

PHASE Safety Net Community Benefit

Hypertension: 2016 Clinical Update



Presented by:

Joseph Young, MD
Hypertension Clinical Lead
Kaiser Permanente Northern California

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Dr. Joseph Young

Hypertension Clinical Lead, Kaiser Permanente Northern California

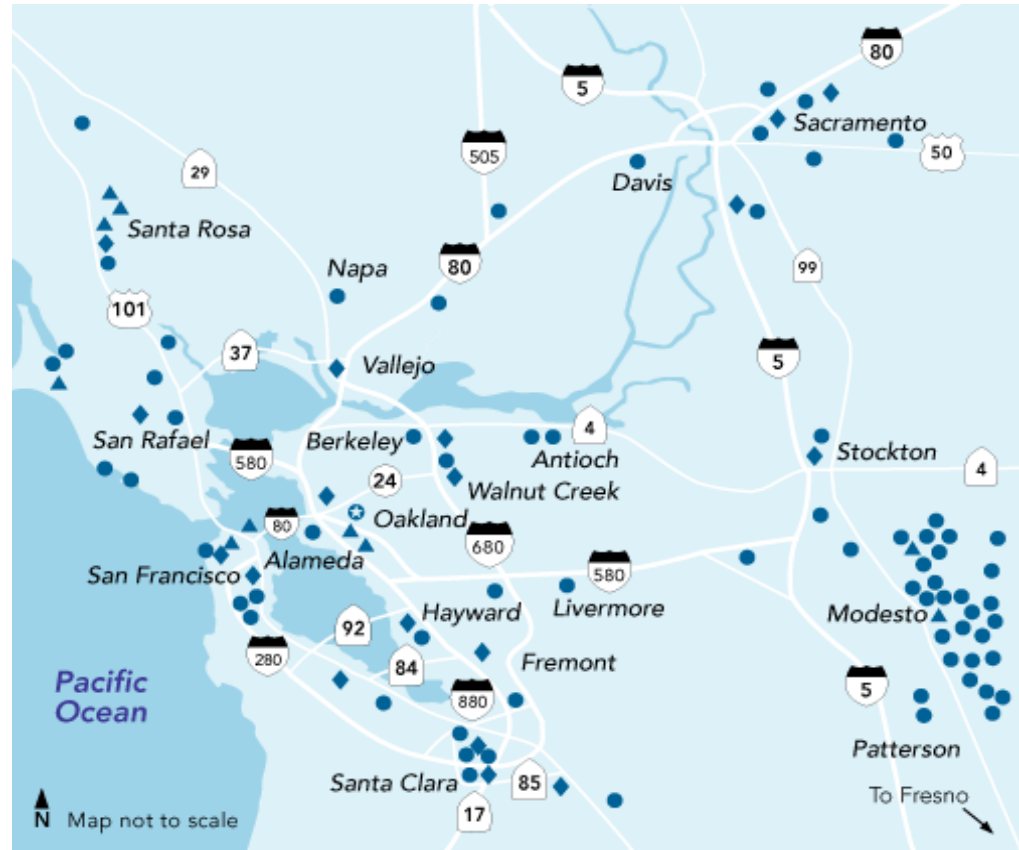


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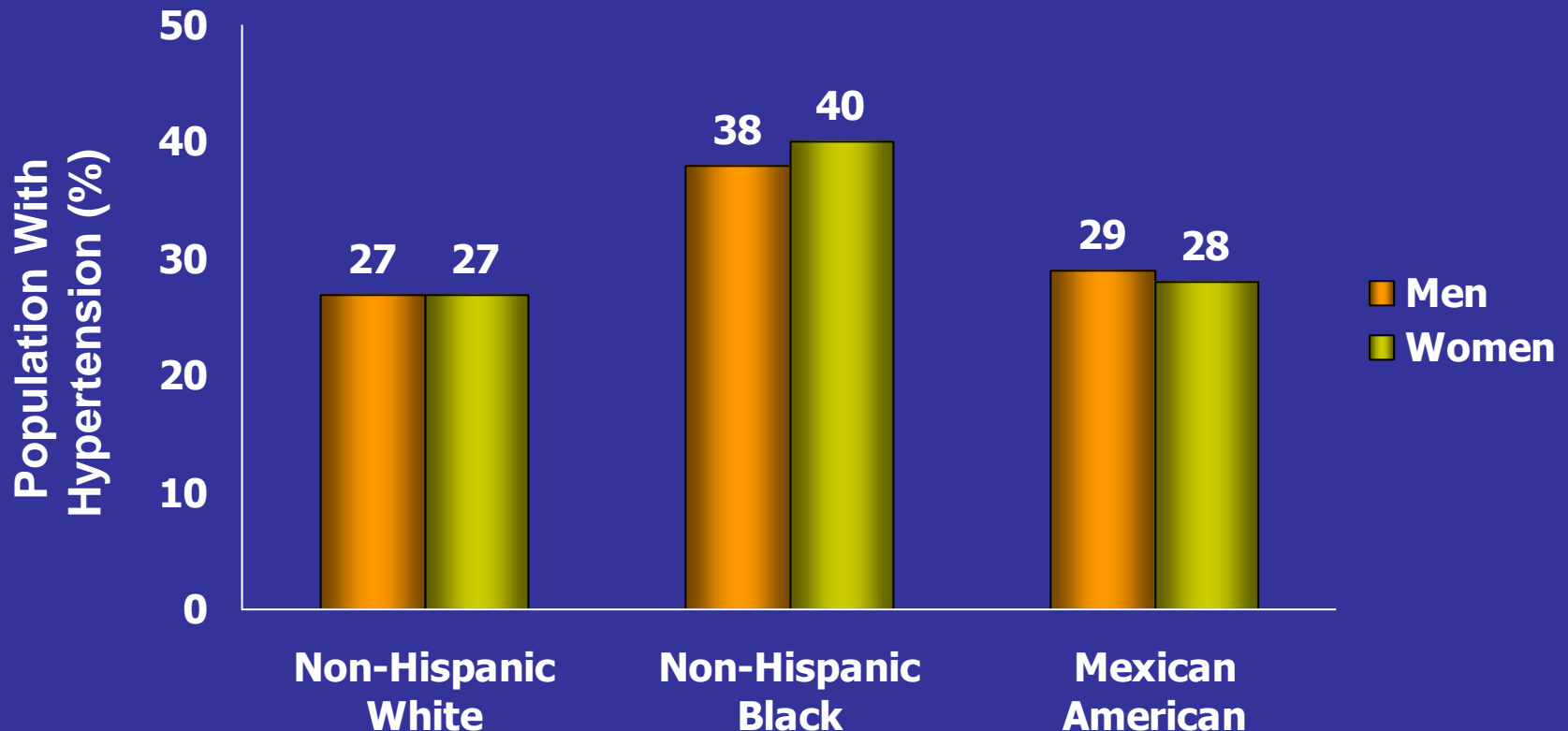
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Kaiser Permanente Northern California

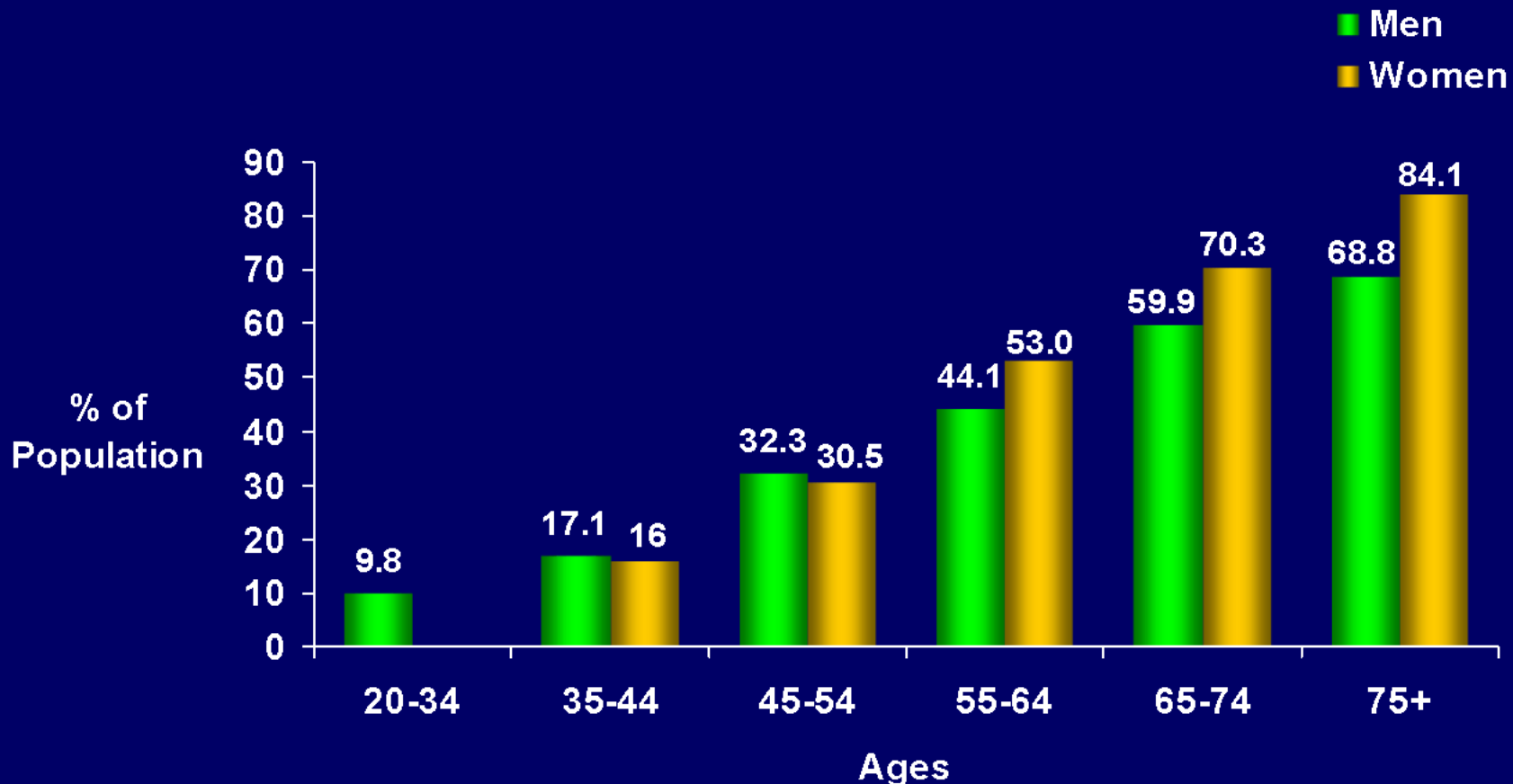
- More than 3.7 million members
- Comprehensive inpatient & outpatient services
- 21 hospitals and 45 medical facilities
- More than 8,000 Physicians



Hypertension Affects Approximately 70 Million Americans: 29% of Adults



Prevalence of High BP in Americans Aged 20 Years and Older by Age and Gender (NHANES IV: 1999-2000)



NHANES = National Health and Nutrition Examination Survey.

Note: Prevalence estimates for women aged 20 to 34 years are considered unreliable.

Heart Disease and Stroke Statistics – 2004 Update. American Heart Association (CDC/NCHS).

JAMA. 2013;310(7):699-705.

Research

Original Investigation

Improved Blood Pressure Control Associated With a Large-Scale Hypertension Program

Marc G. Jaffe, MD; Grace A. Lee, MD; Joseph D. Young, MD; Stephen Sidney, MD, MPH; Alan S. Go, MD

IMPORTANCE Hypertension control for large populations remains a major challenge.

OBJECTIVE To describe a large-scale hypertension program in Northern California and to compare rates of hypertension control in that program with statewide and national estimates.

DESIGN, SETTING, AND PATIENTS The Kaiser Permanente Northern California (KPNC) hypertension program included a multifaceted approach to blood pressure control. Patients identified as having hypertension within an integrated health care delivery system in Northern California from 2001-2009 were included. The comparison group comprised insured patients in California between 2006-2009 who were included in the Healthcare Effectiveness Data and Information Set (HEDIS) commercial measurement by California health insurance plans participating in the National Committee for Quality Assurance (NCQA) quality measure reporting process. A secondary comparison group was included to obtain the reported national mean NCQA HEDIS commercial rates of hypertension control between 2001-2009 from health plans that participated in the NCQA HEDIS quality measure reporting process.

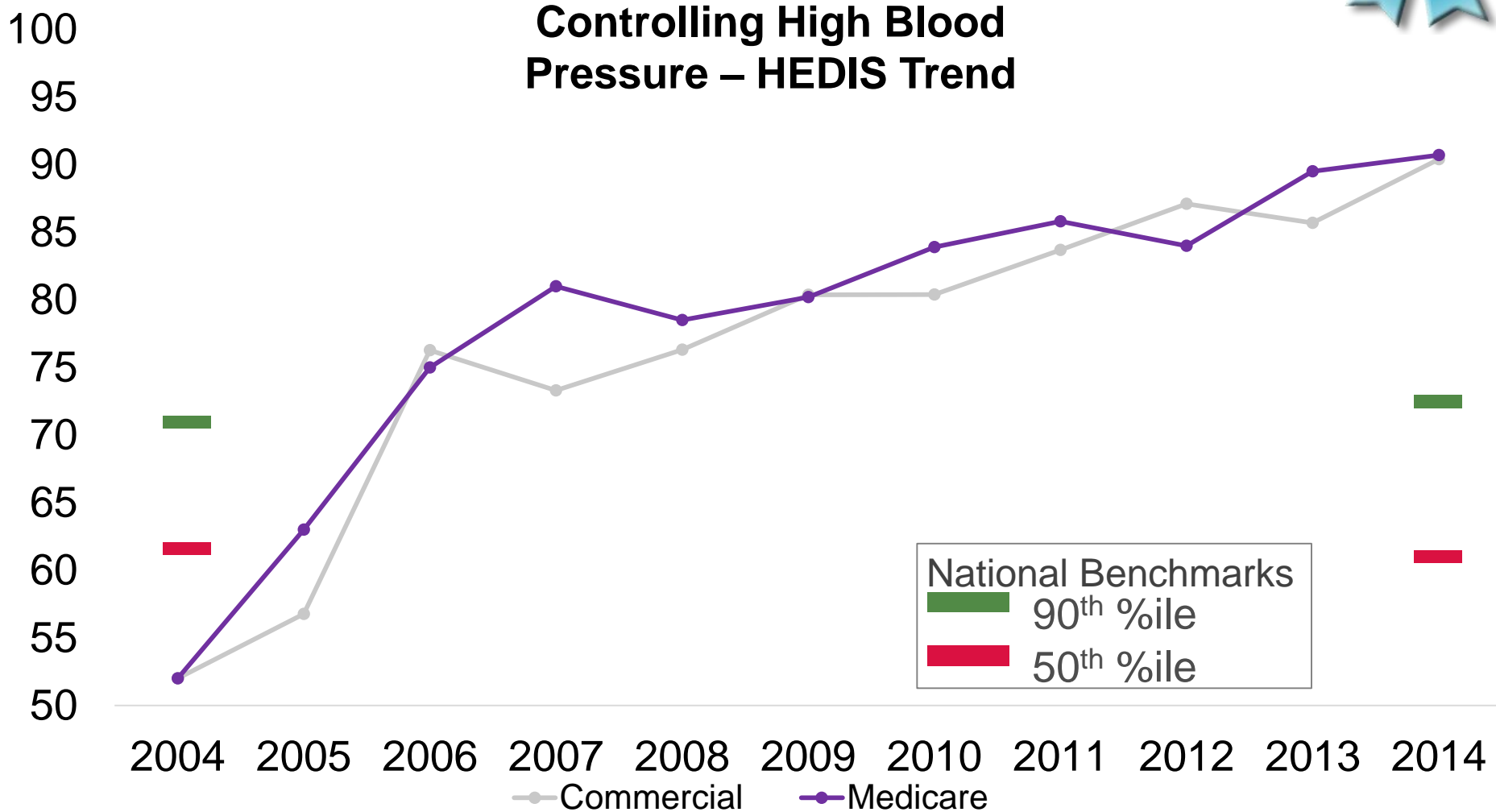
MAIN OUTCOMES AND MEASURES Hypertension control as defined by NCQA HEDIS.

← Editorial page 695

+ Author Video Interview at jama.com

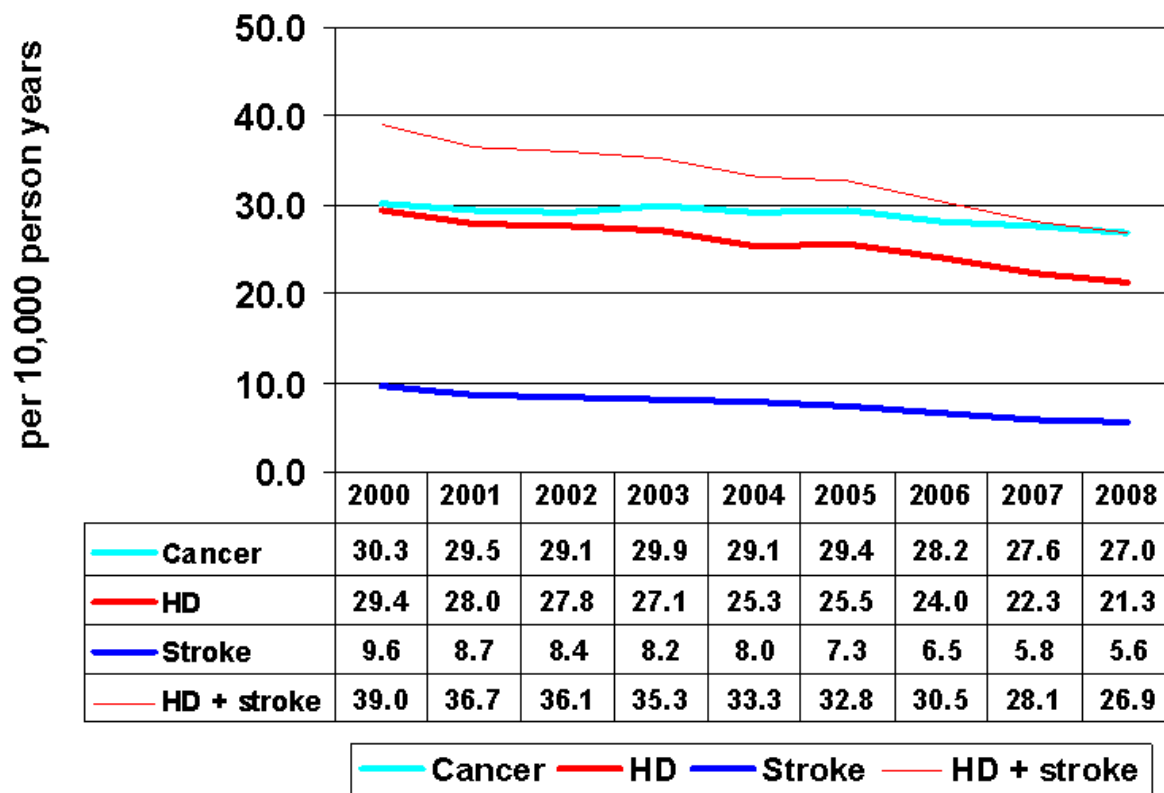
+ Supplemental content at jama.com

Leading the Nation in HTN Control



Falling CV Morbidity and Mortality - KPNC

KPNC Mortality 2000-2008



Since Year 2000:

- 30% reduction in mortality from CVD
- 42% reduction in mortality from stroke
- 11% reduction in mortality from cancer

Sidney S, Jaffe M, Nguyen-Hyunha M, Kushi L, Young J, Sorel M, Selby J, Go A. Closing the Gap Between Cardiovascular and Cancer Mortality in an Integrated Health Care Delivery System, 2000-2008: The Kaiser Permanente Experience. *Circulation* 2011; 124: A13610

It's All About Implementation

**It has to work in
the real world**

Key Elements of a Comprehensive Hypertension Control Program

- Hypertension Registry, Comprehensive
 - Performance Metrics, Transparent and Widely Visible
- Clinic-level feedback to facilitate operational and system-level change.
- Treatment Algorithm
 - Evidence-Based
 - Simple, Implementable
- Single Pill Combination (SPC) pharmacotherapy
- Medical-Assistant BP Checks
 - Better leverage ancillary staff skills
 - Reduced barriers to patients

Browser address bar: <http://millionhearts.hhs.gov/resources/protocols.html> | Search: million hearts hypertension algorithm

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Million Hearts - Tools - Evidence-based Treatment Pro...

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Resources

Evidence-based Treatment Protocols for Improving Blood Pressure Control*

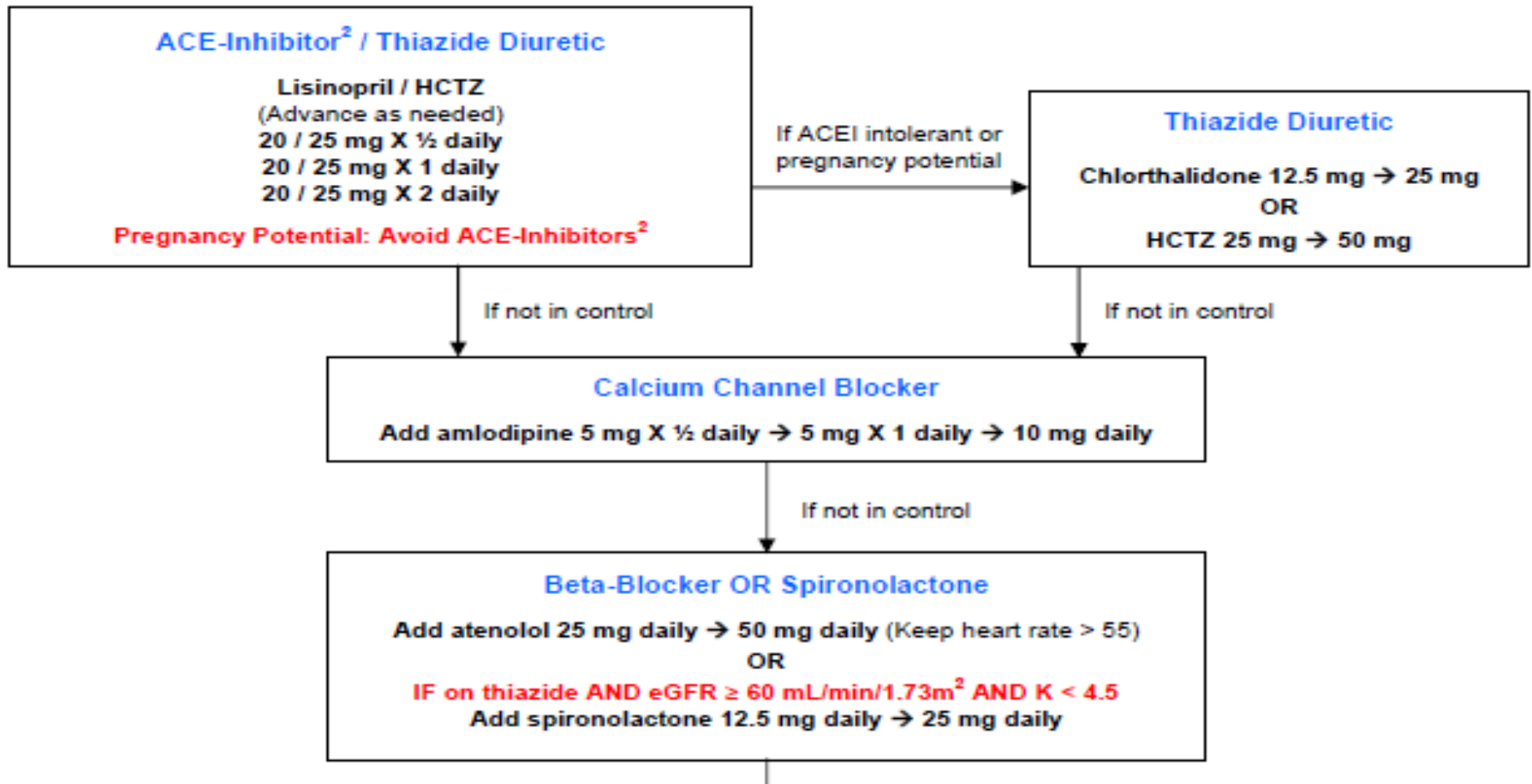
Million Hearts® encourages widespread adoption and use of standardized treatment protocols for improving blood pressure control. Simple, evidence-based treatment protocols can have a powerful impact in improving control by clarifying titration intervals and treatment options, by expanding the types of staff that can assist in timely follow-up with patients, and when embedded in electronic health records, by serving as clinical decision support at the point of care so no opportunities are missed to achieve control. A variety of evidence-based hypertension treatment protocols are available for practices and health care systems to select from, including the following protocols, or a custom protocol can be developed using the template.

**The hypertension protocols featured are examples of a wide variety of available evidence-based hypertension treatment protocols that practices and health care systems may consider for adoption and use. Linking to non-federal sites does not constitute an endorsement by the Department of Health and Human Services, the Centers for Disease Control and Prevention, or any of their employees of the sponsors or the information or products presented on the sites. Links to non-federal sites containing hypertension protocols serve only as a source of guidance. Health care professionals should always consider the individual clinical circumstances of each person seeking hypertension control. Links to the hypertension protocols are not intended to be a substitute for professional medical advice; individuals should seek advice from their health care professionals.*

Template to Create a Hypertension Treatment Protocol

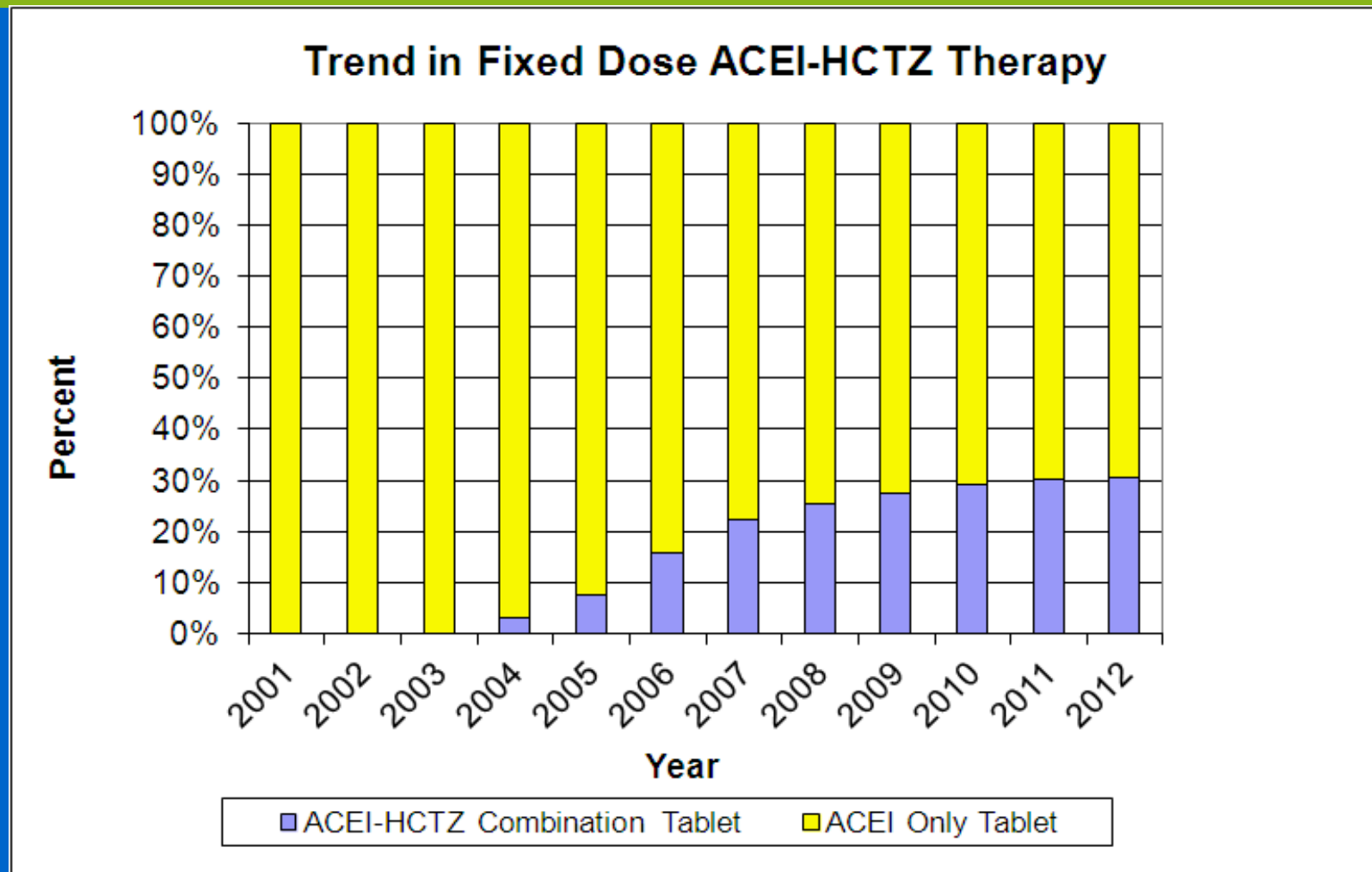
KP HTN Treatment Algorithm

3 Meds to Max Dose in 6 Steps



30% of ACEI Rx's dispensed as Fixed Dose Combination Therapy

% Of All ACEI Rx's



Why Treating HTN Matters? It Saves Lives!

- Stage 1 HTN +
- 1 or more CV risk factors and
- 12 mm drop in SBP for 10 years
- **Prevents 1 death for every 11 pts**

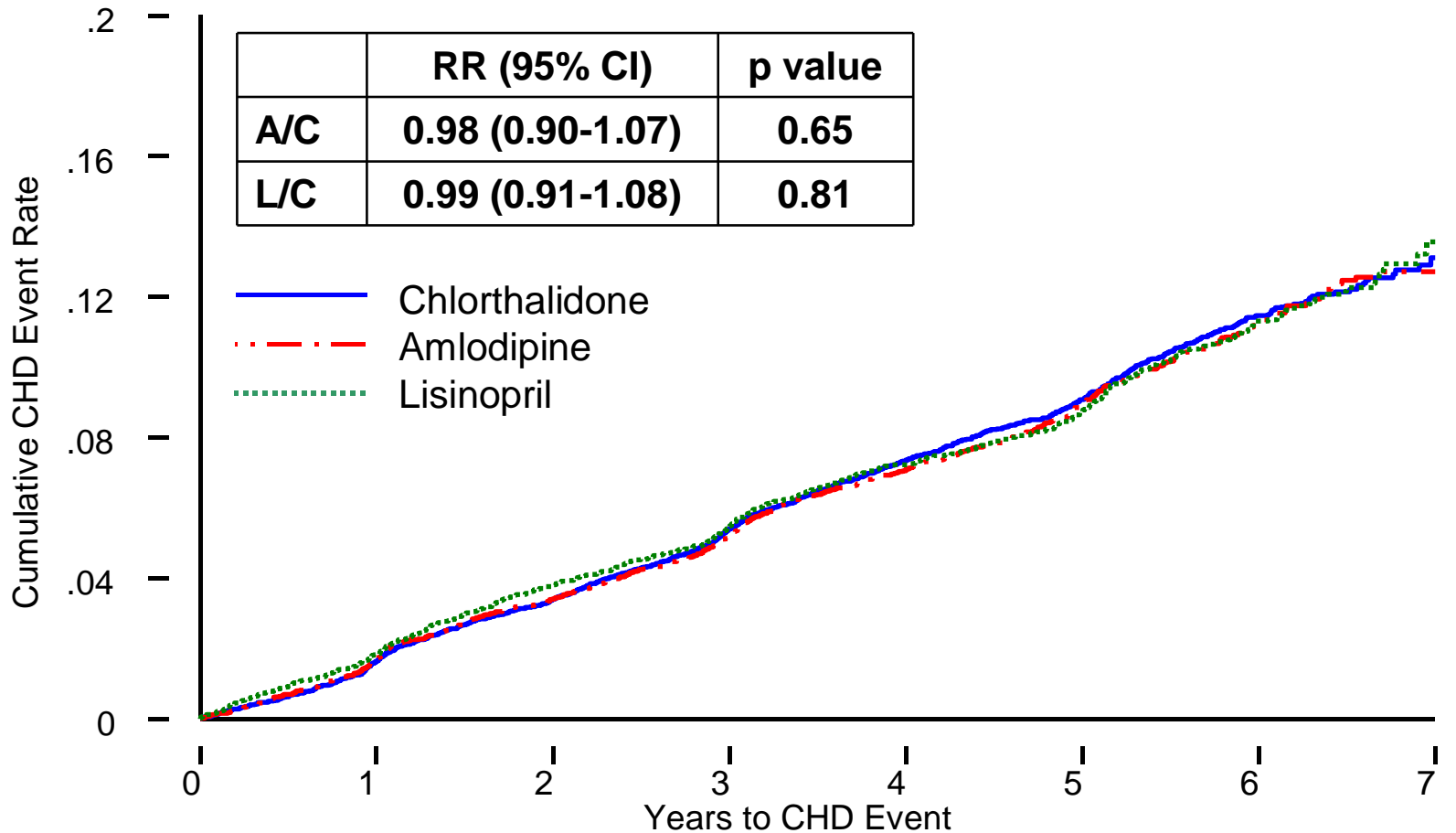
Ogden LG, et al, Hypertension, 2000;35:539-43.

Lifestyle Modifications

| Modification | Approximate SBP Reduction (range) |
|--|--|
| Weight Reduction | 5-10 mmHg/10kg |
| Adopt DASH eating plan | 8-14 mmHg |
| Dietary sodium reduction | 2-8 mmHg |
| Physical activity | 4-9 mmHg |
| Moderation of alcohol consumption | 2-4 mmHg |



Cumulative Event Rates for the Primary Outcome (Fatal CHD or Nonfatal MI) by ALLHAT Treatment Group

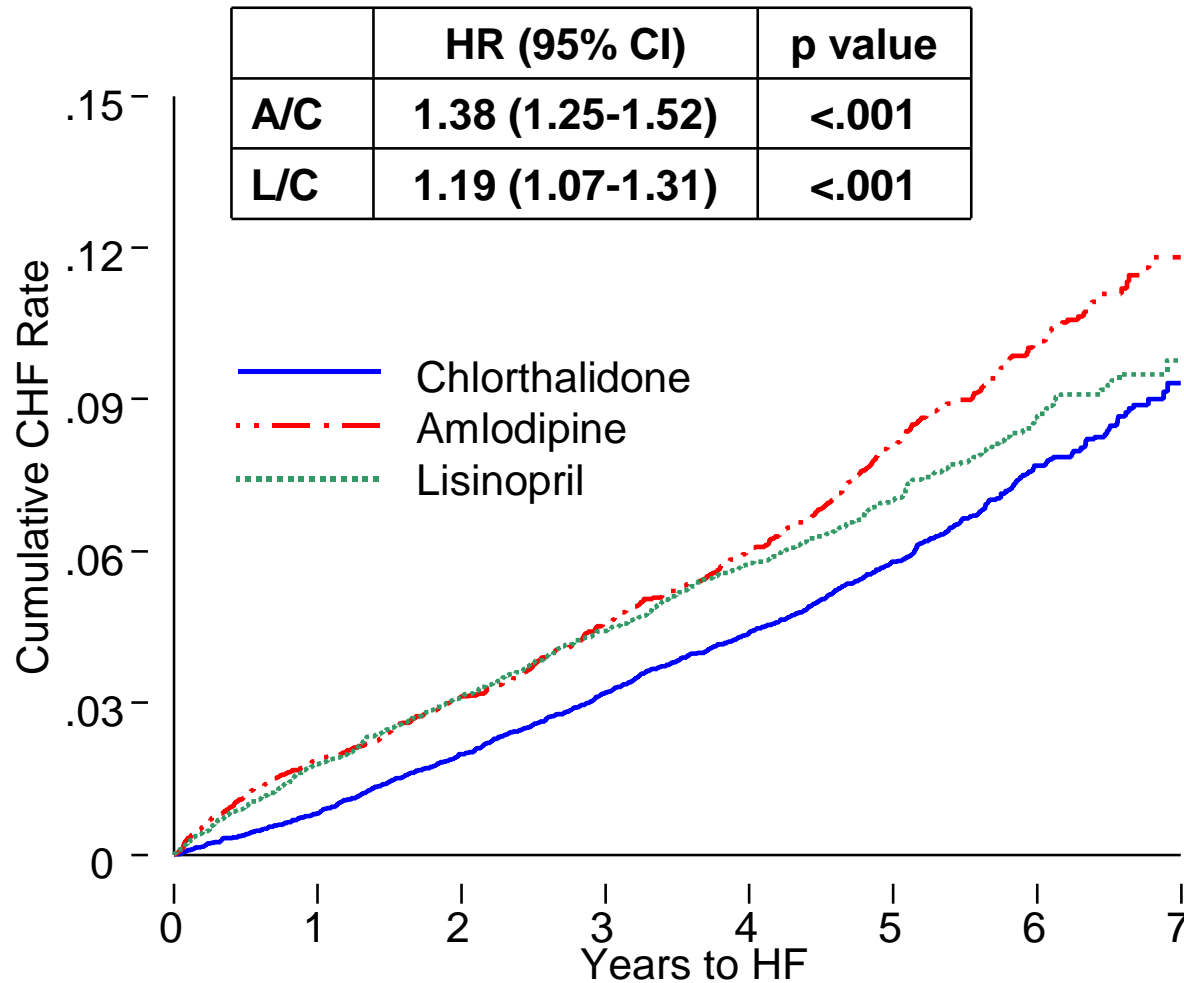


Number at Risk:

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|----------------|--------|--------|--------|--------|--------|-------|-------|-----|
| Chlorthalidone | 15,255 | 14,477 | 13,820 | 13,102 | 11,362 | 6,340 | 2,956 | 209 |
| Amlodipine | 9,048 | 8,576 | 8,218 | 7,843 | 6,824 | 3,870 | 1,878 | 215 |
| Lisinopril | 9,054 | 8,535 | 8,123 | 7,711 | 6,662 | 3,832 | 1,770 | 195 |



Cumulative Event Rates for Heart Failure by ALLHAT Treatment Group



Number at risk:

| | | | | | | | | |
|-------|--------|--------|--------|--------|--------|-------|-------|-----|
| Chlor | 15,255 | 14,528 | 13,898 | 13,224 | 11,511 | 6,369 | 3,016 | 384 |
| Amlo | 9,048 | 8,535 | 8,185 | 7,801 | 6,785 | 3,775 | 1,780 | 210 |
| Lisin | 9,054 | 8,496 | 8,096 | 7,689 | 6,698 | 3,789 | 1,837 | 313 |

AND Remember: Safety First! ACE / ARB's & Statins May be Teratogenic

Avoid ACE-Is, ARBs and Statins in women of child-bearing age unless she is using a highly reliable method of contraception.

Cooper, et. Al., NEJM 354;23, June 8, 2006

Why is Spironolactone Now Best 4th Agent?

PATHWAYS-2

- **RCT: Spironolactone vs Placebo, Doxazosin and Bisoprolol for control of resistant HTN***
 - *Uncontrolled on ACE/ARB + diuretic + CCB.
- **58% of pts controlled on Spironolactone!**

Williams B, MacDonald TM, et al., www.thelancet.com Published online September 21, 2015 [http://dx.doi.org/10.1016/S0140-6736\(15\)00257-3](http://dx.doi.org/10.1016/S0140-6736(15)00257-3)

PATHWAYS-2: Spironolactone is the Best!

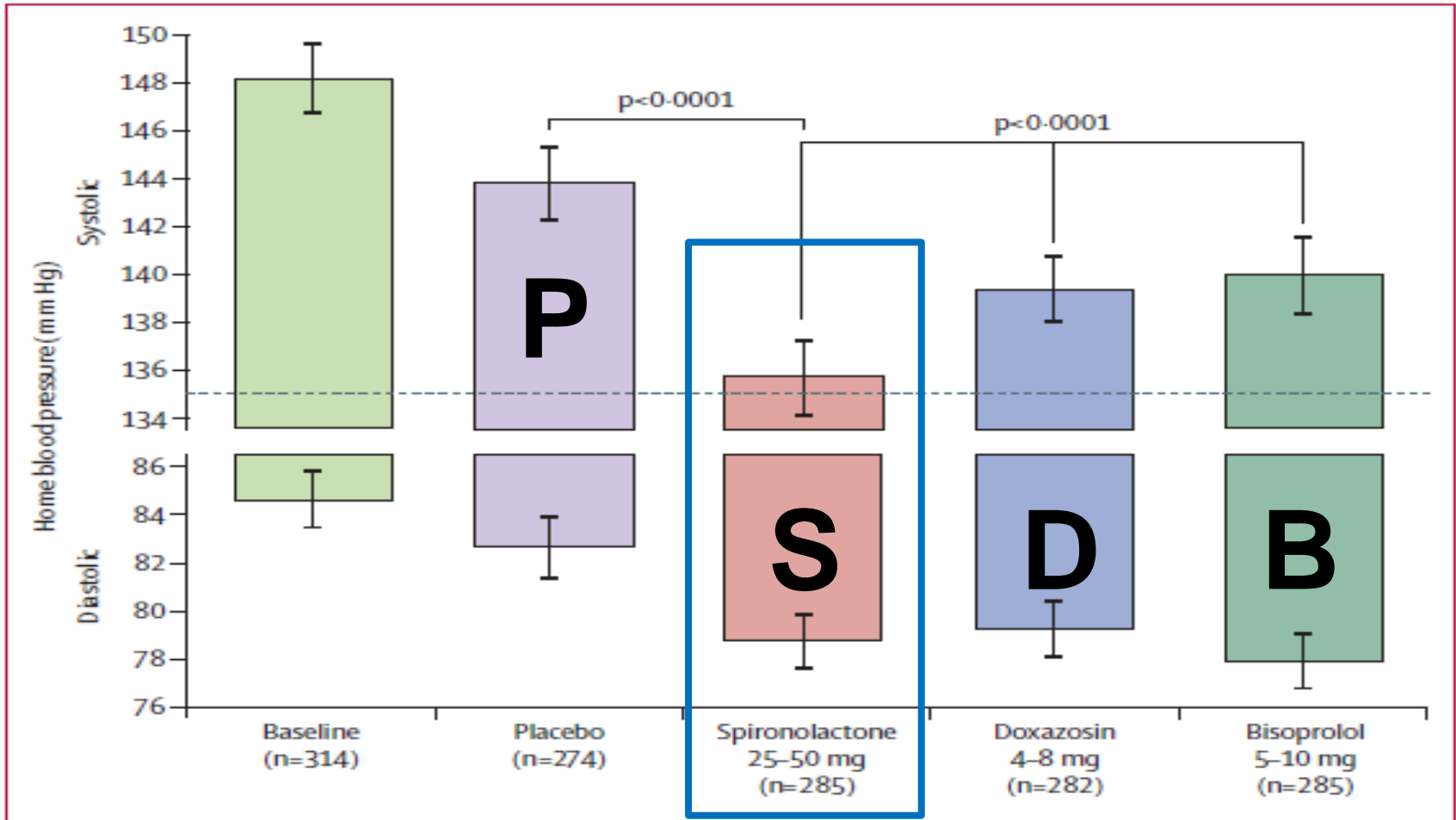


Figure 2: Home systolic and diastolic blood pressures comparing spironolactone with each of the other cycles

AOBPM Technique

- Oscillometric device
- Average of three readings:
 - Following 5 minutes of rest
 - Three readings at 1 minute intervals
- Patient unobserved:
 - Clinic staff prepares patient, pushes button and then leaves patient unattended.
 - Readings and calculated average displayed on device.



Comparisons of blood pressure readings obtained in clinical settings using different methods of blood pressure measurement

| | Mean blood pressure* (mmHg) | | |
|--------------------------|---|---------------------------------|--------------------------|
| | Centre for Studies in Primary Care ₁ | ABPM referral unit ₂ | CAMBO trial ₃ |
| Routine manual office BP | 151/83 | 152/87 | 150/81 |
| Automated office BP | 140/80 | 132/75 | 135/77 |
| Awake ambulatory BP | 142/80 | 134/77 | 133/74 |

*The automated office blood pressure (BP) and awake ambulatory BP were similar, and both were lower than the routine manual BP obtained in community practice.

1. Beckett L et al, *BMC Cardiovasc. Disord.* 2005; 5: 18. 2. Myers MG et al, *J. Hypertens.* 2009; 27: 280. 3. Myers MG, et al. *BMJ* 2011; 342: d286.

BP Measurement in SPRINT vs. Other Trials

Unattended Blood Pressure Measurements in the Systolic, Blood Pressure Intervention Trial Implications for Entry and Achieved Blood Pressure Values Compared With Other Trials

“ ... BPs taken in SPRINT cannot be directly compared with BPs in other trials and (2) the treatment arm <120 mm Hg in SPRINT compares with a higher SBP value in the other trials.

For generalization, the number of mm Hg that should be added must be clarified; suggestions vary from 5 to 10 mm Hg up to 10–20 mm Hg and a recent study indicates 16 mm Hg.

Overall, it means that the lower treatment arm in SPRINT translates into SBP <136 mm Hg, not very different from SBP <140 mm Hg, which is the currently recommended SBP target for most hypertensive people by all hypertension treatment guidelines.”

Kjeldsen SE et al, *Hypertension*. 2016; May67(5):808-12..

“BP measurements taken without observing these conditions are likely to overestimate BP and result in overtreatment, with the potential for higher rates of serious adverse effects and greater utilization of resources. This issue should be carefully considered in the development of any practice-based performance measures for BP control in hypertension that are derived from the SPRINT results.”

Cushman WC, Whelton PK, Fine LJ, Wright JT Jr, Reboussin DM, Johnson KC, Oparil S; SPRINT Study Research Group. SPRINT Trial Results: Latest News in Hypertension Management. *Hypertension*.2016;67:263–265.

SPRINT Research Question

Examine effect of more intensive high blood pressure treatment than is currently recommended

***Randomized Controlled
Trial Target Systolic BP***

***Intensive
Treatment
Goal SBP < 120 mm
Hg***

***Standard
Treatment
Goal SBP < 140 mm
Hg***

SPRINT design details available at:

- [ClinicalTrials.gov \(NCT01206062\)](https://clinicaltrials.gov/ct2/show/study/NCT01206062)***
- [Ambrosius WT et al. Clin. Trials. 2014;11:532-546.](#)***

SPRINT Enrollment Criteria

■ INCLUSION CRITERIA

- ≥ 50 years old
- SBP 130 to 180 mm Hg
 - SBP < 150 if on 4 meds at enrollment
- One or more of the following
 - CVD (clinical or subclinical)
 - $20 < \text{eGFR} < 60$
 - 10-year Framingham Risk $\geq 15\%$
 - Age ≥ 75 years

■ EXCLUSION CRITERIA

- Prior Stroke
- Diabetes Mellitus
- Standing SBP < 110 mm Hg
- Polycystic Kidney Disease
- CHF, symptomatic or with $\text{ef} < 35\%$
- Proteinuria > 1 g / day
- $\text{eGFR} < 20$
- Adherence Concerns

Primary and Secondary Outcomes

■ Primary Outcomes

- CVD Composite, 1st occurrence of:
 - MI
 - ACS (non-MI ACS)
 - Stroke
 - HF, - acute, decompensated
 - CV death

■ Secondary Outcomes

- All cause mortality
- Primary Outcomes + All-cause mortality
- $\geq 50\%$ decline in eGFR in patients with CKD
- $> 30\%$ decline in eGFR in patients WITHOUT CKD
- Incident albuminuria

Target vs. Achieved BP

- For any target BP, there will be a distribution of achieved BPs
- SPRINT is a landmark, federally funded, well designed RCT, analyzed according to pre-specified target BPs
- Beware of post-hoc analyses based on achieved BPs as these are subject to selection bias, e.g. patients with DM in HOT trial

Mean Achieved BPs in SPRINT

- Intensive Treatment Arm – 121.4 mm Hg
- Standard Treatment Arm – 136.2 mm Hg

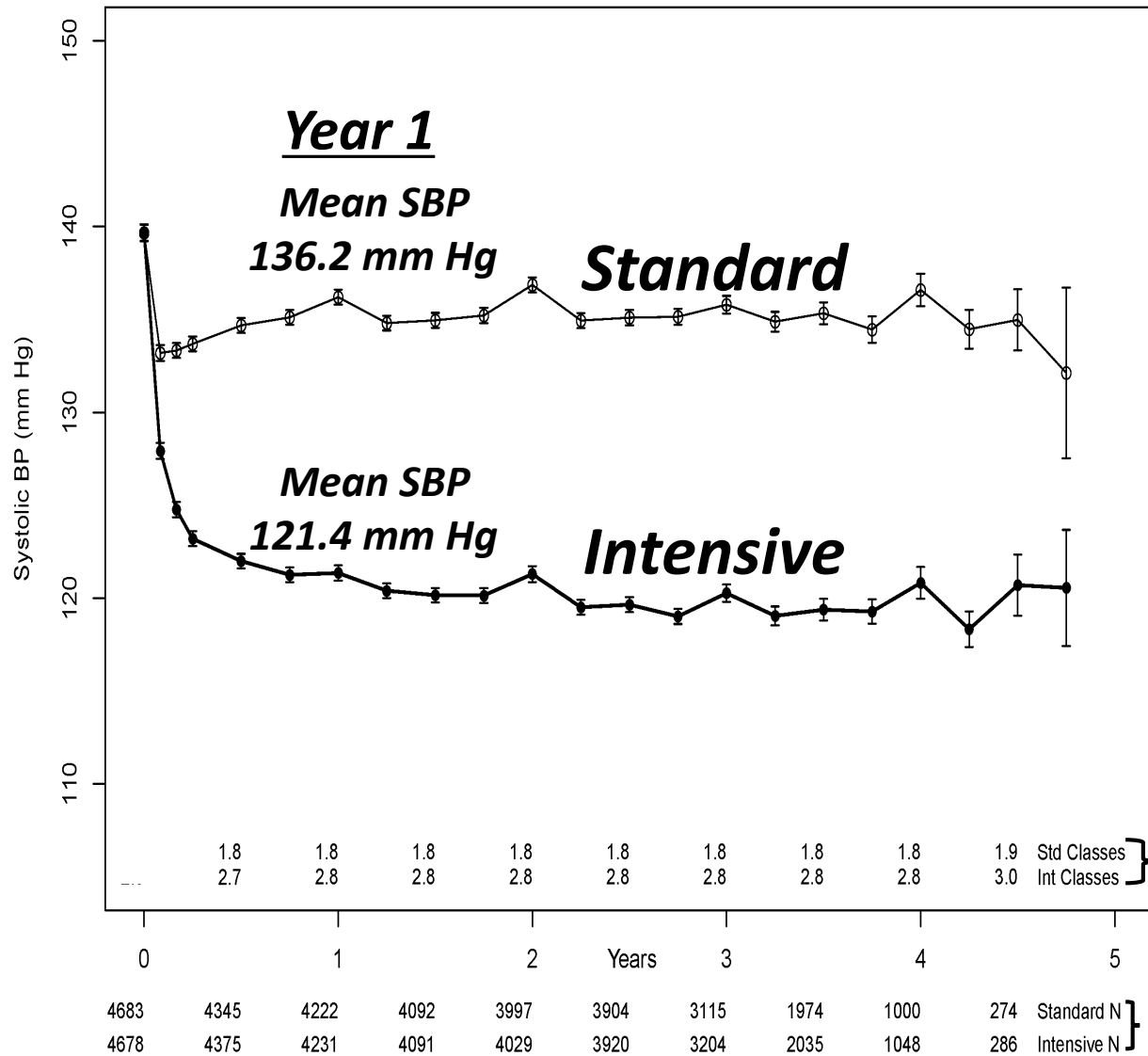
BPs as measured (very well) in SPRINT via AOBPM, correlate to higher conventional office readings of 5 mm Hg or more*

- SPRINT Intensive arm, mean achieved BP corresponds to conventional readings of mid 120s mm Hg or higher

*Myers MG et al. Measurement of blood pressure in the office: recognizing the problem and proposing the solution. *Hypertension*. 2010;55:195–200.

*Filipovský J et al. Automated compared to manual office blood pressure and to home blood pressure in hypertensive patients. *Blood Press*. 2016 Aug;25(4):228-34.

Systolic BP During Follow-up



Average SBP
(During Follow-up)

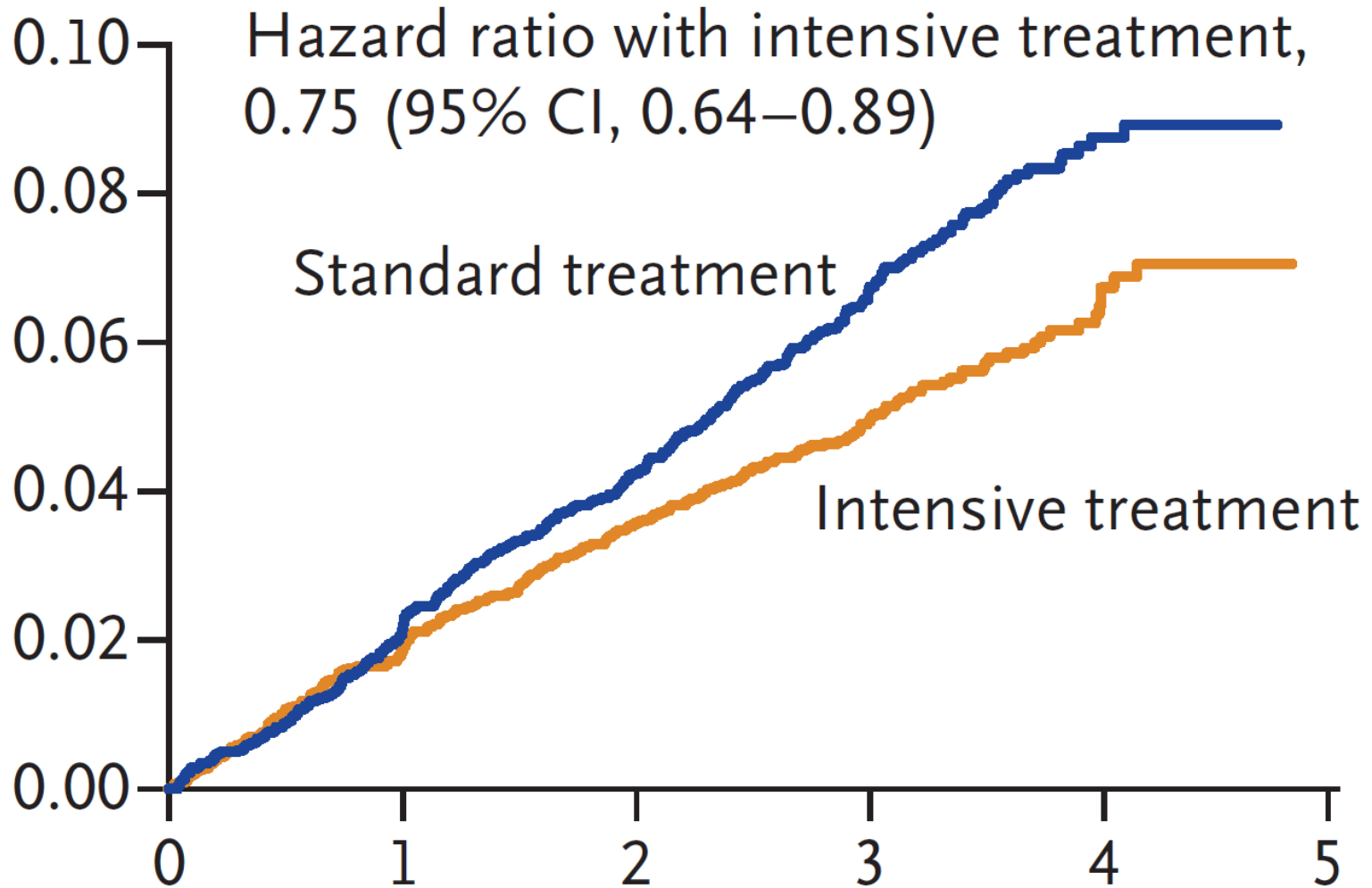
Standard: 134.6 mm Hg

Intensive: 121.5 mm Hg

Average number of antihypertensive medications

Number of participants

25% reduction in 1° Outcomes (p < 0.001)



Hypotension Consequences in SPRINT are nuanced

Statistically Significant

- Syncope
- Orthostatic Hypotension
LESS frequent in
Intensive Treatment Arm.

NO Difference

- Injurious Falls*
- Dizziness
- Patient perceived health status
 - VR12 with physical and mental health sub-scores
 - PHQ-9

*Defined as not resulting from Syncope

Number Needed to Treat/Harm Relative vs. Absolute Risk Reduction

25% Reduction in Composite Primary Outcome.

- 6.8% vs. 5.2% = 1.6% difference

■ NNT

– Primary Outcome – 61; All-cause mortality – 90*

■ NNH

– 45 (2.2%)**

“On the basis of the SPRINT results, we estimate that for 1000 persons treated over 3.2 years to a systolic BP goal less than 120 mm Hg compared with less than 140 mm Hg, an average of 16 persons will benefit, 22 persons will be seriously harmed, and 962 will not experience benefits or harms”*

Benefit is typically cited as relative risk reduction (big #)

Adverse events are typically cited as absolute risk (small #)

* SPRINT Research Group et al. N Engl J Med. 2015 Nov 26;373(22):2103-16.

** Ortiz E, James PA. *Ann Intern Med.* 2016 May 17;164(10):692-3.

Can SPRINT findings be generalized to patients with DM?

■ ACCORD Trial:

- Also target < 120 mm Hg SBP vs. < 140 mm Hg SBP
- Primary Composite CV Outcome – MI, Stroke, CV Death with trend to benefit in Intensive Arm but not statistically significant
- Underpowered – half the size of SPRINT

■ Effect of antihypertensive treatment at different blood pressure levels in patients with DM: systematic review and meta-analysis. (*BMJ* 2016;352:1717)

- “If baseline SBP was less than 140 mm Hg, however, further treatment increased the risk of cardiovascular mortality (1.15, 1.00 to 1.32), with a tendency towards an increased risk of all cause mortality (1.05, 0.95 to 1.16).”

Can SPRINT findings be generalized to patients with h/o Stroke?

- Secondary Prevention of Small Subcortical Strokes (SPS3) Trial
 - Patients randomized to target SBP < 130 vs. 130 to 149.
 - 3020 patients randomized.
 - Mean follow up 3.7 years
- Primary Endpoint: Reduction in all strokes

www.thelancet.com Vol 382 August 10, 2013

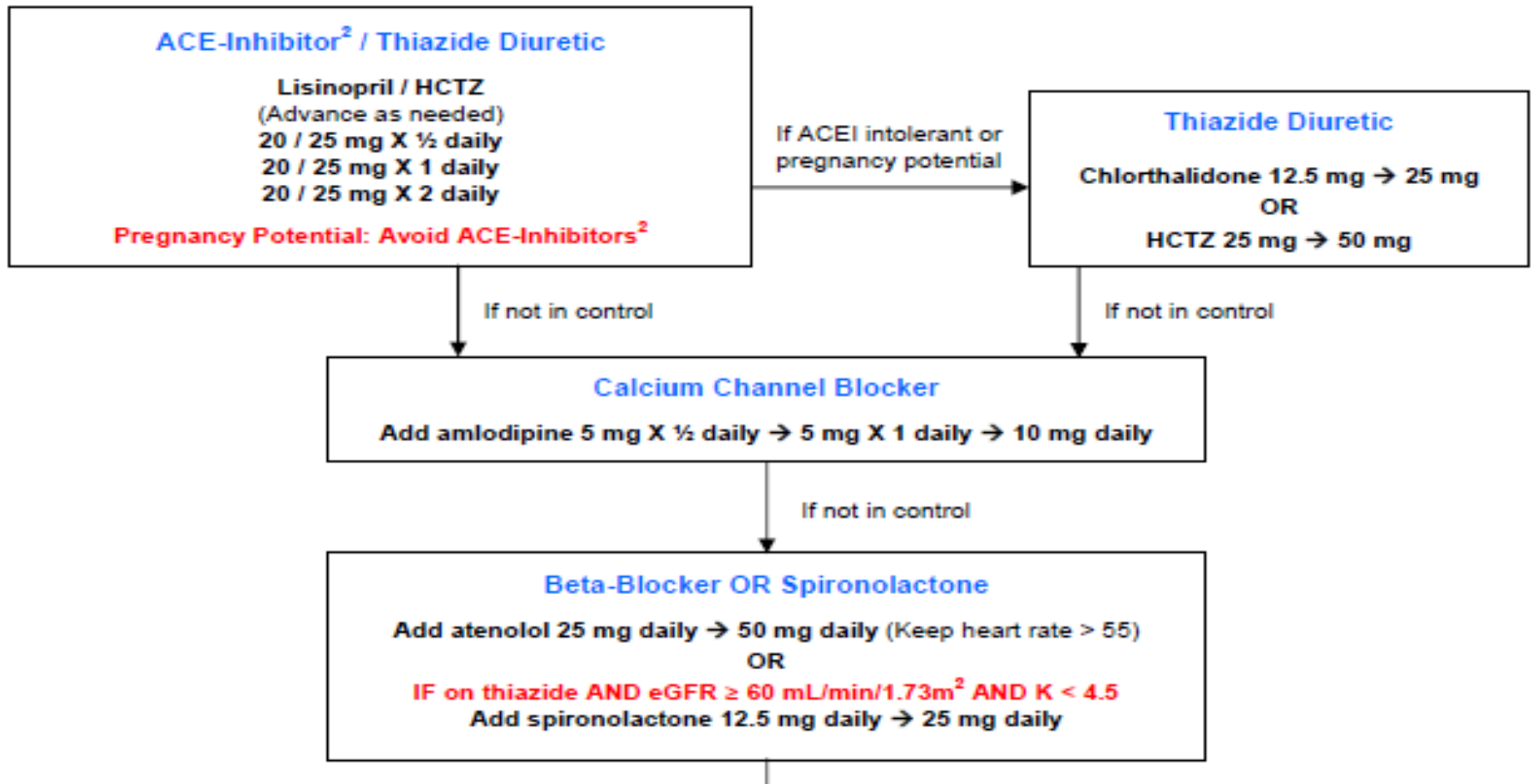
Recommendations

- For patients that meet SPRINT enrollment criteria, i.e. age > 75 years, age 50-74 years with CVD, < 20 eGFR < 60 or 10-year Framingham risk of $\geq 15\%$
 - Pending formal evidence review, shared decision making model of care for target SBP of < 130 mm Hg* is appropriate
 - When lower target SPB is used, close monitoring for syncope and renal function is warranted
- Trial and observational data does not support expansion of SPRINT goals to patients with DM and / or history of stroke

* Conventional office SBP < 130 mm Hg is roughly equivalent to AOBPM reading of < 120 mm Hg

KP HTN Treatment Algorithm

3 Meds to Max Dose in 6 Steps



CASES!

Case 1 – Non-adherence?

- 55 year old man, 156/76, HR 84
 - Lisinopril-HCTZ 20-25 mg qd
 - Amlodipine 10 mg
- BP 132/70 on same regimen one year ago
- “Sometimes it’s hard to remember to take your medicines. I know I sometimes forget to take a dose of my medicines.”
- Explore possible reasons for non-adherence
 - Forgets – would a pillbox help?
 - Side effects?
 - Affordability?

Case 2 – Don't Under-dose the Thiazide

- 55 year old man, 142/76, HR 66
 - Lisinopril-HCTZ 20-25 mg
 - Amlodipine 10 mg
- Recommendation
 - Increase lisinopril-HCTZ 20-25 to ii qd
- Remember not to under-dose the thiazide

Case 3 – Use ARB for ACE-I Cough Intolerance

- 53 year old woman, 144/64, heart rate 58
 - Chlorthalidone 25 mg
 - Cough on lisinopril
- Recommendation: Add losartan 25 mg

Case 4 – Woman of Child Bearing Potential

38 y/o woman. 140/94. Sexually active, uses condoms

– Chlorthalidone 25 mg daily

- Recommendation: add amlodipine 2.5 mg qd
- ACE-Is and ARBs are potentially teratogenic

Case 5 – Resistant HTN

- 55 year old man, BP 156/80, HR 78
 - Lisinopril-HCTZ 20-25 ii qd
 - Amlodipine 10 i qd
 - K = 4.2, eGFR > 60
- Recommendation:
 - Add spironolactone 12.5 mg qd
 - Advance to 25 mg qd if needed

Case 6 – Elderly patient with DM uncontrolled?

- 72 year old man with DM. 148/64, HR 78
 - Chlorthalidone 25 mg qd
 - Lisinopril 20 mg qd
 - Amlodipine 5 mg qd

- Recommendation
 - Stand for two minutes and repeat BP
 - If SBP \geq 140, increase amlodipine to 10 mg qd

Questions?



Next Up...

Don't forget to join us for our next wireside chat!

October 26th at 12pm PT

“Diabetes 2016: Strategies for Achieving Optimal A1c Control”
Presented by Dr. Lisa Gilliam from Kaiser Permanente

To register, go to: <http://tinyurl.com/hpqp63l>