

SUPPORTING EVIDENCE USE IN THE COLOMBIAN HEALTH SYSTEM

SUPPORTING THE USE OF RESEARCH EVIDENCE IN THE COLOMBIAN
HEALTH SYSTEM

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ABSTRACT

During the last decade, there has been growing international interest in generating new knowledge regarding understanding, developing and evaluating mechanisms that support the use of research evidence by policymakers as a strategy to strengthen health systems in low-and middle-income countries (LMICs). This thesis contributes to this knowledge through three original scientific contributions that employ a mixed methods approach, with the goal of supporting the use of research evidence in the Colombian health system. Specifically, in the chapters I present: 1) the development of an analytical schema that explains the conceptualization of the Colombian government, research funder and universities of an evidence-informed health system; 2) two case studies that explain whether and how political factors influenced the role of research evidence in the agenda-setting and policy-development stages of two past health policy decisions in Colombia; and 3) a protocol for a randomized controlled trial evaluating the effectiveness of a multifaceted intervention in increasing the utilization of an evidence service and the intention to use synthesized research evidence by policy advisors and analysts at the Colombian Ministry of Health. As a whole, the chapters presented in this thesis provide substantive, methodological and disciplinary contributions to the field of health systems research and particularly to the study of efforts that aim to support evidence-informed policy in LMICs. They also help to provide insights that can be utilized to support a more nuanced approach to the use of research evidence in LMICs that takes into account the many factors that can influence health system policymaking. Ideally, this will help those engaged in developing mechanisms to support the use of research evidence in the policy process, and contribute to stronger health systems across the world.

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TABLE OF CONTENTS

Chapter 1:	Introduction.....	1
Chapter 2:	How do the government, a research funder and universities conceive the role of research evidence in the health system policymaking process?.....	9
Chapter 3:	Relationship between research evidence and the political factors that influence agendas and decisions. An explanatory case study of two health policies in Colombia	42
Chapter 4:	Increasing policymaker’s CApacity to find and use Research Evidence (The iCARE study). Study protocol of a cluster randomized controlled trial.....	99
Chapter 5:	Conclusion.....	135

LISTS OF FIGURES AND TABLES

Chapter 2

- Figure 1: Why Colombia wants to be a knowledge society33
- Figure 2: How to become a knowledge society34
- Figure 3: The role of industrial and commercial innovation35
- Figure 4: Social appropriation of knowledge36
- Figure 5: Knowledge management37
- Figure 6: Emphasis of the documents on the theory38
- Appendix 1: Documents included in the analysis39

Chapter 3

- Table 1: Timeline of key events related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system74
- Table 2: Factors that influenced agendas and decisions related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system78
- Table 3: Relationship between research evidence and the factors that influenced agendas and decisions related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system81
- Table 4: Timeline of key events related to the strengthening of the regulatory system for pharmaceutical products in 201182
- Table 5: Factors that influenced agendas and decisions related to the strengthening of the regulatory system for pharmaceutical products in 201185
- Table 6: Relationship between research evidence and the factors that influenced agendas and decisions related to the strengthening of the regulatory system for pharmaceutical products in 201189

- Table 7: Similarities and differences between the two cases regarding whether research evidence influenced or was influenced by other factors in the governmental agenda, decision agenda or policy choice stages of the policy process91
- Figure 1: Graphic representation of the main observed relationship between research evidence and the factors that influenced agendas and decisions92
- Appendix 1: Interview Guide93
- Appendix 2: Example of the codebook used in the analysis96

Chapter 4

- Table 1: Number of employees and floor within the building of the areas of the MoH where we will conduct the study, according to information on the phone directory of the MoH114
- Figure 1: Hierarchical representation of the areas where we will conduct our study.....115
- Figure 2: Trial design116
- Appendix 1: Sample of a support letter from the Colombian Ministry of Health.....117
- Appendix 2: Sample email invitation and cover letter with consent form.....118
- Appendix 3: Questionnaire121
- Appendix 4: Invitation letter to register for Health System Evidence127
- Appendix 5: Workshop program adapted from the Health Systems Learning educational program128

DECLARATION OF ACADEMIC ACHIEVEMENT

I, Daniel Patino, declare that I conceptualized, designed, and implemented the research project described in this thesis with some guidance and input from my thesis committee who provided comments on the thesis proposal, study protocols and research instruments. I alone was responsible for data analysis and preparing the written chapters. My committee members provided feedback on earlier drafts of this thesis.

Chapter 1: Introduction

This doctoral dissertation is composed of an introductory chapter, three original research chapters based on data collected in Colombia and a concluding chapter. The present chapter begins with an explanation of why the dissertation topic, *supporting the use of research evidence by health system policymakers in low-and middle-income countries (LMICs)*, is of importance, – I introduce some of the research requirements that need to be addressed in order to provide rigorous information about this topic, as well as some of the theoretical and empirical gaps in the literature. Lastly, this chapter then presents the overarching objectives of the dissertation and summarizes the approaches for each of the subsequent research chapters.

During the last decade, there has been growing international interest regarding understanding, developing and evaluating mechanisms that support the use of research evidence by policymakers as a strategy to strengthen health systems in LMICs (Global Forum for Health Research, 2004; Global Ministerial Forum on Research for Health, 2008; World Health Organization and Partners, 2011; WHO, 2004). This interest emerged from the assertion that research evidence about the effects (i.e., safety, efficacy, effectiveness, and cost-effectiveness) of programs, services and drugs needs to be complemented with a broad range of research evidence about how to organize the health systems in order to get health interventions to those who need them. Several studies support this by attributing the slow progress in achieving the United Nations' Millennium Development Goals, not to a lack of knowledge about what programs, services and drugs work best, but to poorly functioning health systems (Task Force on Health Systems Research, 2004; Travis, Bennett, Haines, Pang, & Bhutta, 2004; WHO, 2005). As a result of this increasing global interest, the field of health systems research has evolved, the global stock of research evidence about governance, financial and delivery arrangements has increased and multiple resources to support the use of relevant research evidence in the formulation of health policies have been developed (Moat & Lavis, 2013; Wilson, Moat, & Lavis, 2013). However, despite the evolution of the field, there is a need for a more rigorous research base. This knowledge base is critical to support health system policymakers in LMICs to create evidence informed decisions (Lavis, Lomas, Hamid, & Sewankambo, 2006).

A more rigorous research base focused on supporting the use of research evidence in LMICs requires three important components. Firstly, it requires gaining helpful insights about the general climate for research use, that is, to understand how those who could use research (e.g., government policymakers), research funders and universities, support or place value on efforts to link research to policy (Lavis et al., 2006). Secondly, it requires the recognition that the influence of research evidence in the policymaking process cannot be studied in isolation, without considering how other political factors influence this process (Lavis et al., 2002). Finally, it requires rigorous evaluation of the effects of interventions that intend to inform health system decisions with the best available

research evidence (Mitton, Adair, McKenzie, Patten, & Wayne Perry, 2007; Perrier, Mrklas, Lavis, & Straus, 2011).

The peer-reviewed literature provides some insights about how to address these requirements. For example, similar to the notion of policy paradigms (Hall, 1993), the support and value that the government, research funders and universities place on using research evidence to inform health system decisions, is articulated in their discourse. More precisely, these actors work within a framework of ideas and concepts about what constitutes research evidence, the role of research evidence in society and its role in the policymaking process. This framework, which is the result of complex social constructions and often taken for granted, plays a significant role in the ways in which these actors define how an evidence-informed health system should look, which goals are attainable through policy and what instruments should be used to achieve those goals. Thus, the scrutiny of this framework of ideas and concepts can provide helpful insights about the climate for research use.

Studying the influence of research evidence in the policymaking processes also requires careful consideration of the factors that influence agendas and decisions. The political science and policy analysis literature provides a framework to identify influential factors. The policymaking process can be divided into three stages, the governmental agenda (the list of subjects getting attention by governmental officials and those around them; Kingdon, 2003), the decision agenda (the lists of subjects that are up for active decision; Kingdon, 2003), and the policy choice stage. Visible participants (e.g., prime minister, journalists) and events in either the “problem stream” or the “political stream” are some of the factors that influence the governmental agenda. The coupling of events within the problem, policy and politics streams influences the decision agenda and creates a window of opportunity for policy choice (Kingdon, 2003).

In addition, the factors that influence policy choice can be separated into four domains – institutions, interests, ideas and external events. Institutions are helpful to explain how state capacity (Immergut, 1992) and past policies (Pierson, 1993) influence subsequent policy choices. Factors related to interests are helpful in explaining the perceptions of political actors (e.g., societal interest groups, elected officials or policy advisors) about who wins and who loses as a result of a given policy and by how much (Lavis et al., 2002). Ideas pertains to factors related to knowledge or beliefs about “what is” (e.g., research knowledge or tacit knowledge) and views about “what ought to be” (e.g., values) (Lavis et al., 2002). Finally, external factors, such as political or economic change, release of major reports or emergence of new diseases, influence policy decisions (Lavis et al., 2012).

The last requirement for a rigorous research base is careful evaluations of the effects of interventions that intend to inform health system decisions with the best available research evidence. Systematic reviews have identified timing/timeliness to access high quality relevant research, the promotion of collaborations between researchers and

policymakers, and skills-building with policymakers as the most important factors that increase the prospects for research use in policymaking (Innvaer, Vist, Trommald, & Oxman, 2002; Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014). The insights from these reviews encouraged researchers to develop interventions such as databases that continuously identify, classify and assess systematic reviews and other review-derived products about different health systems arrangements; or provide workshops that build capacity among health system policymakers on how to identify and use research evidence (Lavis et al., 2006). However, with the exception of a few recent attempts (Champagne, Lemieux-Charles, Duranceau, MacKean, & Reay, 2014; Lavis et al., 2011), the impact of these interventions on organizational practices has seldom been evaluated.

Notwithstanding the recognition of the aforementioned requirements for a more rigorous research base from which to draw, little theoretical work has been undertaken to understand how those who use research evidence, those who fund research and those who produce evidence conceive the role of research evidence in the health system policymaking process. This is an important gap in the literature, given the importance of these conceptions in understanding the support and value that these actors place in using research evidence to inform health systems decisions in LMICs. Researchers have studied the climate for evidence-informed health systems by conducting print media analyses to understand whether and how policymakers and other stakeholders talk about it in the media (Cheung et al., 2011). They have also assessed the availability of health research evidence that is relevant to policymakers (El-Jardali, Ataya, Jamal, & Jaafar, 2012; Law, Lavis, Hamandi, Cheung, & El-Jardali, 2012), the strength of relationships among policymakers and researchers and the policymakers' capacity to support the use of health research evidence in health systems policymaking (El-Jardali et al., 2012). However, studies that assess the climate for evidence-informed health systems by trying to understand the ideas and concepts of these actors about what constitutes research evidence, the role of research evidence in society and its role in the policymaking process are not common.

There is also little empirical work, especially in Latin America, that intends to understand whether and how political factors influence the role of research evidence in the agenda-setting and policy-development stages of the policymaking process. A recent systematic review about the use of evidence in policymaking found that out of the 145 eligible studies, only one, which did not have a focus on health, was from Latin America (Oliver et al., 2014). This is a significant gap given the importance of understanding the use of research evidence in real-world political contexts in the developing mechanisms to support the mobilization of research evidence in the health policymaking process. Finally, knowledge regarding the effectiveness of interventions to improve the use of evidence by policymakers remains underdeveloped (Innvaer et al., 2002; Perrier et al., 2011).

This thesis addresses these gaps through three original scientific contributions that employ a mixed methods approach, with the goal of supporting the use of research evidence in the Colombian health system. The specific aims of this thesis are:

1. to develop an analytical schema (i.e., a theory) that explains the conceptualization of the Colombian government, research funder and universities of an evidence-informed health system (Chapter Two);
2. to understand whether and how political factors influenced the role of research evidence in the agenda-setting and policy-development stages of two past health policy decisions in Colombia (Chapter Three); and
3. to develop a protocol to assess the effectiveness of a multifaceted intervention in increasing the utilization of an evidence service and the intention to use synthesized research evidence by policy advisors and analysts at the Colombian Ministry of Health (Chapter Four)

Chapter two addresses the first aim, to respond to the requirement of gaining helpful insights about the general climate for research use. In this chapter, I inductively develop an analytical schema that explains the ideas and concepts embedded in the documents produced by the Colombian government, a research funder and universities about an evidence-informed health system. To develop this analytical schema, I conduct a document analysis using an interpretative grounded theory approach. I use an interpretative approach to understand how the documents' content reflects taken-for-granted meanings related to my phenomenon of interest. The grounded theory methodology provides a systematic but flexible guide for the collection and analysis of data while allowing for a coherent conceptualization of the sampled documents.

Chapter three addresses the second aim by understanding the role of research evidence in a real world political context by taking careful consideration of the factors that influence agendas and decisions. In this chapter, I employ a multiple case study design to understand whether and how research evidence was used in two health policy decisions in Colombia. Following pre-established theoretical propositions, I analyze data from documents and key informant interviews to present a comprehensive account of the evolution of each policy process over time and the factors that influenced it. In addition, I explore the ways in which the research evidence influences the policy processes.

Chapter four presents a study design that assesses the effects of two strategies that support health system policymakers in finding and using research evidence to inform their decisions. The strategies are the Health Systems Evidence database, which is designed to provide policymakers with timely access to research evidence; and a capacity building strategy which is designed to enhance health system policymakers' skills in acquiring, assessing, adapting, and applying research evidence (McMaster Health Forum, 2014). In this chapter, I propose a cluster randomized controlled trial, with areas of the Colombian Ministry of Health as the clusters and an internal pilot trial to assess its feasibility.

As a whole, the chapters presented in this thesis provide substantive, methodological and disciplinary contributions to the field of health systems research and particularly to the study of efforts that aim to support evidence-informed policy in LMICs.

Substantively, this work contributes a new theoretical framework that provides a detailed approach to considering the ideas and concepts embedded in the documents produced by the Colombian government, research funder and universities about an evidence-informed health system. Additionally, the case studies provide some of the first efforts to understand how political contextual factors influenced the role of research evidence in two Colombian health policy decisions.

Methodological contributions are made through a novel application of grounded theory methodology to the analysis of organizational documents in order to gain helpful insights about the climate for research use. Grounded theory has been used as a metasynthesis methodology for developing new knowledge from the analysis of existing qualitative research findings (Kearney, 2001; Thorne, Jensen, Kearney, Noblit, & Sandelowski, 2004). However, the use of grounded theory in the analysis of organizational documents in the area of health systems research is not common. Chapter 2 validates this application of grounded theory, demonstrating that it yields useful information about the actors' framework of ideas and concepts related to what constitutes research evidence, the role of research evidence in society and its role in the policymaking process. The case studies illustrate the utility of pre-established theoretical propositions when developing comprehensive accounts of policy processes in LMICs, and also present a framework for analysing the interaction between political factors and the use of research evidence on the policy process. Additionally, the protocol for the randomized controlled trial offers an approach to address some of the challenges that other studies have encountered (Kho, Rawski, Makarski, & Brouwers, 2010; Lavis et al., 2011). Specifically, the design incorporates strategies to increase recruitment efficiency, improve the balance between the groups and minimize contamination.

Combined, the three scientific studies presented in chapters two through four also add disciplinary value to the field of health systems research and to the study of efforts that aim to support evidence-informed policy in LMICs. They provide a framework and serve as an example to help those involved with supporting the use of research evidence to gain helpful understandings about the general climate for research use. They offer insight into how to integrate core concepts from the field of political science and policy analysis into the study of health systems policymaking processes. Additionally, they provide an approach to evaluating interventions that support policymakers within the Ministry of Health in their efforts to find and use research evidence. As a result, this thesis provides important scientific contributions towards supporting the use of research evidence in LMICs.

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Chapter 2: How do the government, a research funder and universities conceive the role of research evidence in the health system policymaking process?

Abstract

Context and objective: Understanding the relationship between research evidence and health policy is fundamental for strengthening health systems. This paper addresses this relationship by studying the ideas embedded in the documents produced by the Colombian government, a Colombian research funder and Colombian universities about an evidence-informed health system. **Methods:** We developed an interpretive grounded theory from 38 documents produced by these actors from 2004 to 2013. We identified eligible documents from a number of sources including government, Colciencias (i.e., the country's dominant research funder) and university websites, through consultations with key people within these organizations as well as the principal investigator's personal bibliographic files. **Findings:** The ideas raised in the sampled documents' rhetoric revealed three main theoretical insights about the conceptualization of an evidence-informed health system: (1) governmental documents' emphasis on the concepts of "knowledge society" and "innovation" puts more value on the contribution of research evidence to industry and the economic development of the country than to its contribution to the health system policymaking process; (2) according to government and Colciencias' documents, the "citizens" or the "public" of the "knowledge society" need to appropriate scientific knowledge in order to be in a better position to demand the use of research evidence in policy decision-making process; and (3) the concept of "knowledge management" emerged from the Colciencias and universities' documents to highlight the role of evidence from indicators and evaluation research in identifying health needs and informing coverage decisions. **Discussion:** Those persons interested in supporting the use of research evidence in the Colombian health system need to: (1) understand that the main ideas that define the role of research evidence in the Colombian government's documents are not conducive to using research evidence to inform health systems decisions; (2) develop a broader understanding of what types of research evidence can inform the identification and definition of a health system problem, the framing of policy options, key implementation considerations and the monitoring and evaluation process; and (3) develop mechanisms to mobilize research evidence into the policymaking process.

Introduction

Efforts to promote the use of research evidence in the policymaking process increased over the last decade in global (WHO, 2004), Latin American (COHRED, 2009; PAHO, 2008, 2010) and, with less intensity, Colombian contexts (Ministerio de la Protección Social & CEDETES, 2007). These efforts emerged from the assertion that a key step to strengthening national health systems is the understanding and development of systematic mechanisms that support the mobilization of health systems research¹ into the health policymaking process.

One first step towards understanding and developing such mechanisms, and specifically to gain helpful insights about the general climate for research use, is to inquire about the support and value that the government, the organizations that fund research and universities place on an evidence-informed health system. (Lavis, Lomas, Hamid, & Sewankambo, 2006). The support and value placed on an evidence-informed health system is a social phenomenon that is shaped by the ‘taken-for-granted’ ideas or paradigms that are embedded in the discourse of these actors, and through which they define their goals, the instruments to achieve those goals, and even the nature of the problems (Hall, 1993).

The purpose of this study is to develop an analytical schema (i.e., a theory) that explains the conceptualizations embedded in the documents produced by the Colombian government, a Colombian research funder and Colombian universities about an evidence-informed health system.

Methods

Design Rationale

We conducted a qualitative analysis of documents using an interpretive grounded theory approach. Grounded theory is a suitable method when existing theories are inadequate, nonexistent for the population (which is the case in Colombia) or need to be modified. The grounded theory method provides a systematic, but flexible guide for the collection and analysis of qualitative data with the aim of constructing a theory or an analytical schema that conceptually explains basic social processes (Charmaz, 2006).

In using an interpretative approach, this study aims to understand how the documents’ content reflects the constructs of meanings and actions in specific situations (Charmaz, 2006). It theorizes about the actors’ (i.e., the Colombian government’s, research funder’s and universities’) interpretation of the phenomenon (i.e., the support and value placed on

¹ “Health systems research is a multidisciplinary field of health research which studies governance, financial and delivery arrangements for health care and public health services, implementation considerations for reforming or strengthening these arrangements, and broader economic, legal, political and social contexts in which these arrangements are negotiated and operate. The purpose of health systems research is to improve the understanding and performance of health systems. Health systems research includes all of health services research, most health policy research, and some clinical and population health research, but does not include any biomedical research” (Hoffman et al., 2012; 18).

the use of research evidence as an input in the decision making process) by interpreting what they express as well as what they do not express—in other words, what is ‘taken-for-granted’.

Data collection

This study focused on the analysis of documents produced by or for the Colombian government (e.g., produced by the national planning department), Colciencias² (which is the administrative department of science, technology and innovation and the country’s dominant research funder), and universities (or research centres). Our intention was to collect documents that help us understand how these actors conceptualized the idea of using research evidence to inform health system decisions. Therefore, we were open to include different types of documents (e.g., legislation, annual reports, institutional plans) that could enhance our conceptual and theoretical understanding. The study is confined to the period of 2004 to 2012 in order to capture the influence of one of the first main international statements about using research evidence to inform health policy (i.e., the world health report 2004) in national discourse. Since our focus was at the institutional level, we did not include peer-reviewed articles produced by individual Colombian researchers.

We identified eligible documents from a number of sources, including: government, Colciencias and university websites; consultations with key people within these institutions; reference chaining; and the principal investigator’s personal bibliographic files. As in other theory-generating qualitative reviews (Finfgeld-Connett & Johnson, 2013), our search and inclusion of documents followed an iterative process. After an initial search of the data sources and following a “berry picking” approach, that is, selecting those reports that seemed to provide relevant information on the subject (Finfgeld-Connett & Johnson, 2013), we identified five key documents that contained information relevant to understanding the conceptualization of an evidence-informed health system. These documents are included in the final sample (see appendix 1) and they focused on defining research evidence (e.g., Law 1286, 2009: to strengthen Colciencias and the national science and technology system), the role of research in society (in the health sector or any sector) (e.g., national strategies for social appropriation of knowledge, 2010) and the actors involved in the production, translation or use of research (national policy for the promotion of research an development, 2008). The concepts that emerged from the analysis of these documents informed subsequent sampling, and also helped to shape our analytical procedures. We collected new data in different stages of the process in order to explicate the emergent categories. This iteration between data collection and analysis enhanced our conceptual and theoretical understanding of the phenomenon.

² Colciencias is a governmental organization. However, for the purpose of this study we analyzed the documents produced for or by this actor separate from the other government documents.

Our final sample included 14 documents produced by or for the government (Table 1 in the appendix 1), eight documents produced by or for Colciencias (Table 2 in the appendix 1) and 16 documents produced by universities or research centers (Table 3 in the appendix 1). Two documents were consultant reports suggested by people within one of these organizations for which no publications were located. The other documents could be found in the public domain.

Data analysis

The collected data were processed through three distinct analytical steps, within which constant comparisons were made. First, we conducted initial coding, where relevant sections of the text were coded phrase by phrase. This helped us to identify concepts that have been problematized, as well as any unique terminology and special words that have been used—a process known as *in vivo* coding. Second, we identified the most frequent and conceptually rich codes to characterize larger pieces of text. This is called focused coding, a process through which categories start to emerge. Thus, as part of focused coding, we grouped together and labeled themes that were found to be theoretically similar or connected in meaning. Third we established relationships between these categories, considering how they were connected, how they influenced or whether they contradicted each other. This was the beginning of a coherent analytical story and the first turn in a theoretical direction (Charmaz, 2006). With the aim of understanding the conceptualization of each actor, we performed this last phase of coding independently for each type of actor (i.e., the government, Colciencias and universities).

Another analytical step was to write memos to make comparisons within and across data, codes and categories. Some memos were written after the initial coding to start defining some concepts, while others were written after the focused coding to refine the conceptual categories. After defining some conceptual categories, new data were collected about each category and their properties. The categories that emerged after this analytical process were represented in diagrams to trace the relationships between them and create paths towards the emerging theoretical framework (Charmaz, 2006).

The principal investigator read the documents in Spanish and developed the analysis, including the initial coding, in English. In addition, he translated all the quotes, and kept a memo with the words and expressions that were difficult to translate, with the objective of discussing them within the research group to find the most adequate translation.

All collected data were managed using NVivo software, which was also used to facilitate the stages of data analysis (including coding, memo writing and the development of diagrammatic representations of the emerging theory).

Findings

We started our analysis with the documents that provided relevant information on the relationship between research evidence and the decision making process in the health

sector. These documents highlighted the importance of policy decisions that shaped the Colombian research system and its implication for health research. The analysis of those policy decisions improved our understanding of how the relationship between research evidence and health policymaking was conceptualized within a bigger picture; that is, the role of research evidence in Colombian society.

We organized our findings from a general perspective of explaining the support and value of scientific knowledge to the Colombian society and then moved to a more focused perspective that aimed to explain its value as an input in the health system policymaking process. We used “knowledge society” as a central concept to organize our findings. We started by exploring the impetus (the ‘why’) for becoming such a society, and then we moved to the concepts that explain the mechanism (the ‘how’), to achieve this goal, where we discussed the role of the government and the ideas of innovation, social appropriation of knowledge and knowledge management. Finally, we explained the contribution of the governments’, Colciencias’ and universities’ documents to the development of the theory.

1. Why Colombia wants to become a knowledge society

“[...] The society and economy of knowledge are an imperative of contemporary civilization and a factor of power and international prestige. Only those countries that dominate knowledge and are able to use it to add value and innovation to production will have access to this exclusive international club and their respective markets.” (Departamento Nacional de Planeación, 2006; 42).

During the analysis, we noticed an interest to transform Colombia into a society of knowledge. This interest is clear, explicit and presented as an evident option. It is assumed that: a knowledge-based society will promote the economic development of the country; it will improve its competitiveness and therefore, its possibility to participate in the global market; it will reduce the gap “between us and more advanced countries and even some Latin American courtiers” (Departamento Nacional de Planeación, 2006; 2); it will help the country to meet international standards and to improve its ranking in international classifications; and it will lead to social wellbeing, social equity and to improve democratic processes. The mechanisms that will lead to the establishment of this society of knowledge were also clear in the documents. The intention is to construct a knowledge-based society through the promotion of a knowledge-based economy (see figure 1).

Insert figure 1 approximately here

This intention guided policy towards an emphasis on science, technology and innovation (ST&I) as a key strategy to address modern - national and global- economic and competitive challenges. It is illustrative to observe the position of the science, technology and innovation chapter in the table of contents of the national development

plans. In the 2002-2006 plan, ST&I were under a chapter called “to boost sustainable economic growth and generation of employment”. In the 2006-2010, plan it was considered as a “special dimension for development” and in the 2010-2014 plan, ST&I are not in the table of contents but their role is fundamental in the chapter about “Sustainable growth and competitiveness”, specifically to describe the new innovation-based sectors of society. What is revealing for our purposes is that ST&I were not considered, with a dedicated section, within chapters such as “building social equity” or “increasing transparency and state efficiency” in the 2002-2006 plan, or in the “equal opportunities for social prosperity” of the 2010-2014 plan (which are the chapters that discussed health systems issues). As a consequence, the role of science, research evidence or scientific knowledge in areas that include social policy and health policy, and in the decision making process of domestic politics, is rarely discussed and is constrained to few unconnected ideas.

The interest in using ST&I to support ideas in economic policy and research policy rests on the ‘belief’ that economic growth, which is framed as a result of the knowledge-based society, will lead to social wellbeing and is the solution to poverty and other social disparities (Departamento Nacional de Planeación, 2003, 2007, 2011). Of course, the argument that ST&I will lead to economic growth and therefore, to social well being, does not explain why ST&I are not considered as in input to improve social wellbeing independently of their contribution to economic growth. However, it exposes taken-for-granted ideas engrained in the policy discourse within Colombia about the goals (e.g., to belong to the exclusive club of developed countries) and the instruments (e.g., to promote ST&I) to achieve those goals.

These ‘taken-for-granted’ ideas or ‘worldviews’ reveal a specific vision of science that promotes specific types of research and knowledge at the expense of others. The documents analyzed advocate for the need to produce applied research that can promote the competitiveness of strategic sectors of society, and define strategic sectors as those that are based on innovation, that is, “the use and application of knowledge with economic ends” (Departamento Nacional de Planeación, 2003). The value and usefulness of scientific knowledge is then measured by its possibility to be used in productive sectors and by its possibility to add value to products and services and not by its possibility to inform health system policymakers.

The knowledge society, thus, is a normative discourse; a discourse about what should be the desirable goals of society and what constitutes the appropriate means to achieve them, that is, the production of research knowledge that can promote the competitiveness of strategic sectors of society.

2. How to become a knowledge society

Three emergent categories—innovation, social appropriation of knowledge and knowledge management—helped us to understand the mechanisms through which research evidence could lead Colombia to the ‘benefits’ of the knowledge society.

Innovation is used predominately to understand how to achieve the economic ‘benefits’ for society. Social appropriation of knowledge is important to understand the role of the ‘public’ in the science-society relationship. Knowledge management is key to conceptualizing the relationship between research evidence and the social benefits of the society of knowledge, specifically the health ‘benefits’. However, before we develop these categories, it is important to note that all of them rest on the assumption that the government has to intervene in order to achieve the benefits of the society of knowledge—an assumption to which we now turn before further explicating the concepts of innovation, social appropriation of knowledge and knowledge management.

2.1 The government intervention

“Government entities will [...] adjust the national programs of science and technology to match the strategic areas” (Departamento Nacional de Planeación, 2011; 219).

Through a series of policy reforms, successive governments have intervened in the research system in an effort to align the economic, and marginally the social, interests of the country with research policy. These efforts aim to identify and predict the sectors of society that are characterized by the use of research knowledge and the areas of knowledge that will contribute to economic growth (and social well-being) (see figure 2). Law 1286 of 2009 materializes this intention (Ley No 1286, 2009).

Insert figure 2 approximately here

One of the frequent challenges identified in the documents to align research policy to economic interests and therefore to become a knowledge society is the weak institutionalization of the ST&I system. Since Colciencias did not participate on government bodies that make major public policy decisions prior to 2009, there was an institutional barrier to link research policy with other policies and other sectors of society. (Consejo Nacional de Política Económica y Social, 2009; Departamento Nacional de Planeación, 2003). One of the main actions taken to overcome this challenge was the passing of Law 1286 in 2009, which aimed to strengthen the institutionalization of the system by transforming Colciencias from the Colombian institute for science and technology development to the administrative department of science technology and innovation. This decision granted budgetary independence to Colciencias and allowed it to be part of the national council for economic and social policy (CONPES) and the ministerial council. This change has increased its capacity to influence national policies and, has given the organization more authority to coordinate linking activities between the private sector, universities and other public organizations.

The justification for government intervention rests in two arguments. First, on the production systems side (i.e., industry) there is the explicit argument that due to market

failures (e.g., knowledge is a public good, asymmetry of information, uncertainty in research costs and benefits) the private sector does not have the proper incentives to invest in ST&I activities (Consejo Nacional de Política Económica y Social, 2009; Departamento Nacional de Planeación, 2011). Therefore, as has been understood by “more advanced countries”, it is the responsibility of the state to create the right motivations to increase the demand of knowledge by the productive sector in order to compete in the society of knowledge (Colciencias, 2008; 24).

The second justification for the government intervention is related to the research system. In many of the documents it is assumed that the research system, without regulation, will not produce what society needs. Therefore, the state through its institutions in charge of the research policy authority (i.e., Colciencias) have to create the policy instruments to guarantee the alignment between research production and those taken-for granted ideas about what are the needs of the society. This assumption emerged through different documents from different actors as we illustrate in the following quotes:

“[We] can not have the idea that health research in Colombia has exclusively scientific goals. The Law 1286 of 2009 clearly shows that this is not the aim nor the nature of the innovation system, quite the opposite, the scientific system must produce results in the real sectors [i.e., the economic sector and the health sector]” (Vázquez, Toro, Medina, Aldana, & Angélica, 2013; 24).

“The pragmatism and the establishment of priorities, associated with the established challenges, will give priority to research and innovation that are socially and locally relevant; and internationally competitive. [Without forgetting] that the country also requires the generation of knowledge to create new alternatives and paradigms, which should represent contributions to global knowledge” (Colciencias, 2008; 60).

“According to Type I research, which has being predominant in the world since the last century, the individual interest of researchers or institutions has defined research priorities. The advocates of a type of knowledge that is socially constructed noticed the inconvenience of this practice and have promoted research priority mechanisms that include the values and interest of society” (Ministerio de la Protección Social & CEDETES, 2007; 39).

2.2. Innovation

As a result of these efforts, sectors like biotechnology, information and communication technologies, and health (in areas like molecular biology, genetics, nanotechnology, electronics, and regenerative medicine) are commonly identified as strategic sectors due to their capacity to incorporate knowledge to add value to their products and services (i.e., sectors based on innovation) and therefore increase the economic development of the county (Departamento Nacional de Planeación, 2011; Vázquez, Toro, Medina, Aldana, & Angélica, 2013). Some of the instruments to promote the use of knowledge in industry

include: promoting the linkage between universities and private firms by co-funding of collaborative projects between them (i.e., incentivizing public-private partnerships); introducing tax benefits related to investments in research projects, the development of software and pharmaceutical products and the importing of research equipment or materials; and strengthening the intellectual property system (Consejo Nacional de Política Económica y Social, 2009; Departamento Nacional de Planeación, 2011; Colciencias, 2008) (See figure 3).

Insert figure 3 approximately here

The concept of innovation raised two insights. First, given the predominant discourse about increasing the competitiveness of the country, innovation has gained a privileged position in defining the value of research. Currently, the value of research evidence depends on its contribution to adding economic value to products and services. Second, innovation, and its instrument ‘public-private partnerships’, represents the government’s intentions to align public policy with market priorities in research policy. Two examples provide evidence of these insights. First, it is interesting to observe how the relationship between innovation and science and technology changed throughout the documents. Even though the documents predominantly framed the importance of ST&I in economic terms, science and technology had a value to society independent of their contribution to innovation. However, in the latest national development plan the importance of science and technology depends exclusively on its relationship to innovation. This is reinforced by the Colciencias’ website slogan “the engine of innovation fosters Colombian prosperity”.

Second, Law 1286 of 2009 changed the science and technology national system that was created in 1991 to the science, technology and *innovation* national system. As stated in the document, this reform intended to strengthen the system to “achieve a productive model based on science, technology and innovation in order to add value to the products and services of our economy and foster productive development and new national industry” (Ley 1286, 2009; 1). Innovation emerged as a key concept to frame the relationship between the state, universities and the private sector in order to align research production with specific sectors to improve the competitiveness of the country. In this relationship, the state defines and promotes (e.g., via incentives) specific sectors and areas of knowledge, the universities produce the knowledge within these defined areas, and industry incorporates that knowledge to add value to their products and services.

2.3 Social appropriation of knowledge.

The national policy for science, technology and innovation (Consejo Nacional de Política Económica y Social, 2009) considers social appropriation of knowledge as one of the strategies needed to increase the capacity of the country to produce and use scientific knowledge in order to promote knowledge-based economic and social ‘development’. The policy, in order to introduce the importance of this strategy, asserts:

“Knowledge does not only have the capacity to solve scientific and industry problems; it has also the capacity to offer solutions to society in general” (Consejo Nacional de Política Económica y Social 2009; 2).

The words “not only” in the previous quote support our argument about the emphasis on conceiving scientific knowledge either in terms of its contribution to the research systems or to industry. This conception identifies the state, universities and industry as the principal actors of the society of knowledge. In what follows we will explore the understanding of the concept of social appropriation of knowledge. First, we discuss what it means to “appropriate knowledge”, then we describe the activities to achieve it, and finally we highlight one insight of its conceptualization.

Social appropriation of knowledge (SAK) is conceptualized as an end (or goal) in which society perceives and values ST&I activities as a possibility to solve societal problems. It is argued that by achieving this goal society will be in a better position to demand the use of knowledge in policy decision-making process and in processes related to the production of goods and services (Departamento Nacional de Planeación, 2003, 2006; Colciencias, 2005). It will also empower citizens, organizations and civil society institutions to be part of “public debates and respond as informed participants” (Colciencias, 2010; 28). The ‘dream’ of being a society of knowledge can only be achieved by the social appropriation of knowledge (Ministerio de la Protección Social & CEDETES, 2007). Social appropriation of knowledge has also been conceptualized as a means, that is, as a concept that defines the activities necessary to appropriate knowledge.

The activities have focused on using the mass media to disseminate ST&I actions and results to the general population, and on promoting the interest of children and adolescents in ST&I activities (e.g., training of professors to teach children and adolescents about ST&I or creating interactive science museums). With less intensity, some documents also emphasize the need to promote communication channels between those considered “experts” in the various fields of scientific knowledge, and the general public, as well as the need to create spaces for debate between different stakeholders (i.e., social groups, researchers and politicians) to discuss policy decisions in which science plays an important role (e.g., decisions related to the use and exploitation of genetics material) (Departamento Nacional de Planeación, 2007; Colciencias, 2010).

One important insight about the conceptualization of SAK in documents is that there seems to be a mismatch between the definition of the concept and the activities to achieve it. The definition suggests the need to create mechanisms to allow the general public to participate in the construction of ST&I and its application to societal issues. This implies, as some documents suggest, the creation of spaces for debate among different stakeholders where each actor has the opportunity to communicate her/his ideas to other actors. However, the activities have centered on promoting the flow of information from the ST&I experts to the general public without paying much attention to describing the

mechanisms through which the general public can communicate its ideas to the other stakeholders. The following quote provides an example of this ‘one way’ communication emphasis:

“The social appropriation of knowledge will include the disclosure of research and innovation impacts among the Colombian population through print, Internet, radio and television. The coverage of the Science, Technology and Innovation Week will be expanded to a greater number of departments and municipalities, and we will continue to support initiatives of exhibitions, forums, interactive museums and centers, in order to build common languages and disseminate successful cases about the ability of knowledge to create value and social welfare.” (Departamento Nacional de Planeación, 2011; 78).

A ‘narrow’ conception of SAK explains this ‘one way’ communication emphasis (Colciencias, 2010). This conception considers that knowledge is produced at the intersection of the state, the universities and the industry; and that society (i.e., citizens, the general public), which is not involved in this production, has to be informed about the benefits of research. This conceptualization led to an emphasis on promoting communication activities as a mechanism to achieve the goals of SAK. A ‘broader’ conception of SAK, which relates to the notion of social construction of knowledge, recognizes that society participates actively or passively in the production and use of science through the negotiations of different interests, values, motivations and language. Therefore, it is necessary to shift the emphasis from providing more access to information to the inclusion of citizens in the process of knowledge production and knowledge utilization. As an example, Colciencias promoted the creation of dialogues among researchers, policymakers, the industry and civil society. The objective of these dialogues is to promote the active participation of citizens in the policymaking process related to strategic areas where ST&I plays a relevant role, such as “water and biodiversity, energy and health” (Colciencias, 2010; 38) (See figure 4).

Insert figure 4 approximately here

2.4 Knowledge management

The process of knowledge management emerged as a key concept to understand the link between research evidence and the health policy decision-making process. This is a process that has to be regulated by the government in order to ensure that its results are used by health policymakers. The concept has multiple interpretations across some of the documents and each interpretation has different implications related to the role of evidence that is relevant to inform decision-making. We start by presenting three definitions related to the concept of knowledge management and then we explore the implications of each of them to an evidence-informed health system (see figure 5).

Insert figure 5 approximately here

Three definitions of the concept are worth mentioning. First, knowledge management is a process that goes from the “[...] planning, organization, coordination and control of activities that lead to the capture and creation of indicators to the dissemination of evidence”. The purpose of knowledge management is the “identification of the population health needs and its determinants: environmental, behavioral, genetic and those related to the health services response”. Under this definition knowledge is defined as “[...] structured and organized information that constitutes a higher level of information” (Ministerio de Salud y Protección Social, 2012). Second, knowledge management is a process “[...] to organize, regulate and guarantee the production, dissemination, social appropriation and use of health research results” in order to inform health policymakers (Ministerio de la Protección Social & CEDETES, 2007). Third, social management of knowledge refers to “[...] the actions and activities that allow social agents, especially in the most vulnerable communities and human groups, to produce, assess, validate, legitimize, and apply different ways of knowing and knowledge with the purpose of optimizing the decision making process in order to benefit public interest and improve the quality of life of the population” (La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2005; 46). Social management of knowledge aims to promote the appropriation of knowledge by policymakers, communities, and the people and institutions related to the health sector (La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2005).

The first definition of knowledge management, which is the one adopted by the Ministry of Health (MoH), leads to a focus on organizing information from different sources in order to create indicators and evidence to identify health problems. As an example, the health information system of the MoH integrates different sources of information, such as administrative records (e.g., vital statistics, population records), surveys (e.g., national health survey, demography and health survey), and census data, in order to develop more reliable indicators. These indicators are then organized into issue-specific “observatories” (e.g., national cancer observatory, national mental health observatory) and other resources that allow the monitoring of health changes and the analysis of social determinants of health that lead to health inequities. The purpose of these observatories is to “improve the management of knowledge to inform the health policy decision making process” (Ministerio de Salud y Protección Social, 2013; 40).

This definition of knowledge management has two implications. First, the term evidence does not refer just to “research evidence” but to evidence from different sources of information (e.g., local indicators) that are valuable to inform public policy. This conceptualization implies that research evidence and other policy relevant evidence are complementary inputs into the policymaking process.

Second, this definition constrains the use of “information and evidence” to one stage of the policy process that is, the identification of problems. This is evident by the emphasis on producing indicators to identify the burden of diseases in Colombia (e.g.,

incidence, prevalence and mortality rates), health coverage rates and the number of programs, services and drugs that are being provided. However, this conceptualization does not consider the role of research evidence in other steps that are necessary to clarify the problem or in other stages of the policymaking process, including framing the options available to address problems that have been identified, or identifying key implementation considerations.

The second definition of knowledge management is specifically about the importance of health research to inform health policymakers. The documents that adhere to this definition consider health systems research a sub-field of public health research. Public health research is defined as “production of knowledge to understand the health-disease process, to explain the structures and dynamics of the genetic, environmental, behavioral and social determinants of health and to assess the health interventions” (La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2005; 21). It includes clinical and epidemiological research, research conducted by basic sciences and research conducted by social sciences including “the study, comprehension and assessment of service delivery systems and policies that affect health ” (La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2005; 21).). Within the last group, which seems to include health services and health policy research, the emphasis is on evaluation research about the performance, impact, effectiveness and cost-effectiveness of policy, program or health technology interventions (Ministerio de la Protección Social & CEDETES, 2007).

In fact, we found that the only kind of health policy decisions in which the role of research evidence is mentioned explicitly were those related to the definition of what drugs, services and programs should be included in the health benefit plan. As an example, in 2013 the MoH in close collaboration with the Institute of Health Technology Assessment updated the health benefit plan using research evidence from studies about the burden of disease and changes in the epidemiology profile (to identify the health needs), health technology assessment reports and information from clinical guidelines developed by universities and research centres (Ministerio de Salud y Protección social, 2013b).

The rhetoric of these documents also suggests that the importance of using health research to inform health policymaking rests on the need to “close the gap between the existent knowledge and health actions” in order to meet the millennium development goals (Ministerio de la Protección Social & CEDETES, 2007; 10). The millennium development goals emerged as an umbrella term (to cover poverty reduction, inequity, lack of health coverage and violence) to frame the contribution of ST&I, specifically health research, to social wellbeing (Colciencias, 2008b; La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2005).

The third definition of knowledge management highlights the importance of considering different forms of knowledge as complementary inputs into the policymaking

process. Thus, this definition does not only refer to knowledge produced by modern sciences but it is interested in the management of other ways of knowing like “popular knowledge, and ideology” (La Red Colombiana de Investigación en Políticas y Sistemas de Salud, 2009; 95) with the purpose of optimizing the health decision-making process. However, the mechanisms about how this ‘plurality of knowledge’ can be integrated into the decision making process are not described in the documents.

3. The emphasis of government, Colciencias and university documents on the development of the theory

Even though documents from all the sources helped us to understand the relationships between the emergent categories, some sources played a more significant role in the development of certain categories (see figure 6). For example, government documents were key to understanding ideas about the value and contribution of science to the economic development of the country; therefore, our ideas around “innovation” and “development” rely predominantly on this source. Colciencias documents were key to understanding the concept of social appropriation of knowledge, to reinforce our understanding about the role of research evidence in the economic development of the country, and to shed light on its contribution to the social well being through the concept of knowledge management. The universities’ documents were key to understand the ideas about the role of research evidence in health policy, specifically to develop the concept of knowledge management and its relationship to public health.

Figure 6, presents government documents and documents from universities in different extremes of the analytical schema. This reflects our finding that ideas about the role of research to inform health policy decision making were not considered in the rhetoric of the main documents that inform and guide the country’s decisions, such as the national development plans and the main national policies on ST&I. However, it is important to reinforce that documents from all the sources helped to develop the categories and relationships. For example, documents from the MoH contributed to the understanding of the process to develop indicators in order to identify health needs and documents from the university described their relationship with the industry and, therefore, reinforced our understanding of “innovation”.

Insert figure 6 approximately here

Discussion

Understanding the relationship between research evidence and health policy is fundamental for strengthening health systems. The emergent theoretical insights of this paper, which are summarized in figure 6, address this relationship by studying the ideas embedded in the documents produced by the Colombian government, a Colombian research funder and Colombian universities about an evidence-informed health system.

These theoretical insights can be summarized in five points. First, in the government documents scientific knowledge or research evidence plays an important role in the creation of the ‘knowledge society’ that will lead the country to ‘development’ and economic growth. Within this worldview, research evidence that can be used by industry has more value than other types of research. Second, it is assumed by all actors that science without regulation will not produce what society needs. This assumption has led to an increasing desire to steer priorities in Colombia, a task that was left to the government. Third, given the predominant discourse about increasing the competitiveness of the country, the exercise of steering priorities gave ‘innovation’ a privileged position to define the value of research evidence and revealed the government’s intention to align public policy with market priorities in research policy. Fourth, in some government and Colciencias documents, social appropriation of knowledge is an important concept used to understand the role of the ‘public’ in the science-society relationship. A narrow conception of SAK promotes communication activities as a mechanism to inform the public about research and innovation impacts; whereas a broader conception considers that it is necessary to shift the emphasis from providing more access to information to the inclusion of citizens in the process of knowledge production and knowledge utilization. Fifth, the concept of knowledge management was discussed mainly in the Colciencias and university documents as a strategy to link research evidence to the health policymaking process. The concept focused on the role of indicators and evaluation research to identify health needs and to inform coverage decisions.

To discuss some of the assumptions behind these theoretical insights can improve our understanding of the role of research evidence in the Colombian society and more specifically in the health policymaking process. Below we discuss the assumptions and implications behind the push to become a knowledge society, we highlight some questions regarding the role of policymakers in the concept of SAK and the role of research evidence in the concept of knowledge management, and we present lessons from other studies that can help us to answer some of these questions.

Assumptions and implications of the “knowledge society”

1. Research evidence is valued in terms of its contribution to industry and the economic development of the country

The rhetoric around the concept of “knowledge society” reveals a worldview that is rooted in ideas about ‘development’ as a hegemonic globalized political discourse, a euphemism that, as shown by this study, has permeated the ideas about what Colombia wants as a society and how to achieve it. Development as political discourse can be argued to have begun on 20 January, 1949 with the inauguration speech of Harry S. Truman when more than half of the world’s population became labeled as ‘underdeveloped’ for the first time (Sachs, 2007). They “ceased being what they were, in all their diversity, and were transmogrified into an inverted mirror of other’s reality” (Esteva, 2007; 7). As an example of how engrained this development discourse is in the

documents we reviewed, it is revealing to take note of the similarities between the documents' 'taken-for-granted' ideas about the role of science and president Truman's speech:

“We must embark on a bold new program for making the benefits of our scientific advances and industrial progress available for the improvement and growth of underdeveloped areas. More than half the people of the world are living in conditions approaching misery. Their food is inadequate. They are victims of disease. Their economic life is primitive and stagnant.” January 20, 1949, President Truman.

The development discourse reveals that the ideas in these documents, about the justification for becoming a society of knowledge and about the type of knowledge that should be produced, disseminated and used, approve and perpetuate political and epistemological forms of colonialism—what De Sousa Santos calls the “coloniality of power and knowledge” (de Sousa Santos, 2007; xxxiii). The explicit argument that the society of knowledge will transform Colombia into a more advanced and developed society, and the exclusive emphasis on research that can promote the competitiveness of the country, reveals a world view that supports the developed/underdeveloped dichotomy and in which research that can produce knowledge to be used by industry has more value than other types of research.

2. Economic growth may not lead to social well being

The emphasis on research that can produce knowledge to be used by industry is supported by the assumption that economic growth and its consequences, such as participation on global markets, will lead to social well being. However, this assumption is questionable (Muntaner et al., 2011; Navarro, 1999). One example is the “race to the bottom hypothesis” (Rudra, 2008). Accordingly, expanding international markets and the prioritization of efficiency and competitiveness will force all states to adopt free market policies. The structural power of business³ in this global competition will lead to welfare retrenchment. First, social benefits will be reduced because they increase labor costs and reduce competitiveness. Second, governments, in order to attract foreign investments and avoid capital flight, are forced to reduce taxes on capital and therefore it will be harder to raise the necessary revenues to maintain the welfare programs (Rudra, 2008).

This “race to the bottom” pressure could be more intense in middle-income countries like Colombia, where there is a large population of low-skilled workers who are hard to

³ Rudra explains the race to the bottom hypothesis from a neopluralism perspective (Smith, 1990). According to Smith (1990), neopluralism recognizes that some pressure groups, particularly business, have privileged access to the state, not because of extra resources or lobbyist skills but because of the very structure of society. The need of governments to maintain a healthy economy forces them to make policies that are in the interests of employers without employers having to take any action. From this point of view, it is the structure, not the actions or resources of groups, that gives power to businesses. This is what has been called the structural power of business.

mobilize into collective agreements due to their low education, and inconsistent jobs and the large surplus of labor. The greater the number of low-skilled workers and the larger the amount of surplus, the lower the likelihood that workers will cooperate voluntarily and create strong labor institutions to resolve collective action problems, like defending welfare spending (Rudra, 2008).

Questions regarding the role of policymakers in the concept of SAK

Social appropriation of knowledge emerged as an important concept to understand the role of the ‘public’ in the science-society relationship. However, since the emphasis of the SAK activities is either on informing or including the ‘general public’ or the ‘citizens’ in the processes of knowledge production and knowledge utilization, the mechanism through which other actors, especially policymakers, can appropriate knowledge have not been described. The role of policymakers is principally confined to the coordination of the SAK activities and not as an actor who can benefit from them. Therefore, questions—such as what the best mechanisms to mobilize research evidence into these activities in order to best inform policymakers are, or how research evidence can be integrated with the “[...] different interest, needs, expertise, and heterogeneities” (Colciencias, 2010; 26) that are present in a deliberative dialogue—have not been answered.

Questions regarding the role of research evidence in the concept of knowledge management

Even though the conceptualizations of knowledge management presented here helped us to understand the process of how health systems research is used in the policymaking process, they also present us with some challenges to resolve. For example, how and what types of research evidence can inform the multiple stages of the policymaking process? Or how and what type of research evidence can inform the variety of decisions related to health system? From our results we have a hint that indicators and surveys are important to define a problem, but the conceptualization is silent about the role of other types of information (e.g., results from qualitative research) in understanding and framing the problem. We also know that evaluation research can help to assess the effects of drugs, interventions and programs, and therefore, provide direction about what options are available to address existing problems within the health system problems. However, it is not clear how research evidence can inform other decisions about the governance, financial and delivery arrangements. For example, how and what type of research evidence could help decision maker understand the implications of different forms of raising revenue to finance the system? Finally, the concept of knowledge management leaves us with the challenge of integrating different forms of knowledge into the decision making process.

Lessons from other studies that could address some of these questions

Lessons from other studies could help us to create a more comprehensive notion about how research evidence can inform healthy systems decisions. First, those interested in supporting the use of research evidence in the health policymaking process could focus their efforts on promoting a more conducive environment in which the government, research funders and universities have a mandate to support and place value on promoting the use of research evidence to inform health systems decisions and their own organization decision-making process. In addition, government, research funders and universities should also build partnerships to collectively ask and answer locally relevant health systems questions and promote efforts to link research to action (Lavis et al., 2006).

Second, a more comprehensive notion calls for a better understanding of what types of research evidence can inform the identification and definition of the health system problem (Lavis, Wilson, Oxman, Lewin, & Fretheim, 2009), the framing of policy options (Lavis, Wilson, Oxman, Grimshaw, et al., 2009) and implementation considerations (Fretheim, Munabi-Babigumira, Oxman, Lavis, & Lewin, 2009). For example, the objective of the process of knowledge management identified in this study is to identify changes in indicators or in the operation of current programs that could detect potential problems. However, these conditions are only defined as problems for which governmental actions are required, when they violate important values, when they are compared within and between countries or when they are classified under one category or another (i.e., issue framing). Information derived from research evidence (e.g., qualitative studies) is key to understanding when those changes on indicators violate important values of society or how different framings of problems mobilize particular interest groups (Lavis, Wilson, Oxman, Lewin, et al., 2009).

Third, it is also necessary to have a better understanding of what mechanisms could be used to mobilize research evidence into the policymaking process. Four mechanisms are worth mentioning: evidence briefs, policy dialogues, clearinghouses, and rapid response services. Evidence briefs identify a priority policy issue and then mobilize synthesized research (e.g., systematic reviews) and local evidence (e.g., local program evaluations) to help policymakers understand and systematically think through the problem underlying the priority policy issue, the potential options available for addressing the issue, and the factors that need to be considered when implementing the options (Lavis & Panisset, 2010; Lavis, Permanand, Oxman, Lewin, & Fretheim, 2009). Evidence briefs can be used as an input into policy dialogues where research evidence is considered together with the views, experiences and tacit knowledge of those who are involved, or affected by, a decision regarding a priority policy issue (Lavis, Boyko, Oxman, Lewin, & Fretheim, 2009).

Clearinghouses and rapid response services are efforts that facilitate policymakers and other stakeholders' access to research evidence. Clearinghouses are databases designed to provide policymakers, stakeholders and researchers with timely access to relevant evidence about how to strengthen or reform health systems. Examples of these include

Health Systems Evidence (www.healthsystemsevidence.org), EVIPNet Virtual Health library (<http://global.evipnet.org/>) and the Uganda clearinghouse for health policy and systems research (<http://uchpsr.org/>). Rapid response services are designed to respond to policymakers' urgent needs for evidence related to health systems questions. Some examples of these are the rapid response services developed in Uganda and Burkina Faso as part of the SURE project (<http://www.who.int/evidence/sure/rapidresponses/en/>).

Strengths and limitations

Our study has several strengths. First, it is the first study to develop an analytical schema to explain the assumption of an evidence-informed health system embedded in documents prepared by or for the Colombian government, a major Colombian research funder and Colombian universities. Second, despite the challenges of using grounded theory for the analysis of different types of documents (variations in the language used, length, content, purpose and intended audience made difficult the task of finding common themes and relationships), our decision to focus on written text gave us a privileged position to explore the institutional instead of the individual conceptualization of the phenomena. Institutional written texts have the capacity to transcend time and to transcend individual authors. Third, we enhanced the credibility of our theoretical construction by comparing different types of documents within and between actors and by keeping an audit trail and a journal through the research process to reflect on challenges and to record the rationale for any decisions about the logistics and methods of the study. Fourth, our theoretical sampling strategy allowed us to fill conceptual gaps and build a more cohesive analytical story. Finally, the use of the NVivo software allowed us to keep a transparent account of the research process.

Some limitations have to be highlighted. First, information from sources that we did not include could complement our conceptual understandings of the use of research evidence in the Colombian health system. For instance, the role of industry emerged as an important theme and we did not include documents from this source. Documents from international organizations could also help us to better understand the focus on themes like globalization. However, our selection of actors allowed us to gain helpful insights about the general climate for research use (Lavis et al., 2006). Second, the focus on a limited selection of documents in such a large field implies that our own views and training in health services and policy research, political science and sociology framed our interpretations and explanations. It also implies that the grounded theory relates to a very specific setting. Therefore, readers will have to make their own judgments about how transferable these insights are to their own context. Third, this study provides theoretical insights that emerged from documents, which portray aspirational views about how things 'ought to be'. Study of other data (e.g., interviews) could complement these theoretical insights by providing information about how things are in practice.

Implications for policy and practice

Our results have several implications. First, they provide important insights for those interested in promoting the use of research evidence in the Colombian health system. Researchers can start studying how to improve the conceptualization of what mechanisms can be adopted to promote an evidence-informed health system. Policymakers can begin to recognize the predominant system of ideas and standards under which they define their goals and instruments. Making evident these ideas may also help them make more transparent assessments about their pertinence and performance. For example, policymakers could assess whether the efforts to align research with production are being translated to better health and social wellbeing.

Implications for research

The results of this study serve as a point of departure for future conceptual and empirical studies. For example, they highlight the importance of research about social learning and paradigm shifts to understand better how and when the actual political paradigm will change to create a more conducive environment for an evidence-informed health system. The study also shows the need to develop and evaluate mechanisms to mobilize research evidence to inform health system policymakers. For example, we need studies that: (1) help us identify if universities and research centres are producing the types of research evidence that policymakers need to inform their decisions about the health system; (2) help us understand better how context and issues influence the use of research evidence in specific health system's decisions; and (3) assess the effects of the interventions designed to support the use of research evidence in the policymaking process, interventions such as evidence briefs, policy dialogues, clearinghouses, and rapid response services.

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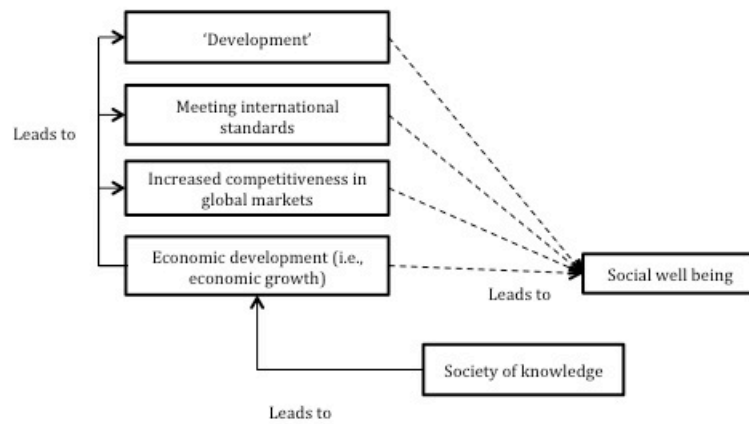
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Tables and figures

Figure 1: Why Colombia wants to be a knowledge society



The dash arrows represent a link that has been critiqued in the text.

Figure 2: How to become a knowledge society

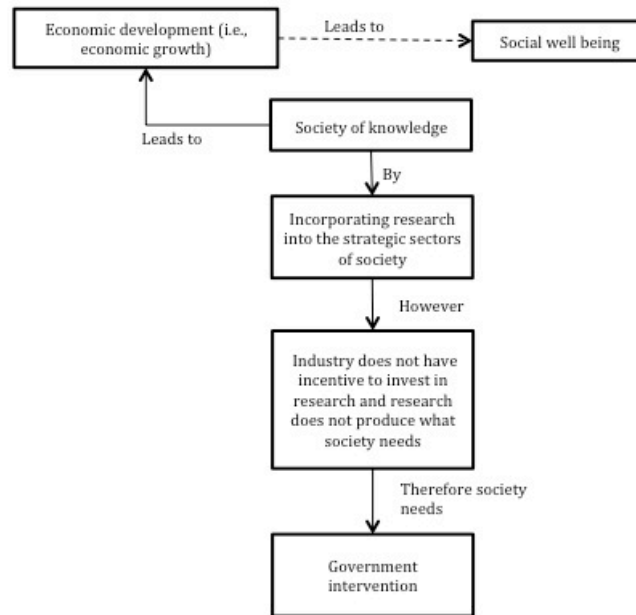


Figure 3: The role of industrial and commercial innovation

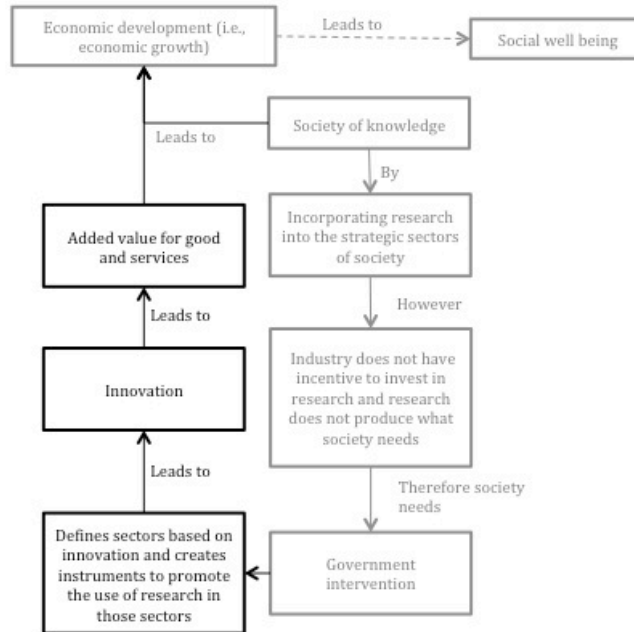


Figure 4: Social appropriation of knowledge

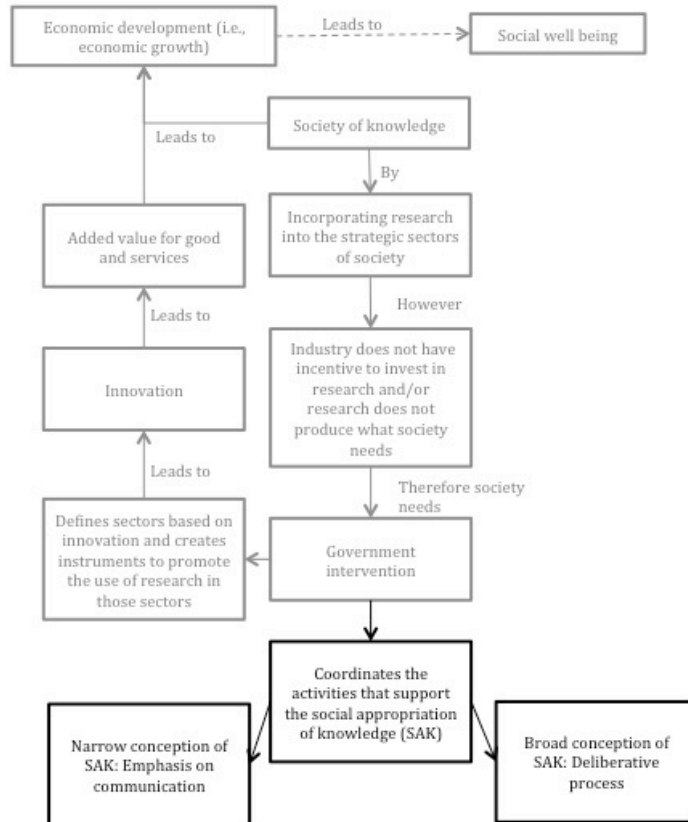


Figure 5: Knowledge management

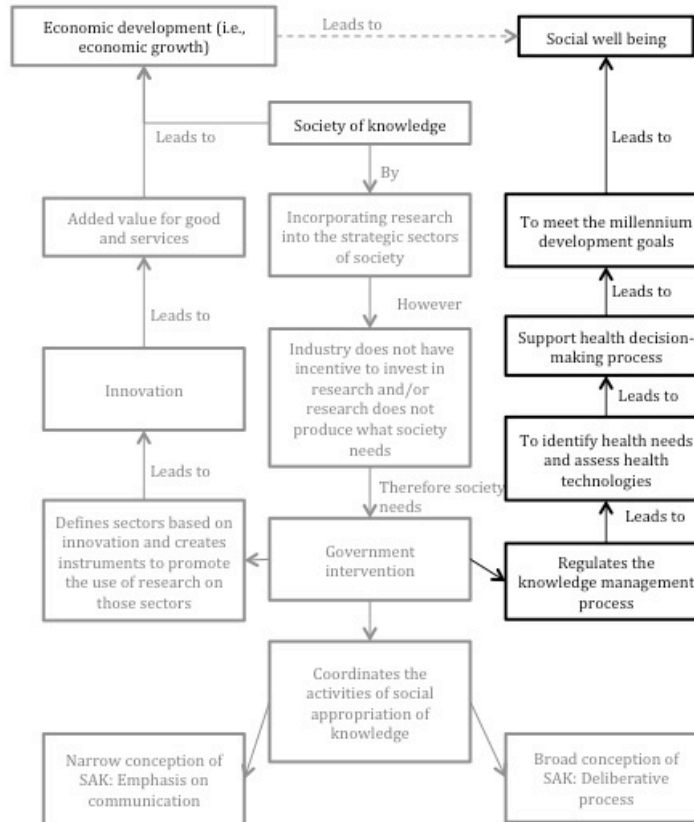
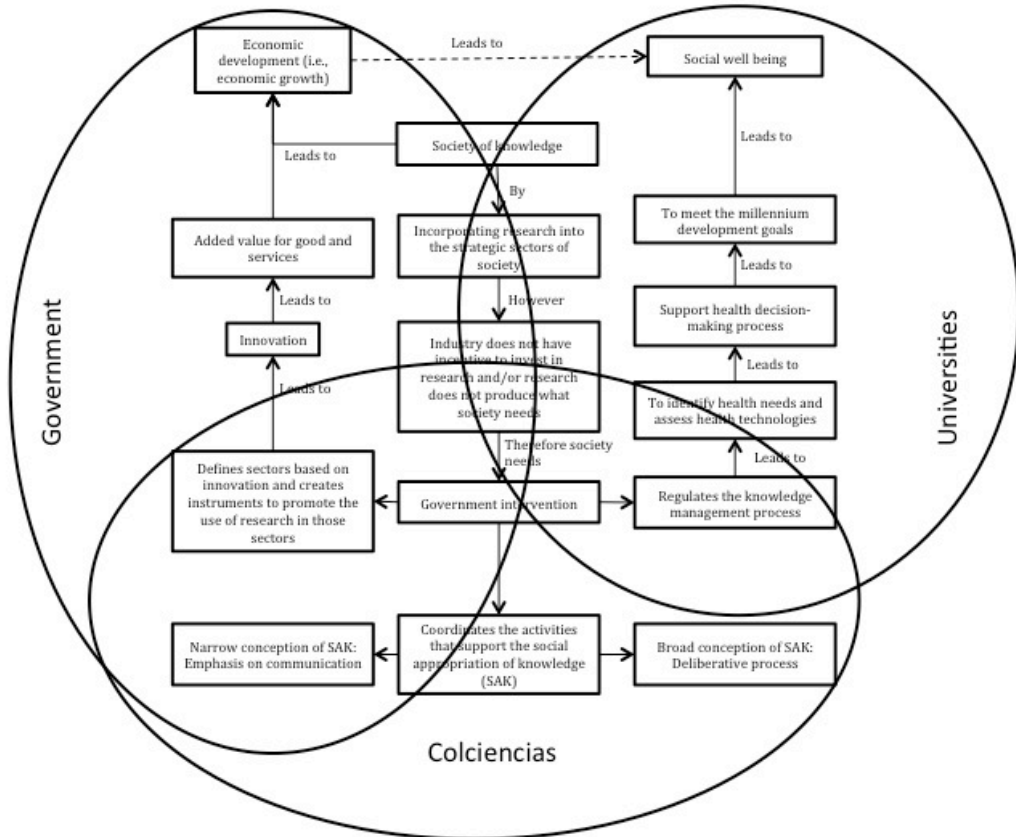


Figure 6: Emphasis of the documents on the theory



Appendix 1: Documents included in the analysis

We included 14 documents produced for or by the Colombian government:

Institution	Title
Presidency, national planning department, 2005	Colombian vision: 2019
Presidency, national planning department and Colciencias, 2006	Vision 2019: To base growth and social development on science, technology and innovation
Presidency, national planning department, 2008	Where do we want to get: Vision 2032 and main strategies
National planning department, 2002	National development plan 2002-2006: Towards a communitarian state
National planning department, 2006	National development plan 2006-2010: Communitarian state: Development for all
National planning department, 2010	National development plan 2010-2014: Prosperity for all: More employment, less poverty and more security
Colombian congress, 2009	Law 1286, 2009: To strengthen Colciencias and the national science and technology system
Colombian congress, 2011	Law 1450 of 2011: To issue the national development plan 2010-2014
National council for economic and social policy (CONPES), 2008	National competitiveness and productivity policy
National council for economic and social policy (CONPES), 2009	National policy on science, technology and innovation
Ministry of Social Protection, 2007	National public health plan 2007-2010
Ministry of Social Protection, 2008	From knowledge production to policymaking: External assessment of the health reform support program 1996-2007
Ministry of Health, 2012	National public health plan 2012-2021: Health in Colombia is built by you
Ministry of Health, 2013	Methodological guideline for registries, observatories, monitor systems and national health situation rooms.

We included eight documents produced by or for Colciencias

Institution	Title
Colciencias, 2005	Policy for the social appropriation of science, technology and innovation.
Colciencias, 2005	Supporting the research priority setting process in Colombia using the combined

	approach methodology
Colciencias, 2008	National policy to promote research and innovation: “Colombia builds and grows its future”
Colciencias, 2008	Strategic plan 2009-2015: Knowledge to transform health, social development and quality of life.
Colciencias, 2010	National strategy for the social appropriation of science, technology and innovation
Colciencias, 2011	Typology of scientific, technological and innovation projects
Colciencias, 2013	Strategies to make productive use of knowledge in the health sector in Colombia, 2013
Colciencias, 2013	Health and quality systems based on knowledge.

We include 16 documents produce by universities or research centres

Institution	Title
National University of Colombia, 2004	Global development plan 2004-2006
University of Antioquia, 2005	Strategic bases for the university development plan
University of Valle, 2005	Strategic plan for development 2005-2015
Colombian network on policy and health systems research, 2005	Guidelines for a national policy: Knowledge management on public health
University of Antioquia, 2006	Development plan 2006-2016
National University of Colombia, 2006	Global development plan 2007-2009
Javeriana University, 2007	University planning 2007-2016
Development and public health technology assessment center (CEDETES). University of Valle, 2007	Strategies for a national policy on health research
University of Valle, 2008	Strategic plan for development 2005-2015
Rosario University, 2009	Analysis of the ‘research and promotion to innovation’ policy of the Rosario University
Colombian network on policy and health systems research, 2009	Knowledge management in public health
Andes University, 2010	Research at Uniandes: Policy construction
Industrial University of Santander, 2010	Action plan 2010-2012
National University of Colombia,	Global development plan 2010-2012

2010	
Rosario University, 2011	‘Research and promotion to innovation’ policy of the Rosario University: Toward a research-based university
University of Valle, 2012	Strategic plan for development 2005-2015

Chapter 3: Relationship between research evidence and the political factors that influence agendas and decisions. An explanatory case study of two health policies in Colombia.

Abstract

Context and objective: The importance of using research evidence to inform health policy decisions and strengthen health systems in low and middle-income countries has been stated in several action-oriented reports. Despite the growing call for studies to understand the use of research evidence in real-world political contexts, empirical studies that explore this relationship remain uncommon in Latin America. This study aims to understand whether and how contextual factors influenced the role of research evidence in the agenda-setting and policy-development stages of two health policy decisions in Colombia. **Methods:** We present theoretical propositions that explain the factors that influence the governmental and decision agenda and the final policy choice, and how these factors influenced or were influenced by the use of research evidence. We then explore and confirm these theoretical propositions using data collected during interviews with policy actors of each policy decision. **Findings:** We studied a large-scale reform that intended to strengthen the system through incremental changes as a response to the financial crisis in the health system in 2011 and a more technical content-driven policy that intended to regulate the pharmaceutical market in 2012. We observed that in the large-scale reform, the combination of new political executive power, strong values about preserving the insurance model and few veto points in the congress constrained the decision-making power to the executive arena. This arrangement of institutions, interests and ideas created the conditions that allowed elected officials' ideas about 'what ought to be' to lead to an instrumental use of research evidence (i.e., they used citable research that resonated with their values) and symbolic use of research evidence (i.e., they selectively used or did not use research that criticized the insurance model). In the pharmaceutical policy, we observed that the symbolic use of research evidence by the previous government helped to create a problem that forced the newly elected government to regulate the prices of pharmaceuticals despite its 'free market' values. In the new government, the transparent and instrumental use of research evidence during the policy-development process became a strategy of elected officials and policy advisors to negotiate with the pharmaceutical industry the introduction of regulatory policies. **Discussion and conclusion:** We provided a comprehensive account of two policy processes in Colombia, as well as detailed explanations of how the problem, policy and political-related factors explain how issues moved into the governmental and the decision agenda, and how institutions, interests, ideas and external factors influenced the policy choice. In addition, we presented an analysis of the interaction between these factors and the use of research evidence, indicating their joint influence in the policy process while suggesting the importance of considering the direction of the interaction, the way in which research was used and the point in time of the interaction. We hope to have highlighted the importance of understanding the factors that influence the policy process and its relationship with research evidence at a time when this understanding is of significant relevance to strengthening health systems in low and middle-income countries.

Introduction

The importance of using research evidence to inform health policy decisions and strengthen health systems in low- and middle-income countries (LMICs) has been emphasized in several global reports (Global Forum for Health Research, 2004; Global Ministerial Forum on Research for Health, 2008; World Health Organization and Partners, 2011; World Health Organization, 2004). These statements call for the development of mechanisms that support the mobilization of research evidence to support the health policymaking process.

One important step in developing such mechanisms is to conduct explanatory studies to understand the use of research evidence in real-world political contexts (Gilson, Hanson, & Sheikh, 2011; Sheikh, Gilson, & Agyepong, 2011). However, while some such research has been done in LMICs, empirical studies that explore the use of research evidence in policymaking in Latin America remain uncommon. For example, a recent systematic review that included – among other types of study designs - primary research studies about how evidence is used in policymaking (not just in the health domain) found 145 eligible studies, of which 32 out of the 33 studies from LMICs were from sub-Saharan Africa and Central America (Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014). Only one, which did not have a focus on health, was from Latin America (Carneiro & Da-Silva-Rosa, 2011).

In Colombia, we are aware of two examples of empirical research about the use of research evidence in health policy decisions that were not included in the aforementioned systematic review. One of them involved interviews with researchers and policymakers at the subnational level about their perceptions of the use of research evidence in public health-related decisions and an analysis using the framework developed by Walt and Gilson (Walt & Gilson, 1994) about - content, actors, process, and context- (Mosquera, Gómez, & Méndez, 2005). The other one is a master's thesis that assessed the factors that influenced the use of research evidence in subnational health policy decisions related to the prevention and control of cardiovascular diseases (Rojas-Núñez & Contreras-Rengifo, 2011). However, neither of these two studies took a comprehensive approach to assess the influence of a full range of potential factors (including research evidence) on agenda setting (for both the governmental and decision agendas) and on policy choice in health.

Based on two case studies at the national level in Colombia, this study aims to understand whether and how political factors influenced the role of research evidence in the agenda-setting and policy-development stages of two past health policy decisions. We start by describing our theoretical propositions about the factors that influence the governmental and decision agendas and that led to the final policy choice, and how these factors influence or were influenced by the use of research evidence. We then use these theoretical propositions to generate descriptive categories to explore the dynamics related to the use of research evidence in two health policy cases in Colombia.

Description of the theoretical propositions

We categorized the theoretical propositions that provided guidance for data collection and analysis into five sections: (1) selection of a sample of policies, (2) definition of research evidence and what constitutes research use, (3) factors that influence the governmental and decision agendas, (4) factors that influence policy choice, and (5) factors that influence the use of research evidence.

Selection of a sample of policies

Some types of policies and policymaking processes may be more amenable to being informed by research evidence than others (Lavis et al., 2002). Therefore, when selecting a sample of policies it is important to distinguish between the following policy categories: those related to governance arrangements (i.e., like those that define the accountability of the state); those related to financial arrangements; those related to delivery arrangements; and those related to program content. This range of policies provides variation on the scale of the policy change, for instance, policies related to governance arrangements may lead to larger-scale changes in the health system than policies related to the content of a program (i.e., which services will be provided and to whom). According to this theoretical proposition, large-scale policies may be more amenable to the influence of research in conceptual ways, whereas technical policies related to the content of a program may be more amenable to the influence of research in instrumental ways (Lavis et al., 2002).

Definition of research evidence and what constitutes research use

Our second set of theoretical propositions assisted us to define research evidence and what constitutes the different types of research use. Policymakers and stakeholders tend to have a broad definition of research evidence that makes difficult the task of separating the influence of information derived from research evidence from the influence of information derived from other sources. Therefore, several authors recommend considering research evidence and other types of policy-relevant information as complementary inputs to the policy process (Culyer & Lomas, 2006; Dobrow, Goel, Lemieux-Charles, & Black, 2006; Dobrow, Goel, & Upshur, 2004). In our study, we were attentive to identify uses of citable research evidence, defined as research that is published in a publicly available form, such as journal articles, books, chapters, working papers and reports (Lavis et al., 2002). In addition, we distinguished between three types of use, namely instrumental, conceptual and symbolic uses of research evidence (Amara, Quimet, & Landry, 2004; Weiss, 1979). Instrumental use is using research in specific and direct ways to solve a particular problem. Conceptual use refers to a more indirect form of enlightenment, for instance when research evidence provides ideas that affect the way policymakers think about a problem or options to addressing it. Symbolic (or political) use refers to using research evidence to justify a position that has already been taken for reasons that had nothing to do with the research findings.

Factors that influence the governmental and decision agendas

Kingdon's framework (2003) guided our data collection and analysis regarding the factors that influence the governmental and decision agendas. This framework explains how the interaction among the problem, policy and politics streams, combined with visible and hidden participants, affects agenda-setting dynamics. Some conditions, like a focusing event, a change in an indicator, or feedback from the operation of current programs can catch the attention of governmental officials. These conditions could be defined as problems, when they violate important values, when they are compared with other countries or when they are classified under one category or another (i.e., issue framing). The political stream is concerned with political events, such as swings in the national mood, changes in the balance of organized forces, or events within government. The governmental agenda, the "list of subjects to which governmental officials and those around them are paying serious attention" (2003, p. 3), is influenced by visible participants (e.g., prime minister, journalists) and events in either the problem or the politics stream. The third stream, the policy stream, refers to the generation of policy proposals. This generation takes place through the diffusion of ideas in a policy area, feedback from current policies, or communication and persuasion. Technical feasibility, coherence with values and the national mood, and the possibility of anticipating future constraints are the characteristics that give policy proposals the possibility to survive to a situation of serious considerations. Hidden participants (e.g., researchers, civil servants) are involved in this process of generating policy alternatives. Finally, the coupling of the three streams influences the decision agenda, which is "the lists of subjects within the governmental agenda that are up for an active decision" (2003, p. 4). Policy entrepreneurs typically facilitate this process (Kingdon, 2003).

Factors that influence policy choice

The synthesis of political science theories in four general categories – institutions, interests, ideas and external factors – is helpful to explain why and how policy decisions are made within a particular context. The institutions category includes how state capacity and past policies influence subsequent policy choices. To focus the analysis on state capacity implies identifying how different decision points and representatives at different political arenas affect political decisions. Accordingly, it is easier to build consensus and exclude opposition groups from the process if there are fewer decision points and opportunities for veto (Immergut, 1992; Jordan, 2009). Paying attention to the influence of past policies implies the identification of policy-feedback mechanisms that promote or hinder policy change. Policy-feedback mechanisms include the resource and incentive effects and the interpretative effects that policies create among government elites (e.g., development of administrative capacities or learning from previous policies), interest groups (e.g., financial rewards or 'spoils' that motivate the mobilization of beneficiary groups and create niches in which policy entrepreneurs can act) and the general public (e.g., policies provide incentives that lead individuals to act in a way that 'lock in' a particular path of policy development) (Pierson, 1993).

The interests category is helpful to explain the perceptions of political actors (e.g., societal interest groups, elected officials or policy advisors) about who wins and who loses as a result of a given policy and by how much. In addition, this category is also helpful to explain the ability of these actors to exercise and attain their interests depending on the distribution of resources and power in a policy domain. Some interest groups may have a structural power that gives them privileged access to the state, not because of extra resources or lobbyist skills but because of the very structure of society (e.g., the need of governments to maintain a healthy economy can condition them to make policies that are in the interests of employers without employers having to take any action). Other interest groups, or the same interest groups at a different point in time, may have an instrumental power in which access to the state is derived by their own resources and/or lobby capabilities and not by the structure of society (Smith, 1990).

The ‘ideas’ category gives analytical attention to the role of policy paradigms and knowledge in a particular policy choice. Focusing on policy paradigms implies trying to identify the ‘taken-for-granted’ ideas, values and norms that are embedded in the discourse of political actors (e.g., views about what ought to be) (Hall, 1993). In addition, it is also helpful to understand how research evidence and/or tacit knowledge influence policy choice (e.g., knowledge about what is) (Lavis, 2002).

Finally, it is also important to pay attention to how external factors, such as political or economic change, release of major reports or emergence of new diseases, influence the policy decisions (Lavis et al., 2012).

Factors that influenced the use of research evidence

The final theoretical proposition that guided our analysis suggests being attentive to the interaction among the factors that influence agendas and policy choice and the different types of research use. The intention is to capture whether and how the problem, policy or politics streams of the agenda-setting stage or the institutions, interests and ideas of the policy-choice stage, influenced or were influenced by the use of research evidence. For example, we are interested in finding if research was embedded in other types of information or in broader political forces like stakeholders’ positions (Lavis, 2002).

Methods

In order to understand whether and how research evidence was used in two health policy decisions in Colombia we used a multiple case study design. The interest in tracing the operational links in the process of using research evidence in policymaking and the blurry boundaries between the phenomenon under study and its context, made the case study an appropriate method to achieve our objective (Yin, 2009).

Definition and selection of cases

We defined the cases as policy processes made up of a series of events leading to a government statement of intent to act on a policy issue. For each case we first sought to understand the factors that influence the agenda-setting and the policy-development stages, and then sought to understand the relationship between those factors and the use of research evidence in each stage.

We purposively selected two policies according to the following criteria: (1) visible policies (i.e., policies that engage large numbers of interested stakeholders and are covered extensively by the media) developed in the last four years, (2) policies with apparent variance (maximum variance) in the use of research evidence, and (3) policies from different policy categories. The purpose of the first criterion was to minimize recall bias and to increase our chances of finding richer information. The rationale for the second criterion was rooted in the study objectives of exploring and confirming the theoretical propositions and identifying different perspectives on the use of research evidence (Seawright & Gerring, 2008). The third criterion helped to improve our chances of finding variation in the use of research evidence. As shown in our theoretical propositions, policies from different policy categories may be amenable to different types of evidence use. In addition, the overall availability of high quality research evidence is different for policy category; for example, there is less research to inform governance arrangements (2708 documents in the Health Systems Evidence database¹, HSE) and financial arrangements (2036 documents in HSE) than to inform delivery arrangements (8080 documents in HSE).

To identify the policies we contacted academic researchers and civil servants and asked them to identify recent visible Colombian policies (from the last four years) related to each of the four broad policy categories, to provide information regarding the factors that influenced the decision, and to provide two other contacts who could give more information regarding the policies that they selected. We collected documentation about each policy and identified and selected those policies that best fit our selection criteria.

Data collection and analysis

We collected data from document reviews and key informant interviews during the period October 2012 – March 2014. We identified policy documents, archival records, print media, published literature, reports and presentations that were related to the cases through ongoing stages of purposive sampling that were underpinned by: referrals from key informants, referral from the congress librarian, hand searches of government organization websites (e.g., the webpages of the Colombian Ministry of Health, Ministry of Commerce, presidency, and national planning department), hand searches of newspapers and magazine websites (e.g., El Espectador, El Tiempo, EL Colombiano and

¹ Health Systems Evidence. Hamilton, ON, Canada: McMaster University ([http:// www.healthsystemsevidence.org](http://www.healthsystemsevidence.org)), consulted on April 20, 2014.

Revista Semana), Google searches, and themes emerging during various stages of the analysis.

We collected interview data through in-depth semi-structured interviews. Potential interviewees were first identified during the case-selection process, by reviewing the organizational charts of the Ministry of Health and by getting input from colleagues at the University of Antioquia. The selection of additional informants was driven by a respondent-driven-sampling technique. We were interested in interviewing policymakers or policy advisors who were involved in the policymaking process; however, we were open to interviewing other actors who had an important perspective or stake in the issue if they were recommended by the interviewees.

We contacted participants with a formal letter and followed up by email and telephone. The first series of interviews occurred during the period February – May 2013, and were followed by a period of analysis, during which time we adopted strategies to improve our access to potential interviewees and increase the response rate among those we approached to interview. During the period of July – August 2013, we conducted another series of interviews. Data collection ended when no additional insights were emerging during the interviews. All interviews were semi-structured, face-to-face, conducted in Spanish by the principal investigator (DP) following a themed guide based on our theoretical propositions (see appendix 1), and audio-recorded. Notes were taken during and after each interview to complement the information. Recordings were transcribed in Spanish and the transcriptions were anonymized.

We transferred all collected data to NVivo 10 qualitative analysis software, which was used to organize the case-study database and to undertake coding and analysis. The analysis was performed in English according to a pre-established codebook based on our theoretical propositions namely, the propositions from Kingdon's framework and from the political science literature around institutions, interests, ideas and external factors (see appendix 2). We started the analysis with a detailed and chronological description of the cases' key events. Then, we identified the contextual factors that influenced the government agenda and the policy choice. Finally we analysed the interaction between these factors and the use of research evidence and developed a cross-case comparison of that interaction. The processes of collecting, analyzing the data and writing the final narrative were interrelated and happened simultaneously in this study.

Ethics approval was obtained prior to data collection from the McMaster University Faculty of Health Sciences Research Ethics Board (Hamilton, Ontario) and the Medical Research Institute at the University of Antioquia (Medellin, Colombia).

Results

Case selection and data collection

Following our case-selection procedures we selected two visible policies to study: (1) the health reform of 2011, known as Law 1438, which aimed to strengthen the system through incremental changes as a response to the financial crisis in the health system; and (2) the strengthening of the regulatory system for pharmaceutical products in 2012. Law 1438 intended to modify a broad range of governance, financial and delivery arrangements in the Colombian health system, and therefore, we coded it as a large-scale policy. The pharmaceutical policy was more specific in the policy issue it addressed and in the arrangements that it intended to modify; namely, it focused only on governance arrangements related to commercial authority and financial arrangements related to the purchasing of products and services, and therefore, we coded the pharmaceutical policy as a technical content-driven policy.

We conducted 15 key-informant interviews across the two cases, with one of the interviewees providing information about both of them. Seven interviews were related to the health reform and nine to the pharmaceutical policy. Interviewees were policy advisors at the ministry of health, the national planning department and other governmental organizations. They also include professionals or researchers at universities, civil society organizations and private consulting firms. The interviews were in average 52 minutes long for the health reform and 62 minutes long for the pharmaceutical policy, and conducted mostly in Bogota.

We start our presentation with the health reform case and then move to the pharmaceutical policy case. For each case we start by presenting the historical summary of key events related to each process, then we analyze the factors that influenced policy agendas and choices, and then we identify the interaction between these factors and the uses of research evidence. Finally, we present a cross-case comparison of this interaction.

Case 1: Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the financial crisis

Historical summary of key events that led to Law 1438 of 2011

The key events that led to reform the health system in 2011 with Law 1438 started in 1993 with the passage of Law 100. This law created four institutional arrangements that were the focus of reform in the coming years. First, Law 100 created two regimes, the contributory regime for those with ability to pay (e.g., employees), and the subsidiary regime for those without such ability (e.g., unemployed). Second, it defined a list of health services and products (i.e., a health benefit plan) for each regime. Citizens in the subsidiary regime had access to fewer services and products than citizens in the contributory regime; a difference in coverage that was intended to be temporary but that lasted until the year 2012. Third, to finance the system, Law 100 mandated a payroll tax of ~12.5% to be collected by insurance companies (which were also introduced in this reform) and then transferred to the national solidarity and guarantee fund (the national fund from now on). The system used 11 of the 12.5% of these payroll taxes to finance the

health benefit plan of the contributory regime. The remaining 1.5%, plus additional general taxes collected by the national government and extra departmental and municipal contributions, were used to finance the health benefit plan of the subsidiary regime. Fourth, Law 100 defined capitation as the method to pay insurance companies in both regimes. The capitation fee was calculated according to the products and services that were included in the health plan. Insurance companies in the contributory regime received their capitation fee directly from the national fund. In the subsidiary regime, local entities (i.e., the departments, districts, municipalities and indigenous territories) collected resources from the central government (i.e., those from the national fund and general taxes) and from their own contributions before subscribing contracts with insurance companies. In both regimes, insurance companies used the capitation fee to pay service-provider institutions to provide the service and products included in the health plan. The payment from insurance companies to service providers could follow different methods, like capitation, fee for service, global budget or prospective payment (Republica de Colombia, 1993).

In the decade and a half after Law 100 was introduced, three main events -- namely a reduction in formal employment rates, the recognition of the challenge created by the lack of systematic mechanisms to update the health benefit plan and periodic delays in the flow of resources -- led to the 2009 ‘financial crisis’ in the system (Ministerio de la protección social, 2009). The first of these events happened between 1996 and 2000, when Colombia suffered an economic recession that, together with the increase in the payroll taxes introduced by Law 100, had a negative impact on formal employment rates (Acosta et al., 2011). As a result, the percentage of the population that was enrolled in the contributory regime and the resources to finance the system were lower than expected.

Moving on to the second event, the list of products and services included in the health plan was not updated systematically between 1998 and 2006. The lack of updating had two important consequences that contributed to the financial crisis in the system. First, patients started to seek judicial action (i.e., tutelas, a writ for the protection of constitutional rights) to access health services and products that were not included in the health benefit plan. Health-related tutelas increased from 21,301 in 1999 to 81,017 in 2005 (Defensoría del pueblo, 2007) and, since the capitation fee did not cover these ‘not-included services,’ the national fund reimbursed all or part of the costs of all the services and products that were granted by judicial action. Second, the policy solutions and decisions that were made between 2004 and 2008 to address this issue, created incentives among insurance companies and other actors to use the ‘tutela’ mechanism to advance their interests.

For example, in 2007-2008 one of the policy solutions to reduce the number of judicial actions stated that if a scientific committee (i.e., committees within insurance companies comprised of one representative from the company, one from among the service provider and one from service users, with a mandate to approve physicians’ prescriptions of ‘not-included services’) approved the provision of a product or service that was not included in

the health benefit plan of either regime, the national fund would reimburse 100% of the cost to the insurance company. On the other hand, if the committee denied the access to the product or service and it was approved later by a judicial action, the national fund would reimburse only 50% of the cost and insurance would cover the other 50%. This decision created an incentive among the scientific committees to approve products and services that were outside the health benefit plan of both regimes and placed a significant burden on the financial resources of the national fund (Corte Constitucional, 2008a; El Congreso de Colombia, 2007). As a result, the constitutional court issued a major report known as the sentence T-760 of 2008 that ordered the government to: (1) adopt measures to approve products and services that were not included in the health plans; (2) update the health plans in a systematic and participatory way before August 2009; (3) guarantee the same health plan for children in both regimes before October 2009; and (4) plan the incremental and sustainable equalization of health plans for the entire population (Corte Constitucional, 2008b).

Turning to the third event that led to the financial crisis in the system – delays in the flow of resources -- in the contributory regime, the delay was related to the reimbursement of product and services that were not included in the health benefit plan². Since these services were not included in the calculations of the capitation fee, the insurance companies had to wait for the national fund to review the documentation and approve the reimbursement of these services. The exponential growth in the volume of these services created delays in the payment of insurance companies and therefore, in the payment of service-provider institutions. The subsidiary regime had similar issues, plus an extra hurdle related to the collection and administration of funds by local entities. In this regime, there were delays related to the legalization of contracts between the local entities and the insurance companies, the updating of the databases related to the persons who were enrolled by insurance companies, and a lack of capacity within local entities to audit and reimburse the high volume of products and services not included in the health plan. All of these factors acted as barriers to the flow of resources from the national government to the local entities, from the local entities to the insurance companies, and from the insurance companies to the service providers (Peñaloza, García, Orozco, Puerto, & Ríos, 2012).

In December 23 of 2009, the cumulative effect of these three key events led the government to declare a state of social emergency (Ministerio de la protección social, 2009). Under a state of social emergency, the executive arm of government had the authority to pass reforms without the approval of the legislature. The government issued 10 decrees to reform the health system. However, in April 2010 and after multiple protests by civil society, the constitutional court declared that the implementation of a ‘social emergency’ to reform the country’s health system was unconstitutional, noting that

² There is also evidence that insurance companies were double billing. They were using the reimbursement mechanism for products and services that were included in the health plans for which they were receiving a capitation fee. Effectively the national fund was paying twice for the provision of these products and services and the insurance companies were increasing their profits. The media reported several such cases of corruption.

the crisis in the health system was not an unforeseen event, and thus the government should have used the traditional legislative channel, the Congress, to pass health reforms (Corte Constitucional, 2010).

In 2010, a newly elected congress and president rushed to pass a health reform to address some of the aforementioned issues. In May 2010, Colombians had elected a new congress in which the ‘social party of national unity’ gained the highest percentage of seats in the senate and the House of Representatives. In July of that year, when the newly elected congress began to meet, senators Dilian Francisca Toro and Jorge Ballesteros, from the same ‘social party of national unity,’ presented the first ‘project’ (or legislative proposal) to reform the health system (Senado de la Republica, 2010c). In August, Juan Manuel Santos, from the same political party, won the presidential campaign and appointed a new minister of social protection who accelerated the momentum for the reform. In just four months, 10 projects to reform the health system were presented and discussed in the legislature, while at the same time, the Ministry of Social Protection held ‘thematic tables’ to gather different stakeholders’ views and perspectives around health system issues and propose recommendations to inform the reform. Finally, in December 2010 the congress approved the reform, and it was finally proclaimed as Law 1438 in January 2011 (see table 1).

Insert table 1 around here

Factors that influenced agendas and choices related to Law 1438 of 2011

The issue of reforming the health system as a response to the financial crisis appeared on the governmental agenda as a result of: (1) the identification of a problem through feedback about the health system’s operation; and (2) the definition of this problem by framing it in different ways. Feedback from the operation of the health system and a report from the constitutional court (sentence T-760) indicated a failure to meet the stated goals of achieving universal coverage and equalizing the health benefits of the two regimes. It also indicated a proliferation in the use of tutelas as a mechanism to access health products and services, the reduction in the resources in the national fund, and delays in the flow of resources between multiple actors. Different actors framed these conditions within different categories. For the government elected in 2010, the problem was the financial sustainability of the system, a problem that could be addressed by making specific changes within the current institutional arrangements created by Law 100. This framing was evident in a press release from the Minister that stated: “the government believes in the insurance model, it has showed results, and it would not be a good thing to throw it away because it will put in danger the users of the system” (Ministero de la protección social, 2010). For actors that were ideologically opposed to the government, the problem was not just the financial sustainability of the system; the problem lay in the main institutional arrangements of Law 100, specifically in the for-profit market relationships between the actors. From this perspective, the problem was caused by a structural design failure in which the economic interests of some actors

introduce the logic of business to the protection of health, without considering the social and economic context of the population and people's 'right to health' (Senado de la Republica, 2010b)

The issue of reforming the health system moved to the decision agenda in mid 2010 as a result of the confluence of the problems mentioned above, the proposal of viable policy options and the political promise of the elected president to pass the reform. The viable policy option was presented in the legislature by two senators (Senado de la Republica, 2010c) and was enriched by ideas from other senators and representatives (Cámara de Representantes, 2010), ideas from the Ministry of Social Protection and its technical team (Acosta et al., 2011), and ideas from other stakeholders consulted in regional dialogues and the 'thematic tables' (Ministerio de la Protección Social, 2010). After the declaration of the social emergency, which was followed by protests of citizens, patients, unionized workers and medical students to demand the repeal of the emergency decrees and the resignation of the minister of health, and by the decision of the court to declare unconstitutional the use of the social emergency to bypass the legislature, there was a general climate in the country that health reform must proceed. This national mood helped to move the issue of reform higher in the agenda to the point that the inaugural speech of president Santos included a statement about his intention to undertake a health reform with an emphasis on prevention, equalization of the health benefit plans, and promotion of good governance (Semana, 2010a).

The political factors at play at the time of the policy choice included a broad array of institutions, interests, ideas and external factors. In Colombia, executive decisions to reform the health system require parliamentary approval. However, at that time the executive government enjoyed stable parliamentary support and parliament did not overturn any executive decisions. Two facts support this assertion: (1) there was an evident rejection of ideas presented by the opposition party in the legislature, and (2) in one of the debates in the chamber of representatives, the minister of health could not pass one article that was related to the vertical integration of insurance companies and service providers (Caracol, 2010); however, this article was approved at a later point, in the form the executive wanted, through a joint session of the senate and chamber of representatives (Semana, 2010b). Three policy legacies played an important role. One policy legacy diminished the prospect for change: Law 1122 of 2007 and decision 463 of the court created incentives to approve products and services that were not listed in the health benefit plan. Since the national fund assumed the costs of these benefits, they did not represent a cost to the insurance companies and therefore, this interest group had an incentive to maintain the status quo (Corte Constitucional, 2008a; EL Congreso de Colombia, 2007). The other two policy legacies were conducive to the reform. First, Law 100 created specific deadlines to achieve universal coverage and to equalize health benefits in the two regimes. The cumulative failure to meet these deadlines over the years, and its implications, sent clear signals of problems that needed to be addressed. Second, the visible and traceable intention to reform the health system under a state of social emergency mobilized mass publics and societal and civil interest groups against the way

in which the government was pursuing the reform. However, this mobilization generated a national mood that demanded a health reform that followed appropriate legislative channels (El Espectador, 2010).

The main interests at play included those from doctors' organizations and elected officials. Doctors proposed the withdrawal of the reform project from the legislature because they did not address the "real" problems in the system (El Tiempo, 2010). Elected officials, specifically the executive branch of the government, had an interest in passing the reform as soon as possible. During the discussion of the reform project in the legislature, the president and the ministers of justice and social protection sent a message to the congress expressing an urgent need to pass the reform. In response to this urgent message, the two chambers of the legislature convened a joint session to expedite the decision (Senado de la Republica, 2010a).

Research-related ideas and ideas about 'what ought to be' also influenced policy choice. The reports made by the association of hospitals and clinics showed that something needed to be done about the flow of resources within the system. In addition the minister of social protection's views about 'what ought to be', namely the value he placed on the importance of maintaining the insurance model triumphed over the values of the opposition party. Representatives from the opposition party endorsed the idea that the problem was the insurance model that promoted for-profit market relationships between the actors. The following quote highlights these contrasting views about 'what ought to be':

"[...] This political group [referring to the opposition party] loves to say that a health system based on the insurance model will not work, they would prefer the state to take care of all Colombians equally. Obviously, this group would reject the reform because it keeps the insurance model in place" (Policy advisor, Ministry of Health, in 2010).

To summarize, the combination of a political change right after the failure of a social emergency, coupled with a new political executive power with strong values about preserving the insurance model and with few veto points in the congress, constrained the decision-making power to the executive arena, thereby allowing the government to pass the health reform (see table 2).

Inset table 2 around here

Relationship between research evidence and the factors that influenced agendas and choices related to Law 1438 of 2011

When the issue initially moved to the governmental agenda, research evidence was used instrumentally to identify the problem (instrumental use of research → problem). Some of the most cited studies in the projects presented to the legislature included:

studies conducted by the ombudsman to identify the number of tutelas that were used to grant the right to health benefits (Defensoría del pueblo, 2013; Defensoría del pueblo, 2007) and research conducted by the association of hospitals and clinics that identified the magnitude of the problem related to the delays in the flow of resources (Giraldo, Delgado, Fernández, & Cuadros, 2012). When the issue of reform moved to the decision agenda, research evidence was used instrumentally to identify potential policy solutions (instrumental use of research → policies). First, during the ‘thematic tables,’ different researchers were given the opportunity to present their research findings and make recommendations to inform the debates. Second, the research previously conducted by the minister of social protection and his team of advisors during their past work at a think tank informed some of the possible solutions. For example, one of the recommendations for reform that resulted from this research was to centralize the management of the subsidiary regime (Acosta et al., 2011). This recommendation may have influenced the decision included in Law 1438 to improve the flow of resources in the subsidiary regime by including direct transfers from the national government to service providers, thereby eliminating the contracts between local entities and insurance companies. The following quote illustrates the instrumental use of the research produced by the minister and his team before they were in office:

“We worked with the minister in this [referring to the book published about the effect of Law 100], then this was like our guide, not everything was translated 100% in what is now the 1438, but let’s say that our research contained some of the elements that we wanted to introduce” (Policy advisor, Ministry of Health).

Research evidence was also related to the interests and ideas that influenced policy choice. During the ‘thematic tables’ the research evidence summarized by interest groups (e.g., civil society organizations, service-provider organizations and researchers) enlightened the discussion about specific issues (interests → conceptual use of research). As one key informant noted, “for instance, the [university] Nacional brought its research on financing [...] So yes, researchers had time to present their findings [at the thematic tables]”. However in the final policy choice, views about ‘what ought to be’, specifically the value placed on a ‘free market’ led to a conceptual use (i.e., some ideas may have informed some broad elements of the reform) or symbolic use (i.e., only those ideas that supported decisions were included in the reform) of the research ideas presented while the issue was on the decision agenda (ideas about ‘what ought to be’ → conceptual or symbolic use of research). Two quotes illustrate the conceptual or symbolical use of the ideas that emerged in the ‘thematic tables’.

“The results and recommendation from these [thematic] tables were analyzed. Some of the recommendations that were considered viable were included in this project, others will be addressed in the process of implementation of this and other laws, in the formulation of the national development plan and administrative decision by the National Government”(Senado de la Republica, 2010a).

“[...] The institutional actors of the system produced in each [thematic] table a group of recommendations about the reforms and structural adjustments that are needed to guarantee the right to health, however, it is important to reveal the fact that the recommendations and inputs obtained from these discussions were not gather in the unified plenary” (Senado de la Republica, 2010b).

Insert table 3 around here

Case 2: strengthening of the regulatory system for pharmaceutical products in Colombia in 2012

Historical summary of key events that led to regulatory-system strengthening in 2012

The key events related to the public policymaking process that culminated in the 2012 national pharmaceutical policy could be grouped into four periods of time. In what follows, we start by describing the events from 1988 to 1993, a period in which two policy decisions had important consequence for the regulation of the prices of goods and services and the modification of select, related health system arrangements. Then, we explain events from 1993 to 2002, when Colombia joined the World Trade Organization and adopted key decisions related to intellectual property rights. Next, we move to the period from 2002 to 2010 where we describe a series of government decisions that affected the regulation of pharmaceutical prices. Finally, we focus our attention on the period from 2010 to 2012 where the newly elected government made several decisions to regulate the prices of pharmaceuticals and to strengthen pharmaceutical policy more generally.

In period 1, Law 81 of 1988 and Law 100 of 1993 changed the regulation of the prices of goods and services and modified select health system arrangements respectively (El Congreso de Colombia, 1988; Republica de Colombia, 1993). Law 81 established three regulatory regimes to control the prices of goods and services: (1) direct control, whereby the government established its authority to fix a maximum price that producers and suppliers had to abide by in order to sell their products; (2) ‘regulated liberty,’ whereby the government established its authority to determine the criteria under which producers and distributors can define or modify their prices; and (3) the ‘observed liberty’ regime, whereby producers and distributors could freely establish the prices of their goods and services. Throughout this period, the Ministry of Economic Development was the arm of government with the policy authority to regulate the price of pharmaceutical products. Law 100 of 1993: created the national institute to monitor pharmaceuticals and edible products (i.e., the sanitary authority); shifted the policy authority to regulate the price of pharmaceutical products from the Ministry of Economic Development to the national pharmaceutical price commission (NPPC), comprised of the minister of economic development, the minister of health, and one representative from the presidency; and formed the national council for social security in health, with the mandate to define and

periodically update the list of essential medicines that were covered under the health-benefit plan.

Turning to period 2, in 1995, Colombia joined the World Trade Organization (WTO) and agreed to comply with the trade-related aspects of the intellectual property rights agreement (TRIPS). TRIPS established the standards for intellectual property rights; for example, patent protection on pharmaceutical products must last for a minimum of 20 years. Countries like Colombia had five years to incorporate these standards in their legislation. In 2000 the Andean community (Bolivia, Colombia, Ecuador and Peru) modified their intellectual property rights legislation to comply with the WTO agreements deadlines (Oliveira, Zepeda, Costa, & Velásquez, 2004).

Period 3 (2002-2010) was characterized by changes in the organization of the Ministry of Health, the attempted development of a national pharmaceutical policy, the deregulation of pharmaceutical prices, and the declaration of the aforementioned ‘state of social emergency due the ‘financial crisis’ of the health system. Alvaro Uribe Velez became the new president of Colombia at the start of this periodo (2002) and he retained the position until the end of the period (2010). Under his government, the Ministry of Health and the Ministry of Labour merged into the Ministry of Social Protection. In 2003, one of the actions of this new ministry was to develop a national pharmaceutical policy to improve the use and quality of, and access to, pharmaceutical products. However, the policy did not have enough political support to be implemented (Econometría, SEI, & Sigil Consulting Group, 2011c). The process of deregulating pharmaceutical prices started in 2005 when the consultant firm Econometría released a report commissioned by the Ministry of Commerce and the Ministry of Social Protection, and financed by the pharmaceutical industry, about pharmaceutical pricing policy (Econometría, 2005). The report recommended that the only criterion to regulate the price of a pharmaceutical product should be its dominant power in the market, and not the criteria currently in use, namely the product’s relevance to public health or its classification as a high cost drug or an essential medicine (Econometría, 2005; pg. vii). In 2006, the national pharmaceutical pricing commission, following the recommendations of this report, made a decision that moved almost all pharmaceutical products to the regime of ‘observed liberty’ (Comision nacional de precios de medicamentos, 2006). This decision, referred to as ‘Circular 04 del 2006,’ meant that prices were not regulated but under watch. As a result, no pharmaceutical products were placed within the direct control regime. This process occurred in tandem with the negotiations of the trade promotion agreement between Colombia and the United States (CTPA), which was characterized by tensions between the Ministry of Social Protection and the Ministry of Commerce regarding the implication of intellectual property protections on the prices of pharmaceuticals (Jiménez, 2006). In 2009, as described in the first case, a Colombian government decree declared a state of social emergency because of the perceived financial crisis in the Colombian health system, a significant contributor to which was the price of pharmaceutical products (Ministerio de la protección social, 2009). Between 2003 and 2009 the average annual growth in the reimbursement of pharmaceutical products that were not covered by the

health benefit plan increased 68%. By 2010 the reimbursement of pharmaceutical policies reached 2.5 billion Colombian pesos or C\$1,4 Million (Ministerio de salud y protección social, 2012).

The main events in period 4 (2010 to 2012) were the election of a new government and the implementation of several decisions that regulated the prices of pharmaceuticals and became part of a new pharmaceutical policy. One of the first decisions taken by the new government, articulated in decree 4474 of 2010, stated that the minister of social protection could establish “maximum values of reimbursement” for the pharmaceutical products that were not included in the health benefit plan (Ministerio de la protección social, 2010). Following this decision, the Ministry of Social Protection issued several resolutions in each of 2010, 2011 and 2012, which provided a list of the maximum value of reimbursement for different active ingredients. In January 2011, the government passed Law 1438, which established the commitment to develop a national pharmaceutical policy to optimize the use of pharmaceutical products, avoid inequity in access to such products, and assure their quality. It also changed the national pharmaceutical pricing commission to the national commission for pharmaceutical prices and medical devices (NCP&MD) but the function of establishing and regulating the prices of pharmaceutical products remained the same (El Congreso de Colombia, 2011). Under this government, the Ministry of Social Protection was divided into the Ministry of Labour and the Ministry of Health and social protection. The new minister of health and social protection, in order to develop the pharmaceutical policy, created the division of pharmaceutical products and health technologies within the new Ministry of Health, and assembled a team of technical experts who coordinated the process until the passing of the pharmaceutical policy in August 2012.

Insert Table 4 around here

Factors that influenced agendas and choices related to regulatory-system strengthening in 2012

The issue of strengthening the regulatory system for pharmaceutical products appeared on the governmental agenda as a result of: (1) the identification of a problem through a change in indicators and a focusing event; and (2) the definition of this problem by framing it in different ways and by comparing Colombia to other countries. Between 2003 and 2010 there was a dramatic increase in the reimbursement cost for pharmaceutical products that were not included in the health benefit plan. This cost increased at an annual rate of 68% between 2003 and 2009, and by the year 2010, the expenditure for these products reached 2.5 billion Colombian pesos (i.e., C\$1.4 million), which was approximately 0.5 % of GDP. However, this problem got the attention of people in and around government when, in December 2009, a decree announced a state of social emergency due to the financial crisis in the health system. People inside and outside government framed the problem as an issue related to one or a combination of: the increase in the prices of pharmaceutical products due to the deregulation policies

introduced by president Uribe's government; the outdated health-benefit plan that led actors to find alternative mechanisms to provide pharmaceutical products; the constitutional court decision to approve the provision of health services that were not included in the health benefit plan and to pay for them with public funds; and the incentive among some actors, like insurance companies, pharmaceutical companies and physicians, to make additional profits. The following quotes provide examples of some of these framings as well as the use of comparisons to define the problem.

“[...] There was a large amount of abuses in the prices of pharmaceuticals in the country, mainly through the reimbursements made to the Fosyga [i.e., the national fund] by the insurance companies, because of the deregulation of prices during the previous government... Colombia was one the countries with the most expensive pharmaceutical products when it was compared to other countries in the region or to countries in Europe” (Researcher, technical advisor during the policy development process).

“[...] I mean, anything is reimbursed, at any price, at any quantity and besides, we have a restrictive health benefit plan. All the actors, from physicians, pharmaceutical companies, insurance companies and hospitals established mechanisms to make additional revenues in addition to the capitation fee [...] I mean, all the incentives aligned to extract the highest revenue possible from the country” (Policy advisor at the Ministry of Health).

The issue moved to the decision agenda as the result of a favourable political climate that provided the appropriate conditions to create viable policy options to address the problems that made it to the governmental agenda. The elected government of president Santos and in particular the minister of health and social protection, Beatriz Londoño³ who is the policy entrepreneur of this issue, were committed to addressing the issue (El Tiempo, 2012; Semana, 2010a). Beatriz Londoño, created the division for pharmaceuticals and health technologies, assembled a technical team (comprised of economists, physicians, pharmacists and lawyers) within the ministry to coordinate the policy process, and defended the pharmaceutical policy-development process until the end of her time as minister in 2012. The technical team developed two viable and complementary policy options to solve the problem. The first one, intended to address the acute growth in the expenditures on pharmaceuticals, involved establishing “maximum values of reimbursement” (i.e., setting the reference price that would be reimbursed by the national fund) for the products that were driving expenditure growth. The second option, which involved a fulsome pharmaceutical policy, would provide a long-term solution to the issue by proposing strategies to improve the access to pharmaceutical products (where the regulation of prices is just one strategy) and the quality and adequate

³ During the first months of Santos' government, Mauricio Santa María was the minister of social protection and Beatriz Londoño was the vice minister of health. In 2012, after the division of the Ministry of Social Protection into the Ministry of Labour and the Ministry of Health and social protection the Beatriz Londoño became the minister of the latter.

use of pharmaceutical products. As the following quotes illustrate both solutions were deemed viable because they were coherent with current values and technically feasible.

“[...] All this issue about transparency [...], about minimizing the possibility to seem that there is arbitrariness by the regulator, all that was really to defend the savings that could be obtained [by applying the maximum values of reimbursement] and to avoid that everything fell apart. I used to say, if we get involved in an honour war [...] the minister will fall, the policy will fall, the system will fall” (Policy advisor).

“[...] To leave it [the pharmaceutical policy] as a CONPES [the national council of economic and social policy] document was key [...] It is a government document, signed by all the ministers [...] Once the document was finished all the ministers assessed it and assumed commitments [...] It even has budget commitments” (Researcher at a civil society organization).

The final policy choice resulted from the convergence of institutions, interests, ideas and external factors. Five institutional factors influenced the policy choice, of which two diminished the prospect for change and three served as a source of models to define the policy choice. The first institutional factor that diminished the prospect for change was the separation of power between the Ministry of Health and the national pharmaceutical pricing commission regarding the authority to regulate the market for pharmaceuticals. This separation created a veto point for possible policy solutions. In October 2012, the state council established that the Ministry of Health did not have the authority to determine “maximum values of reimbursement” and that it was the commission that had the authority. This decision invalidated the resolutions issued by the Ministry of Health in 2010, 2011 and early 2012, which had regulated the reimbursement price for 165 active ingredients (Observamed, 2012). However, this veto point was overcome when the commission recognized the importance of regulating these active ingredients and decided to include them in the direct control regime (Comision nacional de precios de medicamentos y dispositivos médicos, 2012). The second institutional factor that diminished the prospect for change was the policy legacy arising from the decision to deregulate the prices of pharmaceuticals in 2006. This decision created financial incentives and resources (namely differential access to decision makers) that favoured specific interest groups that wanted to maintain the status quo. As one key informant pointed out: “when the minister was Santa María [...] we asked how many meetings he had with the director of AFIDRO [which represents the international pharmaceutical industry], how many times with the director of ASINFAR [which represents the national pharmaceutical industry], and how many times with civil society organizations [...] and the answer was 100 with AFIDRO, 40 with ASINFAR and two with civil society” (Researcher from a civil society organization).

Three past policies served as a source of models to define the policy choice. First, as previously noted, since 1988, Colombia has had a policy to regulate the prices of products

and services using three regimes: direct control, regulated liberty and observed liberty. Second, the circular 04 of 2006' suggested using the prices of other countries as a reference to set the national reference pricing policy. These ideas of defining three regulatory regimes and using reference pricing served as a models that shaped future policies and were used to define the methodology to calculate maximum prices during Santos' government (Comision nacional de precios de medicamentos y dispositivos médicos, 2013). Third, from the failure of the pharmaceutical policy that was developed in 2003, policymakers learned that the new pharmaceutical policy needed to be conceived as a 'CONPES' document in order to include the highest level planning authority - the president and all the ministers – in the adoption of the policy.

The interest of elected officials shaped the power of interest groups and their influence in the policy choice. During Uribe's government, there was an emphasis on promoting 'investment trust' to generate a favourable investment climate for private business. This emphasis led the government to approve policies – like circular 04 of 2006 – that favoured business interests. Therefore, during Uribe's government, private companies, such as the pharmaceutical industry, held a form of structural power (i.e., privileged access to the state, not because of extra resources or lobbyist skills but because of the very structure of society). During Santos' government, the acute problem with the cost of pharmaceuticals left elected officials with no other option than to regulate. The public statements by president Santos and the minister of health about their intent to regulate the prices of pharmaceutical products diminished the structural power of private business (El Tiempo, 2012). During this time, pharmaceutical companies had to rely on their instrumental power in order to compete against other pressure groups for access to the government.

Finally, there are also ideational factors that informed the policy choice. Most of the key informants for this study suggested that the cause of the exponential growth in pharmaceutical expenditures was the increase in prices by pharmaceutical companies and the irrational use of pharmaceutical products by citizens (whose demand, the key informants argued, was effectively induced by providers). They also supported the idea that the problem needed to be addressed by a short-term solution to control prices and a long-term solution to improve access to, and the quality and adequate use of, pharmaceutical products. Views about 'what ought to be' also played a role. 'Free market' values during president Uribe's government led to the deregulation of pharmaceutical prices. These values continued in 2010 under Santos' government, however, the need to contain the costs forced the government to regulate the prices despite their 'laissez-faire' beliefs.

“We had to put an end to it, and the argument, and the instruction of Santa María was: do not even think about controlling the prices, we are not a country that intervenes on prices. The next month, he says: we have to control the prices there is no other way” (policy advisor).

Overall, policy changed as a result of a confluence of four events: a dramatic change in an indicator that led to a social emergency; the election of a new government that, given the magnitude and visibility of the problem, was forced to regulate the prices of pharmaceutical products despite its ‘free market’ values; a policy entrepreneur, Beatriz Londoño, who was willing to invest political resources to find a solution to a prominent problem; and the existence of policy legacies that served as sources of models to inform the solutions (see table 5).

Insert table 5 around here

Relationship between research evidence and the factors that influenced agendas and choices related to regulatory-system strengthening in 2012

The problem that led the issue onto the governmental agenda was influenced by the symbolic use of research evidence in 2006 (symbolic use of research → problem). As suggested by several key informants, one of the causes of the problem was the passing of ‘circular 04 of 2006’ that modified the regulation of pharmaceutical prices. To inform this policy, the Ministry of Social Protection, the Ministry of the Treasury and the Ministry of Commerce commissioned a study from a private consulting firm. Three facts were put forward to suggest the symbolic use this study: (1) the study was financed by the pharmaceutical industry; (2) the technical criteria in ‘circular 04 of 2006’ to decide when to regulate the price of pharmaceuticals was applied to very few products (in fact, from 2007 to 2010 zero products were placed under the ‘direct control’ regime); and (3) one of the partners in the consulting firm that produced the study was the presidential representative in the national pharmaceutical pricing commission.

While the issue was on the decision agenda, research evidence was mainly used instrumentally to clarify the problem (and its causes), and to inform the policy options to address it (instrumental use of research → problem and policies). The Ministry of Health, through the technical team that had the responsibility to coordinate the policy process, commissioned research to inform the pharmaceutical policy about: (1) the diagnosis of the current situation in terms of access to, and quality and rational use, of pharmaceutical products (Econometría, SEI, & Sigil Consulting Group, 2011a); (2) international experiences with pharmaceutical policies regarding access to, and quality and rational use of, pharmaceutical products (Seuba, 2011; Tobar, 2011); and (3) the identification of stakeholders’ positions, interests and influences on the national pharmaceutical policy (Econometría, SEI, & Sigil Consulting Group, 2011b). In addition, different researchers had the possibility to transmit their ideas at different times in the process, sometimes as technical advisors and other times by active participation in forums, debates and seminars that were organized to involve stakeholders in the policymaking process (Econometría, SEI, & Group, 2011).

Research evidence influenced or was influenced by the institutions, interests and ideas that led to the policy choice. In 2006, the symbolic use of research evidence contributed

to a policy decision that deregulated the price of pharmaceuticals and created ‘spoils’ for the period 2007 to 2010 (symbolic use of research → institutions). The interests of elected officials and policy advisors influenced the instrumental use of research evidence during the policy-development process. There was a clear commitment from the Ministry of Health to use research evidence to inform the development of the pharmaceutical policy as a way to improve its transparency and have better political leverage to negotiate the policy option with different actors (interest → instrumental use of research). Policy advisors had a strong link with the academic sector; indeed, some were active researchers with published papers on pharmaceutical issues. Therefore, they were keen on searching for research evidence and using it instrumentally (interests → instrumental use of research). Civil society organizations and other interest groups that produce research evidence on issues related to the pharmaceutical policy transmitted their ideas at different times in the process (interests → conceptual use of research). Finally, views about ‘what ought to be’ influenced which research was used to inform the policy choice. For example, one key informant mentioned that the Ministry of Commerce did not consider research evidence produced by some Colombian civil society organizations about the negative impact of the intellectual property system on the prices of pharmaceuticals. As a result, the pharmaceutical policy recommended undertaking a study to examine such an impact (views about ‘what ought to be’ → symbolic use of research evidence). ‘Free market’ values during president Uribe’s government also led to the symbolic use of research evidence that influenced the deregulation of pharmaceutical prices.

Insert table 6 around here

Cross-case comparison regarding the relationship between research evidence and the factors that influence agendas and decisions.

In what follows we compare the similarities and differences between the two cases regarding whether research evidence influenced or was influenced by other factors in each of the governmental agenda, decision agenda or policy choice stage of the policymaking process. This exercise implies taking into consideration the direction of the influence (i.e., if research evidence influences the factor or the factor influences the use of research evidence), the different uses of research evidence (i.e., instrumental, conceptual or symbolic), and the point in time in which these influences happened (see table 7 and figure 1).

Insert table 7 around here

Insert figure 1 around here

Both cases presented similarities in the relationship between research evidence and the policy stream of the decision agenda and between research evidence and the interests- and idea-related factors that led to the policy choice. In terms of the relationship between research evidence and the policy stream of the decision agenda, both cases involved the instrumental use of research evidence in the policy stream, in part due to the research training of the ministers and their policy advisors. During the development of Law 1438, Mauricio Santa María brought with him a team from Fedesarrollo (i.e., a think tank that advocates free-market economic policies, where he worked before becoming a minister), which was key in the proposal of policy solutions. In addition, during the development of the pharmaceutical policy, Beatriz Londoño created a team of advisors with research training in areas like health, economics and law to coordinate the process and to commission and use research evidence to inform solutions. In both cases, interviewees could highlight how research evidence was used instrumentally to inform specific aspects of the policies. Turning to the relationship between research evidence and interests-related factors, in both cases there were processes that allowed different interest groups to present their research ideas and propose possible solutions, such as the ‘thematic tables’ organized to inform Law 1438 and the forums, debates and seminars organized to inform the pharmaceutical policy. In both cases, the research ideas from different interest groups were used conceptually, that is, in a form of a more general and indirect form of enlightenment. Moving finally to the relationship between research evidence and ideas-related factors, views about ‘what ought to be’, specifically the value placed on ‘free market’ economic policies, led to the symbolic use of research evidence in both cases. In Law 1438, the minister of health showed his support for such ideas explicitly when he stated that he “believed” in the insurance model, which promotes private-for profit competition between different insurance companies and service providers, and that “it was not a good idea to get rid of it”. He also showed his support to these ideas implicitly through all his research work during his time in Fedesarrollo. These values led to the symbolic use of research evidence, whereby ideas derived from research that supported the insurance model, such as the research produced by Fedesarrollo, were used; and ideas derived from research that did not support these values, such as some of the ideas presented at the ‘thematic tables’ or research presented in the legislature, were selectively used or not used at all. Continuing with the relationship between research evidence and ideas-related factors, ‘free market’ values also led to the symbolic use of research evidence in the pharmaceutical policy. During the government of president Uribe, research was commissioned to support a decision that was already made. The intentions of the government to promote private investments through its ‘investment trust’ policies, and to sign the US-Colombia free trade agreement, incentivized the deregulation of pharmaceutical prices in 2006. To justify this decision, the government commissioned a study about how to modify pharmaceutical pricing policy in Colombia, a study that was financed by the pharmaceutical industry. In addition, during Santo’s government, these ‘free market’ values also led to the symbolic use of research evidence. One key informant mentioned that there was no doubt about the negative impact of the intellectual property system on the prices of pharmaceuticals in Colombia, and that this relationship was proven by different studies. However, the Ministry of Commerce did not accept these

studies as valid and, therefore, the pharmaceutical policy recommended the production of a study to assess this impact.

The two cases presented differences in the relationship between research evidence and the problem stream of the governmental and decision agendas, and the institutions and some of the interests that led to the policy choice. In terms of the relationship between research evidence and the problem stream of the governmental agenda, we found clear examples of how research evidence was used instrumentally in Law 1438 and symbolically in the pharmaceutical policy. In Law 1438, studies conducted by the ombudsman and the association of hospitals and clinics were key to identifying the magnitude of the problem. In the pharmaceutical policy case, the symbolic use of research evidence during president Uribe's government favoured the growth in pharmaceutical prices. Turning to the relationship between research evidence and the problem stream of the decision agenda, we found that research evidence did not play a prominent role in the problem stream of Law 1438 case but that in the pharmaceutical policy case the team of policy advisors commissioned research to diagnose the current situation in terms of access to and quality and rational use of pharmaceutical products, to help them defined the problem better. Moving finally to the relationship between research evidence and the institutions and interests that led to the policy choice, first we found that the symbolic use of research evidence in the pharmaceutical policy created a policy legacy that created 'spoils' for different interest groups like the pharmaceutical industry, the insurance companies and service providers. We also found an elected official in charge of the development of the pharmaceutical policy had an interest in using research evidence instrumentally to improve the transparency of the process and have greater political leverage to negotiate the policy with different actors.

Discussion

Principal findings

Our study builds upon existing literature by examining the political factors that influenced agendas and decisions and the relationship between these factors and the use of research evidence. Consistent with these analytical approaches, our findings showed how a specific combination of problem-, policy- and politics-related factors explain how issues moved into the governmental and the decision agenda; and how institutions, interests, ideas and external factors influenced the policy choice. What this study adds is the analysis of the interaction between those factors and the use of research evidence, indicating their joint influence in the policy process, while suggesting the importance of considering the direction of the interaction, the way in which research was used, and the point in time of the interaction. We observed that in Law 1438, the combination of new political executive power with strong values about preserving the insurance model and with few veto points in the congress constrained the decision-making power to the executive arena. This arrangement of institutions, interests and ideas created the conditions that allowed elected officials' ideas about 'what ought to be' to lead to a symbolic use of research evidence (i.e., they selectively used or did not use research that

criticized the insurance model). In the pharmaceutical policy, we observed that the symbolic use of research evidence by the previous government helped to create a problem that forced the newly elected government to regulate the prices of pharmaceuticals despite its ‘free market’ values. In the new government, the transparent and instrumental use of research evidence during the policy-development process became a strategy used by elected officials and policy advisors to negotiate with the pharmaceutical industry the introduction of pricing regulations.

Findings in relation to other studies

We found two patterns that explained the use of research evidence and the variations between the cases: the interaction between researchers and policymakers (specifically here the link between researchers and research institutions and the minister of health) and the type of policy (as reflected here in the two distinct types of policy studied). As the literature suggests, we found that the interaction between researchers and policymakers influenced the use of research evidence in both policymaking processes (Caplan, 1979; Landry, Amara, and Lamri 2001; Lavis 2002). However, in our context this interaction occurred because the main elected officials and policy advisors were researchers by training who moved into government in part because of their technical skills and research experience with the issues. This resembles the findings of another study in a low-and middle-income country, where the small communities of researchers and policymakers has as a consequence the alternation of the same individuals between both functions (Trostle, 1999).

The type of policy also influenced the use of research evidence in the policymaking process. We found that in both policies research was used instrumentally, conceptually and symbolically. However, in the large-scale decision (i.e., Law 1438 that modifies several arrangements of the health systems without particular attention to any product, service or program), the views about ‘what ought to be’ led to a symbolic use of research evidence that was key in the final policy choice. In the content-driven policy the instrumental use of research evidence played a more prominent role in the final policy choice. The literature suggests that large-scale decisions could be more amenable to the conceptual use of research evidence than content-driven policies, which are more amenable to instrumental uses (Lavis, 2002). Our findings correspond with the prominent role of instrumental uses of research evidence in the content-driven policy, however, the conceptual use of research evidence was not more important in the large-scale decision than in the content driven one.

Strengths and limitations

This study provides in-depth understanding of the role of research evidence in the health policymaking process in a country and region where this information is needed and scarce. Furthermore, our choice of relying on interviews as the main source of information was key given that the policies selected were relatively new and therefore

most of the relevant information related to the experiences of people that participated in the process. In addition, we collected data from multiple sources to ensure that there were opportunities to triangulate the results as they emerged. Nevertheless, this study was conducted in a very specific setting, for example both issues moved to the decision agenda when Colombia elected a new government in 2010. Therefore, readers will have to make their own judgments and decide how transferable these results are to other policies and other contexts.

Implication for policy and practice

We hope that this study will provide useful information to policymakers and researchers in several ways. First, we hope to have highlighted the importance of understanding the factors that influence the policy process and its relationship with research evidence in a time when this understanding is of significant relevance to strengthening health systems. Second, we have provided a detailed and reproducible framework that can be used to identify these contextual factors and the relationship between them. Third, we expect that other researchers will use similar approaches in other jurisdictions, but particularly in Latin America where these types of studies are uncommon, and for other policy issues, in order to allow the drawing of cross-national and cross-regional lessons over time, refine and improve the methodology, and overall gain a better understanding of the factors that influence the use of research evidence.

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Tables and figures

Table 1: Timeline of key events related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system

Year	Events
1993	<ul style="list-style-type: none"> • Passage of Law 100 that reformed the Colombian health system and introduced the “General System of Social Security in Health” <ul style="list-style-type: none"> ○ Governance arrangements: Policy authority <ul style="list-style-type: none"> ▪ Created two regimes, the contributory regime for those with ability to pay and the subsidiary regime for those without it (e.g., unemployed) ▪ Gave authority to the government to define a list of health services and products that would be provided within each regime (i.e., health benefit plan). Citizens in the subsidiary regime were given access to fewer services and products. This difference in coverage was intended to be temporary ▪ Required that citizens in the contributory regime purchase health insurance plans from insurance providers ▪ Set the year 2000 as a deadline for universal coverage ○ Governance arrangements: Organizational authority <ul style="list-style-type: none"> ▪ Introduced private (for profit or non-profit), public and mixed health care insurance companies that could also provide services ▪ Introduced private (for profit or non-profit) and public service provider institutions ○ Financial arrangements: Financing system <ul style="list-style-type: none"> ▪ Required a payroll tax of 12.5% collected by the insurance companies and then transfers the revenue to the national solidarity and guarantee fund <ul style="list-style-type: none"> • 11% of the 12.5% is used to finance the health benefit plans of the contributory regime • 1.5% of the 12.5% plus general taxes collected by the national government and transferred to the municipalities and additional departmental and municipal contributions are used to finance the health benefit plan of the subsidiary regime ▪ Let citizens purchase complementary and supplementary private insurance ○ Financial arrangements: Funding organizations <ul style="list-style-type: none"> ▪ Defined capitation as the funding mechanism for insurance companies. <ul style="list-style-type: none"> • The capitation fee was calculated according to the products and services that were included in the health plan • Insurance companies participating in the contributory regime

	<p>received their capitation fee directly from the national fund</p> <ul style="list-style-type: none"> • Insurance companies participating in the subsidiary regime received their capitation fee after subscribing yearly contracts with local entities ▪ Defined a mix of methods such as capitation, global budgets and prospective payments as the funding mechanism for service provider institutions are funded by insurance companies according to different methods like <ul style="list-style-type: none"> • Service provider institutions are paid by the insurance companies ▪ Defined salary, capitation, fee for services and other methods as mechanisms to remunerate providers
1996 2000	<ul style="list-style-type: none"> • Unemployment rate increased and affected the financial sustainability of the health system
1998 to 2006	<ul style="list-style-type: none"> • No systematic and transparent process to update the health benefits plan. <ul style="list-style-type: none"> ○ Patients sought judicial action (i.e., tutelas, which are writs for the protection of constitutional rights) to access health services and products that are not included in the health benefit plan ○ Between 1999 and 2005, 328,191 tutelas were presented to grant the right to health; in 80% of the cases the tutela was granted ○ Tutelas were increasing every year 21,301 in 1999, 42,734 in 2002, and 81,017 in 2005 ○ The national fund reimbursed all the services and products that were not included in the health benefit plan but that were granted by judicial actions
2004	<ul style="list-style-type: none"> • Ministerial resolution 3797 incentivized insurance companies to deny pharmaceutical products that were not included in the health plan and to let patients seek judicial actions to access those products <ul style="list-style-type: none"> ○ Created technical scientific committees within insurance companies to analyze physicians' prescriptions that were not included in the health benefit plan in order filter and reduced the judicial actions <ul style="list-style-type: none"> ▪ If the scientific committee approved the services, the costs were shared between the national fund and the insurance company ▪ If it did not approve the provision of the service but is later approved by a judicial action, the total cost incurred by the insurance companies were reimbursed by the national fund
2006	<ul style="list-style-type: none"> • Ministerial resolution 2933 eliminated the incentive for insurance companies to deny access and send patients to seek judicial actions <ul style="list-style-type: none"> ○ The cost of the products would be shared by the national fund and the insurance company regardless of the scientific committee decision • However, patients kept using tutela due to the effectiveness of this mechanism to grant access to medical products and services

2007	<ul style="list-style-type: none"> • Passage of Law 1122 <ul style="list-style-type: none"> ○ Created a health regulatory commission that had the mandate to update the health benefit plan and define the value of the capitation fee that the national funds pays to the insurance companies ○ Set 2010 as new deadline to achieve universal coverage ○ Article 14 created an incentive in the scientific committees (specifically the insurance representative) to approve pharmaceutical products for high cost diseases that were not included in the health benefit plan of the contributory regime <ul style="list-style-type: none"> ▪ If the scientific committee approved a pharmaceutical product for high cost diseases that was not included in the health benefit plan of the contributory regime, the national fund reimbursed 100% of the cost ▪ If the committee denied access to the product that is later approved by a judicial action, then the national fund reimbursed only 50% of the cost and the insurance company covered the other 50%
2008	<ul style="list-style-type: none"> • Constitutional court decision C-463 of 2008, stated that article 14 of Law 1122 should apply to all health technologies of both regimes • Constitutional court decision C T-760 of 2008, order the government to <ul style="list-style-type: none"> ○ Adopt measures to approve services and products that were not included in the health plans ○ Update the health plans in a systematic and participatory way before August 2009 ○ Guarantee the same health plan for children of both regimes before October 2009 ○ Plan the incremental and sustainable equalization of health plans for all the population
2009	<ul style="list-style-type: none"> • Colombian government decree declared a “state of social emergency” due to the health system’s financial crisis created by <ul style="list-style-type: none"> ○ A steep and rapid growth in the demand of products and services that were not included in the health plans (a demand that is induced by different actors in the system) <ul style="list-style-type: none"> ▪ From 835,000 in 2007 (equivalent to 351.91 million CAD) to 2.000.000 in 2009 (equivalent to 1.04 billion CAD) in the contributory regime only ○ Complex mechanisms to transfer resources between the different actors of the system (the decree uses a study from the hospital association to show the delay in the payment of resources)
2010	<ul style="list-style-type: none"> • Government issued 10 decrees to reform the health system under the terms of a declared social emergency. The decrees intended to <ul style="list-style-type: none"> ○ Improve the surveillance and control of the system ○ Reform the alcohol and cigarettes’ tax policy in order to collect additional resources to finance the health system

	<ul style="list-style-type: none"> ○ Regulate the access to health benefits that were not included in the health plan of the contributory regime ○ Control induced demand by clarifying the mechanisms to update the health plan and regulating professional autonomy ○ Improve the mechanism to transfer the funds between the actors of the system • Approximately 20000 persons, patients, unionized workers, medical students, and citizens protested to demand the repeal of the emergency decrees and the resignation of the minister of health • Colombians elected a new congress where the social party of national unity gained the highest percentage (May) • Constitutional court declared that the implementation of a ‘social emergency’ to reform the health system was unconstitutional <ul style="list-style-type: none"> ○ The rationale is that the crisis in the health system was not an unforeseen event, and thus the government should have used the traditional legislative channel, the congress, to pass healthcare reforms • Senators Dilian Francisca Toro and Jaime Ballesteros presented to the congress a proposal to reform the health system (July) • New president from the social party of national unity was elected and a new Ministry of Social Protection was appointed (August) • Ministry of social protection organized ‘thematic tables’ to gather different stakeholders to discuss issues related to the health system and propose recommendations to inform the reform (September) <ul style="list-style-type: none"> ○ The themes were: governance and structure, human resources, health promotion, public health, insurance, health technology assessment, primary health care, service delivery, surveillance and control, financing, users, pharmaceutical policy • 10 projects to reform the health system were presented in the legislature • Congress approved the health reform (December)
2011	<ul style="list-style-type: none"> • Colombian think tank (i.e., Fedesarrollo) published a book called “Effects of Law 100 and proposals for reforms” <ul style="list-style-type: none"> ○ This book was the result of a research project that started in 2007 and was edited by the minister of social protection, Mauricio Santa María • Passage of Law 1438

The main events are bolded

Table 2: Factors that influenced agendas and decisions related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system

Agendas/ decisions	Events
Governmental agenda	<p>Problems</p> <ul style="list-style-type: none"> • Identification of the problem: Feedback from current programs <ul style="list-style-type: none"> ○ Failure to meet the deadlines set by Law 100 to achieve universal coverage and to equalize the health benefits of the two regimes ○ Raising number of tutelas to obtain health-related goods and services that were not included in the health benefit plan ○ Reduction of the national fund resources due to reimbursement of product and services that were not included in the health plan ○ Delay in the transfer of resources from the government to the insurance companies, from the government to the local entities, from the local entities to the insurance providers and from the insurance companies to the service providers ○ Raising unemployment rates led to a bigger population in the subsidiary regime • Definition of the problem: Framing <ul style="list-style-type: none"> ○ The problem is the financial sustainability of the system and can be address by making changes within the current institutional arrangements (Government frame) ○ The problem is the vertical integration between insurance companies and service provider institutions (frame by one representative in the house) ○ The problem is the for-profit market relationships between the actors (frame by actors that are ideologically opposed to the government) • Definition of the problem: violation of important values <ul style="list-style-type: none"> ○ Actors of the system were making profits that were not fair (policy advisor)
Decision agenda	<p>Problems</p> <ul style="list-style-type: none"> • Same as in the governmental agenda <p>Policies</p> <ul style="list-style-type: none"> • Hidden participants <ul style="list-style-type: none"> ○ Mauricio Santa María, the minister of health and social protection, brought with him a technical team with research experience in the effects of law 100 • Generation of policy proposals: Diffusion of ideas in a policy area <ul style="list-style-type: none"> ○ Sources of ideas: the social emergency decrees, the legislators proposals, ideas from the ‘thematic tables’ and ideas from the

	<p>research produced by the think tank</p> <p>Politics</p> <ul style="list-style-type: none"> • Events within government <ul style="list-style-type: none"> ○ President Santos had the political will and the congress support to address the issue <ul style="list-style-type: none"> ▪ In his inaugural speech Santos promised a health reform with emphasis in prevention, equalization of the health benefit plans and promotion of good governance • Swings in the national mood <ul style="list-style-type: none"> ○ General climate in the country demanded a health reform • Visible participants (policy entrepreneur) <ul style="list-style-type: none"> ○ Dilian Francisca Toro and the minister Mauricio Sata María
Policy choice	<p>Institutions – state capacity (veto points)</p> <ul style="list-style-type: none"> • Decision to reform the health system required parliamentary approval where the executive government enjoyed a stable support <p>Institutions – policy legacies</p> <ul style="list-style-type: none"> • Government elites/policy learning <ul style="list-style-type: none"> ○ Failure to meet the deadlines of Law 100 and its implications (i.e., finding alternative mechanisms to have access to services like tutelas) sent clear signals of problems that need it to be addressed • Interest groups/spoils <ul style="list-style-type: none"> ○ Law 1122 of 2007 and the decision of the court created incentives to approve products and services that were not considered in the health benefit plan, which incentivised insurance companies to maintain the status quo • Interest groups and mass public/visibility and traceability <ul style="list-style-type: none"> ○ Declaration of social emergency led to the mobilization of interest groups and the mass public against the way in which the government was pursuing the reform <p>Interests – societal interests groups</p> <ul style="list-style-type: none"> • Medical interests, represented by the national medicine academy, the Colombian medical federation, representatives from public hospitals and the Colombian association of scientific societies called for the withdrawal of the reform proposals because they did not address the “real” problems of the system <p>Interests – elected officials</p> <ul style="list-style-type: none"> • President Santos had the political will to address the issue • President and the ministers of justice and social protection sent a message to the congress requesting the urgent need to pass the reform <p>Ideas – research evidence</p> <ul style="list-style-type: none"> • Research from the Colombian association of hospitals and clinics helped to define the issue of flow of resources

	<p>Ideas – Views about what ‘ought to be’</p> <ul style="list-style-type: none">• Minister of social protection valued the importance of the institutional arrangements created by Law 100 and the importance of maintaining the insurance model• Opposition party supported the idea that the problem was the insurance model that promoted for-profit market relationships between the actors <p>External factors – political change</p> <ul style="list-style-type: none">• New government is elected in 2010 right after a social emergency was declared <p>External factor – economic change</p> <ul style="list-style-type: none">• After 1993 the rise of the unemployment rate in Colombia did not favour a health system that was based on the formal contribution of employers and employees <p>External Factor – release of major report</p> <ul style="list-style-type: none">• Constitutional court sentence T760 of 2008 order the government to adopt several measures to guarantee the systematic update and equalization of the health benefit plans in both regimes
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Table 3: Relationship between research evidence and the factors that influenced agendas and decisions related to Law 1438 of 2011, a reform to strengthen the system through incremental changes as a response to the 2009 financial crisis in the system

Agendas/ decisions	Events
Governmental agenda	<p>Problems –research evidence¹</p> <ul style="list-style-type: none"> • Instrumental use: research conducted by the ombudsman was used to identify the number of tutelas that were used to grant the right to health • Instrumental use: research conducted by the association of hospitals and clinics was used to identify the magnitude of the problem related to the delay in resources
Decision agenda	<p>Problems –research evidence</p> <ul style="list-style-type: none"> • Same as in the governmental agenda <p>Policies –research evidence</p> <ul style="list-style-type: none"> • Instrumental use: during the ‘thematic tables’ different researchers had the possibility to present their research findings and to make recommendations for the reform • Instrumental use: the previous research conducted by the minister of social protection and his team of advisors during their work at the think tank informed some of the possible solutions
Policy choice	<p>Interests – elected officials and policy advisors/research evidence</p> <ul style="list-style-type: none"> • Conceptual use: the new minister of social protection brought with him a team of policy advisors with expertise in economics <p>Interests – societal interest groups</p> <ul style="list-style-type: none"> • Conceptual use: research produced by several interest groups (e.g., civil society organizations, service provider organizations, universities) enlightened the discussion about specific issues <p>Ideas – knowledge or beliefs about “what is” / research evidence</p> <ul style="list-style-type: none"> • Conceptual or symbolic use: the recommendations of the ‘thematic tables’ were used conceptually (i.e., some ideas may have informed some elements of the reform) or symbolically (i.e., only those ideas that supported decisions were used in the justification of the reform)

¹Research evidence, defined as research that is published in a publicly available form such as journal articles, books, chapters, working papers and reports and research produced by government-funded independent research units

² Instrumental use of research: to solve a particular problem; conceptual use of research: a more general and indirect form of enlighten; and symbolic use research: to justify a position that has already been taken.

Table 4: Timeline of key events related to the strengthening of the regulatory system for pharmaceutical products in 2011

Year	Events
1970	<ul style="list-style-type: none"> • The Colombian institute for social security established a list of essential medicines
1988	<ul style="list-style-type: none"> • Passage of Law 81 that established three regulatory regimes to control the prices of goods and services: (1) direct control, where the government has the authority to fix a maximum price that producers and distributors have to used to commercialize their products; (2) regulated liberty, where the government has the authority to determine the criteria under which producers and distributors can define or modify their prices; and (3) the observed liberty regime in which producers and distributors can freely established the prices of their goods and services • The Ministry of Economic Development had the policy authority to regulate the prices of pharmaceutical products
1993	<ul style="list-style-type: none"> • Passage of Law 100 that reformed the Colombian health system <ul style="list-style-type: none"> ○ Created the national institute for the observatory of pharmaceutical and edible products (i.e., the sanitary authority) ○ Shifted the policy authority to regulate the prices of pharmaceutical products from the Ministry of Economic Development to the national pharmaceutical price commission (NPPC) composed by the minister of economic development, the minster of health and one representative from the presidency ○ Created the national council for social security in health with the mandate to decide and update the list of essential medicines that will be covered under the health benefit plan
1995	<ul style="list-style-type: none"> • Colombia joined the World Trade Organization and commits to comply with the trade-related aspects of intellectual property rights agreement (TRIPS), which established minimum standards for intellectual property rights; for example, patent protection on pharmaceutical products must last for a minimum of 20 years
2000	<ul style="list-style-type: none"> • The Andean community (Bolivia, Colombia, Ecuador and Peru) modified their intellectual property right legislations to comply with the WTO agreements deadlines
2002	<ul style="list-style-type: none"> • The Ministry of Health and the Ministry of Labour merged into the Ministry of Social Protection
2003	<ul style="list-style-type: none"> • The minister of social protection developed a national pharmaceutical policy to improve the use, quality and access to pharmaceutical products; however, the policy lacks the political commitment to be implemented
2005	<ul style="list-style-type: none"> • Report recommended that the only criteria to regulate the prices in pharmaceutical policies should be the dominant power of the market of a

	<p>particular product</p> <ul style="list-style-type: none"> ○ This report was commissioned by the Ministry of Commerce and the Ministry of Social Protection, and financed by the pharmaceutical industry, to study the pharmaceutical pricing policy
2006	<ul style="list-style-type: none"> • Decision by the NPPC to move almost all the pharmaceutical products to the regime of observed liberty <ul style="list-style-type: none"> ○ This decision followed the recommendations of the 2005 report ○ This decision is referred to as the “Circular 04 del 2006” ○ As a result of this decision prices were not regulated but under watch and no pharmaceutical products were placed on the direct control regime • The United States-Colombia trade promotion agreement (CTPA) is signed
2009	<ul style="list-style-type: none"> • A Colombian government decree declared a “state of social emergency” because of the financial crisis in the Colombian health system <ul style="list-style-type: none"> ○ Between 2003 and 2009 the average annual growth in the reimbursement of pharmaceutical products that were not covered by the health benefit plan increased 68%
2010	<ul style="list-style-type: none"> • The reimbursement of pharmaceutical policies achieved 2.5 billion COP or 1,317 million USD • The constitutional court of Colombia declared that the implementation of a ‘social emergency’ to reform the country's health system is unconstitutional • New president from the Social party of national unity is elected and a new Ministry of Social Protection is appointed • A government decree (decree 4474, 2010) stated that the minister of social protection can establish maximum values of reimbursement for the pharmaceutical products that were not included in the health benefit plan <ul style="list-style-type: none"> ○ Following this decision the Ministry of Social Protection issued several resolutions in 2010, 2011 and 2012 with a list of the maximum value of reimbursement for different active ingredients
2011	<ul style="list-style-type: none"> • Passage of Law 1438 which established the need to develop a national pharmaceutical policy to optimize the use, avoid inequity in access and assure the quality of pharmaceutical products <ul style="list-style-type: none"> ○ It also changed the NPPC to the national commission of pharmaceutical prices and medical devices (NPPC&MD) but the function of formulating and regulation the pricing of pharmaceuticals remained the same • The Ministry of Social Protection is divided into the Ministry of Labour and the Ministry of Health and social protection • The president appointed a new minister of health and social protection who creates the direction of pharmaceutical products and health technologies within the new Ministry of Health • Release of reports commissioned by the Ministry of Health and social protection to inform the pharmaceutical policy about:

	<ul style="list-style-type: none"> ○ International experiences in pharmaceutical policies regarding rational use, access and quality of pharmaceutical policies. ○ Identification of stakeholder’s positions, interests and influences in the national pharmaceutical policy. ○ Diagnostic of the current situation on rational use, access and quality of pharmaceutical products.
2012	<ul style="list-style-type: none"> • Release of the national pharmaceutical policy by the national council of economic and social policy • The Ministry of Health and social protection issued a resolution with a list of 165 active ingredients (i.e., approximately 8600 pharmaceuticals) and their maximum values of reimbursement • The state council accepted a demand that states that the Ministry of Health did not have the authority to establish maximum values of reimbursement and that it was the NPPC&MD that had the authority • The NPPC&MD recognized the importance of regulating those active ingredients and therefore, decides to include them in the direct control regime recognizing the same value of reimbursement <ul style="list-style-type: none"> ○ It changed the name from maximum values of reimbursement to maximum sale prices
2013	<ul style="list-style-type: none"> • The NPPC&MD established a new methodology to decide which pharmaceutical products are regulated and how to calculate the maximum sale prices

Table 5: Factors that influenced agendas and decisions related to the strengthening of the regulatory system for pharmaceutical products in 2011

Agendas/ decisions	Events
Governmental agenda	<p>Problems</p> <ul style="list-style-type: none"> • Identification of the problem: change in indicators <ul style="list-style-type: none"> ○ Dramatic increase in the reimbursement cost for pharmaceutical products that were not included in the health benefit plan between 2003 and 2010 ○ Expenditures increased at an annual average increase of 68% between 2003 and 2009 • Identification of the problem: focusing event <ul style="list-style-type: none"> ○ Declaration of a social emergency due to the financial crisis in the health system • Definition of the problem: framing <ul style="list-style-type: none"> ○ Increase in expenditures is driven in part by the consequences of the intellectual property rights and the liberation of prices after 2006 ○ The government failure to update the health benefit plan lead all the actors – physicians, pharmaceutical industry, insurance companies and hospitals- to find other mechanism to provide needed pharmaceutical products ○ The constitutional court decision to approve the provision of health services that were not included in the health benefit plan and to pay them with public funds ○ The actor’s incentive to be reimbursed by the public fund and gain additional profits ○ Analysis within the Ministry of Health showed that the increase in expenditures was not only explained by the increase of the prices but by an increase on the quantities of pharmaceuticals that is not explained by the epidemiological changes • Definition of the problem: comparisons <ul style="list-style-type: none"> ○ Colombia had some of the most expensive pharmaceuticals in the region
Decision agenda	<p>Problems</p> <ul style="list-style-type: none"> • Same as the governmental agenda <p>Policies</p> <ul style="list-style-type: none"> • Hidden participants <ul style="list-style-type: none"> ○ A technical team (economist, physicians, pharmacists and lawyers) within the Ministry of Health and social protection with strong links to the academic sector coordinated the process that lasted more than one year and ended in the national

	<p>pharmaceutical policy</p> <ul style="list-style-type: none"> • Generation of policy proposals: Diffusion of ideas in policy area <ul style="list-style-type: none"> ○ To inform the policy, this team commission several reports in areas related to intellectual property, pricing policies, rational use of pharmaceutical polices and methodologies to involve different stakeholders in the process • Characteristic of the proposal: Technical feasibility <ul style="list-style-type: none"> ○ The pharmaceutical policy is conceived as a “CONPES” document to involve all relevant policy areas ○ The national council of economic and social policy (CONPES) is the highest level national planning authority composed by the president and all the ministers • Characteristic of the proposal: Coherent with current values <ul style="list-style-type: none"> ○ The policy is carefully written in order to be coherent with the current government values ○ The policy recommends to produce a study to assess the impact of the intellectual property system in the prices of pharmaceuticals despite all the evidence that supports this effect ○ The team developed “maximum values of reimbursement” to contain the acute problem of the rising expenditures. A process that also involved several strategies to be coherent with the government values of “no regulation” <p>Politics</p> <ul style="list-style-type: none"> • Change in the balance of organized forces <ul style="list-style-type: none"> ○ During the government of president Uribe there was political interest in signing a free trade agreement with the US, or a “deregulation political ideology”, that led to the liberation of prices of pharmaceutical products (2006) • Events within government <ul style="list-style-type: none"> ○ The elected government of president Santos had the political will to address the issue. ○ Since this government also advocates ‘free market’ and “no regulation” values, the initial idea was not to regulate the prices; however, the magnitude of the problem left the Ministry of Social Protection with no other viable option than to regulate (2010) • Visible participants (policy entrepreneur) <ul style="list-style-type: none"> ○ After the division of the Ministry of Social Protection, the new Ministry of Health and social protection, Beatriz Londoño created the division for pharmaceuticals and health technologies and defended the pharmaceutical policy development process until the end of her time as minister (2012)
Policy choice	<p>Institutions – state capacity (veto points)</p> <ul style="list-style-type: none"> • The separation of power between the Ministry of Health and the

	<p>NPPC regarding the authority to regulate the market of pharmaceuticals created a challenge to build consensus around the possible policy solutions</p> <p>Institutions – policy legacies</p> <ul style="list-style-type: none"> • ‘Spoils’/financing/access <ul style="list-style-type: none"> ○ The decision by the NPPC in 2006 deregulated the prices of pharmaceutical products and created incentives and resources that favour specific interest groups • Administrative capacity/policy learning <ul style="list-style-type: none"> ○ Since 1988, Colombia has had a policy to regulate the prices of services and products, which served as a model to make incremental changes in the system to accommodate to the current situation ○ The idea stated in the “Circular 04 of 2006” to use the prices of other countries as a reference to set the national reference pricing policy, served as a model to shape future policies ○ Colombia had a pharmaceutical policy that was developed in 2003, however it was never implemented or adopted in an administrative act <p>Interests – elected officials</p> <ul style="list-style-type: none"> • During Uribe’s government there was an emphasis on promoting “investment trust” • President Santos and the health minister expressed their interest in regulating the prices of pharmaceuticals <p>Interests – structural power of business</p> <ul style="list-style-type: none"> • The pressure to be part of free trade agreements led politicians to put more value on the commercial benefits of the agreements than on the impacts of intellectual property on access to pharmaceuticals (2006) <p>Interests – instrumental power of pressure groups</p> <ul style="list-style-type: none"> • The methodology to develop the pharmaceutical policy allowed the participation of a variety of interests groups like ASINFAR, representing the national pharmaceutical industry; AFIDRO, representing the international pharmaceutical industry; civil society organizations like IFARMA and the Colombian medical federation; hospitals; insurance companies; and religious organizations. • The regulation of the prices of pharmaceutical were marked as a red flag on the United State trade representative’s annual special 301 report on intellectual property rights <p>Ideas – knowledge about “what is”</p> <ul style="list-style-type: none"> • Pharmaceutical expenditures growing exponentially due to an increase on the prices and an irrational use promoted by an induced demand • The way to control the prices is by establishing reference pricing
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	<p>policies for the pharmaceutical products that have more impact on the expenditure</p> <ul style="list-style-type: none">• The Ministry of Health by establishing maximum values of reimbursement is setting a third-payer policy and not regulating market prices, which are the competence of the NPPC <p>Ideas – research evidence</p> <ul style="list-style-type: none">• Systematic reviews and international published studies show that using international prices as a reference and establishing reference pricing policies are the policy decisions with more impact on access and prices• There were fewer studies about the impact of policies on the rational use of pharmaceuticals• The quality of life survey provided a signal about the access to pharmaceuticals among the Colombian population• Research commissioned by the Ministry of Commerce in 2005 about pharmaceutical prices influenced policy decisions at that time (strategically use of research because there was a clear intention to deregulate the prices).• Research commissioned by the Ministry of health in 2011 to inform the pharmaceutical policy about<ul style="list-style-type: none">○ International experiences in pharmaceutical policies regarding rational use, access and quality of pharmaceutical policies○ Identification of stakeholders' positions, interests and influences in the national pharmaceutical policy○ Diagnostic of the current situation on rational use, access and quality of pharmaceutical products <p>Ideas – views about ‘what ought to be’</p> <ul style="list-style-type: none">• ‘Free market’ values and specifically deregulation of pharmaceutical prices in order to participate in the free trade market and to promote high profit expectations for firms• It was the need to contain cost, not a value placed on equity in access to pharmaceuticals, that was the initial reason that led to government intervention in pharmaceutical prices <p>External factors – political change</p> <ul style="list-style-type: none">• In 2010 a new government is elected right after a social emergency was declared due to a crisis in the financial sustainability of the health system
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Table 6: Relationship between research evidence and the factors that influenced agendas and decisions related to the strengthening of the regulatory system for pharmaceutical products in 2011

Agendas/ decisions	Events
Governmental agenda	<p>Problems –research evidence¹</p> <ul style="list-style-type: none"> • Symbolic use²: research commissioned by the Ministry of Commerce in 2005 about pharmaceutical prices influenced the policy decisions of the NPPC at that time. It is used symbolically because there was already an intention to deregulate the prices of pharmaceuticals <ul style="list-style-type: none"> ○ Three facts were mentioned to confirm the symbolic use: (1) The study was financed by the pharmaceutical industry; (2) the technical criteria used to decide when to regulate a pharmaceutical product could not be applied to any product; and (3) one of the partners of the consulting firm that produced the study was the presidential representative in the NPPC. ○ This deregulation policy is one of the problems addressed in the national pharmaceutical policy
Decision agenda	<p>Problems –research evidence</p> <ul style="list-style-type: none"> • Instrumental use: research commissioned by the Ministry of health in 2011 to inform the pharmaceutical policy about the diagnostic of the current situation in terms of rational use, access and quality of pharmaceutical products <p>Policies –research evidence</p> <ul style="list-style-type: none"> • Instrumental use: systematic reviews and international published studies show that using international prices as a reference and establishing reference pricing policies are the policy decisions with more impact on access and prices. There were fewer studies about the impact of policies on the rational use of pharmaceuticals • Instrumental use: research commissioned by the Ministry of Health in 2011 to inform the pharmaceutical policy about <ul style="list-style-type: none"> ○ International experiences in pharmaceutical policies regarding rational use, access and quality of pharmaceutical policies ○ Identification of stakeholders’ positions, interests and influences in the national pharmaceutical policy • Instrumental use: research from the WHO collaborating centre for pharmaceutical pricing and reimbursement policies and from specific researchers like Dr. Sabine Vogler (senior researcher in the Health economics department of Gesundheit Österreich GmbH, Austrian Health Institute) and Joan Rovira (from University of Barcelona) were sources of ideas in designing the policy solution. <p>Politics –research evidence</p>

	<ul style="list-style-type: none"> • Instrumental use: there was a clear political commitment from the Ministry of Health to use research evidence to inform the development of the pharmaceutical policy
Policy choice	<p>Institutions – policy legacies / research evidence</p> <ul style="list-style-type: none"> • Symbolic use: research commissioned by the Ministry of Commerce in 2005 about the pharmaceutical prices influenced the policy decisions of the NPPC at that time. It is used symbolically because there was already an intention to deregulate the prices of pharmaceutical policies. <p>Interests – elected officials/research evidence</p> <ul style="list-style-type: none"> • Instrumental use: clear commitment from the Ministry of Health to use research evidence to inform the development of the pharmaceutical policy <p>Interests – policy advisors/research evidence</p> <ul style="list-style-type: none"> • Instrumental and conceptual use: The policy advisors had a strong link with the academic sector. Some were active researchers with published papers on pharmaceutical issues. Therefore, they were keen on searching for research instrumentally and also were already enlightened by research ideas from their academic background <p>Interests – societal interests groups/research evidence</p> <ul style="list-style-type: none"> • Conceptual use: civil society organizations that produce research evidence on issues related to the pharmaceutical policy transmitted their ideas at different times in the process, sometimes as technical advisors and other times by active participation in forums, debates and seminars that were organized to involve stakeholders in the policymaking process <p>Ideas – views about ‘what ought to be’ / research evidence</p> <ul style="list-style-type: none"> • Symbolic use: The Ministry of Commerce did not consider research evidence produced by Colombian civil organizations about the negative impact of the intellectual property system in the prices of pharmaceuticals. As a result, the pharmaceutical policy recommends to produce a study to determine this impact • Symbolic use: ‘Free market’ values during president Uribe government also led to the symbolic use of research evidence that influenced the deregulation of pharmaceutical prices

¹Research evidence, defined as research that is published in a publicly available form such as journal articles, books, chapters, working papers and reports and research produced by government-funded independent research units

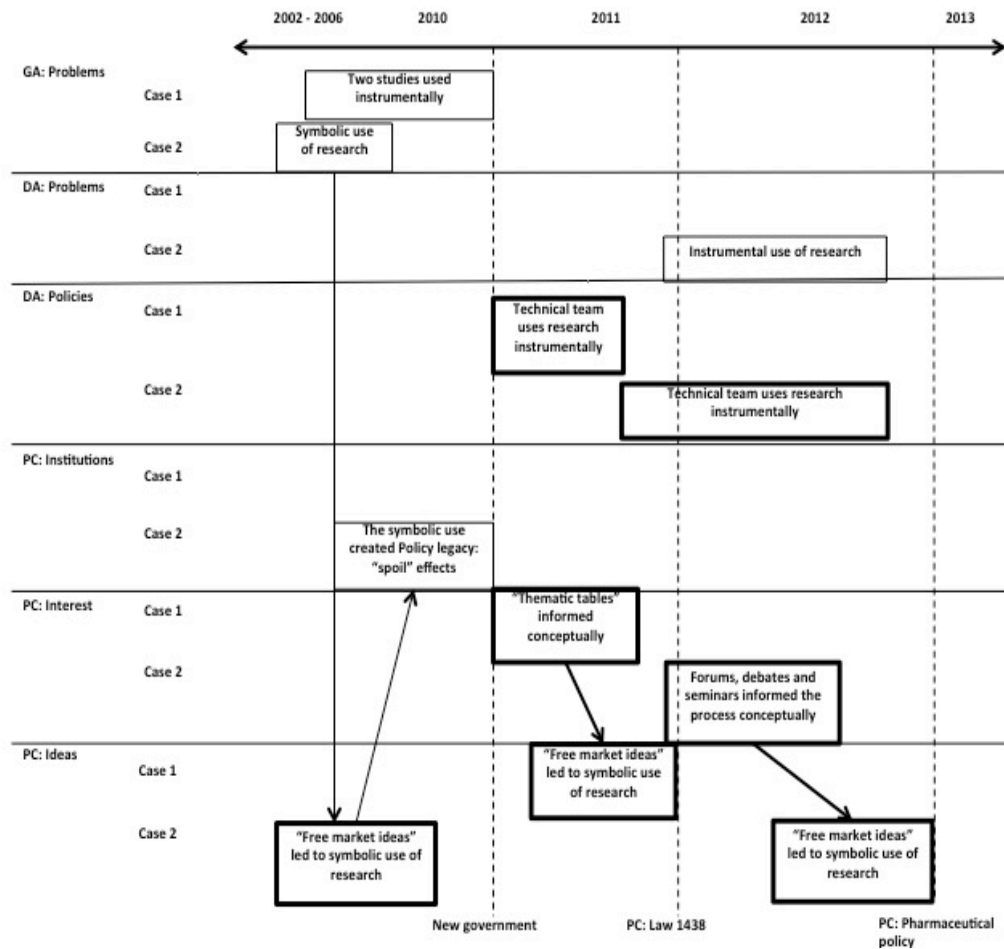
² Instrumental use of research: to solve a particular problem; conceptual use of research: a more general and indirect form of enlighten; and symbolic use research: to justify a position that has already been taken.

Table 7: Similarities and differences between the two cases regarding whether research evidence influenced or was influenced by other factors in the governmental agenda, decision agenda or policy choice stages of the policy process

Agenda/ decisions	Factors	Case 1: Law 1438			Case 2: Pharmaceutical policy		
		I	C	S	I	C	S
Governmental agenda	Problem	←					←
Decision agenda	Problem				←		
	Policies	←			←		
	Politics						
Policy choice	Institutions – policy legacies/ ‘spoils’						←
	Interests- elected officials and policy advisors				→		
	Interest- civil society, service providers, universities		→			→	
	Ideas- views about ‘what ought to be’		→	→			→

← the use of research evidence influenced the factor
 → the factor led to the use of research evidence
 I,C, and S mean instrumental, conceptual or symbolic use of research
 Shaded cells indicate similar uses of research evidence

Figure 1: Graphic representation of the main observed relationship between research evidence and the factors that influenced agendas and decisions



GA: Governmental agenda; DA: decision agenda; PC: policy choice
 Bolded boxes indicate similar uses of research evidence between the cases

Appendix 1: Interview Guide

To introduce the interviewee into the topic, I will ask a broad question (i.e., Could you tell me the story of this policy?) in order to stimulate a conversational interview. As the conversation develops I will ask the questions stated below, without following any specific order. This format will be in constant change according to new questions and topics that might come out during each interview.

_ Denotes probes

Questions:

General

- Could you tell me the story of this policy?
- How did you become involved in this policy process and what was your role in it?

Agenda Setting

- Why did policymakers become interested in this issue?
 - _ Change in indicators
 - _ Focusing event
 - _ Feedback from the operation of current programs

Governmental agenda

- And why was it defined as a problem that needed their attention?
 - _ Violation of important values
 - _ Comparison
 - _ Framing
 - _ Normative frameworks
 - _ Policy paradigms
- Where any political events happening at that time?
 - _ Events within government (e.g., regular cycles like the end of presidential period)
 - _ Swings in the national mood
 - _ Changes in the balance of organized forces
 - _ Visible participants (president, journalists, interest groups leaders)

Decision agenda

- When and why did policymakers decide to something about it?
 - _ The policy solutions came from: diffusion of ideas from other areas, feedback from current policies, communication and persuasion, hidden participants (researchers, civil servants).

The policy solution was considered because: technical feasibility, coherent with values and national mood, possibility to anticipate future constrains (budget constrains, public and politician acceptability).

- Do you remember if any article, book, report or other type of information was used to define the problem?

If yes, (Facilitators)

- How did the information get into the process?
 - Link between researcher and users
 - Pull activities
 - Push activities
 - Deliberative process
- How was the information used?
 - As a possible solution to solve the problems
 - As a form of enlightenment
 - Or to justify a position

If no, (Barriers)

- Why not?
 - Lack of availability of information about that topic
 - Lack of communication between researchers and policymakers
 - Lack of time to consider research results
 - Research was not ready when need it
 - Research was of poor quality or not relevant
 - Policymakers did not have the skills to find and appraise research
 - The format of how research is presented was not helpful
 - Mistrust between policymakers and researchers
 - The political environment is not conducive to the use of research
 - Power and budget struggles
 - Political instability and high turnover
 - The discordance between research results with the values, beliefs, interests and policy goals of policymakers and other stakeholders.
- Where you aware of any research evince related to the topic?

Policy options

- How was the process of arriving to a solution?
 - Diffusion processes
 - External pressure
 - Epistemic communities
 - Past policies, decentralization, veto points, Interest groups, workers, employers, insurance companies, hospitals, policy paradigms, normative frameworks ideas

_Hidden participants

- Was research evidence or other type of information used in the process of defining the options?
 - _ Colloquial evidence
 - _ Scientific evidence about effects (context-free)
 - _ Scientific evidence about context (context-dependend)
- Do you think that the policy option was adequate for the problem?
 - _ Technical feasibility
 - _ Coherence with values and national mood
 - _ Budget workability

Implementation

- Are you aware of any potential problems with the implementation of the policy?
 - _ Barriers and facilitators at different levels

Was research evidence used to inform the implementation process?

Appendix 2: Example of the codebook used in the analysis which is based on the propositions from Kingdon’s framework and from the political science literature around institutions, interests, ideas and external factors

Name of code
Factors that influenced agendas and decisions
• Agenda-setting
• Governmental agenda
○ Visible participants
○ Problems
▪ Identification
▪ Feedback from current programs
▪ Focusing event
▪ Change in indicators
▪ Definition
▪ Framing
▪ Violation of values
▪ Comparison to other countries or programs
○ Politics
▪ Events within governments
▪ Swings in the national mood
▪ Change in the balance of organize forces
• Decision agenda
○ Politics
▪ Events within governments
▪ Change in the balance of organize forces
▪ Swings in the national mood
○ Problems
▪ Identification
▪ Change in indicators
▪ Feedback from current programs
▪ Focusing event
▪ Definition
▪ Framing
▪ Violation of values
▪ Comparison to other countries or programs
○ Policies
▪ Hidden participants
▪ Generation of policy proposals
▪ Diffusion of ideas in a policy area
▪ Feedback from current policies
▪ Communication and persuasion

<ul style="list-style-type: none"> ▪ Characteristic
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Technical feasibility
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Possibility of anticipate future constrains
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Coherence with values and the national mood
<ul style="list-style-type: none"> • Policy choice
<ul style="list-style-type: none"> <ul style="list-style-type: none"> • Institutions
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Government structures (veto points)
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Policy legacies
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Government elites
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Policy learning
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Administrative capacities
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Interest groups
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ 'Spoils'
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Organizing niches
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Financing
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Access
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Policy learning
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Visibility and traceability
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Mass public
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Lock in effects
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Visibility and traceability
<ul style="list-style-type: none"> <ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Policy networks
<ul style="list-style-type: none"> • Interests
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Societal interest groups
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Elected officials
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Pluralism (instrumental power)
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Neo-pluralism (structural power)
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Other interests
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Civil society
<ul style="list-style-type: none"> • Ideas
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Knowledge-research evidence - ideas about what is
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Framing
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Values - views about what ought to be
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Knowledge-personal experience - ideas about what is
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Policy paradigm
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Other
<ul style="list-style-type: none"> • External Factors
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Release of major report
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Political change
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ○ Economic change

<input type="radio"/> Technological change
<input type="radio"/> New disease
<input type="radio"/> Media coverage
<input type="radio"/> Other

Chapter 4: Increasing policymaker's CApacity to find and use Research Evidence (The iCARE study): study protocol of a cluster randomized controlled trial

Abstract

Context and objective: Notwithstanding the emphasis on developing strategies to support health system policymakers to find and use research evidence to inform their decisions, few studies have rigorously evaluated their effects. This study aims to assess the effectiveness of a multifaceted intervention in increasing the utilization of an evidence service and the intention to use synthesized research evidence by policy advisors and analysts at the Colombian Ministry of Health (MoH). **Methods/Design:** We propose a cluster randomized controlled trial (RCT), with areas of the MoH as the clusters. In addition, within the cluster RCT we propose an internal pilot trial to assess its feasibility. During a three-month baseline period, intervention and control areas will receive an invitation to use a self-serve evidence service (i.e., access to Health Systems Evidence). During a six-month intervention period, areas allocated to the intervention group will receive a one-day training workshop on how to find and use research evidence plus full-text article availability upon request. During a three-month follow-up period, areas allocated to the control group will receive the intervention. The primary outcome will be the utilization of the database and the secondary outcome will be the intention of participants to use research evidence to inform their decisions. The feasibility outcomes of this trial will be assessed at the end of the baseline period as well as one month after randomization and will be used to decide whether we should modify or stop the full trial. **Discussion:** To our knowledge, this is one of the first studies that assess the impact of a multifaceted intervention that fosters finding and using research evidence by health system policymakers. This assertion is supported by the findings of a Cochrane systematic review published in 2012, that found only one randomized controlled trial that evaluated an organizational intervention to improve the use of systematic reviews by public health policymakers. However, our study proposes a different multifaceted intervention and is intended to support health system policymakers. As such, the results will lay the groundwork for the strengthening of capacity in the Colombian MoH by supporting the use of research evidence within the organization.

Background

Research evidence can support and inform health system policymakers in their efforts to strengthen the governance, financial and delivery arrangements within which health programs, services and drugs are provided in a given country (JN Lavis, Posada, Haines, & Osei, 2004; A Oxman, Lavis, Lewin, & Fretheim, 2009). Among the multiple sources of research evidence, systematic reviews offer three advantages for health system policymakers. First, systematic reviews can inform different stages of the policymaking process. In the agenda setting stage, systematic reviews of qualitative studies that examine stakeholder's views and experiences with a phenomenon can help to understand how to frame a problem in order to motivate different groups to address a problem. In the policy development stage, systematic reviews of the effectiveness and cost-effectiveness of interventions have the potential to inform policymakers about the options that could be implemented, modified or withdrawn from the health system to address the problem. In the implementation stage, systematic reviews of observational or qualitative studies can help to identify potential barriers to the implementation of the policy option (J. N. Lavis, 2009). Second, systematic reviews, as compared with single studies, save time because the research evidence has already been identified, selected, appraised and synthesized in a systematic and transparent way (The Cochrane Collaboration, 2011); therefore, policymakers can focus on the assessment of the local applicability of the review findings rather than on the credibility of single studies (Lavis et al., 2005).

Third, systematic reviews of effectiveness, which are one category of systematic review, follow explicit methods that minimize bias, providing more reliable findings of the effect that can be expected from an intervention (Antman, Lau, & Kupelnick, 1992; Lavis et al., 2005; Oxman & Guyatt, 2006).

Efforts to promote timely access to research evidence

In order to make informed decisions, health system policymakers need timely access to systematic reviews as well as the skills to find and use research evidence. An important body of evidence supports this assertion. Systematic reviews that identify the barriers and facilitators to the use of research evidence by policymakers found that timely access to good quality and relevant research evidence (Innvaer, Vist, Trommald, & Oxman, 2002; Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014), and skills-building with policymakers (Oliver et al., 2014) are reported to be among the most important factors in influencing the use of evidence. These findings have encouraged efforts to create databases that continuously identify, classify and assess systematic reviews and other review derived products about different health systems arrangement, as well as efforts to build capacity among health system policymakers on how to identify and use research evidence to inform their decisions (J. N. Lavis, 2009).

One of these databases designed to provide timely access is [Health Systems Evidence](#) (HSE), a “continuously updated repository of syntheses of research evidence about governance, financial and delivery arrangements within health systems, and about implementation strategies that can support change in health systems” (McMaster Health

Forum, 2014a). HSE contains systematic reviews that address questions about the effects of interventions, systematic reviews addressing other questions, systematic reviews in progress, systematic reviews being planned, and two other review-derived products, evidence briefs and overviews of systematic reviews. Additionally, HSE contains other non-synthesis documents (e.g., economic evaluations and health reform descriptions), which support policymakers' decisions about health systems. Every document in HSE is assessed for eligibility and coded by two independent raters according to a predefined taxonomy of health system topics (e.g., policy authority) and domains (e.g., non-communicable disease). Also, for each review, HSE presents the last year in which the searches for studies were conducted, countries in which included studies were conducted, a quality score according to the AMSTAR (a measurement tool for the 'assessment of multiple systematic reviews') instrument (Shea et al., 2007), and links to user-friendly summaries, scientific abstracts and full-text reports. Finally, the HSE interface, the search terms and synonyms, and the title of each document are translated into seven languages, including Spanish.

Building capacity is another strategy designed to change practices and behaviors related to the integration of research evidence into decision-making processes. Specifically, this strategy aims to enhance health system policymakers' skills in acquiring, assessing, adapting and applying research evidence, as well as improving their understanding of how different types of systematic reviews are needed to inform health system decisions and raising their awareness about the sources of pre-appraised reviews and review-derived products (J. N. Lavis, 2009). One of the more visible efforts that has intended to build the skills of policymakers across the world in finding and using research evidence is the Health Systems Learning (HSL) educational program developed and managed by the McMaster Health Forum. The program builds on the experience of nearly 100 training workshops in more than 20 countries with health system policymakers. This program, which has been continuously updated based on formative and summative evaluations, has the following objectives: (1) to develop participant knowledge about tools and resources available to help health system policymakers and stakeholders in order to support their use of research evidence; (2) to examine the attitudes that are supportive of using research evidence in health system decision-making; and (3) to enhance participant skills in acquiring, assessing, adapting and applying research evidence (McMaster Health Forum, 2014b).

Evaluation of the efforts to promote timely access to research evidence

Notwithstanding the emphasis on developing strategies to inform health system decisions with the best available research evidence, particularly systematic reviews, few studies have rigorously evaluated their effects (Mitton, Adair, McKenzie, Patten, & Wayne Perry, 2007). A recent randomized controlled trial, intended to assess the effect of full-serve evidence service (HSE database access plus monthly email alerts about new additions to the database and full-text article availability) on the use of research evidence by policy analysts and advisors within a division of the Ontario Ministry of Health and

Long-Term Care (Lavis et al., 2011), failed to reach its recruitment target among policy analysts. As a result, the trial was terminated, however, a qualitative process evaluation of the evidence service was expanded to examine the reasons for the low participation rate. Concerning the evaluation of building capacity strategies, the organizational impacts of two Canadian programs that intend to build capacity among mid- and senior-level healthcare managers in their use of evidence were recently evaluated using a case study methodology (Champagne, Lemieux-Charles, Duranceau, MacKean, & Reay, 2014). The study found that the impact of training could primarily be felt in trainees' work environments but that change was very limited in terms of the skills acquired by others in the organizations for engaging in evidence-informed decision making. In addition, the HSL training workshops have been evaluated using a questionnaire designed to capture participant's formative evaluation of the workshops about acquiring, assessing, adapting and applying research evidence. The last cumulative evaluation results for 14 workshops conducted in Beirut, Copenhagen, Hamilton, Melbourne, Quebec City, Riyadh, Shanghai and Toronto found that the mean rating for "overall assessment of the training workshop" was 6.1 on a scale from 1 (very poor) to 7 (excellent).

Despite these evaluations there is a paucity of experimental research on interventions that encourage policymakers to use systematic reviews in policymaking. The conclusions of three systematic reviews support this assertion. The review by Murthy and colleagues concluded that there is insufficient evidence on the effectiveness of multifaceted interventions that aim to develop awareness of the evidence and skills in accessing and implementing it (Murthy et al., 2012). Perrier and colleagues conducted a systematic review to assess the impact of interventions encouraging the use of systematic reviews by health policymakers and managers (Perrier, Mrklas, Lavis, & Straus, 2011). They also concluded that there is insufficient evidence about interventions for seeking, appraising, and applying evidence from systematic reviews in decision making by health policymakers. Finally, a scoping review conducted by Chambers and colleagues concluded that, even though a variety of systematic review resources are being produced to address policymakers' needs, more evaluations are required to assess their impact (Chambers et al., 2011).

Aims and objectives

Our purpose is to assess the effectiveness of a multifaceted intervention (access to HSE plus a one-day training workshop and full-text article availability upon request) in increasing the utilization of HSE and the intention to use synthesized research evidence by policy advisors and analysts at the Colombian MoH.

To investigate the feasibility of this trial, we included an internal pilot trial to assess: (a) policy analysts' and policy advisors' participation, recruitment and retention rates; (b) degree of communication within and between the areas (defined below); (c) participants' comfort with reading research evidence in English; (d) participants' satisfaction with the learning approach of the workshops (i.e., the length of the training workshop, the pre-session tasks and the visual aids and /or handouts), (e) variation in the outcome measures;

(f) estimates of intra-cluster correlation; (g) the potential effect of the intervention on utilization of HSE; and (h) the characteristics of those participants most likely to gain from the intervention.

The internal pilot study, sometimes also called an adaptive trial, refers to a design that allows modifications to be made to the trial and/or statistical procedures during its conduct based on the review of interim data (Arnold et al., 2009; Chow & Chang, 2008; Thabane et al., 2010). In our case, we will assess the first three feasibility objectives (i.e., feasibility objectives a to c) at the end of the baseline period and the last five objectives (i.e., objective d to h) one month after randomization. After each of these assessment we will consider, based on pre-established criteria, whether we should modify or stop the full trial.

Methods

Study setting

We will conduct the study in 16 specific areas of the Colombian MoH (see table 1 and figure 1). Colombia is a unitary, presidential state with a decentralized health system¹. The role of the central government (i.e., MoH) is to design public policy related to health, public health and social promotion of health. Within the MoH, the policy analysts and policy advisors who have the responsibility to make or inform health system decisions are located in the following areas: (1) the office of the minister of health, (2) the office of the vice minister of public health and service delivery, (3) promotion and prevention, (4) communicable diseases, (5) non-communicable diseases, (6) environmental health, (7) nutritional health, (8) epidemiology and demographics, (9) service delivery and primary health care, (10) service delivery², (11) health infrastructure, (12) pharmaceuticals and health technologies, (13) health human resources, (14) performance of human resources, (15) management of knowledge, and (16) training of human resources.

Insert Table 1 around here

Study design

We will conduct a cluster randomized controlled trial (RCT) of participating areas of the MoH. The trial will have a three-month baseline period during which individuals in each participating area will receive a self-serve evidence service (i.e., notification of the availability of HSE). During a six-month intervention period, participants in the areas allocated to the intervention group will receive a one-day training workshop on how to find and use research evidence plus full-text article availability upon request, while individuals in the control areas will continue to receive the self-serve evidence service.

¹ Colombia is divided into 32 administrative units (which are called departments), 1,098 municipalities, and four capital districts corresponding to the four biggest cities. Municipalities are governed by mayors and departments by governors, with both elected democratically.

² This area is different from the service delivery and primary health care area.

For the final three-month follow-up period, we will offer the areas in the control group all intervention components. The trial will be organized to begin on the Monday nearest to January 15 to minimize the impacts of holidays on the collection of data for the baseline period. The utilization of HSE will be assessed automatically in all periods of the trial and the intention to use research evidence will be assessed at baseline, the end of the intervention period, and the end of the follow-up period. We will assess the feasibility objectives of the pilot trial at the end of the baseline period and one month after the randomization (see figure 1).

Insert Figure 1 around here

Study population and recruitment

We will invite all those professionals who have a mandate to support policymaking processes within the areas of interest. Even though we have referred to these individuals as policy analysts and policy advisors, the formal name of their positions within the Ministry of Health are “office director”, “advisor”, “specialized professional” or “professional”.

According to an administrative database that is publicly available in the webpage of the MoH, which contains the names, email contacts and area of work of all its employees as of August 2013, there are approximately 324 employees working within our areas of interest (see table 1). However, at the time of writing this protocol, Colombia is electing a new president and therefore, the number of employees will be reassessed before starting the trial. To identify and recruit the policy analysts or policy advisors among these 324 employees, we will adopt the following strategies:

1. We will obtain a trial endorsement letter from the office of the minister of health or the office of the vice minister of public health and service delivery (see appendix 1 with a draft of a possible letter). Policy advisors within the areas of interests have expressed their interest in a study like this in previous communications with one of the authors (DP).
2. We will announce/advertise the trial through the internal communication network of the ministry.
3. We (i.e., the researchers from McMaster University and the University of Antioquia) will provide a webinar to anyone interested at the MoH on the need to use research evidence to inform decisions, and will promote the trial during the workshop.
4. We will send an invitation email, a cover letter with a consent form (see appendix 2) and the ministerial endorsement letter to the area coordinators first and then to the employees of each area. If consent is obtained from the area coordinators we will ask them to identify those persons in their area who will benefit from our intervention and contact them.

5. We will follow-up with the area coordinators who do not respond to the invitation one week after we send the invitation. The follow-ups will be made by telephone.
6. We will provide two incentives to participate. Participants will receive a training certificate from the University of Antioquia and McMaster Health Forum and we will organize a raffle for an iPad among participants who complete the study.
7. Members of the research team will be available to answer queries, by telephone, email or site visit during the recruitment phase.

Since previous research has shown that the recruitment of these participants can be challenging (Kho, Rawski, Makarski, & Brouwers, 2010), we adopted the aforementioned strategies to increase our participation rate and recruitment efficiency. Specifically, these strategies aim to increase participants' perception about the relevance of this trial to their work (e.g., strategies one, two and three), to show support from their supervisors and directors (e.g., strategies one and four) and increase the participation of colleagues (e.g., strategy six).

Baseline questionnaire

Those who agree to participate will receive an online questionnaire in Spanish, designed to elicit their intention to use research evidence, their position and area of work within the MoH, their work interactions with other colleagues, their comfort with reading research evidence in English and the resources used to find research evidence (see appendix 3).

Randomization and allocation concealment

We will use a covariate-constrained randomization procedure (Carter & Hood, 2008; G M Raab & Butcher, 2001) to ensure that the intervention and control areas are balanced with respect to area size (i.e., number of participants in each area) and the number of participants who use HSE. This information will be collected through the baseline questionnaire, however, we have evidence that the number of participants who use HSE could be a meaningful covariate. At this moment, there are 159 registered users of HSE indicating Colombia as their country of residence. Of those, 104 have selected Spanish as their preferred language and 61 have identified themselves as policymakers. Since Colombia is a presidential unitary country, we can assume that some of this 61 HSE users work within the MoH.

The covariate-constrained randomization method is recommended when baseline data are available and all the clusters can be identified and recruited prior to allocation (Ivers et al., 2012). To ensure allocation concealment, each area will be coded and only a statistician external to the research team and a research assistant will have access to the baseline data to conduct the randomization. They will communicate to the research team about which areas will receive the intervention in order to start coordinating with the area coordinator when to provide the one-day workshops.

Although participants cannot be blinded to the intervention, the cluster randomization will minimize contamination. Since all the areas share the same building, but are based on different floors within the building (table 1 and figure 1), there might be work-related interactions between the individuals. However, our preliminary inquiries have indicated that the work interactions within areas are more intense than across areas. Across areas, communication exists but it is mainly concentrated in higher-ranking employees within the areas. For example, the communication within the workers of the epidemiology and demography area or the non-transmissible diseases area is more frequent than the communication across these areas. The average number of staff employees per area is 20, with a median size of 17. Therefore, we expect each employee to know most of her/his colleagues in the area. We will confirm these assumptions with the baseline questionnaire.

Additionally, there are two characteristics of the intervention that will reduce contamination. First, there is evidence showing that training some individuals within an organization on how to find and use research evidence does not change, or produces little change in, the skills acquired by others in the organization who did not receive the training. The change occurs mainly in the language used by colleagues within the trainees' immediate work environments and in increasing sensitivity about the use of evidence in decision making (Champagne et al., 2014). Second, one important component of the intervention is having access to full text articles upon request, which is a service that only individuals in the intervention areas will have. Participants in the intervention areas will have the opportunity to contact our non-blinded research assistant to ask for the full text of articles that are not available free online or through any of the subscriptions held by the Colombian ministry of health. Our research assistant will be able to differentiate if the request comes from a participant in one of the intervention or control areas and will inform those in the control group that the service is only available for participants in the intervention group.

Study intervention

Areas allocated to the intervention group will receive:

1. An invitation from the research team for free HSE registration (see appendix 4) and a four-page document that provides background information about the database (http://www.healthsystemsevidence.org/PDF/Using-health-systems-evidence_spanish.pdf). These resources will be in Spanish and sent by email to each participant in these areas. The invitations will encourage users to log in with their institutional email account and to sign up for the monthly email alert service. The four-page document will inform participants about what HSE is, the type of documents that it contains, its importance to health system policymakers, as well as how to use it.
2. A one-day training workshop on how to find and use research evidence based on the educational program developed and managed by the McMaster Health Forum

(<http://www.mcmasterhealthforum.org/stakeholders/health-systems-learning>). The objectives of the workshops are to raise participants' awareness about tools and resources available to health system policymakers and stakeholders in order to support their use of research evidence; to enhance participants' skills in acquiring, assessing, adapting and applying research evidence; and to identify what participants' own areas and their organization as a whole can do to better support the use of research evidence in health system policymaking (see appendix 5 for a detailed description of the workshop program).

3. The opportunity to contact the research assistant to request the full text of any document found on HSE that is not available free online or through any of the subscriptions held by the Colombian MoH.

During the intervention period, the control areas will receive no intervention other than the invitation from the research team to join HSE and the four-page document that provides background information about the database. During the three-month follow-up period we will offer the control areas all components of the intervention.

Measurement of outcomes

The primary outcome will be the mean number of site visits by participant per month in each area, assessed during the baseline, intervention and follow-period. This utilization outcome measure was used in other studies that evaluated evidence services targeted to physicians (Haynes, Holland, & Cotoi, 2006) or to health system policymakers (Lavis et al., 2011). We will also provide descriptive measures such as the proportion of users per month in each of the groups; the proportion of users that sign up for the monthly email alerts in each group; the frequency with which the systematic review records, and the more detailed documentation for each review (e.g., user-friendly summaries and scientific abstracts) are accessed; the number and type of documents that are requested in full text; and the mean number of minutes per month that participants use the database (with a 'time out' set at 60 minutes).

Data for the primary outcome will be collected by automatic monitoring of the HSE database, which is hosted on a secure server at McMaster University. In order to track usage of the database in all groups, participants will be prompted to provide a user login and password every time they use the database.

The secondary outcome will be the policy advisors' and analysts' intention to use research evidence (see appendix 3 section A). Participants will complete an anonymous online self-administered 10-minute questionnaire during each of the baseline, intervention and follow-up periods. Non-respondents will be followed up once per week for three weeks to minimize the number of participants lost to follow-up. The questionnaire is based on the theory of planned behavior and utilized because it has been proposed as a tool to assess the effectiveness of strategies that aim to support evidence-informed health

system decision-making; it was tested with 28 policymakers and researchers from 20 LMICs; and it has good internal consistency and test-retest reliability when applied more than once (Boyko, Lavis, Dobbins, & Souza, 2011). We modified the questionnaire to collect information about participants' characteristics.

In the internal pilot trial, we will assess the feasibility outcomes at the end of the baseline period and one month after randomization. At the end of the baseline period we will assess the following feasibility outcomes and consider continuing with the full trial if:

1. the participation rate (number who agreed to participate over the total number approached) is 25% or greater;
2. recruitment efficiency (baseline questionnaires received over total number approached) is 15% or greater;
3. retention rate (baseline questionnaires received over total number who agree to participate) is 70% or greater;
4. the ratio between the degree of communication within areas (proportion of employees that work mainly by themselves or with other colleagues within the same area) and the degree of communication between areas (proportion of employees that work mainly with other colleagues in other areas) is greater than 1; and
5. the average level of comfort when reading research evidence in English is equal or greater than 3 in a seven point Likert scale (see appendix 3, section C, question 20).

To measure these outcomes, we will record the number of undeliverable invitations, affirmative responses, active declines, and non-responses. In addition, we included two questions in the baseline questionnaire, one to get an indication of the communication practices between colleagues and one to ask about individuals' comfort in reading research evidence in English.

One month after randomization we will assess participants' satisfaction with learning approach in those who completed the workshop sessions (see appendix 3, section B). Additionally we will assess the primary outcome in order to identify estimates of standard deviation and intra-cluster correlation, to estimate potential effects of the intervention on utilization of HSE, and to identify the characteristics (i.e., position, area of work, years of work, comfort reading in English) of those participants most likely to gain from the intervention.

Sample size

We do not have an exact number of potential participants (a number that will be defined after contacting the area coordinators), however, according to a 2012 Ministry-resolution that defines the functions and competencies for MoH jobs (Ministerio de Salud

y Protección Social, 2012), there are approximately 104 professionals with a mandate to support policymaking processes within the public health and service delivery branch (this number does not take into account those participants from the office of the minister or the vice-minister). Nonetheless, regardless of the exact number of potential participants we have a fixed sample size; therefore, a sample size calculation is not relevant. More usefully, the data from the internal pilot trial will provide estimates of the standard deviation and intra-cluster correlation which we will use to calculate the statistical precision we can expect given our fixed sample.

Data management and analysis

The unit of allocation and analysis for the trial will be the areas of the MoH. The analysis will be performed according to the intention-to-treat principle, and no area will be excluded from the analysis after the allocation to the intervention or the control group. For the primary outcome, there will be no missing data since we will be able to track every visit to HSE. For the second outcome, we will try to minimize the possible missing data by following non-respondents with one telephone call every week for three weeks. We will report 95% confidence intervals and p values equal or less than 0.05 will be considered significant without adjustments for the primary analysis, and with adjustment for multiple testing and intra-area correlation for secondary analyses. For the analysis of the continuous variables such as the utilization and intention-to-use outcome, and the change in these measures over time, we will apply a mixed effects linear repeated measures analyses of variance (ANOVA) with the interaction of intervention by time as the main feature of interest. In addition, we will use an analysis of covariance to control for important predictable variables. Finally, since we will use a restricted randomization procedure (i.e., covariate-constrained randomization), we will perform a restricted randomization test to compare the results with the aforementioned analysis and test the robustness of our findings (Gillian M Raab & Butcher, 2005).

The statistical analysis for the feasibility outcomes that will be measured at baseline will be performed using proportions and means and the associated 95% confidence intervals. The trial investigators, research assistants and participants will not be blinded to the group allocation. Codes will be attributed to the areas and the statistician and one investigator will be blinded when analyzing the data.

Ethical considerations

Ethics approval for the trial will be sought from McMaster University and the University of Antioquia Research Ethics Boards. Participants will be provided with a detailed explanation of the study and the possibility to be allocated to the intervention or control group. We will ask participants for consent to be monitored by the HSE team and complete online questionnaires during the course of the study. We will inform them that all of the collected data will be reported in summary form and in a way that does not allow individuals to be identified. Information about registration in HSE and its use will

only be reported in summary form and will not be shared with any other parties. We will inform participants that their participation is voluntary and that they are free to withdraw from the trial at any time.

Discussion

This study will make a significant contribution to understanding the effects of a multifaceted intervention on improving health system policymakers' timely access to policy-relevant research evidence, awareness of synthesized research evidence, and skills in finding and using synthesized research evidence. This is important given the lack of rigorous studies that assess the effectiveness of strategies designed to support evidence-informed health system decisions (Mitton et al., 2007). The latest systematic review – with searches updated until March 2012 – that assessed the effect of interventions to improve the use of systematic reviews by policymakers found only one RCT that evaluated an organizational intervention (Murthy et al., 2012). However, this RCT was different from the one we are proposing in two ways: first, it was focused on supporting public health decisions instead of health systems decisions; and second, it focused on a different intervention that included a knowledge broker, access to a repository of systematic reviews and provision of tailored messages and did not include access to HSE nor the capacity building strategy (Dobbins et al., 2009).

The study faces some feasibility issues that are addressed in the design of the protocol and will be assessed in an internal pilot trial. For example, we adopted several strategies to address the challenge of recruiting policy advisors and policy analysts into research studies; and we used HSE, which is more applicable to the Colombian context than other databases because its interface, the search terms and synonyms, and the fact that the title of each document is translated into Spanish. In addition, we designed an internal pilot trial within the protocol with clear feasibility objectives that will inform the continuation of the larger cluster RCT.

In summary, to our knowledge this is the first study to assess the impact of this multifaceted intervention that fosters finding and using research evidence by health system policymakers. Its results (if they are positive results), will lay the groundwork for the strengthening of the Colombian MoH by supporting the use of research evidence within the organization.

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Tables and figures

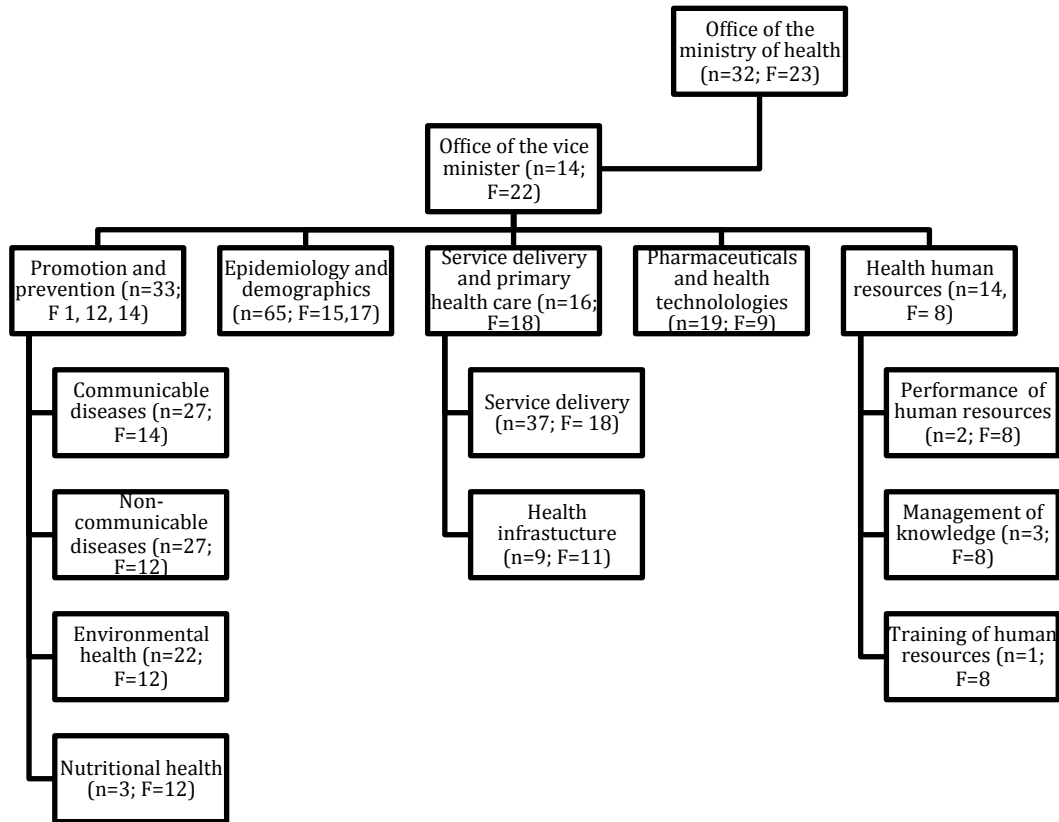
Table 1: Number of employees and floor within the building of the areas of the MoH where we will conduct the study, according to information on the phone directory of the MoH.

Areas ¹	Number of employees ²	Floor within the building
Office of the minister of health	32	23
Office of the vice minister of public health and service delivery	14	22
Promotion and prevention	33	1,12,14
- Communicable diseases	27	14
- Non-communicable diseases	27	12
- Environmental health	22	12
- Nutritional health	3	12
Epidemiology and demographics	65	15, 17
Service delivery and primary health care	16	18
- Service delivery	37	18
- Health infrastructure	9	11
Pharmaceuticals and health technologies	19	9
Health human resources	14	8
- Performance of human resources	2	8
- Management of knowledge	3	8
- Training of human resource	1	8

¹ According to the organizational chart of the MoH, there are more areas than the ones presented in this table that could be interested in our project. However, the phone directory did not provide discriminate information for these other areas.

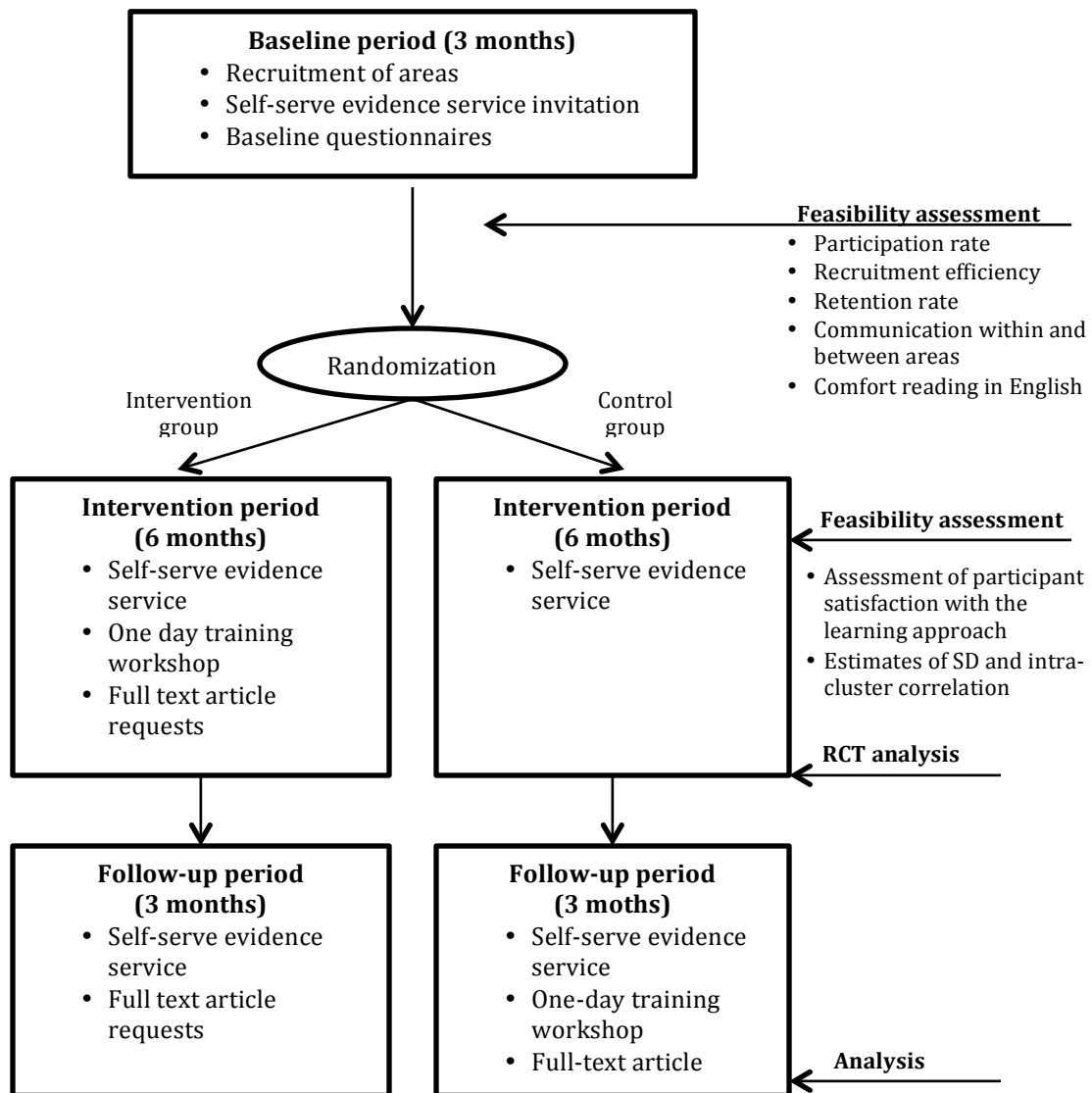
² The number of employees was obtained from the phone directory of the MoH.

Figure 1: Hierarchical representation of the areas where we will conduct our study.



n= number of employees within each specific area
F= floor within the building

Figure 2: Trial design



Appendix 1: Sample of a support letter from the Colombian Ministry of Health

Letterhead of the Colombian Ministry of Health

[Insert date]

Dear policy analysts and policy advisors,

The Ministry of Health has agreed to participate in an intervention study that could improve our capacity to find and use research evidence to support health system decisions.

As part of this study, researchers from the University of Antioquia and McMaster University will provide a series of one-day workshops in different areas of the Ministry and will collect information about the use of an evidence service.

I encourage you to consider participating in this study as it will support the technical capacity of the ministry and it will help to provide the types of evidence needed to continue delivering high-quality services. In addition, this is the first time an intervention such as this has ever been evaluated in a randomized controlled trial and I am very happy that we can help support such a ground-breaking research study.

Thank you for your careful consideration of this request to participate in an important and innovative research study.

Sincerely,

Appendix 2: Sample email invitation and cover letter with consent form

Sample email

Subject: Research study invitation from the University of Antioquia and McMaster University

Email text:

Dear [insert name],

You are being invited to participate in a research study entitled “Increasing policymaker’s Capacity to find and use Research Evidence (The iCARE study)”. The study is an evaluation of whether an evidence service and a training program increases the use of synthesized research evidence by policy analysts and advisors in the Colombian Ministry of Health.

As part of the 12-month cluster randomized trial (3-month baseline period followed by a 6-month intervention period and a 3-month follow-up period), you will receive access to an evidence service and a training program designed to support your efforts to find and use research evidence efficiently. Your involvement would mean having data collected related to your use of the evidence service, participating in a one-day workshop session with other colleagues of the same area, and completing a 10-minute questionnaire at the beginning of the study, approximately nine months later, and at the end of the study period.

By participating in this study you will receive a training certificate from the University of Antioquia and the McMaster Health Forum related to your participation in the one-day workshop session and you will participate in a raffle for one iPad.

Please find attached a letter of invitation (which includes a consent form), a project summary, and a letter of support from _____. If you consent to participate, please complete and scan and e-mail (or fax) the consent form to me.

Thank you for considering participating in our study. I hope to hear from you soon. If you have any questions, please don’t hesitate to contact me.

Sincerely,

Daniel Patiño

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Email: patinodf@mcmaster.ca

Cover letter and inform consent

Title of study: **I**ncreasing policymaker's **C**apacity to find and use **R**esearch **E**vidence (The iCARE study): study protocol of a cluster randomized controlled trial

Principal investigator: Daniel Patiño PhD(c)

Funding sponsor: TBD

Coordinating institution: University of Antioquia, faculty of medicine

[Insert date]

Dear Sir/Madame,

We are inviting you to participate in the iCARE study. This project is aimed at making it easier for you to find and use research evidence to support your decisions about health systems. General background about this study, with our objectives and methods, is available upon request.

If you agree to participate in this study, you will:

- receive an invitation to register for a free online evidence service to find the best available research evidence related to health systems;
- receive an invitation to participate in a one-day workshop on how to find and use research evidence;
- receive the full text of those documents that cannot be accessed through existing Ministry of Health resources;
- receive a training certificate form the University of Antioquia and McMaster University related to your participation in the one-day workshop; and
- entered into a raffle of one iPad

In addition, during the study period:

- your access to the evidence service will be measured for frequency and type of resources used; and
- you will be asked to complete a short questionnaire at three different points of time.

Any data collected as part of this study will be considered confidential. Only data pertaining to your use of the evidence service will be collected and any data containing your computer login identification will be replaced with a participant code before it is shared with the study investigators. We will store the service-usage data and questionnaire data on a security-protected computer at McMaster University and any hard-copy files in a locked cabinet. We will destroy the key identifying the link between your participant code and your identity one year after the completion of the trial, and

destroy the data ten years after the completion of the trial. No transfer of data (especially email accounts) will be done outside the context of the study.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may withdraw from the research study at any time. Study reports will be made available to you prior to, or coincident with, publication.

Please check yes, no, or maybe to the question below to indicate whether you consent to participate in our study. If you consent to participate, please print your name, sign and date the form below and ask a witness to do the same.

<p>Increasing policymaker’s CAPacity to find and use Research Evidence (The iCARE study): study protocol of a cluster randomized controlled trial</p>		
<p>Request for consent</p>	<p>Yes</p>	<p>No</p>
<p>I understand and agree to participate in this study that will evaluate my use of an evidence service using data about my use of the service and through a questionnaire provided at three different points in time.</p>		
<p>Name: _____ Signature: _____</p> <p>Date: _____</p> <p>Witness name: _____ Witness signature: _____</p> <p>Date: _____</p> <p>Investigator name: _____ Investigator signature: _____</p> <p>Date: _____</p>		
<p>Please scan and email to: patinodf@mcmaster.ca or fax to: TBD</p> <p>I will receive a signed copy of this form.</p>		

Thank you for considering our request. If you have questions or would like additional information, please do not hesitate to contact us.

Appendix 3: Questionnaire

Section A – Intention to use research evidence

Each question in this section refers to a scenario where you have been asked to brief or provide advice to policymakers or when you are personally involved in a policy debate or decision-making. Please answer each question as though you are engaged in a typical briefing or decision-making process.

1. I expect to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

2. I want to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

3. I intend to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

4. Using synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide is...

Very harmful	Moderately harmful	Slightly harmful	Neutral	Slightly beneficial	Moderately beneficial	Very beneficial
1	2	3	4	5	6	7

Very bad	Moderately bad	Slightly bad	Neutral	Slightly good	Moderately good	Very good
1	2	3	4	5	6	7

Very unpleasant	Moderately unpleasant	Slightly unpleasant	Neutral	Slightly pleasant	Moderately pleasant	Very pleasant
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(for me)	(for me)	(for me)		(for me)	(for me)	(for me)
1	2	3	4	5	6	7

Very unhelpful	Moderately unhelpful	Slightly unhelpful	Neutral	Slightly helpful	Moderately helpful	Very helpful
1	2	3	4	5	6	7

5. Most people who are important to me in my professional life think that...

I should definitely not	I should almost certainly not	I should probably not	Neutral	I should probably	I should almost certainly	I should definitely
1	2	3	4	5	6	7

... use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

6. It is expected of me that I use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

7. I feel under social pressure to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

8. People who are important to me in my professional life want me to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

9. I am confident that I could use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

10. For me to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide is...

Very difficult	Moderately difficult	Slightly difficult	Neutral	Slightly easy	Moderately easy	Very easy
1	2	3	4	5	6	7

11. The decision to use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide is beyond my control.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

12. Whether or not I use synthesized research evidence of the type contained in Health Systems Evidence to help work through what I will say in a briefing or decide is entirely up to me.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

The question below refers to how useful you found the information from the evidence service. **[used only in the follow-up survey]**

13. I found the synthesized research evidence made available through Health System Evidence to be useful.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1	2	3	4	5	6	7

Section B – Participants satisfaction with learning approach [not used at baseline]

14. What is your overall assessment of the training workshop?

Very poor						Excellent
1	2	3	4	5	6	7

15. The length of the training workshop was?

Much too short						Much too long
1	2	3	4	5	6	7

16. The pre-session tasks were?

Very poor						Excellent
1	2	3	4	5	6	7

17. The visual aids and/or handouts were?

Very poor						Excellent
1	2	3	4	5	6	7

Section C – Participant characteristics

18. Do you work part-time or full-time?

- Full-time
- Part-time

19. What is your position within the Ministry of Health?

- Office director (position code 0137); Level: ____
- Advisor (position code 1020); Level: ____
- Specialized professional (position code 2028); Level: ____
- Professional (position code 2044); Level: ____
- Other: _____; Level: ____

20. What area within the Ministry of Health do you currently work in?

- Office of the minister of health
- Office of the vice minister of public health and service delivery
- Promotion and prevention
 - Communicable diseases
 - Non- communicable disease
 - Environmental health
 - Nutritional health
- Epidemiology and demographics
- Service delivery and primary health care

- Service delivery
- Health infrastructure
- Pharmaceuticals and health technologies
- Health human resources
 - Performance of human resources
 - Management of knowledge
 - Training of human resources
- Other: _____

21. [Baseline only] How many years have you been working at the Ministry of Health?
[open ended response]

22. [Baseline only] When finding and using research evidence to inform your decisions about an issue, do you usually:

- Work by yourself
- Work with other colleagues within the same area
- Work with other colleagues in other areas

23. [Baseline only] How comfortable do you feel reading research evidence in English?

Very uncomfortable	Uncomfortable	Somewhat Uncomfortable	Neither uncomfortable nor comfortable	Somewhat comfortable	Comfortable	Very Comfortable
1	2	3	4	5	6	7

24. Do you look for research evidence in the following databases?

a. The Cochrane Library (for research evidence about clinical programs and services or drugs)

Never	Very rarely	Rarely	Occasionally	Frequently	Very frequently	Always
1	2	3	4	5	6	7

b. Health Evidence (for research evidence about public health programs and services)

Never	Very rarely	Rarely	Occasionally	Frequently	Very frequently	Always
1	2	3	4	5	6	7

c. Health Systems Evidence (for research evidence about health system arrangements or implementation strategies)

Never	Very rarely	Rarely	Occasionally	Frequently	Very frequently	Always
1	2	3	4	5	6	7

d. PubMed

Never	Very rarely	Rarely	Occasionally	Frequently	Very frequently	Always

1	2	3	4	5	6	7
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e. The Virtual Health Library

Never	Very rarely	Rarely	Occasionally	Frequently	Very frequently	Always
1	2	3	4	5	6	7

25. [Follow-up only] Since the trial began, did you change between part-time versus full-time status, change position or change branch? If yes, please describe the change. **[open ended response]**

26. [Follow-up only] Since the trial began, did you take any vacation or leave that lasted more than two weeks? If yes, please describe the duration and timing of the vacation or leave. **[open ended response]**

Appendix 4: Invitation letter to register for Health System Evidence



[Insert name and contact information of participant]

[Insert date]

Dear Sir/Madame,

Thank you for agreeing to participate in the iCARE study. As part of this study you are being invited to register for and use Health Systems Evidence (HSE), which is the world's most comprehensive, free access point for evidence to support policymakers, stakeholders and researchers interested in how to strengthen or reform health systems or in how to get cost-effective programs, services and drugs to those who need them.

HSE (www.healthsystemsevidence.org) is an initiative of the McMaster Health Forum and contains a continuously updated repository of syntheses of research evidence about governance, financial and delivery arrangements within health systems, and about implementation strategies that can support change in health systems. HSE also contains a continuously updated repository of economic evaluations in these same domains, descriptions of health system reforms, and descriptions of health systems, as well as a variety of types of complementary content (e.g., World Health Organization documents about health systems).

In addition to this invitation you are receiving a four-page document with general information about HSE including information on how to register and how to use it.

In order to start using HSE, all you have to do is:

1. Go to: www.healthsystemsevidence.org;
2. Complete the free registration process by providing your email address (please use your institutional email address), password, preferred language, country of residence (i.e., Colombia) and role (i.e., policymaker); and
3. Once registered, update your profile and sign up to receive monthly email alerts with information about new documents related to the health systems topics, themes and domains of your interest.

We hope you find what you are looking for in HSE. For more information please contact us at the email addresses below.

Sincerely yours,

[Insert names and contact information for investigators]

Appendix 5: Workshop program adapted from the Health Systems Learning educational program

Workshop on Finding and Using Research Evidence

Overview of the workshop

This workshop introduces policy analysts and policy advisors of the Colombian Ministry of Health to three types of questions that need to be answered to make improvements in the health system. Each of the questions can be answered in part by research evidence

- what is the problem?;
- what options are best suited to address the problem; and
- how can change be brought about?

This research evidence must be considered alongside institutional constraints, stakeholders' views and concerns, organizational values, and many other types of information (e.g., administrative data, personal experiences).

Brief plenary sessions on these topics are followed by work in pairs and/or small groups that will allow workshop participants to grapple with the questions in light of the issues on which they (or their areas) are currently working. The core sessions are bracketed by sessions that focus on the more general sets of challenges associated with the use of evidence by health system policymakers and stakeholders. One session at the beginning of the workshop focuses on the unique attributes of health system policymaking in relation to using research evidence. The final session focuses on participating in efforts to promote the use of research evidence.

Objectives of the workshop

The workshop addresses three objectives:

- to raise participants' awareness about tools and resources available to health system policymakers and stakeholders in order to support their use of research evidence;
- to enhance participants' skills in acquiring, assessing, adapting and applying research evidence; and
- to identify what participants' own areas and their organization as a whole can do to better support the use of research evidence in health system policymaking.

Pre-workshop tasks

Ten days prior to the start of the workshop, participants should devote (roughly) 25-35 minutes to the three or four pre-workshop tasks:

- 1) Identify one health system policy issue with which you (or your area) will be grappling over the coming weeks and describe (in point form) the problem, options for addressing it, and implementation considerations (10 minutes);
- 2) Provide a brief description (in point form) of any training you've received to date in using or supporting the use of research evidence (5 minutes);
- 3) Describe your unit's or department's capacity to acquire, assess, adapt and apply health research evidence on high-priority policy issues (10 minutes); and

- 4) Consider completing the free online registration for Health Systems Evidence and watching the six-minute video about Health Systems Evidence on YouTube before participating in the workshop.

Session descriptions

9:00-9:15

Session 1

Title: Welcome, introductions, and overview of the workshop

Facilitator TBD

Format: Brief presentation (5 minutes)

Introductions (10 minutes)

- Objectives:
- To be welcomed by and introduced to the workshop faculty
 - To meet fellow workshop participants
 - To become familiar with the objectives, structure and mix of pedagogical approaches used in the workshop

9:15-9:40

Session 2

Title: What's unique about using research evidence in policymaking

Facilitator TBD

Format: Presentation (10 minutes)

Large-group discussion (20 minutes)

- Objectives:
- To discuss the attributes of health system policymaking that differ from the attributes of clinical practice

Resources:

- Walshe K, Rundall TG. 2001. Evidence-based management: From theory to practice in health care. *The Milbank Quarterly* 79(3):440-1.

9:40-10:20

Session 3

Title: Clarifying a problem

Faculty: TBD

Format: Presentation (20 minutes)

Large-group discussion (10 minutes)

- Objectives:
- To become familiarized with a list of questions to consider when clarifying a problem
 - To understand how research evidence can help to respond to two of these questions
 - To understand how to search appropriate sources of research evidence to respond to these two questions

Resources:

- Lavis JN. 2013. Finding and using research evidence. Hamilton, Canada: McMaster Health Forum.
- Lavis JN, Wilson M, Oxman AD, Lewin S, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 4. Using research evidence to clarify a problem. *Health Research Policy and Systems*; 2009, 7(Suppl 1):S4 doi:10.1186/1478-4505-7-S1-S4.
- Lavis JN. Evidence-Informed Healthcare Renewal

- Task sheets:
- Portal: Your window to important evidence and policy contributions on healthcare renewal in Canada. Hamilton, Canada: McMaster Health Forum; 2013.
 - Lavis JN. Finding and using research evidence: Clarifying a problem – Task 2: Problem. Hamilton, Canada: McMaster Health Forum; 2014.
 - Lavis JN. Finding and using research evidence: Clarifying a problem – Task 3 – Problem search. Hamilton, Canada: McMaster Health Forum; 2014

10:20-10:35 Break

10:35-11:15 Session 4

Title: Finding research evidence about the problem you're addressing

Faculty: TBD

Format: Work in pairs (45 minutes)

- Objectives:
- To refine the descriptions of the problem that workshop participants submitted before the workshop
 - To search for a qualitative study that addresses stakeholders' views about and experiences with the problem
 - To search for a research study that compares indicators (related to the problem) over time in participants' own organization (or region, province or country) or across organizations (or regions, provinces or countries)
 - To share lessons learned with the other pairs seated at the same table

- Resources:
- Lavis JN. 2013. Finding and using research evidence. Hamilton, Canada: McMaster Health Forum.
 - Lavis JN, Wilson M, Oxman AD, Lewin S, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 4. Using research evidence to clarify a problem. Health Research Policy and Systems; 2009, 7(Suppl 1):S4 doi:10.1186/1478-4505-7-S1-S4.

11:15-11:45 Session 5

Title: Framing options

Faculty: TBD

Format: Presentation (20 minutes)

Large-group discussion (10 minutes)

- Objectives:
- To become familiarized with a list of questions to consider when framing options to address a problem
 - To understand how research evidence can help to respond to these additional questions
 - To understand the main features of systematic reviews and their advantages over single studies
 - To understand how to search appropriate sources of research

evidence to respond to these questions

- Resources:
- Lavis JN. 2013. Finding and using research evidence. Hamilton, Canada: McMaster Health Forum.
 - Lavis JN, Wilson MG, Oxman AD, Grimshaw J, Lewin S, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 5. Using research evidence to frame options to address a problem. Health Research Policy and Systems; 2009, 7(Suppl 1):S5 doi:10.1186/1478-4505-7-S1-S5.
- Task sheets:
- Lavis JN. Finding and using research evidence: Framing options – Task 4: Options. Hamilton, Canada: McMaster Health Forum; 2014.
 - Lavis JN. Finding and using research evidence: Framing options – Task 3 – Options search. Hamilton, Canada: McMaster Health Forum; 2014

11:45-12:30 Session 6

Title: Finding systematic reviews about the options you're considering

Faculty: TBD

Format: Work in pairs (45 minutes)

- Objectives:
- To refine the descriptions of possible options that workshop participants submitted before the workshop
 - To search for a systematic review of studies of the effects of the options you're considering
 - To share lessons learned with the other pairs seated at the same table

- Resources:
- Lavis JN. 2013. Finding and using research evidence. Hamilton, Canada: McMaster Health Forum.
 - Lavis JN, Oxman AD, Grimshaw J, Johansen M, Boyko JA, Lewin S, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 7. Finding systematic reviews. Health Research Policy and Systems; 2009, 7(Suppl 1):S7 doi:10.1186/1478-4505-7-S1-S7.

12:30-1:00 Lunch

1:00-1:30 Session 7

Title: Assessing the quality and local applicability of systematic reviews about options

Faculty: TBD

Format: Presentation (20 minutes)

Large-group discussion (10 minutes)

- Objectives:
- To observe an assessment of the quality and local applicability of a systematic review

- Resources:
- Lavis JN. 2009. Criteria for assessing systematic

reviews. Hamilton, Canada: McMaster University Program in Policy Decision-making.

- Shepperd S, Iliffe S. Hospital at home versus in-patient hospital care. *Cochrane Database of Systematic Reviews* 2005, Issue 3. Art. No.: CD000356. DOI: 10.1002/14651858.CD000356.pub2, p. 1-30.
- Lavis JN, Oxman AD, Souza NM, Lewin S, Gruen RL, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 9. Assessing the applicability of the findings of a systematic review. *Health Research Policy and Systems*; 2009, 7(Suppl 1):S9 doi:10.1186/1478-4505-7-S1-S9.

1:30-2:15

Session 8

Title: Finding and assessing the quality and local applicability of systematic reviews about options

Faculty: TBD

Format: Work in pairs (45 minutes)

Objectives: – To participate in an assessment of the quality and local applicability of a systematic review

OR

– To continue searching for a systematic review of studies of the effects of the options you're considering, to identify the one systematic review that represents the closest match to one of the options you're considering, and to assess the review's local applicability

– To share lessons learned with the other pairs seated at your table

Resources:

- Gruen RL, Weeramanthri TS, Knight SE, Bailie RS. Specialist outreach clinics in primary care and rural hospital settings. *The Cochrane Database of Systematic Reviews* 2003, Issue 4. Art. No.: CD003798. DOI: 10.1002/14651858.CD003798.pub2, p. 1-27.
- Lavis JN. 2013. Finding and using research evidence. Hamilton, Canada: McMaster Health Forum.
- Lavis JN, Oxman AD, Souza NM, Lewin S, Gruen RL, Fretheim A: SUPPORT Tools for evidence-informed health Policymaking (STP). 9. Assessing the applicability of the findings of a systematic review. *Health Research Policy and Systems*; 2009, 7(Suppl 1):S9 doi:10.1186/1478-4505-7-S1-S9.

Task sheet: ▪ Lavis JN. Finding and using research evidence: Assessing systematic reviews – Task 8: Assess. Hamilton, Canada: McMaster Health Forum; 2014

2:15-2:30

Break

2:30-3:00 Session 9

Title: Identifying implementation considerations

Faculty: TBD

Format: Presentation (20 minutes)

Large-group discussion (10 minutes)

- Objectives:
- To become familiarized with a list of questions to consider when identifying barriers to implementation and possible strategies to address these barriers
 - To understand how different answers to these questions can have important implications for the types of research evidence sought
 - To review good places to search for systematic reviews about implementation strategies

- Task sheets:
- Lavis JN. Finding and using research evidence: Identifying implementation considerations – Task 6: Implementation. Hamilton, Canada: McMaster Health Forum; 2014
 - Lavis JN. Finding and using research evidence: Identifying implementation considerations – Task 7: Implementation search. Hamilton, Canada: McMaster Health Forum; 2014

3:00-3:45 Session 10

Title: Participating in efforts to promote the use of research evidence

Faculty: TBD

Format: Presentation (20 minutes)

Large-group discussion (25 minutes)

- Objectives:
- To become acquainted with possible rationales and definitions for evidence-informed policymaking
 - To discuss themes that emerged from workshop participants' (aggregated) unit / department assessments
 - To become acquainted with the options available to support the use of research evidence in health systems
 - Promoting a climate that supports research use
 - Producing systematic reviews and single studies on high-priority topics
 - Undertaking activities to link research to action, namely
 - Producer/purveyor-push efforts
 - Efforts to facilitate user pull
 - User-pull efforts
 - Exchange efforts
 - Evaluating these efforts
 - To discuss workshop participants' assessments of what their organizations can do to better support the use of research evidence in health system policymaking

- Task sheets:
- Lavis JN. Finding and using research evidence: Participating in efforts to support the use of research

evidence; Task 12 – Rationale. Hamilton, Canada:
McMaster Health Forum; 2014 TWO DAY COURSE
ONLY

- Lavis JN. Finding and using research evidence:
Participating in efforts to support the use of research
evidence – Task 13: Support. Hamilton, Canada:
McMaster Health Forum; 2014
- Lavis JN. Finding and using research evidence:
Participating in efforts to support the use of research
evidence; Task 14: Influence. Hamilton, Canada:
McMaster Health Forum; 2014

3:45-4:00 Session 11

Title: Wrapping up

Faculty: TBD

Format: Presentation (5 minutes)

Large-group discussion (10 minutes)

- Objectives:
- To discuss what went well with the workshop and what could be improved
 - To complete the workshop evaluation form

Chapter 5: Conclusion

The three research chapters in this thesis contribute to a better understanding of the use of research evidence in health systems policymaking in a middle-income country, namely Colombia. This chapter begins by highlighting the principal findings of each of the studies presented in Chapters 2-4. Then I discuss the thesis' major substantive, methodological and disciplinary contributions to the field. Following this, I consider the strengths and limitations of the thesis, and finally, I provide recommendations for future research.

Principal findings

This thesis presents three original scientific contributions to address a different yet important part of supporting the use of research evidence in the Colombian health system. Chapter 2 presented an analytical schema about the ideas and concepts embedded in the documents produced by the Colombian government, a Colombian research funder (Colciencias) and Colombian universities about an evidence-informed health system. The theoretical insights that emerged in this study highlight that: 1) the governmental documents' emphasis on the concepts of a "knowledge society" and "innovation" puts more value on the contribution of research evidence to industry and the economic development of the country than to its contribution to the health system policymaking process; 2) according to government and Colciencias' documents, the "citizens" or the "public" of a "knowledge society" need to "appropriate scientific knowledge" in order to be in a better position to demand the use of research evidence in policy decision-making processes; and 3) the concept of "knowledge management" emerged from the Colciencias and university documents to highlight the role of evidence from indicators and evaluation research in identifying health needs and informing coverage decisions.

Chapter 3 examined the political factors that influenced government agendas and decisions and the relationship between these factors and the use of research evidence in two policy decisions: a large-scale reform in 2011 that intended to strengthen the system through incremental changes as a response to a financial crisis and a more technical content-driven policy in 2012 that intended to regulate the pharmaceutical market. The study found that in the large scale reform of 2011, the combination of new political executive power, strong values about preserving the insurance model and few veto points in the congress constrained decision-making power to the executive arena. This arrangement of institutions, interests and ideas created the conditions that allowed elected officials' ideas about "what ought to be" to lead to an instrumental use of research evidence (i.e., they used citable research that resonated with their values) and symbolic use of research evidence (i.e., they selectively used or did not use research that criticized the insurance model). In the pharmaceutical policy of 2012, we observed that the symbolic use of research evidence by the previous government helped to create a problem that forced the newly elected government to regulate the prices of pharmaceuticals despite its "free market" values. In the new government, the transparent and instrumental use of research evidence during the policy development process became a strategy of elected

officials and policy advisors to negotiate with the pharmaceutical industry and introduce regulation policies.

Chapter 4 presented a protocol for a cluster randomized controlled trial that will be used to assess the effectiveness of a multifaceted intervention in increasing the utilization of an evidence service and the intention to use synthesized research evidence by policy advisors and analysts at the Colombian Ministry of Health (MoH). During the trial, participants in the intervention arm will receive a self-serve evidence service (i.e., notification of the availability of Health Systems Evidence database), a one-day training workshop on how to find and use research evidence plus full-text article availability upon request. Individuals in the control areas will receive only the self-serve evidence service. The utilization of the database will be assessed automatically in all periods of the trial and the intention to use research evidence will be assessed at baseline, the end of the intervention period and the end of the follow-up period.

Study contributions

The three original scientific contributions presented in this thesis collectively begin to fill important gaps in the literature by supporting the use of research evidence in low-and middle-income countries (LMICs). While work has been undertaken to study the climate for evidence-informed health systems (Cheung et al., 2011; El-Jardali, Ataya, Jamal, & Jaafar, 2012; Law, Lavis, Hamandi, Cheung, & El-Jardali, 2012), there has been little theoretical work that aims to understand how those who use research evidence, those who fund research and those who produce evidence conceive the role of research evidence in the health system policymaking process. Additionally, while some have studied the barriers to, and facilitators of, the use of research evidence by policymakers (Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014), there is also little empirical work – especially in Latin America – that intends to understand whether and how political contextual factors influence the role of research evidence in the agenda-setting and policy-development stages of the policymaking process. Similarly, there is a lack of rigorous studies that assess the effectiveness of strategies designed to support evidence-informed health system decisions (Mitton, Adair, McKenzie, Patten, & Wayne Perry, 2007). The work presented in this thesis consists of substantive contributions that provide a better theoretical and empirical understanding of the use of research evidence, methodological contributions providing a range of approaches that can be adopted by others for developing a better understanding of how to support the use of evidence in health systems policymaking, as well as disciplinary contributions.

Substantive contributions

The work presented in Chapter 2 contributes a new substantive theory that: 1) provides a comprehensive approach to understanding the ideas and concepts embedded in the documents produced by the Colombian government, a Colombian research funder and Colombian universities about an evidence-informed health system; 2) identifies in the documents the ideas about the importance of research evidence to society, that is, the

framework identifies the societal goals that will be achieved by producing and using research evidence; 3) identifies the concepts that explain how research evidence would be produced and used in order to achieve those goals; and 4) explains the contribution of the governments', Colciencias' and universities' documents to the development of the theory. These theoretical insights may be useful for those involved in supporting the use of research evidence in Colombia, as it provides them with a comprehensive picture of how conducive are the ideas and concepts embedded in these documents to using research evidence to inform health systems decisions. It may also assist in identifying strengths and weakness in how these actors conceive the role of research evidence. As such, researchers can start studying how to improve the conceptualizations about what should be the mechanisms underlying an evidence-informed health system. It may also be helpful for policymakers who can begin to recognize the predominant system of ideas and standards under which they define their goals and instruments.

Chapter 3 provides a comprehensive account of two policy processes in Colombia, as well as detailed explanation of how research evidence influenced them. In doing so, it highlights how a specific combination of problem, policy and politics related factors explain how issues moved onto the governmental and decision agendas. It also shows how institutions, interests, ideas, and external factors influenced policy choice. An analysis of the interaction between those factors and the use of research evidence is also presented, which indicates their joint influence on the policy process and highlights the importance of considering the direction of the interaction, the way in which research was used, and the point in time of the interaction. The detailed accounts presented in Chapter 3 is useful to those involved on similar processes in Colombia and wish to consider how these factors might influence their own work. Furthermore, it provides those producing research evidence on how to inform similar policies in Colombia with an example of how their work may influence the policy process.

Lastly, Chapter 3 makes a substantive contribution to the design of studies that intend to assess the effects of a multifaceted intervention on improving health system policymakers' timely access to policy relevant research evidence, awareness of synthesized research evidence, and skills in finding and using synthesized research evidence.

Methodological contributions

Chapters 2-4 also contribute to the development of methodological approaches for undertaking work focused on supporting the use of research evidence in health system policymaking. Chapter 2 adopts novel application of grounded theory methodology to the analysis of organizational documents in order to gain helpful insights about the climate for research use; a method ideally suited for developing theories to understand social processes. While past studies used grounded theory as a metasynthesis methodology to develop new knowledge from the analysis of existing qualitative research findings (Kearney, 2001; Thorne, Jensen, Kearney, Noblit, & Sandelowski, 2004), Chapter 2 of

this thesis provides a detailed account of how to use this method for the analysis of organizational documents in the area of health systems in order to understand the actors' framework of ideas about the role of research evidence in the policymaking process. As such, this chapter provides a clear methodological approach for scholars undertaking similar work in the future.

Chapter 3 draws on existing literature that studies the political factors that influenced agendas and decision (Lavis, 2013) to illustrate how to apply political science frameworks to provide detailed accounts of policy processes in Colombia. The chapter also provides new conceptualizations of the interaction between political contextual factors and the use of research evidence on the policy process. As such, this chapter establishes an approach for undertaking similar analyses of other policy processes and the role of research evidence in those processes.

Finally, drawing on similar trials designed for the clinical sector (Haynes, Holland, & Cotoi, 2006) and for a MoH in Canada (Lavis et al., 2011), Chapter 4 presents a cluster randomized controlled trial protocol to assess the effects of a multifaceted intervention in increasing the utilization research evidence at the Colombian MoH. Addressing the challenges that other studies have encountered when recruiting policymakers (Kho, Rawski, Makarski, & Brouwers, 2010; Lavis et al., 2011), this protocol incorporates methodological strategies to increase recruitment efficiency, improve the balance between groups and minimize contamination.

Disciplinary contributions

The original scientific studies that make up this thesis also contribute to the field of health systems research and to the study of efforts that aim to support evidence-informed policymaking in LMICs. By integrating study designs from the field of health systems research with theoretical frameworks from the field of knowledge translation and political science, this thesis provides approaches to inquiry that can yield insights that are more comprehensive, robust and compelling than any single discipline could on its own.

Strengths and limitations

Together, the three studies presented in this thesis have several strengths. First, by focusing on a country with relatively sparse research about how evidence informs health system decisions and by drawing on the knowledge translation and political science literature, I have taken important initial steps towards not only developing this area of research, but also to practically supporting the use of research evidence by policymakers in the Colombian MoH. As such, this thesis provides a unique and potential important contribution to the field. Another related strength is the use of different methods. The in-depth understanding of the climate for research use and policy processes would not have been possible without the use of an interpretative grounded theory approach, qualitative interviews and case study approaches. In addition, to our knowledge, this is the first study that uses a grounded theory approach to explain the 'taken-for-granted' assumptions of an

evidence-informed health system.

Another strength of this thesis is its multi-disciplinary integration of concepts and approaches, relying on theories from political science, knowledge translation and health systems research. This multi-disciplinary perspective provided a comprehensive understanding of the factors that can influence the use of research evidence, as well as the ways in which research evidence can influence the policy process. While the findings of this thesis will be relevant to those who support policy and health systems in LMICs, the study concepts and approaches will be of interest to scholars in political science and health policy. Lastly, to our knowledge the randomized controlled trial (RCT) protocol presented in chapter 4 is one of the first designed to evaluate the effects of a multifaceted intervention in increasing policymaker's capacity to use research evidence. Therefore, if completed, the RCT could contribute to an emerging evidence base about the effects of knowledge translation interventions that can contribute to the findings of future systematic reviews.

There are also some limitations of this thesis that have to be considered. First, all of the original scientific contributions focus on the Colombian context. The theory presented in the chapter 2 draws on documents produced by Colombian organizations, the key informants interviewed for the case study discussed in chapter 3 worked within Colombian organizations, and the RCT protocol presented in chapter 4 will be conducted at the Colombian MoH. This emphasis on the Colombian context implies that although the methods could be applied by researchers interested in this field of research to study other contexts, readers will have to make their own judgments about how transferable are the findings from these chapters to their own context. In addition, collecting further information produced by other actors, for example, including documents produced by international organizations, could complement the conceptual understandings of the use of research evidence in the Colombian health system presented in Chapter 2. Furthermore, the two policy issues that we studied in Chapter 3 share some important characteristics of the political context; both cases moved to the decision agenda when Colombian citizens elected a new government in 2010. Therefore, even within the Colombian context, our findings might not be transferable to policy issues from different political contexts. Finally, the RCT presented in chapter 4 will be conducted only in a Ministry of Health, which provides a fixed, and potentially limiting sample size and limits its transferability.

Future research

While this thesis addressed numerous gaps in the research literature, it identified important areas for future research. First, each of the approaches in this thesis should be tested in additional country settings and in different policy issues to improve generalizability and gain more robust insights about how to support the use of research evidence by health system policymakers. Approaches like the one we used in Chapter 2, could be used in other Latin American countries to assess how different actors in the region conceive the role of research evidence in the health system policymaking process.

This approach could be complemented with other studies that help us identify if universities and research centres are producing the types of research evidence that policymakers need to inform their decisions about the health system, which would help to gain better insights about how conducive is the Latin American climate to research use. In addition, the case studies presented in Chapter 3 are a preliminary attempt at defining whether and how research evidence influence the policy processes, and may be used as a point of departure for other similar investigations in other countries of the region and the world. Moreover, further evaluations of strategies designed to inform health system decisions with the best available research evidence are important for continuing to develop an evidence base that can eventually be synthesized in a systematic review that assesses the effects of efforts to support the use of research evidence, thereby helping the field to have a better idea of 'what works'.

Finally, theoretical studies should also be pursued to address questions that aim to better understand the contextual factors that influence either the use of research evidence or the effect of other mechanisms currently being pursued in LMICs to support the use of evidence in health policymaking (e.g., deliberative dialogues, evidence briefs, clearinghouses and rapid response services). Research that aims to gain additional theoretical insights from other relevant fields in order to revise or strengthen the analytical schema presented in Chapter 2 or the conceptualizations of the interaction between political contextual factors and the use of research evidence presented in Chapter 3, would also be welcome.

Overall, the work in this thesis supports the use of research evidence in the Colombian health system. The first two original studies paint a more nuanced picture than was previously available about the ways in which different actors conceive the role of research evidence and the political contextual factors that influenced the use of research evidence in specific policy decisions. The third study will shed light on the effect of a strategy designed to inform health system decisions with the best available research evidence. While it is clear that there is still much work to be done in supporting the use of research evidence in Colombia and in LMICs in general, this thesis has helped to provide insights that can be utilized to support a more nuanced approach to the use of research evidence in LMICs that takes into account the many factors that can influence health system policymaking. Ideally, this will help those engaged in developing mechanisms to support the use of research evidence in the policy process, and contribute to stronger health systems across the world.

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