HEALTH JUDICIALIZATION: ACCESS TO TREATMENT FOR USERS WITH DIABETES MELLITUS

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ABSTRACT

Objective: to analyze the procedural elements and individual lawsuits filed by users with diabetes mellitus for the supply of drugs, supplies or materials to treat the disease.

Method: an exploratory documentary type quantitative study, where 636 lawsuits were analyzed in a region of São Paulo State, from 2004 to 2013.

Results: it was found that the number of cases increased from three in 2004 to 111 in 2012. In 2013 administrative measures were instituted with the aim of reducing the number of cases. In 457 (71.9%) cases the lawsuits were filed through prescription of private medical practices. Most of the lawsuits were requests for medicine that were not included on the free funding lists supplied by the Unified Health System.

Conclusion: health judicialization favors reflection on health rights and access to information on the restructuring of health services for users with diabetes mellitus.


JUDICIALIZAÇÃO DA SAÚDE: ACESSO AO TRATAMENTO DE USUÁRIOS COM DIABETES MELLITUS

RESUMO

Objetivo: analisar os elementos processuais e as ações judiciais individuais impetradas por usuários com diabetes mellitus para fornecimento de medicamentos, insumos ou materiais no tratamento da doença.


Resultados: constatou-se que o número de processos é crescente de três em 2004 até 111 em 2012. Em 2013 medidas administrativas foram instituídas com o intuito de reduzir o número de ações. Em 457 (71,9%) casos as ações foram impetradas por meio de prescrição de consultórios médicos particulares. A maioria dos processos judiciais foram solicitações de medicamentos que não constavam nas listas de financiamento gratuito pelo Sistema Único de Saúde.

Conclusão: a judicialização à saúde favorece a reflexão sobre os direitos em saúde e o acesso à informação na reestruturação dos serviços de saúde aos usuários com diabetes mellitus.

JUDICIALIZACIÓN DE LA SALUD: ACCESO AL TRATAMIENTO DE USUARIOS CON DIABETES MELLITUS

RESUMEN

Objetivo: analizar los elementos procesales y las acciones judiciales individuales conseguidas por usuarios con diabetes mellitus para el suministro de medicamentos, insumos o materiales para el tratamiento de la enfermedad.

Método: estudio cuantitativo y exploratorio de tipo documental en el que se analizaron 636 procesos judiciales en una región del interior paulista entre el 2004 y el 2013.

Resultados: se constató que el número de procesos creció de tres (3) en el 2004 hasta 111 en el 2012. En el 2013, las medidas administrativas fueron implantadas con el objetivo de reducir el número de acciones. En 457 procesos (71,9%), las acciones fueron realizadas a través de prescripciones de consultorios médicos particulares. La mayoría de los procesos judiciales fueron solicitudes de medicamentos que no constaban en las listas de financiamiento gratuito por el Sistema Único de Salud.

Conclusión: la judicialización de la salud favorece la reflexión sobre los derechos de salud y el acceso a la información sobre la reestructuración de los servicios de salud para los usuarios con diabetes mellitus.


INTRODUCTION

As a result of the Federal Constitution of 1988, health became a fundamental right of the citizen and a duty of the State and generations of fundamental rights were instituted. The first generation refers to individual rights, the second to social rights, and the third to fraternity. The first generation of rights concerns the rights of individual and political freedom and safeguards the limit to the State in the rights considered indispensable to the human person.

The second generation deals with the rights of equality and covers social and economic rights, which aim to improve the living and working conditions of the population. With regard to social rights, health appears in the second generation of fundamental rights. And the third generation of rights contemplates the rights of fraternity and solidarity.1

Unlike the first-generation rights, the second-generation rights require the state to “do”, also termed as a positive provision. Thus, the State becomes responsible for providing for the needs of the population with regard to social and economic rights.1

Thus, created by the Federal Constitution of 1988, and regulated in 1990 by the Organic Health Laws, the Brazilian Unified Health System (SUS) sought to guarantee the universal and integral right to health.1,2 In order to manage, organize, systematize and implement health actions in Brazil, the SUS has basic pillars, which translate into universality in access to services, integral care and equity in the distribution of resources. Despite the advances in public policies and actions aimed at meeting users’ demands for integral health, it is still possible to observe that the SUS faces difficulties to meet the needs of users on a regular basis.3,5 Given this, the unavailability of drugs and therapies is common which results in search for the constitutionally guaranteed right to health.6

The fact that diabetes mellitus (DM) is considered a chronic disease implies the need for continuous control and lifetime treatment, which, in itself, justifies, from a social-medical point of view, the management of the disease. Thus, the definition of health policies must meet the needs of users with DM and guarantee permanent resources for this activity, in this sense the National Commission for the Incorporation of Technologies in the SUS aims to advise the Ministry of Health on health technologies within the scope of SUS, as well as in the elaboration of clinical protocols and therapeutic guidelines.7

However, the World Health Organization reports in the Global Status Report on Noncommunicable Diseases that health systems in several countries need to review the provision of health care standards for people with chronic diseases such as DM. The issues raised for this review should include health guidelines, health information systems, health professionals, and access to essential medicines and technology.8

When considering the list of essential drugs, there is a growing demand for access to health and medicines that are not available through SUS. The State receives an increasing number of court orders that guarantee several benefits to the user. Thus, it can represent an advance in relation to the effective exercise of citizenship by the population. However, at the same time, we have the increase of the responsibility between the elaborators and the executors of the public policies in Brazil. It is acknowledged that public expenditures on health judicialization have had a significant impact on public health management in the country.3,9
In view of the above, this study aims to analyze the procedural elements and individual lawsuits filed by users with diabetes mellitus for the supply of drugs, supplies and materials to treat the disease.

METHOD

An exploratory documentary type quantitative study performed in a region of São Paulo State. The study universe consisted of all lawsuits filed against the Division of Pharmacy and Diagnostic Support of the Municipal Health Secretariat of Ribeirão Preto-SP and the XIII Regional Health Department of the State of São Paulo, demanding medication for the treatment of DM.

The study included 636 lawsuits filed by users with DM from January 2004 to December 2013. January 2004 was chosen for the identification of cases, as it was only in this year that the processes were organized and systematized.

For this study, variables related to procedural elements (case number, year of commencement, and the person responsible for conducting the action - Public prosecutor, private lawyer, public defender, university lawyer or not cited in the process) were considered; variables related to the users with DM (the medicines requested, the materials and supplies, the municipality of residence, presence of the medication in the official lists of public supply - federal, state or municipal, and the origin of the doctor’s prescription - private practice, university hospital, municipal institution, foundations/philanthropic institutions and SUS contracted doctor).

A semi structured instrument was constructed containing the study variables. This instrument was evaluated by three professionals (nurse, lawyer and pharmacist) with experience in the care of users with DM, regarding the pertinence, clarity and adequacy of the information, which was considered adequate for the purposes of the study. A pilot study was also conducted which used ten lawsuits to refine the relevance of the instrument for data collection. There was a need for minor adjustments including questions regarding medicines, supplies and materials.

Data collection was performed manually at the study site, from November 2013 to February 2014, with an average of 20 minutes to analyze each case. The data were organized, double-entered into the Microsoft Excel, XP version (Microsoft Co, USA) program and imported into the SPSS (Statistical Package for Social Sciences) program for Windows base module and exact test version 17.0. Descriptive statistics were used for the data analysis.

The study was authorized by the Municipal Department of Health and the Regional Department of Health of Ribeirão Preto - SP, after approval by the Research Ethics Committee of the Nursing School of Ribeirão Preto USP, under number 06903212.5.0000.5393. Waiver of the application of the Free and Informed Consent Form was requested, as it is a retrospective collection of lawsuits and contacting the users with DM was impossible. The plaintiffs, the prescribers and the lawyers were granted anonymity.

RESULTS

From the 636 lawsuits analyzed by users with DM, the distribution of the number of lawsuits filed by users with DM according to the year of the initiation of the process is verified (Table 1).

Table 1 - Distribution of legal proceedings according to the year in which the proceedings began. Area of coverage of DRS XIII, São Paulo, Brazil, 2014. (n=636)

<table>
<thead>
<tr>
<th>Year</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>2005</td>
<td>15</td>
<td>2.4</td>
</tr>
<tr>
<td>2006</td>
<td>44</td>
<td>6.9</td>
</tr>
<tr>
<td>2007</td>
<td>60</td>
<td>9.4</td>
</tr>
<tr>
<td>2008</td>
<td>72</td>
<td>11.3</td>
</tr>
<tr>
<td>2009</td>
<td>83</td>
<td>13.1</td>
</tr>
<tr>
<td>2010</td>
<td>81</td>
<td>12.7</td>
</tr>
<tr>
<td>2011</td>
<td>90</td>
<td>14.2</td>
</tr>
<tr>
<td>2012</td>
<td>111</td>
<td>17.5</td>
</tr>
<tr>
<td>2013</td>
<td>77</td>
<td>12.0</td>
</tr>
<tr>
<td>Total</td>
<td>636</td>
<td>100</td>
</tr>
</tbody>
</table>

From the 636 (100%) lawsuits, 402 (63.2%) were conducted by the Public Prosecutor’s Office, 199 (31.3%) by private lawyers, 29 (4.5%) by the Public Defender’s Office and five (0.8%) by a university lawyer. In 578 (90.9%) judicial cases, the State and the Municipality went to the defendant institutions, 47 (7.4%) went to the State and 10 (1.6%) went to the Municipality.

With regard to medical prescription, 457 (71.9%) legal proceedings involving drugs, materials and supplies were filed through the medical prescription from private practices, as shown in table 2.
Table 2 - Distribution of the places of the judicial processes analyzed by means of medical prescription. Area of coverage of DRS XIII, São Paulo, Brazil, 2014

<table>
<thead>
<tr>
<th>Medical prescription</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private Clinic</td>
<td>457</td>
<td>71.9</td>
</tr>
<tr>
<td>University Hospital</td>
<td>80</td>
<td>12.6</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>49</td>
<td>7.7</td>
</tr>
<tr>
<td>Municipal Institutions</td>
<td>41</td>
<td>6.4</td>
</tr>
<tr>
<td>Foundations /Philanthropic Institutions</td>
<td>7</td>
<td>1.1</td>
</tr>
<tr>
<td>SUS contracted Doctor</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>Total</td>
<td>636</td>
<td>100</td>
</tr>
</tbody>
</table>

In relation to the municipality where the DM users filed lawsuits, 470 (73.9%) of them were residents of the city of Ribeirão Preto-SP. Table 3 shows the distribution of lawsuits according to public funding.

Table 3 - Distribution of judicial processes according to public funding. Area of coverage of DRS XIII, São Paulo, Brazil, 2014. (n=636)

<table>
<thead>
<tr>
<th>Public Funding</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No funding</td>
<td>618</td>
<td>97.2</td>
</tr>
<tr>
<td>Federal</td>
<td>17</td>
<td>2.7</td>
</tr>
<tr>
<td>State</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Municipal</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>Total</td>
<td>636</td>
<td>100</td>
</tr>
</tbody>
</table>

From the 636 lawsuits filed by users with DM, 325 (51.1%) of the cases were related to obtaining insulin glargine and 25 (3.9%) sought materials or supplies for the treatment of DM. It should be noted that in 618 (97.2%) legal proceedings were requests for medicines that were not included on the SUS free funding list and that in 17 (2.7%) of them the drugs were already offered by SUS. However, in the years in which they were requested, they were not on the list, which may have led to the court order. 88 (13.8%) of the lawsuits requested the continuous infusion pump, such as infusion sets, insulin reservoirs and insulin pumps.

DISCUSSION

The increase in health judicialization found in this study is corroborated by other studies and causes us to reflect on the processes, defendants and the legitimacy of individual demands. In addition, there are still difficulties in meeting collective health needs, which may be related to the complex concept of the “existential minimum”.3-6

When analyzing the decrease in lawsuits in the year 2013, as in shown in table 1, it was observed that this does not result from a real reduction in the number of lawsuits, but from a strategy used by the internal processes service instituted in DRS XIII, called administrative processes. This strategy serves to stimulate the agreements between the Public Prosecutor’s Office, the Public Defender’s Office and those responsible for the pharmaceutical assistance of the State and the Municipality to administratively seek a solution to reduce the legal demands.

Thus, users with DM are firstly asked to open an administrative process, which is analyzed by a committee composed of health managers, pharmacists and physicians. Thus, the demands are met in an administrative and non-judicial manner. If these demands are not met by the administrative process, the user with DM also has the judicial alternative.

The continuous increase in the number of lawsuits (Table 1) and the received demands bring permanent expenses to SUS, as they guarantee the treatment until the death of the user with DM or until there is a change in the established therapy. Accordingly, the quantity of lawsuits jumped from three (0.5%) in 2004 to 77 (12.1%) in 2013. In summary, 636 lawsuits were continuously served in the municipality of Ribeirão Preto-SP and region, referring to the coverage area of DRS XIII in the period studied.

The proportion of lawsuits filed by the plaintiff represents a relevant indicator in the evaluation of such lawsuits.6 In analyzing the representation of the plaintiff, 431 (67.7%) were represented by Public Judicial Institutions, of which 402 (63.2%) were the Public Prosecutor’s Office and 29 (4.5%) were the Public Defender’s Office (Table 2). Thus, there was a predominance of actions filed by Judicial Institutions which is in line with other studies.5,9

The actions filed by private attorneys represented 199 (31.3%) of the cases. These data stimulate the reflection on the possibility of users with DM to cope with the demands of the treatment, besides assuming the procedural costs of the legal proceedings (Table 2). In other regions of Brazil, for example, Brasília (Federal District) and Santa Catarina, the judicial representation was performed by private lawyers.5,10-11

When analyzing that 431 (67.7%) actions were conducted by Public Judicial Institutions, this fact may be related to the gratuitousness of these services, the citizen’s knowledge of their rights and the
possibility of guaranteeing access to constitutionally legal rights. Access to information appears to be crucial in the decision-making process regarding which body to conduct the lawsuit. Thus, it must be considered that information and knowledge are essential public assets and that inequality of access to these assets are determinants of possible health inequities.12

Therefore, it is important to rethink how and to whom judicial actions are given for the supply of medicine or materials and supplies, that is to say, the actions of users with DM represent what they need, or has the judicial system contributed to the maintenance of health inequities? In the meantime, it is verified that these are “individuals less deprived of social protection that are conducting actions against municipal public power which cause doubt regarding the noncompliance with the actions of equity proposed by SUS”.12

A study carried out in the State of Minas Gerais which analyzed the profile of drug claimants filed in legal proceedings, showed that 70.5% of the legal proceedings were related to care in the private health system and 25.8% were also found in the present study, in which 506 (79.6%) of the cases were related to the medical prescription from the private healthcare network, 457 (71.9%) were private practices and 49 (7.7%) health insurance companies. The public health network accounted for 20.4% of the processes, with more than half (12.6%) of institutions linked to universities (Table 3).

Studies show that users who resort to the judiciary are those in satisfactory socioeconomic conditions, since they can afford the expenses of the private health system, in addition to those entailed by judicial processes carried out through private offices.5,10-11

These arguments are based on the premise that private advocacy is not a good indicator of class position and that costs may be being funded by institutions such as pharmaceutical industries interested in the possible outcomes of the judiciary. Therefore we have, for example, the pressure on SUS to incorporate certain drugs on the official lists of free distribution and patients from other localities migrating in search of medical treatment.10

Ribeirão Preto was the municipality with the most frequent lawsuits from users with DM, totaling 470 (73.9%) of the cases. The proportion of the population by municipality of residence of claimant can contribute to the identification of the localities that suffer the greatest pressure for the incorporation of certain drugs.5

When analyzing drug lawsuits, from the 397 (62.4%) cases requested for long-acting insulins, the most requested was glargine and detemir. This type of insulin with proven efficacy and efficiency among long-acting insulins is not yet available through SUS in all Brazilian states. There is a free supply of the Neutral Protamine Hagedorn (NPH) and regular insulin, with intermediate and rapid actions, respectively, according to Ordinance No. 2,583/07.13-14 Thus, all users with DM have effective and safe insulins offered by SUS for the treatment of their disease, but the doctor’s prescription must observe the individuality of the patient and their clinical characteristics. A systematic review study evaluating the efficacy, safety and tolerability of human and analog insulins showed no statistically significant difference in the reduction of HbA1c between the use of glargine or detemir, injected once daily, compared to the use of NPH.15

Thus, the Judiciary has been questioned regarding its legitimacy in health interventions. It is acknowledged that its function is to enforce the law on the basis of the irrefutable right to life. On the other hand, it is necessary to consider the norms and policies of management established by SUS. It also addresses questions related to the different interpretations of the principles of integrity, equity and universality, generating mistrust in the population about possible partnerships between the pharmaceutical industry, doctors and lawyers in the judicialization process.

Regarding the lawsuits related to the materials and supplies required for the application of multiple daily injections of insulin, one process requested the syringes and in two processes needles for the application of insulin were requested.

According to Federal Law 11,347/06, which provides for the free distribution of drugs and materials for the application of insulin and monitoring of capillary glycaemia, as well as Administrative Rule No. 2,583/07, which defines the list of drugs and supplies to be made available, users with DM can benefit from free delivery of: insulin syringes (100 International Units - 1U and 501U) according to the prescribed dose and needles for subcutaneous application since 2007.13-14

However, these requests may reveal the lack of knowledge of users with DM and/or the doctor’s on the laws and ordinances published in the years 2010 and 2013. There were also 17 lawsuits for materials and supplies related to self-monitoring of glucose, through reagent strips, lancets and glucometers. Three out of the seventeen lawsuits began before
the year 2007, when the free distribution was implemented according to Law 11,347/2006.

Among the ways to promote insulin therapy for the user with DM, another option is the use of the continuous subcutaneous infusion pump, which is an apparatus located externally on the body coupled to a device inserted under the skin, it contains an insulin reservoir and batteries as a source of energy and offers safety and comfort to the user with DM, as it dispenses the need for multiple needle punctures and reduces possible complications.7

In contrast, this therapy has high cost for the acquisition of the insulin pump itself, as well as for the maintenance of the same, since several devices are needed, which need to be changed and replaced with a certain timeframe. It should be noted that not all patients are able to use this technology, since it requires continuing education and carbohydrate counting for dose adjustments.

In 40 (6.3%) filed lawsuits, there was a request for the supply of the continuous subcutaneous infusion pump and in 48 (7.5%) court orders the requests were restricted to the infusion sets and insulin reservoirs, which should be changed at intervals recommended by the manufacturer. Due to the advanced technological content used for the operation of such devices, the costs for manufacturing as well as maintenance are high, which drives users to use the judicial route as a way of access.

On the other hand, judicialization may be an ally to SUS, insofar as it indicates deficiencies and encourages reflection on the need for new and updated policies, “in order to reduce the distance between SUS established in the normative framework and the SUS that executes health actions and services.”9

The phenomenon of the judicialization of the right to health is growing and highlights that judicial health demands have the potential to become limitless. There is a mismatch between what the Judiciary and what health managers in the State mean by the right to health. On the one hand, there are health experts who assume that health resources are limited in relation to demand and therefore have to make choices about their use. In this context, the right to health is limited and not absolute. On the other hand, the judiciary has started from the premise that health, as constitutional law since 1988, must be ensured at all costs and thus puts the problem of scarce resources in the background.

CONCLUSION

The results of the study allow to conclude that, in relation to the procedural elements, of the 636 (100%) judicial proceedings, the majority was conducted by the Public Ministry in 2012 in the city of Ribeirão Preto-SP. The individual lawsuits filed by users with DM to provide drugs, supplies and materials to treat the disease was done through medical prescription and the drug most demanded was insulin glargine. Most of the lawsuits were requests for drugs that were not included on the lists of free funding by SUS and 17 (2.7%) of them the drugs were already offered by SUS.

It is recognized that even though they use them, users with DM know little about health rights. On the other hand those provided with greater access to information seek legal redress for various types of treatment, having the recognition that health is a right of all and must be provided by the State as the main argument, a view also shared and defended by the Judiciary. Therefore, information is shown as an important tool in the decision-making process of the user with DM. It is necessary to consider equity in the access to health information, since access to this “asset” can be determinant in the maintenance or not of health inequities.

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