NATIONAL QUALITY FORUM

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 #: 3569e

Corresponding Measures:

De.2. Measure Title: Prediabetes: Screening for Abnormal Blood Glucose

Co.1.1. Measure Steward: American Medical Association

De.3. Brief Description of Measure: Percentage of patients aged 40 years and older with a BMI greater than or equal to 25 who are seen for at least two office visits or at least one preventive visit during the 12-month period who were screened for abnormal blood glucose at least once in the last 3 years

1b.1. Developer Rationale: This measure is critical to identifying patients with prediabetes who are not screened, thus missing potential cases that progress to diabetes. This measure is part of a set that will produce the first measurement set in the U.S. intended to prevent type 2 diabetes. Currently, eighty-four million Americans have prediabetes and 9 out 10 patients are unaware that they have this condition. CDC-recognized lifestyle change programs are included in the health benefit plans and the Medicare Diabetes Prevention Program, including Medicare beneficiaries.

Screening for prediabetes and identifying patients before they progress to Type 2 diabetes is the first step to enabling beneficiaries to utilize this benefit. Furthermore, cost savings for prevention of type 2 diabetes have the potential to be significant. For every beneficiary, at 15 months, costs savings are at least $ 2,650.00 per person.

S.4. Numerator Statement: *Screening for abnormal blood glucose may include using a fasting plasma glucose, 2-h plasma glucose during a 75g oral glucose tolerance test, or A1C.

S.6. Denominator Statement: All patients aged 43 years and older with a BMI greater than or equal to 25 seen for at least two office visits or at least one preventive visit during the 12-month measurement period

S.8. Denominator Exclusions: Denominator Exclusions

"Patient is Pregnant at Encounter"

or "Patient Has Active Diabetes Diagnosis at Encounter"

or "Hospice During Measurement Period"

or "Palliative Care During Measurement Period"

or "Comfort Measures During Measurement Period"

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records

S.20. Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is 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**

Evidence Summary

- This process measure eCQM at the clinician: individual and group level is the percentage of patients aged 40 years and older with a BMI greater than or equal to 25 who are seen for at least two office visits or at least one preventive visit during the 12-month period who were screened for abnormal blood glucose at least once in the last 3 years.
- Developer provided a logic model connecting the measure focus with positive patient outcomes, namely the identification of patient risk factors, lab testing of glucose status, abnormal glucose diagnosis, then management and monitoring to prevent disease progression.
- Developer cites evidence found in guidelines from the United States Preventive Services Task Force (USPSTF) and from the American Diabetes Association (ADA).
    - The focus of the recommendations is lifestyle change.
    - USPSTF incorporated this evidence into the updated recommendation regarding screening for abnormal glucose and type 2 diabetes.
    - The grade B recommendation states that physicians should screen individuals for abnormal glucose if they are between the ages of 40 and 70 and are overweight or obese, or younger if they have additional risk factors.
    - The ADA recommends screening patients who are overweight or obese with one risk factor, regardless of age. Additionally, those who have no risk factors should start screening at age 45.
    - Developer notes that the risk factors included in this measure bring together both the USPSTF and ADA risk factors.
- Testing for prediabetes and risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25kg/mg or ≥23kg/m2 in Asian Americans) and who have one or more additional risk factors for diabetes. (ADA, 2018) (B Recommendation)
    - Grade B recommendation means: “The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.”
    - This suggests a moderate rating.

Questions for the Committee:

- Does the Committee agree with the staff evaluation of the evidence presented by the developer?

- What is the relationship of this measure to patient outcomes? How strong is the evidence for this relationship? Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure based on systematic review (Box 3)→QQC presented (Box 4)→Quantity: high; Quality: moderate (Grade B evidence); Consistency: high (Box 5b)→**Moderate** (NQF Measure Evaluation Criteria Sept 2019, Algorithm 1 pg. 15)

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

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

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

- For this new measure, developer did not provide an analysis of provider performance as the data was not available. Rather, they summarized the literature indicating a performance gap.
- There are substantial numbers of patients with prediabetes; this is an opportunity to intervene when patients present for care.
    - United States has 84 million adults with prediabetes.
    - 9 out of 10 patients who have prediabetes are not aware.
    - Missed opportunities among primary care providers in diagnosing and managing patients with prediabetes represent a gap in care.
- Early detection and management of pre-diabetes is fundamental to preventing diabetes.
    - Despite established national screening guidelines in U.S., suboptimal screening rates are reported, with 45% of those meeting screening criteria being screened
    - Additionally, survey data show that while primary care physicians are aware of the guidelines that support screening for prediabetes, there is a disconnect between this knowledge and actual practice.

Disparities

- Developer provided a summary of the literature related to gaps in care. Developer states that their review of the literature suggests that the uninsured are less likely to be screened; Hispanics and black people are also more likely to be screened than white people.

Questions for the Committee:

- Does the Committee agree with the staff assessment that there is a gap in care that warrants a national performance measure?
- Are you aware of evidence that disparities exist in this area of healthcare?

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

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence

Comments:

- Yes their reported data does support, however, both primary guideline associations have updated or in the process of updating their guidelines. Notations should be added that reflect the ADA's 2020 (living) Standards and the USPSTF is in the process of updating in 2020-the up to date evidence show continued support of screening. Also, they should note that other evidence provided in

literature by diabetes education, care and support providers that apply directly to this measure. This process measure is needed to increase and insure screening of persons that are asymptomatic for prediabetes/diabetes.

- This is a process measure that uses a logic model to show how it is impacting progression to type 2 diabetes. Both the USPSTF and ADA undertook a significant systematic review concluding that there is moderate benefit to the process measure suggested here. This is a fairly robust body of evidence, in moderate support, and should be more than enough to support the measure focus.
- There is good evidence that many patients with prediabetes are unaware and could benefit from timely recognition of their condition
- Evidence is well documented and agree with Moderate rating, but wondered by denominator is age 43. I did not see an explanation.
- Evidence supports the measure.
- It's a national problem for sure. The at-risk population extends below the 40 year old age cut off in the measure and is even an issue in pediatrics, though the BMI/weight criteria might be different. So it's OK to start with the age cutoff for this measure. The impact of screening for pre-diabetes on the outcome of interest (diabetes) is not clear. The developers site the DPP, for which there is good evidence in initial testing of the prototype. However, to my knowledge, there is little (maybe no) evidence that the DPP is effective at its current national scale. Also, initial uptake by people on Medicare is limited, and in any event, that's rather late in life to start remediation. Also, the denominator of two office visits or one preventive visit may be antiquated in the telehealth era. I get the fact that the developers need this to be captured in the EMR, but the criteria for inclusion need to be updated or reconsidered
- This is a newly proposed measure. It is a process measure. I agree that there is moderate evidence to support the conjecture that those with lab values defining the diagnosis of pre-diabetes will have by means of education and counseling on DM or by taking metformin be spared by going on to meeting the criteria for DM and then avoid DM complications and higher medical care costs.
- Process Measure, relates to the desired outcome

1b. Performance Gap

Comments:

- Yes they used current evidence in literature to demonstrate the gap. Especially now with the impact of COVID-19 on persons with diabetes, we witnessing the health inequity in the underserved population.
- The fact that 9 out of 10 patients are unaware they have prediabetes, there is a tremendous need for testing to improve diabetes progression. With 84 million adults estimated to have prediabetes in the US, yet data showed <50% are being screened.
- There is a gap in the timely diagnosis of prediabetes in the USA
- Could be the insurance coverage is a major impact on the screening for different groups of people.
- Gap was based on literature review. Literature suggested a less than optimal performance in referrals to manage diabetes.
- Definitely a gap.
- The USPSTF recommendations call for testing of selected subpopulations for DM and Pre-DM. Both the USPSTF and the American Diabetes Association call for those who fit the Pre-DM criteria are to have referrals for life style modification and nutritional advice. The ADA suggests that those with Pre-DM be considered for metformin treatment. Some published studies indicate that the percentages of persons recently showing Pre-DM levels of lab tests seldom are so referred. Some who are referred do not attend any or few education sessions, with the causes of that failure unclear. These findings argue for a national performance measure.
- Evidence gap provided by synthesis of the literature. Supports under recognition of prediabetes

1b. Disparities

Comments:

- They did not provide or break out any data on population subgroups or demographics. The fact that this is an e-measure for EMR/EHR assumes that subgroups of disparity populations are being seen in the clinics. They used current literature to show the gap of care.
- This is a new measure, so no data was provided. However, data was shared showing limited screening in patients without insurance. There was not robust information in this area, although there is certainly more out there in the literature at large with regard to social determinants of health and access to care.
- No- this was not addressed explicitly in the report
- Since payment coverage appears to be related to income level as measured by payment coverage, could that be addressed as part of the measurement design?
- Disparity for those that do not have coverage for diabetes education, etc.
- I did not see the provided references. If people of color are being screened for than white people, that's interesting, so would like to know more. The uninsured screening gap is not surprising, but it's not clear if the uninsured will be proportionately included given the criteria in the denominator.
- The literature review did not find studies analyzing the care of Pre-DM patients by population subgroups.
- Some information was provided on disparities

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

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

Reliability

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

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

Validity

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

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

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

Evaluators: NQF Primary Care and Chronic Illness Committee Staff

Staff Review

Evaluation Summary:

Specifications

- Submitted measure specification follows eCQM industry specs as indicated Sub-criterion 2a1
- Submitted measure specification is fully represented and is not hindered by any limitations in the eCQM industry specs
- Submission includes simulated data set results demonstrating unit testing covering 100% of the measure logic.

Reliability/Validity

- Developer used same testing for both data element reliability and validity.
- Developer performed data element reliability/validity testing at two facilities on two common EHR systems.
    - Test Site #1: An ambulatory facility in South Carolina, part of a larger health system comprised of 8 inpatient hospitals and more than 100 outpatient facilities. This facility uses Epic EHR in their facility.
    - Test Site #2: An ambulatory facility in South Carolina, part of a larger system comprised of a 1,600+ bed comprehensive integrated health system, serving 1 million patients. This facility uses Cerner EHR in their facility.
- The feasibility assessment indicated the following data elements had issues in the accuracy domain indicating that these data elements may not be correct:
    - "Laboratory Test, Performed: Fasting Plasma Glucose Lab Test Mass Per Volume" (in Cerner and Epic) (*measure developer noted that Fasting status of glucose testing is not captured in discrete fields in either EHR, however capturing A1C testing is feasible. To test for prediabetes, fasting plasma glucose, 2-h plasma glucose during 75-g oral glucose tolerance test, and A1C are equally appropriate)*
    - "Intervention Order: Comfort Measures" (in Cerner) *(measure developer noted that Comfort Care as an exclusion is standard in in NQF endocrine registry measures and it is expected that EMR developers to create a distinct field to collect this data in the future)*
    - "Laboratory Test, Not Performed: Fasting glucose [Moles/volume] in Serum or Plasma" (in Cerner and Epic)
    - "Laboratory Test, Not Performed: Fasting Plasma Glucose Lab Test Mass Per Volume" (in Cerner and Epic)
    - "Laboratory Test, Not Performed: Glucose [Mass/volume] in Serum or Plasma --2 hours post 75 g glucose PO" (in Cerner)
    - "Laboratory Test, Not Performed: Glucose [Moles/volume] in Serum or Plasma --2 hours post 75 g glucose PO" (in Cerner)
    - "Laboratory Test, Performed: Fasting glucose [Moles/volume] in Serum or Plasma" (in Cerner and Epic)
- Data element reliability/validity testing was conducted utilizing Parallel Forms Reliability Testing methodology to determine if data elements found through electronic data pulls could be confirmed by manual abstraction of the same data elements.
    - Verification of the data elements was obtained through automated data search strategies against a reference strategy (considered the gold standard) for obtaining the data elements.
    - Manual review of the data elements was used as the reference strategy against which automated data search and extraction strategies were evaluated.
    - Interrater reliability (crude agreement and Cohen's Kappa) was used to assess the reliability of the measure based on results from two independent reviewers trained in the same way reviewing the same patient record.
- NQF staff consider this an appropriate testing methodology according to current NQF criteria.

- NQF staff were not certain from the submission that the developer had tested all data elements, or minimally numerator, denominator, and all exclusions, as required by NQF criteria.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- Does the Committee agree with the NQF staff's assessment and rating the reliability testing?

Questions for the Committee regarding validity:

- Does the Committee still consider the measure valid given the inaccurate fields demonstrated in the feasibility assessment?
- Do you have any other concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- Does the Committee agree with the NQF staff's assessment and rating the validity testing?

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

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

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability – Specifications

Comments:

- First why is the measure targeting person aged 40 years and older, but the denominator starts with persons aged 43 years and older-I could not quickly find their logic in age differences. With regard to consistency of implementation-I would like to see if pulling SnoMed codes pulled with the ICD10 would better define the data elements. You can only apply their testing to EPIC and CERNER systems used in the SC clinics. Many clinics/groups have different versions of EPIC and CERNER depending on their "package" they are leasing/purchasing. To note other EMRs/EHRs should have the same ONC standards in place to pull the data elements but again it depends on the capabilities of each end user and their version they have inplace. Agree that we need to have a process measure for DM screening-I have concerns that if this inplace and used MIPS payments it may not be ready for full implementation for all groups using EMRs/EHRs.
- The measure is well defined, with clear numerator and denominator definitions. Since it is using EMR data, and not claims, it accounts for offices that may use point-of-care testing that may not result in a claim to do the screening. Implementation should be able to be consistent.
- None
- Concern about NQF staff were not certain from the submission that the developer had tested all data elements, or minimally numerator, denominator, and all exclusions, as required by NQF criteria.
- No concenrs with the reliability of the measure specifications.
- If a fasting glucose is as acceptable as the other measures, I don't get how it can be used if fasting status is not routinely captured in the EMR. Either I'm missing something in the submission, or this is a non-starter. It certainly would need a larger more diverse sample to assess
- Two large health care systems in the same state using different but widely adopted EMRs were studied by computer based record extration against manual chart reviews. Score level testing was not done. Moderate reliability is a fair rating.

- The inability to differentiate whether a glusoe value was fasting or not was identified as a potential issue

2a2. Reliability – Testing

Comments:

- Agree with NQF staff's rating of Moderate for testing specifically in SC's Epic and Cerner EMRs
- Site 1 showed almost perfect reliability testing, whereas Site 2 showed Moderate results. These are at least moderate if not high levels of agreement. There were examples of a manual process finding more data. This will likely become more important as it relates to some of the measures exclusions and where these are found in structured data.
- None
- Some but generally believe the measurement can be conducted in a reliable manner.
- I'm not confident that the data will consistently be available to conduct the measure.
- See question 6
- No
- No concerns

2b1. Validity - Testing

Comments:

- I have concerns regarding the inaccurate fields in the SC test groups. I believe there needs to be refining of the fields pulled and to match them with SnoMed Codes to improve accuracy. I am not sure the every version of EPIC and/or CERNER has fully implemented the use of the clinical SnoMed codes. Again larger clinic/groups with the higher level of EMR version may have access to the updated ONC standards to pair ICD10 with SnoMed codes.
- Face validity was determined by outside group of experts via online survey. The panel of experts was varied and included people with exposure to the patients being measured. There was agree or strongly agree from 86% which would support the case for face validity.
- None
- Generally don't have concerns.
- None, but limited.
- no comment over an above the initial review by NQF
- Yes - see 2b6 below
- No concerns

2b4-7. Threats to Validity

Comments:

- I agree with the NQF staff concern: NQF staff are concerned that not all exclusions were tested as it is not clear from the submission whether this was in fact the case.
- The type of missing data here is a problem across all measures, not just this particular one. I don't think that is a reason to exclude. It is disappointing that they can't speak to the frequency of missing data. There was also not testing on differences in performance; however, I think this is not a problem.
- None
- Minimal concerns.
- The data sources are a concern and pose a threat to the validity.
- No additional comments

- Perhaps. "All elements that were missing on the sample cases were tracked ... full and accurate information could be found in the manual abstraction process than through electronic reporting, ... this seems to be a consistent issue ... given the nature of EHR capabilities and limitations ... We do not have the number of the overall frequency of missing data." I would like to ask that the developers be asked why the numbers of items missing in the electronic reviews and found by manual review were not followed and described.
- NA

2b2-3. Other Threats to Validity

Comments:

- No Risk Adjustment applied.
- The exclusions do appear aligned with other similar measures that have been endorsed by NQF. There is no risk adjustment
- The exclusions seem appropriate
- None
- The measure specifications did not exclude hospice.
- This is a clinician-level process measure and risk adjustment does not seem necessary. However, data must be reported by relevant insurances, SES, and race/ethnicity strata
- No
- No concerns

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.

- The feasibility assessment indicated the following data elements have feasibility issues in the *availability*, *workflow, and standards* domains indicating the data elements are not routinely generated during care or available in electronic sources:
    - "Laboratory Test, Performed: Fasting Plasma Glucose Lab Test Mass Per Volume" (in Cerner and Epic) (*measure developer noted that Fasting status of glucose testing is not captured in discrete fields in either EHR, however capturing A1C testing is feasible. To test for prediabetes, fasting plasma glucose, 2-h plasma glucose during 75-g oral glucose tolerance test, and A1C are equally appropriate)*
    - "Intervention Order: Comfort Measures" (in Cerner) *(measure developer noted that Comfort Care as an exclusion is standard in in NQF endocrine registry measures and it is expected that EMR developers to create a distinct field to collect this data in the future)*
    - "Laboratory Test, Not Performed: Fasting glucose [Moles/volume] in Serum or Plasma" (in Cerner and Epic)
    - "Laboratory Test, Not Performed: Fasting Plasma Glucose Lab Test Mass Per Volume" (in Cerner and Epic)
    - "Laboratory Test, Not Performed: Glucose [Mass/volume] in Serum or Plasma --2 hours post 75 g glucose PO" (in Cerner)
    - "Laboratory Test, Not Performed: Glucose [Moles/volume] in Serum or Plasma --2 hours post 75 g glucose PO" (in Cerner)
    - "Laboratory Test, Performed: Fasting glucose [Moles/volume] in Serum or Plasma" (in Cerner and Epic)

- All value sets used in measure submission are accessible via the VSAC
- Submission includes simulated data set results demonstrating unit testing covering 100% of the measure logic.
- Measure developer notes that the data for the measure are collected as part of the routine provision of care.
- Developer asserts that all data elements reside in defined fields inside the EHR.
- No licensing agreement or fees required for use of the measure.

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?
- Does the eCQM Feasibility Score Card demonstrate acceptable feasibility in multiple EHR systems and sites?

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

RATIONALE: eCQM feasibility assessment demonstrated that key data elements have feasibility issues in the *availability*, *workflow, and standards* domains indicating the data elements are not routinely generated during care or available in electronic sources. The submission did not include a plan for addressing the feasibility issues with each data element.

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility

Comments:

- As stated before I am concerned that all versions of Epic and Cerner for all End users have their clinic set up to routinely generate and use the data without having an idea of the appropriate coding necessary to be inplace. I agree that we should see some testing in other large and small EMR/EHR users and to the growing lists of medical office EMR and EHR software.
- Data elements are all defined in EHRs, although some of the denominator exclusions are less easily captured (palliative care, etc). Both age and BMI are regularly captured
- What about patients who move from one health system to another, or who see different providers, or who do not have a single primary care provider? Which provider is being 'measured' in that case?
- Measurement would be expected to be feasible, if the routine data elements are availble or substitutes could be used.
- Feasibility is a concern. Not all data may be readily available to calculate the measure out of the EHR system.
- See comments above about the fasting glucose
- "Referrals to diabetes prevention program or dietician are often automated messages. These can be seen in manual abstraction and depending on level of access to the EHR system, not all medical staff can see these messages." The systems studied utilize frequently employed EHRs. What percentage of individuals meeting Pre-DM criteria were referred but this was not apparent by electronic coding? This might have an impact on reasibiblity and quaiity of this measure. Asking for EMR developers to address this possible source of error is needed for application but at present, I agree with the rating of low feasibility.
- Data captured in routine care delivery

Criterion 4: Usability and Use

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

4a. Use evaluate 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**

Accountability program details

- Developer provides an implementation plan that includes
    - MIPS to complement the prediabetes IAs; measures to be submitted to the CMS MUC list call for measures in 2020.
    - CMS CMMI has reached out to the AMA to adopt this measure for the Maryland Primary Care Program´s public reporting program for 2021.
    - CMS has met with the AMA to discuss this measure being included (as part of the set) in a Prediabetes MIPS Value Pathway (MVP) for the 2021 performance period.

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

- Developer notes that the measure has not been implemented and therefore they have no feedback from end users.

Feedback on the measure by those being measured or others N/A

Additional Feedback: N/A

Questions for the Committee:

- 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 (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate 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

- N/A

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

- None identified by developer

Potential harms

- None identified by developer

Additional Feedback:

- None identified by 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: Criteria 4: Usability and Use

4a1. Use – Accountability and Transparency

Comments:

- No feedback as it is new.
- It has not been implemented, so there is no feedback. The goal is to be adopted in MIPS QPP and possibly MVP for 2021.
- N/a
- Since new measure, not as clear about use.
- The measure is not currently publicly reported. Planned for public reporting in Maryland in 2021.
- I am surprised that there are no insurance or ACO accountabilty measures for pre-diabetes screening, so we need to be clear on how thorough the developers looked for these - even if the proposed measure differs in some respects from any existing accountability measures.
- This measure is not yet implemented. It is not clear if results were given to the providers in the two studied health systems. There is no mention of feedback from providers/users. Such information would be helpful in evaluating this measure.
- No current use, planned use

4b1. Usability – Improvement

Comments:

- Developer did not identify. Some unintended consequences are over or under reporting that would impact the MIPS calculation. Benefit is increased and earlier intervention for persons at risk for diabetes.
- N/A
- Is there data recommending the 'every 3 year' stipulation in the measure? What is the percent of patients over 40 with BMI >25 who progress to prediabetes over 3 years? Are we sure this is the appropriate frequency to use in this measure?

- Since new, not clear for Usability Improvment or Benefits vs. harms.
- No harms. I am concerned about the usability for purposes of improvement.
- I don't see any harm in this, but if someone is slightly abnormal the test should be repeated before remediation. For example, did the person really fast? I would be very surprised if there were no improvement efforts in the nation on analogous measures, and this one certainly should drive improvement
- It seems reasonable that this measure could be used to further the goal of better health care. No potential harms identified.
- No concerns

Criterion 5: Related and Competing Measures

Related or competing measures

- No related or competing measures were identified by the developer or NQF staff.

Harmonization

- N/A

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing Measures

Comments:

- None in NQF, however have we looked at the CDC DPP and CMS MDPP quality data bases?
- There are no competing measures for prediabetes, so no harmonization at this point.
- Related prediabetes referral measure in evaluation in this cycle
- None suggested.
- No competing measures.
- not sure
- None.
- None

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/22/20

- **No NQF Members have submitted support/non-support choices as of this date.**

NQF Staff Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 3569e

Measure Title: Prediabetes: Screening for Abnormal Blood Glucose

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**
☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☒ **Clinician: Group/Practice** ☒ **Clinician: Individual** ☐ **Facility** ☐ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☒ **New** ☐ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: Testing document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**
   - No concerns identified by staff

RELIABILITY: TESTING

Submission document: Testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☐ **Measure score** ☐ **Data element** ☒ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☒ **Yes** ☐ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   - Developer used same testing for both data element reliability and validity.
   - Developer performed data element reliability/validity testing at two facilities on two common EHR systems.
     - Test Site #1: An ambulatory facility in South Carolina, part of a larger health system comprised of 8 inpatient hospitals and more than 100 outpatient facilities. This facility uses Epic EHR in their facility.

- Test Site #2: An ambulatory facility in South Carolina, part of a larger system comprised of a 1,600+ bed comprehensive integrated health system, serving 1 million patients. This facility uses Cerner EHR in their facility.

- Data element reliability/validity testing was conducted utilizing Parallel Forms Reliability Testing methodology to determine if data elements found through electronic data pulls could be confirmed by manual abstraction of the same data elements.
  - Verification of the data elements was obtained through automated data search strategies against a reference strategy (considered the gold standard) for obtaining the data elements.
  - Manual review of the data elements was used as the reference strategy against which automated data search and extraction strategies were evaluated.
  - Interrater reliability (crude agreement and Cohen's Kappa) was used to assess the reliability of the measure based on results from two independent reviewers trained in the same way reviewing the same patient record.
- NQF staff consider this an appropriate testing methodology according to current NQF criteria.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   - The developer reported Kappa scores and crude agreement by site:

		% Agree	Kappa	N
Site 1	**Denominator**	98	0.955	100
	Numerator	100	1.000	86
Site 2	**Denominator**	83	0.504	72
	Exclusions	76	0.511	67
	Numerator	100	**	23

   **Kappa scores not calculable

   - Measure demonstrates moderate to strong kappa scores at the two testing sites

8. 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.

   Submission document: Testing attachment, section 2a2.2

   ☐ **Yes**

   ☐ **No**

   ☒ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

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

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-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)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**
    - Developer used an appropriate testing methodology for the data element testing.
    - Staff were concerned that the developer notes a few instances across the measure where more full and accurate information could be found in the manual abstraction process than through electronic reporting.
        - "For example, if height is not measured and weight is measured at an office visit, then BMI may not be calculated and reported in a discrete field. In these cases, BMI can be found only by looking at the chart.
        - "Additionally, for exclusions related to the identification of comfort measures, hospice care ambulatory, and palliative care are not always stored in discrete fields, even if these are available. Some information is stored in comments/notes in the EHR."

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

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

    Submission document: Testing attachment, section 2b2.
    - Measure exclusions appear appropriate.
    - NQF staff are concerned that not all exclusions were tested as it is not clear from the submission whether this was in fact the case.
13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4.
    - Developer notes that "Differences in performance were not tested, however during testing, performance was calculated with performance rates of 0.292 and 0.483 for sites 1 and 2, respectively."
    - NQF staff do not consider there to be significant threats to the measure's ability to detect meaningful differences in provider performance.
14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
    Submission document: Testing attachment, section 2b5.
    - N/A
15. **Please describe any concerns you have regarding missing data.**

    Submission document: Testing attachment, section 2b6.
    - Developer notes that, "As part of the reliability testing, sites completed data element tables that assessed for missing elements. All elements that were missing on the sample cases were tracked. Since we found instances across the measures where more full and accurate information could be found in the manual abstraction process than through electronic reporting, this seems to be a consistent issue across all types of measures, not just this particular measure, given the nature of EHR capabilities and limitations."
    - No additional concerns from NQF staff.
16. **Risk Adjustment**

16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☒ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☒ No

16d.**Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

16d.5.Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e**. Assess the risk-adjustment approach**

- N/A

VALIDITY: TESTING

17. **Validity testing level:** ☐ **Measure score** ☒ **Data element** ☐ **Both**

18. **Method of establishing validity of the measure score:**

☐ **Face validity**

☐ **Empirical validity testing of the measure score**

☒ **N/A (score-level testing not conducted)**

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

Submission document: Testing attachment, section 2b2.2

- Developer used same testing for both data element reliability and validity.
- Developer performed data element reliability/validity testing at two facilities on two common EHR systems.
    - Test Site #1: An ambulatory facility in South Carolina, part of a larger health system comprised of 8 inpatient hospitals and more than 100 outpatient facilities. This facility uses Epic EHR in their facility.
    - Test Site #2: An ambulatory facility in South Carolina, part of a larger system comprised of a 1,600+ bed comprehensive integrated health system, serving 1 million patients. This facility uses Cerner EHR in their facility.
- Data element reliability/validity testing was conducted utilizing Parallel Forms Reliability Testing methodology to determine if data elements found through electronic data pulls could be confirmed by manual abstraction of the same data elements.
    - Verification of the data elements was obtained through automated data search strategies against a reference strategy (considered the gold standard) for obtaining the data elements.
    - Manual review of the data elements was used as the reference strategy against which automated data search and extraction strategies were evaluated.

- Interrater reliability (crude agreement and Cohen's Kappa) was used to assess the reliability of the measure based on results from two independent reviewers trained in the same way reviewing the same patient record.

- NQF staff consider this an appropriate testing methodology according to current NQF criteria.
- Staff were concerned that the developer notes a few instances across the measure where more full and accurate information could be found in the manual abstraction process than through electronic reporting.
  - "For example, if height is not measured and weight is measured at an office visit, then BMI may not be calculated and reported in a discrete field. In these cases, BMI can be found only by looking at the chart.
  - "Additionally, for exclusions related to the identification of comfort measures, hospice care ambulatory, and palliative care are not always stored in discrete fields, even if these are available. Some information is stored in comments/notes in the EHR."

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

    Submission document: Testing attachment, section 2b2.3

    - The developer reported Kappa scores and crude agreement by site:

		% Agree	Kappa	N
Site 1	**Denominator**	98	0.955	100
	Numerator	100	1.000	86
Site 2	**Denominator**	83	0.504	72
	Exclusions	76	0.511	67
	Numerator	100	**	23

    **Kappa scores not calculable

    - Measure demonstrates moderate to strong kappa scores at the two testing sites.

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

    Submission document: Testing attachment, section 2b1.

    ☐ **Yes**

    ☐ **No**

    ☒ **Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**

    NOTE that data element validation from the literature is acceptable.

    Submission document*: Testing attachment, section 2b1.*

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (data element testing was not performed)

23. **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 score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-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 score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**
    - Developer used an appropriate testing methodology for the data element testing.

ADDITIONAL RECOMMENDATIONS

25. **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.**
    - None identified by NQF staff.

1. Evidence and Performance Gap – 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.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF_evidence_attachment_Prediabetes_Screening_-637220457699679991.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** Click here to enter NQF number

Measure Title: Prediabetes Screening for Abnormal Glucose

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title

Date of Submission: 4/9/2020

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

☐ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

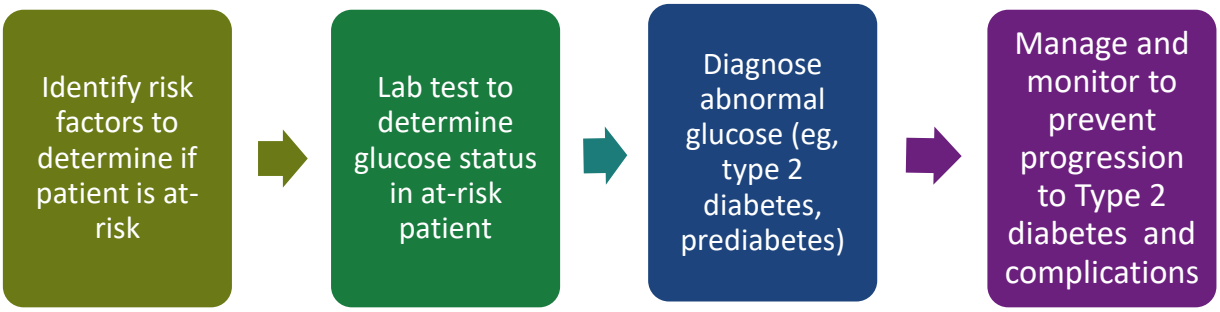
☒ Process: Glucose screening for identifying patients with prediabetes

☐ Appropriate use measure: Click here to name what is being measured

☐ Structure: Click here to name the structure

☐ Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or 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.



1a.3 Value and Meaningfulness: **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. (Describe how and from whom their input was obtained.)

Implementing this measure to increase screening and identifying patients with prediabetes can improve health outcomes for patients by preventing the progression to type 2 diabetes. Cost savings associated with preventing diabetes are significant. In the Medicare Diabetes Prevention Program (Medicare DPP) model test conducted through the Center for Medicare and Medicaid Innovation, implementation of the MDPP preventive service resulted in an estimated cost savings of $ 2,650.00 per participating Medicare beneficiary over 15 months. Individuals with diabetes typically have medical expenses 2.3 times higher than those without it. The longitudinal impact of this measure would be substantial in terms of cost savings and disease prevention.

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

N/A

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? 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. (IOM)

x Clinical Practice Guideline recommendation (with evidence review)

x US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	**Siu L on behalf of the U. S. Preventive Services Taskforce. Screening for abnormal blood glucose and type 2 diabetes mellitus: U. S. Preventive Services Task Force recommendation. Ann Intern Med. 2015;163:861-868.** **American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018. (41) Supplement 1. Available at: http://care.diabetesjournals.org.**
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	The following evidence statements are quoted **verbatim** from the referenced clinical guidelines and other sources, where applicable: U. S. Preventive Services Taskforce. Screening for abnormal blood glucose and type 2 diabetes mellitus: U. S. Preventive Services Task Force recommendation The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years of age who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity. (USPSTF, 2015[i]) (B recommendation) This recommendation applies to adults aged 40 to 70 years who are seen in primary care settings and do not have obvious symptoms of diabetes. Persons who have a family history of diabetes, have a history of gestational diabetes or polycystic ovarian syndrome, or are members of certain race/ethnic groups (that is, African Americans, American Indians, or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders) may be at increased risk for diabetes at a younger age or at a lower body mass index. Clinicians should consider screening earlier in persons with 1 or more of these characteristics. (USPSTF, 2015[i]) American Diabetes Association. Standards of medical care in diabetes—2018. Testing for prediabetes and risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25kg/m2 or ≥23kg/m2 in Asian Americans) and who have one or more additional risk factors for diabetes (Table 2.3). (ADA, 2018[ii]) (B Recommendation) • Table 2.3—Criteria for testing for diabetes or prediabetes in asymptomatic adults 1. Testing should be considered in overweight or obese (BMI ≥25kg/m2 or ≥23kg/m2 in Asian Americans) adults who have one or more of the following risk factors:

	• First-degree relative with diabetes • High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander) • History of CVD • Hypertension (≥140-90mmHg or on therapy for hypertension • HDL cholesterol level <35mg/dL (0.90mmol/L) and/or triglyceride level >250mg/dL (2.28mmol/L) • Women with polycystic ovary syndrome • Physical inactivity • Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans) 2. Patients with prediabetes (A1C ≥5.7% [39mmol/mol], IGT, or IFG) should be tested yearly. 3. Women who were diagnosed with GDM should have lifelong testing at least every 3 years. 4. For all other patients, testing should begin at age 45 years. 5. If results are normal, testing should be repeated at a minimum of 3 year intervals, with consideration for more frequent testing depending on initial results and risk status. To test for prediabetes, fasting plasma glucose, 2-h plasma glucose during 75-g oral glucose tolerance test, and A1C are equally appropriate. (ADA, 2018[ii]) (B Recommendation)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	See above evidence statements with grades
Provide all other grades and definitions from the evidence grading system	USPSTF Grading: A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C: The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. D: The USPSTF recommends against the service. There is moderate or high certainty that the service has : benefit or that the harms outweigh the benefits. I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. ADA Grading: Grade 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 Grade B • Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies • Supportive evidence from a well-conducted case-control study Grade C • Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports • Conflicting evidence with the weight of evidence supporting the recommendation E Expert consensus or clinical experience
Grade assigned to the **recommendation** with definition of the grade	B The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. Grade B • Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies • Supportive evidence from a well-conducted case-control study
Provide all other grades and definitions from the recommendation grading system	See above
Body of evidence: • Quantity – how many studies?	In addition to the USPSTF and ADA guidelines, we reviewed over five evidence-based peer reviewed journal articles that confirmed the gap in care around prediabetes screening.

• Quality – what type of studies?	
Estimates of benefit and consistency across studies	Strong evidence exits that rates of screening patients for prediabetes and undiagnosed diabetes are suboptimal in clinical care, especially in patients who are at high risk for developing type 2 diabetes. Approximately 1/3 of physicians reported screening patients for prediabetes according to guidelines (ADA and USPSTF). In a nationally representative sample of patients from the National Health and Nutrition Examination Survey (NHANES) from 2005-2012, only 45% of those who met screening criteria were screened.[iii] Additionally, survey data show that while primary care physicians are aware of the guidelines that support screening for prediabetes, there is a disconnect between this knowledge and actual practice[iv,v]
What harms were identified?	None
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	None

1a.4 OTHER SOURCE OF EVIDENCE

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

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

This measure is based on evidence-based guidelines from the United States Preventive Services Task Force (USPSTF) and from the American Diabetes Association (ADA). The evidence base for preventing diabetes via intensive lifestyle change is substantial. The United States Preventive Services Task Force (USPSTF) incorporated this evidence into the updated recommendation regarding screening for abnormal glucose and type 2 diabetes. The grade B recommendation states that physicians should screen individuals for abnormal glucose if they are between the ages of 40 and 70 and are overweight or obese, or younger if they have additional risk factors. The ADA recommends screening patients who are overweight or obese with one risk factor, regardless of age. Additionally, those who have no risk factors should start screening at age 45. The risk factors included in this measure bring together both the USPSTF and ADA risk factors.

Testing for prediabetes and risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25kg/m2 or ≥23kg/m2 in Asian Americans) and who have one or more additional risk factors for diabetes. (ADA, 2018) (B Recommendation)

1. Testing should be considered in overweight or obese (BMI ≥25kg/m2 or ≥23kg/m2 in Asian Americans) adults who have one or more of the following risk factors:
    - First-degree relative with diabetes
    - High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
    - History of CVD
    - Hypertension (≥140-90mmHg or on therapy for hypertension
    - HDL cholesterol level <35mg/dL (0.90mmol/L) and/or triglyceride level >250mg/dL (2.28mmol/L)
    - Women with polycystic ovary syndrome
    - Physical inactivity
    - Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
2. Patients with prediabetes (A1C ≥5.7% [39mmol/mol], IGT, or IFG) should be tested yearly.
3. Women who were diagnosed with GDM should have lifelong testing at least every 3 years.
4. For all other patients, testing should begin at age 45 years.
5. If results are normal, testing should be repeated at a minimum of 3-year intervals, with consideration for more frequent testing depending on initial results and risk status.

To test for prediabetes, fasting plasma glucose, 2-h plasma glucose during 75-g oral glucose tolerance test, and A1C are equally appropriate. (ADA, 20181) (B Recommendation)

The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years of age who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity. (USPSTF, 2015) (B recommendation)

Other evidence-based studies to support this measure:

Geiss L. et al. Diabetes risk reduction behaviors among US adults with prediabetes. Am J Prev Med. 2010. 38(4): 403-409.

• Based on data from 1402 adults without diabetes (with preDM) who participated in the 2005-2006 National Health and Nutrition Examination Survey (NHNES) and who had valid fasting glucose and OGTTs.

• Almost 30% of the US adult population had preDM in 2005-2006 but only 7.3% were aware they had the condition.

• About half of adults with preDM reported performing DM risk reduction behaviors in the past year but only one third of adults with preDM received healthcare provider advice about these behaviors in the past year.

Kiefer M, et al. National patterns in diabetes screening: Data from the National Health and Nutrition Examination Survey (NHANES) 2005-2012. J Gen Intern Med. 2014*;30(5)*: 612-618.

• In a nationally representative sample (NHANES), only 45% of those who met ADA criteria (thought to be approximately 76.6% of the US population) for screening were actually

screened.

Mehta S, Mocarski M, Wisniewski T, Gillepsie K, Narayan Venkat KM, Lang K. Primary care physician's utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey linked retrospective study. BMJ Open Diab Res Care. 2017;5:e000406. Doi:10.1136/bmjdrc-2017-000406.

• Online survey of 305 primary care physicians regarding use of guidelines in screening for type 2 guidelines and referral to DPP and DSME for newly diagnosed patients with prediabetes or type 2 diabetes.

• Findings show a disconnect between physician perception of following guidelines and actual practice when physician survey responses are compared to EMR data.

- 38% of physicians reported using guidelines (33% used ADA only, 25% use ADA only)

1a.4.2 What process was used to identify the evidence?

A thorough literature review was conducted to identify evidence-based guidelines and other evidence, gaps in care with supportive evidence, and gaps in measurement to support the identification of measure concepts.

1a.4.3. Provide the citation(s) for the evidence.

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[i] Siu L on behalf of the U. S. Preventive Services Taskforce. Screening for abnormal blood glucose and type 2 diabetes mellitus: U. S. Preventive Services Task Force recommendation. Ann Intern Med. 2015;163:861-868.

[ii] American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018. (41)Supplement 1. Available at: http://care.diabetesjournals.org.

[iii] Kiefer M, et al. National patterns in diabetes screening: Data from the National Health and Nutrition Examination Survey (NHANES) 2005-2012. J Gen Intern Med. 2014;*30(5)*: 612-618

[iv] Mehta S, Mocarski M, Wisniewski T, Gillepsie K, Narayan Venkat KM, Lang K. Primary care physician's utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey-linked retrospective study. BMJ Open Diab Res Care. 2017;5:e000406. Doi:10.1136/bmjdrc-2017-000406.

[v] Tseng E, Greer R C, O'Rourke, P, Yeh, H-C, McGuire, M M, Clark, J M, & Maruthur, N M. Survey of primary care providers' knowledge of screening for, diagnosing and managing prediabetes. Journal of General Internal Medicine, 32(11), 1172–1178.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

This measure is critical to identifying patients with prediabetes who are not screened, thus missing potential cases that progress to diabetes. This measure is part of a set that will produce the first measurement set in the U.S. intended to prevent type 2 diabetes. Currently, eighty-four million Americans have prediabetes and 9 out 10 patients are unaware that they have this condition. CDC-recognized lifestyle change programs are included in the health benefit plans and the Medicare Diabetes Prevention Program, including Medicare beneficiaries.

Screening for prediabetes and identifying patients before they progress to Type 2 diabetes is the first step to enabling beneficiaries to utilize this benefit. Furthermore, cost savings for prevention of type 2 diabetes have the potential to be significant. For every beneficiary, at 15 months, costs savings are at least $ 2,650.00 per person.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, 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 (4b1) under Usability and Use.*

N/A

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, 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.

The United States has 84 million adults with prediabetes, putting them at a higher risk for developing type 2 diabetes. Moreover, 9 out of 10 patients who have prediabetes are not aware. Missed opportunities among primary care providers in diagnosing and managing patients with prediabetes represent a gap in care. Early detection and management of pre-diabetes is fundamental to preventing diabetes. The US Preventive Services Task Force (USPSTF) and the American Diabetes Association (ADA), have recommended screening for diabetes and pre-diabetes. Despite established national screening guidelines in U.S., suboptimal screening rates are reported. The development of this measure is aimed at targeting the large percentage of U.S. adults with prediabetes, and identifying them to provide care and management of their condition to prevent type 2 diabetes.

Overall, screening patients for prediabetes does not occur as often as it should. In a nationally representative sample of patients from the National Health and Nutrition Examination Survey (NHANES) from 2005-2012, only 45% of those who met screening criteria were actually screened. Additionally, survey data show that while primary care physicians are aware of the guidelines that support screening for prediabetes, there is a disconnect between this knowledge and actual practice.

Mehta S, Mocarski M, Wisniewski T, Gillepsie K, Narayan Venkat KM, Lang K. Primary care physician's utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey-linked retrospective study. BMJ Open Diab Res Care. 2017;5:e000406. Doi:10.1136/bmjdrc-2017-000406.

Tseng E, Greer R C, O'Rourke, P, Yeh, H-C, McGuire, M M, Clark, J M, & Maruthur, N M. Survey of primary care providers' knowledge of screening for, diagnosing and managing prediabetes. Journal of General Internal Medicine, 32(11), 1172–1178.

1b.4. 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. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) 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 (4b1) under Usability and Use.

This is a new measure, therefore data from the measure is not available

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, 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 1b.4

The United States has 84 million adults with prediabetes, putting them at a higher risk for developing type 2 diabetes. Moreover, 9 out of 10 patients who have prediabetes are not aware. Missed opportunities among primary care providers in diagnosing and managing patients with prediabetes represent a gap in care. Early detection and management of pre-diabetes is fundamental to preventing diabetes. The US Preventive Services Task Force (USPSTF) and the American Diabetes Association (ADA), have recommended screening for diabetes and pre-diabetes. Despite established national screening guidelines in U.S., suboptimal screening rates are reported. The development of this measure is aimed at targeting the large percentage of U.S. adults with prediabetes, and identifying them to provide care and management of their condition to prevent type 2 diabetes.

Overall, screening patients for prediabetes does not occur as often as it should. In a nationally representative sample of patients from the National Health and Nutrition Examination Survey (NHANES) from 2005-2012, only 45% of those who met screening criteria were actually screened. Additionally, survey data show that while primary care physicians are aware of the guidelines that support screening for prediabetes, there is a disconnect between this knowledge and actual practice.

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Tseng E, Greer R C, O'Rourke, P, Yeh, H-C, McGuire, M M, Clark, J M, & Maruthur, N M. Survey of primary care providers' knowledge of screening for, diagnosing and managing prediabetes. Journal of General Internal Medicine, 32(11), 1172–1178.

2. Reliability and Validity—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.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

De.6. Non-Condition Specific*(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

S.1. Measure-specific Web Page *(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.)*

S.2a. <u>If this is an eMeasure</u>, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is an eMeasure **Attachment:** ScreeningAbnormalBloodGlucose_v5_8_Artifacts_20200106_-2-.zip

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** Copy_of_Screening_Abnormal_Blood_Glucose_Value_Sets_20200106.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. <u>For maintenance of endorsement:</u> Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

S.3.2. <u>For maintenance of endorsement,</u> please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

N/A

S.4. Numerator Statement *(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.*

<u>IF an OUTCOME MEASURE</u>, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

*Screening for abnormal blood glucose may include using a fasting plasma glucose, 2-h plasma glucose during a 75g oral glucose tolerance test, or A1C.

S.5. Numerator Details *(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 S.2b)*

<u>IF an OUTCOME MEASURE,</u> describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

exists "A1c Test Performed Within Past 3 Years"

or exists "Fasting Plasma Glucose Test Performed Within Past 3 Years"

or exists "Two Hour Plasma Glucose During 75 Gram Oral Glucose Tolerance Test Performed Within Past 3 Years"

See additional code sets and materials in attachments

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

All patients aged 43 years and older with a BMI greater than or equal to 25 seen for at least two office visits or at least one preventive visit during the 12-month measurement period

S.7. Denominator Details *(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 S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Denominator

"Initial Population"

and exists (["Patient Characteristic Birthdate": "Birth date"] BirthDate

where Global."CalendarAgeInYearsAt" (BirthDate.birthDatetime, start of "Measurement Period") >= 43

)

and "Highest BMI Documented During Measurement Period is Greater Than or Equal to 25"

See attachment in human readable file in S.2a

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Denominator Exclusions

"Patient is Pregnant at Encounter"

or "Patient Has Active Diabetes Diagnosis at Encounter"

or "Hospice During Measurement Period"

or "Palliative Care During Measurement Period"

or "Comfort Measures During Measurement Period"

S.9. Denominator Exclusion Details *(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 S.2b.)*

See attachment in human readable file in S.2a

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including 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 with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

See attachment in human readable file in S.2a

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

n/a

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

n/a

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Records

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Measure data elements will be collected through health care organization electronic health record query, electronic health data queries

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No data collection instrument provided

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Clinician : Group/Practice, Clinician : Individual

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Outpatient Services

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

2. Validity – See attached Measure Testing Submission Form

NQF_testing_attachment_Prediabetes_Screening-637213437188919709.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** Click here to enter NQF number
Measure Title: Retesting of Abnormal Blood Glucose in Patients with Prediabetes
Date of Submission: 1/6/2020

Type of Measure:

☐ **Outcome (*including PRO-PM*)**	☐ **Composite – *STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

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 in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (***must be consistent with data sources entered in S.17***)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☐ registry	☐ registry
☐ abstracted from electronic health record	☒ abstracted from electronic health record
☒ eMeasure (HQMF) implemented in EHRs	☒ eMeasure (HQMF) implemented in EHRs

☐ other: Click here to describe	☐ other: Click here to describe

1.2. 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*).

1.3. What are the dates of the data used in testing? Click here to enter date range

The measurement period (data collected from patients seen) was 8/1/2018 through 09/30/2019.

1.4. What levels of analysis were tested? (*testing must be provided for <u>all</u> the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	**Measure Tested at Level of:**
☒ individual clinician	☒ individual clinician
☒ group/practice	☒ group/practice
☐ hospital/facility/agency	☐ hospital/facility/agency
☐ health plan	☐ health plan
☐ other: Click here to describe	☐ other: Click here to describe

1.5. How many and which <u>measured entities</u> were 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*)

Two sites were recruited and identified to collect data for testing and analysis at the data element level, reviewing individual patient records from the EHR and comparing to a manual review of the same cases. Testing was completed using a convenience sample, whereas sample size requirements were calculated based on estimated rates for each measure by site using a calculator based on the calculation defined by Donner-Eliasziw (see section 1.6 below).

Using specifications defined by the measure developer, both testing sites were able to access and test the critical data elements that included all components of the numerator, all components of the denominator, and all components of the exclusions. Testing was completed at the data element level and was completed on all patient cases in the sample. It should be noted that although the measure is specified at the physician and physician group level, testing was completed at the individual data element level (as opposed to signal to noise), so therefore there would not be counts of physicians included in the analysis.

- Test Site #1: An ambulatory facility in South Carolina, part of a larger health system comprised of 8 inpatient hospitals and more than 100 outpatient facilities This facility uses Epic EHR in their facility.

- Test Site #2: An ambulatory facility in South Carolina, part of a larger system comprised of a 1,600+ bed comprehensive integrated health system, serving 1 million patients. This facility uses Cerner EHR in their facility.

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

As described in 1.5, we recruited and subcontracted with two sites to collect patient-level EHR data for the measure. Patient cases were included in the testing and analysis that met the following criteria:

- Adults ages 18 and over
- All races
- All genders

Due to the large size of the data available at each site, a sample of the patients at each site were identified through a validated process as described below.

Sample size requirements were calculated based on estimated rates for each measure by site using a calculator based on the calculation defined by Donner-Eliasziw[v]. A discussion and application of the use of the kappa statistic in reliability studies is available in Sim and Wright, 2005.[v] These methods were instituted in order to ensure that reliability testing and analyses occur on data sets that have a large enough sample size to detect statistically significant differences, thus minimizing variation due to the play of chance.

The important variables for the kappa sample size calculation are as follows:

- The value for the expected proportion of positive ratings for the measure being tested could be based on available data on the average performance of clinicians on the measure. If the average performance is 90%, the proportion of positive ratings is 0.90.

- The standard assumptions for testing projects are to specify the 2-tailed test at 80% power required to detect a difference between the value of the calculated kappa statistic and the null value for kappa, for example a kappa of .090 versus the null value of kappa of 0.60. This tests whether the difference in the kappa values of 0.30 (0.6 versus 0.9) is significant.

Each site provided us with preliminary counts of patients meeting the numerator and denominator to be used in sample size calculations. Following is a table that displays the data reported from the sites, the recommended sample size from the sample calculator, and the actual sample size for which the site was asked to collect data.

	Site 1	Site 2
Numerator (preliminary counts)	76	2688
Denominator (preliminary counts)	260	5567
Calculated Sample Size	67	55.8
Actual Sample Used for Testing	**100**	**75**

1.7. 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 reported below.

Reliability and validity of the data elements and exclusion testing utilized the same data from the practice site's respective EHR systems of Epic and Cerner. Risk adjustment and stratification were not applied and not applicable for these measures.

1.8 What were 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.

There were no social risk factors accounted for as elements in the measures. However, the Supplemental Data Elements in the measure specifications include language, race, ethnicity, and payor as elements that can be collected for each measure to allow for the stratification of measure results by these variables to assess disparities and initiate subsequent quality improvement activities.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☒ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☐ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level 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*)

By current NQF standards, data element validity testing results may be reported for reliability results. Testing description, results, and interpretation of results are given here and in 2b1. Validity Testing.

Data element validity testing was conducted utilizing Parallel Forms Reliability Testing methodology. Parallel forms reliability testing considers the analysis of agreement, through assessing the extent to which multiple formats or versions of data abstraction yield the same results. Verification of the data elements was obtained through automated data search strategies against a reference strategy (considered the gold standard) for obtaining the data elements. Manual review of the data elements was used as the reference strategy against which automated data search and extraction strategies were evaluated.

For this electronic clinical quality measure (eCQM), testing was used to determine if data elements found through electronic data pulls could be confirmed by manual abstraction of the same data elements. Testing at the level of the data elements allows for the analysis of each individual required data element included in the performance measure.

Interrater reliability (Cohen's Kappa coefficient) is used to assess the reliability of the measure based on results from two independent reviewers trained in the same way reviewing the same patient record. To perform inter-rater reliability testing we created an electronic data collection tool and trained the reviewers (raters) on its' use. The reviewers separately reviewed every sampled patient and collected all data elements necessary for computation of the performance measure (contained on the electronic data collection tool). Data received was analyzed using SAS to calculate frequencies, level of agreement, and agreement statistics (Cohen's Kappa). Cohen's Kappa coefficient measures inter-rater agreement for qualitative items and takes into account any agreement occurring by chance.

The following table displays the interpretation of the kappa statistic:

Kappa	**Strength of Agreement[v]**
0.00	Poor
0.01 - 0.20	Slight
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Substantial
0.81 - 0.99	Almost Perfect

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

The data element validity testing results including Kappa scores are presented below

		% Agree	Kappa	N
Site 1	**Denominator**	98	0.955	100
	Numerator	100	1.000	86
Site 2	**Denominator**	83	0.504	72
	Exclusions	76	0.511	67
	Numerator	100	**	23

**Kappa scores not calculable with multiple non-responses by raters (i.e., all No/No or all Yes/Yes)

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i*.e., what do the results mean and what are the norms for the test conducted?*)
For this measure, we find moderate to high levels of agreement for all data elements. Kappa scores ranged from .50 to 1.0, which is considered moderate to almost perfect.

We found a few instances across the measure where more full and accurate information could be found in the manual abstraction process than through electronic reporting. For example, if height is not measured and weight is measured at an office visit, then BMI may not be calculated and reported in a discrete field. In these cases, BMI can be found only by looking at the chart. Additionally, for exclusions related to the identification of comfort measures, hospice care ambulatory, and palliative care are not always stored in discrete fields, even if these are available. Some information is stored in comments/notes in the EHR.

_____

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☐ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. 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)*

This measure was tested for data element validity testing, content validity, face validity, and feasibility of the data elements.

Data element validity testing was conducted utilizing Parallel Forms Reliability Testing methodology. Parallel forms reliability testing considers the analysis of agreement, through assessing the extent to which multiple formats or versions of data abstraction yield the same results. Verification of the data elements was obtained through automated data search strategies against a reference strategy (considered the gold standard) for obtaining the data elements. Manual review of the data elements was used as the reference strategy against which automated data search and extraction strategies were evaluated.

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The following table displays the interpretation of the kappa statistic:

Kappa	**Strength of Agreement[v]**
0.00	Poor
0.01 - 0.20	Slight
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Substantial
0.81 - 0.99	Almost Perfect

Evidence of content validity is provided by looking for agreement among subject matter experts. The performance measure was assessed for content validity by a panel of technical expert work group members during the development process. This subject matter expert panel had representation from measure methodologists, patient advocacy groups, and clinical specialties. Additional input on the content validity of draft measures is obtained through a 30-day public comment period. All comments received are reviewed by the expert work group and the measures adjusted as needed.

For face validity, an external group of clinical and methodological experts assessed the measure for face validity through an on-line survey. The survey introduction provided the following definition of face validity: Face validity is the extent to which an empirical measurement appears to reflect that which it is supposed to "at face value." Face validity of an individual measure poses the question of how well the definition and specifications of an individual measure appear to capture the single aspect of care or healthcare quality as intended. Face validity of the measure score as an indicator of quality was systematically assessed as follows:

After the measure was fully specified, the expert panel was asked to rate their agreement with the following statement: "The scores obtained from the measure as specified will accurately differentiate quality across providers".

Scale 1-5, where 1= Strongly Disagree; 3=Neither Agree nor Disagree; 5=Strongly Agree, N/A = Not Applicable

The face validity panel included 22 panel members from the following organizations:

1. American Geriatric Society
2. American College of Occupational and Environmental Medicine
3. Omada Health
4. University of Chicago
5. Drexel University
6. Ascension St. John Detroit
7. American Society of Addiction Medicine
8. Tufts Medical Center
9. Rush University
10. National Institutes of Health
11. NorthShore University Healthcare
12. Northwestern Medicine
13. Rush University
14. Omada Health

15. Northwestern Medicine
16. Centers for Disease Control and Prevention
17. Emory University
18. Cincinnati Children's
19. Northwestern Medicine
20. Stony Brook Medicine
21. Advocate Healthcare
22. University of California San Francisco

Regarding feasibility of the data elements, a 2018 feasibility assessment was performed to assess the extent to which the required data are readily available, can be captured without undue burden, and are feasible for implementation within electronic health record systems. Two entities participated in the feasibility assessment for this measure.

• Test Site #1: a multispecialty academic medical center using EPIC EHR
• Test Site #2: a medical center using Matrix Care EHR

For this process, a testing methodology using a Data Element Tool (DET) to assess the availability of the data and the technical feasibility and implementation feasibility of the measures was employed. The DET is an Excel workbook designed to capture information that will determine whether or not each site can feasibly collect the data for the measures. It is structured to collect metadata about each data element necessary to construct each measure stored in the EHR. It will also collect information related to integrity and validity of data collection. Specifically, the DET is designed to capture the following information:

1. Data element information: Whether or not the data element is captured in the EHR, the data source application, primary user interface data location, data type, coding system, unit of measure, frequency of collection, and calculability within the measure context.
2. Measure integrity information: An assessment by the testing site as to what degree the measure, as specified, retains the originally stated intention of the measure.
3. Measure validity information: An assessment by the testing site as to what degree the scores obtained from the measure, as specified, will accurately differentiate quality performance across providers.

The DETs collected responses used to assess technical and implementation feasibility for each measure. Measure technical feasibility was defined as "Can my EHR do this?" and measure implementation feasibility was defined as "Will workflow be used consistently?" The responses were captured in the form of a rating using the following responses:

· "Feasible. Can do today."
· "Feasible with workflow mod/changes to EHR."
· "Non-feasible. Unable to do today."

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

The data element validity testing results including Kappa scores are presented below

		% Agree	Kappa	N

Site 1	**Denominator**	98	0.955	100
	Numerator	100	1.000	86
Site 2	**Denominator**	83	0.504	72
	Exclusions	76	0.511	67
	Numerator	100	**	23

**Kappa scores not calculable with multiple non-responses by raters (i.e., all No/No or all Yes/Yes)

For face validity, the panel rating of the validity statement for the measure were as follows:

N = 22; Mean rating = 4.27 and 86% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

Frequency Distribution of Ratings

5 (Strongly Agree) – 10

4 (Agree) – 9

3 (Neither Agree nor Disagree) – 2

2 (Disagree) – 1

1 (Strongly Disagree) – 0

X (Not Applicable) – 0

For feasibility, overall, the measures are technically "Feasible. Can do today." in both EHR systems that tested the measures. The majority of the of the data elements are routinely collected as part of clinical care but additional time and programming resources would be needed to implement the missing elements below:

• Laboratory Test, Performed: 2-H Plasma Glucose During a 75g Oral Glucose Tolerance Test

2b1.4. What is 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?*)

For this measure, we find moderate to high levels of agreement for all data elements tested. Kappa scores ranged from .50 to 1.0, which is considered moderate to almost perfect.

We found a few instances across the measure where more full and accurate information could be found in the manual abstraction process than through electronic reporting. For example, if height is not measured and weight is measured at an office visit, then BMI may not be calculated and reported in a discrete field. In these cases, BMI can be found only by looking at the chart. Additionally, for exclusions related to the identification of comfort measures, hospice care ambulatory, and palliative care are not always stored in discrete fields, even if these are available. Some information is stored in comments/notes in the EHR.

The results of the validity testing demonstrate that this measure is valid, supported by the results of the data element validity testing, content validity, face validity, and feasibility testing that was conducted.

_____

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b4*

2b2.1. Describe the method of testing exclusions and what it tests (*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*)

Each site initially pulled a random sample of patients. Site 1 pulled data that met the initial population criteria for the measure, and applied exclusion criteria to the denominator. The site provided a detailed spreadsheet that included the list of exclusions and reasons for exclusions that met the criteria. Site 2 pulled a random sample from the patient population and tested the exclusion criteria and applied inter-rater reliability testing using Cohen's Kappa Score.

2b2.2. What were 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*)

Across the measured entities, there were 67 patients excluded for this measure, with a Kappa score of .51. Performance for this measure was 48%. We would expect a performance score within this range. Because the exclusions for this measure are also widely used in other diabetes-related measures, and are based on evidence-based clinical guidelines, the impact on performance is minimal.

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., 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*)

With a Kappa score of .51, there is moderate agreement of reliability. The exclusions specified for this measure are consistent with other clinical exclusions that are used for measures with this clinical population. The testing results of the exclusions show moderate agreement for this measure.

Furthermore, the individual clinical exclusions specified in this measure are similar/and closely aligned with several already developed NQF endorsed measurement sets. The data elements for the measure exclusions are as follows: patients with diabetes, pregnancy, hospice care, ambulatory, and palliative care. The following NQF-endorsed measures have those data elements, so we are confident that the measure exclusions are appropriate and statistically demonstrate appropriateness:

- Diabetes Care for People with Serious Mental Illness: Hemoglobin A1c (HbA1c) Control (<8.0%): http://www.qualityforum.org/QPS/2608
    - Diabetes, Hospice Care Ambulatory
- Comprehensive Diabetes Care: Medical Attention for Nephropathy: http://www.qualityforum.org/QPS/0062
    - Hospice Care Ambulatory
- Diabetes: Foot Exam: http://www.qualityforum.org/QPS/0056
    - Diabetes
- Comprehensive Diabetes Care: Eye Exam (retinal) performed: http://www.qualityforum.org/QPS/0055
    - Diabetes
- Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (WCC) http://www.qualityforum.org/QPS/0024
    - Pregnancy, Hospice Care Ambulatory
- Depression remission at 12 months: http://www.qualityforum.org/QPS/0710e
    - Palliative Care

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b5.

N/A

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

N/A

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

N/A

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

N/A

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

N/A

2b3.4a. What were the statistical results of the analyses used to select risk factors?

N/A

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

N/A

2b3.5. 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*)
N/A

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

2b3.9. Results of Risk Stratification Analysis:

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. 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 related to performance gap in 1b)*

Differences in performance were not tested, however during testing, performance was calculated with performance rates of 0.292 and 0.483 for sites 1 and 2 respectively.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *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*)

Differences in performance were not tested as this measure was tested for data element validity testing.

	Site 1	Site 2
Numerator	76	2688
Denominator	260	5567
Performance Rate	0.292	0.483

2b4.3. What is 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? (i*.e., what do the results mean in terms of statistical and meaningful differences?*)
Differences in performance were not tested

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

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 eMeasures). 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.***

2b5.1. 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; what statistical analysis was used*)

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i*.e., what do the results mean and what are the norms for the test conducted*)

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

As part of the reliability testing, sites completed data element tables that assessed for missing elements. All elements that were missing on the sample cases were tracked. Since we found instances across the measures where more full and accurate information could be found in the manual abstraction process than through electronic reporting, this seems to be a consistent issue across all types of measures, not just this particular measure, given the nature of EHR capabilities and limitations.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

We do not have the number of the overall frequency of missing data

2b6.3. What is 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 nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., 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, provide rationale for the selected approach for missing data*)

N/A

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.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic health records (EHRs)

3b.2. 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 other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment: Copy_of_NQF_Feasibility_Scorecard_-_AMA_Screening_For_Abnormal_Glucose.xlsx,Bonnie_Report_-_Screening_for_Abnormal_GB.pdf

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. 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.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

N/A

3c.2. Describe 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)*.

None

4. Usability and Use

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.

4a. 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.

4.1. Current and Planned Use

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 performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting Payment Program	

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

This measure has not yet been implemented

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

There are several discussions underway for this measure to be adopted and implemented in public programs, and we describe the plan and expected timeframes below in 4a 1.3

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*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.*)

Plans for this measure to be adopted and implemented in public programs are underway. The AMA's goal is for this measure to be included in the MIPS QPP to complement the prediabetes IAs, so we will be submitting to the CMS MUC list call for measures in 2020. Furthermore, CMS CMMI has reached out to the AMA to adopt this measure for the Maryland Primary Care Program´s public reporting program for 2021. Ongoing discussions are currently underway and there is a plan in place for this measure to be implemented into this program. Additionally, CMS has already met with the AMA to discuss this measure being included (as part of the set) in a Prediabetes MIPS Value Pathway (MVP) for the 2021 performance period.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

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.

This measure has not yet been implemented

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

This measure has not yet been implemented

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

This measure has not yet been implemented

4a2.2.2. Summarize the feedback obtained from those being measured.

This measure has not yet been implemented

4a2.2.3. Summarize the feedback obtained from other users

This measure has not yet been implemented

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

This measure has not yet been implemented

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b 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, what are the reasons? 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.

This measure has not yet been implemented

4b2. Unintended Consequences

The 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).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

This measure has not yet been implemented

4b2.2. Please explain any unexpected benefits from implementation of this measure.

This measure has not yet been implemented

5. Comparison to Related or 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.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

Yes

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

There are no competing measures for prediabetes, this the first set of measures in U.S. to address this condition.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): American Medical Association

Co.2 Point of Contact: Beth, Tapper, beth.tapper@ama-assn.org, 312-933-6636-

Co.3 Measure Developer if different from Measure Steward: American Medical Association

Co.4 Point of Contact: Beth, Tapper, beth.tapper@ama-assn.org, 312-933-6636-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Ronald T Ackermann, MD, MPH (Co-Chair) Northwestern University

Senior Associate Dean for Public Health

Director, Institute for Public Health and Medicine (IPHAM) - Center for Community Health

Director, Center for Diabetes and Metabolism

Professor of Medicine (General Internal Medicine and Geriatrics), Medical Social Sciences and Medicine (Endocrinology)

William Golden, MD, MACP (Co-Chair) Professor of Medicine and Public Health

University of Arkansas for Medical Sciences

Medical Director

Arkansas DHS/Medicaid

Mary Carol Greenlee, MD, FACP, FACE Endocrinologist

Faculty for TCPi (national faculty and Colorado Practice Transformation Network faculty)

Mary E Krebs, MD

Family Medicine Physician and Faculty

HealthSource of Ohio and Soin Family Medicine Residency

Ameldia R. Brown MDiv, BSN, RN

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Leslie Kolb, RN, BSN, MBA

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Ann Albright, PhD, RD

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Beth Tapper, MA

Greg Wozniak, PhD

PCPI Foundation-consultants to this measure development project

Beth Bostrom, MPH

Kerri Fei, MSN, RN

Diedra Gray, MPH

Courtney Hurt, MSW, LCSW

Sam Tierney, MPH

Patrick Yep, MS, MPH

Technical expert panel members played a key role in the evidence review, development of the draft measures through an in-person consensus development process, and refinement and revision of the measures post-public comment. TEP members also helped with final measure revisions and approval of the measures in their current form.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2019

Ad.3 Month and Year of most recent revision: 12, 2019

Ad.4 What is your frequency for review/update of this measure? Yearly

Ad.5 When is the next scheduled review/update for this measure? 12, 2020

Ad.7 Disclaimers: The Measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications.

The Measures, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain.

Commercial uses of the Measures require a license agreement between the user and American Medical Association (AMA). The AMA shall not be responsible for any use of the Measures. The AMA encourages use of the Measures by other health care professionals, where appropriate.

Ad.8 Additional Information/Comments: We believe this measure, as part of the full measure set is necessary to reduce chronic disease burden. An estimated 30 million Americans have diabetes. This epidemic will continue to grow unless clinicians screen patients for prediabetes and manage at risk patients with preventive interventions. This measure addresses important areas that are critical to quality of care, improved outcomes, and lowered costs in the prevention and treatment of chronic disease, specifically:

- Improving patient outcomes by preventing or delaying progression of type 2 diabetes
- Reducing medical expenditures associated with type 2 diabetes and its complications by identifying and addressing prediabetes before progression to type 2 diabetes
- Improving clinical practice burden associated with treating diabetes by referring patients for treatment of their prediabetes

The United States has 84 million adults with prediabetes, putting them at a higher risk for developing type 2 diabetes.