Controversial High Impact Publications in Hypertension: SPRINTing Toward the Goal

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Disclosure

- Faculty have nothing to disclose.

Learning Objectives

- Compare and contrast guidelines and consensus recommendations for the treatment of patients with hypertension.
- Explain the findings from and strengths and weaknesses of the SPRINT trial, and discuss the implications for establishing the blood pressure goal for a patient with hypertension.
- Design patient-centered antihypertensive treatment plans in complex patients with hypertension.

The Landscape of Hypertension

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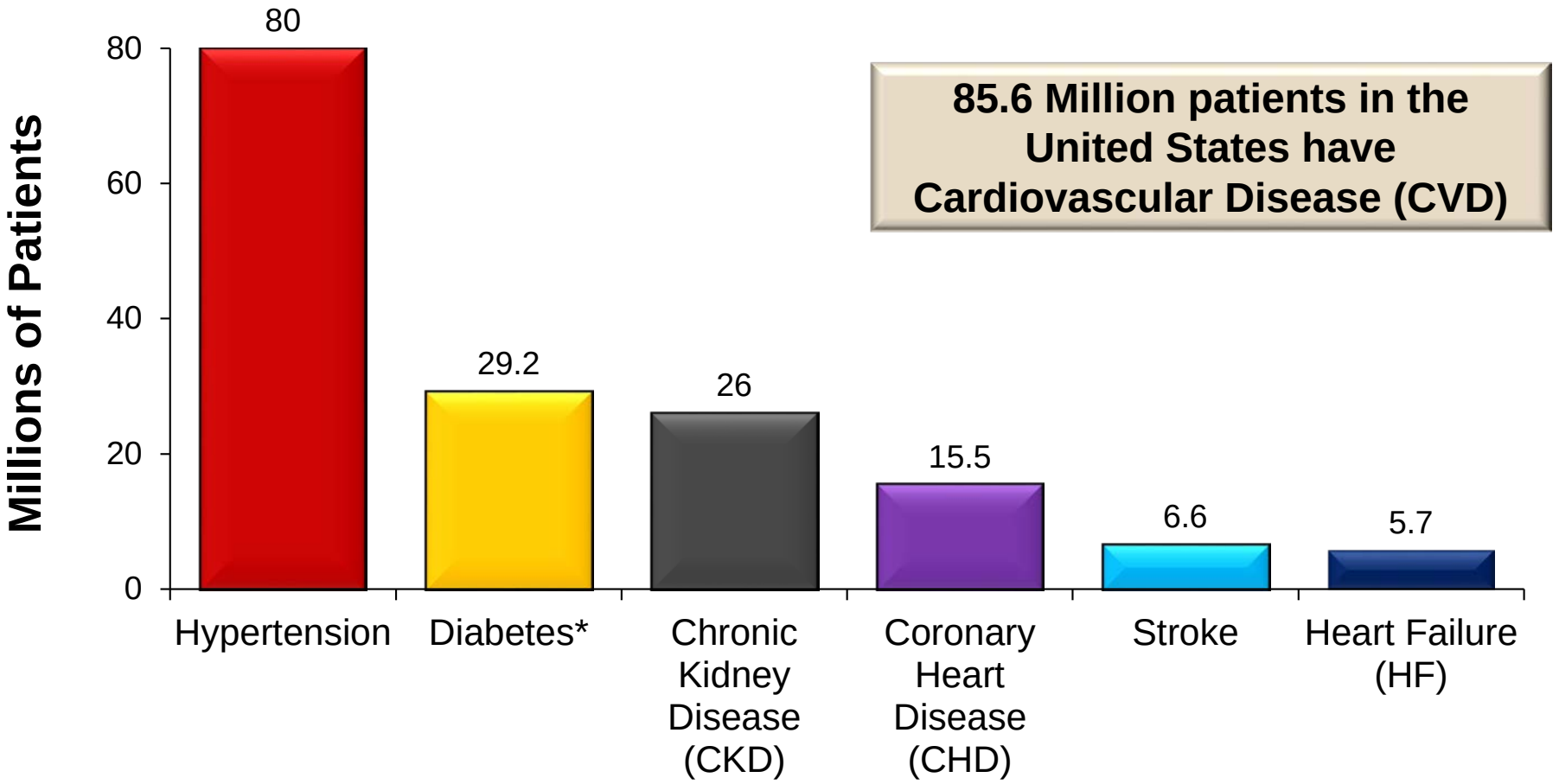
American Heart Association (AHA)

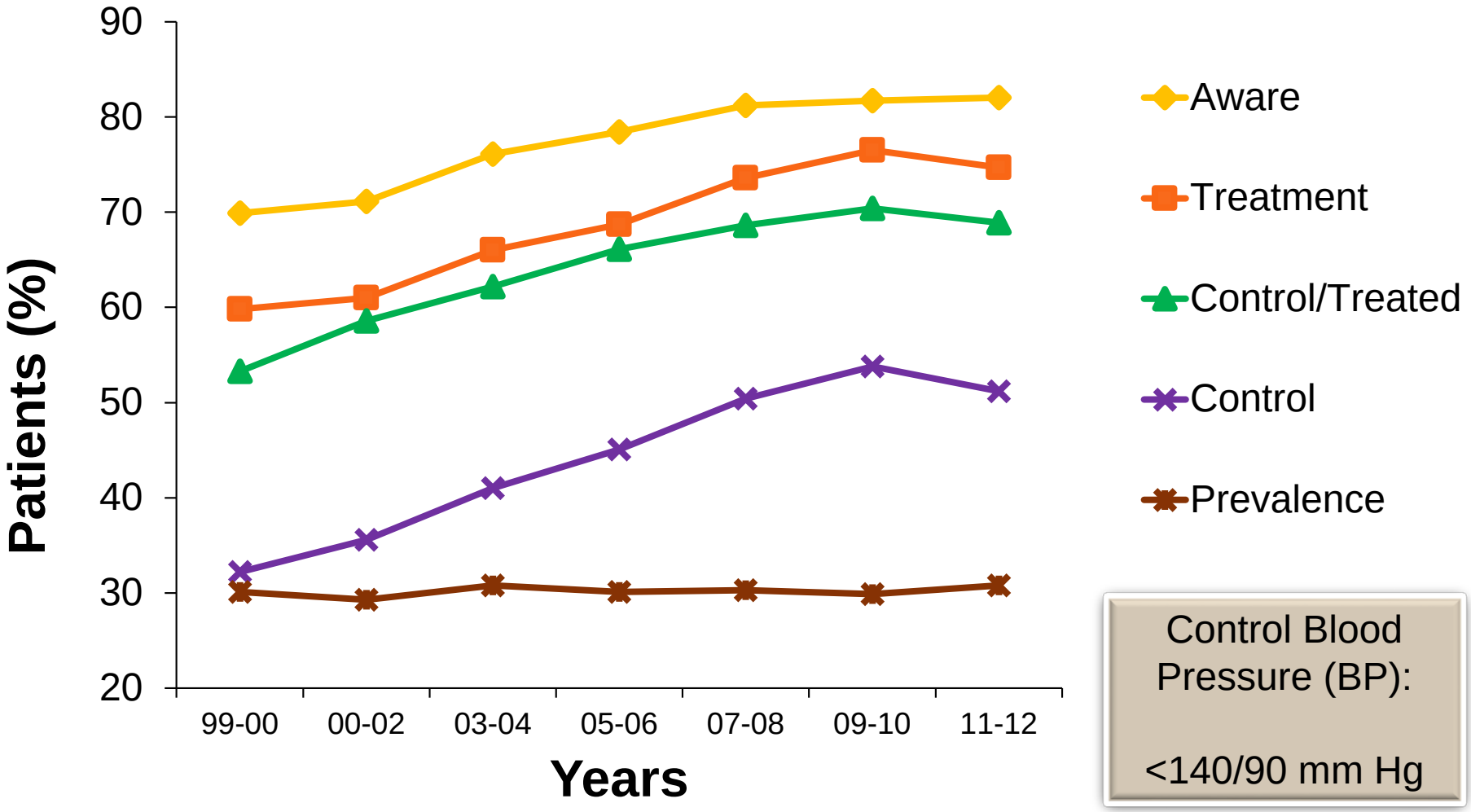
Heart Disease and Stroke Statistics—2016 Update



*Includes diagnosed and undiagnosed patients

Mozaffarian D, et al. *Circulation* 2016;133(4):447-54.

Hypertension in the United States



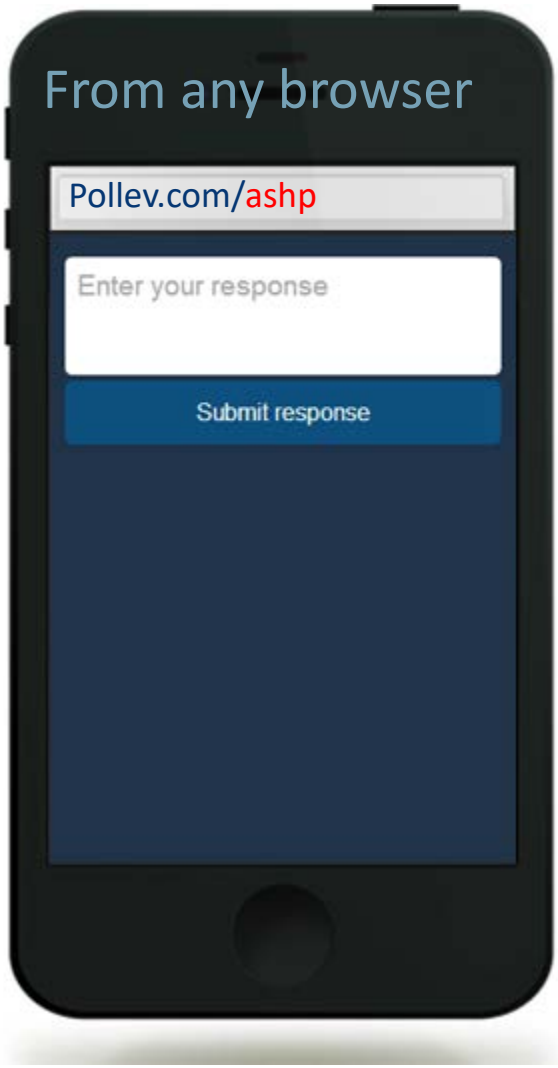
Control Blood Pressure (BP):

<140/90 mm Hg

Egan BM, et al. *Circulation* 2014;130:1692-1699.

Time for a Poll

How to vote via the web or text messaging



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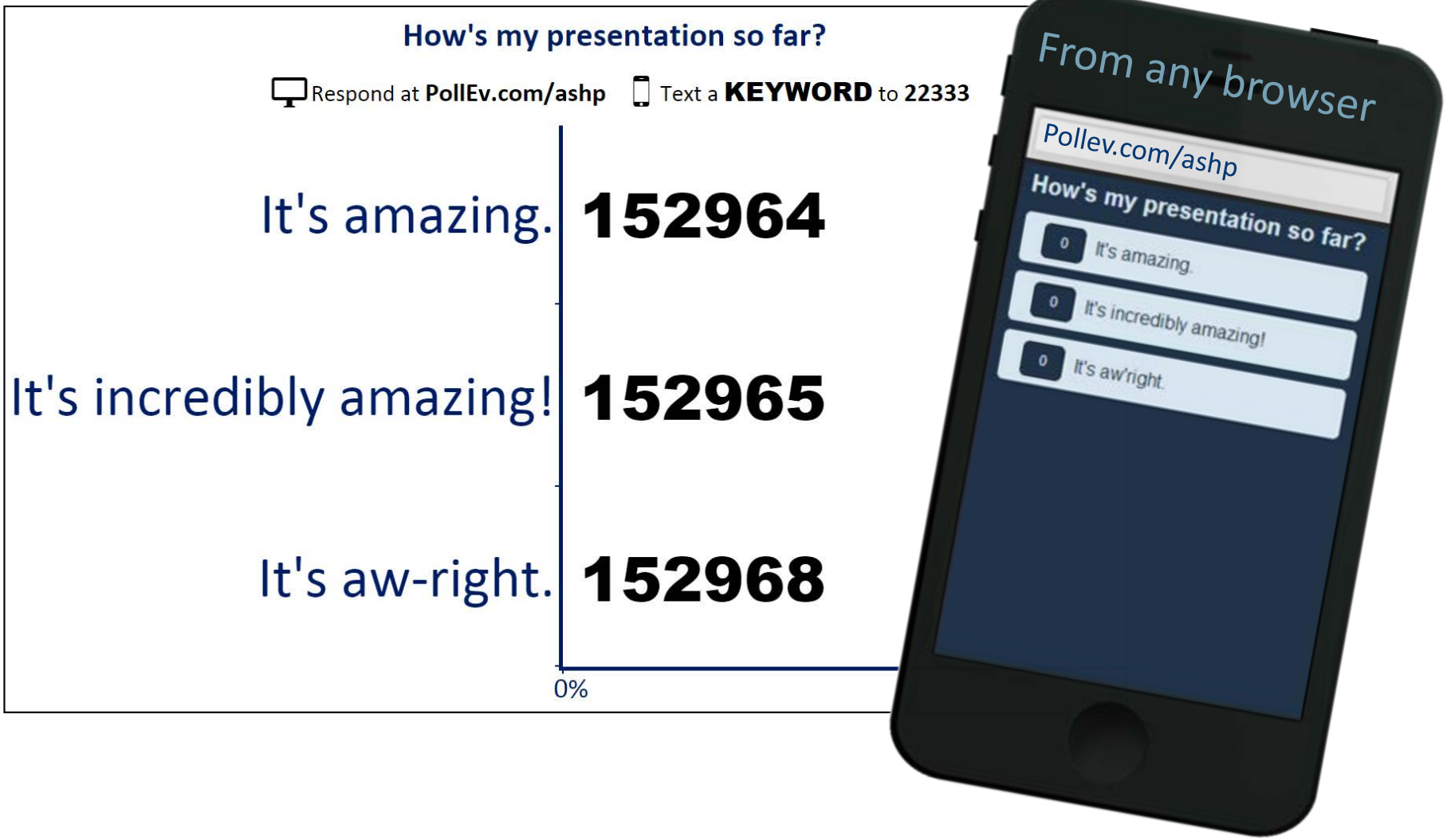
Respond at **PollEv.com/ashp** Text a **KEYWORD** to **22333**

It's amazing.	**152964**
It's incredibly amazing!	**152965**
It's aw-right.	**152968**

0%

How to vote via the web



Question 1: 65-year-old African American man with obesity, hypertension, type 2 diabetes and dyslipidemia. Drinks 2-3 beers/day, follows no particular diet, 1 ppd smoker (x 40 years), limited exercise. Current medications are: atorvastatin 20 mg daily, hydrochlorothiazide 25 mg daily. BP is 154/92 mm Hg, HR 80 bpm, SCr 1.2 mg/dL (eGFR 73 mL/min/1.73m^2), urine Alb:Cr = 10 mg/g.

Which of the following is the most appropriate goal BP for him?

A < 140/90 mm Hg

B < 150/90 mm Hg

C < 130/80 mm Hg

D < 120/80 mm Hg

Question 1

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Which of the following is the most appropriate goal BP for him?

A **< 140/90 mm Hg**

B < 150/90 mm Hg

C < 130/80 mm Hg

D < 120/80 mm Hg

Lifestyle Management to Reduce BP

Dietary Pattern

- Emphasize vegetables, fruits, and whole grains; low-fat dairy, poultry, fish, legumes, nontropical vegetable oils, and nuts; limit sweets, sugar-sweetened beverages, and red meats (e.g., DASH)
- Lower sodium intake (max 2400 mg/day; 1500 mg/day better; at least reduce by 1000 mg/day)
- Limit alcohol (2 drinks/day, men; 1 drink/day, women)

Physical Activity

- Aerobic physical activity 3–4 sessions/week, 40-minute sessions, moderate-to-vigorous intensity

Weber MA et al. *J Hypertens*. 2014;32(1):14-26.
Eckel RH et al. *Circulation.* 2014; 129(suppl 2):s76-s99.

Goal BP Recommendations

ASH/ISH Guidelines

- **Age < 80 years:**
  - <140/90 mm Hg
- **Age ≥ 80 years:**
  - <150/90 mm Hg
  - <140/90 mm Hg if diabetes or CKD

JNC 8 Report

- **Age < 60 years:**
  - <140/90 mm Hg
- **Age ≥ 60 years:**
  - <150/90 mm Hg
  - <140/90 mm Hg if diabetes or CKD

ASH/ISH = American Society of Hypertension/International Society of Hypertension; JNC = Joint National Committee; CKD = chronic kidney disease

Weber MA et al. *J Hypertens*. 2014;32(1):14-26.

James PA et al. *JAMA*. 2014; 311(5):507-20.

BP Goals: Other Organizations

- American Diabetes Association (ADA) 2016:
  - <140/90 mm Hg (A)
  - Systolic BP <130 mm Hg (C) or diastolic BP < 80 mm Hg (B) may be appropriate for some patients

- Kidney Disease: Improving Global Outcomes (KDIGO) 2012:
  - ≤ 130/80 mm Hg in CKD patients with persistent albuminuria

American Diabetes Association. *Diabetes Care* 2016;39 (suppl 1):s60-s71.
KDIGO Clinical Practice Guideline for the Management of Blood Pressure in Chronic Kidney Disease. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO_BP_GL.pdf.

Antihypertensive Agents

First-Line

- Angiotensin Converting Enzyme Inhibitor (ACEi)
- Angiotensin Receptor Blocker (ARB)
- Calcium Channel Blocker (CCB)
- Thiazide Diuretic

Add-on or First-Line in Compelling Indications

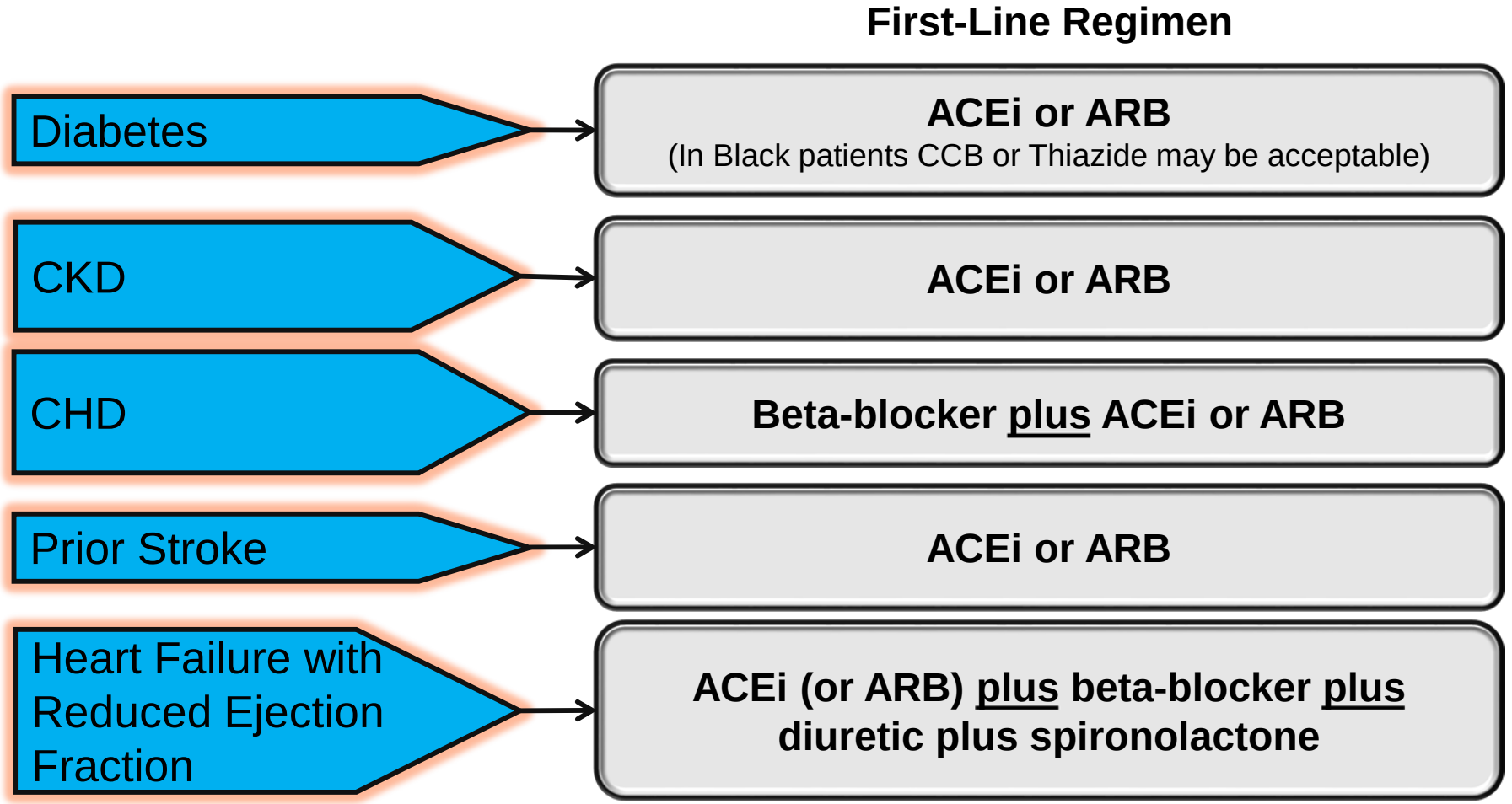
- Beta-Blocker

Alternatives

- Aldosterone Antagonist (e.g., spironolactone)
- Alpha Antagonist (e.g., terazosin)
- Centrally Acting Alpha Agonist (e.g., clonidine)
- Direct Arterial Vasodilator (e.g., hydralazine)
- Direct Renin Inhibitor (i.e., Aliskiren)
- Reserpine

Saseen JJ, MacLaughlin EJ. Chapter 3 - Hypertension. In: DiPiro JT, Talbert RL, Yee GC, eds. Pharmacotherapy, A Pathophysiologic Approach. 10th ed. New York: McGraw-Hill.

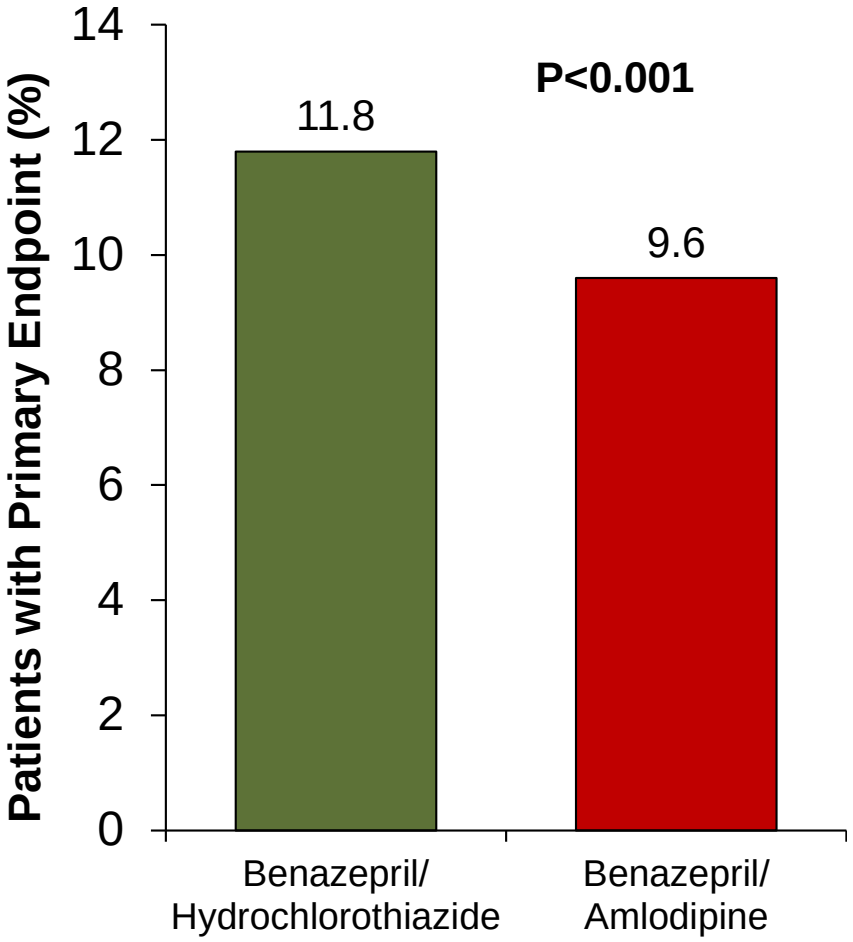
Compelling Indications (Special Cases)



Saseen JJ, MacLaughlin EJ. Chapter 3 - Hypertension. In: DiPiro JT, Talbert RL, Yee GC, eds. Pharmacotherapy, A Pathophysiologic Approach. 10th ed. New York: McGraw-Hill.

ACCOMPLISH Trial

- Randomized, double-blind, controlled trial*
  - Benazepril/Hydrochlorothiazide vs. Benazepril/Amlodipine
- 11,506 patients with hypertension and:
  - Age ≥ 60 yr; or 55-59 yr if multiple CV risk factors
  - SBP ≥ 160 mm Hg or on BP medication
- Primary endpoint: CV events



*Dosages titrated, as tolerated, to benazepril 40 mg/day, hydrochlorothiazide 25 mg/day, amlodipine 10 mg/day

Jamerson K, et al. *N Engl J Med.* 2008; 359:2417-28.

Question 2: Which of the following is true regarding the antihypertensive effects of hydrochlorothiazide 25 mg daily and chlorthalidone 25 mg daily?

A Hydrochlorothiazide is more potent

B Chlorthalidone is more potent

C They are equal in potency

D I do not know

Question 2

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A Hydrochlorothiazide is more potent

B **Chlorthalidone is more potent**

C They are equal in potency

D I do not know

Resistant Hypertension

Patients not at goal BP with ≥ 3 medications (ideally, at full doses), one of which is a diuretic; or requiring 4 or more medications, even if at goal BP

Pharmacotherapy Options:

- Assure appropriate diuretic therapy
  - Switch hydrochlorothiazide to chlorthalidone
  - Add an aldosterone antagonist (e.g., spironolactone)
  - Use a loop diuretic (if stage 4 or 5 CKD) as needed
- Switch typical beta-blocker (e.g., metoprolol, atenolol) to carvedilol or labetalol
- Use an alternative agent(s), combination CCB therapy

Calhoun DA, et al. *Circulation*. 2008;117:e510-526.

A Tale of Two Thiazides

	Hydrochlorothiazide	Chlorthalidone
Category	Thiazide-type	Thiazide-like
Half-life (hrs)	9-10	50-60
Antihypertensive equivalency	25 mg	12.5-18.75 mg
Utilization	• Prescribed more frequently • In most combination products	• Preferred agent in resistant hypertension
Evidence-base	Not used in most landmark trials	Extensive use in landmark clinical trials (e.g., SHEP, ALLHAT)
Hypokalemia/ Hyponatremia	Moderate concern	Slightly higher in elderly patients

Ernst M, et al. *N Engl J Med* 2009;361:2153-64.

MEDPAGE TODAY

Cardiology

CardioBrief: Can 50 Million Prescriptions Be Wrong?

—Innovative trial to determine actual benefit of hydrochlorothiazide

- Diuretic Comparison Project:
  - Hydrochlorothiazide vs. chlorthalidone
  - 13,500 veterans, age ≥ 65 years with hypertension
  - Primary endpoint: CV events over multiple years
  - Will use a new, efficient, and less expensive study design known as “point of care”

Husten L. CardioBrief: Can 50 Million Prescriptions Be Wrong? August 16, 2016. http://www.medpagetoday.com/Cardiology/CardioBrief/59702?xid=nl_mpt_DHE_2016-08-17&eun=g379325d0r&pos=1

Diuretic Comparison Project (DCP). July 2016. https://clinicaltrials.gov/ct2/show/NCT02185417?term=VA+diuretic+comparative+study&rank=1

Key Takeaways

- Key Takeaway #1
  - A BP goal of < 140/90 mm Hg is recommended by most guidelines/experts for **most patients with hypertension**, with lower goals (e.g., <130/80 mm Hg) an option in certain patients
- Key Takeaway #2
  - First-line medications consist of an ACEi, ARB, CCB, or thiazide; recommendations for specific medications provided for compelling indications

SPRINT

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Systolic Blood Pressure Intervention Trial (SPRINT)

- Multicenter, randomized, controlled trial in 9,361 patients with hypertension randomized open-label to:
  - Intensive treatment: SBP <120 mm Hg
  - Standard treatment: SBP <140 mm Hg
- Primary outcome: first the occurrence of a myocardial infarction (MI), acute coronary syndrome, stroke, heart failure, or cardiovascular disease death
- Hypothesis: Intensive treatment compared with standard treatment will reduce the primary outcome
- Prespecified subgroups: CKD, CVD, elderly (≥75 yr)

Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT Inclusion Criteria

- ≥ 50 years old
- Systolic blood pressure
  - 130–180 mm Hg on 0 or 1 medication
  - 130–170 mm Hg on up to 2 medications
  - 130–160 mm Hg on up to 3 medications
  - 130–150 mm Hg on up to 4 medications
- At increased risk for atherosclerotic cardiovascular disease (various criteria)

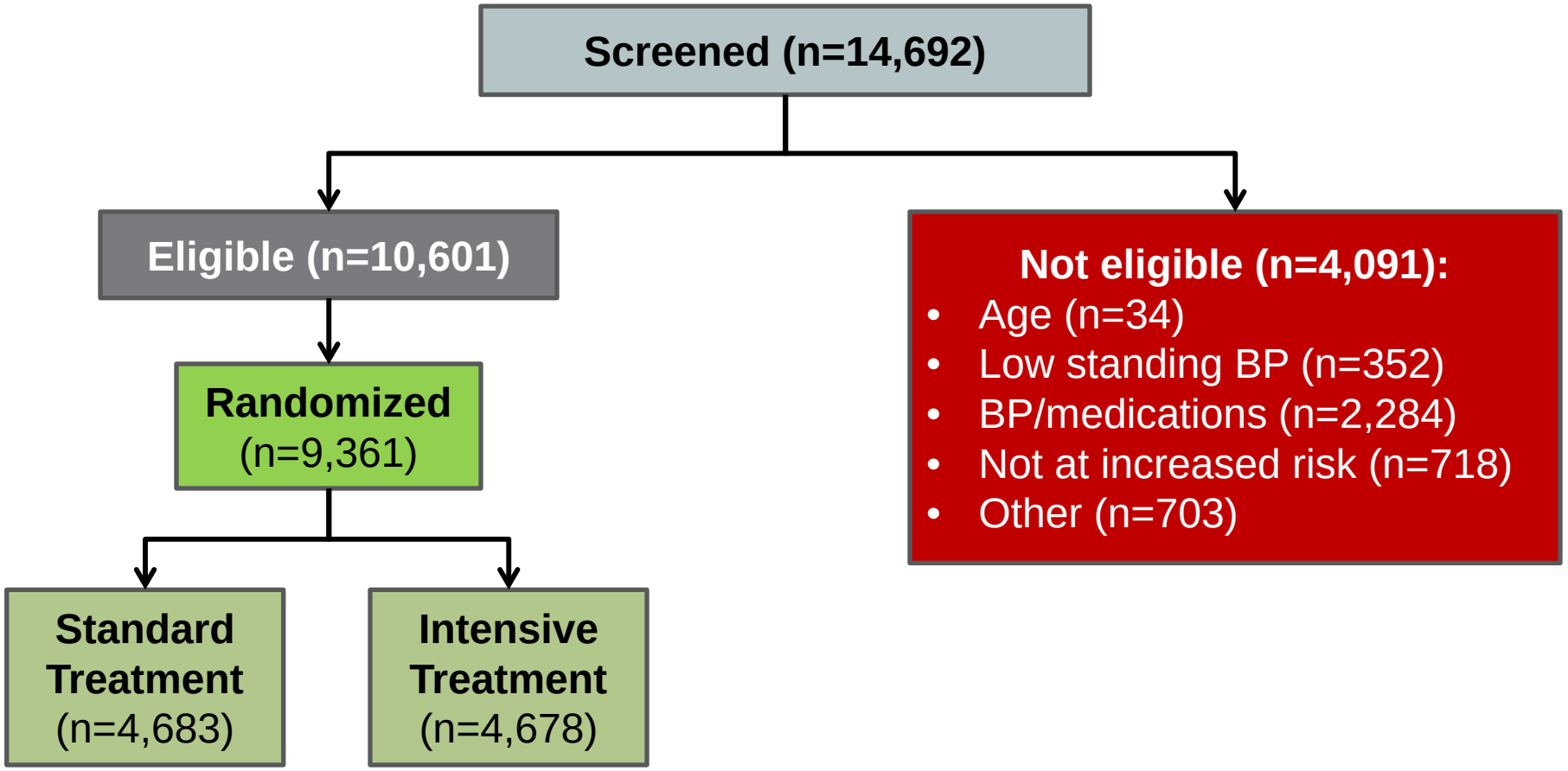
Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT Exclusion Criteria

- Secondary hypertension
- Diabetes mellitus
- Previous stroke
- CV event within 3 months
- Symptomatic HF w/in 6 months or ejection fraction < 35%
- Proteinuria (≥ 1 g/day), polycystic kidney disease, glomerulonephritis, estimated glomerular filtration rate < 20 ml/min/1.73m^2 or end-stage renal disease

Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT: Consolidated standards of reporting trials (CONSORT)



Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT Protocol Procedures

- Medication choice:
  - ACEi, ARB, CCB, thiazide first-line; beta-blocker in CHD
  - Chlorthalidone encouraged as the primary thiazide-type diuretic and amlodipine as the preferred CCB
- Titration of medications was based on:
  - Mean of three office BP measurements obtained in the seated position using an automated device
  - BP measured 1 min after standing at screening, baseline, 1 month, 6 months, 12 months, and annually thereafter; screening for hypotension while standing

Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT: Patient Characteristics

	Intensive Treatment	Standard Treatment
Baseline Characteristics		
• Mean SBP (mm Hg)	139.7	139.7
• Women (%)	36.0	35.2
• Mean Age (yr)	67.9	67.9
• Age ≥75 yr (%)	28.2	28.2
• CKD (%)	28.5	28.1
• Black	29.5	30.4
• Hispanic	10.8	10.3
Results:		
• Mean SBP at 1 year (mm Hg)	121.4	136.2
• Mean no. BP medications	2.8	1.8

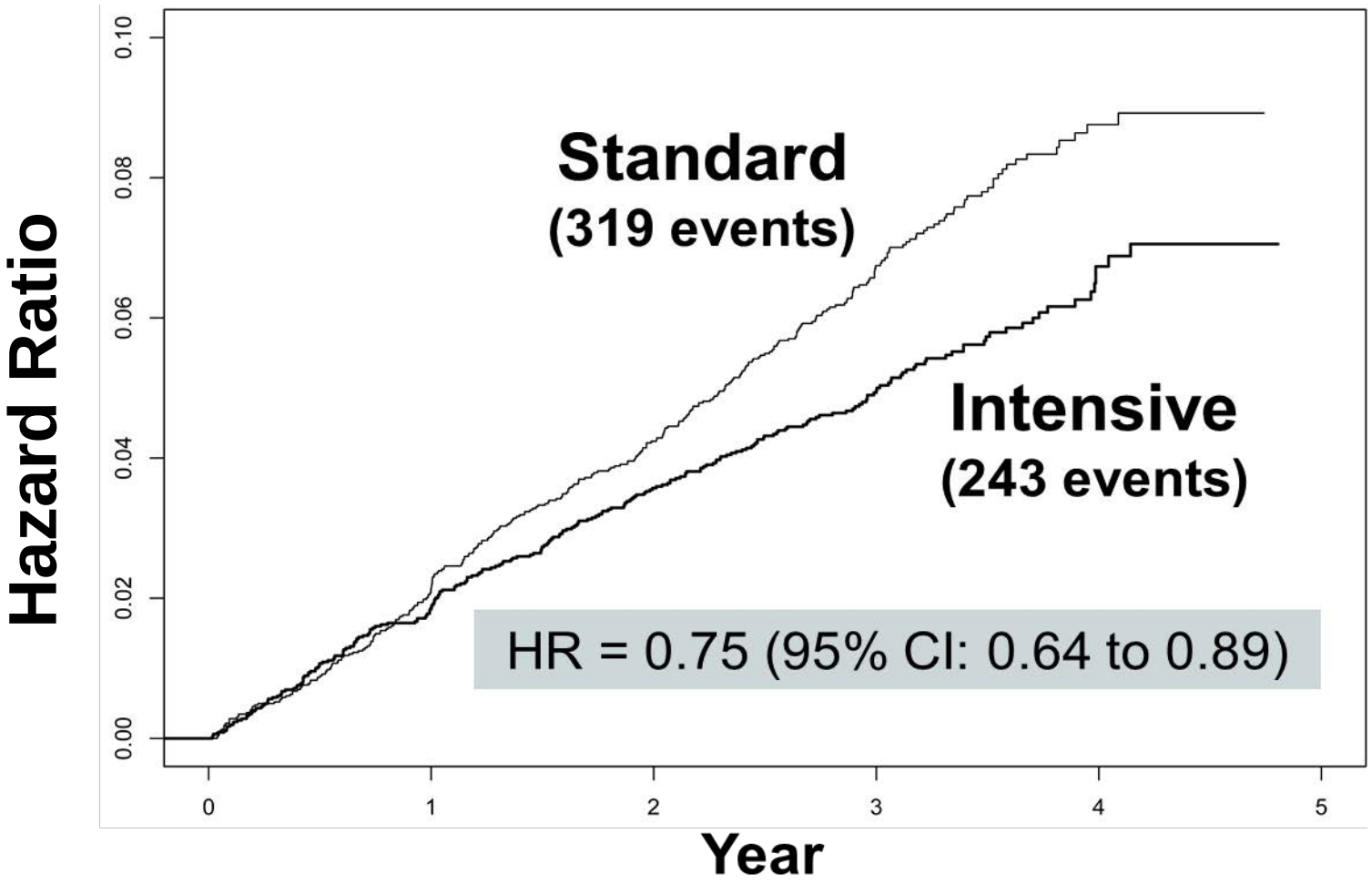
Ambrosius WT, et al. *Clin Trials*. 2014;11(5):532–546.

SPRINT: Medication Utilization

	Intensive Treatment (%)	Standard Treatment (%)
Mean number of agents • 0 • 1 • 2 • 3 • 4+	 • 2.7 • 10.5 • 30.5 • 31.8 • 24.3	 • 11.3 • 31.1 • 33.3 • 17.2 • 6.9
ACEi or ARB	76.7	55.2
Thiazide	54.9	33.3
CCB	57.1	35.4
Beta-blocker	41.1	30.8
Aldosterone antagonist	8.7	4.0
Alpha-blocker/alpha agonist/arterial vasodilator	10.3/2.3/7.3	5.5/0.9/2.4

Sprint Research Group, et al *N Engl J Med.* 2015;373(22):2103-2106.

SPRINT: Primary Endpoint



Whelton PK. Systolic Blood Pressure Intervention Trial (SPRINT): principal results. https://www.sprinttrial.org/public/pubs/SPRINT_AHA.pptx

Sprint Research Group. N Engl J Med. 2015;373(22):2103-2106. doi:10.1056/NEJMoa1511939.

SPRINT Outcomes

Outcome	Intensive Treatment N=4678; no.(%)	Standard Treatment N=4683; no.(%)	HR* (P-Value)
Primary Outcome‡	243 (5.2)	319 (6.8)	0.75 (<0.001)
Secondary Outcomes			
• Myocardial infarction	97 (2.1)	116 (2.5)	0.83 (0.19)
• Acute coronary syndrome	40 (0.9)	40 (0.9)	1.00 (0.99)
• Stroke	62 (1.3)	70 (1.5)	0.89 (0.50)
• Heart failure	62 (1.3)	100 (2.1)	0.62 (0.002)
• Death from CV causes	37 (0.8)	65 (1.4)	0.57 (0.005)
• Death from any cause	155 (3.3)	210 (4.5)	0.73 (0.003)
• Primary outcome or death	332 (7.1)	423 (9.0)	0.78 (<0.001)

* Hazard ratio

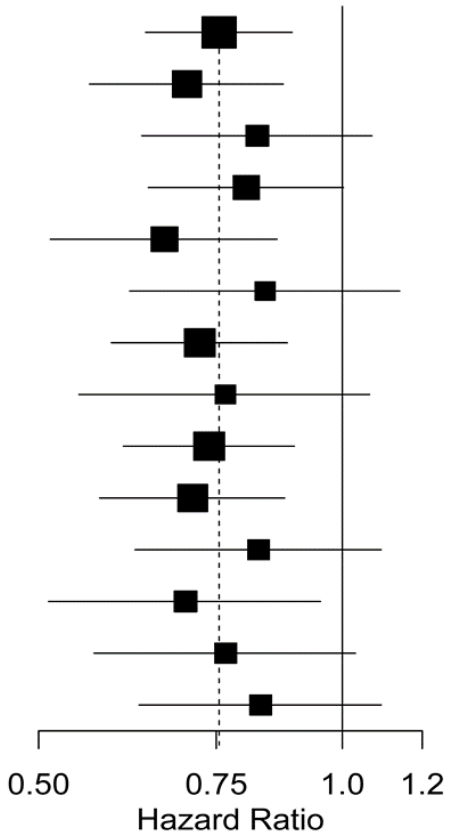
‡First occurrence of MI, acute coronary syndrome (ACS), stroke, heart failure, or death from CV causes

Sprint Research Group, et al *N Engl J Med.* 2015;373(22):2103-2106.

SPRINT: Subgroup Analyses of the Primary Endpoint

Subgroup	HR	P*
Overall	0.75 (0.64,0.89)	
No Prior CKD	0.70 (0.56,0.87)	0.36
Prior CKD	0.82 (0.63,1.07)	
Age < 75	0.80 (0.64,1.00)	0.32
Age ≥ 75	0.67 (0.51,0.86)	
Female	0.84 (0.62,1.14)	0.45
Male	0.72 (0.59,0.88)	
African−American	0.77 (0.55,1.06)	0.83
Non African−American	0.74 (0.61,0.90)	
No Prior CVD	0.71 (0.57,0.88)	0.39
Prior CVD	0.83 (0.62,1.09)	
SBP ≤ 132	0.70 (0.51,0.95)	0.77
132 < SBP < 145	0.77 (0.57,1.03)	
SBP ≥ 145	0.83 (0.63,1.09)	

*Unadjusted for multiplicity



Whelton PK. Systolic Blood Pressure Intervention Trial (SPRINT): principal results. https://www.sprinttrial.org/public/pubs/SPRINT_AHA.pptx
Sprint Research Group, et al *N Engl J Med.* 2015;373(22):2103-2106.

Key Takeaways

- Key Takeaway #3
  - SPRINT provides robust evidence that treating to lower BP goals (SBP < 120 mm Hg) is better than standard BP goals (SBP <140 mm Hg) in reducing CV events for certain high-risk patients

Lower BP Goals are Better

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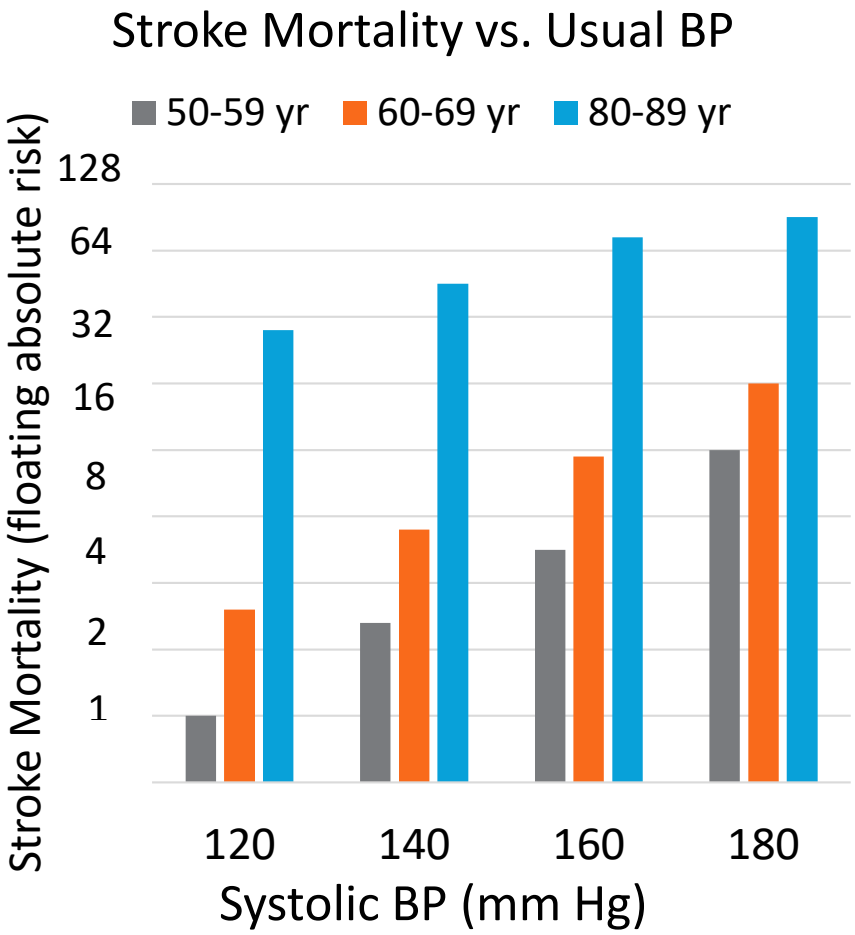
Relationship between BP and ASCVD

- Meta-analysis of patients with no baseline ASCVD
  - >1 million patients from 61 prospective studies
- As SBP ↑ >115 mm Hg
  - Mortality due to ischemic heart disease and stroke ↑
- Risk increases in all age groups
  - Older patients at *greater* baseline risk



Prospective Studies Collaboration. *Lancet.* 2002;360(9349):1903-1913.

SPRINT Outcomes and NNT

Outcome	Intensive Treatment N=4678; no.(%)	Standard Treatment N=4683; no.(%)	HR* (P-Value)	NNT†
Primary Outcome‡	243 (5.2)	319 (6.8)	0.75 (<0.001)	**61**
Secondary Outcomes				
Myocardial infarction	97 (2.1)	116 (2.5)	0.83 (0.19)	-
Acute coronary syndrome	40 (0.9)	40 (0.9)	1.00 (0.99)	-
Stroke	62 (1.3)	70 (1.5)	0.89 (0.50)	-
Heart failure	62 (1.3)	100 (2.1)	0.62 (0.002)	**123**
Death from CV causes	37 (0.8)	65 (1.4)	0.57 (0.005)	**172**
Death from any cause	155 (3.3)	210 (4.5)	0.73 (0.003)	**90**
Primary outcome or death	332 (7.1)	423 (9.0)	0.78 (<0.001)	**52**

* Hazard ratio

† Number needed to treat

‡First occurrence of MI, acute coronary syndrome (ACS), stroke, heart failure, or death from CV causes

Sprint Research Group. *Engl J Med.* 2015;373(22):2103-2106.

Does SPRINT apply to older patients?

Question 3: An 83 year-old patient presents to clinic for follow-up of elevated BP. At his last visit 3 weeks ago, his mean BP was 162/74 mm Hg. The readings today are unchanged, and consistent with home BP monitoring readings. The patient's PMH is significant for osteoarthritis and gout.

Which of the following BP goals is the MOST appropriate for this patient?

A <150/90 mm Hg

B <140/90 mm Hg

C <130/80 mm Hg

D <120/80 mm Hg

Question 3

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C <130/80 mm Hg

D <120/80 mm Hg

Goal BPs in Older Patients per Current Guidelines

- 60-80 years of age
  - <140/90 mm Hg
    - —ASH/ISH
    - —CHEP
    - —ESH/ESC
    - —NICE
  - <150/90 mm Hg
    - —JNC 8
- ≥ 80 years of age
  - <150/90 mm Hg
    - —ASH/ISH
    - —JNC 8
    - —ESH/ESC
    - —CHEP
    - —NICE

ASH/ISH: American Society of Hypertension/International Society of Hypertension
CHEP: Canadian Hypertension Education Program
ESH/ESC: European Society of Hypertension/European Society of Cardiology
JNC: Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
NICE: National Institute for Health and Care Excellence

SPRINT-Senior

- Objective: Evaluate effects of intensive (<120 mm Hg) compared with standard (<140 mm Hg) SBP in persons ≥75 yr with HTN
- Setting: Pre-planned subgroup analysis of SPRINT participants
- Patients:
  - Intensive group: N=1317
  - Standard group: N=1319
- Outcomes:
  - Primary: composite of MI, ACS not resulting in MI, nonfatal stroke, nonfatal acute decompensated HF, death from CV causes
  - Secondary: All-cause mortality

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82. doi: 10.1001/jama.2016.7050.

SPRINT-Senior

- Funded to enhance recruitment of older patients
- Included measures of functional status and frailty
- Exclusion criteria:
  - Diagnosis of or treatment of dementia
  - Expected survival <3 years
  - Unintentional weight loss >10% during preceding 6 mos.
  - SBP <110 mm Hg after 1 min of standing
  - Nursing home resident

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

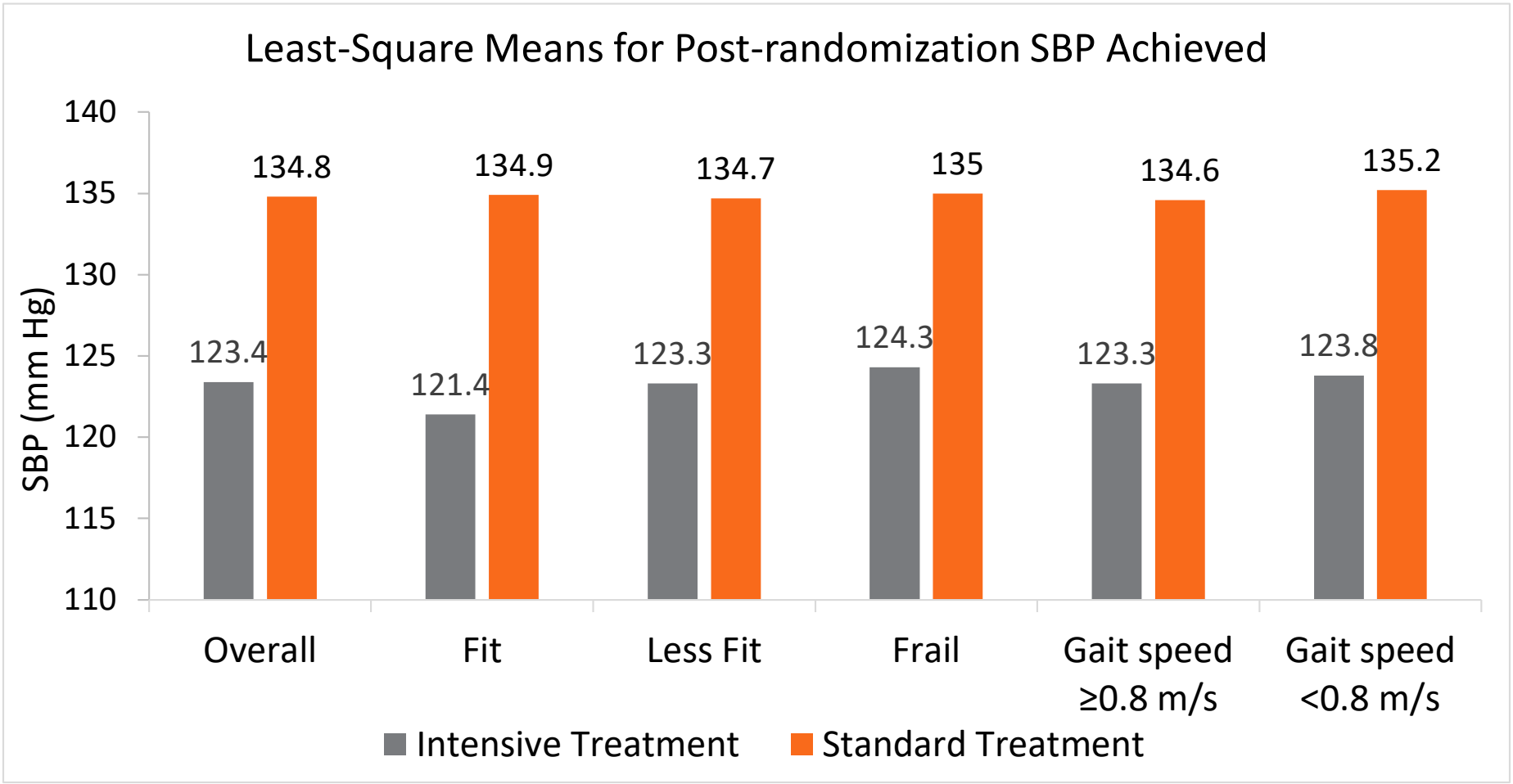
SPRINT-Senior Selected Baseline Characteristics

Characteristic	Intensive Treatment (n=1317)	Standard Treatment (n=1310)
Age, mean (SD), yr	79.8 (3.9)	79.9 (4.1)
Female sex	37.9%	38%
Seated SBP, mean (SD), mm Hg	141.6 (15.7)	141.6 (15.8)
Orthostatic hypotension	9.6%	9.4%
History of CVD	25.7%	23.4%
1-yr Framingham CVD risk, median	27.8%	25.0%
No. BP meds at baseline, mean (SD)	1.9 (1.0)	1.9 (1.0)
Gait speed, median (IQR), m/s	0.90 (0.77-1.05)	0.92 (0.77-1.06)
Frailty status*		
Fit (FI ≤ 0.10)	12.1%	14.4%
Less fit (FI >0.10 to ≤0.21)	54.0%	56.5%
Frail (FI >0.21)	33.4%	28.4%

*Measured using a 37-item frailty index (FI)

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

SBP Results: SPRINT-Senior



Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

Selected Outcomes: SPRINT-Senior

Outcome	Intensive Treatment 1317; no.(%)	Standard Treatment N=1319; no.(%)	HR (95% CI)*	NNT†
CVD Primary Outcome‡	102 (7.7)	148 (11.2)	0.66 (0.51-0.85)	**27**
Myocardial infarction	37 (2.8)	53 (4.0)	0.69 (0.45-1.05)	-
ACS not resulting in MI	17 (1.3)	17 (1.3)	1.03 (0.52-2.04)	-
Stroke	27(2.1)	34 (2.6)	0.72 (0.43-1.21)	-
Heart failure	35 (2.7)	56 (4.2)	0.62 (0.40-0.95)	**67**
CVD Death	18 (1.4)	29 (2.2)	0.60 (0.33-1.09)	-
Nonfatal heart failure	35 (2.7)	55 (4.2)	0.63 (0.40-0.96)	**67**
All-cause mortality	73 (5.5)	107 (8.1)	0.67 (0.49-0.91)	**41**
Primary outcome or death	144 (10.9)	205 (15.5)	0.68 (0.54-0.84)	**22**

*Hazard ratio and 95% confidence Interval

†NNT over mean of 3.41 years; reported CVD Primary Outcome and all-cause mortality indicated

‡Nonfatal MI, ACS not resulting in MI, nonfatal stroke, nonfatal acute decompensated HF, and death from CV causes

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

Primary Outcome by Frailty and Gait Speed

	Intensive Treatment No./Total with Outcome Events	Standard Treatment No./Total with Outcome Events	HR (95% CI)	P-Value	P Value for Interaction
Frailty*					
Fit	4/159	10/190	0.47 (0.13-1.39)	0.20	0.84
Less Fit	48/711	77/745	0.63 (0.43-0.91)	0.01	
Frail	50/440	61/375	0.68 (0.45-1.01)	0.06	
Gait Speed					
≥0.8 m/s	59/880	86/893	0.67 (0.47-0.94)	0.02	0.85
<0.8 m/s	34/371	54/369	0.63 (0.40-0.99)	0.05	
Missing	9/66	8/57	0.86 (0.33-2.29)	0.75	

*Classified using 37-item Frailty index (FI): fit (FI≤0.10), less fit (FI >0.10-0.21), or frail (FI >0.21).

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

Bottom line: SPRINT-Senior

- SBP Goal <120 mm Hg in patients >75 yr result in:
  - ↓ CVD by 33% (NNT=27)
  - ↓ Total mortality by 32% (NNT=41)
- *Greater* benefit estimates in seniors due to greater risk and higher event rates
- Exploratory analysis showed consistent benefits in *frail* and *reduced gait speed*
- Serious adverse events comparable, including by frailty level
- Raise serious concerns about higher BP goals for elderly advocated in current guidelines

Additional data that lower BP may be better?

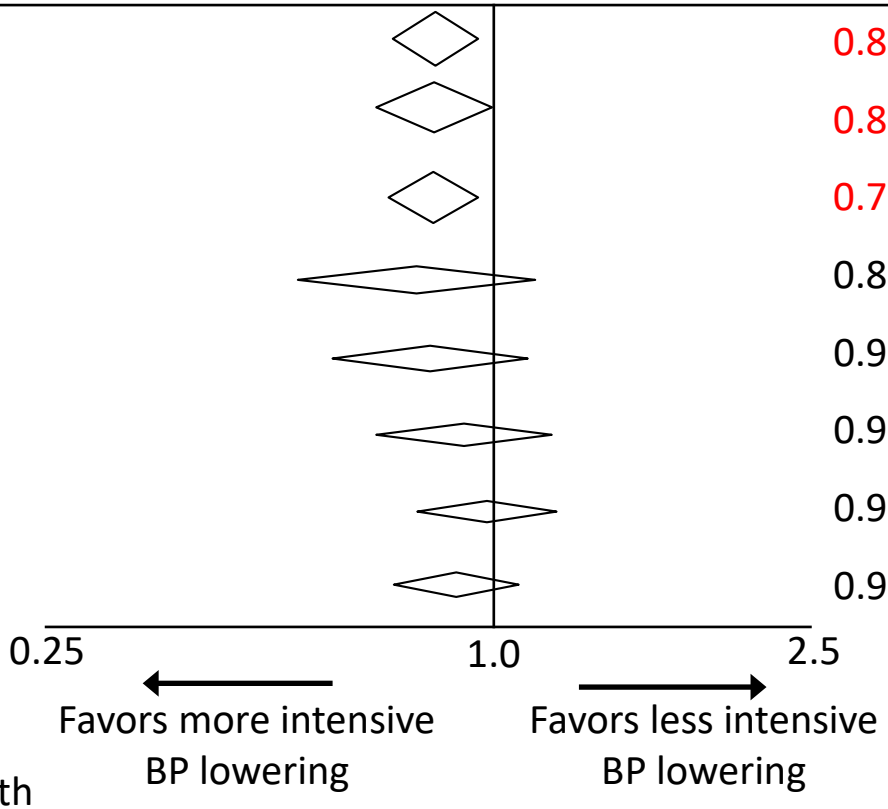
Effects of Intensive BP lowering on CV and renal outcomes

- Objective: Assess safety and efficacy of intensive BP-lowering
- Methods:
  - Updated systematic review and meta-analysis
  - More intensive vs. less intensive BP lowering compared
- Trials and Patients:
  - 19 trials including 44,989 participants; no age restrictions
  - 2,496 CV events recorded during mean follow-up of 3.8 yr.
  - Studies ≥6 mos. follow-up
- Outcomes:
  - Major CV events, non-vascular and all-cause mortality, stroke, HF, end-stage renal disease (ESRD), adverse events, albuminuria, progression of retinopathy

Xie X, et al. *Lancet.* 2016;387(10017):435-443.

Effects of Intensive vs. Less Intensive BP Lowering

Outcome	Trials (n)	BP Difference (mm Hg)	RR (95% CI)*
Major CV events†	14	–6.8/–3.5	0.86 (0.78–0.96)
MI	13	–6.6/–3.4	0.87 (0.76–1.00)
Stroke	14	–6.8/–3.5	0.78 (0.68–0.90)
Heart Failure	10	–7.2/–4.0	0.85 (0.66–1.11)
ESRD	8	–9.4/–5.1	0.90 (0.77–1.06)
CV Death	13	–6.9/–3.5	0.91 (0.74–1.11)
Non-CV Death	12	–6.9/–3.6	0.98 (0.86–1.13)
Overall mortality	19	–6.8/–3.5	0.91 (0.81–1.03)



* Confidence Interval

† Composite of MI, stroke, HF, or CV death

Xie X, et al. *Lancet.* 2016;387(10017):435-443.

If lower BP goals are better, what cutoff values should be used?

Effects of more vs. less intensive BP lowering and different achieved BP levels – updated meta-analysis

- Objective: Identify ideal target BPs in antihypertensive treatment
- Methods:
  - Updated meta-analysis that includes SPRINT
  - More intensive vs. less intensive BP lowering
- Trials and Patients:
  - 16 hypertension trials including 52,235 participants
  - Studies ≥6 mos. follow-up
- Outcomes: Fatal and non-fatal events

Thomopoulos C, et al. *J Hypertens.* 2016;34:613-622.

Effects of BP lowering in trials of active treatment vs. placebo and more vs. less intense treatment*

Outcome	Achieved SBP cutoff (mm Hg)	Trials (n)	Standardized RR† (95% CI)	Absolute RR 1000 pts/5 yr	P-value for trend
Stroke	140–149 vs. ≥150 130–139 vs. ≥140 <130 vs. ≥130	8 15 7	0.68 (0.60–0.79) 0.62 (0.51–0.76) 0.71 (0.61–0.84)	-20 -16 -8	<0.001
CHD	140–149 vs. ≥150 130–139 vs. ≥140 <130 vs. ≥130	8 16 8	0.81 (0.68–0.95) 0.77 (0.70–0.86) 0.86 (0.76–0.97)	-6 -8 -8	0.35
HF	140–149 vs. ≥150 130–139 vs. ≥140 <130 vs. ≥130	7 10 5	0.52 (0.41–0.65) 0.75 (0.35–1.59) 0.81 (0.51–1.30)	-21 -4 -6	0.11
All-Cause Death	140–149 vs. ≥150 130–139 vs. ≥140 <130 vs. ≥130	8 16 9	0.89 (0.82–0.96) 0.83 (0.72–0.96) 0.84 (0.73–0.95)	-16 -10 -10	0.008

* SBP stratification by active or more intensive treatment vs. mean SBP achieved in placebo or less intense treatment

† Standardized RR is to a SBP/DBP difference of -10/-5 mmHg

Thomopoulos C, et al. *J Hypertens.* 2016;34:613-622.

Key Takeaways

- Key Takeaway #4
  - Higher BP goals for older patients in current guidelines not supported by contemporary evidence

- Key Takeaway #5
  - Newer, updated meta-analyses support lower BP goals

Standard BP Goals should be Used

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Is it safe to lower BP using more intensive goals vs standard goals?

SPRINT Safety Outcomes and NNH

Outcome	Intensive Treatment N=4678; no.(%)	Standard Treatment N=4683; no.(%)	HR* (P-Value)	NNH†
Serious Adverse Event (SAE)‡	1793 (38.3)	1736 (37.1)	1.04 (0.25)	--
Individual SAEs				
Hypotension	110 (2.4)	66 (1.4)	1.67 (0.001)	**100**
Syncope	107 (2.3)	80 (1.7)	1.33 (0.05)	-
Bradycardia	87 (1.9)	73 (1.6)	1.19 (0.28)	--
Electrolyte abnormality	144 (3.1)	107 (2.3)	1.35 (0.02)	**125**
Injurious fall	105 (2.2)	110 (2.3)	0.95 (0.71)	--
Acute kidney injury or acute renal failure	191 (4.3)	117 (2.5)	1.66 (<0.001)	**56**

* Hazard ratio

† Number needed to harm/3.3 years

‡A serious adverse event was defined as an event that was fatal or life-threatening or that resulted in clinically significant or persistent disability

Sprint Research Group, et al *N Engl J Med.* 2015;373(22):2103-2106.

SPRINT Safety Outcomes and NNH

Outcome	Intensive Treatment N=4678; no.(%)	Standard Treatment N=4683; no.(%)	HR* (P-Value)	NNH†
Emergency department visit or SAE				
Hypotension	158 (3.4)	93 (2.0)	1.70 (<0.001)	**72**
Syncope	163 (3.5)	113 (2.4)	1.44 (0.003)	**91**
Bradycardia	104 (2.2)	83 (1.8)	1.25 (0.13)	--
Electrolyte abnormality	177 (3.8)	129 (2.8)	1.38 (0.006)	**100**
Injurious fall	334 (7.1)	332 (7.1)	1.00 (0.97)	--
Acute kidney injury or acute renal failure	204 (4.4)	120 (2.6)	1.71 (<0.001)	**56**

* Hazard ratio

† Number needed to harm/3.3 years

‡A serious adverse event was defined as an event that was fatal or life-threatening, that resulted in clinically significant or persistent disability

Sprint Research Group, et al *N Engl J Med.* 2015;;373(22):2103-2106.

Is standard BP lowering safer than intensive BP lowering in the elderly?

SPRINT-Senior Safety Outcomes

Outcome	Intensive Treatment N=1317; no.(%)	Standard Treatment N=1319; no.(%)	HR* (P-Value)	NNH†
Serious Adverse Event (SAE)‡	637 (48.4)	637 (48.3)	0.99 (0.895)	--
Individual SAEs				
Hypotension	32 (2.4)	19 (1.4)	1.71 (0.066)	--
Syncope	39 (3.0)	32 (2.4)	1.23 (0.401)	--
Bradycardia	38 (2.9)	40 (3.0)	0.89 (0.610)	--
Electrolyte abnormality	53 (4.0)	36 (2.7)	1.51 (0.058)	--
Injurious fall	65 (4.9)	73 (5.5)	0.91 (0.605)	--
Acute kidney injury or acute renal failure	72 (5.5)	53 (4.0)	1.41 (0.061)	--

* Hazard ratio

† Number needed to harm/3.3 years

‡A serious adverse event was defined as an event that was fatal or life-threatening or that resulted in clinically significant or persistent disability

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.

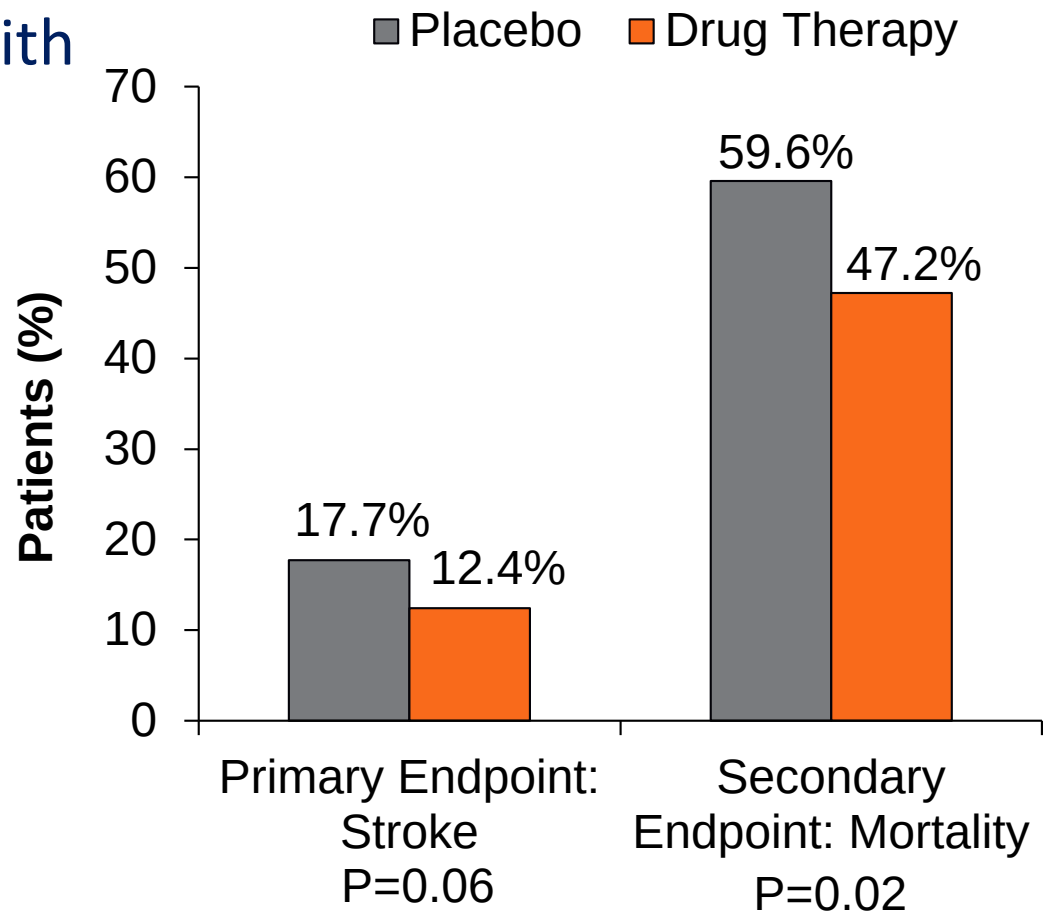
Trials Evaluating BP Treatment Goals in Elderly

Trial	Mean Age (yr)	Age Range (yr)
HYVET	83	80-105
Syst-Eur	70	60+
SHEP	72	60+
JATOS	73	65-85
VALISH	75	70-84
SPRINT (pre-specified subgroup)	79	75-84

Williamson JD, et al. *JAMA.* 2016;315(24):2673-82.
James PA et al. *JAMA*. 2014; 311:507-20.

Hypertension in the Very Elderly Trial (HYVET)

- 3845 patients ≥80 yr with hypertension
- Randomized, double-blind to:
  - Placebo or
  - Perindopril +/- Indapamide
- Stopped early after 1.8 years



Beckett NS, et al. *N Engl J Med* 2008;358:1887-98.

Question #4

A 65 year-old male with chronic hypertension presents to the clinic for follow-up on his blood pressure. The patient's PMH is significant for gout, diabetes mellitus, stage 3 CKD, and an MI 3 years ago. His current BP is 146/80 mm Hg and he takes amlodipine 10 mg daily and lisinopril 40 mg daily.

Which of the following would exclude him from meeting the SPRINT Trial Criteria?

A. Stage 3 CKD

B. Diabetes mellitus

C. MI 3 years ago

D. Gout

Question #4

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Which of the following would exclude him from meeting the SPRINT Trial Criteria?

A. Stage 3 CKD

B. **Diabetes mellitus**

C. MI 3 years ago

D. Gout

Who do the SPRINT results not apply to?

SPRINT Exclusion Criteria

- Secondary HTN
- Proteinuria ($\geq$ 1 g/day)
- Diabetes mellitus
- History of stroke
- CV event within 3 months
- Symptomatic HF within 6 months or EF < 35%
- Polycystic kidney disease
- Glomerulonephritis
- eGFR < 20 mL/min/1.73m^2 or ESRD

How does automated office blood pressure (AOBP) compare to manual auscultatory blood pressure measurement?

Automated Office Blood Pressure (AOBP) Measurement

- AOBP
  - More accurate than manual office BP measurement
  - More closely related to awake ambulatory and home BP
- Omron HEM-907 (used in ONTARGET, ACCORD, and SPRINT)
  - In SPRINT patients resting alone in an examining room
  - Protocol included a 5-min rest period before the device was activated to record three BP readings automatically, at 1-min intervals.
  - AOBP measurement used in SPRINT is similar to AOBP as performed in other studies using BpTRU

Myers MG. *J Clin Hypertens* 2016;18:721-24.

AOBP vs. Manual BP

- Systolic/diastolic BP measured in research studies was on average 10/7 mm Hg lower than BP measured in routine clinical practice
- If standard office BP measurement used without a resting period and without automatic cycling of measurements
  - Adjust SBP goal 5-10 mmHg higher than the BP trials using AOBP
- Application of the SPRINT intensive BP targets
  - Correspond to a SBP target range of 125-135 mmHg to be similar to the level of BP control achieved in the SPRINT intensive BP group

Armstrong D. *Blood Press Monit.* 2015;20:204-8.

Bakris GL. *Circulation*. 2016 Aug 30. pii: CIRCULATIONAHA.116.022536.

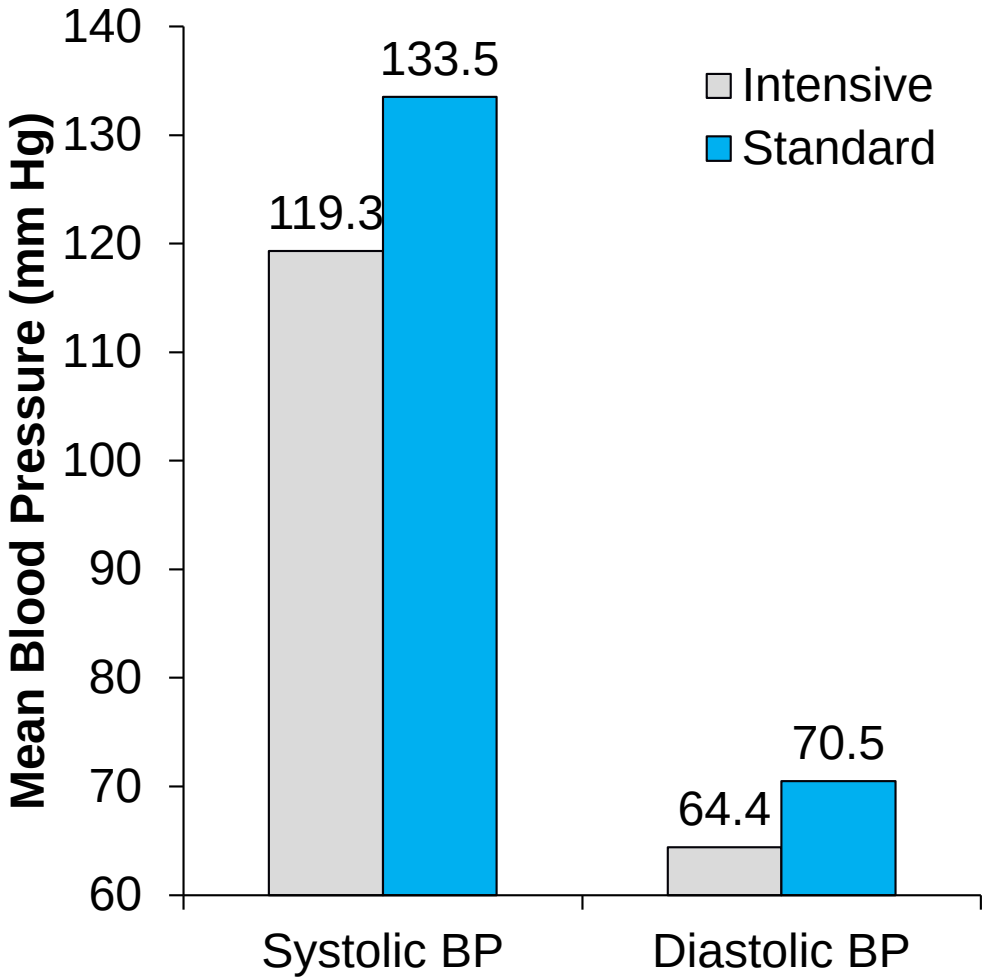
How about intensive vs. standard BP lowering in other subpopulations?

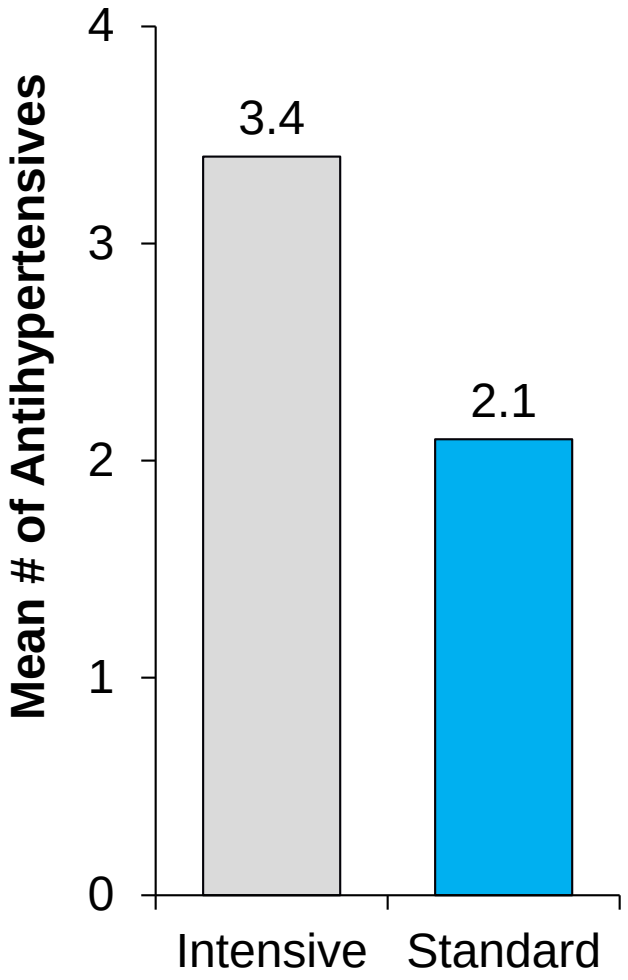
The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Blood Pressure Trial

- Randomized, open-label, multicenter trial
- Intensive (SBP <120 mm Hg) vs. standard (SBP < 140 mm Hg) BP lowering
- 4733 patients with hypertension and:
  - Stable type 2 diabetes and high CVD risk
  - 40-79 years if established clinical CVD, or 55-79 years if ≥ 2 CV risks or subclinical CVD
- Primary Outcome:
  - Nonfatal MI, nonfatal stroke, or CV death

Cushman WC, et al. *N Engl J Med* 2010;362:1575-85.

ACCORD: Results at year 1





Cushman WC, et al. *N Engl J Med* 2010;362:1575-85.

ACCORD: Primary & 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
CV Death	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**

NNT for nonfatal stroke = 589/year
NNT for total stroke = 477/year

Cushman WC, et al. *N Engl J Med.* 2010;362:1575-85.

ACCORD-BP vs. SPRINT

	ACCORD-BP	SPRINT
SBP Target (mm Hg)	< 120 vs. < 140	< 120 vs. < 140
Inclusion	Diabetes SBP 130-180 mm Hg	No Diabetes SBP 130-180 mm Hg
Age	Age ≥ 40 with CVD Age > 55 + one of the following: • Atherosclerosis • Albuminuria • Left ventricular hypertrophy • ≥ 2 risk factors	Age ≥ 50 + one of the following: • CVD • CKD • Framingham risk score ≥ 15% Age ≥ 75
Key Exclusion		Stroke and HF
Primary Outcome	MI, Stroke, CV death*	MI, ACS, Stroke, HF, CV Death
Prespecified Secondary Outcomes	Primary + Revascularization or HF HF Individual Major CV Events	Primary + All-Cause Death All-Cause Death Individual Major CV Events

*Underpowered to detect a different in primary CV outcome

Sprint Research Group, et al *N Engl J Med.* 2015;373(22):2103-2106.

Cushman WC, et al. *N Engl J Med.* 2010;362:1575-85.

2016 ADA Standards of Medical Care in Diabetes: Hypertension

"People with diabetes and hypertension should be treated to a systolic blood pressure goal of **<140 mm Hg** and diastolic blood pressure goal of **< 90 mm Hg**." (A)

"Lower systolic targets, such as <130 mm Hg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden." (C)

"Patients with diabetes should be treated to a DBP of **<80 mm Hg**." (B)

American Diabetes Association. *Diabetes Care.* 2016;39 (suppl 1):s60-s71.

Cardiovascular Events and Mortality Relative to Average BP in CAD Patients

- Prospective observational study
- Stable CAD + HTN (N=22,672)
- Primary Outcome: CV death, MI, or stroke
- SBP: (< 120 mm Hg) vs (120-129 mm Hg)
  - HR = 1.56 (95% CI: 1.36 - 1.81)
- DBP: (< 60 mm Hg) vs (70-79 mm Hg)
  - HR = 2.01 (95% CI: 1.50 - 2.70)
- DBP: (60-69 mm Hg) vs (70-79 mm Hg)
  - HR = 1.41 (95% CI: 1.24 - 1.61)

Vidal-Petiot E, et al. *Lancet*. 2016 Aug 26. pii: S0140-6736(16)31326-5.

2015 AHA/ACC/ASH SCIENTIFIC STATEMENT: HTN in Patients With CAD

BP Goal (mm Hg)	Condition	Class/LOE
< 140/90	CAD ACS HF	IIa/B IIa/B IIa/B
<130/80	CAD Clinical ASCVD	IIb/B IIb/B

ACC = American College of Cardiology
LOE = Level of Evidence

Rosendorff C et al. *J Am Coll Cardiol* 2015;65:1998–2038.

Key Takeaways

- Key Takeaway #6
  - BP goal of < 140/90 mm Hg still appropriate for most patients with hypertension
- Key Takeaway #7
  - If using standard office BP measurement without a resting period or automatic cycling of measurements, use target SBP 5-10 mmHg higher than clinical trials (e.g., SPRINT)

Complex Case Discussion

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Case 1

- RP is a 57-year-old African-American man with a history of type 2 diabetes that is treated with metformin 1000 mg po twice daily. His current A1C is 6.8%. His BP is 156/90 mm Hg, which is similar to his previous values. He is a smoker (1 ppd), is obese, and drinks 2 alcoholic beverages weekly.
- He is diagnosed with hypertension and is started on lisinopril and eventually hydrochlorothiazide. After titration to lisinopril/hydrochlorothiazide 40/25 mg po daily (fixed-dose combination), his BP is 134/84 mm Hg.

Case 1:

Question 5: Which of the following lifestyle modifications should be recommended in him to specifically lower his BP?

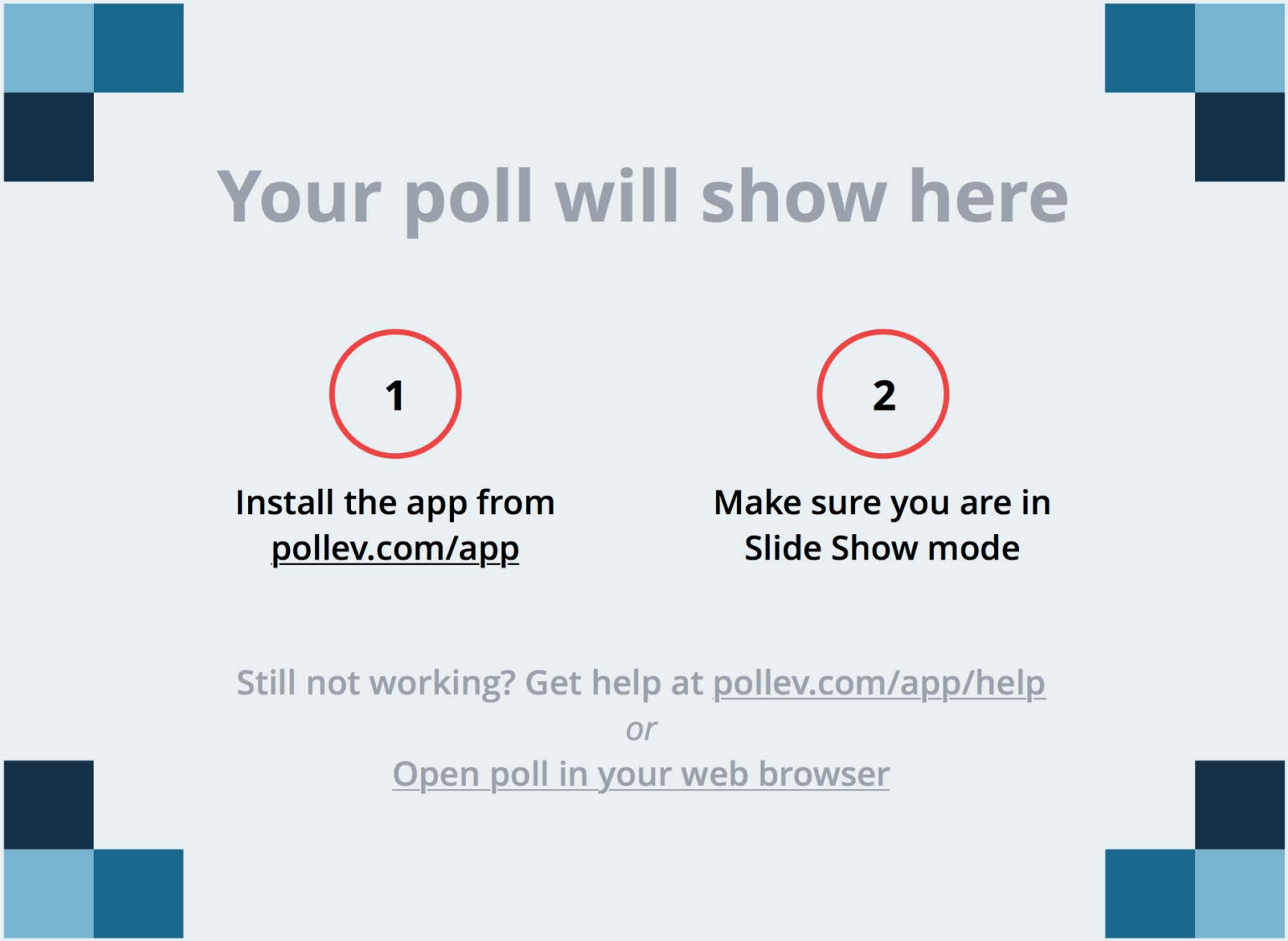
A Weight loss

B Smoking cessation

C Alcohol restriction

D All of the above

Question 5 – Case 1:



Case 1:

Question 5: Which of the following lifestyle modifications should be recommended in him to specifically lower his BP?

A **Weight loss**

B Smoking cessation

C Alcohol restriction

D All of the above

Case 1:

Question 6: Which of the following BP goals is the MOST appropriate for this patient?

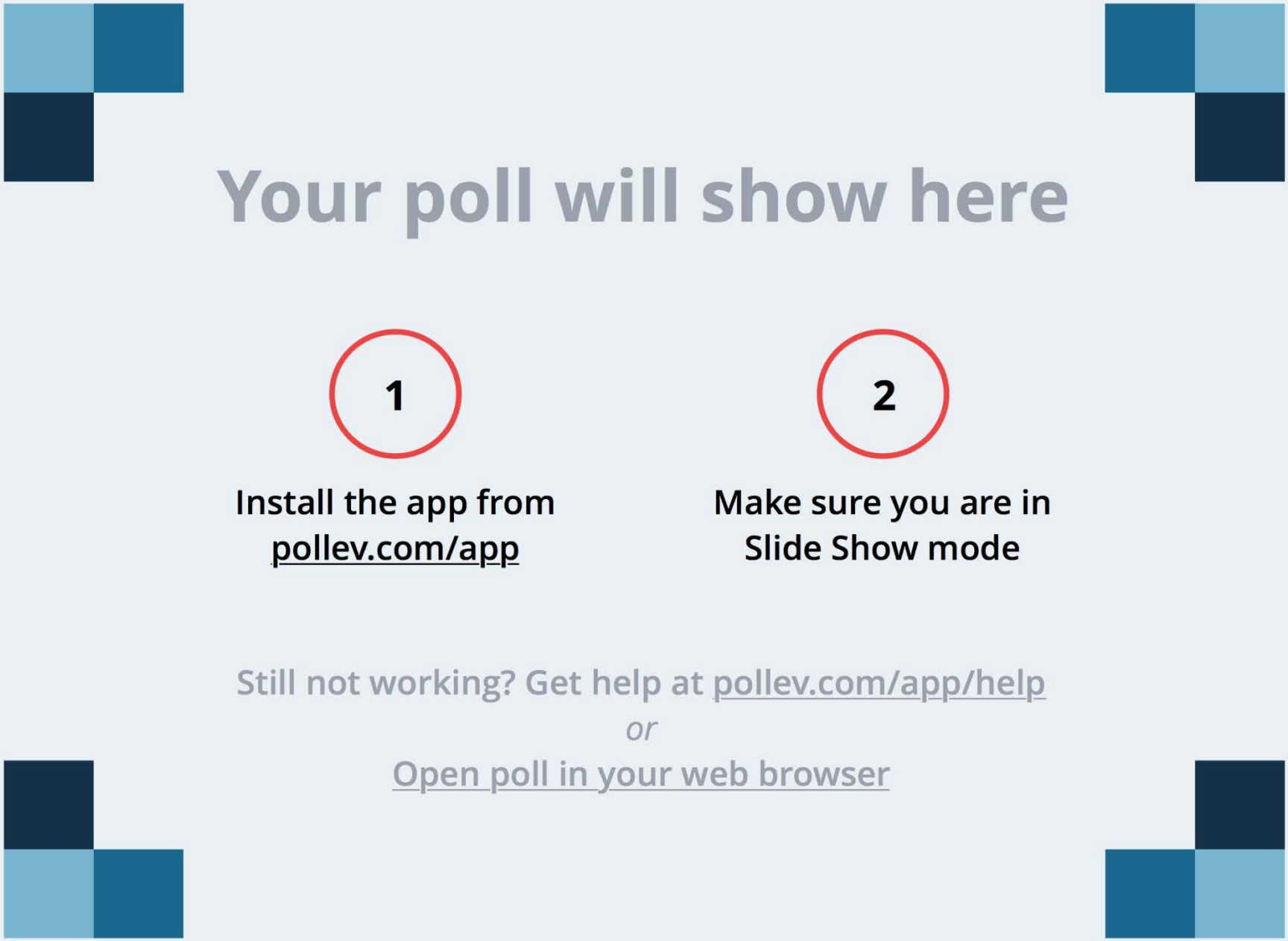
A <150/90 mm Hg

B <140/90 mm Hg

C <130/80 mm Hg

D <120/80 mm Hg

Question 6 – Case 1:



Case 1:

Question 6: Which of the following BP goals is the MOST appropriate for this patient?

A <150/90 mm Hg

B <140/90 mm Hg

C <130/80 mm Hg

D <120/80 mm Hg

Case 1:

Question 7: Which of the following is your greatest concern regarding treating this patient to a BP goal that is lower than the traditional < 140/90 mm Hg?

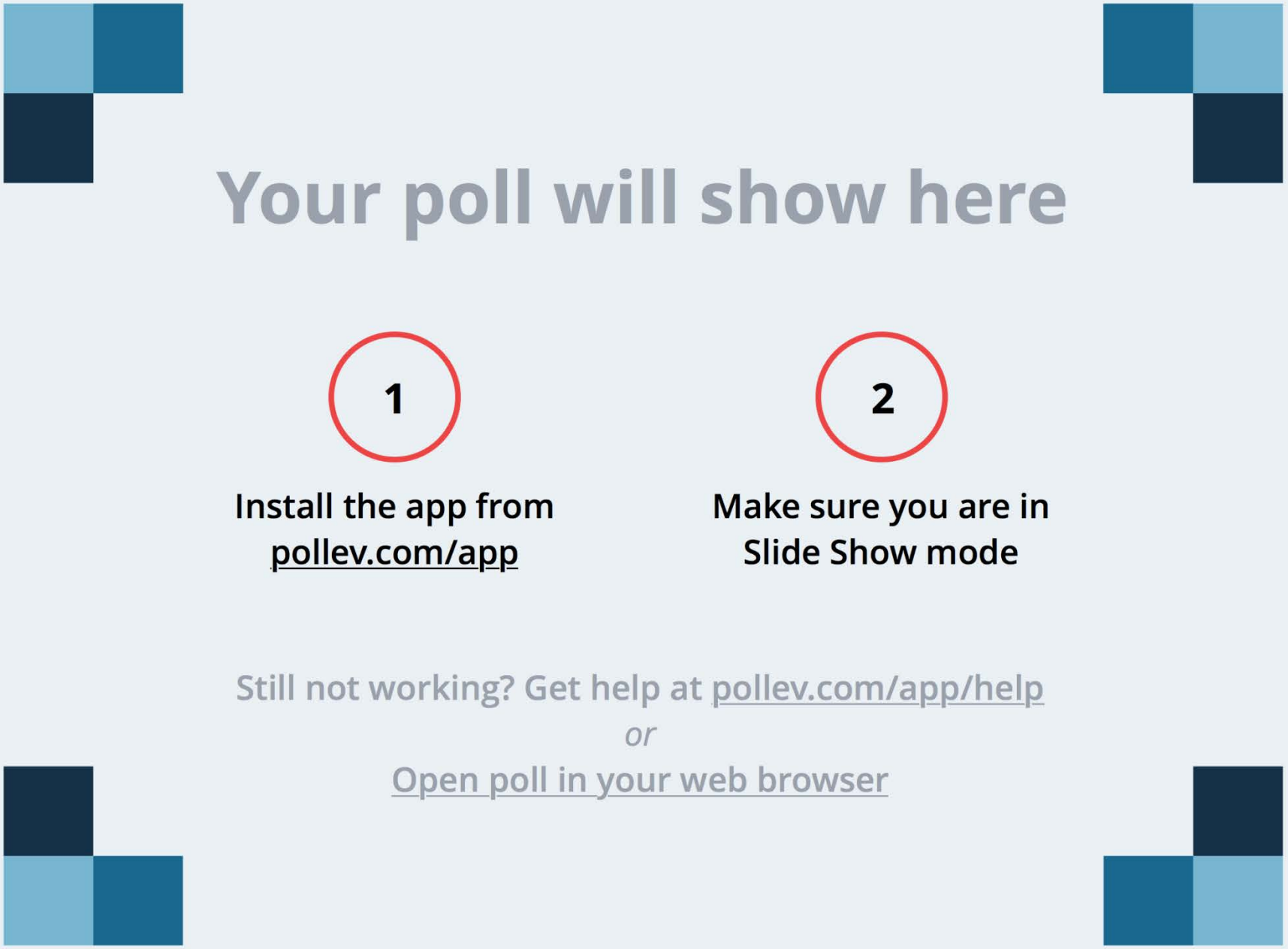
A. Lack of proven benefit that lower is better

B. Increased risk of orthostatic hypotension

C. Higher cost of therapy needed for intensive BP lowering

D. Risk of worsened glycemic control

Question 7 – Case 1:



Case 1:

Question 7: Which of the following is your greatest concern regarding treating this patient to a BP goal that is lower than the traditional < 140/90 mm Hg?

- A **Lack of proven benefit that lower is better**
- B **Increased risk of orthostatic hypotension**
- C Higher cost of therapy needed for intensive BP lowering
- D Risk of worsened glycemic control

Case 1:

Question 8: Upon further investigation, this patient reports an annoying dry cough. He thinks it is from his antihypertensive medication. Which of the following is the most appropriate replacement for his current lisinopril/hydrochlorothiazide?

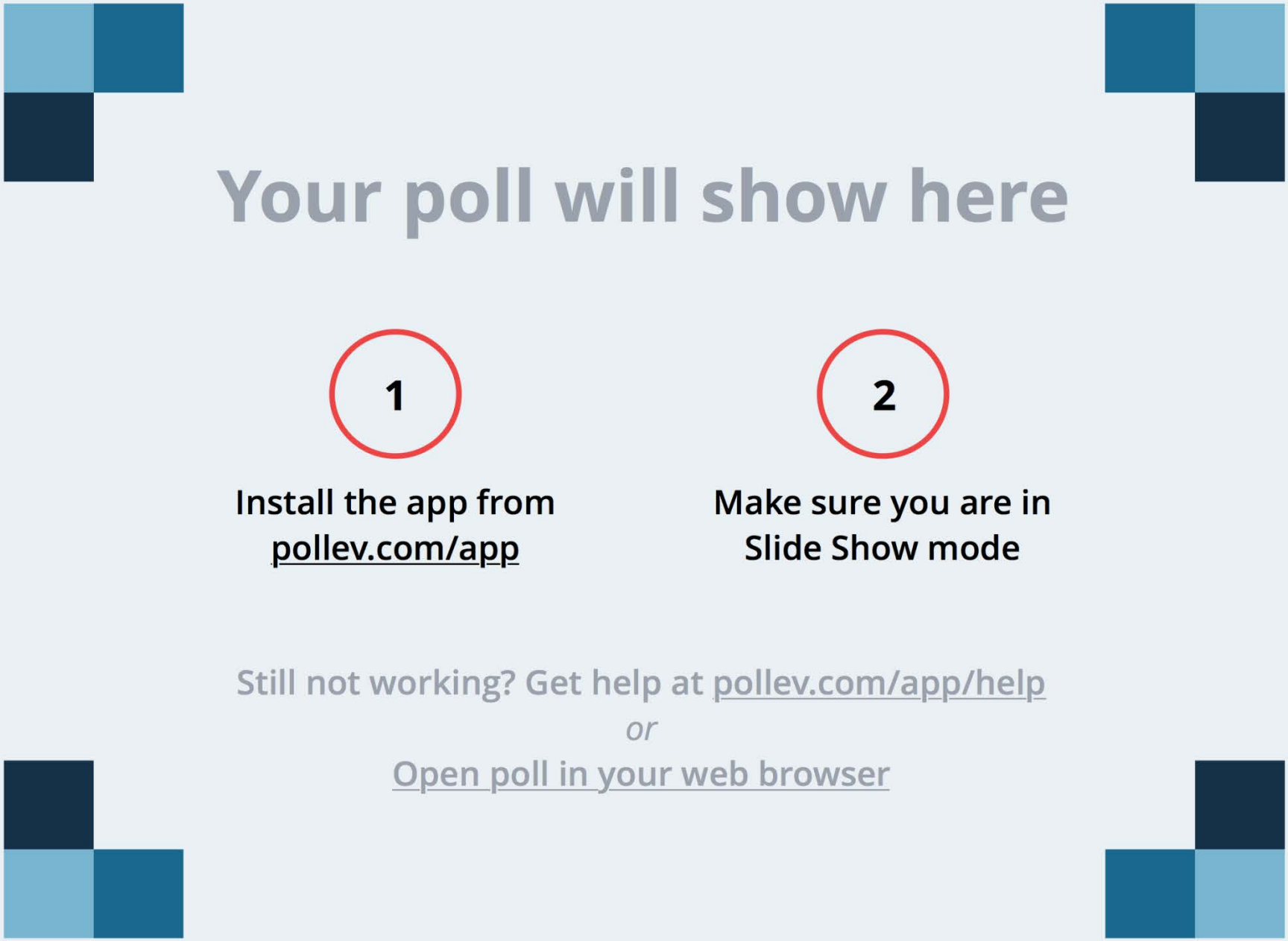
A Chlorthalidone

B Hydrochlorothiazide with amlodipine

C Hydrochlorothiazide/valsartan

D Amlodipine/olmesartan

Question 8 – Case 1:



Case 1:

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A Chlorthalidone

B Hydrochlorothiazide with amlodipine

C Hydrochlorothiazide/valsartan

D **Amlodipine/olmesartan**

Case 2

- An 81-year-old woman with a long-standing history of hypertension is currently treated with chlorthalidone 25 mg po daily and felodipine 5 mg po daily. She feels great, and other than dyslipidemia and osteoporosis (both well controlled on atorvastatin and alendronate) she is quite healthy.
- While on her current antihypertensive regimen, her BP is 144/80 mm Hg. She follows a strict low-sodium diet, has a BMI of 20 kg/m^2, and exercises 4 times a week (swimming for 30 minutes).

Case 2:

Question 9: Based on her current antihypertensive regimen, what potential drug-related side effect is she at risk for?

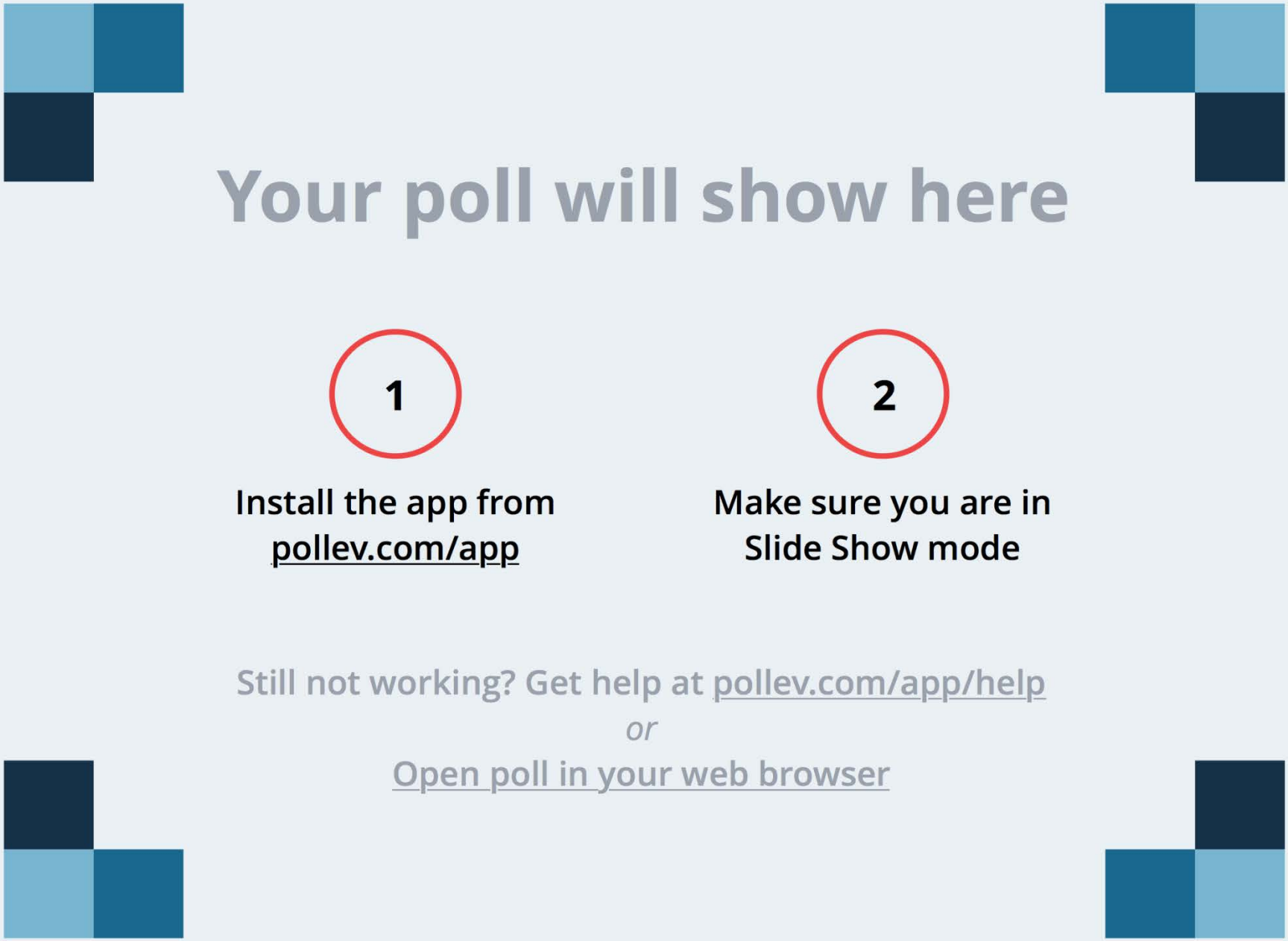
A Bradycardia

B Hyperkalemia

C Kidney stones

D Hyponatremia

Question 9 – Case 2:



Case 2:

Question 9: Based on her current antihypertensive regimen, what potential drug-related side effect is she at risk for?

A Bradycardia

B Hyperkalemia

C Kidney stones

D **Hyponatremia**

Case 2:

Question 10: Which of the following BP goals is the MOST appropriate for this patient?

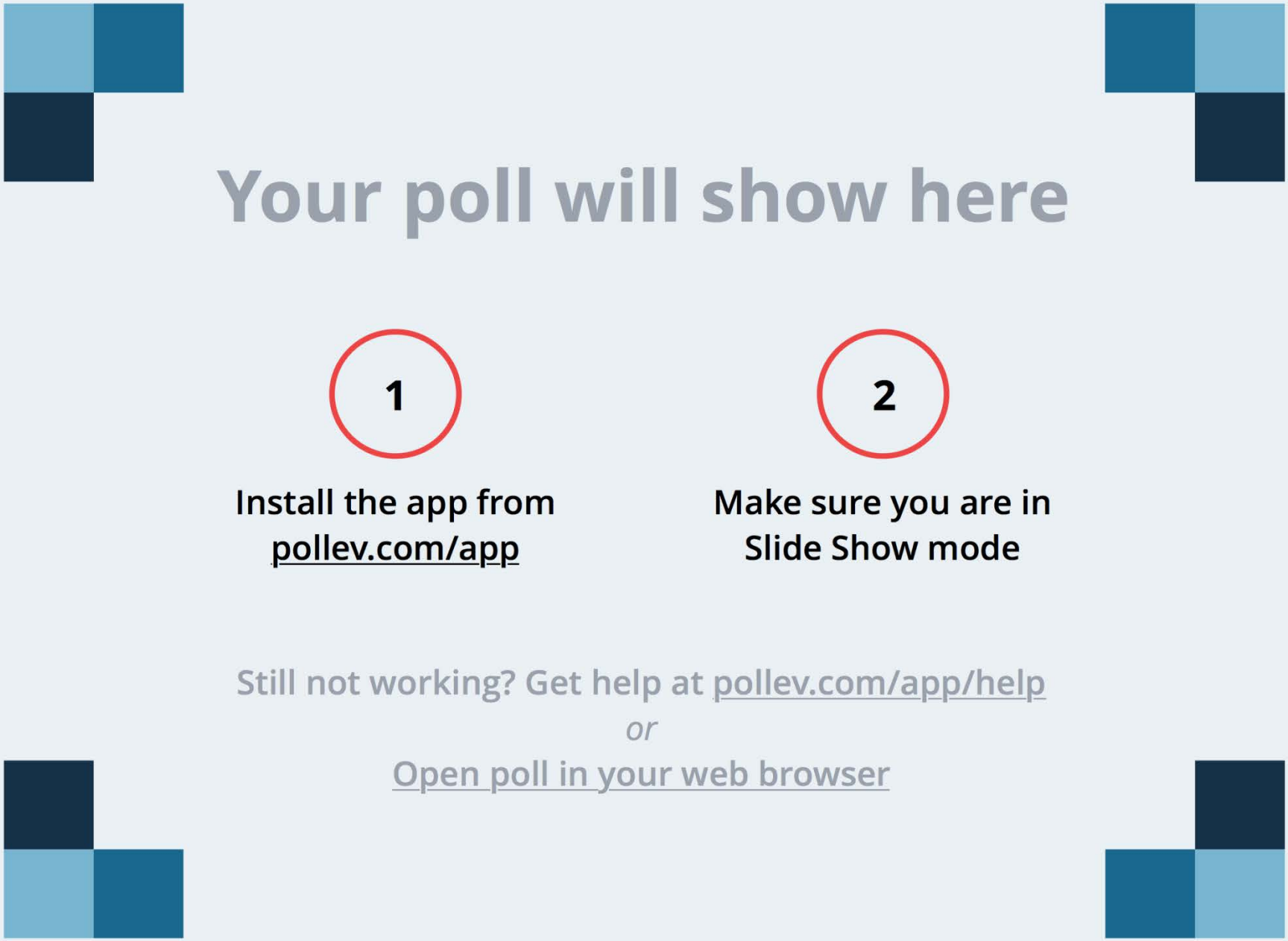
A <150/90 mm Hg

B <140/90 mm Hg

C <130/80 mm Hg

D <120/80 mm Hg

Question 10 – Case 2:



Case 2:

Question 10: Which of the following BP goals is the MOST appropriate for this patient?

A <150/90 mm Hg

B <140/90 mm Hg

C <130/80 mm Hg

D <120/80 mm Hg

Case 2:

Question 11: Which of the following is your greatest concern regarding additional BP lowering?

A. Lack of proven benefit that lower is better
B. Increased risk of orthostatic hypotension
C. Higher cost of therapy needed for intensive BP lowering
D. Risk of worsened glycemic control

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Case 2:

Question 11: Which of the following is your greatest concern regarding additional BP lowering?

A **Lack of proven benefit that lower is better**

B **Increased risk of orthostatic hypotension**

C Higher cost of therapy needed for intensive BP lowering

D Risk of worsened glycemic control

Management Case

- Assume that you are an ambulatory care clinical pharmacist working in a primary care internal medicine clinic. Your scope of practice broadly includes direct patient care services.
- The clinical pharmacy services provided include managing chronic diseases under collaborative drug therapy management (CDTM) protocols.
- You currently have CDTM protocols for hypertension, dyslipidemia, and diabetes. You are currently starting in the process of annually updating your hypertension CDTM, and it must reflect current evidence, including the SPRINT findings.

Question 12: In your CDTM protocol, which BP goals will you include assuming that your clinic sees a typical internal medicine population?

A < 120/80 mm Hg

B < 140/90 mm Hg

C < 150/90 mm Hg

D A and B

E A, B and C

Question 12

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Question 12: In your CDTM protocol, which BP goals will you include assuming that your clinic sees a typical internal medicine population?

A < 120/80 mm Hg

B < 140/90 mm Hg

C < 150/90 mm Hg

D A and B

E **A, B and C**

Question 13: In your CDTM protocol, did you include preferential use of chlorthalidone instead of hydrochlorothiazide?

A Yes

B No

C Did not think about it

Question 13

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Question 13: In your CDTM protocol, did you include preferential use of chlorthalidone instead of hydrochlorothiazide?

A Yes

B No

C Did not think about it

Question 14: In your CDTM protocol, did you include specific drug therapy considerations for patients with resistant hypertension?

A Yes

B No

C Did not think about it

Question 14

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Question 14: In your CDTM protocol, did you include specific drug therapy considerations for patients with resistant hypertension?

A Yes

B No

C Did not think about it

Management Case Discussion

Think/Pair/Share:

- What BP goals will you use and in which populations will they apply?
- What criteria will you use to safely implement therapy for patients with a SBP goal of < 120 mm Hg?
- Which specific medications will you include in your CDTM protocol?

American Heart Association/American Stroke Association Newsroom:

Hypertension Guideline Writing Process Underway

- Multi-disciplinary writing panel led by ACC/AHA
- Guidelines for the management of hypertension to update 12-year-old recommendations
- Nine additional medical societies are partners
- The writing process will include the use of a separate evidence review committee that will develop a systematic review on specific critical questions, which will inform recommendations in the 2016 Guideline on the Management of Hypertension
- Will update the 2003 guideline, officially the JNC 7, which was empaneled by the National Heart Lung and Blood Institute

American Heart Association/American Stroke Association. Hypertension guideline writing process underway. February 17, 2014. http://newsroom.heart.org/news/hypertension-guideline-writing-process-underway.

Final Takeaways

- Key Takeaway #1
  - ACEi, ARB, CCB, and thiazide are first line
- Key Takeaway #2
  - SPRINT provides robust evidence that treating to lower BP goal is better at reducing CV events than standard BP goal in certain high-risk patients
- Key Takeaway #3
  - Higher BP goals for older patients are not supported by contemporary evidence
- Key Takeaway #4
  - BP goal of < 140/90 mm Hg still appropriate for most patients and standard office BP measurement can adjust measurement

Questions?