Global Standardized Hypertension Treatment Project

Identification of a Core Set of Medications & Care Delivery Models for the Medical Treatment of Hypertension

Workshops 1 & 2 Meeting Summaries
March 4–8, 2013

Presented by
The U.S. Centers for Disease Control and Prevention (CDC),
in collaboration with the Pan American Health Organization (PAHO)

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Summary of the Project

Noncommunicable diseases, primarily cardiovascular disease, diabetes, cancer, and chronic respiratory disease, are responsible for an estimated 65% of all deaths globally (Lozano et al., 2013). Hypertension is a leading risk factor for heart attack and stroke and is responsible for over 9 million largely preventable deaths globally each year (Lim et al, 2012). Similarly, throughout the Latin American and Caribbean (LAC) region, hypertension is common (prevalence of 7–49%) and poorly controlled (Burroughs et al, 2012).

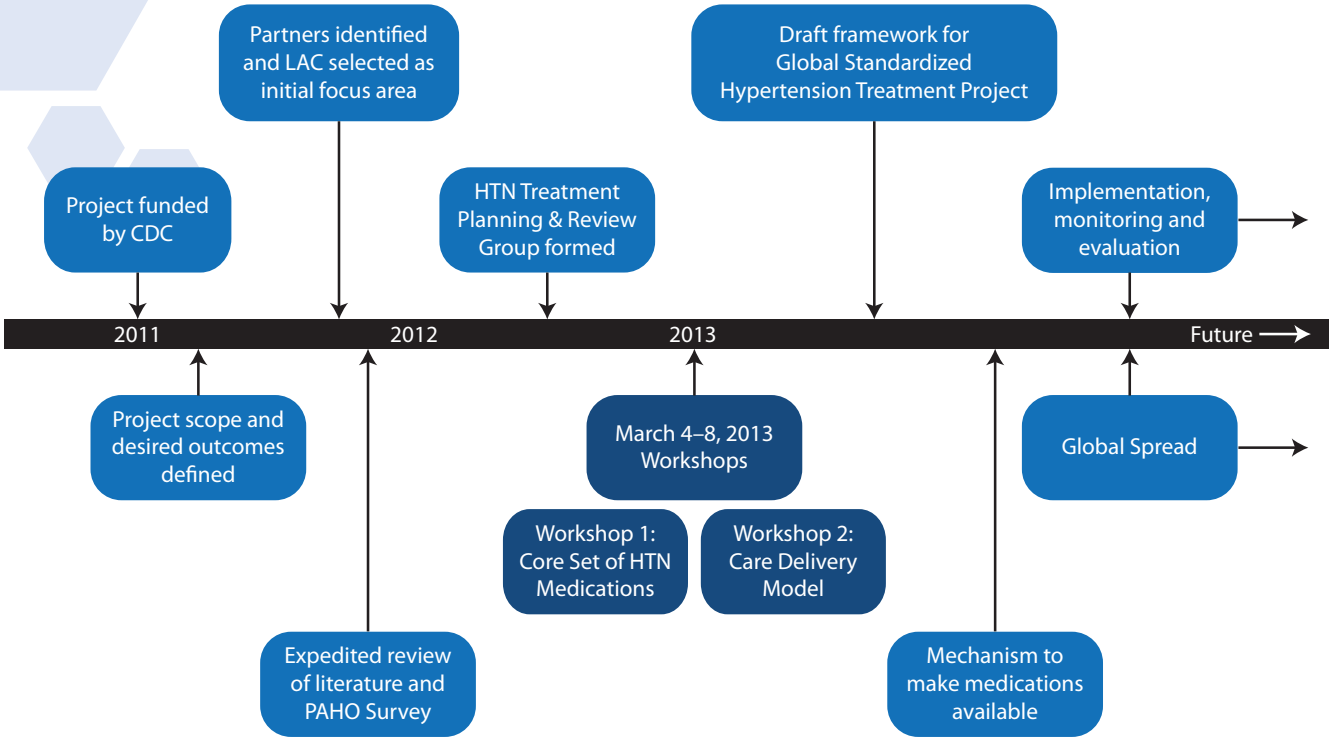
The broad-scale control of hypertension is an achievable goal, even in low and middle-income countries. Still, it remains a challenge. Essential treatment components for persons with hypertension include the prescription of appropriate medications, availability and adherence to prescribed medications, and sustained long-term monitoring and adjustment of medications. Some important conditions that prevent effective control include complex treatment regimens, limited availability and affordability of medications, and health care systems that are overburdened and under-resourced.

The Global Standardized Hypertension Treatment Project aims to support the development of an approach for standardizing the pharmacologic treatment of hypertension that will improve control rates. The framework was inspired by successful treatment models for infectious diseases such as those applied in global tuberculosis and HIV management. Central elements include a structured treatment approach with a core set of medications, treatment protocols with targets, and patient cohort monitoring (Seita and Harries, 2013). The project design aims to be feasible and flexible so it can be applied worldwide and complement existing hypertension guidelines.

Project development begins with a focus on the LAC region. During the first phase of the project, the CDC is supporting the development of the framework, in collaboration with the Pan American Health Organization (PAHO) and other partners. The resulting framework will consist of the following components:

- **Medication Treatment:** Identification of a core set of medications appropriate for the treatment of most adults with hypertension.
- **Availability of Core Medications:** Identification of mechanisms to support broad scale availability of the core set of medications.
- **Key Elements of Care Delivery:** Recommendations for key elements of care delivery to support effective hypertension treatment.

Timeline of the Project



CDC: Centers for Disease Control and Prevention; LAC: Latin American and Caribbean region; HTN: hypertension; PAHO: Pan American Health Organization; HTPRG: Hypertension Treatment Planning and Review Group

Formative research for this project included an inventory and review of current knowledge and literature on hypertension treatment protocols, medications, and care delivery models for hypertension with a focus on low and middle income nations. Three expedited literature reviews were conducted:

- Summary 1: First-Line Medications and Protocols in Published Guidelines
- Summary 2: Selection and Availability of Key Medications
- Summary 3: Elements of Care Delivery Models

Surveys were developed and conducted in the region by PAHO and professional societies. Their purpose was to assess clinical practice in hypertension management and Ministry of Health capacity to address hypertension at the population level (including the availability of anti-hypertensive medications).

A Hypertension Planning and Review Group (HTPRG) was created to provide input on workshop development. Members of this group included Maria Cristina Escobar, Pedro Ordunez, Trevor Hassell, and Daniel Pineiro (see workshop participant list, p.5). Two consecutive workshops were then held in Miami, Florida, USA during March 4–8, 2013, and were attended by global and regional clinical, scientific, and policy experts.

- **Workshop 1:** Identification of a Core Set of Medications to Treat Hypertension
- **Workshop 2:** Key Elements of Care Delivery for Medical Treatment of Hypertension

Development of the framework for the Global Standardized Hypertension Treatment Project was informed by the literature reviews and other formative research discussed previously, by HTPRG input, and by input from experts during the workshops. Key next steps will focus on securing mechanisms to make core medications available in the region, as well as piloting implementation, including monitoring and evaluation, and global spread (see Timeline on page 2).

All members of the HTPRG and workshop participants completed a Conflict of Interest statement and disclosed any financial, professional or other interests relevant to the initiative, including participation in the workshops, as well as any interest that could be significantly affected by the outcome of the initiative or workshops. No real or perceived conflicts were reported.

Workshop 1: Identification of a Core Set of Medications to Treat Hypertension—March 4–6, 2013

Workshop 1 Objective

Workshop 1 aimed to identify a core set of medications to treat hypertension to facilitate increased availability and affordability throughout LAC. The workshop did not aim to create separate guidelines from those that are scientifically-based and current, nor was it intended as a scientific review of medications since these have been previously conducted. Instead, the intent of this workshop was to build upon existing knowledge to identify a core set of medications that would be practical to support the successful implementation of effective treatment of hypertension throughout the region.

Participants

Twenty experts and key stakeholders, including physicians representing various disciplines, pharmacists, epidemiologists, and representatives from the International Society of Hypertension, the Latin American Society of Hypertension, the Caribbean Cardiac Society, PAHO, the World Heart Federation, Ministries of Health from the LAC region, and the CDC met on March 4–6, 2013. Participants were chosen based on their expertise in the field of hypertension treatment. In preparation for the workshops, participants were provided with questions concerning hypertension control* and were asked to consider responses based on knowledge of practices in his or her country or region, organization, or practice setting, and to come prepared to contribute expertise to the discussion.

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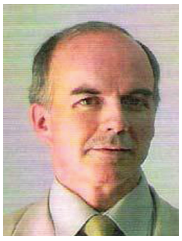

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* Questions related to barriers, guidelines, medication use and availability in hypertension treatment.

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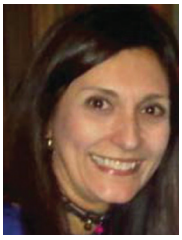

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Overview of Speaker Presentations

Hypertension and Barriers to Hypertension Control in Latin America and the Caribbean (LAC)

Pedro Ordúñez and Fernando Lanas

- They described the burden and impact of hypertension globally and in LAC.
- They remarked that overcoming barriers such as medication cost and availability, adverse medication effects, complex treatment regimens with high pill burden per day, complicated physician relationships, and limited patient knowledge related to hypertension could result in greater hypertension control.

Treatment of Hypertension with a Focus on Medications

Sonia Angell and Trevor Hassell

- They provided overviews of two regional* and seven national† guidelines within the LAC region, as well as overviews of other guidelines from outside of the LAC region, noting that specific medications to be used was rare within the guidelines.
- They noted that the broad scale availability of a core set of medications in the region would allow for standardization of medications used to treat hypertension and could complement existing protocols since the majority lacked specification.
- They emphasized that a simplified approach to hypertension treatment that includes a core set of medications can reduce complexity of care for providers and ultimately improve hypertension control for patients.

Standardized Medications in an Existing Model

Jose Miguel do Nascimento and Marc Jaffe

- Jose Miguel do Nascimento discussed the Brazilian Public Popular Pharmacy program, which incorporates a core set of 14 antihypertensive medications, included in the national list, and are provided free of charge to persons with hypertension.
- Marc Jaffe presented the Kaiser Permanente model of improving hypertension control in a large patient population, which included the use of treatment protocols that specified the medications to be used, for example, initiating therapy with a single combination pill of

* Caribbean Health Research Council, Latin America Society of Hypertension

† Belize, Bermuda, Brazil, Chile, Colombia, Cuba, and El Salvador

lisinopril and hydrochlorthiazide. Hypertension control rates improved from 43.6% in 2001 to 80.4% in 2009.

Medications to Treat Hypertension

Rafael Hernández

- He presented a review of the medications and classes commonly used to treat hypertension and their advantages and disadvantages (including side effects), dosages, rates of metabolism, bioavailability, and duration of action.
- He concluded that hypertension control can be achieved using existing medications from the five examined classes: diuretics, calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), and beta-blockers.

Expert Deliberations: Selection of a Core Set of Medications

At the conclusion of the presentations, participants were asked to consider methods for selecting a core set of hypertension medications. The group decided they would organize the discussion around commonly recommended classes of medications, then consider specific medications within each class with the goal of agreeing to a set of core medications. Participants were then separated into two smaller facilitated working groups.

Each working group independently determined selection criteria for recommended core medications. Using these criteria, they identified a primary medication from each class, as well as a "backup" or alternative. The "primary" would be the medication for that class that the project would focus on making available broadly throughout the region for use during phase II. If, for some reason, it was not possible to make the primary broadly available, the effort would then turn to make the "backup" available.

The needs of specific patient populations were considered (those with diabetes or pregnant women) when selecting medications.

Reaching Consensus: Finalizing a Core Set of Medications

Following the two working group deliberations, they were reconvened as one. A representative from each working group reported their selection criteria and recommended medications for each class of medications. There was substantial overlap in the selection criteria used and the specific medications selected. A facilitated discussion followed to reach consensus on a consolidated list of selection criteria.

Final Medication Selection Criteria (not in rank order)

1. Efficacy (from a pharmacologic perspective) and Safety
2. Evidence-based clinical and effectiveness outcomes
3. Scored tablet
4. Tolerability (few side effects)
5. Once-a-day dosage (also including variability in dose)
6. Cost/Affordability/Availability

7. Inclusion on the WHO Model List of Essential Medicines* (this was not an exclusionary criterion)

8. Regional considerations (e.g., diversity of the population)

Once these final selection criteria were agreed on, primary and backup medication recommendations by class from each group were reviewed and discussed together to explore the potential for larger group agreement on a core set of medications to treat hypertension.

Given increasing interest in the use of single-pill combination medications, the group also felt that advocating for widespread availability of single-pill combination medication would be of value. As the group already identified the leading candidate drugs from each class, the formulation of a fixed-dose combination tablet that included an appropriate combination of two of the primary medications would be ideal for treatment purposes. The group first considered currently available combinations and found that none achieved this goal. They selected some options from existing medications and then discussed fixed-dose combinations that might be ideal, but are not currently available. The final core set of medications is found on the next page.

Following the selection of the core medications, there were presentations focused on methods for increasing the availability of core medications that are described below.

Making Core Medications Available

Thomas Gaziano

- Described the economic impact of non-optimal blood pressure and cost-effective solutions to improve the management and effective control of hypertension.

Formal Structures and Informal Processes to Increase Availability of Core Medications

Jose Luis Castro

- PAHO's Strategic Fund was identified as a possible mechanism for increasing the availability of core hypertension medications in the region.

- The two main services of PAHO's Strategic Fund are international procurement and technical advice on supply management. In 2012, 17 countries had used the Strategic Fund.

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* Hypertension medications included on the WHO Model List of Essential Medications: amlodipine, bisoprolol, enalapril, hydralazine, hydrochlorothiazide, methyldopa. Available at **http://www.who.int/medicines/publications/essentialmedicines/en/**

Final Core Set of Medications

Medication Class	Primary	Backup
Diuretic	Chlorothalidone	Hydrochlorothiazide (HCTZ)
Angiotensin Converting Enzyme (ACE) Inhibitor	Lisinopril	Enalapril
Angiotensin Receptor Blocker (ARB)	Losartan	Valsartan
Calcium Channel Blocker (CCB)	Amlodipine	None
Beta Blocker	Bisoprolol	Metoprolol SR
Other	Spironolactone	None
**Fixed-Dose Combinations (Single-Pill)*		
Angiotensin Receptor Blocker + Calcium Channel Blocker	Losartan + Amlodipine OR Valsartan + Amlodipine	N/A
ACE Inhibitor + Calcium Channel Blocker	Benazepril + Amlodipine	N/A
ACE Inhibitor + Diuretic	Lisinopril + HCTZ	N/A
Angiotensin Receptor Blocker + Diuretic	Losartan + HCTZ	N/A
Angiotensin Receptor Blocker + Diuretic + Calcium Channel Blocker	Valsartan + HCTZ + Amlodipine	N/A
***Ideal Fixed-Dose Combinations (Single-Pill)*		
Angiotensin Receptor Blocker + Chlorthalidone + Calcium Channel Blocker	ARB + Chlorthalidone + CCB	N/A
ACE Inhibitor + Calcium Channel Blocker	Lisinopril + Amlodopine	N/A
ACE Inhibitor + Diuretic	Lisinopril + Chlorthalidone	N/A
Angiotensin Receptor Blocker + Diuretic	Losartan + Chlorthalidone	N/A
Angiotensin Receptor Blocker + Calcium Channel Blocker	Losartan + Amlodopine	N/A

**Single-pill combinations were not stratified into primary and backup choices; all combinations were equally recommended.*

***Further investigation is needed for these ideal fixed-dose single-pill combinations*

Workshop 2: Care Delivery Model for Medical Treatment of Hypertension—March 7–8, 2013

Workshop 2 Objective

To recommend effective key elements of a care delivery model for the medical treatment of hypertension throughout the LAC.

Participants

Nineteen experts and key stakeholders met on March 7–8, 2013, including physicians from various disciplines, pharmacists, epidemiologists, and representatives from CDC, PAHO, the Barbados Drug Service, the Healthy Caribbean Coalition, the Interamerican Society of Cardiology, the Latin American Federation of Obstetrics and Gynecology, the Latin American Society of Internal Medicine, the Pharmaceutical Forum of the Americas, and Ministries of Health (MOH) from the LAC region. Participants were chosen based on their expertise in the field of hypertension treatment and care delivery. Prior to arrival, participants were asked to consider a number of questions pertaining to hypertension care delivery models. In order to maximize the potential input, each participant was asked to consider the perspective of his or her region, organization, or practice and come prepared to contribute this context to the discussion.

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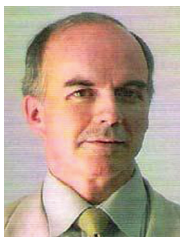

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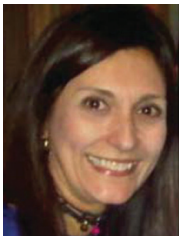

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Overview of Speaker Presentations

Perspectives on Global Hypertension

Pedro Ordúñez and Daniel José Piñeiro

- They described the epidemiology of hypertension in the LAC region, with an emphasis on awareness, treatment, and control.
- Survey data from a 2013 Interamerican Society of Cardiology (IASC) of 20 national societies of cardiology were presented and respondents indicated that important barriers to hypertension control existed.

Models for Care Delivery

Specific Examples

- Presentations were given by María Cristina Escobar, Daniel Ferrante, José Ortellado, Jose Miguel do Nascimento Junior, and Marc Jaffe describing care delivery models for Chile, Argentina, Paraguay, Brazil, and Kaiser Permanente, respectively. In each presentation they highlighted key elements that contributed to the effectiveness of the presented models.

Successful Key Element Discussion

Following these presentations, the workshop participants discussed systems-level tasks necessary to achieve control of hypertension. Some examples include: maximization of opportunities to track and monitor blood pressure at traditional health services and beyond, such as pharmacies and community centers; and targeted messaging and health education at multiple levels—for policymakers, health care professionals, educators, and the public. Data should be collected, maintained, and used for decision-making. Efforts should be made to gain high level support from all stakeholders, including policymakers and sponsors. Multiple sectors, (e.g., industry, education, and advertising) should be engaged in strategic planning, with movement towards building operational capacity to treat hypertension at a population level. Also, efforts should be made to involve and empower the community.

Expert Deliberations: Key Elements of Care Delivery Models

While the original charge of the workshop was to identify care "models" for the effective treatment of hypertension, workshop participants concluded that focusing on key care delivery "elements" for hypertension control would be more appropriate. They noted that most countries

already had invested in large care delivery models. Therefore, the most efficient approach would be to identify elements that could be adopted into all types of models and care delivery systems for improved outcomes.

Participants recommended that elements be clear and concise and that each should include a guide to action with specific tasks. It was noted that key care elements for effective hypertension care delivery are likely to be relevant to care delivery for other chronic conditions.

Based upon the discussions, participants reached consensus on a list of elements of care delivery models for hypertension treatment:

1. **Strategy**
2. **Guidelines** (protocol for treatment)
3. **Registries/Information Systems** (including patient tracking and feedback mechanisms)
4. **Medications** (available and integrated core set)
5. **Patient-Centeredness** (including self-management interventions)
6. **Care System** (organizational management to implement a primary health care-led system)
7. **Community**

Strategy

Participants discussed the need for a strategy to prepare for the development of a patient-centered care delivery model. This strategy should:

- Identify specific stakeholders with clearly defined roles and responsibilities. Involved parties should include patients, clinicians, pharmacists, and others (e.g., policy makers, health educators, etc.) to comprise a multi-disciplinary team.
- Establish concrete targets and goals at all levels – noting that different strategies will be needed at the organizational and individual levels.
- Consider financial resources, including funding sources and procurement mechanisms.
- Create an environment where treating hypertension is a priority. One identified mechanism involves presenting to policy makers the case for the high return on investment and efficiency, especially when considering certain patient groups and classification by risk factor.
- Conduct monitoring and evaluation, which are critical components of any cohesive strategy.

Guidelines

Standardized, protocol-driven care, facilitated through the use of a single hypertension treatment guideline remains essential.

- Within a country, a single treatment protocol developed and/or endorsed by key stakeholders, nationally relevant, evidence-based, clear, simple and implementable should be used.
- Core medications should be integrated into guidelines and the treatment protocol.

- An implementation plan for the guidelines must consider potential barriers and mechanisms of support.

Registries/Clinical Information Systems

- Hypertension registries collect and store clinical information on all patients within the system with the condition.
- This allows for the efficient management of 'populations' of patients with hypertension within a care system. For example, all patients within the registry with uncontrolled blood pressure could be identified and contacted for follow-up on a quarterly basis.
- Data generated from these systems can also be used to create indicators, set targets, and assess the impact of changes in the system and care delivery with an eye on improving quality of care.
- These information systems can be used to track the care and outcomes of individual patients and would ideally have the capacity to capture information from the community and other related systems such as pharmacies and hospitals.

Medications

- A core set of standardized medications that are consistently available, safe, high-quality, and efficacious is needed.
- Efforts should be undertaken to ensure the quality and safety of medications in the core set.
- A procurement mechanism should be implemented to ensure a consistent supply of medications for the core set.

Patient-Centeredness

- In a patient-centered care delivery system, patients are informed about their hypertension, involved in decisions related to their treatment, are comfortable expressing their concerns to their health care providers, and the relationship between patient and provider is based on mutual respect.
- Together, a patient and provider set the hypertension treatment goals, plan how to achieve these goals, and solve problems.
- Tools, education, and support systems should be included in care delivery models that improve patients' knowledge, attitudes, and medication-taking behaviors. Examples may include educational materials, the creation of peer support groups, the provision of self-blood pressure monitors and other tracking devices.

Care System

- A system for the effective delivery of hypertension treatment should be led and managed in the primary care setting where patients receive most of their health care.
- A multidisciplinary team of health care providers in the primary care setting who communicate with each other and coordinate patient care delivery is needed.
- A focus on continuity of care is a high priority, and blood pressure should be checked and addressed at every visit.

Community

- Community engagement in addressing hypertension as a priority health problem should be systematically supported by clinical systems.
- Key related services and support that should be grounded in the community includes access to regular blood pressure checks to support the detection and treatment of hypertension at the population level, and consideration of non-traditional care settings as venues for care advocacy and education.
- Potential community partners include: civil society organizations or representative organizations, technical communities, media, advertising, and other industries. The role of NGOs could include facilitating the integration of the community care providers to work collaboratively with regional governments.

Expert Deliberations: Key Considerations for Implementation and Spread of Core Medications

Prior to concluding Workshop 2, the participants were asked to identify and discuss barriers to and incentives for the systematic integration and use of core medications in care. This was an open discussion and the group was not asked to prioritize or rank any barriers or incentives. Following is a summary of the barriers and incentives noted.

Barriers	Description
Lack of inclusion on other medication lists	Absence of any of the recommended core medications on lists, such as the WHO Model List of Essential Medicines
Regional/Cultural acceptance	Regional and cultural variance with respect to familiarity with medications, potentially leading to a reluctance to pay, prescribe, or use recommended medications
Bureaucratic	Bureaucratic barriers to adoption, such as systems-level inertia
Therapeutic inertia	Physician therapeutic inertia and resistance to change current medications commonly in use, further complicated by system-level difficulties in obtaining the recommended medications
Patient resistance to change	Patients achieving controlled blood pressure with current medications may not see reason to change to new medications
Public health acceptance	Convincing those who shape clinical guidelines to incorporate a global public health perspective
Supply chain	Fragmentation of the procurement system and uncoordinated supply and demand modeling
Prioritization of initiatives	Competing priorities of patients, health care professionals, and health systems

Incentives	Description
PAHO Strategic Fund	PAHO Strategic Fund adopting medications from the core medication list
National list inclusion	Government purchasing of core medications through adoption of medications into their national lists
Physician adoption	Integration of core medications into new guidelines could influence clinicians towards increased usage
Single-pill combination, medication testing, production, and adoption	Educating providers to make the case for changing medications, including the testing, production, and adoption of single-pill combination medications that may not have been part of usual practice previously
Reduced medication cost	Successfully market a core set of medications, making them broadly available to patients and health systems throughout the region
Improved messaging	Clear messaging demonstrating the benefits of treatments
Improved industry partnerships	Stronger liaison with the pharmaceutical industry to foster support for core medications and their role in effective care delivery
Increased awareness	Raising awareness of prevalence and urgency of addressing chronic non-communicable diseases

Conclusion and Next Steps

The goal of these workshops and discussions was to provide the building blocks upon which to further develop the needed global hypertension treatment care delivery elements and medical treatment. As the project continues, the ongoing engagement of stakeholders will prove invaluable to identify needs, establish guidelines, anticipate barriers and incentives to implementation in the region, and spread implementation.

During Workshop 1, Identification of a Core Set of Medications, experts identified medication selection criteria and a core list of medications for the effective treatment of hypertension based on their collective experiences and opinions. There was consensus among the experts that further stakeholder involvement is needed to better support this project.

During Workshop 2, Care Delivery Model for Medical Treatment of Hypertension, experts discussed the key elements needed for standardizing the pharmacologic treatment of hypertension and improving hypertension care delivery. Consensus among the experts was reached on key elements of a care delivery model that should be considered throughout the project.

Next steps for the project include the following:

- Outcomes of this first phase will be used to inform the development of a strategic framework for reducing global hypertension; this will be forthcoming.
- Future phases will involve soliciting additional stakeholder input for implementation, evaluation, and spread.

Acknowledgements

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