect our population of primarily older white males, for whom subgroup-specific benefits of navigation are less pronounced.

  p2_V_N  = 0.30, if Stage1=VetText, NR -> Nurse

- Stage1 = VetText, Stage2 = Letter + VetText (repeat/combined reminder): As with p2_L_LV above, no direct literature was identified supporting this assumption in an analogous population. This estimate (25%) represents a conservative expert-informed assumption based on the same reasoning:
  - Non-responders to an initial VetText are unlikely to respond strongly to a repeat text reminder alone.
  - Adding a mailed letter provides a different modality that may reach some patients who did not engage with the initial text, justifying a marginally higher estimate than p2_L_LV (25% vs 24%).
  - Both estimates are set below the nurse navigation assumption (30%) to reflect lower intervention intensity.

  p2_V_LV = 0.25, if Stage1=VetText, NR -> Letter+VetText repeat text/reminders among NR

| DTR | Stage 1 | Stage 2 (NR only) | Overall completion |
|---|---|---|---|
| 1 | Letter (25%) | Letter+VetText (24%) | 0.25 + 0.75×0.24 = **43.0%** |
| 2 | Letter (25%) | Nurse (30%) | 0.25 + 0.75×0.30 = **47.5%** |
| 3 | VetText (29%) | Letter+VetText (25%) | 0.29 + 0.71×0.25 = **46.75%** |
| 4 | VetText (29%) | Nurse (30%) | 0.29 + 0.71×0.30 = **50.3%** |

## APPENDIX D: ISRCTN Additional Information

- US FDA Regulated Drug: No
- US FDA Regulated Device: No
- FDA IND/IDE: No
- Human Subjects Review: Non-research QI (not subject to human subjects)
- Data Monitoring: No

## APPENDIX E: Randomization Procedures

- Participant list generated using query of EHR/eQM
- Random allocation using blockrand or similar, run in R version 4.3.1

- Stratification as specified (dmg23h_ec status in month prior to randomization, applied only to patients eligible for the dmg23h_ec subgroup at enrollment)
- For re-randomization, eligibility confirmed from outcomes database (non-response on all eligible components at 12 weeks); randomization re-applied among non-responders.

**APPENDIX F: Electronic technical manual entries for component eQMS**

- **<u>Component Measure (subgroup only used in trial): dmg23h_ec (DM: HbA1c Poor Control)</u>**
  - **Overview**
    - **dmg23h_ec** is a national electronic quality measure (eQM) monitoring the proportion of Veterans with diabetes who have poor glycemic control, defined as a most recent HbA1c greater than 9% or no HbA1c result documented during the reporting year. It is a lower-is-better measure and serves as one of three component measures of the dmg91_ec Electronic Composite – Diabetes. The measure has been an accountability indicator in SAIL since FY2025.
  - **Eligible Population**
    - Veterans aged 18–75 years on the last day of the reporting period who have an active diagnosis of diabetes, identified by either of the following:
      - **Encounter-based:** At least two diabetes diagnoses (per the Diabetes Value Set) on different dates of service during the reporting period or the prior year; or
      - **Pharmacy-based:** Dispensed insulin or a hypoglycemic/antihyperglycemic agent (per the Diabetes Medications List) during the reporting period or the prior year, with at least one diabetes diagnosis during the same window.
  - **Exclusions**
    - Veterans are excluded from the eligible population if they meet any of the following criteria during the reporting period:
    - Younger than 18 or older than 75 years of age on the last day of the reporting period
    - Died during the reporting period
    - Received hospice services at any time during the reporting period
    - Received palliative care (including ICD-10-CM code Z51.5) at any time during the reporting period

        - Aged 66 years or older with both frailty (at least two frailty indicators on different dates of service) and advanced illness (advanced illness on at least two different dates of service, or dispensed a dementia medication, during the reporting period or prior year)
    - **Denominator**
        - Eligible Veterans with diabetes as defined above.
    - **Numerator**
        - Eligible Veterans whose most recent HbA1c result during the reporting year was greater than 9%, or for whom no HbA1c was performed during the reporting year. Non-VA laboratory HbA1c values documented via the national Health Factor "VA-HEMOGLOBIN A1C OUTSIDE LAB" are included in numerator calculation; Oracle non-VA A1c data are additionally included beginning CY2024.
    - **Score Direction and Interpretation**
        - dmg23h_ec is scored as **lower is better**: a higher reported percentage indicates a greater proportion of the diabetic population with poor or unmonitored glycemic control, which is an adverse outcome. Within the dmg91_ec composite, the raw numerator (count of patients with poor control) is used directly in the composite calculation without arithmetic inversion; the inversion occurs only at the individual measure display level.
- **<u>Component Measure: dmg31h_ec (DM: Retinal Exam, Timely by Disease)</u>**
    - **Overview**
        - **dmg31h_ec** is a national electronic quality measure (eQM) monitoring the proportion of Veterans with diabetes who received timely screening or monitoring for diabetic retinal disease. It is a higher-is-better measure and serves as one of three component measures of the dmg91_ec Electronic Composite – Diabetes. The measure has been an accountability indicator in SAIL since FY2025.
    - **Eligible Population**
        - Veterans aged 18–75 years on the last day of the reporting period who have an active diagnosis of diabetes, identified by either of the following:
            - **Encounter-based:** At least two diabetes diagnoses (per the Diabetes Value Set) on different dates of service during the reporting period or the prior year; or
            - **Pharmacy-based:** Dispensed insulin or a hypoglycemic/antihyperglycemic agent (per the Diabetes

Medications List) during the reporting period or the prior year, with at least one diabetes diagnosis during the same window.

- **Exclusions**
  - Veterans are excluded from the eligible population if they meet any of the following criteria during the reporting period:
  - Younger than 18 or older than 75 years of age on the last day of the reporting period
  - Died during the reporting period
  - Received hospice services at any time during the reporting period
  - Received palliative care (including ICD-10-CM code Z51.5) at any time during the reporting period
  - Aged 66 years or older with both frailty (at least two frailty indicators on different dates of service) and advanced illness (advanced illness on at least two different dates of service, or dispensed a dementia medication, during the reporting period or prior year)
- **Denominator**
  - Eligible Veterans with diabetes as defined above.
- **Numerator**
  - Eligible Veterans with evidence of timely retinal screening or monitoring for diabetic retinal disease, based on administrative data. The examination interval required depends on retinopathy status: Veterans with no prior evidence of retinopathy must have a qualifying exam at least every two years; Veterans with known retinopathy must have a qualifying exam annually. Numerator criteria are met by any of the following:
  - A retinal or dilated eye exam by an eye care professional (ophthalmologist or optometrist) during the measurement year
  - A negative retinal or dilated eye exam (no retinopathy) by an eye care professional during the year prior to the measurement year
  - Bilateral eye enucleation at any time in the member's history through the end of the measurement month
  - Qualifying unilateral eye enucleation combinations (bilateral modifier, two unilateral procedures ≥14 days apart, or laterality-specific left/right combinations) documented in the measurement year or prior year
  - Automated eye exam or exam with or without evidence of retinopathy billed by any provider during the measurement year, or exam without evidence of retinopathy billed by any provider in the prior year

        - National clinical reminder health factor data meeting numerator criteria (included beginning January 2023)
        - Eye exams may be conducted in person and must be performed or read by an ophthalmologist or optometrist. Care modality is in-person only.
    - **Score Direction and Interpretation**
        - dmg31h_ec is scored as **higher is better**: a higher reported percentage indicates a greater proportion of the diabetic population receiving timely retinal screening, which is a favorable outcome.
    - **Specification Notes Relevant to Longitudinal Analysis**
        - Legally blind Veterans are not excluded from this measure's denominator per NCQA specifications, as it is not possible to distinguish algorithmically between those who require retinal examination and those who do not. Such cases should be acknowledged as potential outliers in any facility-level analysis.
- **<u>Component Measure: ked01_ec (Kidney Health Evaluation for Patients With Diabetes)</u>**
    - **Overview**
        - **ked01_ec** is a national electronic quality measure (eQM) monitoring the proportion of Veterans with diabetes who received a kidney health evaluation during the measurement year, defined as completion of both an estimated glomerular filtration rate (eGFR) and a urine albumin-to-creatinine ratio (uACR). It is a higher-is-better measure and serves as one of three component measures of the dmg91_ec Electronic Composite – Diabetes. The measure has been an accountability indicator in SAIL since FY2025.
    - **Eligible Population**
        - Veterans aged 18–85 years on the last day of the reporting period who have an active diagnosis of diabetes, identified by either of the following:
            - **Encounter-based:** At least two diabetes diagnoses (per the Diabetes Value Set) on different dates of service during the reporting period or the prior year; or
            - **Pharmacy-based:** Dispensed insulin or a hypoglycemic/antihyperglycemic agent (per the Diabetes Medications List) during the reporting period or the prior year, with at least one diabetes diagnosis during the same window.
        - Note that the eligible age range for ked01_ec (18–85 years) is broader than that of the other two component measures of

dmg91_ec (18–75 years), which contributes to ked01_ec having a substantially larger denominator than dmg23h_ec and dmg31h_ec.

- **Exclusions**
  - Veterans are excluded from the eligible population if they meet any of the following criteria:
  - Younger than 18 or older than 85 years of age on the last day of the reporting period
  - Died at any time during the reporting period
  - Evidence of end-stage renal disease (ESRD) or dialysis at any time in the Veteran's history on or prior to the end of the reporting year
  - Received hospice services at any time during the reporting period
  - Received palliative care (including ICD-10-CM code Z51.5) during the reporting period
  - Aged 66–80 years with both frailty (at least two frailty indicators on different dates of service during the reporting period) and advanced illness (advanced illness on at least two different dates of service, or dispensed a dementia medication, during the reporting period or prior year)
  - Aged 81–85 years with at least two frailty indicators on different dates of service during the reporting period (advanced illness criterion not required for this age group)
- **Denominator**
  - Eligible Veterans with diabetes as defined above.
- **Numerator**
  - Eligible Veterans who received **both** of the following laboratory tests during the measurement year, on the same or different dates of service:
  - At least one eGFR (per the Estimated Glomerular Filtration Rate Lab Test Value Set); and
  - At least one uACR, satisfied by either: (a) a direct uACR test (per the Urine Creatinine Ratio Lab Test Value Set), or (b) both a quantitative urine albumin test (Quantitative Urine Albumin Lab Test Value Set) and a urine creatinine test (Urine Creatinine Lab Test Value Set)
  - Patient refusals are not excluded from the denominator. Non-VA laboratory results entered via national clinical reminder health factors or structured Oracle Health data fields are included in numerator calculation.
- **Score Direction and Interpretation**

- ked01_ec is scored as **higher is better**: a higher reported percentage indicates a greater proportion of the diabetic population receiving complete kidney health evaluation, which is a favorable outcome.

**References**


1. See template references and relevant literature on adaptive designs.
2. Electronic technical manual for metrics, date accessed 5/26/26: http://pm.rtp.med.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fPerformance+Reports%2fMeasure+Management%2fMeasure&Measure=3850&Year=2026&rs%3aCommand=Render
3. Interactive algorithm, date accessed 5/26/26: https://eqm.va.gov/COR/#/ia
4. Kiran, T., Davie, S., Moineddin, R. and Lofters, A., 2018. Mailed letter versus phone call to increase uptake of cancer screening: a pragmatic, randomized trial. *The Journal of the American Board of Family Medicine*, *31*(6), pp.857-868.
5. Percac-Lima, S., Grant, R.W., Green, A.R., Ashburner, J.M., Gamba, G., Oo, S., Richter, J.M. and Atlas, S.J., 2009. A culturally tailored navigator program for colorectal cancer screening in a community health center: a randomized, controlled trial. *Journal of general internal medicine*, *24*(2), pp.211-217.
6. Lasser, K.E., Murillo, J., Lisboa, S., Casimir, A.N., Valley-Shah, L., Emmons, K.M., Fletcher, R.H. and Ayanian, J.Z., 2011. Colorectal cancer screening among ethnically diverse, low-income patients: a randomized controlled trial. *Archives of internal medicine*, *171*(10), pp.906-912.
7. Kidwell, K.M. and Almirall, D., 2023. Sequential, multiple assignment, randomized trial designs. *Jama*, *329*(4), pp.336-337.
8. Freeman, N.L., Browder, S.E., Rowland, B., Jones, E.P., Hoch, M., Kim, A., Zhou, C.W., Kahkoska, A.R., McGinigle, K.L., Ivanova, A. and Kosorok, M.R., 2025. Design characteristics of sequential multiple assignment randomised trials (SMARTs) for human health: a scoping review of studies between 2009 and 2024. *BMJ open*, *15*(12), p.e105506.
9. Kilbourne, A.M., Almirall, D., Eisenberg, D., Waxmonsky, J., Goodrich, D.E., Fortney, J.C., Kirchner, J.E., Solberg, L.I., Main, D., Bauer, M.S. and Kyle, J., 2014. Protocol: Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program. *Implementation Science*, *9*(1), p.132.