INSTITUTIONAL STRATEGIES AS A MECHANISM TO RATIONALIZE THE NEGATIVE EFFECTS OF JUDICIALIZATION OF ACCESS TO MEDICINE IN BRAZIL

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Abstract

Background: Recently, the Executive Branch and Judiciary in Brazil increased spending due to larger numbers of lawsuits that forced the State to provide health goods and services. This phenomenon, known as health judicialization, has created challenges and required the Executive Branch and Judiciary to create institutional strategies such as technical chambers and departments to reduce the social, economic and political distortions caused by this phenomenon. This study aims to evaluate the effects of two institutional strategies deployed by a Brazilian municipality in order to cope with the economic, social and political distortions caused by the phenomenon of health judicialization regarding access to medicines. Methods: A longitudinal study was carried out in a capital in the Central-West Region of Brazil. A sample of 511 lawsuits was analyzed. The variables were placed into three groups: the sociodemographic characteristics and the plaintiffs' disease, the characteristics of the claimed medical products and the institutional strategies. To analyze the effect of the interventions on the total cost of the medicines in the lawsuits, bivariate and multivariate linear regressions with variance were performed. For the categorical outcomes, Poisson regressions were performed with robust variance, using a significance level of 5%. Results: A reduction in the costs of medicines in the lawsuits and of the requests for medicines within the SUS formulary was verified after the deployment of the Department of Assessment of Non-Standardized Medicines (DAMNP) and the Technical Chamber of Health Assessment (CATS); an increase in processed prescriptions from the Brazilian Universal Health System was observed after the deployment of the CATS; and an increase in medicines outside the SUS formulary without a therapeutic alternative was verified after the CATS. Conclusion: The institutional strategies deployed were important tools to reduce the high costs of the medicines in the lawsuits. In addition, they represented a step forward for the State, provided a benefit to society and indicated a potential path for the health and justice systems of other countries that also face problems caused by the judicialization of health.

Background

In Brazil, the integral right to health is an obligation of the State, written in the Federal Constitution, and it depends on the creation and implementation of public health policies. However, since the 1990s, Brazilian citizens have resorted to the judicial system in order to have access to medications and other health goods and services [1]. This phenomenon is called health judicialization, and drugs are the most requested good [2,3,4]. The flaws in health policies and insufficient funds for the State to meet the growing demands in health care are the attributed causes of this phenomenon [5].

To guarantee the effectiveness of the right to health, the Brazilian justice system established the proceeding of state and non-state institutions. The former is organized into three branches: Judiciary, Executive and Legislative; and the latter is composed of the other institutions, one of which is the Public Prosecutor's Office. The Public Prosecutor's Office is an entity that is not within these powers. It has the role of inspecting and protecting the fundamental principles and interests of society and filing lawsuits when such interests are not at hand; it is essential to justice [6].

In healthcare, the Executive Branch is responsible for managing the Brazilian public health system – Sistema Único de Saúde (SUS) – which also guarantees access to essential medicines, guided by the National Medicines Policy [7] and by other laws and policies that define the medicines within the SUS formulary (belonging to the official lists of medications of SUS [8]). However, the SUS cannot meet the unlimited demands of Brazilians. When the State faces difficulties in offering health services and adequate universal well-being to all citizens, many people seek these rights through the Judiciary [9]. The lawsuits are used by citizens to overcome the inaccessibility of medicines, caused either by the lack of financial resources to acquire them, by their unavailability in public health services or by the high cost of treatment, especially for the treatment of genetic diseases and neoplastic drugs outside the pharmaceutical care policy and represent an important part of the problem [5,10].

In the Brazilian democratic context, the health judicialization can express legitimate claims and ways of acting citizens. On the other hand, it bolsters an imbalance in rights by giving the privilege of obtaining these rights to groups of people who have the knowledge about the lawsuits and financial resources to appeal to the justice system [11].

Some studies show that users who use the Judiciary to request a medicine usually have better socioeconomic conditions because they can pay the procedural expenses generated by the judicialization. Thus, this phenomenon privileges certain social segments, favoring those who have greater access to the justice system and aggravates the inequities in access to health of a system already marked by inequalities [12].

The search for a guarantee of one´s right to health services and goods using the courts in the legal system is not a case isolated to Brazil and occurs in other countries such as Colombia, Costa Rica and Chile [13,14,15]. What stands out in the Brazilian case is the high rate of the lawsuits deferred by the judge, which has sparked discussions between professionals and managers of the health sector, as health judicialization not only can provide a useful mechanism for society to force the State to implement public policies but also can cause negative economic, social and political distortions [4].

In economic terms, judicialization creates costly unscheduled expenses for the Executive Branch and Judiciary. For the Executive, the spending in the federal sphere on such judicial demands has increased 1,000% (in the requested items) between 2008 and 2015, increasing from approximately US$32,928,388.75 to US$351,662,404.09, which has displaced the budget for other sectors of the Ministry of Health, such as the supply of drugs to primary care and the treatment of patients with STIs /AIDS; in addition, the Ministry of Health budgets showed a limited variation in this time period, which made planning and managing the public budget difficult [16]. This is a distortion where some are benefiting while others are losing. It is a matter of only those who win in this process benefit while others may lose and/or have no recourse.

For the judiciary, it was observed that the spending on cases increased to approximately US$11,319,112,008 on lawsuits (administrative cost of appeals), which corresponded to 1.2% of the gross national product and was equivalent of handling an overall procedural burden of approximately 86.6 million cases [17]. In 2011, there were 240,980 lawsuits in the health area, and they were primarily for requests of medications [18].

With regard to social distortions, studies have revealed that lawsuits can deepen the inequity of access to care in a health system already characterized by socioeconomic inequality. When individuals with better socioeconomic conditions, who are not participants of the SUS and are financially able to afford the lawsuits, are therefore favored. By favoring a few individuals, lawsuits interfere negatively with the principles of the SUS (universality and equity) because these demands shift the resources that should serve the majority (especially those who need it the most) in order to serve a few with smaller necessities [3,5,19].

The political distortions, lawsuits can interfere and cause distortions in the national medicines policy and force the government to provide medicines outside the SUS formulary, with little evidence of their efficacy and safety and which have higher costs.

This event may occur due to the members of the judiciary and the Public Prosecutor's Office lacking the technical knowledge to interpret these policies. In lawsuits, there is no trial with competing experts and the judge decides based solely on the information provided in the plaintiff's request. In this case, the Government has not given an opportunity to answer the plaintiff's demand. The government has to comply with the judicial decision within the deadline stipulated by the judge. Such distortions can compromise the rational use of medicines [20].

Therefore, health judicialization has created tensions and motivated discussions about its legitimacy and the technical and/or legal and institutional competence of the judiciary system to decide about the content and the implementation issues of the state provision as implemented by the Executive Branch. In addition, it has caused an increasing number of individual demands for medications that increase public spending [2,3].

To rationalize these distortions, Brazil and other Latin American and Caribbean countries such as Chile, Costa Rica, Mexico, Peru, Uruguay and Argentina have proposed strategies, such as the creation of spaces for discussion between the actors in the health and judicial systems that help in the decision-making process according to the necessities of the population. For that, technical and scientific consultation committees were created to aid operatives of the law before filing a health-related lawsuit. Such strategies have helped in rationalizing the finite health resources, creating interinstitutional dialog between the actors of the Executive Branch and Judiciary and reducing new judicial demands, but initially, this is an increase in the bureaucratic system [21,22,23].

In Brazil, the creation of the Department of Assessment of Non-Standardized Medicines (Departamento de Avaliação de Medicamentos Não Padronizados - DAMNP) and the Technical Chamber of Health Assessment (Câmara de Avaliação Técnica em Saúde - CATS) were strategies deployed by a Brazilian state. The DAMNP was a department created by the Executive Branch in 2006 to exclusively analyze the technical and scientific rationality of medicines solicited by the users of the public health system by using an administrative case that has a prescription and a medical report. The technical analysis is performed by the pharmacists who evaluate the demands according to the norms of policies and the national legislation in force. When the solicited medicine outside the SUS formulary, the pharmacists suggest its replacement by one that belongs to the official lists of SUS. This strategy is responsible for establishing access protocols to medications in the Executive Branch and, when necessary, for the inclusion or exclusion of medicines on the official lists of the SUS medicines [24].

The CATS was created in 2009 by the Public Prosecutor's Office of the same Brazilian state in order to offer technical support to public prosecutors about medicines solicited by the users of the public and private health systems [25]. The opinions are from medical experts and pharmacists who analyze the content of the medical prescriptions and the report based on medical and scientific criteria and on pharmaceutical policies in force. Beyond that, these professionals, when possible, can train the providers to prescribe therapeutic alternatives made available by the SUS. It has contributed to perfecting access protocols for medicines in the Executive Branch, suggesting medicines to be incorporated into the policies and cut down on legal costs and bring evidence and expertise to the issue rather than just having lawyers try to sort this out [25].

The purview of the CATS was reaffirmed in 2010 when a technical cooperation agreement was signed between the Executive Branch and the Public Prosecutor's Office. This agreement decreed that all demands for medicines not available under the official SUS lists would be resolved through the creation of an administrative case in the Executive Branch; institutionalizing the administrative case was viewed as a way to reduce the number of lawsuits [26].

It was noted that these strategies were adopted by jurists and health managers in many Brazilian states and conveyed respect for constitutional principles, such as the right to health as an aspect of human dignity and an access to justice [27,28,29]. However, little is known about the effects of these strategies regarding the negative repercussions caused by the judicialization of the health system. This gap in knowledge motivates the question: Do institutional strategies reduce social, economic and political distortions that the judicialization of medicine access brings to public administration?

In this context, the objective of this study was to evaluate the effects of two institutional strategies adopted by a Brazilian municipality in order to face economic, social and political distortions that involved the judicialization of access to medicine phenomenon.

Methods

Data source and study setting

This was a longitudinal study whose objective was to assess the lawsuits that sued for the requests of medicine from the Executive Branch before and after the deployment of two institutional strategies in a state capital in the Central-West Region of Brazil. These were deployed in order to contend with the distortions caused by the judicialization of access to medicine.

To analyze these lawsuits, a period from 2003 to 2015 was chosen. The data were collected in July of 2016 in the Pharmacy of Health-related Products and Special Medications, a unit responsible for archiving and attending to such demands. Lawsuits that solicited at least one medicine were included in the study.

In total of 3,335 lawsuits that requested health goods or services from January 2003 to December 2015 were identified; of these, 2,557 solicited at least one medication.

The random simple type of calculation for the sample was used that was stratified by the year of the lawsuit, using a statistical power of 80 (β = 20%), a confidence interval of 95% (α = 0,05) and an accuracy level of 5%. A total of 568 lawsuits were selected, of which 31 were excluded due to incomplete information and 26 were excluded for non-retrieval of the solicited medication, yielding a total sample size of 511 lawsuits during the analyzed time period. The lawsuits that occurred during the year of the deployment of the policy (a transitional period) were removed from the analysis. Were pulled out 50 lawsuits in the CATS implementation year, and 97 lawsuits in the DAMNP implementation year (Figure 1).

Variables

The lawsuit data were collected using a form standardized by the researchers after reviewing variables that were investigated in a prior study done in Brazil [30], which included the following: (i) sociodemographic characteristics and the disease(s) of the plaintiffs; (ii) characteristics of the medications solicited in the lawsuits; and (iii) the institutional strategies.

(i) Sociodemographic characteristics and the disease(s) of the plaintiffs

The sociodemographic characteristics and the disease of the plaintiffs included age (years), sex (male/female), the prescription's origin (were prescribed by a SUS clinician or private system clinician), and income (mean monthly income of the head of the household, expressed in U.S. dollars) estimated according to the 63 Territorial Planning Units (Unidade Territorial de Planejamento-UTP) of the capital and acquired from the 2010 census data [31]; disease(s) were classified according to the International Statistical Classification of Diseases and Related Health Problems (ICD) [32] and reported in the medical report included within the lawsuit.

(ii) Characteristics of the medications solicited in the lawsuits

The characteristics of the requested medicines in the lawsuits were as follows: the amount of medication(s) requested; the classification of the medications according to the *Anatomical Therapeutic Chemical Classification* [ATC] [33]; and the total cost of the medicines in the lawsuit (relative only to the sum of the costs of the medicines requested based on the price of the Bank of Health Prices of the Ministry of Health) [34]. Medications were also classified according to their position with regard to the official lists (it is on the medicines list and is provided free of charge). The categories included: (1) within the SUS formulary (belonging to the official lists of medications of SUS); (2) outside the SUS formulary (per the official SUS lists of medications) but with a therapeutic alternative available from SUS through the third level of the ATC classification (No or Yes) [32]; or (3) outside the SUS formulary and without a therapeutic alternative available from SUS (No or Yes) [8].

(iii) Institutional strategies

The group of institutional strategies considered by the Department of Assessment of Non-Standardized Medicines (Departamento de Avaliação de Medicamentos Não Padronizados-DAMNP) and the Technical Chamber of Health Assessment (Câmara de Avaliação Técnica em Saúde-CATS).

The variables related to the interventions were used according to previously published studies [35,36]. Two dummy variables were created in a dichotomized fashion: (0) pre-intervention period and (1) post-intervention period. In this manner, the lawsuits were coded with "0" if they were filed before the deployment of each intervention and with "1" if they were filed after the deployment of the interventions. The lawsuits that occurred in the year of the intervention deployment (the transitional period) were removed from the analysis in order to avoid potential bias (Figure 2). The coding was done by a specialist researcher. The coding of the variables analyzed in the study is shown in Table 1.

Statistical Analysis

The data were analyzed using the SATA software, version 14.0. The Shapiro-Wilk (SW) test was used to verify the normality of the quantitative variables [37]. An initial descriptive analysis of the lawsuits included in the sample was performed, and the qualitative variables were represented as absolute and relative frequencies and the quantitative variables as the mean, standard deviation (SD), median and interquartile range (IQR) [38].

To verify the effect of the three institutional strategies on the economic and political characteristics of the lawsuits, the following were considered dependent variables: (i) total cost of medications in the lawsuit; (ii) lawsuits with medicines within the SUS formulary; (iii) lawsuits with medicines outside the SUS formulary but with a therapeutic alternative available from SUS; and (iv) lawsuits with medicines outside the SUS formulary and without a therapeutic alternative available from SUS. For the statistical analysis, the deployment of the strategy was entered as a variable. This variable was further categorized by period of occurrence as a pre-deployment or a post-deployment strategy. To prevent potential bias, the lawsuits that occurred during the year of the deployment of the policy (a transitional period) were removed from the analysis.

To analyze the effects of the interventions and the determinants of the total cost of the medications, bivariate and multiple linear regressions with robust variance were performed [39,40]. The following were considered determinants in the cost of the process: prescription's origin, quantity of medicines and disease. Variables with $p<0.20$ in the bivariate analysis were included in the multiple regression model. Characteristics of the plaintiffs (age, sex and income)

were also included in the adjustment of the regression model. Due to the asymmetrical nature of the date related to the costs, bootstrapped standard errors (based on 1,000 replications) were calculated to obtain 95% confidence intervals to adjust the regression coefficient [41,42] beyond the logarithmic transformation of the data [38]. The models were analyzed for multicollinearity using the variance inflation factor (VIF) test [43], for the distribution of residues using the SW test [37] and for homoscedasticity using the White test [44].

To verify the effect of interventions on categorical outcomes, Poisson regressions with robust variance were performed [45,46]. The models were adjusted by the following variables: prescription's origin and interventions. In all analyses, values of p<0,05 were considered statistically significant.

Results

In the 511 processes analyzed, 1501 medicines were requested. The mean age of the plaintiffs was 42.8 years (SD+24.7), 57.1% were males, the median age was 43.0 years (20.0-64.00); the mean income was US$1409.6 (SD±1101.8) (above poverty), and the median was US$1036.9 (680.5-1506.5); the mean cost of medications of the lawsuits was US$1.483.3 (SD+4.345.7), and the median was US$406.2 (143.9-1198.6); and the mean quantity of medications requested was 2.9 per lawsuit (SD±2.4), and the median was 2.0 (1.0-4.0) (Table 2).

Regarding the origins of the prescriptions, a greater proportion of prescriptions in administrative cases were prescribed by a SUS clinician (71.8%). The most frequent diseases were of the genitourinary system (27.2%), the circulatory system (21.3%) and the nervous system (16.4%) (Table 2).

In relation to the classification of the medicines requested in the lawsuits, a majority of medicines outside the SUS formulary was observed (54.6%) as follows: 27.7% for the digestive tract and metabolism, 27.6% for the cardiovascular system and 20.9% for the nervous system (Table 3).

The table 4 and 5 show the number of medicines requested in lawsuits by Anatomical Therapeutic Chemical Classification by year (2003-2015).

The costs of medicines requested were less after the deployment of the DAMNP (p<0.005) and the CATS (p<0.001); there was a reduction in the frequency of medicines within the SUS formulary after the deployment of the DAMNP (p=0.039) and of the CATS (p=0.020); there was an increase in the requests for medicines outside the SUS formulary with a therapeutic alternative after the deployment of the DAMNP (p=0.028) and the CATS (p<0.001); and there was an increase in lawsuits with prescriptions prescribed by a SUS clinician after the deployment of the CATS (p<0.002) (Table 6).

Table 7 shows the bivariate and multivariate regression of the effects of the strategies and the other determinants of the total medicine cost in the lawsuits. The effects of the strategies and the determinants on the total cost of the medications in the lawsuits are shown in Table 7. The final model explained 14.0% of the variability of the costs of the medications in the lawsuits (R2:14.0). A reduction in the costs was noted after the deployment of the DAMNP (β:-0.20; p<0.001) and of the CATS (β:-0.25; p<0.001) (Table 7). The income of the plaintiff and the quantity of the medications were positively and independently associated with the cost.

Table 8 shows an 19% reduction in the prevalence of medicines within the SUS formulary (APR:0.81; p=0.032) and an increase in the prevalence of medicines outside the SUS formulary with a therapeutic alternative (APR:1.38; p=0.011) after the deployment of the CATS. The effect of the two interventions was not verified in the proportion of lawsuits with medicines outside the SUS formulary and without a therapeutic alternative.

Discussion

It was observed that institutional strategies that work in an interinstitutional manner are effective in mitigating some of the side effects of the judicialization of the right to health, such as in the reduction in the filing of new lawsuits and the people who really need access to medicines now have more barriers to it's access. A similar reduction was also observed in a previous study in Brazil [30].

For the justice system, the reduction in the procedural burden involving the requests for medicines can contribute to a reduction in the administrative cost of lawsuits, such as: employee expenses, consumables, paper and etc. Although these costs are hard to measure, the Institute of Applied Economic Research (Instituto de Pesquisa Econômica Aplicada - IPEA) determined that the cost of a first-degree process of tax enforcement is US$2,143.56, and this serves as a parameter for the cost of a lawsuit in the health area [47]. Therefore, the reduction of these costs allows for the allocation of the resources of the Judiciary to cases that are not related to health care.

However, the reduction in the costs of the medicines in the lawsuits does not necessarily imply a reduction in the spending by the secretaries of health for medicines outside of the paths that are institutionalized by public policy. In this case, although the Executive is able to reduce the purchase of medicines by lawsuits, the expenses still remain. What happens is a management and better control of what is being requested. CATS can manage better because it can modify the prescription order and replace it with some medicines within the SUS formulary, while in court this does not happen anymore, the judge orders the supply of the medicine, without the option to check if there is an available and cheaper alternative for the Executive.

In addition, if the State remains inefficient in promoting the access to such items, the necessities of the citizens will still remain, and the needs of the citizens may motivate a shift of requests for medicines from the lawsuits to the administrative cases.

It is evident that a reduction in the costs of medicines in the lawsuits benefits society, which is responsible for the financing of the health and justice systems in Brazil through social contributions and the payment of taxes. In this way, the deployment of institutional strategies favors the collective well-being and guarantees access to medicines within the SUS formulary and at a more acceptable cost to society.

The observed reduction in the medicines within the SUS formulary is related to the creation and deployment of institutional strategies adopted by the municipality; the necessities of the users were evaluated by a technical team that was knowledgeable about public health policies, had the ability to

comprehend and assess the individual needs of the plaintiffs, and could provide feedback to instruct users about the SUS formulary for the requested medication, making litigation unnecessary in the justice branch. The two strategies prioritized the requests of citizens through the institutionalized or the administrative cases; therefore, the requests for medicines that were not included on the official lists were addressed using the legal route, as demonstrated by other studies [2,3,48].

However, the deployment of the CATS strategies increased the prevalence of requests for medicines outside the SUS formulary but with a therapeutic alternative. It was assumed that these institutional strategies would lower these requests because in their feedback they proposed options for treatment with medications that had the same efficacy and were available through the SUS. This finding is likely a result of prescribing medicines in an acritical manner, often without scientific evidence, or because of pressure from the pharmaceutical industry or the prescribers' non-adherence to the SUS formulary [49]. These situations indicate how pharmacological and economic irrationalities could be avoided if magistrates took advantage of the technical opinions of the CATS before filing a lawsuit, as recommended by the National Council of Justice [28].

The prevalence of requests for medicines outside the SUS formulary without a therapeutic alternative was not influenced by institutional strategies, proving the need to update policies and incorporate new technologies by the SUS. Legal demands for medicines are justified when the provision that is provided for in the policies is not guaranteed or when the request involves medicines whose treatment is not covered by the policies and those that do not have a therapeutic alternative, reflecting gaps in care [4].

It is known that the process of incorporating new technologies is a determining factor in the increase in spending on health systems in many countries [50]. Accordingly, Brazil has passed law number 12,401/2011 [51] and the decree number 7,508/2011 [52], which introduce modifications and additions to the law number 8,080 of 1990 [53], referring to therapeutic assistance and the incorporation of technologies in the SUS. However, political and market pressure is still observed in favor of incorporating the medicines that are most requested in the lawsuits on the SUS formulary [54].

In relation to another political aspect of health judicialization, the increase in cases with prescriptions prescribed by a SUS clinician after the deployment of the CATS that was observed in this study demonstrated two possible situations. The first indicates that an improvement in access to medical appointments in the public system by the plaintiffs is responsible; the second entails the use of the SUS by users of the private system only to obtain a transcription of the prescription by a professional accredited to the SUS. This last situation has been a recurrent practice in which users seek to overcome the lack of coverage of medications in the private system and exhibit a private public mix, that is, they seek medical assistance that is guaranteed by the private system and access to medications provided by the public system [55].

With regard to the social aspects, it was observed that the profile of the plaintiffs filing the lawsuits did not change after the deployment of the strategies; the population was still characterized by a higher income, and they were privileged by their ability to afford doctor appointments in the private system and the expenses related to the lawsuits. Other studies have also suggested that health judicialization benefits those citizens with better economic status, and therefore, it worsens the inequities in the access to health care [19,56].

It is well known that health judicialization is a multidimensional problem, but the larger concern is the actual effectiveness of the pharmaceutical care provided by the health system. The management of the pharmaceutical service must reorient its actions and guarantee access to essential medications that are established in the pharmaceutical policy according to the principles of the SUS. The justice system should only be used when this access is not guaranteed.

As a matter of fact, health judicialization brought changes in the social and institutional relationships to guarantee the integrity of health care in the face of the social demands and deficiencies of the public health system. In addition, it created formal spaces for dialog between the justice and health systems, which is fundamental for ensuring effective public policy, such as the DAMNP and CATS strategies. These strategies did not eliminate lawsuits, but they rationalized some economic and political distortions and normalized access to medicines outside the SUS formulary and took into consideration the alternatives made available by the SUS and other clinical protocols in force.

The benefits generated by the deployment of institutional strategies should not be analyzed only from the perspective of the health system. The clinical rationality and the right to health benefits, physical integrity and well-being aspect of human dignity of the population should be considered. The Brazilian citizens who pay taxes and finance the public health system expect that resources destined to health treatment are used in an adequate manner that benefits their own health and that of their families. Thus, it is important to assess at what point the economic interests of the State to reduce spending with health judicialization overcomes the real necessities of the user.

With the implementation of institutional strategies, the necessities of the users were evaluated by a technical team that was knowledgeable about public health policies had the ability to comprehend and assess the individual needs of the citizens, proving the need to update policies and incorporate new technologies, with evidence, efficacy and safety and which have lower costs. These actions improve access to medicines.

Hopefully, the results of this study can serve as a model for many health and justice systems in other countries where health judicialization is practiced, and these findings can contribute to restructured and enhanced policies, guaranteed access to essential medicines in an equanimous manner and special attention to the needs of the people who depend on the health systems for their therapeutic treatment.

Limitations

The limitations of this study that require consideration in the interpretation of the results include the unavailability of data in a few of the analyzed lawsuits, such as age, the plaintiff´s income, the origin of the prescription, the information on the health care provider and the clinical history of the plaintiff. The

lawsuits with incomplete data (n=31) that were not analyzed may have influenced the results of the analyses. The inability to determine the social conditions of the plaintiffs also limited providing a deeper discussion on the equity and the social aspects that are involved in the judicialization phenomenon.

Conclusions

The strategies have helped in rationalizing the finite health resources, creating interinstitutional dialog between the actors of the Executive Branch and Judiciary and reducing new judicial demands, but initially, this is an increase in the bureaucratic system. The DAMNP and CATS deployed by the Executive Branch and Public Prosecutor's Office were important tools in the reduction of the elevated costs of medications in the lawsuits, representing progress for the State and a benefit to society. The results show that adopting these institutional strategies can be an effective path for other health and justice systems in Brazil and in other countries.

New studies are needed to evaluate the effects of institutional strategies on the inequalities caused by health judicialization, with the objective of guaranteeing access to health care for people in an equanimous way.

In fact, the judicialization of health brings significant changes in institutional relations, with challenges for management. In practice, pharmaceutical service management must reorient its actions and guarantee access to essential medications that are established in the pharmaceutical policy, proving the need to update policies and incorporate new technologies, making litigation unnecessary in the justice branch.

Abbreviations

ATC: Anatomical Therapeutic Chemical; APR: Adjusted Prevalence Ratio; CI: Confidence Interval; ICD: International Statistical Classification of Diseases and Related Health Problems; CATS: Technical Chamber of Health Assessment; DAMNP: Department of Assessment of Non-Standardized Medicines; IQR: Interquartile Range; PR: Prevalence Ratio; SD: Standard Deviation; SUS: Brazilian Universal Health System; UTP: Territorial Planning Units.

Declarations

Ethics approval and consent to participate

Administrative permission to use the raw data was provided by the Municipal Secretary of Health after the author registered the above research for approval by the Research Ethics Committee of the Federal University of Goiás (Comitê de Ética em Pesquisa da Universidade Federal de Goiás) (Protocol nº 713.754/2014). Access was given on three conditions. First was that the data is used only by the author and only for the purpose of the registered research or study. Secondly, the should be treated as confidential, and no effort should be made to identify any granted cases. Thirdly, the author is required to submit a copy of any reports/publications resulting from using the granted cases. The institutional review board waived the informed consent because used secondary data.

Consent to publish

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to the data belong to the Pharmacy of Health-related Products and Special Medications that is a public institution where data of granted cases are kept. According to the regulations of the entity, data cannot be disseminated or shared but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

All of the authors participated in writing the manuscript. Data analysis was performed by RAG; data collection was performed by VOC and PAPM; study design, ethical oversight, interpretation and critical revision of results was provided by VOC, MPP, PAPM, RAG and RGA. All authors read and approved the final manuscript.

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Tables

Table 1. Codding of the variables in the study

Variables	Operational definition	Categories or unity
Characteristics of the lawsuits		
Sex	Plaintiff's sex	0 - Male 1 - Female
Age	Plaintiff´s age	Age in years
Income	Plaintiff´s income	Dollars
Cost of medicines	Total cost of medicines in the lawsuit	Dollars
Quantity of medicines	Total amount of medicines in the lawsuit	Number (n)
Prescription´s origin	Type of healthcare establishment in which the requested medicine was prescribed	0 – Prescribed by a SUS clinician 1 – Prescribed by a private system clinician
Diseases	Plaintiff´s disease according to ICD[1] [30]	0 - Certain infectious and parasitic diseases 1- Neoplasms 2 - Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism 3 - Endocrine, nutritional and metabolic diseases 4 - Mental and behavioural disorders 5 - Diseases of the nervous system 6 - Diseases of the eye and adnexa 7 -Diseases of the circulatory system 8 - Diseases of the respiratory system 9 - Diseases of the digestive system 10 -Diseases of the musculoskeletal system and connective tissue 11 -Diseases of the genitourinary system
Characteristics of the medicines		
ATC[2] Classification	Classification of the medicines according to the World Health Organization's classification [31]	1. Alimentary tract and metabolism 2. Blood and blood forming organs 3. Dermatological 4. Cardiovascular system 5. Genital and urinary system and sex hormones 6. Systemic hormonal preparations 7. Anti-infective for systemic use 8. Antineoplastic and immunomodulation agents 9. Muscular-skeletal system 10. Nervous system 11. Anti-parasitic products, insecticides and repellents 12. Sensory organs 13. Various
Classification of the medicines	Classification of medicines according to official lists of SUS[3] [8]	
Within the SUS formulary (belonging to the official lists of medications of SUS)		0 - No 1 – Yes
Outside the SUS formulary (per the official SUS lists of medications) but with a therapeutic alternative available from SUS		0 – No 1 - Yes
Outside the SUS formulary and without a therapeutic alternative available from SUS		0 – No 1 - Yes

Interventions	
DAMNP	0 – Period before deployment (2003-2005)
	1 – Period after deployment (2007-2015)
CATS	0 – Period before deployment (2003-2008)
	1 – Period after deployment (2010-2015)

[1]Diseases classified according to the chapter of International Statistical Classification of Diseases and Related Health Problems (ICD); [2]Anatomical Therapeutic Chemical; [3] Sistema Único de Saúde.

Table 2. Sociodemographic characteristics and diseases of plaintiffs requesting medicines from January 2003 to December 2015

Variables	n=511
Sex n (%)	
Male	292 (57.1)
Female	219 (42.9)
Age (years)	
Mean (SD)[1]	42.8 (24.7)
Median (IQR)[2]	43.0 (20.0-64.0)
Income (US$)	
Mean (SD)[1]	1409.6 (1101.8)
Median (IQR)[2]	1036.9 (680.5-1506.5)
Total costs of medications in the lawsuit (US$)	
Mean (SD)[1]	1.483.3 (4.345.7)
Median (IQR)[2]	406.2 (143.9-1198.6)
Quantity of medications n (%)	
Mean (SD)[1]	2.9 (2.4)
Median (IQR)[2]	2.0 (1.0-4.0)
Prescription´s origin n (%)	
Prescribed by a SUS clinician	77 (28.2)
Prescribed by a private system clinician	196 (71.8)
Diseases[3] n (%)	
Certain infectious and parasitic diseases	5 (1.0)
Neoplasms	7 (1.4)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	4 (0.8)
Endocrine, nutritional and metabolic diseases	71 (13.9)
Mental and behavioural disorders	77 (15.1)
Diseases of the nervous system	84 (16.4)
Diseases of the eye and adnexa	17 (3.3)
Diseases of the circulatory system	109 (21.3)
Diseases of the respiratory system	17 (3.3)
Diseases of the digestive system	27 (5.3)
Diseases of the musculoskeletal system and connective tissue	28 (5.5)
Diseases of the genitourinary system	139 (27.2)

[1]Standard deviation; [2]Interquartile range; [3]Diseases were classified according to the chapters of International Statistical Classification of Diseases and Related Health Problems (ICD).

Table 3. Characteristics of medicines requested in lawsuits from January 2003 to December 2015 (n=1.501)

Variables	n (%)
ATC Classification[1]	
Alimentary tract and metabolism	416 (27.7)
Blood and blood forming organs	75 (5.0)
Cardiovascular system	414 (27.6)
Dermatological	20 (1.3)
Genital and urinary system and sex hormones	42 (2.8)
Systemic hormonal preparations	15 (1.0)
Anti-infective for systemic use	23 (1.5)
Antineoplastic and immunomodulation agents	13 (0.9)
Muscular-skeletal system	63 (4.2)
Nervous system	314 (20.9)
Anti-parasitic products, insecticides and repellents	11 (0.7)
Respiratory system	42 (2.8)
Sensory organs	47 (3.1)
Various	5 (0.4)
Classification of medicines	
Within the SUS formulary	685 (45.7)
Outside the SUS formulary with a therapeutic alternative	430 (28.6)
Outside the SUS formulary without a therapeutic alternative	386 (25.7)

[1] *Anatomical Therapeutic Chemical*

Table 4. Number of medicines requested in lawsuits by Anatomical Therapeutic Chemical Classification by year (2003-2009)

Variables	2003 n (%)	2004 n (%)	2005 n (%)	2006 n (%)	2007 n (%)	2008 n (%)	2009 n (%)	Total n
ATC Classification								
Alimentary tract and metabolism	6 (12.8)	16 (11.7)	80 (22.0)	110 (39.0)	70 (48.3)	36 (26.9)	15 (10.7)	333
Blood and blood forming organs	2 (4.3)	3 (2.2)	25 (6.9)	8 (2.8)	9 (6.2)	7 (5.2)	10 (7.1)	64
Cardiovascular system	11 (23.4)	41 (29.9)	146 (37.5)	62 (22.0)	32 (22.1)	42 (31.3)	42 (30.0)	376
Dermatological	1 (2.1)	-	3 (0.8)	3 (1.1)	-	-	9 (6.4)	16
Genital and urinary system and sex hormones	1 (2.1)	9 (6.6)	13 (3.6)	6 (2.1)	-	2 (1.5)	6 (4.3)	37
Systemic hormonal preparations	2 (4.3)	3 (2.2)	5 (1.4)	2 (0.7)	-	1 (0.7)	1 (0.7)	14
Anti-infective for systemic use	1 (2.1)	4 (2.9)	6 (1.7)	4 (1.4)	-	3 (2.2)	4 (2.9)	22
Antineoplastic and immunomodulation agents	-	-	2 (0.6)	5 (1.8)	2 (1.4)	-	1 (0.7)	10
Muscular-skeletal system	4 (8.5)	7 (5.1)	8 (2.2)	7 (2.5)	-	6 (4.5)	8 (5.7)	40
Nervous system	16 (34.0)	37 (27.0)	53 (14.6)	59 (20.9)	30 (20.7)	27 (20.1)	30 (21.4)	252
Anti-parasitic products, insecticides and repellents	-	1 (0.7)	5 (1.4)	5 (1.8)	-	-	-	11
Respiratory system	1 (2.1)	10 (7.3)	11 (3.0)	5 (1.8)	-	4 (3.0)	8 (5.7)	39
Sensory organs	2 (4.3)	6 (4.4)	16 (4.4)	6 (2.1)	2 (1.4)	6 (4.5)	4 (2.9)	42
Various	-	-	-	-	-	-	2 (1.4)	2
Total	47 (100.0)	137(100.0)	373(100.0)	282(100.0)	145(100.0)	134(100.0)	140(100.0)	1258

Table 5. Number of medicines requested in lawsuits by Anatomical Therapeutic Chemical Classification by year (2010-2015)

Variables	2010 n (%)	2011 n (%)	2012 n (%)	2013 n (%)	2014 n (%)	2015 n (%)	Total n
ATC Classification							
Alimentary tract and metabolism	36 (52.9)	25 (43.9)	17 (29.3)	2 (28.6)	2 (5.3)	1 (4.0)	83
	2 (2.9)	3 (5.3)	2 (3.4)	-	2 (5.3)	2 (8.0)	11
Blood and blood forming organs							
Cardiovascular system	8 (11.8)	17 (29.8)	11 (19.0)	-	7 (18.4)	5 (20.0)	48
Dermatological	1 (1.5)	-	-	-	3 (7.9)	-	4
Genital and urinary system and sex hormones	1 (1.5)	-	2 (3.4)	-	2 (5.3)	-	5
Systemic hormonal preparations	-	-	-	-	1 (2.6)	-	1
Anti-infective for systemic use	-	1(1.8)	-	-	-	-	1
Antineoplastic and immunomodulation agents	-	-	1 (1.7)	1 (14.3)	1 (2.6)	-	3
Muscular-skeletal system	3 (4.4)	4 (7.0)	8 (13.8)	-	8 (21.1)	-	23
Nervous system	11 (16.2)	5 (8.8)	14 (24.1)	4 (57.1)	12 (31.6)	16 (64.0)	62
Anti-parasitic products, insecticides and repellents	-	-	-	-	-	-	
Respiratory system	1 (1.5)	2 (3.5)	-	-	-	-	3
Sensory organs	4 (5.9)	-	1 (1.7)	-	-	-	5
Various	1 (1.5)	-	2 (3.4)	-	-	1 (4.0)	4
Total	68 (100.0)	57 (100.0)	58 (100.0)	7 (100.0)	38(100.0)	25(100.0)	253

Table 6. Plaintiffs´ incomes, cost of medicines of the lawsuits, origin of the prescription and classification of medicines in the lawsuits in periods before and after the deployment of the Department of Assessment of Non-Standardized Medicines (DAMNP) and Technical Chamber of Health Assessment (CATS)

Variables	DAMNP (2006)		*p*	CATS (2009)		*p*
	Before deployment (2003-2005)	After deployment (2007-2015)		Before deployment (2003-2008)	After deployment (2010-2015)	
Income of Plaintiffs						
Mean (SD)[1]	1231.4 (858.7)	1458.2 (1182.8)	**0.009**[3]	1393.4 (999.8)	1458.2 (1215.2)	0.575[3]
Median (IQR)[2]	1004.5 (680.5-1263.8)	1137.8 (680.5-1263.8)		1004.5 (680.5-1263.8)	972.1 (680.5-1263.8)	
Cost of medicines in the lawsuit						
Mean (SD)[1]	1.661.1 (4.561.7)	779.2 (1.589.6)	**0.005**[3]	1.884.1 (5.054.8)	586.7 (1.640.3)	**< 0.001**[3]
Median (IQR)[2]	659.7 (188.6-1622.1)	285.6 (101.0-195.8)		541.1 (191.6-1759.4)	250.3 (94.5-616.3)	
Prescription´s origin, n (%)						
Prescribed by a SUS clinician	20 (25.6)	38 (31.4)	0.382[4]	46 (22.4)	24 (43.6)	**0.002**[4]
Prescribed by a private system clinician	58 (74.4)	83 (68.6)		159 (77.6)	31 (56.4)	
Classification of medicines, n (%)						
Within the SUS formulary	261 (47.7)	281 (41.8)	**0.039**[4]	548 (49.5)	104 (41.1)	**0.020**[4]
Outside the SUS formulary with a therapeutic alternative	145 (26.5)	217 (32.3)	**0.028**[4]	289 (26.1)	94 (37.2)	**< 0.001**[4]
Outside the SUS formulary without a therapeutic alternative	141 (25.8)	174 (25.9)	0.963[4]	271 (24.4)	554 (21.7)	0.360[4]

Standard deviation; [2]Interquartile range; [3]*Mann-Whitney Test;* [4]Pearson´s chi-squared test.

ble 7. Determinants and effects of institutional strategies on the costs of medications requested in lawsuits from January 2003 to December 2015

Variables	Bivariate regression		Multivariable regression[3]	
	β[1] (IC 95%)[2]	p	β[1] (IC 95%)[2]	p
aintiffs´ characteristics				
ge (years)	0.05 (-0.10; 0.21)	0.517		
ex				
ale	1.00			
emale	-0.09 (-0.38; 0.18)	0.502		
come (US$)	0.45 (0.23; 0.66)	< 0.001	0.41 (0.22-0.61)	< 0.001
haracteristics of the lawsuits				
uantity of medicines	0.13 (0.07; 0.19)	< 0.001	0.17 (0.12-0.23)	< 0.001
rigin of the prescriptions				
escribed by a SUS clinician	1.00			
escribed by a private system clinician	0.84 (0.42; 1.27)	< 0.001		
seases				
ertain infectious and parasitic diseases	-0.84 (-2.29; 0.60)	0.252		
eoplasms	1.40 (0.18; 2.62)	0.024		
seases of the blood and blood-forming organs and certain disorders involving the immune mechanism	-1.84 (-3.45; -0.23)	0.025		
ndocrine, nutritional and metabolic diseases	-0.25 (-0.80; 0.01)	0.057		
ental and behavioural disorders	0.07 (-0.33; 0.46)	0.740		
seases of the nervous system	-0.26 (-0.64; -0.12)	0.178		
seases of the eye and adnexa	-0.55 (1.34; 0.24)	0.172		
seases of the circulatory system	-0.21 (-0.56; 0.13)	0.220		
seases of the respiratory system	-0.04 (-0.83; 00.75)	0.917		
seases of the digestive system	0.19 (-0.43; 0.83)	0.543		
seases of the musculoskeletal system and connective tissue	-2.42 (-4.99; 0.15)	0.066		
	-0.29 (-0.92; 0.32)	0.348		
terventions				
AMNP[4]				
efore deployment	1.00		1.00	
ter deployment	-0.36 (-0.51; -0.20)	< 0.001	-0.20 (-0.37; -0.10)	< 0.001
ATS[5]				
efore deployment	1.00		1.00	
ter deployment	-0.48 (-066; -0.31)	< 0.001	-0.25 (-0.30; -0.10)	< 0.001
			R^2: 0.140 R^2 adjusted: 0.132	

egression coefficient; [2]Confidence interval of 95% ;[3]Model adjusted by sex, age, origin of the prescription, quantity of medicines, neoplastic diseases, blood diseases, endocrine diseases, diseases of the eomuscular system and strategies (DAMNP e CATS); [4]Period before the deployment of [5]Department of Assessment of Non-Standardized Medicines: 2003-2005/Period after the deployment of Department of essment of Non-Standardized Medicines: 2007-2015; [5]Period before deployment of Technical Chamber of Health Assessment: 2003-2008/ Period after deployment of Technical Chamber of Health essment: 2010-2015.

Table 8. Analysis of Poisson´s regression of the effects of the deployment of DAMNP and CATS on the prevalence of medicines that are within the SUS forr outside the SUS formulary with a therapeutic alternative and without therapeutic alternative available by the SUS

Variables	Medicines within the SUS formulary[3]		Medicines outside the SUS formulary with a therapeutic alternative[3]		Medicines outside the SUS formulary without a therapeutic alternative[3]	
	APR[1] (95.0% CI)[2]	p	APR[1] (95.0% CI)[2]	p	APR[1] (95.0% CI)[2]	p
DAMNP[4]						
Before deployment	1.00		1.00		1.00	
After deployment	1.07 (0.93-1.24)	0.307	1.38 (0.80-1.29)	0.867	0.83 (0.63-1.34)	0.183
CATS[5]						
Before deployment	1.00		1.00		1.00	
After deployment	0.81 (0.67-0.98)	**0.032**	1.38 (1.07-1.78)	**0.011**	0.97 (0.70-1.34)	0.866

[1]Adjusted Prevalence ratio; [2]Confidence interval of 95%; [3]Model adjusted according to the origin of the prescription, DAMNP and CATS. [4]Department of Assessment of Non-Standardized Medicines; [5]T Chamber of Health Assessment.

Figures

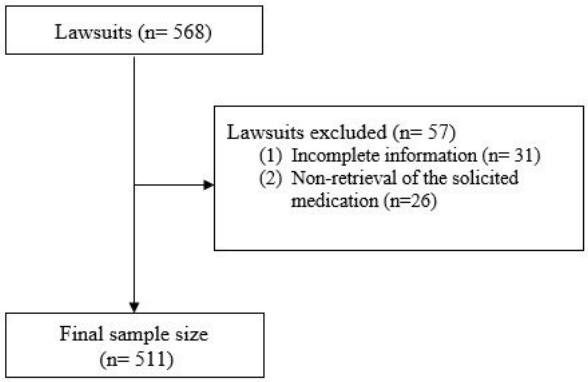

Figure 1

Flow chart of the sample size.

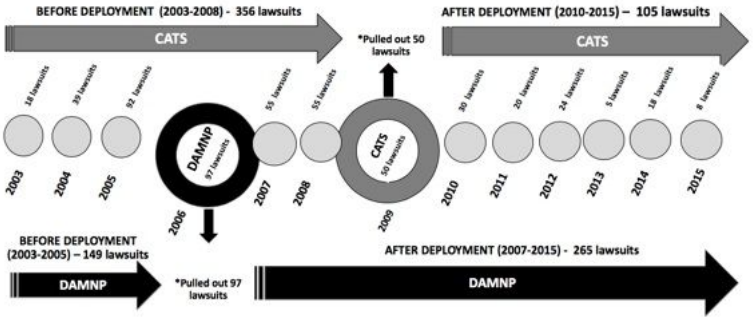

Figure 2

Scheme of data collection of lawsuits in the period before and after deployment of the Technical Chamber of Health Assessment(CATS) and the period before and after deployment of Department of Assessment of Non-Standardized Medicines (DAMNP). *pulled out 50 lawsuits in the CATS implementation year, and 97 lawsuits in the DAMNP implementation year