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Standardized, Simple Pharmacologic Treatment Protocols: A Critical Component of Effective Hypertension Control

August 24th, 2022

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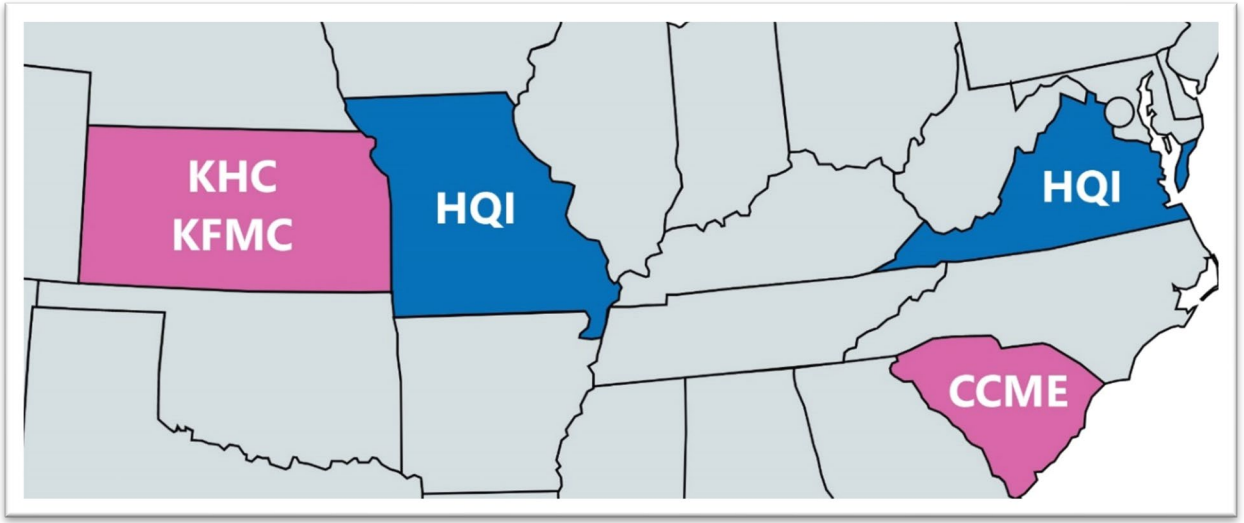

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Disclosures

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Southern Medical Association (SMA) requires instructors, planners, managers, and all other individuals who are in a position to control the content of this activity to disclose all conflicts of interest (COI) with ineligible entities within the last 24 months of the development of this activity. All identified COIs have been thoroughly vetted and mitigated prior to the activity. SMA is committed to providing its learners with high quality activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

Invited Faculty:

Donald DiPette, MD
No Financial Relationships Were Declared

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Logistics – Zoom Meeting

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Raise your hand if you want to verbally ask a question.

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Purpose & Learning Objectives

1. Understand the ideal characteristics of pharmacologic antihypertensive medications.
2. Discuss the importance of a standardized pharmacologic protocol in the treatment of hypertension in the primary care setting.
3. Develop guiding principals for an ideal pharmacologic protocol.
4. Understanding the significance of pharmacologic treatment with two antihypertensive medication in the initial treatment step of the newly diagnosed individual with hypertension.

Donald J. DiPette, MD, FACP, FAHA

Donald DiPette M.D., FACP, FAHA is currently the Health Sciences Distinguished Professor at the University of South Carolina and the University of South Carolina School of Medicine in Columbia, South Carolina. He has previously held the positions of Special Assistant to the Provost for Health Affairs, Vice President for Medical Affairs and Dean of the School of Medicine at the University of South Carolina. He was Interim Senior Executive Dean and Chairman of Medicine and Professor of Medicine at the Texas A&M Health Sciences Center College of Medicine.
Dr. DiPette has served as the Director of Hypertension Research Program at Allegheny General Hospital and at University of Texas, he was Director of the Division of General Internal Medicine, Director for the Hypertension Section, and Vice Chairman for Educational Affairs and In-patient Affairs.

Dr. DiPette earned his bachelor's degree from Seton Hall University in South Orange, N.J. and his M.D. degree from Pennsylvania State University in Hershey, P.A. He is board certified in internal medicine and clinical pharmacology and has a specialist certification in hypertension. His major areas of research, which have been funded by the American Heart Association and the National Institutes of Health, include the pharmacologic treatment of hypertension and the role of novel neuropeptides in the pathophysiology of hypertension.

Dr. DiPette is actively involved in the Global HEARTS Initiative of the Centers for Disease Control and the World Health Organization, as well as the HEARTS in the Americas Program of the Pan American Health Organization. He currently serves as the Envoy for Latin American and the Caribbean to the World Hypertension League and is a member of the Editorial Board of the Journal of Clinical Hypertension.

He was the awardee of the World Hypertension League 2022 Detlev Ganten Excellence in Hypertension Award and Global Health Implementation.

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Standardized, Simple, Pharmacological Treatment Protocols: A Critical Component of Effective Hypertension Control

"E" Module-HEARTS Technical Package
The "HEART" of "HEARTS"

Donald J DiPette MD, FACP, FAHA

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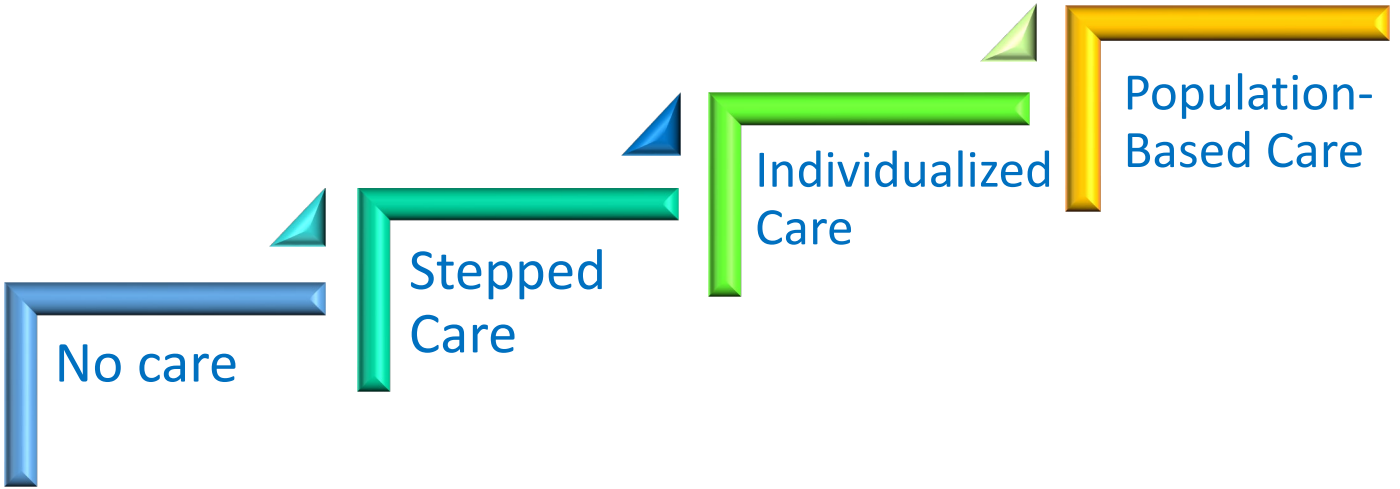
Most Important for Change: Establish a "Sense of Urgency/Burning Platform" (Kotter)

- Noncommunicable diseases (NCDs) especially cardiovascular disease (CVD) is the leading cause of morbidity and mortality globally, in the nation, and in South Carolina. **Hypertension is the leading risk factor for CVD.**
- **Hypertension control rates (>140/90 mmHg) globally are approximately 20%** (Lancet 2021).
- Safe, effective, and affordable pharmacologic treatment for hypertension is available.
- Start honest discussions regarding how current practices have not been successful.
- Examine opportunities to increase the control rates of hypertension.
- **The definition of insanity is doing the same thing over and over again and expecting different results!**

Recent U.S. Population NHANES Data: A "burning platform" and "call to action"! (JAMA 2020)

- Hypertension control rates (using <140/90 mmHg) continued to increase to 53.8% in the 2013-2014 survey
- However, hypertension control rates (**using <140/90 mmHg**) have significantly **decreased to 43.7%** in 2017-2018 survey with only a small increase in the latest survey
- Using the ACC-AHA **criteria of <130/80 mmHg**, the hypertension control rate is **19%** in the 2017-2018 survey
- This decrease in control rate parallels the recent increase in CVD-related morbidity and mortality! **Prompted 2020 U.S. Surgeon General's Call to Action to increase hypertension control: includes use of a standardized protocol and initial combination pharmacologic treatment**

Approaches to Care in the Pharmacologic Treatment of Hypertension



Barriers to Blood Pressure Control Addressed by a Standardized Formulary, Treatment Protocol, Initial Combination Pharmacological Treatment: E-Module

Patient

- Limited access to treatment
- POOR ADHERENCE TO TREATMENT

Health Care Provider

- Raised blood pressure attributed to “white coat hypertension”
- Reluctance to treat an asymptomatic condition
- Lack of adequate time with patient
- THERAPEUTIC INERTIA
- LACK OF ADHERENCE TO TREATMENT GUIDELINES

Health Systems

- Failure to delegate responsibility to non-physicians
- Inappropriate follow-up
- Absence of feedback to clinicians
- ISSUES RELATED TO SUPPLY, DISTRIBUTION, AND COST OF MEDICATIONS
- COMPLEX MEDICATION REGIMENS

Modules of the HEARTS Technical Package

MODULES OF THE HEARTS TECHNICAL PACKAGE

Module	What does it include?	Who are the target users?		
		National	Subnational	Primary care
Healthy-lifestyle counselling	Information on the four behavioural risk factors for CVD is provided. Brief interventions are described as an approach to providing counselling on risk factors and encouraging people to have healthy lifestyles.		✓	✓
Evidence-based protocols	A collection of protocols to standardize a clinical approach to the management of hypertension and diabetes.	✓	✓	✓
Access to essential medicines and technology	Information on CVD medicine and technology procurement, quantification, distribution, management and handling of supplies at facility level.	✓	✓	✓
Risk-based CVD management	Information on a total risk approach to the assessment and management of CVD, including country-specific risk charts.		✓	✓
Team-based care	Guidance and examples on team-based care and task shifting related to the care of CVD. Some training materials are also provided.		✓	✓
Systems for monitoring	Information on how to monitor and report on the prevention and management of CVD. Contains standardized indicators and data-collection tools.	✓	✓	✓

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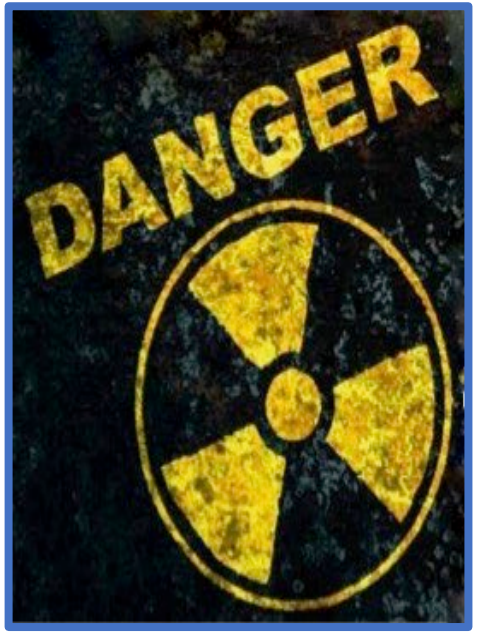
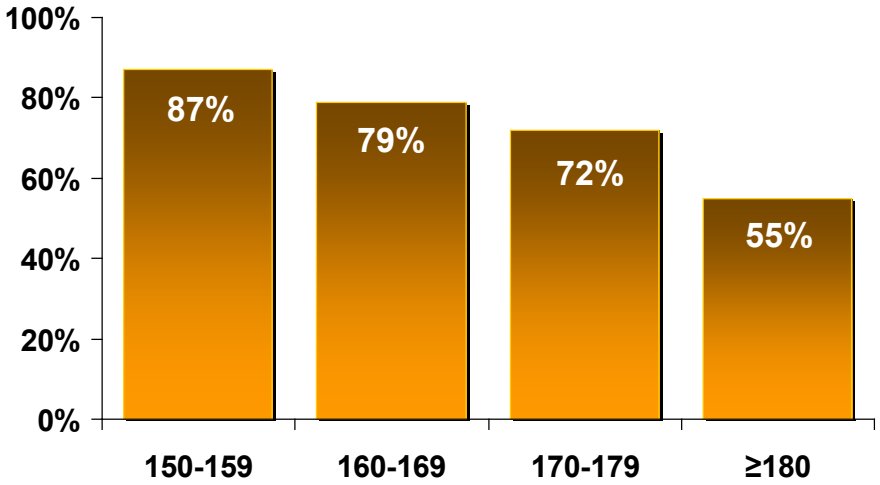
Clinical/Therapeutic Inertia

*The failure of health care professionals to **initiate** or **intensify** treatment when indicated*



The Closer to Goal the Less Providers Initiate or Change Treatment

Percentage of visits *without* medication intensification

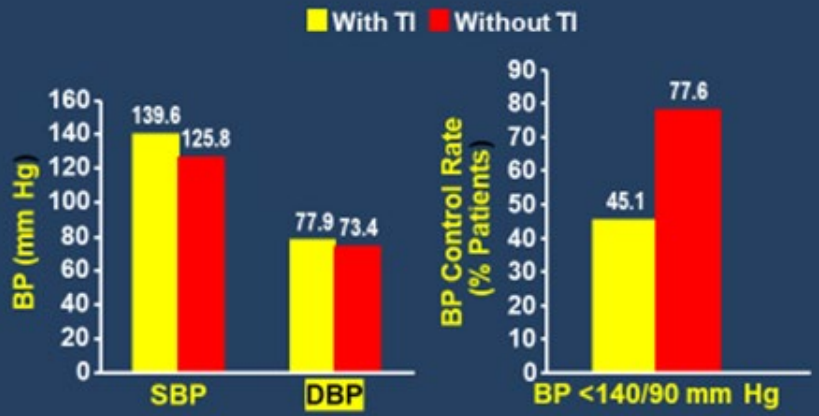


Baseline SBP (mm Hg)

Adapted from Andrade et al. Am J Manag Care. 2004;10:481-486

The Effect of Therapeutic Inertia: South Carolina

- 62 practices in N.C., S.C., Ga. Part of the Hypertension Initiative
- N=7,253 hypertensive patients that had ≥4 visits and ≥1 elevated BP
- Therapeutic inertia = SBP ≥140 mm Hg and/or DBP ≥90 mm Hg with no change in antihypertensive therapy
- Occurred in 86.9% of visits



Okonofua EC et al. Hypertension 2006;47:1-7

Hypertension Treatment Algorithm: Key to a Population-base, Public Health, Primary Care Approach

- Critical strategy to increase hypertension control rates
- Addresses clinical/therapeutic inertia
- Simple, straightforward, and standardized
- Adopted: local/system, state, and/or country-wide

GUIDING PRINCIPLES:

- Primary care based
- Algorithm is for the “rule” NOT the “exception”
- Few medication titration steps: linear with no branch points
- **Half-maximal effective dose of selected agent(s) for initial treatment**
- **Two medications (two pills or in FDC/SPC) for initial treatment**

Advantages of Initial Combination Pharmacologic Therapy

- Most eventually need multiple drugs
- Greater efficacy (additive or synergistic)-improves blood pressure control rates
- Allows lower dosages of each of the 2 drugs
  - More effective than a higher dose of either single drug
  - Reduced side effects
- Simplified treatment regimen: better adherence
- Reduces clinical inertia
- When complementary drug classers are chosen, lowers BP equally across diverse demographic groups
- Economic benefits
  - Lower health care costs and fewer office visits

Mitigation of Side Effects

Renin angiotensin aldosterone system inhibition blunts many side effects of dihydropyridine calcium channel blockers

- Activation of the SNS leading to increased heart rate
- Pedal edema

Mitigation of Side Effects

Renin angiotensin aldosterone system (RAAS) inhibition blunts many of the side effects of diuretics and visa versa

- Activation of the sympathetic nervous system and RAAS system
- Hypokalemia
- Hyperglycemia
- Hyperuricemia

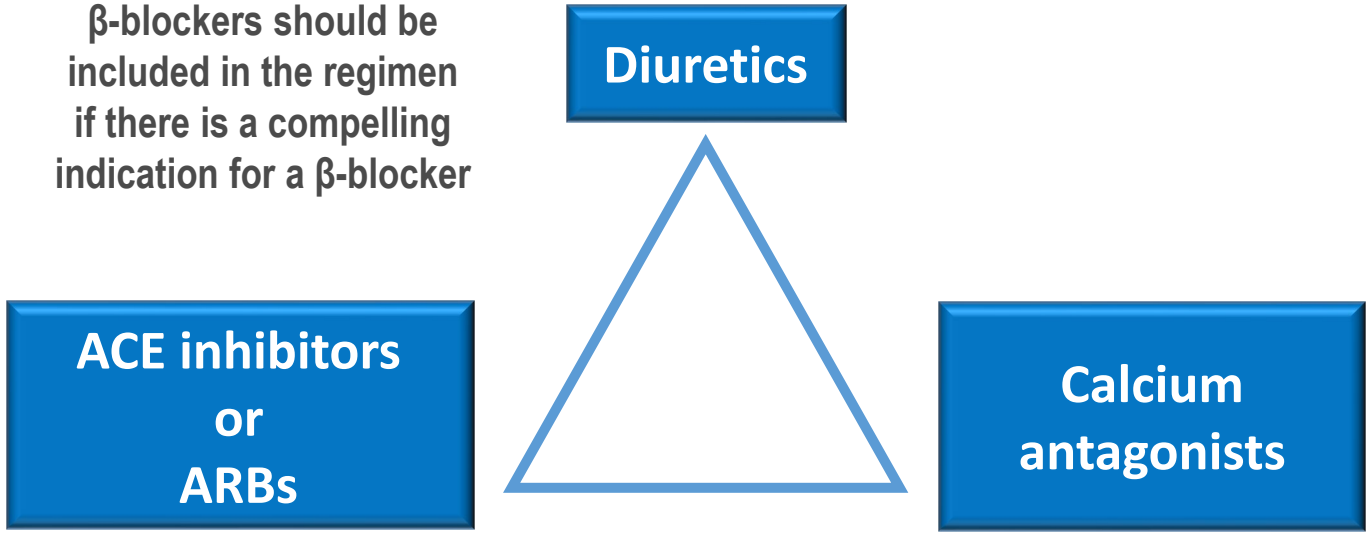
Ideal Characteristics of Combination (FDC) Medications in the Initial Treatment of Hypertension

Characteristics
High Efficacy (blood pressure reduction)
Additive/synergistic blood pressure reduction
Supported by clinical trials
Mitigation of side-effects of either or both individual agents
Potential for wide availability and affordability
Safe and efficacious in diverse demographic settings (i.e. race, ethnicity, sex, geography, salt-sensitivity)
Daily dosing formulation
Scored tablet with multiple doses which permit split tablet dosing and easy titration

Patel P, Ordunez P, DiPette D, et al. Journal Clinical Hypertension 2016

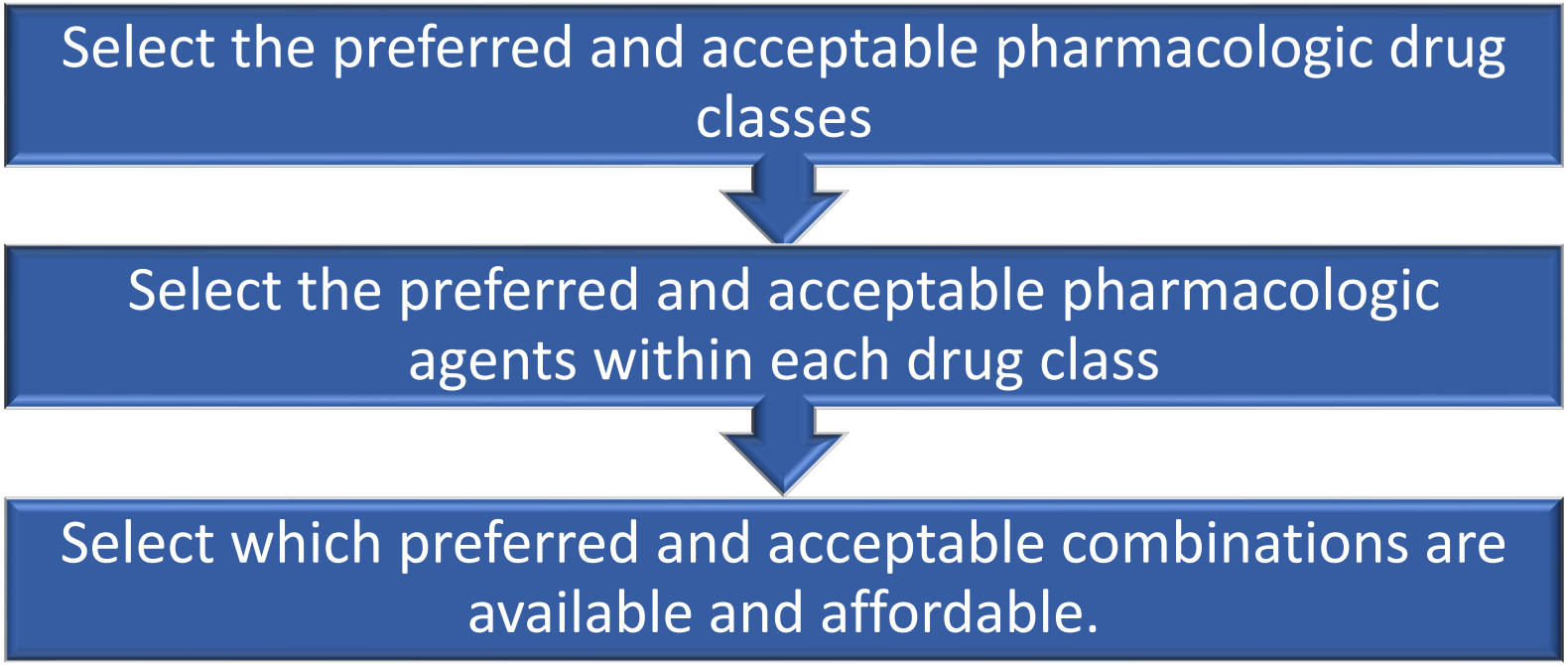
Initial Classes of Medications for the Management of Hypertension

β-blockers should be included in the regimen if there is a compelling indication for a β-blocker



*JAMA.*2014;311(5): 507-520.

Steps in Selecting the Ideal Fixed Dose Combination Drug (DiPette et al. JCH, 2018)



Which Classes of Two-Medication Combinations?

(DiPette et al. JCH 2019)

Renin angiotensin aldosterone system (RAAS) inhibitor-Calcium channel blocker (CCB): **Preferred** in the following order:

1. Angiotensin-Receptor Blocker (ARB)-CCB
2. Angiotensin-Converting Enzyme inhibitor (ACEI)-CCB
3. ARB-Thiazide or Thiazide-like diuretic (DIU)
4. ACEI-DIU

CCB-DIU and all others **Not-Preferred** unless other indications

Building the Ideal Fixed Dose Combinations
(DiPette et al. J Clinical Hypertension 2018)

ARB + CCB	
Azilsartan OR Telmisartan OR Irbesartan	Amlodipine
ACE-I + CCB	
Lisinopril OR Ramipril OR Benazepril	Amlodipine
ARB + Thiazide/Thiazide Like Diuretic	
Azilsartan OR Telmisartan OR Irbesartan	Chlorthalidone OR Hydrochlorothiazide
ACE- I + Thiazide/Thiazide Like Diuretic	
Lisinopril OR Benazepril	Chlorthalidone OR Hydrochlorothiazide

Stepwise, Staged Approach to Transition Hypertension Treatment

Step 1
A Formulary and Current Protocol, which can be immediately put in place given current and available antihypertensive pharmacologic classes and medications.
Step 2
A Formulary and Acceptable Protocol, which includes classes and medications with some/more "ideal characteristics" than currently available and can be implemented, while not immediately, within 6 to 12 months (note: this protocol may be the same as the Current/Present Protocol).
Step 3
A Formulary and Preferred Protocol, which includes classes and medications with all of the ideal characteristics, however, implementation would require a longer time such as 1 to 2 years.

Example of Shift From Current to Preferred Protocol: Combination (fixed-dose) Initial Treatment

Step 1 (once the diagnosis of hypertension has been made)	Step 1 (once the diagnosis of hypertension has been made)
Losartan 50 mg and amlodipine 5 mg	Telmisartan 40 mg and amlodipine 5 mg *(in a FDC preparation and once daily)*
Step 2 (titration, if warranted)	Step 2 (titration, if warranted)
Losartan 100 mg and amlodipine 10 mg	Telmisartan 80 mg and amlodipine 10 mg
Step 3 (titration, if warranted)	Step 3 (titration, if warranted)
Losartan 100 mg and amlodipine 10 mg and hydrochlorothiazide 25 mg	Telmisartan 80 mg and amlodipine 10 mg and chlorthalidone 12.5 mg
Step 4 (titration, if warranted)	Step 4 (titration, if warranted)
Losartan 100 mg and amlodipine 10 mg and hydrochlorothiazide 50 mg	Telmisartan 80 mg and amlodipine 10 mg and chlorthalidone 25 mg
Step 5 (if blood pressure not at control level)	Step 5 (if blood pressure not at control level)
Start a fourth medication or refer to specialist	Start a fourth medication or refer to specialist

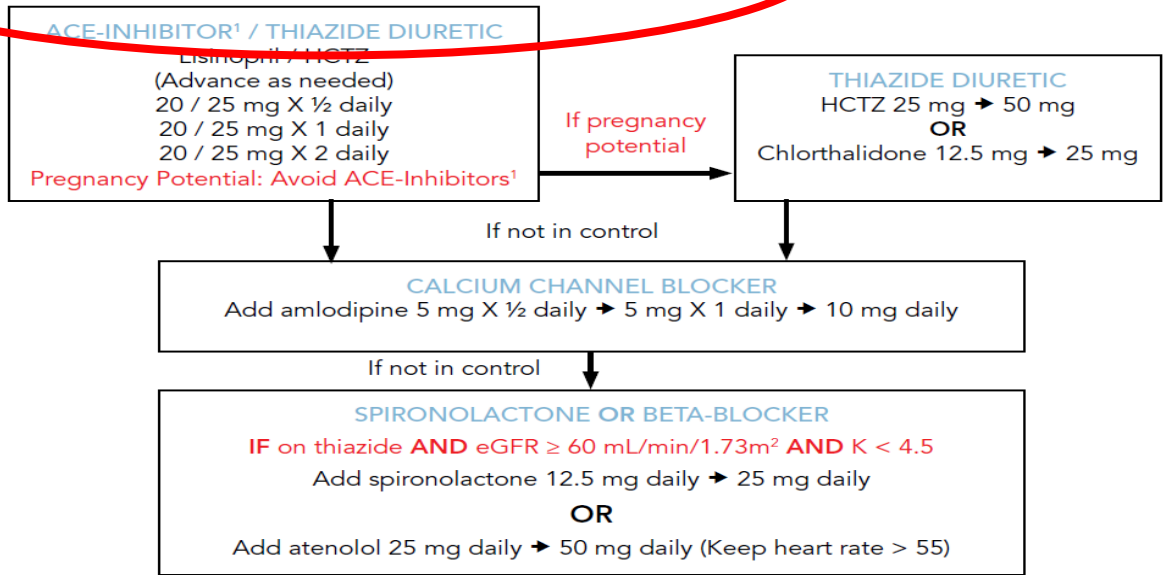
Adult Hypertension

care management | institute

NNT CVA[2] = 63
NNT MI[2] = 86
NNT CVA or MI[2] = 36

BLOOD PRESSURE (BP) GOAL

≤ 139 / 89 mm Hg – All Adult Hypertension



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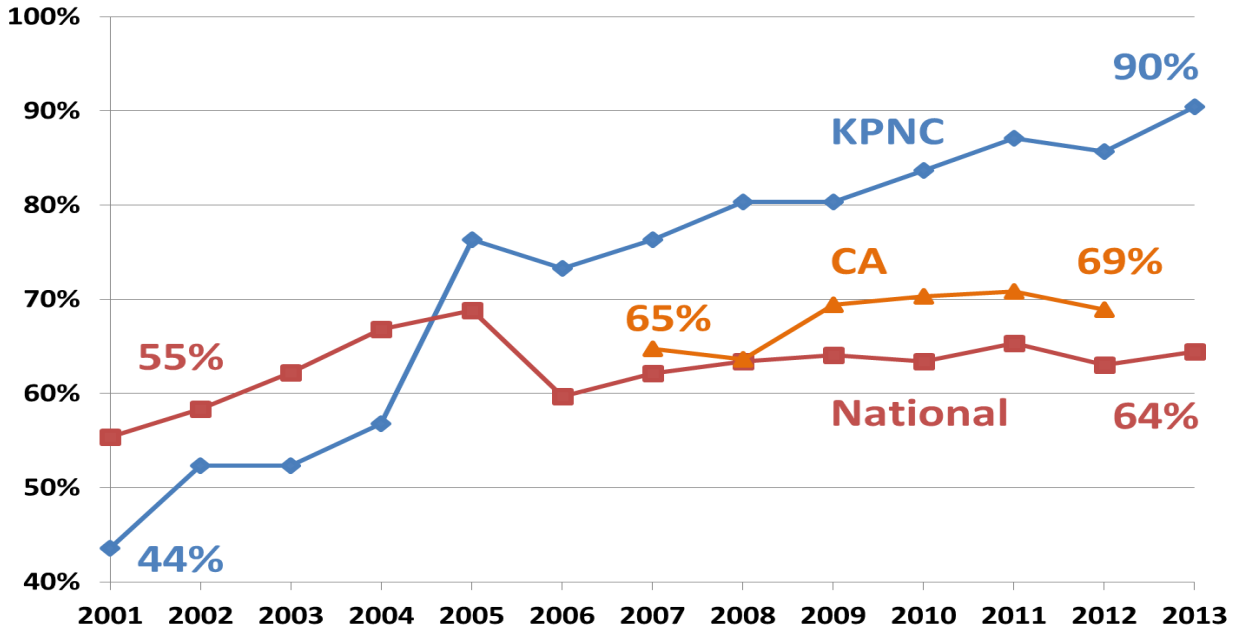
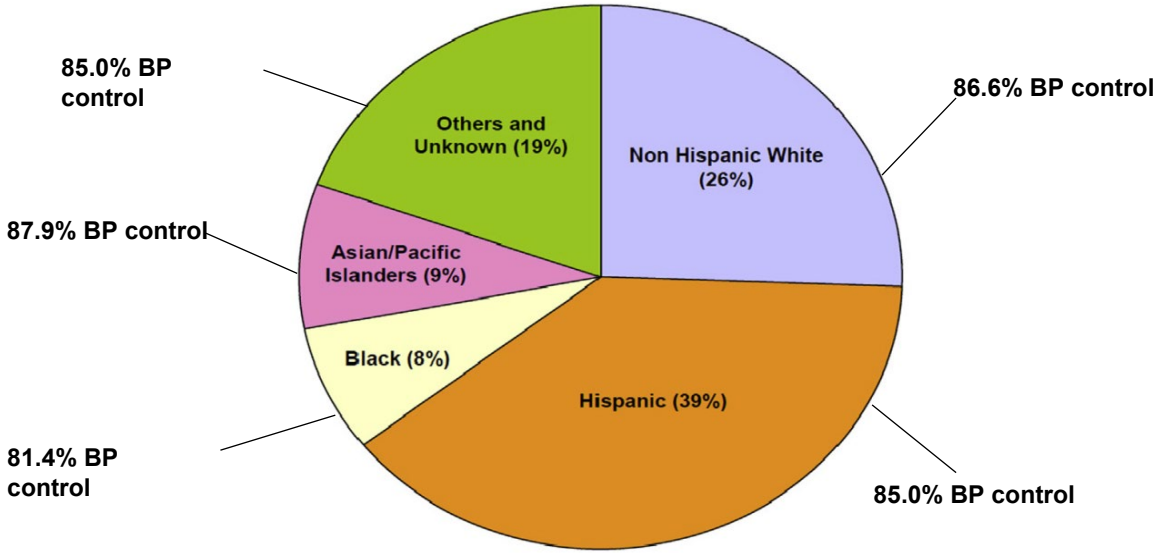
Kaiser Permanente Northern California vs. Statewide and National HTN Control



Standardized Treatment Protocols Can Help Reduce Disparate Outcomes Kaiser Permanente Southern California

"Across all ages, races, and sexes, hypertension control exceeded 80%."



Shaw KM, Handler J, Wall HK, Kanter MH. Improving Blood Pressure Control in a Large Multiethnic California Population Through Changes in Health Care Delivery, 2004–2012. Prev Chronic Dis 2014;11:140173.
DOI: http://dx.doi.org/10.5888/pcd11.140173

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Early Results

	BARBADOS	CHILE	COLOMBIA	CUBA
Secured political commitment	✓	✓	✓	✓
Demonstration site in place	✓ (2)	✓ (2)	✓ (2)	✓ (1)
Target (adult) population size	21,000	50,000	75,000	26,000
Staff, trained and certified in BP measuring & PAHO virtual course	✓	✓	✓	✓
Algorithm defined	✓	✓	✓	✓
Core set of medications	✓	✓	✓	✓
• **Fixed dose combination**	O **(LIS + HTZ)**	✓ **(VAL-AMP)**	✓ **(LOS-HTZ)**	0 **(ENA-HTZ)**
Registry	✓ (electronic)	✓ (electronic)	✓ (manual)	✓ (manual)
• **Registry completeness (%)**	45% & 49%	87%	73%	89%
Metrics M & E defined	✓	✓	✓	✓
Redistribution of Task well defined	✓	✓	✓	✓

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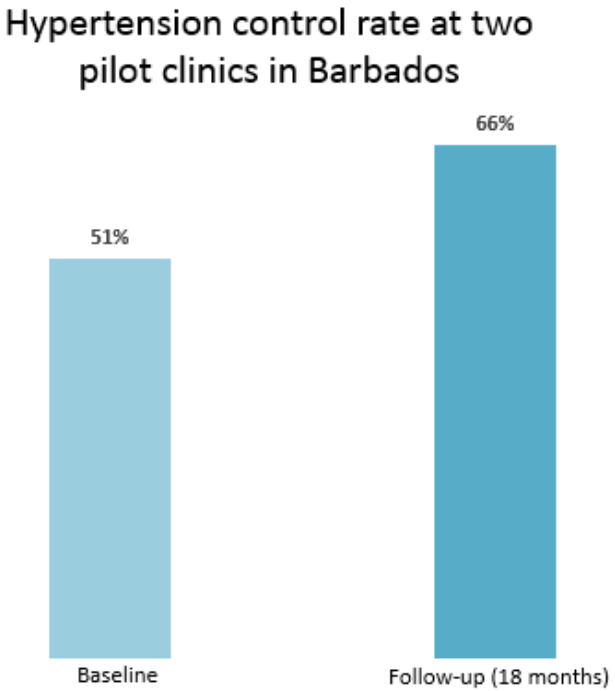
Global Standardized Hypertension Treatment Project

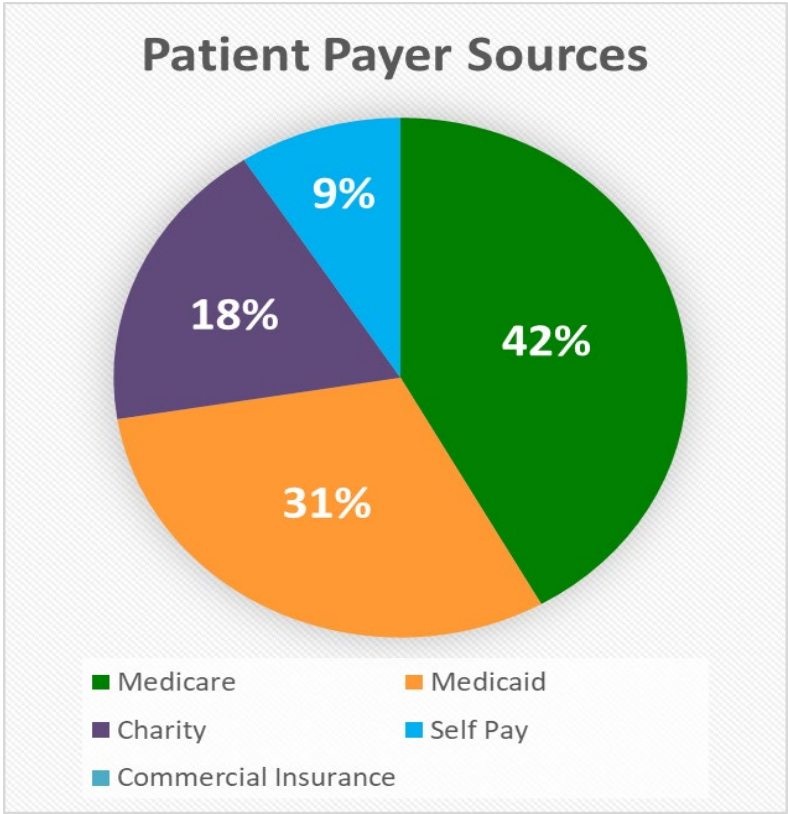


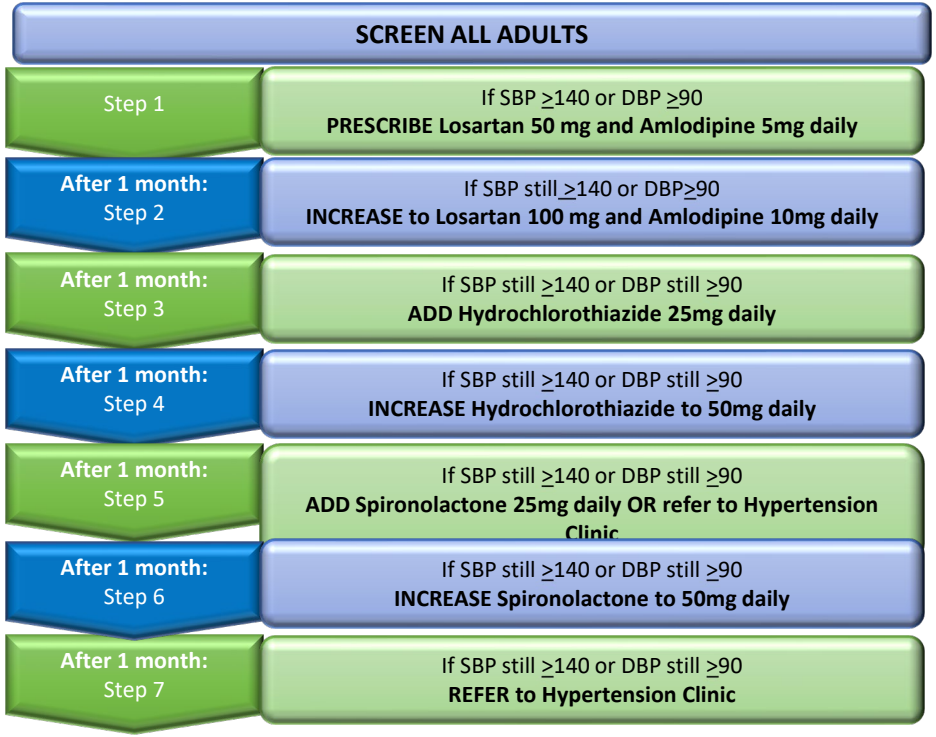
Global Standardized Hypertension Treatment Project

Sources: GSHTP Barbados Pilot Analysis Report, 2014-2016; Transforming Hypertension Treatment in Barbados, https://blogs.cdc.gov/global/2016/09/29/transforming-hypertension-treatment-in-barbados/

PRISMA-USCSOM-Columbia Primary Care Clinic Demographics

- Age
  - <29y – 7%
  - 30-49y – 29%
  - 50-69y – 54%
  - 70-89y – 9%
  - ≥90y – <1%
- Gender
  - 66% female
- **Race**
  - **79% black**
  - 16% white
  - 3% Hispanic
  - 2% Native American, Asian, other





Prisma Health-USCSOM-Columbia

Internal Medicine Primary Care Clinic

Hypertension Treatment Protocol/Algorithm
(2 medication initiation)

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WHO Guideline for the Pharmacological Treatment of Hypertension in Adults: Recommendation of Combination Therapy

(Almakki, DiPette, Whelton Hypertension, 2021)

- **For adults with hypertension requiring pharmacological treatment, WHO suggests combination therapy**, preferably with a single-pill combination, as initial treatment. Antihypertensive medications used in combination therapy should be chosen from the following three classes **(Conditional recommendation, moderate-certainty evidence)**

1. Thiazide and thiazide-like agents
2. Angiotensin converting-enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs)
3. Long-acting dihydropyridine calcium channel blockers (CCBs)

- **Implementation remarks:**
  - Combination therapy may be especially valuable when baseline BP is >/= 20/10 mmHg higher than the target blood pressure
  - Single-pill combination therapy improves medication adherence, persistence, and BP control

Recommendations for Developing an Algorithm in the Treatment of Hypertension

- Must:
- Include the various stakeholders especially key primary care leadership in the development.
- Be simple.
- Be aimed at the hypertensive individual cared for in the primary care setting and NOT the patient exception, who are referred to the specialist setting.
- Address the barrier of clinical inertia, including timely patient care visit intervals with up-titration of agents.
- Use complementary pharmacologic anti-hypertensive classes of agents.
- Use fixed-dose combination agents where possible.

Transitioning From Individualized to Population-Based Treatment for Hypertension

- Use a standardized, simplified approach to hypertension detection and treatment
- Develop a primary care-based approach for the patient “rule” not the “exception”.
- HEARTS in the Americas including the HEARTS Technical Package is a comprehensive blueprint across a spectrum of populations: economic, geographic, racial, ethnic, and cultural.
- The launch of HEARTS can significantly improve the detection and treatment and importantly the control of hypertension in our state.
- HEARTS in America is in addition and complementary to programs already in place.

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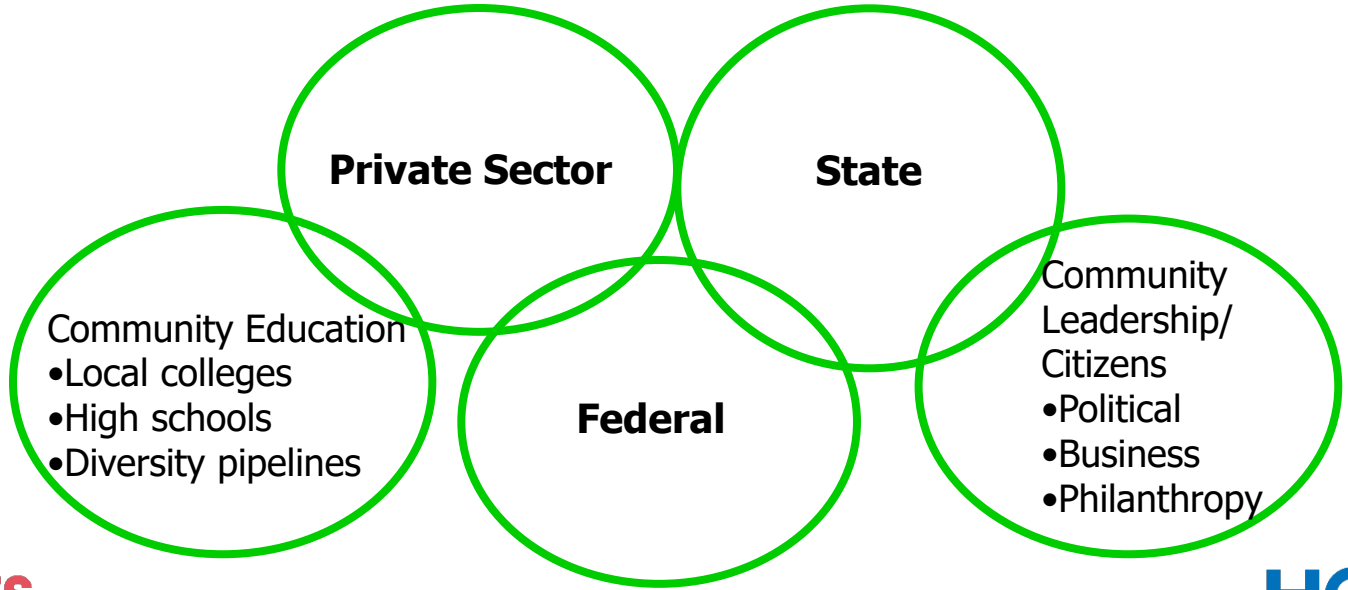
Must Engage and Embrace Multiple Partnerships!



Questions?

Join us for our next HEARTS in America event:

CVD Risk Assessment and Monitoring

September 7th

CME Process

CME credit and certificate distribution are managed through SMA's **online process**. Within one week after the conclusion of the webinar, **please be on the lookout for an email from the Southern Medical Association (customerservice@sma.org) that will include your unique link to an online form** to complete the evaluation, attendance attestation, and claim credit. Please review the following process to receive your certificate awarding credit (for physicians), or a certificate of participation (for non-physician attendees).

- Southern Medical Association (SMA) **will create an online account for you** including your unique login, **using the email address you provided during registration** (your username/ID is your email address).
- Upon receipt of your post-meeting email, click the link provided, and please **make sure that your name and email address appear at the top of the form before completion**.
- **After you complete and submit your evaluation and attendance documentation, your certificate will be emailed to you as a .pdf attachment from customerservice@sma.org within 24 hours.**

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