



EAS Briefing Note 2

**Evidence Advisory System Briefing Notes:
COLOMBIA**

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GETTING RESEARCH INTO HEALTH POLICY AND PRACTICE

GRIPHEALTH

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1 Introduction

There has been a growing global concern for improving the use of evidence to inform health policy in recent years. Increasingly there is recognition that individual projects or programmes building evidence synthesis skills, may be limited in their effect without a broader consideration of the systems in place which 'embed' or 'institutionalise' evidence informed policy making practices (Alliance for Health Policy and Systems Research and WHO 2007).

The GRIP-Health programme is a five- year project supported by the European Research Council which studies the political nature of health policy to understand how to best improve the use of evidence. This explicitly political lens enables us to focus on the contested nature of health issues as well as the institutions that shape the use of evidence in health policy making. We understand institutions as including both formal structures and rules, as well as informal norms and practices (Lowndes and Roberts 2013). The GRIP-Health programme follows the World Health Organization's view that Ministries of Health remain the ultimate stewards of a nation's health, and further play a key role in providing information to guide health decisions (World Health Organization 2000, Alvarez-Rosette, Hawkins et al. 2013). As such, GRIP-Health is particularly concerned with the structures and rules created by government to gather, synthesise, or otherwise provide evidence to inform policy making.

This working brief is one of a series of six briefs covering a set of countries in which the GRIP-Health programme is undertaking research. This brief presents an overview of what is termed the 'Evidence Advisory System' (EAS) for health policy making within the country of interest, which is taken to encompass the key entry points through which research evidence can make its way into relevant health policy decisions. This can include both formal (government mandated) and informal structures, rules, and norms in place.

Individual reports in this series can be useful for those considering how to improve evidence use in specific country settings, while taken together the reports identify the differences that can be seen across contexts, permitting reflection or comparison across countries about how evidence advisory systems are structured – including which responsibilities are given to different types of bodies, and how well evidence advice aligns with decision making authority structures.

This paper describes the evidence advisory system (EAS) for health policymaking in Colombia, an upper-middle income country located in north-west South America. Colombia is challenged by ongoing armed conflict between various groups in different regions of the country, acts of terrorism associated with these armed conflicts, and the social and political consequences of Colombia's central position within the global trade in illegal narcotics. These contextual factors have influenced the formation of the political culture, leading to the formation of deeply embedded patron-client relationships within all levels of government, and corruption (Dargent 2015). As an example of the extent of social and political conflict, at the time of writing (November

2016), the agreement reached through a peace process negotiated between the Revolutionary Armed Forces of Colombia (FARC) and the Colombian government has been rejected by referendum.

These deep-rooted and long standing political and societal divides are reflected in health policy and health policymaking. Colombia has mandatory health insurance under regulated competition of both insurance and care providers through a managed care model (Bernal, Forero et al. 2012). Since its inception in 1993, the Colombian health system has remained deeply contested. Deep ideological disagreements have been sustained on issues such as the financing of the system (insurance versus taxation based); the involvement of the private sector; and whether limits can or should be placed on the right to health care. Policy debates almost exclusively focus on health system reforms, to the exclusion of other policy issues. Still, despite the various proposals, it has also proven resilient to decisive reform.

Throughout this 20-year long process of reform, scientific research has been conducted on the extent of the health system sustainability problem and on the scope of the solutions pursued. Most of this evidence has been produced in-country, either by government departments or by research institutes, universities or other organisations commissioned by the government. While this reflects a long-standing interest in the use of evidence to inform health policy, an increase in such interest has taken place over the last five years. To illustrate, changes have been made to the EAS, including the establishment of new evidence advisory bodies, and health technology assessment (HTA) has been embraced – reflected in the setting up of the Institute of Health Technology Assessment (*Instituto de Evaluación de Tecnologías Sanitarias, IETS*).

2 Background to Colombia

As of 2015, the Colombian population was estimated at just over 48 million, with a GDP of US\$ 292.1 billion. This represents a GDP per capita of US\$ 6056 (The World Bank 2016).

Colombia is a presidential democracy. The President of the Republic is elected every four years to become the Chief of State, the Chief of Government and the highest administrative authority. Parliament is formed of a bicameral Congress with a Senate (*Senado*), and a Chamber of Representatives (*Cámara de Representantes*). Both chambers have similar roles in the formulation and passing of policies. The electoral system is proportional; however, there is very low electoral participation (below 50% in legislative elections) and the party system is very weak (parties do not have strong bureaucracies and structures, but are dependent upon their charismatic leaders). Formal legislation is passed through the bicameral legislature, although

many controversial issues are unable to be passed and are resolved through judicial mechanisms. The constitutional court (and lower order courts) is an extremely powerful actor, playing a quasi-legislative role through its guarantee of citizens' rights to health services - e.g. through its adjudication on 'tutelas' - formal legal challenges brought by individuals to have insurance companies provide treatments (Cepeda-Espinosa 2004).

Colombia is "mildly" decentralized, with power transferred to 32 departments and 5 districts (including the Distrito Capital de Bogotá) and to lower local authorities (sub-departmental entities, municipalities and villages). Departments have autonomy to manage their own sectional affairs and to plan and promote economic and social development within their territory.

The health policy process in Colombia involves a range of different institutions across the different branches of government as well as non-state actors (e.g. civil society organisations, health insurers, service providers, academia and professional organisations). The governance of the health system is extremely fragmented, reflecting the complexity of the health system itself (Yamin and Parra-Vera 2010, Bernal and Gutiérrez 2012). Mandatory health insurance under regulated competition was introduced in 1993. The *Empresas Promotoras de salud* (EPS) manage the affiliation and registering of people, and organise and ensure the provision of basic services called the *Plan Obligatorio de Salud* (POS). The POS includes the integral protection of families, maternity care, health information, health promotion, diagnostics, treatment and rehabilitation for all diseases. Multiple private health care providers (the *Instituciones Prestadoras de Servicios*, IPS) enter into contractual arrangements with the EPS. People receive health care services within the health insurance system by entering through either the contributory regime (all residents with a legal work contract or with fixed income able to pay insurance contributions) or the subsidized regime for the poor and vulnerable. Those affiliated to the contributory and subsidized regimes freely choose their EPS to register with the beneficiary. The health insurance system is financed through the Solidarity and Guarantee Fund, which is supported by the insurance contributions of those under the contributory regime. In addition, the public health component of the system, which includes collective interventions for health promotion and prevention - such as awareness and information campaigns- is financed by the territorial health entities and provided by local hospitals (Giedion and Uribe 2009, Bernal, Forero et al. 2012, Chernichovsky, Guerrero et al. 2012).

The Colombian health system has achieved high public coverage rates and has made significant progress in the control of infectious diseases as well as reducing maternal and infant mortality

(World Health Organization 2012). To illustrate, the maternal mortality ratio has declined significantly from 118 deaths per 100,000 live births in 1990 to 64 deaths in 2015 (World Health Organization 2015). Similarly, reported confirmed cases of malaria have steadily declined over the last decade with 40,760 confirmed cases in 2014 compared with 142,241 confirmed cases in 2004 (World Health Organization 2015). Total expenditure on health as % of GDP (2014) was 7.2 (World Health Organization 2016).

3 Primary decision making points for health

While there is a general use of terminology such as 'Evidence Based Policy' or 'Evidence Informed Policy' in the health sector, what 'policy' is, is all but unambiguous. 'Policy' can refer to a range of concepts from projects and programmes, to sector-specific plans, to broad statements of intent (Hogwood and Gunn 1984). Policy is also not the responsibility of a single body; rather, policy decisions affecting health take place across a range of governmental levels and authorities.

This lack of a universal object of study complicates health policy research. However, there are some types of decisions common to many countries' health sectors for which research evidence is often held as critical. This allows a basic classification of decision types to provide at least a starting point for comparisons/analyses of country evidence advisory systems, as follows:

- **Public Health and Health Promotion:** Usually high level decisions affecting large segments of the population. Can involve agencies outside the health service and broader sectoral interests. Often the responsibility of national legislatures, ministries of health, or devolved authorities. Common examples include: tobacco control, occupational health, healthy eating, sanitation, etc. A broad range of evidence will be relevant to such decisions, including epidemiological, economic, social attitude, and others which speak to relevant decision criteria.
- **Health Service Priority Setting and Management:** Decisions concerned with the allocation of resources across the health system or the structure of service provision and funding, including priorities within the system. Often the responsibility of Ministries of Health or national health services. Common examples: Health system priorities, health worker responsibilities, resource generation or allocation decisions, etc. Relevant evidence forms include health technology appraisals/assessments (HTA), epidemiological and clinical studies, health services research, etc.
- **Programme Planning:** Decisions within the remit of specialised agencies, such as programmes dedicated to individual conditions (malaria, HIV, cancer, etc.). Decisions within these bodies often require evidence both about efficacy or cost effectiveness of different prevention and treatment options, but equally often are informed by locally generated data (e.g. routine data from surveillance or facility information).
- **Service Provider Decision Making** is the most specific and tailored to individual cases. It can be health centre or hospital policies, or individual clinician decisions about patient care. Relevant evidence may include specific case details or specific realities of the context as well as more top-down use of guidelines.

In addition to these types of health decisions, this working paper also recognises that decision making for health can take place at different levels within government hierarchies, with authority for decisions, and entry points for evidence resting in: national level bodies, sub-national (regional) level bodies, and local level bodies at times. In different country settings the various decision types listed above might be addressed at any of these three levels or may cut across more than one level. For instance, at the national level, the Ministry of Health usually functions as a decision point for certain types of decisions, but movements towards de-centralisation might lead to the shifting of decision-making from national levels to sub-national or local levels (England is a case study of that). This permits consideration of whether systems of evidentiary advice are well aligned with the decision authority structures in a setting. There can also be important considerations on the ways that national evidence systems link to influential non-state decision makers (e.g. development partners in low and middle income settings, or corporate bodies granted authority for health policy decisions).

3.1 National Bodies

3.1.1 Legislature

Congress (Camara de Representantes/ Senado);

The legislative branch of the government is formed of a bicameral Congress – with a Senate (*Senado*), and a Chamber of Representatives (*Cámara de Representantes*). Both chambers have a similar role: in addition to discussing laws submitted by the government, both can initiate the formulation of policies. Draft laws need to be approved by both chambers (Alcántara 1999).

The Congress passes laws. There are different types of laws according to the topic: Statutory Laws (*leyes estatutarias*), Organic Laws (*leyes orgánicas*) and Ordinary Laws (*leyes ordinarias*). The hierarchy of laws is therefore granted by the importance of the topic they legislate. Typically, the types of health policy decisions taken by the Congress are in the form of *ordinary* laws, indeed all health laws passed since 1991 have been in the form of ordinary laws, with the exception of one statutory law. Statutory laws are determined by the nature of the themes that these norms regulate, which are explicitly stated in the Constitution, and thus may be applicable to a potential health policy if it affects “fundamental rights and obligations for people and the procedures and resources for the protection of these”. Statutory laws are reviewed by the Constitutional Court before the President signs them. In health policy, there has only been one statutory law, the recently passed Law 1751 of 2015 (Congreso de Colombia 2015), because it aimed to establish the content of the right to health and the responsibility of the State on health, as well as the criteria to ensure that compliance with the right to health is met (Hernández 2013).

3.1.2 Executive

President of the Republic

As Head of State and Head of Government, the President signs laws and norms approved by Congress, has special presidential prerogatives, makes executive policy decisions, and acts as arbitrator over policy conflicts.

Recent examples of health policy decisions illustrate these three roles:

a) Settling over (health) policy conflict:

- In the scenario of high ideological confrontation over the reform of the Law 100 of 1993 that created the health system, Minister Gaviria had intended a health reform through ordinary legislation. However, reflecting the substantial power over health policy in Colombia, the National Doctors Council (Gran Junta Médica Nacional) made a 14-points

presentation to President Santos himself in December 2012. The president took on board their proposals and decided to take these forward through a Statutory Law to establish the content of the right to health and the responsibility of the State on health, as well as the criteria to ensure that compliance with the right to health is met. In parallel, Minister Gaviria's Ordinary law was also to be introduced in Parliament to define the structure of the health system that would make real the right to health regulated by the Statutory Law.

b) Using special presidential prerogatives:

- The congress' regulation allows a series of extraordinary procedures to deal with certain situations. One of them is an "urgency message" where the president requests a higher priority for an issue in the decision-making process, requiring it to last no more than 30 days in each chamber. This was the case of the recently promulgated Law 1751 of 2015 (which materialised the draft Statutory Law *Proyecto de ley estatutaria 209 de 2013 Senado, 267 de 2013 Cámara*) that regulated that the right to health care went through the urgency procedure which meant joint deliberation and voting of the First Commission of the Senate and the First Commission of the Chamber of Representatives.
- Emergency Decrees are special decrees that have the strength of a law, but which require the prior declaration by the president of a "state of exception" that gives him the power to produce these kind of norms. These decrees are subject to immediate constitutional evaluation by the Constitutional Court. For example, in 2009, president Uribe declared a "state of economic, social or ecological emergency" which granted him special powers to produce a series of decrees to reform particular aspects of the health system. However, the Constitutional Court finally declared the state of emergency unconstitutional and annulled the Emergency Decrees.

c) Making executive decisions in health:

- Health policies are presented to the Congress as "project laws" by the Minister of Health, but these will have been previously agreed and decided collectively within the executive branch. Recently, a directive of President Santos has strengthened the role of the President over lower norms produced by ministers, requesting that all resolutions (norms which are below laws and decrees) proposed by ministries be first reviewed by the President Office.

The Executive

While long-term (effective) planning does not seem to happen regularly in public policy in Colombia (some interviewees declaring that “long-term planning is absent”), the National Planning Department (*Departamento Nacional de Planeación*) is a technical-administrative department with Ministerial status (e.g. Cabinet representation) that contributes to making programmatic plans in health.

3.1.3 The Ministry of Health

In 2011, the Ministry of Social Protection, which previously included labour, social security and health, was split in two. The new Ministry of Health and Social Protection (*Ministerio de Salud y Protección Social, MSPS*) was then established, with responsibility for: (i) formulating health policy/setting goals; (ii) identifying intervention strategies; (iii) policy coordination; (iv) capacity planning; (v) resource allocation; (vi) securing resources (financing); (vii) regulation; (viii) cost control; (ix) monitoring and information control; and (x) international relations (Ministry of Health and Social Protection 2012).

Being an insurance based health system, the MSPS primarily steers health care by setting the mandatory basic service package (the *Plan Obligatorio de Salud (POS)*) and regulating the system, although it does not have a direct managerial input on health care facilities.

The Minister is appointed and removed by the President but there appears to be quite strong independence of the bureaucracy. According to Minister of Health Gaviria, for instance, the Ministry is now “a technocratic fortress”, implying that the Ministry itself and dependent bodies are no longer politicised. Quoting Minister Gaviria, “decisions are now made independently of electoral politics” (Amat 2015).

3.1.4 The Judiciary

The judiciary plays a particularly important role in health policymaking in Colombia. It has been described as a “protagonist” in health and health policymaking to an extent unparalleled in any other country (Rodríguez Garavito 2012). Some literature has coined the term “judicialization of health policy” to mark the involvement of the judiciary in health and health policy development as well as the tendency to take to the courts issues that would, in other countries (of a similar level of economic development or comparable level of judicial activism), be resolved by the health system administrative and regulatory instruments (Rodríguez Garavito 2012).

The Constitutional Court

The Constitutional Court (*Corte Constitucional*) (CC), created in 1991, has a quasi-legislative role over health policy issues, often on the most controversial issues in which legislation is politically problematic or when the legislative and executive bodies have failed to act (i.e. the update of the POS). It has been noted that “in recent times, social and political actors have gradually deferred to the Court for the resolution of their most difficult questions”, giving the CC the ultimate say in cases where fundamental human rights are called into question (Cepeda-Espinosa 2004). This has the potential to create precedents and set parameters for future judgements. The CC is composed of magistrates elected by the Senate of the Republic. The elected justices of the CC serve for a non-renewable eight-year period (Cepeda-Espinosa 2004).

3.2 Sub-National Bodies

Colombia devolves some power and authority to 32 departments and 5 districts and other sub-departmental entities and local authorities (municipalities and villages). Departments have autonomy to manage their own sectional affairs and to plan and promote economic and social development within their territory. In particular, public health (including collective interventions for health promotion and prevention – such as awareness and information campaigns) are financed by the territorial departments.

4 Entry points for research evidence – The evidence advisory system

For research evidence to inform policy, it must have a conduit through which it can reach decision makers who might be usefully informed by it. There may be a wide range of structures and norms in place, both formal and informal, which, when taken together, form the evidence advisory system for health decision making. Taking as our starting point the stewardship role of Ministries of Health (and, by extension, national legislatures which govern ministries), we separate between

1. 'Formal systems'- taken here to represent the officially mandated agencies tasked with evidence synthesis and provision for decision making processes. These can be within national governments (for example, Ministry of Health Research Departments), Semi-autonomous bodies (such as the National Institute of Health and Care Excellence – NICE – in the UK), or independent agencies, so long as they have a formal mandate to provide evidence to inform policy; and
2. 'Informal systems' - representing the systems of evidence provision that are not dictated by any formal decree or rule to provide evidence, but which are found to play important roles in evidence provision.

In Colombia, a wide range of evidence is produced 'in-country' (by research institutes or other organisations commissioned by the government or the ministries) and even 'in-house' (i.e. within the MoH or other health authorities, including surveys and primary health data).

For example, as an attempt to generate knowledge to support the implementation of Law 100 which set up the Colombian health system, a Program for Supporting the Health Reform (*Programa de Apoyo a la Reforma de Salud, PARS*) was introduced in 1996 with the financial and technical support of the Inter-American Development Bank. The Program aimed to provide technical assistance and capacity building, to produce specialised research and strategies to transfer such knowledge to decision-makers at the MoH. More than 100 analytical studies and consultancy projects were developed over the years the PARS was in operation until it finished in 2008, producing 18 publications on different aspects of the project (Ministerio de la Protección Social and Gesaworld 2008).

At the national government level, the *Departamento Nacional de Planeación* (DNP) is a technical-administrative department with Ministerial status (e.g. Cabinet representation), responsible for the planning and development of economic and social policies. The DNP acts as executive secretariat of the national council of economic and social policies (CONPES, *Consejo Nacional de*

Políticas Económicas y Sociales), which is the maximum national advisory body for the government in charge of policy planning. However, as the policy capacity of ministries, and specifically the MoH, has increased, they are assuming some planning functions from DNP. A key activity of the DNP is the production of strategy documents (CONPES) for the government in specific economic and social policy areas, within the remit of the National Development Plan (Departamento Nacional de Planeación 2016)¹.

A recent analysis has argued that “[t]he interest of the Colombian government in relying on scientific evidence to better inform health policies began in the mid-2000s, but it has only been in the last three years [since 2011] that policymakers have paid attention to the methods and processes for assessing and appraising the evidence used in other countries” (Castro 2014). This has led to a change in the EAS and the establishment of new institutional arrangements explained below.

4.1 Formal systems

There is no formal body responsible for setting health research priority at the national policy level in Colombia. The MoH and dependent bodies, such as the *Instituto Nacional de Salud* (INS), aim to align their research strategies and objectives annually (i.e. the INS strategic plan has to be approved by the MoH); however, the MoH does not have an identifiable research unit. As such there is no unique central hub of evidence generation in the Ministry; the closest seems to be the Advisory Office for Planning and Sectoral Studies (*Oficina Asesora de Planeación de Estudios Sectoriales*) within the Minister Office – a MSPS unit that provides advice to the Minister of Health. Instead, each unit and directorate within the Ministry appears to be responsible for its own areas of expertise. Units contract out research to produce evidence for designing policies (i.e. a series of studies on the financing of the subsidized regime were paid by the Ministry from a loan given by the Inter-American Development Bank).

Prior to 2012, the EAS for health in Colombia was structured around the Regulatory Commission for Health (*Comisión de Regulación en Salud*, CRES), a decision-making body set up in 2007, ascribed to the MoH with the role of, among other tasks, updating the basket of services (POS). “In December 2011, in compliance with the constitutional court’s mandate, POS content was updated by the CRES. However, it received considerable criticism from the media and the

¹ We have concluded that the DNP has not a role in evidence synthesis and dissemination as well, but rather as “user of evidence” for policy making. Hence it is not included in the formal EAS mapping.

academic community due to the inadequate use of evidence and weakness of methods, but also the lack of transparency within the decision-making process”(Castro 2014). In an effort to respond to such criticisms, the government created the Institute of Health Technology Assessment (*Instituto de Evaluación de Tecnologías Sanitarias*, IETS) in September 2012 to inform the CRES (see below). However, only a few months later, in December 2012, the CRES was abolished and the MoH “re-assumed its role of resource-allocation decision-maker” (Castro 2014). While there may not be a central coordinated *research* unit, the MoH does have a series of organizations ascribed to it with responsibilities for *evidence provision* through their mandate to advise on decisions in health, including: the Instituto Nacional de Salud (INS) (the National Health Institute); the Instituto de Evaluación de Tecnología en Salud (IETS) (Institute of Health Technology Assessment); and the Instituto Nacional de Vigilancia de Medicinas y Alimentos (INVIMA) (National Institute for the Vigilance of Medicines and Food).

IETS

Created in September 2012, the Institute of Health Technology Assessment (*Instituto de Evaluación Tecnológica en Salud*, IETS) is a not-for profit public-private partnership (*corporación sin ánimo de lucro, de participación mixta y de carácter privado*)(Instituto de Evaluación Tecnológica en Salud 2013) participated by four public sector members (the Ministry of Health (MSPS); the drug regulator INVIMA; the National Health Institute (INS); and the administrative department of science, technology and innovation (Colciencias) (Colciencias 2016) and two private sector members (the Colombian Association of Faculties of Medicine (ASCOFAME)(Ascofame 2016); and the Colombian Association of Scientific Societies (Asociación Colombiana de Sociedades Científicas 2013).

The role of IETS is to provide non-binding recommendations about health technologies and clinical practice. Modelled on the British National Institute for Health and Clinical Excellence (NICE), the IETS:

- (i) conducts evaluations of health technologies (including medicines, medical devices, diagnostics and clinical procedures, public health programs);
- (ii) supports the design, evaluation and dissemination of evidence-based clinical practice; and
- (iii) provides training to health professionals on evidence-based medicine, best clinical practice, decision-making.

The IETS has developed a policy of transparency that stipulates conflicts of interest (Instituto de Evaluación Tecnológica en Salud 2013); for example, IETS members would not participate as speakers in any event directly organized or funded by the pharmaceutical industry. All IETS

collaborators or actors involved in their health technology appraisals (HTA) have to sign conflict of interest declarations that are then reviewed by a Conflict of Interest Committee who would ultimately decide whether the person is authorised to participate or collaborate with IETS.

Direct public participation and consultation is limited for IETS. Assessments are made public on the IETS website, which has an area called 'participation' in which members of the public can upload information or request information about existing IETS activities.

INS

The National Health Institute (*Instituto Nacional de Salud*) (INS) is an arm's length scientific-technical body with its own legal status, own budget and administrative autonomy, ascribed to the MoH. The INS is responsible for knowledge transfer and dissemination in health. It works closely with universities and scientific and professional associations, undertaking and commissioning research.

Of a 23-long list of INS functions stated by law, those of special relevance for the purpose of the GRIP-research project are to (Instituto Nacional de Salud 2016):

1. "Generate, develop, apply and transfer scientific knowledge...which should speed up the use of that knowledge in strategies prediction, prevention, diagnosis, treatment and control desirable for the benefit of the health of the human population".
2. "Conduct research and knowledge management in public health, in accordance with policies, plans and guidelines of the Administrative Department of Science, Technology and Innovation and the Ministry of Health and Social Protection".
3. "Participate and provide advice on the development of scientific and technical standards and technical procedures in public health".
4. "To promote, coordinate, direct and conduct studies and research to evaluate the effectiveness of interventions to improve public health in the context of the powers of the state".
5. "Create and coordinate a network of scientific and technical research in public health, in which all the entities that carry out research, validation and technology transfer in public health sciences, in order to contribute to the achievement all rational scientific capacity available in the country in this field".
6. "Participate in the evaluation of public health technologies, in matters within its competence".
7. Research, develop, produce, market and provide essential goods and services in public health, in accordance with the parameters set by the Ministry of Health and Social Protection, directly or through alliances or strategic partnerships.

The INS may also evaluate policies and health technologies, and thus has some overlap with IETS. One of the roles of the INS has been providing technical assistance to local authorities to strengthen their research capacity. However, interviewees have been sceptical about the ability of INS to carry out these tasks (“INS don’t go to medical congresses!”, interview 11). Dependent upon the INS, the health observatory (*Observatorio Nacional de Salud*) conducts analyses of the health situation in Colombia by monitoring health indicators and identifies knowledge gaps that require research prioritization (Instituto Nacional de Salud 2016).

INVIMA

The National Institute for the Vigilance of Medicines and Food (*Instituto Nacional de Vigilancia de Medicinas y Alimentos*, INVIMA) is the food and drug regulator. It was set up as a technical scientific public body with its own legal status, administrative autonomy and own budget, ascribed to the MoH. INVIMA is responsible for: (i) drug quality control; (ii) the inspection, vigilance and control of the medicines manufacturing and distribution processes; (iii) the inspection, vigilance and control of food manufacturing and distribution processes; (iv) establishing the technical norms and guidelines for medicines use; etc (Instituto Nacional de Vigilancia de Medicinas y Alimentos (INVIMA) 2016).

4.2 Informal systems

A great deal of knowledge synthesis is undertaken by universities and research institutes for the government on a consultancy basis (interview 13; interview 14). The list of institutes includes: PROESA; the Centro Economía Salud, CES (linked to Universidad de Antioquia); the Centro de Investigación de Desarrollo (Universidad Nacional); the Universidad de los Andes; CENDEX (Universidad Javeriana); and the Centro de Investigaciones Salud de la Fundación SantaFe de Bogotá.

The World Bank also has played an important de-facto advisory role, supporting the country with technical studies on different health issues including the definition of the health benefits packages, risk assessment, and decentralisation in health. In particular, the World Bank is supporting the development of health indicators through the funding of projects led by research centres.

4.3 The Courts

The Constitutional Court (CC) justices who review *tutelas* are able to consult with experts, public officials and organizations before resolving, in order to “bring facts and conflicting perceptions of social reality to the Court’s attention” (Cepeda-Espinosa 2004). The participatory nature of the CC’s decision-making process thus brings the opportunity to present and incorporate relevant evidence.

5 Discussion

There are a range of challenges and concerns that our overview of the EAS in Colombia has highlighted that can affect how well evidence can be used to inform health policy making.

First, Ministers are changed frequently by the President, and, with each replacement, the top civil servants and cadres are also changed. Thus, the timeframe for implementing policies is very short.

There is also great disparity between departments regarding their ability to design, formulate and implement health decisions (let alone evidence-informed decisions). Particularly strong in generating local evidence on health needs and formulating local health interventions is the Distrito Capital de Bogotá.

The existence of the IETS does not guarantee a NICE-like (political-technical) approach to decision making in Colombia. Interviewees pointed that such approach is currently impossible because nobody wants to discuss placing limits on service provision or even to discuss the metrics which could be used to do that e.g. to come up with a price per DALY (interview 8; interview 11). For example, doctors’ associations openly reject the legitimacy of IETS in setting up limits to and rationing health benefits and services. In addition, the constitutional court put a barrier to this type of mechanism through its expansionist rulings on health service provision (via constitutional right to services). Moreover, the strong independence of the bureaucracy appears to insulate technical advisory bodies like IETS from significant engagement with the public, which includes consideration of social values outside those established as important within HTA (e.g. cost-effectiveness is a social value build into much HTA thinking). While modelled on the British system, it is worth noting that NICE has explicit consideration of other social values used to guide final decisions on services to provide, and further holds public consultations to this effect. In commenting on the differences between the UK and Colombian system, Castro states that: “[i]t is worth noting that the UK has a relatively long tradition of performing and using the results from economic evaluations, applying willingness to pay (WTP) thresholds and including stakeholders

throughout assessment processes (Castro 2014). In Colombia, on the other hand, stakeholder engagement or the consideration of societal values are not current practice and the institutional arrangements for reimbursement decision-making and communicating of decisions to the general public are yet to be implemented (Castro 2014).

One of the roles of the INS is to provide technical assistance to local authorities to strengthen their research capacity. However, interviewees have been sceptical about the ability of INS to carry out these tasks (“INS don’t go to medical congresses!”, interview 11).

The establishment of new evidence advisory bodies and the embrace of HTA is also fairly recent. According to interview 21, until 2011-2012, “decision-making has been ad-hoc and has not considered the best available evidence”. The existence of evidence and a strong research capacity (both within and outside national government) in Colombia does not guarantee the uptake of evidence in health policy making. While the technical capacity of the MoH is basically good, it lacks the ability to lead the health policy making process and to be strategic (it is rather reactive to issues) (interview 6). Further, the country has not had a tradition of up-taking evidence for health priority setting, long-term planning, health sector reforms, etc. (Castro 2014). For example, HTA has “played a limited role in Colombia in terms of providing information to set priorities, allocate resources or formulate evidence-based policies for health and health care” (Castro 2014). During the early 1990s, a few academics who had been trained on HTA techniques overseas produced “isolated pieces of research using methods related to those of evidence-based medicine (EBM) and health technology assessment (HTA)” (Castro 2014). However, it did not gain sufficient prominence as to become common practice for decision makers or as to become formalised. It remains to be seen how well the newly established systems will function or whether they will be sustained.

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