**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**: 2602 (New Measure)**

**Measure Title**: **Controlling High Blood Pressure for People with Serious Mental Illness**

**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**: **7/25/2014**

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| **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](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **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**](#Note3) 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**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) 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**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) 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](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **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](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**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*): **Controlling high blood pressure for people with Serious Mental Illness**

☐ Process: Click here to name the process

☐ Structure: Click here to name the structure

☐ Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**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.**

**Not applicable.**

**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*).**

**Not applicable.**

*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.*

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**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.

**The rate in this measure relates to the desired outcome in the following way: Patient with a serious mental illness (schizophrenia, bipolar I disorder, or major depression) is diagnosed with hypertension ­­🡪 Health care provider monitor patient’s blood pressure 🡪 Patient’s blood pressure level is adequately controlled 🡪 Patient has significant reduction in potentially serious complications of uncontrolled hypertension and improved long-term clinical outcomes (Desired outcome).**

**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***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

☐ US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

☐ Other – ***complete section*** [***1a.8***](#Section1a8)

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

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

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

**James PA, Oparil S, Carter BL, et al. (2014). 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC-8). 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**.

**Joint National Committee-8 (Evidence Based Guideline) – 2014**

**Page E4-E7**

* **Recommendation 1: In the general population aged ≥ 60 years, initiate pharmacologic treatment to lower blood pressure (BP) at systolic blood pressure (SBP) ≥ 150 mm Hg or diastolic blood pressure (DBP) ≥ 90 mm Hg and treat to a goal SBP < 150 mm Hg and goal DBP < 90 mm Hg. (Strong Recommendation – Grade A)**
* **Recommendation 2:** **In the general population < 60 years, initiate pharmacologic treatment to lower BP at DBP ≥ 90 mm Hg and treat to a goal DBP < 90 mm Hg. (For ages 30-59 years, Strong Recommendation – Grade A; For ages 18-29 years, Expert Opinion – Grade E)**
* **Recommendation 3:** **In the general population <60 years, initiate pharmacologic treatment to lower BP at SBP ≥ 140 mm Hg and treat to a goal SBP < 140 mm Hg. (Expert Opinion – Grade E)**
* **Recommendation 5: In the population aged ≥ 18 years with diabetes, initiate pharmacologic treatment to lower BP at SBP ≥ 140mmHg or DBP ≥ 90 mm Hg and treat to a goal SBP < 140 mm Hg and goal DBP < 90 mm Hg. (Expert Opinion - Grade E)**

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

**Joint National Commitee-8 Grading System:**

|  |  |
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| **Evidence Quality Rating** | |
| **Quality Rating** | **Type of Evidence** |
| **High** | **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** |
| **Moderate** | **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** |

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| **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.*)

**Joint National Commitee-8 Grading System:**

|  |  |
| --- | --- |
| **Evidence Quality Rating** | |
| **Quality Rating** | **Type of Evidence** |
| **Low** | **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.** |

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| **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 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*)**:**

**Not applicable.**

**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***](#Section1a7)

☐No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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

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

**Not applicable.**

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

**Not applicable.**

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**Not applicable.**

**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.*)

**Not applicable.**

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

**Not applicable.**

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**Not applicable.**

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

***Complete section*** [***1a.7***](#Section1a7)

**Not applicable.**

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**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?**

**Evidence highlights the need and importance of monitoring, controlling, and treating high blood pressure in both the general population and special populations (i.e. elderly populations, those with diabetes). The Joint National Committee-8 recommends achievement of blood pressure lower than 140/90 mmHg for the general population, age 18-59 years, and those with diabetes, and blood pressure lower than 150/90 mmHg for those over 60 years of age without diabetes. Both hypertension and controlled blood pressure should be regularly monitored and treated (if necessary) to reduce the risk of macrovascular diabetic complications and cardiovascular disease. Treatment of high blood pressure should include both pharmacological remedies (i.e. antihypertensives), diet, weight control, and regular exercise.**

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

**Recommendation 1: *moderate* to *high-quality* evidence from RCTs showing that treating high BP to a goal of < 150/90 mm HG reduces stroke, heart failure, and coronary disease (CHD) among individuals 60 years or older in the general population.**

**Recommendation 2: is based on *high-quality* evidence from 5 DBP trials (HDFP, Hypertension Stroke Cooperative, MRC, ANBP, and VA Cooperative) that demonstrate improvements in health outcomes among adults aged 30 through 69 years with elevated BP. Initiation of antihypertensive treatment at a DBP threshold of 90 mm Hg or higher and treatment to a DBP goal of lower than 90mm Hg reduces cerebrovascular events, heart failure, and overall mortality. There are no good or fair quality RCTs that analyzed the benefits of treating high diastolic blood pressure on health outcomes for adults younger than 30. Given this absence of evidence, the panel recommended extending the DBP threshold and goal of the 30-59 year old population those 18-29 years of age.**

**Recommendation 3: is based on *expert opinion*. While there is high-quality evidence to support a specific SBP threshold and goal for persons aged 60 years or older, the panel found insufficient evidence from good- or fair-quality RCTs to support a specific SBP threshold or goal for persons younger than 60 years.**

**Recommendation 5: 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 in adults with diabetes and hypertension.**

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| **Evidence Quality Rating** | |
| **Quality Rating** | **Type of Evidence** |
| **Moderate** | **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** |
| **High** | **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** |

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

**Joint National Committee-8 Grading System:**

|  |  |
| --- | --- |
| **Evidence Quality Rating** | |
| **Quality Rating** | **Type of Evidence** |
| **Low** | **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.** |

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: **1974-2010**

**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*)

**Joint National Committee-8:**

**When developing their guidelines, the Joint National Committee-8 drew from evidence obtained from randomized controlled trials. Specifically, the Joint National Committee-8 reviewed:**

* **4 randomized controlled trials assessed initiating antihypertensive pharmacological therapy at SBP thresholds ≥ 160 mm Hg.**
* **8 randomized controlled trials assessed initiating antihypertensive pharmacological therapy at DP thresholds ≥ 90 mm Hg.**
* **6 randomized controlled trials assessed treatment with antihypertensive pharmacological therapy to specified SBP goals**
* **7 randomized controlled trials assessed treatment with antihypertensive pharmacological therapy to specified SBP goals**
* **7 randomized controlled trials assessed treatment with antihypertensive pharmacological therapy to BP goals in patients with diabetes**

**1a.7.6.** **What is the overall quality of evidence across studies 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 evidence review used to develop the Joint National Committee-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 included a substantial number of studies with large numbers of patients. Studies with sample sizes of less than 100 were excluded from the review as well as studies that had follow-up periods of less than a year. The quality rating across all studies that support the blood pressure control recommendations described above range from moderate to high quality. There was strong evidence to support treating hypertensive adults aged 60 and older to a BP goal of less than 150/90 mm Hg and hypertensive adults aged 30 through 59 years of age to a diastolic goal of less than 90 mm Hg. The Joint National Committee-8 panel used expert opinion to recommend a BP of less than 140/90 mm Hg for those younger than 60 years in the general population.**

**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) across studies 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*)

**The RCTs included in this evidence review demonstrate the benefits of antihypertensive drug treatment in reducing adverse health outcomes in adults with hypertension including diabetics and those with chronic kidney disease. Strong evidence shows that controlled blood pressure (<150/90 mm hg) for adults 60 years and older reduces stroke, heart failure, and coronary heart disease (CHD). Evidence also shows improved health outcomes for adults between 30 and 69 years of age with elevated BP. Specifically, individuals who received antihypertensive treatment to lower a diastolic BP to less than 90 mm Hg showed reduced cerebrovascular events, heart failure, and overall mortality. In the Joint National Committee guidelines, recommendation for the SBP treatment threshold of 140 mm Hg or lower was based on expert opinion. However, evidence from the diastolic BP trials showed that a majority of the study participants who achieved a lower than 90 mm Hg were also likely to achieve an SBP of lower than 140. Evidence from trials showing the benefit of reducing SBP to 140 mm Hg or lower in adults with diabetes and chronic kidney disease also supports a similar SBP goal in the general population younger than 60 years of age.**

**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 Joint National Committee-8 panel 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 the guidelines 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 each 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.**

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**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?**

**Not applicable.**

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

**Not applicable.**