Implementation of a Resistant Hypertension Control Program in a Low-income Primary Care Setting in a High-Income Country: Lessons Learned and Global Applicability

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Abstract

Hypertension is one of the leading causes of cardiovascular disease-related morbidity and mortality globally. Over the last several decades, there has been a broad shift in the management and pharmacologic treatment, specifically of hypertension, from a step-care approach to an individualized approach, and now to a population-based approach to increase the control rate of hypertension with the overall goal of decreasing major cardiovascular events related to poor control of hypertension. The Global HEARTS initiative of the World Health Organization and the HEARTS in the Americas Program of the Pan American Health Organization, in addition to the efforts of other organizations, serve as a blueprint for the implementation of a standardized, population-based approach to treating hypertension in the primary health-care setting. We have implemented components of such a program in our primary care clinic and resistant hypertension clinic here in Columbia, South Carolina, U.S. While the U.S. is a high-income country, the demographics of our clinic is one of low income and health literacy and our population is primarily black and Hispanic, female, and of an older age. Our clinic has successfully applied population-based treatment principles on an individualized basis to improve hypertension control rates and cardiovascular disease in our local community.

Key words: Hypertension, Hypertension clinic, Population-based care, Resistant hypertension

Introduction

Despite advances in the detection, treatment, and control of hypertension and its related target organ damage, hypertension remains one of the leading causes of cardiovascular disease-related morbidity and mortality worldwide. Globally, roughly one-third of all adults have hypertension, but two-thirds of these adults live in low- and middle-income countries.¹ Unfortunatly, globally only approximately 14% of individuals with hypertension are controlled to a systolic blood pressure <140 mm Hg and a diastolic <90 mm Hg.² Controlling hypertension and reducing cardiovascular morbidity and mortality have been a major goal of the World Health Organization and other prominent organizations and stakeholders. In general while higher than in low-income countries, hypertension control rates in high-income countries such as the United States are dismal and are approximately 50–60%.² More ominous is the recent observation that in the U.S., hypertension control rates have suddenly started decreasing to currently approximately 44% from a high of 54% within the last decade.² This decrease has been accompanied by an increase in major cardiovascular events including stroke. It is important to recognize that even in high-income countries, heterogenous local communities with lower socioeconomic levels exist and the population of such communities faces many of the same challenges low-income countries face. The local population in Columbia, the capital of the state of South Carolina, located in the southeastern region of the U.S., mirrors that of the majority of the world. Approximately one-third of South Carolinians have been diagnosed with hypertension, but less than one-fifth is controlled – sobering data given that those

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with uncontrolled hypertension are 3 times as likely to die of heart disease.\cite{3,4,5,6} Although a high-income state, we serve a low-income community and our patients face some of the same issues as their global counterparts such as disjointed healthcare, lack of health insurance, difficulty with transportation, socioeconomic struggles, and low education level, among others. We recognized the need to address these struggles and treat hypertension aggressively to improve the overall cardiovascular health of those that we medically serve. In addition to controlling hypertension, we strive to address these issues at the local and individual level. At the same time, we educate our learners – medical students, resident physicians, pharmacy residents, and pharmacy students – about the complexities of hypertension management and control. Although we are a resistant hypertension clinic, because of the population that we serve, a significant number of our patients battle poor adherence to lifestyle and pharmacologic anti-hypertensive management. One of our most important goals and challenges is to identify the reason for non-adherence and address the reason(s) on an individual basis. Importantly, the concepts that have been implemented in our hypertension clinic are generalizable to treating individuals with hypertension in the primary care setting. Based on the positive results we have seen over a short period of time, we have expanded the program to include another specialty clinic focused solely on diabetes mellitus, again embedded in the primary care setting.

**Implementing a Team-based Hypertension Clinic in a Low-income Primary Care Setting**

The leadership of the internal medicine residency training program at the University of South Carolina School of Medicine and our health-care system partner, Prisma Health, in Columbia, SC, recognized the need to address these critical local issues. In 2015, we responded to these needs by implementing a resistant hypertension clinic whose overarching goal was to increase the hypertension control rates of our primary care health clinic by counseling on healthy lifestyles; investigating barriers to the use of simple, evidence-based treatment regimens/protocols/algorithms; and providing in-depth education on hypertension using an interdisciplinary team of pharmacist, social worker, nurse, physicians, and learners. We strive to address the issues common to all individuals struggling with controlling hypertension and its comorbidities, as well as the issues unique to our specific population. Where appropriate, the clinic implemented interventions that are currently recommended in the WHO HEARTS technical package including standardized blood pressure measurements; a small anti-hypertensive pharmacologic formulary; a simple, standardized pharmacologic treatment algorithm; and clinical training on hypertension. Our internal medicine residents now have a structure for in-depth learning about hypertension. A large part of our model also includes intense counseling and close, frequent follow-up.

The HEARTS technical package, part of the broader World Health Organization and the Centers for Disease Control Global Hearts Initiative that includes two other packages that address prevention of cardiovascular disease, contains six modules that model an approach to the management of cardiovascular disease including hypertension. The HEARTS modules are:

- Healthy-lifestyle counseling
- Evidence-based treatment protocols
- Access to essential medicines and technology
- Risk based cardiovascular disease management
- Team-based care
- Systems for monitoring\cite{5}

- The structure and activities of our resistant hypertension clinic align with most of the content of these modules.

**Healthy lifestyle**

The healthy-lifestyle module identifies four main behavioral risk factors for cardiovascular disease and describes techniques to encourage changing these risk factors. The four risk factors – unhealthy diet, tobacco use, physical inactivity, and harmful use of alcohol – plague our population in the resistant hypertension clinic. A diet low in fruits and vegetables and high in salt, fats, and sugars is a common diet of many of our patients. The typical diet of our patient population is high in sodium, as much as 8–10 g per day, and unfortunately low in potassium as well. Nineteen percent of our patients smoke. Most are inactive and the COVID-19 pandemic has worsened already limited access to gyms and pools; many of the neighborhoods in which our patients live are dangerous, preventing local outdoor exercise. We do not presently have data on alcohol use, but plan to obtain this information in the future. We provide a great deal of counseling on a healthy diet to address hypertension, including a variety of foods and at least 400 g of vegetables and fruits per day. We spend time identifying how much sodium each individual patient consumes and counseling on ways to reduce that consumption yet maintains appetizing meals. Many patients receive our handout on salt substitutes [Figure 1]. Given the key role that adequate dietary intake of potassium plays in lowering blood pressure and maintaining cardiovascular health, we have begun to provide dietary counseling on foods rich in potassium as well. We emphasize regular physical activity, focus on reducing tobacco use, and provide pharmacologic and non-pharmacologic approaches to smoking cessation. Because we intentionally limit the number of patients on our schedule, we have the necessary time to spend on intense counseling that many primary care clinics simply cannot afford.

**Evidence-based Protocols**

The evidence-based protocols module includes how to measure blood pressure and provides sample hypertension treatment protocols. In our clinic, we follow a precise guideline for measuring blood pressure. Our nursing staff is responsible for the correct and accurate measurement of blood pressure and follows the method for measuring blood pressure outlined in the SPRINT protocol.\cite{6} Nursing ensures the use the appropriate cuff size and...
| Product Name                                    | Ingredients                                                                 | Sodium chloride content | Potassium content  |
|------------------------------------------------|-----------------------------------------------------------------------------|-------------------------|--------------------|
| Mrs. Dash Original Salt Free Blend             | Onion, spices (black pepper, parsley, celery seed, basil, bay marjoram, oregano, savory, thyme, cayenne pepper, coriander, cumin, mustard, and rosemary), garlic, carrot, orange peel, tomato, lemon juice powder, citric acid, and oil of lemon. | 0mg                    | 10mg per 1/4 tsp. serving |
| Mrs. Dash Onion and Herb Seasoning Blend       | Onion, garlic, spices (black pepper, sweet chili pepper, parsley, celery seed, basil, bay, marjoram, oregano, savory, thyme, cayenne pepper, coriander, cumin, mustard, and rosemary), orange peel, and natural flavor. | 0mg                    | 0mg                |
| Mrs. Dash Garlic and Herb Seasoning Blend      | Garlic, onion, spices (black pepper, parsley, fennel, basil, bay, marjoram, oregano, savory, thyme, cayenne pepper, coriander, cumin, mustard, rosemary, and celery seed), carrot, orange peel, and spice extractives. | 0mg                    | 0mg                |
| Mrs. Dash Lemon Pepper Seasoning Blend         | Onion, spices (black pepper, basil, oregano, celery seed, dill weed, sage, bay leaves, and turmeric), garlic, carrots, ground onion, minced onion, citric acid, toasted sesame seeds, red bell peppers, orange peel, corn starch, parsley flakes, and lemon peel. | 0mg                    | 0mg                |
| Lawry’s Salt Free 17 Seasoning                 | Spices (black pepper, basil, oregano, celery seed, dill weed, sage, bay leaves, and turmeric), garlic, carrots, ground onion, minced onion, citric acid, toasted sesame seeds, red bell peppers, orange peel, corn starch, parsley flakes, and lemon peel. | 0mg                    | 0mg                |
| Nu-Salt Salt Substitute                        | Potassium chloride, potassium bitartrate, silicon dioxide, and natural flavor derived from citrus fruits and honey. | 0mg                    | 530 mg per 1/6 tsp. serving |
| Morton Lite Salt Mixture                       | Potassium chloride, L-lysine mono-hydrochloride, and calcium stearate         | 0mg                    | 610 mg per 1/4 tsp. serving |
| Morton Salt Substitute                         | Potassium chloride, L-lysine mono-hydrochloride, and calcium stearate         | 0mg                    | 170 mg per 1/4 tsp. serving |
| MySALT Original Salt Substitute                | Potassium chloride, L-lysine mono-hydrochloride, and calcium stearate         | 0mg                    | 450 mg per 1/4 tsp. serving |
| MySALT garlic Salt Substitute                  | Potassium chloride, L-lysine mono-hydrochloride, garlic, and calcium stearate | 0mg                    | 356 mg per 1/4 tsp. serving |
| Diamond Crystal Salt Sense                     | Salt, silicon dioxide, tricalcium phosphate, sodium bicarbonate, dextrose, and potassium iodide (0.006%) | 0mg                    | 650 mg               |

**Figure 1:** Sodium content of common salt substitutes
patient position and uses a validated, oscillometric, automated electronic device to measure the blood pressure at least 3 times in a quiet room without an observer. This method minimizes the chance for observer biases and manual collection errors. The goal blood pressure is <140/90 mm Hg in most patients and <130/80 mm Hg for those with cardiovascular disease, diabetes, chronic kidney disease, or high cardiovascular risk. We have recognized that standardized protocols, tailored for our specific environment, are successful in achieving blood pressure control. The clinic uses two protocols in the treatment of the patient with newly diagnosed hypertension – one initiating a single medication and the other initiating two medications [Figure 2]. Both protocols use the angiotensin-converting enzyme inhibitor lisinopril and the calcium channel blocker amlodipine in the initial steps. The angiotensin-converting enzyme inhibitor was chosen instead of an angiotensin receptor blocker solely due to its availability and low cost, even free. The starting dose of each is the half-maximal effective dose, which allows for only one titration step for blood pressure control if needed. Although these two protocols exist, we strongly recommend starting with two medications as the initial treatment. This dual antihypertensive approach as initial treatment is particularly appropriate for our clinic because these medications are free at one of the national supermarket pharmacy chains in our location; therefore, they are available to the majority of our patients who live or work near one of those pharmacies. It is extremely important given that approximately 500,000 South Carolinians (of a total state population of 5 million) lack health insurance. Furthermore, both of these two medications are available through a local medication assistance program that provides free prescription medications to uninsured South Carolina residents with income constraints. There is no charge to join the non-profit program and, once approved, patients are enrolled for up to 1 year. They usually have combination antihypertensives as well, such as lisinopril/hydrochlorothiazide, losartan/hydrochlorothiazide, and valsartan/hydrochlorothiazide. Because of the protocol-based approach we can mitigate clinical/therapeutic inertia which would otherwise prolong the duration of patients’ uncontrolled hypertension, putting them at increased risk of hypertension-related complications.

Access to Essential Medications

The access to essential medicines and technology module provides information on supply chain management of cardiovascular medications, including procurement, distribution, management, and handling supplies. Since supply chain management is not typically at the clinic level and we do not dispense medications on site, our clinic is not actively or primarily involved with ensuring a steady supply of medications. However, we do try to confirm that our patients receive medications appropriate to their clinical needs, and we make every effort to encourage adherence. The fragmented health-care system in the U.S. means our patients often receive healthcare at multiple locations; therefore, health-care providers frequently do not have access to records outside of their own organizations. This situation leads to duplicate medications, unknown medications or doses, and health-care providers delivering conflicting care. This fragmentation is a constant struggle for our staff, and we simply do the best we can in requesting records and contacting outside health-care providers individually. Furthermore, many different healthcare insurance plans with varying cost coverage and medication formularies can complicate selecting medications that patients can afford. If access to medications hampers adherence, then the pharmacist’s knowledge of different insurance plan formularies aids the resistant hypertension team in choosing medications which our patients can obtain and afford. Our pharmacist assesses patient adherence to medication at every visit by checking refill history, admittedly an imperfect assessment since many patients regularly may receive their meds through mail order or automated pharmacy fills, yet they may not take them.

Risk-based Cardiovascular Disease Management

The risk-based cardiovascular disease management module describes using a risk-based approach to assess and manage cardiovascular disease. Poor control of risk factors often stems from a result of a lack of awareness and our pharmacist, nurses, social worker, and physicians make every effort to tie adherence to reduced risk of heart attacks and strokes. We do not routinely measure cardiovascular risk unless it factors into the treatment decision of a given diagnosis or would enhance the educational value of the individual discussion regarding non-pharmacologic and pharmacologic therapy.

Team-based Care

The team-based care module explains the advantages of using an interdisciplinary team. Our particular interdisciplinary team consists of a pharmacist, often with a pharmacy resident or pharmacy students; a nurse specifically trained in cardiovascular disease; a social worker; two physicians; an internal medicine resident physician; and often medical students. The entire team plays an integral role in providing patient care centered around evidenced-based protocols. Our team collaborates extensively before each patient visit to develop a tentative plan for each patient and spends time teaching hypertension concepts. We have termed this group discussion “the huddle.” Having an expanded team improves patient access to care in that at least one team member is almost always available to talk further to the patient before or after the visit. We use the diversity of our team members to try different approaches to counseling the patient, earning the patient’s trust, and encouraging adherence to the treatment plan. We have been extremely fortunate in that we have had no staff turnover since the clinic’s inception and believe it is, at least in part, because team members are valued, engaged, and feel important. Our patients know and like our team, and we have built a great deal of trust and fostered open communication. We are aware, however, that staff turnover, including physicians,
is a major problem and barrier to success in other clinic settings, especially in low- to middle-income countries.

**Systems for Monitoring**

The module systems for monitoring contain information on monitoring and reporting on hypertension prevalence, awareness, treatment, and control. In our clinic, we use a very simple approach. Each patient has a running document that the resident updates after each visit. The document describes what was found on the initial visit of the patient (history, physical exam, average blood pressure, and laboratory results if obtained), what our team did and why, and any learning points. In the future, we would like to implement a treatment card, recording clinic blood pressures, to serve as a reminder to the patient of the importance of adhering to medications to control blood pressure, and to reduce cardiovascular risk.

**Discussion**

Hypertension is responsible for more deaths than any other single non-communicable disease risk factor. Thus, improved hypertension control at the population and individual level could have a substantial positive impact. Given the prevalence, human and economic consequences, and dismal control rates of hypertension, there is an urgency to change the approach to detecting and treating hypertension. Global control rates are estimated to be approximately 14%. Even in high-income countries, recent data show declining control rates. According to NHANES surveys in the U.S., hypertension control rates have decreased from 53.8% in the 2013–2014 survey to 43.7% in the 2017–2018 survey. If we use the blood pressure goal from the American College of Cardiology/America Heart Association of <130/80 mm Hg, the recent hypertension control rate in the U.S. is only 21%. This decrease in control rates parallels
the increase in cardiovascular disease-related morbidity and mortality. Clearly, the present approach to the detection and especially management and treatment of hypertension is less than optimal. The U.S. Surgeon General’s recent call to action to control hypertension highlights the fact that nearly half of adults in the U.S. have hypertension (using the criterion of $\geq 130/80$ mm Hg for the diagnosis of hypertension). However, as mentioned above, only about 1 in 4 of those individuals are controlled,\(^8\) which increases the risk for heart disease and stroke for millions of Americans. The U.S. Surgeon General’s call to action identifies specific hypertension control goals and evidence-based interventions that can be implemented, adapted, and expanded in multiple settings across the U.S. and echoes a significant amount of the content in the Global HEARTS Initiative.

Given this background, there is an urgent need for a paradigm shift and a different way in approaching the detection, management, and treatment of hypertension. It is important to recognize that not very long ago there were no treatment recommendations and no effective pharmacologic agents for hypertension. However, when evidence clearly demonstrated that pharmacologic treatment of hypertension significantly decreased morbidity and mortality and safe, effective, and well tolerated pharmacologic agents became available, the health-care community adopted the step-care approach to treat hypertension. The step-care approach involved using a diuretic as first-step therapy and maximizing the dose if needed. If the blood pressure was still uncontrolled the next step was to add another agent and maximize the dose if needed. If the individual remained hypertensive, adding an additional agent was the third step, and so on. During this time, it was demonstrated that there were demographic differences in the blood pressure response to different antihypertensive classes. For instance, low-renin, salt sensitive individuals responded to a greater extent to diuretics and calcium channel blockers while high-renin, salt resistant individuals responded to a greater extent to beta blockers and renin angiotensin aldosterone inhibitors. Given this data, a more individualized approach to the pharmacologic treatment of hypertension gained favor. This individualized approach allowed for the use of any of the four primary antihypertensive classes as initial treatment, depending on race, gender, ethnicity, age, and comorbid conditions. The individualized approach initially included beta-blockers as a choice for initial treatment. However, given the concern that the use of beta-blockers may not reduce the incidence of stroke as much as the other classes of agents, most hypertension guidelines now recommend the use of any of the three present classes (diuretics, calcium-channel blockers, and renin angiotensin aldosterone inhibitors) as initial therapy in the newly diagnosed individual with hypertension. Although these efforts and programs were initially successful, they only have taken the control rates of hypertension so far. The step-care approach and the individualized approach both take time to control blood pressure and largely fail to address adequately the important barrier of clinical inertia, now recognized as a major obstacle to blood pressure control. These past efforts have led to a paradigm shift in the approach to hypertension that being a population-based approach to treatment. We obviously always treat one patient at a time, considering individual differences, but the overarching concept is to move to a population-based approach that is straightforward, simple, and importantly, primary care and health-system based [Figure 3].

Interestingly, earlier healthcare models have successfully addressed control of chronic medical conditions including hypertension. One such model is Kaiser Permanente. Established in 1945, Kaiser Permanente is one of the largest health-care systems in the U.S., with approximately 12 million members.\(^9\) Kaiser Permanente uses evidence-based protocols embedded in an electronic medical record with access to essential medications, team-based care, robust progress monitoring, and timely clinician feedback. The Kaiser Permanente hypertension program rapidly exceeded national blood pressure control rates with control rates of up to 90%.\(^{10}\) The improved population control of hypertension was associated with reductions in cardiovascular events.\(^{11}\) The pharmacologic treatment protocol improved blood pressure control by initiating two anti-hypertensive agents in the initial treatment of the newly diagnosed individuals with hypertension, as well as detailing the use of additional anti-hypertensive agents if needed to achieve blood pressure control. In addition, medication titration intervals were clarified and the types of staff that could assist in timely patient follow-up was expanded (i.e. team-based care). The Kaiser Permanente model – with its dramatic improvements in hypertension control rates and reductions in major adverse cardiovascular events – serves as a prototype for the change required to decrease the burden of cardiovascular disease.

![Figure 3: Approaches to care in the treatment of hypertension](image)
If the paradigm shift to population-based hypertension care is to succeed, the system needs a blueprint for change. Patel et al. describe an approach the Centers for Disease Control and the Pan American Health Organization launched in 2013 to improve cardiovascular disease prevention and management using the treatment of hypertension as the entry point. The project, initially known as the Standardized Hypertension Treatment and Prevention Project, builds on lessons learned from treating communicable diseases, such as HIV and tuberculosis, and advocates for standardized hypertension management protocols using a core set of available and affordable medications. In addition to guideline-based standardized treatment protocols and widely available medications, the project includes a registry to monitor and evaluate all patients within the system, promoting efficient management of populations of patients with hypertension and collecting data to track outcomes. Additional elements of the program are patient empowerment by involving patients in the decisions related to their treatment and a multidisciplinary team-based care approach. Finally, the project promotes increased awareness of hypertension as a public health priority. The Standardized Hypertension Treatment and Prevention Project has now been assimilated into the Global HEARTS Initiative and the HEARTS in the Americas Program.

Recently, the progress of the HEARTS in the Americas Initiative as a model of cardiovascular risk management, particularly hypertension, in the Caribbean and Latin America has been detailed. The program is designed to be planned and implemented at the primary health-care level. The four founding countries (Barbados, Colombia, Chile, and Cuba) implemented the HEARTS program and demonstrated the model can rapidly and markedly improve hypertension control rates. At present, 12 countries have voluntarily implemented the initiative, with more to follow. Specifically, González et al. describe the implementation and success of HEARTS in Cuba. With the assistance of the Pan American Health Organization, the Cuban Ministry of Public Health implemented HEARTS initially in a 26,000-patient clinical setting in Matanzas, Cuba, in 2016. The interventions of the Matanzas project included:

1. Standardized training on the management of hypertension
2. Education regarding lifestyle modifications
3. A simple hypertension management algorithm that included assessment of cardiovascular risk
4. A registry
5. A framework for monitoring and evaluation
6. Funding.

One of the most important steps in a population-based hypertension control program is the development of a small yet comprehensive medication formulary and a simple, straightforward treatment algorithm. The key component of the treatment algorithm is the use of two medications either as two single pills or better yet in a fixed-dose combination, also termed single pill combination. All 12 countries presently in the HEARTS in the Americas Program use dual medication therapy in the initial treatment step. DiPette et al. highlight the importance of incorporating this strategy of initial pharmacologic combination treatment to improve hypertension control rates and outcomes. For instance, it is well known that at least two or more pharmacologic agents are often required to control blood pressure. In many studies (UKPDS, HOT, ALLHAT, ACCORD, HOPE-3, and SPRINT) participants often required two or more drugs – and some required as many as four – to achieve the goal blood pressure. Therefore, the use of initial combination treatment especially in a fixed-dose, single-pill combination makes sense and can be advantageous in the management of hypertension by decreasing pill burden, medication side effects, and clinical inertia while improving adherence. Meta-analysis has demonstrated adding a drug is 5 times more effective than titrating a drug to its full dose. Incorporating wider use of combination treatment is a practical and effective strategy to improve hypertension control rates and benefits the patient, provider, and health-care system.

Conclusion

It is important to acknowledge that planning and implementing the use of evidenced-based protocols in the treatment of hypertension exemplifies a paradigm shift into population-based hypertension care. The HEARTS program and the Kaiser Permanente experience facilitated the incorporation of a population-based framework while also allowing for individualization of care based on the demographics of our local community. Our clinic provides evidence and encouragement that change on a global level can begin by medically serving these local communities that mirror the demographics of the world. Not only does this clinic directly benefit our current patients but also we hope it will continue to benefit coming generations of patients and providers. As the learners who rotate through the clinic continue to accumulate lessons learned from this resistant hypertension clinic, they take with them the potential to practice medicine, specifically hypertension management, using a population-based approach. While hypertension management will inevitably continue to change and improve over the coming years, having an already existing specialty clinic positions us on the forefront of evidence-based medicine. A recently published paper describing implementation of the HEARTS initiative in 12 countries highlights that the initiative can be integrated into already existing health-care delivery systems. This concept mirrors how our existing interdisciplinary team was able to apply similar principles.
in an existing low-income primary care clinic setting. We hope the success of our model will offer a prototype for population-based treatment of other non-communicable diseases worldwide.

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