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Judicial activism and public policy in Colombia: health system reform, the 'tutela' system and the implications for evidence informed policy.

Abstract

Current debates in Colombian health policy are dominated by the reforms to the health system initiated under the Presidency of Juan Manuel Santos. These debates turn on the issue of health systems financing and the ability of the government to place limits on the package of benefits (POS) available to citizens under the national health insurance scheme. Attempts by government to circumscribe treatment occurs in the context of a constitutionally enshrined right to health services enjoyed by citizens. Consequently, legal avenues exist through which citizens are able to exercise their right to treatments at public expense. The *tutela* system allows citizens to initiate court proceedings to obtain treatments (including the supply of particular medications) in cases where these have been denied by insurers. This includes instances where patients have been denied treatments included in the POS and the instances in which they demand the provision of other treatments not included in the benefits package. In some circumstances, the cost of treatment for services obtained through the *tutela* procedure are met not by health insurers (EPS), but by the national government through central funds (FOSYGA), with clear implications for public spending and democratic accountability. The right to health services and the *tutela* process restricts the ability of governments to place limits on health services included in the POS, and thus control health spending. It has important implications also for the use of research evidence to inform public policy. Policy making involves complex trade-offs between different political priorities (including healthcare), competing for finite resources. The objective of evidence informed policy is to maximise efficiency and efficacy of policy making and policy outcomes, and to provide legitimacy for policy decisions. Given the influence of the Court system over the provision and financing of health services, and thus public spending, questions arise about the basis on which judges take decisions affecting citizens as both service users and taxpayers. Drawing on a series of semi-structured interviews with health policy stakeholders and recent court judgements, this paper focuses on the extent to which the Courts takes account of research evidence in the formulation of its judgements and assesses the implications for public policy in Colombia. In so doing it assesses ways in which evidence may inform judgements in ways in keeping with constitutionally enshrined rights and protections in the context of the constraints of the health budget. We place these

discussion in the context of a broader analysis of evidence use by other branches of the Colombian government.

1. Introduction

The role of scientific evidence in policy making is a key debate in the field of policy studies. The discourse of evidence-based policy-making (EBPM) reflects moves to understand the causes of social problems more accurately and to develop effective solutions to these (Lavis et al., 2008, Mitton et al., 2007b, Innvaer et al., 2002b, Oliver et al., 2014). At the same time, it speaks to policy makers' need to justify or legitimate their actions, and to ensure an effective use of finite, and often limited, public resources. A now extensive literature exists on EBPM within the field of health policy, and beyond with scholars from Weiss (1979) to Nutley and colleagues (2007) identifying a range of ways in which 'evidence use' or 'research utilisation' occur and may be understood. More recently, the language of evidence-*based* policy making has given way to evidence *informed* policy making (EIPM) (see Oxman et al., 2009). This shift in tone recognises the fundamentally political nature of the decision-making process in which there are competing political priorities, often with their own supporting evidence bases (Barnes and Parkhurst, 2014). The language of EIPM reflects the increasing recognition that whilst policy should be made *in light of* relevant bodies of research evidence, the direction of policy cannot be determined by that evidence. This recalls Deborah Stone's (1997) observation that policy debates are often debates about values masquerading as debates about facts. However, the logic of EIPM retains a clear emphasis on the importance of evidence in generating effective, cost-effective and legitimate policies.

Unsurprisingly, debates about evidence-based and evidence informed policy making focus predominantly on the role of the legislative and executive branches of the state,

including the role of government bureaucracies, agencies and non-governmental stakeholders (e.g. civil society and non-governmental organisations, corporations and business associations, professions bodies and activist networks) in the policy making and legislative processes (Shaxson et al., 2012, see also Contandriopoulos et al., 2010, Innvaer et al., 2002a, Mitton et al., 2007a, Nutley et al., 2007, Walter et al., 2005). However, this legislative/executive nexus is not the only channel through which policy is made. The judiciary, and judicial activism in sentencing, can have profound implications for the development of policy, which are largely ignored by the EIPM literature.

This article seeks to explore the implications of a powerful judiciary for the objective of evidence informed policy making through a case study of the Colombian Constitutional Court (CC). Within different constitutional systems, the judiciary plays widely differing role, with differing capacities to shape laws and policy. Here we focuses on the role of the CC– regarded as one of the most powerful Constitutional Courts in the world (Landau, 2010) – in the development of health policy in that country. In Colombia, the CC plays an active role in developing health policy in two principle ways:

- by participating in the law making process through the review of legal instruments prior to their enactment;
- in deciding what rights are granted to citizens by reviewing decisions adopted by judges in lower courts in protection writs known as *tutelas.*

According to (Cepeda-Espinosa, 2004: 564), the CC adopts two principle types of decisions. First, it adopts abstract review judgments, as a result of the constitutional scrutiny of constitutional reforms, treaties, laws, legislative decrees issued under states of emergency or in exercise of delegated legislative powers, and bills vetoed by the President. Second, the

court adopts concrete review judgments, which result from the scrutiny of specific *tutela* decisions.

The importance of the CC emerges in the context of weak, ineffective government, which has suffered from widespread corruption in addition to its constitutional deficiencies. The CC has stepped into this vacuum to tackle crucial policy issues which the other branches of government have proven unable or unwilling to address. Consequently, the process through which the CC reaches its decisions, and the role played by scientific evidence within this, has important implications for evaluations of Colombian policy making.

By examining the case of the Colombian CC we seek to explore the different norms and processes of evidence use which prevail in different settings, which we term legislative/executive policy making and judicial decision making. In particular, we are keen to explore the implications which the assumption of a quasi-legislative role by the CC has for principles of EIPM and the institutional structures which are put in place to govern the generation and use of evidence in policy decisions. In order to do this it is necessary to examine the role of the Courts in the context of the ongoing process of health system reform.

2. Methodology

This paper is drawn from a six country comparative case study of evidence use in health policy making in high, middle and low income settings (GRIP-Health), based at the London School of Hygiene and Tropical Medicine. It focuses on the process through which evidence informs policy in different constitutional, political and institutional settings, in

countries with different levels of economic development, administrative effectiveness and democracy. In each country we analyse three key health policy issues which offer insights into the role of evidence in decision making at different points of the policy process and in different institutional settings.

The project employs a qualitative methodology consisting of semi-structured interviews, analysis of key policy documents and a review of the relevant literature on policy making in each country and the health issues at hand. We conducted 26 semi-structured interviews with health policy actors[1] in Bogota in February 2014, including representatives of the main government ministries and agencies with responsibility for health policy making, and policy advocates including representatives of NGOs and industry associations. These interviews were anonymised, transcribed and analysed using Nvivo software to identify the emergence of key themes. References to the interviews in the current text are also anonymised, but the sector from which each respondent emerges is given to contextualise their insights and perspective.

3. The CC and the Reform the Colombian Health System

The current health system was brought into effect by Law 100/1993, which established a two tier insurance system – a contributory regime for those in employment and a subsidised regime for those without formal employment – with multiple private insurers and providers under regulated competition. Law 100 also brought into existence a

[1] 'Policy actors' is employed in this article as an umbrella term to cover all participants in policy debates and the associated policy making, implementation and evaluation processes. The terms thus includes policy makers (those in government, or government designated entities, performing key decision making or decision facilitating functions) as well as policy advocates (those outside of government advocating for specific policy objectives.

defined package of health benefits (*Paquete Obligatorio de Servicios*, POS), which insurers must provide. The main objective of the Law 100 was to improve access to health care amongst the Colombian population, and particularly the poor. The system brought into effect by Law 100 was highly controversial, being lauded in some quarters, but widely criticised in others.

Given the controversy around its adoption, Colombia has been debating the virtues and deficiencies of the health system ever since its creation in 1993 (Defensoria del Pueblo, 2013: 83). Basic agreement on the fundamental assumptions underpinning the health system has never existed in Colombia. According to one commentator, "seismic ideological disagreements" have remained on issues such as: the financing of the system (i.e. insurance versus taxation based), the involvement of private sector, and whether limits can and should be placed to the right to health care (Author Interview, Health Consultant). The ideological tensions at the heart of Colombian health policy debates– and the significant challenges posed in providing adequate health coverage in such an economically, geographically and ethnically diverse middle-income country as Colombia, with extensive regional disparities and a well-documented history of armed conflict – has meant the health system has been in an almost constant state of reform since its very inception.

The CC has been instrumental in this process through decisions made in fulfilling the two key tasks attributed to it by the 1991 Constitution. First, the CC is responsible for the constitutional evaluation of "states of exception" declaration by the President of the Republic. This is of great importance as certain special decrees exist within the Colombian legal order that have the strength of a law, but which require the prior declaration of a "state of exception" by the President before they can be issued. Precise constitutional

requirements must be met in order for the President to declare a "state of exception" and three different types "states of exception" are identified by the Constitution:

(i) a "state of internal commotion," to be declared for up to ninety days in cases of severe disruption to internal public order;

(ii) a "state of foreign war"; and

(iii) a "state of economic, social or ecological emergency" (from here on referred to "state of emergency").

One of these particular situations, the "state of emergency," has been particularly relevant in the context of Colombian health policy and will be discussed in greater depth below.

Second, the CC undertakes revision of Statutory Laws before they are signed into law by the President of the Republic. If the changes included by the CC are substantial, the draft law has to return to Congress. If changes are small (e.g. deleting/replacing a word, sentence or paragraph), the President may simply give assent to the law with those changes included. Statutory laws are one of five principle types of legal instrument in Colombia, alongside Ordinary Laws, organic Law, Decrees and Resolutions (Vanegas Gil, 2012).

Statutory laws are the required legal instrument for a specific set of issues issue that the law aims to regulate, which are set out explicitly in the Constitution. According to Article 152 of the 1991 Constitution, the issues that require Statutory Legislation include:

(i) Fundamental rights and obligations for people and the procedures and resources for the protection of these;

(ii) Justice;

(iii) Political opposition, parties and movements;

(iv) citizen participation;

(v) States of Exception (see above);

(vi) Presidential Elections.

As a result of these powers the CC has played an influential role in shaping health policy in Colombia. In 2009, president Uribe declared the "state of economic, social or ecological emergency" which allowed the government to issue a series of decrees to reform particular aspects of the health system. This provoked strong opposition amongst medical associations, student groups and the general public, leading to street protests designed to put pressure on the CC to annul the state of emergency (Author Interview, Colombian Academic). According to one interviewee in the field of health policy, the CC received over 1000 documents from different organisations and civil society groups to consider in relation to the State of Emergency (Author Interview, Colombian Academic). The CC annulled the State of Emergency concluding that the crisis was foreseeable and thus the state of emergency was unconstitutional (Bernal et al., 2012). In addition, the judgement enshrined healthcare as "a legally enforceable right," setting a 1 year deadline for the implementation of universal access to a basic package of care (Bernal et al., 2012: 26).

In 2010, President Juan Manuel Santos was elected on the back of commitments to undertake further major reforms of the health system, in order to guarantee its long-term financial sustainability (Bernal et al., 2012). Law 1438, enacted in January 2011, set up the National Health Observatory (*Observatorio Nacional de Salud*, ONS), a directorate within the National Institute of Health (*Instituto Nacional de Salud*, INS) tasked with the generation of evidence to inform health policy. In addition, it aimed to unify of the contributory and the subsidized regimes, whilst strengthening primary care. However, this was not followed up

with secondary legislation to implement the reforms (Author Interview, Manager of a Public Hospital).

In the context of extensive ideological confrontation about the type of health system pursued, Health Minister Gaviria aimed to introduce health reforms via ordinary legislation (*Ley Ordinaria*). However, the National Doctors Council (*Gran Junta Médica Nacional,* GJM) presented a 14-point plan to President Santos in December 2012, who consequently took these proposals forward through an "urgency process" (*Trámite de Urgencia*) to develop a Statutory Law (*Ley Estatutaria*), reflecting the substantial influence of the GJM over both the President and, ultimately, over Colombia health policy. The aim of the Statutory Law was to establish definitively the substantive content of the right to health, the precise responsibility of the State to guarantee that right, and the criteria to be used to evaluate whether that the right to health is being upheld (Hernández 2012). In parallel with this, Gaviria´s Ordinary Law was also introduced in Parliament in an attempt to set out the structure of the health system that would be tasked with realising the right to health enshrined within the Statutory Law. The proposed Ordinary Law failed to gain approval in Congress and, as it had gone through two legislative periods without success, the draft legislation had to be withdrawn. The Statutory Law 1751 was finally passed on 16 February 2015.

4. The "Judicialisation" of Health

The history and rationale of Colombia's ongoing health system reforms is inextricably linked with the judicialisation of health policy. Under its 1991 constitution, Colombia has suffered from endemic weaknesses of both the legislative and executive branches of the state, resulting in an absence of effective policy responses to a range of pressing social

issues. The weak, unstructured party system (Landau, 2010: 341, Leongomez, 2006) and endemic corruption amongst parliamentarians (Landau, 2010: 342, López and Sevillano, 2008), and a history of authoritarianism and political violence (Yamin and Parra-Vera, 2009: 147) have contributed to Congress' consistent failure to perform its constitutionally mandated functions of initiating and enacting effective legislation, and holding the Executive to account (Landau, 2010: 362). Within this political vacuum, the CC has emerged as perhaps the most important policy actor in the Colombian political system (Author Interviews Colombian Academic; Human Rights Ombudsman). David Landau (2010: 322) has argued that the CC "has viewed these political conditions as a licence to become perhaps the most activist court in the world." At times, the court has performed a quasi-legislative role "injecting policy into the system, by managing highly complex, polycentric policy issues and by developing a thick construct of constitutional rights that it uses to check executive power" (Landau, 2010: 321).

The principal mechanism through which the CC has been able to expand its remit into areas which are usually the preserve of parliaments has been via the *tutela* process. *Tutelas* are "writs of protection of fundamental rights" (Cepeda-Espinosa, 2004: 552), by which any legal person who believes their fundamental rights (as set out in the Constitution) are being threatened or violated can go before a relevant judge in the Civil, Criminal or Labour Courts and request protection of those rights. The judge is required to give priority attention to the request over any other business before the Court and pass judgement on the case within 10 days. In addition, they can take preliminary decisions to prevent damage occurring to plaintiffs that could eventually not be repaired. As such, *tutelas* provide citizens with a quick, efficient, often effective and relatively inexpensive means of guaranteeing their fundamental rights. The importance of the *tutela* process in the Colombian context, is

reflected by the much higher number of process brought in Colombia than in other countries (e.g. Mexico) with a similar level of economic development or comparable level of judicial activism (Rodríguez Garavito, 2012: 519). In certain cases, decisions of judges in courts of first instance are referred for review by the CC, giving it the ultimate say in cases where fundamental rights are called into question, creating precedents and setting parameters for future judgements.

In the context of health, the *tutela* process thus created a mechanism through which patients could obtain treatment included in the core package of health entitlements (POS), and expand the range of treatments, drugs and services available to them to cover those excluded from the POS. Following the passage of the 1991 Constitution, *tutelas* started to be used by citizens to claim their "right to health" through its connection with the constitutionally guarantee to the fundamental right to life. Whilst the constitution did not establish the right to health as a first order constitutional right, the CC held that cases in which the lack of access to health care treatment or drugs could endanger the life of the individual, constituted an indirect infringement of the right to life. As such, the CC guaranteed the right to health services in connection with the right to life, setting out additional protections for especially vulnerable groups, such as children, pregnant women and the elderly (Yamin and Parra Vera 2009: 147). The overwhelming majority of judgements in *tutelas* on health are decided in favour of the patient (Rodríguez Garavito, 2012: 527). The Office of the Human Rights Ombudsman estimated in 2007 that over 80% of cases brought forward by patients were upheld by the CC (Defensoria del Pueblo, 2013). This has led to increased access to a range of services and treatments including provision of cancer and anti-retroviral drugs and covering the cost of treatment of patients overseas (Yamin and Parra-Vera, 2009: 148).

The increases in treatment provision brought about through the *tutela* process has had significant implications for public spending and the financial sustainability of the health system. The system of recovery (*recobros*) meant that in many cases health insurers were able to pass the costs of treatments provided via *tutelas* onto the central government. CC judgement SU-480/1998 allowed health insurers (EPS) to recover the costs of treatments prescribed by a doctor, but not included in the main benefits package (POS), from the government's Solidarity and Guarantee Fund (FOSYGA). The tendency of judges to find in favour of patients petitioning for access to health services and treatments – and the expansive rulings of the CC in those cases referred to it for review – have led to significant increases in the provision of health services and treatments outside the POS. Consequently, the government attempted to put in place measures both to reduce the number of *tutela* actions brought, and to define more clearly the core package of health benefits.

Law 1122/2007 established the Regulatory Commission for Health (*Comisión de Regulación en Salud*, CRES); an arm´s length body affiliated to the Ministry of Health whose role included updating the POS. However, CRES received considerable criticism from both the media and the academic community due to its apparently inadequate use of evidence and the weakness of methods it employed in evaluating this evidence and reaching its decisions, as well as a lack of transparency in its decision-making processes (Castro, 2014: 22). In an effort to respond to these criticisms, the government passed the Law 1438/2011 which required the POS to be updated every two years. Law 1438 also paved the way for the creation of the Institute of Health Technology Assessment Institute (*Instituto de Evaluación de Tecnologías Sanitarias*, IETS) in September 2012. Modelled on the British National Institute for Health and Care Excellence (NICE), IETS was established as a not-for-profit public-private partnership (*Corporación Sin Ánimo de Lucro, de Participación Mixta y de Carácter Privado*

under Colombian law). The participants in IETS included four public sector actors – the Ministry of Health MSPS; the national drug regulatory authority (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos,* INVIMA); the INS; and the Administrative Department of Science, Technology and Innovation (Colciencias) – and two private sector members – (the Colombian Association of Faculties of Medicine (ASCOFAME) and the Colombian Association of Scientific Societies.

IETS' initial remit was to undertake health technology assessment in order to inform the CRES's decisions on the inclusion and exclusion of treatments within the POS. However, only a few months later, in December 2012, the CRES was abolished and the Ministry of Health "re-assumed its role of resource-allocation decision-maker" (Castro 2014: 22; 131). This left IETS with the key task of providing non-binding recommendations to government about health technologies and clinical practice. Assessments of drug safety and market licencing are undertaken by INVIMA.

In addition, Law 1122/2007 sought to counter the expanding costs of healthcare through the introduction of Scientific and Technical Committee (CTC) within the health insurers to evaluate requests for treatment from patients, which are excluded from the POS. Where treatment is denied by the CTC, patients still had recourse to the *tutela* process, but the CTCs created an additional mechanism to resolve disputes about service provision without recourse to the courts. The introduction of CTCs represented also an attempt by the Government to control the increasing costs associated with the expanding package of benefits. In those cases where the relevant CTC had denied access to specific treatments, procedure or drug and the patient subsequently brought a successful *tutela* action to secure its provision, the EPS could only claim back 50% of the cost of the treatment, procedure or drug from the government, as opposed to the full amount recoverable if approved by the CTC.

Despite its intentions, Law 1122/2007 created an incentive for insurers to authorize all treatments requested by patients via the CTC, and thus failed to control health spending costs. Consequently, it was later repealed.

The period since 2008 has seen further attempts by both the government and the CC to adopt a "structural approach" to the right to health, with the aim of "de-judicialising" health care provision (Rodríguez Garavito, 2012). Judgement T-760/2008 introduced a new mechanism – "Complex Orders" (*Órdenes Complejas*) – in an attempt to orientate the judgements of lower courts through a structured route rather than on a case by case (casuist) basis. This same period has seen ongoing attempts to reform the health system, with the dual aims of increasing access to healthcare and ensuring the financial sustainability of the system. However, attempts to place limits on the health spending by placing limits on the package of benefits available to citizens have been consistently thwarted in this constitutional context.

5. Evidence Use in a Judicialised Health System

From the preceding discussions it is clear that the CC plays a vital role in health policy making in Colombia. Attempts to reform the health system through legislation are dependent on the adjudication of the CC that the proposed reforms are in keeping with the fundamental tenets of constitution. Similarly, the judiciary, with the CC at its apex, plays a vital role by determining the range of treatments and health services available to patients with significant budgetary implications. The *de facto* delegation of vital policy decisions to the CC raises important questions for advocates of evidence informed policy making. To what extent does the CC take into account relevant bodies of evidence on the effectiveness and cost effectiveness of treatments when ruling on their provision from public funds? To what extent does it take into account the broader political implications of its rulings for the

sustainability of the health system and the implications of expanding health care costs for other areas of public policy? Perhaps most fundamentally, to what extent is it either possible or desirable for the court to do any of the above, given its clear constitutional mandate to uphold fundamental rights and ensure the rule of law.

Tutelas are regulated by the Legislative Decree 2591/1991. Article 22 of the Decree states that judges can reach a decision or give a provisional order without requesting additional evidence if it can be demonstrated that there is an imminent and serious threaten to the fundamental right being protected. In the case of health service provision, this would be in connection to the fundamental right to life. Since they lack dedicated resources, technical capacity and specialist training on the wide range of issues with which they are confronted, as well as, judges in these cases often make decisions based simply upon the opinion of the prescribing doctor involved in the case at hand; the assumption being that in the view of the attending physician a particular treatment was necessary, it can be deemed medically necessary.

According to a former employee of the Ministry of Health, judges often rely on subjective interpretations of the current state of medical knowledge, placing equal weight on all the evidence available to them without an adequate process of critical appraisal (Author Interview, former Ministry of Health employee):

> For example, a doctor might have prescribed a medication that is not licensed in the country. The health care system regulation is clear that this type of drug cannot be covered, so the health insurer denies the patients access to it. Some patients would start a *tutela* action to get access to the prescribed drug, with the judge ruling in favour of the patient, ordering the insurer to import and provide the drug, using as evidence just the prescription and a summary written by the doctor where he states that the drug is needed and that [denying the drug]

> poses a threat to the patients' health. From the previous example it can be seen that evidence is part of the process, with all available evidence put at the same level. Drugs that are not licensed in the country because they have not been proven to a technical authority to be safe, efficacious and of good quality are granted access through a judge that puts the regulatory agency and an individual doctor at the same level.

The reliance on the opinion of prescribing physicians assumes that adequate mechanisms are in place to ensure that doctors themselves are following specific prescribing guidelines and/or that their clinical decisions are grounded in sound evidence about the effectiveness and safety of the treatments they are administering. This is in a context in which doctors vehemently defend their professional freedom (i.e. the ability to exercise clinical judgement) and their "freedom to prescribe" within the context of the ongoing health system reforms (Author Interview, GJM). Moreover, this approach seemingly sets aside independent reviews by relevant regulatory bodies (i.e. INVIMA) about the safety of drugs which may not currently be licensed, assuming individual doctors are able to judge this adequately. As many *tutelas* involve the refusal of health insurers to provide medication or services prescribed by physicians, the tendency for judges to defer to medical opinion in this way explains in part why the overwhelming majority of *tutelas* judgements find in favour of the plaintiff. This has led to expansion in coverage, but also to significant additional costs of the health system.

The Justices of the CC who review *tutela* actions do have mechanisms available to them through which 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: 556). The CC´s decision-making process thus brings the opportunity to present and incorporate relevant evidence within the decision-making process

of the court. However, according to a former employee of the Ministry of Health, the way the CC appraises evidence is problematic despite the opportunity:

> The recently enacted statutory law that regulates the right to health was subject to Constitutional Court evaluation, and shows how within its judgement that the CC collapses the hierarchy of evidence into one single strata. It cites the case where a woman was denied access to a drug for treating symptoms related to a chronic bladder disease because it was not licensed in the country. In the court of first instance, the judge ruled against the patient on the basis that the regulations were clear that providing this type of drugs is not allowed. The CC selected this *tutela* for review and changed the ruling in favour of the patient. The CC argues that the doctor that prescribed this drug used the best available evidence, thus it sees the doctor himself as representing the highest level of evidence. The CC court says that drugs should be provided when they are required based on the best available evidence even if they have not been licensed. Regulatory agencies have been set up to protect the population by allowing only drugs and devices that can show their safety, efficacy and quality to enter the market, and having someone accountable for its commercial use. These agencies – in the case of Colombia it is INVIMA – have standardized procedures for the critical appraisal of the evidence presented by the producer to grant market access to ensure that benefits exceeds the risk, thus using high quality evidence to support its decision.

The case presented above highlights the central problem that the current paper seeks to address: the different norms governing the use of evidence between the legislative/executive domain and the judiciary, and the implications this has for policy-making as the judiciary assumes quasi-legislative functions. Within the former, evidence use is institutionalized within an 'Evidence Advisory System' (EAS) for health policy making. The EAS encompasses the various entities tasked with the production and communication of policy

relevant evidence and the key entry points through which research evidence can make its way into health policy decisions. This can include both formal (government mandated) and informal structures, rules, and norms in place.

The EAS in health in Colombia formally includes a series of organizations ascribed to the Ministry of Health with responsibilities for *evidence provision* through their mandate to advise on decisions in health, including INS, IETS and INVIMA. The role of IETS is to provide non-binding recommendations about health technologies and clinical practice. Whilst there are no obligations on government to adhere to IETS' advice, their recommendations carry significant political weight in policy-making.

Government agencies such as IETS, INS and INVIMA exist for the specific purpose of making technical decisions on policy issues which require a high degree of technical proficiency and a detailed engagement with a relevant body of evidence. The expansion of these types of agency across the globe is indicative of the increasingly complex nature of policy making and regulation, especially in areas of rapid technical advancement such as health. The need for effective, well informed policies means decisions are beyond the competence of many elected representatives and are delegated instead to designated experts. Removing decision-making competence from elected officials implies a loss of democratic oversight over policy-making, but this is often regarded as a price worth paying for more efficient decisions and more effective policy, leading in turn to greater political legitimacy (Beetham, 2013). It might be expected that the court would rule in favour of the patient in those cases where it can be established that the expected (or even potential) benefits of receiving the drug in question outweigh the risk of harm occurring to the patient through the treatment, for example through allergic reactions or potential side effects. Judgements about the safety and efficacy of a drug are reached through a critical appraisal of

the relevant by the designated regulatory authority, INVIMA, but their risk evaluations are seemingly overruled by the CC in cases such as this. By ruling in this way, the CC is placing similar (if not greater) weight on the clinical opinion of the prescribing doctor as on the judgement of INVIMA on its suitability to bring the drug to market.

In the model of policy-making described above, agencies such as INVIMA play a clearly defined role within the legislative/executive policy-making process, whereby their organisational remit and the legal-normative status of their decisions (i.e. the degree to which other government actors are bound to adhere to their rulings) are set out in their constitutions, terms of reference or in the legal acts which bring them into being. INVIMA, for example, was set up by Decree 1290/1994 as a technical scientific public body with own legal status, administrative autonomy and own budget, ascribed to the Ministry of Health. The situation becomes more complicated when decisions taken by such agencies (e.g. on the licensing of a drug) are called into question by judges, without the existence of clearly defined norms and procedures governing how and when they may do this, and the processes through which they must evaluate the relevant evidence. Such judgments may have the effect of undermining the coherence of the evidence advisory system, and the policy making architecture more widely. Perhaps most crucially they may lead to the implementation of poor-quality, inconsistent policy.

According to Landau (2010: 344), the CC is aware of the quasi-legislative role it has come to assume under the 1991 constitution and has sought to increase the legitimacy by "assuming some legislative-like attributes," including the information-gathering and monitoring functions usually assumed by legislatures. The wide range of cases brought before the CC via the *tutela* process means the court is confronted with information on a wide range of social issues affecting Colombian society. The CC has engaged extensively with the Human

Rights Ombudsman, and other civil society groups and NGOs, in order to gather and assess information in important policy areas (Landau, 2010: 344). The Court has used a variety of techniques to receive policy-relevant information in assessing the constitutional compatibility of different legislative measures; issuing orders to requested information from the various governmental and non-governmental agencies, particularly about how much money they are spending on the problem and how they are spending it (Landau, 2010: 360). Perhaps most notably from the perspective of the current paper, the CC has also held its own legislative-style hearings:

> In July 1999, the Court held a public hearing [on the issue of reforming housing finance system] in the style of a legislative committee or an administrative agency, in which it heard from about twenty-five leaders and officials, including the Colombian ombudsman, the Minister of Housing, the Head of the Colombian Central Bank, several deputies and senators, the heads of various trade groups, and the head of a labor union association. In addition, throughout the process the Court requested—and received—written comments on the problem at issue from an extraordinary number of figures, including economists, academics, public officials, and civil society groups (Landau 2010: 357).

The question remains however, whether the mechanisms put in place by the CC are sufficient to ensure that effective, evidence informed public policies are made. Setting aside the wider concerns about the democratic accountability and legitimacy associated with judicial activism (which have been articulated extensively in relation to the US Supreme Court and the ECJ in particular), it can be argued that legislating through the judiciary in this way represents a sub- optimal form of policy making compared to the processes and

mechanisms which exist within the legislative/ executive domain. That this state of affairs has emerged by default in Colombia, as a result of the shortcomings of the legislature and the executive, is indicative of this. The examples of INVIMA presented above identifies some of problems raised for evidence use by judicial activism of the Colombian variety. To fully examine the implications of judicialisation of policy making for the use of evidence we require a more detailed account of what a 'good' use of evidence might look like and the extent to which the judicialised policy making model in Colombia fulfils these.

6. Conclusion

The judiciary, with the CC at its apex, plays a vital role in the development of health policy in Colombia with significant consequences both for the provision of health service and for public spending. To a large extent this reflects the shortcomings of the executive and legislative in providing effective responses to key policy problems identified by citizens. Within a context of finite resources, and a constitutionally guaranteed right to health services (pertaining to the right to life), this raises important issues of equity and social justice. Can limits be placed on the provision of health benefits which are in keeping with the fundamental tenets of the constitution? If limits are to be placed on the availability of health services, on what basis should these decisions be made and how can they be justified to the citizens affected by them?

Within modern government systems recourse is often made to scientific evidence to arbitrate in such cases. The shift towards evidence informed policy-making, or at least a rhetorical commitment to it, is driven by a desire for more effective and efficient policies but reflects also the need for governments to identify widely accepted sources of legitimacy

for their decisions. Relevant bodies of evidence may clarify both the effectiveness and cost effectiveness of specific treatments, in isolation and in relation to other treatments which could potentially be funded from the same pot of money. The development of evidence advisory systems is designed to provide policy makers with relevant, high-quality information on which to base their decisions. Governments may put in place specialist regulatory agencies, or call on panels of experts, to examine this evidence and advise decision makers. At other times, decisions on the provision of specific treatments or their inclusion in the benefits package may be delegated to non-governmental or quasi-non-governmental agencies.

Debates about the role of evidence in policy making have largely neglected the role of the judiciary in the development of law and policy. In cases such as Colombia, in which an activist constitutional court has had a significant impact on health and public policy, this represents a significant gap in our understanding of the way evidence shapes policy. This paper begins the process of addressing that gap by examining the role of the judiciary, and the CC more specifically, in the development of Colombian health policy. In so doing it raises questions about the relationship between the executive, legislative and the judiciary, and the role of evidence in the execution of their responsibilities by each branch of the state. Is it possible to have evidence-informed policies in a context in which the decision making space is circumscribed by the decisions of the judiciary? Is it within the remit of the CC to consider issues of financial sustainability when interpreting the Constitution? What would the consequences be of expanding or reshaping the role of the CC in this way? Would it undermine the ability of the court to hold government to account or to a reduction in health services?

Arguably, the CC has been a driving force for social justice in a country in which other political institutions have often failed the population, and vulnerable or marginalised groups in particular. However, the almost continuous process of reform the health system has undergone since its creation points to the underlying issues which the government faces in financing health services. Evidence informed policy making offers a potential route for imposing limits on the healthcare in a rational, equitable and legitimate manner. However, it remains unclear whether such an approach is possible within the context of the current Colombian consititution.

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