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Evaluation of the implementation of a technical package for cardiovascular disease reduction with emphasis on hypertension control in Colombia using the Consolidated Framework for Implementation Research

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Evaluation of the implementation of a technical package for cardiovascular disease reduction with emphasis on hypertension control in Colombia using the Consolidated Framework for Implementation Research

A dissertation submitted in partial satisfaction of the requirements

for the degree Doctor in Public Health

in Public Health

by

Gloria Patricia Giraldo Arcila

2020

ABSTRACT OF THE DISSERTATION

Evaluation of the implementation of a technical package for cardiovascular disease reduction with emphasis on hypertension control in Colombia using the Consolidated Framework for Implementation Research

by

Gloria Patricia Giraldo Arcila

Doctor of Public Health in Public Health

University of California, Los Angeles, 2020

Professor Steven P. Wallace, Chair

Worldwide, more people die from cardiovascular diseases (CVDs) than from any other diseases. Of these deaths, 80% are due to heart attacks and strokes, and about three quarters occur in low-and-middle income countries (LMICs). In the Region of the Americas, CVDs result in 1.9 million annual deaths of which one third occur before the age of 70. Hypertension is the underlying cause of 60.1% of all ischemic heart disease and 63.7% of all strokes. The estimated prevalence of hypertension ranges between 20% to 40%. To respond to CVDs, the World Health Organization (WHO) launched the Global Hearts Initiative in 2016 for the prevention and management of CVDs through policy and health system strengthening interventions organized in a set of technical packages. The HEARTS Technical Package is a group of evidence-based interventions: **H**ealthy-lifestyle counseling, **E**vidence-based treatment protocols, **A**ccess to essential medicines and technology, **R**isk-based management, **T**eam-based care,

and **S**ystems for monitoring. The Pan American Health Organization (PAHO) has been guiding the HEARTS implementation in the Americas, and Colombia is part of the first cohort of HEARTS implementing countries.

The main purpose of this study is to analyze the current implementation of the HEARTS Initiative in Colombia, first by describing overall implementation conceptual underpinnings and second, by mapping the current implementation strategies onto the Consolidated Implementation Research Framework (CFIR). The method used is a qualitative inquiry based on semi-structured interviews of 54 implementers in Colombia from the twelve original public primary care health centers that are implementing HEARTS and few referenced national and state level health officials. Inductive analyses of the themes from the interviews allowed for the construction of a program theory of change from the ground up. Deductive analyses that applied the CIRF to the data identified higher order factors that also shaped implementation. The results show high homogeneity in the level of information and absorption of the model across the twelve public primary health centers. The core components proposed by the HEARTS model were adapted to the context of Colombia which was still undergoing a health care reform that started in 2015, which created policies and a health care model into which the HEARTS model was being inserted. HEARTS driven data cleaning processes, development of standardized hypertension treatment protocols and redesigning of patient workflows were important milestones of implementation. Leadership at all levels, human resources stability and continuous training were determining cross-cutting factors that affect the adoption of the HEARTS model. The simplicity of the HEARTS model, the inclusion of front-line practitioners from the onset and the support of the external international organizations have positively affected implementation. Lack of coordination with financing actors, such as insurance entities, may pose one of the greatest challenges to implementation and sustainability. Mapping the implementation of HEARTS in Colombia contributes to the knowledge base on effective implementation of chronic disease management models in LMIC.

The dissertation of Gloria Patricia Giraldo Arcila is approved.

Arun Karlamangla

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James Macinko

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2020

Dedication

Just like it takes a village to raise a child, it took a global village to complete my doctorate. I deeply thank all of you who have accompanied me in this long journey. To thank you all individually would require a dedication section longer than the dissertation itself. You know who you are, my dear friends from Santa Ana, California to Pereira, Bogota, Cali, flying over Havana passing by Matanzas, to Buenos Aires, back to Washington and completing the full circle back to Los Angeles. First and foremost, my deepest gratitude to my family, to my mother, Aliria Arcila, who, since I can remember, has not only encouraged but expected that I would attain the highest degree in my field, for her tenacity and audacity that have driven us. To my father, Danilo Giraldo, whose quiet nature and love-of-learning and love-of-books I have inherited, and to my aunt, Adiela Arcila, for her unwavering and unconditional support. To my sister, Milena, my niece, Caterina, and my nephew, Mauricio, who keep me real, and to my partner, Cesar, who keeps me sane by bringing laughter and music into my life and does not let me forget my story. To all my transnational family and friends, in Colombia, in the U.S. and in the Americas, thank you for forgiving my chronic absenteeism causing me to miss many important life milestones and simple everyday rituals (and for hosting my unannounced visits). Special mention to my friend K. Zulliger, thank you for your support and thought provoking conversations which motivated me to continue pursuing my studies. To my teachers and professors who have guided me through the many years of studying. Thank you to my colleagues throughout the years, to the LHA promotoras/es who embody compassionate public health, to my mentor and compañera, Dr. America Bracho. To my colleagues in Oakland and Washington who have broadened my horizons in global health and allowed me to work with passionate and caring public health practitioners throughout the Americas; to Dr. Pedro Orduñez for the encouragement and support. Special thanks to the colleagues in the primary care centers in Colombia for the generosity with their time and dedication. Thank you to the excellent and caring interviewers, Alejandra Martinez and Laura Jurado. To my dissertation committee chair, Dr.

Steve Wallace who never gave up on me and has shepherded this work through with firmness and solidarity. To my committee members, Dr. Arun Karlamangla, Dr. Randall Kuhn and Dr. James Macinko who patiently plowed through the dissertation with care and thoughtfulness. And finally, this work is dedicated to the late Dr. E. Richard Brown, whose lifework was the embodiment of public health for social justice.

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Glossary

ACTIVE	Initiative for physical activity, active environments, active societies, active systems, active people
AHA	American Heart Association
AIDS	Acquired immunodeficiency síndrome
CARMELA	Cardiovascular Risk Factor Multiple Evaluation in Latin America Study
CD	Communicable disease
CDC	Centers for Disease Control and Prevention
CESCAS	South American Centre of Excellence in Cardiovascular Health
CFIR	Consolidated Framework for Implementation Research
CHP	Cardiovascular Health Program, in Spanish: *Programa de Salud Cardiovascular*, PSCV (Chile)
CVD	Cardiovascular disease
CVRF	Cardiovascular risk factors
DALYs	Disability adjusted life years
ECAES	Colombian State Exam, in Spanish: *Exámenes de Calidad de Educación Superior*
ECOPETROL	Colombian Petroleum Company
FCTC	WHO Framework Convention on Tobacco Control
HBP	High blood pressure, hypertension
HEARTS	Healthy-lifestyle counseling, Evidence-based treatment protocols, Access to essential medicines and technology, Risk-based management, Team-based care, and Systems for monitoring
ICR	Integral Care Route (Colombia)
IES	Higher Education Institution, in Spanish: *Instituciones de Educación Superior*
IHME	Institute for Health Metrics and Evaluation (University of Washington)
LMIC	Low-and-Middle Income Countries
MPOWER	Initiative for tobacco control: Monitor, Protect, Offer, Warn, Enforce, Raise
NCD	Non-communicable disease
PAHO	Pan-American Health Organization

PAIS	Integrated Health Care Policy, in Spanish: *Política de Atención Integral en Salud* (Colombia)
PDSP	Ten-year Public Health Plan (Colombia), in Spanish: *Plan Decenal de Salud Pública*
PURE	Population Urban and Rural Epidemiology Study
RE	Realist evaluation
RECCETA-A	Acronym for Colombian version of CDC Million Hearts
REPLACE	Initiative for the elimination of industrially produced trans-fat, Review, Promote, Legislate, Assess, Create, Enforce
SCRC	Socio Cultural Research Consultants
SHAKE	Initiative for salt consumption: Surveillance, Harness Industry, Adopt standards for labelling and marketing, Knowledge, Environment
WHO	World Health Organization

Glossary for terms specific to the Colombian health system

BDUA	Health system member database. It is the base that contains the information of the fully identified members of the different regimes of the SGSSS (Subsidized, Contributory and Special Regimes). In Spanish: *Base de Datos Única de Afiliados*
COPAY	Copays are money contributions that correspond to a part of the value of the service requested and are intended to help finance the system
EPS	Health insurance agency. These are the entities responsible for the affiliation and provision of the POS of the Subsidized Regime to its beneficiaries. In Spanish: *Entidad Promotora de Salud*
EAPB	Health Benefit Plans Administrative Entities are comprised by the health insurance agencies of the contributory and subsidized regimes, collective health companies, mutual associations in their health activities, health insurance agencies for indigenous peoples, welfare funds in their health activities, the entities that administer additional health plans, the entities obliged to compensate, the adapted entities of health, the entities belonging to

	the health exception regime and the universities in their health activities. In Spanish, *Entidades Administradoras de Planes de Beneficios*
FOSYGA	It is an account attached to the Ministry of Social Protection that is managed by fiduciary commission, in which the resources of the SGSSS are deposited. In Spanish: *Fondo de Solidaridad y Garantía*
IPS	Health care provider. These are the institutions in charge of providing health services at their corresponding level of care to affiliates and beneficiaries within the parameters and principles indicated by the Law. In Spanish: *Institución Prestadora de Servicios de Salud*
POS	Basic benefits package. It is the set of activities, procedures, and interventions, services, supplies and medicine to which the affiliates of the RS are entitled. In Spanish: *Plan Obligatorio de Salud*
RS	It is a set of regulations and procedures that oversees the affiliation off the poor and vulnerable population to the SGSSS, with resources from the Nation and Territorial Entities. In Spanish: *Régimen Subsidiado*
SISBEN	System for determining individuals' eligibility for social programs, which organizes individuals according to their standard of living and allows the technical, objective, uniform, and equitable selection of beneficiaries of social programs run by the State, according to their socioeconomic condition. In Spanish: *Sistema Integral de Información de la Protección Social*
SGSSS	National Health System: the set of public and private entities, norms, and procedures, which seek to provide health services and set access conditions at all levels of care, based on guaranteeing comprehensive care for all populations. In Spanish: *Sistema General de Seguridad Social en Salud*

Curriculum Vitae

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EDUCATION

Master of Public Health
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University of Michigan at Ann Arbor, Michigan, degree awarded Spring 1999

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- Experience leading public health projects in Latin America and the Caribbean
- Held key position in the implementation of a Healthy Cities Model Initiative in California
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PUBLICATIONS
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Chapter 1: Introduction

Worldwide, more people die from cardiovascular diseases (CVDs) than from any other diseases. Of these deaths, 80% are due to heart attacks and strokes, and about three quarters occur in low-and-middle income countries (LMICs). (World-Health-Organization, 2013) CVD mortality declined steadily in the Americas, with an overall reduction of 19% from 2000 to 2010 (de Fatima Marinho de Souza, Gawryszewski, Ordunez, Sanhueza, & Espinal, 2012), but it continues to be the leading cause of all deaths. Cardiovascular diseases result in 1.9 million annual deaths of which one third occur before 70 years of age. (Pan-American-Health-Organization-&-World-Health-Organization, 2019) Hypertension is the underlying cause of 60.1% of all ischemic heart disease and 63.7% of all strokes among this age group in the Americas. (Institute of Health Metrics, 2020)

Uncontrolled hypertension kills an estimated 9.4 million people annually worldwide—about as many as all infectious diseases combined. (World-Health-Organization, 2013) The age-standardized prevalence of hypertension for the world's adults was 31.1% and decreased by 2.6% between 2000 and 2010 in high income countries but increased by 7.7% in LIMCs.

In the Americas, the estimated prevalence of hypertension ranges between 25% to 40%. (Ordunez, Prieto-Lara, Pinheiro Gawryszewski, Hennis, & Cooper, 2015) The Cardiovascular Risk Factor Multiple Evaluation in Latin America study (CARMELA) reported that between 24.3 to 46.9% of people with hypertension were unaware of their hypertensive condition, more than half of those with hypertension were untreated, and only 12.0% were controlled. (Hernandez-Hernandez et al., 2010) Similar findings have been reported from the Population Urban and Rural Epidemiology study (PURE), stating that only 57% of people with hypertension knew of their condition, 52.8% of those who were aware received treatment but only 18.3% had adequate control. (Chow et al., 2013) Low levels of

hypertension control result in higher CVD morbidity and mortality, therefore, addressing hypertension and overall CVD health is a global health priority. Elevated blood pressure is the strongest modifiable risk factor for cardiovascular disease, and hypertension management and control at primary care level is a cost-effective intervention. (Perel et al., 2015), (Karmali et al., 2018), (Law, Morris, & Wald, 2009) Although several countries have developed national action plans to address non-communicable diseases and have prioritized CVD prevention, treatment and control; in most countries of the Americas, important gaps remain to improve cardiovascular health. (Ordunez, Mize, Barbosa, Legetic, & Hennis, 2015) Challenges to blood pressure control in some geographical areas are the absence of comprehensive primary healthcare services, including limited access to medications, and the lack of systems to effectively deliver prevention and treatment. However, evidence based on lessons from the treatment of communicable diseases in LIMCs, as well as successful models of hypertension control in the United States and Canada, show that controlling hypertension is achievable using a health system-strengthening approach. Key actions of this approach include standardized treatment protocols, effective drug procurement mechanisms using a core set of medications, accountability by tracking progress and control using registries, patient empowerment, team-based care, and community engagement. (Ordunez, Mize, et al., 2015), (Seita & Harries, 2013), (Patel et al., 2016)

WHO Best Buys Interventions

The World Health Organization (WHO) and the Pan American Health Organization (PAHO) have developed actions plans to drive multi-sectoral approaches to address non-communicable diseases (NCDs). These include technical cooperation to improve access to cost-effective prevention, treatment, and care. As part of these action plans, WHO has recommended interventions to address NCDs. These interventions, known as “best buy” interventions, are assessed for cost-effectiveness and feasibility, as well as non-financial considerations, such as implementation capacity, and impact on health equity.

(World-Health-Organization, 2017), (World-Health-Organization), (Pan-American-Health-Organization, 2014) One way in which these "best buy" interventions are promoted is through the creation of initiatives which include technical packages. One such initiative recently developed by WHO and global partners is Global Hearts, which includes five technical packages that address the prevention of CVD, namely MPOWER for tobacco control, SHAKE for salt consumption reduction, ACTIVE for physical activity, REPLACE for the elimination of industrially produced trans-fat, and HEARTS for CVD management in primary care, which is being implemented in the Region of the Americas as "HEARTS in the Americas." HEARTS is an acronym for the six modules of the package: **H**ealthy-lifestyle counseling, **E**vidence-based treatment protocols, **A**ccess to essential medicines and technology, **R**isk-based management, **T**eam-based care, and **S**ystems for monitoring. (World-Health-Organization, 2016) In 2015, during the early preparation phases of the Global Hearts Initiative, PAHO started rolling out a set of components of the HEARTS technical package in four countries in the Americas: Barbados, Chile, Colombia and Cuba. This early roll-out intervention eventually became the HEARTS in the Americas Initiative.

Research gap

As of early 2020, twelve countries in Latin America and the Caribbean are participating the HEARTS in the Americas Initiative at different levels of development. This dissertation focuses on the early implementation in Colombia through an implementation science lens. Central to this research is the exploration and understanding of how HEARTS in the Americas implementation occurs in practice in the first twelve public primary care health centers in Colombia. Implementation is defined as the dynamic organizational process that happens between the organizational decision to adopt an innovation and the innovation's assimilation into existing organizational practices. (Klein & Sorra, 1996)

The above mentioned "best buys" that are included in the Global Action Plan for the prevention and control of NCDs include a set of such health policies and interventions. The "best buys"' are identified

from the global evidence base, however a systematic review (Allen et al., 2018) confirmed the dearth of research focused on evaluations of "best buy"' interventions and highlighted a general lack of published evidence for the "best buy" interventions in LMICs. Moreover, half of the identified studies evaluated tobacco-related interventions only. The same review highlighted the need for prioritizing NCD "best buys" in national research agendas in LMICs as this would contribute to the generation of more "context specific" evidence for NCD prevention and control and improve the implementation of those policies and interventions.

To address this important research gap, this research is the first qualitative inquiry into the implementation of the HEARTS Initiative (an application of a "best buy") in one middle-income country in the Americas, Colombia, utilizing an implementation science lens. Due to the recency of the initiative globally and regionally, this study focuses on early stages covering the transition period during which members of an organization (health centers) incorporate an innovation intended to be adopted into sustained use. The results of this evaluation will contribute to building the knowledge base to improve the implementation of "best buy" interventions in similar settings.

In implementation science, several frameworks have been developed; one of the most widely cited is the Consolidated Framework for Implementation Research (CFIR). The CFIR offers an overarching classification of barriers and facilitators to implementation success into 5 domains: i) intervention characteristics; ii) the outer setting (e.g., policy environment, patient needs, social and professional norms, etc.); iii) the inner setting (organizational characteristics, culture, implementation climate, etc.); iv) characteristics of individuals, and v) the implementation process. (L. J. Damschroder & Lowery, 2013) As the name implies, the CFIR was developed to consolidate existing constructs from published implementation theories and frameworks and was heavily influenced by Greenhalgh's Conceptual model for the considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery which, itself, was a comprehensive synthesis of nearly 500

published sources, (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004) including Rogers' seminal work on the diffusion of innovations. (Wagner, 1998)

An important distinction between the CFIR and its preceding theories is that it refers to health interventions as opposed to innovations. An innovation, according to Rogers and Greenhalgh is defined as "an idea, practice or object that is perceived as new by an individual or another unit of adoption" (Mark et al., 2007). Although similar in many respects, an intervention is defined by the World Health Organization as "an activity or set of activities aimed at modifying a process, course of action or sequence of events in order to change one or several of their characteristics such as performance of expected outcome." (Sandoval et al., 2012)

Study Aim and Research Questions

Due to the newness of the initiative, this study is one of the first evaluations of the early implementation of the HEARTS Initiative within the health system of Colombia. It was conducted within the structure of the national health system, collecting data directly from the staff of the 12 public primary health centers that have been implementing the core components since September 2015 and some state and national level staff that were referenced by the primary care center staff. Therefore, the overall aim of the study is to generate a deep understanding of implementation in the ground through a systematic process and to construct an implementation map, and analysis through a widely used implementation framework. The recommendations and insights from this analysis will be made available to stakeholders at the different levels of implementation including the Ministry of Health of Colombia and will be shared with the international organization (PAHO) that is propelling the introduction, uptake, scale-up and institutionalization of the HEARTS Initiative. These insights may lead to a refinement of the implementation process and acceleration of scale-up in the country and in the rest of the region.

The **research questions** were:

1. What is the program theory of the HEARTS Initiative in Colombia and how it links to the overall rationale of the HEARTS technical package?
2. How is the HEARTS Initiative implementation unfolding?
    a. What are the contexts in which the implementation of HEARTS is unfolding?
    b. What are the mechanisms at work in the implementation of HEARTS?
3. What main barriers and facilitators may act upon the implementation of HEARTS in Colombia?

Chapter 2: Background

Noncommunicable Disease Burden: global, regional, and national levels

Noncommunicable diseases (NCDs) are responsible for nearly 40 million deaths per year worldwide, with almost three-quarters of NCD deaths occurring in low- and middle-income countries (LMICs). Between 2006 and 2016, deaths from NCDs rose by more than 5 million globally, and in 2016 they accounted for more than 70% of all deaths. (G.-B.-D.-Causes-of-Death-Collaborators, 2017). The global burden of NCDs is expected to rise further with increases in the global population (especially the older population) and demographic shifts. In 1960 less than 5 percent of the global population was older than age 65 years, and 15 percent was younger than age 5 years. By 2015, these proportions had converged and were projected to reverse by 2040. The result of this demographic change is that a larger total number of persons in LMICs are living to older ages and are more exposed to NCD risks and CVDs themselves (WHO-and-U.S.-National-Institute-on-Aging., 2011)

The breakdown of NCD deaths by condition is 17.5 million were from CVDs, followed by respiratory diseases (4 million); diabetes mellitus and kidney diseases followed, with 1.5 million and 864,000 deaths, respectively. (G.-B.-D.-Causes-of-Death-Collaborators, 2017) Because of a convergence of population size and the epidemiological transition, the vast majority of NCD deaths worldwide occur in LMICs, including 74 percent of cardiovascular deaths, 83 percent of diabetes deaths, 84 percent of respiratory disease deaths, and 76 percent of kidney disease deaths (Bollyky, Templin, Cohen, & Dieleman, 2017). Cardiovascular diseases—the predominant cause of NCD mortality—demonstrate marked and increasingly disparate trends in age-standardized mortality rates. Rates in high- and low-income countries were similar in 2000, but much more rapid progress had been made in High Income Countries (HICs) by 2012. Lower-middle-income and upper-middle-income countries had higher rates than HICs in 2000, and their rates have continued to decline modestly, as they have in low-income

countries. This inequality in cardiovascular health has been the focus of CVD epidemiology and in general, reflects rapid epidemiological change in LMICs and the absence of a strong health systems response to address cardiovascular morbidity and mortality. (WHO-and-U.S.-National-Institute-on-Aging., 2011)

Hypertension is a major preventable cause of CVD morbidity and mortality globally. This has been clearly demonstrated in the INTERHEART and INTERSTROKE studies in which the odds ratios (OR) of hypertensives versus non-hypertensives for acute myocardial infarction (AMI) were 1.91 and for acute stroke were 2.64, respectively. (Yusuf et al., 2004), (O'Donnell et al., 2016), (Teo & Dokainish, 2017) Uncontrolled hypertension kills an estimated 9.4 million people annually worldwide—about as many as all infectious diseases combined. (World-Health-Organization, 2013) The age-standardized prevalence of hypertension for the world's adults was 31.1% and decreased by 2.6% between 2000 and 2010 in high income countries but increased by 7.7% in LMICs.

These findings are confirmed by a recent worldwide study pooled 1479 studies that had measured the blood pressures of 19.1 million adults from 1975 to 2015 and concludes that raised blood pressure has transitioned from a risk factor largely affecting high-income countries to one that is now most prevalent in low-income countries in south Asia and sub-Saharan Africa, while being a persistent health issue in central and eastern Europe. Although favorable trends continue in high-income countries and might also be happening in some middle-income regions, other low-income and middle-income regions are affected by rising, or at best stable but high, blood pressure. The number of adults worldwide with high blood pressure increased from 594 million in 1975 to 1.13 billion in 2015, with the increase largely in LMICs. The global increase in the number of adults with raised blood pressure is a net effect of increase due to population growth and aging and decrease due to declining age-specific prevalence. (N.-C.-D.-Risk-Factor-Collaboration, 2017)

Other studies show that hypertension may be associated with socio-economic inequalities in LMICs: prevalence estimates for hypertension were inversely proportional to educational attainment, resulting in a downward socioeconomic gradient for hypertension. Evidence of health inequalities associated with hypertension in LMICs are not uncommon. Given that hypertension drives the global burden of cardiovascular disease, being widely acknowledged as the most common cardiovascular disorder and number one risk factor for mortality. (Sarki, Nduka, Stranges, Kandala, & Uthman, 2015) Given that hypertension drives the global burden of CVD, being widely acknowledged as the most common cardiovascular disorder and number one risk factor for mortality. (N.-C.-D.-Risk-Factor-Collaboration, 2017), (Global-Burden-of-Metabolic-Risk-Factors-for-Chronic-Diseases, 2014), (World-Health-Organization, 2013) This dissertation focuses on the implementation of a localized initiative in Colombia that emanated from the global response to NCD morbidity and mortality.

Hypertension in Latin America

In the Americas, epidemiological studies coverage and quality are diverse; some studies present the estimated prevalence of hypertension ranges between 25% to 40%. (Ordunez, Prieto-Lara, et al., 2015) The CARMELA study reported that between 24.3 to 46.9% of people with hypertension were unaware of their hypertensive condition, more than half of those with hypertension were untreated, and only 12.0% were controlled. (Hernandez-Hernandez et al., 2010) Similar findings have been reported from the PURE study, which found that only 57% of people with hypertension knew of their condition, 52.8% of those who were aware received treatment, but only 18.3% were under adequate control. (Chow et al., 2013)

More recently, researchers from the same PURE consortium added new urban and rural communities in Latin America in a new study of 33, 276 participants from six Latin American countries

(Argentina, Brazil, Chile, Colombia, Peru and Uruguay) and found hypertension prevalence of 44.0%, with the lowest rates in Peru (17.7%) and the highest rates in Brazil (52.5%), and 58.9% of participants with hypertension reported being aware of hypertension diagnosis and 53.3% receiving treatment. The prevalence of hypertension was higher in urban (44.8%) than rural (42.1%) communities in all countries. Most participants who were aware of hypertension were receiving medical treatment (90.5%), but only 37.6% of patients receiving medical treatment had their BP controlled (< 140/< 90 mmHg), with the rates being higher in urban (39.6%) than in rural (32.4%) communities.

Hypertension in Colombia

In Colombia, CVD is the leading cause of mortality (150 per 100,000). In 2017, the prevalence of hypertension was 16.9% in men and 21.5% in women; reporting that it is below the prevalence for Latin America. (Ministerio-de-Salud-y-Protección-Social, 2019) Nevertheless, some authors state that the overall prevalence of hypertension in Colombia may not have been well established. For instance, the 2007 the prevalence of high blood pressure in the Colombian population aged 18-69 years old was estimated to be 23.0% (95% CI 21.8-23.8). An author states that this estimate may be problematic because the study only included untreated and uncontrolled cases –that is, individuals whose blood pressure was measured as systolic blood pressure (SBP) ≥ 140 mmHg or DBP ≥ 90 mmHg at the time of the study, irrespective of whether they had been previously treated – thus omitting controlled hypertensives. Thus, this value of uncontrolled high blood pressure in the population may underestimate the overall prevalence of hypertension in Colombia. (Lucumi, 2014)

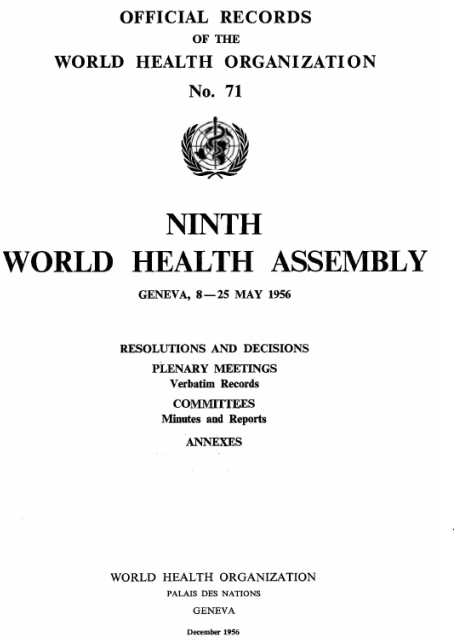
Response to CVD and hypertension globally and regionally (brief historical perspective)

The epidemiological landscape described above demonstrates the breadth and extent of the issue, it is worthwhile to contextualize this body of work through a quick historical summary to place

CVD epidemiology and the public health response in its larger historical context. According to pioneer clinical leader in hypertension, Dr. Marvin Moser (Moser, 2006):

> *As late as the 1950s, elevated blood pressure was considered by many expert physicians to be necessary for the adequate perfusion of vital organs. Although the morbidity and mortality risks of hypertension were known at that time to insurance companies, which often refused life insurance policies to people with high blood pressure, there was a lag in the recognition of the dangers of hypertension in the medical community.*

Despite these characterizations of hypertension from the 1950s, CVD was first identified as a global health issue in 1956, as reflected in the original transcripts of the resolution at World Health Assembly of May 1956 (World-Health-Organization, 1956):


OFFICIAL RECORDS
OF THE
WORLD HEALTH ORGANIZATION
No. 71

NINTH
WORLD HEALTH ASSEMBLY
GENEVA, 8—25 MAY 1956

RESOLUTIONS AND DECISIONS
PLENARY MEETINGS
Verbatim Records
COMMITTEES
Minutes and Reports
ANNEXES

WORLD HEALTH ORGANIZATION
PALAIS DES NATIONS
GENEVA
December 1956

Figure 1. WHO Officials Records Cover 1956.

Dr LAKSHMANAN (India), introducing the document submitted by his delegation, said cardiovascular diseases were an important factor in mortality and morbidity all over the world. Of the nine etiological groups listed in the document (congenital, rheumatic, syphilitic, bacterial, hypertensive, coronary, pulmonary, miscellaneous and of unknown etiology), the rheumatic, hypertensive and coronary groups were the most important, as they included the majority of cases of heart disease… In 1950 an International Society of Cardiology had been established but, although it had stimulated some co-operative research, there had not yet been any concerted attempt to deal with the problem from the public - health point of view. In view of the incidence of those diseases and their increasingly deleterious effects on national economies, his delegation felt that they were a suitable subject for WHO, which was being asked to make a world -wide study of the situation, stimulate research and co- ordinate results. The Committee might wish to consider the convening of an expert committee on cardiovascular diseases.

In the late 1960s, as safe and effective anti-hypertensive therapy was becoming available, a series of clinical trials set ups, resulting in progressive evidence that severe, then moderate, then mild hypertension, then isolated systolic hypertension in the elderly, could be safely and effectively treated to prevent CVD events. Cardiovascular disease epidemiology was being consolidated by then into a new field of scientific endeavor that developed with the growing burden of disease among western industrial countries following World War II. (University-of-Minessota, 2012) Therefore, the clinical and epidemiological fields were converging to propel a public health response.

This brief history shows that CVD and hypertension in particular have been salient topics in global health arena for the last 64 years, concomitant with major demographic and epidemiological transitions and advances in medicine and public health. Although a historical analysis is well beyond the scope of this work, putting the current efforts into a larger historical perspective may aid in situating the current work within a longer timeline. After the 1956 WHO's Resolution, there have been many more resolutions and declarations which have called on governments to invest more in CVDs, to develop laws to protect health, and to ensure access to cardiovascular services. Similarly, international conference recommendations have demanded action and delineated plans of actions from and within the global health organizations (Institute-of-Medicine, 2010) as shown in the extensive timelines depicted in figures 2 and 3 below.

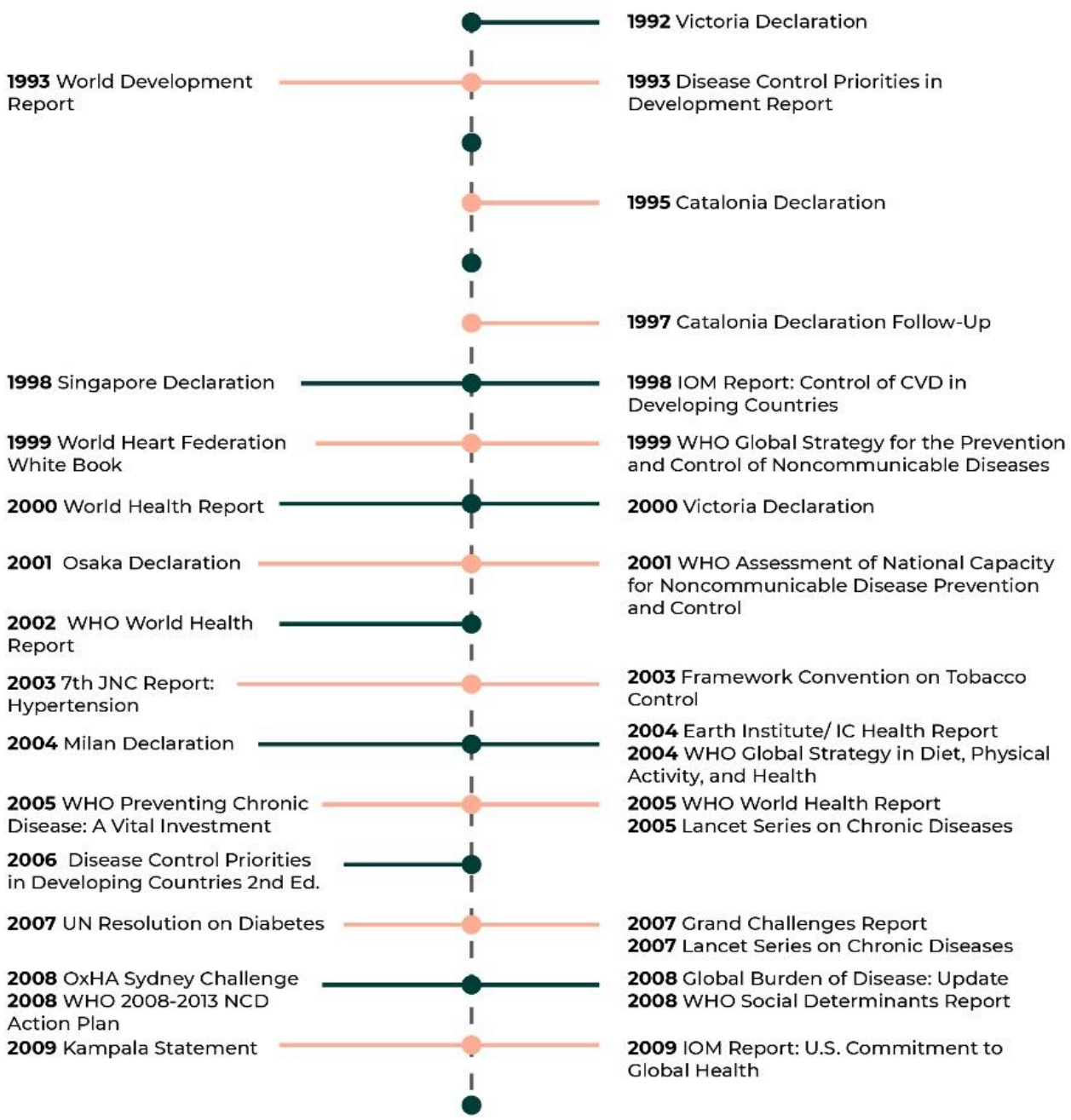


Figure 2. Timeline of major documents related to global CVD 1992 – 2010 adapted from Institute of Medicine, 2010. Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health. Page 21 (Institute-of-Medicine, 2010)

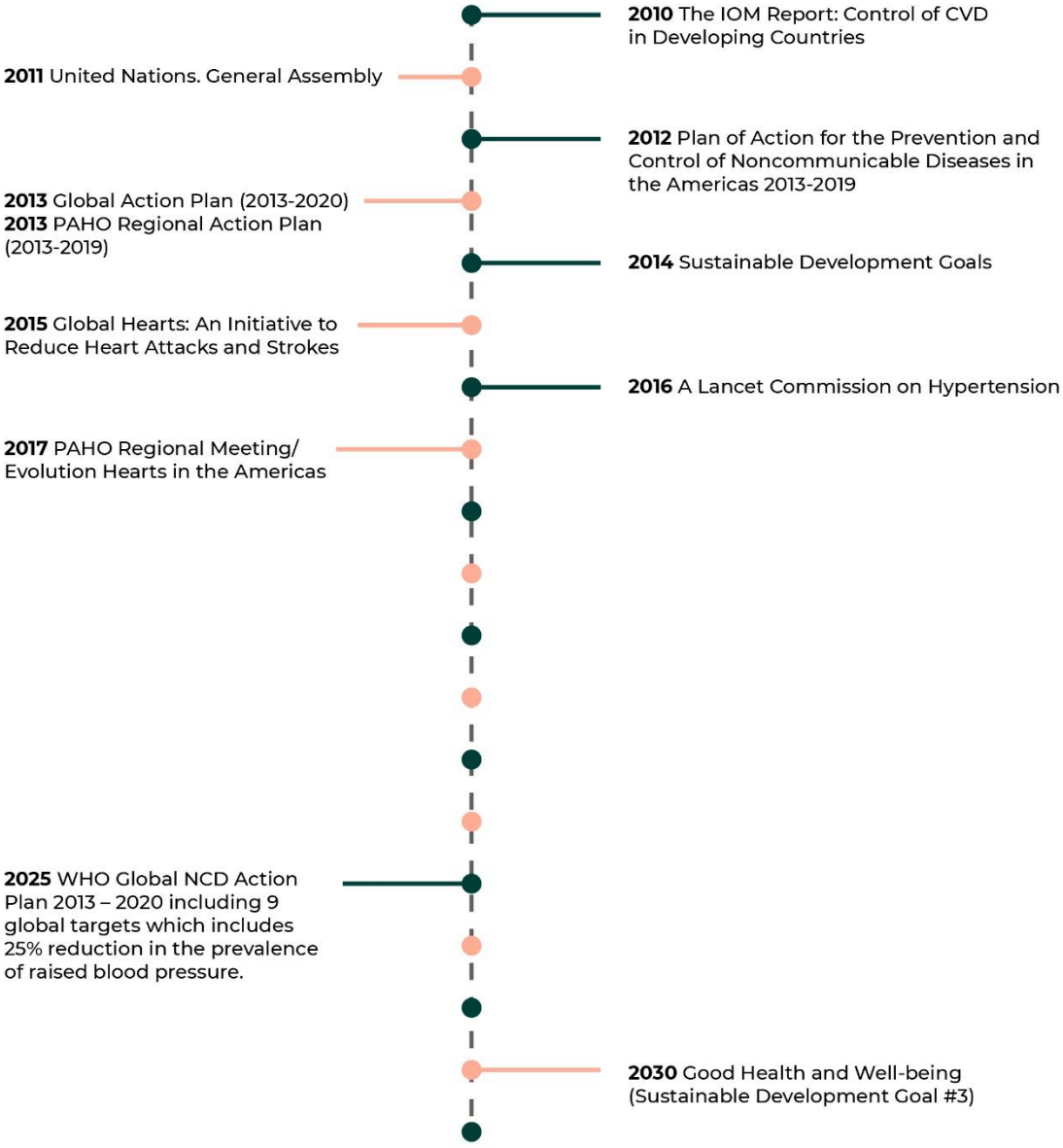


Figure 3. Timeline created from 2010 on (original prepared by author for this study).

More recently, studies on the human, social and economic consequences of NCDs and their devastating burden on the most vulnerable populations have fueled major efforts to combat NCDs. For example, the UN Member States in 2011 showed their desire to control NCDs by approving the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases. (World-Health-Organization, 2013) The declaration acknowledges that prevention is essential for responding globally to NCDs, and that it is crucially important to reduce the level of exposure of individuals and populations to the avoidable risk factors common to NCDs. Such risk factors are tobacco use, unhealthy diet, physical inactivity, and harmful alcohol consumption. The declaration also calls for a more rapid implementation of the Framework Convention for Control of Tobacco.

Response to NCD, CVD and hypertension in Latin America

Against a background of this rising global concern about NCDs, in 2006 the Directing Council of PAHO approved a comprehensive regional strategy for the prevention and control of chronic NCDs. (Hospedales et al., 2012) The resolution urges member states to implement integrated policies and plans, guided by the regional strategy, and requests the director of PAHO to strengthen country capacity to implement comprehensive, multisector approaches, as well as to strengthen or establish new partnerships, as necessary.

In 2009 and 2010, PAHO prepared a compilation of the Latin American and English-speaking Caribbean countries' legislation on prevention, obesity control, diabetes, and cardiovascular

diseases. They also drafted guidelines to help in the upgrading of legislation when needed. (Ordunez, Mize, et al., 2015) At the same time, PAHO initiated a regional consultation process to refine CVD priorities based on the available evidence, cost-effectiveness, and social value and equity. The main prioritized interventions, considered highly cost-effective, are:

- Reduction of tobacco consumption
- Reduction of salt consumption
- Combination of medications to treat CVD high risk patients, specifically persons with hypertension and diabetes.

To cover these priority areas, PAHO has supported countries to strengthen health information systems to monitor NCDs by providing guidance, tools, and training for implementing the PanAm STEPS methodology. It focuses on adult risk factor surveillance as part of a WHO-wide effort to help countries build and strengthen capacity. STEPS uses population-based surveys and contains questionnaires, anthropometry, and blood test components. It provides an entry point for low- and middle-income countries to get started on NCD surveillance.

Tobacco control plays an essential role in controlling NCDs, such as cardiovascular and respiratory diseases, different types of cancer, and diabetes, which constitute one of the greatest challenges for health and development. The WHO Framework Convention on Tobacco Control (FCTC) was instituted in 2005 and has become one of the most rapidly embraced international agreements in the history of the United Nations. As of today, there are 181 states parties signed on to the Convention, including 30 of the 35 countries of the Region of the Americas. The FCTC includes mechanisms to reduce tobacco products supply and demand, and its mandates apply to the entire chain of production, distribution, and sale of these products. Its comprehensive implementation is intended to achieve several goals: to prevent young people from taking up smoking, protect non-smokers from exposure to second-hand smoke, help smokers to quit tobacco and ex-smokers to remain abstinent. Many of its measures are now being considered to tackle other NCD risk factors. (World-Health-Organization-

Regional-Office-for-the-Americas-&-Pan-American-Health-Organization., 2016) Finally, the Trans-Fat Free Americas Initiative was launched by PAHO in 2007 in collaboration with the private sector, which promotes regulations, guidelines, and voluntary actions to eliminate trans-fats from processed foods. To reinvigorate these efforts in 2019, the Plan of Action for the Elimination of Industrially Produced Trans-Fatty Acids 2020-2025 was approved by the directing council of PAHO. A Dietary Salt Reduction Initiative to prevent cardiovascular disease in the Americas was launched by PAHO in 2009 with a consumption target of < 5 g/person/day by 2020. (N. Campbell et al., 2014)

NCD Management

PAHO has promoted the organization of evidence based, patient-centered care as established by the Chronic Care Model (Wagner, 1998) and works closely with ministries of health, professional associations, and other partners supporting the development and implementation of evidence-based guidelines and protocols for the integrated management of NCDs. In 2009, a rapid assessment of the disease management capacity in 24 countries showed the availability of guidelines or protocols for hypertension and diabetes in 23 countries (97%). Twenty countries (86%) had protocols for cancer, but very few had guidelines and protocols for weight control and physical activity. There were no policies for the access to some medications and services, particularly for low-income groups, though all countries had a list of essential medicines for NCDs. (Ordunez, Mize, et al., 2015), (Ordunez, Luciani, Barojas, Fitzgerald, & Hennis, 2015). Within this NCD landscape, a reinvigorated focus on CVD and hypertension control is the subject that will be fully developed in this dissertation.

Focused efforts on hypertension control in the Americas

Public health programs began in the U.S. in 1973 and worldwide thereafter to screen, treat, and control hypertension, with improved coverage and a significant influence on CVD risk and rates in the

population. In 1978, Dr. Jeremiah Stamler presented a conference titled the "The mass treatment of hypertensive disease: Defining the problem." (Stamler, 1978) It is worth to note a few points from his extensive conference:

> *Question number 8: What can the American public health system contribute to solving the problem of the mass treatment of hypertensive disease?*
>
> *Decades of experience in efforts to control mass disease problems teach an important lesson: by itself, the doctor-patient relationship is not enough to accomplish the mission. It must be supplemented by a significant societal effort, planned, and carried out by the organized forces of the community. In the United States, this has typically meant cooperative undertakings by voluntary and public health agencies.*
>
> *Whenever mass disease is related to lifestyle as is obviously the case for hypertensive disease, the societal effort has an especially big contribution to make to control. This means effective on-going health education first of all. But it goes beyond that – to the broad public policy issues related to the norms of human behavior—e.g. the many aspects of public health policy relating to the smoking, eating, and drinking habits of the population.*
>
> *The organized public health effort can also utilize registries, with the informed consent of patients and the cooperation of physicians to assist in delivering optimal long-term care. For example, such registries aid physicians in assuring continuity of long-term care, identify and minimize problems of overlap and duplication in care.*

Thus, as demonstrated by this quote, as early as the 1970's there was an increasing recognition that a comprehensive strategic approach must not only focus on hypertension as a pathological entity, but also consider the wider environment in which hypertension interacts with a cluster of other well-known modifiable risk factors such as obesity, physical inactivity, unhealthful diet and tobacco use, and for which there are effective up-stream policy solutions as well. In tandem with the developments in the

U. S. Similarly, international programs focused on blood pressure control have been reported as early as 1962. (Litvak, Boffi, Pisa, & Strasser, 1979) Despite the vast body of knowledge about hypertension, the translation of that evidence into actionable programs to improve the quality of health care and impact health outcomes has proven difficult. (Institute-of-Medicine, 2010)

Given that hypertension is a chronic condition that requires an integrated continuum of care, which is often absent in the health systems of most countries in the region. Specifically in Chile, Colombia and Cuba, cardiovascular health programs have been in existence as these are possibly some of the most mature health systems in the region (Sandoval et al., 2012); however, major gaps remain. As previously noted by the aforementioned epidemiological studies (CARMELA and PURE), only 18% of people with hypertension had the condition controlled; therefore, there are major deficiencies in the diagnosis and treatment of hypertension that hinder the prevention of CVD. For instance, issues related to a lack of a steady supply of appropriate, high quality and accessible medications and poor treatment adherence compound these problems, as do clinical inertia and systemic barriers, such as a lack of health coverage. (Patel et al., 2016), (Institute-of-Medicine, 2010), (Pater, 2005). Additionally, diagnosing hypertension poses challenges despite blood pressure measurement being a common screening test in medical practice. There seems to be gaps in the basic theoretical and practical knowledge among health care providers. Human error is compounded by variables such as inconsistent cuff selection and application, inadequate positioning of the patient, not considering if patient is resting and digit bias (which refers to occurrence of a particular end digit in the readings more frequently that would be expected by chance alone) and lack of repeated measurements. Adding to potential human error is the condition of the devices utilized. Studies aimed at assessing accuracy of calibration and evaluation of the physical condition of devices have shown a high magnitude of inaccuracy and unreliability. (Campbell, N, McKay, 1999, Jones D et al., 2003)

Low levels of hypertension control result in higher CVD morbidity and mortality. Therefore, addressing hypertension and overall CVD health is a global and regional health priority. Elevated blood pressure is the strongest modifiable risk factor for CVD, and hypertension management and control at primary care level is a cost-effective intervention. (Perel et al., 2015), (Karmali et al., 2018), (Law et al., 2009) Although several countries have developed national action plans to address non-communicable diseases and have prioritized CVD prevention, treatment, and control, in most countries of the Americas, important gaps remain to improve cardiovascular health. (Ordunez, Mize, et al., 2015)

The abovementioned barriers to effective CVD care in Latin America (as well as in other LMICs in other regions) fall under three major domains: patient barriers, health care providers and health systems. From the perspective of international organizations, at least two domains –health care providers and health systems– can be clustered as systemic barriers. In the provision of care, human resources for CVD care are insufficient, there is a low health worker to patient ratios reducing the time to see and counsel patients. Additionally, health care professionals may have inadequate training in evidence-based management of CVD and related risk and this may be compounded by lack of motivation to change current practice patterns resulting in unwillingness to accept evidence-based guidelines or holding on to beliefs that guidelines are too complex and/or difficult to implement. (Patel et al., 2016)

On the other hand, from an economics standpoint, hypertension has a negative economic impact on healthcare systems in Latin American countries. In some of these , the total treatment of hypertension can reach up to 2% of the national gross domestic product (GDP) and 5-8% of the country's health budget (Lucumí, 2014). Similarly, a lack of financing or pre-payment mechanisms to reduce point of service costs may be a problem because evidence-based medications, even when available, are often unaffordable. (Schwalm, McKee, Huffman, & Yusuf, 2016)

Very few interventions that tackled these barriers simultaneously or even as sub-group of barriers were found; however, a systematic review of quality improvement for CVD in LMICs reported on a study that evaluated the health impact of the expansion of health insurance coverage. One study evaluated the health impact of *Seguro Popular* (public health insurance for the poorest uninsured) that rolled out in Mexico in 2002 where approximately 50 million people gained coverage. Bleich et al. found that compared with matched hypertensive adults without insurance, hypertensives with *Seguro Popular* had 1.5-times higher odds of receiving hypertension treatment and 1.4-times increase of having controlled blood pressure. (Bleich et al., 2007) Therefore, implementation of universal health insurance may lead to significant improvements in chronic disease.

Challenges to blood pressure control in some geographical areas are the absence of comprehensive primary healthcare services, including limited access to medications, and the lack of systems to effectively deliver prevention and treatment. However, evidence based on lessons from the treatment of communicable diseases in low-and-middle income countries, as well as successful models of hypertension control in the U. S. and Canada, show that controlling hypertension is achievable using a health system-strengthening approach. Key actions of this approach include standardized treatment protocols, effective drug procurement mechanisms using a core set of medications, accountability by tracking progress and control using registries, patient empowerment, team-based care, and community engagement. (Ordunez, Mize, et al., 2015), (Seita & Harries, 2013), (Patel et al., 2016)

Therefore, the challenge is not only to increase clinical knowledge, but also to gain political support for the implementation of population wide and systems strengthening initiatives such those that seek to introduce technical packages for hypertension control. To guarantee the successful implementation of evidence-based models, whether through norms and standards setting from international health organizations or through the persuasion of individual clinicians and opinion leaders, or daily practice at the most basic organization unit, additional understanding is required. To conclude, although much has

been done in the region by the international health organizations and the individual ministries of health, the fundamental indicators around awareness (diagnosis), treatment and control remain low. While the knowledge about the factors that affect the control of hypertension at the clinical level has continued to develop, less is known about what affects the adoption of evidence-based models for population control of hypertension.

This is the scope of implementation science and through its lens, this dissertation seeks to dissect the current global efforts on hypertension control and explain how the application of a global initiative has unfolded in one of the first implementing countries in Latin America: Colombia. The subject of this dissertation is the application of a WHO technical package, HEARTS Technical Package, that aims to mitigate CVD morbidity and mortality.

HEARTS Technical Package

Basic concepts

The HEARTS Technical Package as presented by WHO is based on the concept that individual risk factors can be used as entry points for the integrated management of multiple risk factors, because integration is more cost-effective in all settings. Integrated management is considered by WHO as one of the “best buys” for noncommunicable disease prevention and control (“best buys” strategies were described above). HEARTS offers a strategic approach feasible in all settings for the prevention of heart attacks, strokes and kidney disease through the integrated management of diabetes and hypertension and seeks to address the cascade of care by offering strategies to increase the awareness, treatment, and control of hypertension. (World-Health-Organization, 2016) The next sections elucidate the theoretical underpinning and foundations of the HEARTS Technical Package and the initiative that propels its application in the Americas and specifically in the localized context of Colombia.

Chapter 3: Theoretical underpinnings

Implementation science is the study of the process of putting to use evidence-based interventions within a setting. It has been recognized as a potential catalyst for health system reform, as it offers well-grounded theories including conceptual frameworks. (Damschroeder, 2020) From a theoretical standpoint, the literature abounds with explanatory models that attempt to draw pathways of causation among different factors, distal and proximal and macro to micro explaining chronic disease, many have been developed from the health services research literature and many more have recently been developed under the newer implementation science literature. (Nilsen, 2015) This chapter describes the development of the nascent theory of change of the HEARTS Initiative and its underlying premises.

The disciplines that have been involved in designing public health programs to address hypertension had come from clinical and academic medicine and epidemiology; today, social epidemiology, evaluation, health economics, and public health scientists from many fields of origin are participating in the design of new approaches. At least during the last two decades, where interdisciplinarity and multidisciplinary have been summoned to tackle public health issues, an increasing number of diverse scientists and public health practitioners have developed approaches to hypertension control. Since 2007, technical packages such as the Package of Essential Noncommunicable disease interventions (PEN) have been developed. (World-Health-Organization, 2010) A technical package is "a selected group of related interventions that, together, will achieve and sustain substantial and sometimes synergistic improvements in a specific risk factor or disease outcome. A technical package of proven interventions sharpens and focuses what otherwise might be vague commitments to 'action' by committing to implementation of specific interventions known to be effective." (Frieden, 2014)

In 2013, WHO presented a brief on hypertension and delineated an overall schematic or pathway of cardiovascular disease. This WHO brief brought back the focus on hypertension with occasion of World Health Day in 2013 (previously highlighted in 1978), laying out a strong case for countries to adopt strategies to tackle hypertension. The first part of the brief presents the epidemiology of hypertension followed by the factors that contribute to its CVD, including social determinants such as globalization and urbanization, behavioral risk factors, metabolic risk factors leading to CVD and organ failure ultimately (figure 4).

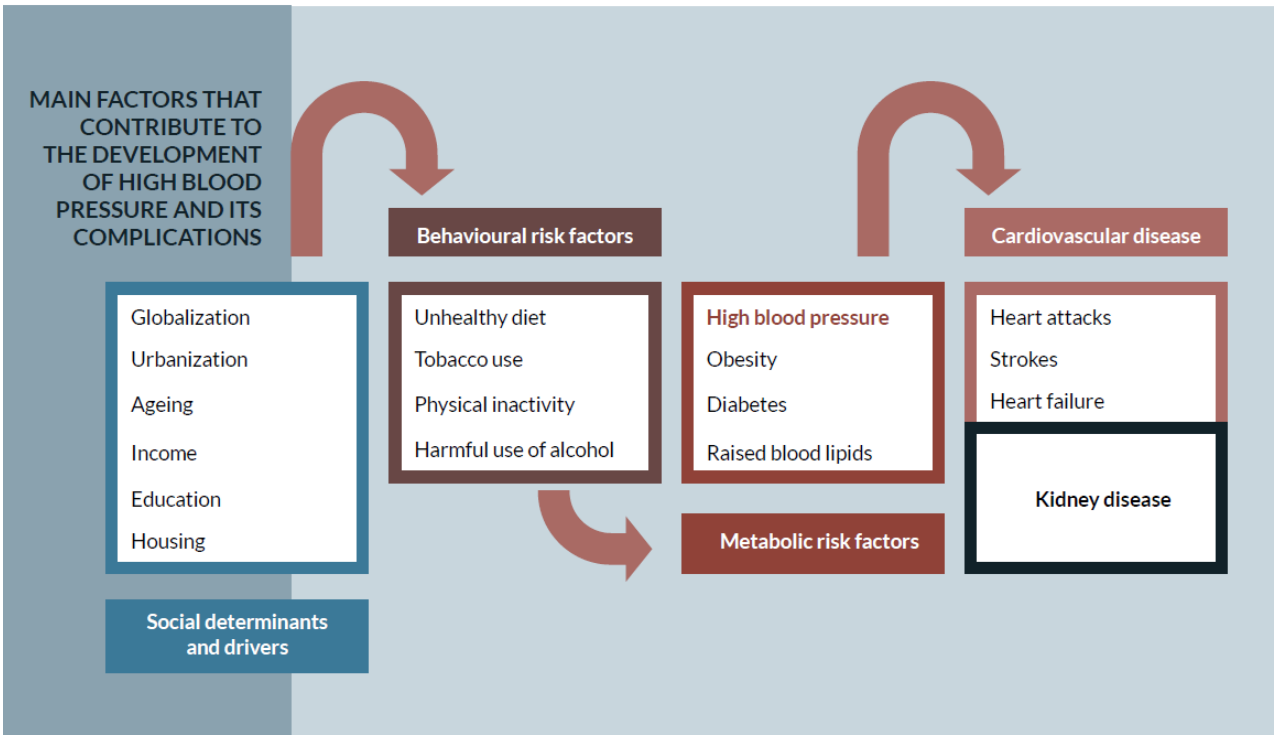


Figure 4. Factors that contribute to the development of high blood pressure and its complications, from WHO Brief on Hypertension, 2013, page 18 (World Health Organization, 2013)

The HEARTS Technical Package appears to be a point of convergence of frameworks drawing upon clinical hypertension, epidemiology, public health, policy, among other disciplines (figure 5). It takes elements from preceding models, distilling a practical strategy from the previous models.

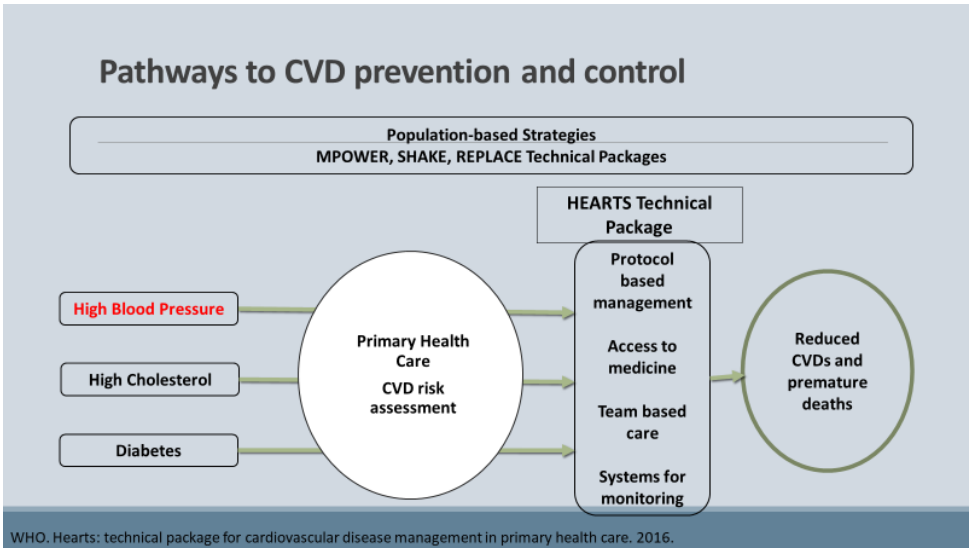


Figure 5. 2016 The WHO HEARTS Technical Package 2016.(World-Health-Organization. (2016)

The HEARTS Technical Package emerges as a collective response to provide effective, practical interventions for strengthening the management of risk factors for CVD in primary health care. Implementation science, introduced earlier, broadens the field from solely focusing on the technical tool to zoom out and understand the processes through which this tool becomes a trigger for action, change and results.

Additionally, the public health field has long been influenced by psychology and the well-known Bronfenbrenner's ecological framework and Stokol's social ecological theory (Green & Kreuter, 2005) have paved a strong foundation for utilizing a multilevel approach to implementation processes. Therefore, understanding that the introduction and delivery of a tool, such as a technical package is embedded within a rich, nuanced, and complex ecosystem, is ingrained in the public health perspective.

In order to situate the HEARTS implementation in Colombia, it is necessary to zoom out and see the global and regional development of HEARTS utilizing the progressive lens of implementation science.

Taking the HEARTS Technical Package to the ground through the HEARTS in the Americas Initiative

One of the six core functions of PAHO is "establishing technical cooperation, catalyzing change, and building sustainable institutional capacity" in member states (the countries of the Americas). (Pan-American-Health-Organization-&-World-Health-Organization, 2017) Technical cooperation for CVD is being conducted principally through the implementation of the HEARTS Initiative in the Americas with an emphasis on hypertension control and secondary prevention of CVD through the promotion and application of the HEARTS technical package core components are:

1. A simplified, evidence-based hypertension treatment algorithm.
2. The availability and affordability of a core set of high quality anti-hypertensive medications.
3. A registry of hypertensive patients for monitoring and performance evaluation.
4. Task sharing in a team-based approach in the primary care level.

The HEARTS in the Americas is an initiative to promote the adoption of the HEARTS technical package as model. Throughout the last 4 years, a systematization process has been unfolding which at starts with introducing the HEARTS Initiative to the Ministries of Health of PAHO region countries and upon securing their agreement to participate, a series of pre-implementation and implementation actions are started. The main components of the pre-implementation phase are: i) selection of a geographical area or several geographical areas based on a set of criteria (details about selection of sites will be presented at later section), ii) engagement of a coordination team and diverse stakeholders, iii)

conducting baseline assessments, iv) planning implementation and adaptation of HEARTS technical package modules, v) on-going capacity building, vi) implementing adapted treatment algorithms in the implementation sites, vii) monitoring, and viii) data collection for program evaluation.

The overall ecosystem of HEARTS

HEARTS is a complex, multi-level intervention containing several interacting components, multiple and often difficult behaviors by those delivering or receiving the intervention, multiple groups or organizational levels targeted by the intervention, and multiple and variable outcomes. (Craig et al., 2008) From the implementation literature and the HEARTS documents and materials reviewed, there are three main dimensions of implementation: first, contexts of implementation --where is implementation happening--and simultaneous application or coexistence at multiple levels; second, implementation systems (stakeholders) and their functions and, third, demarcation of content and process with an emphasis on effective adaptation to contexts.

To understand the implementation of HEARTS in the Americas, a description of its multiple nested levels is necessary. The implementation takes place in at least four nested levels as depicted in figures 7 and 8. The first figure illustrates the conceptual domains for implementation and the second shows the HEARTS systems per geographic level to which the domains are applied and the correspondence is shown through color coding.

Systems (stakeholders) at different levels fulfill different functions within the ecosystem

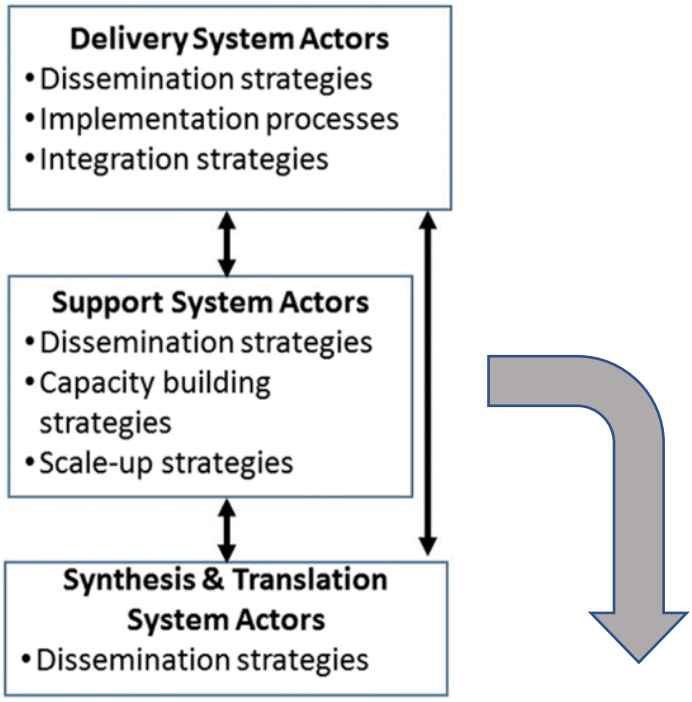
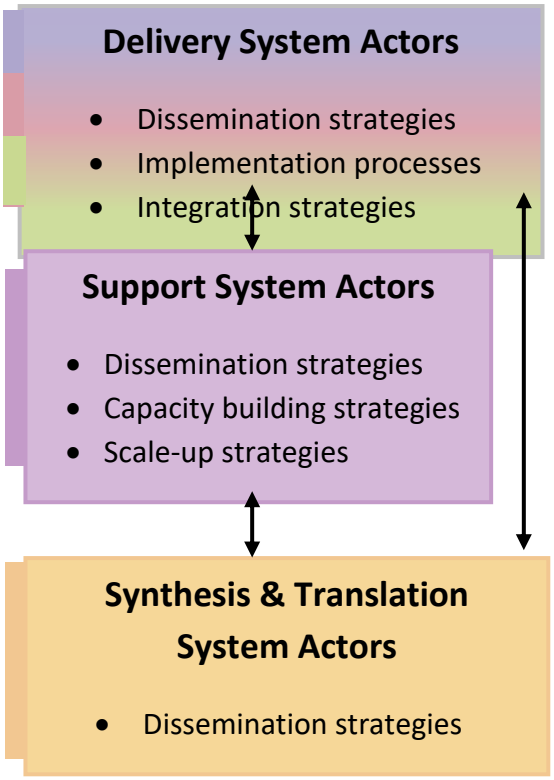


Figure 6. Classes of implementation strategies within the Interactive System Framework from (Leeman, Birken, Powell, Rohweder, & Shea, 2017)



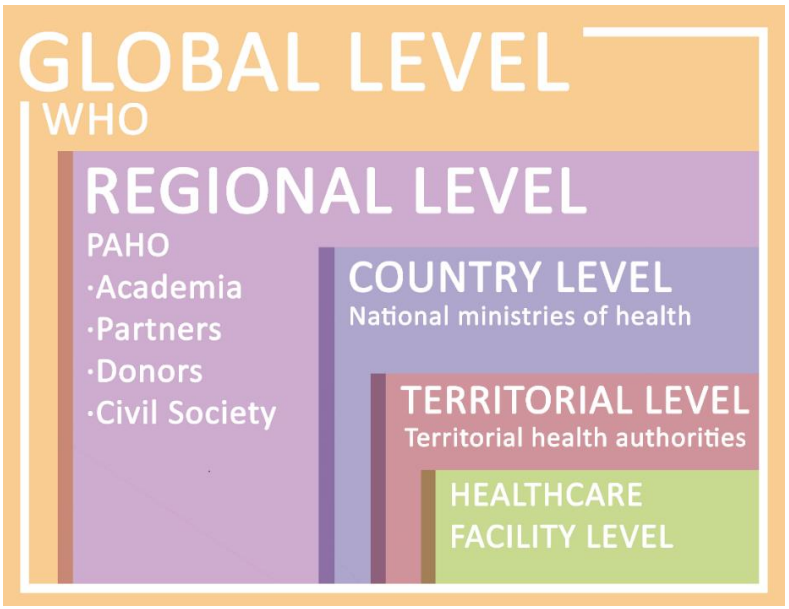


Figure 7. Levels of implementation of HEARTS in the Americas with corresponding key actors (original prepared by author for this study).

These levels are: A supra-national level, globally, WHO and regionally, PAHO supports the implementation of a technical package in selected countries in the region with the objective of disseminating the intervention to reach a critical mass of implementing countries (spread at regional level).

a. A national level where the ministry of health formally agrees to take on the implementation of the intervention and scale it up in the entire country.
    i. Provincial/state level health authorities: the national authorities must work with the health care administrative divisions to bring the implementation of the technical package to the territories.
        1. Individual health center level: smallest units of primary care provision in each health system where individual clinicians and non-clinicians work with people who have hypertension.

The Interactive Systems Framework for Dissemination and Implementation (Wandersman et al., 2008), (Leeman, Birken, Powell, Rohweder, & Shea, 2017) provides useful labels for the functions of each of the different multi-level actors. The **prevention and translation system** is conceptualized as distilling information about innovations and preparing them for implementation. The translation process of converting scientific knowledge into practitioner-friendly products to be used by implementers is the prime function of this system-level. In HEARTS implementation, the WHO distilled evidence-based practices and along with major global scientific organizations, packaged them into didactic, synthetic modules. The next level is the regional office of the Americas, PAHO, which may be defined as an **implementation support system**. The rationale of this system derives from studies demonstrating that simply providing the evidence-based information distilled by the first system about an innovation is not enough to drive change in health care practice. Therefore, this support system is conceptualized as carrying out two primary support functions: innovation-specific capacity building and general capacity

building. PAHO has provided both types of capacity building by developing a methodology for building consensus on a standardized treatment algorithm, in the case of innovation-specific capacity building. In general capacity building, there is a methodology for introducing the HEARTS package at national levels. Finally, the third system is the **delivery system**, which actually carries out the activities necessary to ensure the implementation of the innovations. In the HEARTS implementation, this system is the Ministries of Health, the territorial health authorities, and the health care facility personnel. Implementation scopes vary at each administrative level but include activities related to maintaining a functioning organization such as ensuring adequate staffing, developing organizational leadership, leading change of practices, and ensuring sustainability.

Demarcation of content and process within implementation process

Implementation science requires that a clear distinction between the clinical and public health intervention and the implementation intervention. The clinical and public health interventions are the content or **what** will be implemented. The clinical and managerial components of the HEARTS technical package and the implementation intervention corresponds to the **how** those clinical and public health interventions will be implemented, operationalized and scaled up.

The Standards for Reporting Implementation Studies (StaRI) describe these dual strands, although the implementation of HEARTS is not conceived as a multi-site research study, the structure of these standards is helpful to understand overall implementation. One strand, A, is the clinical or public health intervention being implemented and the second strand, B, is the implementation strategy. (Pinnock et al., 2017a), (Pinnock et al., 2017b; World-Health-Organization, 2017). This distinction is fundamental to analyze the actual implementation in the ground. The rest of this paper will focus on

how this technical package is being implemented and scaled up highlighting the enablers and accelerators that facilitated it (table 1).

Strand A (content) Intervention refers to the clinical or public health intervention being implemented.	**Strand B (process)** Implementation Strategy refers to **how** the intervention is implemented.
SERVICE DELIVERY SYSTEM ACTORS Clinical, managerial interventions are described in the HEARTS technical package with its individual core components: • Healthy-lifestyles counseling • Evidence-based protocols • Access to essential medicines and technologies • Risk-based CVD management • Team-based care • Systems for monitoring	WHO acts as the **synthesis and translation system** distilling "best-buy" intervention: HEARTS technical package PAHO acts as the **implementation support system.** Provision of guidance and vision about HEARTS as a model. Guidance and capacity building on specific technical strategic axes: **I.** Constructing and building consensus on **II.** Blood measurement devices and regulations **III.** Data standardization and innovation **IV.** Implementation research and evaluation **V.** General training and education Ministry of health is the **delivery system** **I.** Convene, train stakeholders **II.** Coordinate national implementation • Select initial implementation sites • Plan national and local implementation

	• Plan and implement a monitoring mechanism

Table 1. Strands of implementation science reporting of implementation studies

Situating the implementation intervention within the literature

The HEARTS Technical Package is delivered within existing health delivery systems. Health care delivery is a very complex activity. Care is delivered by frontline staff often working in groups or teams and in many different settings, supported by managerial and administrative staff and using increasingly complex technologies. The patient care outcomes depend on a multitude of factors that are a function of the context of care delivery at many different levels as presented in the preceding section. At a macro level, delivery of care is affected by national health policies, health care financing which can be simultaneously influenced by international, national, and local initiatives designed to improve care. At a meso level, it includes clinical practice guidelines and at the micro level it involves the quality of interactions between staff and patient. (Raine et al., 2016) All these elements combined may be captured by Roemer's classic definition of a health system: "A combination of resources, organization, financing and management that culminate in the delivery of health services to the population." (Roemer, 1993)

The dynamic interactions between and among all these components within this multi-level structure puts health care delivery in the domain of complex systems. (Massoud et al., 2016) Complex systems inherently demand complex interventions, and, in turn, complex interventions require

evaluations that can account for nuanced complexity. To address this complexity, the current evaluation of the HEARTS Initiative implementation is being explored, analyzed, and interpreted by blending several germane but different bodies of knowledge as illustrated in figure 9. The initial bodies of knowledge are: i) implementation science, ii) complexity science, iii) scale-up frameworks, and iv) evaluation research (specifically realist evaluation).

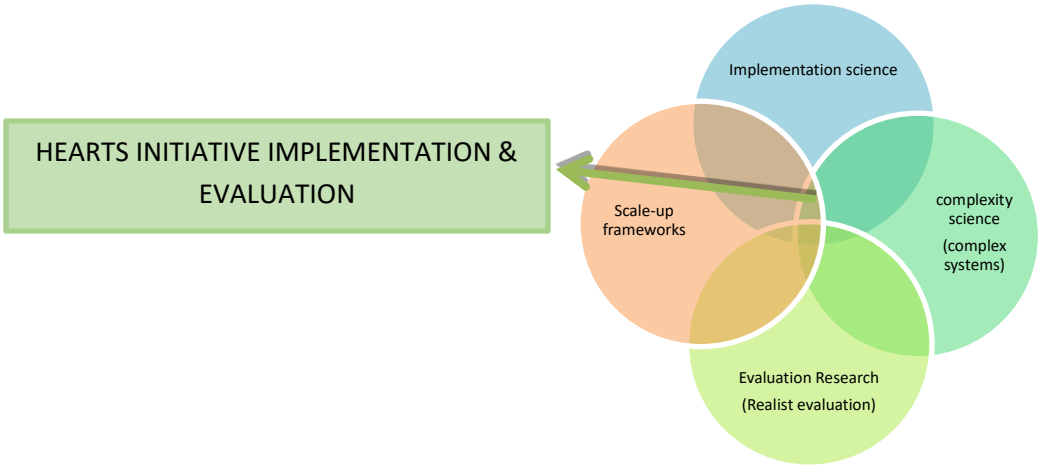


Figure 8. The HEARTS Initiative implementation evaluation stands at the intersection of several bodies of knowledge, original diagram by author.

There are a multitude of theories, models, and frameworks within each body of knowledge whose usefulness to the study will be better discerned in the analysis, discussion, and recommendation sections. In the meantime, basic working definitions are provided to set the stage for positioning this dissertation within this rich confluence of bodies of knowledge.

Implementation science

WHO defines implementation science as "the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices (the 'know-do' or 'evidence to program's gap). And it rests on the public health value of applying what we already know

to achieve long-term health benefits that are within reach." (Peters, Tran, & Adam, 2013) Other commonly found definition is: "Implementation science is the scientific study of the methods that take evidence-based interventions into practice" (Rapport et al., 2018). Several authors view implementation science as bridging the gap between developing and evaluating effective interventions and implementation in routine, real world practice to improve patient and population health. (Hawe, Shiell, & Riley, 2004), (May, 2013).

Complex interventions

Complex interventions consist of multiple behavioral, technological, and organizational components and introduce resources such as knowledge, information and relations, and whose results are conditional upon human reaction and reasoning of both the intervention recipients and the individuals providing the intervention. (May et., 2007) Other authors define "a complex intervention as a deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care." (Rapport et al., 2018) Viewing healthcare as an inherent complex adaptive system implies that: "Getting evidence into routine practice through a step-by-step model is not feasible. Complexity science forces us to consider the dynamic properties of systems and the varying characteristics that are deeply enmeshed in social practices, whilst indicating that multiple forces, variables, and influences must be factored into any change process, and that unpredictability and uncertainty are normal properties of multi-part, intricate systems." (May et al., 2007) Therefore, complexity of an intervention and complexity of the systems in which the interventions will be imbedded need to be considered in any attempt to understand implementation processes fully.

Scale-up

WHO ExpandNet defines scaling up more specifically as: “deliberate efforts to increase the impact of successfully tested health innovations to benefit more people and to foster policy and program development on a lasting basis”; and “innovation” refers to service components, other practices or products that are new or perceived as new. Typically, the innovation consists of a “set of interventions” including not only a new technology, clinical practice, educational component or community initiative, but also the managerial processes necessary for successful implementation. (World-Health-Organization-&-ExpandNet, 2010).

As established, the HEARTS technical package emanates from the consensus of international organizations, key actors of the global health governance structure. PAHO, in congruency with the level of urgency reiterated to member states through WHO’s recent call to action and report, Time to Deliver, where the director of WHO through a high level commission exhorts countries to act: (World-Health-Organization, 2018):

> *The 2030 Agenda for Sustainable Development, with its pledge to leave no one behind, is our boldest agenda for humanity. It will require equally bold actions from Heads of State and Government. They must deliver on their timebound promise to reduce, by one-third, premature mortality from noncommunicable diseases (NCDs) through prevention and treatment and promote mental health and well-being.*
>
> *Because many policy commitments are not being implemented, countries are not on track to achieve this target. Country actions against NCDs are uneven at best. National investments remain woefully small and not enough funds are being mobilized internationally. There is still a sense of business-as-usual rather than the urgency that is required. Plenty of policies have been drafted, but structures and resources to implement them are scarce.*

The HEARTS technical package is one of the "best buys" interventions put forth by WHO to achieve the Sustainable Development Goals, and countries are encouraged to adapt, adopt, and apply them. Therefore, the technical packages are not presented as pilots, nor finite projects with external financing nor initiatives with philanthropic dedicated financing. The explicit aim of the HEARTS Initiative is for ministries of health to adopt and insert the proposed model into the existing delivery system by scaling up into the health care delivery system of a country and with the country's own resources. Given that this premise of country ownership and country responsibility to scale-up, permeates the entire approach to technical advising and technical cooperation provision on implementation of the technical package, a scale-up mindset influences the implementation methodology from the very first health center in a country. Albeit not the focus of this dissertation, scale-up is an important cross-cutting concept that will remain in the background of the current work.

The intersection of implementation science, complex interventions and scale-up

From the literature reviewed, there are very few mentions of complexity science and implementation science in the same article, possibly indicating that these two disciplines have been developing independently. However, utilizing a complexity lens may help understand the concept of the implementation intervention. Few authors do highlight that the introduction of clinical or organizational changes into practice do not occur in static environments; these take place in settings comprised of diverse actors, different levels of influence and capacities all interacting in culturally defined ways, underlying the complex nature of changes into complex environments. (May et al., 2007) In a similar line of thought, there is great overlap between the focus of interest of implementation science and the definition of scale-up; however, there seems to be a predilection of terms resulting, in the one hand, the topic of scale-up being common in the global health literature overlapping as a topic of implementation

science, but not in the context of complex systems or complexity science. Thus, the topic of public health interventions, defined as complex interventions that need to be scaled-up is less often discussed. A recent opinion article explicitly addressed this gap by stating that "the two sciences of complexity and implementation need not be mutually exclusively, though they have been largely seen and treated as such (…) and complexity-informed approaches to implementation are particularly important when attempting to scale-up interventions". (Braithwaite, Churruca, Long, Ellis, & Herkes, 2018) Furthermore, implementation science has been recognized as a potential catalyst for health system reform, partially due to its contributions of well-grounded conceptual theories, often encapsulated in frameworks. (L. Damschroder, 2020) This dissertation follows this recommendation of adhering to a complexity-informed approach to understand implementation, and subsequently to be epistemologically coherent, to design a fitting evaluation.

Complexity and standardization

The HEARTS interventions and its implementation are complex when introduced into multifaceted health systems. As a result, evaluation poses problems because complex intervention components may act independently or interdependently, and it is often difficult to tease out the relationships between them. (May et al., 2007; World-Health-Organization, 2016) Traditional evaluation efforts that recommend linear sequential phases of development, feasibility testing, and evaluation focused on aggregate effectiveness represent a vast oversimplification of both the environment and the interventions themselves. (Perel et al., 2015) This over-simplified model of evaluation provides little information for policymakers and practitioners about the effectiveness of a complex intervention within uncontrolled real-world scenarios, particular contexts, and may be insufficient to inform future implementation and scale-up efforts. (Institute of Medicine, 2010) A complexity-informed approach

changes the focus of implementation from fidelity of the intervention to its **effective adaptation to contexts**. Complex intervention thinking requires a new way of viewing context and intervention-context interaction which is an alternative approach to focus on standardizing the process by function and not by form. This perspective accounts for the dynamic properties of the context in which the intervention is introduced. (Karmali et al., 2018) A real-world intervention such as the implementation of the HEARTS technical package may be standardized by function as illustrated in table 2 below.

Component	**Type of standardization**	
	By form	**By function**
A standardized, evidence-based hypertension treatment **algorithm or protocol**	All countries/sites utilize the same standardized treatment algorithm	Countries develop a treatment algorithm based on options defined by best-practice criteria, customized to local culture, health system, political context, available resources, and sustainability
The availability and affordability of **a core set of high-quality anti-hypertensive medications**	All countries/sites have the same core set of medications	National health authorities are provided with an Essential List of Medications (a core set of medications), medication class/family with primary and back up for each country to derive its own set of core medications based on global best practices and WHO List of Essential Medicines
A **registry** of hypertensive patients	Develop a unique registry software to be distributed to all countries/sites	Each country develops its own registry based on its own health system design and capacity and compatible with existing registry modalities

Component	Type of standardization	
	By form	**By function**
for monitoring and performance evaluation		electronically, or not; guidance provided on core minimum data to be collected by all countries to be compatible with the core indicators
Task sharing in a **team-based approach** in the primary care level	All health care team members are assigned a role within the healthcare team	Methods to modify staffing, roles, task-shifting, and task-sharing are tailored to the country's health care labor codes and health system specificities

Table 2. HEARTS components by type of standardization

Germain to the role of context, Braithwaite and colleagues call attention to the sustainability of the change produced by an intervention, which requires continuous adaptation to multi-level contexts with expectations of lasting improvement in the system. Therefore, this intersection of complexity and implementation science demands attention not only to context but also to interactions between elements and consequences of the intervention for the system. (Braithwaite et al., 2018) The current implementation experience of HEARTS in the Americas deliberately encourages standardization by function as its context diversity requires effective adaptation.

Evaluation Approach

As previously discussed, the HEARTS implementation represents several interventions introduced into complex health systems leading to a characterization of the implementation of HEARTS as a complex intervention. However, adopting a complexity lens poses special evaluation problems because complex intervention components may act independently or interdependently, and it is often

difficult to tease out the relationships between them. (M. Campbell et al., 2000) Under these conditions, traditional evaluation efforts that recommend linear sequential phases of development, feasibility testing and evaluation focused on aggregate effectiveness represent a vast oversimplification of both the environment and the interventions themselves. (Peters et al., 2013) In the real world, this over-simplified model of evaluation provides little information for policymakers and practitioners about the effectiveness of a complex intervention within uncontrolled real-world scenarios, particular contexts and may be insufficient to inform future implementation and scale-up efforts. (Salter & Kothari, 2014) As noted earlier, a complexity-informed approach changes the focus of implementation from fidelity of the intervention to its effective adaptation to contexts. Complex intervention thinking requires a new way of viewing "context" and the intervention-context interaction. Important insights about the role of the context-intervention interaction was cited above, underscoring the imperative of standardizing the process by function and not by form. Accordingly, an evaluation of an implementation that hinges on effective adaptation to context needs to be epistemologically coherent with this view and a type of congruent evaluation approach is realist evaluation.

Realist Evaluation

The realist evaluation (RE) approach was developed by Ray Pawson and Nicholas Tilley (Pawson & Tilley, 2004) and is increasingly being applied in the field of evaluation of complex healthcare interventions. Realist evaluation is an explanation-driven, generic approach to evaluation in the realm of theory-driven evaluation or program theory evaluation and is grounded in scientific realism. The goal of scientific realism is to examine patterns that exist within actual operating programs. These analyses offer a more comprehensive understanding of these patterns by providing in-depth explanations through exploration of generative causal mechanisms which are sensitive to contextual and social influences. Realist evaluation is not a method or technical procedure; it is method neutral and is a logic

of inquiry that attempts to answer the question: “What works, for whom and in what circumstances and why”. (Pawson & Tilley, 2004)

Realist evaluation has a focus on understanding causation and is designed to improve the understanding of how and why interventions work or do not work in particular contexts. It is particularly appropriate for evaluating new initiatives, pilot programs and trials, or programs that seem to work but ‘for whom and how’ is not yet understood. It can also be used for evaluating programs that will be scaled up, for adapting the intervention to new contexts, for evaluating programs that have previously demonstrated mixed patterns of outcomes, or to understand how and why differences in implementation occur. (Pawson & Tilley, 2004) This approach is appropriate since HEARTS has been designed based on the best available evidence, mostly from randomized control trials and large-population models of hypertension control programs which were developed and implemented in North America and Western Europe. It now needs to be evaluated in a non-controlled, routine implementation setting. (Mendis, Yach, Bengoa, Narvaez, & Zhang, 2003), (Ebrahim & Smith, 2001)

A RE orientation requires a framework that is grounded in its philosophy or approach. The Consolidated Framework for Implementation Research (CFIR) (L. J. Damschroder & Lowery, 2013) is a conceptual framework that was developed to guide systematic assessment of multilevel implementation contexts to identify factors that might influence intervention implementation and effectiveness. The CFIR provides a repository of standardized implementation-related constructs that can be applied across the spectrum of implementation research. A more detailed description of the CFIR will be provided in the methods section below.

Chapter 4. Characteristics of Colombia (intervention location)

Colombia is the fourth largest country in Latin America and is an extremely heterogeneous country, both geographically and demographically. Colombia is located in the northwest of South America, and borders Brazil, Ecuador, Panama, Peru, and Venezuela. It is divided into 32 departments (equivalent to US states), a capital district, and 1,121 municipalities. The majority of Colombia's population of 48.3 million lives in the mountainous regions in the west of the country or along the Caribbean coast, with fewer in the plains and rainforest to the south and the east. Urbanization has occurred very rapidly, with 77.1% of the population living in cities by 2018. (DANE, 2020) Like most emerging economies, Colombia is characterized by a high rate of informal employment, estimated to represent around 60% of the workforce. Informality tends to be concentrated among low-skilled workers, those aged over 55, and those in rural areas. Formal jobs tend to pay nearly three times more, on average, than informal ones and the gap has been widening in recent years due to a steady growth of formal sector earnings. This situation contributes to Colombia having one of the highest inequality levels in Latin America, evidenced by a Gini coefficient of 0.522 and 27.8% of the population living below the poverty line. (Pan-American-Health-Organization, 2017b)

Demographic profile

Life expectancy at birth in 2010-2015 was estimated at 73.74 years (77.39 for women and 70.19 for men); the crude death rate was 5.8 deaths per 100,000 population; the birth rate, 18.8 births per 1,000 population; and the total fertility rate, 1.93 children per woman, with average growth of 1.3% annually. The natural growth rate fell from 22.03 per 1,000 population in 1985-1990 to 13.07 in 2010-2015, with a rate of 12.08 per 1,000 population expected for 2015 -2020. (Pan-American-Health-Organization, 2017a)

Colombia, as other countries in Latin America, has often been described as having a “triple burden of disease”, which refers to “the onset of significant burden from noncommunicable diseases (NCDs), while the burden from communicable diseases (NCDs) remains high, plus increased injuries, suicides and homicides”. (Frenk & Gomez-Dantes, 2011) Of the total burden of disease in Colombia estimated at 28,015 disability adjusted life years (DALYs) per 100,000 inhabitants in 2010), (Institute-for-Health-Metrics-and-Evaluation-(IHME), 2018) noncommunicable diseases accounted for 83%, injuries for 8% and communicable, maternal, perinatal and nutritional conditions for 9%. These data show a substantial change from 2005 when communicable diseases accounted for 15% and non-communicable for 76%, showing that Colombia has experienced a rapid epidemiologic transition towards the predominance of non-communicable diseases. (Pan-American-Health-Organization, 2017b) However due to the sociohistorical factors, the country is highly diverse, and the distribution of morbidity and disease follow different patterns. The map displayed on figure 10 shows the distribution of causes of death per region.

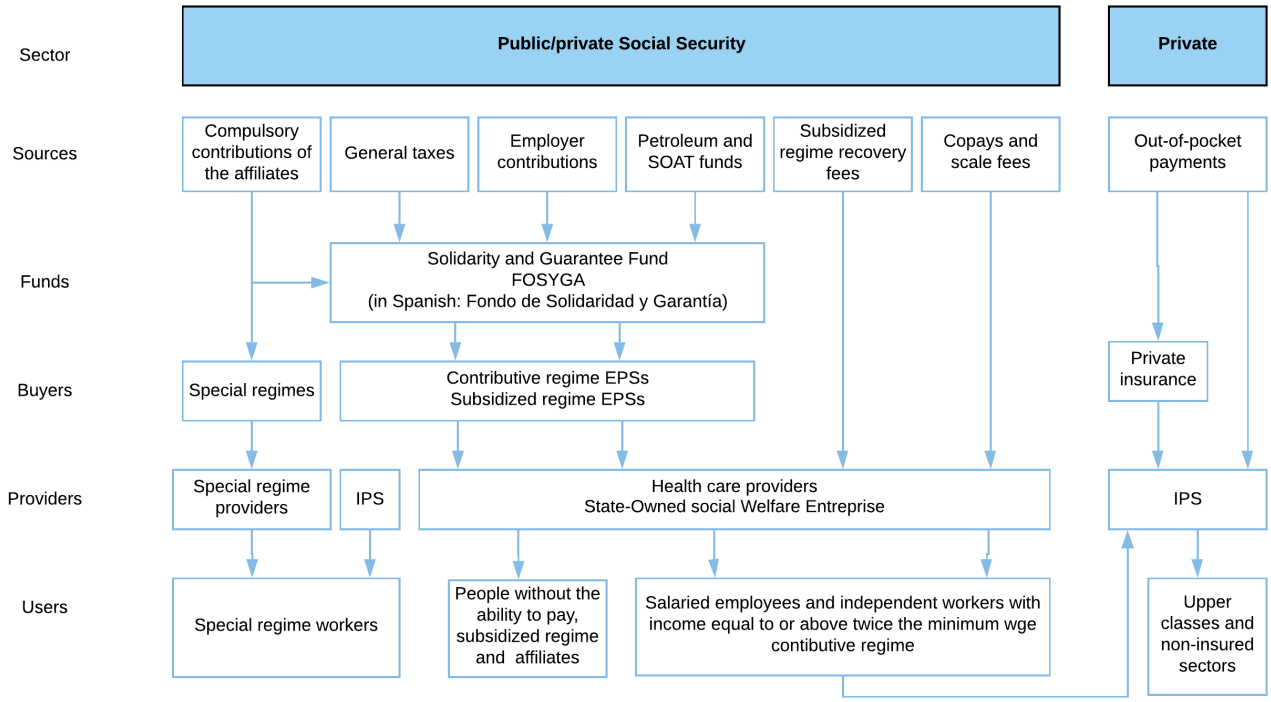
Legend	Main cause of death, 2016
	External causes
	Chronic diseases
	Infectious diseases
	Child maternal health

Figure 9. Main causes of death by geographical distribution in Colombia, 2016 (Ministerio-de-Salud-y-Protección-Social, 2019)

Health System

The basis for the current Colombian health system was established by the 1991 Constitution, which established the right of Colombians to healthcare and which is provided under the direction,

coordination and control of the state with participation of the private and public sector. The health system is composed of a social security system financed with public resources and a private sector. Universal enrollment is mandatory. The two main actors are insurance companies known as Health Plan Administrators (*Entidades Promotoras de Salud*, EPS) and the Organizations of Health Care Providers (*Instituciones Proveedoras de Salud*, IPS). Both are required to cover a specified minimum set of benefits. Originally, the EPS were established to administer health resources and offer a basic benefit package by contracting an IPS. The most recent iteration of the EPS is the Administrators of Health Benefit Plans (*Administradora de Planes de Beneficios de Salud*, EAPB). EPS is the original designation; this term is still commonly used. Both EPS and EAPBs are health insurance companies that purchase health care services. They are expected to manage both clinical and financial risks. (Pan-American-Health-Organization, 2017b), (Bernal & Barbosa, 2015). Figure 11 graphically displays the Colombian Health System.



SOAT: Mandatory Accident Insurance Policy, in Spanish: *Seguro Obligatorio de Accidentes de Tránsito*
Special regimes: Military forces, Law Enforcement, Colombian Petroleum Company (ECOPETROL), Education, Universities

EPS: Health insurance agency. These are the entities responsible for the affiliation and provision of the POS of the Subsidized Regime to its beneficiaries. In Spanish: *Entidad Promotora de Salud*

IPS: Health care provider. These are the institutions in charge of providing health services at their corresponding level of care to affiliates and beneficiaries within the parameters and principles indicated by the Law. In Spanish:*Institución Prestadora de Servicios de Salud*

Figure 10. Colombian Health System/ translation of figure from the Spanish by author for this study, original from Guerrero et al. 2011 (Guerrero, Gallego, Becerril-Montekio, & Vásquez, 2011).

Two insurance regimens, linked through a resource fund known as the Fund of Solidarity and Guarantee, operate in tandem: the contributory regime and the subsidized regime. All salary-based workers, retired individuals, and self-employed individuals who make at least the minimum wage must enroll in the contributory system. Enrollment means selecting an insurance company or plan administrator/EPS (public or private) and contributing 12.5% of earned income; however, for salaried workers or retired individuals, employers are mandated to pay 8.5%, making the individual solely

responsible for a 4% contribution. Self-employed individuals must pay the 12.5% entirely. The subsidized system covers the rest of the population who cannot pay and who are not covered under the contributory system. The uncovered population is the responsibility of the local municipal government and is enrolled through a universal identification system for social programs. The subsidized system is funded in part by 1.5% of the individual contribution of the 12.5% of the contributory system and additional national and state-level funding. Additionally, there are special subsystems that cover special populations: teachers, military personnel, police personnel, public university personnel and the state-owned Colombian Petroleum Company (ECOPETROL). (Guerrero, Gallego, Becerril-Montekio, & Vásquez, 2011), (OECD, 2015)

The insurers contract with health care providers (IPS) and offer the enrollees a network of providers which may include private and public ones. Public hospitals have been transformed into autonomous organizations known as "social state enterprises" which sell their services to the plan administrators/EPS. According to the government database REPS, there were 8461 IPS. Private IPS represent 71% and public 29%. Approximately, 1404 were categorized as hospitals (both private and public). All but two of the initial 13 implementing HEARTS sites are social state enterprises. At a minimum, the public and/or private providers must ensure that a minimum set of benefits is provided, which includes health promotion, disease prevention, disease management, urgent care, newborn care, general medicine and dental care, and referrals to specialists, labs, hospitalization, outpatient surgery, and physical rehabilitation. Additionally, high-cost illnesses such as AIDS, chronic kidney disease and cancer are covered. As of 2015, health system enrollment covered 97.6% of the population. (Guerrero et al., 2011), (OECD, 2015)

Colombia's primary care system is seen as fundamental to meeting population health care needs. A governance framework to support the role of primary care within the wider health system was brought in by a 2011 legislation (Law 14) specifying coordinated action between the government, health

care insurers, providers, and civil society. Its mandate was to place primary care front and center in any efforts to improve population health. The ministry has set out an expectation that 90% of health problems should be resolved at the primary care level, without the need for referral to secondary care. There is a clear hierarchy of service levels, with the primary level serving as the main point of entry into the health system for patients, except for emergency services. A registration system is in place, and referral from a primary care provider is necessary to access subsequent levels of care. Primary care providers increasingly work within multidisciplinary teams. (Personal communication, current study interview results)

Further strengthening of the primary care level was propelled by the latest health reform, known as the Statutory Health Law 1751, 2015, which aims to "guarantee the right to health, regulate it and establish its protective mechanisms." This law was the response to the cumulative effects of high cost, high inequity and high dissatisfaction, and highly publicized insurance fraud that spanned the health system into crisis (Webster, 2012), (Bernal & Barbosa, 2015) In 2011, even the then president, Juan Manuel Santos, admitted as much in a declaration in which he noted the mixed-market model needed reform to ensure the "basic principle which says that health cannot be a business and cannot be approached as a business. Health is a social service, is a right of Colombians" (Webster, 2012). Therefore, the new health care reform law was an attempt to ameliorate issues related to governance, as role of the Ministry of Health had been diminished, such as higher oversight of insurance companies and finances.

Additionally, as the core of the law is an unequivocal declaration of health as a fundamental right, universal coverage should mean more than insurance enrollment but high quality health care through the spectrum of prevention (health promotion, prevention, care, rehabilitation and palliative care). This integral health care model is intended to be delivered through integrated routes for care and prevention. (Bernal & Barbosa, 2015) Integrated care networks that focus on long term conditions are

an increasingly important feature of the primary care teams. The Integrated Health Care Policy (PAIS) is a new model of care that aims to better integrate primary care, public health activities and wider inter-sectoral action at the community level. Enhanced work force capacity and new technologies are also addressed with the PAIS program. Individual and population risk management is a central element and is expected to deliver the goals of the 10-Year Public Health Plan 2012-21 (PDSP) whose objectives are to attain equity in health, positively influence the social determinants of health, and mitigate the impact of the burden of disease.

Integral care routes (ICRs) are a set of a tools that define the system agents (territory, insurer, provider) and other sectors, the necessary conditions to ensure the seamless continuum of care. It includes descriptions of the actions expected of an individual, the actions designed to promote the development and well-being of individuals in their surroundings, as well as the interventions expected by systemic agents for prevention, diagnosis, treatment, and rehabilitation. To date, Colombia has a Route for health promotion and maintenance, and six ICRs related to cardiovascular health promotion (hypertension, diabetes mellitus type 2, acute coronary syndrome, stroke, chronic renal disease and overweight and obesity). (Personal communication)

Introduction of the HEARTS Initiative in Colombia was intended to fit into the overall current health system organization. The implementation of this intervention began in October 2015 through the selection of two training/demonstration centers, located in the Agua Blanca district of the city of Cali (Coomeva-Oriente Clinic and Carlos Holmes Trujillo Hospital). Since then a national scale-up started currently reaching 11 additional health centers started implementing in four different states of the country.

The Integrated Care Routes (ICR) and HEARTS in Colombia: The Integral Route for the Prevention, Control and Treatment of Hypertension

The ICRs incorporate a set of three implementation strategies for the management of cardiovascular risk which operate in an articulated and complementary manner. The design and implementation of two of these strategies (RECCETA-A and "Take Control", where HEARTS ultimately fit) occurred through technical assistance that the Ministry of Health and Social Protection has received from the Pan American Health Organization and the CDC in Atlanta. The following paragraphs describe the objectives and characteristics of each strategy as well as the main progress achieved:

"Know Your Risk and Healthy Weight" strategy: implementation of this strategy started in November 2014, with an objective for the year 2026 to identify the risk of cardiovascular disease of 23 million Colombians older than 18 years. By September 2017, the strategy had been implemented in 20 departments of the country, and 88,402 cardiovascular risk assessments have been done using the calculator designed for this purpose**.**

The **RECCETA-A strategy** is the Colombian version of Million Hearts, the U.S. CDC-developed strategy designed to reduce the number of cases of myocardial infarctions and stroke by one million. RECCETA-A means prescription and is an acronym for Risk, Exercise, Cholesterol, Smoking Cessation, Blood Pressure, Pharmacological Therapy, Aspirin and Healthy Eating. The concept was to assess risk and identify the target population with moderate cardiovascular and metabolic risk as determined by the "Know Your Risk and Healthy Weight" strategy; once risk is determined, persons are referred to health services and theoretically guaranteed access to the entire range of evidence-based interventions to manage cardiovascular and metabolic risk. The HEARTS Initiative arrives at the time that these activities are being launched. This evolution and blending of strategies will be discussed in depth in the analysis sections.

Human resources for health

In 2012, the ratio of health professionals per 10,000 population was 17.7 for physicians, 10.3 for nurses, and 8.3 for dentists. WHO recommends a minimum parameter of 25 health professionals per 10,000 population, therefore the country meets the minimum; however, geographical distribution varies. The country has 56 medical schools, of which 18 are public and 38 are private. They can be accessed by students who have completed the cycle of secondary education (11 years) and graduate an average of 5,000 physicians annually, and 65 nursing programs, graduating an average of 3,600 nurses annually. (Pan-American-Health-Organization, 2017b)

Chapter 5: Methods

Sampling and Data Collection

Sample description

Fifty-four participants were recruited from three organizational levels: one from the national level, two from the state level and 51 from the twelve health centers participated in the face-to-face interview. These centers were selected because they were the original centers were HEARTS was introduced and the Ministry of Health approved the study to be conducted under the condition that all centers were included.

Basic socioeconomic characteristics of the 12 municipalities where the centers are located will be provided below in section titled “Site characteristics”.

Sampling procedure

First, the Ministry of Health of Colombia was asked to recommend officers who have been directly responsible for the coordination and implementation of the HEARTS Initiative at the national and regional levels.

Second, the Ministry of Health of Colombia required that all directors of the implementing health centers be approached and asked for permission to participate. Full authorization from national and local authorities was received. Subsequently, the directors provided the list of the participants based on current or past participation with the HEARTS Initiative at the health center. The recommended participants were contacted by the interviewer by telephone and an appointment was set for the in-person interview at date and time selected by the participant. Interviews were conducted from October 15 to December 14, 2019.

To elicit diverse perspectives from different stakeholders in the implementation at the health care center level at least two interviewees were selected each site. A total of 54 individuals were

interviewed with the breakdown by profession shown in table 3. In-person interviews were conducted at the ministry of health offices, regional health authorities' offices and the health centers. Structured interviews were conducted in Spanish, audio-recorded (with appropriate informed consent) and transcribed in-language (Spanish). The researcher has native fluency in Spanish and conducted one third of the interviews herself and was aided by two local professional Spanish-speaking interviewers with master's degrees in social science to collect the data from the 12 sites.

Municipality	Physicians	Nurses	Nursing assistants	Other
Oiba	2	4	0	
Cerrito	3	1	0	
Giron	2	2	1	
Pueblo Rico	1	0	1	
Belen De Umbria	2	1	1	
La Virginia	2	1	1	
Dosquebradas	2	2	2	
Nobsa	1	1	0	
Duitama	2	3	1	1
Sogamoso	1	1	0	
Cali 1	4	2	1	
Cali 2	1	0	0	1
Sub-total per profession	**23**	**18**	**8**	**2**
National level				**1**
State level				**2**

Table 3. Number of interviewees by profession per municipality

Each interview lasted approximately 60 minutes with physicians, nurses and administrators or coordinators and about 30 minutes with nursing assistants, although in some cases, interviews with some very experienced nursing assistants lasted 60 minutes as well.

Interview Guide

The Consolidated Framework for Implementation Research (CFIR was used to guide the systematic assessment of multilevel implementation contexts to identify factors that might influence intervention implementation. The semi-structured interview guide (Appendix A, conceived in Spanish) was designed to ensure alignment with the research questions, which were guided by existing literature and the CFIR framework. The semi-structured interview guide prompted respondents to discuss their experiences with implementing individual HEARTS components. The interview guide also probed respondents regarding the challenges and facilitators they experienced when implementing each component. Respondents were asked about i) how each component was being operationalized in their specific health center; (ii) how did specific health center workflows and staff configuration support (or did not support) each component; (iii) what had been challenging with operationalizing each component; (iv) what had been helpful with operationalizing each component; and (v) how patients and peer health personnel are reacting to each component and to the intervention overall.

Data Analysis

Data analysis followed Bradley and colleagues' (Bradley, Curry, & Devers, 2007) guidance for health services researchers, as follows:

Immersion in the data: To review the data overall as an important first step helps to identify emergent themes without losing connections between concepts and the context. An initial review of the entire transcripts was conducted to illuminate common issues or themes.

Preparation of the data: The goal was the conversion of the raw data into words presented in an intelligible format that can be read, edited, checked for accuracy, coded, and analyzed. The first step

in this study has been to transcribe the interviews verbatim in the original language (Spanish). The transcriptions were then uploaded into the Dedoose™ software.

Coding the data: In the first pass, open coding was conducted directly on Dedoose™ identifying themes, paying close attention to language usage, and specific ways of naming components and implementation processes. Seventy-four codes were created. Figure 12 shows a code cloud showing saliency and frequency of themes.

Figure 11. Initial seventy-four codes packed code cloud by Dedoose™.

After this primary inductive coding process, codes were clustered into eight major clusters based on affinity and themes. Five of these eight clusters naturally match the six HEARTS content components and three clusters are the how-to, or operational elements that make implementation of content possible. These three elements are: leadership support, training, and staffing. All of them are dimensions of actual implementation that have not been described in depth in the HEARTS modules. Appendix B shows the complete list of initial codes and the subsequently created clusters of themes and their correspondence with the HEARTS modules.

The next step was to review the CFIR, checking its 39 CFIR constructs and their definitions and creating clustering codes to capture contextual factors that might influence the implementation of HEARTS components. These CFIR constructs require a higher level of interpretation of the data to apply the CFIR code that reflects a potential barrier or facilitator being described, which was one the main theoretical drivers of the study.

Site Characteristics

TWELVE SELECTED HEALTH CENTERS IN FOUR DIFFERENT DEPARTMENTS

In the context of the HEARTS in the Americas Initiative implementation, PAHO provided a recommended set of characteristics for the selection of initial implementation sites for all four initial countries in the Americas.

The selection of countries was based on two basic premises:

1. Presence of a health system oriented to primary care in place with at least a basic infrastructure and resources.

2. Political commitment to introduce, conduct, and sustain the changes needed at the health systems level as evidenced by Ministries of Health assigning national coordinators who report directly to the Minister of Health or the Deputy Minister of Health.

Ultimately, receptivity to the technical package on the part of the Ministry of Health and the PAHO national office representative was the deciding factor to select Colombia as one of the first countries to implement the HEARTS technical package. Based on their own national situational analysis conducted by the ministries and their corresponding PAHO technical officers, the sites in Colombia (table 4) were selected with the following considerations:

- Located in an active clinical site at first level of care with a reference population of 20,000 to 50,000 in the initial phase.
- The site is part of a network of active clinical centers.
- Basic information is available about the population it serves (i.e. clinical information to build a clinical registry) and epidemiological information regarding the prevalence and control of hypertension.
- Basic healthcare infrastructure facilities to meet the designated educational/training function goals.
- Basic pharmacy support and facility or facilities that are integrated with the service network to maintain systematic communication.
- A referral hospital and experienced staff that can properly record and document morbidity, mortality, and cost, related to hypertension and CVDs.
- Formal affiliations and relationships with academic institutions that are willing to participate in the project and assume the critical role of evaluation and monitoring, in addition to teaching.
- Motivated and trained staff, including a technical leader and champion.

Department	Health Center	Municipality	Date of inception of HEARTS
Valle del Cauca	2	City of Cali (District of Agua Blanca)	November 2015
Risaralda	4	Pueblo Rico Belén de Umbría La Virginia Dos Quebradas	March 2017
Santander	3	Oiba Cerrito Girón	June 2017
Boyacá	3	Nobsa Duitama Sogamoso	June 2017

Table 4. Distribution of public primary care health centers per Colombian departments and date of inception of HEARTS implementation, presentation by Ministry of Health, PAHO (Ministry-of-Health-(PAHO), 2019)

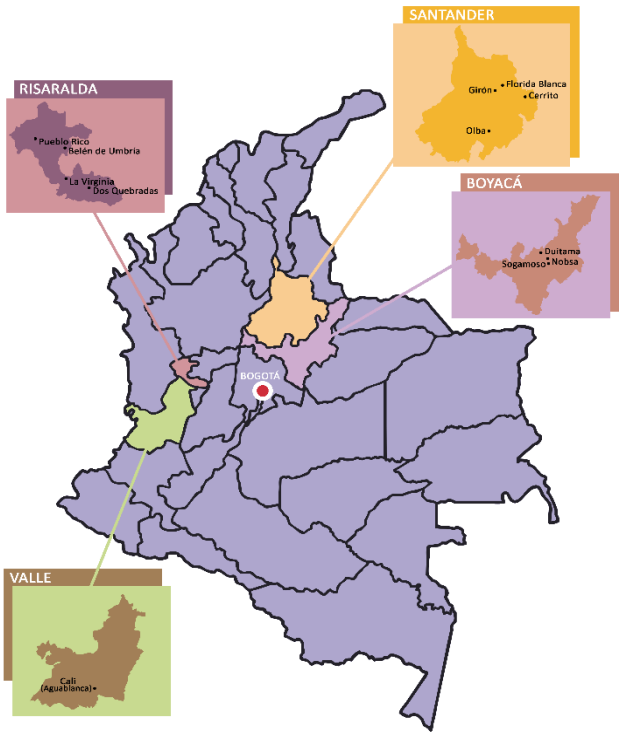


Figure 12. Map illustrating location of departments where health centers are located, original map by author.

Contextualizing the study sites: Overview of communities where health centers are located[1]

Population and age distribution

The sites selected were geographically and demographically diverse. As the data in table 5 shows population ranged from 6,000 residents to 200,000 among all centers outside the large city of Cali.

[1] All the data in this section comes from the National Statistical System which provides society and the state with national and territorial official statistics of quality, in a coordinated manner between the producing entities and with common language and procedures, respectful of international statistical standards, which contribute to the transparency, relevance, interoperability, access, timeliness and consistency of the statistics produced in the country. (DANE, 2020)

Table 5. Population and age distribution of municipalities where HEARTS health centers are located (DANE 2020)

Municipality	Total population	Male PERCENT	Fem PERCENT	Adult POP_PERCENT	Age 35 - 54	Age 55-75	Age 75 & over
Oiba	10.117	49,14	50,86	72,13	27,63	46,16	26,21
Cerrito	6.460	49,11	50,89	70,74	21,67	37,77	40,56
Giron	150.610	45,15	54,85	72,78	34,84	45,33	19,83
Pueblo Rico	14.429	47,87	52,13	53,61	32,53	39,51	27,96
Belen de Umbria	21.450	49,91	50,09	73,03	30,96	48,66	20,37
La Virginia	25.900	44,67	55,33	75,26	32,16	46,8	21,04
Dosquebradas	194.890	42,81	57,19	77,21	29,43	46,12	24,45
Nobsa	14.651	45,45	54,55	73,70	31,01	42,76	26,22
Duitama	117.606	44,89	55,11	73,88	29,27	42,04	28,69
Sogamoso	120.462	45,04	54,96	74,23	29,30	42,64	28,06
Cali 1	1.822.869	41,50	58,50	78,04	32,12	42,94	24,94
Cali 2	1.822.869	41,50	58,50	78,04	32,12	42,94	24,94

The city of Cali, is very different from the other municipalities where the health centers are located, as it is the third most important city in the country; a special district and urban epicenter of the Pacific region with 1,822,869 people duly registered for 2018. It has an Unmet Basic Need Index (NBI) of 4.08%. Of all the municipalities, Cali stands out for having the highest percentage of Afro-descendant population with 14.41%, and the lowest illiteracy rate, at 2.03%. It is important to note that there were only two health centers participating in the City of Cali. Both are located in the district of Agua Blanca, which is characterized as a low-income district and for which the demographic data is quite different than for the city as whole. Therefore, the census data for Cali overall is less relevant to the specific context of the two health centers. Figures 13 and 14 show the large population difference between all 10 municipalities and the city of Cali.

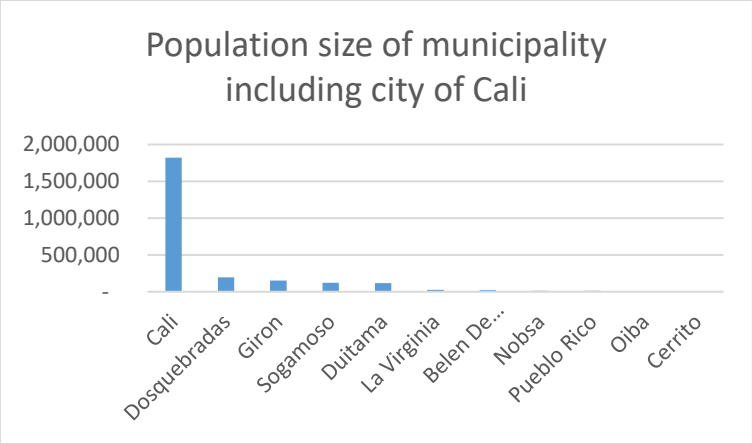


Figure 13. Population size of municipality including city of Cali.(DANE 2020)

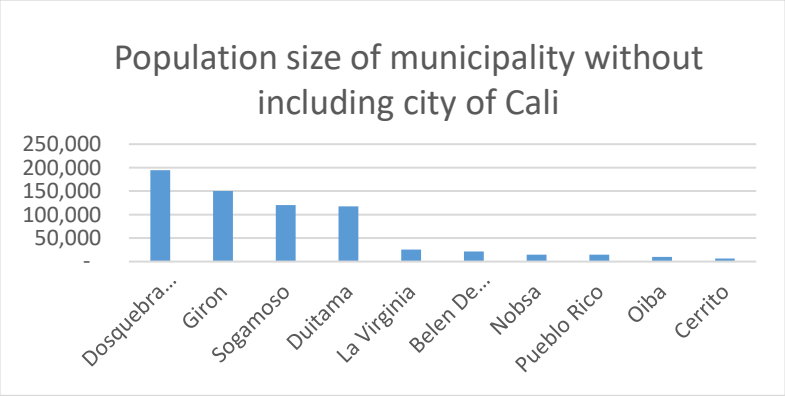


Figure 14. Population size of municipality including city of Cali (DANE 2020).

Basic socio-demographic characteristics

Municipalities that register populations of less than 100,000 have their main economic activity in livestock, agriculture, and mining, including Oiba and Cerrito in Santander; Pueblo Rico, Belén de Umbría and La Virginia in Risaralda; and Nobsa in Boyacá. And as it is often the case, around the world, the highest rates of Unmet Basic Needs (NBI) are found among this group of rural municipalities, with Pueblo Rico being the most critical with 55.4% of residents falling below the NBI level, followed by Cerrito with 15.56%, and Oiba and Belén de Umbría at about 12%. Girón in Santander, Dosquebradas in Risaralda, Duitama and Sogamoso in Boyacá and Cali in Valle del Cauca register over 100,000 residents, and are characterized, by main economic activity being industrial (steel, manufacturing or mining),

commercial or services, except for Duitama, which despite having 117,606 inhabitants, is still mainly engaged in agricultural activity. These municipalities have fewer residents below the NBI, ranging between 6.58% and 3.6%, the lowest being Duitama. Contrasting with the smallest municipalities whose average of Unmet Basic Need rate is 17.8%, the largest municipalities are better off, with an average of 4.3%.

Table 6. Demographic characteristics of municipalities where HEARTS health centers are located (DANE 2020)

Municipality	Self Report Indigenous	Self report Afrodescendent	Self report No ethnic group	Iliteracy rate	Unstatisfied Basic necessity index	Main economic activity
Oiba	0,03	0,22	99,02	7,76	12,4	Agricultural and livestock
Cerrito	1,02	0,03	97,80	6,89	15,56	Agriculture
Giron	0,03	0,36	98,72	2,89	6,58	Agriculture
Pueblo Rico	52,52	12,57	34,01	21,44	55,42	Agriculture
Belen de Umbria	2,48	0,48	96,63	7,70	12,97	Services
La Virginia	0,14	1,30	97,85	6,28	6,49	Agroindustry
Dosquebradas	0,18	1,84	97,29	2,58	4,31	Manufacturing
Nobsa	0,00	0,09	99,09	2,39	4,02	Agriculture
Duitama	0,04	0,20	98,38	2,27	3,36	Agriculture
Sogamoso	0,04	0,19	98,16	2,56	3,6	Mining
Cali 1	0,00	14,41	83,61	2,03	4,08	Industry
Cali 2	0,00	14,41	83,61	2,03	4,08	Industry

The Pueblo Rico municipality is unique in several ways: 52.5% of its population self-identifies as indigenous and 12.5% as of African descendant, being the only municipality in which ethnic minorities are the majority. It is a young municipality, as its adult population does not exceed 53%, with the highest illiteracy rate at 21.4%.

Health insurance coverage

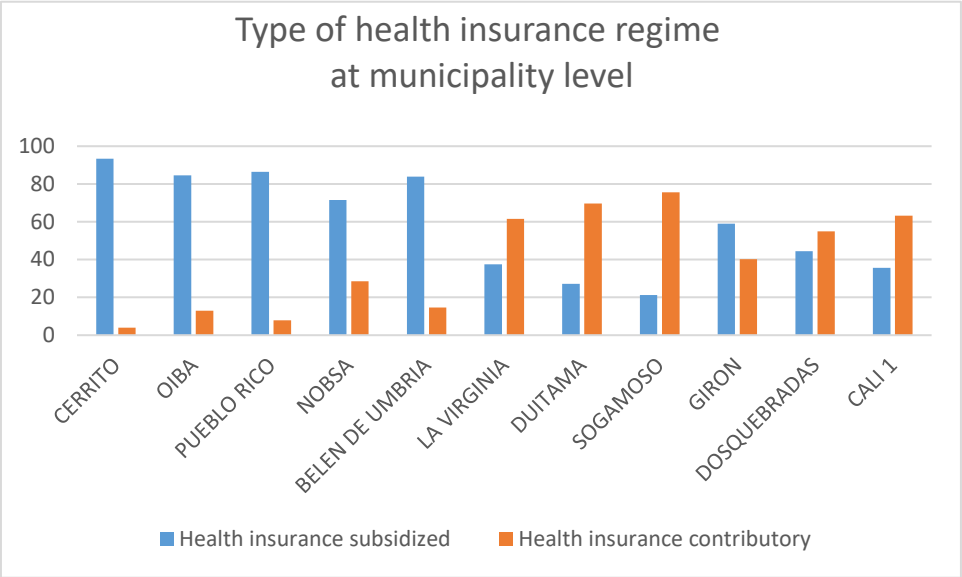


Figure 15. Type of health insurance coverage or regime by municipality where HEARTS health centers are located. All data in this section is from DANE (DANE 2020)

As previously mentioned, Colombia has achieved a high level of health insurance coverage and the distribution of the subsidized versus the contributory regimes in the twelve municipalities are shown in figure 14, organized by population size, starting with the smallest municipalities on the right to the largest on the left. Population size is correlated with the municipality's rurality status as well as with higher poverty (as measured by the Unmet Need Index) which naturally corresponds to a high ratio of subsidized insurance coverage. This is of relevance to the study since in the smaller rural municipalities there are few health care providers (IPS) and it is highly likely that the study site is the only health care provider organization in town.

These basic socio-demographic data are important to situate the health centers within the larger context of Colombia and provide a glance into the places where the interviews for the current study took place.

Chapter 6: Results

Inductive Analysis

HEARTS Implementation through the lens of the implementers

A first analysis was conducted following an inductive approach, where themes were coded as they were emerging from the words of the interviewees without a pre-selection of themes. The rationale for utilizing an inductive approach first was to capture the words that have been chosen to describe the HEARTS interventions by the health personnel in primary care centers who are the ultimate implementers. Although, the interview guide was written following the Consolidated Framework for Implementation Research (CFIR), the questions were open-ended and therefore, interviewees were able to spend the time and detail desired on each response. The inductive analysis shows the most salient topics as revealed by the length and detail of the description, and reiteration of topics in some related questions. Moreover, the order of presentation of themes starts to shape the story of implementation; the chronological order is important in reconstructing the implementation pathway of the HEARTS Initiative in Colombia.

Through the inductive analysis, words, and expressions that interviewees used to describe the steps taken to establish, strengthen, and/or modify existing data management systems. Theses codes were clustered around the larger theme of Systems of Monitoring which is one of the six HEARTS modules. As the description will show, in Colombia, the establishment of a reporting mechanism to the national ministry of health, constituted a first step in the installation of the implementation. In other words, a “benchmark” or a “milestone” that indicated that a health center was implementing HEARTS was the tangible step of utilizing “the analysis book”, next in implementation order was organizing a new way of in reach and outreach of patients and screening based on the new numbers and gaps uncovered by the “analysis book” and in tandem the development of a new hypertension treatment

protocol or algorithm and revision of patient workflows. These four steps seemed to be the main "milestones" of signaling onset of implementation. Additionally, different ways in which lifestyle interventions were being conducted were considered a second tiered milestone. Ultimately, these clinical and managerial interventions, were considered constitutive components of the new model in chronic care. These interventions are made possible by cross-cutting strategies: team-based care with staffing configuration considerations, training at every stage of implementation and leadership support from all levels of the system. In Table 8 below presents at-a-glance view of the main themes aforementioned, and how they connect to the HEARTS core components, topic that will be discussed in depth in the upcoming section.

Table 8. At-a-glance description of themes and connection to HEARTS components

ORDER AND NAME OF COMPONENTS AT GROUND LEVEL (FROM INTERVIEWS)	HEARTS COMPONENTS (FROM WHO/PAHO)	MECHANISMS AT WORK TO SUPPORT THESE COMPONENTS
Introduction of the Analysis Book	**S**ystems for monitoring	• Leadership support • Training • Human Resources
Active search of new patients	**T**eam-based care	
	Risk-based management	
Hypertension treatment algorithm development and Reviewing Patient Workflows	**E**vidence-based treatment protocols	
	Access to essential medicines and technology	
Healthy lifestyle spaces, self-management and mutual help groups	**H**ealthy-lifestyle counseling	

Before diving into the first milestone, a brief review of the integrated care route of Colombia's most recent health reform is in order to further contextualize the HEARTS implementation.

The Integrated Care Routes and HEARTS in Colombia

The Integral Route for the Prevention, Control and Treatment of Hypertension, previously mentioned in the health system description in chapter 4, incorporate a set of implementation strategies for the management of cardiovascular risk. “Know Your Risk and Healthy Weight” strategy and RECCETA-A, which identifies as its target population persons with moderate cardiovascular and metabolic risk as determined by the “Know Your Risk” strategy, have the goal of “triaging” Colombians towards health services and should guarantee access to the entire range of evidence-based interventions to manage cardiovascular and metabolic risk.

The HEARTS Initiative in Colombia was incorporated to complement these two strategies with another package in the form of the “Take Control” strategy. For respondents in the study, “Take Control” Strategy is the same as HEARTS. In figure 16, the timeline of overall implementation of HEARTS is illustrated, showing an early start in late 2015 with two health centers, which originally were named “training centers”. The idea was that these would become HEARTS model training centers, and so, the majority of health centers started only in 2017. Therefore, by the time of the study interviews in late 2019 the span of time of implementation was approximately 24 months.

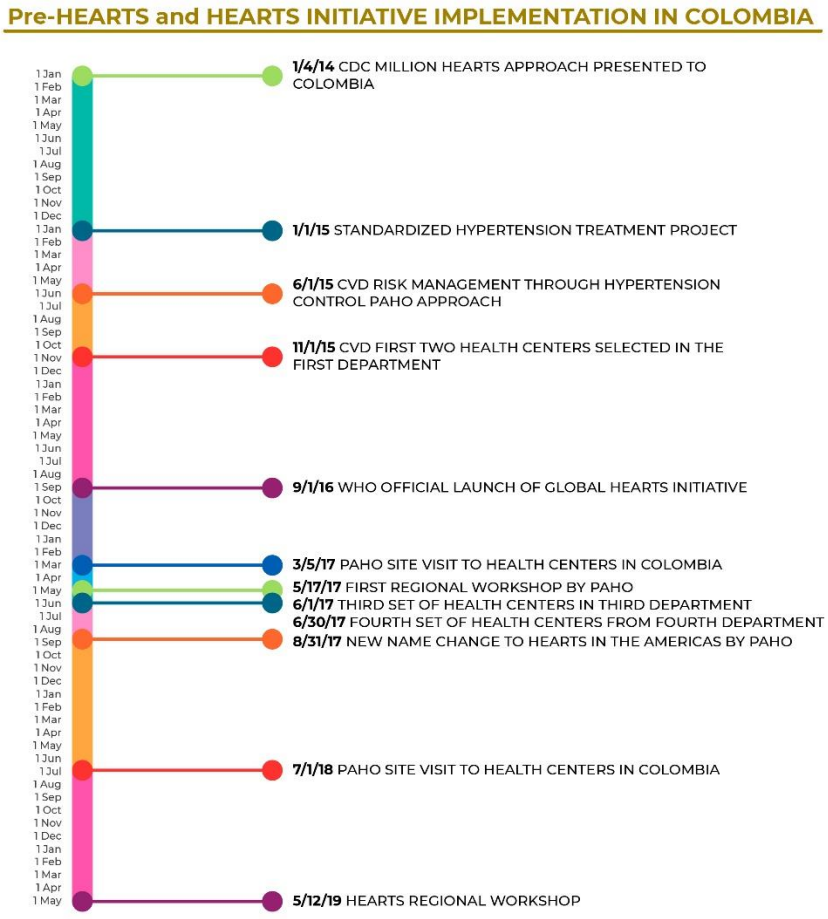


Figure 16. Timeline of HEARTS implementation, original diagram by author.

Detailing the process of implementation from the voices of those in the ground allows for the dissection of the introduction of the HEARTS model into the field, in real world scenarios. Ultimately this process will answer the research questions regarding the theory of change through the mapping of the implementation, describing contexts and mechanisms.

The order in which the implementation is being presented mirrors the real world trajectory of the tangible steps taken:

1. Adoption of a monitoring system, through the analysis book.
2. Active search of patients via in reach and outreach.
3. Development of the standardized treatment algorithms.

4. Review of patient workflows.

5. Enhancement of lifestyle counseling.

These five elements match the HEARTS modules, therefore showing a high degree of affinity or fidelity with the guiding principles. Each step is also considered a milestone as it was pointed out by the interviewees that initiating the implementation had turning points that signaled a step in the process. Figure 18 provides a graphical overview of the implementation process as described by respondents, which is then explained in detail in the narrative that follows.

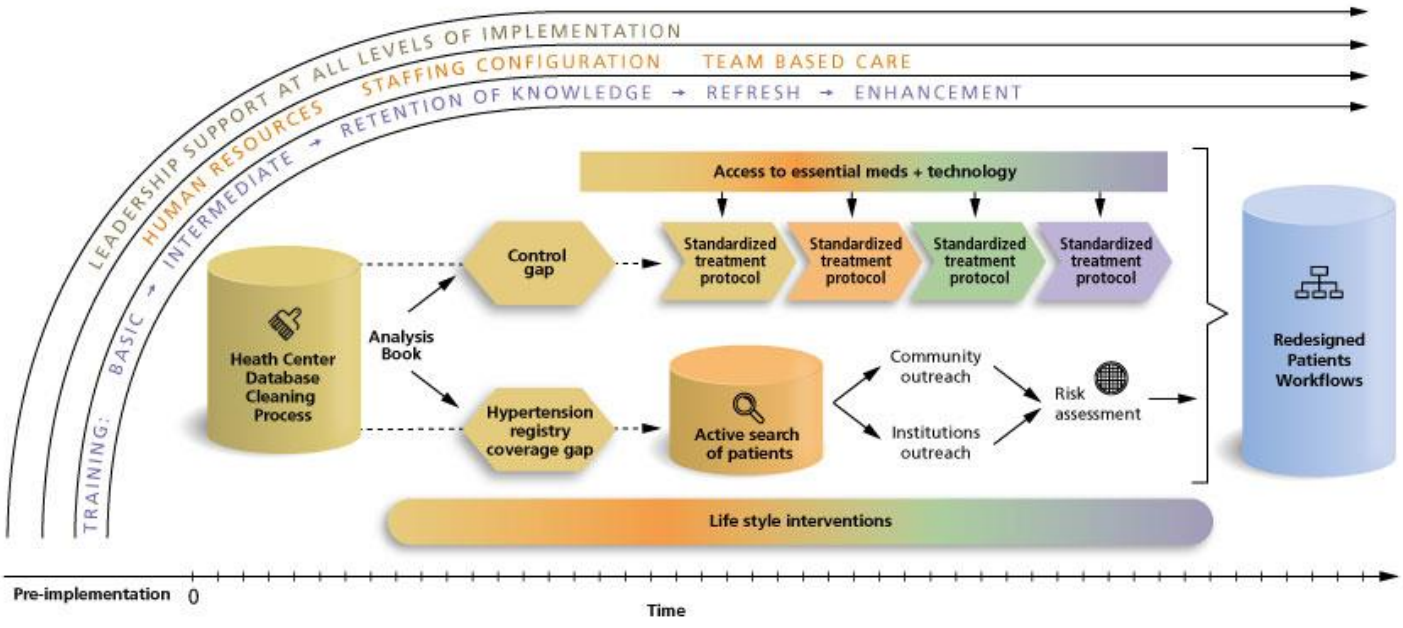


Figure 17. Emerging program theory for HEARTS implementation, original diagram by author.

First milestone of implementation: "*The Analysis Book*"

Understanding the analysis book"

The national coordinator described the “analysis book” as an Excel™ workbook designed by the Ministry of Health based on the guidance of PAHO on basic core indicators. The main core indicators include registry coverage which is the estimated number of adults with hypertension in the catchment area who are registered in the hypertension program and the hypertension control rate in the catchment area. There are several other indicators that PAHO recommends and the country has the option of selecting those that were most relevant. The Excel™ workbook was introduced by the national coordinator to every center as they were joining the implementation and during a period of at least four to six months, intensive training was conducted with health center staff on how to utilize it. The “analysis book” seems to be a pivotal/key ingredient of implementation of HEARTS in Colombia. Nearly every interviewee was brought it up by name and explained its purpose. This name is unique to Colombia; no other country names its system as such.

Most health center coordinators, staff physicians and nurses named the reception, and inception of utilization of the analysis book as a milestone of initiating the HEARTS implementation. The analysis book led to a first step into characterization of the patient population. Although a chronic care program (which goes by different names depending on the health center: Hypertension/chronic/cardiovascular risk program) already existed in several of the health centers prior to the advent of HEARTS, respondents stated that they did not have clear, explicit indicators for monitoring and evaluating the program and often the databases with which they worked were outdated, or had duplicates and other non-standardized information.

> *I think that the first thing that was important was when we started organizing our patients. Why? We had a database where we knew that in the program we had almost five hundred people and other databases had two hundred, so already with the re-organization of these patient databases we were able to find almost a number close to 760 registered patients, so if we know they were here, we know*

they're still with us, we are now able to find out, search and learn what happened to this patient, and what happened to that patient.

-Physician, coordinator, rural health center, Department W

Starting to implement the data entry and analysis into the analysis book was a process that in all cases required changes in the existing systems and databases. Some interviewees highlighted the contribution of IT systems staff and of nurses in updating medical records, databases and software to be more aligned with new needs, changes in medical history charts in turn required a re-introduction of the chart to the physicians and creating higher awareness of the importance of completing all the fields in the electronic records in an appropriate manner, even if new mandatory items could take several additional minutes of the medical consultation. This type of increased attention to detail and precision became necessary because some interviewees mentioned that before HEARTS/Take control, physicians did not adequately fill out the medical history/ER chart, completing only the minimum information, affecting the creation of the aggregate reports due to high levels of missing or inconsistent data.

As we moved forward in the strategy, higher level of specific details were needed and the data produced were more thorough or covered more information, then the IT systems team was very receptive and there was full acceptance and there was no problem in modifying the structure of the clinical chart, modifying the structure of how consultations were carried out to collect data.

- *Physician from Department Y*

One of the changes in the medical history mentioned by the interviewees was the standardization of how to calculate whether a patient is controlled or not. In some cases, this item was recorded in the patient's medical history according by only having to choose a response from a binary form [Controlled patient: yes_ no_]. The main change made was replacing the "yes or no" with an exact figure field, to fill in the systolic blood pressure and the diastolic blood pressure, adding a risk calculator to the medical

history and making the calculation of the Findrisk and Framingham scale data mandatory. In some cases, the risk calculator has not yet been added but respondents say that a short-term goal is to include this as mandatory in the medical history. The obligation to process these items would be ensured by not allowing the physician to save/update/complete the medical chart during a consultation without having completed all the information, thus ensuring that there is no missing data.

In addition to data on controlled and uncontrolled patients and risk stratification, respondents stated that the analysis book required information on BMI, healthy lifestyle habits, risk of diabetes, High-cost Account[2], population characterization, overweight, coverage percentages, percentage of new patients, number of patients "non-attending patients or with missed appointments" and crosstabulation with other databases such as Know Your Risk/ Healthy Weight.

> *Well, the first thing we did was to clean the databases, so we started doing the whole process with the IT systems area. Initially we started with a huge population and when we cleaned the databases, we saw that we had about half of what we had said that we had initially [hypertension patients], due to sub-registration produced in many ways, by type of diagnosis. When diagnostic criteria are considered and the diagnosis of high blood pressure is made, utilizing the ICD-10; it allows us to put high blood pressure reading as a potential diagnosis and not a confirmed diagnosis. Then we saw that a lot of sub-registration went hand in hand with that kind of data and we started the whole process.*
>
> *- Nurse in charge of databases, urban health center, Department Y*

[2] The High Cost Account (CAC) is a non-governmental technical body of Colombia's General Social Security System in Health created by Decree 2699 of 2007 that obliges EPS of both regimes and other EPOs (Entities Required to Compensate) to partner to address the High Cost diseases and operates as a self-managed Fund that contributes to stabilizing the health system, ensuring the actual enactment of solidarity and discouraging the selection and discrimination of the population through a risk adjustment of the basic premium according to high-cost cases. ("Fondo Colombiano de Enfermedades de Alto Costo,") https://cuentadealtocosto.org/site/quienes-somos/

The technical support for the utilization of the analysis book was provided, first by the Ministry of Health national program coordinator and long after inception, by some state health secretariats through video teleconference or face-to-face meetings. These intense follow up was instrumental in keeping the analysis book updated monthly, thus guaranteeing feedback, and continuous guidance on the strategy, monitoring advances, goals, and setbacks. The Medical Coordinator of the one rural health center described the accompaniment of the Ministry of Health in reviewing these data regularly together "*convinced us of small wins, of early wins, which motivated a lot [the health personnel] so that the municipality [health center] would not stagnate and that kept us moving forward*".

These intense technical advising and support were also mentioned by other interviewees who emphasized its importance in resolving issues, clarifying doubts and being able to standardize indicators, as in the case of Boyacá in which a process was carried out to standardize the criteria of all the three health centers of the department. While the accompaniment by the Ministry of Health at time of the interview is no longer so close, in all cases the interviewees stated that the analysis book is still filled out monthly and sent to either the Ministry of Health or the state Secretariat of Health. It also serves to complement the monthly or bimonthly reports that they send to each insurer and is sometimes shared with health personnel, as in the case of the "coordinating committee" (a full description of coordinating committee is provided in the next section). However, in other cases, respondents who are not directly responsible for the management of information and databases mentioned that they did not have much knowledge about the monthly results because only very occasionally this information was shared with them. Although they knew that monitoring was carried out. it seemed to be an isolated task farther removed from their functions.

According to the people interviewed, this new type of continuous monitoring has allowed them to show the increase in the percentage of their controlled patients, prioritize those patients who present very high risk, carry out continuous evaluation of their programs, make more accurate decisions on how

to improve processes, identify gaps and devise solutions and systematize processes. It has also called for the development of indicators and has encouraged work in multidisciplinary teams.

In some health centers, the analysis book is prepared by nurse coordinators of the chronic/hypertension/cardiovascular risk program and in other cases by physicians. In both cases, they receive different types of data from other nurses, nursing assistants, and sometimes from the IT systems team. At a few health centers, the need to have a person dedicated exclusively to performing program monitoring and database management was mentioned, as these tasks are an extra burden for health personnel.

In tandem with the re-organization of the patient population, another aspect of data was characterizing the population or classifying patient and catchment area population by risk score. The characterization of the population allowed to gain clarity on the number of inhabitants over the age of 18 in the catchment area, the number of patients diagnosed with hypertension in the health center, number of patients controlled, as well as socio-demographic information, which in turn allowed for the setting of goals for the number of patients with hypertension to be outreached, identified and brought into the programs. For example, the figure 18 and 19 below shows an estimate of the population over the age of 18 and potential number of persons with hypertension in the catchment areas of the public primary health centers.

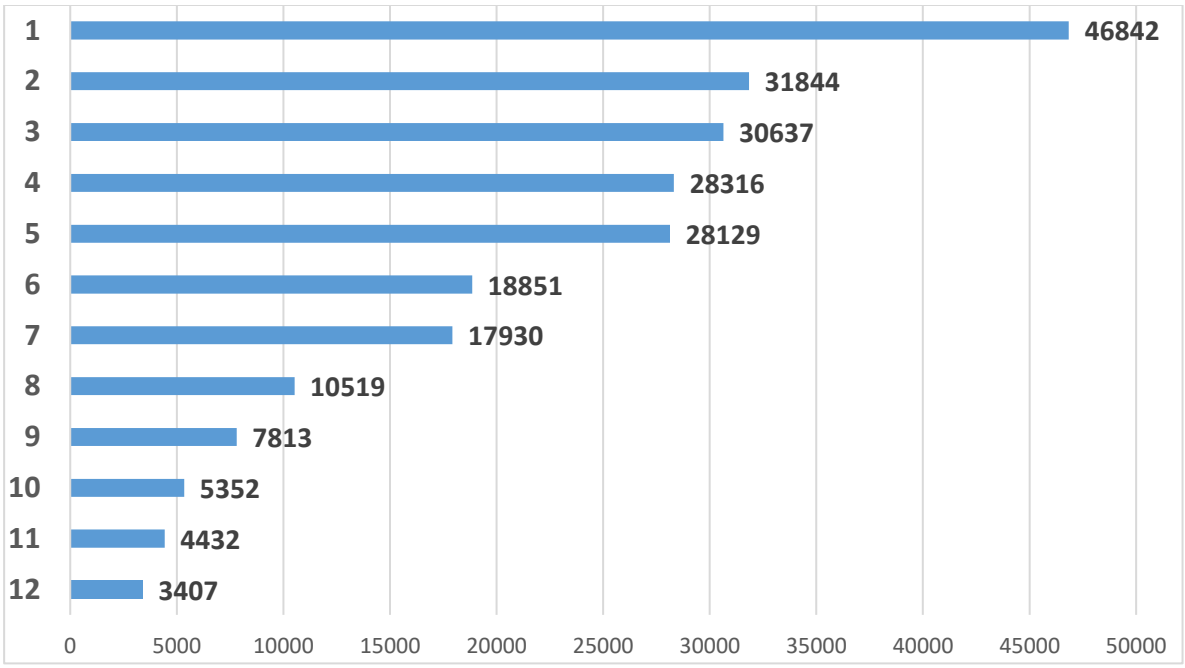


Figure 18 Population over the age of 18 in catchment area of each health center as of December 2018 presentation accessed from PAHO, HEARTS in the Americas website) (Ministry-of-Health-(PAHO), 2019)

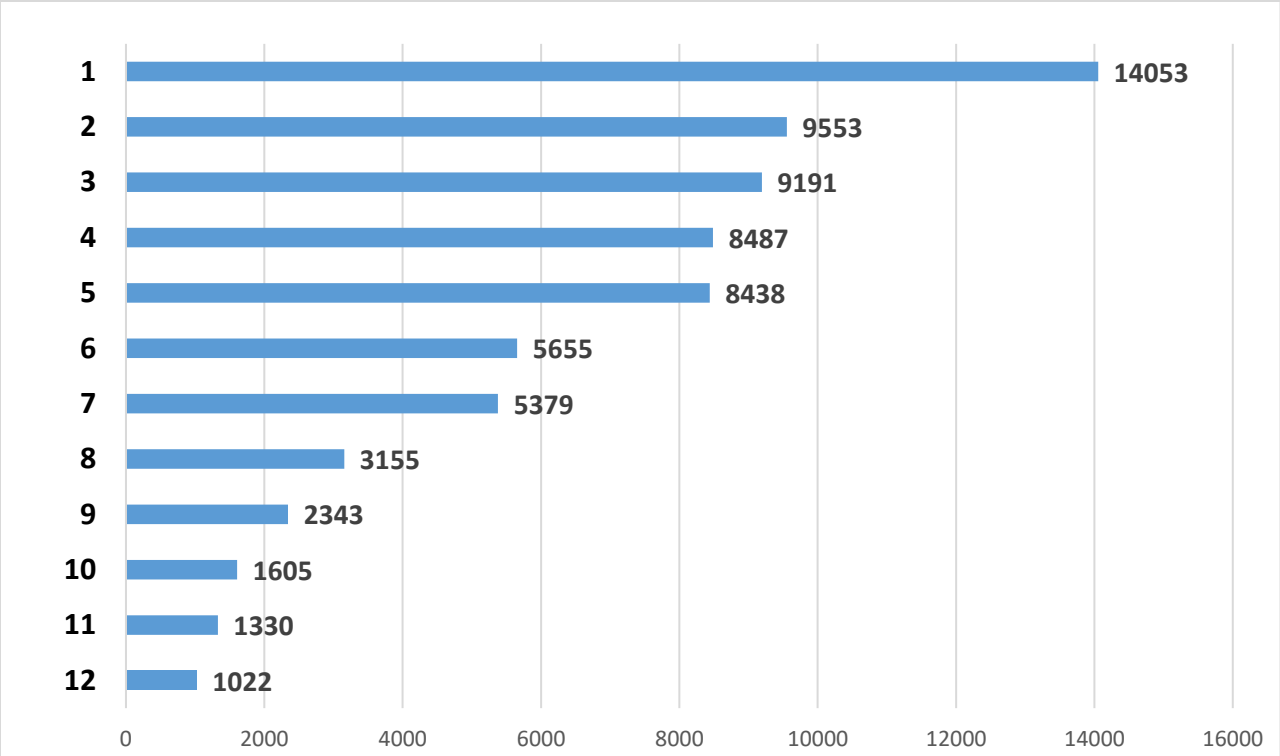


Figure 19 Potential number of persons with hypertension within the geographical catchment area of the initial public primary health centers presentation accessed from PAHO, HEARTS in the Americas website) (Ministry-of-Health-(PAHO), 2019)

The next tangible step in the adoption of HEARTS at a health center was directly linked to the first element of cleaning, updating data systems and starting a reporting routine specifically on hypertension related indicators. This next step was actually making changes to find the persons who were missing or were being missed in three possible ways:

1. Those known and previously registered hypertensive patients who had stopped coming to the health center.
2. Those who are coming to the health centers for other reasons and happen to be unaware hypertensives.
3. Those who do not know that are hypertensives and are out there in the community and have never been seen before.

Second milestone of implementation: Active search of new patients

In addition to referrals provided by urgent care staff or outpatient or regular family practice consultation physicians who find patients with high blood pressure in the course of their activities, there are a variety of activities, strategies, programs, and alliances in health centers to actively search for new patients with hypertension. These strategies are carried out both inside and outside the health centers, through extramural or outreach activities conducted in the catchment area community of the health centers. Among the activities carried out internally is the screening of people in the general waiting areas through the installation of special posts at the entrance of the health center or the regular family practice clinic waiting area to screen people circulating through those spaces. An example is the permanent installation of fixed screening areas such as "*Punto crónico*" (Chronic Point) in health center 10, a place where patients, mainly elderly patients, are screened. This screening activity is usually carried out by nurses and nursing assistants belonging to the chronic/hypertension/cardiovascular risk programs and other health promotion and prevention programs. Some health centers have an "active institutional search" or in reach, a process carried out by nurses and nursing assistants in which the emergency/priority appointment databases and the chronic program database are cross-referenced to identify those patients who have high blood pressure figures and who have not yet been admitted to the program.

In outreach activities, nursing assistants from the health centers jointly with programs or initiatives outside the hospital or health center also participate, such as the Municipal Health Secretariat, the PIC (Collective Intervention Plan, Spanish acronym) or other municipal and departmental government agencies that have to do with health and sports, such as the "*Salud en Mi Barrio*" (Health in my Neighborhood) program. These activities are very diverse and range from face-to-face encounters to mass media outreach, such as: dissemination through local radio stations; door to door visits; screening, education and prevention events in parks, cultural centers and *ciclovías*; and sport and dance therapy

sessions in which screening is also done. Additionally, nurse assistants also participate in health brigades in nearby villages, in which, in addition to carrying out services such as general medicine and dentistry, screening and identification of people with high blood pressure are performed. These brigades are very relevant considering that several of the health centers are located in places with a significant number of spread out rural population that cannot easily access services in the larger medical facilities.

Some of these initiatives, both in reach and outreach, are linked to the *Conoce Tu Riesgo Peso Saludable* (Know Your Risk-Healthy Weight) program, a program through which all types of patients are screened, seeking to identify not only the risk of hypertension but also diabetes, overweight, among others. Some physicians interviewed identified the arrival of HEARTS as a factor that influenced the deployment of this variety of screening and outreach initiatives.

If during the development of these activities people with high blood pressure are identified, they are referred for a medical appointment to begin the process of diagnosis and treatment of hypertension at the health center. Several people interviewed state that these initiatives of active patient search have helped to significantly increase the number of patients that became part of the chronic/hypertension/cardiovascular risk programs and that are now under treatment.

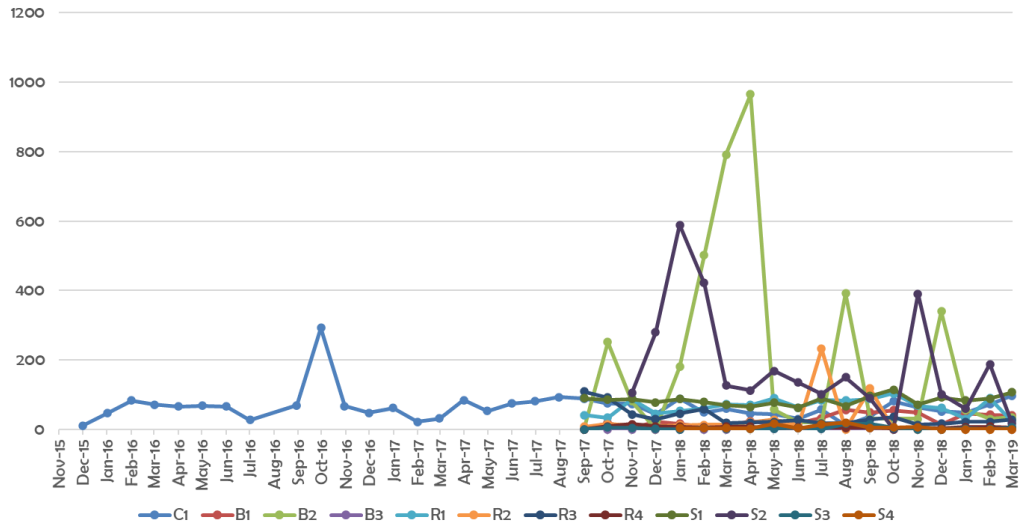


Figure 20. Number of new or re-contacted people with hypertension and included in new or existing hypertension registry in all health centers, by month, presentation PAHO. (Ministry-of-Health-(PAHO), 2019)

Data obtained from publicly available presentations made by the Ministry of Health of Colombia show that there were periods of marked increase in outreach and registering of new or previously existing patients that had gone missing into the hypertension program displayed in figure 20 (Ministry-of-Health-(PAHO), 2019) However, the zigzagging of the data may also be reflective of initial data cleaning and other factors that influence continuous capacity to maintain outreach and in reach activities to be discussed further in next section.

Another aspect of community outreach highlighted by interviewees is that screening and identification strategies have generated higher awareness for the detection of hypertension, because many patients are unaware that they have this pathology. Although most of the interviewees consider that these strategies have been very positive, in one case in Health center 4, a nurse said that these activities were not always carried out in the best way due to lack of dedicated full-time screening staff and added that that having to participate in campaigns through the health brigades and other activities of active patient search interrupts or competes with the performance of other responsibilities of nurses and assistants within the health center, such as provision of health education to those who are already patients.

Third milestone of implementation: Hypertension treatment algorithm or protocol

"*We had the treatment algorithm provided by the Ministry, but we had not created one, we did that through HEARTS, the construction of a treatment algorithm for [our department] to be able to provide all patients with* ***a unified treatment***."

-Physician from Department Y

The development of the treatment algorithm has involved arduous teamwork, both internally, within health centers, and externally, with other health centers, some insurers and external advisors. In general, the health centers have met with their peers to create a unified treatment algorithm by department. However, this development process is in different phases depending on the department and health center. In some cases, the algorithm is already being used by all physicians seeing all hypertensive patients and in other cases, it is still necessary to make adjustments to the algorithm and reach new agreements.

Three main difficulties were identified in the protocol development process: (i) difficulty in reaching agreements with the medical team on the best treatment to follow, (ii) difficulty in articulating or coordinating the first level care with the second level care, and (iii) difficulty in guaranteeing the delivery of medicines by the insurer.

Regarding the difficulty in reaching agreements, the interviewees state that challenges arise in unifying the criteria due to the different schools of training or schools of thought with which physicians identify.

> *The one [algorithm] for the treatment has taken much longer to develop, that one has required more meetings, let's say, with the other health centers here in our department. We have met and found many interesting things, like for example, that we have employed here the fixed dose combination medicines, while the other two centers, being so close, and dealing with the same insurers, do not [have it]. Then, at the meeting we had in Bogotá with several doctors from, even from North Carolina, from South [Carolina], there was a doctor who compared Seventh and Eighth joint Commission with the new ones... well, He talked about the combination and it was noticeable, let's say, the improvement in patient adherence, and we've seen it here [too].*
>
> *- Physician from Department X*

Resistance to change was a relatively common factor in the acceptance of an algorithm. As primary care team physician coordinator commented: "*What I really need is a pharmacological combination, which really, really convinces my medical team that it is better over all the others*".

On the other hand, it seems that the difficulty in coordinating the primary care level with the secondary level of care is mainly a result of health centers lacking their own specialists; and therefore, the patient has to be referred to a second level facility for specialist care. This lack of coordination is exacerbated by not having included the specialists in the development of the algorithm causing them to not feel involved. This disconnection results in the specialists treating patients in a totally different way from the primary care physicians, sometimes causing the patient's overmedication in one extreme case or lack of adherence to the primary care treatment on the end of the continuum. Where the specialists have been convened and have taken leadership roles in the development of the protocols, articulation between levels seems easier, although still highly dependent on the organization of the system at the local level and which insurers are involved.

> *We agreed on a lot [of things] with them about the same medications, including fixed dose combination. And from those meetings we were finally able to [get] help from the specialists too. The making of the final treatment algorithm was a joint effort with the specialists.*
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> *- Physician from Department X*

Finally, guaranteeing the delivery of medicines by the insurance companies is perhaps the most widespread difficulty and causes great concern among the medical staff interviewed. This happens even in instances where efforts have been made to include insurers in some phases of the algorithm development process. Although there are internal efforts to unify the treatment, there are obstacles due to the different types of insurance schemes that exist for each of the insurers linked to the health centers. The insurance type determines whether a patient receives coverage of the medications or not. Some patients must request authorization from their insurer to claim the medicines and others can

obtain directly from the very same health center where they have received care. This differential treatment on how a patient obtains medications occurs despite patients being treated at the same health center. This differential manner of obtaining the medications seem to be less pronounced at larger centers, because they have their own pharmacy and patients do not need to go to an independent pharmacy that contracts with a specific insurer. Even with this infrastructure in place, however, problems such as pharmacy supply shortage usually arise due to internal administrative reasons.

The lack of medication availability is one of the reasons pointed out by physicians, who have recently started working in the health centers, for not adhering to the treatment algorithm. These physicians who did not participate in the development of the treatment algorithm state that sometimes the importance of the algorithm has not been adequately relayed and they are simply given a sheet with the names of the medications and the recommended doses. When they notice that some of these medications are not available to patients, they choose to continue the treatment in alternative ways to the algorithm.

Some of the medications referred to when talking about the treatment algorithm are angiotensin converting enzyme inhibitors (ACEIs) and angiotensin II receptor blockers (ARBs) losartan, hydrochlorothiazide and amlodipine. These medications are mostly not managed as fixed dose combinations, although several interviewees stated that they are aware that these types of combinations are better suited to improve treatment adherence of patients with hypertension. The main barrier to the delivery of fixed dose combination medicines is that they are not included in the Mandatory Health Benefits Plan (POS in Spanish), so it is very difficult for the insurer to authorize their use. For this reason, in some departments they decided to ignore these combinations and included only single dose medications with easier access in their treatment algorithm. Likewise, some physicians interviewed state that they find it confusing that the fixed dose combination medications are included in

some treatment algorithms, considering that they are not easily accessible to patients. Only in Health center 12 was it known that the fixed dose combination medications were being used and were delivered regularly by pharmacies. In some health centers, the only ones authorized to prescribe fixed dose combination medications are specialists, so it is customary to refer patients to the secondary level, increase the chances of patients receiving these medications. Although the algorithm development processes are in different phases, there seems to be a consensus among the interviewees that the treatment should start with the minimum dose of each medication and gradually increase, depending on the patient's response. This avoids overmedication, a situation that, according to some interviewees, happened before having a treatment algorithm.

Despite these difficulties, several of the interviewees highlight the importance of the construction of the treatment algorithm as one of the important results of the implementation of HEARTS, achieving a higher unification of concepts and criteria with the team, improved team work with other health centers and more dialogue with specialists. In all cases, the development of the algorithm has been a team effort that has required a review of the literature, evidence review, physician prescribing preference assessment and the evaluation of different algorithm proposals.

> *Being able to implement the algorithm allows to unify the treatment provided by that doctor who graduated from this or that university, different schools. So, if the doctor was on leave for a month, any other doctor can see [the patient] without any problem. It also allows me to have a greater control over the patient[´s treatment] for a longer period of time, not because the first medication I gave to the patient, from internal medicine once did not work, but rather to strengthen the doctor who can treat them a longer, up to 8 more months, before sending them to internal medicine, gradually introducing medications such as hydrochlorothiazide, then Losartan, then Amlodipine and others.*
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> - *Medical director, specialist from Department Z*

Finally, this process of algorithm development been used to identify and standardize factors to be considered for management of hypertension in different groups of the population, based on gender, race, age and other pathologies of the patient. Several interviews noted that this process has sometimes been accompanied by specialists or external consultants who have contributed with other visions and helped in the evaluation of the proposals.

Fourth milestone: Reviewing patient workflows

The process of care for patients with hypertension shows variations in workflow configuration and phases in the different HEARTS health centers. Care for patients with hypertension had been delivered through pre-established programs that had different names at different: chronic care program, cardiovascular risk program, or hypertension and diabetes program. Despite the variations, these processes could be characterized as having five main phases that are common in all cases: i) patient identification, ii) serial blood pressure measurement, iii) diagnosis/admission into the program, and iv) risk stratification and follow-up.

Initial Identification/Screening

Initial identification is the first phase of the process, when patients with high blood pressure levels are identified and referred to medical care to be diagnosed and admitted into a program for treatment. The point of entry may be the emergency department due to a hypertensive crisis or when they go to a general practitioner for any type of morbidity and high blood pressure levels are identified. The identification phase is carried out by emergency room staff, outpatient consult physicians, nurses, and nursing assistants, as described in the active patient search previously described.

Serial Blood Pressure Measurement

After the first blood pressure measurement, in which it has been identified that the patient has high blood pressure readings and requires follow-up (identification process), they are referred for a serial blood pressure measurement, where multiple measurements will be taken to make a more accurate hypertension diagnosis and rule out "white coat hypertension", a phenomenon when the blood pressure readings at a health care provider's office are higher than they are in other settings, such as the home or in self-monitoring station. This process of serial measuring the blood pressure is carried out differently in each health center: (i) in some health centers, continuous 24-hour monitoring, also called "MAPA", is performed (ii) two blood pressure measurements are taken on consecutive days, (iii) blood pressure measurements are taken on three consecutive days, in different positions (patient sitting, standing and again sitting), (iv) blood pressure measurements taken on five consecutive days, (v) blood pressure measurements on six consecutive days, and (vi) blood pressure measurements on ten consecutive days. As it will be discussed later, these documented differences show this early stage of development where even though some changes may have been done on existing patient workflows; there is still great diversity even in centers in the same department.

Diagnosis/Admission into the Program

With the results of the serial blood pressure measurements, the physician, either from the regular general clinic or from the program (chronic/cardiovascular risk/hypertension) can make the hypertension diagnosis. In all health centers in Colombia, the physician is the only one authorized to make this diagnosis, no matter how high the patient's blood pressure measurements are. This diagnosis by the physician is necessary for the patient to be admitted to the program by nurses or nursing assistants who enroll the patients in the databases and assign a follow-up appointment. Additionally, in some health centers, if the physician defines that a patient is not hypertensive, although he/she is not

admitted to the program, he/she still receives advice and is screened by nurses and nursing assistants, who also schedule a new screening within a year as part of a prevention process. In the case of Cali, the already diagnosed patient has a first appointment with a nurse, where an initial evaluation is conducted, and a series of routine laboratory tests are ordered. In other cases, the physician who diagnoses hypertension must order these tests. At this time in the process, some patients, depending on the type of insurer, must request an authorization to be able to receive these laboratory tests.

Risk Stratification/Follow-Up

Once the patient has been diagnosed and the basic laboratory tests have been made, the patient is scheduled for an exclusive chronic care appointment with one of the physicians from the program. At that appointment, the physician once again takes his/her blood pressure and stratifies the patient's risk in high, medium or low according to the analysis of the test results and other pathologies of the patient. The physician also initiates pharmacological treatment or reviews the treatment, to verify any previous prescriptions from general consult clinic physicians. Depending on this stratification, the physician schedules follow-up appointments. Regarding the frequency of follow-up appointments, there seems to be no pattern between health centers. Some centers schedule appointments within one, two, three, six months or one year. On the other hand, in some cases, these follow-up appointments are not only made by the physicians themselves, but also by nurses, who can measure the blood pressure periodically, but then again are not authorized to change the pharmacological treatment. If problems with the treatment are identified, nurses should refer the patient back to the program physician. In addition to follow-up appointments, the program physician also refers the patient to appointments with specialists, usually to internal medicine, family medicine, nutrition, psychology, ophthalmology, among others.

Patient follow-up

Nurses and nursing assistants play an important role in patient follow-up. In addition to being, in many cases, responsible for assigning follow-up appointments with doctors of the chronic/hypertension/cardiovascular risk programs and attending patients with hypertension in additional nurse-dedicated appointments, they are also responsible for maintaining close and constant communication with patients. This communication is carried out mainly by telephone and in two modalities: appointment reminders and “non attending patients or patients with missed appointments”. Calls for appointment reminders are made only in some of the health centers and are usually a task under the responsibility of nursing assistants or external, outsourced staff, such as young high school students who perform their mandatory social service in health centers, and of initiatives such as TENSIA, a tele-assistance program that is in charge of telephone patient follow-up for one of the insurers that has a contract with the health center 1. This type of call aims to remind the patient of the date of their next appointment, motivate them to attend on time and if necessary, remind them of the process to follow prior to the medical appointment. Additionally, it is also often asked if the assigned laboratory tests have been performed, if they have been authorized by their insurer, and if they have received their medications.

On the other hand, the calls to “missed appointment patients” are made in all health centers and include the participation of nurses, nursing assistants, and sometimes personnel from the billing and/or IT systems departments. Hypertension patient registries are a critical piece of these calls, since these databases store the information on those patients who do not attend their appointments or who have not requested a follow-up appointment for a long time. Nurses, sometimes with the support of someone from the billing and/or IT systems department, identify this type of patients and extract contact information from the databases so that the nursing assistants make the follow-up calls. The

tracing of patients who have stopped attending their appointments is part of the efforts to maintain a good “induced patient demand”. Some interviewees stated that during these calls it is important to inquire into the patient's reasons for not attending appointments, as some live in rural areas and have transportation problems. In these cases, the patient is usually informed about health brigades or extramural days that are going to be carried out near their home so that they can be screened and receive care from the brigade doctors. Additionally, it also involves including family members or caregivers when it comes to patients who are older adults, to raise awareness of taking them to appointments and/or to the health brigades.

> *In the past, patients were more dispersed. Yes, we had, I don't know how many, but a smaller population, patients were more dispersed. They came, but [only] when they remembered, when they didn't remember, then they didn’t come. For example, verifying the databases, for instance, I see that this patient that I am checking has an appointment on the 8th , on the 15th , then I call them: “remember, please, that your appointment is on such date”, this [is] to remind them, because there are many who are who are elderly people, so we remind them of their appointment, so that they keep it in mind. The program, let's say, that it was not as strong or as solid before, because there was no monitoring.*
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> - *Nursing assistant from Department X*

The majority of the interviewees identify the increase in follow-up as one of the positive changes after the implementation of HEARTS, as they attest that previously only medical attention was provided to the patients but there was no control of whether they attended or not, or the reasons for their non-attendance, which made patients more “dispersed” or “loose” or “left alone”. These terms were all used to describe the perception that HEARTS has promoted an organizational shift towards higher attentiveness to patient attendance. In several health centers, by reviewing the databases, it has been possible to identify that they have reduced the number of patients/users who do not attend

annuals, follow-up or labs, which in turn has contributed to more patients being reinstated to a more continuous treatment.

Fifth milestone of HEARTS Implementation: Healthy lifestyle counseling interventions

From the reports of the interviewees, there are three approaches to healthy lifestyle counseling that the clinics conduct: (i) the counseling provided by physician, nurses and nursing assistants of the cardiovascular/chronic/hypertension risk programs during medical consultations and screening; (ii) specific counseling provided by nutritionists, sports or physical activity professionals or physiotherapists, and (iii) group-based interventions through the creation of support groups with an emphasis on improving lifestyles.

The counseling provided by physicians, nurses and auxiliaries is carried out in all health centers, primarily in the medical and nursing consultation. For example, the physician should devote a few minutes of their consultation to instruct the patient about changes they must implement in their lifestyle to improve health. As stated by the interviewees, these are simple and routine recommendations, for instance, to reduce the consumption of salt, sugar, flours, fats, exercise 30 minutes a day, and quit alcohol and cigarettes. Some interviewees state that it is difficult to follow up on the proper implementation of these instructions by the patient, while others say that many patients have a “predisposition” (a negative predisposition) when they are told to change their eating habits or have many difficulties to make these changes due to customs (*costumbres*), lack of financial resources or the area where they live. A nurse mentioned she tries to adapt the recommendations on food to the rural context in which patients live.

In general, the interviewees consider that the few minutes spent in the consultation are not always sufficient to achieve the necessary impact on patients. This concerns especially physicians whose medical appointments with each patient only last 20 minutes. In addition to the physician, the nursing

assistants and nurses in all health centers are responsible for reinforcing these instructions when they meet the patients, using a few minutes either during the nursing appointment, during identification and screening, or during the assignment of the follow-up appointments. The program coordinators of the chronic/cardiovascular risk/ hypertension programs also mentioned that there has been an effort to raise awareness among physicians about the importance of counseling on healthy lifestyles and that what the patient requires is not only pharmacological treatment.

The specific counseling provided by nutritionists, sports/physical activity professionals and/or physiotherapists is something that not all health centers have. In some places located in remote rural areas, such as the case of Pueblo Rico, Risaralda, interviewees consider that the absence of such professionals is a barrier for patients to improve their lifestyles. In health centers where the support of these specialists is available, all patients with hypertension are referred, or at least those at greater risk due to overweight. Some nursing assistants and nurses mentioned that sometimes patients did not want to attend these appointments, so they tried to emphasize the importance of physical activity as part of a comprehensive treatment. The incorporation of exercise professionals was highlighted because many patients do not know how to exercise and these professionals provide them with personalized exercise plans according to their condition, mobility situation, age, among others.

On the other hand, the implementation of extra activities such as the creation of support groups or collectives with an emphasis on improving lifestyles only occurs in some health centers. Groups like "Corazones Sanos” (Healthy Hearts) in health center 10 and "Vive tu Corazón” (Live Your Heart) in health center 12 promote the collective learning of patients with hypertension and other conditions related to cardiovascular risks. During the meetings of these groups, support and assistance are provided on the pharmacological management, and on how to achieve a better diet. Physical activity is also carried out collectively. In the case of "Corazones Sanos”, patients meet three times a week, and in the case of “Vive tu Corazón”, once a week, on Wednesdays. In Health center 6 there is also a group of cardiovascular risk

patients which functions with the support of students from the local university. Additionally, although they do not have such a group in Health center 3, the nursing assistants conduct weekly training sessions on healthy lifestyles for patients and sometimes a physician may attend or a medical student. In the latter case, the assistants mentioned that making the call for these sessions is somewhat complicated because patients may be very resistant to attend. In the case of the health center in Cali, the physiotherapist and gerontologist manage a space for physical activity and exercise for chronic patients. An interviewee says that green areas are needed in the health center, so they have to do the sessions in nearby parks.

The vast majority of interviewees acknowledged that the implementation of counseling services and programs to improve patient lifestyles has been a very important change in the way patients are treated and that efforts have been made to promote this improvement. However, there seems to be a lack of specific indicators to measure the impact of these lifestyle changes consultations and a lack of individualized follow-up to see whether the patient has made these changes or not.

Strategies that Support Delivery of Described Content Interventions

Training

The process of implementing the HEARTS program has required that health center staff obtain or refresh a new set of aptitudes, skills, and practices. These skills sets play a decisive role in how health care staff have been adopting the HEARTS components from initial introductory stage to its current operative levels.

The training processes of health personnel related to the HEARTS program have been implemented in different ways in the health institutions of the four departments. Cases range from those who say they have not received training to those who have used HEARTS as a tool to consolidate a regular, organized, and collective educational practice.

A good starting point are the health centers 3, 9 and 10, where PAHO virtual courses (of the HEARTS program) were disseminated and established as mandatory for all staff who work with patients with hypertension. In these places, the program leader or the physicians who have taken the lead, usually hold meetings where the material is presented (guides, manuals, etc.), some evaluate effectiveness of the material through questionnaires and encourage discussions so that questions are answered collectively. In Cali, the medical director at one clinic facilitated a room with computers during specific schedules so that physicians could access the virtual HEARTS course and they also chose a facilitator for each session. They, then, replicated the methodology with the nursing staff.

Physicians from the Health center 8 center also shared successful experiences around the training of staff. The head of nursing says that, together with medical specialists, they have built their own academic spaces accessible to all staff. She also mentions *individual training spaces,* led by the physician in charge of auditing the Integrated Care Route: *"She visits doctors and all staff to receive individual feedback based on the "high-cost account" observations"*. In this way, each time the cardiovascular risk route is modified (because new components, such as psychological and nutrition services may be added) the training opportunities are offered. A physician describes a set of trainings that have been offered at this center:

One of the first trainings we had was the training that the delegation that came from the Pan American Health Organization and the Ministry gave us all. Subsequently trainings for the management of the "Know Your Weight/Know your Risk" strategy. Afterwards, PAHO's course for staff, initially for hypertension program leaders, then extended to most healthcare professionals, general practitioners, and specialists in family medicine and internal medicine. Training in standardization of anthropometric and biometric measurements. And we have also subsequently been training in what is already the clinical practice guidelines for cardiovascular risk-related diseases. Then clinical practice guide for hypertension, dyslipidemia, diabetes, and chronic obstructive pulmonary disease as with morbidity associated with cardiovascular risk.

- Physician from Department Y

In several of the interviews reporting positive experiences, respondents also noted that the processes of training staff have not been based exclusively on the material of the HEARTS program but have been complemented by other training tools provided by public and private actors. In health center 1, for example, the support of the Fundación Corazones Saludables, the Colombian Association of Cardiology, the Departmental Association of Hospitals, which provide assistance and administrative accompaniment is highlighted. And in Health center 3, they highlighted the support of Ministry of Health:

With the Ministry there are virtual meetings once a month and with the State Secretariat we have a cardiovascular work group also monthly, this to review the progress, to share the difficulties, to generate commitments, because all these activities require managerial support and political will to be carried out.

- Physician from Department Y

Thanks to the Ministry of Health, some physicians from various departments have the opportunity to travel three or four times each year to Bogota, in order to train and to acquire skills to train their staff back in their institution. Support has also resulted in the acquisition of basic equipment for the measurement of hypertension. In the same way, local administrations, universities and even insurers have been part of the training processes, as we see in this quote of a medical coordinator from Santander:

The head of epidemiology at Academia Private Foundation who has come to present to us and we have also had other activities, for example, where we have involved doctors who work in hypertension with some insurers and who have provided us with the successful experiences with the management of the hypertension in other scenarios (...) and in addition to that we have had other invitations, for example, from the departmental health secretary, the academy, the private Industrial University of Santander that enrolled us in a certificate program last year on hypertension management.

- Physician from Department W

Furthermore, when these components come into synergy, namely when the efforts of the staff of the institutions are integrated, with the support of public and private sector entities, innovative initiatives emerge that are worth noting. In Health center 3, in-house training opportunities were consolidated into an initiative called “The Scientific Hour”, as a space for discussion and collective academic training from which an academic summary on the topic is generated every week, to be shared with all the team members.

Another training aspect has been the HEARTS costing tool. A nurse in health center 11 explains why she finds the program's cost tool useful:

In order to guarantee all these activities that HEARTS proposes to us (and that have shown us utility and that are evidence-based) we had mentioned to the boss that, since there is change of government in territorial entities and also in my role as manager, we could write a plan utilizing the costing tool and show the new director why it is important to keep HEARTS and how to implement it next year.

These overwhelmingly positive training experiences have as a common denominator that the institution itself provides the time and space within working hours, so that its staff can access the training tools, whether virtual or in person. When this does not happen, as is the case of Health center 4, the staff is unfamiliar with the tools that the program provides. Here, the interviewees agree that although it is known that there is a material available virtually to train on the HEARTS program, no clear instruction has been issued from the institution's higher management that it is mandatory to take the trainings, nor has a timetable or space been allocated for this purpose. For this reason, throughout the institution there is only one doctor and one nursing chief who have completed the process and a few others who have started it without being able to finish it for lack of time.

Similarly, in Health center 5, interviewees are not that familiar with the material available virtually, but they do consider team meetings where the patient management guides are mentioned as informal training spaces. In health center 6 , for their part, rural doctors do not recall receiving any training upon arriving at the health center, and even some of them were unaware, until the time of the interview, that material was available virtually.

Finally, despite the obstacles described, those who have accessed the trainings and material, highlight its usefulness, clarity and its value and relevance to day-to-day practice in health centers:

[the materials] are clear, it's clear language, they can be studied by the nursing assistant to the professional doctor and there's no problem with the courses not being understood.

Very, very useful indeed, for me, it has enriched me as a doctor, it has enriched me a lot because (...) let's say that I have fallen in love with the care of our patients again, also because I find them very practical, I have the [HEARTS] booklets here in my office, I have been just starting to do the virtual course of HEARTS, but the booklets have helped us a lot.

Team configuration

The HEARTS program faces specific challenges to achieve its full implementation in the health centers and hospitals of the four departments of Colombia where they have been implemented. Based on the views of the staff interviewed at these centers, the challenges revolve around the operational obstacles caused by the inverse relationship between limited human personnel and the number of patients that tends to increase due to the relative success of one of the main interventions, which is active patient search. Hence, in each institution visited, various strategies have been carried out involving the redistribution of functions, the reorganization of time, division of labor and support by different disciplines, responding to the particular needs that each institution faces in its own context.

To begin with, there is a general consensus on the assumption that the proper implementation of the HEARTS program requires a staff specifically designated for the tasks involved, as there are key tasks of the program (such as coordination of processes, monitoring of indicators, hypertension screenings, patient education on habits and community outreach) that are not contemplated within the basic functions of existing staff. Hence, it is often perceived that these parts are developed as extra tasks by those who are engaged or those who have the will and time to execute them. In this sense, they consider that a person whose main function is the coordination of the strategy should be appointed, someone who believes in the program and understands it fully so that s/he will motivate the staff and, sustains the process.

It is worth noting, however, that in some of the centers interviewed, key figures are identified on which the coordination of the program is supported, such as Health center 8. Here, in the framework of the implementation of HEARTS, a new nursing chief who is trained on data management and information systems was included in the team, in order to specifically maintain, update and monitor the program databases.

In cases where this does not happen, the lack of staff results, in the words of the interviewees, is *tediousness, overload and disinterest* on the part of the staff. Physicians, for their part, regret that administrative activities take a long time, and this negatively influences the quality of care for their patients, as well as it reduces the time available to spend on academic and training activities.

In several of the municipalities, respondents considered the major hindrance to implementing the strategy fully was due to the lack of sufficient **human resources.** The interviewees point out that the high turnover of staff, the high reliance on rotating rural doctors as well as the instability of the hiring process and short-term contracting, make it impossible to provide high quality care to patients; this in turn makes it difficult to oversee and evaluate the knowledge and training necessary for the program and delays the onboarding and training processes of new staff.

The statement from a Health center 12 team member gives an account of all the variables that come into play when it comes to overcoming staff limitations:

> *Nursing is a very nice career because it teaches you how to do everything, I mean, empirically I started managing databases for three years, three years watching, or with my coordinator who is a really good working with databases because she manages the whole part of PIP [Collective Interventions Program] of the [HOSPITAL], imagine how many patients we manage, I manage 4,600, she manages the whole population, vaccination, chronic patients, pregnancies, everything, then, empirically she dared to learn Excel™, and because, obviously, already, with a little more technical training , one looks for tutorials, looking, determining how it best done, looking, that the information is not skewed.*
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> *-Nurse from Department X*

On the other hand, beyond the understaffing, other obstacles were identified on acceptance and utilization of the treatment protocol. Some interviewees stated that, on some occasions (especially in the case of health center 5 and 12), some physicians are not interested in fully complying with the protocols of care stipulated in the program, either because of lack of commitment because they conceive of their work as provisional or due to lack of time due to the number of patients for whom to be cared. In addition, nursing assistants express that during the initial phase of implementation of the program, many more tasks than what they used to perform are being imposed in their daily routines, which they find "*tiring*" and "*tedious*". Faced with such shortcomings, nursing chiefs claim that they in turn need to be stricter and that more feedback, monitoring and follow-up to staff is needed. Ultimately this personnel issues may impact patient satisfaction.

Other important challenge to be considered according to the interviewees is the assignment and delegation of functions. A recurring example of this is the obstacles faced in appropriate data entering and data management. According to some interviewees, in some health centers, the vital signs and

biometrics, either due to lack of training or time at appointments, are not entered accurately, therefore the information obtained will be inaccurate and skewed, which will subsequently be crucial for monitoring the patient's health status as well as for the impact medication of the program itself. A nursing chief explains the type of common errors that she has observed:

> *If the information is biased, it is already affected by the human error, when a doctor does do the job properly, of the assessing abdominal perimeter, when he does not take appropriate measurements of weight, if it is solely based on what the patient's national ID card says, when the weight is taken with heavy clothes such as jackets and shoes, that is what we are working with right now, because that also affects the information that can be generated.*
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> *- Nursing chief of Department X*

Although almost all respondents recognize that it is ideal that all members of health care teams are able to screen patients, as screening is a fundamental pillar of the program, but it is not always clear who or how it should be done. The specificity and clarity of role assignment varies from center to center. In cases where this assignment is clearer, it is the nursing assistants who do the screenings, so that the nursing chief subsequently enters the data into the system and determines the next step in the patient workflow. In or in cases, nursing assistants are engaged in administrative work (e.g. in Santander) and it is the physician who performs the screening, which leads back to the problem described above about the strictness with which this procedure is performed taking into account the lack of time during consultations and training.

Similarly, in some centers, nurses (in the absence of social workers) are dedicated to streamlining patient procedures or performing educational functions, so the performance of their other functions, such as appointment assignment and follow-up to patients, is relegated to second place. In Department X, for example, it is the exclusive task of nursing assistants the community outreach and all that this entails: assign appointments, ensure that patients attend, close the processes, check that

laboratory tests are up to date, provide information about healthy lifestyle habits, include the caregiver in this process and ensure adherence to treatment. In the case of Department Y, the nursing team is particularly responsible for the collective intervention plan (community outreach program), while doctors are responsible for the individual care of the patient, from the initial assessment and counseling in healthy habits, to the management of their pharmacological treatments and the evaluation of the results of cardiovascular risk tests. However, there are individual interviewees such as a medical coordinator, who implements the clinical care model and is responsible for the entire plan of care services and supports the administrative management of the program. Here, the organizational value of being able to delegate the basic functions as screenings and blood pressure measurements to any staff of the team is highlighted, since this could speed up processes and reduces risks.

Another variable that influences the assignment of functions is the patient's health status. In some facilities, the criterion for assigning the route of care is whether the patient is "controlled" or not, whether it is a chronic case or not, since this will depend on nursing consultation is performed or if it goes directly to be attended by the doctor.

However, given staff shortages and variation in the delegation of functions, multidisciplinary teamwork is one of the strategies that staff use to continue the development of the program. Several of the interviewees recognize this is considered one of the main learnings from HEARTS implementation. The multidisciplinary team is identified as an empowering factor for adherence to treatment by patients, as well as for the training of the staff themselves, as it enhances teamwork and the integration of knowledge.

Initially we had only committed to the nursing group that oversaw the cardiovascular risk program, family medicine which we already named as leading the entire implementation process. We had only one nutritionist and psychologist who supported the process in the early stages and nursing assistants at the peripheral health centers and those of the Santa Monica Hospital. Later with the

introduction of the strategy, we strengthened and involved other actors. So very important was the arrival that I already mentioned of Chief nurse Jeison for part of the high cost account and that he also in his own way also strengthened the organization of the cardiovascular risk team. Based on this, we managed to involve a couple of doctors who specialize in internal medicine. The family medicine team also grew having more hours available and hired as a specialist physician in this area. Today, we already have a team with an additional nutritionist, with more nursing assistants and with a new psychologist, who are strengthening the team too. So, let's say that that the multidisciplinary team of the cardiovascular team has been strengthened.

-Physician from health center 8

For specific cases, such as Department Y, the implementation of HEARTS has strengthened the team, as professionals from different disciplines (psychology, nutrition, specialists in internal medicine, professionals in sports/exercise/ physical activity, nursing assistants) are pulled in to cover different areas. All this contributes to a better distribution of work. Social workers, in this specific health center, play an important role, as they can accelerate important processes to expedite the care of chronic patients, processes that are also often unknown to the rest of the health personnel. It also highlights the important role of exercise professionals, nutritionists and psychologists, because they are particularly focused on educational/pedagogical work on healthy habits, a fundamental task for the treatment of cardiovascular diseases, which is often not fully addressed in the context of the medical consultation or which falls on the busy agenda of the nursing team. Other teams include different professions as in Risaralda (Health center 3) who considered the information technicians and systems engineers as part of the primary care team for a more efficient systematization and evaluation. Other centers consider the support staff of billing departments and pharmacy clerks as part of the multidisciplinary team.

In contrast, as the staff is considerably smaller in other centers, these centers use other partner institution, through referrals, to provide services that they cannot provide and provide comprehensive patient care. An example is in the Department X, where they say that because of limitations of public

resources allocated to the center, the program only has physicians, nurses, and assistants. In Santander, the work related to community outreach is based on outsourced personnel because there is no nursing consultation, as the nursing team is solely dedicated to data collection and education. During these limitations, it is emphasized that at least one physician in each health center or hospital is dedicated to chronic patients, thanks to the workflows proposed by the implementation of the program. However, it is clear that this is not always enough, and staff configuration varies among all health centers.

Furthermore, most interviewees identify the limitations in the time provided to carry out their tasks as a critical aspect that must be improved for best delivery of the program. Medical staff generally consider that the process of calculating cardiovascular risk, which involves performing measurements and risk screening correctly (taking into account that sometimes they do so without the help of the information system, because the medical history does not calculate it on its own), translates into less time in the consultation for care and interaction with the patient. This, coupled with the other tasks that need to be carried out during consultation (inputting the basic data, examining the patient, explaining the conditions, and giving recommendations), far exceeds the actual time it takes for each patient. For this reason, some say that a chronic patient consultation not only exceeds the twenty minutes allocated but lasts from half an hour to almost an hour, so it is common for them to finish their shift much later than they should.

It would take more time in the consultation, we need more staff because if you increase the time we are still going be seen a great number of people and you need more specialists to consult with us because as it is, if you look there is only ONE internist for the whole health center, it is not enough and a family medicine doctor for all the health center you can't. If you only say that there can be more or less than nine thousand patients for the hospital, imagine what the whole system may have.

- Physician from Department Z

Thus, they suggest that for the consultation to last, in fact, the twenty minutes stipulated, it is imperative to hire new personnel to carry out several of the aforementioned processes, so that the functions are better distributed. Otherwise, as we continue to extend in the times of consultation and attention, less and less patients would be seen per day and appointments will not be made with the frequency that they should be made. From this scenario, the case of Health center 3, in Risaralda, whose medical staff is considered fortunate because, as they self-report, “they are "pioneers" in hypertension control” in the area, they have managed administratively to be given at least half an hour to do the hypertension checks.

Finally, the obstacle of limited economic resources is manifested not only in the inability to hire more personnel but also, as evidenced in the cases of Health center 8 and Health center 3, in the lack of some basic supplies and equipment whose acquisition should be the responsibility of the health center. Ultimately, it ends up directly affecting the functioning of the HEARTS program. Some physicians had to buy their own digital manometers if they wanted to have better blood pressure readings.

Support and leadership for HEARTS program

The implementation and sustainability of the HEARTS program require the joint work of a network of actors, whose actions and spheres of influence vary depending on the characteristics of the departments, municipalities, and health centers.

By inquiring about institutional support and leadership, the interviewees unanimously identified the importance of political will, commitment, and active involvement of management at three organizational levels: the macro level which is the national/ministerial level; the mezzo level, including the departmental and municipal public bodies and their respective secretariats; and the health centers, with their internal leaders such as managers, coordinators, physicians, and other staff, who assume

strategic roles for program management. PAHO appears as a cross-cutting agent operating at different moments.

The Ministry of Health, the Departmental Health Secretariats and the municipal health secretariats and mayoral offices appear often in the interviewees' testimonies. However, some differences may be glanced between departments. City of Cali, capital of the Valle del Cauca Department, and first place where HEARTS implementation began, is recognized by other municipalities as an example of good articulation between public municipal bodies and health centers. In health center 1 a primary care physician attributes the program implementation success in Cali to "good governance" and states that the process of establishing the strategy was built "from top to bottom", "from macro to micro", which means that the bureaucratic procedures (through the chain of command) ordered from the Ministry of Health to the Secretariats and subsequently to the health centers, facilitated the administrative and political work. In contrast, in health center 1, the process was reversed and is described as "swimming against the current", since the task of requesting support to higher administrative levels lies then with the lower-level entities.

Nonetheless, at the regional levels, the main (recognized/acknowledged) actors are departmental secretariats and mayors. This level seems to operate, from the perspective of the interviewees, as mediating agents between the centers and the central government and PAHO, so it becomes quite relevant. Departmental Secretariat of Health, from Department X, for example, has received praise thanks to the good development of its own comprehensive chronic care strategy with PAHO. This local initiative that precedes HEARTS and stands for Comprehensive Care Plan for Chronic Disease, and is a department-wide application of the chronic care model, through which they trained the staff of the health centers and contributed positively to the introduction of the multidisciplinary approach of HEARTS.

In other cases, most of the staff at the centers report that they had great support from the Ministry, especially in the initial phase of implementation regarding training; however, they claim that support has declined over time or has been, at the very least, intermittent. For example, in health center 11r, a nurse highlights the initial accompaniment of the Ministry of Health who, together with PAHO, promoted training and accompaniment; at the time of the interview these activities have ceased, yet there is a sense that more training is still needed. Similarly, in Health center 8, a doctor believes that the implementation of the HEARTS program could be easier if there were more "political will." He reports it is needed from the Ministry of Health and the departmental and municipal secretariats because there are processes that are hindered due to "political decisions."

In some cases, the Secretariats have been less active or absent altogether. This absence leads to not having a mediated communication channel between the Ministry and the health centers as it may be expected in a hierarchical chain of command. Therefore, the staff of the health centers resort to other means to resolve their own issues, possibly skipping steps in the chains of communication.

Changes in governmental posts (departmental and municipal level) directly affect the relationship between health centers and national bodies. This can be an obstacle or an opportunity for improvement, depending on the political will of the representatives, the relationship established between them and the managers and coordinators of the centers and their ability to manage resources and attract the attention of the Ministry and other national or private sector actors. In Health center 4, the change of the local government weakened the support that the program received initially. A nurse half-way humorously explains that the support they receive from the Departmental Health Secretariat is limited to convoking staff members to working groups in the capital, but that in practical terms they do not present a tangible response to their needs, namely improvements in recruitment, human resources, nor financial support. Another nurse has found no alternatives but to resorting to herself buying at

private pharmacies the medicines needed by some of the elderly people in the program because there is a shortage of supplies at the center's pharmacy that provides medicines at no cost to patients.

The experience in health center 8, in Department Y showed some fluctuation in the type and timing of support of the departmental secretariat:

> *The support was absolute, as I think we have reiterated in the previous questions. He who oversaw this part in Colombia, in the Ministry, was Dr. ABC, and he was a great and important bastion in this learning process of knowledge, implementation, and follow-up as well. So, let's say the first part was with the Ministry and the other great external support we initially received was from the Departmental Health Secretariat. What happens is that this participation has not been entirely constant but fluctuates, due to the limitations and obligations of the Secretariat itself. The Municipal Health Secretariat…we ourselves, from the hospital, looked for ways to let them know, especially in Health center 8 (…), we asked for an appointment with the directors there, we told them what we were doing. They looked positively surprised and offered their support. But it has not been neither constant nor close support, as we would have wanted.*
>
> *- Physician in Department Y*

This quote is enlightening because it highlights bidirectionality in terms of communication from the bottom to the mid-level managers and to the top-level and vice versa to the next organizational level where support for the program is essential, i.e. the medical staff of the center. Furthermore, it was also noticeable that, even in governmental institutions, there are officials who assume individual leadership, not solely in representation of the institution but as individual conveners and leaders. And at the facility level, individual managers become important as they are the ones who intercede with the regional and national authorities on behalf of each center.

> *With the[national] Ministry, there are virtual meetings once a month, and with the Secretariat we have a cardiovascular work table also every month, to discuss the progress, share the difficulties, create commitments since all these activities require management-level support and political will so that they can be carried out.*
> - Physician from Department Y

Management support makes a difference in the effectiveness of the implementation of the program: When this does not fully occur, the consequences are noticeable, as in the case of health center 11:

> *They could be strengthened, but to be honest, the administrative area of the clinic is a little disconnected from the program. Yes! I mean, I think that if the administrative support as such was provided by the management of the program, it could be further strengthened, because many times having particularly the support of the manager, the physicians comply more, you have more support in logistics, in consulting rooms. We had to stay in the hallway or look for an office. So, with adequate administrative support, the program would yield better results.*
>
> - *Nurse from Department W*

For these reasons, as claimed by the medical coordinator of this municipality, managers are usually evaluated by the Ministry through the results of the implementation of the program in each center: *"a first-level or second-level hospital manager whose figures of their hypertensive controlled patients are not clear is not exercising their administrative role well."* In other words, good management renders good results for the program. When this is the case, it incentivizes the centers and secretariats to start working in an integrated way and the program develops a larger scope. Again, a report from Department Z is appropriate:

> *So, we have had support from the ministry, support from the municipal public health secretariat with S and A have always been provided as well, and so has the [private health insurer], headed by TT. TT has always been there, supporting us with everything, because they also have the health center. So, it's like little brothers, what is done in one place is also done in the other*
>
> - *Nursing Chief from Department Z*

Local government authorities and funding issues

The lack of financial support from territorial authorities differentially affects centers in the most rural areas, as their normal operating costs are coupled with a lack of equipment and shortage of specialized personnel, thus having to establish a relationship with the Department Z health centers. This ends up affecting the patients on the CVD care route, in health center 5, who, due to being low-income

patients and cannot afford to travel to the capital when referred to specialist care and therefore, cannot either follow the treatment.

Despite these difficulties, the work of the secretariats has proved crucial to the program in certain departments. Interestingly, in the same case of Health center 4, whose difficulties have already been described, the role of the mayor and some officials stands out, without whom, it is claimed, the implementation of the program would have been difficult:

> *We arrived at the program via an invitation from the Mayor, Dr. HH, and the social affairs manager, Dr. CC. That first meeting was at private academic center, with people in leadership. They were there that time when they gave us the welcome to start this strategy*
>
> *- Nurse from Health center 4*

At least an early stage, the mayor of health center 4 filled the gap in personnel by sending two nursing assistants to the health center along with briefcases equipped with digital weights, scales, and blood pressure monitors. Interviewees called this a kit for the correct gathering of information required by the program.

Finally, it is important to mention that although the figure of managers and coordinators is usually critical; when it comes to leadership, it is also common to meet people who have assumed important roles for the optimal development of the program and come from other entities, such as academic associations, insurers or private bodies that also position themselves as strategic allies for the centers. This is the case of Department W a private health entity has contributed significantly to the implementation of the strategy, through lending equipment, jointly with the ministry. In the next section a discussion of strategic alliances follows.

Strategic alliances for collective work in health services

This section addresses the strategies that indirectly support the development of the HEARTS program, such as communication between partners, the creation of coordination committees, the relationship with the representative of the Ministry of Health, the regulatory framework that the public health policies in the country provide, and the involvement of insurers. First, the coordination committees that have been formed in a few health centers are the result of the network of actors involved in the program within each respective center. These are workgroups in which at least one representative from each discipline or area (medicine, nursing, psychology, physiotherapy, nutrition, etc.) participates and where decisions about the program are made, as well the monitoring of patients and general indicators and feedback on the performance of professionals is provided.

> *The committee considerably helps to observe what is happening inside each process and each service, so guiding actions to improve the quality of care will help your patient, not only to come for their medicines and other things, but to receive comprehensive care that will help them, while at the same time, allowing them to transmit the message.*
>
> *-Physician coordinator in Department X*

This teamwork methodology is essential, the patient information is cross-cutting, either from one clinical area to another or from one stage of the intervention to another, so that the whole process is more organic [not vertical nor horizontal]. This coordinating committee meets monthly or bi-monthly, depending on the possibilities of each center. Data from programs are reviewed, emerging issues are discussed and potential solutions to those are explored. There is a very formal process of creating minutes and follow up items. This is documented in digital format and reviewed at the following meeting.

Collective work is also seen through networks that often involve actors from more than one health center and even from different municipalities or departments. These networks function as communication channels in which the professionals of the centers where the program is implemented exchange experiences, but which also may include other institutions that can contribute to interdisciplinary teamwork, such as SENA (National Learning Service), universities or academic research groups, technical teams in health of different governmental instances such as the EAPBs (benefit plan managing entities), the ESEs (social state enterprises), the hospital associations and other IPS (health service institutions). Another way in which networks are built around the program is by groups of professionals who specialize in various chronic diseases like cardiovascular risk, hypertension, diabetes, or obesity, in order to promote a comprehensive understanding of the patients' problems.

From the alliances with these actors, a variety of actions are deployed that strengthen the program in its different moments of implementation. Some interviewees point to the continuous training of staff on clinical topics; others are aimed at the joint evaluation of the methods used to measure the program, such as [the private consortium] in Department W. Other alliances aim to disseminate and enhance the scope of the program in terms of population reach, as is the case with the mobile health care units, [other] strategies, or the Collective Intervention Plan of the Ministry of Health. The result of this is the creation of new teams.

> *Support groups, that is, PIC work teams, external nurses, work teams of the local secretary of health, that is, who work in entire territory and involves publicizing the strategies so that in some way a mental change was generated, so that everyone had the strategy in their hearts and activities were carried out in the park, in cultural centers and activities were carried out in programs such as this "dance therapies", the program was taken there ... so, it was a total deployment of the implementation of Know your Risk throughout the municipality, (it) was an important milestone.*

- Nursing assistant from Department W

Strategic alliances are numerous across the health sector, but do not stop there. In some cases, actors outside the health sector have been involved and may have a high impact on the community outreach phase. That is the case of community broadcasters, local action committees, community leaders or citizen participation programs from the secretariats, such as recreation, culture, and sports. This form of collaboration has been described in the sections related to community outreach and screening; and the collaborations with the academia and vocational training in previous section titled: *Second Milestone: Active Search of New Patients*.

Finally, one of the actors who stands out most within the joint work network is Dr. ABC, from the Ministry of Health. He is a figure that appears repeatedly in the interviews as a leader for both the understanding and implementation of the HEARTS strategy. In the words of the staff, he is recognized as "the main facilitator", "the head of the team", "he who has always been present". The representative of the Ministry for all the centers, was responsible for accompanying (every week, every bi-weekly or monthly) the center's staff, from the time of training and introduction of the program, to the evaluation and monitoring, and through consulting and answering questions that arose regarding developing protocols. There is collective regret/sense of loss among interviewees on the departure of Dr. ABC because they believe that his leadership was key to the success of the program:

> *The follow-up he did every fifteen days, the demands, the tasks, the step-by-step plan he had for us, we followed it well, it seems to me that that was another reason for success. Although we did not have the local territorial entity, at least we had the national entity guiding us in the implementation process, which was the most difficult part. If we had not, it would have ended like most of the programs in our country: they are issued, planned, organized at the macro level, but at the micro-level are not applied.*
>
> *-Physician from Department Y*

This last idea is recurrent in the interviews. Some express that the management carried out by Dr. ABC should be continued and assumed by the Ministry of Health, since it is a fundamental task for the program and should not depend on the presence and will of one person.

Institutionalization of functions

In order to sustain HEARTS program, several interviewees recommended developing public policies that commit health authorities to implement the pillars of the program in a rigorous and mandatory manner. In this regard, the interviewees identify a series of normative frameworks that justify the program, stipulate the health care guidelines, and promote the unification of concepts and data. Among the most recognized entities are the Integrated Health Care Routes, the Territorial Health Plan, and the Ten-Year Health Plan, all of which are contemplated within the National Development Plan. Particularly, the interviewees place the national resolution 412 of 2000 and its update, resolution 3280 of 2018, as the main operational allies of HEARTS. Within this framework, the health centers are obliged to send to the Ministry of Health the databases of the population being screened under the cardiovascular and metabolic routes every month, in order to consolidate a population risk statistic. Within the Department X, a report called PAICEC (described above) is delivered as part of "a report that integrates the database that comes in resolution 2436, which is mandatory and that all EPS need to report every year." Implementing HEARTS relies on data such as this, so the program helps show health providers that usefulness of collecting this data while not creating a new administrative burden.

The health center in Health center 12 has developed its own version of HEARTS, and uses the acronym of CARDIO and highlights public policy coordination:

> *"Cardio" is broken down by each letter with a specific health intervention, evidently because of what we wanted to achieve, based on the models already studied. (…) The "c" of "cardio" stands*

for policy Coordination; then, ideally, the first and the second levels of health should be restructured in the basic handling of the treatment algorithm for patients with chronic disease (…) And the "o", which is the health care organization, tells us about the adoption of the roadmaps, of the 3,280, for the management of the user and, obviously, of patients with a hypertensive pathology, or diabetic pathology. So far, the Ministry is contemplating and trying to structure it. That is what we have done.

- Nursing chief from Department X

This unique experience of creating its own branding shows a highly advanced level of planning and implementation at this specific site; as it was explained that they saw some gaps in HEARTS, specifically on this policy aspect. Despite this development in one center, in some health centers, there is little knowledge of the regulatory health framework that covers the strategy, due to the weak relationship of the staff with the Departmental and Municipal Health Secretariats. It is manifested that there is no articulation with such areas.

Finally, another of the relevant actors in the interviewees' opinions are the EAPBs. These are usually associated, in most cases, with the economic constraints and bureaucratic obstacles that health centers face for the proper development of the program in administrative terms. To these entities and their particular relationship with the health authorities are attributed the obstacles in the hiring of personnel, the procurement of medical equipment, medicines and optimal working conditions:

As I was saying: for example, here we do not have the nutritionist, psychology, or internal medicine specialties, but they also told us that it was a matter concerning the EAPB (insurer)], if they were to reach an agreement with the IPS to be able to hire. Anyway, everything is delayed with the EAPB.

What other barriers? As I was mentioning, the EAPBs are responsible for all those aspects, they are the ones that hire those services that the patients require. That is a very a big problem, as I see it. Even regarding what I told you about the medications, where some [patients] have to go to Health center 3 for their medication.

Per this general disagreement, this complicated relationship with insurers is perceived as more problematic and represented one of the most cited obstacles to provision of medications on a timely manner and difficulties to refer patients to a higher level of care if needed. The recommendations by the interviewees for the improvement of the program will be included in the final recommendations section as some consider that it is necessary for insurers to have greater awareness of the significance of the program, in order to get involved in the process and commit to its results.

After this detailed account of the mechanisms, such as training, team configurations, staffing, human resources factors and leadership, the concluding section of this chapter is the meaning and definition the HEARTS model or intervention or program for the health staff, in their own words. This section is rich in meaning and is placed here at the end to wrap up the entire inductive analysis section.

Definition and meaning of HEARTS for health care staff

One of the research questions is how the HEARTS Initiative implementation is unfolding and its corollary is how closely does the current implementation follow the guiding principles put forth in the HEARTS modules. To answer this question, the interviews were designed to tap on to how implementers on the ground understand the Initiative.

The following section compiles how the interviewees have understood and conceive the Initiative in their particular contexts. Implementers in the ground use the word program to signify HEARTS or the *Take Control* program.

First, the interview had a few questions about the first impressions and interactions that staff had with the program prior to its onset, as well as the dynamics that existed between the health center and other entities in the different departments. For the health centers of Risaralda, Boyacá and Santander, the information that was initially presented on the implementation of the first “health

centers" in the city of Cali were recurrently mentioned as important in obtaining buy in. The Cali experience showed the benefits that implementation had brought as well as the obstacles they had to overcome.

In municipality of Health center 3, in particular, they recognized that the arrival of the program at the hospital was related to the status the institution enjoyed as a recognized center for the work on continuing medical education on hypertension developed jointly with the Risaralda Hospital Association and the Ministry had taken notice of their work. In health center 11, they had heard of the program prior to its implementation through the strategy that had been developed in 2016 and 2017 with Academic Private Foundation (a private health care provider and research institution). In their first site selection process, the Ministry and the Departmental Health Secretariat explained to the institution's staff that it had the potential to be part of the pilot strategy in the department. In the case of health center 12, the center was already working with the Comprehensive Care Plan for Chronic Disease) program, which embraced a multidimensional approach to the management of chronic disease patients. A nurse from Department X commented that, upon learning of the invitation to participate, their first impression was "that implementation would be a big challenge for the hospital, but that they could take it on if they had the support of management and the team as a whole. Further, by the time of the first meeting with PAHO, the hospital had heard of the site visit and this generated some expectation and openness".

These early experiences of "receiving" the program at the selected centers, created a set of expectations, and the first impressions about the program were formed. Early dissemination practices, such as the information presented by the Ministry of Health and first meetings conducted jointly with PAHO appear to have had a significant impact on staff seeing feasibility of the program in which they would be partaking. In this regard, it is worth highlighting the statement of the head of nursing of Health center 8:

It was very interesting to see that they (PAHO and Ministry of Health) started from the basics, which was the population characterization and the cleaning of databases and then led us to comment on treatment algorithms, fixed dose combination drugs, things that at this time and in this environment , in a public environment, it's hard to see for the cost that they have. Then you start to imagine that this idea, that this is really is going to benefit the population and we're going to be a model in that process. So even though the cardiovascular risk team hadn't been formed yet, but everyone who would end up becoming a member of the hospital's cardiovascular risk team was there in the auditorium, and although we were working separately at that moment, we gained a perspective, we started talking about that this model and the process, and it was from this that it all got started.

- Chief of Nursing from Department Y

Some figures were key in this first onboarding of the other members to the program. Dr. ABC, representing the Ministry of Health, for example, is well known in all municipalities for having taken the lead, showing health center staff the positive results that other countries had achieved with the program, as well as promoting judicious monitoring and measurement of patient data through the "centralization and organization of algorithms".

The Initiative provided staff with evidence-based tools to enrich medical practice, to work collectively and led to agreements to standardize the processes of diagnosis, treatment and use of technologies. This involves teamwork and increased peer dialogue. Thanks to this, there is a sense of confidence and credibility on the part of the staff of the HEARTS methodology.

For me it (HEARTS) has been excellent, having been part of the group of specialists that led the construction of this algorithm; we did so with a previous study duly supported from medicine and scientific evidence, based on much dialogue and consultation, even with sub specialties such as cardiology and nephrology, and that consensus allowed us to have a lot of confidence in the application [of the algorithm]. So, I'm one of the main proponents that the algorithm applies to

for about 80 or 90 percent of patients. There are 10 to 20 percent of patients who are outside of the general group and who require other pharmacological measures outside those established in the algorithm, but since we are looking to impact the majority of the population, the algorithm is absolutely valid.

-Medical director from Department Z

Several physicians agree that training staff on the utilization of the protocol, has provided a common language to all, and has been fundamental to the initial phase of implementation. Several interviewees, mostly physicians and nurses, utilized the specific expression of "**unification of concepts"** as crucial element in the implementation of the strategy and, above all, aiding staff see the feasibility of the model. Furthermore, there seems to be a direct relationship between the rigor of the training processes and the unification of concepts achieved in each center. On the one hand, there are respondents who emphasized that through collective training aided by HEARTS materials, staff are using "the same language ", which ensures that the care provided to the patient and the decisions that are made about their case will not vary from professional to professional. This is manifested, for example, in the centers 8 and 12. On the other hand, in health center 4 and 11, there are those who say that it is necessary to work harder on this component, because there are still different perspectives and practices carried out by different members of the teams.

Despite this difference by health centers, teamwork and the continuous evaluation of the practices themselves has been a constant throughout the process to improve the program in several centers, as national and regional meetings have allowed representatives of each respective center to share progress, learn from the experiences of the other centers and participate in sessions with experts who present on the scientific evidence that support the treatment protocols and methodologies proposed by HEARTS.

Another important milestone that has been developing and that has been beautiful work, led by family medicine but with the participation of other specialties such as internal medicine here at the hospital and the general practitioners of the programs in which we also created links with the other health centers, was the standardization of a treatment protocol for the department of [Y], which was also one of the things that we had the honor and pride of presenting as a model at the most recent HEARTS meeting in *Punta Cana.*

- Physician/group coordinator, Department Y

It starts to become apparent in the testimonies how such practices of co-creation and collective professional growth also influence how staff conceive their work and identify personally with the Initiative:

About eight years ago, I was in general medicine, but, two, three years ago, since the HEARTS project began, "Take control Colombia" and I started the process of the "chronic" program, as a leading physician, (...) , there was the opportunity to grow in every aspect, so "Take control" is supremely important, because it teaches us to do things right, to redirect what was being done, whatever was disorganized and re-organize it.

- Physician coordinator from health center 12

These meaningful individual experiences result from physicians being able to place themselves within the program, defining it as a comprehensive strategy that aims to improve conditions to properly manage cardiovascular and metabolic risk of the population. The following quote is complete definition of the program in the words of a doctor from health center 1:

Well, I would tell you that it is part of a plan designed globally and landed locally through the Ministry of Health and Social Protection in order to properly manage the cardiovascular and metabolic risk of patients, which consists of three strategies, Know Your Healthy Weight Risk, Take Control and RECCETA-A. They were so named in Colombia with the sole purpose of carrying

out a proper implementation of the management of hypertensive patients as it should be carried out, in any health institution of the country.

An added value identified by some staff members is that the program functions as a built-in assessor or evaluator of the performance of the health center, as amid implementation, the question arises about the patients' health status and the health center response. In this way, several interviewees wanted to highlight that a good implementation generates a positive response among patients and in public health in general. A general physician of Health center 10 celebrates the pragmatism of HEARTS, as its tools facilitate the control and monitoring of all the integrated variables that affect the health of patients, whether they are at risk or not. Similarly, one of Cali's nursing chief states that "this is a complete and optimal program thanks, among other things, to its call for interdisciplinary work". Similarly, staff value HEARTS' intention to extend hypertension education to the general population where many may not be aware of already be suffering from hypertension, alluding to the preventive and educational dimension of the program.

Finally, a factor that was mentioned, almost unanimously, as a determining ingredient of success of the HEARTS strategy: commitment. The lack of commitment, a theme that is often repeated among interviewees, can affect the strategy at different levels. The first refers to the little support provided by some government entities that fail to obtain resources to support implementation; the second, points to management positions at the individual health center, who have the responsibility to ensure that the institution has the spaces and times necessary to take on the tasks that the strategy demands; and the third, it is up to each of the staff members, who, according to the interviewees, have a duty to do everything possible to contribute to the good development of the program.

Deductive Analysis: HEARTS through the Consolidated Framework for Implementation Research (CFIR) lens

Through the deductive approach, themes and codes are pre-selected based on previous literature. In this case, the application of the Consolidated Framework for Implementation Research (CFIR) is presented identifying domains and constructs that facilitate or hinder implementation (figure 18). Through this identification of factors, recommendations will be drafted to enhance potential levers of change, and refine components of the implementation intervention In addition, utilizing the CFIR creates a common language to compare implementation experiences with other HEARTS implementing countries in the near future.

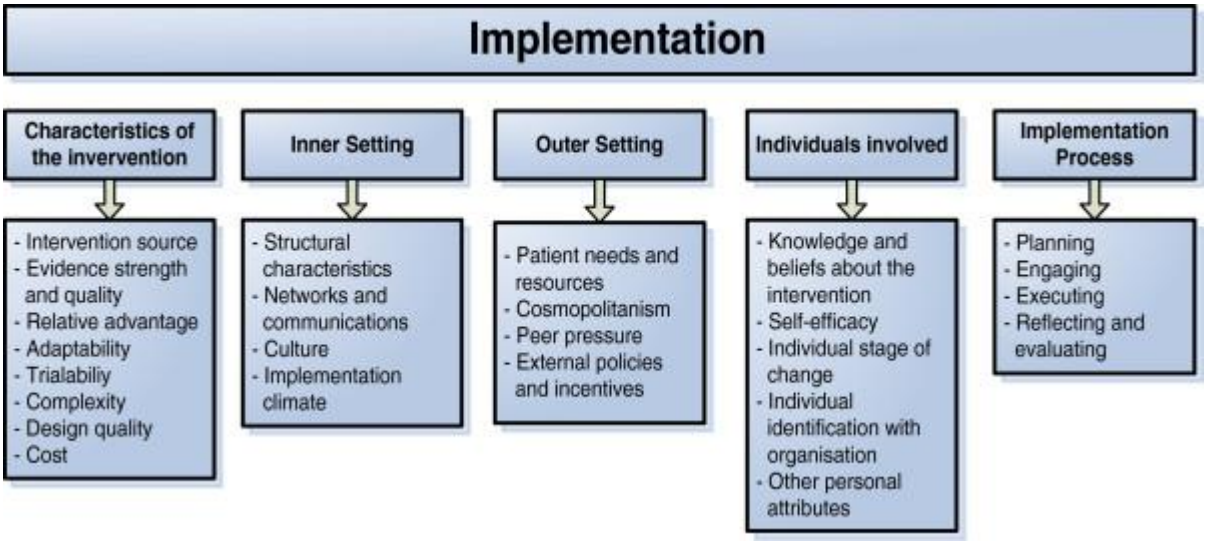


Figure 21. Consolidated Framework for Implementation Research (L. J. Damschroder & Lowery, 2013)

CFIR DOMAIN: Intervention characteristics

A. Intervention source

Perception of key stakeholders about whether the intervention is externally or internally developed. Stakeholders recognize that the intervention was externally developed, and unanimously this was seen as a positive attribute. With the exception of very few interviewees, who

may have been new to their post, the great majority recognize that either the World Health Organization (WHO) and/or the Pan-American Health Organization (PAHO) have been the promoters of the HEARTS Initiative and a very high number had taken a virtual course, seen the modules or participated in at least a webinar about HEARTS. The following statement from a physician reflects the understanding of most stakeholders:

> *Well, I would tell you that (the Initiative) is part of a plan designed globally and landed [implemented in the ground] locally through the Ministry of Health and Social Protection in order to properly manage the cardiovascular and metabolic risk of patients.*
>
> *- Primary care physician from Department Y*

From the national and state levels, the externally driven intervention was seen as fostering alignment with international standards and was a positive attribute and an attractive feature of the initiative. Additionally, exposure to on-going experiences from other countries of the region, and intra-national experiences such as those of the first "health centers" in Cali was cited as important models to facilitate the adoption of the interventions.

> *Q: "Do you consider that the HEARTS Implementation was externally or internally promoted?*
>
> *A: "Yes, initially it was externally. As we got started to know the meaning of the strategy and all of that, you know, there was a bit of a sense of having to do many more things, and I would not say there was a sense of rejection but it was as if we were assuming a risk, a resistance, initially; but getting to know everything, the strategy, the benefits, the trainings, and also to see what had been done in the places where we visited, experiences such as in Cali, as the first initiator in Colombia and see those processes , and we could see results, we saw those results as internal motivation…*
>
> *-Primary care physician from Department X*

B. Evidence strength and quality

Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have the desired outcomes.

Stakeholders perceive the evidence to be strong and of high quality. There was a consistent mention of the HEARTS modules as a good source of information and WHO/PAHO authorship was identified to be credible sources of evidence and guidance. This was especially important for the component of treatment algorithm, possibly the most sensitive component due to inherent aspects of medical education and medical practice. The intervention proposes that a standardized treatment protocol be developed based on a limited set of principles. Several interviewees expressed that the presence of international scholars on hypertension was important in assessing the evidence:

> *"During the initial stages we conducted bibliographic review, we reviewed the current clinical guides and met intensively with primary care physicians and specialists… this was a long process…The support obtained from the international doctors, Dr. MJ, from Kaiser Permanente, helped us see that we were on the wrong track, but we then moved faster and we were better convinced and of course, the involvement of Dr. PJ, whom with his experience showed a lot of evidence, that was the base of our discussions, were basing our discussions on evidence"*
>
> *-Health center director from Department Z*

However, one primary care physician who oversaw his group of primary care physicians did express a feeling of needing more evidence about the standardized treatment algorithm:

> *What we need to improve is our work on the pharmacological combination, [we need] to work on finding a pharmacological combination that truly convinces my medical team that it is better over the other existing ones.*
>
> *- Physician coordinator from Department Y*

Several other primary care physicians underscore the importance of seeing HEARTS as a complement to the national guidelines:

> *… that the HEARTS strategy complements with the clinical guidelines; that is a work in concert. Then we are not working in isolation, we work in a coordinated manner, the HEARTS strategy and the clinical guidelines too."*
>
> *- Primary care physician coordinator from Department Y*

Overall, the HEARTS initiative is perceived as being backed up by strong evidence. However, especially the physicians note that the treatment algorithm is a sensitive element and needs careful elaboration. Similarly, compatibility with existing clinical guidelines was underscored.

C. Relative advantage

Stakeholders perception of the advantage of implementing the intervention versus an alternative solution. This construct of relative advantage has been manifested in almost every one of the HEARTS components as well as through the descriptions of the Initiative as a whole. And this is important in characterizing the implementation thus far. Among the novel components that interviewees mentioned that present a relative advantage to the way that the care of patients with hypertension was being provided before the implementation, is the actual active search for new patients. As previously described the outreach and in-reach have been directly motivated by the HEARTS Initiative:

> *Well, the truth is, the implementation of the cardiovascular risk route in our center has been really good because we have brought back people from the general population who knew they had hypertension or diabetes but were not coming to their check-up (or follow-up) of anything then we went to do the screenings and finding people in the general population to bring them in for treatment with a general practitioner, doctor from the integrated care route, with a nutrition, with psychology, with sport or exercise professionals.*

-Nursing assistant from department Y

Other important aspects that have been reported as having an advantage over previous practice seems to start creating a virtuous cycle: monitoring of patients more closely by nursing assistants has led in some centers to create new posts for nursing assistants to focus exclusively patient monitoring.

> *But what we've never done, and, what we're doing now, with the implementation of the program, you know, it's calling to check on the patient, to verify that he or she will come to the checkup, check how is his or her health status, if it's improved, if it is deteriorating, all of that we didn't do before, this started to be done from 2018.*
>
> *- Nursing assistant from Department W*

Furthermore, the entire systems for monitoring, having indicators, conducting an assessment or auditing of their current chronic disease program was mentioned as being a major catalyst for improving care. Ultimately, most respondents saw the model or initiative as an improvement over what has been done; as an organizing methodology, a way of streamlining processes; therefore, the relative advantage is in respect to “business as usual”.

Adaptability

Adaptability is the degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs.

Adaptability stands out as major strength of the HEARTS implementation. Almost every health center staff described a way in which elements of the model were being adapted, albeit a high degree of apparent homogeneity in the guiding principles of HEARTS. The adaptation by function (described earlier in the dissertation, chapter 3) seems to best describe the quality of adaptability. An illustrative case is the standardized treatment algorithm; where there was mention of an existing, newly developed

standardized treatment algorithm in every department, there was a different treatment algorithm following the basic guiding principles and based on the availability of medications at each center, and determined by the type of insurance regimen of the patient. Other adaptations were related to the workflows at each clinic which also showed different staffing configuration and patient flow. Similarly, outreach activities were being carried out differently, for example, by phone, door-to-door, and some outreach was carried out through community partners.

Complexity

Complexity is defined as the perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality and intricacy and number of steps required to implement. At the health center level, many interviewees spoke of the simplicity of the model as an important quality.

> *I give the intervention an 8 (in a scale of 0 – 10) in its ease of implementation, it is a strategy that leads to higher control of patients without the need of advanced technology nor a high, exaggerated level of training that would prevent us from implementing.*
>
> -Primary care physician from Department Y

Several spoke of HEARTS as being complementary to what existed, but being an improvement, a simple, yet effective way to improve health care delivery.

Outer setting

The CFIR domain of outer setting operationalizes the inter-organizational economic, political and social context within which an organization operates. Cosmopolitanism, peer pressure and external policies and incentives in the CFIR model account for characteristics of how an organization relates to other external organizations with respect to networking, competition or responding to mandates and incentives. The twelve health centers were public health entities, except for one; and in Colombia's

decentralized health system, they have different links and accountability pathways within the complex health system structure.

Cosmopolitanism is defined as the degree to which an organization is networked with other external organizations. The health centers are networked as public health entities and report to department secretariats of health and are regulated by the Ministry of Health; however, the private insurers exert major influence on the health centers.

As previously described in section titled *Health system*, in this system based on managed competition (Londono & Frenk, 1997), public and private institutions compete to provide health insurance and health services, meaning that different types of insurers (public, private, local, regional, national, and multinational) coexist. Public and private hospitals sell health services to public, private and health insurance companies. In the case of the HEARTS implementation, the great majority of these initial health centers are public primary care hospitals and public health centers that sell health services to private insurance companies. And contractual agreements between each center and each insurer results in different types of configurations of health coverage, ranging from specialists' referrals to specific medications covered, despite renewed efforts through the 2015 Statutory Law to equalize the different benefits plans.

Across the primary care centers, there is a pre-existing level of collaboration from which it seems easier to build upon through the HEARTS implementation. In most departments, the Ministry of Health, and the Secretariat of health acted as conveners; there was a department (Risaralda) where an Association of Public Health Hospitals served as an important partner in convening along with the Ministry of Health. Therefore, cosmopolitanism is a positive attribute to the implementation of HEARTS, in fact, it facilitates training, development of a standardized treatment algorithm, defining a core of medications and staff training through peer exchanges. Peer exchanges also lead to a healthy peer pressure, where health centers were exposed to the work of the pioneering centers in the city of Cali and were motivated by the

progress shared. Peer pressure is defined as competitive pressure to implement an intervention; typically, because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.

The third element of the outer setting dimension is external policy and incentives. This is a broad construct that includes external strategies to spread interventions, including policy and regulations (government or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting).

External policy and incentives emerged from the data in two ways, one was the frequent reference to the integrated care routes by the majority of interviewees which evidenced that HEARTS was being incorporated into existing national policy frameworks. This was highlighted by the staff at the departmental secretariats of health and at the national level, since by having the policy framework it allowed for a rapid adoption and seamless incorporation of the HEARTS model into actions.

An interesting cultural characteristic noted but one that is difficult to substantiate from a purely public health perspective, is regarding the high value placed on laws, regulations, decrees, ordinances, and policy frameworks in Colombia. Without detouring to a labor-intensive search in the humanities and social science literatures, one article is worth mentioning to illustrate this apparent national characteristic. An article with the suggestive titled: “The obsolescence of some laws in Colombia ‘between rationalization and the culture of legality,’ which takes the reader through detailed charts of the production of laws in Colombia showing that 552 new laws were passed by legislators within a period of nine years resulting in 61 new laws per year and 23,510 presidential decrees (2,398 decrees per year). (Olano-García, 2018) This signifies that a legalistic approach to all processes is part of the national identify. Similarly, another scholar explains that Colombia is one of the countries worldwide that has an extreme high number of norms to regulate all types of behaviours including all social relations (Atienza, 2013).

During the interviews, I was surprised by so many interviewees from physicians to nurses to hear them cite the different laws that regulate public health. It became apparent and was ratified by interviews with the representatives from the Secretariat of Health that articulating HEARTS under existing health laws and the public health policy frameworks was a prerequisite for implementation.

Inner setting

The CFIR domain of inner setting operationalizes the intra-organizational context of organizations and includes five broad factors, two of which have multiple sub-factors, characterizing organizational structure, politics, culture, and capacity for change.

Structural characteristics is a broad category, defined as the social architecture, age, maturity, and size of the organization. The size of the health center did determine the level of resources, with the larger health centers such as in health centers 8, 9 and 12 enjoying a number of important resources, such as easier access to specialists, its own pharmacies in the premises, access to more disciplines that constituted multi-disciplinary teams, and more human resources overall.

Culture includes norms, values and basic assumptions of a given organization. In this care, the health centers seem to have many characteristics in common as by definition they were public primary care centers. One particular cultural aspect that seems notable was the legalism described in the previous section. This notion of highly valuing laws, regulations and decrees may also explain aspects related to the adoption of standardized treatment algorithms only if they are seen congruent with Colombia's national clinical practices. Similarly, during the visit at least two different health centers, it was evident that accreditation programs were highly valued. One such program is the *Estrategia Instituciones Amigas de la Mujer y la Infancia con enfoque Integral (IAMII,* Strategy for the Women and Infant Friendly Institutions with a holistic approach). This strategy is a continuous quality improvement instrument for maternal and child health that is applicable to all Colombian health institutions, ranging from primary to tertiary level of care. The level of mobilization around the re-accreditation time noted during my visits to at least two

health centers suggest that an accreditation process may be an interesting vehicle or instrument to consider for HEARTS. As this approach seems to be culturally appropriate for the expectations of the participants. This aspect of culture as approached here may be germane to another CFIR Inner setting domain construct, "**organizational incentives and rewards**" which is defined as extrinsic incentives such as goal-sharing awards, performance reviews, promotions and raises in salary, and less tangible incentives such increased stature and respect. It had been previously mentioned that the externally motivated trigger of the adoption of the HEARTS model, by an international health organization is seen as a positive factor in implementation. Additionally, participation in adopting the HEARTS model did not translate into significant financial resources (no major additional funding, nor supplies were provided); therefore organizational incentives tend to be more intangible such as prestige in the departmental and national milieu and newer networking capabilities with national and international peers and experts.

Implementation climate: The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of the intervention will be rewarded, supported and expected within the organization.

An important and less explicit aspect of implementation of HEARTS in Colombia is that carefully selected centers were invited first to participate or to join the HEARTS Initiative implementation. The Ministry of Health, in conjunction with the departmental secretariats, selected and invited specific sites which seemed to have had to distinguish themselves for having receptive leadership and having had embarked on special projects related to chronic care management in the past. Therefore, the majority of centers seem to have had special characteristics such as high receptivity of involved individuals, or at least from the health center leadership, and had been prime candidates to participate in this type of special initiative.

Nonetheless, the health centers share conditions that seem to be widespread in the public health systems, one of them being the instability of human resources. Turnover and contracting

practices are aspects that emerged and are germane to this inner setting discussion. Turnover, initially defined as a highly fluctuating duration of employment at the health centers, emerged as important barrier to HEARTS implementation. Hiring or contracting practices were a source of great uncertainty and instability in the overall functioning of the health center. The gaps created by this instability was often compounded by using recent medical and nursing graduates that must complete their mandatory social/rural year of service. By definition of their roles, these young professionals remain at the health center for a year maximum; therefore, there is a continuous need to train incoming professional staff. Similarly, low wages and short-term contracting were also important factors mentioned.

This construct of implementation climate opens space for inclusion of two other constructs: **Readiness for implementation and compatibility**: These initial health centers displayed tangible and immediate indicators of organizational commitment to the decision to implement the intervention; and as the national coordinator has explained, this first set of centers were self-selected and stayed on because the staff, especially those at coordination, mid-management level, showed genuine interest through their participation, which as previously pointed out, did not translate into direct significant additional resources. And secondly, the construct of **compatibility** is defined as the degree of tangible fit between meaning and values attached to the intervention by stakeholders, its alignment with norms, values and perceived risks, needs and fit with existing workflows and systems. Throughout the inductive analysis of the previous section, a compatibility of the HEARTS model with existing practices, is almost universal, where most practitioners described that HEARSTS was complementing adding value and improving the health center's workflows, mechanisms, and practices.

Leadership engagement defined as commitment, involvement and accountability of leaders and managers with the implementation. As described in the leadership section, leadership sponsorship is fundamental to any change introduced in a system. Across the health centers, a palpable difference was seen between the sites where the health center director directly or indirectly supported the initiative

and those centers were the directors were not supportive. The interviewees from the centers with support felt a higher sense of ownership, optimism about the possibilities of improvement, even if incorporating elements of the initiative may have felt as adding more to their workload, there seemed to be less resistance. In the centers, where there was no leadership support, staff sounded more stressed and felt that implementing HEARTS was a upfield battle even if recognizing the virtues of the model. Another dimension of leadership is the role of political figures as such mayors due to the decentralized nature of the Colombian health system, mayors are responsible for the local fiscal oversight and allocation of funds to public health centers; therefore having buy in from the mayors, as occurred with a few of the centers, seemed to be important to complement and fill in gaps related to material resources and temporary staff for activities such community outreach.

Finally, the large macro changes at national level, with a new president of the country being elected in 2018, leading to the changing the minister of health and the entire leadership including the subdivision of noncommunicable diseases, led to changes in mid-managers such as the person who had been coordinating HEARTS and who was seen unanimously by all interviewees as a critical driver to implementation. This type of centralized leadership had a very positive impact on the homogeneity/uniformity of information and knowledge transfer to the state and local level. And the personalized approach to providing technical assistance from the Ministry of Health all the way down to the health centers was reported as a great asset to the progress of HEARTS implementation. On the other hand, the over-reliance on one individual seems to have had an important negative impact in absence of this dedicated minister of health representative. As it was recurrently mentioned by interviewees that the support and technical cooperation activities from the Ministry of Health had nearly ceased or slowed down dramatically. At the time of the interview, several interviews indicated a desire to voice their sense of feeling having been left without further support from the Ministry. And although work was being carried out, in some health centers there was a sense that with only a few mid-

mangers and coordinators trying to fortify the implementation and the lack of communication from the Ministry of Health could truly jeopardize the advances that had been made.

Final Domain of the CFIR Model: Process

Taking advantage of the existing constructs identified by the CFIR domain labelled "Process", this section will construct or re-construct the theory of the implementation at the health center level, illustrating the domain constructs, which have affinity to elements of implementation pathways.

Process

The CFIR domain of process and its constructs seem to map well with the natural, quasi-organic development/unfolding of the initiative in Colombia. The themes previously described are now inserted into CFIR process constructs to illustrate the implementation pathway or implementation mapping. Similarly, as previously mentioned implementation has been unfolding at different levels, the proposed program theory is presented for the health center level in the context of the implementation at the country level, because they are intrinsically linked.

Planning construct

Planning is defined as the degree to which tasks for implementing the intervention are developed in advance. In Colombia, as previously mentioned there another health law was introduced to strengthen the notion of health as right; this law was briefly described in section on the Colombian health system, the enactment of the Law 1751, 2015 (Statutory Health Act) which aims to "guarantee the right to health, regulate it and establish its protective mechanisms." From this law, new policies and a health care model were designed resulting in the integral routes of health care (*rutas integrales de atención en salud,* RIAS) which are the instruments to define the agents of the system (territorial entity, insurer, provider) and agents from other sectors to ensure the necessary conditions for

comprehensiveness in care based on the actions expected of the individual, actions aimed at promoting well-being and in the environments in which it develops, as well as interventions for prevention, diagnosis, treatment, rehabilitation and palliative care. There is a "RIA" for specific health conditions, and risk groups, therefore, HEARTS was inserted into the "Cardio-metabolic-cerebro-vascular Route". Therefore, there was much planning at a national level that created a good scenario in which to incorporate the HEARTS model.

It is at this juncture that Ministry of Health rolls out, their Route Implementation Strategy which contained the "Know Your Weight & Know Your Risk", which is the operationalization of the *Comprehensive Health Risk Management* approach through community based screening. Ultimately, HEARTS becomes the *Take Control* implementation strategy. At the health centers, there seemed to have been exposure to this new model of care and expectations had been created about were these new routes going to be operationalized in practical terms. In sum, the planning process for the reception of the HEARTS model, was extensive as there was an opportunity and a need for a practical model of hypertension control interventions that would fit the new model of care. The Ministry of Health capitalized on this window of opportunity.

Engaging

The Ministry of Health worked closely with the state Secretariats of Health to select the initial implementing sites and the sites that responded positively and by a process of self-selection, centers became part of this first group of participating centers. The engaging phase included intensive training on the data collection and data cleaning mechanism previously described in detail in the *Analysis book*. Provision of technical assistance through the training on this specific and tangible tool became a vehicle for engagement, for persuasion and pedagogically, as the Ministry of Health coordinator describes it: "This tool allowed the health center staff to see themselves in the mirror." It was revealing to see the number of hypertensives that were being treated at the facility, the number that were reaching control

and the number that were not coming in for follow up as it was extensively demonstrated in the inductive analysis (starting on page 65). This construct of engaging also took place at the local level by the secretariats further engaging the health centers and the health centers engaging their staff. As previously discussed, the centers have used different modalities, including utilizing standing coordination committees or creating a coordination committee. And training of all staff through virtual methods have also played a role in engaging staff.

Executing

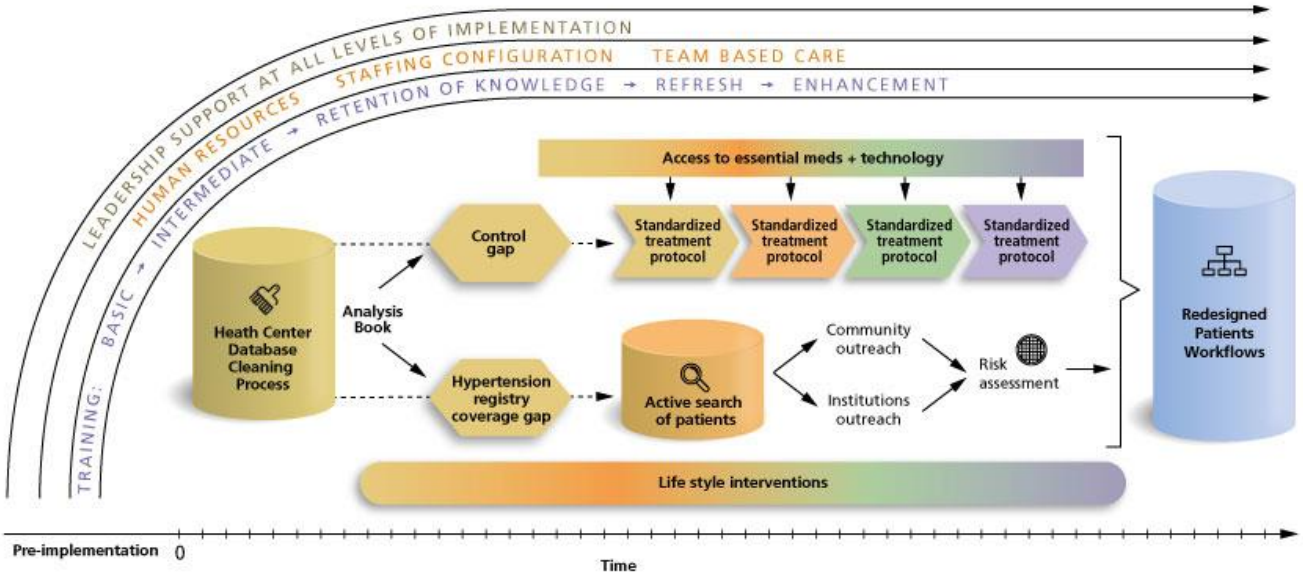
Executing is per definition carrying out and accomplishing the implementation.

The data cleaning process revealed two gaps: hypertension registry coverage gap and control gap. The data became triggers to action. The hypertension registry coverage is defined as the number of people with hypertension that needed to be seen (and be registered) according to an overall expected prevalence rate. To address the coverage gap, strategies for community outreach and institutional in reach were implemented. These strategies are described in detail in the section on community outreach and in reach (active patient search). These activities are also mediated by the risk assessment strategies which also correspond to the overall framework of the integrated health care route. Almost in tandem, the data uncovered the control gap, defined as the number of hypertensives who have their condition under control in relation to all hypertensives in being seen at the health center, to improve the control gap two major actions were triggered. In one hand, the development of the standardized treatment protocols whose process is described in detail in the section under the same name. It is important to highlight that the standardized treatment protocol development takes place on its own timeline as it takes building consensus among several actors in a complex web of relations as described previously which entail providers, regulators (ministry and secretariats), scientific societies, specialists and the key player: insurers. The development of standardized treatment protocols is directly linked to access to essential medications and technology, aspects which were discussed in the context of major hurdles due

to the apparent diversity of benefits plans covered by different insurance companies and prescribing privileges of primary care physicians versus specialists. And finally, almost in a simultaneous fashion, the patient workflows are being transformed to different degrees in the different centers to accommodate the changes being implemented as described also in the section named *Patient workflows*.

These three constructs: planning and, especially, engaging and executing, are graphically displayed in the program theory diagram that is emerging, shown in figure 17 and is again provided below for ease of reference. Similarly, observed on a timeline and cross-cutting trajectory, the following constructs are the elements that acted as drivers of the implementation: training and leadership (constructs that are described in depth in the previous section on deductive analysis).

To finalize the mapping of the CFIR, a cluster of process constructs: opinion leaders, formally appointed internal implementation leaders, and champions are further discussed as part of the leadership cross-cutting strand of the program theory diagram.



(Reutilization of figure 17, emergent program theory presented earlier, original diagram prepared by author for this study)

Opinion leaders

There has been an uneven relationship with opinion leaders, specialists are perceived as very important opinion leaders in anything related to hypertension; therefore, cardiologists and organizations that represent them such as scientific societies (the Colombian Cardiology Association) are seen as important influencers in matters related to hypertension control. The Colombian Cardiology Association has been receptive in certain moments due to the relationship of the Colombian Association with the Latin American Society of Cardiology (SIAC). There have been individual cardiologists who are well respected in the country and/or in their region and have become important champions and supporters of HEARTS. At other times, there has been less support or seemingly different agendas which could be construed as conflicting more in terms of timing than on substance. Nonetheless, there has been active attempts at engaging specialists and representatives of the scientific societies.

Formally appointed internal implementation leaders

As described earlier, there has been a very visible representative from the Ministry of Health whose performance and approach was instrumental in the advancement of HEARTS and accordingly, his absence, due to major changes in the Ministry of Health that may be related to the expected changes in the new administration in the country, seems to have slowed down or impacted in the continuation of the implementation.

External change agents

Throughout the interviews, several participants recalled having participated in trainings via webinar or in person with external international experts, these individuals were recalled by name and reportedly had an impact on increasing receptiveness and credibility of the intervention. These external change agents were facilitated by PAHO which has capitalized in bringing to the country architects of

successful hypertension control strategies such as Hypertension Canada and Kaiser Permanente. This construct is in close affinity with the first construct discussed related to the intervention source which highlighted the externally driven nature of the initiative as positive factor in implementation.

Finally, the construct of **Reflecting and Evaluation** is defined as the quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. As described in the sections on data cleaning and analysis (the analysis book in previous section), the team configuration section on page 92 where some health centers had committees and finally the description of the HEARTS program on previous section, illustrate different components of evaluation and reflection that was built in within the model by placing data at the inception of implementation.

To conclude, mapping the CFIR constructs onto the program theory that has emerged from this qualitative study will fulfil two goals, first, to answer one of the research questions, what is the emerging program theory which with further elaboration can become an implementation map or pathway. Second, by utilizing constructs that have been built through a consensus in the implementation science field; it will allow for the utilization of a common language among implementers in cross-regional and cross-country comparative future work as the HEARTS Initiative is being implemented in twelve countries in the Region of the Americas and over ten countries in other WHO regions.

Chapter 7: Conclusions and recommendations

Cardiovascular diseases (CVDs), and hypertension in particular, have been priority topics in the global health arena for over 60 years, concomitant with major demographic and epidemiological transitions and advances in medicine and public health. Over the years, international conference recommendations have demanded action and delineated plans from and within global health organizations, with varied effectiveness (Institute-of-Medicine, 2010) In the last decade, technical packages such as the Package of Essential Noncommunicable disease interventions, PEN, (World-Health-Organization, 2010) have been developed. As previously described, a technical package is "a selected group of related interventions that, together, will achieve and sustain substantial and sometimes synergistic improvements in a specific risk factor or disease outcome. A technical package of proven interventions sharpens and focuses what otherwise might be vague commitments to 'action' by committing to implementation of specific interventions known to be effective." (Frieden, 2014) These packages are promoted through initiatives that have been designed by international multilateral bodies and endorsed by major scientific organizations such as the Global Hearts Initiative. These initiatives provide benchmarks, best practices and standards which are critical to guiding global policy discussions and fostering high-level commitment. However, there is always the risk that these initiatives may lose their relevance on the ground, where program implementation takes place in diverse social, political, and cultural contexts. Therefore, the subject of this study is how such an initiative is being implemented on the ground in a LMIC to improve our overall understanding of transferability and navigation through the different levels of implementation—from global to the basic health system, and then to the primary care health center.

The HEARTS Initiative presents a multifaceted model of care comprised of several guiding principles and operational components (see Chapters 1 and 2). The pathways to CVD prevention and

control proposed by the HEARTS technical package is predicated upon improving clinical preventive services in primary health care using highly effective, scalable, sustainable and proven interventions. As depicted below, the main conceptual shift is the introduction of CVD risk assessment, the use of a simplified treatment protocol using a core set of medications and basic technology, improved care delivery by team-based care and strong clinical monitoring. Although HEARTS has produced an important number of guiding documents, this is the first study to present implementation from the ground up in a country; re-constructing the program theory from the experiences of the implementers in the front lines.

In summary, this study has taken the foundational general pathway to CVD control from the published manuals on HEARTS, (World-Health-Organization, 2016) and developed a new implementation map based on the experience of Colombia's first twelve health centers. Accordingly, the two following figures, 22 and 23, synthesize graphically this relationship, and an elaboration of implementation mapping follows.

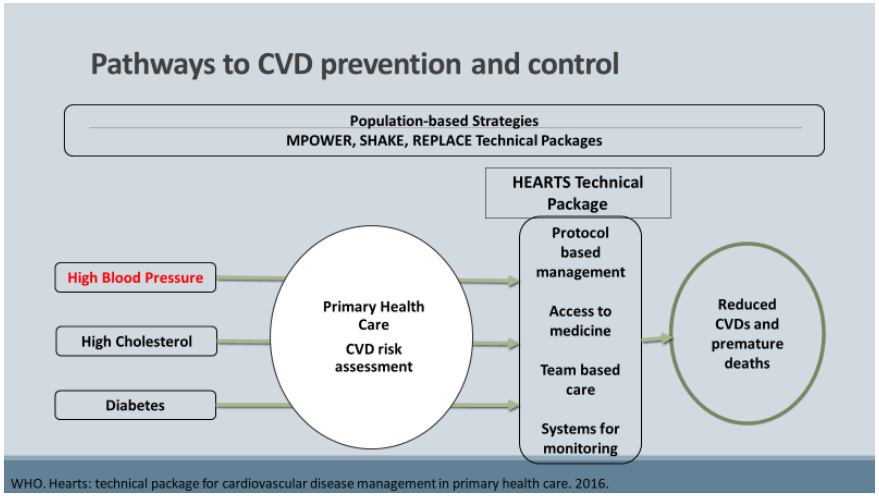


Figure 22. CVD prevention and control DIRECTLY from the HEARTS Technical Package introduction.

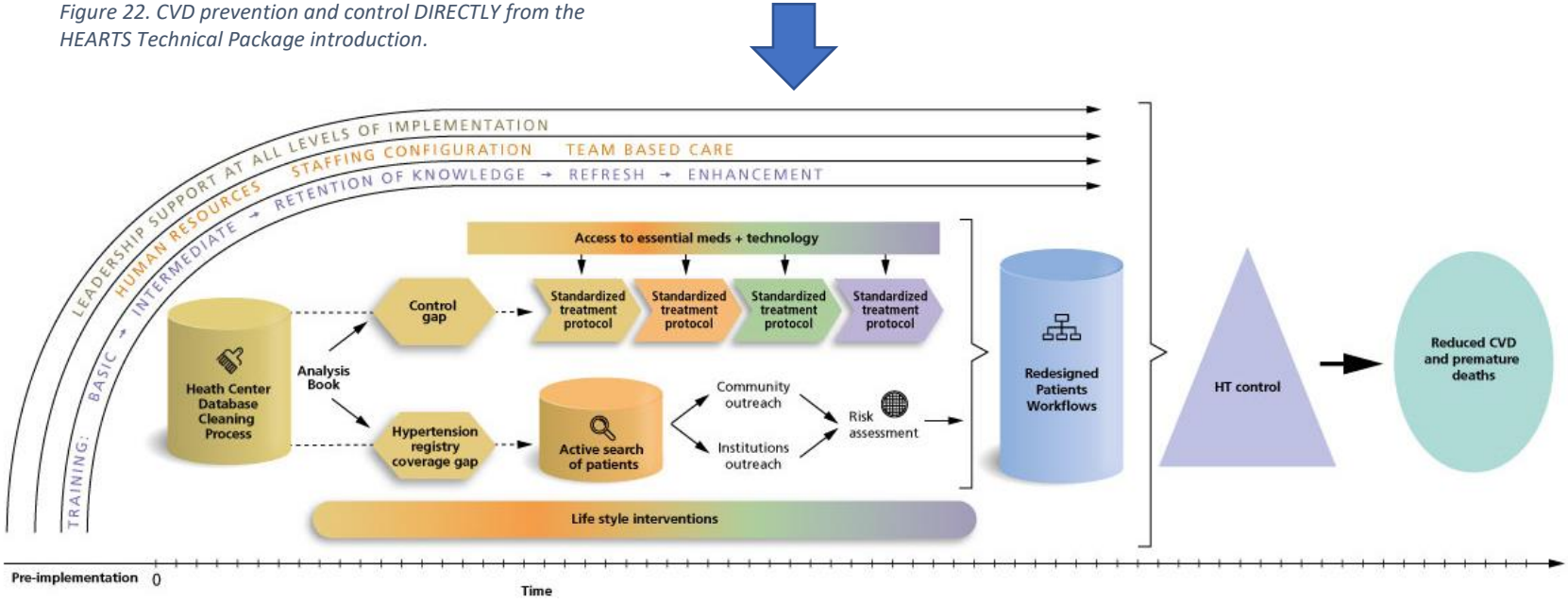


Figure 23. HEARTS implementation in Colombia diagram, product of the current study, shown in conjunction here to show relationship between macro pathway of model to implementation model. Original diagram by author.

Recently, with the refinement of planning tools in the health promotion field and the newer practice of intervention mapping, some authors have taken **intervention** mapping to the next phase to **implementation** mapping. Researchers have argued that "Implementation mapping can advance the field of Implementation science by (1) elucidating mechanisms of change (i.e., how implementation strategies influence outcomes through change in implementation determinants) (2) better guiding the use of implementation models and frameworks during the planning process, and (3) improving the impact of implementation strategies on outcomes". (Fernandez et al., 2019)

As previously described, figure 22 depicts the published pathway from the WHO HEARTS materials. The pathway is predicated on the concept of individual risk factors being used as entry points for the integrated management of multiple risk factors, because integration is more cost-effective in all settings. The HEARTS package includes the promotion of healthy lifestyles; adoption of evidence-based treatment protocols and simple, standardized algorithms for clinical care; access to a core set of affordable medications and technology; risk-based management, including total cardiovascular risk assessments, treatment and referral; team-based care and task-sharing; and systems for monitoring through patient data collection and program evaluation. (World-Health-Organization, 2016) The basic premise is that by controlling risk factors, as precursors to CVD, mortality and morbidity can be averted.

In the current study, the implementation map developed through this research (figure 23) details the emerging causal pathways and mechanisms of how the implementation of the core HEARTS components in Colombia may lead to higher hypertension control at the health center level, which eventually would lead to higher hypertension control at the population level and that subsequently would lead to reductions of CVD and eventually a reduction in mortality.

The utility of these mappings, theories of change and/or causal pathways is that they can create common language and vision among practitioners, aid in the selection of determinant or explanatory models such as the CFIR and may serve as the basis for different types of evaluations. Additionally,

recent literature has shown growing recognition that for successful implementation, the **processes or pathways** for introducing and scaling up interventions can be as important to its success as the content of the intervention itself. (Janovsky, Peters, Arur, & Sundaram, 2006)

Identified pathways (mechanisms)

The implementation mapping above (figure 23) depicts the mechanisms that occur in the actual process of rolling out the program. In this study, sites followed the HEARTS model when they conducted the first prescribed action, the data cleaning, de-duplication of databases and the application of the two key indicators, hypertensive registry coverage and control (depicted by the yellow cylinder and hexagons). The population-based hypertensive registry coverage is based on using the best hypertension prevalence estimate for the geographical area, which leads to obtaining a hypothetical but feasible number of hypertensives in the catchment area of the health center. This number became an action trigger if in the catchment area there are x-number of expected adults with hypertension and the health center only has a fraction (determined by the ministry or local implementing organization) of that number registered, indicating a large hypertensive coverage gap. Interviewees revealed that finding this gap led to activating a search for patients (in the orange cylinder) through outreach (community screenings) and in-reach strategies (missed appointment calls, lost-to follow up calls, hypertension screenings within waiting areas). All these activities led to higher number of patients coming into the health centers, which simultaneously triggered another action point based on the HEARTS components: CVD risk assessment in pre-consultation and consultation (depicted as a filter or strainer). Through these risk assessments, patients were triaged into a corresponding chronic disease program which would ensure follow up. For providers these two action triggers, patient active search and CVD risk assessment, also became triggers for provider agency activation. In tandem with this sub-pathway, the development of standardized treatment protocols was taking place on core set of medications and diagnosis protocols. These two pathways converged in redesigned patient workflows (depicted by the blue

cylinder). These mechanisms showed variations, as naturally expected, but their identification as necessary processes may aid in the rapid replication in other health centers and improvement of the introduction process of the HEARTS model.

This elucidation of initiation mechanisms also starts to answer the second research question, what are the mechanisms at work in the implementation of HEARTS. Finally, since the utilization of the CFIR to map the implementation itself was a tool and objective of this research at the same time, the following section summarizes key factors for implementation as revealed by the CFIR construct mapping.

Of the three overarching constructs of leadership engagement, resources (human resources) and training (learning climate), leadership engagement from the ministry of health is one of the most sensitive factors. Although this study does not involve cases of other types of on-going initiatives nor other health centers, the reach and scope of change described by interviewees is congruent with the implementation and scale-up literature: government buy-in allowed for a fairly rapid progress of adoption of the HEARTS model after the second department started implementing the program in 2017, which was quickly followed by three additional departments. This is significant because no financial resources were allocated from the international organizations promoting the adoption of HEARTS. As mentioned, there are other incentives and rewards such as perceived prestige and credibility to be working with global and international partners, in addition to receiving learning opportunities. Nonetheless, to recruit approximately ten health centers to participate in implementation in the span of approximately six months was possible largely due to the convening power of the Ministry of Health.

Another construct was compatibility as revealed by homogeneity and consistency in perceptions, understanding and ownership of the model. This is evidenced by the same language and concepts being used by WHO and PAHO, the Ministry of Health of Colombia, local officials, and clinic service providers. There are several explanations for this consistency. One obvious one is that we live in

a globalized world where communications travel fast and access through connectivity makes transmission of content almost instantaneous. However, through the interviews, it was possible to discern a level of depth that goes beyond simple basic communication. This high transfer of knowledge through the multiple levels of implementation previously discussed was attributed to consistent technical assistance provided by the Ministry of Health through a plethora of modes: site visits, face to face interaction, in-person trainings in the capital and wide use of virtual communication where centers organized by cohorts of affiliation to the HEARTS initiative. Different cohorts would hold meetings on a weekly basis during approximately the first six months of implementation. This type of technical assistance provision was labor-intensive but seemed to play a homogenizing role and it was aided by a high reliance on virtual communications.

Other factors such as identification of supporting implementing partners with strong commitment, experience and availability also proved to be an important driver of adoption, especially in the early stages when a task such as the development of standardized treatment protocols needs to be coordinated. The process needed to involve specialists who were not part of the public health system but who showed personal and professional commitment. Again, the ministry of health representative with his counter parts at the local levels played a significant role in galvanizing support for the initiative. However, as previously mentioned, there was no succession or transition plan implemented when this ministry of health official left his position. This lack of transition planning and lack of diversifying leadership seems to be placing a toll in the continued development of the initiative in Colombia. These factors gleaned from a detailed analysis of implementers' experiences lead to a set of implications that follow. Recommendations from this study was promised to the Ministry of Health of Colombia as part of their agreement to allow the study access to the implementing sites.

Recommendations

This section builds upon the previous summary of the milestones of implementation during the early phases, as well as the identified challenges and facilitators from interviewees' perspectives to provide recommendations for continued implementation of HEARTS in Colombia. The following observations are presented as recommendations that may be considered by national and regional stakeholders. Although, implementation is not a linear process, there has been an initial sequential order of implementation steps (milestones) presented. The following recommendations mirror that sequence with the intent of guiding implementers and systems that support implementation to situate recommendations in their respective space-domain of action continuum. Similarly, as described in Chapter 2, systems (stakeholders) at different levels fulfill different functions within the ecosystem of the HEARTS Initiative implementation; therefore, these systems are referenced below as potential actors who have the authority, policy levers and resources to execute recommendations.

Stakeholder: delivery system

National and department level health authorities

1. Selection of initial implementing sites and need to expand: The selection and engagement method at initial phases seem appropriate for the highly segmented Colombian health system, specifically the public health system. The Ministry of Health worked closely with the departmental secretariats of health to invite health centers to participate. This early self-selection was important to gain traction in the country and obtain the support of the leadership at local, departmental, and national levels. Selecting diverse health centers in diverse regions, as demonstrated in the health center descriptions and context earlier in the dissertation, was a strength since it showed that implementation could successfully occur in wide range of sites that varied in size, resources, and expertise. Strengthening the implementation of the model at these health centers by continued support from the ministry of health, collection of regular

reporting, continuous capacity building and peer exchange would facilitate having these initial implementing sites become training or information resources sites as initially conceptualized, especially for new sites located near geographically. This spread approach would allow continued expansion to larger territories with support to build and/or strengthen learning networks. Interviewees expressed a concern about a seemingly lack of expansion and scale-up which could pose a serious risk to the work that has been carried out. If no new health centers are engaged, it is likely that the momentum may be lost and the actual gains of the implementation of the model will be forgotten. This is exacerbated by the lack of publications or reports on the intermediate results of the implementation that could serve as a guide to other centers.

RECOMMENDATION: Implement original idea of supporting initial centers to become training centers to accelerate scale-up

2. **Direct provision of technical assistance to health center staff and health center directors:** The intense technical assistance provided by the Ministry of Health is a key element in the uptake of the model; it was a recurrent theme from the interviewees that it was important to have a dedicated national coordinator who was in touch directly with the clinical staff who were actually carrying out the work. Having included on-the-ground clinic staff as targets, and not just local leaders or clinic managers, for outreach early on and throughout the discussions and processes is an important facilitator of implementation. It was mentioned that in previous initiatives, when only health center directors or management are convened to participate in the trainings of a new initiative, given the multiple and competing priorities of a health center director, the new initiative rationale and operating principles may not be clearly communicated to the clinical staff and the effort can get lost as there is no knowledge transfer to implementing staff. On the other hand, it seems that there was a bit of disengagement from management as they had not been convened;

therefore, a strategic approach to creating spaces for the participation of management would also be beneficial to continue garnishing support for the implementation.

RECOMMENDATION: Continue direct technical assistance provision to health center staff and create tailored technical assistance for health center directors to ensure sustainability

3. **Continue development processes of standardized treatment protocols:** A fundamental pillar of the HEARTS model is standardized treatment algorithms; achieving this milestone has proved extremely difficult in Colombia due to the fragmented structure of the health system. As previously mentioned, the organizations that constitute the administrators of insurance benefits (EAPB) are responsible for being the fiscal intermediaries, organizing insurance plans and collecting premiums from individuals and government subsidies, and paying providers in their networks. There are both private and public EAPBs, and they have autonomy to define what medications are covered. Additionally, some interviewees mentioned that not all medications can be prescribed by primary care physicians, with the decision about whether recommended medications can be prescribed solely under the authority of specialists varying between EAPBs. This complicates building a consensus on department-wide standardized treatment protocols since HEARTS is a primary care program and requiring that only specialists prescribe hypertension medication is barrier to treatment.

Recommendation: Pursue work at the national level to create greater cohesiveness around a core set of hypertension medications available through primary care and centralized procurement that could support standardized treatment protocols based on global best practices

4. **Human resources:** Insufficient numbers and high turnover of staff, especially of physicians and nursing assistants, seem to pose an important challenge to implementation. The coordinating physicians and nursing chiefs responsible for overseeing implementation seem to be more stable in urban and semi-rural areas. As in most places around the world, the rural areas seem to have the most unstable workforce. Talent retention is also directly related to stable funding. In Colombia, public primary care centers are among the most vulnerable institutions of the country's health system. In 2019, the insurers owed public health centers and hospitals 9 billion pesos in unpaid billings according to the Colombian Association of Hospitals and Clinics, out of a total of debt of 33 billion pesos owed by the insurers to all providers in Colombia. (Cabrera, 2019) The annual public sector allocation to health care is about 32 billion pesos, suggesting that these arrears are a significant part of their budgets. (Ministerio-de-Salud-y-Protección-Social, 2020) Since the HEARTS Implementation relies on a trained workforce, stabilizing the work force through secured funding is important.

Recommendation: Resource allocation to sustain a stable trained workforce is needed to ensure institutionalization of the HEARTS model.

5. **Coordination among levels of care**: Since only larger health centers are staffed with their own specialists, there is frustration among primary care providers in smaller centers due to their inability to influence the behavior of specialists as these are autonomous and deal directly with the insurer without having to communicate or coordinate with the primary care providers. This lack of coordination also constitutes a barrier for standardized treatment protocol utilization. Once a patient is referred to a specialist, the specialist is usually at another institution and does

not have to abide by the standardized treatment protocol of the referring entity. Coordination needs to happen in at least two spaces. First, between insurers and the primary and secondary levels of care providers and institutions. Many health centers have a variety of ad hoc methods they must pursue to obtain timely notification and discharge information from secondary and tertiary hospitals, but it is based on the arrangements dictated by the insurers. Second, another way in which coordination between primary and secondary levels may be facilitated is through collegial collaboration; this happens between primary care physicians and specialists through their respective professional organizations. Although efforts have been attempted to bring the two groups of professionals to work on building consensus on protocols, more work is needed in this area.

Recommendation: Increased coordination between primary and secondary level of care is necessary.

6. **Shared leadership:** Dedicated HEARTS champions were important for supporting implementation. Interviewees noted that essential role of champions, at different levels, in obtaining clinician and staff support for changes, building staff commitment and communicating the vision and goals of the HEARTS model. Leadership at every level of implementation is paramount. However, cultivation of collective leadership should be a high priority. This was especially evident when the Ministry of Health representative departed and the lack of a clear succession plan for the continued development of the Initiative and direct support to the health centers from the Ministry was reported by the interviewees. There is a risk in centering leadership in one or few individuals, especially in a context of high staff turn-over due to macro political changes.

Recommendation: Develop and cultivate coordinating teams at every level of the HEARTS implementation as an important safeguard against centralizing leadership in just a few persons.

7. **Quality improvement processes:** At its core, the HEARTS model is a quality improvement strategy, however it is not explicitly presented this way. Although several lead physicians describe the model as such, it may be beneficial to frame the model as a quality improvement strategy and provide more technical assistance on the conceptual and practical applications of this methodology. Additionally, by emphasizing a quality improvement perspective, other key stakeholders such as the private and public insurers may be more interested in participating. Similarly, as previously noted, an accreditation process may be a way of formalizing and institutionalizing the HEARTS model in culturally acceptable way. There are many examples of types of accreditation in the health care delivery field and expertise from which to borrow.

Recommendation: Develop a robust quality improvement methodology and train participants on it to further advance implementation.

Department health authorities and health centers:

8. **Health information systems:** There is great enthusiasm, acceptance, and technical capacity around information systems. The public health centers, in essence, sell their services to the private insurers who are intermediaries for public programs, making data for billing paramount. Therefore, there is an abundance of software and systems that may or may not be inter-operable. At one health center, there were at least five different systems for different purposes but with major overlap. Similarly, other entities and levels have their own systems and new ones were being created and rolled out at the time of the study. There is a strong culture of data collection; however, there seemed to be an overwhelming amount of data being collected for so many

different purposes and by many different people that there is clearly much duplication as well. In several health centers, nursing chiefs were now in charge of data and this constituted their core scope of work to the extent that they did not see many patients at all. On the other hand, there are challenges that primary care centers face in obtaining timely data, electronic or otherwise, from specialist providers outside of their organizations, including from both private and even public hospitals. Finding a way to streamline health information systems from data collection to software freelance vendors, increase interoperability and organize data for quality improvement purposes should be prioritized. This area is a ripe opportunity for enhanced technical assistance and will facilitate meeting a core component of the HEARTS protocol.

Recommendation: Streamline data collection operations and create feedback mechanisms to strengthen the overall implementation.

9. **Teamwork is an important facilitator for progress:** Technical assistance on teamwork might help health center teams to learn to delegate certain types of work (for example, blood pressure measurement and titration of medicines) and promote more efficient and effective workflows. For teamwork to be effective, though, workflows, role definitions, scope of practice clarifications need to be carefully understood across the team. To increase effective team-based care continuous training of new personnel needs to be in place.

Recommendation: Continuous training should happen in tandem to efforts to ensure institutionalization of the team-based model.

10. **General change overload:** Some health center staff noted that the implementation of many different reforms at a time (the Statutory health law, integrated health care routes, and several other new policies, programs, strategies, and models), paired with ongoing data collection requirements and learning to use new software for new reporting requisites, was overwhelming. It is important to keep the pulse on the concurrent efforts and high sensitivity to staff needs through the creation of mechanisms where staff can provide feedback on the pace and absorption capacity for too much innovation at the same time.

Recommendation: Inclusion of health center leadership and direct service staff in committees or coordinating teams may help mitigate or prevent change overload among staff.

11. **Trainings through conferences, workshops and webinars:** This modality of technical assistance addressed directly to providers was also put in place by PAHO and it received praise from the participants for whom the opportunity to partake in national and international conferences is scarce, considering that an important number of health centers were located in rural and semi-rural areas with less connections to national and international networks. Similarly, virtual education through the HEARTS virtual courses and webinars was very well received, with the caveat that some health centers did not provide the time nor space for providers to take the courses and thus the responsibility to find the time (outside of work hours) was passed on the providers. The best experiences were those with structured learning opportunities at work. Therefore, making arrangements for staff to take advantage of the virtual learning opportunities may afford a great and low-cost opportunity to invest on staff development.

Recommendation: Peer exchanges among health centers with a focus on training modalities may facilitate the inclusion of structured learning spaces and opportunities for staff in all centers.

12. **Patient engagement:** Although at the health center level there is a lot of energy, creativity, and efforts in terms of patient engagement, there is relatively little guidance, support, and recognition of this component from the international sponsors. Strengthening and lifting the best practices being implemented in this area would incentivize and reinvigorate aspects of the implementation that are currently less visible but equally important. Efforts should also be directed to obtain patient feedback to improve patient-staff interaction and patient engagement.

Recommendation: Peer exchanges among health centers and feeding back recommendations to international partners may increase the visibility and uplifting patient engagement as part of the aim of having activated patients.

These recommendations aim to promote conversations among practitioners and recognize that the challenges to a full adoption of the model are numerous and diverse at every level of implementation, there are many moving parts to address the multiple components of HEARTS simultaneously. For instance, health centers face challenges in different domains, first those related to related to resources and leadership, which often may act together, for example, changes in government from the top all way to the health center leadership; passing through municipal mayors, ultimately may result in different resource allocation patterns. It is important to note that mayors have not been considered at all in the implementation of HEARTS and should be considered key stakeholders. In addition, health care provider and patient cultural scripts sustain long-entrenched behaviors which pose resistance to change. Additionally, even when change is implemented at the primary care level,

other providers (specialists and hospitals) treating the same patients often do not share the same incentives to coordinate care. Overcoming these challenges require time, resources and effort in a consistent manner on a time horizon that differs from political office terms; unfortunately, political office terms may exert excessive weight over the shoulders of health administrators and providers. Finally, the Achilles heel of the implementation in Colombia may be the **influence of insurers** and the lack of involvement of this group thus far. Finding a strategy to engage insurers into the HEARTS implementation may prove one of the most important steps towards the advancement of the initiative.

LIMITATIONS

Four criteria, often cited when assessing the rigor of qualitative research, are credibility, dependability, confirmability and transferability. These four qualities were considered throughout the execution of the study. (Shenton, 2004; Guba & Lincoln, 1985) Credibility refers to the believability of the research findings and is enhanced through prolonged engagement, peer debriefing, and triangulation. In this dissertation work, high quality rapport was built with interviewees as a result of the high level of familiarity of the researcher with the overall HEARTS initiative background and intimate knowledge of the Colombian culture; in addition, the prestige enjoyed by the university with which the researcher is affiliated may have also aided in building rapport. Being from a well-known U.S. university created a feeling of respect for the work and the seriousness of the interview. Due to timing issues related to completion of degree on a constricted timeline, there has not been debriefing with participants; however, immediately after dissertation process finalization, there is a firm commitment to present findings to participants through a report. However, no formal feedback from participants has been obtained. Finally, triangulation through obtention of quantitative data would greatly enrich the current findings.

Dependability and credibility are related concepts, which refer to the stability and accuracy of the data. These qualities may be enhanced using audit trails and reflexivity. (Houghton et al. 2013). The analyses conducted are well documented with the tools provided through the Dedoose program with features such as memos, and saved analysis history.

Applied reflexivity to condition and potential bias resulting from researcher's affiliations

The researcher has been working with the international team that is leading the implementation in the Americas providing technical and coordination support. As such, the possibility of researcher bias arises as the researcher has been interacting with some of the stakeholders who lead the national and local work at the implementation sites. Some disadvantages may be that intervention stakeholders may be more cautious and less candid in their responses, and methodological rigor and credibility of findings may be questioned by external audiences. To prevent any perceived or real bias, the following measures were taken:

1. Researcher sought official approval of the Ministry of Health of Colombia and of every health center director demarcating clearly the academic nature of the study whose purpose was to fulfill the requisites of a doctoral program and its strict separation and independence from the temporary employment arrangements with the international organization. The Ministry of Health of Colombia approved the study as it responded to the need of documenting and evaluating the HEARTS implementation and requested that results be reported back as they are to be utilized to enhance implementation.
2. To reduce researcher bias during interviewing period, the researcher contracted experienced master's degree-level interviewers. These two interviewers were trained by the researcher and were completely independent from the relationship with the international organization.
3. Although the researcher has been part of the implementing team, her affiliation with the international organization is relatively recent. Her outsider perspective, as a recent temporary hire,

and her training and background in program implementation at the community level, triggered the questions about the absence of an explicit theory of change and curiosity about the understanding of the Initiative at ground level. The timing of the concept proposal coincided with her assignment as a short term professional with the organization without having anticipated an extended temporary assignment of more than a 12-months.

4. The study has been entirely self-funded by the researcher and the data collection phase was conducted while the researcher was on leave from the organization. Additionally, there has been complete independence from the international organization during the entire research process, including the results analysis.
5. The utilization of a qualitative data analysis software, Dedoose™, allows for safe storage and management of the data and the analysis trail; creating the possibility of review of the data by additional researchers for future analysis, utilizing the inter-reliability testing tools, among others.
6. To honor the confidentiality of all participants, the data are presented with careful redaction of names and potential identifiers.

Additionally, as this dissertation has attempted to weave together bodies of knowledge, an important resulting recommendation is a more focused and intentional utilization of quality improvement approach and methods. And within the quality improvement literature, an interesting discussion has emerged about a new framework for learning about improvement and it calls for exploring the role and location of evaluation within implementation. The authors (Barry et al., 2018) explain how collaboration between evaluator and improvers [implementers] may be enhanced through "embedded evaluation design to create rigorous, adaptive evaluation and improvement program designs…" The article reports on the consensus reached among evaluators, scale-up experts and other improvement and implementation scientists and posits that:

> *The field of improvement should move toward more highly embedded models for evaluation and improvement design. Embedded evaluation allows for closer communication, coordination and potential co-location of implementers and evaluators. Embedded evaluations tell us not just whether an improvement program "worked" but also provides information about why an improvement program did or did not work in consideration of the context and theory of change of the improvement program…*
> *[Authors] favor more highly embedded evaluation to facilitate shared learning between implementers and evaluators so that the theory of change and associated activities can be amended in close to real-time, thus accelerating adaptation and improvement.*

Therefore, some advantages to having researcher act as a quasi-embedded evaluator may be:

1. Researcher approached the study with an in-depth knowledge about the background, local and regional context as well as the policy landscape
2. As this study was conducted to comply with the partial requisite of the doctoral degree and was entirely self-financed; it results in a no-cost qualitative evaluation for the Ministry of Health of Colombia.
3. The data collection process provided an opportunity for intervention staff to reflect upon and understand the complexity of the intervention in a much more nuanced way.
4. Researcher has a direct channel to share evaluation results with international bodies that can influence enhancement of intervention in the Region and the world.

Additionally, transferability refers for the potential generalizability of results. This may be an important limitation of the study due the inherent selection bias due to the way that primary care centers were originally selected to be HEARTS implementers in Colombia. As it became obvious through the interviewees, these centers were selected to be part of HEARTS as early adopters due to their highly motivated staff and other characteristics that may increase the chance of successful implementation; therefore, these original health centers may not be truly representative of health centers in their own departments (states) or in a Colombia overall. However, the rich and nuanced information obtained does represent the voices of fifty implementers in Colombia. On the other hand, most data are self-reported, and they were collected at one point in time so there may be some recall bias; however, the high number of participants and their rich and textured information provided may counterbalance these potential

limitations. Finally, Colombia has a complex health care system, with some unique characteristics in the region and in the world, which provides useful lessons but must be viewed with caution when looking to lessons that can extrapolated for other countries.

FUTURE RESEARCH

Implementation science provides an approach to study a diversity of aspects related to the implementation of the HEARTS model. Therefore, there is a fertile landscape to conduct intra-national and international research. Researchers may select a subset of domains from the CFIR for example in the Outer setting domain, the construct of external policies and incentives may facilitate the study of powerful incentives within the health system that may fuel asymmetry among health care system actors (insurers, providers and patients) and consequently affect implementation. Similarly, the CFIR can be utilized in multi-country comparisons given the regional and global implementation of HEARTS, offering a common set of domains and constructs and converging on a common language. Other topics for future research may include the application of a quality improvement lens to implementation in health centers in Colombia. And given the fundamental intent to scale-up implementation, future research should focus on elements related to successful scale-up. As after the data collection period, through personal communication, it was informed that there is an ongoing effort of expansion and scale-up in the capital city of Bogota. A successful implementation in the capital city, with the largest population in the country and a relatively well financed city health department, may be an inflection point to continue with scale-up inside the currently implementing departments and the rest of the 27 departments of the country. Therefore, future research may be greatly enhanced by studying these new geographical areas of implementation. Finally, where the CFIR provides a common language and the basis for comparability among HEARTS implementers throughout the Americas and the world, utilizing other models from other disciplines such as Complex Adaptive Systems, from complexity science may bring a fresh tool that can also help accelerate implementation and scale-up.

Final remarks

> *From the edge of everyday life, due to the fragmentation and segmentation of the health system and health services in Colombia, what is observed is that the hypertensive patient falls in a monotonous cycle of passive interaction with his doctor who manages his disease; seeding in him expectations that do not go farther than receiving a periodic prescription and being left at the expense of the uncontrolled risks due to lack of follow up, resulting in failures in treatments (both pharmacological and non-pharmacological), or left at the mercy of the complications of the condition itself.*
>
> - (Rúa-Moncada, 2017)

This description of a hypertension scholar in Colombia captures a composite of voices from primary care providers who share this view about some current care delivery scenarios that may be leaving patients on their own, lacking standardized protocols, and especially lacking systems for patient follow up, monitoring and performance feedback loops. Through this qualitative study, the perspectives of primary care physicians, nurses and nursing assistants from the initial public primary care centers implementing the HEARTS Initiative in Colombia have been gathered. A salient theme has been that the innovations brought by the HEARTS model triggered actions that are conducive to a reorganization of elements of health care delivery for hypertension and in general chronic care at the primary care level, based on global best practices. Many of these innovations were already delineated in Colombia's integral health care routes. HEARTS seemed to allow for a swift operationalization of the cardiovascular health care route through insertion of the HEARTS model, offering a pragmatic pathway to action.

This study is one of the first implementation science based qualitative evaluations of the implementation of the HEARTS technical package, a WHO "best buy", with emphasis on hypertension control in a middle income country in Latin America. The ultimate contribution is practical knowledge about implementation that may be utilized by Ministries of Health and local health authorities to scale-

up the implementation of the technical package across the Americas. The study has yielded a nuanced, richly textured, multi-dimensional implementation mapping of HEARTS from the ground up in Colombia.

This stepwise implementation mapping may serve as a platform to continue forging forward with implementation by visualizing the current actions and processes that have taken place in the original primary health centers. It also creates opportunities to add quantitative evaluation components to this and other HEARTS implementation scenarios and leaves the terrain ready for harvesting multi-site and inter-country comparative studies as the Consolidated Framework for Implementation Research provides the common language and aids to unify concepts on implementation.

Finally, the results may assist all countries participating in the implementation of HEARTS and new countries contemplating to implement, to develop and to tailor implementation science based studies and methods with the ultimate aim of improving health care services for the people in the region of the Americas.

APPENDIX A

INTERVIEW GUIDE (SPANISH LANGUAGE)

Evaluación de la implementación de un paquete técnico para la reducción de enfermedades cardiovasculares con énfasis en el control de la hipertensión en Colombia

Guía de Entrevista Semiestructurada dirigida a Personal de Salud
ENTREVISTADOR:
LEER EL CONSENTIMIENTO INFORMADO (DOCUMENTO ADJUNTO)

Fecha: _____ Hora: _____ IPS:_____
Municipio: _____ Departamento: _____

- Descripción de su cargo
- ¿Cuál es su cargo dentro de su institución prestadora de servicios en salud?

Profundizar

- ¿Cuál es su título y rol dentro de la institución?
- ¿Qué cargo desempeña su jefe inmediato?
- ¿Cuál es su papel en la implementación de las *HEARTS?*

EXPERIENCIAS PREVIAS A LA IMPLEMENTACIÓN

- *[Identificar el lenguaje utilizado: RUTAS Integrales de Atención (RIAS) de Cardiovasculares y/o Modelo de Acción de Acción Integral Territorial (MAITE) o Estrategia HEARTS, Tome el Control u otra expresión para referirse al conjunto de estrategias para mejorar el control de la hipertensión*
- ¿Cómo identifica usted la intervención o programa que se esta realizando en este centro de salud para la mejora de la atención al paciente con hipertensión?
- ¿Cómo describiría usted la intervención o programa para un colega de otro centro de salud donde se va iniciar la implementación y la persona no tiene ningún conocimiento previo al respecto?

- ¿Cómo fue la introducción de la intervención o conjunto de estrategias inicial que se hizo en la IPS?
- ¿Cómo usted entendió el programa [HEARTS] antes de que se implementara?
- ¿Hubo alguna información que permitiera vislumbrar si [HEARTS] pudiese funcionar en esta IPS?

Profundizar

- ¿Información indagada por usted mismo, guías clínicas, literatura publicada u otras fuentes? ¿De compañeros de trabajo? ¿De supervisores? ¿De la secretaria de salud? ¿Del Ministerio de salud?
- ¿Hasta qué punto influyó en su opinión la evidencia de HEARTS antes de que se implementara?

¿Qué tipo de servicios se ofrecían antes a los pacientes que tienen presión arterial alta esta IPS?

- Profundizar
- ¿Cómo se estaban tratando a los pacientes con hipertensión?
- ¿Hasta qué punto?
- ¿Hubo iniciativas similares a HEARTS?

- ¿Cómo percibe HEARTS frente a otras alternativas para el control de la hipertensión?
- ¿En qué medida hubo "competencia" por los fondos, el tiempo o la atención debido a otras iniciativas que pueden haber tenido lugar simultáneamente?

¿Identificó necesidades que requirieran una intervención como HEARTS?

- Profundizar
- En ese momento ¿cómo pensaba que HEARTS podría satisfacer las necesidades identificadas por el personal de salud y los administradores?
- ¿Qué resultados iniciales han obtenido los pacientes con hipertensión después del inicio de la implementación de HEARTS?
- Actualmente, ¿qué tanto el programa satisface las necesidades identificadas?

¿Cuáles fueron los debates o conversaciones que se dieron para abordar esta cuestión de adoptar medidas o estrategias como HEARTS?

¿Cuáles fueron las alternativas consideradas? Si fue más de una ¿por qué se adoptó esta?

Profundizar

- ¿Favorece de alguna manera en el proceso de trabajo?, ¿de qué manera? (cantidad o tipo)
- **¿Cómo fue la participación de las personas encargadas de introducir HEARTS en esta IPS previo a su implementación?**

ETAPA DE IMPLEMENTACIÓN

- **¿Hizo parte de la introducción de la implementación de HEARTS?**
- **¿Cuáles considera que fueron los momentos o hitos principales de la implementación?**
- Profundizar
- Fechas exactas y/o aproximadas, sucesos que considere clave en la implementación
- **¿Qué aspectos recuerda o conoce sobre la implementación de HEARTS en su institución?**
- **¿Cómo se involucró esta IPS en la implementación de HEARTS?**

Profundizar

- ¿Considera que la implementación de HEARTS fue impulsada externamente o motivada internamente?
- ¿Cómo se decidió su participación en HEARTS?
- **¿Con qué infraestructura cuenta la IPS para el desarrollo de HEARTS?**
- ¿Cuentan con la infraestructura y equipos adecuados?
- ¿Tienes computadoras?
- ¿Cuentan con espacios adecuados?, ¿Cuáles?
- ¿Dispositivos para medir la presión arterial? ¿Sabe si los dispositivos son validados?
- Señale si faltan elementos de infraestructura básica para el adecuado desarrollo de HEARTS

¿Con qué otras unidades/servicios ha trabajado para implementar HEARTS?, ¿De qué manera?

EXPERIENCIAS DE IMPLEMENTACIÓN

- Según su experiencia con HEARTS, en una escala de 0 a 10, donde cero (0) es muy fácil y diez (10) casi imposible:
- Implementar HEARTS en mi IPS recibe una puntuación de ____ en viabilidad.
- **¿Qué tan difícil fue el funcionamiento de HEARTS en sus centros o instituciones de salud? ¿Por qué?**

Profundizar
- ¿Qué barreras experimentó en la implementación de cada componente?
- ¿Cuáles fueron los facilitadores que experimentó en la implementación de cada componente?

- **Protocolo simplificado de tratamiento de la hipertensión ó algoritmo:**
- ¿Se esta utilizando un protocolo simplificado de tratamiento?
- ¿Cuál ha sido su experiencia con este protocolo de tratamiento?
- ¿Qué barreras existen para la utilización del protocolo?

- **Acceso a Medicamentos y tecnologías esenciales**
- ¿Tiene conocimiento si los medicamentos incluidos en el protocolo están siendo de fácil acceso para los pacientes?
- ¿Hay medicamentos antihipertensivos de dosis fija combinada disponible a los pacientes? ¿Para todos los pacientes? ¿O para un subgrupo de pacientes?
- ¿Cuáles son los tipos de dispositivos que se utilizan para la medición de la presión arterial?
- ¿Hay dificultades para tener acceso a dispositivos para la medición de la presión arterial?

- **Atención basada en equipo multidisciplinario**
- ¿Se ha promovido la atención del paciente en el equipo de atención? ¿Cómo?
- ¿Cuál es la configuración del equipo de trabajo?
- ¿Cómo describiría los roles de cada miembro del equipo?

- **Sistema de Monitoreo**
- ¿Se está utilizando un registro clínico de seguimiento de los pacientes?

EXPERIENCIAS OPERATIVAS
- **Una vez que HEARTS se implementó completamente y usted comenzó a referir a los pacientes, ¿cuánto tiempo y esfuerzo fue necesario para su funcionamiento cotidiano?**
- Profundizar
- ¿Se incurrió en tiempo o esfuerzo adicional o imprevisto para implementar todo? Por ejemplo, soporte de TI, equipos de resolución de problemas, etc.
- ¿Qué recursos se necesitarían para mantener a HEARTS en marcha a largo plazo?

- **¿Qué disciplinas o servicios están involucrados con HEARTS en sus centros o instituciones de salud?**

Profundizar
- Enfermeras
- Médicos
- Farmacéuticos

- ¿Sólo dietistas? ¿Médicos (qué especialidades)? ¿Otro?
- Trabajadores de la salud de la comunidad
- Describa su participación

- **¿**Qué actividades se desarrollan en la IPS en el marco de HEARTS?
- ¿Cómo considera el nivel de capacitación del personal para mejorar la atención del paciente con hipertensión? (Alto, mediano, bajo) ¿Por qué?
- ¿Qué actividades se han llevado a cabo para mejorar la preparación del personal de salud en el contexto de esta intervención?

Profundizar sobre medición de la presión arterial
- ¿Cómo hace(n) en esta IPS el diagnóstico para identificar la presión arterial alta?
- ¿Cuál es el personal que realiza la medición de la presión arterial? ¿Dónde lo hacen?
- ¿Quién(es) documenta(n) las lecturas de presión arterial en los registros de HEARTS?
- ¿Cuál es el procedimiento de inscripción de pacientes en el registro de HEARTS?,
- ¿Qué actividades o estrategias de difusión se realizaron en el territorio?
- Profundizar sobre el seguimiento del paciente con hipertensión
- ¿Quién programa las citas de seguimiento de HEARTS?
- ¿Estás usando recordatorios clínicos?, ¿Cuáles?
- ¿Quién hace las llamadas telefónicas de seguimiento? ¿Cómo se documentan las llamadas?
- ¿Quién realiza el seguimiento al progreso de los pacientes?
- ¿Cómo se comunican las consultas de Segundo Nivel?

Profundizar en el asesoramiento de estilos de vida saludable

- ¿Quién(es) se encarga(n) de la asesoría sobre estilos de vida saludable?
- ¿Qué tiempos se dedican a la asesoría? (Duración, Frecuencia, periodicidad)

- **¿Podría describir el proceso que utilizó para programar visitas de control de hipertensión HEARTS con los pacientes?**
- Profundizar
- ¿Qué tipo de soporte tenía de TI?
- ¿Qué tipo de apoyo tuvo del resto de personal? por ejemplo, supervisores y apoyo para asignar espacios de citas a pacientes con control de hipertensión

- **¿Qué tipo y nivel de participación tienen los líderes de esta IPS con el programa HEARTS?**
- Profundizar
- ¿Qué tipo de apoyo recibió? Ejemplo específico
- ¿Sabían de la implementación de HEARTS?

EXPERIENCIA DEL PACIENTE
- **¿Se les ha comunicado a los pacientes de que se esta implementando una intervención para mejorar la atención?**
- **¿Cómo los pacientes se enteraron del programa?, ¿hubo preguntas de los pacientes que sobre HEARTS al conocer la estrategia o después de empezar a participar en la IPS?**

- **¿Qué pensaron los pacientes sobre HEARTS?**
- **¿Qué tipo de impacto tuvo HEARTS en los pacientes?**
- Profundizar
- ¿Oportunidad de mejorar su salud?, ¿por qué?
- ¿Motivación para mejorar el control de su presión arterial?
- ¿Recibe atención extra?, ¿cuál?

EXPERIENCIA GENERAL

- **¿Qué tipo de apoyo externo recibió del Ministerio de Salud, Secretarías de Salud Departamental y/o Municipal durante la Implementación?**
- Profundizar
- Apoyo técnico, resolución de problemas, capacitación. Ejemplos específicos.
- ¿Cómo considera que fue la comunicación con el personal del Ministerio de Salud? ¿Secretarías de Salud? (Externamente, internamente)
- ¿Considera que el apoyo brindado por el personal del Ministerio de Salud, Secretarías de Salud fue suficiente?
- ¿Hay reuniones periódicas con el Ministerio de Salud y las Secretarías de Salud?
- ¿Cómo se utilizan los materiales del Programa HEARTS distribuidos a través de kits de herramientas de institución de salud y disponibles en el sitio web de HEARTS? Por ejemplo, los módulos HEARTS
- ¿Qué tan útil fue la información?

- **En términos generales, ¿qué piensan los [médicos] [enfermeras] [Asistentes de enfermería] de esta IPS sobre HEARTS?**

- **¿Considera que es capaz de hacer todo lo que te gustaría en un día corriente? ¿Por qué? ¿Es igual para sus colegas de la IPS? ¿Por qué?**

Profundizar

- ¿Describir otras prioridades que compiten con el control de la hipertensión?
- ¿Cuál es la naturaleza de los conflictos?
- ¿A corto plazo? ¿A largo plazo?

- **¿Cómo describiría las relaciones de trabajo entre unidades/servicios en esta IPS?**

Profundizar

- ¿Qué tan capacitados se siente al hacer su trabajo?
- ¿Tienen relaciones cercanas y de alto rendimiento entre el personal médico?
- ¿Cómo fueron las relaciones entre médicos, personal no médico, personal administrativo o personal de apoyo, es decir, empleados, gerentes de IPS?
- ¿Cómo afectan estas relaciones la capacidad de referir a los pacientes, programar citas, llevar a cabo asesoramiento de estilo de vida, configurar cosas, etc.?

- Algunas personas confían más en la comunicación formal, por ejemplo, comunicaciones por correo electrónico a través de la cadena de mando; mientras que otras utilizan la comunicación informal, por ejemplo, una conversación en el pasillo con un compañero de trabajo para lograr cosas.
- **¿Qué tipo de comunicación ha tendido a ser más útil para que usted realice sus actividades relacionadas con HEARTS?**

Profundizar

- Centrarse en las comunicaciones informales que incluyen discusiones no programadas entre el personal fuera de las reuniones formales.
- ¿Fueron útiles las comunicaciones informales? Ejemplos relacionados con HEARTS
- Si no hubo mucha comunicación informal, ¿por qué no la hubo? ¿Fue perjudicial la falta de comunicación informal?

- **¿Se comunica con otros médicos/profesionales que están fuera de esta IPS? Si es así, ¿podría describir la naturaleza de esas relaciones?**

Profundizar

- ¿Es miembro de un grupo o sociedad profesional? ¿Qué nivel de participación tiene?
- ¿Asiste a conferencias profesionales o relacionadas con el trabajo? ¿Entrenamiento externo?
- ¿Cómo han influido su red de contactos el trabajo?

NIVEL DE APOYO Y RECOMENDACIONES

- **En una escala de 0-10, ¿qué tan exitoso cree que es HEARTS en esta IPS? ¿Por qué?**
- **Si usted tuviera la opción, ¿recomendaría continuar HEARTS en esta IPS? ¿Por qué?**
- Profundizar
- Frente a otras iniciativas en salud para el control de la hipertensión, ¿qué tan efectivo considera que ha sido HEARTS?

- ¿Qué se necesitaría para mantener HEARTS en esta IPS?
- ¿Qué tipo de justificación tendría que demostrar para mantener esta intervención a largo plazo?

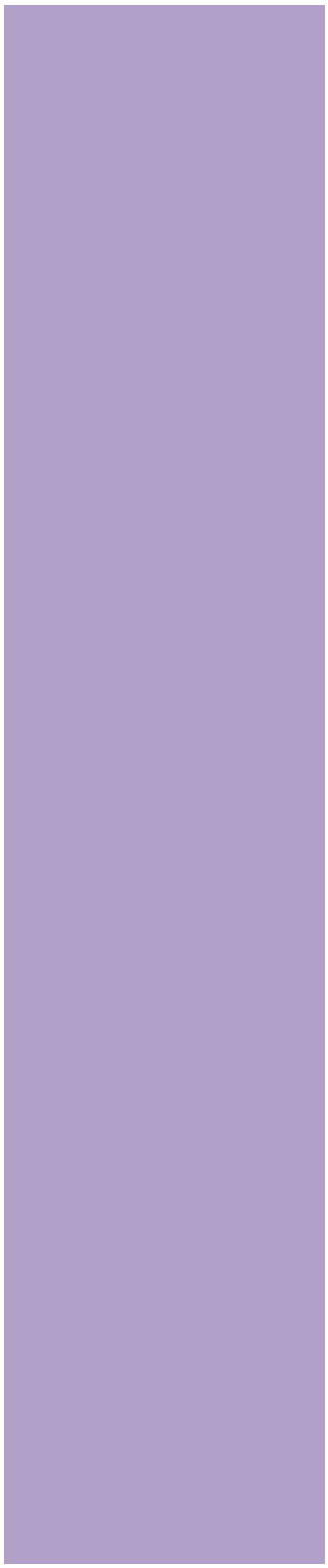
- **¿Recomendaría HEARTS a otras IPS? ¿Por qué?**
- **¿Tiene alguna sugerencia específica para otras IPS que aún no han comenzado a implementar HEARTS?**
- **¿Cómo mejoraría HEARTS? ¿por qué?**

MUCHAS GRACIAS POR SU PARTICIPACIÓN

APPENDIX B

TABLE - DATA CODING

PRIMARY INDUCTIVE ANALYSIS	INDUCTIVE CLUSTERING	CLUSTERING BY HEARTS COMPONENTS
Accuracy in blood pressure measurement	Active search of new patients	
Active search of new patients	Appointment periodicity	
Analysis book	Community based screening	
Appointment periodicity	Missed appointments	
Availability of electronic information system	Analysis book	
Availability of electronic manometers	Availability of electronic information system	SYSTEMS FOR MONITORING
Brief definition or objective of program	Reception of indicators	
Characterization of the population	Characterization of the population	
Chronic care model	Continuous monitoring	
Commitment	Costing Tool	
Communication or feedback to physician	Brief def or objective of program	IMPLEMENTATION GUIDE AND RATIONALE
Community based screening	Rationale or justification of Program	
complement to national clinical guidelines		


Unifying concepts
Comprehensive program for patients
conscientious patients
Continuous monitoring
Coordinating committee
Coordination between first and second level of care
Costing tool
Creating a common language
Customization of strategy to local specificities
CVD Risk consultation
Development of treatment algorithm
Diagnostic algorithm
Difficulties with meds delivery due to insurer
Difficulties with meds due to other reasons
Discipline
Comprehensive program for patients
Coordinating committee
Commitment
Creating a common language
Customization of strategy to local specificities
IMPLEMENTATION EXPERIENCE (Other centers)
Key facilitator for successful implementation
Chronic care model
Simplicity
Strengthening institution
success of implementation
Managerial tool
Leadership support

Partners

Ministry of health representative

National coordinator

Education to low literacy or illiterate patient

PAHO support

Exclusive or dedicated nurse

Type of Insurer contracting

Exclusive or dedicated physician

Need of insurer involvement

Fixed dose combination medications availability

Type of communication

Allies

Mention of public health policies

Greater organization of patient care

1. Development of treatment algorithm

Healthy lifestyle counseling space

complement to national clinical guidelines

Hypertensive patient workflow

Titration

IMPLEMENTATION EXPERIENCE (Other centers)

Treatment differentiation by black race

Key facilitator for successful implementation

Fixed dose combination medications availability

Leadership support

Diagnostic algorithm

Managerial tool

a. Accuracy in blood pressure measurement

Materials or kits for screening and measurement

Availability of electronic manometers

MD resistance to change

EVIDENCE BASED TREATMENT PROCOTOCOLS

Mention of patient adherence

Mention of "MAPA"
Mention of downstream evaluation
Mention of public health policies
Missed appointments

Multidisciplinary team

Need of insurer involvement
Not enough time for consult
Only MD diagnoses hypertension

PAHO support
Partners

patient feedback
Patient follow up

Perception of medical personnel
Personnel
Physician activation - being more alert
Rationale or justification of Program
Reception of indicators
Regular training spaces (structured)
Simplicity
Smoking cessation programs (or lack of)
Strengthening institution

success of implementation
Task shifting

Training
Undergraduate training
Titration
Treatment differentiation by black race
Type of communication

CVD Risk consultation

Healthy lifestyle counseling space

Smoking cessation programs (or lack of)
Patient follow up

Hypertensive pt workflow
Materials or kits for screening and measurement
Education to low literacy or illiterate patient
Mention of patient adherence conscientious patients

Greater organization of patient care
patient feedback
Task shifting

Multidisciplinary team
Communication or feedback to physician
MD RESISTENCE TO CHANGE
Perception of medical personnel
Physician activation - being more alert
Not enough time for consult
Only MD diagnoses hypertension
Personnel
Discipline

Training
Regular training spaces (structured)
Virtual courses
Undergraduate training

RISK BASED MANAGEMENT

HEALTHY LIFESTYLE

TEAM BASED CARE

Type of Insurer contracting
Unifying concepts
Virtual courses

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