

## *Update on Current Trends in Hypertension Management*

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#### **Educational Objectives**

By the end of this activity, the participant should be better able to:

1. Review previous Hypertension treatment guidelines.
2. Discuss the SPRINT trial design and results.
3. Discuss anticipated changes in hypertensive care based on the new data.

#### **Speaker Disclosure**

Dr. Nesbitt has disclosed that she is on the speaker's bureau for Amgen and Lundbeck, and she is on the advisory board for the American Heart Association and Lundbeck.

#### **Supporter Disclosure**

This project is funded in part by "State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health," CDC-RFA-DP13-1305, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, through Texas Department of State Health Services. It has been planned and produced by the Texas Area Health Education Center (AHEC) East and TAFP strictly as an accredited continuing medical education activity.

## Update on Current Trends in Hypertension Management

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## Disclosure of Relationships Over the Past 12 months

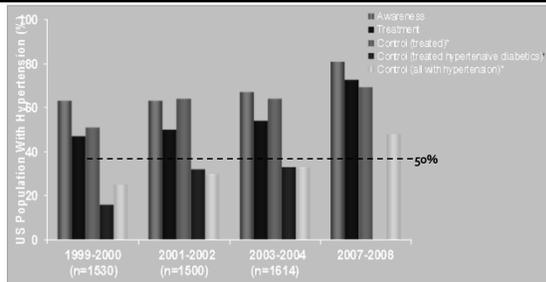
- Speakers Bureau: Lundbeck, Amgen
- Consultant: Lundbeck, Amgen
- Major Stock shareholder: None
- Other support, Tangible or intangible: None

## Objectives

- Present the current epidemiology of hypertension
- Review the core elements of hypertension diagnosis and classification which are essential to all of the guidelines.
- The SPRINT Trial Results and implications for treatment goals

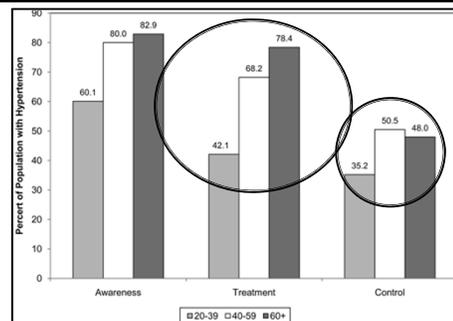
## EPIDEMIOLOGY

### Nearly One in Three US adults has Hypertension: Prevalence of 33.5% Rates of Blood Pressure Control Are Low



\* Blood pressure (BP) <140/90 mm Hg in non-diabetic patients or BP <130/80 in diabetic patients.  
† BP <130/80 mm Hg.  
Ong KL et al. *Hypertension*. 2007;49:69-75. Egan BM *JAMA* 2010;303:2043  
AHA Statistics 2011 *Circ* 2011;123:e18

### 2005-2008 NHANES Data on Hypertension by Age



Roger V *Circulation* 2011;123:e18

# Diagnosis and Classification of Hypertension

**What Is Hypertension?:  
Classification of Hypertension  
JNC 7 Definitions**

Blood Pressure (mm Hg)		Category
Systolic	Diastolic	
<120	and <80	Normal
120-139	or 80-89	Prehypertension
140-159	or 90-99	Stage 1 hypertension
≥160	or ≥100	Stage 2 hypertension

Chobanian AV, et al. Hypertension 2003;42:1206-52

**Hypertension Writing Group: Proposed New Definition of Hypertension**

- Hypertension is a progressive cardiovascular syndrome arising from complex and interrelated etiologies. Early markers of the syndrome are often present before blood pressure elevation is sustained; therefore, hypertension cannot be classified solely by discrete blood pressure thresholds. Progression is strongly associated with functional and structural cardiac and vascular abnormalities that damage the heart, kidneys, brain, vasculature and other organs and lead to premature morbidity and death.

Giles TD et al. J Clin Hypertens. 2005;7:505-512.

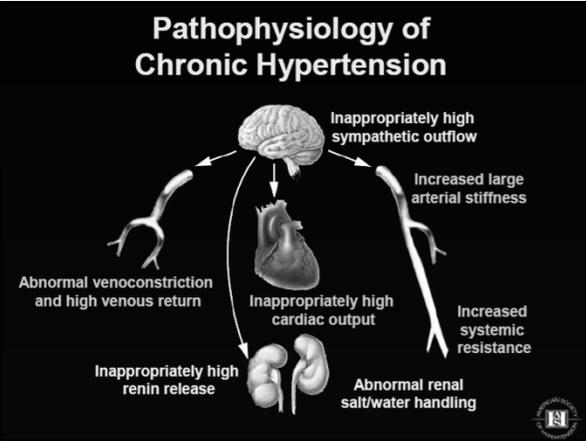
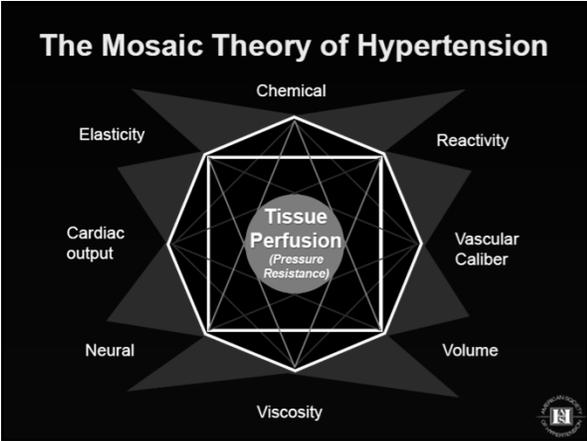
**Blood Pressure Regulatory Systems**

- Interactive regulatory systems integrate short-term and long-term cardiovascular and metabolic responses

System	Response Time
SNS	Seconds to minutes
RAAS	Minutes to hours
Kidney (salt and water balance)	Hours to days

- These regulatory systems remain the major target of antihypertensive drugs

Izzo JL, Sica DA, Black HR, eds, and the Council for High Blood Pressure Research (American Heart Association). Hypertension Primer: The Essentials of High Blood Pressure. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2008:110-119, 128-132.



## Resistant Hypertension

- Blood pressure that remains uncontrolled with use of 3 antihypertensive agents. Ideally one of the agents should be a diuretic and all agents should be prescribed at doses to provide optimal benefit.
- Estimated prevalence 10%–15% of hypertensive population or 7–10 million Americans

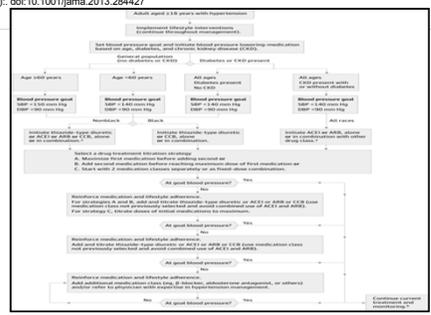


## Hypertension Guidelines and Consensus Statements

How did they get there?

The JAMA Network

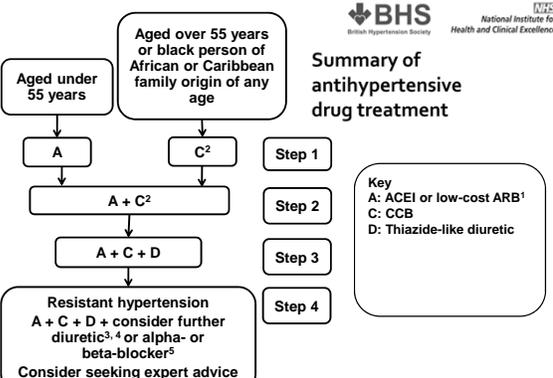
From: 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8)  
 JAMA. 2013;(310):doi:10.1001/jama.2013.284427



2014 Hypertension Guideline Management Algorithm. SBP indicates systolic blood pressure; DBP, diastolic blood pressure; ACEI, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; and CCB, calcium channel blocker. ACEIs and ARBs should not be used in combination. If blood pressure fails to be maintained at goal, reenter the algorithm where appropriate based on the current individual therapeutic plan.

BHS  
British Hypertension Society  
National Institute for Health and Clinical Excellence

### Summary of antihypertensive drug treatment



NICE Guidelines 2012

## Treatment Goals According to Risk Category or Stratum

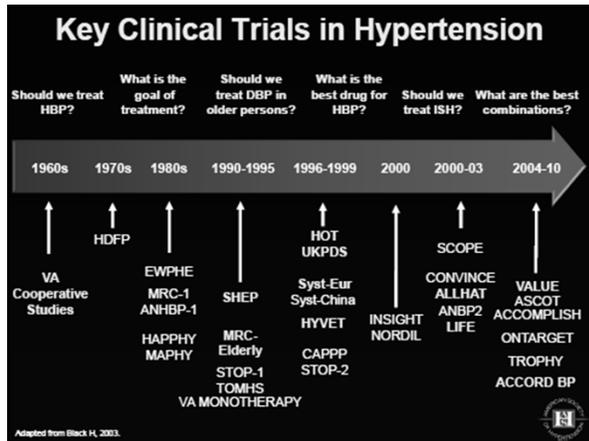


Risk Category	Recommendation	Goal BP
<b>Primary Prevention</b> BP $\geq$ 135/85 mmHg <b>without</b> target-organ damage, <sup>†</sup> preclinical CVD, <sup>‡</sup> or CVD <sup>§</sup>	Lifestyle Modification* (up to 3 months without drugs) + Drug Therapy	<135/85 mmHg
<b>Secondary Prevention/Target-Organ Damage</b> BP $\geq$ 130/80 mmHg <b>with</b> target-organ damage, <sup>†</sup> preclinical CVD, <sup>‡</sup> and/or the presence of CVD <sup>§</sup>	Lifestyle Modification + Drug Therapy	<130/80 mmHg

<sup>\*</sup>Up to 3 months of comprehensive lifestyle modification without drugs if BP <145/90 mmHg without target-organ damage or other risk-enhancing comorbidities.  
<sup>†</sup>Target-organ damage is defined as albumin:creatinine ratio >200 mg/g, estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m<sup>2</sup>, or electro- or echocardiographic evidence of left ventricular hypertrophy (LVH).  
<sup>‡</sup>Indicators of preclinical CVD: metabolic syndrome, Framingham risk score  $\geq$ 20%, prediabetes (impaired fasting glucose [100–125 mg/dL] and/or impaired glucose tolerance [2-hr postload glucose of 140–199 mg/dL]), diabetes mellitus.  
<sup>§</sup>CVD includes heart failure (systolic or diastolic), CHD/post-myocardial infarction, peripheral arterial disease, stroke, transient ischemic attack, and/or abdominal aortic aneurysm.

Hypertension 2010;56:780

## How did they come to these recommendations?



- ## Questions Addressed by Landmark Clinical Trials
- Does the treatment of hypertension reduce the risk of morbid events?
  - At what BP level is treatment beneficial?
  - To what level should BP be reduced?
  - Which drugs are most effective?

## BP Targets and Achieved BP in HTN Intervention Studies in Elderly

	SHEP <sup>1</sup>	Syst-Eur <sup>2</sup>	HYVET <sup>3</sup>
Subjects (n)	4736	4695	3845
Inclusion BP Criteria (mm Hg)	160-219 / <90	160-219 / <95	160-190 / <110
Goal SBP (mm Hg)	<160 or ≥20 reduction	<150 or ≥20 reduction	<150
Mean Achieved BP (mm Hg)	143/68	151/79	144/78
Follow-up (y)	4.5 (mean)	2.0 (median)	1.8 (mean)

1. SHEP Cooperative Research Group. JAMA. 1991;265(24):3255-3264.  
2. Staessen JA, et al. Lancet. 1997;350(9086):757-764.  
3. Beckwith ND, et al. for HYVET Study Group. N Engl J Med. 2008;359(18):1887-1896.

- ## Questions Addressed by Landmark Clinical Trials
- Does the treatment of hypertension reduce the risk of morbid events?
  - At what BP level is treatment beneficial?
  - To what level should BP be reduced?
  - Which drugs are most effective?

## ACCORD Blood Pressure Trial

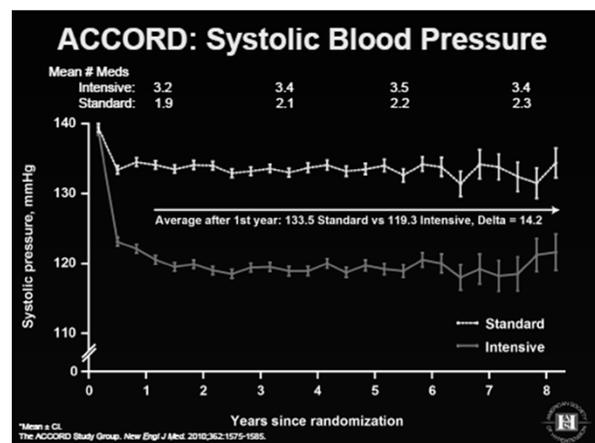
### Study Population

- 4,733 patients with type 2 diabetes (mean age 62.2 years)
  - Age 40+ with cardiovascular disease, or
  - Age 55+ with significant atherosclerosis, albuminuria, LVH, or at least 2 cardiovascular risk factors

### Treatment Groups

- **Intensive therapy:** Using treatments that targeted SBP <120 mm Hg
- **Standard therapy:** Using treatments that targeted SBP <140 mm Hg

The ACCORD Study Group. New Engl J Med. 2010;362:1575-1585.



## ACCORD: Primary and Secondary Outcomes

	Intensive Events (%/yr)	Standard Events (%/yr)	HR (95% CI)	P
Primary	208 (1.87)	237 (2.09)	0.88 (0.73-1.06)	0.20
Total Mortality	150 (1.28)	144 (1.19)	1.07 (0.85-1.35)	0.55
Cardiovascular Deaths	60 (0.52)	58 (0.49)	1.06 (0.74-1.52)	0.74
Nonfatal MI	126 (1.13)	146 (1.28)	0.87 (0.68-1.10)	0.25
Nonfatal Stroke	34 (0.30)	55 (0.47)	0.63 (0.41-0.96)	0.03
Total Stroke	36 (0.32)	62 (0.53)	0.59 (0.39-0.89)	0.01

Also examined:

- Fatal/Nonfatal HF (HR=0.94, P=0.67)
- Composite of fatal coronary events, nonfatal MI and unstable angina (HR=0.94, P=0.50)
- Composite of the primary outcome, revascularization and unstable angina (HR=0.95, P=0.40)

The ACCORD Study Group. *N Engl J Med* 2010;362:1575-1585.

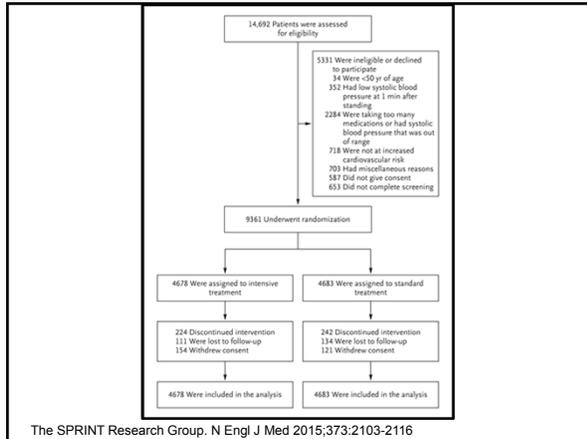


## SPRINT TRIAL: Systolic Blood Pressure Intervention Trial

A Randomized Trial of Intensive versus Standard Blood-Pressure Control

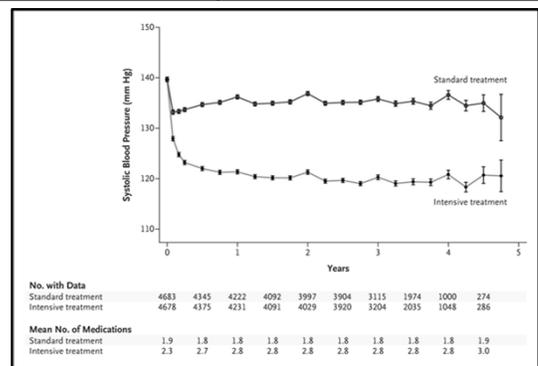
- Patients at increased cardiovascular risk but without diabetes were assigned to intensive treatment of systolic BP (target, <120 mm Hg) or standard treatment (target, <140 mm Hg).
- After a median of 3.26 years, the rate of cardiovascular events was significantly lower with intensive treatment.

*N Engl J Med* 373(22):2103-2116 November 26, 2015



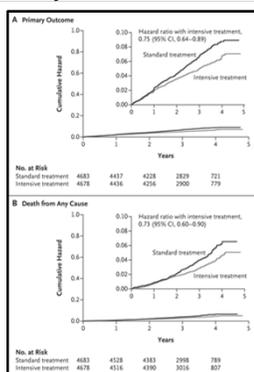
The SPRINT Research Group. *N Engl J Med* 2015;373:2103-2116

## SPRINT TRIAL: Systolic Blood Pressure Trend



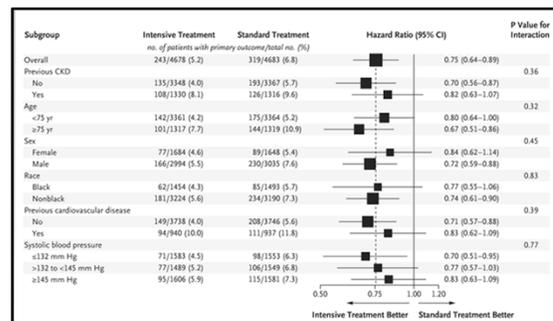
The SPRINT Research Group. *N Engl J Med* 2015;373:2103-2116

## SPRINT Trial: Primary Outcome and Death from Any Cause.



The SPRINT Research Group. *N Engl J Med* 2015;373:2103-2116

## SPRINT Study Primary Outcome According to Subgroups



The SPRINT Research Group. *N Engl J Med* 2015;373:2103-2116

### SPRINT Trial: Baseline Characteristics of the Study Participants.

Characteristic	Intensive Treatment (N=4678)	Standard Treatment (N=4633)
Age (mean ± SD)	63.5 ± 11.2	63.5 ± 11.2
Male sex (%)	93.2	93.2
White race (%)	88.1	88.1
Black race (%)	10.1	10.1
Hispanic race (%)	1.8	1.8
Other race (%)	0.8	0.8
Median systolic blood pressure at baseline (mm Hg)	160	160
Median diastolic blood pressure at baseline (mm Hg)	95	95
Median pulse rate at baseline (per minute)	72	72
Median serum total cholesterol at baseline (mg/dL)	200	200
Median serum LDL cholesterol at baseline (mg/dL)	130	130
Median serum HDL cholesterol at baseline (mg/dL)	40	40
Median serum triglyceride level at baseline (mg/dL)	150	150
Median serum creatinine level at baseline (mg/dL)	1.2	1.2
Median estimated GFR at baseline (mL/min/1.73 m <sup>2</sup> )	60	60
Median time to first major cardiovascular event (months)	10.5	10.5
Median time to first major renal event (months)	10.5	10.5
Median time to first major mortality event (months)	10.5	10.5

The SPRINT Research Group. N Engl J Med 2015;373:2103-2116

### SPRINT TRIAL: Primary and Secondary Outcomes and Renal Outcomes.

Outcome	Intensive Treatment (N=4678)	Standard Treatment (N=4633)	Hazard Ratio (95% CI)	P Value
<b>All participants</b>				
Primary outcome†	243 (5.2)	165 (3.6)	2.19 (1.64-2.95)	<0.001
Secondary outcomes				
Myocardial infarction	97 (2.1)	65 (1.4)	1.53 (1.11-2.11)	0.01
Acute coronary syndrome	40 (0.9)	27 (0.6)	1.66 (1.11-2.48)	0.01
Stroke	42 (1.3)	70 (1.5)	0.87 (0.63-1.20)	0.39
Heart failure	42 (1.3)	41 (0.9)	1.48 (1.03-2.11)	0.03
Death from cardiovascular causes	37 (0.8)	35 (0.8)	1.03 (0.73-1.45)	0.90
Death from any cause	155 (3.3)	103 (2.3)	1.47 (1.11-1.95)	0.003
Primary outcome or death	332 (7.1)	225 (5.0)	1.43 (1.07-1.90)	<0.001

\*CI denotes confidence interval, and CKD chronic kidney disease.  
†The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes.  
‡The composite renal outcome for participants with CKD at baseline was the first occurrence of a reduction in the estimated GFR of 50% or more, long-term dialysis, or kidney transplantation.  
§Reductions in the estimated GFR were confirmed by a second laboratory test at least 90 days later.  
¶Incident albuminuria was defined by a doubling of the ratio of urinary albumin (in milligrams) to creatinine (in grams) from less than 30 at baseline to greater than 30 during follow-up. The denominators for number of patients represent those without albuminuria at baseline.  
||No long-term dialysis or kidney transplantation was reported among participants without CKD at baseline.

The SPRINT Research Group. N Engl J Med 2015;373:2103-2116

### SPRINT TRIAL: Primary and Secondary Outcomes and Renal Outcomes.

Outcome	Intensive Treatment (N=1310)	Standard Treatment (N=1316)	Hazard Ratio (95% CI)	P Value
<b>Participants with CKD at baseline</b>				
Composite renal outcome†	14 (1.1)	15 (1.1)	0.96 (0.42-2.17)	0.76
≥50% reduction in estimated GFR‡	10 (0.8)	11 (0.8)	0.96 (0.36-2.60)	0.93
Long-term dialysis	4 (0.3)	0	0.57 (0.19-1.54)	0.27
Kidney transplantation	0	0		
Incident albuminuria§	49 (3.8)	39 (3.0)	1.30 (0.98-1.72)	0.11
≥30% reduction in estimated GFR to <40 mL/min/1.73 m <sup>2</sup> ¶	127 (9.8)	97 (7.4)	1.34 (1.00-1.80)	0.05
Incident albuminuria	110 (8.4)	81 (6.2)	1.34 (1.00-1.80)	0.05

\*CI denotes confidence interval, and CKD chronic kidney disease.  
†The primary outcome was the first occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes.  
‡The composite renal outcome for participants with CKD at baseline was the first occurrence of a reduction in the estimated GFR of 50% or more, long-term dialysis, or kidney transplantation.  
§Reductions in the estimated GFR were confirmed by a second laboratory test at least 90 days later.  
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The SPRINT Research Group. N Engl J Med 2015;373:2103-2116

### SPRINT Trial: Serious Adverse Events, Conditions of Interest, and Monitored Clinical Events.

Variable	Intensive Treatment (N=4678)	Standard Treatment (N=4633)	Hazard Ratio (95% CI)	P Value
<b>Serious adverse events*</b>	176 (3.8)	176 (3.8)	1.04	0.25
Conditions of interest				
Serious adverse events only				
Hypertension	130 (2.8)	40 (0.9)	1.67 (1.11-2.51)	0.01
Stroke	97 (2.1)	70 (1.5)	1.33 (0.98-1.80)	0.08
Brachyuria	42 (0.9)	41 (0.9)	1.19 (0.84-1.68)	0.34
Encephalopathy	100 (2.1)	100 (2.1)	1.00	0.98
Hypotension	100 (2.1)	100 (2.1)	1.00	0.97
Acute kidney injury or acute renal failure	100 (2.1)	100 (2.1)	1.00	<0.001
Emergency department visit or serious adverse event				
Hypertension	130 (2.8)	40 (0.9)	1.76 (1.20-2.51)	<0.001
Stroke	97 (2.1)	70 (1.5)	1.44 (1.00-2.07)	0.05
Brachyuria	42 (0.9)	41 (0.9)	1.25 (0.89-1.75)	0.13
Encephalopathy	100 (2.1)	100 (2.1)	1.00	0.98
Hypotension	100 (2.1)	100 (2.1)	1.00	0.97
Acute kidney injury or acute renal failure	100 (2.1)	100 (2.1)	1.00	<0.001
Monitored clinical events				
Adverse laboratory results†				
Serum sodium <120 mmol/L	100 (2.1)	100 (2.1)	1.76 (1.20-2.51)	<0.001
Serum sodium <120 mmol/L	100 (2.1)	100 (2.1)	1.00	0.98
Serum potassium <3.0 mmol/L	100 (2.1)	100 (2.1)	1.00	0.98
Serum potassium <3.0 mmol/L	100 (2.1)	100 (2.1)	1.00	0.97
Orthostatic hypotension‡				
None	77 (1.6)	87 (1.9)	0.88 (0.63-1.20)	0.41
With dizziness	47 (1.0)	47 (1.0)	0.95 (0.68-1.33)	0.75

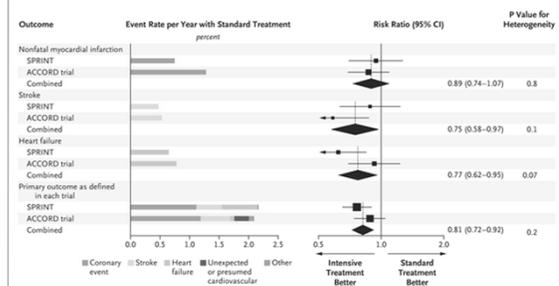
\*A serious adverse event was defined as an event that resulted in death, required hospitalization, or required a procedure to prevent death or permanent disability, that required or prolonged a hospitalization, or that was judged by the investigator to represent a clinically significant hazard or harm to the participant that might affect the safety or efficacy of the study or the results of the study.  
†Adverse laboratory results were defined as a serum sodium level less than 120 mmol/L, a serum potassium level less than 3.0 mmol/L, or a serum creatinine level greater than 2.0 mg/dL.  
‡Orthostatic hypotension was defined as a drop in systolic blood pressure of at least 20 mm Hg or a diastolic blood pressure of at least 10 mm Hg at 1 minute after the participant stood up, as compared with the seated blood pressure was seated. Standing blood pressure was measured after the participant had been seated for at least 5 minutes, and pulse rate was measured after the participant had been seated for at least 5 minutes at the time the orthostatic blood pressure was taken.

The SPRINT Research Group. N Engl J Med 2015;373:2103-2116

### SPRINT TRIAL CONCLUSION

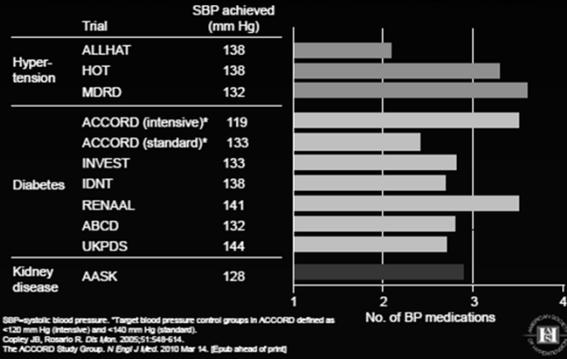
Among patients at high risk for cardiovascular events but without diabetes, targeting a systolic blood pressure of less than 120 mm Hg, as compared with less than 140 mm Hg, resulted in lower rates of fatal and nonfatal major cardiovascular events and death from any cause, although significantly higher rates of some adverse events were observed in the intensive-treatment group.

### Outcomes Data from SPRINT and the ACCORD Trial and Combined Data from Both Trials.



Perkovic V, Rodgers A. N Engl J Med 2015;373:2175-2178.

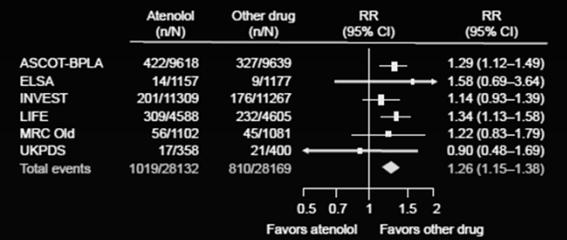
## Multiple Medications Are Required to Achieve BP Control in Clinical Trials



## Questions Addressed by Landmark Clinical Trials

- Does the treatment of hypertension reduce the risk of morbid events?
- At what BP level is treatment beneficial?
- To what level should BP be reduced?
- What are the best drugs for hypertension?

## β-Blocker Meta-analysis Stroke: Atenolol vs Other Antihypertensive Agents



ASCOT-BPLA, Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm; CI, confidence interval; ELSA, European Lactipine Study on Atenolol; INVEST, International Verapamil-Translucine Study; LIFE, Losartan Intervention for Endpoint reduction in Stroke; Medical Research Council; RR, relative risk; UKPDS, United Kingdom Prospective Diabetes Study.  
 Lindholm LH et al. Lancet. 2005;365(9362):1561-1563.

## National Institute for Health and Clinical Excellence (NICE) Places β-Blockers as Fourth-Line Treatment for Uncomplicated Hypertension

- Beta-blockers are not a preferred initial therapy for hypertension
- If treatment with three drugs is required, the combination of ACE inhibitor or ARB, calcium-channel blocker and thiazide-like diuretic should be used
- Beta-blockers may be considered in younger people, particularly:
  - those with an intolerance or contraindication to ACE inhibitors and ARB's
  - women of child-bearing potential
  - people with evidence of increased sympathetic drive
- If therapy is initiated with a beta-blocker and a second drug is required, add a calcium-channel blocker rather than a thiazide-like diuretic to reduce the person's risk of developing diabetes

NICE Clinical Guideline 127, August 2011.

## Drug Combinations in HTN: ASH Recommendations

<b>Preferred</b>	<ul style="list-style-type: none"> <li>• ACE inhibitor/diuretic*</li> <li>• ARB/diuretic*</li> <li>• ACE inhibitor/CCB*</li> <li>• ARB/CCB*</li> </ul>
<b>Acceptable</b>	<ul style="list-style-type: none"> <li>• β-blocker/diuretic*</li> <li>• CCB (dihydropyridine)/β-blocker</li> <li>• CCB/diuretic</li> <li>• Renin inhibitor/diuretic*</li> <li>• Renin inhibitor/ARB**</li> <li>• Thiazide diuretics/K<sup>+</sup> sparing diuretics*</li> </ul>
<b>Less effective</b>	<ul style="list-style-type: none"> <li>• ACE inhibitor/ARB</li> <li>• ACE inhibitor/β-blocker</li> <li>• ARB/β-blocker</li> <li>• CCB (nondihydropyridine)/β-blocker</li> <li>• Centrally acting agent/β-blocker</li> </ul>

\*Single-pill combinations available in the United States.  
 Gradman AH et al. J Am Soc Hypertens. 2010;4:42.

## Generalized Treatment Recommendations

- Life style modifications (weight loss, exercise, low-salt/high fiber diet)
- Standard triple regimen of ACE inhibitor or ARB, thiazide diuretic, and long-acting calcium channel blocker
- Preferential use of chlorthalidone
- Consider use of aldosterone antagonist (spironolactone, eplerenone, amiloride) as fourth drug
- Vasodilating beta-blocker as fifth drug
- Centrally-acting agent as fifth drug (clonidine, guanfacine)
- Vasodilating agents (hydralazine, minoxidil) as last resort

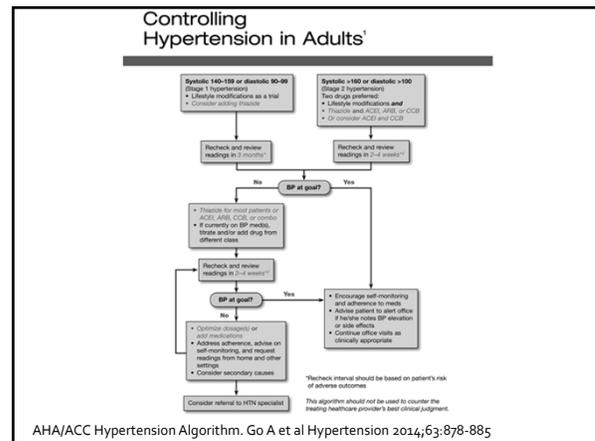
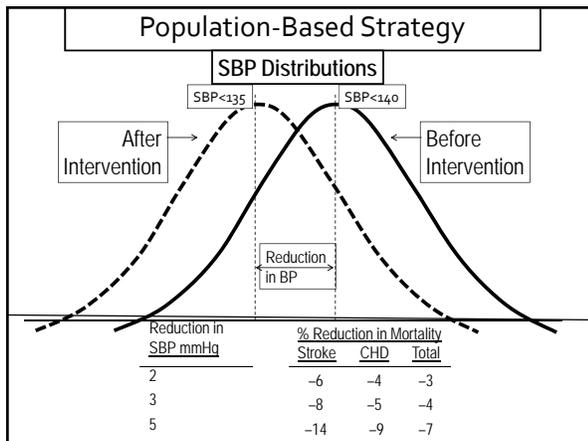
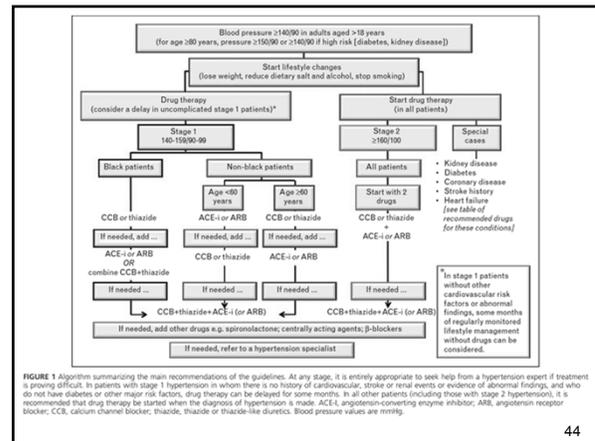
**Guideline**

## Clinical Practice Guidelines for the Management of Hypertension in the Community.

A Statement by the American Society of Hypertension and the International Society of Hypertension

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## Summary

- ❖ Previous Guidelines recommend treatment goal of <140/90/140/90 for most of the population.
- ❖ Recent trials such as ACCORD and SPRINT suggest different goals for specific populations
  - ❖ ACCORD: Diabetics <140/90
  - ❖ SPRINT: Non-diabetics <120/80
  - ❖ SPRINT: There are differences in outcomes by CKD and age. This may affect new recommendations
- ❖ All of the guidelines have removed beta blockers from the first line of therapy. (ACE/ARB, CCB, Diuretics are first line treatment options)
- ❖ EXPECT NEW GUIDELINES FROM AHA/ACC/ASH in 2016-2017



