The Surprising Role of the Judiciary in Health Care Decision Making in Latin America: Insights from Local Experts

At the 4th ISPOR Latin America Congress in 2013 in Buenos Aires, Argentina, the ISPOR Argentina Regional Chapter presented a fascinating forum entitled, "Health Technology Assessment and Health Prosecution: A Dialogue Between the Two Worlds."

The presenters contrasted the goals of health technology assessment (HTA), of which all of us in the ISPOR community are well familiar, with the legal implications of restricting access to treatment in a region in which the right to health care is inscribed in the constitution of many countries. This sets up an unexpected obstacle to the use of pharmacoeconomic data to inform health care decision making—namely, the potential for the judiciary to intervene and declare that a patient's constitutional rights had been violated if a given treatment was denied based on cost-effectiveness criteria.

Value & Outcomes Spotlight had the opportunity to catch up with four experts from the Latin American region who have some interesting insights to share on this issue: **Federico Augustovski, MD, MSc, PhD**, of the Institute for Clinical Effectiveness and Health Policy and University of Buenos Aires, Argentina; **Ximena Burbano-Levy, MD**, of Zilonis Health Economics Consulting Group, Boca Raton, FL, USA; **Jaime Caro, MD**, of McGill University and Evidera, Lexington, MA, USA; and **Leonardo Cubillos, MD, MPH**, of World Bank Group, Washington, DC, USA. Our conversation follows.

David Thompson: Let's start with some basics. On the simplest level, what we're talking about here is the judicial system taking an active role in health care decision making in Latin America. Exactly how does this occur? What's the process?

Caro: The basic process is simple: a patient whose doctor has recommended an intervention that is not covered by health insurance appeals to the supreme or constitutional court for "amparo" (roughly translated "safe harbor") under the "right to health" which has been enshrined in many countries' constitutions. The appeal to the highest court does not pass through lower courts because the matter concerns a constitutional right. The justices consider the case based on the fact the patient presents a need and an expert (the physician) has made a recommendation. HTA is not considered.

Cubillos: That's essentially correct, but I disagree that the lower courts are not involved. For example, the Costa Rican judiciary does not involve lower courts and citizens resort directly to the Supreme Court of Justice. On the contrary, in the judiciary systems of Brazil, Uruguay, or Colombia lower courts initially do receive the cases, and only through appeals or revisions the cases move to higher courts. Just as there are heterogeneous health care systems in the region, Latin American also has important heterogeneity in its judiciaries.

Augustovski: That´s right. The details can vary from country to country, but as in most constitutions in the region, health is considered as a universal right, anybody can claim almost anything that a health professional has indicated. In Argentina, for example, these "amparos" or "tutelas" are totally decentralized, and judged by decentralized courts, with judges that usually are not aware of HTA concepts, that have to make a decision regarding an individual patient, usually having very short time to decide. In that sense, it is not surprising that the great majority of sentences are in favor of providing the health technology in question to the patient. As one professor of mine –Don Berwick- said (and often the quote is attributed to him), "Every system is perfectly designed to achieve exactly the results it gets".

Thompson: So how did this come about?

Cubillos: Enshrinement of the Constitutional Right to Health imposes a number of obligations to states for which governments are held accountable. Hereby, judicialization or judicial accountability should be then understood as a mechanism by which citizens claim what the Constitution or other regulations entitled them to. This is a tremendous positive step! Two centuries ago when democratic states began to shape, it was unimaginable

that one (any) citizen could challenge a governmental decision, thus (judicial) accountability ought to be understood as a historical evolution of democratic states to put individuals at the center of their actions.

While data are quite scattered and inaccurate, one may assert that in Latin America, judicialization takes place in two big categories: 1) services/technologies that are included in public or private benefit plans yet are not delivered at all or at least not satisfactorily, and 2) services/technologies that are NOT included in these benefit plans, and for which there is not a clear rationale for their exclusion or not inclusion. The former cases point at failures in the service delivery and at the management of health systems, while the latter cases point at weaknesses in the benefit plan design, the health technology assessment and the resource allocation.

Interestingly, decision makers (like myself! [sic]) worry more for the latter cases while sometimes saying that judges are overstepping boundaries of the check-and-balances modern state. I believe this statement fails to consider that judges are also pointing at failures in the service delivery mechanisms.

Thompson: Ximena, you've spoken of the "tutela" process in Colombia and how easy it is for patients to appeal to the courts to intervene when reimbursement is denied for their prescriptions. Can you characterize that for us?

Burbano-Levy: The "tutela" in Colombia was established in 1991. As previously explained by my colleagues, the tutela is a writ of protection of fundamental rights; it is "an action that provides immediate protection of a person's 'fundamental constitutional rights, when any of these are violated or threatened by the actions or omissions of any public authority" – (in this case, the health system is the authoritative party in question). In order to invoke an action of tutela, four requirements must be satisfied:

1. A fundamental right must be threatened;
2. A procedure or a treatment cannot be replaced by another medication included in POS (Plan Obligatorio de Salud) with the same effectiveness;
3. A patient is unable to afford the cost of the medication or treatment plan required, and is unable to access health care via an alternative system; and
4. The medication, procedure, or treatment plan must be prescribed by a doctor affiliated to the Health Promoting Entities (EPS –Empresas Promotoras de Salud), to which the applicant is insured;

However, officials from the judiciary system do not have ample knowledge on comparative effectiveness in order to make sound decisions based on the aforementioned requirements. Such requirements are oftentimes ignored or overlooked at the time of the judicial sentence.

Many players from the judiciary system are involved and decisions are made based on the information provided by the patient or his/her legal advisor. The patients, with or without a legal advisor, may present an action of tutela and the judge can write the document on behalf of the individual if the person is illiterate.

In 2012, according to the Defensoria del Pueblo [1], the number of tutelas for health care services or medications presented was 114,313, which comprises approximately 26.9% of the total number of tutelas processed in the country. Of this number, 80.6% of cases were resolved in the first instance in favor of the patient. Changes and a subsequent decrease in the number of tutelas are expected after a reform of the basic plan was conducted in 2013.

Thompson: So where does this leave things for those of us who believe an appropriate role for value considerations in health care decision making? It sounds as if health authorities are constantly at risk of having their decisions overturned, even if there is clearly a solid basis for doing so in the pharmacoeconomic analysis. What's the path forward?

Cubillos: Moving forward I would say governments and health systems should further understand what is needed to better deliver those services that they have already promised (i.e., breach the gap between the jure and the facto – one of the two big categories related to judicialization). Apparently, the majority of the cases in Costa Rica, Colombia, and Brazil could be solved should more emphasis be paid to service delivery.

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On the second category related to litigation, we all agree that an appropriate use of health technology assessment is a good step forward. However, one question remains: In reality how much benefit plans are designed, updated, and cost based on sounded health technology assessment? It seems to me that as of now, HTA and benefit plans are not necessarily talking a whole lot amongst themselves. Furthermore, in doing HTA, prices should not be modeled (or understood) as constant. Latin America's ever-growing market size demands that we innovate in the way we negotiate and procure new and expensive medicines.

Caro: Complicated topics with substantial variation across geographies. "Appropriate use" is not a very clearly defined concept. What is appropriate for one person, country, or situation may not be appropriate for another. I suspect that despite some advances in HTA in LA, there is still very little use in benefit plan design. That is also true of countries that have been doing HTA for 20 years or more – much of HTA today has some effect at a very broad picture level but very little at the level of benefit plan design itself. Modeling of prices is also a difficult aspect that is very superficially implemented across the world. Most analyses use some sort of constant "list" price and it is very rare that any attempt is made at more realistic estimates of price or costs. I think Latin America should innovate in these areas – but it could start by not copying the procedures implemented in some parts of EU and elsewhere, which have failed to deliver on many dimensions and are largely being rejected now by citizens and practitioners alike.

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Augustovski: I agree, there are contextual issues in each country, and there could be no "one-size fits all" kind of solution. Also, the two situations mentioned by Leonardo are very different and require different solutions (i.e., services or technologies agreed as appropriate but inadequately delivered vs. technologies or services not agreed or included in the benefit packages). An interesting case in that regard in the region is Chile, with its explicit guarantees plan (AUGE-GES), which in each different update, included a list of health problems whose health care needs to be guaranteed by law, not only the services and technologies but also regarding process aspects (for example, when the maximum amount of time that should elapse between the day you have a cervical cancer diagnosis and the surgery or treatment of choice). Another issue mentioned by Jaime is also very important. Some studies have shown that the cost of technologies in our region is similar or even higher than in developed countries, which is somewhat counterintuitive if our societies use value-based pricing concepts that relate the willingness to pay for a technology with our affordability of wealth.

Burbano-Levy: Several aspects may be considered in these pathways. Specifically, we must stop and consider how health plans are planned around the world. For some physicians and other health professionals, the value of decision analyses and HTA (as a science in itself) is not well recognized. In particular, the limited applicability of HTAs in Latin America has contributed to an incoherency in health insurance plans and a scarcity of important resources within clinical practice.

Health plans, designed based on clinical protocols and pharmacoeconomic evaluations, must be conducted on a regular basis. Considering the rapid advance of heath technology, HTA processes must be dynamic and continuously updated in order to ensure that population groups are able to access the most cost-effective systems. Additionally, health outcomes studies that are funded by decision makers or by agencies responsible for the design of health plans should be actively promoted. These health outcomes may serve as helpful tools for decision making as related to clinical expectations and services offered.

Thompson: Well, that was a very good discussion on a difficult issue. It will be interesting to see how things develop over time. Thank you all for your contributions. ■

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