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Primary Care and Chronic Illness, Spring 2020 Measure Review Cycle

Standing Committee Post-Comment Web Meeting

Samuel Stolpe, Senior Director
Erin Buchanan, Manager
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September 24, 2020

Welcome

Project Team — Primary Care and Chronic Illness Standing Committee

Sam Stolpe, PharmD, MPH
Senior Director

Erin Buchanan, MPH
Manager

Isaac Sakyi, MSGH
Analyst

Agenda

- Welcome and Review of Meeting Objectives
- Attendance
- Discussion and Re-vote on Consensus Not Reached (CNR) Measures
- Review of Reconsideration Request
- NQF Member and Public Comment
- Next Steps
- Adjourn

Attendance

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Primary Care and Chronic Illness Spring 2020 Cycle Standing Committee

- Dale Bratzler, DO, MPH (Co-chair)
- Adam Thompson, BA (Co-chair)
- Robert Bailey, MD
- Kenneth Benson, BS
- Lindsay Botsford, MD, MBA, FAAFP
- William Curry, MD, MS
- James M. Daniels, MD, MPH, RMSK, FAAFP, FACOEM, FACPM
- Kim Elliott, PhD
- Laura Evans, MD, MSc
- William Glomb, MD, FCCP, FAAP
- Donald Goldmann, MD
- V. Katherine Gray, PhD
- Faith Green, MSN, RN, CPHQ, CPC-A
- Stephen Grossbart, PhD
- James Mitchell Harris, PhD
- Starlin Haydon-Greatting, MS, BS, PharmD, FAPhA
- Ann Kearns, MD, PhD
- David Lang, MD
- Grace Lee, MD
- Anna McCollister-Slipp
- Janice Miller, DNP, CRNP, CDE
- Crystal Riley, PharmD, MHA, MBA, CPHQ, CHPIT
- Steven Strode, MD, MEd, MPH, FAAFP

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Primary Care and Chronic Illness Spring 2020 Cycle Expert Reviewers

- Amesh Adalja, MD
- Esther Babady, PhD, D(ABMM)
- Carlos Bagley, MD, FAANS
- Kathleen Brady, MD, MSCE
- Craig Butler, MD, MBA, CPE
- Piero Garzaro, MD
- Daniel Greninger, MD
- Jeffrey Hart, MS
- Marci Harris Hayes, PT, DPT, MSCI, OCS
- Mark Jarrett, MD, MBA
- Michael Lane, MD, MSc, MPHS, CPPS
- Jeffrey Lewis, BA
- Catherine MacLean, MD, PhD
- Jason Matuszak, MD, FAAFP, CAQSM, RMSK
- John McClay, MD
- Kevin McVary, MD
- Melinda Neuhauser, PharmD, MPH, FCCP, FASHP
- Catherine Roberts, MD
- James Rosenzweig, MD
- Rishi Singh, MD
- Kimberly Templeton, MD
- John Ventura, DC
- Christopher Visco, MD
- Jacquelyn Youde, AuD, CCC-A

Spring 2020 Cycle Measures

Two New Measures - Consensus Not Reached

- **3569e** Prediabetes: Screening for Abnormal Blood Glucose (American Medical Association)
- **3571e** Retesting of Abnormal Blood Glucose in Patients with Prediabetes (American Medical Association)

One New Measure - Not Recommended by Committee

- **3570e** Intervention for Prediabetes (American Medical Association)

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Questions?

Vote on Consensus Not Reached Measures

Achieving Consensus

- Quorum: 66% of the Committee
- Pass/Recommended: Greater than 60% “Yes” votes of the quorum (this percent is the sum of high and moderate)
- Consensus not reached (CNR): 40-60% “Yes” votes (inclusive of 40% and 60%) of the quorum
- Does not pass/Not Recommended: Less than 40% “Yes” votes of the quorum
- CNR measures move forward to public and NQF-member comment and the Committee will revote during the Committee post-comment web meeting

Committee Re-vote on "Consensus not Reached" Measures

For measures that did not reach consensus during the evaluation meeting, the Committee must re-vote on any "must-pass" criterion that did not reach consensus in the initial evaluation.

- If the measure then passes all must-pass criteria (greater than 60% high plus moderate or PASS) either at the initial vote or the re-vote, the Committee must vote on the final recommendation for the measure.
- If a "must-pass" criterion does not receive >60%, at the re-vote at the post-comment call, the evaluation stops, and the measure is not recommended for endorsement.
- There is no grey zone for the re-vote at the post-comment call. A measure must pass all "must-pass" criteria and the overall vote by >60%. If a measure does not receive >60%, the measure is not recommended for endorsement.

Reconsideration Request

- Measure developers may submit a reconsideration request if a measure does not pass
- Reconsideration will be used to promote consistency, transparency, fairness, and completion of the CDP within project timelines. There are two reasons that may justify a request to reconsider a measure that is not recommended for endorsement:
  - REASON 1: NQF's measure evaluation criteria were not applied appropriately
  - REASON 2: NQF's consensus development process (CDP) was not followed appropriately

Voting Test

Consideration of Candidate Measure 3569e

- **3569e** Prediabetes: Screening for Abnormal Blood Glucose

Consensus Not Reached on Validity, a must-pass criterion.

- **Developer**: American Medical Association
- **Measure Type**: Process
- **Data Source**: Electronic Health Records
- **Level of Analysis**: Clinician : Group/Practice, Clinician : Individual
- **Care Setting**: Outpatient Services
- **Status**: New submission

3569e Prediabetes: Screening for Abnormal Blood Glucose

- **Measure Steward: American Medical Association**
  - New measure
- **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
- **Summary of Comments Received:** 9 Comments Received
  - Preferred “abnormal blood glucose” over “prediabetes” which is suggested to be a risk factor rather than a disease.
  - Oppose the missing upper age limit (40-70 years) included in AAFP and USPSTF guidelines.
  - Suggest the requirement of confirmation of results.
  - Concerns with data capture, such as fasting glucose or exclusions not in EHR distinct field, and that the measure was only tested in EPIC and Cerner

Consideration of Candidate Measure 3571e

- **3571e** Retesting of Abnormal Blood Glucose in Patients with Prediabetes

Consensus Not Reached on Evidence and Validity, both must-pass criteria.

- **Developer**: American Medical Association
- **Measure Type**: Process
- **Data Source**: Electronic Health Records
- **Level of Analysis**: Clinician : Group/Practice, Clinician : Individual
- **Care Setting**: Outpatient Services
- **Status**: New submission

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3571e Retesting of Abnormal Blood Glucose in Patients with Prediabetes

- **Measure Steward: American Medical Association**
  - New measure
- **Brief Description of Measure:**
  - Percentage of patients aged 18 years and older who had an abnormal fasting plasma glucose, oral glucose tolerance test, or hemoglobin A1c result in the range of prediabetes in the previous year who have a blood glucose test performed in the one-year measurement period.
- **Summary of Comments Received:** 9 Comments Received
  - "There is limited evidence on the best rescreening intervals for adults with normal results; however screening every 3 years is a reasonable option." In contrast, this measure requires re-testing at least annually.
  - In addition, the exclusions for this measure are different from the others. Comfort care not included in this measure.
  - Other comment agreed that retesting is needed but that the testing should include a variety of tests, a specific timeframe, coverage by insurance, and ease of access to tests.

Review of Reconsideration Request

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3570e Intervention for Prediabetes

- **Measure Steward: American Medical Association**
  - New measure
- **Brief Description of Measure:**
  - Percentage of patients aged 18 years and older with identified abnormal lab result in the range of prediabetes during the 12-month measurement period who were provided an intervention
- **Summary of Reconsideration Request:**
  - Inconsistency of recommendations: the developer noted that the discussion for measures 3569e-71e covered similar issues, but resulted in very different votes.
  - Conflation of validity and feasibility: 3570e passed on validity, did not pass on feasibility (which is not must-pass), and then did not pass the overall vote.

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3570e Intervention for Prediabetes (continued)

- **Summary of Comments Received:** 11 Comments Received
  - Preferred intensive behavioral counseling interventions, rather than prescribing metformin or referring the patient out. Suggestion that this does not align with AAFP or USPSTF recommendations or best practices.
  - Referrals can unnecessarily drive up costs and may lead to unnecessary treatment. In addition MDDPs or CDC-recognized programs are not accessible to many areas in the country, so are not a viable alternative, particularly in rural areas.
  - Suggests that prediabetes is not a disease and should not be treated as such.

NQF Member and Public Comment

Next Steps

Activities and Timeline – Spring 2020 Cycle

Meeting	Date/Time
CSAC Review	October 13-19, 2020
Appeals Period (30 days)	November 23-December 22, 2020

Fall 2020 Cycle Updates

Intent to submit deadline was August 3, 2020

- 4 new measures
- 4 maintenance measures
- 2 complex measures sent to the Scientific Methods Panel for review of scientific acceptability criterion

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Activities and Timeline – Fall 2020 Cycle

***All times ET**

Meeting	Date/Time
Orientation Web Meeting	January 8, 2021 2-4pm
Measure Evaluation Web Meeting #1	February 10, 2021 9am to 5pm
Measure Evaluation Web Meeting #2	February 15, 2021 11am to 3pm
Draft Report Comment Period (30 days)	March 30 – April 28, 2021
Fall 2020 Post-Comment Web Meeting	May 28, 2021 11am to 1pm
CSAC Review	June 29 – 30, 2021
Appeals Period (30 days)	July 7 – August 5, 2021

Project Contact Info

- Email: primarycare@qualityforum.org
- NQF phone: 202-783-1300
- Project page: http://www.qualityforum.org/Primary_Care_and_Chronic_Illness.aspx
- SharePoint site: http://share.qualityforum.org/Projects/Primary%20Care%20and%20Chronic%20Illness/SitePages/Home.aspx

Questions?

THANK YOU.

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Appendix – Full Comments

3569e – AAFP Comment

The AAFP opposes Measure 3569e for the following reasons. First, the measure creates a “disease” out of a risk factor. The term “prediabetes” should be deleted from the title and remaining specifications/discussion. The measure should be titled “Abnormal blood glucose.”

In addition, the measure has no upper age limit, which is not consistent with the AAFP or the USPSTF recommendations, both of which recommend screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese.”

Finally, the AAFP recommends abnormal results be confirmed prior to intervention, and this proposed measure does not require confirmation of results, which may lead to unnecessary, excessive, and harmful treatments. Although the AAFP concludes there is currently inadequate evidence whether early detection of abnormal blood glucose or diabetes leads to improvements in mortality or cardiovascular morbidity, screening is consistent with AAFPs' recommendations in adults who are obese or are overweight with additional cardiovascular risk factors.

The AAFP also has concern with data capture. Fasting glucose status may not be captured in EHR in distinct field; and the exclusions (comfort care, hospice, palliative care) may not be captured in distinct field. (Only Site 2 was assessed for reliability of exclusions at a rate of 76%--is this an issue?) We have concern that the measure was only tested in EPIC and Cerner EHRs. Independent practices frequently use other less expensive EHRs which may not be as robust. This metric has the potential to cause a litany of errors that offices would have to manually reconcile, prove exceptions, report on office-based results etc. The AAFP agrees that screening is important but opposes this measure unless the measure steward corrects the stated deficiencies.

3569e – NKFM Comment

Please make sure the screening can include not only the gold standard A1c measures but others such as FPG, OGTT. This will allow for a variety of clinic options. Additionally, is there a way to make this test a larger part of a normal blood panel in a physical. We need to make these tests more accessible and affordable. Then, we can make a positive difference.

3569e – FAH Comment

The FAH requests that the Committee consider whether sufficient information has been provided to satisfy criteria requirements for data element validity testing. Currently, the results were aggregated and reported at the numerator, denominator, and exclusions level, which is not, given our understading, consistent with NQF requirements and that additional information is needed to meet the validity criterion.

3569e - ACPM Comment

The American College of Preventive Medicine deems this measure to be both reasonable and appropriate.

3569e - ACDES

Screening for prediabetes and undiagnosed type 2 diabetes is critical to improving both prevention and care of type 2 diabetes. One third of adults in the U.S. are estimated to have prediabetes, yet only 15% of them know that they have this condition.[i] Approximately 21% of people with type 2 diabetes are undiagnosed.1 Early identification of both prediabetes and type 2 diabetes is crucial so individuals can receive effective interventions to decrease the likelihood that their condition progresses or they develop complications. This eCQM is modeled on the United States Preventive Services Task Force Abnormal Glucose Screening Recommendation.[ii] This is a major strength because the recommendation was developed based on a high-quality systematic review of clinical literature.[iii] Physicians and other healthcare providers, like diabetes care and education specialists, widely respect and use USPSTF's recommendations to guide evidence-based care of the patients they serve.

ADCES believes this eCQM is clinically appropriate and meaningful for improving care. The measure targets an appropriate patient population that clearly benefits from abnormal glucose screening. We believe that this measure's specifications will validly capture the measure concept. This eCQM would be feasible to implement at most health care organizations. We believe that screening for abnormal glucose is an important preventive service and is reasonable to include in accountability programs. We also believe that health systems must prioritize screening of prediabetes.

3569e – CDC Comment

Screening for prediabetes and undiagnosed type 2 diabetes is critical to improving both prevention and care of type 2 diabetes. One third of adults in the U.S. are estimated to have prediabetes, yet only 15% of them are aware of their condition.[i] Approximately 21% of people with type 2 diabetes are undiagnosed.i Early identification of both prediabetes and type 2 diabetes is crucial so that patients can receive effective interventions to decrease the likelihood of disease progression or complications. This eCQM is modeled on the United States Preventive Services Task Force Abnormal Glucose Screening Recommendation.[ii] This is a major strength because the recommendation was developed based on a high-quality systematic review of clinical literature.[iii] Physicians widely respect and use USPSTF's recommendations to guide evidence-based care of their patients. This eCQM would be recognized by physicians as clinically appropriate and meaningful for improving patient care. The measure targets an appropriate patient population that clearly benefits from abnormal glucose screening. We believe that this measure's specifications will validly capture the measure concept. This eCQM would be feasible to implement by most health care organizations; most organizations routinely capture these data elements in their EHR. We believe that screening for abnormal glucose is an important preventive service and is reasonable to include in accountability programs.

3569e – AGS Comment

The American Geriatrics Society (AGS) wishes to comment on measure 3569. We agree that screening is supported by evidence, but question if the current electronic health record (EHR) is able to accurately distinguish fasting versus nonfasting labs, and therefore able to accurately capture the data for this measure.

Additionally, we think there should be exclusion of patients who are older and/or have multiple comorbidities and limited life expectancy. Similar exclusions in other measures like cancer screening have been implemented so we believe that the same can be implemented here. Since treatment of diabetes in older adults with multiple serious illnesses is controversial, we do not necessarily see benefit in screening, repeatedly testing, or intervening upon prediabetes in older adults in situations such as the clinician already deeming a borderline high HbA1c acceptable as-is and not recommending treatment. Furthermore, we are concerned that providers may be penalized in cases where these older patients are not on medications, yet progress to a low HbA1c.

3569e – Prisma Health Comment

Screening for prediabetes and undiagnosed type 2 diabetes is critical to improving both prevention and care of type 2 diabetes. One third of adults in the U.S. are estimated to have prediabetes, yet only 15% of them know that they have this condition (i). Early identification of both prediabetes and type 2 diabetes is crucial so patients can receive effective interventions to decrease the likelihood that their condition progresses or they develop complications. This eCOM is modeled on the United States Preventive Services Task Force Abnormal Glucose Screening Recommendation (ii). This is a major strength because the recommendation was developed based on a high-quality systematic review of clinical literature (iii). Physicians widely respect and use USPSTF's recommendations to guide evidence-based care of their patients.

This eCOM would be recognized by physicians at our organization as clinically appropriate and meaningfuil for improving patient care. The measure targets an appropriate patient population that clearly benefits from abnormal glucose screening. We believe that this measure's specifications will validly capture the measure concept. This eCOM would be feasible to implement at our organization/by most health care organizations; our organization routinely captures these data elements in our EHR. We believe that screening for abnormal glucose is an important preventive service and is reasonable to include in accountability programs.

3569e – Weight Watchers Comment

We support adoption of this measure to screen for abnormal glucose among those at risk, as outlined by the USPSTF in its B rated recommendation.

3570e – AAFP Comment

The AAFP opposes measure 3570e for the following reasons. The USPSTF and the AAFP recommend physicians "Offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity." The proposed quality measure requires physicians to either prescribe metformin or refer the patient out, which is not consistent with AAFP or USPSTF recommendations, and does not reflect scope of practice for primary care physicians. Primary care physicians are well-qualified to offer intense behavioral counseling and numerous other interventions to manage abnormal blood glucose without the need for a referral. Referrals can unnecessarily drive up costs and may lead to unnecessary treatment. In addition MDDPs or CDC-recognized programs are not accessible to many areas in the country, so are not a viable alternative, particularly in rural areas. (https://innovation.cms.gov/innovation-models/medicare-diabetes-prevention-program/mdpp-map; https://www.cdc.gov/diabetes/programs/national-dpp-maps/index.html). Of equal concern are the issues discussed in our general comments. The evidence rests solely on expert opinion;

Prediabetes is not a disease and should not be treated as such. Most patients with the risk factors will not develop diabetes within five years. Cut-off points are arbitrary. A large number of patients (1/3 of American adults) would be labeled as having “prediabetes” according to these thresholds. Labeling a patient with “prediabetes” can lead to emotional stress and treating borderline glucose values does not improve quality of life, mortality or other patient-oriented outcomes. The options for intervention presented are too limited. The measure promotes treatment with pharmaceutical and ignores the potential harms associated with such treatment. We offer the following: “Because people with prediabetes may develop diabetes but may also change back to normoglycaemia almost any time, doctors should be careful about treating prediabetes because we are not sure whether this will result in more benefit than harm, especially when done on a global scale affecting many people worldwide. - Cochrane Database

The measure does not take a whole person view of managing risk factors, which must consider co-morbid conditions, socioeconomic factors, and patient goals, values, and readiness for change. The AAFP favors discussing with patients the pros and cons of medications for borderline glucose values along with lifestyle changes, smoking cessation, blood pressure control, and cardiovascular prevention and determining a patient-centered plan of care. The measure promotes use of pharmaceuticals and other treatments by labeling patients with a “diagnosis” and then recommending a treatment for that diagnosis. We also have concern that the measure was only tested in EPIC and Cerner. Independent practices frequently use other less expensive EHRs which may not be as robust. Data capture may be an issue. Finally, there are differences in the exclusion criteria for these 3 measures--this measure does not include patients in hospice/palliative care or comfort care. Is this intentional? Are there real differences or did the steward just fail to align the wording?

3570e – NKFM Comment

Available interventions should include evidence-based programs delivered by recognized providers including community health workers and other trained staff.

3570e – SRHS Comment

I support the adding the MDPP to the list of approved telehealth services.

3570e – ACPM Comment

The American College of Preventive Medicine supports this measure, which includes the National Diabetes Prevention Program (NDPP) as well as metformin and medical nutrition therapy. There are substantial barriers to the uptake of the NDDP, despite the evidence of its importance as well as widespread promotion by the Centers for Disease Control and Prevention. This metric could be a significant step to improve referrals to the NDPP.

3570e – ACDES Comment

This eCQM addresses a major gap in preventive care as only 4% of people with prediabetes report receiving a referral to an evidence-based lifestyle change program (e.g., the diabetes prevention program), and only 1-8% of people with prediabetes receive a prescription for metformin.[i],[ii] This measure leverages both the USPSTF Abnormal Glucose Screening Recommendation and the American Diabetes Association Standards of Medical Care – both widely-accepted and evidence-based resources that guide clinical care.2,[iii] The three interventions proposed to meet the denominator of this measure (i.e., referral to a CDC-recognized diabetes prevention program, prescription for metformin, and referral to medical nutrition therapy) all have sound evidence to support their utilization. Providing three options allows for shared decision-making and supports a person-centered approach to care, while providing physicians and other healthcare providers multiple pathways to improve the quality of care they deliver.

Since 2012, ADCES has worked alongside the CDC to scale and sustain the National Diabetes Prevention Program (National DPP). Through this work, we have helped thousands of people with prediabetes access CDC-recognized programs proven to prevent or delay type 2 diabetes, yet there is still much work to do to reach the estimated 88 million American adults with prediabetes. Screening and program awareness are critical factors in preventing or delaying the onset of type 2 diabetes. ADCES supports efforts to promote healthcare provider understanding of prediabetes and diabetes risk factors includes simplifying and promoting existing guidelines, like the U.S. Preventive Services Task Force (USPSTF) guideline for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening released on October 26, 2015.[1] ADCES believes that this guideline helps to better define who might be at risk for type 2 diabetes and provides a basis for improving screening, diagnosis, and referrals. We believe this measure will help increase awareness of and referrals/recommendations to participate in necessary evidence-based lifestyle change programs.

Based on ADCES' strategy for preventing type 2 diabetes, we believe this measure targets an appropriate patient population. The numerator is met by offering individuals effective preventive interventions. We believe that this measure's specifications will validly capture the measure concept. This eCQM would be feasible to implement at most health care organizations. We believe this measure is unique among prevention-oriented measures because it goes beyond screening to improve the utilization of interventions that can prevent the development of a chronic disease; this measure is reasonable to include in accountability programs. ADCES views this as a critical component to ensuring that screening translates to the appropriate intervention.

3570e – Trinity Health Comment

Trinity Health partners with the American Medical Association to implement the Diabetes Prevention Program (DPP) within the communities we serve across the nation. This program provides an evidenced based intervention designed to reduce obesity and prevent the onset of Type II Diabetes. This intervention relies on screening patients for risk, testing for prediabetes lab values, referring eligible patients for intervention, and monitoring patient success in program engagement and loss of body mass. The proposed diabetes prevention measures support DPP. Trinity Health endorses the use of these measures.

3570e – CDC Comment

This eCQM addresses a major gap in preventive care as only 4% of people with prediabetes report receiving a referral to an evidence-based lifestyle change program (e.g., the National Diabetes Prevention Program), and only 1-8% of people with prediabetes receive a prescription for metformin.[iv],[v] This measure leverages both the USPSTF Abnormal Glucose Screening Recommendation and the American Diabetes Association Standards of Medical Care – both widely-accepted and evidence-based resources that guide clinical care.2,[vi] The three interventions proposed to meet the numerator of this measure (i.e., referral to a Centers for Disease Control and Prevention-recognized provider of the National Diabetes Prevention Program, prescription for metformin, and referral to medical nutrition therapy) all have sound evidence to support their utilization. Providing three options allows for shared decision-making and supports a person-centered approach to care, while providing physicians with multiple pathways to improve the quality of care they deliver. The measure targets an appropriate patient population. The numerator is met by offering patients effective preventive interventions to which most patients currently have access. We believe that this measure's specifications will validly capture the measure concept. This eCQM would be feasible to implement by most health care organizations; most organizations routinely capture these data elements in their EHR. We believe this measure is unique among prevention-oriented measures because it goes beyond screening to improve the utilization of interventions that can prevent the development of a chronic disease; this measure is reasonable to include in accountability programs.

3570e – AGS Comment

The American Geriatrics Society (AGS) wishes to comment on measure 3570. We agree that there is no easy way to capture what an intervention is currently, and it is likely not well-documented in EHRs, therefore it does not appear feasible.

Additionally, we think there should be exclusion of patients who are older and/or have multiple comorbidities and limited life expectancy. Similar exclusions in other measures like cancer screening have been implemented so we believe that the same can be implemented here. Since treatment of diabetes in older adults with multiple serious illnesses is controversial, we do not necessarily see benefit in screening, repeatedly testing, or intervening upon prediabetes in older adults in situations such as the clinician already deeming a borderline high HbA1c acceptable as-is and not recommending treatment. Furthermore, we are concerned that providers may be penalized in cases where these older patients are not on medications, yet progress to a low HbA1c.

3570e – Weight Watchers Comment

We support an intervention quality measure that measures referral to a CDC-recognized diabetes prevention program and/or a prescription for metformin. The NIH and the CDC invested significant resources to identify the services that delay onset of Type 2 diabetes. The CDC operates a recognition program (NDPP) for providers that ensures those offering lifestyle diabetes prevention programs meet evidence-based standards. Importantly, the CDC monitors ongoing performance of these programs on a variety of outcomes. This allows CDC to continuously update clinical evidence AND ensures providers meet outcomes-based standards. Measures that promote and support evidence-based treatment by providers are essential. In the case of diabetes prevention, significant public resources have led to the development of effective low-cost prevention interventions, and it is vital for quality measures to mirror the evidence base developed and maintained by public resources. Finally, it is unclear the degree to which medical nutrition therapy, as a stand-alone service that does not include all the components of diabetes prevention programs (nor does it hold CDC recognition as a diabetes prevention program), prevents type 2 diabetes. In summary, we recommend that rather than measuring referral to any DPP program, MNT, or other provider, the quality measure should leverage an already existing, national, and rigorous standard

3570e – Prisma Health

This eCOM addresses a major gap in preventive care as only 4% of people with prediabetes report receiving a referral to an evidence-based lifestyle change program (e.g., the diabetes prevention program), and only 1-8% of people with prediabetes receive a prescription for metformin (iv,v). This measure leverages both the USPSTF Abnormal Glucose Screening Recommendation and the American Diabetes Association Standards of Medical Care - both widely-accepted and evidence-based resources that guide clinical care (ii,vi). The three interventions proposed to meet the denominator of this measure (i.e., referral to a CDC-recognized diabetes prevention program, prescription for metformin, and referral to medical nutrition therapy) all have sound evidence to support their utilization. Providing three options allows for shared decision-making and supports a person-centered approach to care, while providing physicians with multiple pathways to improve their quality of care they deliver.

Our physicians offer preventive interventions to patients with prediabetes as part of our organization's strategy for preventing chronic diseases like type 2 diabetes. The measure targets an appropriate patient population. The numerator is met by offering patients effective preventive interventions to which our/most patients currently have access. We believe that this measure's specifications will validly capture the measure concept. This eCOM would be feasible to implement at our organization /by most health care organizations; our organization routinely captures these data elements in our EHR. We believe this measure is unique among prevention-oriented measures because it goes beyond screening to improve the utilization of interventions that can prevent the development of a chronic disease;this measure is reasonable to include in accountability programs.

3571e – AAFP Comment

The AAFP opposes measure 3571e for the following reasons:

AAFP policy states, “There is limited evidence on the best rescreening intervals for adults with normal results; however screening every 3 years is a reasonable option.” In contrast, this measure requires re-testing at least annually. In addition, the exclusions for this measure are different from the others--is this intentional and a meaningful difference or do they simply lack alignment in the way the measures are specified/worded? Is "comfort care" intentionally removed from the exclusions (compared to Measure 3569e)?

We thank the NQF for this opportunity to comment on the Prediabetes Measure Set.

3571e – NKFM Comment

I agree that retesting is needed and necessary. Please make sure that the testing includes a variety of tests, a specific timeframe, coverage by insurance, and ease of access to test

3570e – FAH Comment

The FAH requests that the Committee consider whether sufficient information has been provided to satisfy criteria requirements for data element validity testing. Currently, the results were aggregated and reported at the numerator, denominator, and exclusions level, which is not, given our understading, consistent with NQF requirements and that additional information is needed to meet the validity criterion.

3571e – FAH Comment

The FAH requests that the Committee consider whether sufficient information has been provided to satisfy criteria requirements for data element validity testing. Currently, the results were aggregated and reported at the numerator, denominator, and exclusions level, which is not, given our understading, consistent with NQF requirements and that additional information is needed to meet the validity criterion.

3571e – ACPM Comment

Although the American College of Preventive Medicine supports this measure, follow-up testing is far less important than receiving effective interventions such as those provided by the National Diabetes Prevention Program led by the Centers for Disease Control and Prevention. Clinicians can do follow-up abnormal blood glucose testing of patients, but not necessarily improve patient outcomes. Substantial health system effort around a process metric without a resultant benefit to patients' health is not ideal.

3571e – ADA Comment

This eCQM is based on the American Diabetes Association's Standards of Medical Care expert-level recommendation.6 The natural history of prediabetes is well-documented, and progression rates from prediabetes to type 2 diabetes are rapid enough to merit annual laboratory testing among people with prediabetes to monitor their glycemic status.[i] It is reasonable to grant an exception to the evidence for this measure because randomized controlled trials to clarify the ideal frequency of laboratory re-testing may not be considered ethical or necessary. Regular laboratory monitoring of people with prediabetes is important so health care organizations can track the incidence of type 2 diabetes in their populations and assess the impact of their diabetes prevention quality improvement efforts. Screening, combined with effective interventions like the CDC's National Diabetes Prevention Program, is critical to improving health outcomes for people with prediabetes.

ADCES believes that monitoring glucose status among people with prediabetes would be recognized by many health systems as clinically appropriate and meaningful for improving care. The specifications of this eCQM will validly capture the measure concept. This eCQM would be feasible to implement by most health care organizations. We believe that monitoring glycemic status among people with prediabetes is important for tracking population health and is reasonable to include in accountability programs.

3571e – Novo Nordisk Comment

For measure 3571e: Retesting of Abnormal Blood Glucose in Patients with Prediabetes (American Medical Association): Consensus Not Reached; the Committee questioned whether there was evidence to suggest that testing within one year is the correct timeframe and if there may be unintended consequences resulting in false positives and increasing testing frequency. (Measure Description: Percentage of patients aged 18 years and older who had an abnormal fasting plasma glucose, oral glucose tolerance test, or hemoglobin A1c result in the range of prediabetes in the previous year who have a blood glucose test performed in the one-year measurement period).
The Committee may want to consider findings from the USPSTF: Screening and Diagnostic Confirmation: The USPSTF concludes with moderate certainty that there is a moderate net benefit to measuring blood glucose to detect IFG, IGT, or diabetes and implementing intensive lifestyle interventions for persons found to have abnormal blood glucose. The diagnosis of IFG, IGT, or type 2 diabetes should be confirmed; repeated testing with the same test on a different day is the preferred method of confirmation.

Harms of Early Detection and Treatment: The USPSTF found that measuring blood glucose is associated with short-term anxiety but not long-term psychological harms. The USPSTF found adequate evidence that the harms of lifestyle interventions to reduce the incidence of diabetes are small to none. The harms of drug therapy for the prevention of diabetes are small to moderate, depending on the drug and dosage used. (Source: Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening; https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes; accessed 8/22/20) In addition to the ADA and USPSTF clinical recommendations utilized by the developer to support these measures, we offer those from the American Association of Clinical Endocrinologists:

Diagnostic Criteria: A diagnosis of prediabetes should be made according to glucose criteria, although the metabolic syndrome is considered a prediabetes equivalent. Glucose criteria. Glucose criteria for the diagnosis of prediabetes and diabetes appear in Table 1 (1,4). Prediabetes may be identified by the presence of impaired glucose tolerance (IGT; plasma glucose 140-199 mg/dL 2 hours after ingesting 75 g of glucose) and/or impaired fasting glucose (IFG; fasting glucose 100-125 mg/dL). A1C values between 5.5% and 6.4% inclusive should be a signal to do more specific glucose testing but should not be considered diagnostic. For prediabetes, A1C testing should be used only as a screening tool; FPG measurement or an oral glucose tolerance test (OGTT) should be used for definitive diagnosis. Monitoring patients with prediabetes to assess their glycemic status should include at least annual reassessment of FPG and/or an OGTT. For individuals in whom progression is suspected, annual measurements of FPG and A1C, with 2-hour OGTT, should be conducted. (Source: AACE/ACE Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan - © 2015; https://www.aace.com/disease-state-resources/diabetes/depth-information/screening-and-monitoring-prediabetes; accessed 8/22/2020) In 2019, the Endocrine Society released the Primary Prevention of ASCVD and T2DM in Patients at Metabolic Risk: An Endocrine Society* Clinical Practice Guideline. This guideline also offers clinical recommendations on appropriate testing and intervals which support these measures under consideration: 1.2 In individuals aged 40-75 years in the office setting who do not yet have atherosclerotic cardiovascular disease or type 2 diabetes mellitus and already have at least one risk factor, we advise screening every 3 years for all five components of metabolic risk as part of the routine clinical examination. (Ungraded Good Practice Statement) 1.4 In individuals previously diagnosed with prediabetes, we suggest testing at least annually for the presence of overt type 2 diabetes mellitus. (2|⊕⊕⊕◯)

Technical Remark: Prediabetes is defined in a variety of ways (fasting plasma glucose, 2-hour plasma glucose following a 75-g oral glucose tolerance test, or hemoglobin A1c) by different organizations in different countries, and the writing committee does not endorse preferential use of one definition over another. (Source: James L Rosenzweig, George L Bakris, Lars F Berglund, Marie-France Hivert, Edward S Horton, Rita R Kalyani, M Hassan Murad, Bruno L Vergès, Primary Prevention of ASCVD and T2DM in Patients at Metabolic Risk: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 9, September 2019, Pages 3939–3985, https://doi.org/10.1210/jc.2019-01338)

3571e – AGS Comment

The American Geriatrics Society (AGS) wishes to comment on measure 3571. We question what the data are for annual testing. It seems that some follow-up should occur once prediabetes is identified, but we do not necessarily believe it needs to be yearly, especially if younger healthier patients only come in once a year. The yearly cutoff could be missed by just a few months without really having meaningful detriment to patient care.

Additionally, we think there should be exclusion of patients who are older and/or have multiple comorbidities and limited life expectancy. Similar exclusions in other measures like cancer screening have been implemented so we believe that the same can be implemented here. Since treatment of diabetes in older adults with multiple serious illnesses is controversial, we do not necessarily see benefit in screening, repeatedly testing, or intervening upon prediabetes in older adults in situations such as the clinician already deeming a borderline high HbA1c acceptable as-is and not recommending treatment. Furthermore, we are concerned that providers may be penalized in cases where these older patients are not on medications, yet progress to a low HbA1c.

3571e – Prisma Health Comment

This eCOM is based on the American Diabetes Association's Standards of Medical Care expert-level recommendation (vi). The natural history of prediabetes is well-documented, and progression rates from prediabetes to type 2 diabetes are rapid enough to merit annual laboratory testing among people with predaibetes to monitor their glycemic status (vii). It is reasonable to grant an exception to the evidence for this measure because randomized controlled trials to clarify the ideal frequency of laboratory re-testing may not be considered ethical or necessary. Regular laboratory monitoring of people with prediabetes is important so health care organizations can track the incidence of type 2 diabetes in their populations and assess the impact of their diabetes prevention quality improvement efforts.

Monitoring glucose status among people with prediabetes would be recognized by physicians at our organization as clinically appropriate and meaningful for improving patient care. The specifications of the eCOM will validly capture the measure concept. This eCOM would be feasible to implement at our organization/by most health care organizations. We believe that monitoring glycemic status among people with prediabetes is important for tracking population health and is reasonable to include in accountability programs.

General Draft – AAFP Comment

The American Academy of Family Physicians (AAFP) appreciates the opportunity to comment on the proposed measure set for prediabetes.

The AAFP acknowledges that glucose intolerance, insulin resistance, and ultimate beta cell failure warrants diligent attention by primary care physicians. This is a clinical issue which should be recognized through screening and treated with lifestyle changes, first and foremost.

Primary care physicians are often involved with the NDPP and MDPP program development and delivery in their states. DPP programs are evidence based and show good results for people that stick with the program, and they are well-adapted to meet the needs of different cohorts (language, cultural identity, ages, geographic needs, online, in-person). However, physicians face substantial barriers to this program for many urban, rural, insured and uninsured populations, and applying performance measures to reward/punish physician behavior is premature. Better infrastructure and awareness are needed to drive referral to DPP programs. There are no programs for intense interventions in many areas and better training and reimbursement are needed to allow primary care physicians to build infrastructure in their offices to provide MNT in collaboration with a team of local professionals. Community resources and support systems must be available prior to holding providers accountable.

The AAFP is extremely concerned with the lack of evidence for improvement of outcomes and the large potential for harms of treatment with medications for prediabetes. We are also concerned with the proposition of taking a risk factor for a disease (diabetes mellitus) and attempting to make it a disease that is treated pharmacologically. This opens the gate for use of other drugs outside of metformin (there are already trials) and the movement to combat therapeutic inertia by subspecialists and pharma WITH LITTLE REGARD TO THE COMPLEX PATIENT OR SOCIAL DETERMINANTS OF HEALTH, CONCERNS THAT FAMILY PHYSICIANS RESPECT AND CONSIDER AS A CORE COMPONENT OF THEIR RELATIONSHIP WITH PATIENTS.

EVIDENCE:Supporting documentation for these measures rest solely on expert opinion.

* “At least annual monitoring for the development of diabetes in those with prediabetes is suggested. (ADA, 2018) (E Recommendation)”. This is expert opinion according to ADA.
* The developer provides evidence of disease prevalence and systematic misses of opportunities to intervene by clinicians, but does not provide studies that offer evidence that annual monitoring is associated with positive outcomes. While NQF staff recommend an exception to the evidence, the AAFP does not agree with the NQF recommendation.

RISK FACTOR VERSUS DISEASE: We offer insight from Steven R. Brown, MD, FAAFP, University of Arizona College of Medicine and former chair of the AAFP Commission on Health of the Public and Science, in his /www.aafp.org/afp/2019/0801/p136.html"">editorial comments and supporting references regarding treating adults with prediabetes by prescribing metformin. (1) “Prediabetes is not a disease. It is a risk factor for a disease (diabetes mellitus). Most people with so-called prediabetes will not develop diabetes within five years.”(2) The threshold values set by the ADA and reflected in these measures for defining prediabetes dramatically expand the number of people who meet the definition of prediabetes, with one-third of Americans meeting the criteria.(3) Many people will be mislabeled as having prediabetes using a single A1C. Cutoff values for diabetes and prediabetes are arbitrary.(4) Although some randomized controlled studies have shown a lower incidence of diabetes with metformin treatment versus lifestyle or placebo changes, treating borderline glucose values does not improve quality of life, mortality or other patient-oriented outcomes.(5)(6)

TREATING THE WHOLE PATIENT:Dr. Brown points out that, “It is unlikely that initiating metformin before diabetes is diagnosed improves outcomes compared with waiting for a formal diagnosis. When the clinically meaningful benefit of a treatment is marginal, harms become more important to consider. Although metformin is inexpensive and simple to use, many patients experience gastrointestinal symptoms such as diarrhea, flatulence, nausea, and vomiting.(5) Long-term use is associated with vitamin B12 deficiency.”(7)

DISEASE MONGERING: Labeling patients with a diagnosis of “prediabetes” is an example of selling a sickness to grow the markets for those that sell and deliver treatments (i.e., “disease mongering”).(8) The medical community should not cave-in to such practices.

The AAFP opposes these three measures and favors discussing with patients the pros and cons of medications for borderline glucose values along with lifestyle changes, smoking cessation, blood pressure control, and cardiovascular prevention.

General Draft – FAH Comment

The Federation of American Hospitals (FAH) appreciates the opportunity to comment and vote on this report. The FAH requests clarification on the final votes and recommendations of the Committee and how the measure evaluation criteria was applied to these three measures as we note some possible inconsistencies. First, within and between the body of the report describing the evaluation of each measure and the evaluation tables in Appendix A there seem to be inconsistencies. For example, the report states that feasibility was not passed for NQF #3570e and usability was not passed for NQF #3571e. This is confusing as neither feasibility or usability are "must pass" so the current language is confusing and inconsistent with the measure evaluation criteria. In addition, it does not seem the Committee reached consensus on validity per the discussion on page 8 and votes on page 13 for NQF #3571e; yet, the rationale on page 14, last bullet, states that the "Committee passed the measure on validity".

What is most troubling is the discussion of the Committee's concerns with the accuracy of the data elements as they relate to the feasibility of data collection. Per the NQF measure evaluation criteria, effective September 2019, 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." While the feasibility scorecard captures information on the accuracy of the data element, that domain is specifically intended to understand whether the information is captured by an authoritative source and/or is highly likely to be correct. The FAH has concerns that some of the issues raised by the Committee truly relate to the feasibility of the data elements and they would be more accurately characterized as concerns with the validity of the data. It would also be helpful if you could clarify what information was used to assess and pass the measures on reliability since the information provide in the testing forms meet the minimum requirements around data element validity for eCQMs and no information was provided for reliability, which is consistent with NQF requirements for eCQMs. The mixing of the evaluation of feasibility, reliability, and validity for each of the three measures within the scientific acceptability discussion makes it difficult for the FAH to determine whether the discussion and votes were applied appropriately. We would appreciate clarification on this matter. As a result, the FAH is unable to truly assess the concerns of the Committee on these three measures as it is not clear whether the measure evaluation criteria may have been misapplied or whether further editing of the report to clarify the Committee's discussion would suffice.

Thank you for future clarifications and the opportunity to comment.

General Draft – Novo Nordisk Comment

As a global healthcare company, founded in 1923, Novo Nordisk's purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity, and rare blood and rare endocrine diseases. We appreciate the opportunity to comment on the following measures under consideration by the National Quality Forum's Primary Care and Chronic Illness (PCCI) Standing Committee:

- 3569e Prediabetes: Screening for Abnormal Blood Glucose (American Medical Association)
- 3571e Retesting of Abnormal Blood Glucose in Patients with Prediabetes (American Medical Association)
- 3570e Intervention for Prediabetes (American Medical Association)

We recognize and appreciate the PCCI Standing Committee's efforts in conducting their review and encourage NQF to offer the measure steward appropriate technical guidance and support to rectify areas of weakness in the submissions should they not be moved forward for endorsement.

The term and classification of "prediabetes" is recognized by the Centers for Disease Control and Prevention (CDC), the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), the Endocrine Society, the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association as "a state of increased health risk that is defined by elevated blood glucose."

Screening for prediabetes and intervening before a patient has progressed to type 2 diabetes offers a host of benefits:

- Successful lifestyle changes resulting in 5 to 7 percent weight loss and increased physical activity can improve patients' health-related quality of life while helping them to avoid missed work days, reduce medication needs for high blood pressure and high cholesterol, and avoid the psychosocial stress associated with developing type 2 diabetes.
- Because patients who progress from prediabetes to type 2 diabetes assume an even greater risk for cardiovascular disease, microvascular disease, and other co-morbidities, knowing one's risk status and taking early action to prevent or delay type 2 diabetes can have numerous long-term benefits. The first step is completing a screening test.
- Identifying prediabetes and offering or referring high-risk people to interventions and support are consistent with evidence-based guidelines for preventive care and constitute important ways of assisting patients and families in self-care management.
- There are three recommended blood testing methods to identify or diagnose prediabetes: A1C, fasting plasma glucose, and 2-hour post 75 g oral glucose challenge. These are the same tests currently recommended to identify undiagnosed type 2 diabetes. The A1C test offers advantages for patients and providers because it removes the burden of fasting and/or lengthy lab visits.

(Source: The National Institute of Diabetes and Digestive and Kidney Diseases (https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/diabetes/game-plan-preventing-type-2-diabetes/prediabetes-screening-how-why/why-screen-for-prediabetes) Accessed 8/22/2020)

We understand there are also feasibility concerns evident in the eCQM feasibility assessment which may be impacting the Committee's consideration; however, without the benefit of having measure submission forms (eCQM feasibility assessment, measure information form, evidence form and testing form) available for review we are not able to offer additional comment beyond hoping the Committee has clearly delineated the "must pass" criteria (Importance, Scientific Acceptability) from feasibility in a consistent matter. The draft report is not clear on how reliability and validity were considered in numerous places and seem to suggest that the feasibility assessment may be confounding the Scientific Acceptability criteria.

Novo Nordisk is committed to driving change to improve outcomes in diabetes and obesity, both diseases impacted by the actions of health care providers and patients and that can benefit from early detection and intervention. Performance measures are essential tools for driving change in the U.S. healthcare system and we urge NQF to consider these prediabetes measures as important starting points for process change and the need to address conditions earlier in their lifecycle to prevent long-term negative health outcomes.

General Draft – Weight Watchers Comment

We strongly support the adoption and use of quality measures on prevention of Type 2 diabetes that follow the USPSTF B rated recommendations for screening for blood glucose and providing evidence-based prevention services for those with high blood glucose (prediabetes.) The October 2015 USPSTF evidence review demonstrates that for those with prediabetes participation in evidence-based intensive lifestyle behavioral counseling programs recognized by the CDC and/or metformin (for a subset) delays progression to Type 2 diabetes. Given the increasing prevalence and serious consequences of Type 2 diabetes, promoting evidence-based screening and prevention interventions through quality measures is essential for the health of our nation.

General Draft – DAA Comment

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to comment on three proposed quality measures: screening for abnormal blood glucose, (measure 3569e), retesting of abnormal blood glucose in patients with prediabetes (measure 3571e), and intervention for prediabetes (measure 3570e).

The DAA is a coalition of 25 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. While the DAA is not a member of NQF, some of our member organizations are and they will separately be submitting their comments.

The DAA realizes the need for, and value of, quality measures related to screening for abnormal blood glucose, as such measures can help encourage payers and health care providers to more routinely screen appropriate patient populations at risk. In this regard, we support the efforts of the American Medical Association, a DAA member, to put forth these three proposed quality measures.

The Centers for Disease Control and Prevention (CDC) presents sobering data about the scope of elevated blood glucose values in the United States. In its National Diabetes Statistics Report: 2020, the CDC states that 88 million adults (34.5%) have blood glucose values that are higher than normal but not in the range for diagnosable type 2 diabetes, based on either their fasting plasma glucose or A1c test levels.1 Of interest, 9.2 million (10.5%) were in the prediabetes range as measured by both tests.1 Somewhat surprisingly, only 15.3% of the 88 million said that a health professional had told them they had prediabetes1, which underscores the importance of screening and increasing health care provider awareness to screen those at risk.While the DAA recognizes that not all adults with prediabetes go on to develop type 2 diabetes, a sizeable percentage do, and intervention in those at high risk can help prevent or delay type 2 diabetes onset and its many health complications and potentially reduce healthcare utilization and costs. Plus, screening adults at high risk for prediabetes could help identify some of the estimated 7.3 million adults with undiagnosed diabetes.1

The members of the DAA have worked long and hard to raise awareness among members of Congress and the Administration of the need to assess blood glucose values in adults at high risk for developing type 2 diabetes, in order to identify adults that might benefit from an evidence-based behavior change program to reduce their risk of developing type 2 diabetes. We also have worked tirelessly to support funding for and the establishment of the CDC's National Diabetes Prevention Program and the Centers for Medicare and Medicaid Services' Medicare Diabetes Prevention Program, because these evidence-based programs work to improve the health and quality of life of adults with prediabetes. We believe the development of quality measures to ensure more widespread screening of abnormal blood glucose will help to address the high rate of prediabetes in the United States.

1 Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2020.