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Health Rights Litigation and Access to Medicines: Priority Classification of Successful Cases from Costa Rica's Constitutional Chamber of the Supreme Court

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Abstract

Although Costa Rica has no explicit constitutional right to health, its constitutional chamber of the Supreme Court (Sala IV) has become increasingly central to the resolution of many health care decisions. Some argue that courts' decisions about individuals' access to very expensive medications could upset the country's medical priorities and harm the state's general health care provision capacity. This article assesses whether health rights litigation concerning the right to medications leads to more fairness in access to medications in Costa Rica. We review randomly selected access to medicines cases successfully claimed at the Sala IV in 2008 and classify them into four priority groups using standard priority-setting criteria. We find that 2.7% of the successful cases fall into priority group I (highest priority), 27% in group II, 48.6% in group III, and 21.6% in group IV (experimental treatment). Our analysis reveals a majority of successful health rights litigation for medications results in court-mandated provision of new, expensive drugs, many with only marginal benefits. More than 70% of the successful cases evaluated concerned medications judged to be of low priority. Based on these cases, we cannot conclude that litigation leads to more fairness in access to medications.

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Introduction

IN RECENT YEARS, court cases litigating a right to health have grown rapidly in many countries, which has sparked a major debate concerning whether this litigation leads to more fairness in access to medicines and distribution of health benefits. While a major study led by Varun Gauri and Daniel Brinks draws relatively positive, if nuanced, conclusions concerning the impact of litigation on social rights, including health rights, a subsequent multi-country study led by Alicia Yamin and Siri Gloppen that focuses exclusively on health rights litigation is more agnostic in its conclusions and finds "that health rights litigation is neither a dangerously infectious trend to be urgently contained nor a panacea for health inequity."[1] Here, we investigate the effects of litigation on priority setting and social justice through a case study of Costa Rica, which has experienced an explosion in health rights litigation since the late-1990s. The many court cases gave rise to a vocal debate between the leaders of the health care system and constitutional magistrates. The debate has been played out in court decisions and scholarly publications as well as in the national media. To assess the health impacts of the court decisions, we need to know who benefits from them, in terms of patient groups, as well as the distribution of benefits: how much are these persons helped, compared to other patients in need?[2] A starting point is to look at the forms of treatment that are successfully litigated, and then use medical evidence regarding the individual burden of disease and the effectiveness of treatment for the condition in question to assess the distributional consequences of the court decisions.

We know that some of the earliest successful health rights litigation cases, in Costa Rica and many other countries in the early 1990s, concerned people living with HIV/AIDS.[3] Since then, there have been many other medical cases litigated ranging from essential medicines to high-cost cancer treatments, multiple sclerosis, and kidney failure, as well as cases concerning waiting times for surgeries and in vitro fertilization (IVF). What we don't know is whether according these successfully litigated treatments higher priority makes the health system fairer. The answer, in part, depends on the prior situation of different patient groups: do other patients have unmet needs for which they could have been helped more with the same resources? These questions are examined through an in-depth study of the nature and impact of successful litigation for medications in Costa Rica.

Costa Rica

Costa Rica is a small Central American country with a population of 4.8 million and is one of the oldest, most democratic countries in the Americas.[4] Costa Ricans enjoy an extensive, government-provided social welfare system covering insurance, health care, pensions, and education, among other services.[5] The success of this generous welfare system and virtually universal health care system is reflected in the country's relatively high Human Development Index (HDI) rank of 54th in the world.[6] Despite a GNI per capita (PPP) of US$10,863 and per capita government expenditure on health at (PPP) is $932 (in 2012), key health indicators are very good, especially in comparison with the country's Central American neighbors.[7] For example, life expectancy at birth is 78.7 years (77.4 years for males and 81.3 for females), and the under-five mortality rate is 10 per 1,000 live births; these are among the best rates in the Americas.[8]

Courts and health rights

Historically, Costa Rica's Supreme Court was, like most Latin American Supreme Courts, a moribund institution that was unable and unwilling to protect people's individual or collective constitutional rights. A 1989 constitutional reform created a Constitutional Chamber of the Supreme Court (Sala Constitucional or Sala IV) with far-reaching judicial review powers: the Sala IV has become one of the most assertive and politically significant courts

in the Americas. Apart from exercising an emphatic accountability function, the court has been willing and able to support and enforce an expansive range of individual rights.[9] The court effectively opened a significant new legal opportunity structure that political parties, individuals, and groups from virtually every sector of society have used. These range from the weakest, most marginalized individuals, including prisoners and people living with HIV/AIDS, to the most powerful, including multinational businesses and former presidents.[10] The superior court abandoned its previous legal formalism and instead allows any individual to file a case directly with the Sala IV with no charge and no need to hire legal representation. The court is open 365 days a year, 24 hours a day. Thus, the court leveled the judicial playing field for all claimants and has had a profound impact on the balance of political power in the country. It has brought the constitution to life, placing it at the center of all political and rights questions in the country. According to one Sala IV magistrate, Eduardo Sancho, the role of the constitutional court from its inception has been to "protect the rights of people."[11]

The right to health in Costa Rica

Figure 1 shows a rapid increase in litigation following the inauguration of the Sala IV, but it was not until the early 1990s that the first health rights cases were filed. This is in part because Costa Rica's current (1949) Constitution contains no explicit, fundamental right to health. Rather, the Constitutional Chamber of the Supreme Court after its creation in 1989 constructed a constitutional right to health. According to the court, this right to health is derived from the Constitution's protection of human life (Article 21), the right to social security protection (Article 73), and many international Human Rights conventions to which Costa Rica is a signatory.[12] These international human rights treaties are treated by the Sala IV as having an "almost supra constitutional value," which has helped facilitate a gradual expansion of a justiciable right to health that the court has been willing and able to respond to positively and quickly.[13]

One of the earliest health rights cases the Sala IV examined, in 1992, involved a person living with HIV/AIDS who filed a claim with the court to demand that the state-funded health care system (the Costa Rican Social Security Fund, Caja Costarricense de Seguro Social, CCSS) provide and pay for the anti-retroviral (ARV) medication azidothymidine. The CCSS had denied the patient's access to the medication. In response to the litigation, the CCSS argued that the drugs were not on the country's list of essential medicines because they were too expensive and were not a cure for HIV/AIDS. The Sala IV accepted the CCSS's argument, noting that an individual's right to health were necessarily limited by scarce financial resources, and ruled against the claimant, denying him state-funded access to the medication.[14] The Court's restricted notion of a right to health was maintained over the following five years, during which time only 25 more medication cases were filed with the Sala IV; these resulted in only nine successful claims. Of those nine, seven were merely patients requesting permission to take their current medications at home instead of at a medical facility.[15]

The Sala IV's health rights jurisprudence began to change in 1997, when three HIV/AIDS patients filed a similar case to the failed 1992 ARV case. In 1997, highly effective triple combination ARV therapy had been developed and was in use in the US and other countries. In response to the new litigation, however, the CCSS made the same cost-based argument it had successfully employed in the 1992 case. This time, though, the Sala IV's health rights jurisprudence had developed to the point where the right to health was considered to be a justiciable constitutional right. The Sala IV's 1997 decision reversed its 1992 ruling, deciding in favor of the plaintiffs and ordering the CCSS to supply and pay for the necessary medications. The court argued, "What good are the rest of the rights and guarantees . . . [or] the advantages and benefits of our system of liberties, if a person cannot count on the right to life and health assured?"[16] The justification for the court's ruling in this case became the foundation stone of all health rights jurisprudence and has been expanded and clarified in subsequent rulings.

In 2003, for example, the Sala IV deliberated for just one hour before ruling against the CCSS's medical experts and forcing it to pay for Cerezyme, at an annual cost of $175,000, for a young girl with Gaucher disease.[17] The court's jurisprudence relating to the provision of high-cost medications is clearly stated in a 2007 decision when the court argued that the CCSS cannot decline to fill prescriptions prescribed by a patient's treating physician for "eminently economic reasons."[18] Instead, the court argued, the CCSS is "under the undeniable obligation" to supply them, even if they are not on the CCSS's official list. This increasingly expansive definition of the right to health has been frequently cited in many subsequent cases and, as seen in Figure 1, lit a slow-burning jurisprudential fuse that eventually resulted in an explosion of health rights cases.[19]

Although the ruling was originally *inter partes* (applying only to the people involved in this particular case), the subsequent deluge of cases filed by HIV/AIDS patients were decided by the Sala IV in the same manner and with the same reasoning, effectively making it *erga omnes (*a court decision that applies to all similar situations). Consequently, the CCSS provides ARV medications to all patients with a valid prescription from a CCSS doctor, resulting in the highest coverage of HIV/AIDS patients in Latin America. The impact of this decision was remarkable and fast; morbidity rates for people living with HIV and AIDS declined significantly after the 1997 decision, reversing the trend of the 1980s and 1990s.[20]

The lessons of the Sala IV's HIV/AIDS medication decision were recognized not just by other people living with HIV/AIDS, but by patients suffering from other chronic illnesses who subsequently used the legal opportunity provided by the Sala IV to claim and win access to expensive medications, even if the CCSS had previously denied their claims.[21] According to Carlos Zamora—a medical doctor who works in the actuarial division of the CCSS—the 1997 decision was "perhaps the most relevant case in the rights to medication arena…the arguments put forth and the Sala IV's interpretation has served as a model that has shaped the field of health rights."[22]

Since the success of the 1997 decision, the number of *amparo* (a writ to protect or reestablish constitutional rights or human rights contained in international instruments to which Costa Rica is a signatory) cases claiming a right to medications increased gradually with some fluctuations before it exploded from 2002 onwards. While this rapidly increasing quantity of cases might discourage claimants from filing claims, the court has made great effort to reduce the length of time it takes to reach a decision on *amparo* cases. In the court's early years of operation, the average time to resolve an *amparo* case was 12 weeks, then, as a result of the rapid growth in caseload, it increased to five months by 2003. From 2003 onward, that time fell, reaching an average of seven weeks in 2011.[23] While the vast majority of health rights claims are *amparo* cases, the court treats these cases as a special category and requires *letrados* (clerks to the court) to give them priority above all other cases except *habeas corpus* cases, dedicating one day per week to resolving health cases as quickly as possible. Also, while the vast majority of *amparo* cases are unsuccessful (approximately 75 percent), medical *amparo* cases tend to succeed more often. In the period under discussion here, medical *amparo* claims against the CCSS succeeded in over 60 percent of the cases.[24] In most cases, the court has argued that "the specialist doctor who treats a patient knows better than anyone else their reality and needs" and that a prescription from that doctor outweighs the technical medical criteria used by the CCSS's Comité Central de Farmacoterapia (Central Committee of Pharmacotherapy) to determine which medicines should be on the essential drugs list.[25]

While it is clear that the number of cases has been increasing since 1997, little is known about the scope, outcome, and impact of those cases. Hogerzeil et al. report that in 2006, seven cases related to essential medicines won in Costa Rica. Their impact on the health system and its allocation of scarce health care resources is not known. As noted by Hogerzeil et al.: most public budgets are not infinite and at a certain moment choices have to be made. Progressive implementation of the right to health requires a State to choose which components should be implement-

ed first. Under such circumstances, should courts of justice or national committees of experts decide how public funds are spent in the most equitable and cost-effective manner?[26]

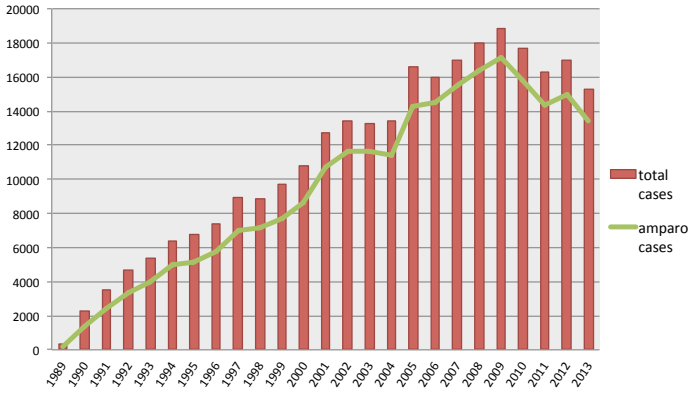
Although several types of health-related cases are brought to the constitutional court, such as cases related to non-discrimination, surgeries, waitlists, quality of care, and others, a particularly interesting class of cases concerns access to medications. These cases are also the source of much of the criticism against the Sala IV from members of the CCSS who argue that these health rights medication decisions lead to the misallocation of scarce resources, corruption by unscrupulous lawyers and doctors acting on behalf of pharmacy companies, and by foreigners accessing court-mandated free medicines. Does the court secure individuals' access to high-priority medicines that the publicly funded health care system in Costa Rica should have provided or, arguably, should have put them on the essential drugs list? Or does the court decide with claims that from a public health or social justice perspective would be seen as a low priority? In short: does health rights litigation concerning the right to medications lead to more fairness in access to treatment and distribution of health benefits?

In this paper, we review 37 successful cases from Costa Rica concerning access to medicines brought to the Sala IV in 2008. We classify them according to standard fairness criteria from the public health and priority-setting literature.

Material and methods

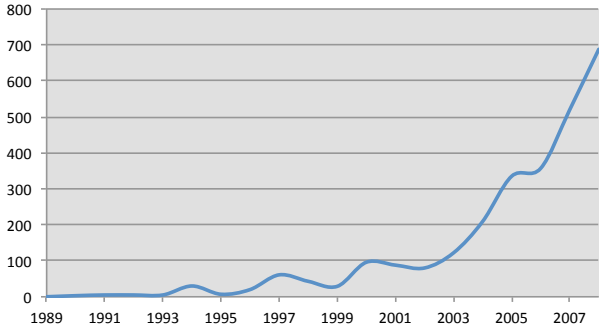
The bars in Figure 1 show the rapid increase in the total number of cases filed with the Sala IV since its inception in 1989; the solid line reflects the number of *amparo* cases filed, which have historically accounted for almost 80% of the total caseload. Figure 2 illustrates the growth in the total number of cases based on the right to health. Figure 3 shows the development of a litigation strategy used by patients to file cases at the Sala IV against the CCSS to make a claim for a specific medication. The solid line in Figure 3 shows the increasing number of successful cases claiming a right to medications that the CCSS

FIGURE 1 Sala IV total caseload and amparo cases, 1989-2013



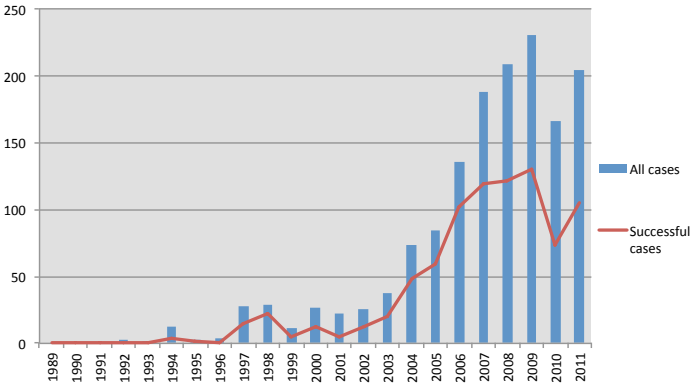
Source: Sala IV, 2014

FIGURE 2 Health rights claims filed against CCSS, 1989-2008



Source: Zamora Zamora, 2010

FIGURE 3 Medication claims filed against CCSS, 1989-2011



Source: Zamora Zamora, Amparos contra la Caja Costarricense de Seguro Social, 2009 to 2011. Preliminary report, February 2014

had previously denied. Taken together, these figures clearly demonstrate a delayed learning effect where claimants appear to have slowly recognized the creation of an effective legal opportunity that would allow them to approach the court to obtain medications that the CCSS had previously denied.

To investigate the impact of this health rights litigation, we created a database of all the right to health cases filed with the Sala IV against the CCSS in Costa Rica for the year 2008. This database allows us to look deeper into these cases and conduct an evaluation of their impact on the equitability of the health system. In total, there were almost 18,000 cases filed, the vast majority (16,345) writs of *amparo,* of which approximately 500 were right to health cases.[27] Of those cases, 192 were claims for medications, with approximately 50% of those cases winning their litigation. We then randomly selected 37 successful cases and extracted a brief description of the case, the medication involved, and the judicial basis of the court's decision. Second, we searched for published cost-effectiveness studies and reports where these medicines have been evaluated according to the methods of health technology assessment (HTA).[28] We used PubMed to identify published academic studies, and the website of the National Institute for Health and Clinical Excellence (NICE) in the UK as a starting point for relevant and up-to-date publicly available HTA reports. Third, we extracted priority-relevant medical evidence concerning health outcomes and costs from the identified studies and reports. "Priority-relevant evidence" was defined as information necessary to evaluate the effectiveness of a given medication, its overall costs, and the severity of condition for a typical patient in need of medication. In addition, we extracted information about the quality of evidence concerning health outcomes and costs. After extracting priority-relevant evidence for the medications in question, we explicitly evaluated each medicine according to predefined criteria for priority classification. Finally, we summarized all evidence for each criterion, combined it into an overall assessment, and classified each medicine into one of four priority groups with declining rank of importance from a standard public health priority-setting perspective.

Analytical framework

Most scholars agree that the two main goals for health systems are: efficiency and fairness in the distribution of health and health care.[29] While people disagree on the relative weight accorded to the different concerns, almost all theories of resource allocation in health care would recognize the following as criteria for assessing the priority of a given condition and its intervention:[30]

1. The severity of disease without the new medicine
2. The effectiveness of the new medicine
3. The cost-effectiveness of the new medicine
4. The quality of evidence on 1-3

In concrete cases, this information can be formulated in terms of the patient's characteristics, the nature of the condition, and the health intervention in question. We developed a framework for priority classification based on such standard fairness criteria from the public health and priority-setting literature:

Priority group I = High priority
Priority group II = Medium priority
Priority group III = Low priority
Priority group IV = Experimental interventions

By experimental interventions, we mean interventions judged as experimental according to evidence by a trustworthy health technology assessment agency. An intervention for a given condition is assigned high priority if it addresses a severe condition (where the prognosis is poor in terms of lost life years or reduced quality of life), if it is highly effective (improves the prognosis with regard to life years or quality of life), and if it is reasonably cost-effective. The measure of effectiveness used in most HTA reports and cost-effectiveness studies is the quality-adjusted life year (QALY). We grade clinical effectiveness in terms of QALYs. We use a threshold of > 1 QALY for very effective (grade I).

For studies where severity of disease was not reported, we extracted relevant information and indirectly estimated the health gap by using QALY gain with standard treatment with the help of life tables for the relevant country. For example, if a 40-year-old patient from Costa Rica with terminal breast cancer had a prognosis of 1 QALY, her health gap was calculated as life expectancy at age 40 (= 42.2) minus 1 QALY (= 41.2). We use this as an indicator of her severity of disease. We classified a condition as very severe (grade I) if the loss is more than 5 QALYs; severe (grade II) if the loss is between 1 and 5 QALYs; and not severe (grade III) if the loss is less than 1 QALY (for further discussion of this framework and its application, see Norheim and Gloppen).[31] Ideally, these thresholds should be discussed and determined in health-policy deliberations, but in the absence of agreement on thresholds, we believe that these are not unreasonable. In addition, we assessed whether effectiveness and cost-effectiveness had been documented in high-quality studies (preferably from randomized controlled trials). For the detailed framework, see Table 1.

Results

In our material of 37 randomly selected cases which concerned access to medicines and were brought to the Constitutional Chamber of the Supreme Court, we found that 2.7% fell into priority group 1 (highest priority), 27% in group II, 48.6% in group III, and 21.6% in group IV (see Table 2). Only three of the drugs are already on the official WHO essential drugs list.

Table 2 provides more detail and summarizes all evidence for each criterion and combines it into an overall assessment of each medicine. Each medicine is classified into one of four priority groups with declining rank. In order to qualify for priority group I, the condition and medication in question must be evaluated as grade I for each criterion. The kind of conditions and number of cases are also listed.

A summary of priority-relevant evidence is listed in Table 3. Although there is uncertainty concerning evidence for effectiveness, severity, and cost-effectiveness for many cases, the evidence available from studies and HTA reports enabled us to evaluate each medicine according to predefined criteria for priority classification. For comparison, we have also included an evaluation of ARV therapy for HIV/AIDS that was introduced in 1997 in Costa Rica. Only one of the successful medications from 2008 is as effective or addresses such a severe condition as antiretroviral therapy for HIV/AIDS. Table 4 shows evaluation and grading of each medication according to the predefined priority criteria. We see from Tables 3 and 4 that some medications provide a QALY gain (effectiveness) of less than 1 QALY (grade II and III), while several have higher gains in terms of quality-adjusted life years.

Criterion	Information needed	Measure*	Grading
Effectiveness	Mortality Morbidity	QALY gain**	I > 1 QALY II < 1 & > 0.5 QALY III < 0.5 QALY
Severity of disease	Mortality Morbidity	QALY loss***	I > 5 QALY loss II > 1 QALY loss < 5 QALY loss III < 1 QALY loss
Cost-effectiveness	Total and incremental cost effectiveness	Cost per QALY gained	I Cost-effective: < GDP per capita II Intermediate: > GDP per capita < 3 x GDP per capita III Not cost-effective: > 3 x GDP per capita
Quality of evidence	Type of studies documenting treatment effects	Evidence grading systems****	I Meta-analysis or randomized clinical trial II Observational, non-comparative studies III Single case reports

TABLE 1 Criteria for priority classification
* = Quality-Adjusted Life Years = QALYs
** = Compared to standard intervention
*** = Compared to normal healthy life expectancy
**** = Such as the AGREE instrument or others

Medicine	Condition	Cases	I	II	III	IV
Bevacizumab	Colon cancer	3			3	
Carvedilol	Heart disease	1	1			
Cyclofosfamid	Breast cancer	1		1		
Erlotinib	Lung cancer	1			1	
Imatinib (Glivec)	Leukemia	2			2	
Lactulosa	Portosystemic encephalopathy	1			1	
Escitalopram (Lexapro/Cipralex)	Depression	1		1		
Medication for dialysis (serum)	Kidney insufficiency	1			1	
Nilotinib (Tasigna)	Leukemia	1				1
Octreotidelar	Pituitary adenoma	1				1
Omeprazol	Stomach ailments	1		1		
Pamidronato de sodio	Osteogenesis imperfecta	1				1
Clopidogrel (Plavix)	Heart disease	2			2	
Clopidogrel (Plavix)	Cerebral insult	2			2	
Potassium gloconate	Hypothyroidism	1				1
Risperdal	Autism	1				1
Risperidona	Vascular dementia	1				1
Alendronate	Osteoporosis	2			2	
Rituximab	Lymphoma Hodgkin's desease	1		1		
Sunitinib	Kidney cancer with metastasis	2			2	
Ralidomid	Spinal cord cancer	1				1
Trastuzumab	Breast cancer	6		6		
Zometa	Breast cancer with bone metastasis	1			1	
Sildenafil (Viagra)	Pulmonary hypertension	1				1
Capecitabine (Xeloda)	Bilateral lung metastasis	1			1	
Sum (%)			**1 (2.7)**	**10 (27.0)**	**18 (48.6)**	**8 (21.6)**

TABLE 2 Priority classification of cases

Medication	Condition	Effectiveness (individual QALY gain)	Severity of disease (QALY loss)	Cost ($) per QALY	Quality of evidence	References
Bevacizumab	Colon cancer	0.85	18	51,120	2 RCT[#]	69
Carvedilol	Heart disease			2,309	RCT	70
Ciclofosfamida	Breast cancer					
Erlotinib	Lung cancer					
Imatinib (Glivec)	Leukemia	1.00	>10	74,315	4 RCT	7172
Lactulose	Portosystemic encephalopathy	1.4	28.4	57,000	Decision model + metanalysis of 10 RCT (low quality, weak evidence)	73
Escitalopram (Lexapro/Cipralex)	Depression	3	>5	28,167		74
Medication for dialysis	Kidney insufficiency	10	20	100,000	Standardly used in high-income countries	75
Nilotinib (Tasigna)	Leukemia	Not found	Not found	Not found	Experimental. Rejected by NICE UK 2009	76
Octreotidelar	Pituitary adenoma	Not found	Not found	Not found	Experimental?	No HTA[§]/CEA study found
Omeprazol	Stomach ailments/hiatus hernia	1	2	3.000	Standardly used in high-income countries	No HTA/CEA study found
Pamidronatode sodio	Osteogenesis imperfecta	Not found	Not found	Not found	Experimental? Approved by Atnea (US)	No HTA/CEA study found
Clopidogrel (Plavix)	Heart disease	0.1	9.19	15.400	RCT + CEA[$]	77
Clopidogrel (Plavix)Carvedilol (Coreg)	Cerebral insult	Search			RCT	7870
Potassium gloconate	Hypothyroidism	Not found	Not found	Not found	-	No HTA/CEA study found
Risperdal	Autism	Not found	Not found	Not found	Experimental. Not approved in 2005 by US Food and Drug Administration (FDA)	No HTA/CEA study found
Risperidona	Vascular dementia	NE	NE	Not found		No HTA/CEA study found
Alendronate	Osteoporosis	0.15	2	11,600	RCT	79
Rituximab	Lymphoma Hodgkin's disease	0.82	>5	17,271	1 RCT	80
Sunitinib	Kidney cancer with metastasis	0.20	19,5	74,000	1 RCT + CEA	81
Talidomida	Spinal cord cancer	Not found	Not found	Not found	Experimental?	No HTA/CEA study found
Trastuzumab	Breast cancer	1.54	10,45	18,970	RCT + CEA	82

Medical treatment with zometa	Breast cancer with bone metastasis					
Sildenafil (Viagra)	Pulmonary hypertension	0.2	>5	Not found	Only one small open label trial of Sildenafil 50 mg orally	83
Capecitabine (Xeloda)	Bilateral lung metastasis	0.2	>5	Uncertain	1 RCT for combination therapy, weak evidence	84
Comparison case: Antiretroviral therapy	*HIV eligible for treatment*	*> 3.5*	*> 20*	*1180 **	*RCT + CEA*	85

TABLE 3 (CONTINUED) Evidence for grading and priority classification
** = cost in recent analysis, not at the point of introduction (1997)*
 # RCT = Randomized clinical trial
§ HTA Health technology assessment
$ CEA = Cost-effectiveness analysis

Medication	**Condition**	**Number of cases**	**WHO Essential drug list**	**Effectiveness**	**Severity**	**Cost-effectiveness**	**Strength of evidence**	**Priority group**
Bevacizumab	Colon cancer	3	0	II	I	III	II	III
Carvedilol	Heart disease	1	0			I	I	I
Ciclofosfamida	Breast cancer	1	0					II
Erlotinib	Lung cancer	1	0					III
Imatinib (Glivec)	Leukemia	2	0	I	I	III	I	III
Lactulosa	Portosystemic encephalopathy	1	0	I	I	III	III	III
Escitalopram (Lexapro/Cipralex)	Depression	1	0	I	I	II	II	II
Medication for dialysis (serum)	Kidney insufficiency	1	0	I	I	III	I	III
Nilotinib (Tasigna)	Leukemia	1	0	NE*	NE	NE	Experimental	IV
Octreotidelar	Pituitary adenoma	1	0	NE	NE	NE	Experimental	IV
Omeprazol	Stomach ailments	1	YES	I	II	I	I	II
Pamidronato de sodio	Osteogenesis imperfecta	1	0	NE	NE	NE	Experimental	IV
Clopidogrel (Plavix)	Heart disease	2	0	III	I	II	I	III

Clopidogrel (Plavix)	Cerebral insult	2	0					III
Potassium gloconate	Hypothyroidism	1	0	NE	NE	NE	Experi-mental	IV
Risperdal	Autism	1	0	NE	NE	NE	Experi-mental	IV
Risperidona	Vascular dementia	1	0	NE	NE	NE	Experi-mental	IV
Medication alendro-nato sodico	Osteoporosis	2	0	III	II	II	I	III
Rituximab	Lymphoma Hodgkin's desease	1	0	II	I	II	II	II
Sunitinib	Kidney cancer with metastasis	2	0	III	I	III	II	III
Talidomida	Spinal cord cancer	1	0	NE	NE	NE	Experi-mental	IV
Trastuzumab	Breast cancer	6	0	I	I	II	I	II

TABLE 4 (CONTINUED) Evaluation and grading of each medication according to the priority criteria
* *NE = no evidence*

Most conditions, however, are severe. We see from Table 3 that many conditions imply a QALY loss of five or more. Some groups can expect 1-5 QALYs lost, while there are no non-severe cases with conditions in category III, that is, with expected losses of less than 1 QALY.

In terms of cost-effectiveness, few interventions are evaluated as highly cost-effective; many are evaluated as not cost-effective; some as intermediate; and for 10 cases, there were no cost-effectiveness analyses available.

Eight of the medications are evaluated as experimental, according to evidence by an HTA agency deemed trustworthy as of 2008; all the others are proven effective in large randomized clinical trials.

Discussion

In this study, we review 37 cases from Costa Rica concerning access to medicines brought to the court and won in 2008. After considering available evidence, we classified them according to standard fairness criteria from the public health and priority setting literature. Of the 37 cases evaluated, 73% can be classified as either low priority or experimental. These medications can be described as providing 'marginal' health benefits for very severe conditions at a high cost for the health care system. For the remaining 27% of the cases falling into priority class I or II, it is not unreasonable—according to our evaluation—that those were successful. Trastuzumab (herceptin) for breast cancer is the largest group in this category.

How robust is our system for priority classification? There is some agreement on priority criteria, but reasonable people may disagree on classification. Every system of priority classification is bound to be controversial. Our method is based on all available evidence, and we use explicit criteria grounded in theories of fair priority setting in health.

Priority setting according to cost-effectiveness is particularly controversial. WHO and others have suggested that interventions be classified as highly cost-effective if cost per QALY is less than one GDP per capita; intermediate if cost per QALY is more than 1 x GDP per capita and less than 3 x GDP per capita; and not cost-effective if cost per QALY is above 3 x GDP per capita.[32] For example, if treatment for advanced breast cancer would cost

less than $10,800 per QALY gained, it would be considered highly cost-effective. According to this rule of thumb, all interventions costing more than approximately $32,400 per QALY gained would be judged as not cost-effective. The underlying ethical rationale for considering cost-effectiveness is that there may be unmet needs in the system for which there exist more cost-effective interventions, and that population health is more efficiently improved if priority is given to the most cost-effective interventions first.

Moreover, our framework requires that all criteria be satisfied cumulatively, that is, each condition must be severe enough, and the treatment effective and cost-effective enough to qualify for a priority group. An alternative would be to balance the criteria against each other so that, for example, since HER2+ breast cancer is very severe (grade I) and the treatment (Trastuzumab) effective (grade I) in terms of effectiveness but only grade II in cost-effectiveness, a judgment could be made to adjust the cost-effectiveness threshold so that overall the case is classified as priority group I. This accords with commonly held notions of fair distribution of health benefits. However, there is no agreement on *how much* the cost-effectiveness threshold should be adjusted when the intervention targets a very severe condition where the QALY loss is particularly great.[33] We therefore used the cumulative grading system instead of a weighted grading system.

It is important to note that this method does not capture all aspects relevant for evaluation of equity. Classification in priority groups is only one part of the evaluation. The method focuses on fair and efficient distribution of health outcomes, but is not assessing fair access to medicines in terms of the socioeconomic status of patients or other issues related to non-discrimination. For an overall assessment, we also need to know more about whether there are many other unmet medical needs that would have fallen into priority group I or II. It is worth noting that invariably, all cases concerned claimants with high severity of disease that would have a large impact on health inequality if not treated. This fact is probably given high weight in the court's deliberation on individual cases. One may question whether our classification has assigned enough weight to this criterion. This issue can be seen as an aspect of the familiar trade-off between efficiency and equity.[34] Moreover, we evaluate the conditions and medicines for the typical patient, and are aware that particular characteristics of individual patients may vary.

By taking a random sample of cases from our database, we attempted to create a representative set of medical cases. We know from follow-up studies conducted by the Sala IV that the CCSS's compliance with the court's decisions is almost universal, and patients regularly receive the medications claimed in successful health rights cases.[35] However, while the original database is the most comprehensive representation of all health rights cases filed and decided by the court, it is possible that some cases have been overlooked due to the difficulties of searching through the 18,000 cases filed in 2008. Adding to the difficulties understanding the success or failure of medication claims is the court's tendency to combine similar individual cases together with a single decision number. Our sample, even if randomly selected, is quite small.

More importantly, as Figures 2 and 3 show, our database of cases concerning medicine is not representative of all health rights cases brought to the court. We have not assessed cases concerning non-discrimination, waiting lists, quality of care, infrastructure, or surgery. Nor have we examined the cases in which the court's decision was followed by the CCSS's inclusion of the claimed medication into the official medications list, as happened with the AIDS medications in 1997, and more recently, the multiple sclerosis cases.[36] Finally, we have not examined the recent health rights decisions decided in favor of entire classes of people. Further analysis of a larger and more comprehensive sample, using the same methods, is clearly warranted.

A 2009 decision ruled that everyone aged over 65 years should be granted access to vaccinations for pneumococcus, which was previously provided only to children under 2 years (a high-risk category).[37] A group of senior citizens filed the case, arguing that they, too, were a high-risk group for pneumococcal infection, and that the CCSS was denying their right

to health. Their claim was successful, and the CCSS was forced to vaccinate them (and all other people over 65) against pneumococcus and rotavirus at a total cost of $8 million per year.[38] This confirmed the fears of the health rights litigation critics that the Sala IV's decisions were diverting scarce resources from the higher priorities set by the CCSS's experts. In the pneumococcus case, though, the Sala IV invited the Minister of Health to present her medical experts' views to the court before it made its decision. According to one senior *letrado*, this evidence "probably tilted the case in favor of the seniors' demand to have access to the vaccine."[39] That is, the actions of the court were more dialogic than previous decisions and were more of a class settlement than the previous *inter partes* health rights decisions (i.e. binding only on the parties involved in the case).[40]

Conclusion

Does health rights litigation that seeks access to medications not covered by an official medications list lead to more fairness in access to medicines and distribution of health benefits? For the case of Costa Rica, we have shown that of the 37 cases evaluated, about 70% could be classified as either low priority or experimental and can be described as providing 'marginal' health benefits for very severe conditions at a high cost to the health care system. For the remaining 30% of the cases falling into priority class I or II, it is not unreasonable—according to our evaluation—that these were successful.

The priority classification system applied here makes it possible to distinguish medications that could be assigned high, medium, low or no priority, according to available evidence and relatively standard fairness criteria from the public health and priority-setting literature. Further studies of a representative set of cases are needed to evaluate whether health litigation contributes to a more or less fair distribution of health in Costa Rica. Like the current analysis, it could be based on a framework specifying widely agreed principles of fair distribution, and assigning high priority to health services that have a large impact on life expectancy (improves average health), and targeting those with least lifetime health measured in terms of quality of life and premature mortality (reducing overall health inequality). If a majority of the successful litigated medication cases results in access to new expensive medications with only marginal benefits, we cannot conclude that litigation led to more fairness in access to medications in Costa Rica. More than 70% of the successful cases analyzed concerned medications judged to be of low priority.

While consistently pushing back against criticism that it is making poorly informed medical decisions and placing an untenable financial burden on the CCSS, the court actively sought partners and input to create a process that would allow the magistrates to make more informed decisions on health rights cases. The court recently signed a Technical Cooperation Plan (*Plan de cooperación técnica*) with the Cochrane Collaboration that involved all major stakeholders in the health care system. This new collaboration, signed in May 2014, will facilitate an ongoing dialogue between interested health specialists on important questions of "equity, efficiency, design and implementation of public policies concerned with prioritization, law, and the judicialization of health."[41] It will also provide the Sala IV with access to the Cochrane Collaboration's extensive medical databases and provide training to relevant court personnel to better understand specialized medical information.[42] As a consequence of the collaboration, the Sala IV should be able to make better-informed health rights decisions that benefit from previously unavailable technical medical information and input from relevant stakeholders.

To include all stakeholders in mechanisms for systematic and impartial consideration of the medical evidence, the costs, and the distributional impact of introducing new medications is an important first step toward making the priority-setting process fairer.

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