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Judicial Activism and Health Policy in Colombia: The Implications for Evidence Informed Policy Making.

Abstract

The ongoing reforms to the Colombian health system initiated under the Presidency of Juan Manuel Santos centre 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 and a widely utilised system of protection writs (*tutelas*) through which citizens are able to enforce their right to treatments. The right to health services and the *tutela* process curtails the ability of the government to place limits on health services included in the POS. Furthermore, 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). The judicialisation of health policy through the proliferations of *tutelas* has clear implications for both public finances and democratic accountability. Of central importance to both these concerns are the implications of the judicialisation of health for the use of research evidence. Policy making involves complex trade-offs between different political priorities competing for finite resources. The objective of evidence informed policy is to identify effective policy approaches, to maximise efficiency, and provide legitimacy for policy decisions. Given the influence of the Court system over the provision and financing of health services, questions arise about the basis on which judges take decisions, and the information they use to inform these. 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. We place these discussions in the context of a broader analysis of evidence use by other branches of the Colombian government, and the most recent contributions to the literature on evidence informed policy making.

1. Introduction

The role of scientific evidence in policy making is a key focus of scholars in the field of health policy. 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 and legitimate their actions, and to ensure an effective use of 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 policy-making process in which there are multiple, competing values and political priorities in play, often with their own supporting evidence bases (Barnes and Parkhurst, 2014). Advocates of different causes may draw on valid evidence to highlight the need for action on a given issue and the effectiveness of specific policy measures in addressing these problems. Policy makers, meanwhile, must decide which of these issue to prioritise and where to allocate finite resources. They may be presented with multiple bodies of valid evidence about the importance of multiple policy issues, and/or the different effects of a range of interventions and must weigh up which issues to address and the advantages and disadvantages of the different ways to do this. 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 controversies are often debates about values masquerading as debates about facts. However, the logic of EIPM retains a clear emphasis on the importance of evidence use in generating effective, cost-effective and legitimate policies.

Building on the acceptance that policies cannot be derived from evidence alone, Hawkins and Parkhurst (Hawkins and Parkhurst, 2016) have developed a process based account of evidence use based on the concept of 'good governance'. The good governance of evidence underlines that policy makers may take decisions which seem to contradict the

prevailing evidence base, but that this does not necessarily mean this has been disregarded or ignored or that this is an example of poor legislative practice. Whilst there may be a sound body of evidence that policy measure A would be effective in tacking issue X, there may nevertheless be valid reasons for pursuing another course of action. For example, the policy in question may be a lower political priority (or have lower levels of popular support) than another policy issue which may be addressed instead, but not as well as, issue X. Alternatively, the externalities from pursuing policy measure A may be so significant that politicians (and the publics they represent) may reject them on balance. Perhaps the policy would contravene deeply held social values or ethical principles, e.g. personal autonomy or dignity. It is not difficult to imagine scenarios in which there is evidence for a policy intervention being effective but nonetheless being rejected because it is morally objectionable or may have deleterious economic consequences.

The good governance of evidence suggests that the decision to reject a given body of evidence is acceptable in such cases, but that policy makers have an obligation to identify and consider relevant bodies of evidence in making their decisions, and to explain and justify their decision to apply or set aside its findings. A 'good' use of evidence, therefore, does not equate to the decision to follow the course of action indicated by that evidence but that policy decisions should be taken in light of appropriate bodies of evidence, in an open and transparent manner, acknowledging explicitly the role which specific bodies of evidence played in reaching the decision adopted (Hawkins and Parkhurst, 2016). This in turn allows policy decisions, and the evidence on which they are based, to be scrutinised and contested, and policy makers to be held to account for the choices they make.

Perhaps unsurprisingly, debates about evidence informed policy making have focused 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.

Within different constitutional systems, the judiciary plays widely differing role, with differing capacities to shape laws and policy. This article seeks to explore the implications of judicial activism for the objective of evidence informed policy making through a case study of the Colombian Constitutional Court (CC) – regarded as one of the most powerful Constitutional Courts in the world (Landau, 2010) – and its impact on the development of health policy in that country. This paper builds on the expanding body of scholarship on the judicialisation of health policy in Latin America in general (Vargas-Peláez et al., 2014, Gargarella, 2013, Wang, 2013, Menicucci and Machado, 2010, Biehl et al., 2012, Brinks and Forbath, 2014, Daniels et al., 2015, Ferraz, 2009, Figueiredo et al., 2013), and in Colombia more specifically (Uprimny, 2007, Nunes, 2010, Yamin and Parra-Vera, 2009, Yamin and Parra-Vera, 2010, Landau, 2010, González and Durán, 2011, Bernal et al., 2013, Cepeda-Espinosa, 2004).

The importance of the CC as a health policy actor emerges in the context of weak, ineffective government, which has suffered from widespread corruption in addition to its constitutional deficiencies (OECD, 2013, Lizarazo and Londono, 2009). 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 (Lizarazo and Londono, 2009, OECD, 2013, Cepeda-Espinosa, 2004). As such the court has arguably articulated popular demands for health coverage more effectively than the legislative of executive branches of the state, leading to a progressive expansion of healthcare provision (Yamin and Parra-Vera, 2010). However, this has had significant implications of the financial sustainability of the health system as well as raising concerns about the safety and effectiveness of treatments and equity of service provision (Vargas-Peláez et al., 2014). Questions of this type are often resolved with recourse relevant bodies of evidence (e.g. on drug efficacy) to determine which treatments are provided and on what basis. The shift away from decision making via the legislative and executive branches towards the judiciary has potentially significant implications for evidence use. Consequently, the process through which the CC reaches its decisions, and the role played by scientific evidence within this, warrants further investigation and consideration.

2. Methods

This paper is emerges from a six country comparative case study of evidence use in health policy making in high, middle and low income settings, which examines the processes through which evidence informs policy in different constitutional, political and institutional settings. In each country we analyse 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.

This study is informed by a narrative literature review on the judicialisation of policy making. In particular, we sought to identify studies of judicial activism in the area of health policy in Latin American. Beyond Colombia, the region has a number of strong constitutional courts which have exerted significant influence over the policy making process and thus provide interesting parallel with the Colombian case.

In addition, we analysed key policy documents and undertook 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 in keeping with the ethical guidelines for the project, but the sector from which each respondent emerges is given to contextualise their insights and perspective.

3. The Colombian Health System: A Case of Perpetual Reform

[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.

The current Colombian health system was brought into effect by Law 100/1993, which sought to improve the quality of health service and to address the widespread lack of coverage for large sections of the population which persisted under the previous regime (Giedion and Uribe, 2009). Law 100 established a two tier insurance system – a contributory regime for those in employment and a subsidised regime for those without formal employment – centred on multiple private insurers and service providers under a regulated competition model (Escobar et al., 2009, Chernichovsky et al., 2012, Bernal et al., 2012, Glassman et al., 2009). Law 100 also brought into existence a defined package of health benefits (*Plan Obligatorio de Salud*, POS), which all health insurers must provide.[2] An equivalent benefits package for the subsidiary regime was also introduced (*Plan Obligatorio de Salud Subsidiario*, POSS) (Yamin and Parra-Vera, 2009).

The design of the new health system brought was highly controversial during the development and passage of Law 100 and contestation over the organisation and delivery of healthcare continued after its implementation (González-Rossetti and Bossert, 2000). Agreement on the basic assumptions underpinning the health system has never existed in Colombia and its virtues and deficiencies are widely contested by stakeholders (Defensoria del Pueblo, 2013: 83). According to one commentator, "seismic ideological disagreements" have remained on issues such as the financing of the system (i.e. insurance versus taxation based models); 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 with a history of armed conflict – has meant the health system has faced an almost constant series of reforms since its inception, which continue to the present day (Bernal et al., 2012, Giedion and Uribe, 2009, Hernández, 2005, Hernández and Torres-Tovar, 2010, Rodríguez Garavito, 2012). Policy debates have centred on two key issues facing the system: the lack of access to effective

[2] In this article we use the Spanish acronyms current in policy debates in Colombia. In the text we give both the English and Spanish names of organisations to make the article accessible to as wide an audience as possible and avoid confusion.

healthcare and significant economic pressures faced by the system due to the expansion in service provision (Chernichovsky et al., 2012).

Despite increases in health coverage brought about by Law 100 , large sections of the population also remain without access to adequate healthcare (Bernal et al., 2012, Giedion and Uribe, 2009). Even those covered by the health insurance system remain unable to access certain services and treatments. In part, this results from the lack of clarity in the definition of the benefits package and the existence of significant grey areas over what treatments are, and are not, included (Yamin and Parra-Vera, 2010). The failure of successive governments to address these issues, and the extensive rights guaranteed to citizens in the 1991 Constitution, have led citizens to turn to the Courts in their attempts to secure access to health services. In particular, citizens have had recourse to the *tutela* process; a protection writ through which citizens are in an attempt to guarantee their constitutional rights, including the right to healthcare (Cepeda-Espinosa, 2004). As will be examined below, the exponential expansion in the use of *tutelas* in order to access health services has created additional financial pressure on the health system, with significant implications for public finances (Chernichovsky et al., 2012). This in turn has created additional pressure to reform the health system in order to reduce the use of *tutelas*, and to create more equitable and sustainable mechanism for allocating resources.

4. Evidence Use in Colombian Health Policy

The history of health systems reform in Colombia demonstrates that, in the last two decades at least, a clear belief has emerged amongst decision-makers about the importance of evidence informed policy making for ensuring efficiency in the health system in an attempt to control costs financial viability in the system (Dargent, 2014, Castro, 2014). Much of the shift towards evidence informed policy making is associated with the need to place limits on the services accessible by citizens and to devise fair equitable mechanisms for deciding the allocation of resources.

The various reforms to the health system have introduced a number of mechanisms through which evidence enters in to the formulation of health policy and a range of different institutional structures for generating, processing and operationalising policy relevant evidence. Many of the recent reforms to the health system have pursued the explicit objective

of increasing and improving evidence use in policy-making. 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 sought (unsuccessfully) to amalgamate the POS and the POSS and required the POS to be updated every two years. In addition, Law 1438 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.

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 (Departamento Administrativo de Ciencia, Tecnología e Innovación, Colciencias) – and two private sector members – the Colombian Association of Faculties of Medicine (*Asociación Colombiana de Facultades de Medicina*, ASCOFAME) and the Colombian Association of Scientific Societies (*Asociación Colombiana de Sociedades Científicas)*.

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.

Interview respondents both within, and outside of, government indicated that the Ministry of Health possesses a relatively high the level of technical capacity in the generation, interpretation and operationalisation of research evidence (Author Interviews; various). In addition the Ministry, along with other health sector actors, is able to draw on significant capacity and expertise which exists within universities and research institutes, which undertake knowledge generation and synthesis for the government on a consultancy basis (Author Interview Colombian Academic; Author Interview Pharmaceutical Trade Association. These include: the Research Centre in Social Protection and Health Economics (*Centro de Estudios en Protección Social y Economía de la Salud*, PROESA, linked to the Universidad Icesi and the Fundación Clínica Valle del Lili); the Centre for Health Economics (Centro Economía Salud, CES, linked to Universidad de Antioquia); the Centre for Research on Development (*Centro de Investigación de Desarrollo*, CID, and the Universidad Nacional); the Universidad de los Andes; the Centre for Development Projects (*Centro de Proyectos para el Desarrollo*, CENDEX, at the Universidad Javeriana); and the Centre for Health Studies and Research (*Centro de Estudios e Investigación en Salud* at the Fundación SantaFe). In addition, the World Bank also has played an important advisory role, supporting the country with technical studies on different health issues including the definition of the health benefits packages, risk assessment, decentralisation of health, and the development of health indicators through the funding of projects led by research centres.

The evidence advisory system (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, evidence 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).

5. The "Judicialisation" of Health Policy in Colombia

The Colombian Judiciary is divided into a number of specialised sections, with the three principle jurisdictions each headed by a specific court last instance (Cepeda-Espinosa, 2004).[3] The "administrative jurisdiction" resolves conflicts derived from the exercise of public administrative powers and is headed by the Council of State. The "ordinary jurisdiction" hears cases in the areas of civil, criminal and labour law and is headed by the Supreme Court of Justice, which presides above two other levels of court: municipal and circuit courts (courts of first instance), and district courts (second instance). A *tutela* action can be started at any municipal court. Finally, the "constitutional jurisdiction" is headed by the CC which is the highest judicial body in Colombia.

The CC is given three principle responsibilities under the 1991 Constitution: (i) interpreting and preserving the integrity of the 1991 Constitution; (ii) safeguarding the rights of all citizens; (iii) maintaining a progressive, peaceful and fair society as envisioned during the formulation of the Constitution (Cepeda-Espinosa, 2004). In practice, the CC acts as the court of last instance in matters affecting the constitutional rights and obligations and reviews the constitutional validity of decision taken in lower courts, as well as the

[3] The "disciplinary" jurisdiction is in charge of the branches' organization and budget administration and disciplinary actions. It is headed by the Superior Council of the Judiciary. In addition, there are the special military criminal jurisdiction, the indigenous jurisdiction, and "judges of peace" (private citizens granted specific judicial powers by the Constitution and the law in minor cases)" (Cepeda-Espinosa, 2004).

constitutional compatibility of legislation and other executive decisions. In the case of *tutelas*, the CC reviews selected cases adjudicated by judges in lower courts.

Despite the attempts to rationalise and improve resources allocation through the reforms detailed above, problems of access to health services, and the economic sustainability of the health system, continue to endure. Both the legislative and executive branches of the state have proved ineffective in addressing these issues. 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), has 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). Thus the legislature has failed to act as an effective mechanism through which citizens can articulate dissatisfactions with the health systems and through which their needs and interests can be articulated, with Congress acting more as a blocker of presidential policy than as an effective agent of policy change (Leongomez, 2006). Yamin and Parra Vera (2010) cite the process through which Law 100 itself was passed – in curtailed parliamentary debates lasting a matter of minutes, shoehorned into the legislative programme immediately before Christmas – as indicative of the inadequacy of Congress as a mechanism capable of responding to citizens' concerns or as a focus for articulating popular concerns on key issues of public policy. Similarly, subsequent attempts to reform the health system between 2003 and 2007 have demonstrated similar deficiencies in the system (Bernal et al., 2012).

Within this political vacuum, the court system, with the CC at its apex, has emerged as perhaps the most important policy set of actors in the Colombian political system (Author Interviews, Colombian Academic; Human Rights Ombudsman). David Landau (2010: 322) argues that the CC has viewed the political conditions in Colombia "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). In so doing, the legislature has become a far more

effective agent for political change, and reflecting popular will more closely, than the other branches of the state to which this function traditionally belongs (Landau, 2010: 328, Yamin and Parra-Vera, 2009).

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, by which any legal person can go before a relevant judge in the Civil, Criminal or Labour Courts and request protection of their constitutional rights (Cepeda-Espinosa, 2004: 552). Whilst the constitution did not establish the right to health as a first order constitutional right, the jurisprudence of the court has expanded the right to health services in relation to the right to life. 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. Judges are required to give priority attention to *tutela* actions over other business before the court and pass judgement on the case within 10 days. In addition, judges 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, inexpensive and effective means of guaranteeing access to health services. The importance of the *tutela* process in the Colombian context, is underlined 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).

The *tutela* process created a mechanism to obtain treatments to which patients were entitled in the benefits package, but had been denied and a means through which patients can seek to expand the range of treatments, drugs and services within the POS (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). From this perspective the court is viewed as a drive of progressive social change (Author Interview, NGO Sector).

The increase 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 POS, from the government's Solidarity and Guarantee Fund (FOSYGA). The tendency of judges to find in favour of patients in *tutela* actions has led to significant increases in the provision of health services and treatments not included in the POS.

Successive governments have sought to address the consequences of this judicialisation of health policy, and to reduce the number of *tutela* actions, through various reforms. 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 in which 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 by the CC and its tendency to rule in favour of plaintiffs' right to health.

6. Evidence Use in a Judicialised Health System

From the preceding discussions it is clear that the courts have come to play a vital role in health policy making in Colombia, 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 courts raises important questions for evidence informed policy making. These relate to the ability and the disposition of judges to take into account relevant bodies of evidence on the effectiveness and cost effectiveness of treatments when ruling on their provision from public funds. Moreover, it concerns the extent to which judges (should) consider the broader political implications of their rulings, for example the sustainability of the health system and the implications of expanding health care costs for other areas of public policy.

Judges, particularly in the lower courts, often lack dedicated resources, technical capacity and specialist training on the wide range of issues with which they are confronted (Bernal et al., 2013). In these cases, decisions are often based simply upon the opinion of the prescribing doctor that the treatment in question was medically necessary. According to a former employee of the Ministry of Health, judges often rely on the prescribing doctors' interpretations of the current state of medical knowledge about the treatment in question, with evidence supplied to the court by the doctors in question to support their initial decision (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.

The reliance on the opinion of prescribing physicians assumes that their clinical decisions are grounded in sound evidence about the effectiveness and safety of the treatments they are administering in a context in which doctors vehemently defend their "freedom to prescribe" (Author Interview, GJM). Moreover, this approach seems to undermine the organisations and mechanism put in place to undertake independent reviews of this evidence and approve medications for specific indications (i.e. INVIMA). As many *tutelas* involve the refusal of health insurers to provide medication or services prescribed by physicians, the tendency for judges to defer to individual clinicians in this way explains partly why such a high percentage of *tutela* judgements find in favour of the plaintiff. This has led to expansion in coverage, but also to significant additional costs of the health system. This potentially results in a sub-optimal use of health system resources through ineffective prescribing practices and may result in patients receiving inappropriate treatment.

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, the way in which the CC appraises evidence is often problematic nonetheless, suffering from similar deficiencies as the lower order courts. A former employee of the Ministry of Health, cites the case of a woman denied access to a drug for treating a chronic cystitis because it was not yet licensed in the country (Author Interview; see also judgement T-945/2004):

> 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.

This is not an isolated example. In case T-975/1999, the CC again sided with the evidence of the attending doctor, having heard evidence from a range of relevant medical organizations and scholars. This went against the decision of the lower courts to deny treatment on the grounds that the treatment in question had not been approved by INVIMA.

In these cases, the CC appears not to distinguish adequately between different types of evidence, placing significant faith in the interpretation of the prescribing doctor. This reflects a tendency by the court to assume that the attending physician has the best overall understanding of the case at hand and to privilege their opinion over that of the key institutions in the evidence advisory system. Whilst this may be true in terms of the clinical history and the particular circumstances of the patient in question, it does not follow from this that the doctor is best placed to judge the effectiveness and/or safety of the drugs in questions, or their appropriateness for off label usage. Yet judgements about the safety and efficacy of a drug reached through a critical appraisal by the designated regulatory authority, INVIMA, are often overruled by the courts.

The cases cited above underline that the judiciary is informed by a very different set of norms and priorities to the legislative and executive branches. Within the CC, for example, justices act to guarantee individual rights in specific cases through its interpretation of the constitution, but it is beyond the court's remit or competence to take into consideration the wider implications of ruling of the health system or the allocation of resources within society. This includes the willingness to overrule limits placed on treatments by the government. In case T-945/2004, for example, the CC is very clear about the priority of fundamental rights over what it terms 'legal or administrative regulations' which may undermine fundamental right. The court is ill placed to take complex political decisions between competing needs and imperatives in the context of limited resources. However, the cumulative effect of its rulings on individual cases has long term distributive effects (Yamin, 2014). The above analysis is also in keeping with the findings of Vargas-Pelaez and colleagues (2014) that judicialised forms of decision making on the access to medicines can lead to a suboptimal use of resources and create significant financial pressure on the health system.

7. Addressing the Consequences of Judicialized Health Policy Making

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).

Yamin and Parra Vera (2010) highlight that the actions of the courts in attempting to ensure the right to health has had the effect of promoting debate about the right to health in Colombia and the have thus provided much of the impetus for the proposed reforms to the system, including the institutionalisation of evidence use detailed above. At the same time, it has tried to create greater coherence and consistency in its own jurisprudence, for example through ruling T-760/08 which sought to clarify the outer limits of the right to

health services and " to make those grey zones [in the POS] less grey" (Yamin and Parra-Vera, 2010: 113).

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, 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 in Colombia as a result of the shortcomings of the legislature and the executive, is perhaps indicative of this. It is also crucial to highlight that many *tutela* cases do not arrive at the CC for adjudication, but have significant consequences for the health system. Issues around the effectiveness of evidence in lower order courts are not affected by reforms processes in the CC.

To fully examine the implications of judicialisation of policy making for the use of evidence it is informative to return to the concept of the 'good governance' of evidence set out above and to assess extent to which the judicialised policy making model in Colombia fulfils these. The good governance of evidence model suggests that EIPM should be assessed in terms of *appropriateness* of the evidence used to inform decisions and the *transparency* of the decision making process and the *contestability* of decisions and hold decision makers to *account*.

These criteria envisage a parliamentary model of decision making in which elected assemblies serves as a mechanism through which citizens are able to hold legislators and the executive to account and which functions as a point of contestation for policy decisions. As argued above, in the case of Colombia, Congress has consistently failed to fulfil this function, with the CC emerging not just as an agent for policy change but as a focus for the articulation of popular needs and desires. Yet despite the legitimacy of the CC in the eyes of many citizens, the CC lacks mechanisms of popular control and oversight. There is not obvious form of recourse by which judges can be held to account for decisions or which a system which systematically favours the interests of those with access to legal means of address can be curtailed and reformed to reflect principles of distributive justice. As we have seen above, it has proved extremely difficult for the government to reverse decisions

or to introduce changes to the allocation of health benefits in the face of contradictory CC rulings.

In addition, the types of evidence used by judges are not necessarily the most appropriate, relying for example on the view of a prescribing doctor over the overall body of evidence on the efficacy and cost effectiveness of the drug. The CC has taken measures to improve evidence use taking public hearings, but it is not structured to undertaking the kind of evidence review which policy bureaucracies and parliaments can undertake. Similarly, whilst the recent decisions by the CC have sought to create more consistency in sentencing and to set some limits on the constitutional right to health, the Court is not designed to take evaluate the competing claims of different social groups to finite resources. This type of deliberative, evidence informed debate can occur much more effectively and appropriately in parliamentary settings which facilitate citizen engagement and oversight. Instead judges have tended to rule on the validity of claims to a certain treatment in isolation from broader concerns about the public interests and the sustainability of public finances. As such they are not taking into account all relevant evidence for the decision they are taking which are framed in very different terms by jurists than they would be by policy makers who have to take a wider conception of the public good.

7. 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 forms of government, 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 find 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. It appears to be extremely difficult to implement evidence-informed policies, which seek to manage the allocation of finite resources, in a context in which the decision making space is so extensively circumscribed by the decisions of the judiciary. Moreover, it is outside the remit of the CC to consider issues of financial sustainability when interpreting the Constitution and applying the rights of citizens to 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 significant underlying issues which the government faces in securing the ongoing financial viability of the health service. Evidence informed policy making offers a potential route for imposing limits on the healthcare in a rational, equitable and legitimate manner. The ability of policies to be made in light of this

evidence in open and transparent manner in which decision makers can be held to account for their actions appears to be undermined by the judicialised nature of policy making in Colombia.

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