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Health technology assessment and judicial deference to priority-setting decisions in healthcare: Quasi-experimental analysis of right-to-health litigation in Brazil

Daniel Wang [a,*], Natália Pires de Vasconcelos [b], Mathieu JP Poirier [c,d], Ana Chieffi [e], Cauê Mônaco [f], Lathika Sritharan [c], Susan Rogers Van Katwyk [c], Steven J Hoffman [c,d,g]

[a] Fundação Getulio Vargas (FGV), Law School in São Paulo, Brazil
[b] Insper, São Paulo, Brazil
[c] Global Strategy Lab, Dahdaleh Institute for Global Health Research, Faculty of Health & Osgoode Hall Law School, York University, Toronto, Canada
[d] School of Global Health, York University, Toronto, Canada
[e] Deapartment of Health of the State of São Paulo, São Paulo, Brazil
[f] Centro Universitário São Camilo, School of Medicine, São Paulo, Brazil
[g] Department of Health Research Methods, Evidence, and Impact, McMaster Health Forum, McMaster University, Hamilton, Canada

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ABSTRACT

The constitutional right to health in Brazil has entitled patients to litigate against the government-funded national health system (SUS), claiming access to various health treatments including those excluded from the health system's benefits package. Courts have tended to rely on a single medical prescription to judge these cases in favor of individual patients and against the health system. The large volume of cases has had a substantial financial impact on the government's health budget and has created unfairness in accessing healthcare. To change courts' behavior, a new health technology assessment (HTA) body – CONITEC – was created in 2011. Its creation was accompanied by an administrative procedure that made decisions about the health system's benefits package more transparent, accountable, participative and evidence-informed. It was expected that this HTA system would bring more legitimacy to the government's priority-setting decisions and promote deference from the courts. This study tests whether Brazil's new HTA system succeeded in encouraging judicial deference by analyzing a stratified random sample of 13,263 court decisions for whether the existence of a CONITEC report resulted in less frequent court orders to provide treatment for individual litigants. The results show that the creation of CONITEC did not change courts' behavior; courts still decide in favor of patients in most cases. Indeed, even when there was a CONITEC report recommending against government funding for a particular healthcare treatment, the vast majority of the relatively few patients who were unsuccessful in obtaining a health benefit at their first court hearing later obtained a favorable decision after appealing to a higher court. This finding was confirmed through an interrupted time-series analysis that did not find an impact of having a CONITEC report on courts' willingness to override a government priority-setting decision. In fact, CONITEC was rarely cited in court decisions, even when litigants mentioned the existence of a CONITEC report.

1. Introduction

Courts have been involved in decisions about the provision of healthcare in many jurisdictions (Yamin and Gloppen, 2011; Landau, 2012; Norheim and Wilson, 2014; Flood and Chen, 2010; Flood and Gross, 2014; Syrett, 2011; Gauri and Brinks, 2008; Exeter and Buijsen, 2012; Ettelt, 2018). This involvement is largely due to the recognition of legal rights to receive healthcare in several jurisdictions (Hogerzeil et al., 2006; Backman et al., 2008; Heymann et all, 2013); to the increasing review powers of courts to cover policy issues that were previously left to the complete discretion of politicians and government officials (Tate and Vallinder, 1997; Wang, 2017); and to the mismatch between patients' expectations and health systems capacity to meet them, driven especially by the cost of new technologies (OECD, 2006;

* Corresponding author.
E-mail address: daniel.wang@fgv.br (D. Wang).

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Sorenson and Chalkidou, 2012).

Legal entitlements and judicial accountability have been described as fundamental for countries to achieve universal health coverage, which is a target of the United Nations Sustainable Development Goals (Yamin and Frisancho, 2015; Cotlear et al., 2015; Chapman, 2016). However, there are concerns that courts can be used to force governments to spend disproportionately more on expensive treatments for those who can afford to hire lawyers and litigate matters, at the expense of more cost-effective interventions benefiting larger segments of the population (Rumboldt et al., 2017). Such outcomes can be particularly harmful in contexts of constrained budget and large health inequalities.

Brazil is a relevant case in this respect. The constitutionalization of the right to health in 1988 has entitled citizens to sue the country's public national health system known as "Sistema Único de Saúde" (SUS) seeking funding for treatments that have not been provided to them. In most cases, courts have accepted a claimant's right to receive healthcare whenever a need for a treatment is certified by a medical prescription for a treatment (Wang, 2015). This generous interpretation of the right to health, coupled with improvements in access to justice (Wang, 2015) and a severely underfunded and overstretched health system (Castro et al., 2019), resulted in the significant growth in the number of claims over the last two decades.

There were over 150,000 cases filed in Brazilian courts claiming the provision of treatments in 2013 and 2014 (Tribunal de Contas da Uniao, 2017). In 2016, the Federal Government spent over R$1.3 billion (U $350 million) to buy drugs following judicial orders, which is more than what was spent on drugs for HIV/AIDS in the same year (Vieira, 2018). In Brazil, such litigation has created inequality and inefficiency as healthcare budget decisions are being made by courts without rigorously weighing the available scientific evidence. As a result, patients who litigate receive privileged access to publicly funded healthcare and governments lose control over decision-making processes that should prioritize cost-effectiveness, equity, and population health needs (Wang, 2015). Moreover, there is evidence that litigation is more often used by the middle classes to access treatments that are not regularly available for the rest of the population, which amplifies concerns about inequity (Ferraz, 2020).

As a response to this phenomenon, Brazil's Federal Law 12401 was enacted in 2011 to clarify that SUS can only be obliged to provide treatments that have been included in the national health system's official list of treatments and clinical protocols. It also created a new health technology assessment (HTA) system, which includes a new entity – the National Commission for the Incorporation of Health Technologies in the National Health System (CONITEC) – responsible for assessing technologies and making reports with recommendations about their inclusion in the SUS's benefits packages for publicly funded universal coverage. CONITEC reports are addressed to the Secretariat of Science, Technology, and Strategic Inputs (a unit within the Ministry of Health) for a final decision. Only in exceptional circumstances can the Secretariat depart from CONITEC recommendations (AGU, 2018). If a decision to include a treatment in the SUS's benefits packages is made, it must be regularly and universally available for SUS users within 180 days.

Federal Law 12401 also establishes an administrative procedure aimed at making CONITEC recommendations more transparent, accountable, inclusive and evidence-informed. This new system represented an important milestone for the institutionalization of HTA (the interdisciplinary systematic evaluation of the properties, effects, and impacts of a health technology to informing policy decision making) in Brazil. Previously, HTAs did not have to be publicly disclosed, there was no clear timeline for an assessment to be concluded, the process was almost entirely conducted by officials within the Ministry of Health with very limited space for stakeholder participation, and fewer technologies were assessed each year (Borges, 2018).

Federal Law 12,401 was based on two draft bills that explicitly mentioned healthcare rights litigation as the main justification for its enactment (Wang, 2015). CONITEC's founding board of directors mentioned that the Commission's objectives include reducing litigation and changing courts' negative perception of Brazil's government-funded health system (Capucho et al., 2011; Petramale, 2011). The expectation was that a robust HTA system – and officials' reliance on HTA in making coverage decisions – would provide courts with trusted evidence against which to examine individual claims based only on a physician's prescription. By increasing courts' confidence in and deference to the priority-setting decisions made by government officials, this new HTA system was expected to reduce court orders for the individual provision of treatments not covered by SUS. HTA would then allow the government-funded health system and courts to better navigate the tension between the right to health and the need for the health system to set priorities fairly and efficiently (Ottersen et al., 2010).

At the time, this HTA strategy was supported by research literature and advice from the World Health Organization, which attributed Latin American courts' willingness to make ad hoc decisions ordering the provision of treatments to the absence of formal, transparent and evidence-informed systems for healthcare priority-setting (Dmytraczenko and Almeida, 2015, p.190; Chalkidou et al., 2016; Cubillos et al., 2012; PAHO, 2012). However, the existing research literature is mostly silent on whether or how HTA actually impacts judicial decisions. As affirmed by Dittirich et al. (2016, p.29.), there are some critical questions about the impact of HTA on courts' decision-making that are yet to be fully answered, including: Are courts more likely to uphold government decisions to not fund treatment when those decisions have been made using HTA? Will courts rely on the clinical and cost-effectiveness evidence demonstrating the collective impact of access to a product despite the individual needs of litigants?

Qualitative studies from Canada (Flood and Chen, 2010; Flood and Essajee, 2012) and England (Syrett, 2011; Newdick, 2004; Wang, 2017) indeed suggest that a more transparent and evidence-informed procedure is perceived by courts as more legitimate and attracts greater judicial deference. However, this connection has never been quantitatively tested given the small number of cases in these jurisdictions. Yet such a test would be possible and interesting in Brazil for at least two reasons. First, there is a very large number of court cases appealing healthcare funding decisions – tens of thousands cases each year. Brazil also represents an extreme case. In Canada and England, courts have started from very deferential approaches and still hesitate to second-guess government decisions on the allocation of healthcare resources, whereas in Brazil, courts tend to be more willing to intervene to secure access to most treatments desired by patients. Therefore, if the new HTA system is able to convince Brazilian courts to give more weight to scientific evidence and public health considerations, then the hypothesis that priority-setting decisions informed by a more transparent and evidence-informed procedure will attract greater judicial deference will pass a very difficult test.

2. Methods

2.1. Study sample

We obtained an exhaustive list of court cases with claims for healthcare treatments that were filed against Brazil's government-funded health system from 2011 to 2015 in the capital cities of three Brazilian states: São Paulo, São Paulo; Porto Alegre, Rio Grande do Sul; and Florianópolis, Santa Catarina. The capital cities in each state were chosen with the assumption that the public attorneys defending the national health system there are best prepared to defend the government in court and justify its policy choices. The public attorneys and the government-funded health system have their regional headquarters and most of the staff specialized in responding to claims for healthcare treatments located in the capital cities (Vasconcelos, 2018). Therefore, these are the jurisdictions where any impact from the creation of CONITEC would most likely have occurred.

The states selected for analysis are three of the five states with the highest volume of litigation for healthcare treatments in Brazil (Ferraz, 2020). Both the state and the federal court cases were included in Porto Alegre and Florianópolis, but only the state court cases could be included in São Paulo because the federal court there lacks an electronic database which prevented a search for relevant court files. Even though court files are publicly accessible, it was not feasible to hand-search the court's voluminous paper records to locate the relatively small subset of cases involving claims for healthcare treatments.

Given the large number of cases, a simple random sampling technique was used for each state-year-court. The sample size for each state-year-court combination was chosen to achieve a margin of error of ±4% at the 95% confidence level within each state-year. We excluded cases when protected by a court order, when they involved a class action with indeterminate claimants, and when the court files were missing either the claimants' or respondents' briefs or the judgments. Judicial decisions falling outside the date range of January 2011 to April 2016 were also excluded from analysis. Decisions made before 2011 were excluded due inconsistencies in the dates within the court files. Data collection in São Paulo (where the field research started) ended in April 2016, so this date was chosen as the final cut point to guarantee comparability across all the places and courts.

2.2. Data collection

All court files pertaining to each included case were manually obtained and reviewed by eight specially trained research assistants during a series of visits to the relevant public attorneys' office in each city (i.e., *Procuradoria Geral do Estado de São Paulo*, *Procuradoria Geral do Estado do Rio Grande do Sul*, *Secretaria de Saude do Estado de Santa Catarina*, and *Advocacia Geral da União*). Each court case may include more than one claim for health treatment (for instance, within the same court case a patient may claim access to several drugs). For each claim, information was manually extracted following a pre-determined codebook to create a novel database of key variables, including the claimant's illness, the healthcare treatments requested by the claimant, whether the treatment had marketing authorization by ANVISA (the medical products regulatory agency in Brazil), whether it was included in the health system's benefits basket (i.e., covered by SUS for publicly funded universal provision), and whether a CONITEC assessment was cited by litigants. Claims were categorized according to whether the claimant sought a drug, procedure, medical device, special nutrition, or another item. We restricted our statistical analysis to those involving claims for drugs because CONITEC is primarily focused on assessing drugs (Fig. 1).

Each claim can generate more than one judicial decision, including the preliminary decision, the 1st instance decision, and the instances of appeal allowed for each of the preliminary and 1st instance decisions (i.e., the 2nd instance courts, the Superior Court of Justice (STJ) and the Supreme Federal Court (STF)). Data were extracted for each judicial decision related to the outcome of the judgement, and evidence used by the judges in the judgements.

Data obtained from court files in the public attorneys' offices were supplemented with additional information gathered from websites of the relevant courts (i.e., *Tribunal de Justica do Estado de São Paulo*, *Tribunal de Justica do Estado do Rio Grande do Sul*, *Tribunal de Justica do Estado de Santa Catarina,* and *Tribunal Regional Federal 4ª Região*). This additional information included information related to decisions in appeal levels that were occasionally missing in the electronic files of public attorney offices.

A pharmacist and a medical doctor reviewed all extracted data, standardized treatment names, and added information to the database for each case on whether there was a CONITEC assessment for the claimed treatment, the date of the assessment, whether CONITEC recommended government funding for assessed treatment, and whether the patient's illness matched the illness for which the treatment was assessed. Throughout the data collection process, the principal investigator reviewed sample cases in the database for quality-assurance purposes and used identified inconsistencies for further team training.

2.3. Statistical analysis

Two methods were used to detect an expected decrease in court decisions granting claimants' requests for treatment following a CONITEC recommendation (either in favor or against) regarding its coverage by SUS.[1] The primary outcome for both methods was a decision by the court which was coded as either granting or not granting a patient's claim (a positive or negative judicial decision for the patient). Judgements for all claims meeting inclusion criteria were analyzed using logistic regression and interrupted time-series (ITS) analysis.

Exploratory logistic regression was used to evaluate different explanatory models for the binary dependent variable of a court granting a patient's claim. We used cluster-robust standard errors which allowed for intragroup correlation between the same claims advancing through the appeals process. Different models were estimated by layering combinations of court type, jurisdiction, SUS coverage, ANVISA registration, a CONITEC report existing for the requested drug, and the outcome of CONITEC recommendation (in favor or against its coverage by SUS).

For the drugs in our sample that were assessed by CONITEC, ITS was used to evaluate whether a significant change in either slope or level of positive court decisions (i.e., in favor of the patient claimant) occurred following the CONITEC report for each drug. Time-series data without any statistically significant discontinuities would prevent us from rejecting the null hypothesis, namely that a CONITEC report does not change the probability of positive decision by the court (Wagner et al., 2002; Bernal et al., 2017). To do this, the data was first aligned by the month of the CONITEC report (intervention year) and then the proportion of positive court decisions and the total number of court decisions for each treatment were aggregated by month.

Time series for all treatments that were assessed by CONITEC, treatments with a positive CONITEC report (recommendation for SUS coverage), and treatments with a negative report (recommendation against SUS coverage) were tested for stationarity using Dickey-Fuller tests. Stata program ITSA was then used to conduct ITS analysis using the number of decisions returned in a month as analytical weights, the percentage of judicial decisions in favor of the patient per month as the dependent variable, and the month of CONITEC recommendation (whether positive or negative) as the intervention period (Linden, 2015, 2017). Treatments were analyzed both as a single group ITS, and separately against a control of all other treatments. In the case of multi-group ITS analysis, a significant difference in either trend or level refers to a significant difference between those treatments receiving a positive or negative CONITEC report.

3. Results

In total 5,831 claims for drugs were included in our study, generating 13,263 judgements in Brazil (Fig. 1). Most of the claims captured in our dataset are for drugs that are not included in the national health system's official list of treatments or clinical protocols for regular and universal provision (71%). There are also a relatively small number of judgements for unregistered treatments, namely those without marketing authorization by ANVISA (5%). By law, unregistered treatments cannot be assessed by CONITEC and thus cannot be included in SUS benefits baskets.

Claimants have an extremely high success rate in both Federal and State courts. If a patient decides to litigate, it is ultimately almost certain

[1] Interferon peguilado was dropped because a CONITEC recommendation has not been made, and Rituximabe dropped because there were several conflicting CONITEC recommendations.

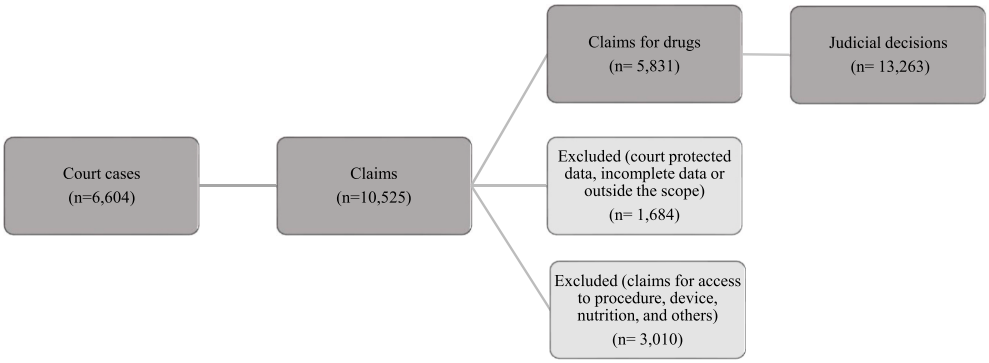

Fig. 1. Flowchart of court cases, excluded claims, claims for drugs, and judgements included for analysis.

that the health system will have to provide the treatment claimed (Table 1). Patients' rate of success grows from 92% in preliminary injunctions to 98% in appeal decisions at the second instance, and almost 100% in the two highest courts in the Brazilian Judiciary (STJ and STF). There is a significant difference in patients' rate of success between State and Federal courts in preliminary and 1st instance decisions, but this difference is significantly reduced in 2nd instance decisions. In fact, for claimants that reach the appeal level, the probability that they will receive a favorable decision reaches nearly 100%, including for medications that have not had their safety and efficacy certified through an ANVISA market authorization or that are not covered by SUS.

3.1. Use of evidence in court decisions

In 68% of judicial decisions ordering the provision of treatments not covered in the national health system benefits basket, and 45% of decisions ordering treatments without marketing approval, a prescription from the patient's physician was the sole source of evidence mentioned by the court. Overall, a prescription was the most commonly mentioned piece of evidence used to justify a court decision, although some cases also cited scientific literature or court appointed health experts. No source of scientific evidence was mentioned by the judge in 3% of decisions to provide treatment not covered by the national health system, and in 4% of decisions to provide treatment without marketing approval.

Table 1
Frequency and proportion of judicial decisions in favor of litigant patients for all judicial decisions, judicial decisions with and without a CONITEC recommendation, and judicial decisions with a positive and negative CONITEC recommendation for every trial stage[a].

Stage	All	CONITEC recommendation exists?		CONITEC recommends SUS coverage?	
	decisions	No[b]	Yes	No	Yes
Preliminary injunction	5,831 (91.9%)	3,647 (89.1%)	2,184 (96.4%)	1,953 (96.3%)	231 (97.4%)
Preliminary injunction – 2nd instance	937 (91.0%)	725 (90.3%)	212 (93.4%)	134 (92.5%)	78 (94.9%)
Preliminary injunction – 3rd instance	120 (95.0%)	85 (95.3%)	35 (94.3%)	20 (100.0%)	15 (86.7%)
Decision – 1st instance	4,151 (92.2%)	3,113 (91.1%)	1,038 (95.5%)	701 (94.6%)	337 (97.3%)
Decision – 2nd instance	2,077 (97.8%)	1,484 (97.5%)	593 (98.5%)	381 (97.9%)	212 (99.5%)
Superior Court of Justice (STJ)	130 (99.2%)	61 (98.4%)	69 (100.0%)	48 (100.0%)	21 (100.0%)
Supreme Federal Court (STF)	17 (100.0%)	7 (100.0%)	10 (100.0%)	8 (100.0%)	2 (100.0%)
Total	13,263	9,122	4,141	3,256	896

[a] Proportion of judicial decisions in favor of litigant patients in parentheses.
[b] This column includes decisions regarding treatments that were not assessed by CONITEC during the analyzed period and for treatments that were assessed after the judicial decision.

Table 2
Logistic regression of judicial decisions in favor of litigant patients presented in the form of odds ratios with cluster robust p-values in parentheses.

Category	(1)	(2)	(3)	(4)
State court[a]	7.34* (<0.01)	6.60* (<0.01)	8.15* (<0.01)	5.47* (0.02)
Rio Grande do Sul[b]	1.95* (<0.01)	1.43 (0.26)	3.25* (0.01)	3.30 (0.08)
Santa Catarina[b]	6.34* (<0.01)	4.90* (<0.01)	6.96* (<0.01)	13.17* (<0.01)
Covered by SUS	0.77 (0.13)	0.64* (0.04)	0.95 (0.86)	0.48 (0.14)
Registered with ANVISA		2.45* (0.01)	1.91 (0.39)	8.08 (0.10)
Has medical prescription		7.99* (<0.01)	3.60 (0.13)	3.07 (0.45)
CONITEC report exists			1.13 (0.67)	
Positive CONITEC recommendation				3.16* (0.02)
Observations	11,008	6,724	3,342	1,385
Pseudo R^2	0.06	0.09	0.06	0.08

*p < 0.05.
[a] As compared to federal court.
[b] As compared to São Paulo.

Table 2 shows contextual factors affecting patients' rates of success. When all the judicial decisions are pooled together, there is some evidence that the fact that a drug is not authorized by ANVISA affects the odds of a decision being in favor of the patient. However, and contrary to our expectations, the probability of a court decision favorable to the patient was not affected when the court was presented with information that the drug was not covered by SUS. The only exception appears in preliminary decisions, where there is some evidence that a patients' odds of success increase in claims for non-incorporated drugs, and especially if treatments that are not market authorized are excluded from the analysis. In any case, it is still almost certain that the patient will eventually be given access to uncovered, and even unregistered, treatment funded by SUS when the case reaches the appeal levels.

For drugs assessed by CONITEC, there is no strong evidence to suggest that the existence of a CONITEC report has had an effect. We found a small positive effect for the existence of a CONITEC report, either recommending or not treatment coverage by SUS, on the odds of courts reaching a decision in favor of the claimant (Appendix Table 1), but this effect is made not significant after controlling for national health system coverage, ANVISA marketing approval, medical prescription, and the

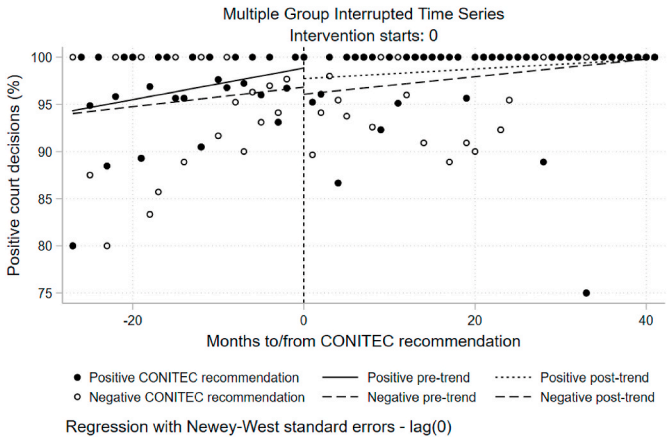

Fig. 2. Interrupted time series analysis of positive (treatment) and negative (control) CONITEC recommendation on the percentage of positive judicial decisions per month with standardized time to/from CONITEC recommendation.

evidence considered by the courts. There is also no strong evidence that a CONITEC recommendation to cover the treatment (i.e. a positive CONITEC decision) makes a difference in court decisions, except when taking ANVISA approval, national health system approval, and presence of medical prescription into account, after which a positive and significant effect on court decisions appears. Even more tellingly, a CONITEC report was mentioned by litigants in 1,130 in judgements, but only in 26 judicial decisions was a CONITEC report used as evidence by courts.

Interrupted time series analysis reinforces the finding that there is no strong evidence showing that existence of a CONITEC report has an effect on court decisions using a larger number of datapoints than is possible with logistic regression (Fig. 2). The results of the ITS show that there is no significant difference in either trend or level when pooling all treatments together, which indicates no effect of the existence of a CONITEC report. In cases where CONITEC conducted an HTA, there was no change in the trend or level of positive court decisions, regardless of whether CONITEC's recommendation to cover the treatment was positive or negative (Table 3). These results are further supported by a multiple group interrupted time series, using cases not assessed by CONITEC as controls. This analysis found no difference between the CONITEC recommended and non-recommended treatments before or after the assessment.

4. Discussion

The creation of a new HTA system has not changed the way in which judicial claims for health treatments are decided by the courts in Brazil.

Table 3
ITS results for all treatments that received a CONITEC recommendation, treatments that received a positive recommendation, treatments that received a negative recommendation, and a multiple group ITS comparing treatments that received a positive recommendation (treatment) with treatments that received a negative recommendation (control). Linear regression coefficients with p-values in parentheses.

	All (Single group)	Negative CONITEC recommendation	Positive CONITEC recommendation	All (Multiple group)
Time trend	0.001	0.001	−0.000	0.001
	(0.15)	(0.07)	(0.47)	(0.43)
Level change	0.001	−0.005	0.003	0.003
	(0.94)	(0.72)	(0.84)	(0.93)
Trend change	−0.001	−0.001	0.001	0.001
	(0.32)	(0.45)	(0.08)	(0.71)
Observations	104	86	85	138

*p < 0.05.

Even the existence of a CONITEC report that recommends against coverage for public funding of a particular treatment is unlikely to affect whether patients receive a favorable outcome in court. The high number of successful claims for treatments that are not regularly covered by the national health system, not recommended by CONITEC and not market authorized by ANVISA shows the enormous weight that is given to a physician's medical prescription, at the expense of policy, scientific and regulatory considerations. Having a medical prescription appears to be the strongest predictor of a court's willingness to decide in favor of the patient.

Analogue insulin (eg, Lantus, Humalog, Levemir), the most frequently claimed drugs in our sample, are a very telling example of the lack of impact CONITEC had on judicial decisions. During the period covered in our analysis, analogue insulins were assessed by CONITEC for patients living with type I and II diabetes. CONITEC recommended against its inclusion in SUS because there was insufficient evidence that they were more effective and safer than the universally provided human insulin (CONITEC, 2013a; CONITEC 2013b). Moreover, providing analogue insulin instead of human insulin would cost the health system over R$16 billion (around US$7 billion in 2014) over a 5-year period. Nevertheless, these CONITEC reports had no effect on judicial decisions in claims for analogous insulin, with courts deciding in favor of analogue insulin claimants in 94.6% of 932 judicial decisions prior to the CONITEC report in September 2014 and in 95.7% of 418 judicial decisions after the negative CONITEC recommendations.

Courts willingness to override regulatory and policy decisions coupled with the overreliance on physicians' medical prescriptions is troublesome for many reasons. First, due to the high volume of new scientific evidence, physicians may not base their clinical decisions on the most recent and highest quality scientific evidence. Second, the prescribing physicians' motivations in recommending uncovered treatments may be unclear, and the role of pharmaceutical companies in influencing prescribing behaviors should not be ignored. Third, treatments that may be the best for the individual patient may not be cost-effective or affordable for universal provision. Court orders to provide treatment may not represent the best value-for-money for the health system, which can result in inefficient allocation of scarce resources. Providing treatment to patients with the resources to make a court claim also reinforces inequalities in health and access to healthcare and will result in patients with similar conditions receiving unequal care.

While it may have been optimistic to believe that a new HTA system would dramatically change courts' attitudes in general, it is still surprising that a CONITEC HTA did not result in a noticeable change in court decision-making. These results will frustrate those who expect that better administrative decision-making will result in better judicial decision-making and, therefore, that HTA can be an effective strategy for reducing the number of successful individual claims against the health system. As our study shows, judges and courts in Brazil tend to replace policy assessments and decisions with their own assessment of the claim or, in the vast number of cases, for the assessment of the prescribing physician. Our evidence suggests that even when courts are aware of a CONITEC assessment, the CONITEC recommendation is largely ignored by the courts.

Where courts tend to ignore recommendations from HTA bodies, one policy alternative is to assist courts to produce their own technology evaluation. This is currently being attempted in Brazil through the creation of scientific entities within the Judiciary (*Núcleos de Assistência Técnica*) with health professionals dedicated to providing judges with medical information. A similar policy was implemented in Costa Rica, where the Supreme Court response to the growing number of legal claims for health technologies was to train law clerks to analyze scientific evidence and to request independent medical opinion to inform its decisions. However, this is a very limited form of technology assessment as important policy considerations are left out (eg, cost-effectiveness, budget impact and equality). This explains why, even though the Supreme Court of Costa Rica has relied on these sources of evidence, they

are still frequently ordering the provision of treatments that are considered of low priority from a public health perspective (Loaiza et al., 2018). In sum, even if courts are more likely to adhere to assessments made under their own supervision, this is no adequate substitute for rigorous and comprehensive HTA by specialist bodies.

5. Strengths and limitations

This article represents one of the first studies to quantitatively measure the role of HTA in judicial deference. No previous research on this topic has gathered a sample of court documents of this size (most of which are not easily accessible to the public but only available on site) covering federal and state courts in first and appeal levels. Because of the size of the underlying dataset, we were able to triangulate regression analyses with quasi-experimental approaches to evaluating the impact of CONITEC HTA assessments on judicial decisions.

The study was limited to the comprehensive database maintained by Public Attorneys' Offices and state health authorities, as well as on the quality of their search tools. Although we cannot exclude the possibility that the database is incomplete or that the search tools available were not sufficiently accurate, we have no reason to believe that there was any systematically missing information that would compromise or bias the results. Inconsistencies identified in coding were addressed as they were identified in the revision process and consistency was ensured through thorough data validation in the analysis phase. Some regression models were underpowered due to missing information, but overall results were broadly consistent across methodological approaches.

6. Conclusions

This article by no means suggests that SUS decisions and CONITEC assessments should be accepted without question by stakeholders and courts. Judicial accountability can play a very important role in enforcing fairness in HTA, making sure the process was lawful, informed by evidence, transparent, inclusive, consistent and unbiased. However, instead of holding CONITEC or SUS accountable, Brazilian courts are simply ignoring HTA. The Judiciary still consider that individual needs and the right to health trump priority-setting decisions, even when they are made through HTA. This provides no incentive for better HTA or health system decision-making. Moreover, courts are also undermining and diminishing the work of CONITEC since they allow patients access to treatments before, or even despite, a CONITEC assessment.

Both healthcare litigation and the increasing use of HTA by health systems are phenomena that coexist in many jurisdictions, particularly in Latin America. The case of Brazil discussed in this article invites more caution from those that see the relationship between right to health adjudication and HTA as mutually reinforcing. It also highlights that, despite the calls for Latin American countries to institutionalize and mainstream HTA in their health systems (PAHO, 2015; PAHO, 2012), there are challenges for incorporating HTA in a context where courts can veto explicit priority-setting decisions.

Given the particularities of each legal and health system, further research in more jurisdictions is necessary to fully understand the complex relationship between the right to health, courts, and HTA. However, based on the case of Brazil discussed in this paper and on the specialized literature in HTA, it is possible to suggest some strategies to give HTA more prominence in courts. First, HTA dissemination strategies should be considered. The dissemination of HTA information and its use by policy-makers should not be taken for granted, particularly when the recipient of information, like courts, may have limited understanding of health policies and lack scientific literacy (Banta, 2015, p.148). Such active dissemination of information should be coupled with constant communication and dialogue with courts to convince them of the importance of providing prima facie validity to HTA decisions. Moreover, more information and interaction must be accompanied by an increasing emphasis on transparency, evidence and accountability in HTA. Judicial deference is more likely if courts trust the body responsible for HTA. Lastly, dissemination strategies need also be accompanied by changes in legal interpretation. Priority-setting, no matter how necessary for efficient, sustainable and fair service provision, will play no role if courts interpret the right to health as absolute (ie, no competing consideration can justify their non-fulfilment). This judicial interpretation results in the allocation of scarce resources based on the "rule of rescue", a sense of immediate moral duty to do everything possible to save an identified life. This comes at the expense of the health needs of others who bear the opportunity costs of court rulings (Wang, 2013).

Credit author statement

Daniel Wang (Fundação Getúlio Vargas): Conceptualization, Funding acquisition, Investigation, Methodology, Project administration; Supervision; Writing - original draft; Writing - review & editing. **Natália Pires (Insper)**: Conceptualization; Data curation; Investigation; Methodology; Writing - review & editing . **Mathieu Poirier (York University)**: Formal analysis, Methodology, Writing - review & editing. **Ana Chieffi (University of São Paulo)**: Data curation, Investigation. **Cauê Mônaco (University of São Paulo)**: Data curation, Investigation. **Lathika Sritharan (York University)**: Writing - review & editing, Methodology. **Susan Rogers Van Katwyk (York University)**: Writing - review & editing; **Steven Hoffman (York University)**: Conceptualization, Funding acquisition, Methodology, Supervision, Writing - review & editing.

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Appendix

Appendix Table 1
Frequency of decisions in favor of litigant patients for every trial stage for State and Federal courts[a].

Stage	State court		Federal court	
	Negative	Positive	Negative	Positive
Preliminary injunction	329 (6.7%)	4,604 (93.3%)	145 (16.2%)	753 (83.9%)
Preliminary injunction – 2nd instance	41 (8.2%)	457 (91.8%)	43 (9.8%)	396 (90.2%)
Preliminary injunction – 3rd instance	0 (0%)	27 (100%)	6 (6.5%)	87 (93.6%)
Decision – 1st instance	218 (6.3%)	3,219 (93.7%)	107 (15.0%)	607 (85.0%)
Decision – 2nd instance	28 (1.7%)	1,638 (98.3%)	18 (4.4%)\	393 (95.6%)
Superior Court of Justice (STJ)[b]			1 (0.8%)	129 (99.2%)
Supreme Federal Court (STF)[b]			0 (0%)	17 (100%)
Total	616 (5.8%)	9,951 (94.2%)	320 (11.9%)	2,376 (88.1%)

[a] Frequency in percentages in parentheses.
[b] STJ and STF are federal courts that can hear appeals against federal and state courts decisions.

Appendix Table 2
Additional logistic regression of decisions in favor of litigant patients presented in the form of odds ratios with cluster robust p-values in parentheses.

Category	(1)	(2)	(3)	(4)	(5)
State court[a]	6.14* (<0.01)	6.32* (<0.01)	6.25* (<0.01)	7.03* (<0.01)	6.18* (<0.01)
Rio Grande do Sul[b]	1.32 (0.37)	2.46* (<0.01)	4.75* (<0.01)	2.51* (<0.01)	4.69* (<0.01)
Santa Catarina[b]	4.72* (<0.01)	4.60* (<0.01)	9.53* (<0.01)	4.37* (<0.01)	9.26* (<0.01)
Covered by SUS	0.63* (0.03)				
Registered with ANVISA	3.01* (<0.01)				
Has medical prescription				5.54* (0.03)	2.21 (0.52)
CONITEC report exists		1.53 (0.05)		1.38 (0.14)	
Positive CONITEC report		1.52 (0.26)			1.56 (0.24)
Observations	6,826	6,443	2,436	6,319	2,405
Pseudo R^2	0.08	0.05	0.06	0.05	0.06

*p < 0.05.
[a] As compared to federal court.
[b] As compared to São Paulo.

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