

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

Special Report

## 2014 Hypertension Guideline: Recommendation for a Change in Goal Systolic Blood Pressure

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*Editor's note: A copy of the August 2014 Kaiser Permanente Adult Hypertension National Guideline follows this article.*

**ABSTRACT**

The 2014 Kaiser Permanente Care Management Institute National Hypertension Guideline was developed to assist primary care physicians and other health care professionals in the outpatient treatment of uncomplicated hypertension in adult men and nonpregnant women aged 18 years and older. The new guideline reflects general acceptance, with minor modifications, of the "Evidence-Based Guideline" report by the panel members appointed to the National Heart, Lung, and Blood Institute 8th Joint National Committee. A major practice change is the recommendation for goal systolic blood pressure less than 150 mmHg in patients aged 60 years and older who are treated for hypertension in the absence of diabetes or chronic kidney disease. This article describes the reasons for, evidence for, and consequences of the change, and is followed by the National Guidelines handout.

**INTRODUCTION**

The 2014 Kaiser Permanente (KP) Care Management Institute National Hypertension Guideline was developed to assist primary care physicians and other health care professionals in the outpatient treatment of uncomplicated hypertension in adult men and nonpregnant women aged 18 years and older. The new guideline reflects general acceptance of the "Evidence-Based Guideline" report by the panel members appointed to the National Heart, Lung, and Blood Institute (NHLBI) 8th Joint National Committee (JNC 8).<sup>1</sup> A major practice change is the recommendation for goal systolic blood pressure less than 150 mmHg in patients aged 60 years and older who are treated for hypertension in the absence of diabetes or chronic kidney disease (CKD) compared with the previous standard less than 140 mmHg. This change has major consequences for the routine primary care management of patients with hypertension.

**How Large Is the Affected Population and How Strong Is the New Recommendation?**

Using the results of the National Health and Nutrition Examination Survey between 2005 and 2010, it has been estimated that the US treatment-eligible adult hypertension population would decrease from 20.3% to 19.2% compared

with that of the 7th Joint National Committee guideline, and the population with treatment-eligible hypertension who are aged 60 years and older would decline from 68.9% to 61.2%.<sup>2</sup> As of October 2014, with an 85% hypertension control rate less than 140/90 mmHg, there are 18,690 patients aged 60 years and older without diabetes or CKD in the KP Southern California hypertension registry who have systolic blood pressures of 140 to 149 mmHg and are affected by the new recommendation. These patients represent 2.5% of the total KP Southern California adult hypertension registry of 740,003 individuals.

Evidentiary support for this recommendation was strong, according to the Care Management Institute Grading of Recommendations Assessment, Development and Evaluation standard for grading the quality of evidence scale, and it received a strong rating using principles evaluating the strength of the body of evidence and degree of certainty developed by the NHLBI before it convened the first JNC 8 panel meeting in August 2008. This recommendation was a segue from the relevant Evidence Statements, which evaluated randomized clinical trials passing scrutiny from a 14-category evidence assessment scale used by a trained and independent methodology team collaborating with those experts appointed to the JNC 8 panel. These Evidence Statements are available in the full online Evidence-Based Guideline report.<sup>1</sup>

**What is the Basis of the Supportive Evidence?**

The age 60 years threshold for the systolic blood pressure target was decided on the basis of the Systolic Hypertension in the Elderly Program (SHEP) trial findings and the Systolic Hypertension in Europe (Syst-Eur) trial results.<sup>3,4</sup> In these highly rated randomized controlled trials, stroke, the primary endpoint, was reduced by 36% and 42%, respectively, and major cardiovascular events were reduced by 32% and 31%, respectively. These two large trials containing representative population samples fulfill the NHLBI strong evidence requirement for multiple supportive randomized controlled trials. The JNC 8 Evidence Statements 1 to 3 for Clinical Question 2 describe the evidence, and a strong recommendation is the logical result.<sup>1p82-3</sup>

There is no evidence from a randomized controlled clinical trial to support the opinion that a systolic blood pressure goal less than 140 mmHg in the elderly hypertensive population is superior to a systolic goal less than 150 mmHg. The absence

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of evidence for a lower blood pressure target does not equal benefit. One opinion properly criticizes the strength of the Japanese Trial to Assess Optimal Systolic Blood Pressure in Elderly Hypertensive Patients<sup>5</sup> and Valsartan in Elderly Isolated Hypertension Study<sup>6</sup> results demonstrating equivalency of goal systolic pressure less than 140 mmHg compared with goal systolic pressures less than 150 mmHg and less than 160 mmHg, because these were short-term trials.<sup>7</sup> However, that critique does not offer additional information to the previously published Evidence-Based Guideline Clinical Question 2: Evidence Statement 6, which attached low-quality evidence to these trials.<sup>1p84-5</sup>

### PROBLEMS WITH USE OF ACHIEVED BLOOD PRESSURE TRIALS

Achieved blood pressure trials are those in which the intervention is to introduce antihypertensive medication to examine the effect of medication on cardiovascular risk reduction rather than to examine outcomes achieving a prespecified goal blood pressure. These trial results should not be used to inform blood pressure targets because they ask a different question. Retrospective analyses correlating achieved blood pressures to outcome measures are inherently biased.

The NHLBI process followed by the panel appointed to JNC 8 is in agreement with The Cochrane Collaboration methodologists who independently decided the following:

*The cohort of patients with low blood pressure as identified by achieved blood pressure selects for patients who did not have sustained elevated blood pressure in the first place ... , for patients in whom the blood pressure is most easily reduced with low doses of antihypertensive drugs, for patients with the lowest baseline blood pressure, and for patients who are most compliant with drug and non-drug therapy to lower blood pressure ... . All of these factors are also most likely associated with a lower risk of having an adverse cardiovascular event. The approach is thus heavily biased for finding [fewer] cardiovascular events in the patients with lower blood pressure, and thus must not be encouraged.*<sup>8</sup>

These limitations of analyses based on post hoc achieved blood pressures were confirmed in an analysis of the African American Study of Kidney Disease and Hypertension, which concluded that the retrospective use of achieved blood pressures would have erroneously led to the opposite conclusion of the intention-to-treat goal blood pressure analysis in this landmark study.<sup>9</sup>

The Felodipine Event Reduction study,<sup>10</sup> the Perindopril Protection against Recurrent Stroke trial,<sup>11</sup> and Blood Pressure Trialists' Collaboration reports<sup>12-14</sup> purport to show that additional blood pressure lowering is beneficial. These are examples of clinical trials and meta-analyses representing on-treatment achieved blood pressure results rather than intention-to-treat goal blood pressure outcomes and were rejected by the NHLBI methodology team because of bias. Notably, reference to mean achieved systolic blood pressures in the SHEP and Syst-Eur trials of 142 mmHg and 144 mmHg,

respectively, fails to mention the mean achieved systolic blood pressure in Syst-Eur, which was 151 mmHg.<sup>4</sup>

The argument to use "totality of evidence" does not constitute sufficient rationale for inclusion of clinical trials and meta-analyses containing inherent bias.

### Where Does the Lower-is-Better Blood Pressure Hypothesis Originate, and Has It been Validated?

Much of the "lower is better" paradigm is based on strong prospective observational data of more than 1 million patients in 61 prospective studies<sup>15</sup> as well as on many retrospective analyses of achieved blood pressures in the clinical trials. However, the retrospective findings are mixed. A more recent population-based retrospective cohort study revealed no difference between systolic intensification thresholds of 130 mmHg to 150 mmHg across a broad spectrum of baseline cardiovascular risk.<sup>16</sup> Analyses of large numbers of hypertensive KP patients with hypertension, as well as US military veterans with hypertension and CKD, suggest increased mortality and end-stage kidney disease associated with lower attained blood pressures.<sup>17,18</sup>

Does the treatment of blood pressure to lower blood pressure targets, as opposed to higher blood pressure targets, reverse cardiovascular risk? Seven randomized clinical trials have investigated this hypothesis in high-risk patients with CKD, diabetes, older age, and a personal history of stroke. None has shown significant benefit for meeting the primary endpoint with more intense antihypertensive therapy that seeks a lower blood pressure goal.<sup>5,6,19-23</sup>

### WHAT IS THE RISK OF REVERSING POPULATION GAINS IN CARDIOVASCULAR BENEFIT?

How can we be sure that a higher systolic goal will not reverse gains already made in stroke and cardiovascular disease reduction? Gains in cardiovascular disease reduction have been associated with hypertension control, widespread use of high-potency statins, and improved secondary prevention in patients with known coronary artery disease and stroke.<sup>24,25</sup> Because patients are receiving better overall care, power calculations for recent hypertension treatment trials on the basis of adverse rates of cardiovascular events for historic cohorts often fall short of forecasts, leading to underpowering.<sup>19,20</sup> Given the success of population care strategies achieving very high rates of blood pressure control and eliminating racial performance gaps in large diverse populations,<sup>26-29</sup> we need to ensure that we use the highest evidence base to define blood pressure targets. Implementation difficulties and problems with clinical inertia are independent issues and should not be used to justify inappropriately low blood pressure goals.

### What are the Risks of Overtreatment?

Overtreatment needs to be a concern. In the KP Southern California adult hypertension registry in which nearly 90% of patients attained blood pressure control less than 140/90 mmHg, the mean systolic pressure is 127 mmHg, and almost 10% of patients receiving antihypertensive therapy have a most recent systolic pressure less than 110 mmHg. The

disadvantages of overtreatment include: 1) exposure to side effects of unnecessary medications and excessive medication doses; 2) polypharmacy in the elderly<sup>30</sup>; 3) reduced medication adherence associated with a large number of medications<sup>31</sup>; 4) a possible increase in falls with serious injury<sup>32</sup>; 5) possibly a J- or U-curve increase in cardiovascular risk<sup>17</sup>; and 6) unnecessary use of limited health care resources, including office visits, population care outreach, medication prescriptions, and laboratory testing. A general review of 16 treatment trials indicated the potential for harm with more aggressive antihypertensive therapy in the absence of benefit.<sup>33</sup>

### Is There a Risk of Changing Goal Blood Pressure in the Presence of Uncertainty?

How can we be certain that the systolic blood pressure target less than 150 mmHg for patients with hypertension aged 60 years and older is accurate? The purpose of guideline development is to gather evidence with the least chance of bias, and this sort of evidence is best obtained from higher-quality randomized controlled clinical trials. All the panelists appointed to JNC 8 concurred with the NHLBI evidence review process, and, following several straw votes

during more than one year, the final recorded vote at a face-to-face meeting conducted in Bethesda, MD, at the National Institutes of Health on February 27-28, 2013, on Recommendation 1 was 15 in favor and 2 against. The final recorded vote on the 3 evidence statements supporting Recommendation 1 was unanimously in favor. The SHEP and Syst-Eur trial results<sup>3,4</sup> provide strong evidence to support the Evidence-Based Guideline's recommended goal blood pressure in elderly patients. In contrast, there are no known clinical trials that address goal blood pressure that have examined the 18- to 59-year age stratum, and therefore recommendation for less than 140/90 mmHg for this population is based on expert opinion.

There is a need for additional clinical trials examining the question of goal blood pressure for various populations of hypertensive individuals. Those trials should include examination of important health outcomes at a goal systolic pressure less than 150 mmHg compared with less than 130 mmHg in elderly patients with diabetes and CKD. There is good evidence to justify such a randomized clinical trial in patients with diabetes,<sup>3,4,34</sup> including Evidence Statement 18 for Clinical Question 2 in James et al.<sup>1</sup> If the ongoing Systolic Blood Pressure Intervention Trial does not find a significant outcome difference treating to goal systolic pressure less than 140 mmHg compared with less than 120 mmHg in patients with CKD, a future trial comparing less than 150 mmHg with less than 130 mmHg would be justified in this population as well.

### IS THE EVIDENCE-BASED GUIDELINE RECOMMENDATION FOR GOAL SYSTOLIC PRESSURE LESS THAN 150 MMHG FOR AGE 60 AND OLDER AN OUTLIER COMPARED WITH OTHER GUIDELINES?

Recommendations from the 2013 European Society of Hypertension/European College of Cardiology for blood

pressure goals in the treatment of hypertension in elderly patients include a few “may consider,” “if treatment is well tolerated” recommendations along with a top “solid evidence” recommendation.<sup>35</sup> That single, solid-evidence recommendation targets a goal systolic blood pressure 140 mmHg to 150 mmHg “in the elderly.” In the SHEP and Syst-Eur trials, “elderly” enrollment began at age 60 years. In an e-mail from Giuseppe Mancia, MD, co-chair of the European Society of Hypertension/European College of Cardiology guideline, which was circulated to panel members appointed to JNC 8, *elderly* was defined as beginning at age 65 years (G Mancia, MD; personal communication, 2013 Dec).<sup>2</sup> In a letter to the European Society of Hypertension/European College of Cardiology guideline authors in the December 2013 issue of the *Journal of Hypertension*, a writer expressed concern regarding the new blood pressure goal stating that it was “rational” but worried about the impact on clinical inertia. In their letter of reply, Mancia et al<sup>36</sup> stated, “Clinical inertia has to be fought ... by other means than by recommending inappropriately low [blood pressure] targets.”

Therefore, there is fair concordance in the age group targeted for a systolic blood pressure goal target less than 150 mmHg in hypertension guidelines submitted by hypertension experts on both sides of the Atlantic.

### Why Not Make the Threshold for the less than 150 mmHg Goal Recommendation Age 80 Rather than Age 60?

Given the findings of the SHEP and Syst-Eur trials,<sup>3,4</sup> there is greater certainty defining the age group 60 years and older, rather than age 80 years and older, for goal systolic pressure less than 150 mmHg. Only a single trial, the Hypertension in the Very Elderly Trial, has established goal systolic blood pressure in the age 80 years and older population less than 150 mmHg, a population described as the “very elderly.”<sup>37</sup>

A single randomized clinical trial does not constitute sufficient evidence to merit a strong recommendation at this age level in the presence of multiple randomized clinical trials in support of the age 60 threshold.

### Does the less than 150 mmHg Goal Recommendation Include Higher Risk Groups?

Epidemiologic data have defined higher cardiovascular risk strata in the general population, but randomized controlled clinical trials demonstrating statistically significant reversal of risk with lower blood pressure goals in higher-risk groups have been notably absent.<sup>5,6,19-23</sup>

SHEP and Syst-Eur enrolled patient populations that were representative of a broad spectrum of cardiovascular risk. Increasing age alone is a dominant cardiovascular disease risk factor.<sup>15</sup> Additionally, the SHEP trial population included 14% African-American patients compared with 12.6% in the US population. Both SHEP and Syst-Eur also included patients with a history of myocardial infarction and stroke.<sup>1,3</sup> Sixty-one percent of patients in SHEP had a baseline electrocardiographic abnormality. Thirty percent of patients in Syst-Eur had a prior “cardiovascular complication.” The

... there is greater certainty defining the age group 60 years and older, rather than age 80 years and older, for goal systolic pressure less than 150 mmHg.

Hypertension in the Very Elderly Trial included patients with myocardial infarction, stroke, and heart failure.<sup>36</sup>

Attention has been drawn to the Secondary Prevention of Small Subcortical Strokes trial comparing goal systolic pressure less than 150 mmHg to less than 130 mmHg in patients with a personal history of lacunar stroke.<sup>20</sup> Although the primary endpoint of recurrent stroke was non-significant ( $p = 0.08$ ), confidence intervals (0.64 to 1.03) did not preclude benefit of the lower goal. Furthermore, the subgroup of intracerebral hemorrhage was significantly reduced ( $p = 0.03$ ).<sup>6</sup> However, “there was no heterogeneity in treatment effect on the primary outcome in any of the demographic or clinical subgroups,” the annual primary stroke rate in the control group was only 2.77% vs 7% predicted, and intracerebral hemorrhage comprised fewer than 10% of total strokes.<sup>20</sup> The nonstatistically significant separation of total stroke in the more intensively treated group compared with the less intensively treated group in the Secondary Prevention of Small Subcortical Strokes trial was only 0.5% events per year. Therefore, the evidence favoring a goal systolic pressure other than lower than 150 mmHg in hypertensive individuals aged 60 years and older with a personal history of stroke is speculative.

#### ENDORSEMENTS OF THE EVIDENCE-BASED GUIDELINE

The American Academy of Family Physicians, representing more than 100,000 primary care physicians, has endorsed the Evidence-Based Guideline. That approval is important because nearly all hypertensive patients receive hypertension care from primary care physicians. Additionally, the National Quality Committee for Quality Assurance has adopted the new reform, and goal systolic blood pressure less than 150 mmHg in the absence of diabetes is a 2014 performance measure for the Healthcare Effectiveness Data and Information Set. The Veteran's Administration and Department of Defense patient care systems have adopted goal systolic blood pressure less than 150 mmHg for general population hypertension patients age 60 and over.<sup>38</sup>

It will be difficult to reproduce the methodologic rigor and independent sponsorship of the Evidence-Based Guideline now that the NHLBI has unfortunately decided to remove itself from stewardship of future hypertension guidelines, and will not approve any guideline. The level of evidence-based medicine used to develop this hypertension guideline, on the basis of Institute of Medicine principles, is unsurpassed.

An essential point is that blood pressure goals for patients with hypertension must be based on a high degree of evidence, and bias is best removed by reliance on the randomized controlled clinical trials to make this determination. A common rationale for recommending blood pressure goals lower than those that are evidence based is to combat clinical inertia. However, implementation is a separate issue, and high-performing systems of health care have addressed clinical inertia successfully.<sup>26-29,39</sup> ❖

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#### Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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#### References

1. James PA, Oparil S, Carter BL, 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* 2014 Feb 5;311(5):507-20. DOI: <http://dx.doi.org/10.1001/jama.2013.284427>.
2. Navar-Boggan AM, Pencina MJ, Williams K, Sniderman AD, Peterson ED. Proportion of US adults potentially affected by the 2014 hypertension guideline. *JAMA* 2014 Apr 9;311(14):1424-9. DOI: <http://dx.doi.org/10.1001/jama.2014.2531>. Erratum in: *JAMA* 2014 Aug 27;312(8):848. DOI: <http://dx.doi.org/10.1001/jama.2014.10343>.
3. Prevention of stroke by antihypertensive drug treatment in older persons with isolated systolic hypertension. Final results of the Systolic Hypertension in the Elderly Program (SHEP). SHEP Cooperative Research Group. *JAMA* 1991 Jun 26;265(24):3255-64.
4. Staessen JA, Fagard R, Thijs L, et al. Randomised double-blind comparison of placebo and active treatment for older patients with isolated systolic hypertension. The Systolic Hypertension in Europe (Syst-Eur) Trial Investigators. *Lancet* 1997 Sep 13;350(9080):757-64. DOI: [http://dx.doi.org/10.1016/S0140-6736\(97\)05381-6](http://dx.doi.org/10.1016/S0140-6736(97)05381-6).
5. JATOS Study Group. Principal results of the Japanese trial to assess optimal blood pressure in elderly hypertensive patients (JATOS). *Hypertens Res* 2008 Dec;31(12):2115-27. DOI: <http://dx.doi.org/10.1291/hypres.31.2115>.
6. Ogihara T, Saruta T, Rakugi H, et al; Valsartan in Elderly Isolated Systolic Hypertension Study Group. Target blood pressure for treatment of isolated systolic hypertension in the elderly: valsartan in elderly isolated systolic hypertension study. *Hypertension* 2010 Aug;56(2):196-202. DOI: <http://dx.doi.org/10.1161/HYPERTENSIONAHA.109.146035>.
7. Wright JT Jr, Fine LJ, Lackland DT, Ogedegbe G, Dennison Himmelfarb CR. Evidence supporting a systolic blood pressure goal of less than 150 mmHg in patients aged 60 years or older: the minority view. *Ann Intern Med* 2014 Apr 1;160(7):499-503. DOI: <http://dx.doi.org/10.7326/M13-2981>.
8. Arguedas JA, Perez MI, Wright JM. Treatment blood pressure targets for hypertension. *Cochrane Database Syst Rev* 2009 Jul 8;(3):CD004349. DOI: <http://dx.doi.org/10.1002/14651858.CD004349.pub2>.
9. Davis EM, Appel LJ, Wang X, et al; African American Study of Kidney Disease and Hypertension Research Collaborative Group. Limitations of analyses based on achieved blood pressure: lessons from the African American study of kidney disease and hypertension trial. *Hypertension* 2011 Jun;57(6):1061-8. DOI: <http://dx.doi.org/10.1161/HYPERTENSIONAHA.111.169367>.
10. Liu L, Zhang Y, Liu G, Li W, Zhang X, Zanchetti A; FEVER Study Group. The Felodipine Event Reduction (FEVER) Study: a randomized long-term placebo-controlled trial in Chinese hypertensive patients. *J Hypertens* 2005 Dec;23(12):2157-72.
11. PROGRESS Collaborative Group. Randomised trial of a perindopril-based blood-pressure-lowering regimen among 6,105 individuals with previous stroke or transient ischaemic attack. *Lancet* 2001 Sep 29;358(9287):1033-41. DOI: [http://dx.doi.org/10.1016/S0140-6736\(01\)06178-5](http://dx.doi.org/10.1016/S0140-6736(01)06178-5). Erratum in: *Lancet* 2002 Jan 15;359(9323):2120. DOI: [http://dx.doi.org/10.1016/S0140-6736\(02\)08935-3](http://dx.doi.org/10.1016/S0140-6736(02)08935-3). Erratum in: *Lancet* 2001 Nov 3;358(9292):1556. DOI: [http://dx.doi.org/10.1016/S0140-6736\(01\)06617-X](http://dx.doi.org/10.1016/S0140-6736(01)06617-X).
12. Staessen JA, Wang JG, Thijs L. Cardiovascular protection and blood pressure reduction: a meta-analysis. *Lancet* 2001 Oct 20;358(9290):1305-15. DOI: [http://dx.doi.org/10.1016/S0140-6736\(01\)06411-X](http://dx.doi.org/10.1016/S0140-6736(01)06411-X). Erratum in: *Lancet* 2002 Jan 26;359(9303):360. DOI: [http://dx.doi.org/10.1016/S0140-6736\(02\)07527-X](http://dx.doi.org/10.1016/S0140-6736(02)07527-X).
13. Turnbull F; Blood Pressure Lowering Treatment Trialists' Collaboration. Effects of different blood-pressure-lowering regimens on major cardiovascular events: results of prospectively-designed overviews of randomised trials. *Lancet* 2003 Nov;362(9395):1527-35. DOI: [http://dx.doi.org/10.1016/S0140-6736\(03\)14739-3](http://dx.doi.org/10.1016/S0140-6736(03)14739-3).
14. Blood Pressure Lowering Treatment Trialists' Collaboration, Sundström J, Arima H, Woodward M, et al. Blood pressure-lowering treatment based on cardiovascular risk: a meta-analysis of individual patient data. *Lancet* 2014 Aug 16;384(9943):591-8. DOI: [http://dx.doi.org/10.1016/S0140-6736\(14\)61212-5](http://dx.doi.org/10.1016/S0140-6736(14)61212-5).

15. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R; Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet* 2002 Dec 14;360(9349):1903-13. DOI: [http://dx.doi.org/10.1016/S0140-6736\(02\)11911-8](http://dx.doi.org/10.1016/S0140-6736(02)11911-8). Erratum in: *Lancet* 2003 Mar 22;361(9362):1060. DOI: [http://dx.doi.org/10.1016/S0140-6736\(03\)12816-4](http://dx.doi.org/10.1016/S0140-6736(03)12816-4).
16. Xu W, Goldberg SL, Shubina M, Turchin A. Optimal systolic blood pressure target time to intensification, and time to follow-up in treatment of hypertension: population based retrospective cohort study. *BMJ* 2015 Feb 5;350:h158. DOI: <http://dx.doi.org/10.1136/bmj.j148>.
17. Sim JJ, Shi J, Kovessy CP, Kalantar-Zadeh K, Jacobsen SJ. Impact of achieved blood pressures on mortality risk and end-stage renal disease among a large, diverse hypertension population. *J Am Coll Cardiol* 2014 Aug 12;64(6):588-97. DOI: <http://dx.doi.org/10.1016/j.jacc.2014.04.065>.
18. Kovessy CP, Bleyer AJ, Molnar MZ, et al. Blood pressure and mortality in US veterans with chronic kidney disease: a cohort study. *Ann Intern Med* 2013 Aug 20;159(4):233-42. DOI: <http://dx.doi.org/10.7326/0003-4819-159-4-201308200-00004>.
19. ACCORD Study Group, Cushman WC, Evans GW, Byington RP, et al. Effects of intensive blood-pressure control in type 2 diabetes mellitus. *N Engl J Med* 2010 Apr 29;362(17):1575-85. DOI: <http://dx.doi.org/10.1056/NEJMoa1001286>.
20. SPS3 Study Group, Benavente OR, Coffey CS, Conwit R, et al. Blood-pressure targets in patients with recent lacunar stroke: the SPS3 randomised trial. *Lancet* 2013 Aug 10;382(9891):507-15. DOI: [http://dx.doi.org/10.1016/S0140-6736\(13\)60852-1](http://dx.doi.org/10.1016/S0140-6736(13)60852-1).
21. Wright JT Jr, Bakris G, Greene T, et al; African American Study of Kidney Disease and Hypertension Study Group. Effect of blood pressure lowering and antihypertensive drug class on progression of hypertensive kidney disease: results from the AASK trial. *JAMA* 2002 Nov 20;288(19):2421-31. DOI: <http://dx.doi.org/10.1001/jama.288.19.2421>. Erratum in: *JAMA* 2006 Jun 21;295(23):2726. DOI: <http://dx.doi.org/10.1001/jama.295.23.2726-c>.
22. Klahr S, Levey AS, Beck GJ, et al. The effects of dietary protein restriction and blood-pressure control on the progression of chronic renal disease. Modification of Diet in Renal Disease Study Group. *N Engl J Med* 1994 Mar 31;330(13):877-84. DOI: <http://dx.doi.org/10.1056/NEJM199403313301301>.
23. Ruggenenti P, Perna A, Loriga G, et al; REIN-2 Study Group. Blood pressure control for renoprotection in patients with non-diabetic chronic renal disease (REIN-2): multicentre, randomised controlled trial. *Lancet* 2005 Mar 12-18;365(9463):939-46. DOI: [http://dx.doi.org/10.1016/S0140-6736\(05\)71082-5](http://dx.doi.org/10.1016/S0140-6736(05)71082-5).
24. Ford ES, Ajani UA, Croft JB, et al. Explaining the decrease in US deaths from coronary disease, 1980-2000. *N Engl J Med* 2007 Jun 7;356(23):2388-98. DOI: <http://dx.doi.org/10.1056/NEJMsa053935>.
25. Yeh RW, Sidney S, Chandra M, Sorel M, Selby JV, Go AS. Population trends in the incidence and outcomes of acute myocardial infarction. *N Engl J Med* 2010 Jun 10;362(23):2155-65. DOI: <http://dx.doi.org/10.1056/NEJMoa0908610>.
26. Jaffe MG, Lee GA, Young JD, Sidney S, Go AS. Improved blood pressure control associated with a large-scale hypertension program. *JAMA* 2013 Aug 21;310(7):699-705. DOI: <http://dx.doi.org/10.1001/jama.2013.108769>.
27. Sim JJ, Handler J, Jacobsen SJ, Kanter MH. Systemic implementation strategies to improve hypertension: the Kaiser Permanente Southern California experience. *Can J Cardiol* 2014 May;30(5):544-52. DOI: <http://dx.doi.org/10.1016/j.cjca.2014.01.003>.
28. Shaw KM, Handler J, Walli HK, Kanter MH. Improving blood pressure control in a large multiethnic California population through changes in health care delivery, 2004-2012. *Prev Chronic Dis* 2014 Oct 30;11:E191. DOI: <http://dx.doi.org/10.5888/pcd11.140173>.
29. Ayanian JZ, Landon BE, Newhouse JP, Zaslavsky AM. Racial and ethnic disparities among enrollees in Medicare Advantage plans. *N Engl J Med* 2014 Dec 11;371(24):2288-97. DOI: <http://dx.doi.org/10.1056/NEJMsa1407273>.
30. Fung V, Huang J, Brand R, Newhouse JP, Hsu J. Hypertension treatment in a medicare population: adherence and systolic blood pressure control. *Clin Ther* 2007 May;29(5):972-84. DOI: <http://dx.doi.org/10.1016/j.clinthera.2007.05.010>.
31. Tinetti ME. Clinical practice. Preventing falls in elderly persons. *N Engl J Med* 2003 Jan 2;348(1):42-9. DOI: <http://dx.doi.org/10.1056/NEJMcp020719>.
32. Tinetti ME, Han L, Lee DS, et al. Antihypertensive medications and serious fall injuries in a nationally representative sample of older adults. *JAMA Intern Med* 2014 Apr;174(4):588-95. DOI: <http://dx.doi.org/10.1001/jamainternmed.2013.14764>.
33. Filippone EJ, Foy A, Newman E. Goal-directed antihypertensive therapy: lower may not always be better. *Cleve Clin J Med* 2011 Feb;78(2):123-33. DOI: <http://dx.doi.org/10.3949/ccjm.78a.10101>.
34. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. *BMJ* 1998 Sep 12;317(7160):703-13. DOI: <http://dx.doi.org/10.1136/bmj.317.7160.703>. Erratum in: *BMJ* 1999 Jan 2;318(7175):29. DOI: <http://dx.doi.org/10.1136/bmj.318.7175.29p>.
35. Mancia G, Fagard R, Narkiewicz K, et al; Task Force Members. 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). *J Hypertens* 2013 Jul;31(7):1281-357. DOI: <http://dx.doi.org/10.1097/01.hjh.0000431740.32696.cc>.
36. Mancia G, Fagard R. New blood pressure control goals, more rational but facilitating therapeutic inertia?: reply. *J Hypertens* 2013 Dec;31(12):2462-5. DOI: <http://dx.doi.org/10.1097/HJH.0000000000000005>.
37. Beckett NS, Peters R, Fletcher AE, et al; HYVET Study Group. Treatment of hypertension in patients 80 years of age or older. *N Engl J Med* 2008 May 1;358(18):1887-98. DOI: <http://dx.doi.org/10.1056/NEJMoa0801369>.
38. VA/DoD clinical practice guidelines: management of hypertension (HTN) in primary care (2014) [Internet]. Washington, DC: US Department of Veterans Affairs; 2014 [cited 2015 Apr 6]. Available from: [www.healthquality.va.gov/guidelines/CD/htn](http://www.healthquality.va.gov/guidelines/CD/htn).
39. Choma NN, Huang RL, Dittus RS, Burnham KE, Roumie CL. Quality improvement initiatives improve hypertension care among veterans. *Circ Cardiovasc Qual Outcomes* 2009 Jul;2(4):392-8. DOI: <http://dx.doi.org/10.1161/CIRCOUTCOMES.109.862714>.

## Normal

If we possessed instruments delicate enough we might be able to determine what the normal arterial pressure of a given individual was, and to note any variation from it ... . We are ... driven to depend upon the most treacherous of all methods, the impressions conveyed to our minds through the sensory nerves of the fingers ... . By constant practice and study, each physician makes for himself a standard of atrial pressure which he recognizes as normal.

— *The Study of the Pulse*, Sir James Mackenzie, MD, 1853-1925,  
Scottish cardiologist and pioneer in the study of cardiac arrhythmias

# Kaiser Permanente National Guideline Adult Hypertension

CLINICIAN GUIDE  
AUGUST 2014



## TOOL 1. Key Points

- ▶ Hypertension is an important and modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD).
- ▶ For all adults, encourage a heart-healthy lifestyle to reduce the risk of ASCVD. This includes regular physical activity, weight reduction and maintenance, smoking cessation, and controlling blood pressure, cholesterol, and diabetes.
- ▶ For adults aged 60 and older without diabetes or chronic kidney disease (CKD), treat to a goal systolic blood pressure (SBP) <150 mmHg and goal diastolic blood pressure (DBP) <90 mmHg.
- ▶ For all adults aged under 60, and those aged 60 and older with diabetes or chronic kidney disease (CKD), treat to a goal SBP <140 mmHg and goal DBP <90 mmHg.

## Introduction

This Clinician Guide is based on the 2014 KP National Hypertension Guideline. It was developed to assist primary care physicians and other health care professionals in the outpatient treatment of hypertension in nonpregnant adults aged 18 and older. The drug treatment algorithm excludes patients with known stage 4-5 chronic kidney disease, coronary artery disease, and heart failure. The KP National Hypertension Guideline has adopted the new recommendations from the 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) with minor modifications. It is not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners.

## Definitions

The KP National Hypertension Guideline Team uses the JNC 7 classification of hypertension, which is based on the mean of two or more properly measured seated BP readings on each of two or more office visits.

## TOOL 2. Definition of Hypertension (JNC 7)

The JNC 7 Report defines blood pressure (BP) as:	Systolic Blood Pressure (SBP) mmHg	Diastolic Blood Pressure (DBP) mmHg
Normal	<120	<80
Prehypertension	120 - 139	80 - 89
Stage I Hypertension	140 - 159	90 - 99
Stage II Hypertension	≥160	≥100

## Screening for Hypertension

- ▶ Screen all adults aged 18 and older for hypertension.
- ▶ Screen adults with normal blood pressure (<120/<80) every two years.
- ▶ Screen adults with pre-hypertension or cardiovascular risk factors annually.

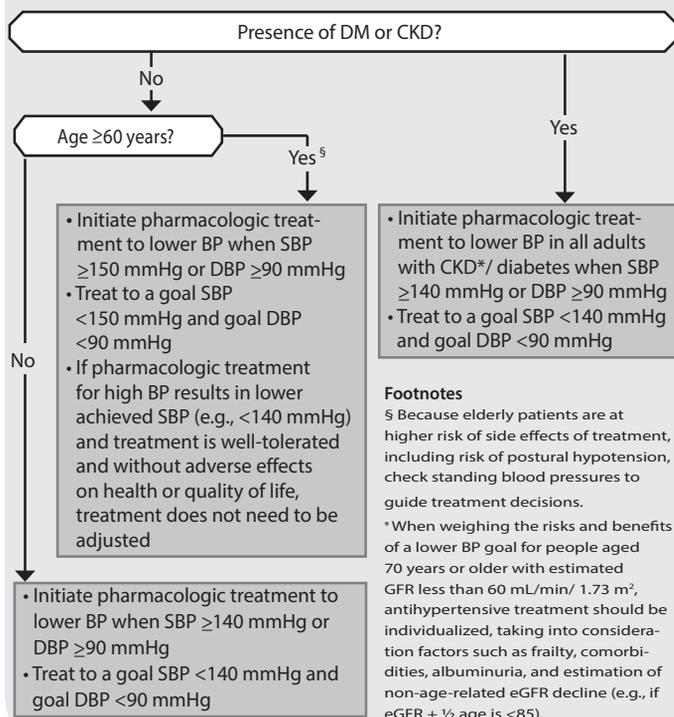
## Treatment Initiation and BP Targets

In addition to lifestyle interventions, the following are recommendations for the general population without diabetes or chronic kidney disease (CKD):

## TOOL 3. Treatment Initiation

### Lifestyle modifications:

- Consume a diet that is moderately low-sodium, low-fat with a high intake of fruits and vegetables (DASH diet)
- Weight reduction - for patients with a BMI ≥25 kg/m<sup>2</sup>
- Limit alcohol consumption
- Exercise - at a moderate pace to achieve 150 min/week (i.e., 30 min/5 days/week)
- Stop smoking or use of tobacco products
- Assist patients to achieve medication and lifestyle adherence by means of a vigorous step-care approach to therapy and an organized system of regular medical follow-up and review
- Prescribe once-daily medication and combination therapy, whenever possible
- Address depression/anxiety issues in order to maximize patient adherence
- Use patient education in conjunction with other strategies, particularly in the context of team care utilizing nurses and pharmacists
- Educate patients about their goal blood pressure



**GENERAL POPULATION**

- ▶ **Aged ≥60 years without diabetes or chronic kidney disease (CKD):**
  - Initiate pharmacologic treatment to lower blood pressure (BP) when systolic blood pressure (SBP) ≥150 mmHg or diastolic blood pressure (DBP) ≥90 mmHg.
  - Treat to a goal SBP <150 mmHg and goal DBP <90 mmHg.
  - If pharmacologic treatment for high BP results in lower achieved SBP (e.g., <140 mmHg) and treatment is well-tolerated and without adverse effects on health or quality of life, treatment does not need to be adjusted.
- ▶ **Aged <60 years and those aged > 60 with diabetes or chronic kidney disease (CKD):**
  - Initiate pharmacologic treatment to lower BP when SBP ≥140 or DBP ≥90 mmHg.
  - Treat to a goal SBP <140 mmHg and goal DBP <90 mmHg.

**CHRONIC KIDNEY DISEASE (CKD)**

- ▶ *NOTE: When weighing the risks and benefits of a lower BP goal for people aged 70 years or older with estimated GFR less than 60 mL/min/ 1.73 m<sup>2</sup>, antihypertensive treatment should be individualized, taking into consideration factors such as frailty, comorbidities, albuminuria, and estimation of non-age-related eGFR decline (e.g., if eGFR + ½ age is <85).*

**TOOL 4. eGFR Calculator**

- ▶  $eGFR (mL/min/1.73m^2) = 186 \times SCr^{-1.154} \times age^{-0.203}$  (in men)  
(in women multiply with 0.74; in Afro-American multiply with 1.21)

**RISK OF POSTURAL HYPOTENSION IN THE ELDERLY**

- ▶ Because elderly patients are at higher risk of side effects of treatment, including risk of postural hypotension, check standing blood pressures to guide treatment decisions.

**First-Line Drug Treatment for Hypertension\***

- ▶ In the general nonblack population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic, calcium channel blocker (CCB), angiotensin-converting enzyme inhibitor (ACEI), or angiotensin receptor blocker (ARB).
- ▶ In the general black population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic or CCB.
- ▶ In the population aged ≥18 years with CKD, initial (or add-on) antihypertensive treatment includes an ACEI or ARB to improve kidney outcomes. This applies to all CKD patients with hypertension, regardless of race or diabetes status.
- ▶ Medication up-titrations are recommended at intervals of 2-4 weeks (for most patients) until control is achieved. Consider follow-up labs when up-titrating or adding lisinopril, lisinopril/HCTZ, chlorthalidone, HCTZ, or spironolactone.

**\*TOOL 5. Management of Adult Hypertension (see next page)**

**INITIAL COMBINATION TREATMENT OF HYPERTENSION**

- ▶ The main objective of hypertension treatment is to attain and maintain goal BP.
- ▶ If goal BP is not reached within 4 weeks of treatment, increase the dose of the initial drug or add a second drug from one of the classes listed for first-line treatment (thiazide-type diuretic, CCB, ACEI, or ARB).

- ▶ **Continue to assess BP and adjust the treatment regimen until goal BP is reached.** If goal BP cannot be reached with 2 drugs, add and titrate a third drug from the list provided. Do not use an ACEI and ARB together in the same patient.
- ▶ **If goal BP cannot be reached using only the drugs listed for first-line treatment due to a contraindication or need to use more than 3 drugs to reach goal BP, use antihypertensive drugs from other classes.**
- ▶ Consider referral to a hypertension specialist for patients in whom goal BP cannot be attained using the above strategy or for the management of complicated patients for whom additional clinical consultation is needed.

**STEP-CARE THERAPY**

Because most people with hypertension will need more than one drug to control their hypertension effectively:

- ▶ **Initial single-pill combination therapy with lisinopril-hydrochlorothiazide is preferred.**
- ▶ **For three drugs:** If blood pressure is not controlled on a thiazide-type diuretic + ACEI, then use a thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker.
- ▶ **For four drugs:** If blood pressure is not controlled on a thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker, then use thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker plus spironolactone or beta-blocker.

**Lifestyle Modifications**

- ▶ Supplement treatment of uncomplicated hypertension with lifestyle modifications:
  - **Consume a diet that is moderately low-sodium, low-fat with a high intake of fruits and vegetables** (DASH diet), Sodium restriction (≤2.4 gm sodium daily)
  - **Weight reduction** for patients with a BMI ≥25 kg/m<sup>2</sup>

**TOOL 6. BMI Calculator**

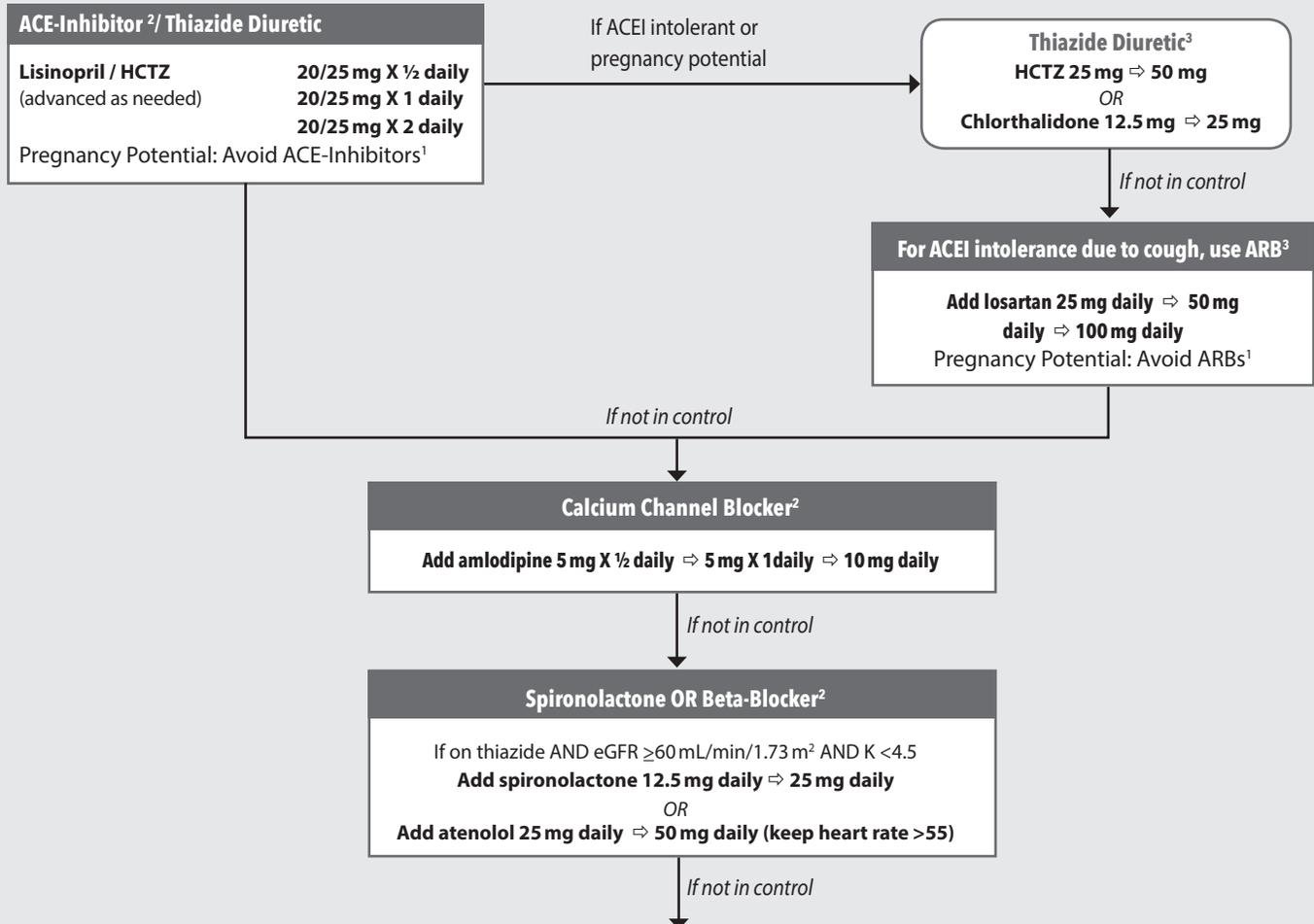
$$BMI = \frac{\text{weight (kg)}}{\text{height squared (m}^2\text{)}} \quad BMI = \frac{\text{weight (pounds)} \times 703}{\text{height squared (inches}^2\text{)}}$$

- **Limit alcohol consumption** - no more than one alcoholic drink (for women) or two alcoholic drinks (for men) daily
- **Exercise** - at a moderate pace to achieve 150 min/week (i.e., 30 min/5 days/week)
- **Stop smoking or use of tobacco products**
- ▶ Encourage adherence to medications and lifestyle modifications:
  - **Assist patients to achieve medication and lifestyle adherence** by means of a vigorous step-care approach to therapy and an organized system of regular medical follow-up and review.
  - **Prescribe once-daily medication and combination therapy**, whenever possible.
  - **Address depression and anxiety issues** in order to maximize patient adherence. See KP National Depression Guideline at: <http://cl.kp.org/pkc/national/cmi/programs/depression/guideline/index.html>
  - **Use patient education in conjunction with other strategies**, particularly in the context of team care utilizing nurses and pharmacists.
  - **Educate patients about their goal blood pressure**, because patients who are knowledgeable about their goal BP are more likely to achieve it.

**TOOL 5. Management of Adult Hypertension**

**BLOOD PRESSURE (BP) GOALS**

- ≤139/89 mmHg: Aged 18-59, and aged 60 and over with Chronic Kidney Disease (CKD)<sup>1</sup> or Diabetes
- ≤149/89 mmHg: Aged 60 and over in the absence of Chronic Kidney Disease (CKD)<sup>1</sup> or Diabetes



- Consider medication non-adherence.
- Consider interfering agents (e.g., NSAIDs, excess alcohol).
- Consider white coat effect. Consider BP checks by medical assistant (e.g., two checks with 2 readings each, 1 week apart).
- Consider discontinuing lisinopril/HCTZ and changing to chlorthalidone 25 mg plus lisinopril 40 mg daily. Consider additional agents (hydralazine, terazosin, minoxidil).
- Consider stopping atenolol and adding diltiazem to amlodipine, keeping heart rate >55.
- Avoid using clonidine, verapamil, or diltiazem together with a beta-blocker. These heart rate-slowng drug combinations may cause symptomatic bradycardia over time.
- Consider secondary etiologies.
- Consider consultation with a hypertension specialist.

1. CKD is defined as albuminuria (>30 mg of albumin/g of creatinine) at any age and any level of GFR, or an estimated GFR or measured GFR <60 mL/min/1.73 m<sup>2</sup> in people aged <70 years. When weighing the risks and benefits of a lower BP goal for people aged 70 years or older with estimated GFR < 60 mL/min/1.73 m<sup>2</sup>, antihypertensive treatment should be individualized, taking into consideration factors such as frailty, comorbidities, albuminuria, and estimation of non-age-related eGFR decline (e.g., if eGFR + ½ age is <85).

2. ACE-inhibitors and ARBs are contraindicated in pregnancy and not recommended in most women of childbearing age. calcium channel blockers and spironolactone (Pregnancy Risk Category C), and beta-blockers (Pregnancy Risk Category D) should only be used in pregnancy when clearly needed and the benefits outweigh the potential hazard to the fetus. In the general black population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic or CCB.

3. For patients with CKD, age 18-75 and intolerant to ACEI with cough and lacking pregnancy potential, losartan should be started prior to adding thiazide.

## Special Considerations

### HYPERTENSION TREATMENT FOR WOMEN OF CHILDBEARING POTENTIAL

- ▶ Because half of all pregnancies are unplanned, unless there is a compelling indication, do not prescribe medications contraindicated in pregnancy, such as ACEIs/ARBs, to women of childbearing potential.
- ▶ For women of childbearing potential taking medications contraindicated in pregnancy, such as ACEIs/ARBs:
  - Discuss the potential risks to the fetus should they become pregnant.
  - Discuss practicing contraceptive measures with extremely low failure rates (sterilization, implant, or IUD).
- ▶ Advise women using ACEIs/ARBs to stop these medications and contact their OB/GYN provider immediately if they become pregnant.
- ▶ Advise women using ACEIs/ARBs for heart failure or cardiomyopathy and become pregnant to contact their obstetrician immediately. Their obstetrician, in consultation with cardiology, will substitute a suitable alternative to avoid decompensation.

### LIPID THERAPY IN PATIENTS TAKING HYPERTENSION MEDICATIONS

- ▶ Evaluate patients with hypertension for dyslipidemia and initiate or continue statin treatment according to their total cardiovascular risk profile.

- ▶ Refer to the KP National Cardiovascular Risk and Dyslipidemia Clinician Guide at: <http://cl.kp.org/pkc/national/cmi/programs/dyslipidemia/guideline/index.html>
- ▶ Determine the need to initiate or continue lipid-lowering therapy based on ASCVD risk assessment using the AHA/ACC Pooled Cohort Equations: <http://my.americanheart.org/cvriskcalculator> and <http://tools.cardiosource.org/ASCVD-Risk-Estimator/>

### ASPIRIN THERAPY IN PATIENTS TAKING HYPERTENSION MEDICATIONS

- ▶ Evaluate patients with hypertension for aspirin use and initiate or continue statin treatment according to their total cardiovascular risk profile and risk of adverse events
- ▶ Refer to the KP National Aspirin Clinician Guide at: [http://cl.kp.org/national/cmi/programs/cvd\\_risk\\_reduction/guideline/index.html](http://cl.kp.org/national/cmi/programs/cvd_risk_reduction/guideline/index.html)

### RECOMMENDATIONS FOR PATIENTS WITH ACEI INTOLERANCE DUE TO COUGH

- ▶ HCTZ 25 mg, then 50 mg to achieve BP goal
- ▶ Add losartan 25 mg, then 50 mg, then 100 mg to achieve BP goal
- ▶ Add amlodipine 2.5 mg, then 5 mg, then 10 mg to achieve BP goal

#### TOOL 7. Dosage Range for Selected Antihypertensive Medications\*

SELECTED ANTIHYPERTENSIVE MEDICATION	USUAL DOSAGE RANGE	
Thiazide-type Diuretics	Chlorthalidone (Hygroton)	12.5 - 25 mg daily
	Hydrochlorothiazide (HCTZ) (Esidrix)	25 - 50 mg daily
Thiazide-type Diuretic Single Pill Combinations	HCTZ /lisinopril (Prinzide)	10/12.5 mg - 20/25 mg BID
	Spirolactone/HCTZ (Aldactazide)	25/25 mg daily
ACE Inhibitors (ACEI)	Lisinopril (Zestril, Prinivil)	10 - 40 mg daily
	Captopril (Capoten)	12.5 - 50 mg BID
Long-Acting Dihydropyridine Calcium Channel Blockers (CCB)	Amlodipine (Norvasc)	2.5 - 10 mg daily
	Felodipine ER (Plendil)	2.5 - 20 mg daily
	Nifedipine ER (Procardia XL)	30 - 90 mg daily
Angiotensin II Receptor Blockers (ARB)	Losartan (Cozaar)	25 - 100 mg daily
Aldosterone Receptor Blocker	Spirolactone (Aldactone)	12.5 - 25 mg daily
Beta-Blockers (BB)	Atenolol (Tenormin)	25 - 100 mg total, daily or BID
	Bisoprolol (Zebeta)	5 - 10 mg daily
	Carvedilol (Coreg)	3.125 - 37.5 mg BID
	Metoprolol (Lopressor)	25 - 100 mg BID
	Metoprolol ER (Toprol XL)	25 - 200 mg daily

\*Availability of medications may vary depending on regional formularies.

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#### DISCLAIMER

Kaiser Permanente Clinical Practice Guidelines, Clinician Guides, and Clinical Tools/Resources have been developed to assist clinicians by providing an analytical framework for the evaluation and treatment of selected common problems encountered in patients. They are not intended to establish a protocol for all patients with a particular condition. While the guidelines provide one approach to evaluating a problem, clinical conditions may vary significantly from individual to individual. Therefore, the clinician must exercise independent judgment and make decisions based upon the situation presented. While great care has been taken to assure the accuracy of the information presented, the reader is advised that KP cannot be responsible for continued currency of the information, for any errors or omissions in this guideline, or for any consequences arising from its use. These recommendations are not used to make utilization management determinations regarding the medical necessity of a member's care.