To Whom It May Concern:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to HEDIS 2015 Public Comment. The AHA is committed to reducing hypertension and has made this a primary focus area of its 2014-2017 strategic plan as it seeks to improve the cardiovascular health of all Americans by 20% and reduce the death rate from cardiovascular disease and stroke by 20% by 2020.

We limit our comments to the proposed modifications of the Controlling High Blood Pressure measure. In this letter, we strongly urge NCQA not to adopt the proposed modifications. Many of the statements expressed below are expressed in more detail in the recently published statement entitled Evidence Supporting a Systolic Blood Pressure Goal of Less Than 150 mm Hg in Patients Aged 60 Years or Older: The Minority View.¹

NCQA’s Proposed Stratification of Patients and BP Control Goal

In the proposed announcement of the 2015 HEDIS measures, the NCQA proposes to modify the existing language of the measure to read as follows: “The percentage of members 18 and older who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled during the measurement year using the following criteria:

- Members 18–59 years of age whose BP was <140/90 mm Hg.
- Members 60 years of age and older whose BP was <150/90 mm Hg.”

The basis for this and other changes in the measure is due to a writing group report published in JAMA last year. This report is often incorrectly referred to as JNC 8 by the lay media, and by some science reporters and physicians.

¹ Evidence Supporting a Systolic Blood Pressure Goal of Less Than 150 mm Hg in Patients Aged 60 Years or Older: The Minority View. JAMA 2013;309(4):367-370.
However, this report is not a JNC 8 report, as it was not sanctioned or endorsed by the NHLBI, and was also not endorsed by several other organizations from whom endorsement was sought, including the AHA and ACC. Therefore, throughout this letter we refer to this group and its work as “the writing group publishing its report in JAMA” or more briefly as the “writing group” or the “writing group recommendations.”

The AHA/ASA take this opportunity to strongly urge NCQA not to stratify this measure by age (18-59) and (60+). With evidence demonstrating a reduction of coronary heart disease (CHD) and stroke mortality in this country and particularly in the latter age group, we believe the evidence to raise the systolic blood pressure (SBP) target should be at least as strong as the evidence that would be required to lower it and strongly believe that the blood pressure control should remain at <140/90 to ensure that hypertension is appropriately managed in patients until we have more scientific studies about the likely impact of raising the SBP goal on cardiovascular disease and stroke. The AHA/ASA agrees with the writing group report’s overarching theme of controlling hypertension, the AHA/ASA does not support stratified blood pressure targets for the reasons discussed below.

**Adoption of a Stratified Blood Pressure Goal in Quality Measure May Adversely Affect Community and Public Health Efforts to Reduced Hypertension**

While it is important to consider how hypertension recommendations may affect individuals, it is equally important to consider how these might affect community care and general public health. Despite the JNC 7 goals and national performance metrics, only about half of patients with hypertension in the United States currently have a SBP of 140 mm Hg or less, which is far from ideal. However, in patients age 60 and above, SBP has been steadily decreasing in this age group with concomitant reduction in CHD and stroke mortality. Data from NHANES (National Health and Nutrition Examination Survey) from 2001 to 2008 show that among treated and untreated hypertensive adults aged 60 years or older, median SBPs were 136 mm Hg and 152 mm Hg, respectively, and SBPs have been decreasing in this age group over the past 5 decades. We believe that a higher SBP target of less than 150 will adversely affect public health. We further believe the higher SBP target in this age group will increase health disparities among populations at greatest risk, especially African Americans, patients with multiple risk factors, including those with existing cardiovascular disease.

**There is Currently Insufficient Randomized Controlled Trials (RCTs) Evidence to Support a Differential Hypertension Treatment Benefit for Patients Older and Younger Than 60 Years**

There is little RCT evidence of risk or benefit in treating persons younger than 60 years to this target, except in those with diastolic hypertension. The guideline indicates that no qualifying evidence was found comparing an SBP less than 140 mm Hg to any other SBP goal for persons younger than 60 years. Persons aged 60 years or older, the SHEP (Systolic Hypertension in the Elderly Program) trial showed benefit of treating hypertension to an SBP goal between 140 and 145 mm Hg. The HYVET (Hypertension in the Very Elderly Trial) found a benefit of an SBP target of less than 150 mm Hg on health outcomes, including mortality in persons aged 80 years or older. Patients in the HYVET treatment group achieved an SBP of 144 mm Hg at 2 years compared with 159 mm Hg in the control group, and blood pressures continued to decrease in both groups until the end of the trial. Both the HYVET and the SHEP trial provide evidence that reducing SBP to around
140 mm Hg has substantial benefit without major harm in older persons. Thus, the best evidence available for an SBP target around 140 mm Hg, which meets the guideline RCT criteria, is in persons older than 60 years.

The writing group publishing its report in JAMA refers to 2 trials in older individuals (JATOS [Japanese Trial to Assess Optimal Systolic Blood Pressure in Elderly Hypertensive Patients] and the VALISH [Valsartan in Elderly Isolated Systolic Hypertension] trial) in order to substantiate the higher SBP target, but these trials were underpowered. Both the SHEP trial and HYVET together reported 365 strokes and more than 285 coronary heart disease events, whereas JATOS (participants 65 to 85 years old) and the VALISH (participants from 70 to 84 years old) trial only had a combined total of 125 strokes and 67 coronary heart disease events. While underpowered to show a difference in benefit between the two treatment groups, JATOS and VALISH did not find any increase risk of adverse effects in the lower goal participants.

In addition, the much larger FEVER (Felodipine Event Reduction) trial did not meet criteria for inclusion in the panel's deliberation. This trial, which was conducted in a Chinese population (age range, 50 to 79 years; mean age, 62 years), reported a significant 27% reduction in its primary outcome, as well as significant reductions in all CVD, total mortality, coronary heart disease, and heart failure in patients treated to an SBP of 137 mm Hg with a thiazide diuretic–calcium-channel blocker combination versus 143 mm Hg with a thiazide diuretic plus placebo. The authors of the Annals of Internal Medicine article argue that the evidence to recommend raising the SBP target should be at least as strong evidence required to lower the target. We agree with their assessment that the current evidence is insufficient.

The Methodology Used in Preparing the Writing Group Recommendations Failed to Consider Evidence Beyond the Use of Randomized Controlled Trials

Previous JNC publications were based on the totality of evidence, and had included observational studies, RCTs, and meta-analyses, as well as expert opinion when formulating recommendations. However, the writing group recommendations departed from this usual methodology and used a highly focused review of randomized controlled trials, thus failing to incorporate important other sources of evidence, as was noted above. In addition, unlike previous NHLBI endorsed JNC guidelines, the “2014 US HTN guideline” though like previous JNCs, it was sent out for to external reviewers, it failed to include a period of public comment from professional organizations and in the end was neither published nor endorsed by NHLBI. In developing guidelines it is important to utilize a variety of resources in formulating recommendations. In contrast to the writing group report process, the American Heart Association/American College of Cardiology (AHA/ACC) process relies on a wider breadth of science and incorporates the opinion of expert panels, as well as rigorous peer review) to develop our guidelines.

Below we provide examples of metaanalyses of a more diverse set of clinical trials and guidelines that support maintaining the target SBP at less than 140.
Current Metanlyses Do Support Systolic Blood Pressure Control of <140/90

2 meta-analyses supported the SBP goal of less than 140 mm Hg.11-12 A meta-analysis involving 16 trials analyzed whether treatment with antihypertensive drugs compared with placebo significantly reduced risk for all strokes in trials with an average baseline SBP less than 140 mm Hg and diastolic blood pressure less than 90 mm Hg. It found benefit with an SBP less than 140 mm Hg.11 A second meta-analysis examined the effects of blood pressure reduction in patient groups defined a priori by baseline blood pressures in 32 trials (n = 201,566 participants) and found no evidence that benefit of treatment differed in patients with a baseline SBP below or above 140 mm Hg for major cardiovascular events.12 A third meta-analyses of multiple randomized trials including 464,000 patients demonstrate the benefit of BP reduction below 150 in patients between 60 and 79 in terms of reducing both coronary heart disease events and stroke (See Figure 1).13

Figure 1:

Current Guidelines From Various Countries Recommend that Systolic Blood Pressure SBP < 140/90

A target SBP of less than 140 mm Hg for patients younger than 80 years would also be in line with guidelines from Europe,14 Canada,15 the American College of Cardiology Foundation and the American Heart Association,16 the United Kingdom,17 and the American Society of Hypertension and the International Society of Hypertension,18 each after reviewing the same randomized controlled trial evidence upon which the “2014 US HTN guideline” is based. The AHA/ACC is
currently in the process of revising its guidelines. At this point, the “2014 US JAMA HTN
guideline” is the only national or international guideline to recommend raising the SBP target in
patients as young as age 60 years.

While our updated guidelines are yet to be published, we are committed to advocating for the a
target of <140/90 as evidence by our recently released advisory with the American College of
Cardiology (ACC) and The Centers for Diseases Control and Prevention (CDC), where all three
organizations describe the value of hypertension treatment algorithms, provide criteria for effective
hypertension management algorithms, describe an AHA/ACC/CDC-recommended treatment
algorithm based on current guidelines and describe examples of other specific algorithms that have
been associated with improved blood pressure on a large scale.\(^2\)

**Conclusion**

In conclusion we would strongly urge NCQA not to adopt a SBP of less than 150 in those > age 60
at this time. Should you have any questions or require any additional information do not hesitate to
contact Penelope Solis, Healthcare Quality Manager via email Penelope.Solis@heart.org or via
phone 202.423.3124.

Sincerely,

Mariell Jessup, M.D., FAHA
President
American Heart Association

\(^1\) Jackson T. Wright Jr., Lawrence J. Fine, Daniel T. Lackland, Gbenga Ogedegbe, Cheryl R. Dennison Himmelfarb;
Evidence Supporting a Systolic Blood Pressure Goal of Less Than 150 mm Hg in Patients Aged 60 Years or Older: The
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doi:10.1161/HYP.0000000000000003.
\(^3\) Lackland DT, Roccella EJ, Deutsch AF, Fornage M, George MG, Howard G, et al; American Heart Association Stroke
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Council on Functional Genomics and Translational Biology. Factors influencing the decline in stroke mortality: a
\(^4\) Wright JD, Hughes JP, Ostchega Y, Yoon SS, Nwankwo T. Mean systolic and diastolic blood pressure in adults aged
\(^5\) James PA, Oparil S, Carter BL, Cushman WC, Dennison-Himmelfarb C, Handler J, et al. 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. 2013.
\(^6\) Prevention of stroke by antihypertensive drug treatment in older persons with isolated systolic hypertension. Final
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