

Impact of 2017 ACC/AHA guidelines on prevalence of hypertension and eligibility for antihypertensive treatment in United States and China: nationally representative cross sectional study

Rohan Khera, ¹ Yuan Lu, ² Jiapeng Lu, ³ Anshul Saxena, ⁴ Khurram Nasir, ^{2,5} Lixin Jiang, ⁶ Harlan M Krumholz^{2,5,7}

For numbered affiliations see end of article.

Correspondence to:

H M Krumholz harlan.krumholz@yale.edu (or @hmkyale on Twitter)

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ABSTRACT

OBIECTIVE

To examine the effect of the 2017 American College of Cardiology (ACC)/American Heart Association (AHA) hypertension guidelines on the prevalence of hypertension and eligibility for initiation and intensification of treatment in nationally representative populations from the United States and China.

DESIGN

Observational assessment of nationally representative data.

SETTING

US National Health and Nutrition Examination Survey (NHANES) for the most recent two cycles (2013-14, 2015-16) and China Health and Retirement Longitudinal Study (CHARLS) (2011-12).

PARTICIPANTS

All 45-75 year old adults who would have a diagnosis of hypertension and be candidates for treatment on the basis of the ACC/AHA guidelines, compared with current guidelines.

MAIN OUTCOME MEASURES

Diagnosis of hypertension and candidacy for initiation and intensification of antihypertensive treatment.

RESULTS

Adoption of the 2017 ACC/AHA hypertension guidelines in the US would label 70.1 (95% confidence interval 64.9 to 75.3) million people in

WHAT IS ALREADY KNOWN ON THIS TOPIC

The 2017 American College of Cardiology (ACC)/American Heart Association (AHA) guideline recommendations for hypertension decreased the threshold blood pressure used to define hypertension

They also lowered the target blood pressures for antihypertensive treatment

WHAT THIS STUDY ADDS

Adopting the new 2017 ACC/AHA hypertension guidelines would be associated with a substantial increase in the prevalence of hypertension in both the US and China

This would be accompanied by a marked increase in the recommendation to start and intensify treatment in several million patients

The number of people labeled as having hypertension in the US and China would increase by 26.8% and 45.1%, respectively

In the US and China, respectively, 7.5 million and 55.3 million people would be newly recommended for treatment, and 13.9 million and 30 million newly recommended for intensification

the 45-75 year age group as having hypertension, representing 63% (60.6% to 65.4%) of the population in this age group. Their adoption in China would lead to labeling of 266.9 (252.9 to 280.8) million people or 55% (53.4% to 56.7%) of the same age group as having hypertension. This would represent an increase in prevalence of 26.8% (23.2%) to 30.9%) in the US and 45.1% (41.3% to 48.9%) in China. Furthermore, on the basis of treatment patterns and current guidelines, 8.1 (6.5 to 9.7) million Americans with hypertension are untreated, which would be expected to increase to 15.6 (13.6) to 17.7) million after the implementation of the ACC/ AHA guidelines. In China, on the basis of current treatment patterns, 74.5 (64.1 to 84.8) million patients with hypertension are untreated, estimated to increase to 129.8 (118.7 to 140.9 million. In addition, the ACC/AHA guidelines would label 8.7 (6.0 to 11.5) million adults in the US and 51 (40.3 to 61.6) million in China as having hypertension that would not require antihypertensive treatment, compared with 1.5 (1.2 to 2.1) million and 23.4 (12.1 to 35.1) million with the current guidelines. Finally, even among people receiving treatment, the proportion that are candidates for intensification of treatment is estimated to increase by 13.9 (12.2 to 15.6) million (from 24.0% to 54.4% of treated patients) in the US, and 30 (24.3 to 35.7) million (41.4% to 76.2% of treated patients) in China, if the ACC/AHA treatment targets are adopted.

CONCLUSIONS

If adopted, the 2017 ACC/AHA hypertension guidelines will markedly increase the number of people labeled as having hypertension and treated with drugs in both the US and China, leading to more than half of those aged 45-75 years in both countries being considered hypertensive.

Introduction

The American College of Cardiology (ACC) and the American Heart Association (AHA) recently released guideline recommendations for treatment strategies for hypertension with lower blood pressure values used to define elevated blood pressure, and lower treatment thresholds, ¹ than those recommended in current guidelines. ² These new guidelines define hypertension as a systolic blood pressure of 130 mm Hg or greater or a diastolic blood pressure of 80 mm Hg or greater, ¹ in contrast to a systolic blood pressure of 140 mm Hg or greater or a diastolic blood pressure of 90 mm Hg or

greater that was used to define hypertension in all previous guidelines.

Furthermore, treatment recommendations have been extensively revised. The ACC/AHA guidelines recommend treatment of only a subset of patients with a diagnosis of hypertension. This includes all those with a systolic blood pressure of 140 mm Hg or greater or a diastolic blood pressure of 90 mm Hg or greater. Treatment is recommended for additional patients with lower blood pressures. Among people with a systolic blood pressure of 130-139 mm Hg or a diastolic blood pressure of 80-89 mm Hg, treatment is recommended only for those who meet any of the following criteria: aged 65 years or older, preexisting atherosclerotic cardiovascular disease or a 10 year predicated risk of developing it of 10% or greater, chronic kidney disease, or diabetes mellitus. Furthermore, a target systolic blood pressure below 130 mm Hg and a target diastolic blood pressure below 80 mm Hg is recommended for all patients, regardless of their baseline blood pressures. These recommendations contrast with currently suggested systolic blood pressure targets of less than 140 mm Hg and diastolic targets of less than 90 mm Hg for most patients, other than targets of less than 150/90 mm Hg for those aged 60 years or over without concomitant diabetes or chronic kidney disease.²

The recommendations in these new guidelines received a mixed response from several clinical societies.^{3 4} They received criticism for labeling people at low risk as having hypertension, many of whom do not have any clear evidence for benefit from such intensive treatment.⁵⁻⁷ while putting patients at risk for psychological morbidity from the disease label, 8 as well as inadvertent drug associated adverse events.9 Furthermore, the choice of a predicted 10 year risk of atherosclerotic cardiovascular disease of 10% or higher to define the threshold for treatment and the use of the pooled cohort equations to quantify this risk-neither of which has been tested in clinical studies-have been challenged.^{3 10} Health policy makers would need to better understand the population impact of these changes on the identification and treatment of people with hypertension before instituting changes to their health programs based on these guidelines. 11

The population impact of changes in guideline recommendations in the US has been evaluated, both previously and for the ACC/AHA guidelines. 12-15 understanding However. an of how recommendations translate to non-US populations, in which they are often implemented, could also provide valuable insight into their overall impact. Furthermore, as several major clinical studies rely on non-US populations, such international assessments of US guidelines are essential to appreciate their effect in other countries. China, in particular, has a high prevalence of hypertension and the world's largest population.¹⁶ Recent studies suggest that, even with current guidelines, a large proportion of adults in China are classified as hypertensive and few people achieve blood pressure targets. 16-18 Therefore, it is

important to understand the impact of the adoption of these standards in China.

Using nationally representative data from the United States and China, two diverse health systems, we examined the changes in prevalence of hypertension and eligibility for antihypertensive therapy and treatment intensification, on the basis of current guidelines and the revised 2017 ACC/AHA guidelines.

Methods

Data sources and study population

We used contemporary data from large, nationally representative datasets from the US and China, which have been designed to assess the health status of people living in the community. For the US, we used the National Health and Nutrition Examination Survey (NHANES) for the most recent two cycles-2013-14 and 2015-16; for China, we used the baseline survey of the China Health and Retirement Longitudinal Study (CHARLS) conducted in 2011-12. 19 20 The structure of these datasets and their use to identify hypertensive adults have been described previously. Briefly, NHANES is a nationally representative database comprised of cross sectional national surveys with information on demographic characteristics, medical history, prescription drug use, and laboratory testing on a set of individuals. 21 The data in NHANES can be weighted to obtain nationally representative estimates. CHARLS is a longitudinal study of 17 500 people aged over 45 years from 150 counties/districts and 450 villages in China with a detailed baseline clinical evaluation in 2011-12 when data on demographic characteristics, medical history, prescription drug use, and laboratory testing were collected. 19 20 Similarly to NHANES, the data in CHARLS are nationally representative and can be weighted to obtain national estimates for China.

In both these datasets, we identified all adults aged 45 to 75 years with at least two blood pressure measurements and information on prescription drug use. This information was available for all participants.

Study variables

From each dataset, we obtained information on all blood pressure measurements as well as variables necessary to classify patients into risk groups for antihypertensive treatment. This included information on demographic characteristics (age, sex, and ethnicity) and clinical history (known atherosclerotic cardiovascular disease, defined as history of myocardial infarction, stroke, angina, or reported coronary heart disease; smoking; diabetes, defined as a hemoglobin A_{1c} >6.5% or self reported history of diabetes; and use of antihypertensive treatment), as well as laboratory values for serum creatinine, total cholesterol, and high density lipoprotein cholesterol.

Statistical analysis

Firstly, we calculated the average systolic and diastolic blood pressures based on all available readings for each patient. Secondly, we assessed the prevalence of hypertension, defined as the number of people who would have a diagnosis of hypertension on the basis of current guidelines for both study populations. We use the 2014 evidence based guidelines for the management of high blood pressure in adults developed by the panel members appointed to the eighth Joint National Committee (INC-8). We used INC-8 as the current standard for both the US and China to allow for a comparative assessment of the impact of the new guidelines in both countries. The most recent Chinese hypertension guidelines from 2010 are substantively similar to the recommendations from JNC-8, ^{22 23} so the population assessments in this study likely capture current clinical practice in China. These guidelines defined hypertension as an average systolic blood pressure of 140 mm Hg or higher, and/ or a diastolic blood pressure of 90 mm Hg or higher, and/or treatment with an antihypertensive agent. We then identified people with hypertension on the basis of the 2017 ACC/AHA guidelines. This included all adults who met a definition based on the previous INC-8 guidelines, but additionally included all adults with a systolic blood pressure of 130-139 mm Hg or a diastolic blood pressure of 80-89 mm Hg.

Next, we assessed the adults who qualified for treatment with one or more antihypertensive agents on the basis of the current guidelines and the 2017 ACC/AHA guidelines but were not receiving treatment ("non-treatment"). This included all patients with a systolic blood pressure of 140 mm Hg or higher or a diastolic blood pressure of 90 mm Hg or higher in both guidelines. In addition, in the ACA/AHA guidelines, those with a systolic blood pressure of 130-139 mm Hg or a diastolic blood pressure of 80-89 mm Hg were also candidates for treatment if they were in one or more high risk group: age 65 years or above, a history of atherosclerotic cardiovascular disease (defined as history of myocardial infarction, stroke, angina, or reported coronary heart disease), chronic kidney disease (based on an estimated glomerular filtration rate of <60 mL/kg/h calculated using serum creatinine and the Modification of Diet in Renal Disease study equation), diabetes (defined as hemoglobin A₁₀ >6.5% or self reported history of diabetes), or an expected 10 year risk of atherosclerotic cardiovascular disease of 10% or greater (defined using the pooled cohort equations).24 Finally, we assessed the number of patients who would be considered "under-treated", on the basis of being above the treatment targets defined in the older JNC-8 guidelines and the recent guidelines. In JNC-8, treatment thresholds for hypertension were set at below 150/90 mm Hg for adults aged 60 years or above without diabetes or chronic kidney disease and below 140/90 mm Hg for all others. In the ACC/ AHA guidelines, treatment targets were set at 130/80 mm Hg for all patients. We used survey analyses with patient level weights to obtain national estimates for both the US and China.

All statistical tests were two sided, and the level of significance was set at an α of 0.05. The study was reported in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology

(STROBE) recommendations, and the corresponding checklist is included in the online supplement.

Patient involvement

No patients were involved in the development of the research question or the outcome measures, or in developing plans for the design and implementation of the study. The data are de-identified and, therefore, cannot be shared with the study participants directly.

Results

Prevalence of hypertension: United States

In NHANES, a nationally representative dataset from the US, we found 2973 participants, representing 55.3 (95% confidence interval 51.1 to 59.5) million people nationally, or 49.7% (47.5% to 52.0%) of the population, who were labeled with the diagnosis of hypertension on the basis of the JNC-8 guidelines. An additional 685 people, representing 14.8 (12.9 to 16.7) million, or 13.3% (11.8% to 14.8%) of the population, would be classified as having hypertension with the use of blood pressure thresholds suggested in the 2017 ACC/AHA guidelines. Therefore, 70.1 (64.9 to 75.3) million adults aged between 45 and 75 years would be classified as having hypertension on the basis of the 2017 ACC/AHA guidelines, representing a 26.8% (23.2% to 30.9%) relative increase. The proportion of the US adult population aged between 45 and 75 years classified as hypertensive would increase from 49.7% (47.5% to 52.0%) based on the JNC-8 guidelines to 63.0% (60.6% to 65.4%) based on the 2017 ACC/AHA guidelines. The adoption of the new guidelines would be associated with a higher prevalence of hypertension across subgroups of sex and age (supplementary figure A). Compared with people labeled with a diagnosis of hypertension according to JNC-8 criteria, those newly labeled as hypertensive according to the 2017 ACC/ AHA guidelines were younger (mean age 60 v 56 years) and less frequently were of black ethnicity (14.1% ν 9.9%) or had diabetes (26.7% ν 9.6%), chronic kidney disease (11.3% ν 4.3%), or atherosclerotic cardiovascular disease (15.9% v 3.7%) (P<0.01 for all). They also had a lower 10 year predicted risk of developing atherosclerotic cardiovascular disease among those without pre-existing disease (P<0.01) (table 1).

Prevalence of hypertension: China

In CHARLS, a nationally representative dataset from China, 5133 people in the 45-75 year age group met the JNC-8 criteria for hypertension, representing 184.2 (171.6 to 196.8) million, or 38.0% (36.1% to 39.9%) of the population, labeled as having hypertension nationally. An additional 2588 people, representing 82.7 (76.1 to 89.3) million, or 17.0% (15.8% to 18.4%) of the population, nationally would be classified as hypertensive according to the 2017 ACC/AHA criteria. Therefore, 266.9 (252.9 to 280.8) million Chinese adults aged between 45 and 75 years would be classified as having hypertension on the

Table 1 | Characteristics of people with diagnosis of hypertension, candidates for treatment, and candidates recommended treatment intensification in US based on 2014 evidence based guidelines for management of high blood pressure in adults developed by eighth Joint National Committee (JNC-8) and 2017 ACC/AHA hypertension guidelines. Values are percentages (95% CI) unless stated otherwise

	Diagnosis of hypertension			Candidates for treatment			Candidates recommended treatment intensification		
Characteristics	JNC-8	ACC/AHA minus JNC-8	P value*	JNC-8	ACC/AHA minus JNC-8	P value*	JNC-8	ACC/AHA minus JNC-8	P value*
No of people with hypertension, million	55.3 (51.1 to 59.5)	14.8 (12.9 to 16.7)	-	8.1 (6.5 to 9.7)	7.5 (6.5 to 8.5)	<0.01	11.0 (9.8 to 12.2)	13.9 (12.2 to 15.6)	-
Demographics									
Mean (95% CI) age, years	60 (46 to 74)	56 (45 to 73)	<0.01	57 (45 to 73)	62 (47 to 75)	<0.01	60 (45 to 75)	61 (46 to 74)	0.12
Sex:			0.92			0.58			0.76
Men	48.6 (46.0 to 51.3)	49 (43.3 to 54.7)		56.8 (49.9 to 63.5)	59.8 (52.7 to 66.6)		49.3 (43.3 to 55.2)	47.8 (41.3 to 54.3)	
Women	51.3 (48.7 to 54.0)	51 (45.3 to 56.7)		43.2 (36.4 to 50.1)	40.2 (33.4 to 47.3)	_	50.7 (44.8 to 56.7)	52.2 (45.7 to 58.7)	_
Ethnicity:			<0.01			0.68			<0.01
Black	14.1 (10.7 to 18.2)	9.9 (7.4 to 12.9)		11.2 (6.9 to 17.1)	10.3 (7.5 to 13.7)	-	20.5 (15.5 to 26.3)	13.4 (9.8 to 17.9)	
Non-black	85.9 (81.8 to 89.3)	90.1 (87.1 to 92.6)		88.8 (82.9 to 93.1)	89.7 (86.3 to 92.5)	-	79.5 (73.7 to 84.5)	86.6 (82.1 to 90.2)	_
Comorbidities									
Diabetes	26.7 (24.2 to 29.2)	9.6 (6.5 to 13.6)	<0.01	16.2 (12.9 to 20)	18.7 (13.1 to 25.5)	0.39	35.5 (29.7 to 41.7)	24.4 (20.1 to 29.1)	<0.01
Smoking	67.1 (63.1 to 70.9)	70 (64.8 to 74.9)	0.35	67.2 (57.6 to 75.9)	70.5 (63 to 77.2)	0.47	72.3 (67.1 to 77.1)	67.7 (61.3 to 73.8)	0.15
Chronic kidney disease	11.3 (10.0 to 12.8)	4.3 (2.8 to 6.5)	<0.01	6.2 (3.5 to 10.2)	8.5 (5.3 to 12.7)	0.35	14.5 (11.1 to 18.5)	7.3 (5.4 to 9.6)	<0.01
ASCVD (MI, CHD, angina, stroke)	15.9 (14.4 to 17.6)	3.7 (2.2 to 5.8)	<0.01	6.2 (3.9 to 9.2)	8.6 (5.6 to 12.4)	0.09	14.6 (10.5 to 19.5)	15.9 (12.9 to 19.2)	0.61
Mean (95% Cl) 10 year ASCVD risk, %	16.5 (2.7 to 45.9)	9.4 (0.9 to 26.4)	<0.01	14.6 (1.9 to 41.5)	16.1 (3.0 to 33.8)	<0.01	24.7 (4.6 to 57.1)	18.2 (3.9 to 44.2)	<0.01
Mean (95% CI) laborator	y values								
Glomerular filtration rate, mL/min/1.73 m2	83.0 (38.6 to 114.4)	89.0 (56.7 to 114.4)	<0.01	88.9 (51.7 to 116.2)	82.9 (50.3 to 111.8)	<0.01	83.1 (34.1 to 115.5)	83.5 (50.0 to 112.9)	0.81
Total cholesterol, mg/dL	195 (121 to 291)	208 (137 to 289)	<0.01	209 (137 to 291)	210 (125 to 300)	0.86	200 (125 to 301)	194 (168 to 289)	0.03
HDL cholesterol, mg/dL	54 (28 to 99)	56 (28 to 95)	0.05	53.7 (28 to 100)	55.7 (27.8 to 97.9)	0.38	55.5 (26 to 98)	53 (29 to 88)	0.26
Treatment with antihypertensive agents, %	82.7 (80.1 to 85.1)	0	<0.01	0	0	-	100	100	-

ACC=American College of Cardiology; AHA=American Heart Association; ASCVD=atherosclerotic cardiovascular disease; CHD=congestive heart disease; HDL=high density lipoprotein;

Columns represent people meeting these criteria according to JNC-8, compared with those newly meeting these criteria under ACC/AHA guidelines (ACC/AHA minus JNC-8).

basis of the ACC/AHA criteria, representing a relative increase of 45.1% (41.3% to 48.9%). The proportion of the Chinese adult population between 45 and 75 years of age classified as having hypertension would increase from 38.0% (36.1% to 48.9%) based on the INC-8 guidelines to 55.0% (53.4% to 56.7%) based on the 2017 ACC/AHA guidelines. Similarly to the US, the adoption of the new guidelines would be associated with a higher prevalence of hypertension across subgroups of sex and age (supplementary figure A). Compared with people labeled with a diagnosis of hypertension on the basis of JNC-8 criteria in China, those newly labeled as hypertensive on the basis of the 2017 ACC/AHA guidelines were more frequently men (46.3% v 55.1%; P<0.01). Also similarly to the US, these people less frequently had diabetes, chronic kidney disease, and atherosclerotic cardiovascular disease and had a lower 10 year risk of developing atherosclerotic cardiovascular disease (table 2).

Eligibility for antihypertensive treatment: United States

In the US, of the 55.3 million people with hypertension according to INC-8 criteria, 82.7% (80.1% to 85.1%) were receiving one or more antihypertensive drugs, whereas 14.6% (12.7% to 16.3%), or 8.1 (6.5 to 9.7) million people, were eligible for treatment but not receiving it. Furthermore, 1.5 (1.2 to 2.1) million people would be classified as hypertensive and would qualify for lifestyle modifications alone according to INC-8. Of the 70.1 million classified as having hypertension according to the ACC/AHA guidelines, only 65.3% (62.6% to 67.9%) were receiving antihypertensive treatment, suggesting a recommendation to start treatment in 22.3% (20.9% to 23.5%) or 15.6 (13.6 to 17.7) million people with hypertension (an additional 7.5 (6.5 to 8.5) million people). Notably, under the 2017 ACC/AHA guidelines, the remaining 12.4% (8.6% to 16.5%) or 8.7 (6.0 to 11.5) million US adults in the 45-75 year age group would have hypertension but not

^{*}P value for comparison of characteristics in "JNC-8" column and those in "ACC/AHA minus JNC-8" column.

Table 2 | Characteristics of people with diagnosis of hypertension, candidates for treatment, and candidates recommended treatment intensification in China based on 2014 evidence based guidelines for management of high blood pressure in adults developed by eighth Joint National Committee (JNC-8) and 2017 ACC/AHA hypertension guidelines. Values are percentages (95% CI) unless stated otherwise

	Diagnosis of hypertension			Candidates for treatment			Candidates recommended treatment intensification		
Characteristics	JNC-8	ACC/AHA minus JNC-8	P value*	JNC-8	ACC/AHA minus JNC-8	P value*	JNC-8	ACC/AHA minus JNC-8	P value*
No of people with hypertension, million	184.2 (171.6 to 196.8)	82.7 (76.1 to 89.3)	-	74.5 (64.1 to 84.8)	55.3 (50.9 to 59.6)	<0.01	35.7 (32.7 to 38.8)	30.0 (24.3 to 35.7)	-
Demographics									
Mean (95% CI) age, years	59 (46 to 74)	57 (46 to 74)	<0.01	57 (45 to 74)	65 (48 to 75)	<0.01	59 (46 to 74)	61.5 (46 to 75)	0.06
Sex:			<0.01			<0.01			0.32
Men	46.3 (43.1 to 49.6)	55.1 (51.8 to 58.3)		46.4 (39.6 to 53.3)	57.8 (54.2 to 61.3)		47.1 (42.9 to 51.4)	41.9 (32.5 to 51.8)	
Women	53.7 (50.4 to 56.9)	44.9 (41.7 to 48.2)		53.6 (46.7 to 60.4)	42.2 (38.7 to 45.8)		52.9 (48.6 to 57.1)	58.1 (48.2 to 67.5)	
Comorbidities									
Diabetes	17.4 (14.4 to 20.7)	11.2 (7.9 to 15.2)	0.01	15 (8.9 to 23.1)	16.7 (12 to 22.3)	0.68	28.2 (24 to 32.8)	12.3 (9.4 to 15.7)	<0.01
Smoking	27.6 (24.9 to 30.5)	33.3 (29.8 to 36.9)	0.01	31.6 (25.8 to 37.8)	37 (33.4 to 40.7)	0.12	26.4 (22.4 to 30.6)	18.4 (14.2 to 23.1)	0.01
Chronic kidney disease	4.6 (3.7 to 5.6)	1.8 (0.9 to 3.2)	<0.01	3.8 (2.7 to 5.2)	2.8 (1.4 to 4.9)	0.34	8.2 (6 to 10.8)	3.7 (1.7 to 7)	0.02
ASCVD (MI, CHD, angina, stroke)	19.4 (17.4 to 21.5)	9 (7.5 to 10.7)	<0.01	9.4 (7.1 to 12.1)	18.3 (15.6 to 21.3)	<0.01	29 (25.3 to 33)	27.7 (21.6 to 34.6)	0.73
Mean (95% CI) 10 year ASCVD risk, %	14.4 (1.3 to 43.7)	8.5 (0.7 to 25.5)	<0.01	12.6 (1.2 to 42.1)	14.9 (2.2 to 30.0)	<0.01	19.1 (1.8 to 51.8)	13.6 (1.1 to 36.9)	<0.01
Mean (95% CI) laboratory	values								
Glomerular filtration rate, mL/min/1.73 m2	89.5 (51.3 to 112.2)	93.6 (61.9 to 116.2)	<0.01	91.8 (54.3 to 112.9)	87.5 (59.3 to 110.9)	<0.01	87.7 (49.2 to 111)	88.9 (52.8 to 114)	0.27
Total cholesterol, mg/dL	197 (131 to 281)	193 (129 to 282)	0.03	196 (133 to 278)	197 (128 to 288)	0.87	198 (134 to 281)	198 (126 to 300)	0.91
HDL cholesterol, mg/dL	48 (24 to 83)	50 (27 to 86)	<0.01	48.5(23 to 85)	49.3 (25 to 86)	0.44	46.5 (23.7 to 80.8)	45.9 (25.5 to 73.1)	0.56
Treatment with antihypertensive agents, %	46.8 (43.4 to 50.3)	0	<0.01	0	0	to	100	100	-

ACC=American College of Cardiology; AHA=American Heart Association; ASCVD=atherosclerotic cardiovascular disease; CHD=congestive heart disease; HDL=high density lipoprotein; Ml=myocardial infarction

Columns represent people meeting these criteria according to JNC-8, compared with those newly meeting these criteria under ACC/AHA guidelines (ACC/AHA minus JNC-8).

be candidates for antihypertensive treatment because they had a systolic blood pressure of 130-139 mm Hg and/or a diastolic blood pressure of 80-89 mm Hg and did not have any of the high risk conditions, such as age 65 years or over, known atherosclerotic cardiovascular disease, a 10 year predicted risk of atherosclerotic cardiovascular disease of 10% or more, chronic kidney disease, or diabetes (table 1). Moreover, of those receiving antihypertensive treatment, 24.0% (21.5% to 26.6%) were above the treatment targets for JNC-8 and 54.4% (50.7% to 58.1%) were above the treatment targets based on the ACC/AHA criteria. Therefore, an additional 13.9 (12.2 to 15.6) million people would be candidates for intensification of treatment (table 1). The rates of non-treatment and under-treatment of hypertension among subgroups of age and sex are shown in supplementary figures B and C.

Eligibility for antihypertensive treatment: China

In China, on the basis of JNC-8 blood pressure targets, 46.8% (43.4% to 50.3%) of the 184.2 (171.6 to 196.8) million people with hypertension were receiving one or more antihypertensive drugs. Among the 266.9 (252.9 to 280.8) million classified as having hypertension

according to the 2017 ACC/AHA guidelines, 32.3% (30.0% to 34.7%) were receiving antihypertensive treatment. The use of JNC-8 and 2017 ACC/AHA criteria to define people eligible for treatment would recommend that treatment be started in 74.5 (64.1 to 84.8) million and 129.8 (118.7 to 140.9) million patients (an additional 55.3 million), respectively. Those recommended for treatment on the basis of the new guidelines more frequently were women and had a history of atherosclerotic cardiovascular disease (table 2). Furthermore, 23.4 (12.1 to 35.1) million people according to JNC-8 and 51.0 (40.3 to 61.60) million people according to the ACC/AHA guidelines would be classified as having hypertension and would qualify for lifestyle modifications alone. This group includes people with a systolic blood pressure of 130-139 mm Hg and/or a diastolic blood pressure of 80-89 mm Hg, without any of the high risk conditions, such as age 65 years or over, known atherosclerotic cardiovascular disease, a 10 year predicted risk of atherosclerotic cardiovascular disease of at least 10%, chronic kidney disease, or diabetes.

Finally, of those receiving antihypertensive treatment in China in from 2011 to 2012, 41.4% (37.7% to

^{*}P value for comparison of characteristics in the "JNC-8" column and those in the "ACC/AHA minus JNC-8" column.

45.1%) were above the treatment targets for JNC-8 and 76.2% (73.3% to 79.0%) were above the treatment targets based on the ACC/AHA criteria. Therefore, an additional 30 (24.3 to 35.7) million people would be candidates for intensification of treatment, on the basis of the change in the guidelines. Table 2 shows the characteristics of people who were candidates for treatment intensification according to both guidelines. The rates of non-treatment and under-treatment of hypertension among subgroups of age and sex are shown in supplementary figures B and C.

Discussion

The adoption of the 2017 ACC/AHA guidelines for hypertension would dramatically increase the number of people with hypertension and those recommended for treatment. In the US, the new guidelines would classify 70.1 million people in the 45-75 year age group as having hypertension, representing 63% of the population in this age group. The adoption of these guidelines in China would lead to the classification of 267 million (55%) people in the same group as having hypertension. This would represent a relative increase of 26.8% in the US and 45.1% in China from the prevalence based on current recommendations. Furthermore, based on the observed treatment patterns and current guidelines, 8.1 million Americans with hypertension are untreated. However, this number is expected to increase to 15.6 million after the implementation of the 2017 ACC/AHA guidelines. In China, based on current treatment patterns, 74.5 million patients with hypertension are untreated. likely to increase to 129.8 million if the 2017 ACC/AHA guidelines are adopted. Finally, even among those treated with antihypertensive drugs, the proportion of undertreated patients-that is, those above target blood pressures despite receiving antihypertensive treatment-is likely to increase by 13.9 million (from 24.0% to 54.4% of the treated patients) in the US and 30 million (from 41.4% to 76.2% of patients on treatment) in China if the 2017 ACC/AHA treatment targets are adopted into clinical practice.

The lowering of the treatment target for high risk subgroups in the 2017 ACC/AHA guideline is guided by evidence for a reduced rate of major adverse cardiovascular events. ²⁵⁻²⁷ However, even with the more conservative guidelines, the appropriate management of patients with antihypertensive treatment has posed major implementation challenges, with high rates of non-treatment and under-treatment in both the US and China. 16 21 28 The ACC/AHA guidelines would require expansion of the public health infrastructure necessary to manage the substantial increase in the public health burden of hypertension in the US and China. Health policy interventions focused on appropriately treating people in whom it is recommended would need to identify 7.5 million additional untreated Americans in the 45-75 year age group, beyond the 8.1 million who are not receiving treatment based on current recommendations. However, a similar effort in China would require identification of an additional

55.3 million untreated patients with hypertension, beyond the 74.5 million currently with an unmet need for antihypertensive treatment. The rates of non-treatment, in combination with rates of undertreatment, suggest that health system interventions would need to provide treatment in nearly all patients with hypertension.

Health policy implications

The public health impact of these guidelines should be interpreted in light of the expected effects on outcomes. The guidelines would label 8.7 million adults in the US and 51 million adults in China, who are currently recommended only lifestyle modification. as having hypertension. Therefore, millions are at risk of psychological morbidity due to the label of a chronic disease.8 as well as for adverse events due to potential inappropriate use of drug therapy. Moreover, the expansion of treatment to people at lower risk may dilute the focus of health programs on identification and treatment of high risk groups, which are likely to derive the most benefit. This is particularly relevant as the number needed to prevent one major event for patients at age 40 is 13-fold higher than among those aged 70 (number needed to treat each year to prevent one event 333 v 26 for coronary heart disease and 250 v 18 for stroke). ²⁹⁻³¹ Moreover, in people with low cardiovascular risk and mild hypertension, the risk:benefit ratio for treatment may be unfavorable.⁶ ⁷ These factors are vital for public health programs challenged by resources to identify and treat all people at high risk, who are likely to derive the most benefit from treatment. Expanding the pool of patients who merit treatment to include those at low risk could potentially render public health programs less efficient and viable.9

Relation to published evidence

The recommendations are not firmly rooted in evidence. The improvement in outcomes among adults without diabetes who were at high risk for cardiovascular disease, which was observed in SPRINT and prompted the changes in recommendations in the ACC/AHA guidelines, 27 has not been observed among people at low to intermediate risk or among those with diabetes. 5 6 27 32 33 In addition, risk stratification based on the pooled cohort equations for treatment decisions in hypertension, and a 10 year threshold of 10%, were not assessed in SPRINT, which used a 10 year risk threshold of 15% using the Framingham risk score to define high risk. The use of these equations and risk thresholds translate to treatment eligibility for a vast majority of adults in their 70s who have a blood pressure over 130/80 mm Hg,³ without any consideration for lack of evidence among patients in this age group who were not included in SPRINT or those who experienced excess harm. Furthermore, the choice of the pooled cohort equations to quantify risk is fraught with potential limitations arising from possible overestimation of the predicted risk of cardiovascular disease in both the US and China.34-44 Patients'

preference as well as the downsides of antihypertensive treatment, particularly adverse events, may therefore be underemphasized.¹⁰

The health policy implications of guideline recommendations for the diagnosis and management of hypertension have been frequently assessed using nationally representative data in the US. These include studies focusing on the impact of the JNC-7 guidelines, 45-49 INC-8, 14 50 and the 2017 ACC/ AHA guidelines. 12 However, these analyses do not assess the international impact of such guideline recommendations, which is critical given their wide adoption. One such analysis from the US assessed the population impact of the 2017 ACC/AHA guidelines using NHANES data for the years 2011-14 and primarily compared them with the INC-7 guidelines as the current standard. 12 In our study, we used more contemporary US data (NHANES 2013-16). To allow for a direct comparison of the population impact of these guidelines in the US and China, we restricted this study to the assessment of adults aged 45 to 75 years, the age group captured in data from China. In addition, to ensure comparability of estimates, we defined the study populations for both the US and China in a similar manner. Finally, in contrast to the other study from NHANES, 12 we used the JNC-8 guidelines as the current standard. This is because although the JNC-8 guidelines represented a period of transition from the administrative process used in previous guideline iterations and were not released by the National Institutes of Health directly, they have been published and are widely cited.² Furthermore, whereas modest differences exist in national estimates between the two studies, these differences are due to our focus on adults in the 45-75 year age group compared with estimates that represent all US adults (>18 years of age) in the other study. 12 Finally, since the publication of the preprint of this study,⁵¹ the impact of the prevalence of hypertension based on these guidelines has been assessed in several countries. 52-58 However, ours is the first assessment of nationally representative data from China and is the only head-to-head assessment of the impact of these guidelines in comparable data from two vastly different health systems.

Limitations of study

The study has some limitations. Firstly, the data are based on cross sectional surveys, with a potential for sampling error. However, as our estimates are based on a large subset of sampled participants in both NHANES and CHARLS, and are associated with a relative standard error of less than 10% for all estimates, the observations are likely to be reliable. Secondly, the assessment of national estimates was limited to adults aged 45-75 years, corresponding to the age group of people surveyed for the CHARLS study. Therefore, additional people aged under 45 and over 75 years of age in both the US and China may have hypertension and be candidates for antihypertensive treatment. Thirdly, administrative differences exist between

NHANES and CHARLS: whereas NHANES data are collected by an agency of the US federal government. CHARLS is designed and conducted by the National School of Development at Peking University in China. However, the datasets have a similar structure and are designed to collect nationally representative data. Fourthly, certain variables in NHANES and CHARLS are based on self reporting and are subject to recall bias. However, wherever appropriate we used objective data to define conditions (for example, serum creatinine to assess chronic kidney disease status) or complement the diagnoses derived from self reporting (for example, the use of hemoglobin A, data to assess diabetes status). Furthermore, data in NHANES and CHARLS are collected by trained and experienced interviewers with the goal of reducing the effect of such biases. Fifthly, a history of atherosclerotic cardiovascular disease in CHARLS includes people who may have congestive heart failure or other heart disease in addition to previous myocardial infarction, stroke, coronary heart disease, and angina, Hence, the rates of atherosclerotic cardiovascular disease are higher than in the US. This did not affect classification of participants as having hypertension, which was solely based on a blood pressure above 130/80 mm Hg. A total of 3.7 million patients (that is, 1.3% of overall patients) became eligible for treatment owing to atherosclerotic cardiovascular disease status in CHARLS. However, the vast majority of these patients likely had true atherosclerotic cardiovascular disease, and the proportion of those with solely "congestive heart failure" or "other heart disease" is likely to be

Sixthly, we compared the recent guidelines against definitions of and target for blood pressure suggested by the members of the expert panel of the 8th Joint National Commission, but physicians may follow different guidelines. However, hypertension has been defined consistently across all previous guidelines as a blood pressure of 140/90 mm Hg or higher. Moreover, treatment targets in guidelines such as the JNC-7 were more stringent,59 thereby suggesting an even higher rate of non-treatment and under-treatment of hypertension in patients. Seventhly, whereas we used the most contemporary data from the US and China, those from China were collected in the years 2010-11, compared with the US data from 2013 to 2016. Therefore, although underestimation of the current use of antihypertensive treatment in China is possible, other contemporary investigations from China would argue against any major recent improvements in either the use or the adequacy of antihypertensive treatment. 16 17 Finally, we do not know whether China will adopt these guidelines. Our study, however, focuses only on the potential impact of the uptake of these guidelines in China.

Conclusions

The adoption of the new 2017 ACC/AHA guidelines would be associated with a marked increase in the prevalence of hypertension in the US and China. More

than 7 million more US adults would require treatment, but adoption in China would increase the number of patients eligible for treatment by more than 55 million. The change occurs at a time when both countries have substantial numbers of people who are not aware of having hypertension and who have hypertension that is not controlled even according to the previous standards.

AUTHOR AFFILIATIONS

¹Division of Cardiology, University of Texas Southwestern Medical Center, Dallas, TX 75219, USA

²Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT 06510, USA

³National Clinical Research Center for Cardiovascular Diseases, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing 102308, China

⁴Center for Healthcare Advancement and Outcomes, Baptist Health South Florida, Miami Beach, FL 33139, USA

⁵Section of Cardiovascular Medicine, Department of Internal Medicine, Yale School of Medicine, New Haven, CT 06510, USA

⁶State Key Laboratory of Cardiovascular Disease, National Clinical Research Center for Cardiovascular Diseases, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing 102308, China

⁷Department of Health Policy and Management, Yale School of Public Health, New Haven, CT 06510, USA

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Ethical approval: The study was exempt from the purview of Yale's Institutional Review Board as it uses de-identified data.

Data sharing: The technical appendix, statistical code, and dataset are available from the corresponding author.

Transparency: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Supplementary materials