NATIONAL QUALITY FORUM
Driving measurable health improvements together

Measure Worksheet

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 0729

Corresponding Measures:

Measure Title: Optimal Diabetes Care

Measure Steward: MN Community Measurement

sp.02. Brief Description of Measure: The percentage of patients 18-75 years of age who had a diagnosis of type 1 or type 2 diabetes and whose diabetes was optimally managed during the measurement period as defined by achieving ALL of the following:

- HbA1c less than 8.0 mg/dL
- Blood Pressure less than 140/90 mmHg
- On a statin medication, unless allowed contraindications or exceptions are present
- Non-tobacco user
- Patient with ischemic vascular disease is on daily aspirin or anti-platelets, unless allowed contraindications or exceptions are present

Please note that while the all-or-none composite measure is considered to be the gold standard, reflecting best patient outcomes, the individual components may be measured as well. This is particularly helpful in quality improvement efforts to better understand where opportunities exist in moving the patients toward achieving all of the desired outcomes. Please refer to the additional numerator logic provided for each component.

1b.01. Developer Rationale: Achieving the intermediate physiological outcome targets related to blood pressure and glycemic control, in addition to being tobacco free and use of daily aspirin and statins where appropriate, are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by achieving several intermediate physiological targets.

In 2018, a study of over 200,000 patients with type 2 diabetes found that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. [Rawshani, A et al Risk Factors, Mortality, and Cardiovascular Outcomes in Patients with Type 2 Diabetes N Engl J Med 2018; 379:633-644 DOI: 10.1056/ NEJMoa1800256]

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sp.12. Numerator Statement: The number of patients in the denominator whose diabetes was optimally managed during the measurement period as defined by achieving ALL of the following:

- The most recent HbA1c in the measurement period has a value less than 8.0 mg/dL
- The most recent Blood Pressure in the measurement period has a systolic value of less than 140 mmHg AND a diastolic value of less than 90 mmHg
- On a statin medication, unless allowed contraindications or exceptions are present
- Patient is not a tobacco user
- Patient with ischemic vascular disease (Ischemic Vascular Disease Value Set) is on daily aspirin or anti-platelets, unless allowed contraindications or exceptions are present

sp.14. Denominator Statement: Patients ages 18 to 75 with a diagnosis of diabetes (Diabetes Value Set) with any contact during the current or prior measurement period OR had diabetes (Diabetes Value Set) present on an active problem list at any time during the measurement period. Both contacts AND problem list must be queried for diagnosis (Diabetes Value Set).

AND patient has at least one established patient office or telehealth visit (Established Pt Diabetes & Vasc Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period.

sp.16. Denominator Exclusions: Valid allowable exclusions include patients who were a permanent resident of a nursing home, pregnant, died or were in hospice or palliative care during the measurement year.

Measure Type: Composite

sp.29. Data Source: Electronic Health Records

sp.07. Level of Analysis: Clinician: Group/Practice

IF Endorsement Maintenance – Original Endorsement Date: 03/28/2011

Most Recent Endorsement Date: 6/11/2019

IF this measure is included in a composite, NQF Composite#/title: Optimal Diabetes Care

#0729 - Optimal Diabetes Care

#0729 - Optimal Diabetes Care

IF this measure is paired/grouped, NQF#/title:

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement, endorsed measures are evaluated periodically to ensure that the measure still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a ***health outcome*** measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a maintenance, patient level all-or-none composite measure that addresses five modifiable risk factors to reduce macrovascular and microvascular complications associated with diabetes.
- The developer provides a logic model that depicts five separate components (i.e., HbA1c, blood pressure, cholesterol, tobacco, and aspirin/antiplatelet) assessed for each patient to achieve multiple intermediate physiological clinical outcome and medication use targets to best reduce overall risk of developing long-term complications.

Summary of prior review in 2018

- This all-or-none composite measure is comprised of five components of which the developer provided a systematic review and grading of empirical evidence for each component of the composite. Based on the Institute for Clinical Systems Improvement (ISCI) guidelines (2014), empirical studies, and clinical practice guidelines, evidence was presented to support the link to optimal diabetes care which the Standing Committee found sufficient.
- The Standing Committee noted that there is a lack of evidence to support the use of all five components to improve outcomes for patients diagnosed with diabetes.
- Several Standing Committee members expressed concern that the measure targets patients with "mild" diabetes and does not address the needs of advanced or complicated diabetes.
- Several Standing Committee members were concerned with the all-or-none construct and the expectation that all five components must be achieved to demonstrate quality care; good providers may be penalized for only meeting components of the measure.
- The Standing Committee ultimately agreed that the evidence was sufficient and supported the components of the composite measure.
- The Standing Committee passed the evidence criterion with rating of moderate.

Changes to evidence from last review

☐ The developer attests that there have been no changes in the evidence since the measure was last evaluated.

☒ The developer provided updated evidence for this measure:

- The developer provided updated evidence from the 2022 Professional Practice Committee (PPC) of the American Diabetes Association (ADA) Standards of Care (SOC), which supports the prevention and reduction of long-term complications and maximizing health outcomes.
- The developer used the ADA evidence-grading system to assign a level of evidence for all component recommendations and notes that most of the recommendations included are rated as Level A and Level B.

1a. Evidence. The evidence requirements for a ***structure, process or intermediate outcome*** measure are that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- Systematic Review of the evidence specific to this measure? ☒ Yes ☐ No
- Quality, Quantity and Consistency of evidence provided? ☐ Yes ☒ No
- Evidence graded? ☒ Yes ☐ No
- **Composite Component #1: Hemoglobin A1c less than 8.0 (intermediate outcome)**
    - The developer summarized the link between assessing blood sugar control monitored by annual HbA1c lab test, maintaining the patient with an A1C less than 8.0, and reducing the risk of long-term complications associated with macro and microvascular complications hyperglycemia.
    - The developer provided recommendations from the American Diabetes Association (ADA) 2022 Standards of Care related to glycemic monitoring and control, individualizing patient targets, and reevaluating over time as patient factors change.
    - The developer used the ADA classification system to assess and summarize the Quality, Quantity, and Consistency of the body of evidence associated with the practice guidelines and recommendations.
    - Less stringent A1C goals (such as <8% [64 mmol/mol]) may be appropriate for patients with limited life expectancy or where the harms of treatment are greater than the benefits. Grade B
- **Composite Component #2: Blood Pressure less than 140 systolic and less than 90 diastolic**
    - The developer summarized the link between the importance of continuous blood pressure monitoring and interventions that the provider can perform if correction treatment plans are needed to manage blood pressure for patients with diabetes and reduce the risk of long-term cardiovascular complications associated with hypertension.
    - The developer provided recommendations from the American Diabetes Association (ADA) 2022 Standards of Care related to blood pressure monitoring (routine, at-home) and setting individualized blood pressure targets through a shared decision-making process that addresses cardiovascular risk, potential adverse effects of antihypertensive medications, and patient preferences.
    - The developer used the ADA classification system to assess and summarize the Quality, Quantity, and Consistency of the body of evidence associated with the practice guidelines and recommendations.
    - For individuals with diabetes and hypertension at lower risk for cardiovascular disease (10- year atherosclerotic cardiovascular disease risk <15%), treat to a blood pressure target of <140/90 mmHg. Grade **A**
- **Composite Component #3: Cholesterol Statin Use**
    - The developer summarized the link between assessment of patient variables and risks to determine appropriate statin use and monitoring to avoid long-term cardiovascular complications related to increased cholesterol levels.
    - The developer provided recommendations from the American Diabetes Association (ADA) 2022 Standards of Care related to the benefits of statin therapy on atherosclerotic cardiovascular disease (ACVD) outcomes for patients living with diabetes.
    - The developer used the ADA classification system to assess and summarize the Quality, Quantity, and Consistency of the body of evidence associated with the practice guidelines.
    - Grade is dependent on the age band and cardiovascular disease risk level of the patients in the measured population.

- **Composite Component #4: Tobacco Free**

- The developer provided a summary of healthcare processes from the American Diabetes Association (ADA) 2022 Standards of Care that providers can take to assess patients with diabetes for tobacco use and interventions that providers can implement to achieve the outcome (i.e., cessation counseling, advice, referral, pharmacotherapy).
- The developer noted evidence supports the link between cigarette smoking and health risks; adults with chronic medical conditions are more likely to use tobacco products and people diagnosed with diabetes who either smoke, or exposed to second-hand smoke, are more at risk of premature death and negative health outcomes (i.e., cardiovascular disease, microvascular complications, and poor glycemic control).
- The developer used the ADA classification system to assess and summarize the Quality, Quantity, and Consistency of the body of evidence associated with the practice guidelines and recommendations.
- Advise all patients not to use cigarettes and other tobacco products or e-cigarettes, including smoking cessation counseling and other forms of treatment as a routine component of diabetes care. Grade A

- **Composite Component #5: Aspirin/Antiplatelet Use**
  - The developer summarized the link between the assessment and management of potential clotting for patients diagnosed with diabetes and ischemic vascular disease leading to effective treatment with aspirin or antiplatelet medication to reduce the risk of subsequent cardiovascular events.
  - The developer provided recommendations from the American Diabetes Association (ADA) 2022 Standards of Care related to medication therapy (aspirin and antiplatelet medications) to reduce morbidity and mortality associated with cardiovascular events in high-risk patients (i.e., previous acute myocardial infarction [AMI] or stroke).
  - The developer used the ADA classification system to assess and summarize the Quality, Quantity, and Consistency of the body of evidence associated with the practice guidelines.
  - Daily aspirin or anti-platelets as a secondary prevention strategy in those with diabetes and a history of atherosclerotic cardiovascular disease if no contraindications/ exceptions.

Exception to evidence

- N/A

Questions for the Committee:

- *The evidence provided by the developer is updated, directionally the same, and stronger compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence?*
- *What is the relationship of this measure to patient outcomes?*
- *How strong is the evidence for this relationship?*

Guidance from the Evidence Algorithm

Not a Health Outcome or PRO (Box 1) -> Process measure or intermediate clinical outcome measure (Box 3) Summary without QQC from systematic review (Box 4) -> Quality of evidence Mod/High (Box 6) -> Moderate

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer noted that statewide results show that 55 percent of patients diagnosed with diabetes has at least one component of the measure that is not optimally managed.

- The developer noted that a 2018 study showed that a patient diagnosed with diabetes has a lower risk of an experienced cardiovascular event for every risk factor variable that is within the target range and those patients who achieved all five risk factors had little to no excess risk of mortality or morbidity (myocardial infarction or stroke) when compared to the general population.
- The developer provided performance data for the year prior to the COVID-19 pandemic (2019) and during the pandemic (2020) to demonstrate the impact of COVID-19 on healthcare delivery and measure performance (e.g., statewide measure decreases from 45.4 percent in 2019 to 40.6 percent in 2020).
- The developer also notes that Optimal Diabetes Care rates decreased significantly among females (-4.8 percentage points), the 40-49 age group (-5.4 percentage points), the uninsured (-12.9 percentage points), and people considered higher socioeconomic status (-6.0 percentage points) since the beginning of the pandemic in 2020.
- Rate changes across all five components were provided and ranged from a decrease in 0.1 percentage points (Tobacco-free) to 7.0 percentage points (Blood Pressure Control); HbA1c rates significantly increased in 2020.

Disparities

- The developer provided rates of optimal care for racial and ethnic groups in 2020, noting a significant decrease among Asian (-6.3 percentage points), Black (-5.4 percentage points), White (-4.6 percentage points) Indigenous/Native (-2.7 percentage points), Not Hispanic/Latinx (-4.8 percentage points), and Hispanic/Latinx (-4.4 percentage points) populations.
- There was a range of performance across racial and ethnic groups in 2020, with White and Asian patients with the highest rate at 42.4 percent to Indigenous/Native with the lowest rate at 23.3%. The developer noted it is unclear if this range is statistically significant.
- The developer provided rates of optimal care among sex, age group, insurance type, and neighborhood socioeconomic (SES) variables, noting the largest significant decrease in rates occurred among females (-4.8 percentage points), 40-49 age group (-5.4 percentage points), uninsured (-12.9 percentage points), and high socioeconomic status (-6.0 percentage points).

Questions for the Committee:

- *Is there a gap in care that warrants a national performance measure?*

Preliminary rating for opportunity for improvement: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

1c. Composite – Quality Construct and Rationale

Maintenance measures – same emphasis on quality construct and rationale as for new measures.

1c. Composite Quality Construct and Rationale. The quality construct and rationale should be explicitly articulated and logical; a description of how the aggregation and weighting of the components is consistent with the quality construct and rationale also should be explicitly articulated and logical.

- This is an all-or-none composite measure; each component reduces the modifiable risks associated with diabetes mellitus.
- The quality construct is an all-or-none composite with the goal for the patient to best reduce their overall risk of developing long term complications by targeting all five components (blood pressure control, blood sugar control, tobacco-free patient, statin use, and daily aspirin or anti-platelet use as appropriate)

- The developer notes that measuring provider performance separately on individual targets is not as patient centric as a measure that aims to reduce multiple risk factors for each patient, reducing their overall risk, and maximizing health outcomes.
- The numerator is calculated at the patient level and numerator compliance is defined as the patient achieving all five components of the measure. The components are treated equally; there is no weighting.
- Two of the components have an exception methodology which allows a "free-pass" on the component if the component does not apply to the patient (Statin Use, Aspirin/Antiplatelet Use).
- The developer cited evidence to support a multifactorial approach to diabetes care which demonstrated a decreased risk of a cardiovascular event outcome for each risk factor variable within the target range. Furthermore, patients who successfully achieved all five targets had little or no excess risk of death, myocardial infarction, or stroke compared to the general population.

Questions for the Committee:

- *Are the quality construct and a rationale for the composite explicitly stated and logical?*
- *Is the method for aggregation and weighting of the components explicitly stated and logical?*

Preliminary rating for composite quality construct and rationale: ☒ High ☐ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

1a. Evidence

- appropriate updated evidence from developer.
- All or none composite measure. Noted that measuring individual components may identify opportunities for patients to achieve optimal outcomes. The evidence directly applies to what is being measured. The developer provided updated data. A 2018 study identified that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. The developer also provided updated ADA guidelines that continued to support the intent and components of the measure. The evidence was consistent with the previous review.
- Moderate level evidence

1b. Gap in Care/Opportunity for Improvement and Disparities

- Performance data show decline during pandemic and variability by racial group.
- The updated 2020 data identified a continued racial/ethnic performance gap, though was unable to determine if the gap was statistically significant. Highest rate was for White/Asian at 42.4% and Indigenous/Native with the lowest rate 23.3%. The largest significant decrease was in women - 4.8 percentage points, 40-49 age group -5.4 percentage points uninsured -12.9 percentage points and high socioeconomic status -6.0 percentage points.
- Opportunity for improvement exists, indicating a performance gap.

1c. Composite – Quality Construct and Rationale

- The quality construct is clearly and logically stated.
- The quality composite construct supports the all-or-none measure design which is focused on reducing the modifiable risks associated with diabetes mellitus and improving health outcomes. The measure

also allows for passing on two components that do not apply to the patient, statin use and antiplatelet use.

- Quality construct and rationale are strong

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Evaluators: NQF Staff

2a. Reliability: Specifications and Testing

For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented.

For maintenance measures – less emphasis if no new testing data provided.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- Measure specifications have not changed since last review.
- Measure specifications are clear and precise.
- Measure specifications for the composite performance measure also include component measure specifications; aggregation and weighting rules; handling of missing data; standardizing scales across component measures; required sample sizes.

Reliability Testing:

Reliability testing at the Accountable Entity Level

- The developer conducted a signal to noise analysis using a beta-binomial model for 618 reportable clinics (n≥ 30 patients) in Minnesota (mean 0.888, SD 0.103, range 0.519-0.994).
- Reliability correlated with the number of eligible patients at the clinic and ranged from 0.519 for clinics with a minimum patient level of 30 to 0.994 for larger clinics.
- The developer states the results indicate an overall high level of reliability to the measure score.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure cannot be consistently implemented (i.e., are measure specifications adequate)?

Preliminary rating for reliability: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

2b. Validity: Validity testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

For maintenance measures – less emphasis if no new testing data provided.

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Validity Testing

- Validity testing at the Patient/Encounter Level
    - The developer validated the data elements by performing an audit and quality check of 53 medical groups: 37 percent of those submitting data.
        - A total of 89 percent of the medical groups passed the initial audit, 11 percent required a correction plan.
        - Of those medical groups who re-submitted data, all passed the audit with greater than 90 percent accuracy.
- Validity testing at the Accountable Entity Level
    - The developer conducted validity testing for the computed composite score by testing the correlation of medical group performance with their performance on the Optimal Vascular Care measure, #0076, hypothesizing that the quality of care provided would be similar.
        - Linear regression analysis of the medical group's performance on the Optimal Diabetes Care measure demonstrates a fairly strong correlation with its performance on the Optimal Vascular Care measure (r2 = 0.629).
    - The developer conducted validity testing for the individual components of the composite and, for all possible combinations of the components, using Pearson r correlation analysis (CORR Procedure).
        - HbA1c (0.77714); Blood Pressure (0.71245); Tobacco Free (0.54201); Aspirin or Antiplatelet Use (0.26254); Statin Use (0.68083).

Exclusions

- This composite measure excludes patients who are pregnant, who are permanent nursing home residents, or who died or were in hospice or palliative care during the measurement year.
- The developer tested exclusions on a sample of 11 medical groups (232 clinics, >109,000 patients) that were excluded from the measure.
- The developer noted that while the exclusions to this measure have clinical importance to achieving targets or utilizing medication to reduce cardiovascular risk, the number of exclusions is relatively small (1.0 percent); therefore, exclusions do not significantly impact measure performance.

Risk-Adjustment

- The developer used a logistic regression model as the outcome (dependent variable) is binary (i.e., did a patient diagnosed with diabetes receive the optimal care, yes/no)
- Statistical Risk model with four risk factors: patient age and deprivation index as continuous variables, insurance product type and diabetes type as categorical variables.
- The developer tested the effect of risk adjustment on clinical ranking by calculating a Pearson's correlation using the clinic's unadjusted and adjusted quality measures, and a comparison between clinics is conducted by performing significance testing using a chi square test.
- The developer noted that there was significant heterogeneity across clinics in insurance product mix ($\chi2 = 65,617$, $p < .001$), patient age ($\chi2 = 12,522$, $p < .001$), gender ($\chi2 = 5,256$, $p < .001$), depression ($\chi2 = 4,290$, $p < .001$), Type 1 Diabetes ($\chi2 = 67,297$, $p < .001$), and distance to the clinic ($\chi2 = 63,638$, $p < .001$).
- The developer compared decile rankings for adjusted and unadjusted clinical performance scores and ranked clinicians into categories (below average, average, and above average) using confidence intervals calculated from the number of patients each clinic reports.

- The average Optimal Diabetes Care (ODC) clinic score average was 35.1% (SD= 12%), and the average number of patients reported was 348 (SD=405).
- Clinics with ≤ 30 eligible patients were excluded from the clinic level analysis; all eligible patients were included in the statewide analysis.
    - Gender; Pearson's r= 0.081
    - Patient Age; Pearson's r=0.233
    - Diabetes Type (Type I); Pearson's r= -0.058
    - Insurance Product (Commercial, Medicare, Medicaid, Uninsured); Pearson's r= -0.293 to 0.424
    - Deprivation Index; Pearson's r=0.0398
- Independent group t-tests comparing insurance product type with Commercial
    - Medicare (n=111,797); t-test= -31.44 (p<0.001)
    - Medicaid (n=45,743); t-test= 70.54 (p<0.001)
    - Uninsured (n=8,203); t-test= 48.33 (p<0.001)
    - Unknown (n=13,566); t-test= -16.43 (p<0.001)
- Independent groups t-test comparing diabetes type groups with type 2
    - Type 1 (n=23,157); t-test= -32.72 (p<0.001)
    - Unknown (n=1,320); t-test= 10.56 (p<0.001)
- The overall risk adjustment model fit in terms of calibration and discrimination statistics was unclear from the developer submission materials.
- The developer noted that the measure is not stratified.

Meaningful Differences

- The developer assessed meaningful differences among medical groups and clinics in the following three ways.
    - Identifying top performers by calculating an overall group average rate and comparing individual medical group rates to the mean for each measure (range 9%-63.8%, mean= 43.2%, IQR=12.9).
    - Calculating performance rates for report year 2017 and then conducing a retrospective review of the prior year (2016) to determine percentage point increase.
    - Analyzing medical group and clinical performance over a three-year (2015, 2016, 2017) period observing patterns of improvement, stability, decline, or inconsistent variation.
- The developer noted that the measure continues to demonstrate opportunity for improvement and demonstrates statistically significant and clinically meaningful differences between medical group practices and clinics.

Missing Data

- The developer noted that this an all-or-none composite measure; therefore, missing data from any component are counted as a numerator fail and the patient would not be accounted for in the numerator yet remain in the denominator.
    - The developer explains that missing data is not excluded from the measure and that elements missing from the components are counted as numerator component fails and remain in the denominator.
    - Rates for variables submitted within the measure period and the percentage of invalid values were calculated for all five components using 2013 data (230,800 patients diagnosed with diabetes). Values ranged from 89.8%-99.8% and 0.003%-0.9%, respectively.

Comparability

- The measure only uses one set of specifications for this measure.

Questions for the Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?*

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

2c. Composite – Empirical Analysis

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

- This is an all-or-none composite measure; each component reduces the modifiable risks associated with diabetes mellitus.
- The desired goal of the composite measure is for patients to achieve intermediate physiological outcomes and medication use targets to best decrease their overall risk of developing microvascular and macrovascular complications related to diabetes.
- The developer used Pearson product-moment correlation to measure the strength of linear regression of the relationships between the composite and its components.
- The developer noted a strong correlation between the components and to the composite with the following Pearson r coefficient values.
    - Blood pressure= 0.7124
    - Hemoglobin a1c= 0.7771
    - Statin use= 0.6808
    - Aspirin use= 0.2625
    - Tobacco use= 0.5420
- The developer notes that the components are all treated equal and are not weighted.

Questions for the Committee regarding composite construction:

- *Do you have any concerns regarding the composite construction approach (e.g., do the component measures fit the quality construct and add value to the overall composite? Are the aggregation and weighting rules consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible?)?*

Preliminary rating for composite construction: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

2a1. Reliability - Specifications

- all elements clearly defined. No concerns from previous endorsement.
- All data elements are clearly defined. The measure specifications are clear and precise. The measure can be consistently implemented.
- High

2a1. Reliability - Testing

- No concerns
- The developer conducted a signal to noise analysis using a beta-binomial model that included 618 reportable clinics with a numerator of equal to or greater than 30 patients. The mean was 0.888, SD 0.103, with a range of 0.519-0994.
- Non concerns.

2b1. Validity

- No concern.
- The developer validated the measure data for the overall measure and the individual components of the composite measure using Pearson r correlation analysis (CORR Procedure). The developer also tested the effect of risk adjustment on clinical ranking by calculating a Pearson's correlation usign the clinic's unadjusted and adjusted quality measures and a clinic comparison by performing the chi square test.
- No concerns.

2b2-2b3. Potential threats to validity

- No concerns.
- Exclusions and risk-adjustment were not identified as a threat to validity of the measure.
- No concerns

2b4-2b7. Potential threats to validity

- No threats.
- The developer assessed meaningful differences among medical group by calculating overall group average rates and individual groups to the mean; a retrospective review of the prior year, and analyzing performance over a three-year (2015-2017) period. No identified threats to validity.
- No concerns.

2c. Composite – Empirical Analysis

- Yes.
- The developer identified a strong correlation between the components and to the composite measure. The component measures fit the quality construct and add value to the overall composite. The developer measured the strength of the linear regression of the relationships between the composite and its components.
- Moderate rating.

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Data elements needed to compute the measure score can be generated in the following ways: generated or collected by and used by healthcare personnel during the provision of care or coded by someone other than person obtaining original information.

- All clinical data elements required to calculate and risk adjust the measure can feasibly be captured in standardly available fields in the electronic health record (EHR).
- The developer is implementing a new electronic data warehouse system, Process Intelligence Performance Engine (PIPE) for data collection and storage.
- The developer does not identify any difficulties related to feasibility/implementation issues.
- The developer indicates that there are no fees associated with participation or data submission. Resource costs occurs when medical groups request data extraction from their electronic medical records systems.

Questions for the Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form, e.g., EHR or other electronic sources?*
- *Is the data collection strategy ready to be put into operational use?*

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

3. Feasibility

- All routinely generated and available electronically. No concerns.
- The data elements to calculate the measure are fields within an EHR. All are also coded. All are routinely generated during care for a patient with diabetes mellitus. No concerns with operationalizing the measure.
- Moderate feasibility.

Criterion 4: Use and Usability

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ Yes ☐ No

Current use in an accountability program? ☒ Yes ☐ No ☐ UNCLEAR

Planned use in an accountability program? ☒ Yes ☐ No ☐ NA

Accountability program details

- The measure is in two state regulatory programs: The MN Statewide Quality Reporting System and the MN Health Care Homes Certification/Recertification Program.
- The measure is publicly reported on MN HealthScores (a consumer-facing public website) and as part of the MNCM Annual Health Care Quality Report, Annual Disparities by Insurance Type, and Disparities by Race, Ethnicity, Language, Country of Origin, and several issues briefs.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The developer provides measure results to all medical groups through the MNCM data portal and public reporting website.
- The developer provides education on measure specifications, measure calculation, and how to interpret results through recorded webinars and in the hard copy reports.
- Opportunities for feedback can be provided in several ways: those being measured are invited to comment during the annual rule making process; a year-round staff supported helpline or email support; and through periodic surveys of medical groups in which all clinics in the state are invited to participate in.
- A medical group survey showed that most medical groups found the measure valuable (78.5 percent) and easy to obtain the data elements needed for submission (63.4 percent).
- The measure has undergone three-component re-design activities (A1c, cholesterol, and blood pressure), involving multi-stakeholder measure development workgroups and a consensus-based decision-making process in reviewing changes in evidence and guidelines.

Questions for the Committee:

- *How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?*
- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ Pass ☐ No Pass

4b. Usability (4b1. Improvement; 4b2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer provided statewide performance gap data for achieving all five components in the composite measure, as well as the individual performance rates of the each of the five components.
    - Statewide rates increased from 9.5 percent in 2006 to 53.5 percent in 2015. Between 2016 to 2019, composite rates decreased (46.3 percent to 44.9 percent) and subsequently increased to 45.4 percent in 2020. Since the beginning of the COVID-19 pandemic, the developer notes a decrease in statewide rates from 2020 to 2021 (40.6 percent).

- A study of more than 200,000 patients with T2DM decreased their risk of a cardiovascular even outcome for each risk factor variable that was within target range.
- A 2018 study showed that patients who could achieve all five targets had little to no excess risk of death, myocardial infarction, or stroke compared to the general population.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer noted two unexpected findings over the years.
    - Adults aged 65 years and older with Medicare have better outcome rates than younger adults with diabetes due to generational differences related to compliance with providers' orders.
    - Statewide A1c averages are trending upward, which is a trend that the ADA has confirmed.
- The developer also notes the impact of the COVID-19 pandemic on measure results (i.e., decrease in denominator population and some individual components) which could the developer attributed to fewer patients seeking care.
- Health systems use this measure for internal use (benchmarking, provider performance bonuses) and to communicate performance on diabetes care to patients (posting rates in common areas).

Potential harms

- No potential harms were identified by the developer.

Questions for the Committee:

- *How can the performance results be used to further the goal of high-quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and use: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

4a. Use

- Feedback is given and results are publicly reported.
- The measure is being publicly reported, is used in an accountability program and appears to be included in plans for additional accountability programs. it is used in the MN Statewide Quality Reporting System and the MN Health Care Homes Certification/Recertification Program. The developer provided data back to provider groups. 78.5 percent of medical groups found the measure valuable, easy to report and the 63.4% found that data elements needed were available.
- Currently in use.

4a. Usability

- Benefits are clear.
- Evidence provided by the developer showed that by using the measure, statewide rates increased from 9.5% in 2006 to 53.5% in 2015. However, in subsequent years the rates decreased, which were

attributed to the COVID-19 pandemic. The developer also noted more benefits than harm from reporting the measure.

- No concerns.

Criterion 5: Related and Competing Measures

Related measures

- NQF #0061 Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)
- NQF #0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)

Harmonization

- The developer indicates that the measure's numerator has been harmonized to the extent possible.
- The developer notes differences in the denominator data sources between NQF #0729 (EMR data), NQF #0061 (claims data), and NQF #0057 (claims data).
- NQF #0061 and NQF #0057 include patients on oral medications and insulin who do not have a diagnosis of diabetes and patients who are currently pregnant during the measurement year.

Committee Pre-evaluation Comments:

5: Related and Competing Measures

- Harmonized as much as possible. Differences exist in denominator data source.
- Related measures included NQF #061 Comprehensive Diabetes Care Blood Pressure Control; NQF #0057 CDC Hemoglobin A1c Control <8.0%. Efforts were made by the developer to harmonize the measure.
- No concerns.

Public and NQF Member Comments (Submitted as of June 14, 2022)

Member Expression of Support

- No members submitted an expression of support for this measure.

Comments

- No NQF member and public comments were received in advance of the Standing Committee evaluation.

Scientific Acceptability Evaluation

RELIABILITY: SPECIFICATIONS

1. **Have measure specifications changed since the last review? ☐ Yes ☒ No**
2. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? ☒ Yes ☐ No**
3. **Briefly summarize any changes to the measure specifications and/or concerns about the measure specifications.**
   - The developer noted that the specifications have not changed since the last review.

RELIABILITY: TESTING

4. **Did the developer conduct new reliability testing? ☐ Yes ☒ No**

4a. If no, summarize the Standing Committee's previous feedback:

- The Standing Committee raised concern with reliability and validity in other parts of the country that may not have the high level of electronic health record (EHR) use compared to Minnesota.
- One Standing Committee member recommended weighting of the components in this composite to the developer.

4b. If yes, describe any differences between the new and old testing and summarize any relevant Standing Committee's feedback from the previous review:

- Not applicable.

5. **Reliability testing level: ☒ Accountable-Entity Level ☒ Patient/Encounter Level ☐ Neither**
6. **Reliability testing was conducted with the data source and level of analysis indicated for this measure:**

   ☒ Yes ☐ No
7. If accountable-entity level and/or patient/encounter level reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ Yes ☐ No
8. **Assess the method(s) used for reliability testing:**

   - The developer conducted a signal to noise analysis using a beta-binomial model for 618 reportable clinics (n≥ 30 patients) in Minnesota (mean 0.888, SD 0.103, range 0.519-0.994).
9. **Assess the results of reliability testing**

   - Reliability correlated with the number of eligible patients at the clinic and ranged from 0.519 for clinics with a minimum patient level of 30 to 0.994 for larger clinics.
   - The results indicate an overall high level of reliability to the measure score.
10. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? **NOTE:** If multiple methods used, at least one must be appropriate.

    ☒ **Yes** ☐ **No** ☐ **Not applicable**
11. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

    ☐ **Yes** ☐ **No** ☒ **Not applicable** (patient/encounter level testing was not performed)
12. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☒ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

    ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)
13. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    - Measure specifications precise, unambiguous, and complete (Box 1) -> Empirical reliability testing conducted with the measure as specified (Box 2) -> Reliability testing conducted with computed measure scores (Box 4) -> Method appropriate for assessing variability (signal-to-noise analysis) (Box 5) -> High certainty or confidence that the performance scores are reliable (Box 6a) -> High

VALIDITY: TESTING

14. **Did the developer conduct new validity testing? ☐ Yes ☒ No**

14a. If no, summarize the Standing Committee's previous feedback:

- The Standing Committee questioned the replication of the reliability and validity results, given that Minnesota has a higher level of EHR use than other parts of the country.
- One Standing Committee member raised concern with the correlation testing conducted with the Optimal Vascular Care (NAF #0076) measure and the literature to support the clinical supposition.

14b. If yes, describe any differences between the new and old testing and summarize any relevant Standing Committee's feedback from the previous review:

- N/A

15. **Validity testing level (check all that apply):**

    ☐ **Accountable-Entity Level** ☐ **Patient or Encounter-Level** ☒ **Both**

    NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

16. **If patient/encounter level validity testing was provided, was the method described and appropriate for assessing the accuracy of ALL critical data elements? NOTE:** Data element validation from the literature is acceptable.

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (patient/encounter level testing was not performed)

17. **Method of establishing validity at the accountable-entity level:**

    ☐ **Face validity**

    ☒ **Empirical validity testing at the accountable-entity level**

    ☐ **N/A (accountable-entity level testing not conducted)**

18. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (accountable-entity level testing was not performed)

19. **Assess the method(s) for establishing validity**

    - The developer conducted validity testing at the patient or encounter level by validating the data elements through an audit and quality check of 53 medical groups.
    - The developer conducted validity testing for the computed composite score by testing the correlation of medical group performance with their performance on the Optimal Vascular Care measure, #0076, hypothesizing that the quality of care provided would be similar.
    - The developer conducted validity testing for the individual components of the composite and, for all possible combinations of the components, using Pearson r correlation analysis (CORR Procedure).

20. **Assess the results(s) for establishing validity**

    - Results of the audit are as follows: A total of 89 percent of the medical groups passed the initial audit; 11 percent required a correction plan; and of those medical groups who re-submitted data, all passed the audit with greater than 90 percent accuracy.
    - Linear regression analysis of the medical group's performance on the Optimal Diabetes Care measure demonstrates a fairly strong correlation with its performance on the Optimal Vascular Care measure ($r2 = 0.629$).

- Results of the Pearson r correlation analysis: HbA1c (0.77714); Blood Pressure (0.71245); Tobacco Free (0.54201); Aspirin or Antiplatelet Use (0.26254); Statin Use (0.68083).

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

21. **Please describe any concerns you have with measure exclusions.**

- This composite measure excludes patients who are pregnant, who are permanent nursing home residents, or who died or were in hospice or palliative care during the measurement year.
- The developer tested exclusions on a sample of 11 medical groups (232 clinics, >109,000 patients) who submitted files of patients that were excluded from the measure.
- The developer noted that while the exclusions to this measure have clinical importance to achieving targets or utilizing medication to reduce cardiovascular risk, the number of exclusions is relatively small (1.0 percent); therefore, exclusions do not significantly impact measure performance.

22. **Risk Adjustment**

22a. **Risk-adjustment method**

☐ None (only answer Question 20b and 20e) ☒ Statistical model ☐ Stratification

☐ Other method assessing risk factors (please specify)

22b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

22c. **Social risk adjustment:**

22c.1 Are social risk factors included in risk model? ☒ Yes ☐ No ☐ Not applicable

22c.2 Conceptual rationale for social risk factors included? ☒ Yes ☐ No

22c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☒ Yes ☐ No

22d.**Risk adjustment summary:**

22d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No

22d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

22d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

22d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☒ No

22d.5.Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☐ No

22e**. Assess the risk-adjustment approach**

- The developer used a logistic regression model as the outcome (dependent variable) is binary (i.e., did a patient diagnosed with diabetes receive the optimal care, yes/no)
- Statistical Risk model with four risk factors: patient age and deprivation index as continuous variables, insurance product type and diabetes type as categorical variables.
- The developer tested the effect of risk adjustment on clinical ranking by calculating a Pearson's correlation using the clinic's unadjusted and adjusted quality measures, and a comparison between clinics is conducted by performing significance testing using a chi square test.
- The developer noted that there was significant heterogeneity across clinics in insurance product mix ($\chi2 = 65,617$, $p < .001$), patient age ($\chi2 = 12,522$, $p < .001$), gender ($\chi2 = 5,256$, $p < .001$), depression ($\chi2 = 4,290$, $p < .001$), Type 1 Diabetes ($\chi2 = 67,297$, $p < .001$), and distance to the clinic ($\chi2 = 63,638$, $p < .001$).

- The developer compared decile rankings for adjusted and unadjusted clinical performance scores and ranked clinicians into categories (below average, average, and above average) using confidence intervals calculated from the number of patients each clinic reports.
- The average Optimal Diabetes Care (ODC) clinic score average was 35.1% (SD= 12%), average number of patients reported 348 (SD=405).
- Clinics with ≤ 30 eligible patients were excluded from the clinic level analysis; all eligible patients were included in the statewide analysis.
    - Gender; Pearson's r= 0.081
    - Patient Age; Pearson's r=0.233
    - Diabetes Type (Type I); Pearson's r= -0.058
    - Insurance Product (Commercial, Medicare, Medicaid, Uninsured); Pearson's r= -0.293 to 0.424
    - Deprivation Index; Pearson's r=0.0398
- Independent group t-tests comparing insurance product type with Commercial
    - Medicare (n=111,797); t-test= -31.44 (p<0.001)
    - Medicaid (n=45,743); t-test= 70.54 (p<0.001)
    - Uninsured (n=8,203); t-test= 48.33 (p<0.001)
    - Unknown (n=13,566); t-test= -16.43 (p<0.001)
- Independent groups t-test comparing diabetes type groups with type 2
    - Type 1 (n=23,157); t-test= -32.72 (p<0.001)
    - Unknown (n=1,320); t-test= 10.56 (p<0.001)
- The overall risk adjustment model fit in terms of calibration and discrimination statistics was unclear from the developer submission materials.
- The developer noted that the measure is not stratified.

23. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    For cost/resource use measures, does this measure identify meaningful differences about cost and resource use between the measured entities?

- The developer assessed meaningful differences among medical groups and clinics in the following three ways.
    - Identifying top performers by calculating an overall group average rate and comparing individual medical group rates to the mean for each measure (range 9%-63.8%, mean= 43.2%, IQR=12.9).
    - Calculating performance rates for report year 2017 and then conducing a retrospective review of the prior year (2016) to determine percentage point increase.
    - Analyzing medical group and clinical performance over a three-year (2015, 2016, 2017) period observing patterns of improvement, stability, decline, or inconsistent variation.

The developer noted that the measure continues to demonstrate opportunity for improvement and demonstrates statistically significant and clinically meaningful differences between medical group practices and clinics.

24. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

- The measure only uses one set of specifications for this measure.

25. **Please describe any concerns you have regarding missing data.**
    - The developer noted that this an all-or-none composite measure; therefore, missing data from any component are counted as a numerator fail and the patient would not be accounted for in the numerator yet remain in the denominator.
        - The developer explains that missing data is not excluded from the measure and that elements missing from the components are counted as numerator component fails and remain in the denominator.
        - Rates for variables submitted within the measure period and the percentage of invalid values were calculated for all five components using 2013 data (230,800 patients diagnosed with diabetes). Values ranged from 89.8%-99.8% and 0.003%-0.9%, respectively.

For cost/resource use measures ONLY:

If not cost/resource use measure, please skip to question 25.

26. **Are the specifications in alignment with the stated measure intent?**

    ☐ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**

27. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**
28. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☐ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has NOT been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the accountable-entity level and the patient/encounter level is required; if not conducted, should rate as INSUFFICIENT.)

29. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**
    - Potential threats empirically assessed (Box 1) -> Empirical validity testing conducted with the measure as specified (Box 2) -> Validity testing conducted with computed measure scores (Box 5) -> Method appropriate for assessing conceptually and theoretically sound hypothesized relationships (Box 6) -> Moderate certainty or confidence that the performance scores are valid indicator of quality (Box 7a) -> Moderate

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

30. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☐ **High**

    ☒ **Moderate**

    ☐ **Low**

    ☐ **Insufficient**

31. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**
    - This is an all-or-none composite measure; each component reduces the modifiable risks associated with diabetes mellitus.
    - The desired goal of the composite measure is for patients to achieve intermediate physiological outcomes and medication use targets to best decrease their overall risk of developing microvascular and macrovascular complications related to diabetes.
    - The developer used Pearson product-moment correlation to measure the strength of linear regression of the relationships between the composite and its components.
    - The developer noted a strong correlation between the components and to the composite with the following Pearson r coefficient values.
        - Blood pressure= 0.7124
        - Hemoglobin a1c= 0.7771
        - Statin use= 0.6808
        - Aspirin use= 0.2625
        - Tobacco use= 0.5420
    - The developer notes that the components are all treated equal and are not weighted.

ADDITIONAL RECOMMENDATIONS

32. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**
    - No concerns.

Criteria 1: Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

2021 Submission:

Updated evidence information here.

2018 Submission:

Evidence from the previous submission here.

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All sub-criteria must be met to pass this criterion. See guidance on evidence .

Please include individual entries for each component measure, unless several components were studied together. If a component measure is submitted as an individual performance measure, complete the evidence section as part of that individual measure submission.

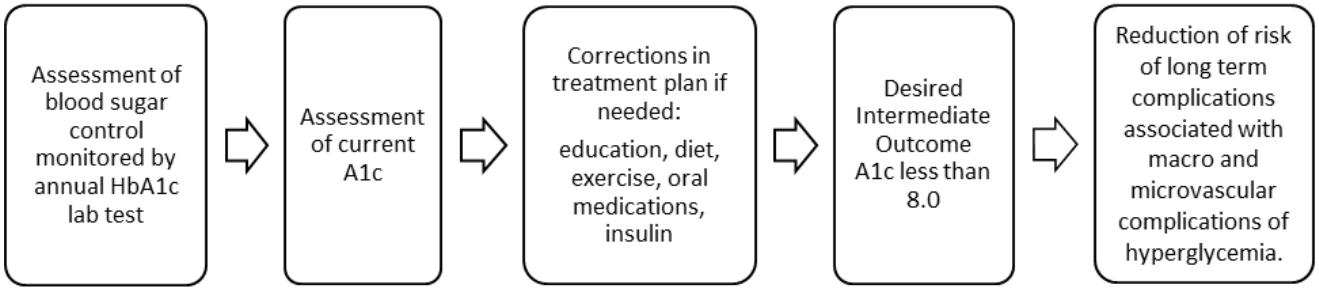
1a. Evidence

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

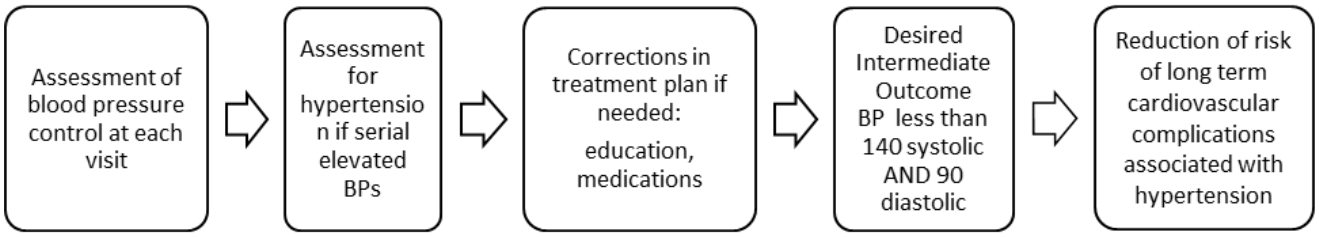
[Response Begins]

Component- A1c is < 8.0 (intermediate outcome)



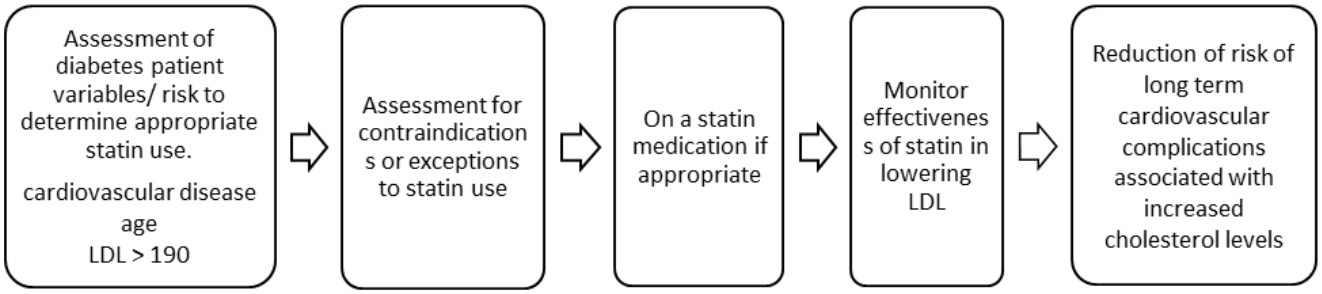
Health care processes for management of A1c control for patients with diabetes leading to the intermediate outcome with reference to the goal of avoiding long term complications related to increased blood sugar

Component- BP is < 140/90 (intermediate outcome)



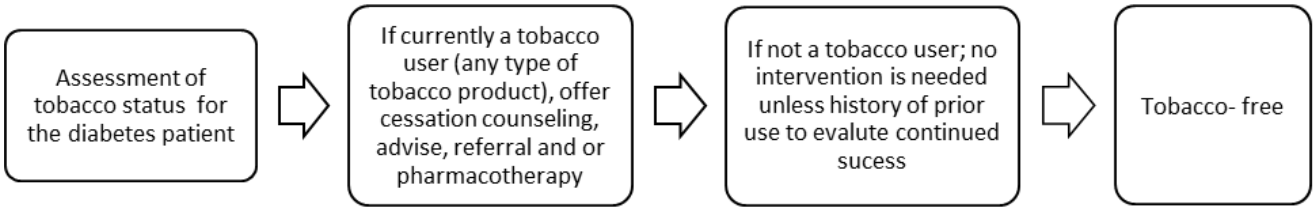
Health care processes for management of blood pressure for patients with diabetes leading to the intermediate outcome with reference to the goal of avoiding long term complications related to hypertension

Component- Cholesterol Statin Use (medication adherence)



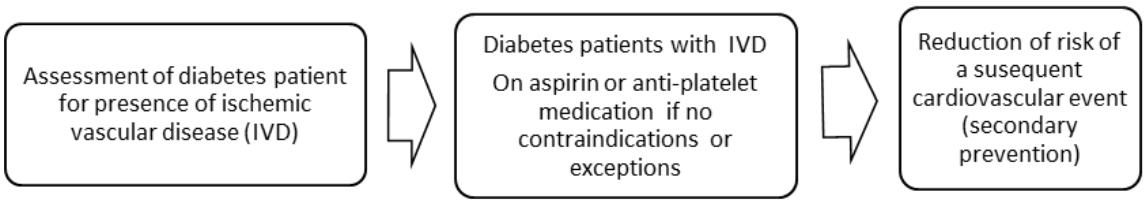
Health care processes for management of cholesterol patients with diabetes leading to the intermediate outcome of medication compliance with reference to the goal of avoiding long term cardiovascular complications related to increased cholesterol levels

Component- Tobacco Free (outcome)



Health care processes for assessment of tobacco use for patients with diabetes leading to the desired outcome of being tobacco free and avoiding cardiovascular risk associated with tobacco use

Component- Aspirin/ Antiplatelet Use (medication adherence)



Health care processes for management of potential clotting for patients with diabetes and ischemic vascular disease leading to the intermediate outcome of medication compliance with reference to the goal of avoiding a second cardiac event

[Response Ends]

1a.02. If this measure is derived from patient report, provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful. Otherwise, enter "N/A."

Describe how and from whom input was obtained.

[Response Begins]

N/A

[Response Ends]

1a.03. If this measure is derived from intermediate outcome, process, or structure performance measures, including those that are instrument-based, select the type of source for the systematic review of the body of evidence that supports the performance measure. Otherwise, select "N/A."

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

[Response Begins]

Clinical Practice Guideline recommendation (with evidence review)

[Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking “Add” after the final question in the group.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.04. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.05. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.06. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]

N/A

[Response Ends]

1a.07. Provide all other grades and definitions from the evidence grading system.

[Response Begins]

N/A

[Response Ends]

1a.08. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins]

N/A

[Response Ends]

1a.09. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]

N/A

[Response Ends]

1a.10. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins]

N/A

[Response Ends]

1a.11. Provide the estimates of benefit, and consistency across studies.

[Response Begins]

N/A

[Response Ends]

1a.12. Indicate what, if any, harms were identified in the study.

[Response Begins]

N/A

[Response Ends]

1a.13. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.14. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

[Response Begins]

American Diabetes Association 2022 Standards of Care

A1c Component

Glycemic Targets- Chapter 6

Recommendations:

- 6.5a An A1C goal for many nonpregnant adults of <7% (53 mmol/mol) without significant hypoglycemia is appropriate. **A**
- 6.5b If using ambulatory glucose profile/glucose management indicator to assess glycemia, a parallel goal for many nonpregnant adults is time in range of >70% with time below range <4% and time <54 mg/dL <1% (Fig. 6.1 and Table 6.2). B
- 6.6 On the basis of provider judgment and patient preference, achievement of lower A1C levels than the goal of 7% may be acceptable and even beneficial if it can be achieved safely without significant hypoglycemia or other adverse effects of treatment. B
- 6.7 Less stringent A1C goals (such as <8% [64 mmol/mol]) may be appropriate for patients with limited life expectancy or where the harms of treatment are greater than the benefits. **B**
- 6.8 Reassess glycemic targets based on the individualized criteria in Fig. 6.2. E

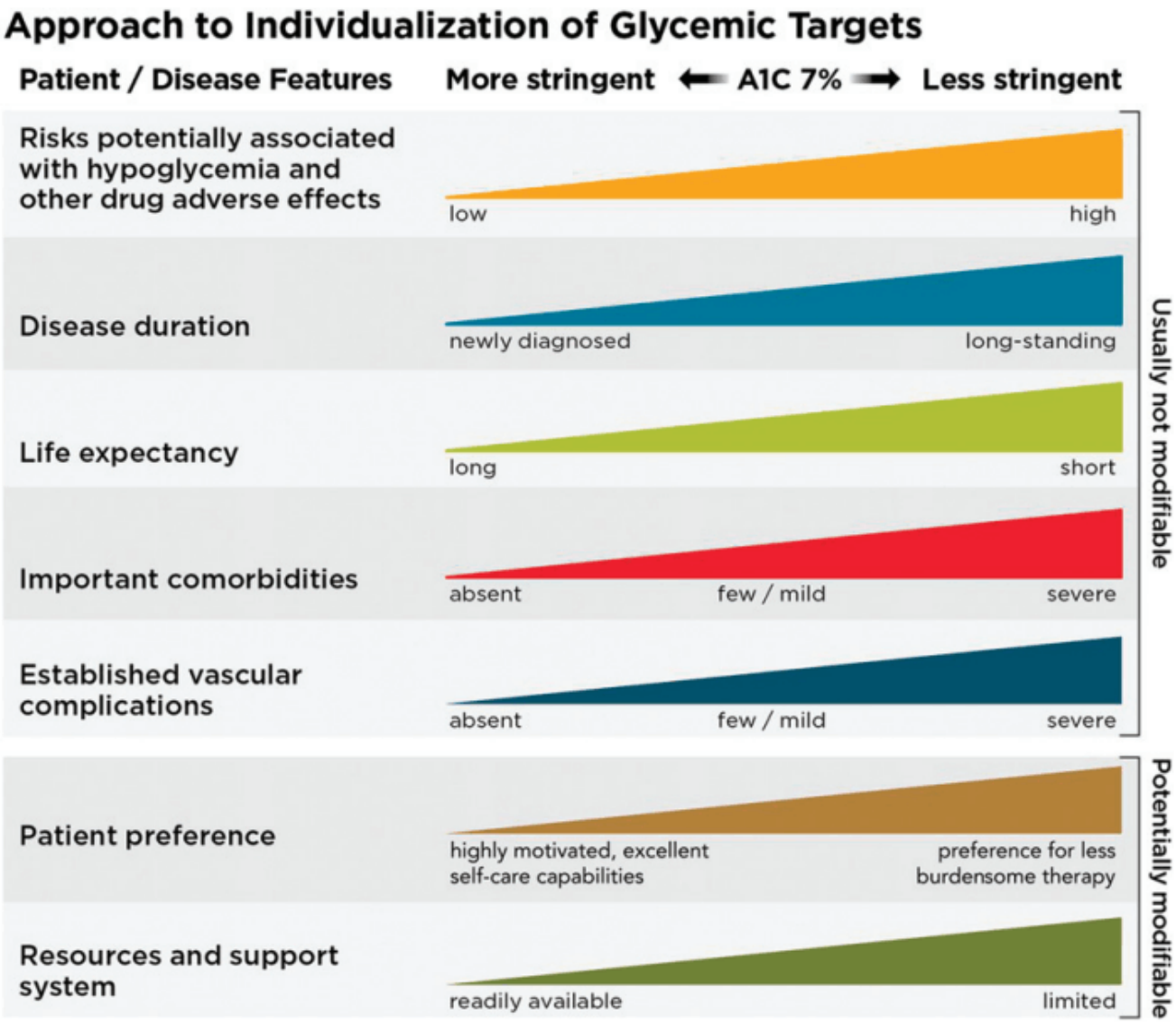


Figure 6.2—Patient and disease factors used to determine optimal glycemic targets. Characteristics and predicaments toward the left justify more stringent efforts to lower A1C; those toward the right suggest less stringent efforts. A1C 7% = 53 mmol/mol. Adapted with permission from Inzucchi et al. (68).

American Diabetes Association 2022 Standards of Care - Chapter 6 Glycemic Targets; Table of Approaches to Individualize Targets

A1C and Microvascular Complications

Achieving A1C targets of <7% (53 mmol/mol) has been shown to reduce microvascular complications of type 1 and type 2 diabetes when instituted early in the course of disease (2,44). Epidemiologic analyses of the DCCT (32) and UKPDS (45) demonstrate a curvilinear relationship between A1C and microvascular complications. Such analyses suggest that, on a population level, the greatest number of complications will be averted by taking patients from very poor control to fair/good control.

Given the substantially increased risk of hypoglycemia in type 1 diabetes and with polypharmacy in type 2 diabetes, the risks of lower glycemic targets may outweigh the potential benefits on microvascular complications. Three landmark trials (Action to Control Cardiovascular Risk in Diabetes [ACCORD], Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation [ADVANCE], and Veterans Affairs Diabetes Trial [VADT]) were conducted to test the effects of near normalization of blood glucose on cardiovascular outcomes in individuals with long-standing type 2

diabetes and either known cardiovascular disease (CVD) or high cardiovascular risk. These trials showed that lower A1C levels were associated with reduced onset or progression of some microvascular complications (46–48). The concerning mortality findings in the ACCORD trial discussed below and the relatively intense efforts required to achieve near euglycemia should also be considered when setting targets for individuals with long-standing diabetes, such as those populations studied in ACCORD, ADVANCE, and VADT. Findings from these studies suggest caution is needed in treating diabetes to near-normal A1C goals in people with long-standing type 2 diabetes with or at significant risk of CVD

Measure Development Workgroup:

An individualized approach to setting glycemic targets is important and most patients will do well with an A1C < 7.0, however many of the criteria for setting a less stringent target are somewhat subjective, difficult to define and capture consistently (reliably). Because measurable criteria can not consistently be defined to assign patients with type 1 and type 2 diabetes to targets of < 7.0 or < 8.0., a target of < 8.0 was selected. This target is safe for most patients and providers can chose (individualize) lower targets when appropriate.

Blood Pressure Component

Cardiovascular Disease and Risk

Chapter 10

Recommendations

- 10.1 Blood pressure should be measured at every routine clinical visit. When possible, patients found to have elevated blood pressure (≥140/90 mmHg) should have blood pressure confirmed using multiple readings, including measurements on a separate day, to diagnose hypertension. A Patients with blood pressure ≥180/110 mmHg and cardiovascular disease could be diagnosed with hypertension at a single visit. E
- 10.2 All hypertensive patients with diabetes should monitor their blood pressure at home. A
- 10.3 For patients with diabetes and hypertension, blood pressure targets should be individualized through a shared decision-making process that addresses cardiovascular risk, potential adverse effects of antihypertensive medications, and patient preferences. B
- 10.4 For individuals with diabetes and hypertension at higher cardiovascular risk (existing atherosclerotic cardiovascular disease [ASCVD] or 10-year ASCVD risk $15%), a blood pressure target of <130/80 mmHg may be appropriate, if it can be safely attained. B
- 10.5 For individuals with diabetes and hypertension at lower risk for cardiovascular disease (10- year atherosclerotic cardiovascular disease risk <15%), treat to a blood pressure target of <140/90 mmHg. **A**

Among trials with lower baseline or attained blood pressure, antihypertensive treatment reduced the risk of stroke, retinopathy, and albuminuria, but effects on other ASCVD outcomes and heart failure were not evident. Taken together, these meta-analyses consistently show that treating patients with baseline blood pressure ≥140 mmHg to targets <140 mmHg is beneficial, while more intensive targets may offer additional (though probably less robust) benefits.

Measure Development Workgroup:

The workgroup convened in 2018 to review new ACC/AHA guidelines for the prevention, diagnosis and management of hypertension in adults. These guidelines redefined the diagnosis of hypertension, moving from ≥ 140/ 90 to a new definition of stage 1 hypertension (130-139/ 80-89). With the new definition, it is estimated that 46% of Americans will now be considered to have hypertension, up from 32% with a definition of ≥ 140/90. The release of the guidelines is not without controversy, and while most agree that a lower blood pressure is better, it is within the context of a patient's individualized goal. Less than 130/80 may not be an appropriate target for every patient. The American College of Physicians and the American Academy of Family Practice have declined endorsement of the new guidelines. They cite concerns with the methodology used in making recommendations and perceived conflict of interest. They are recommending reliance on 2014 JNC8 and ACP/AAFP guidelines for older adults.

Patients with diabetes and cardiovascular disease represent two very high-risk subgroups; in an effort to reduce their modifiable risk factors, the blood pressure component target of the Optimal Diabetes Care (ODC) and Optimal Vascular Care (OVC) measures has reflected a goal that is below the hypertension definition cut-point.

In similar measure development activities, the National Committee for Quality Assurance (NCQA) convened three expert panels (diabetes, cardiovascular and geriatric) for their evaluation of blood pressure targets for the HEDIS Controlling

High Blood Pressure measure and concluded that for patients with hypertension ages 18 - 85 the blood pressure target is < 140/90.

Cholesterol Component

Cardiovascular Disease and Risk

Chapter 10

Recommendations

33. 10.19 For patients with diabetes aged 40–75 years without atherosclerotic cardiovascular disease, use moderate-intensity statin therapy in addition to lifestyle therapy. **A**
34. 10.20 For patients with diabetes aged 20–39 years with additional atherosclerotic cardiovascular disease risk factors, it may be reasonable to initiate statin therapy in addition to lifestyle therapy. C
35. 10.21 In patients with diabetes at higher risk, especially those with multiple atherosclerotic cardiovascular disease risk factors or aged 50–70 years, it is reasonable to use high intensity statin therapy. B
36. 10.23 For patients of all ages with diabetes and atherosclerotic cardiovascular disease, high-intensity statin therapy should be added to lifestyle therapy. **A**
37. 10.24 For patients with diabetes and atherosclerotic cardiovascular disease considered very high risk using specific criteria, if LDL cholesterol is >/= 70 mg/dL on maximally tolerated statin dose, consider adding additional LDL lowering therapy (such as ezetimibe or PCSK9 inhibitor) **A**

Tobacco Component

Chapter 5 Behavior Change

Recommendations

- 5.33 Advise all patients not to use cigarettes and other tobacco products or e-cigarettes. **A**
- 5.34 After identification of tobacco or e-cigarette use, include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. A
- 5.35 Address smoking cessation as part of diabetes education programs for those in need. B

Aspirin/Antiplatelet Component

Recommendations:

- 10.34 Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes and a history of atherosclerotic cardiovascular disease. **A**
- A 10.35 For patients with atherosclerotic cardiovascular disease and documented aspirin allergy, clopidogrel (75 mg/day) should be used. B
- 10.36 Dual antiplatelet therapy (with low-dose aspirin and a P2Y12 inhibitor) is reasonable for a year after an acute coronary syndrome and may have benefits beyond this period. **A**

Risk Reduction Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous MI or stroke (secondary prevention) and is strongly recommended. In primary prevention, however, among patients with no previous cardiovascular events, its net benefit is more controversial (136,137).

American Diabetes Association Evidence Grading

Table 1—ADA evidence-grading system for “Standards of Medical Care in Diabetes”

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies 1. Evidence from a well-conducted prospective cohort study or registry 2. Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies 1) Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results 2) Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) 3) Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

GRADING OF SCIENTIFIC EVIDENCE Since the ADA first began publishing clinical practice guidelines, there has been considerable evolution in the evaluation of scientific evidence and in the development of evidence-based guidelines. In 2002, the ADA developed a classification system to grade the quality of scientific evidence supporting ADA recommendations. A 2015 analysis of the evidence cited in the Standards of Care found steady improvement in quality over the previous 10 years, with the 2014 Standards of Care for the first time having the majority of bulleted recommendations supported by A level or B level evidence. A grading system (Table 1 above) developed by the ADA and modeled after existing methods was used to clarify and codify the evidence that forms the basis for the recommendations. All recommendations are critical to comprehensive care. ADA recommendations are assigned ratings of A, B, or C, depending on the quality of the evidence in support of the recommendation. Recommendations with A level evidence are based on large well-designed clinical trials or well-done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population for which they are appropriate.

For each of the components utilized as part of this composite measure, there is supporting evidence rated as High A- clear well-conducted random control trials or B well-conducted case control studies. Please see grade assigned to each recommendation.

[Response Ends]

1a.15. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

N/A

[Response Ends]

1a.16. Briefly synthesize the evidence that supports the measure.

[Response Begins]

The intent of this composite measure is to reduce the modifiable risk factors associated with long term macrovascular and microvascular complications associated with diabetes. Diabetic patients are more likely to reduce their overall risk, prevent or reduce complications and maximize health outcomes by simultaneously achieving several intermediate physiological targets and medication adherence components.

Setting and Modifying A1C Goals

Numerous factors must be considered when setting glycemic targets. The ADA proposes general targets appropriate for many people but emphasizes the importance of individualization based on key patient characteristics. Glycemic targets must be individualized in the context of shared decision-making to address individual needs and preferences and consider characteristics that influence risks and benefits of therapy; this approach will optimize engagement and self-efficacy. The factors to consider in individualizing goals are depicted in Fig. 6.2. This figure is not designed to be applied rigidly but to be used as a broad construct to guide clinical decision-making (68) and engage people with type 1 and type 2 diabetes in shared decision-making. More aggressive targets may be recommended if they can be achieved safely and with an acceptable burden of therapy and if life expectancy is sufficient to reap the benefits of stringent targets. Less stringent targets (A1C up to 8% [64 mmol/mol]) may be recommended if the patient's life expectancy is such that the benefits of an intensive goal may not be realized, or if the risks and burdens outweigh the potential benefits. Severe or frequent hypoglycemia is an absolute indication for the modification of treatment regimens, including setting higher glycemic goals. Diabetes is a chronic disease that progresses over decades. Thus, a goal that might be appropriate for an individual early in the course of their diabetes may change over time. Newly diagnosed patients and/or those without comorbidities that limit life expectancy may benefit from intensive control proven to prevent microvascular complications. Both DCCT/ EDIC and UKPDS demonstrated metabolic memory, or a legacy effect, in which a finite period of intensive control yielded benefits that extended for decades after that control ended. Thus, a finite period of intensive control to near-normal A1C may yield enduring benefits even if control is subsequently deintensified as patient characteristics change. Over time, comorbidities may emerge, decreasing life expectancy and thereby decreasing the potential to reap benefits from intensive control. Also, with longer disease duration, diabetes may become more difficult to control, with increasing risks and burdens of therapy. Thus, A1C targets should be reevaluated over time to balance the risks and benefits as patient factors change.

Managing Cardiovascular Risk

Blood Pressure- Among trials with lower baseline or attained blood pressure, antihypertensive treatment reduced the risk of stroke, retinopathy, and albuminuria, but effects on other ASCVD outcomes and heart failure were not evident. Taken together, these meta-analyses consistently show that treating patients with baseline blood pressure $\geq$140 mmHg to targets <140 mmHg is beneficial, while more intensive targets may offer additional (though probably less robust) benefits.

Cholesterol Medication Adherence- Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of ASCVD. Multiple clinical trials have demonstrated the beneficial effects of statin therapy on ASCVD outcomes in subjects with and without CHD (89,90). Subgroup analyses of patients with diabetes in larger trials (91–95) and trials in patients with diabetes (96,97) showed significant primary and secondary prevention of ASCVD events and CHD death in patients with diabetes. Meta-analyses, including data from over 18,000 patients with diabetes from 14 randomized trials of statin therapy (mean follow-up 4.3 years), demonstrate a 9% proportional reduction in all-cause mortality and 13% reduction in vascular mortality for each 1 mmol/L (39 mg/dL) reduction in LDL cholesterol (98).

Aspirin/ Antiplatelet Use- Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous MI or stroke (secondary prevention) and is strongly recommended. In primary prevention, however, among patients with no previous cardiovascular events, its net benefit is more controversial.

Tobacco Free- Results from epidemiologic, case-control, and cohort studies provide convincing evidence to support the causal link between cigarette smoking and health risks (237). Recent data show tobacco use is higher among adults with chronic conditions (238) as well as in adolescents and young adults with diabetes (239). People with diabetes who smoke (and people with diabetes exposed to second-hand smoke) have a heightened risk of CVD, premature death, microvascular complications, and worse glycemic control when compared with those who do not smoke (240–242).

[Response Ends]

1a.17. Detail the process used to identify the evidence.

[Response Begins]

The Professional Practice Committee (PPC) of the American Diabetes Association (ADA) is responsible for the "Standards of Medical Care in Diabetes," referred to as the Standards of Care. The PPC is a multidisciplinary expert committee comprising physicians, diabetes care and education specialists, and others who have expertise in a range of areas, including, but not limited to, adult and pediatric endocrinology, epidemiology, public health, cardiovascular risk management, microvascular complications, preconception and pregnancy care, weight management and diabetes prevention, and use of technology in diabetes management. Appointment to the PPC is based on excellence in clinical practice and research, with attention to appropriate representation of members based on considerations including but not limited to demographic, geographical, work setting, or identity characteristics (e.g., gender, ethnicity, ability level, etc.).

Relevant literature was thoroughly reviewed through 1 July 2021; additionally, critical updates published through 1 August 2021 were considered. Exceptions were made for ADA-convened consensus reports, like "The Management of Type 1 Diabetes in Adults. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)" (https://doi.org/ 10.2337/dci21-0043). Recommendations were revised based on new evidence, new considerations for standard of care practices, or, in some cases, to clarify the prior recommendations or revise wording to match the strength of the published evidence. A table linking the changes in recommendations to new evidence can be reviewed online at professional .diabetes.org/SOC. The Standards of Care is reviewed by ADA scientific and medical staff and is approved by the ADA's Board of Directors, which includes health care professionals, scientists, and lay people.

[Response Ends]

1a.18. Provide the citation(s) for the evidence.

[Response Begins]

Professional Practice Committee: Standards of Medical Care in Diabetes—2022 Diabetes Care 2022;45(Suppl. 1):S3 | https://doi.org/10.2337/dc22-SPPC

https://professional.diabetes.org/content-page/practice-guidelines-resources

[Response Ends]

1b. Gap in Care/Opportunity for Improvement and Disparities

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

Achieving the intermediate physiological outcome targets related to blood pressure and glycemic control, in addition to being tobacco free and use of daily aspirin and statins where appropriate, are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by achieving several intermediate physiological targets.

In 2018, a study of over 200,000 patients with type 2 diabetes found that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. [Rawshani, A et al Risk Factors, Mortality, and Cardiovascular Outcomes in Patients with Type 2 Diabetes N Engl J Med 2018; 379:633-644 DOI: 10.1056/ NEJMoa1800256]

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Optimal Diabetes Care in 2020

MNCM published an additional Issue Brief for this measure to begin to understand the disruptions in care related to the COVI-19 pandemic. Comparisons were made against two years, 2019, prior to the pandemic and 2020 during the pandemic. 2020 was a year like no other, with the COVID-19 pandemic having dramatic impacts on most aspects of life including how patients sought care and how health care providers delivered it.

Key Findings:

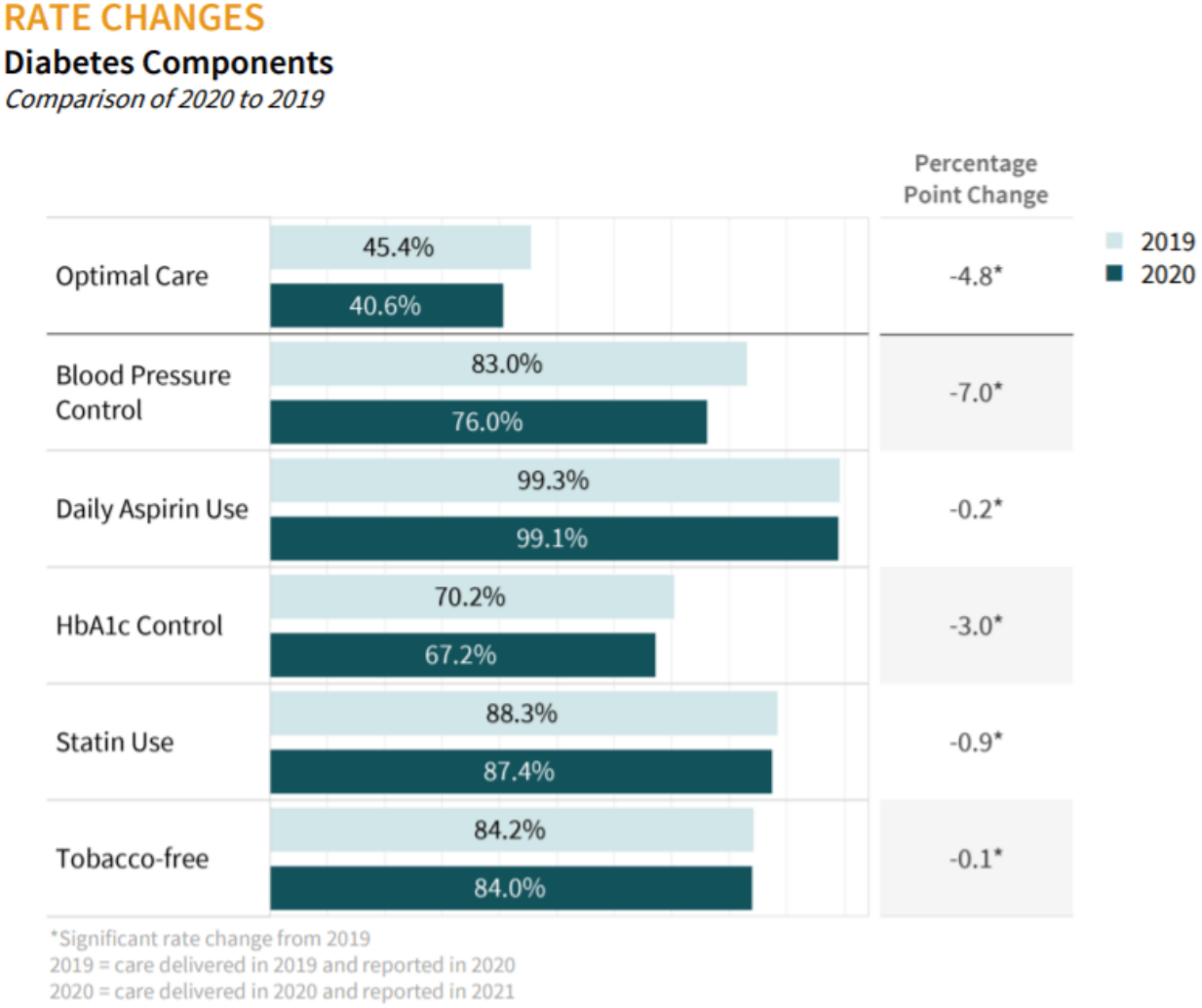
Statewide, the Optimal Diabetes Care measure decreased from 45.4% in 2019 to 40.6% in 2020.

In general, all demographic categories showed a decline in patient volume between 2019 and 2020.

Groups who experienced a significant worsening in their existing disparities for optimal diabetes care include patients with the following demographic characteristics: Black patients, aged 40-59, on commercial insurance, uninsured or in the lowest socioeconomic status (SES) quartile. Additionally, disparities worsened in some regions more than others.

Optimal Diabetes Care rates decreased across all demographic groups. The largest significant decreases in rates occurred in the following groups within each demographic category:

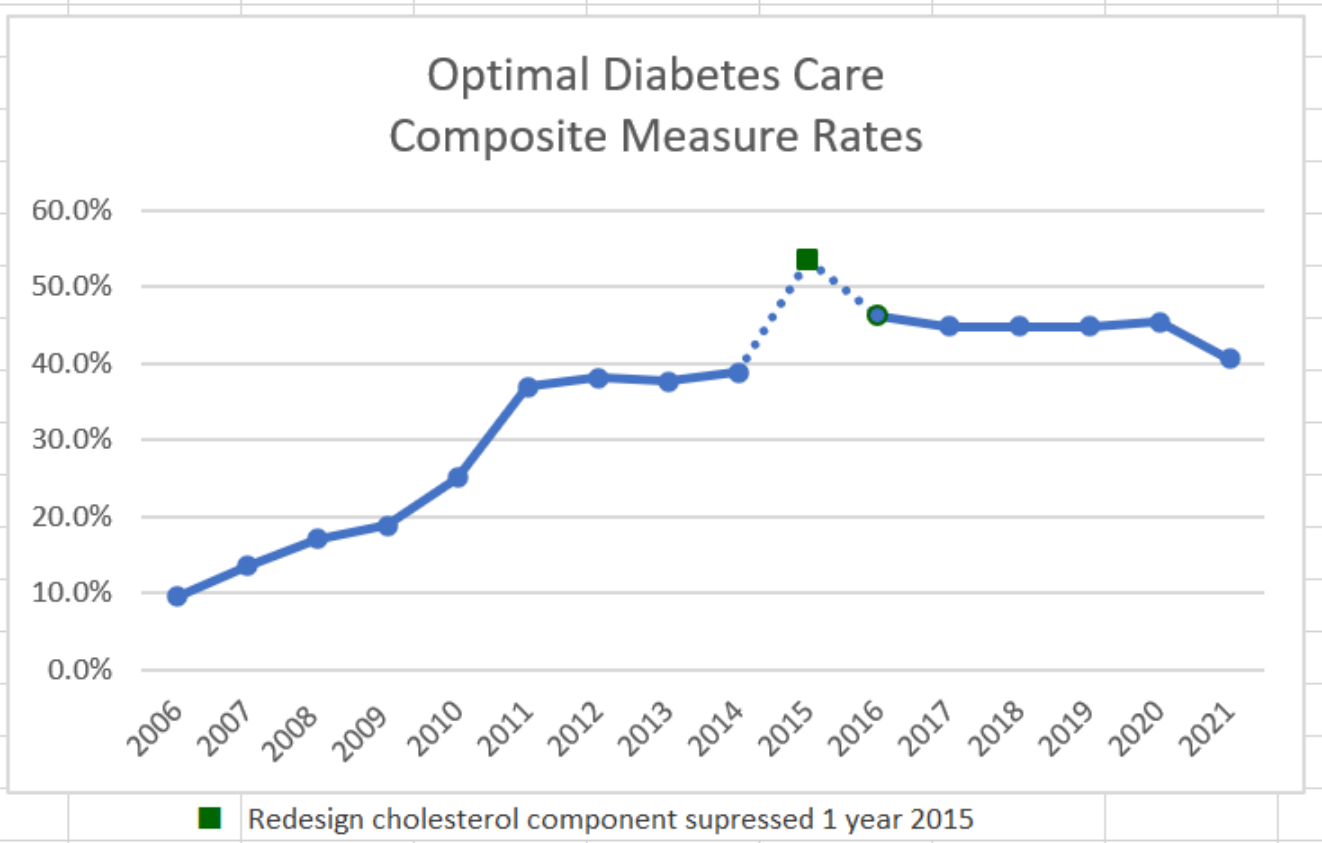
- Females (-4.8 percentage points)
- 40-49 Age Group (-5.4 percentage points)
- Uninsured (-12.9 percentage points)
- High SES (-6.0 percentage points)



Issue Brief: Optimal Diabetes Care in 2020 MN Community Measurement

https://mncmsecure.org/website/Reports/Spotlight%20Reports/2020%20MY%20Issue%20Brief%20-%20ODC.pdf

Measure Rates Over Time



Optimal Diabetes Care Composite Trend of Statewide Rates Over Time

Year	Rate	Patients (Den)	Numerator	Eligible	% submit/elig
2021	40.6%	314,316	127,612	-	-
2020	45.4%	321,962	146,171	322,178	99.9%
2019	44.9%	313,454	140,741	313,857	98.9%
2018	44.9%	307,158	137,985	307,661	99.8%
2017	44.8%	295,049	132,106	295,199	99.9%
2016	46.3%	257,078	119,194	260,197	98.8%
2015	53.5%	245,241	131,847	249,878	98.1%
2014	38.9%	230,818	90,499	237,354	97.2%
2013	37.7%	208,809	80,190	223,036	93.6%
2012	38.2%	184,234	73,037	212,077	86.9%
2011	37.0%	158,770	61,930	209,479	75.8%
2010	25.1%	140,945	40,078	216,290	65.2%

Year	Rate	Patients (Den)	Numerator	Eligible	% submit/elig
2009	18.9%	112,819	23,470	178,748	63.1%
2008	17.1%	83,034	15,772	130,019	63.9%
2007	13.5%	58,911	8,297	85,225	69.1%
2006	9.5%	8,401	798	41,831	20.1%

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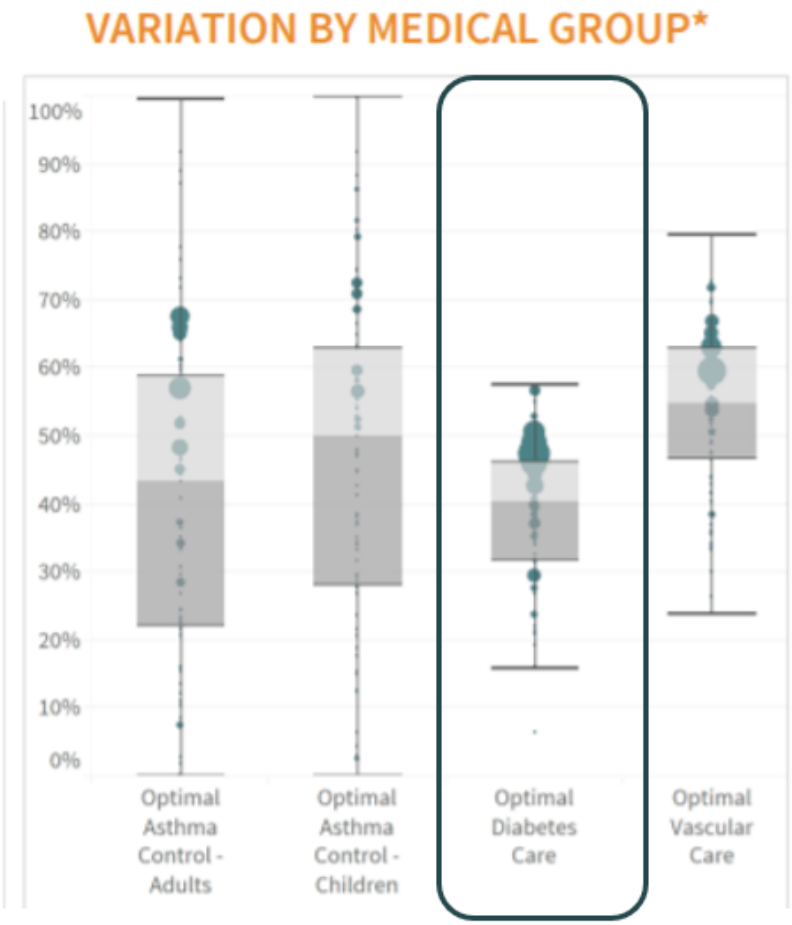
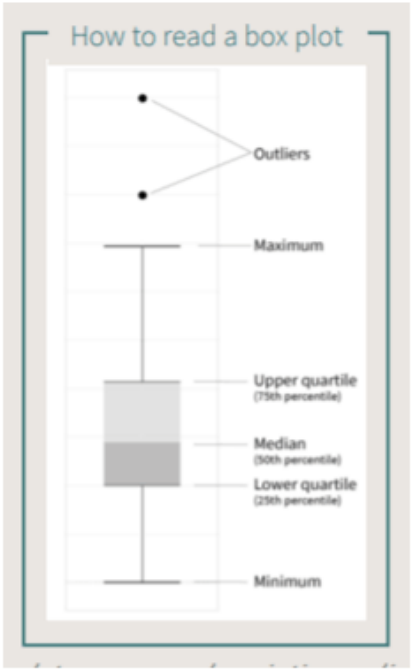
Optimal Diabetes Care Composite Trend of Statewide Rates Over Time





MNCM 2020 Health Care Quality Report Chronic Conditions Measures page 8

https://mncmsecure.org/website/Reports/Community%20Reports/Health%20Care%20Quality%20Report/2020%20HCQR%20Chartbook%20FINAL.pdf

STATEWIDE RESULTS

• Of the measures included here, the Optimal Diabetes Care measure has the most room for improvement

• Approximately 55 percent of patients with diabetes have at least one component of the measure that is not optimally managed

Component	2017	2018	2019	2020
HbA1c Control *HbA1c < 8.0 mg/dL*	69.4%	69.2% ▼	69.5%	70.2% ▲
On Daily Aspirin *If ischemic vascular disease present and not contraindicated*	99.4%	99.5%	99.4% ▼	99.3% ▼
On Statin Medication *Unless contraindicated*	86.9%	87.8%	88.1% ▲	88.3%
Tobacco-free	83.7%	83.9%	84.0%	84.2%
BP Control BP < 140/90 mm Hg	83.7%	83.4% ▼	83.1% ▼	83.0%
OPTIMAL CARE	44.8%	44.9%	44.9%	45.4%

▼ Significantly lower than previous year (95% confidence interval)

▲ Significantly higher than previous year (95% confidence interval)

MNCM 2020 Health Care Quality Report Chronic Conditions Measures page 9

STATEWIDE TREND OVER TIME:

The rate of performance for the Optimal Diabetes Care measure significantly increased in the 2020 report year (2019 dates of service) compared to the 2019 report year. Additional analyses of the components show that the rate for the Hemoglobin A1c component significantly decreased in the 2018 report year and then remained constant in the 2019 report year. However, in the 2020 report year, the HbA1c rate significantly increased, leading to a significant increase in optimal care overall. The rate of performance for the Optimal Vascular Care measure significantly decreased in the 2020 report year compared to the 2019 report year. Additional analyses of the components shows that the rates for the aspirin component have been significantly decreasing since the 2018 report year, which has significantly contributed to the overall decline in optimal vascular care performance.

MNCM Annual Health Care Quality Report

https://mncmsecure.org/website/Reports/Community%20Reports/Health%20Care%20Quality%20Report/2020%20HCQR%20Chartbook%20FINAL.pdf

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

N/A

[Response Ends]

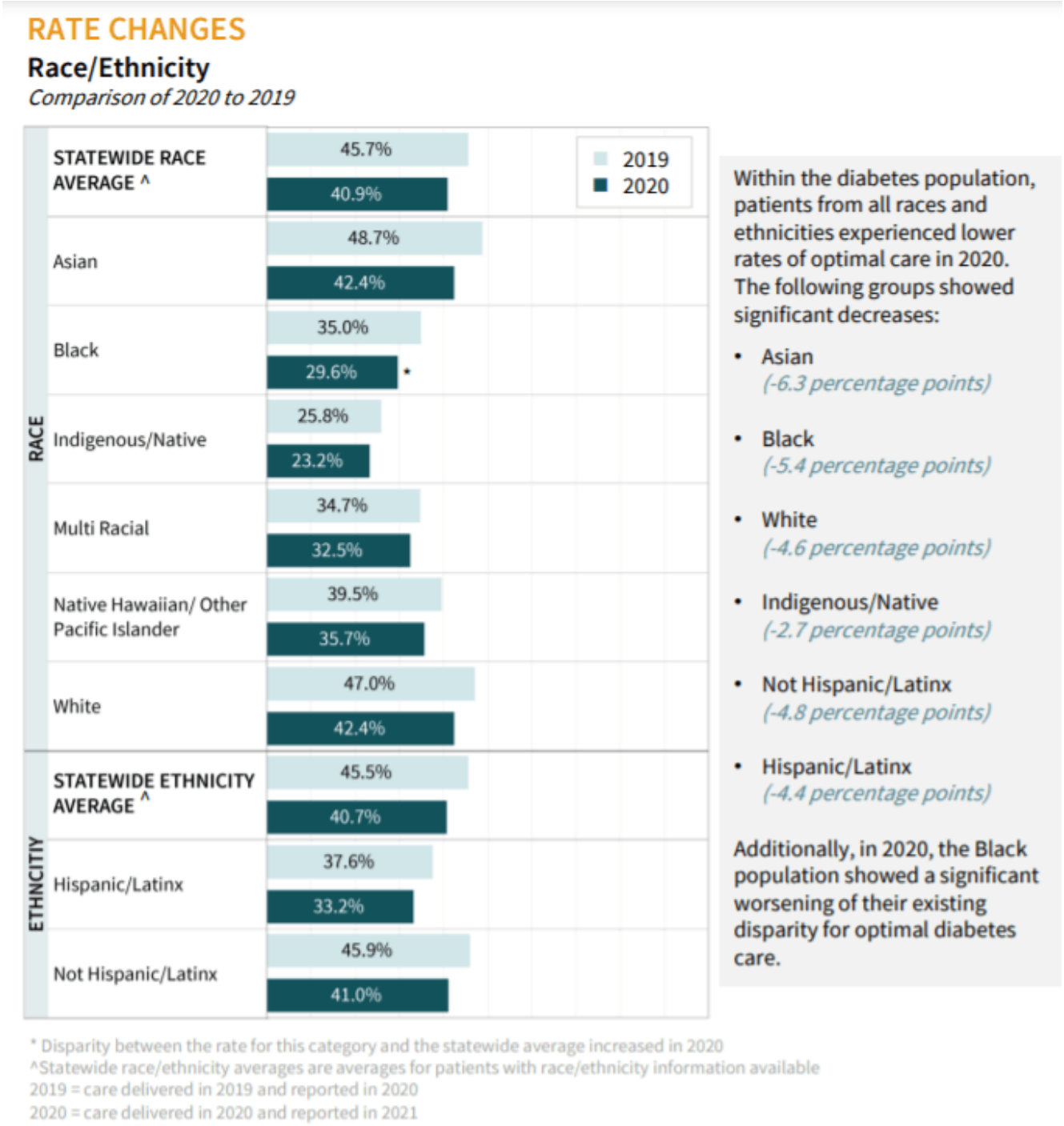
1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

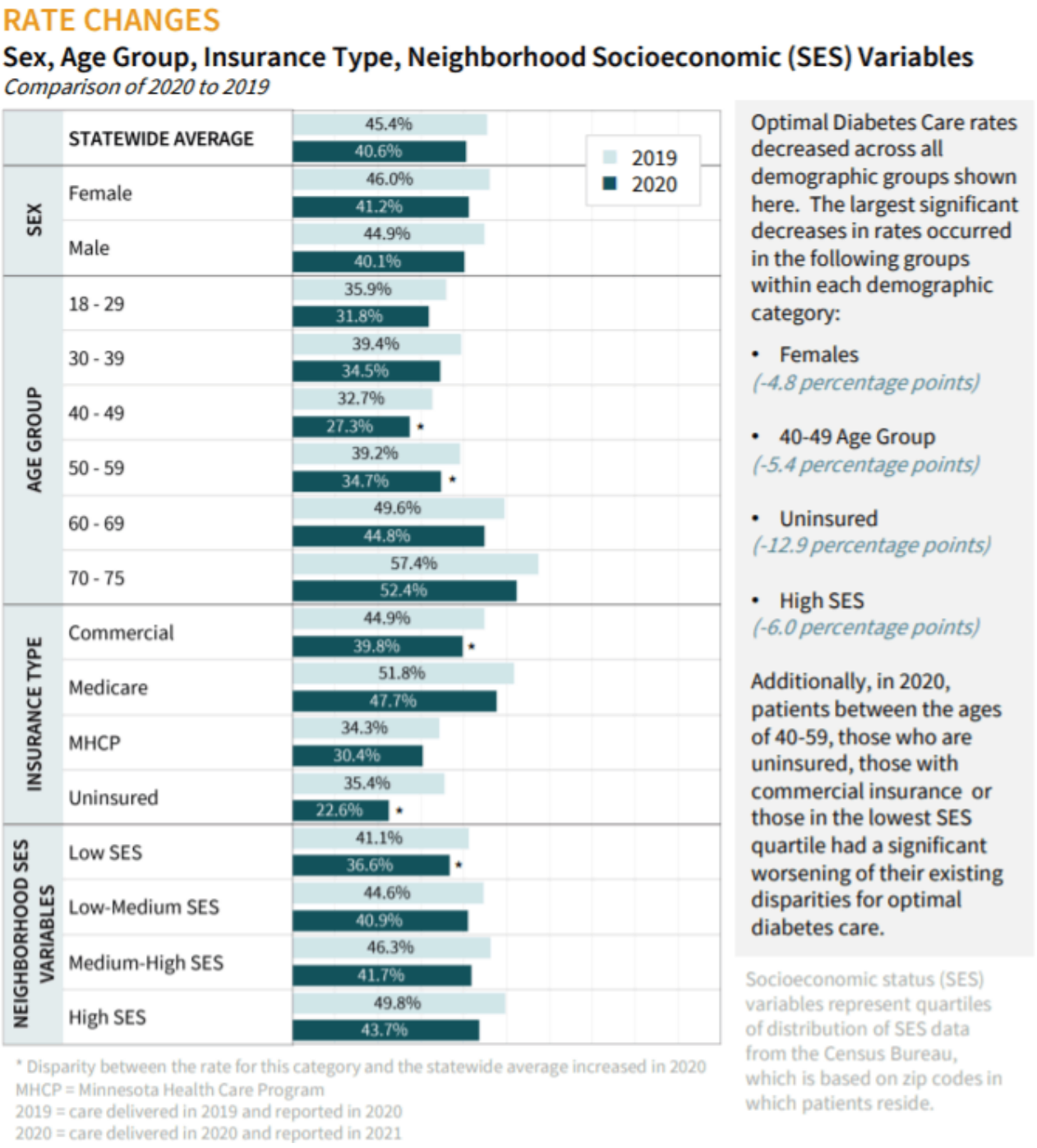
Issue Brief Optimal Diabetes Care in 2020

https://mncmsecure.org/website/Reports/Spotlight%20Reports/2020%20MY%20Issue%20Brief%20-%20ODC.pdf



Issue Brief: Optimal Diabetes Care in 2020 MN Community Measurement

https://mncmsecure.org/website/Reports/Spotlight%20Reports/2020%20MY%20Issue%20Brief%20-%20ODC.pdf



Issue Brief: Optimal Diabetes Care in 2020 MN Community Measurement

https://mncmsecure.org/website/Reports/Spotlight%20Reports/2020%20MY%20Issue%20Brief%20-%20ODC.pdf

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

N/A

[Response Ends]

1c. Composite – Quality Construct and Rationale

1c.01. Select the method of composite measure construction.

A composite performance measure is a combination of two or more component measures, each of which individually reflect quality of care, into a single performance measure with a single score. For purposes of NQF measure submission, evaluation, and endorsement, the following will be considered composites:

- Measures with two or more individual performance measure scores combined into one score for an accountable entity.
- Measures with two or more individual component measures assessed separately for each patient and then aggregated into one score for an accountable entity.
- all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient)

[Response Begins]

two or more individual component measures assessed separately for each patient and then aggregated into one score

[Response Ends]

1c.02. Describe the quality construct.

Describe the area of quality measured, component measures, and the relationship of the component measures to the overall composite and to each other (whether reflective or formative model was used to develop this measure, and whether components are correlated).

[Response Begins]

This composite measure is a patient level all-or-none composite in which the desired goal is for the patient is to achieve multiple intermediate physiological clinical outcome and medication use targets to best reduce their overall risk of developing long term complications (acute MI, cardiovascular and peripheral vascular disease, kidney damage and failure, loss of vision, amputation, etc.) Reducing modifiable risks was the reason why this measure was developed. The components of this measure include blood sugar and blood pressure control, being tobacco-free, appropriate use of statins and daily aspirin or anti-platelet use if ischemic vascular disease.

1. HbA1c less than 8.0

2. Blood pressure less than 140 systolic and less than 90 diastolic

3. Statin use if no contraindications/ exceptions

4. Tobacco-free

5. Daily aspirin or anti-platelets if has ischemic vascular disease and no contraindications/ exceptions

Numerator is calculated at the patient level and numerator compliance is defined as the patient achieving all five components of the measure. The components are treated equall**y.**

[Response Ends]

1c.03. Describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually.

[Response Begins]

Achieving the intermediate physiological outcome targets related to blood pressure and glycemic control in addition being tobacco free and use of daily aspirin and statins where appropriate are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by achieving several intermediate physiological targets.

In 2018, a study of over 200,000 patients with type 2 diabetes found that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. [Rawshani, A et al Risk Factors, Mortality, and Cardiovascular Outcomes in Patients with Type 2 Diabetes N Engl J Med 2018; 379:633-644 DOI: 10.1056/ NEJMoa1800256]

[Response Ends]

1c.04. Describe how the aggregation and weighting of the component measures are consistent with the stated quality construct and rationale.

[Response Begins]

Numerator is calculated at the patient level and numerator compliance is defined as the patient achieving all five components of the measure. The components are treated equally; there is no weighting. Some of the components have an exception methodology within allowing a "free-pass" on the component if it does not apply to the patient.

Most recent HbA1c in the measurement period is less than 8.0 (applies to all denominator patients)

AND

Most recent blood pressure in the measurement period is less than 140 systolic AND less than 90 diastolic (applies to all denominator patients)

AND

Statin Use if appropriate and no contraindications/ exceptions

Diabetic age 18-20 "free-pass"

Diabetic Age 21 to 75 and ischemic vascular disease? on statin unless LDL < 40 or contraindications/

exceptions

Diabetic Age 21 to 39 and LDL greater than or equal to 190? on statin or contraindications/ exceptions. If in this age group and LDL less than 190 is a "free-pass"

Diabetic Age 40 to 75 ? on statin unless LDL < 70 or contraindications/exceptions.

AND

Patient's tobacco status (documented within the last 2 years) is tobacco free (applies to all denominator patients)

AND

Daily aspirin or anti-platelet use if patient has ischemic vascular disease. If the patient does not have ischemic vascular disease, this component is a "free-pass"

[Response Ends]

1ma.01. Indicate whether there is new evidence about the measure since the most recent maintenance evaluation. If yes, please briefly summarize the new evidence, and ensure you have updated entries in the Evidence section as needed.

[Response Begins]

Yes

The source of the guidelines and evidence support was changed from the 2019 endorsement. The previous diabetes guideline utilized was from the Institute for Clinical Systems Improvement (ICSI), which ceased operations 1/1/2022. The American Diabetes Association (ADA) Standards of Care is now referenced as evidence supporting the composite components. As a note, ICSI guidelines relied heavily on ADA guidelines and demonstrated complete alignment for these components. Therefore, not really new evidence or guideline changes, rather a change in the source.

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

---

spma.01. Indicate whether there are changes to the specifications since the last updates/submission. If yes, update the specifications in the Measure Specifications section of the Measure Submission Form, and explain your reasoning for the changes below.

[Response Begins]

No

[Response Ends]

spma.02. Briefly describe any important changes to the measure specifications since the last measure update and provide a rationale.

For annual updates, please explain how the change in specifications affects the measure results. If a material change in specification is identified, data from re-testing of the measure with the new specifications is required for early maintenance review.

For example, specifications may have been updated based on suggestions from a previous NQF CDP review.

[Response Begins]

No changes to the measure specification since its last endorsement in 2019

[Response Ends]

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Optimal Diabetes Care

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

The percentage of patients 18-75 years of age who had a diagnosis of type 1 or type 2 diabetes and whose diabetes was optimally managed during the measurement period as defined by achieving ALL of the following:
• HbA1c less than 8.0 mg/dL
• Blood Pressure less than 140/90 mmHg
• On a statin medication, unless allowed contraindications or exceptions are present

• Non-tobacco user
• Patient with ischemic vascular disease is on daily aspirin or anti-platelets, unless allowed contraindications or exceptions are present

Please note that while the all-or-none composite measure is considered to be the gold standard, reflecting best patient outcomes, the individual components may be measured as well. This is particularly helpful in quality improvement efforts to better understand where opportunities exist in moving the patients toward achieving all of the desired outcomes. Please refer to the additional numerator logic provided for each component.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Endocrine: Diabetes

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Person-and Family-Centered Care: Person-and Family-Centered Care

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

1. *Clinician: Clinician*
2. *Population: Population*

[Response Begins]

Clinician: Group/Practice

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Outpatient Services

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

https://helpdesk.mncm.org/helpdesk/KB/View/24186774-optimal-diabetes-care-guides

[Response Ends]

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff . Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: 0729_MNCM Diabetes Measure Data Dictionary and Risk Adj 11-15-2021.xlsx

Please respond to the following questions about the numerator, denominator, and exclusions to describe the composite measure, as opposed to the individual component measures.

sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

The number of patients in the denominator whose diabetes was optimally managed during the measurement period as defined by achieving ALL of the following:
• The most recent HbA1c in the measurement period has a value less than 8.0 mg/dL
• The most recent Blood Pressure in the measurement period has a systolic value of less than 140 mmHg AND a diastolic value of less than 90 mmHg
• On a statin medication, unless allowed contraindications or exceptions are present
• Patient is not a tobacco user
• Patient with ischemic vascular disease (Ischemic Vascular Disease Value Set) is on daily aspirin or anti-platelets, unless allowed contraindications or exceptions are present

[Response Ends]

sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Please note that while the all-or-none composite measure is considered to be the gold standard, reflecting best patient outcomes, the individual components may be measured as well. This is particularly helpful in quality improvement efforts to better understand where opportunities exist in moving the patients toward achieving all of the desired outcomes. Please refer to the additional numerator logic provided for each component and note that all of the denominator criteria apply to the numerator as well, but are not repeated in the numerator codes/ descriptions.

HbA1c Date [Date (mm/dd/yyyy)] AND

HbA1c Value [Numeric]

Numerator component calculation: numerator component compliant is HbA1c during the last 12 months (measurement year) AND most recent HbA1c value is less than 8.0.

Enter the date of the most recent HbA1c test during the measurement period.

Enter the value of the most recent HbA1c test during the measurement period.

Leave BLANK if an HbA1c was never performed.

• A test result from a provider outside of the reporting medical group is allowed if the result is documented in the reporting medical group's patient record and is the most recent test result during the measurement period.

• If the HbA1c result is too high to calculate, still enter the HbA1c test date if it is the most recent test result during the measurement period.

Blood Pressure Date [Date (mm/dd/yyyy)] AND

BP Systolic [Numeric] AND

BP Diastolic [Numeric]

Numerator component calculation: numerator component compliant is BP during the measurement year AND Systolic < 140 AND Diastolic < 90.

Enter the date of the most recent blood pressure result during the measurement period.

Leave BLANK if a blood pressure was not obtained during the measurement period.

• A test result from a provider outside of the reporting medical group is allowed if the result is documented in the reporting medical group's patient record and is the most recent test result during the measurement period.

• Blood pressures that are taken by the patient on a digital device in the context of a virtual (online or telephone) visit are acceptable.

• Do not include BP readings:

- Taken during an acute inpatient stay or an ED visit.
- Taken during an outpatient visit which was for the sole purpose of having a diagnostic test or surgical procedure performed.
- Obtained the same day as a major diagnostic or surgical procedure.

BP Systolic

Enter the value of the most recent systolic blood pressure result during the measurement period.

If more than one value is recorded on the most recent date, the lowest systolic value from multiple readings on the same date may be submitted.

NOTE: The systolic blood pressure is the upper number in the recorded fraction. For example, the systolic value for a blood pressure of 124/72 mmHg is 124.

BP Diastolic

Enter the value of the most recent diastolic blood pressure result during the measurement period.

If more than one value is recorded on the most recent date, the lowest diastolic value from multiple readings on the same date may be submitted.

• NOTE: The diastolic blood pressure is the lower number in the recorded fraction. For example, the diastolic value for a blood pressure of 124/72 mmHg is 72.

LDL Date [Date (mm/dd/yyyy)] AND

LDL Value [Numeric]

Numerator component calculation: Is used for the cholesterol component for statin use; patients with low untreated LDL values may not be appropriate for the initiation of statin medication.

Enter the date of the most recent LDL test on or prior to the end of the measurement period.

Leave BLANK if an LDL was never performed.

• A test result from a provider outside of the reporting medical group is allowed if the result is documented in the reporting medical group's patient record and is the most recent test result within the allowable time period.

• If the LDL result is too high to calculate, still enter the LDL test date if it is the most recent test result within the allowable time period.

LDL values within the last five years will be used to calculate potential exceptions to being on a statin medication. Leave BLANK if an LDL test was not performed between 01/01/201x and 12/31/201x (five-year increments).

Statin Medication [Numeric] AND

Statin Medication Date [Date (mm/dd/yyyy)] AND/OR

Station Medication Exception [Numeric] AND

Station Medication Exception Date [Date (mm/dd/yyyy)]

Numerator component calculation: numerator component compliant if on a statin (prescribed/ ordered) or low LDL value (see above) or documented contraindication/exception is present.

Statin Medication:

Enter the code that corresponds to whether the patient was prescribed a statin medication or if a statin medication was active on the patient's medication list during the measurement period.

Please refer to Appendix C for a list of statin medications.

1 = Yes, patient was prescribed a statin medication or a statin medication was indicated as active on the patient's medication list during the measurement period.

2 = No, patient was not prescribed a statin medication and a statin medication was not indicated as active on the patient's medication list during the measurement period.

The following exceptions to statin medication use will be identified by the Data Portal based on the submitted LDL values:

• Patients with ischemic vascular disease aged 21 to 75 years and an LDL result less than 40 mg/dL

• Patients aged 40 – 75 years with an LDL result less than 70 mg/dL

• Patients aged 21 – 39 years with an LDL less than 190 mg/dL

Statin Medication Date:

Enter the most recent date of a statin prescription, order or review of active medications list during the measurement period.

If no statin prescribed, ordered, or reviewed as an active medication during the measurement period, leave blank

Statin Medication Exception:

If the patient was NOT prescribed or did not have a statin medication active on their medication list during the measurement period, enter the value that corresponds to any of the following contraindications or exceptions:

1 = Pregnancy at any time during the measurement period

2 = Active liver disease (liver failure, cirrhosis, hepatitis)

3 = Rhabdomyolysis

4 = End stage renal disease on dialysis

5 = Heart failure

8 = Allergy to statin

9 = Drug interaction with a listed medication taken during the measurement period (valid drug-drug interactions include HIV protease inhibitors, nefazodone, cyclosporine, gemfibrozil, and danazol).

10 = Intolerance using Intolerance (CHOL-06) or Myopathy and Myositis (CHOL-05) Value Sets to document intolerance to statins.

If none of the above contraindications or exceptions are documented, leave BLANK. NOTE: Items 1 – 5 above can be defined by diagnosis codes that may be used in data collection. Value Sets include: Pregnancy V/Z Codes (PREG-01), Pregnancy Diagnosis Codes (PREG-02), Liver Disease (CHOL-01), Rhabdomyolysis (CHOL-02), ESRD on Dialysis (CHOL-03), and Heart Failure (CHOL-04)

Statin Medication Exception Date:

If the patient has a documented contraindication or exception enter the date of the contraindication or exception. If only the month and year are known, enter the first day of the month.

Tobacco Status Documentation Date [Date (mm/dd/yyyy)] AND

Tobacco Status [Numeric]

Numerator component calculation: numerator component compliant if tobacco status within the last two years and status is tobacco-free.

Tobacco Status Documentation Date:

Enter the most recent date that the patient's tobacco status was documented during the measurement period or year prior.

• If the patient's tobacco status is not documented or the date of documentation cannot be determined, leave BLANK

Tobacco Status:

Enter the code that corresponds to the patient's most recent tobacco status during the measurement period or year prior.

1 = Tobacco free (patient does not use tobacco; patient was a former user and is not a current user)

2 = No documentation

3 = Current tobacco user (tobacco includes any amount of cigarettes, cigars, pipes or smokeless tobacco)

• If the date of the tobacco status documentation is not documented in the patient record, enter 2

• E-cigarettes are not considered tobacco products.

Aspirin or Anti-platelet Medication [Numeric] AND

Aspirin or Anti-platelet Date [Date (mm/dd/yyyy)] AND/OR

Aspirin or Anti-platelet Exception [Numeric] AND

Aspirin or Anti-platelet Exception Date [Date (mm/dd/yyyy)]

Numerator component calculation: Calculation applied only if patient has ischemic vascular disease (IVD); if no IVD indicated, is a numerator component "free-pass". For patients with IVD, numerator component compliant if indicated on daily aspirin or anti-platelet medication (prescribed/ ordered) or documented contraindication/exception is present.

Aspirin or Anti-platelet Medication:

For patients with Ischemic Vascular Disease (IVD), enter the code that corresponds to whether the patient is prescribed a daily aspirin product or antiplatelet medication or if an aspirin product or anti-platelet medication was active on the patient's medication list during the measurement period.

Please see Appendix D for methods to identify appropriate aspirin products or antiplatelet medications.

1 = Yes, patient was prescribed a daily aspirin product or antiplatelet medication, or one was indicated as active on the patient's medication list during the measurement period.

2 = No, patient was not prescribed a daily aspirin product or antiplatelet medication and one was not indicated as active on the patient's medication list during the measurement period.

Aspirin/narcotic combination medications do not qualify as a daily aspirin product.

Aspirin or Anti-platelet Date:

For patients with IVD, enter the date of the most recent daily aspirin product or anti-platelet medication prescription, order or review of an active medication list that included a daily aspirin product or anti-platelet medication during the measurement period.

If a daily aspirin product or anti-platelet medication was not prescribed, ordered or reviewed as an active medication during the measurement period leave blank

Aspirin or Anti-platelet Medication Exception:

For patients with IVD who were not prescribed or taking a daily aspirin product or anti-platelet medication during the measurement period, enter the code that corresponds to any of the following contraindications or exceptions:

1 = Prescribed anti-coagulant medication during the measurement period

2 = History of gastrointestinal bleeding

3 = History of intracranial bleeding

4 = Bleeding disorder

5 = Allergy to aspirin or anti-platelets

If none of the above contraindications or exceptions are documented, leave BLANK.

NOTE: Items 2 and 3 above can be defined by diagnosis codes that may be used in data collection. Value Sets include: GI Bleed (ASA-01) and Intracranial Bleed (ASA-02).

Aspirin or Anti-platelet Medication Exception Date:

If the patient has a documented aspirin product or anti-platelet medication exception enter the date of the contraindication or exception.

[Response Ends]

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Patients ages 18 to 75 with a diagnosis of diabetes (Diabetes Value Set) with any contact during the current or prior measurement period OR had diabetes (Diabetes Value Set) present on an active problem list at any time during the measurement period. Both contacts AND problem list must be queried for diagnosis (Diabetes Value Set).

AND patient has at least one established patient office or telehealth visit (Established Pt Diabetes & Vasc Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period.

[Response Ends]

sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Please also refer to all code lists included in the data dictionary attached in S.2b.

• 18 years or older at the start of the measurement period AND less than 76 years at the end of the measurement period

• Patient had a diagnosis of diabetes (Diabetes Value Set) with any contact during the current or prior measurement period OR had diabetes (Diabetes Value Set) present on an active problem list at any time during the measurement period. Both contacts AND the active problem list must be queried for diagnosis (Diabetes Value Set).

• At least one established patient office or telehealth visit (Established Pt Diabetes & Vasc Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period

Eligible specialties: Family Medicine, Internal Medicine, Geriatric Medicine, Endocrinology

Eligible providers: Medical Doctor (MD), Doctor of Osteopathy (DO), Physician Assistant (PA), Advanced Practice Registered Nurses (APRN)

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Valid allowable exclusions include patients who were a permanent resident of a nursing home, pregnant, died or were in hospice or palliative care during the measurement year.

[Response Ends]

sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

- Patient was pregnant (*Diabetes with Pregnancy* Value Set) at any time during the measurement period
- Patient was a permanent nursing home resident during the measurement period
- Patient was in hospice or palliative care at any time during the measurement period
- Patient died prior to the end of the measurement period

[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

The diabetes population is not currently stratified when publicly reported on our consumer website, MN HealthScores. The data is, however, stratified by public (MN Health Care Programs- Prepaid Medical Assistance including dual eligibles, MinnesotaCare, and General Assistance Medical Care) and private purchasers for our 2020 Health Care Disparities Report. This report notes a gap in outcomes of 11.4% percentage points between patients with diabetes in public programs and other purchasers. However, trend reporting indicates that the gap is starting to narrow.
https://mncmsecure.org/website/Reports/Community%20Reports/Disparities%20by%20Insurance%20Type/2020%20RY%20Disparities%20by%20Insurance%20Type.pdf

[Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Statistical risk model

[Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Rate/proportion

[Response Ends]

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

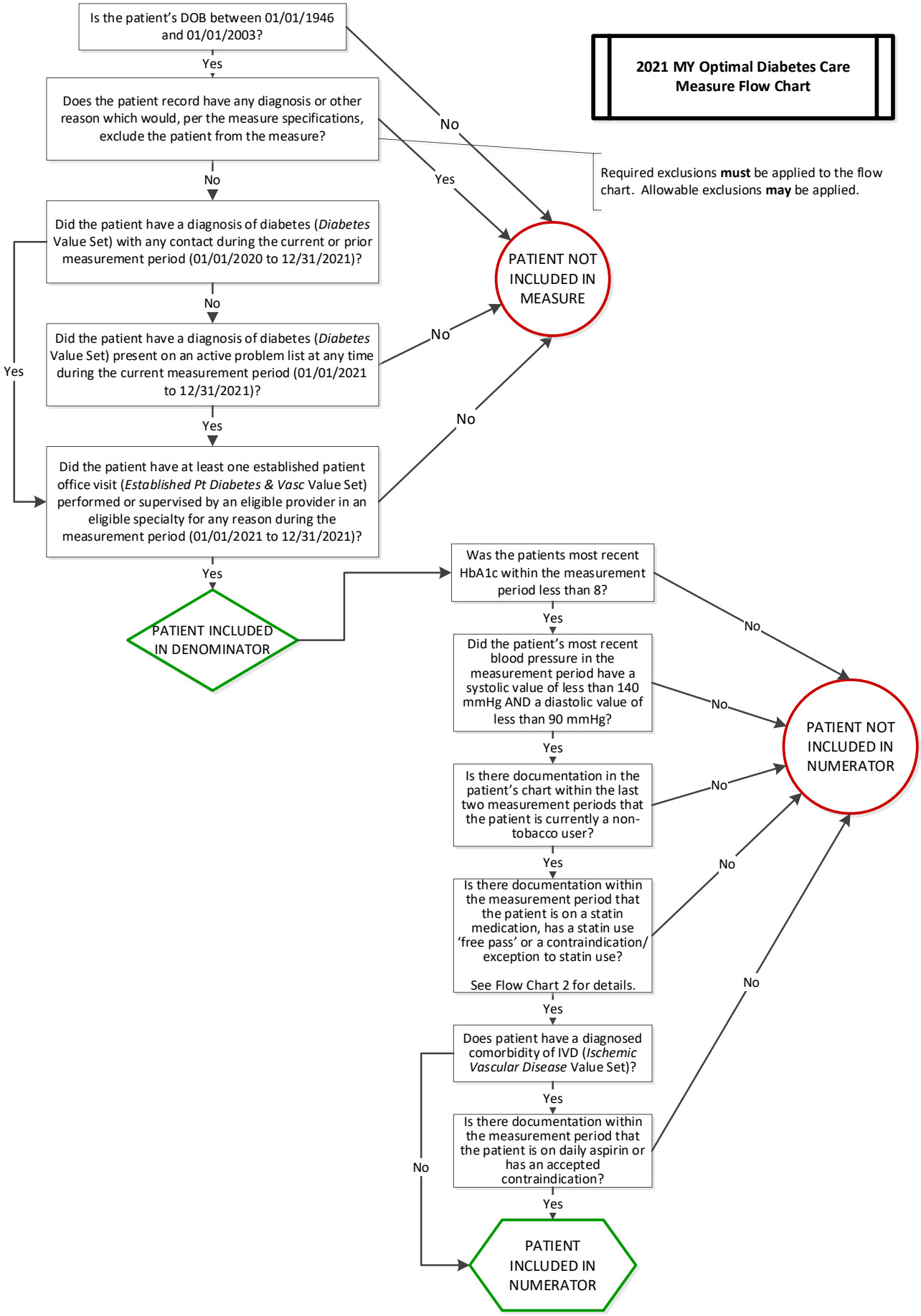
Better quality = Higher score

[Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]


2021 MY Optimal Diabetes Care Measure Flow Chart
Is the patient's DOB between 01/01/1946 and 01/01/2003?
Yes
No
Does the patient record have any diagnosis or other reason which would, per the measure specifications, exclude the patient from the measure?
Yes
No
Required exclusions **must** be applied to the flow chart. Allowable exclusions **may** be applied.
Did the patient have a diagnosis of diabetes (*Diabetes* Value Set) with any contact during the current or prior measurement period (01/01/2020 to 12/31/2021)?
No
Did the patient have a diagnosis of diabetes (*Diabetes* Value Set) present on an active problem list at any time during the current measurement period (01/01/2021 to 12/31/2021)?
Yes
No
Yes
Did the patient have at least one established patient office visit (*Established Pt Diabetes & Vasc* Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period (01/01/2021 to 12/31/2021)?
No
Yes
PATIENT NOT INCLUDED IN MEASURE
PATIENT INCLUDED IN DENOMINATOR
Was the patients most recent HbA1c within the measurement period less than 8?
Yes
No
Did the patient's most recent blood pressure in the measurement period have a systolic value of less than 140 mmHg AND a diastolic value of less than 90 mmHg?
Yes
No
Is there documentation in the patient's chart within the last two measurement periods that the patient is currently a non-tobacco user?
Yes
No
Is there documentation within the measurement period that the patient is on a statin medication, has a statin use 'free pass' or a contraindication/ exception to statin use?
See Flow Chart 2 for details.
Yes
No
Does patient have a diagnosed comorbidity of IVD (*Ischemic Vascular Disease* Value Set)?
Yes
No
Is there documentation within the measurement period that the patient is on daily aspirin or has an accepted contraindication?
Yes
No
PATIENT NOT INCLUDED IN NUMERATOR
PATIENT INCLUDED IN NUMERATOR

Measurement Year 2021 Measure Calculation Algorithm

This measure is calculated by submitting a file of individual patient values (e.g. blood pressure, A1c value, etc.) to a HIPAA secure data portal. Programming within the data portal determines if each patient is a numerator case and then a rate is calculated for each clinic site.

If any component of the numerator is noncompliant for any one of the five components, then the patient is numerator noncompliant for the composite patient level all-or none optimal diabetes care measure.

Numerator logic is as follows:

A1c Component:

Is the HbA1c date in the measurement period? If no, is numerator noncompliant for this component. If yes, assess next variable.

Is the HbA1c value less than 8.0? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component.

Note: A1c needs to occur during the measurement year AND most recent value less than 8.0

Assess next component.

Blood Pressure Component:

Is Blood Pressure date in the measurement period? If no, is numerator noncompliant for this component. If yes, assess next variable.

BP Systolic < 140? If no, is numerator noncompliant for this component. If yes, assess next variable.

BP Diastolic < 90? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component.

Note: BP needs to occur during the measurement year AND most recent BP systolic less than 140 AND BP diastolic less than 90

Assess next component.

Cholesterol Statin Use Component:

Is the patient on a statin medication? If yes, and most recent date is in the measurement year, is numerator compliant for this component. If no, assess next variable.

For patients not on a statin the following variables are used to assess numerator compliance related to contraindications or exceptions to statin use:

Is the patient age 18 to 20? If yes, numerator compliant (free-pass), if no, assess next variable.

Is the patient age 21 to 75? Do they have ischemic vascular disease (IVD)?

If Yes IVD, is their most recent LDL in the last five years less than 40? If Yes, numerator compliant (free-pass), if no, assess next variable.

Does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, end stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance? If yes, is numerator compliant for this component. If no, fail this numerator component and remains in the denominator.

If No IVD, is the patient age 21 to 39 and is their most recent LDL in the last 5 years greater than or equal to 190? If No, numerator compliant (free-pass).

If Yes LDL greater than or equal to 190, does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, ends stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance ? If yes, is numerator compliant for this component. If no, fail this numerator component and remains in the denominator.

If No IVD, no LDL greater than or equal to 190 for patients ages 40 to 70, is their most recent LDL in the last five years less than 70? If Yes, numerator compliant (free-pass), if no, assess next variable.

Does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, ends stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance? If yes, is numerator compliant for this component. If no, fail this numerator component and remains in the denominator.

Note: Patient is either on a statin (prescribed/ ordered) during the measurement year or has a valid exception either by age, presence or absence of ischemic vascular disease, low untreated LDL or valid contraindication/ exception.

Assess next component.

Tobacco-Free Component:

Is Tobacco Status = 1 (Tobacco Free) and Tobacco Assessment Date a valid date? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next component.

Daily Aspirin/ Anti-platelet Component:

Does the patient have cardiovascular/ ischemic vascular disease? If no, is numerator compliant (free-pass), if yes assess next variable.

Is the patient on daily aspirin or an antiplatelet? If yes, and date of most recent aspirin/ anti-platelet is in the measurement year is numerator compliant, if no, assess next variable.

Does the patient have a valid contraindication/ exception to aspirin anti-platelet use defined as one of the following: anti-coagulant medication, history of gastrointestinal bleed, history of intracranial bleed, or allergy. If yes, is numerator compliant for this component. If no, fail this numerator component and remains in the denominator.

Note: Patients with ischemic vascular disease are either on daily aspirin (indicated/ prescribed/ ordered) or an anti-platelet prescribed/ ordered) during the measurement year or has a valid contraindication/ exception.

If all of the above numerator components are in compliance, then the patient calculated as a numerator case for the optimal diabetes care measure.

[Response Ends]

sp.23. Indicate the responder for your instrument.

[Response Begins]

Other (specify)

The measure is not instrument based.

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins]

Medical groups are encouraged to submit their full population of patients when possible (EMR) however clinics who are on a paper chart system are allowed to create a random sample of no less than 60 patients per clinic site. MNCM recommends that medical groups submit total population for each measure. By submitting total population, the

confidence interval around the rate narrows, indicating a higher confidence that the rate accurately reflects the clinics' performance. If total population is not an option for a medical group, MNCM encourages medical groups to submit a large sample. The minimum required sample is 60 patients per clinic site, per measure. If a clinic site has less than 60 patients in the total population for the measure, the entire population must be submitted.

In 2017, 99.5% (615 clinics) submitted total population, 0.5% (3 clinics) submitted a sample.

Excel's Random Number Generator Instructions:

For lists generated in Excel, use the "RAND" function to assign a random number to each record (please also see Microsoft Excel Help, topic RAND for more information):

1. Insert a blank column on the leftmost side of the spreadsheet

2. Label new column "RAND"

3. Place cursor in the first blank cell (A2) and type =RAND()

4. Press enter (a number like 0.793958 will appear)

5. Place the cursor back into this cell; resting over the corner to have the pointer change to a black cross, double click or drag the formula down to the last row/patient

6. Highlight the whole column and click Edit, Copy, Paste Special = Values to freeze the random number (otherwise it will change with every click on the spreadsheet)

7. Sort entire patient population by this new random number

8. Work down the list row by row, starting with row 1 until the number of records in the sample is met for submission (at least 60 patients per clinic, per measure)

9. If a patient meets one of the accepted exclusions, keep working down the list and use oversamples that are after the number of records in the sample. For example, if 60 records will be submitted and 2 exclusions were found, include patient rows 61 and 62 to replace the excluded records.

[Response Ends]

sp.26. Identify whether and how proxy responses are allowed.

[Response Begins]

Not applicable

[Response Ends]

sp.28. Provide the data collection instrument.

[Response Begins]

Available at measure-specific web page URL identified in sp.09

[Response Ends]

sp.29. Select only the data sources for which the measure is specified.

[Response Begins]

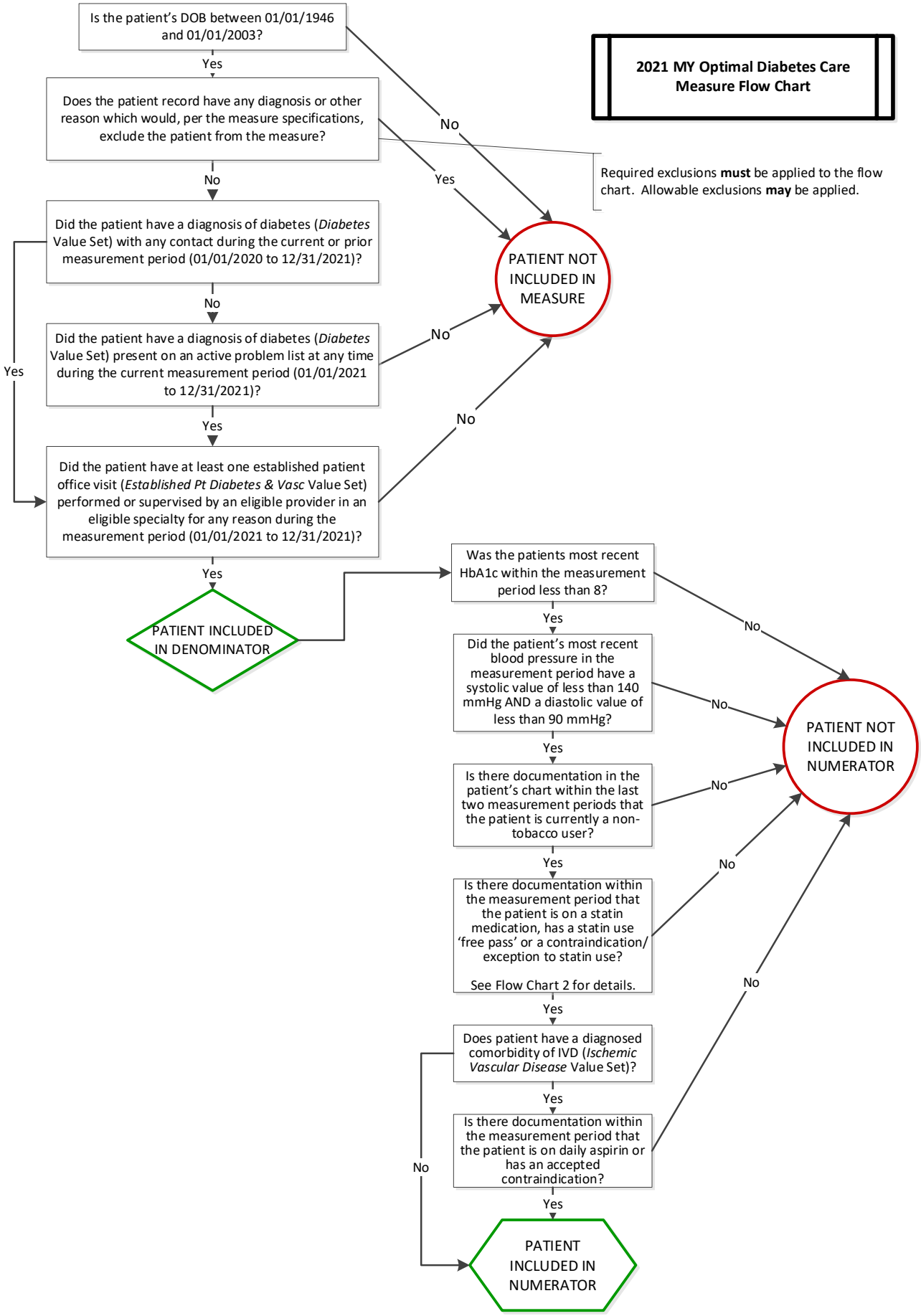
Electronic Health Records

[Response Ends]

sp.30. Describe the component measures and composite construction.

Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.

[Response Begins]


2021 MY Optimal Diabetes Care Measure Flow Chart
Required exclusions **must** be applied to the flow chart. Allowable exclusions **may** be applied.
Is the patient's DOB between 01/01/1946 and 01/01/2003?
Yes
No
Does the patient record have any diagnosis or other reason which would, per the measure specifications, exclude the patient from the measure?
Yes
No
Did the patient have a diagnosis of diabetes (*Diabetes* Value Set) with any contact during the current or prior measurement period (01/01/2020 to 12/31/2021)?
No
Yes
Did the patient have a diagnosis of diabetes (*Diabetes* Value Set) present on an active problem list at any time during the current measurement period (01/01/2021 to 12/31/2021)?
No
Yes
Did the patient have at least one established patient office visit (*Established Pt Diabetes & Vasc* Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period (01/01/2021 to 12/31/2021)?
No
Yes
PATIENT INCLUDED IN DENOMINATOR
PATIENT NOT INCLUDED IN MEASURE
Was the patients most recent HbA1c within the measurement period less than 8?
No
Yes
Did the patient's most recent blood pressure in the measurement period have a systolic value of less than 140 mmHg AND a diastolic value of less than 90 mmHg?
No
Yes
Is there documentation in the patient's chart within the last two measurement periods that the patient is currently a non-tobacco user?
No
Yes
Is there documentation within the measurement period that the patient is on a statin medication, has a statin use 'free pass' or a contraindication/ exception to statin use?
See Flow Chart 2 for details.
No
Yes
Does patient have a diagnosed comorbidity of IVD (*Ischemic Vascular Disease* Value Set)?
No
Yes
Is there documentation within the measurement period that the patient is on daily aspirin or has an accepted contraindication?
No
Yes
PATIENT INCLUDED IN NUMERATOR
PATIENT NOT INCLUDED IN NUMERATOR

Calculation of the patient level all-or-none composite measure algorithms are provided in the data dictionary. The individual components are treated equally (not weighted). Please note that while the all-or-none composite measure is considered to be the gold standard, reflecting best patient outcomes, the individual components may be measured as well. This is particularly helpful in quality improvement efforts to better understand where opportunities exist in moving the patients toward achieving all the desired outcomes. Individual component logic is included below:

Denominator is the same for calculating individual component rates as the patient level all-or-none composite measure:

Patients ages 18 to 75 with a diagnosis of diabetes (Diabetes Value Set) with any contact during the current or prior measurement period OR had diabetes (Diabetes Value Set) present on an active problem list at any time during the measurement period. Both contacts AND problem list must be queried for diagnosis (Diabetes Value Set).

AND patient has at least one established patient office or telehealth visit (Established Pt Diabetes & Vasc Value Set) performed or supervised by an eligible provider in an eligible specialty for any reason during the measurement period.

Component for HbA1c Control:

Is the HbA1c date in the measurement year? If No, fails the numerator. If Yes, assess next variable.

Is the most recent HbA1c value less than 8.0? If Yes, is in the numerator for this component.

Expressed as a rate:

Patients with most recent A1c during the measurement year is less than 8.0/

Eligible patients with diabetes

Component for Blood Pressure Control:

Is the BP date in the measurement year? If No, fails the numerator. If Yes, assess next variable.

Is the most recent BP value less than 140 systolic AND less than 90 diastolic? If Yes, is in the numerator for this component.

Expressed as a rate:

Patients with most recent BP during the measurement year is less than 140 systolic AND 90 diastolic/

Eligible patients with diabetes

Component for Cholesterol/ Statin Use:

Is the patient on a statin medication? If yes, and most recent date is in the measurement year, is in the numerator for this component.

For patients not on a statin the following variables are used to assess numerator compliance related to contraindications or exceptions to statin use:

Is the patient age 18 to 20? If yes, in the numerator (free-pass), if no, assess next variable.

Is the patient age 21 to 75? Do they have ischemic vascular disease (IVD)?

If Yes IVD, is their most recent LDL in the last five years less than 40? If Yes, in the numerator(free-pass), if no, assess next variable.

Does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, ends stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance? If yes, is in the numerator. If no, fail this numerator component and remains in the denominator.

If No IVD, is the patient age 21 to 39 and is their most recent LDL in the last 5 years greater than or equal to 190? If No, is in the numerator (free-pass).

If Yes LDL greater than or equal to 190, does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, ends stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance? If yes, is in the numerator. If no, fail this numerator component and remains in the denominator.

If No IVD, no LDL greater than or equal to 190 for patients ages 40 to 70, is their most recent LDL in the last five years less than 70? If Yes, is in the numerator (free-pass), if no, assess next variable.

Does the patient have a valid contraindication/ exception to statin use defined as one of the following: pregnancy, active liver disease, rhabdomyolysis, ends stage renal disease on dialysis, heart failure, allergy to statin, drug-drug interaction with statin, or intolerance? If yes, is in the numerator. If no, fail this numerator component and remains in the denominator.

Expressed as a rate:

Patients with statin use unless with contraindications/ exceptions/

Eligible patients with diabetes

Component for Tobacco-Free:

Is the date of smoking status in the measurement year or the year prior? If No, fails the numerator. If Yes, assess next variable.

Is the patient's tobacco status noted as tobacco-free ? If Yes, is in the numerator.

Expressed as a rate:

Patients with most recent tobacco status during the measurement year or the year prior is free of all tobacco products (tobacco free)/

Eligible patients with diabetes

Component for Daily Aspirin/ Anti-platelet Component:

Does the patient have cardiovascular/ ischemic vascular disease? If No, is in the numerator (free-pass)

Is the patient on daily aspirin or an antiplatelet? If yes, and date of most recent aspirin/ anti-platelet is in the measurement year is numerator compliant, if no, assess next variable.

Does the patient have a valid contraindication/ exception to aspirin anti-platelet use defined as one of the following: anti-coagulant medication, history of gastrointestinal bleed, history of intracranial bleed, or allergy? If yes, is numerator compliant for this component. If no, fail this numerator component and remains in the denominator.

Expressed as a rate:

Patients with ischemic vascular disease with daily aspirin/ anti-platelet use unless with contraindications/ exceptions/Eligible patients with diabetes

[Response Ends]

2ma.01. Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

No

[Response Ends]

2ma.02. Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

No

[Response Ends]

2ma.03. For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.

Please update the Scientific Acceptability: Validity - Other Threats to Validity section.

Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.

[Response Begins]

No additional risk adjustment analysis included

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing must be conducted at the composite score level.

If a component measure is submitted as an individual performance measure, the Scientific Acceptability sections must be completed and submitted as part of the individual measure's submission.

• Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.

• All required sections must be completed.

• For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.

• If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.

• An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.

• Contact NQF staff with any questions. Check for resources at the

Submitting Standards webpage .

• For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the

2021 Measure Evaluation Criteria and Guidance .

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument-based measures (including-PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

• an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; and has demonstrated adequate discrimination and calibration

OR

• rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse), demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to the computed measure score. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to the computed measure score. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, (e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method); correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference: Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

Meaningful differences: With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing (e.g., reliability vs. validity), be sure to indicate the specific differences below.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:

Updated testing information here.

2018 Submission:

Testing from the previous submission here.

2a. Reliability

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Electronic Health Records

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

Please note: Since the measure's last maintenance endorsement in 2019, the measure has not undergone redesign, therefore original testing from the 2019 submission is submitted.

Patient level data was submitted from 103 medical groups representing 618 reportable clinics (n $\geq$ 30) in Minnesota and bordering communities. Data submission is an annual process; for 2017 dates of service reported in 2018, 307,158 patients were submitted for rate calculation and this represents 99.8% of all eligible diabetic patients in MN.

Sampling is allowed for those clinics with paper records or those who have not had their EMR in place for one year prior to the measurement period; in MN there are very few clinics not yet on an EMR. For 2017 dates of service 99.5% submitted total population, 0.5% submitted a sample.

Types of fields included in the submission for 2017 dates of service include the following:

Clinic ID * Patient ID * Patient Date of Birth * Patient Gender * Zip Code * Primary Residence * Race/Ethnicity1 * Race/Ethnicity2 * Race/Ethnicity3 * Race/Ethnicity4 * Race/Ethnicity5 * Country of Origin Code * Country of Origin "Other" Description * Preferred Language Code * Preferred Language "Other" Description * Provider NPI * Provider Specialty Code * Insurance Coverage Code * Insurance Coverage "Other" Description * Insurance Plan Member ID * Patient Has IVD? * Patient Has Depression? * Type 1 or Type 2 Diabetes? * HbA1c Date * HbA1c Value * LDL Date * LDL Value * BP Date * BP Systolic * BP Diastolic * Statin Medication Date * Statin Medication Exception * Statin Medication Exception Date * Aspirin or Antiplatelet Medication * Aspirin or Antiplatelet Medication Date * Aspirin or Antiplatlet Medication Exception * Aspirin or Antiplatelet Medication Exception Date * Tobacco Status Documentation Date * Tobacco Status

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

1/1/2017 to 12/31/2017

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

1. *Clinician: Clinician*
2. *Population: Population*

[Response Begins]

Clinician: Group/Practice

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

2018

Patients: 307,158

Medical Groups: 103

Clinics: 669

Clinics with ≥ 30 eligible: 618 clinic sites and 306,509 patients

Clinics with < 30 eligible: 51 clinic sites with 649 patients

Includes all primary care and endocrinology clinics in MN; rates for public reporting and associated reliability and clinic level statistics only include those clinic sites with 30 or more eligible diabetic patients meeting denominator criteria; in 2017 dates of service/ 2018 report year this was 618 clinics representing over 306,000 patients. All patients submitted are used to calculate statewide averages, risk adjustment models and aggregate descriptive statistics.

Level of analysis is the clinic site level and the data source is patient level discrete fields submitted from the clinic's electronic medical records systems.

1. 476 clinics had an EMR and pulled all data via query
2. 176 clinics had an EMR and used a combination of query and manual look up for data collection
3. 15 clinics had an EMR and looked up all data manually
4. 1 clinic had a hybrid EMR and paper record system
5. 1 clinic had paper records only

71% of practices are able to extract all of the information needed via query.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Patient level data was submitted from 103 medical groups representing 618 reportable clinics (n ≥ 30) in Minnesota and bordering communities. Data submission is an annual process; for 2017 dates of service reported in 2018, 307,158 patients were submitted for rate calculation and this represents 99.8% of all eligible diabetic patients in MN.

Sampling is allowed for those clinics with paper records or those who have not had their EMR in place for one year prior to the measurement period; in MN there are very few clinics not yet on an EMR. For 2017 dates of service 99.5% submitted total population, 0.5% submitted a sample.

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

Clinic level analysis of rates is conducted only for clinics with ≥ 30 patients (n = 618 clinics)

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

The social risk factors that were available and analyzed include insurance product type and deprivation index as proxies for socioeconomic status and race, Hispanic ethnicity, preferred language and country of origin (RELO) data.

1. Health insurance coverage information is included in the patient level file that is submitted from the medical group and is translated to specific insurance product type (commercial, Medicare, Medicaid, uninsured and unknown). Insurance product type has demonstrated properties for inclusion in risk adjustment models (p-values < 0.01 to 0.02).
2. The deprivation index is a calculation based on US Census Data at the patient's zip code level that considers the percentage of people in that zip code with supplemental nutrition assistance program (SNAP) benefits, in poverty, unemployed, on public assistance and single females with children. The five census variables are centered to zero and are run through a factor analysis to create a single deprivation index for each patient.
3. MNCM considered the inclusion of race, Hispanic ethnicity, preferred language and country of origin (RELO) as potential risk adjustment variables. While there are significant differences in outcome when segmenting the data by RELO variables, these variables are not used in risk adjustment because it is impossible to separate the disparity in outcome between the patient's environment and the clinic's contribution to the disparity specific biases from healthcare providers that influence their interactions with patients.
4. MNCM convened a panel of social science researchers from the University of Minnesota in August 2016 to understand if RELO variables were confounded by the clinic's contribution. For every measure and for every factor, as a group, the researchers were hard pressed to find a conceptual relationship that was not confounded by the clinic's contribution. This is confirmed in the social science literature available on the topic.
5. The panel recommended use of geography instead, specifically neighborhood characteristics which lead to the development of the deprivation index mentioned above.

[Response Ends]

Note: Current guidance for composite measure evaluation states that reliability must be demonstrated for the composite performance measure score.

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

Used paper "Reliability in Provider Profiling" by John L. Adams, Ph.D as a reference

The BETABIN macro was used on each measure (SAS).

1. First, we need to find the provider-to-provider variance:
2. $\sigma^2 = (\alpha\ \beta) / (\alpha + \beta + 1)(\alpha + \beta)^2$
3. $= (6.3684 * 11.1559) / (6.3684 + 11.1559 + 1)(6.3684 + 11.1559)^2$
4. = **0.0125** (plug this value into the reliability equation)
5. Reliability = $\sigma^2 / (\sigma^2 + (p(1 - p)/n))$
6. p = rate
7. n = number of eligible patients
8. Determine reliability rate for each provider.
9. Average the reliability rate.

Beta-binomial model: A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one plan from another. A reliability score greater than or equal to 0.7 is considered very good.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

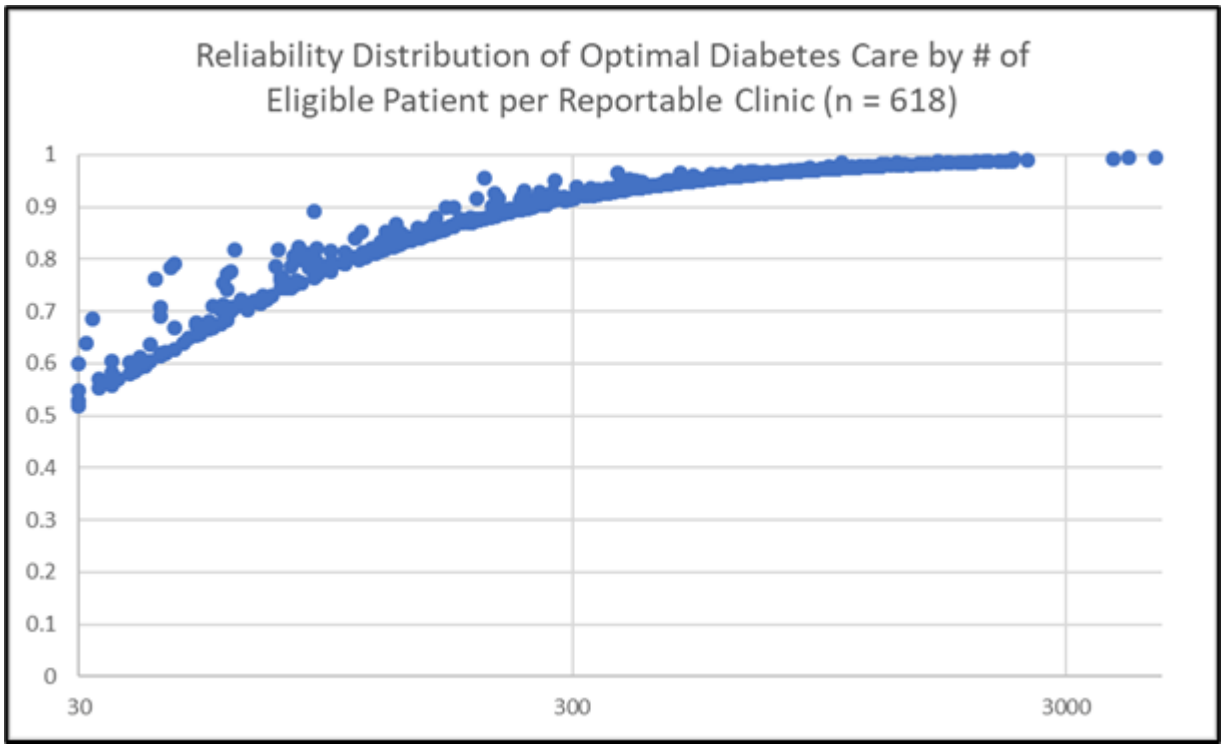
[Response Begins]

2018 Reliability Statistics

618 clinics with 306,509 patients

Logarithmic Scale

Average Reliability: 0.888



Beta-Binomial Reliability Score Distribution for 618 clinics and 306,509 patients; Report Year 2018

Descriptive Statistics

for Reliability Scores

618 observations (clinics)

Mean	0.887818
Median	0.929769
Standard Deviation	0.102883
Minimum	0.519081
Maximum	0.993923

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

In terms of understanding reliability in detecting signal to noise, a reliability score of 0.70 or greater is considered acceptable for drawing conclusions about groups. This data analysis, along with precise specifications and excellent validation results of critical data elements, demonstrates this measure construct to be reliable and detect meaningful differences among provider groups.

[Response Ends]

2b. Validity

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Patient or Encounter-Level (data element validity must address ALL critical data elements)

Accountable Entity Level

Empirical Validity Testing of the Composite (Measure Score)

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Critical Data Elements

Validating the submitted data via the direct data submission process is completed in four steps: denominator certification, data quality checks, validation audit, and the two-week medical group review period.

Denominator certification prior to data collection and extraction/ abstraction ensures that all medical groups apply the denominator criteria correctly and in a consistent manner. MNCM staff review the documentation to verify all criteria were applied correctly, prior to approval for data submission.

Denominator certification documentation for this measure includes:

- Date of Birth (range) Date of Service (range)
- ICD-9 /ICD-10 Codes used
- Eligible specialties and provider types
- Exclusions to the measure and attest to mechanism for exclusions
- Attestations related to changes in medical record or billing systems
- Supplying all query code for review

Following data submission to the MNCM Data Portal, there are additional data quality checks in place for evaluating the accuracy of data submitted. During file upload, program checks for valid dates, codes and values and presents users with errors and warnings. Additionally, MNCM staff review population counts (denominator) and outcome rates for any significant variance from the previous year's submission and may prompt further clarification from the medical group.

Validation audits verify that the clinical data submitted for the numerator component of the measure matched the data in the patient record. Other data elements are also audited to verify the patient was included in the denominator correctly (e.g., diagnosis of diabetes).

[2018] Validation Audit Results

In 2018, for the diabetes measure, MNCM audited 53 medical groups; 37% of those submitting data. 89% passed the initial audit, 11% required a correction plan and all re-submitted their data and passed the audit with ≥ 90% accuracy. Please note that all data elements comprising each component of the composite measure are reviewed against the medical record.

Types of discrepancies and # with issue noted on audit: blood pressure date or values (5), incorrect diabetes type (2), incorrect tobacco status (2), statin medication or date (2), HbA1c date or values, (2) LDL date or values (2), IVD co-morbidity diagnosis (1), and exception for statin or aspirin (1)

Composite Performance Measure Score

Validity was tested for the computed composite score by testing the correlation of medical group performance with their performance on the Optimal Vascular Care measure (NQF# 0076). Ischemic vascular disease and diabetes are chronic conditions that require ongoing management of multiple risk factors to reduce a patient's overall risk of developing long term complications. It is expected that the quality of care provided by a medical group to patients with diabetes would be of similar quality as the care provided to patients with ischemic vascular disease, and the respective performance measure scores should demonstrate this.

Validity Testing Component Measures

Validity was tested for the individual components of the composite measure with correlation analysis (CORR Procedure) and the analysis of rates of all possible combinations of components (e.g. each individual component, aspirin + blood pressure, tobacco + A1c, etc.)

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Critical Data Elements

[2018] 100% of groups achieved the desired > 90% data accuracy when submitted data was compared to medical record data (EMR or paper) of the patient.

Composite Performance Measure Score

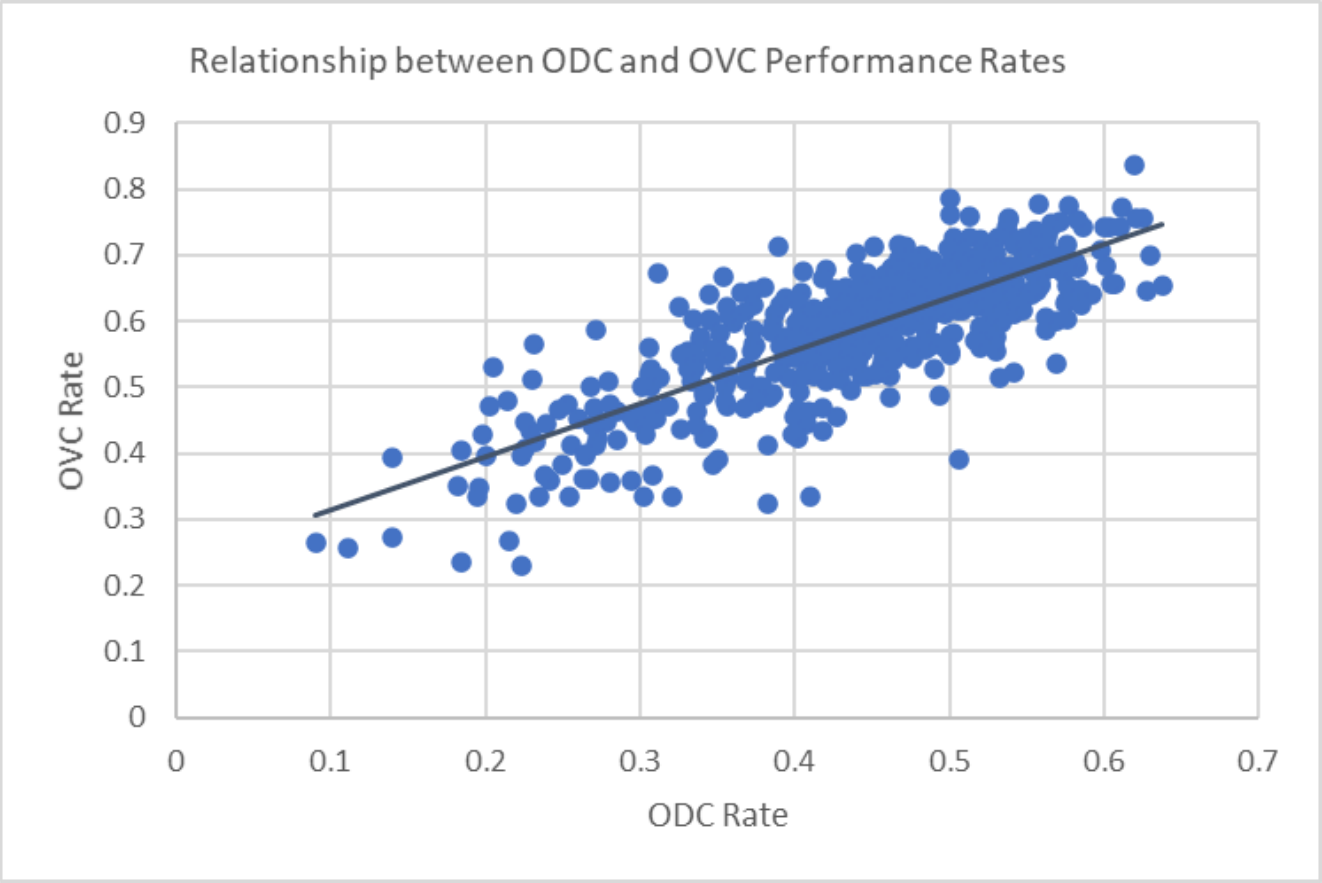
2018 Report Year/ 2017 Dates of Service

618 clinics with 306,509 patients

Correlation of performance with another similar chronic disease composite measure

ODC = Optimal Diabetes Care and OVC = Optimal Vascular Care

r^2 value = 0.629



Correlation between Optimal Diabetes Care and Optimal Vascular Care Measure Rates 2018 Report Year/ 2017 Dates of Service (618 clinics with 306,509 patients)

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

[2018] Based on linear regression analysis, a medical group's performance on the Optimal Diabetes Care measure is associated with its performance on the Optimal Vascular Care measure, as demonstrated by an r^2 value of .629, representing a fairly strong correlation.

Validity testing of the individual components demonstrate strong correlation between the components and the composite measure. Pearson r coefficient values: HbA1c at 0.77714, Blood Pressure at 0.71245, Tobacco Free at 0.54201, Aspirin or Antiplatelet Use at 0.26253, and Statin Use at 0.68083. Please refer to section 2c for statistical results of testing the composite.

[Response Ends]

Note: Applies to the composite performance measure.

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

[Unchanged from 2018 submission] Annual Health Care Quality Report and Health Care Disparities reports available at

https://mncm.org/wp-content/uploads/2020/01/2018-Health-Care-Quality-Report-Final.pdf

Methodology:

Identifying High Performing Medical Groups/Clinics

For each measure, both individual medical group rates and a medical group average rate were calculated. Medical groups that achieved high performance were identified by comparing the individual medical group/clinic rate with the medical group average. Medical groups that had rates that were fully above the medical group average and 95 percent confidence intervals were noted as high performers.

Additionally, the Top 15 performers are identified.

Identifying Medical Groups and Clinics with Biggest Improvements

For each measure, individual medical group and clinic rates during report year 2017 were compared with their rates during report year 2016, calculating an absolute percentage point difference. Medical groups and clinics with the largest percentage point increases were identified.

Medical Group and Clinic Performance Over Time (Three Years)

This analysis was done to determine patterns of medical group and clinic performance over time per measure. Patterns were reviewed for the three reporting years (2015, 2016 and 2017).

The percent and number of medical groups were reported for each of the following patterns of rate changes over the past three years for each measure:

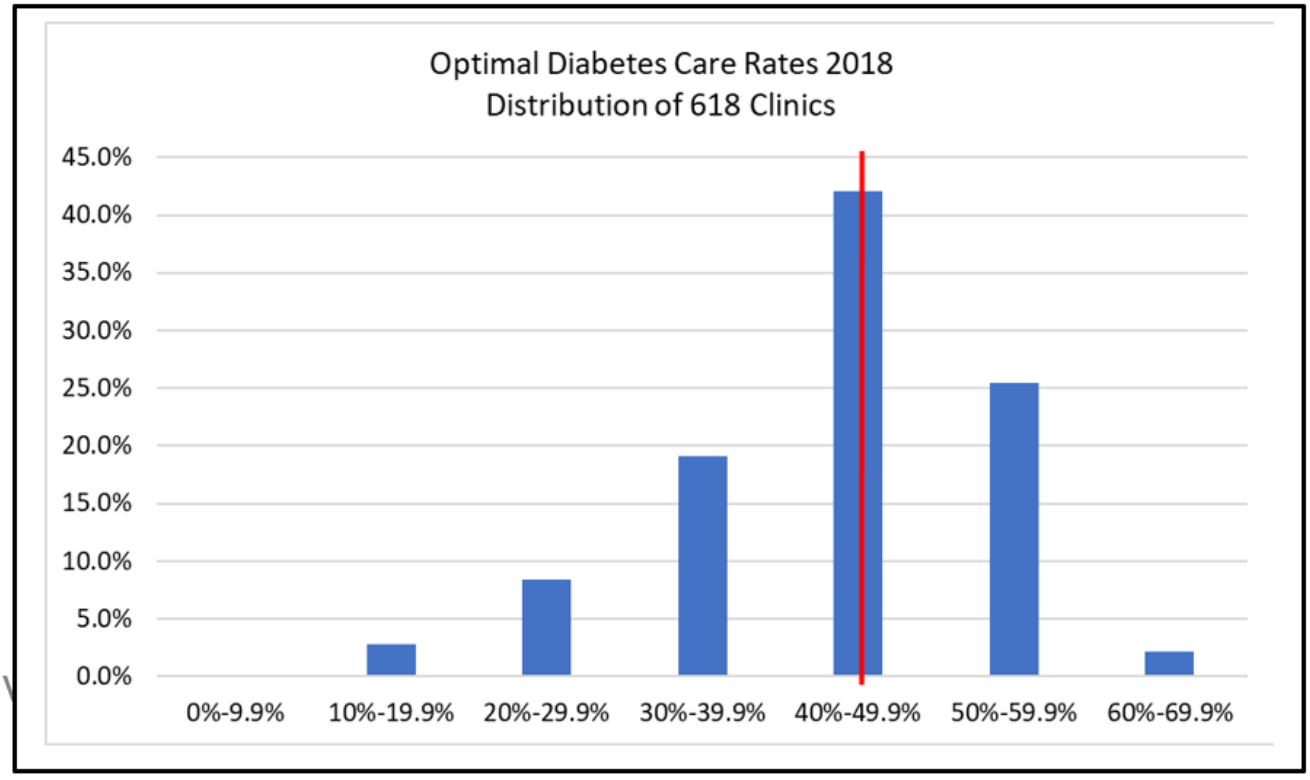
- Consistently improved: Medical groups with more than a two percentage point increase between each consecutive year.
- Relatively stable: Medical groups that had no more than a two percentage point increase or decrease between each consecutive year (-2 percent – +2 percent).
- Consistently decreased: Medical groups with more than a two percentage point decrease between each consecutive year.
- Variable performance (with an improvement or with a decline): Medical groups with an up/down pattern that was not consistent and did not fall into one of the other categories.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]



Distribution of Optimal Diabetes Care Composite Rates; 618 clinics with a statewide average of 44.9%

Performance Rates Over Time

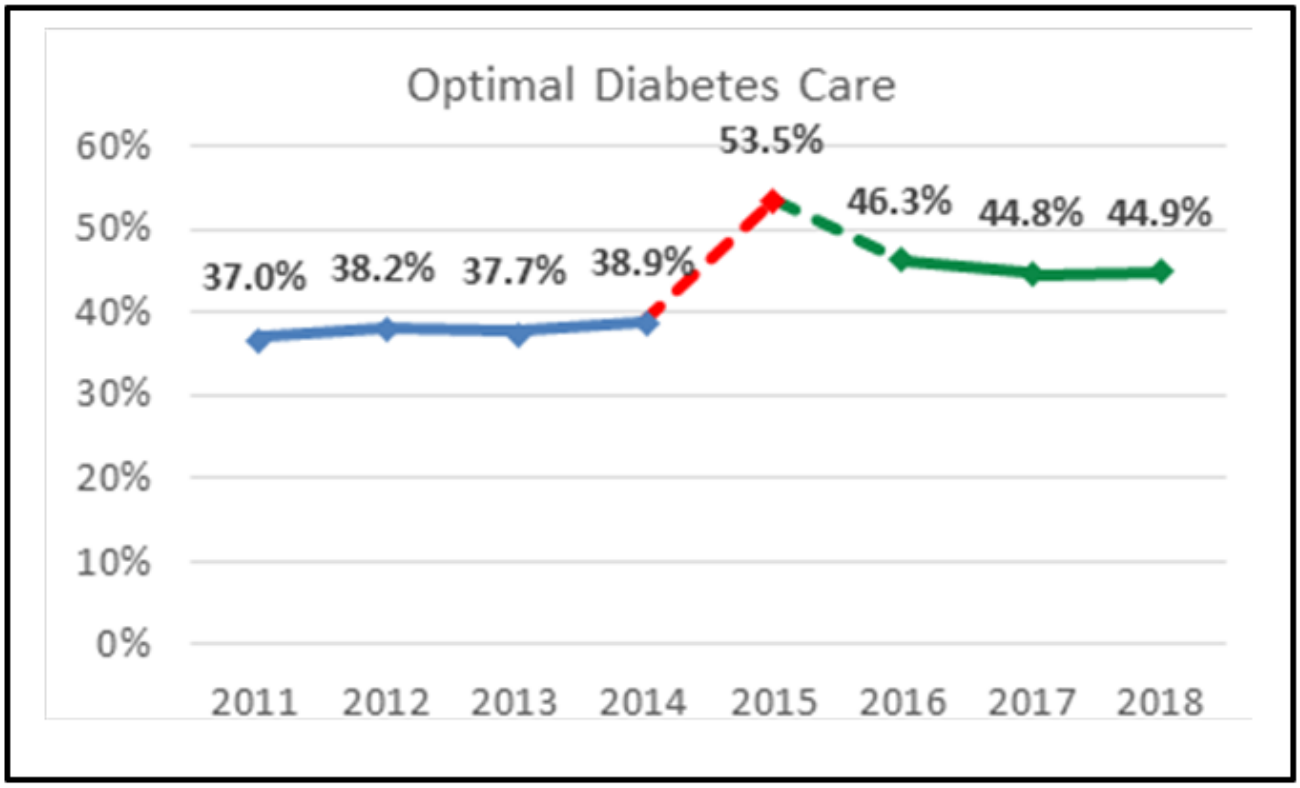
Report Year	Statewide Average	Numerator	Denominator
2018	44.9%	137,985	307,158
2017^	44.8%	132,106	295,049
2016+	46.3%	119,194	257,078
2015*	53.5%	131,847	249,878
2014	38.9%	90,499	230,818
2013	37.7%	80,190	208,809
2012	38.2%	73,037	184,234
2011	37.0%	61,930	158,770

* No cholesterol component during redesign

+ New cholesterol component for statin use in place

^ Established patient criteria replaces visit counting

Optimal Diabetes Care Composite Rates over Time



Optimal Diabetes Care Composite Rates over Time

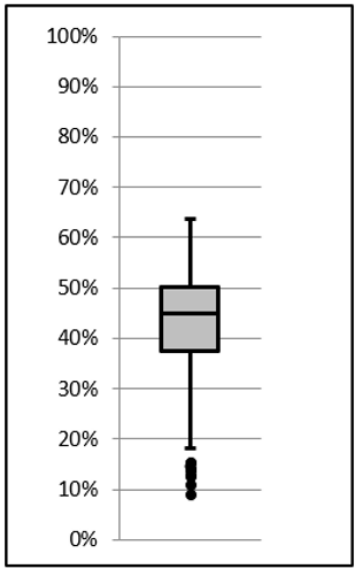
Performance Rates Most Recent Reporting Period

Performance variation 2018 (2017 DOS): (618 reportable clinics)

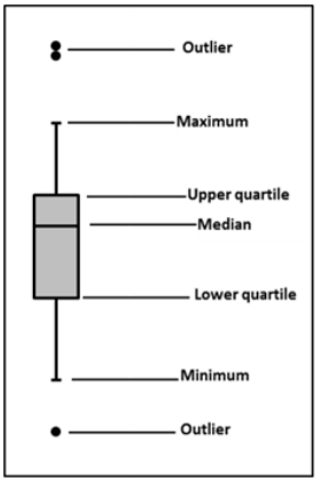
Percentiles:
10th: 28.1%
25th: 37.4%
50th: 45.0%
75th: 50.3%
90th: 55.2%

Range: 9.0% - 63.8%

Mean: 43.2%



BOX PLOT KEY:



* quartile box plot analysis comparing clinic level results includes only clinics with ≥ 30 patients; n = 618 clinics and 306,509 patients

Optimal Diabetes Care Composite Distribution by Percentile and Box Plot Diagram

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

[2018] Measure continues to demonstrate opportunity for improvement as well as statistically significant and clinically meaningful differences between medical group practices and clinics.

[Response Ends]

Note: Applies to the overall composite measure.

2b.08. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

[2018] For this patient level all-or-none composite measure, elements missing from any component (e.g. visit but no blood pressure during the measurement year) are counted as a numerator component fail and therefore the patient would be accounted for and remain in the denominator.

[Response Ends]

2b.09. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

[2018] The impact of missing data on measure calculations is minimal. For 2013 dates of service on over 230,800 diabetic patients submitted for rate calculation two variables were considered 1) with in the appropriate measurement timeframe and 2) valid values submitted:

Variable	Within measure period	Invalid values
A1c	96.8%	0.003%
Blood Pressure	99.8%	0.02%
LDL	89.8%	0.9%

Tobacco Status documented – 99.8%

Aspirin or anti-platelets if IVD- 97.2% had documented aspirin or anti-platelet in the measurement year or the date of a valid contraindication.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

[2018] Patients with missing data are **not** excluded from the measure. Elements missing from any component are counted as a numerator component fail and remain in the denominator.

[Response Ends]

Note: Applies to all component measures, unless already endorsed or are being submitted for individual endorsement.

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

not applicable, only one set of specifications used

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

not applicable, only one set of specifications used

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

not applicable, only one set of specifications used

[Response Ends]

Applies to the composite performance measure, as well all component measures unless they are already endorsed or are being submitted for individual endorsement.

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

No changes in exclusions since the 2018 maintenance endorsement.

Medical groups submitting patient level data to MNCM have the option of either excluding patients appropriately via their EMR query process and provide an attestation through our process of denominator certification and providing their query code for MNCM staff to review and/or submitting a file of excluded patients. Exclusion testing was performed on a sample of groups who submitted files of patients they excluded from the measure. Sample included 11 medical groups representing metro, rural, endocrinology, federally qualified health care centers and teaching/ tertiary. Included were 232 clinics and over 109,000 diabetic patients with dates of service 1/1/2013 to 12/31/2013.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

Use of Denominator Exclusions by Medical Group, Number and Types of Clinic

Medical Group Code	Clinics	Type	Diabetic Patients	Nursing Home	Hospice	Deceased	Coded in Error	Pregnancy	Total
Medical Group A	51	Metro	32,110	0	0	266	09	118	384
Medical Group B	8	Rural	2,588	2	2	33	0	1	38
Medical Group C	12	Rural	3,757	24	1	52	0	8	85
Medical Group D	1	Metro; Endo	80	0	0	1	0	0	1
Medical Group E	39	Metro	17,289	0	0	124	0	30	154
Medical Group F	28	Metro	15,182	61	64	3	0	51	179
Medical Group G	13	Metro, FHQC	5,461	3	1	0	0	1	5
Medical Group H	12	Rural	2,490	0	0	20	0	1	21
Medical Group I	23	Metro	17,628	6	6	95	2	88	197
Medical Group J	44	Metro, Rural	9,733	34	0	1	0	17	52
Medical Group K	1	Metro, Teach	3,346	0	0	1	7	8	16
-	**232**	-	**109,664**	**130**	**74**	**596**	**9**	**323**	**1,132**

Cells marked by a dash (-) are intentionally left blank.

Use of Denominator Exclusions by Medical Group, Number and Types of Clinic

[2018] During the CMS Measure Under Consideration process, the exclusion for “diagnosis coded in error” was removed from the measure specification. Note the above very low occurrence (0.01%). This exclusion had a purpose prior to 2015 because in the ICD-9 classification of disease there was no code to signal a pre-diabetes state to support billing for an A1c test and patients with pre-diabetes were given a 250.xx code for diabetes. With the advent of ICD-10, there is now a code for pre-diabetes [R73.03] and this exclusion is no longer necessary.

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

While the exclusions to this measure are have clinical importance related to patient safety in achieving targets or utilizing medications to reduce cardiovascular risk, the total number of exclusions is relatively small, 1.0% and therefore do not significantly impact measure performance.

[Response Ends]

Note: Applies to all outcome or resource use component measures, unless already endorsed or are being submitted for individual endorsement.

2b.19. Check all methods of controlling for differences in case mix that was used.

[Response Begins]

Statistical risk model with risk factors (specify number of risk factors)

Risk factors are

- patient age (continuous variable)
- insurance product (proxy for socioeconomic status)
- diabetes type (1, 2 or unknown)
- deprivation index (proxy for socioeconomic status based on 5-digit zip code)

Comprised of percentage with SNAP benefits, percentage in poverty, percentage unemployment, percentage on public assistance and percentage single female with child

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

Risk factors are

- patient age (continuous variable)
- insurance product (proxy for socioeconomic status)
- diabetes type (1, 2 or unknown)
- deprivation index (proxy for socioeconomic status based on 5-digit zip code)

Comprised of percentage with SNAP benefits, percentage in poverty, percentage unemployment, percentage on public assistance and percentage single female with child

Since our outcome (dependent) variable is binary (yes/no optimal care was obtained), we use a logistic regression model with the following risk factors included:

- patient age as a continuous variable
- insurance product type as a categorical variable including commercial, Medicare, Medicaid, uninsured, and unknown insurance type as categories, commercial is the reference group in the model, this variable is a proxy for socioeconomic status

- diabetes type as a categorical variable including type 1, type 2 and unknown diabetes type, type 2 is the reference group
- deprivation index as a continuous variable, this variable is a proxy for socioeconomic status based on patient 5-digit zip code, it considers the percentage of people in that 5-digit zip code with SNAP benefits, in poverty, unemployed, on public assistance and single females with children using US Census Data.

Indirect standardization is used for risk adjustment. In this method, **the actual clinic result is not changed**, no matter the degree of patient risk. Instead, an expected value is calculated for each clinic using the logistic regression model run at the patient level and results are aggregated to the clinic level as described above. In this process, the clinics are not to be compared to the state or regional average but instead to their own expected rate. Comparisons between clinics are achieved with a calculation of actual result/expected result and significance testing is performed by using a chi square test.

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

Not applicable.

[Response Ends]

2b.22. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

During the measure development process, the expert panel discusses potential variables for risk adjustment that are important to consider for the measured population. Variables are included in public comment and collected during pilot testing to assess feasibility. For this measure, which has been in place since ~ 2004, MNCM was not the developer but has taken on the stewardship. Variables for risk adjustment have been selected and tested over the years. In addition to our standard demographic variables (gender, age, zip, race/ethnicity, country of origin, primary language and insurance product), we have also assessed clinical variables including type of diabetes, major depression, and ischemic vascular disease. The potential risk adjustment variables are then evaluated for appropriate inclusion in the model based on a t value outside the range of -2.0 and +2.0.

The variables that have been selected are insurance product (commercial, Medicare, MN government programs, self-pay/uninsured), age bands (18-25, 26-50, 51-65 and 65 to 75) and diabetes type (1 or 2) and deprivation index.

Guiding Principles adopted by the MNCM Risk Adjustment & Segmentation Committee (June 2017)

Risk Adjustment: Framework and Guiding Principles For Selecting Risk Factors of Clinical Quality Measures

Risk adjustment refers to statistical methods to control or account for patient-related factors when computing performance measure scores. Risk adjusting outcome performance measures seeks to account for differences in patient health status, clinical factors and, when appropriate, socio-demographic status (SDS). The selection of risk factors for

adjustment of clinical quality performance measure scores is directed by a framework of criteria that must be considered for each factor. The following criteria are to be applied during:

1.) Measure development when recommending variables for data collection and testing for potential risk adjustment, and

2.) Selection of tested variables for the application of risk adjustment.

3.) Reevaluation of currently applied risk adjustment factors

Criteria	**Rationale**
Clinical/conceptual relationship with the outcome of interest	A logical theory must explain the association between the factor and the outcome. Begin with conceptual model informed by research and experience; does not require a direct causal relationship
Empirical association with the outcome of interest	A statistical association to confirm the conceptual relationship
Variation in prevalence of the factor across the measured entities	If there is no variation in prevalence across providers being measured, it will not bias performance results
Not confounded with quality of care – risk factors should: • be present at the start of care and • not represent the quality of care provided (e.g., treatments, interventions, expertise of staff)	Trying to isolate effects of the provider – quality of care Ensures not a result of care provided Although these could explain variation in outcome, trying to isolate differences in performance due to differences in the care provided
Resistant to manipulation or gaming – generally, a diagnosis or assessment data (e.g., functional status score) is considered less susceptible to manipulation than a clinical procedure or treatment (e.g., physical therapy)	Ensures validity of performance score as representing quality of care (vs. for example, up coding)
Accurate data that can be reliably and feasibly captured at a reasonable cost	Data and resource limitations often represent a practical constraint to what factors are included in risk models.
Contribution of unique variation in the outcome (i.e., not redundant or highly correlated with another risk factor)	Prevent over-fitting and unstable estimates, or coefficients that appear to be in the wrong direction, reduce data collection burden
Potentially, improvement of the risk model (e.g., risk model metrics of discrimination – i.e., sensitivity/specificity, calibration) and sustained with cross validation	Change in R-squared or C-statistic may not be significant, but calibration at different deciles of risk might improve May not appear to be a big change but could represent meaningful differences in terms of the outcome (e.g., lives, dollars) Order of entry into a model may influence this result
Potentially, face validity and acceptability	Some factors may not be indicated empirically, but could improve acceptability – need to weigh against negative impact on model, feasibility and burden of data collection

Segmentation

Segmentation is the process of dividing a population into meaningful categories and reporting them separately. For example, the reporting of performance measures by payer type (commercial, Medicare, Medicaid) is appropriate when the differences between the populations are the main objective of the report (to highlight disparities) or when the different groups are independently measured and evaluated. The criteria for the selection of risk adjustment factors and meaningful categories for segmentation are not necessarily identical, as the application of these types of comparative reporting serve different purposes.

Application of Risk Adjustment and Segmentation

When appropriate, risk adjustment and segmentation will be applied to measures as was approved by MARC on March 13, 2013.

Patient age continues as a statistically significant variable for risk adjustment; however, we are now applying age as a continuous variable and not restricting to age band categories. Additionally, insurance product type and diabetes type are also still included in the model and continue to be statistically significant.

Insurance product affects diabetes outcomes as shown in ODC analyses stratified by product (MCHP is Medicaid and Other Purchasers include all other insurance types):

Results of Stratification by Insurance Product

Year	**MHCP Rate**	**MHCP CI (U/L)**	**MHCP Denominator** (patients sampled	**Other Purchaser Rate**	**Difference** (Other - MHCP)
2017	32.5%	32.1% - 33.0%	45,023	47.6%	15.1% **
2016	33.6%	33.2% - 34.1%	36,757	48.9%	15.3%**

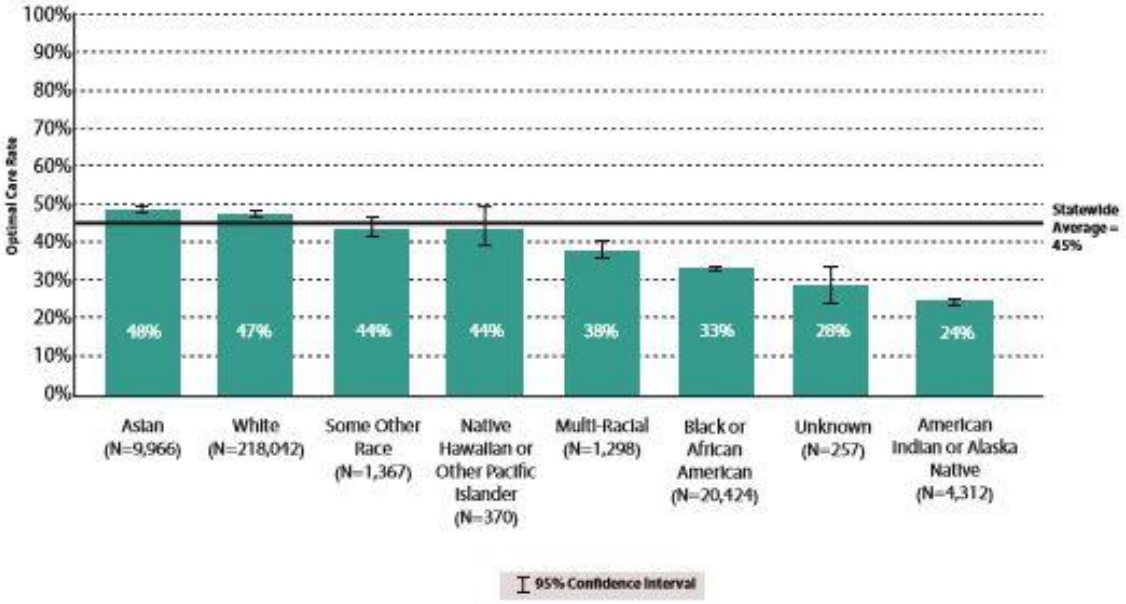
* A confidence interval gives an estimated range of values from a given sample of data. A 95% confidence interval implies a 95 percent level of confidence that the interval includes the true mean of parameter

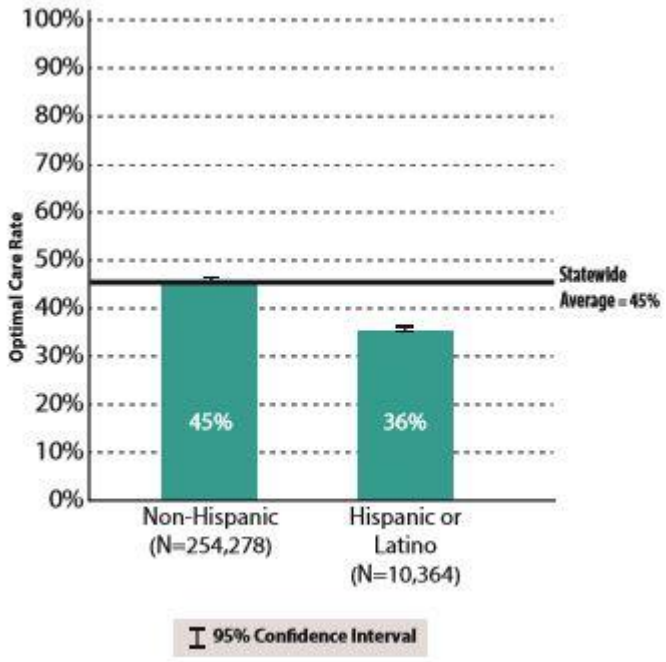
** Denotes statistically significant difference

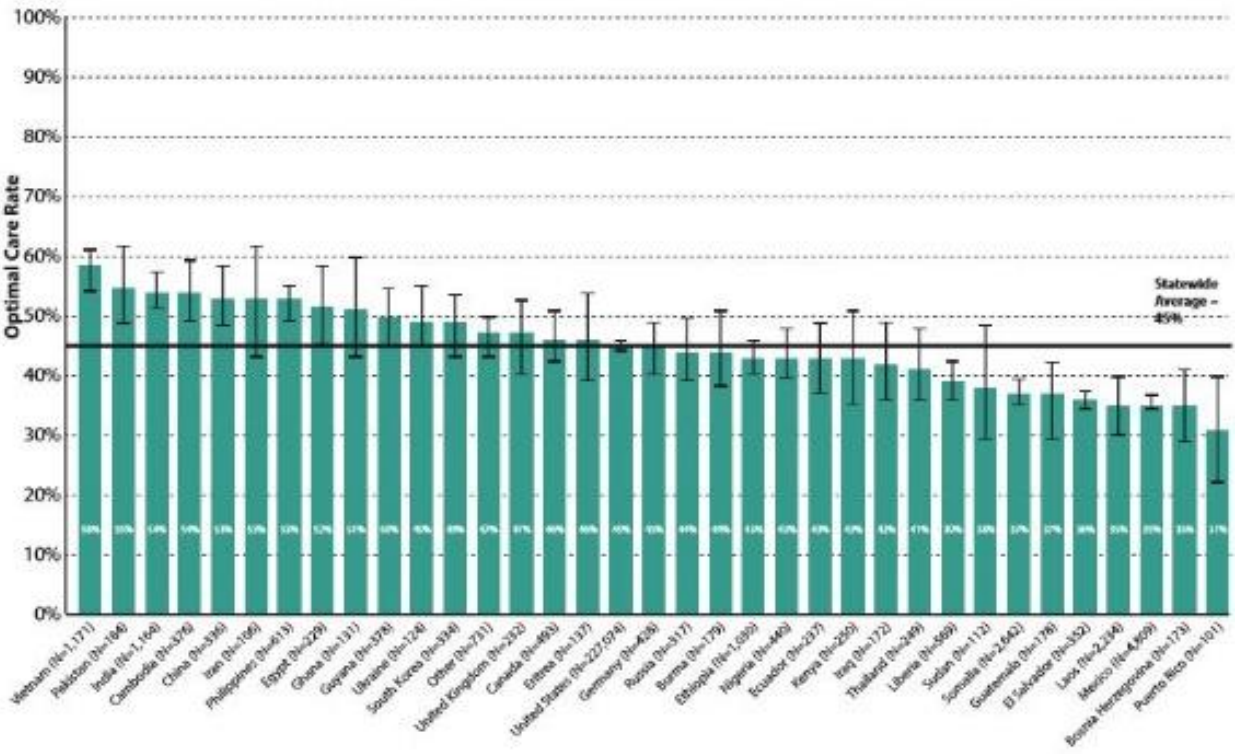
Annual MNCM Health Care Disparities Report

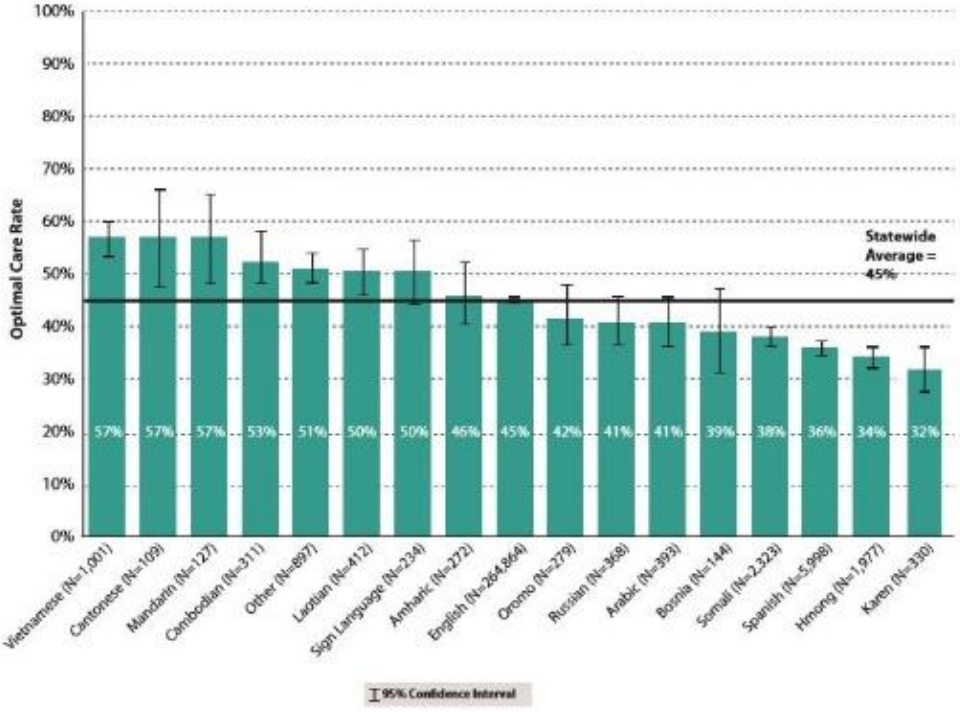
2017-Disparities-Report-FINAL-3.26.2018

Empirical analysis on Race, Ethnicity, Langauage and Country of Origin (RELO) showed that there were differences in diabetes outcomes based on these social risk factors:


100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Optimal Care Rate
48%
47%
44%
44%
38%
33%
28%
24%
Statewide Average = 45%
Asian (N=9,966)
White (N=218,012)
Some Other Race (N=1,367)
Native Hawaiian or Other Pacific Islander (N=370)
Multi-Racial (N=1,298)
Black or African American (N=20,424)
Unknown (N=257)
American Indian or Alaska Native (N=4,312)
95% Confidence Interval


100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Optimal Care Rate
45%
36%
Statewide Average = 45%
Non-Hispanic (N=254,278)
Hispanic or Latino (N=10,364)
95% Confidence Interval



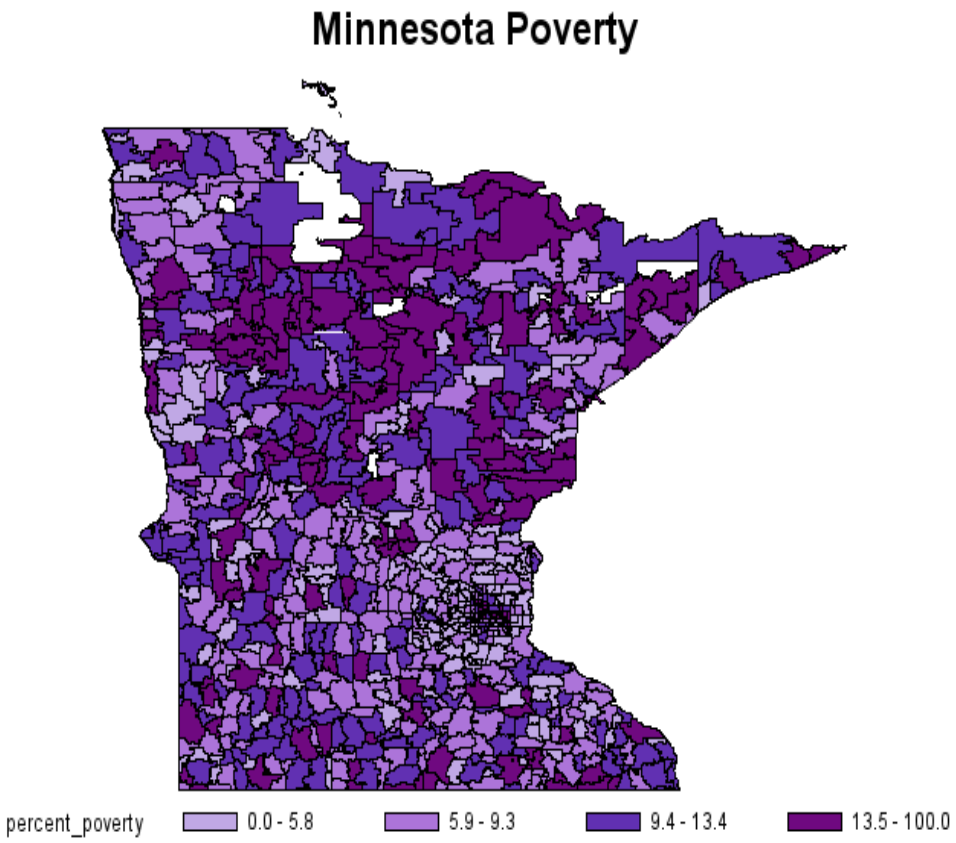


As mentioned in section 2a.08 RELO variables were analyzed and MNCM decided not to use in a risk adjustment capacity. (Excerpt from 2a.08)

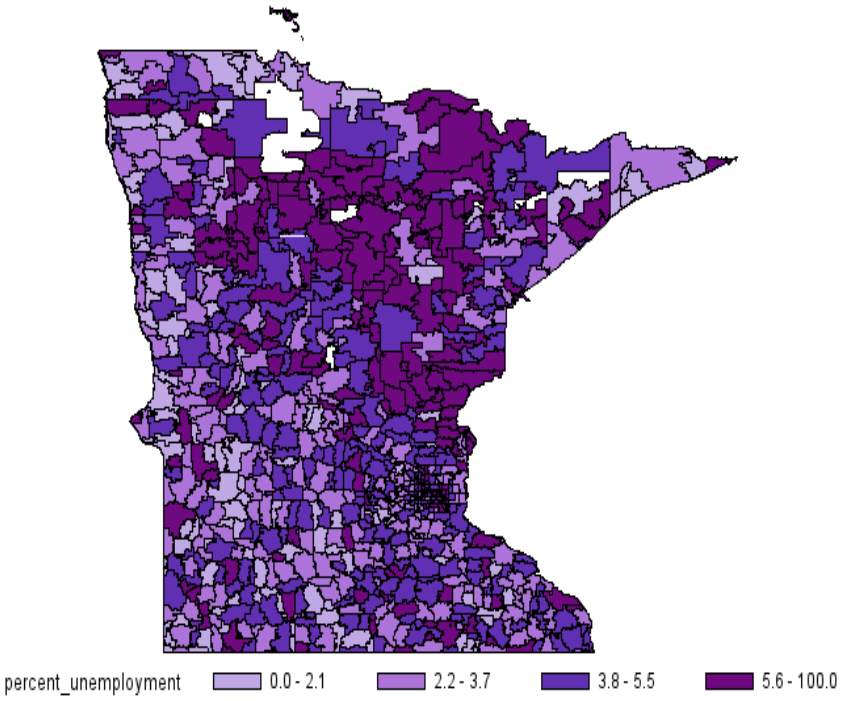
MNCM considered the inclusion of race, Hispanic ethnicity, preferred language and country of origin (RELO) as potential risk adjustment variables. While there are significant differences in outcome when segmenting the data by RELO variables, these variables are not used in risk adjustment because it is impossible to separate the disparity in outcome between the patient's environment and the clinic's contribution to the disparity specific biases from healthcare providers that influence their interactions with patients.

- MNCM convened a panel of social science researchers from the University of Minnesota in August 2016 to understand if RELO variables were confounded by the clinic's contribution. For every measure and for every factor, as a group, the researchers were hard pressed to find a conceptual relationship that was not confounded by the clinic's contribution. This is confirmed in the social science literature available on the topic.
- The panel recommended use of geography instead, specifically neighborhood characteristics which lead to the development of the deprivation index mentioned above.

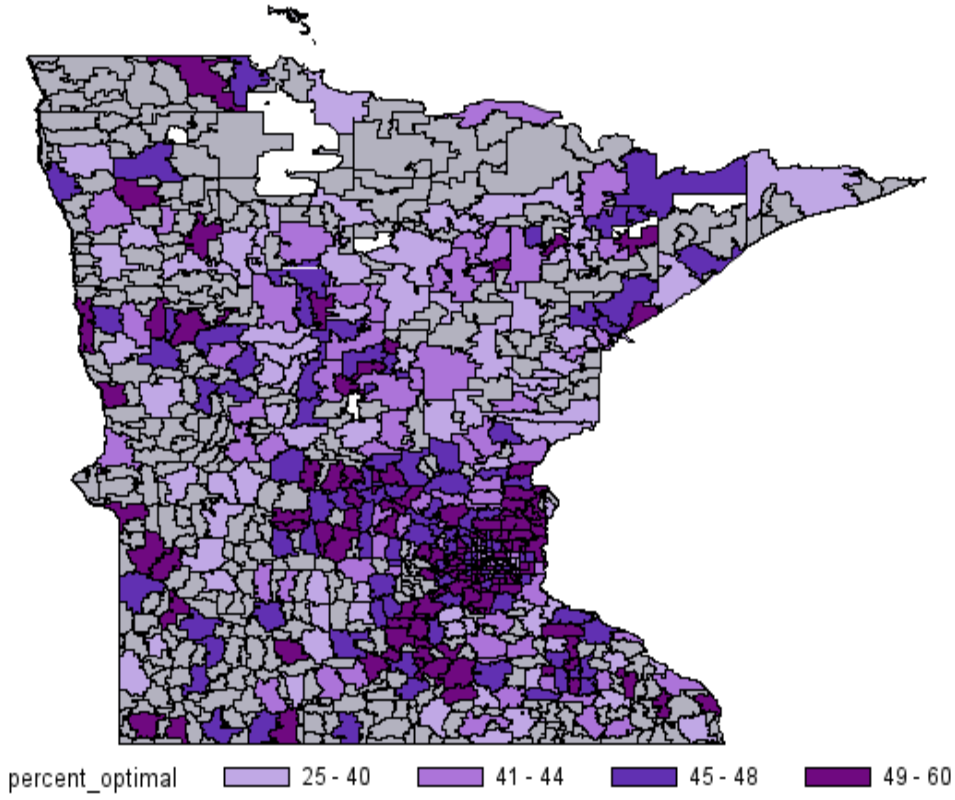
MNCM investigated optimal diabetes care and several social risk factors by patient zip code and observed that there is significant variation by location:



Minnesota Unemployment



Minnesota ODC



Stratification of Optimal Diabetes Care Rates by Minnesota County

These empirical results led us to the development of the deprivation index which is described in detail in section 2a.08 and in section 2b.25. The deprivation index calculated from U.S. Census information on socioeconomic factors based on the patient's 5-digit zip code.

[Response Ends]

2b.23. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

Internal data analysis

[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

[2018] The effect of risk adjustment on clinic ranking was examined. First, the clinic's unadjusted and adjusted quality measures were compared using correlation analysis. Pearson's correlation examined the correlation when the measures are treated as continuous measures. A high correlation (close to 1) means that the two measures strongly co-vary, when one is high the other is high.

The second comparison ranked the clinics into performance rank deciles based on the unadjusted and adjusted scores and then examines how decile rankings based on unadjusted measures compared to decile rankings based on adjusted measures. The third comparison ranks clinics into Below Average, Average, and Above Average categories using statistical methods that consider the quality measure's confidence interval which is calculated based on the number of patients each clinic report. These two methods are compared directly in our accompanying report on the quality deviations ranking approach.

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

[2018] Because ODC is a binary variable (0 or 1), the risk adjustment model was estimated using a logistic model implemented in the SAS Logistic Procedure that accounts for its non-continuous nature. The risk adjusters and an indicator for each clinic were included in the model. The estimated coefficient for the clinic indicator measures the clinic's ODC adjusting for the patient risk adjusters that were included in the model. The clinic level indicator was used to construct a risk adjusted ODC score at the clinic level that ranged from 0 to 1 (0% to 100%). The effect of risk adjustment

on clinic rankings was calculated by comparing the risk adjusted ODC to the unadjusted ODC measure, the average ODC for all patients reported by the clinic.

The social risk factors included in our model are patient's insurance type and a deprivation index which have been described above. Because deprivation index is a new risk factor since our last submission, a description of the process used to determine inclusion of the deprivation index in our risk adjustment model is included.

Summary of MNCM Study: Impact of Adjusting Measures for Patients' Neighborhood Socio-Economic Status

Reminder of Goal and Methodology:

- Goal: to isolate the clinic/medical group's true impact on patients' health and allow them to be compared more easily.
- MNCM utilizes an indirect standardization methodology for risk adjustment.
- Each clinic/medical group's rate is compared to a unique benchmark rate for that clinic/medical group that is based on the mix of patient risk seen at that clinic/medical group

Study question:
How to measure the impact of where patients live on MNCM quality measures?
1. Literature Review

- We examined published, peer-reviewed articles on the creation of a measure for areas socioeconomic status (SES).
- Key findings:
    - Census data at the ZIP code level is typically used
    - There was not consistent evidence that a more granular geographical unit (Census Track, Census Block) always produced more significant results. It was very measure and situation dependent.
    - Principal Components Analysis is use
    - A Deprivation Index is generated

2. Variable Selection
In line with published literature, we chose the following variables (from the 2015 census data) to evaluate for our deprivation index:

- % with SNAP benefits
- % in poverty
- % unemployment
- % on public assistance
- % single female w/ child

Staff note: Median Income was tested and not retained as a component of the index because this variable behaves differently from the other variables listed above

3. Correlation Analysis
The high correlation coefficients among the selected variables told us that these variables are likely to converge together into a single deprivation index.

- All correlations significant (p<.0001)

*	**% with SNAP benefits**	**% in poverty**	**% unemployment**	**% on public assistance**	**% single female w/ child**
% with SNAP benefits	1	0.82	0.82	0.99	0.77
% in poverty	-	1	0.71	0.83	0.75

*	% with SNAP benefits	% in poverty	% unemployment	% on public assistance	% single female w/ child
% unemployment	-	-	1	0.83	0.65
% on public assistance	-	-	-	1	0.78
% single female w/ child	-	-	-	-	1

* Cell intentionally left empty

4. Variables' contribution to the model

We evaluated the impact of our deprivation index on already established risk adjustment models for four of our quality measures: depression remission at 12 months, asthma (both adult and pediatric populations) and colorectal cancer screening.

Variables' contribution was assessed through logistic regression by comparing R2 values (a measure of a model explanatory power) and comparing variable standardized estimate values (a measure of the "importance" of each variable in a model). Below are the results of the analyses:

- The depression remission at 12 months measure is adjusted by insurance product, initial depression severity, age and we added the deprivation index. Here are the results obtained through logistic regression:
  - Patient level R2: 0.0089 (vs. 0.0085 without the deprivation index)
  - All control variables reach statistical significance (p <.0001)

For the ODC patient population, the Deprivation Index ranges from -6.84 to 1.42. The index is centered at 0 and a higher number indicates a higher socioeconomic level.

The table below is a snapshot of a larger table that shows the impact of the deprivation index. The larger table included clinics with 750-1250 patients and ranked the clinics by impact of adding the zip code deprivation index to the indirect standardization risk adjustment model. The smaller snapshot table (next page) shows the 10 clinics where the expected value (indirect standardization) is increased the most by the addition of the deprivation index and the 10 clinics where the expected value is decreased the most with the addition of the deprivation index. It is important to note that the 10 clinics with raised expected values are all in wealthier suburbs and the 10 with lower expected values are either rural or inner city. This is exactly the result that was anticipated and shows that the deprivation index is working as expected.

Sample Impact of Adding Zip Code Level Economic Averages to the 2017 Diabetes Measure

Clinics with 750 to 1,250 patients

Clinic	Patients	Actual Rate	Expected Rate without SES	Expected Rate with SES	Rate Difference	Impact of SES Variable	Change in significance Test
1	970	48.1%	43.8%	45.6%	1.8%	raised expectation	Above to Average
2	834	45.2%	44.7%	46.4%	1.6%	raised expectation	*
3	873	46.2%	44.5%	45.9%	1.5%	raised expectation	*
4	1001	54.8%	46.7%	48.2%	1.4%	raised expectation	*
5	1092	47.0%	45.9%	47.3%	1.4%	raised expectation	*

Clinic	Patients	Actual Rate	Expected Rate without SES	Expected Rate with SES	Rate Difference	Impact of SES Variable	Change in significance Test
6	1079	51.8%	45.6%	46.9%	1.3%	raised expectation	*
7	930	51.8%	47.1%	48.5%	1.3%	raised expectation	*
8	871	35.6%	48.6%	49.9%	1.3%	raised expectation	*
9	827	51.8%	46.1%	47.3%	1.3%	raised expectation	*
10	1034	51.1%	45.1%	46.3%	1.3%	raised expectation	*
…	…		…	…	…	…	…
78	829	41.0%	43.8%	42.2%	-1.6%	lowered expectation	*
79	711	45.9%	43.5%	41.7%	-1.8%	lowered expectation	Average to Above
80	906	30.4%	45.9%	44.1%	-1.8%	lowered expectation	*
81	1097	44.3%	44.4%	42.5%	-1.9%	lowered expectation	*
82	1030	42.9%	45.8%	43.9%	-2.0%	lowered expectation	Below to Average
83	1093	46.2%	44.3%	42.1%	-2.2%	lowered expectation	Average to Above
84	1107	35.8%	41.4%	38.8%	-2.6%	lowered expectation	*
85	914	44.5%	47.2%	44.6%	-2.7%	lowered expectation	*
86	709	40.3%	40.7%	37.6%	-3.1%	lowered expectation	*
87	1057	18.5%	36.2%	33.0%	-3.2%	lowered expectation	*
88	703	30.7%	40.6%	37.2%	-3.4%	lowered expectation	*
89	833	37.3%	40.9%	37.5%	-3.4%	lowered expectation	Below to Average

* Cell intentionally left empty

Example of Detail Level to Understand Impact of Segmentation by Neighborhood Socioeconomic Status

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

[2018] Because ODC is a binary variable (0 or 1), the risk adjustment model was estimated using a logistic model implemented in the SAS Procedure Logistic that accounts for its non-continuous nature. The risk adjusters and an

indicator for each clinic were included in the model. The estimated coefficient for the clinic indicator measures the clinic's ODC adjusting for the patient risk adjusters that were included in the model. The clinic level indicator was used to construct a risk adjusted ODC score at the clinic level that ranged from 0 to 1 (0% to 100%). The effect of risk adjustment on clinic rankings was calculated by comparing the risk adjusted ODC to the unadjusted ODC measure, the average ODC for all patients reported by the clinic.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

[2018] At the clinic level, the average ODC measure was 35.1% (standard deviation = 12%). The average number of patients reported by a clinic was 348 (standard deviation = 405). At the patient level, the average ODC was 39.7%. The average age in the examined population was 58, 46% were female, 7.3% had Type I diabetes, 19.6% were depressed, 48.8% had commercial insurance, 33.1% had Medicare coverage, and 7.1% had Medicaid coverage.

Risk adjustment is necessary only when there is heterogeneity across clinics. There was significant heterogeneity across clinics in insurance product mix ($\chi 2 = 65617$, $p < .001$), patient age ($\chi 2 = 12522$, $p < .001$), gender ($\chi 2 = 5256$, $p < .001$), depression ($\chi 2 = 4290$, $p < .001$), Type 1 Diabetes ($\chi 2 = 67297$, $p < .001$), and distance to the clinic ($\chi 2 = 63638$, $p < .001$).

At the clinic level*, the average ODC measure was 43.2% (standard deviation = 10.2%). The average number of patients reported by a clinic was 495 (standard deviation = 519). At the patient level**, the average ODC was 44.9%. The average age in the examined population was 58, 54% were male, 8.0% had Type I diabetes, 40.5% had commercial insurance, 36.4% had Medicare coverage, 15.0% had Medicaid coverage and 2.7% had no insurance.

* When evaluating rates and comparison among clinics, a clinic is only included in the analysis if they have $\geq$ 30 eligible patients in the measurement period (calendar year).

** When evaluating the entire population (statewide), all eligible patients submitted for rate calculation are included even if their clinic's number of eligible patients was < 30.

Pearson Correlation Coefficient Correlation between specific risk variable and overall result Value between -1 and 1 where 1 is a total positive correlation and -1 is a total negative correlation	*
Variable	Pearson
Gender	0.081
Patient Age	0.233
Diabetes Type- Type 1	-0.058
Insurance Product	
Commercial	0.424
Medicare	0.151
Medicaid	0.151

Pearson Correlation Coefficient **Correlation between specific risk variable and overall result** **Value between -1 and 1 where 1 is a total positive correlation and -1 is a total negative correlation**	*
Uninsured	-0.293
Deprivation Index (socioeconomic ratio for patient zip code)	0.398

* Cell intentionally left empty

T-Tests for Insurance Product and Diabetes Type Variables

Independent groups t-tests comparing insurance product type groups with Commercial*

*	N	Optimal Care Rate	T value	p-value
Commercial	127,849	44.95%	*	*
Medicare	111,797	51.37%	-31.44	<0.001
Medicaid	45,743	32.65%	70.54	<0.001
Uninsured	8,203	26.69%	48.33	<0.001
Unknown	13,566	43.91%	-16.43	<0.001

* Cell intentionally left empty

Independent groups t-tests comparing diabetes type groups with type 2*

*	N	Optimal Care Rate	T value	p-value
Type 1	23,157	34.71%	-32.72	<0.001
Type 2	282,681	45.82%	*	*
Unknown	1,370	32.30%	10.56	<0.001

* Cells intentionally left empty as this is the comparative value

Pooled t-tests were calculated when variances were equal and Satterthwaite were calculated when variances were unequal

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

Logistic Regression Output Results for Each Variable

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr >ChiSq
Intercept	1	-1.5500	0.0232	4479.8773	<.0001
Patient_Age	1	0.0252	0.000405	3857.8729	<.0001
Medicare	1	-0.0521	0.00961	29.3463	<.0001
Medicaid	1	-0.4350	0.0118	1354.3824	<.0001
Uninsured	1	-0.7222	0.0259	776.4681	<.0001
Unknown	1	-0.1363	0.0185	54.3630	<.0001
Type1	1	-01673	0.0153	119.4319	<.0001
Unk_type	1	-0.4271	0.0603	50.2018	<.0001
Dep_Index	1	0.1346	0,00459	858.3075	<.0001

Logistic Regression Output Results for Each Variable

Pearson Correlation Coefficients, N = 307,158

Prob > [r] under H0: Rho=0

*	medicare	medicaid	commercial	uninsured	unknown	patient_age	type1	type2	unk_type	dep_index
medicare	1	-0.31644	-0.63877	-0.12531	-0.16261	0.52416	-0.11265	0.11081	-0.00408	0.01944
	*	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	0.0237	<.0001
medicaid	-0.31644	1	-0.35322	-0.06929	-0.08992	-0.20847	0.00133	-0.00469	0.01404	-0.20136
	<.0001	*	<.0001	<.0001	<.0001	<.0001	0.4613	-0.0094	<.0001	<.0001
commercial	-0.63877	-0.35322	1	-0.13987	-0.18151	-0.324	0.10372	-0.09962	-0.0062	0.13291
	<.0001	<.0001	*	<.0001	<.0001	<.0001	<.0001	<.0001	0.0006	<.0001
uninsured	-0.12531	-0.06929	-0.13987	1	-0.03561	-0.09471	-0.01518	0.01549	-0.00286	-0.0588
	<.0001	<.0001	<.0001	*	<.0001	<.0001	<.0001	<.0001	0.1134	<.0001
unknown	-0.16261	-0.08992	-0.18151	-0.03561	1	-0.0146	0.02456	-0.02451	0.00235	0.03067
	<.0001	<.0001	<.0001	<.0001	*	<.0001	<.0001	<.0001	0.1928	<.0001

*	medicare	medicaid	commercial	uninsured	unknown	patient_age	type1	type2	unk_type	dep_index
patient_age	0.52416	-0.20847	-0.324	-0.09471	-0.0146	1	-0.30913	0.30708	-0.0236	0.06906
	<.0001	<.0001	<.0001	<.0001	<.0001	*	<.0001	<.0001	<.0001	<.0001
type1	-0.11265	-0.11265	0.00133	0.10372	-0.01518	-0.30913	1	-0.9704	-0.01876	0.03128
	<.0001	0.4613	<.0001	<.0001	<.0001	<.0001	*	<.0001	<.0001	<.0001
type2	0.11081	-0.00469	-0.09962	0.01518	-0.02451	0.30708	-0.9704	1	-0.22326	-0.02747
	<.0001	0.0094	<.0001	<.0001	<.0001	<.0001	<.0001	*	<.0001	<.0001
unk_type	-0.00408	0.01404	-0.0062	-0.00286	0.00235	-0.0236	-0.01876	-0.22326	1	-0.01252
	0.0237	<.0001	0.0006	0.1134	0.1928	<.0001	<.0001	<.0001	*	<.0001
dep_index	0.01944	-0.20136	0.13291	-0.0588	0.03067	0.06906	0.03128	-0.02747	-0.01252	1
	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	*

* Cell intentionally left empty

Correlation Output Results for Each Variable

[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

Comparison of Unadjusted and Adjusted Decile Ranks (N/Percent of Row)

Risk Adjusted Decile Rank

Unadjusted Decile Rank	0% to 10%	10% to 20%	20% to 30%	30% to 40%	40% to 50%	50% to 60%	60% to 70%	70% to 80%	80% to 90%	90% to 100%	Total
0% to 10%	0/0.00^	0/0.00	0/0.00	1/100.00+	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	1
10% to 20%	0/0.00	0/0.00^	0/0.00	8/44.44+	10/55.56+	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	18

Unadjusted Decile Rank	0% to 10%	10% to 20%	20% to 30%	30% to 40%	40% to 50%	50% to 60%	60% to 70%	70% to 80%	80% to 90%	90% to 100%	Total
20% to 30%	0/0.00	0/0.00	0/0.00^	21/41.18+	30/58.52+	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	51
30% to 40%	0/0.00	0/0.00	0/0.00	18/15.00^	102/85.00+	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	120
40% to 50%	0/0.00	0/0.00	0/0.00	9/3.42*	248/94.30^	6/2.29+	0/0.00	0/0.00	0/0.00	0/0.00	263
50% to 60%	0/0.00	0/0.00	0/0.00	0/0.00	151/98.69*	2/1.31^	0/0.00	0/0.00	0/0.00	0/0.00	153
60% to 70%	0/0.00	0/0.00	0/0.00	0/0.00	11/91.67*	1/8.33*	0/0.00^	0/0.00	0/0.00	0/0.00	12
70% to 80%	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00^	0/0.00	0/0.00	0
80% to 90%	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00^	0/0.00	0
90% to 100%	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00^	0
Total	0	0	0	57	552	9	0	0	0	0	618

Cells shaded gray/ ^ symbol indicate no change in rank. Cells shaded blue/ + symbol indicate an increase in rank after risk adjustment and green cells/ * symbol indicate a decrease in rank after risk adjustment. N is the number of clinics in each cell and the percent of the row is the precent of the total unadjusted decile ranked clinics in each cell.

Comparison of Adjusted and Unadjusted Clinic Ratings

Impact of Risk Adjustment on Clinic Level Measurement (N/Overall Percent)

*	With Risk Adjustment	With Risk Adjustment	With Risk Adjustment	With Risk Adjustment
Without Risk Adjustment	Below Expected	As Expected	Above Expected	Total Counts
Below	125/20.2%^	38/6.2%+	0/0.0%	163
Average	8/1.3%*	282/45.6%^	7/1.1%+	297
Above	0/0.0%	63/10.2%*	95/15.3%^	158
Total Counts	133	383	102	618

Cells marked by a dash (-) are intentionally left blank.

Cells shaded gray/ ^ symbol indicate no change in rank. Cells shaded blue/ + symbol indicate an increase in rank after risk adjustment and green cells/ * symbol indicate a decrease in rank after risk adjustment. ** Cell intentionally left empty

Impact of Adjustment on Clinic Rankings

Direction of Impact	N	Percent
Moved toward As Expected	101	16.3%
Moved Away from Average	15	2.4%
Improved	45	7.3%

Direction of Impact	N	Percent
Worse	71	11.5%
Impacted	116	18.8%

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

[2018] NA, measure is not stratified.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

Our analysis of risk adjustment factors for the Optimal Diabetes Care measure indicates that age, diabetes type, deprivation index and insurance product variables are related to ODC and warrant attention for risk adjustment.

For most clinics there is no change in clinic ranking due to risk adjustment, although some increase in ranking and others decrease in ranking. For clinics whose rankings are impacted by the risk adjustment, it is valid and based on disparate differences among these clinics.

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

no additional testing

[Response Ends]

Note: If empirical analyses do not provide adequate results—or are not conducted—justification must be provided and accepted in order to meet the must-pass criterion of Scientific Acceptability of Measure Properties. Each of the following questions has instructions on what to provide if no empirical analysis was conducted.

2c.01. Provide empirical analysis demonstrating that the component measures fit the quality construct, add value to the overall composite, and achieve the object of parsimony to the extent possible.

[Response Begins]

Refer to the analysis in subsequent questions. The measure construct of equally weighted components in a patient level all-or-none adds value to the overall composite as each component is important in reducing the modifiable risks associated with the condition of diabetes.

[Response Ends]

2c.02. Describe the method used to support the composite construction.

Describe the steps—do not just name a method; indicate what statistical analysis was used; if no empirical analysis, provide a justification.

[Response Begins]

The methods used for analysis demonstrating soundness of the composite construct include distribution rates of performance for the individual components over time, rates of performance for all possible combinations of the components and Pearson product-moment correlation as a measure of the strength of linear regression of the relationships between the composite and the components.

The Pearson product-moment correlation coefficient (or Pearson correlation coefficient, for short) is a measure of the strength of a linear association between two variables and is denoted by *r*. Basically, a Pearson product-moment correlation attempts to draw a line of best fit through the data of two variables, and the Pearson correlation coefficient, *r*, indicates how far away all these data points are to this line of best fit (i.e., how well the data points fit this new model/line of best fit).

The Pearson correlation coefficient, r, can take a range of values from +1 to -1. A value of 0 indicates that there is no association between the two variables. A value greater than 0 indicates a positive association; that is, as the value of one variable increases, so does the value of the other variable. A value less than 0 indicates a negative association; that is, as the value of one variable increases, the value of the other variable decreases.

The stronger the association of the two variables, the closer the Pearson correlation coefficient, r, will be to either +1 or -1 depending on whether the relationship is positive or negative, respectively. Achieving a value of +1 or -1 means that all your data points are included on the line of best fit - there are no data points that show any variation away from this line. Values for r between +1 and -1 (for example, r = 0.8 or -0.4) indicate that there is variation around the line of best fit. The closer the value of r to 0 the greater the variation around the line of best fit.

[Response Ends]

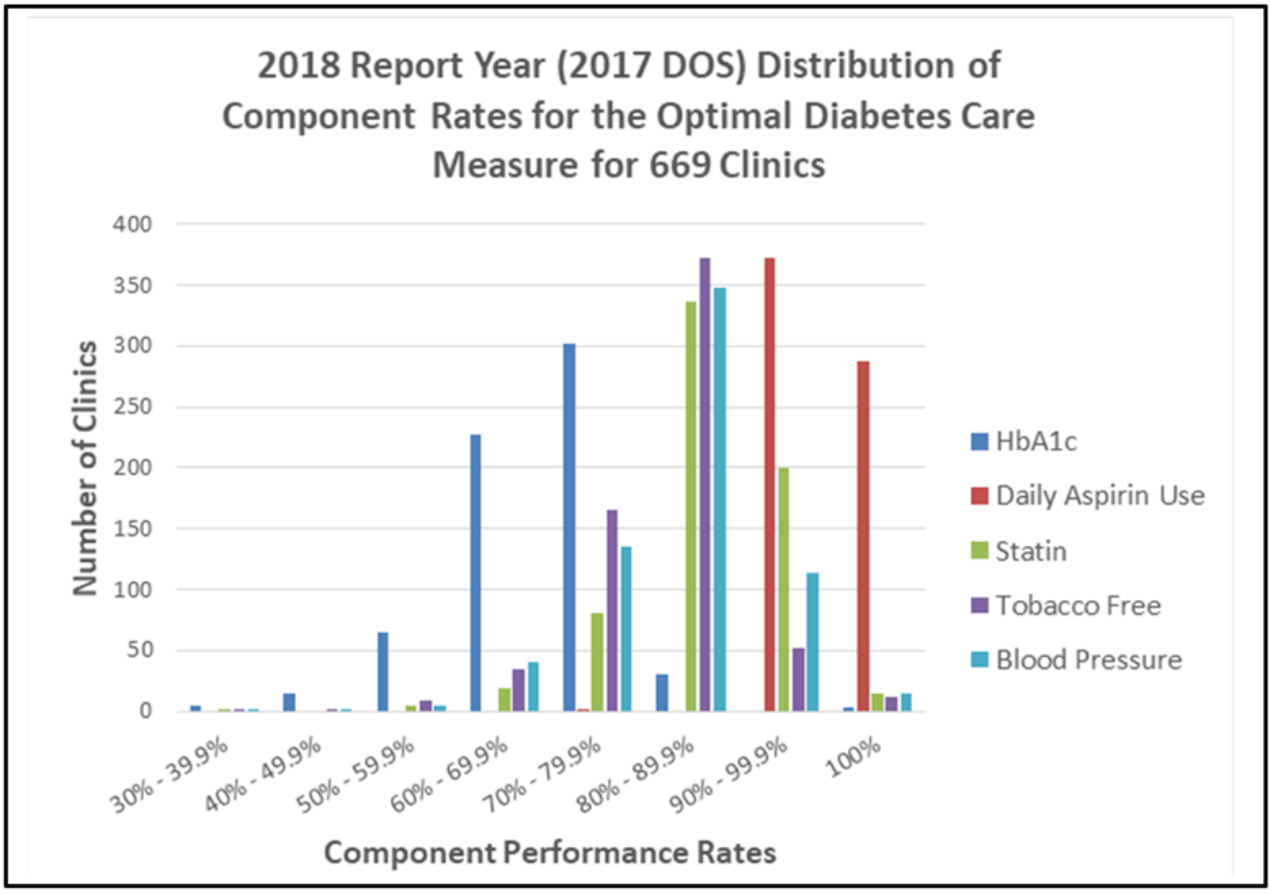
2c.03. Provide the statistical results obtained from the analysis of the components.

Examples include correlations, contribution of each component to the composite score, etc.; if no empirical analysis, identify the components that were considered and the pros and cons of each.

[Response Begins]

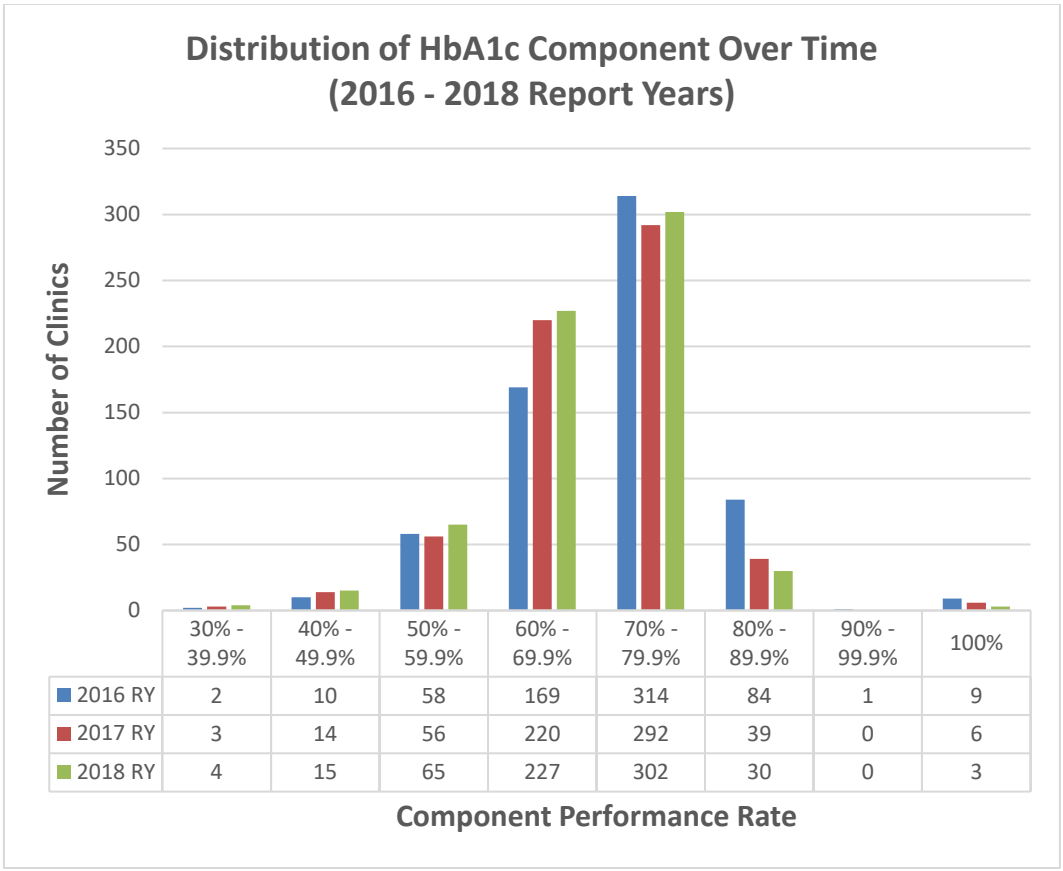
Composite Component Testing Distribution of Component Rates by Clinic In Relation to Each Other and Over Time

Proportion of how many patients are meeting component targets (2018)

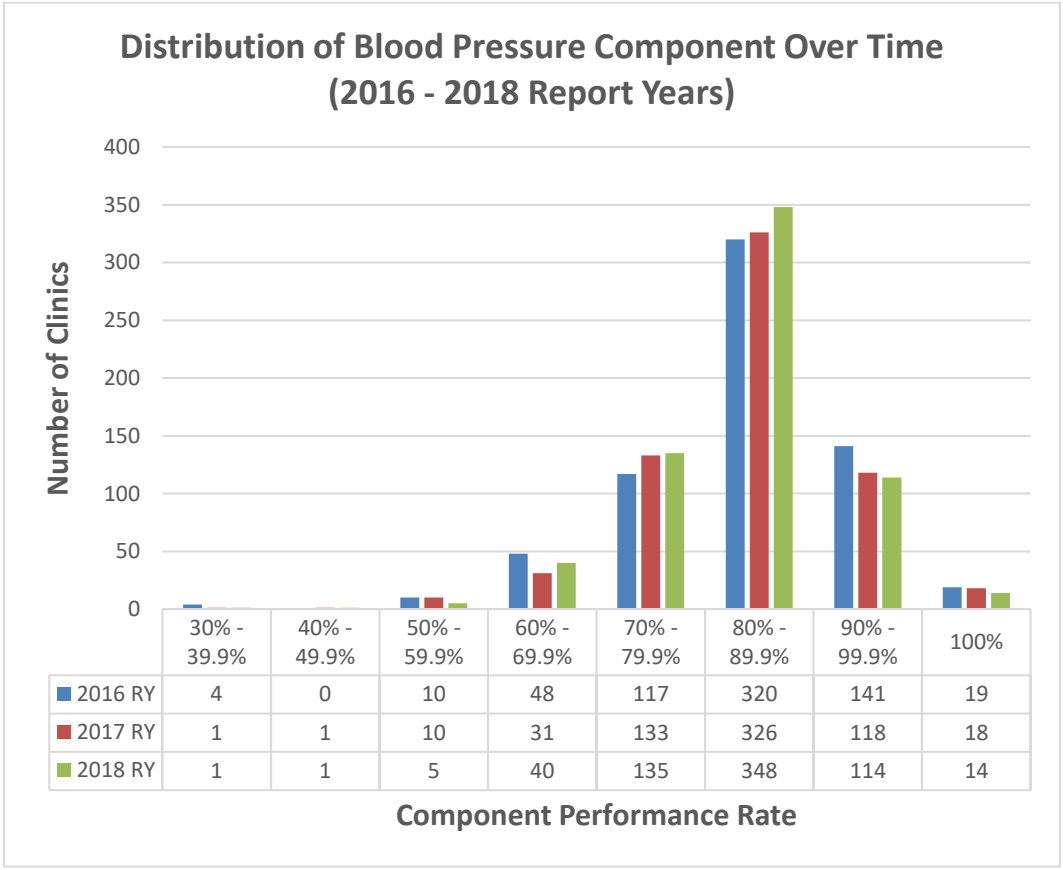


Distribution of Component Rates by Clinic

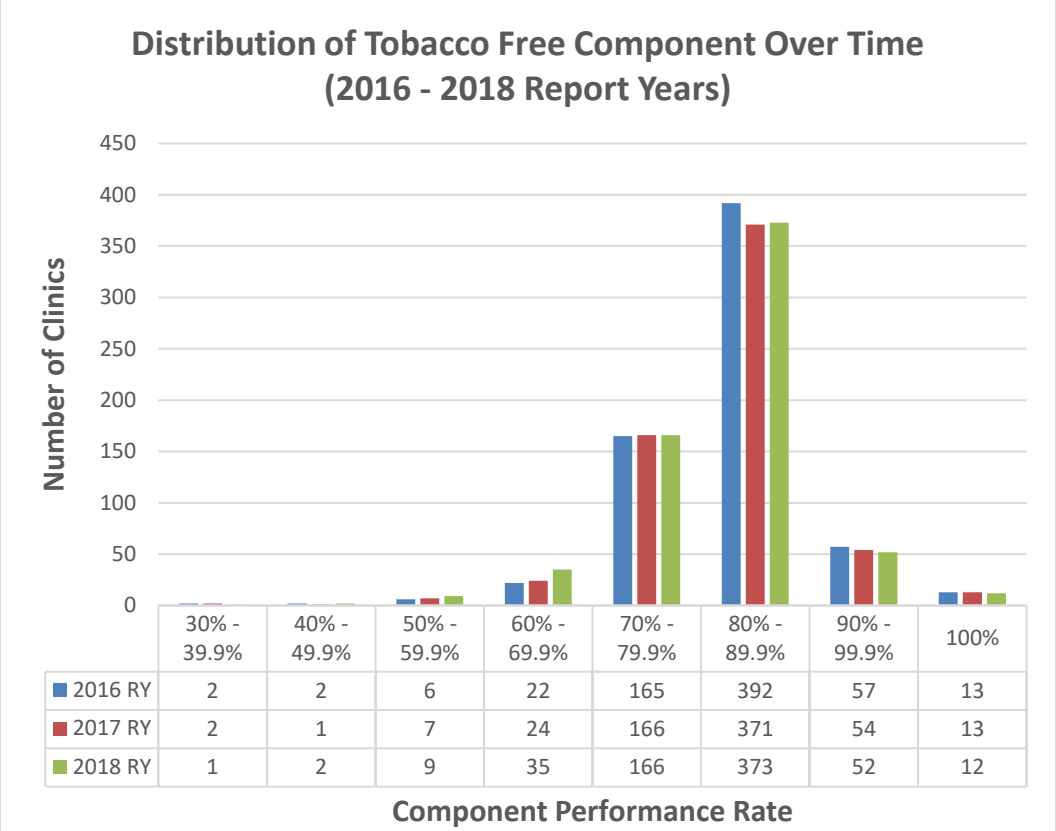
Individual component Rates Over Time



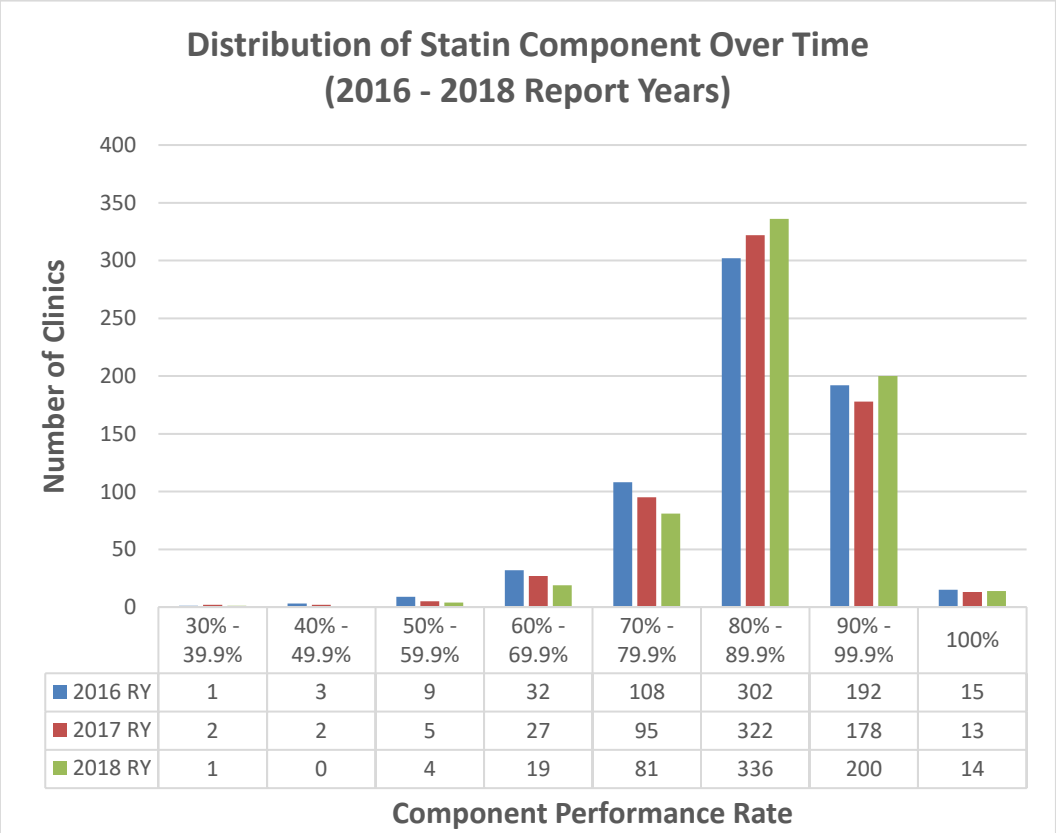
	30% - 39.9%	40% - 49.9%	50% - 59.9%	60% - 69.9%	70% - 79.9%	80% - 89.9%	90% - 99.9%	100%
2016 RY	2	10	58	169	314	84	1	9
2017 RY	3	14	56	220	292	39	0	6
2018 RY	4	15	65	227	302	30	0	3



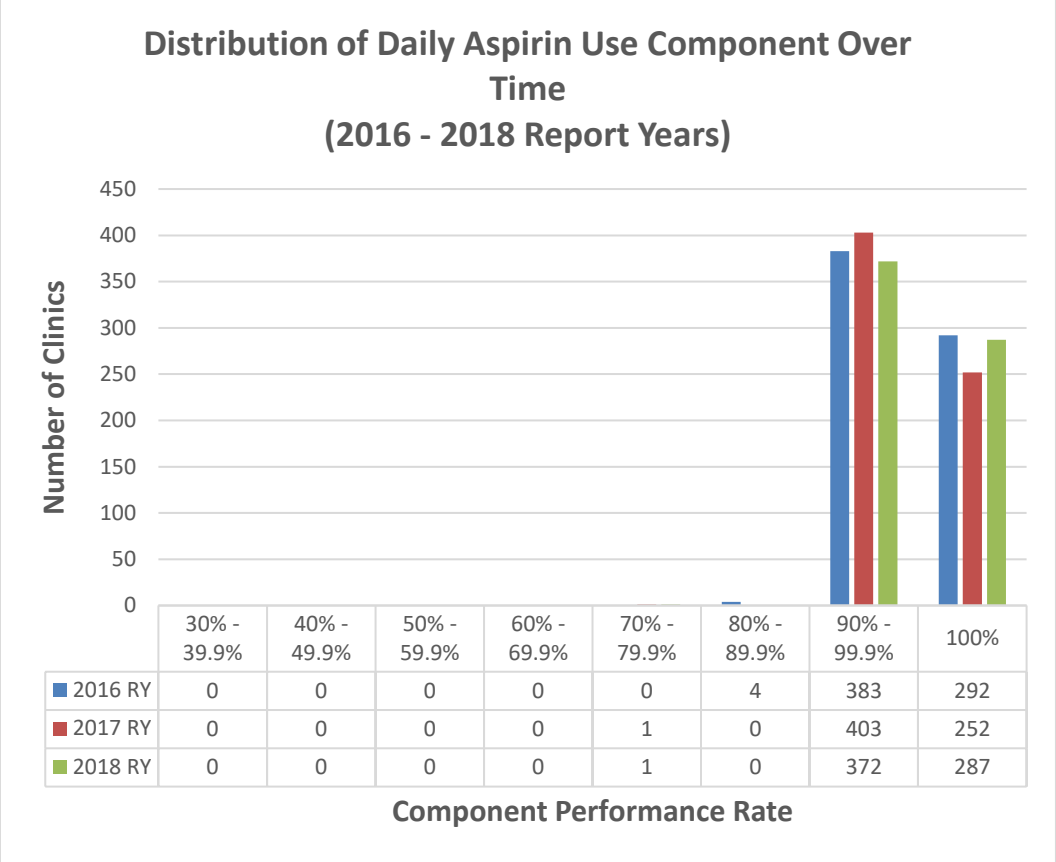
	30% - 39.9%	40% - 49.9%	50% - 59.9%	60% - 69.9%	70% - 79.9%	80% - 89.9%	90% - 99.9%	100%
2016 RY	4	0	10	48	117	320	141	19
2017 RY	1	1	10	31	133	326	118	18
2018 RY	1	1	5	40	135	348	114	14



	30% - 39.9%	40% - 49.9%	50% - 59.9%	60% - 69.9%	70% - 79.9%	80% - 89.9%	90% - 99.9%	100%
2016 RY	2	2	6	22	165	392	57	13
2017 RY	2	1	7	24	166	371	54	13
2018 RY	1	2	9	35	166	373	52	12



	30% - 39.9%	40% - 49.9%	50% - 59.9%	60% - 69.9%	70% - 79.9%	80% - 89.9%	90% - 99.9%	100%
2016 RY	1	3	9	32	108	302	192	15
2017 RY	2	2	5	27	95	322	178	13
2018 RY	1	0	4	19	81	336	200	14



Distribution of Component Rates by Clinic Over Time

Proportion of how many patients are meeting component targets (2018)

This table represents every possible combination of components from single stand-alone to all combinations.

Category	# of Patients	Proportion
HbA1c alone	212,638	69%
Daily Aspirin Use alone	305,619	99%
Statin alone	269,592	88%
Tobacco Free alone	257,808	84%
Blood Pressure alone	256,323	83%
HbA1c + Daily Aspirin Use	211,658	69%
HbA1c + Statin	188,357	61%
HbA1c + Tobacco Free	181,729	59%

Category	# of Patients	Proportion
HbA1c + Blood Pressure	180,705	59%
Daily Aspirin Use + Statin	268,358	87%
Daily Aspirin Use + Tobacco Free	256,586	84%
Daily Aspirin Use + Blood Pressure	255,127	83%
Statin + Tobacco Free	226,784	74%
Statin + Blood Pressure	226,670	74%
Tobacco Free + Blood Pressure	216,209	70%
HbA1c + Daily Aspirin Use + Statin	187,546	61%
HbA1c + Daily Aspirin Use + Tobacco Free	180,928	59%
HbA1c + Daily Aspirin Use + Blood Pressure	179,933	59%
HbA1c + Statin + Tobacco Free	161,175	52%
HbA1c + Statin + Blood Pressure	161,088	52%
HbA1c + Tobacco Free + Blood Pressure	155,226	51%
Daily Aspirin Use + Statin + Tobacco Free	225,790	74%
Daily Aspirin Use + Statin + Blood Pressure	225,702	73%
Statin + Tobacco Free + Blood Pressure	191,582	62%
HbA1c + Daily Aspirin Use + Statin + Tobacco Free	160,506	52%
HbA1c + Statin + Tobacco Free + Blood Pressure	138,517	45%
HbA1c + Daily Aspirin Use + Statin + Blood Pressure	160,448	52%
Daily Aspirin Use + Statin + Tobacco Free + Blood Pressure	190,801	62%
All 5 components (statewide average)	**137,985**	**45%**

Distribution of the Interaction Between All Combinations of Components

Pearson Correlation Coefficients for Each Component

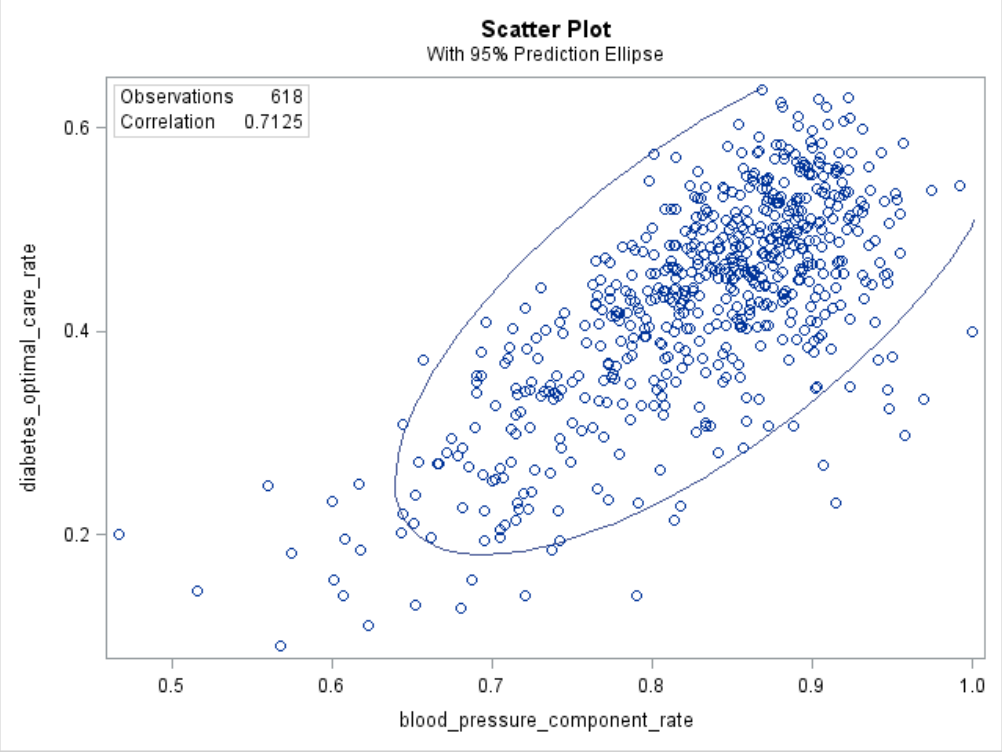
Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
blood_pressure_component_rate	618	0.83170	0.07832	513.98962	0.46667	1.00000
diabetes_optimal_care_rate	618	0.43182	0.10228	266.86641	0.09045	0.63781

Pearson Correlation Coefficients, N = 618
Prob > |r| under H0: Rho=0

*	diabetes_optimal_care_rate
blood_pressure_component_rate	0.71245
*	<.0001

* Cell intentionally left empty



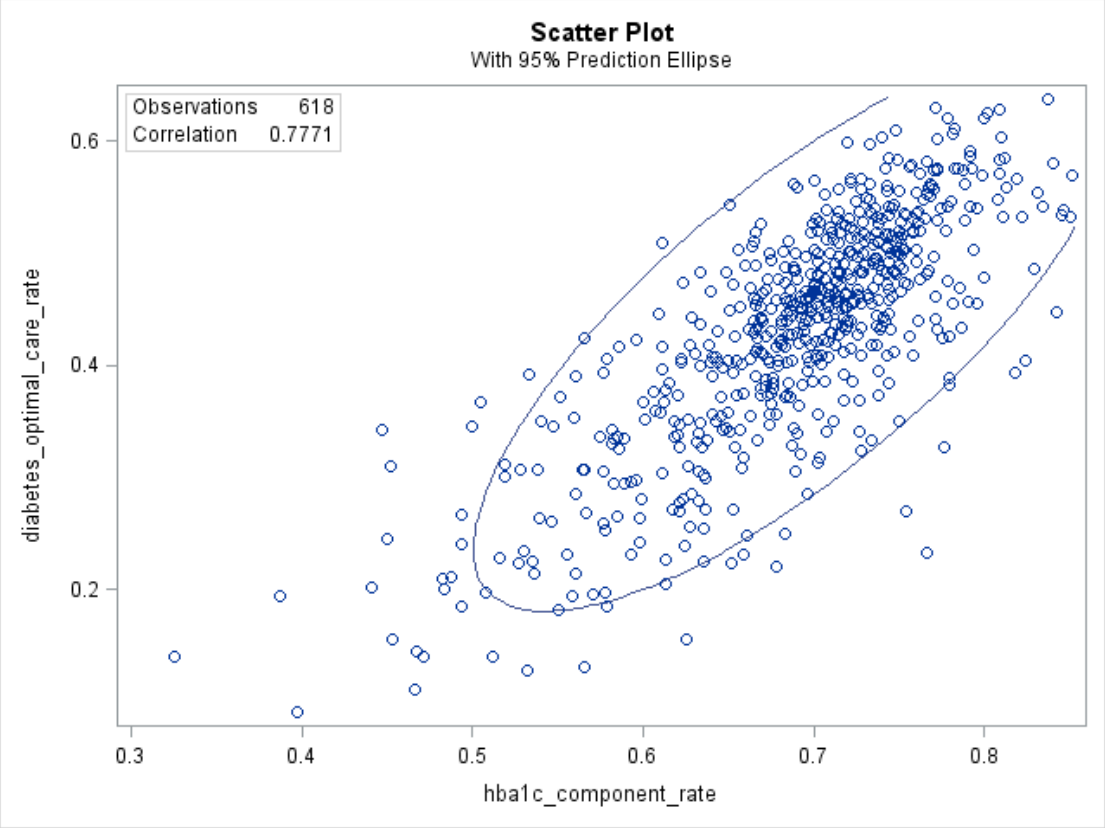
Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
hba1c_component_rate	618	0.68937	0.07686	426.02911	0.32558	0.85128
diabetes_optimal_care_rate	618	0.43182	0.10228	266.86641	0.09045	0.63781

Pearson Correlation Coefficients, N = 618
Prob > |r| under H0: Rho=0

*	diabetes_optimal_care_rate
hba1c_component_rate	0.77714
*	<.0001

* Cell intentionally left empty



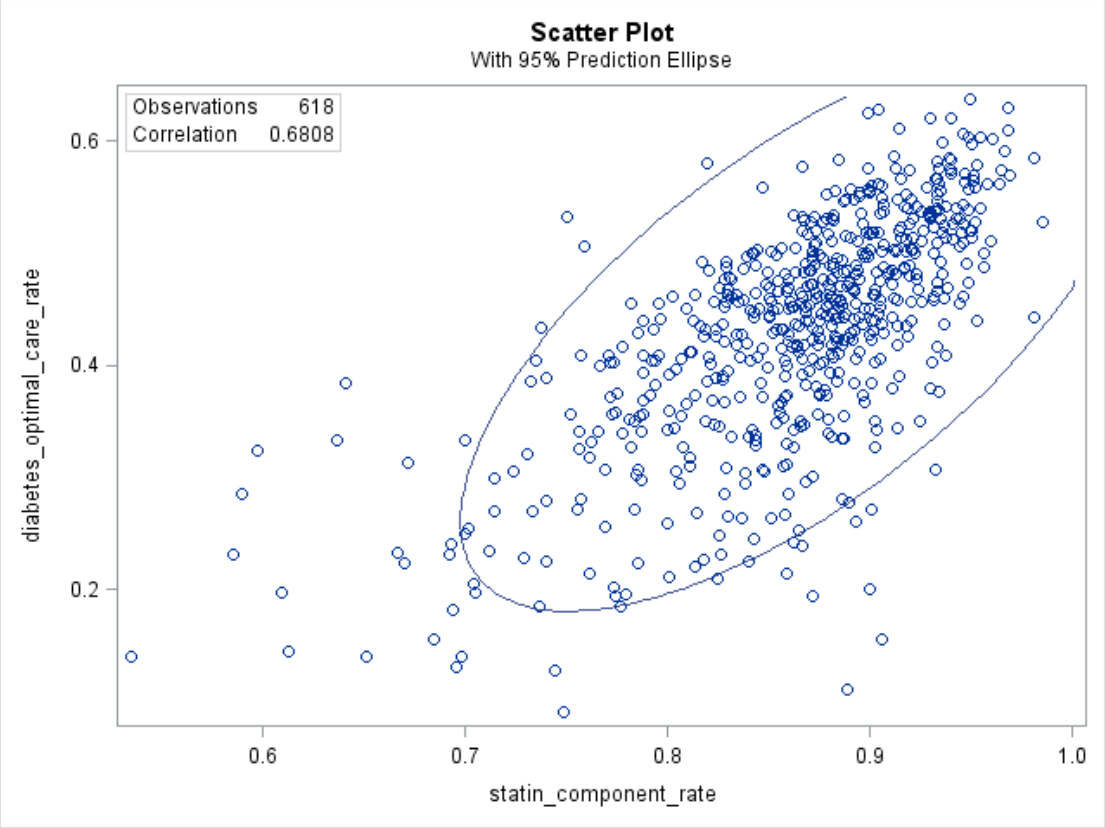
Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
statin_component_rate	618	0.86328	0.06742	533.50798	0.53488	0.98571
diabetes_optimal_care_rate	618	0.43182	0.10228	266.86641	0.09045	0.63781

Pearson Correlation Coefficients, N = 618
Prob > |r| under H0: Rho=0

*	diabetes_optimal_care_rate
statin_component_rate	0.68083
*	<.0001

* Cell intentionally left empty



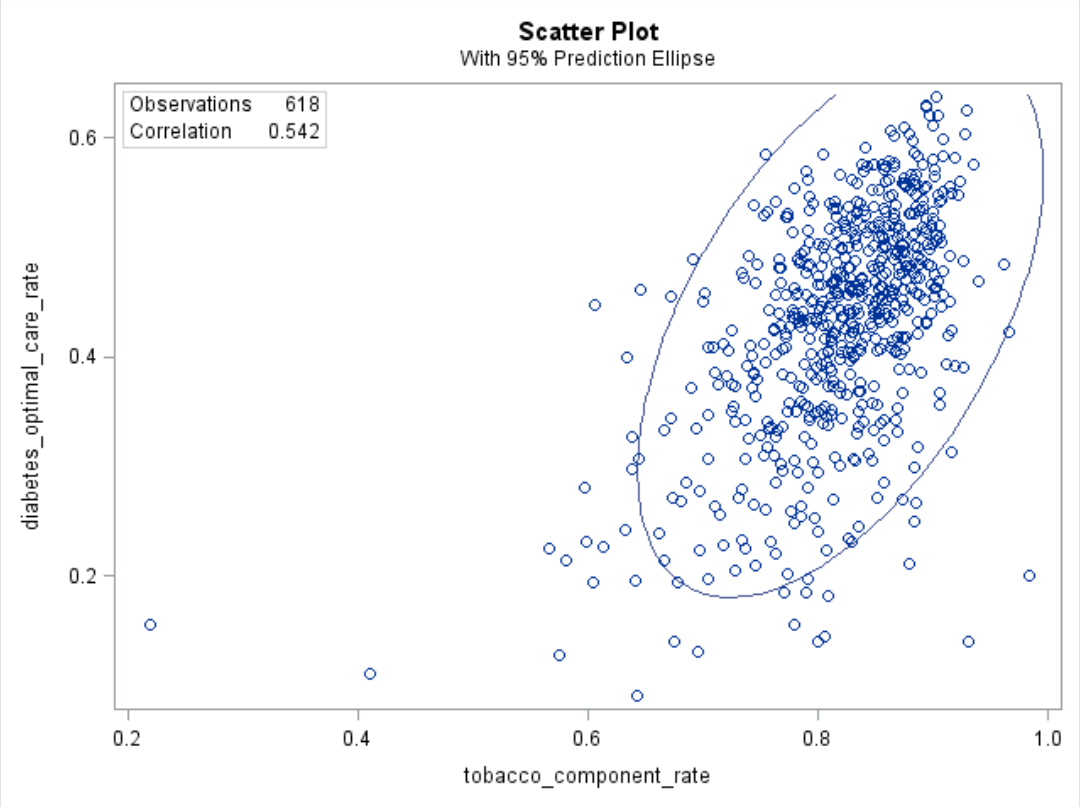
Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
tobacco_component_rate	618	0.81948	0.07189	506.44022	0.21875	0.98333
diabetes_optimal_care_rate	618	0.43182	0.10228	266.86641	0.09045	0.63781

Pearson Correlation Coefficients, N = 618
Prob > |r| under H0: Rho=0

*	diabetes_optimal_care_rate
tobacco_component_rate	0.54201
*	<.0001

* Cell intentionally left empty



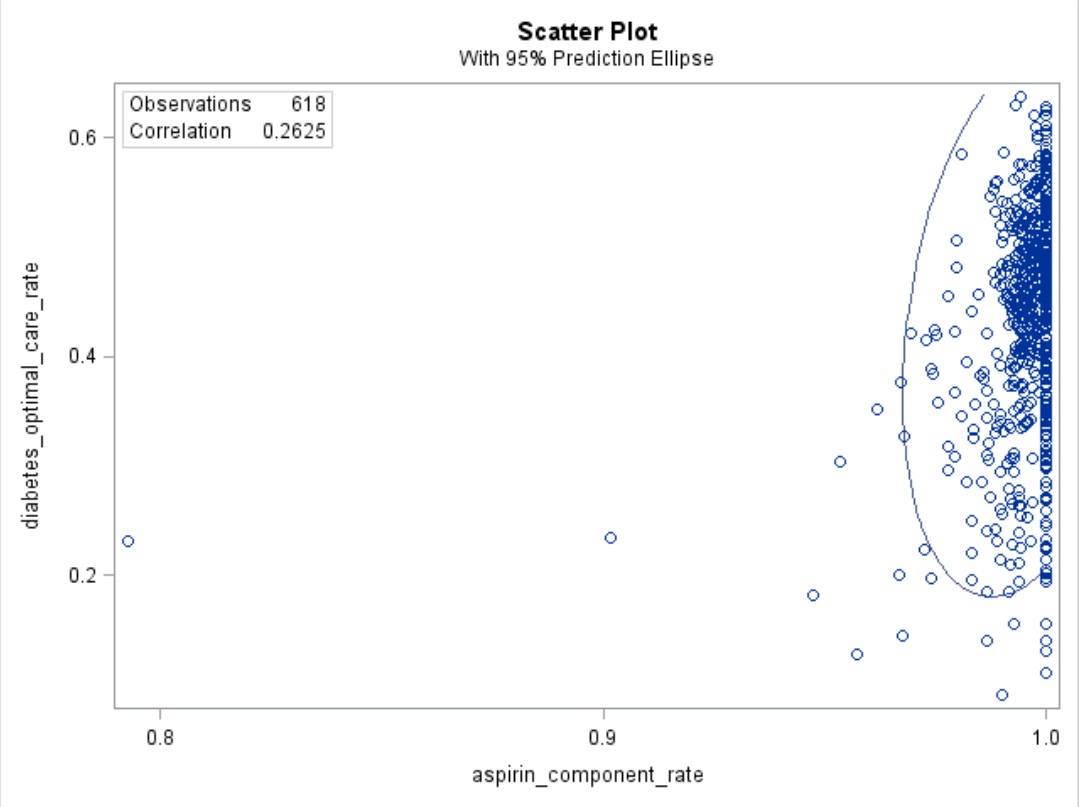
Simple Statistics

Variable	N	Mean	Std Dev	Sum	Minimum	Maximum
aspirin_component_rate	618	0.99495	0.01114	614.87973	0.79268	1.00000
diabetes_optimal_care_rate	618	0.43182	0.10228	266.86641	0.09045	0.63781

Pearson Correlation Coefficients, N = 618
Prob > |r| under H0: Rho=0

*	diabetes_optimal_care_rate
aspirin_component_rate	0.26253
*	<.0001

* Cell intentionally left empty



[Response Ends]

2c.04. Provide your interpretation of the results, in terms of demonstrating that the components included in the composite are consistent with the described quality construct and add value to the overall composite.

In other words, what do the results mean in terms of supporting inclusion of the components; if no empirical analysis, provide rationale for the components that were selected.

[Response Begins]

A multifactorial approach to diabetes care that includes emphasis on blood pressure, lipids, glucose, aspirin use and non-use of tobacco will maximize health outcomes far more than a strategy that is limited to just one or two of these clinical domains (American Diabetes Association, 2014; Duckworth, 2009; Gaede, 2008; Holman, 2008a).

Four of the components have very high correction with the overall Optimal Diabetes Care result and Aspirin Use is effectively topped out so therefore does not have the same correlation as the other four components. In Minnesota, this measure and statewide efforts to increase the use of aspirin / antiplatelets have been in place for over 10 years and this component is essentially topped out, but this is not necessarily the case for other areas of the United States. Paerkh A.K. et al cite rates as low as 34.8% in primary care settings. [Aspirin in the Secondary Prevention of Cardiovascular Disease, NEJM Jan 2013)

Pearson Correlation Analysis

Components as compared to the composite Optimal Care Rate demonstrate a strong correlation with the following Pearson r coefficient values: Blood Pressure at 0.7124, Hemoglobin A1C at 0.7771, Statin Use at 0.6808, Aspirin Use at 0.2625 and Tobacco use at 0.5420

[Response Ends]

2c.05. Provide an empirical analysis demonstrating that the aggregations and weighting rules are consistent with the quality construct and achieve the objective of simplicity to the extent possible.

[Response Begins]

Not applicable; no weighting applied to the components.

[Response Ends]

2c.06. Describe the method used for composite aggregation.

Describe the steps—do not just name a method; what statistical analysis was used; if no empirical analysis, provide justification.

[Response Begins]

Not applicable; no weighting applied to the components.

[Response Ends]

2c.07. Provide the statistical results obtained from the analysis of the aggregation and weighting rules.

If no empirical analysis was conducted, identify the aggregation and weighting rules that were considered and the pros and cons of each.

[Response Begins]

Not applicable; no weighting applied to the components.

[Response Ends]

2c.08. Provide your interpretation of the results, in terms of demonstrating the aggregation and weighting rules are consistent with the described quality construct.

In other words, what do the results mean in terms of supporting the selected rules for aggregation and weighting; if no empirical analysis, provide rationale for the selected rules for aggregation and weighting.

[Response Begins]

Not applicable; no weighting applied to the components.

[Response Ends]

Criteria 3: Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in electronic health records (EHRs)

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

All data elements needed to calculate and risk adjust this measure are available in standardly available fields stored discretely in EHRs (e.g. date of birth, zip code, race/ ethnicity, provider NPI, provider specialty, insurance coverage, diagnosis codes- ICD, lab values, blood pressure values, smoking status, medications).

MNCM is implementing a new method for data collection which significantly reduces the burden for providers in terms of submitting data, identifying the denominator and the new system efficiently centralizes application of specifications. This warehouse system, PIPE (Process Intelligence Performance Engine) receives and stores all ambulatory encounters, diagnosis, problem lists, medications, labs, etc.

https://mncmsecure.org/website/Services/05%20-%20Overview%20of%20PIPE.pdf

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

Data elements for measure calculation are being captured in a digital format. See 3.03

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

No difficulties were identified. This measure has been collected from all primary care and multi-specialty (including endocrinology) in MN for about 15 years. See discussion in 3.03.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

There are no fees associated with participation and submitting data for this measure. Results are available to 1) all data submitters within the HIPAA secure MNCM data portal and 2) to the public on our consumer facing website MN Health Scores at www.mnhealthscores.org and 3) annual health care quality report on our corporate website at www.mncm.org. There are resource costs to the medical groups in terms of creating extracts from their EMR systems.

[Response Ends]

Criteria 4: Use and Usability

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a. Use

4a.01.

Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Public Reporting

Payment Program

Measure is included in two state regulatory programs: MN Statewide Quality and Reporting System and is included in the MN Health Care Homes Certification/ Recertification Program.

https://www.health.state.mn.us/data/hcquality/measures/index.html

https://www.health.state.mn.us/facilities/hchomes/certification/certification/docs/certassessmenttl.pdf

Several mechanisms for publicly reporting this measure are in place. Consumer-facing public website MN HealthScores is located at https://www.mnhealthscores.org/ rates (including actual, expected and health score rating) are available for every clinic in MN and surrounding border communities. Measure is published as part of the MNCM Annual Health Care Quality Report, Annual Disparities by Insurance Type and Disparities by Race, Ethnicity, Language, Country of Origin and the focus of several issue briefs. https://mncm.org/reports/#community-reports

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

Regulatory and Accreditation Program

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

Not applicable, used in public reporting and accountability applications.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

Not applicable, used in public reporting and accountability applications.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

Performance results are provided to all medical groups who submit data for this state-wide measure via several options:

• Preliminary measure rates are provided immediately after file upload to HIPAA secure, password protected data portal

• A two-week review process is conducted to allow groups to review and potentially appeal prior to public reporting of rates

• Rates are reported by medical group and clinic level on public website MN Healthscores at www.mnhealthscores.org/

• Additionally, rates including all historical rates can be obtained from the MNCM data portal (pass-word protected)

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Currently, data is collected once per year and results are provided on an annual basis. See question 4a.05 for the process and list of multiple mechanisms for receiving results and providing feedback.

MNCM provides recorded webinars for each measure or measure set that provides education for measure specification (denominator, numerator, exclusions) measure calculation and understanding results.

Education and explanation are also included in our hard copy reports. The annual Health Care Quality Report provides descriptive information along with the results for each measure plus appendices for guidelines for comparing measures over time, data sources and data collection, and methodology (attribution, weighting, rate calculation, risk adjustment). http://mncm.org/reports-and-websites/reports-and-data/health-care-quality-report/

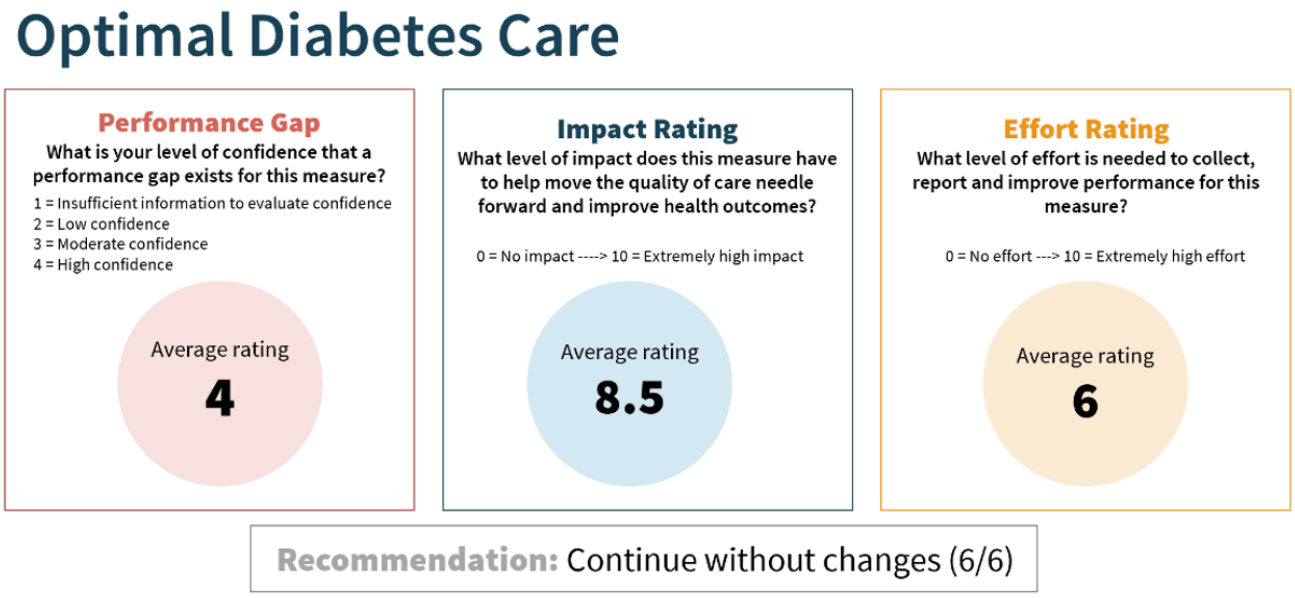
[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

MNCM's Measure Review Committee (MRC) is tasked with the review of all publicly reported measures on MN HealthScores. As part of this process, each measure is reviewed for performance gap and continued opportunity for improvement, impact on health care and feasibility/burden with a determination for appropriateness to continue reporting. MRC recommendations are reviewed by MNCM's multi-stakeholder Measurement and Reporting Committee and the slate of publicly reported measures is approved by the MNCM Board of Directors.

For Optimal Diabetes Care review in 2020 Committee ratings were as follows:



Measure Review Committee Results for Optimal diabetes Care

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

Feedback from those being measured is obtained in several ways.

The MN Department of Health conducts several comment periods during its annual rule making process, those being measured are invited to comment. Comments are reviewed by measure development staff to identify areas of concern for potential redesign.

MNCM provides a year-round staffed support through a helpline 612-746-4522 or email support@mncm.org.

During the measure development process, formal public comment is sought from the clinics and medical groups who will be measured. All comments are reviewed by the measure development workgroup for identifying any redesign or tweaks to the measure specifications prior to pilot testing the measure. Pilot testing provides an additional source for feedback from users; pilot participants are surveyed with questions around feasibility and data element ease or difficulty.

MNCM periodically conducts a survey of medical groups in which all clinics in the state are invited to participate and provide feedback. There are structured questions asking the users about measure value and burden.

2018 Medical Group Survey

To what degree does your medical group find value in the measure? (n = 112)

High Value 45.5% (51)

Moderate Value 33.0% (37)

Minimal Value 14.3% (16)

No Value 7.1% (8)

How easy or difficult is it to obtain the data needed for DDS submission for this measure? (n = 104)

Very Easy 19.2% (20)

Easy 44.2% (46)

Difficult 29.8% (31)

Very Difficult 8.7% (9)

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

Please refer to feedback, rating and voting by the MNCM Measure Review Committee in question 4a.0.7. Feedback from this review committee is included in the annual approval of the MNCM Slate of Measures https://mncm.org/mncm-services/#measurement-and-reporting

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

This measure, originally developed by HealthPartners with stewardship transferred to MNCM in ~2008, has undergone three component re-design activities based on changes in evidence and guidelines. Each re-design has involved a multi-stakeholder measure development workgroup who use a consensus-based decision making process. To recap briefly:

• The A1c component was changed from < 7.0 to less than 8.0 following ACCORD study results

• The cholesterol component was changed from LDL < 100 to appropriate statin use in 2015

• The blood pressure component has undergone some changes based on guidelines and alignment with other national measures until stabilizing at < 140/90 in 2010. Blood pressure component workgroup was convened in 2018 to review evidence and guideline change with the recommendation to remain at <140/90

[Response Ends]

4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

Since the start of public reporting of this measure in 2004, there has been steady improvement in composite rates for achieving all targets; statewide average from 9.5% to 40.6% with demonstrated variability and opportunity for improvement. What this translates to is 127,612 patients with diabetes in MN and surrounding communities are managing their modifiable risks and are less likely to develop long term complications.

HealthPartners, a large integrated health system in MN, has reduced the incidence of long-term complications of diabetes (heart attacks, amputations and blindness) by more than 30% since 1994 by focusing on optimal diabetes care. Incidence of long-term complications per 1000 members between 2000 and 2016 fell from 17.8 to 11.3 for acute myocardial infarction, from 4.8 to 4.2 for amputations, and from 68.0 to 37.9 for retinopathy.

In 2018, a study of over 200,000 patients with type 2 diabetes found that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. [Rawshani, A et al Risk Factors, Mortality, and Cardiovascular Outcomes in Patients with Type 2 Diabetes N Engl J Med 2018; 379:633-644 DOI: 10.1056/ NEJMoa1800256]

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

Two unexpended findings over the years:

• Adults of Medicare age 65 and older with the potential for more co-morbidities, have better outcome rates than their younger counterparts with diabetes. This may be in part due to generational differences related to compliance with providers' orders.

• We have noticed over time that statewide averages of A1c values are drifting upward and this is a trend also confirmed by the American Diabetes Association.

Additionally, measure results have been impacted by the coronavirus pandemic with a decrease in the overall denominator (fewer patients seeking care) and decreases in some of the individual components (e.g., lab and blood pressure).

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

Statewide focus on the measure has led to a common way of measuring performance and communicating results. Many health systems create this measure internally and use for benchmarking and provider performance bonuses. Many clinics post their rates over time in the hallways for patients to view. Comparison provided through transparency provides competition and motivation to improve.

[Response Ends]

Criteria 5: Related and Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

0057: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Testing

0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

N/A

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

Yes

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

N/A

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

2 measures are part of a composite measure that is stewarded by NCQA.

0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)

0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)

NCQA's composite for comprehensive diabetes care is no longer endorsed.

These two measure's numerators are harmonized.

We have philosophical differences in the denominator definitions and this is due in part to the data source. NCQA uses claims data to identify diabetic patients, MNCM used EMR based data. NCQA's methodology looks for diabetes diagnosis codes but additionally will include patients on oral medications and insulin who do not have the diagnosis. We also believe that is important to exclude diabetic women who are currently pregnant during the measurement year, related to cholesterol management. NCQA's denominator value sets intentionally include these patients.

[Response Ends]

Appendix

Supplemental materials may be provided in an appendix. : Available at measure-specific web page URL identified in sp.09

Contact Information

Measure Steward (Intellectual Property Owner): MN Community Measurement

Measure Steward Point of Contact: , , pitzen@mncm.org

Measure Developer if different from Measure Steward: MN Community Measurement

Measure Developer Point(s) of Contact: , , pitzen@mncm.org

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins]

Available at measure-specific web page URL identified in sp.09

[Response Ends]

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]

An expert panel was convened in December 2008 to determine the most appropriate A1c target for this composite. The group reviewed literature and incorporated current ICSI Diabetes Guideline discussions as this guideline was also undergoing revision. Members included:
Beth Averbeck, MD Assoc Medical Director, Health Partners, MNCM Board
Barry Bershow, MD Medical Director, Quality & Informatics, Fairview, Co-Chair MNCM Reporting Advisory Committee (RAC) and MNCM Board Member
Rich Bergenstal, MD Executive Director, International Diabetes Center, ICSI Diabetes Guideline Workgroup
John Fredrick, MD Exec Vice President & Chief Medical Officer PreferredOne, MARC Member
Gene Ollila, MD Allina Medical Clinic, ICSI Diabetes Guideline Workgroup

Expert panel was re-convened in March 2010 to address the aspirin component and again in July 2010 to address the blood pressure component of the composite measure. This technical advisory panel included:
Beth Averbeck, MD | HealthPartners
Barry Bershow, MD | Fairview Health Services
Rich Bergenstal, MD | International Diabetes Center, Park Nicollet
John Fredrick, MD | Preferred One
Gene Ollila, MD | Allina Medical Clinic
Linda Walling, MD | HealthEast
Mark Nyman, MD | Mayo Clinic
JoAnn Sperl-Hillen, MD | HealthPartners
Victor Montori, MD | Mayo Clinic
Kari Retzer | ICSI Facilitator for Diabetes Guideline

Measure development work group was convened March 2014 thru October 2014 to redesign the cholesterol component for both the Optimal Diabetes Care (#0729) and Optimal Vascular Care (#0076) measures whose previous target of LDL < 100 was no longer appropriate or supported by updated evidence and guidelines (American College of Cardiology/ American Heart Association Treatment of Cholesterol Guidelines Nov 2013). Members included:

Beth Averbeck, MD | Chair Internal Med MNCM Board | HealthPartners
Mark Nyman, MD | Internal Med MARC member | Mayo Clinic
Victor Montori, MD | Endocrinology | Mayo Clinic
JoAnn Sperl-Hillen, MD | Internal Med | HealthPartners
Courtney Baechler, MD | Cardiologist | Allina Penny George Institute
J. Ward Godsall, MD | Endocrinology | Allina Medical Group
Christopher Restad, DO | Family Medicine | Health East
Rebecca Moxness, MD | Endocrinology | Park Nicollet
Thomas Knickelbine, MD | Cardiologist | Minneapolis Heart Inst.
Woubeshet Ayenew, MD | Cardiologist | Hennepin County Med Cen
Terry Murray, RN | Data Analyst | Allina Medical Group
Jeanine Rosner, RN | QI or Clinic Admin | Park Nicollet
Monica Simmer | Health Plan | Metropolitan Health Plan
Pam York | State Agency | MDH/ Chronic Disease
Kris Soegaard | Consumer/ Empl/ MARC Member | MN Health Action Group
Collette Pitzen | Facilitator/ Measure Dev | MNCM

Measure development workgroup was convened in April of 2018 to evaluate and discuss recent changes in guidelines and evidence surrounding blood pressure targets for patients with diabetes and vascular disease.

Name | Member Type | Organization
Beth Averbeck, MD | Internal Medicine; Chair | HealthPartners
Joseph Bianco, MD | Family Medicine & MARC | Essentia Health- Ely
Andrew Greenland, MD | Internal Medicine | Mayo Clinic

Christopher Fallert, MD | Family Medicine | University of Minnesota
Christian Anderson, MD | Family Medicine | Entira Family Clinics
Steven Bradley, MD MPH | Cardiology | Minneapolis Heart
David Homans, MD | Cardiology | Park Nicollet
Jesse Wheeler, MD | Nephrology & MARC | Park Nicollet
Nicole Paterson, PharmD | Pharmacist | Fairview Health Services
Karen Margolis, MD MPH | Data Analyst | HealthPartners
Cindy Ferrara, RN | Quality Improvement | Essentia Health- Duluth
Patrick Schultz, ACNS-BC| Clinic Administrator | Sanford
James Peacock, PhD MPH | State Agency | MN Dept. of Health
Cynthia Toher, MD | Health Plan/ Cardiology |Blue Cross/Blue Shield MN
David Klocke, MD | Health Plan/Hosp Med | Blue Cross/Blue Shield MN
Christine Norton | Consumer and MARC | Retired
Deb Krause | Employer | MN Health Action Group
Collette Pitzen | Facilitator/ Measure Dev | MNCM

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]

2007

[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]

10/20/2015

[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]

Annual, but can be more frequently as evidence emerges and guidelines change.

[Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins]

November, 2022

[Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins]

[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]