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## HEALTH POLICY STUDIES

## Colombian Health System on its Way to Improve Allocation Efficiency—Transition from a Health Sector Reform to the Settlement of an HTA Agency

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## ABSTRACT

Over the past 20 years, Colombia has invested major efforts in ensuring universal health care access to its citizens while facing epidemiological transition and demographic changes. The country, as any other region in the world, is challenged by financial constraints and market pressures for entry of new and frequently costly technologies. After the 1993 health sector reform, Colombian citizens are entitled to health care access via mandatory health insurance through a benefits plan. Inclusions to this plan were the first attempt to establish a formal methodology of health technology assessment. Later on, the dynamics of insurers, market pressure, reimbursement

decisions, and judicial actions drove the government toward the formulation of an infrastructure to improve efficiency in the use of resources. This article accounts for the steps undertaken by the Colombian health system until the establishment of a health technology assessment body and outlines the most important issues that can be learned from this process.

**Keywords:** Colombia, health care sector, health care technology, health technology assessment, policy.

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### Introduction

From 1993 Colombian citizens are entitled to health care access via mandatory health insurance through a benefits plan [1]. Health coverage as well as most performance indicators improved vastly, but the country faced the issue of needing a rational strategy to allocate resources. Between 2005 and 2010, the consumption of nonincluded technologies increased at rates as high as 855.89% [2]. Alongside, judicial interventions became the most common means for citizens to gain access to nonincluded technologies, a fact that has threatened the financial sustainability of the system in the midterm.

Various actions over these past two decades have been undertaken by current and past governments with the aim to control costs and strengthen the system's institutional capability to allocate resources. It is only in the last 2 years that the formal methods of health technology assessment (HTA) have seized the attention of policymakers. Last January 2011, Colombia enacted by law its own HTA agency, which is still under organizational design [3].

This article accounts for the steps undertaken by the Colombian health system to achieve its aim to improve the allocation of

resources and describes how the health system reform (HSR) led to the creation of the agency.

### Colombian Health System

Colombia is a middle-income economy with an estimated population of 46,581,823 million inhabitants (22,997,087 men and 23,584,736 women) for the year 2012 [4]. Over the last 30 years, Colombia has experienced demographic and epidemiological changes such as a rapid decrease in total fertility rates, a significant increase in life expectancy, and fast urbanization rates.

Before the HSR only a third of the population was covered by social insurance, and more than half of the total expenditure for health was attributable to out-of-pocket spending. In 1993, Colombia launched the HSR that replaced the previously segmented and low-coverage model. These changes prompted a competitive market that included insurers and health care providers. According to figures from the Ministry of Health and Social Protection, Colombia reached a health coverage of 96% in 2011 Figs 1-3 [5].

Law 100 of 1993 unified public and private health systems into one called the "General System of Social Security in Health" [1].

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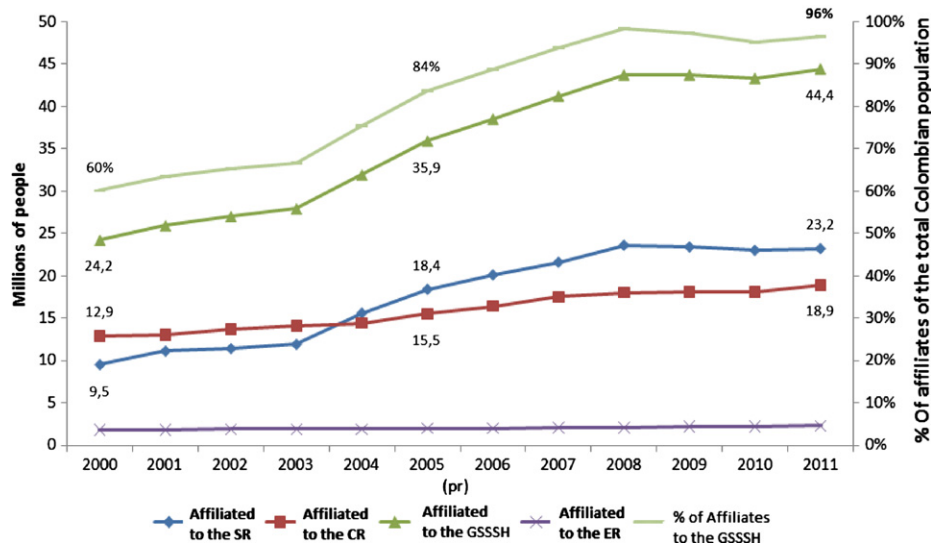


Fig. 1 – Colombian health system coverage. Source: Fedesarrollo, Ministry of Health, and Fund of Solidarity and Guarantees.

Legislation aligned the system into functions and responsibilities rather than into groups of populations [6]. There is a contributive regimen for those with ability to pay and a subsidized one for those without it. The population covered by the subsidized regimen (mostly unemployed) is selected on the basis of a survey performed by the government. Funding of the system is based on a combination of social security and payroll taxes of formal employees.

Health care providers are both public and private in this system, and all affiliates have access to a benefits plan defined by the government periodically. Alongside the official list of benefits, the system also reimburses more than 700 nonincluded drugs and technologies that are claimed by patients through exceptional mechanisms (judicial actions).

Insurers play a very important role by administering these benefits plan to patients. At this moment, concentration is taking place in the health sector and the smaller and less efficient insurers are being absorbed by stronger competitors. Insurers operate with an insurance premium known as the Capitation Payment Unit, an amount of money transferred by the government for each individual enrolled in

each company. In 2012, there was a differential unit between the two regimens: \$304.24 USD per year for the contributive regime and \$240.94 USD per year for the subsidized regime, a fact that contributed to inequity within the system. This premium is adjusted against epidemiological variables and geographical differences [7].

There are also supplementary (voluntary) health insurances known as prepaid medicine, all of which offer additional coverage to the basic benefits plan. These plans are completely funded from private spending [1]. The system also comprises coverage for special populations such as military forces, public education workers, and the national oil company employees, all of whom have different benefits plans and do not pool their resources within the system.

Finally, there is a Basic Health Plan that addresses public health issues and covers all citizens regardless of their insurance status. Municipalities and local health authorities provide health promotion and disease prevention programs through the BPH. BPH is funded from alternative sources than those of the general system. There are two complementary plans that cover health care services derived from road accidents and natural disasters.

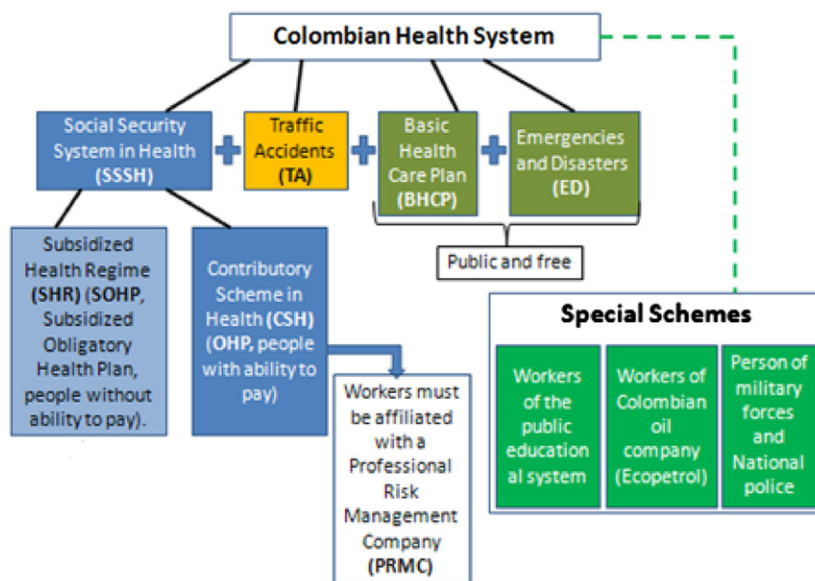
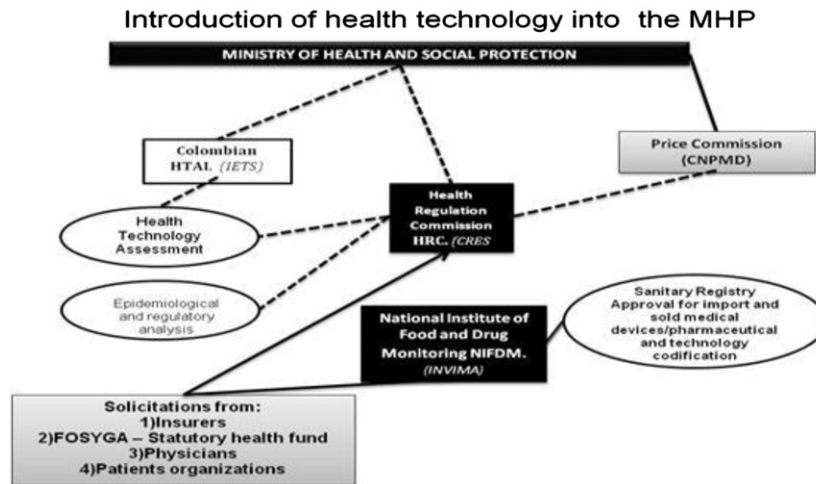


Fig. 2 – Colombian health system composition.



**Fig. 3 – Stakeholders involved in the eventual HTA process. HTA, health technology assessment.**

According to the World Bank, Colombian spending on health in 2010 was nearly 7.6% of the gross domestic product and Colombia was one of the Latin American countries that expend more in health as a percentage of the gross domestic product. The HSR separated funding from health care delivery and gave an important stimulus to the creation of private health institutions [8].

### **The Efforts Invested Aimed at Improving Allocation Efficiency Over the Past Two Decades**

This section accounts for the steps undertaken by the Colombian system to conduct and use HTA to inform decision making. From early nonsystematic methodological approaches to early attempts at institutionalization to the recent enactment of its own HTA agency, this section describes the incremental process of policy making toward the use of HTA.

### **Mechanisms for Updating the Benefits Plan (1998–2007)**

From 1998 to 2000, no updates were made to the plan (with the exception of Decree 806/1998 [9]). From 2000 to 2006, only specific inclusions were made. Before 2002, update proposals were prepared and presented by the National Council for Social Security to the Ministry of Health (MOH).

In 2002, the Health Technology and Medicines Committee was set up to support the former and the general council [10]. This new committee, however, found it challenging to meet its remit because of methodological and financing issues (e.g., lack of resources for commissioning research, organizing meetings, and rewarding its members). As a result, the MOH progressively took over council's responsibilities for updating the plan, some of which included commissioning research to inform such updates (a role later transferred to the Health Regulatory Commission [GRES]) [11].

### **Draft of HTA Legislation (2004)**

In 2004, the creation of an HTA coordination center at the MOH and a technical advisory committee to assist the committee were proposed. It considered stakeholders at three levels: macro MOH, Ministry of Finance, National Council for Social Security (now CRES), National Institute for Surveillance of Medicines and Food (Instituto Nacional de Vigilancia de Medicamentos y Alimentos), National Department for Planning, regional health secretariats;

meso (insurers, providers, and industry); and micro (professionals, patients and their families, and community).

By this moment, judicial actions were becoming the most important medium of access for nonincluded technologies. But it was only in 2004 that technical scientific committees were created to try to filter and control these actions. Ministerial Resolution 3797 [12] regulated submissions of nonincluded services, and all insurers were obliged to form their committees.

The burden of disease between different subpopulations was very different and adverse selection among insurers became an issue that the government had to control. Therefore, Decree 2699 of 2007 created the National Account of High Cost, as an effort to adjust for primary risk and adverse selection among insurers of catastrophic spending cases; this account is administered by insurers. Chronic renal failure and HIV/AIDS among others were considered as catastrophic diseases by Decree 5261 of 1994 [13]. After piloting in 2008, the committee started operations focused on renal failure but subsequently added diseases including cervical, breast, stomach, colorectal, and prostate cancers, acute lymphoid leukemia, acute myeloid leukemia, Hodgkin and non-Hodgkin lymphomas, epilepsy, and rheumatoid arthritis to the list.

From 2006 onward, evidence-based clinical guidelines were introduced for HIV/AIDS, chronic renal failure, and family planning for both regimes (contributory and subsidized), and for type 2 diabetes and hypertension for the subsidized one [14].

### **National Plan for Public Health (2007–2010)**

By Presidential Decree 3039 of 2007, the MOH adopted the National Plan for Public Health, which established main priorities such as neonatal care, sexual and reproductive health, oral health, mental health, communicable diseases, chronic noncommunicable diseases, disabilities, nutrition, health, and safety at the workplace and enhancement and strengthening of national public health. The technical mechanisms used to choose over priorities are not clear.

### **Creation of the Health Regulatory Commission**

- In 2007, by Law 1122 [11], the Health Regulatory Commission was created as an autonomous, special unit, ascribed to the MOH, responsible for updating contents of the benefits plan. Over the past 3 years, this commission has worked toward the establishment of a methodology for HTA and its appraisal.

### Constitutional Court Mandate T-760 (2008)

Judges at local and regional levels have been involved in decision making within the health sector from late 1990s and early 2000s onward. Judicial actions have ordered the provision of services not explicitly included in the benefits package at the expense of health system's funds. According to figures from "Defensoria del Pueblo" (People's advocates), in 2005 there were more than 250,000 judicial actions, 36% of them directly related to health care [15]. According to official data from the MOH, 86.9% of exceptionally reimbursed costs in 2009 (Col \$1.7 billion) were derived from nonincluded services within the contributory regimen [16].

In late 2008, the Constitutional Court's mandate analyzed 22 judicial actions cases and ordered the executive (MOH, CRES, Committee and National Superintendence for Health) to address structural issues that have threatened equity, financial stability, and control of the reimbursement process. To comply with this mandate, an additional Col \$350,000 million were added to the total budget for health in 2008 and Col \$585,000 million in 2009. A number of institutional reforms have taken place as well as part of the effort to improve efficiency within this health system.

In 2009, the Health Regulatory Commission [17] proposed three courses of action as policy solutions: 1) To gather information and relevant data for priority setting (national health surveys, burden of disease, actuarial analysis of insurance premiums, cost and utilization analyses, inputs from relevant stakeholders); 2) To carry out prioritization of services and technologies (stakeholder consultation, evidence-based clinical guidelines, introduce new coding methods to increase reliability of data, and to strengthen the communication strategy); and 3) institutional strengthening. This commission updated the benefits plan last December 2011, but its methods were resisted because of the methodological weakness on the application of HTA principles. Nevertheless, an important process of consultation with citizens was performed and first efforts to debate issues such as prioritization, inclusion or exclusion of technologies, and budget assessments were made.

### Law 1438 as a New Attempt of an HSR (2011)

In January 2011, Law 1438 was enacted as an effort to put together different policy solutions to a list of structural weaknesses within the health sector [3]. It aimed at pursuing universal coverage, portability of entitlement, equalization of benefit plans, institutional strengthening, and financial sustainability. This law commands the government every 4 years to evaluate the macro-level performance of the health system. With regard to priority setting, the more remarkable articles of the law state the following:

- The National Observatory for Health is created to monitor relevant indicators of public health, provide technical support to national-level authorities, improve epidemiological data, advise the MOH and CRES, and report to the Congress key performance indicators (Article 8).
- It enquired the regulatory commission to update the benefits plan for children and adolescents (Article 17).
- Allowed insurers to enroll citizens from both regimens.
- Mandates benefits plan to be updated every 2 years, using epidemiological data, burden of disease, and budget and financial considerations.
- Mandates that methods to be used for updating the benefits plan should be clear and transparent and with stakeholder engagement (provider's organizations, professional bodies, service users, scientific societies, and other relevant stakeholders).
- Mandates that decision making on reimbursement should be made only by the administrative authority responsible for these matters with the first update to be completed by December 2011.
- Required that every prescription of nonincluded services and technologies ought to be assessed by technical scientific

committees in an independent manner.

- Creates the Technical Scientific Board of Peer Reviewers to assess each physician's nonincluded prescription (both approved and denied by the committee) within 7 days of submission.
- Establishes a new national policy for medicines, medical supplies, and devices, to improve efficiency, equity of access, and quality. A new National Commission for Prices of Medicines and Medical Devices will be in charge of price regulation for medicines and devices. The MOH will establish a price negotiation mechanism for medicines and devices on the basis of reference pricing, and IPS will not be allowed to pay above these reference prices.

### The legal entitlement to the MOH to create the Institute for Health Technology Assessment [3]

Colombia experienced a process of transition for HTA assessments and appraisals. Market pressures and innovation process within the industry made these types of evidence available for various stakeholders, and yet the structure was not entirely assumed. The creation of the IETS is a first step toward the consolidation of local evidence and the empowering of decision makers.

The most important aspects of this new agency are (for now) entitled by law and will be as follows:

- IETS's objectives will be to develop the HTA process on the basis of safety, efficacy, effectiveness, utility, and economic impact of the technologies evaluated.
- IETS will be the body to ensure assessment of evidence and will return evidence to the MOH for it to be the appraisal organization.
- IETS will be a not-for-profit, public-private organization that may include, among others, scientific societies and the Colombian Academy of Medicine.
- IETS will develop evidence-based HTA, clinical guidelines, and protocols to guide the use of medical procedures and medicines, influencing decisions about medical pertinence.
- IETS will make use of accredited centers for HTA at national and international levels.

## Discussion

The case of the Colombian health system provides information on how context, policy, and political challenges and solutions could incrementally lead to the systematic use of evidence to inform health policy. The country's financial constraints, competing priorities, fragmentation, and citizens' tradition to challenge health care coverage, as well as the lack of institutional capacity, led the government to enact by law a new HTA agency.

It is expected that the agency in its beginning will attend to technical issues such as the prioritization of technologies, creation of local data, relevance of modeling (health economic models, quality-adjusted life-years, expert elicitation, etc.), role of real-life studies, whether there is a specific threshold, the relevance of budget impact analysis, and so on.

The interaction between all the relevant governmental bodies and the flow of information between them will be a key factor that needs to be taken into account for the assessment of the impact of the agency's role. Whether the recommendations of the agency will be in the form of guidance or mandatory and which groups would be targeted to implement are issues that heavily rely on communication between bodies.

There is a certain development in many countries to move from a pure evidence-based decision making to a larger extent of participation of patients, a larger focus on real-world data

(comparative effectiveness), and budget impact rather than cost-effectiveness. In this context, Colombia has experienced the quandaries of judicial actions within the core of the system and should learn to integrate these experiences within the process of HTA.

The issue of reallocation of resources will also have to be addressed not only by the agency but also by the government. Kluge [18] states that the nature of medicine also plays a role in resource allocation because there must be a coherent and consistent model of the goods and services that are allocated by members of the medical profession. Interactive and efficient ways to integrate the medical profession into the process of allocation sooner in the process rather than in the end or as a result of an autonomous decision taken by governments should be considered.

Colombia has assumed HTA as a path to improve efficiency in the allocation of resources in the short term. Nevertheless, challenges such as lack of capacity must be overcome for the agency to have an influence over decision makers. Historical efforts toward the creation of the architecture will also have to be considered when the new agency starts to function.

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