NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0061
Measure Title: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)
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: 12/5/2014

Instructions

- *For composite performance measures:*
  - *A separate evidence form is required for each component measure unless several components were studied together.*
  - *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.***
- Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.

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

1a. Evidence to Support the Measure Focus
The measure focus is evidence-based, demonstrated as follows:

- Health outcome: [3] a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [4] that the measured intermediate clinical outcome leads to a desired health outcome.
- Process: [5] a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [4] that the measured process leads to a desired health outcome.
- Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [4] that the measured structure leads to a desired health outcome.
- Efficiency: [6] evidence not required for the resource use component.

Notes
3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
4. The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) grading definitions and methods, or Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines.
5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.
6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

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

☐ Health 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

☒ Intermediate clinical outcome (*e.g., lab value*): Blood Pressure <140/90 mm Hg

☐ Process: Click here to name the process

☐ Structure: Click here to name the structure

☐ Other: Click here to name what is being measured

_____

HEALTH OUTCOME/PRO PERFORMANCE MEASURE *If not a health outcome or PRO, skip to 1a.3*

1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

N/A

1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).

N/A

Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.

_____

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes. Include all the steps between the measure focus and the health outcome.

Patient 18-75 years of age with diabetes (type 1 and type 2) >>> Health care provider monitors patient's blood pressure level >>> Patient's blood pressure level result is <140/90 mm Hg (adequately controlled) >>> Patient has a significant reduction in microvascular and macrovascular complications, hospitalization and death.

1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?

☒ Clinical Practice Guideline recommendation – ***complete sections 1a.4, and 1a.7***

☐ US Preventive Services Task Force Recommendation – ***complete sections 1a.5 and 1a.7***

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections 1a.6 and 1a.7***

☐ Other – ***complete section 1a.8***

Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.

_____

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):

Eighth Joint National Committee (JNC 8)- 2014

James PA, Oparil S, Carter BL, Cushman WC, Dennison-Himmelfarb C, Handler J, Lackland DT, et al. (2014). 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults. Report from the Panel Members Appointment to the Eighth Joint National Committee (JNC 8). Journal of the American Medical Association. JAMA 311:507-520.
URL: http://jama.jamanetwork.com/article.aspx?articleid=1791497

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
Eighth Joint National Committee (JNC 8) - 2014

Page Number	Recommendation	Verbatim Quote
Page 4	Recommendation 1	"In the general population aged 60 years or older, initiate pharmacologic treatment to lower BP at systolic blood pressure (SBP) of 150 mmHg or higher or diastolic blood pressure (DBP) of 90mmHg or higher and treat to a goal SBP lower than 150mmHg and goal DBP lower than 90mmHg. *Strong Recommendation – Grade A*"
	Corollary Recommendation	"In the general population aged ≥60 years, if pharmacologic treatment for high BP results in lower achieved SBP (eg, <140mmHg) and treatment is well tolerated and without adverse effects on health or quality of life, treatment does not need to be adjusted. *Expert Opinion – Grade E*"
Page 5	Recommendation 2	"In the general population younger than 60 years, initiate pharmacologic treatment to lower BP at DBP of 90 mm Hg or higher and treat to a goal DBP of lower than 90mmHg. *For ages 30 through 59 years, Strong Recommendation – Grade A* *For ages 18 through 29 years, Expert Opinion – Grade E*"
Page 5	Recommendation 3	"In the general population younger than 60 years, initiate pharmacologic treatment to lower BP at SBP of 140 mm Hg or higher and treat to a goal SBP of lower than 140mmHg. *Expert Opinion – Grade E*"
Page 6	Recommendation 5	"In the population aged 18 years or older with diabetes, initiate pharmacologic treatment to lower BP at SBP of 140mmHg or higher or DBP of 90 mm Hg or higher and treat to a goal SBP of lower than 140mmHg and goal DBP lower than 90mmHg. *Expert Opinion – Grade E*"

Please Note: This measure aligns with the most recent guideline recommendations for hypertension management in the general population and patients with diabetes. The guidelines recommend against the use of other blood pressure thresholds for patients with diabetes. See section 1a.7 for additional details on the systematic review of the evidence for this measure.

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:

JNC 8

Table 3. Strength of Recommendation	
Grade	**Strength of Recommendation**
A	Strong Recommendation: There is high certainty based on evidence that the net benefit is substantial.
E	Expert Opinion: ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the committee recommends.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the committee thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.

1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system. (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

JNC 8

Table 3. Strength of Recommendation	
Grade	**Strength of Recommendation**
B	Moderate Recommendation: There is moderate certainty based on evidence that the net benefit is moderate to substantial or there is high certainty that the net benefit is moderate.
C	Weak Recommendation: There is at least moderate certainty based on evidence that there is a small net benefit.
D	Recommendation Against: There is at least moderate certainty based on evidence that it has no net benefit or that risks/harms outweigh benefits.
N	No Recommendation for or Against: ("There is insufficient evidence or evidence is unclear or conflicting.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the committee thought no recommendation should be made. Further research is recommended in this area.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**

1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?

☒ Yes → ***complete section 1a.7***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

_____

1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

1a.5.1. Recommendation citation (*including date*) and **URL for recommendation** (*if available online*):
N/A

1a.5.2. Identify recommendation number and/or page number and **quote verbatim, the specific recommendation**.
N/A

1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:
N/A
1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system. (*Note: the grading system for the evidence should be reported in section 1a.7.*)
N/A
1a.5.5. Citation and URL for methodology for grading recommendations (*if different from 1a.5.1*)**:**
N/A
Complete section 1a.7

_____
1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE
1a.6.1. Citation (*including date*) and **URL** (*if available online*):

1a.6.2. Citation and URL for methodology for evidence review and grading (*if different from 1a.6.1*)**:**

Complete section 1a.7

_____
1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE
If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?
The evidence focuses on the importance of monitoring, controlling and treating high blood pressure in patients with diabetes to improve health outcomes. There are no studies that directly support a blood pressure goal of <140/90 mm Hg for patients with diabetes. Evidence does exist, however, for a blood pressure goal of <150/90 mm Hg in patients with diabetes. The eighth Joint National Committee (JNC 8) panel recommends treating patients 18 years of age and older with diabetes to a blood pressure goal of less than 140/90 mmHg. This is the same blood pressure goal for the general population under the age of 60. The guideline recommends against the use of other blood pressure goals for patients with diabetes. Blood pressure goal evidence for the diabetes population (Recommendation 5) is detailed in questions 1a.7.5 through 1a.7.8.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:

JNC 8

Table 2. Evidence Quality Rating	
Type of Evidence	**Quality Rating**

RCTs with minor limitations affecting confidence in, or applicability of, the results Well-designed, well-executed non-randomized controlled studies and well-designed, well-executed observational studies Well-conducted meta-analyses of such studies Moderately certain about the estimate of effect; further research may have an impact on our confidence in the estimate of effect and may change the estimate	Moderate

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.

JNC 8

Table 2. Evidence Quality Rating	
Type of Evidence	**Quality Rating**
Well-designed, well-executed RCTs that adequately represent populations to which the results are applied and directly assess effects on health outcomes Well-conducted meta-analyses of such studies Highly certain about the estimate of effects; further research is unlikely to change our confidence in the estimate of effect	High
RCTs with major limitations Non–randomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports) Physiological studies in humans Meta-analyses of such studies Low certainty about the estimate of effect; further research is likely to have an impact on our confidence in the estimate of effect and is likely to change the estimate.	Low

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1996-2010

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1a.7.5. How many and what type of study designs are included in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

JNC 8

Recommendation 5:
5 randomized controlled trials (SHEP, Syst-EUR, UKPDS, ACCORD, HOT)
Please note: There are no randomized controlled studies that directly support treating patients with diabetes to a blood pressure goal of <140/90 mm Hg. Therefore, the JNC 8 found and described evidence for a blood pressure goal of <150/90 mm Hg in patients with diabetes.

1a.7.6. What is the overall quality of evidence <u>across studies</u> in the body of evidence? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

The overall quality rating across studies that for recommendation 5 is described as moderate. The evidence review used to develop the JNC 8 guidelines was limited to randomized-controlled trials because they are less subject to bias and represent the best scientific evidence. The RCTs included in the evidence review for recommendation 5 included studies with large numbers of patients with diabetes to address the question: does treatment with antihypertensive pharmacologic therapy to a specified BP goal lead to improvements in health outcomes?

The evidence review excluded studies with sample sizes of fewer than 100 patients as well as studies that had follow-up periods of less than a year. An excerpt from the JNC 8 guideline is below to provide details on studies reviewed for recommendation 5 and the rationale for the expert opinion recommendation grade:

Recommendation 5 Pg 6-7

"There is moderate-quality evidence from 3 trials (SHEP, Syst-Eur, and UKPDS) that treatment to an SBP goal of lower than 150 mm Hg improves cardiovascular and cerebrovascular health outcomes and lowers mortality (see question 2, evidence statement 18) in adults with diabetes and hypertension. No RCTs addressed whether treatment to an SBP goal of lower than 140 mm Hg compared with a higher goal (for example, <150 mm Hg) improves health outcomes in adults with diabetes and hypertension. In the absence of such evidence, the panel recommends an SBP goal of lower than 140 mm Hg and a DBP goal lower than 90 mm Hg in this population based on expert opinion, consistent with the BP goals in recommendation 3 for the general population younger than 60 years with hypertension. Use of a consistent BP goal in the general population younger than 60 years and in adults with diabetes of any age may facilitate guideline implementation. This recommendation for an SBP goal of lower than 140 mm Hg in patients with diabetes is also supported by the ACCORD-BP trial, in which the control group used this goal and had similar outcomes compared with a lower goal [for the intervention group].

The panel recognizes that the ADVANCE trial tested the effects of treatment to lower BP on major macrovascular and micro-vascular events in adults with diabetes who were at increased risk of CVD, but the study did not meet the panel's inclusion criteria because participants were eligible irrespective of baseline BP, and there were no randomized BP treatment thresholds or goals.

The panel also recognizes that an SBP goal of lower than 130 mm Hg is commonly recommended for adults with diabetes and hypertension. However, this lower SBP goal is not supported by any RCT that randomized participants into 2 or more groups in which treatment was initiated at a lower SBP threshold than 140 mm Hg or into treatment groups in which the SBP goal was lower than 140 mm Hg and that assessed the effects of a lower SBP threshold or goal on important health outcomes. The only RCT that compared an SBP treatment goal of lower than 140 mm Hg with a lower SBP goal and assessed the effects on important health outcomes is ACCORD-BP, which compared an SBP treatment goal of lower than 120 mm Hg with a goal lower than 140 mm Hg. There was no difference in the primary outcome, a composite of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. There were also no differences in any of the secondary outcomes except for a reduction in stroke. However, the incidence of stroke in the group treated to lower than 140 mm Hg was much lower than expected, so the absolute difference in fatal and nonfatal stroke between the 2 groups was only 0.21% per year. The panel concluded that the results from ACCORD-BP did not provide sufficient evidence to recommend an SBP goal of lower than 120 mm Hg in adults with diabetes and hypertension.

The panel similarly recommends the same goal DBP in adults with diabetes and hypertension as in the general population (<90 mm Hg). Despite some existing recommendations that adults with diabetes and

hypertension should be treated to a DBP goal of lower than 80 mm Hg, the panel did not find sufficient evidence to support such a recommendation. For example, there are no good- or fair-quality RCTs with mortality as a primary or secondary prespecified outcome that compared a DBP goal of lower than 90 mm Hg with a lower goal (evidence statement 21). In the HOT trial, which is frequently cited to support a lower DBP goal, investigators compared a DBP goal of 90 mm Hg or lower vs a goal of 80 mm Hg or lower. The lower goal was associated with a reduction in a composite CVD outcome (question 2, evidence statement 20), but this was a post hoc analysis of a small subgroup (8%) of the study population that was not prespecified. As a result, the evidence was graded as low quality. Another commonly cited study to support a lower DBP goal is UKPDS, which had a BP goal of lower than 150/85 mm Hg in the more-intensively treated group compared with a goal of lower than 180/105 mm Hg in the less-intensively treated group. UKPDS did show that treatment in the lower goal BP group was associated with a significantly lower rate of stroke, heart failure, diabetes-related end points, and deaths related to diabetes. However, the comparison in UKPDS was a DBP goal of lower than 85 mm Hg vs lower than 105 mm Hg; therefore, it is not possible to determine whether treatment to a DBP goal of lower than 85 mm Hg improves outcomes compared with treatment to a DBP goal of lower than 90 mm Hg. In addition, UKPDS was a mixed systolic and diastolic BP goal study (combined SBP and DBP goals), so it cannot be determined if the benefits were due to lowering SBP, DBP, or both."

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1a.7.7. What are the estimates of benefit—magnitude and direction of effect on outcome(s) <u>across studies</u> in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

Studies reviewed for Recommendation 5:

The Syst-Eur study found that treatment with antihypertensives in patients with diabetes to a systolic blood pressure lower than 150 mm Hg reduced overall mortality by 55%, reduced all cardiovascular events by 69%, reduced fatal and non-fatal strokes by 73% and reduced all cardiac events by 63%.

The SHEP study found that treating patients with diabetes to a systolic blood pressure goal lower than 150 mm Hg resulted in an absolute cardiovascular disease risk reduction that was twice as great when compared to patients without diabetes.

The UKPDS study did not find a reduction in fatal and non-fatal major cardiovascular events when treating patients with diabetes to a blood pressure goal of <120 mm Hg as compared to a goal of <140 mm Hg. However, the study did find significant results for the reduction of total stroke and nonfatal stroke with intensive blood pressure treatment in patients with diabetes.

The ACCORD-BP trial compared an systolic blood pressure treatment goal of lower than 120 mm Hg with a goal lower than 140 mm Hg. There was no difference in the primary outcome, a composite of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. There were also no differences in any of the secondary outcomes except for a reduction in stroke. However, the incidence of stroke in the group treated to lower than 140 mm Hg was much lower than expected, so the absolute difference in fatal and nonfatal stroke between the 2 groups was only 0.21% per year. The JNC 8 concluded that the results from ACCORD-BP did not provide sufficient evidence to recommend a systolic blood pressure goal of lower than 120 mm Hg in adults with diabetes and hypertension.

The HOT trial compared a diastolic blood pressure goal of 90 mm Hg or lower vs a goal of 80 mm Hg or lower. The lower goal was associated with a reduction in a composite CVD outcome, but this was a post hoc analysis of a small subgroup (8%) of the study population that was not prespecified. As a result, the evidence was graded as low quality by the JNC 8.

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?
While the harms of antihypertensive treatment were considered in the JNC 8 recommendations, the evidence review was not designed to determine whether adverse events resulted in harms that significantly changed or outweighed the beneficial health outcomes. No other harms were mentioned as part of this evidence review. While authors of this guideline did not conduct an evidence review of lifestyle modifications, they emphasize the importance for all hypertensive persons to engage in healthy diet, weight control and regular exercise and that these behavior changes can improve BP control and reduce medication needs.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1a.7.9. If new studies have been conducted since the systematic review of the body of evidence, provide for <u>each</u> new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

There have been no new studies that contradict the current body of evidence.

_____

1a.8 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.8.1 What process was used to identify the evidence?

1a.8.2. Provide the citation and summary for each piece of evidence.