Effectiveness of the law on priority for the elderly in health claims in Rio de Janeiro

Efetividade da lei de prioridade dos idosos nas demandas judiciais de saúde no Rio de Janeiro

Aldilene Abreu de Azevedo[1], Vania Reis Girianelli[2], Renato José Bonfatti[3]

DOI: 10.1590/0103-11042022E610I

ABSTRACT The growth of older adults is a global event. The study aimed to evaluate the effectiveness of the law on priority for the elderly in relation to the procedural processing of health claims made in the Lower Courts of Justice of the judicial district of the Capital of Rio de Janeiro State. A descriptive cross-sectional study of the proceedings assigned in the period from 2018 to 2019 was conducted. The total sample included 1,040 identified cases, but only 240 were eligible (23%). Most claims were related to home care services (26.3%), particularly for adults aged 80 years and over (54.7%). The legal effectiveness of the law for the 60- to 79-year-old age group was 86% and 97.3% for other elderly people. The processing time of the lawsuits, however, was shorter for mature adults than for older people (p=0,020) and similar between older adults aged 80 years or above and other elderly adults (p=0,400). Monitoring the impact of this law on society is essential, older people are at a stage of life in which the issue of time is essential, particularly when the claim is related to health.

KEYWORDS Aged rights. Aged, 80 and over. Legislation. Human rights. Health judicialization.

[1] Fundação Oswaldo Cruz (Fiocruz), Escola Nacional de Saúde Pública Sergio Arouca (Ensp) – Rio de Janeiro (RJ), Brasil. *aldilene27@hotmail.com*

[2] Fundação Oswaldo Cruz (Fiocruz), Escola Nacional de Saúde Pública Sergio Arouca (Ensp), Departamento de Direitos Humanos, Saúde e Diversidade Cultural (DIHS) – Rio de Janeiro (RJ), Brasil.

[3] Fundação Oswaldo Cruz (Fiocruz), Escola Nacional de Saúde Pública Sergio Arouca (Ensp), Centro de Estudos da Saúde do Trabalhador e Ecologia Humana (Cesteh) – Rio de Janeiro (RJ), Brasil.

RESUMO *O crescimento da população idosa é um evento mundial. No Brasil, esse processo tem ocorrido de forma mais acelerada. O estudo teve por objetivo avaliar a efetividade da lei de prioridade dos idosos quanto à tramitação processual das demandas judiciais de saúde na Comarca da Capital na 1ª Instância do Tribunal de Justiça do Estado do Rio de Janeiro. Foi realizado um estudo transversal descritivo dos processos distribuídos no período de 2018 a 2019. Um total de 1.040 processos foi identificado, mas apenas 240 elegíveis (23%). O serviço de assistência domiciliar foi a principal demanda (26,3%), em particular, para os idosos com 80 anos ou mais (54,7%). A efetividade jurídica da lei de prioridade para faixa etária de 60 a 79 anos foi 86%, e 97,3% para os demais idosos. O tempo de tramitação do processo, entretanto, foi menor para os adultos maduros do que para as pessoas idosas (p = 0,020) e similar entre idosos com 80 anos ou mais e demais idosos (p = 0,400). O acompanhamento da repercussão dessa lei na sociedade é fundamental, pois o idoso se encontra em uma fase da vida em que a questão temporal é essencial, principalmente quando a demanda está relacionada com a saúde.*

PALAVRAS-CHAVE *Direitos dos idosos. Idoso de 80 anos ou mais. Legislação. Direitos humanos. Judicialização da saúde.*

Introduction

The progressive growth of the elderly population is a worldwide event[1]. Some countries, such as Brazil, China and India, have witnessed a faster process of demographic transition[2]. In Brazil, the elderly population almost doubled between the last two censuses, but with large regional differences, with the States of Rio de Janeiro (20.4%) and Rio Grande do Sul (19.8%) reporting the highest proportion of elderly people in the country[3]. Prior to the COVID-19 pandemic, it was e stimated that the elderly would account for 29.4% of the population by 2050[4].

Physical vulnerability, which stems from the natural ageing process, leads the elderly to seek more health care than other age groups. This has contributed to an increase in legal actions to guarantee rights to medication, care and other claims[5]. Although existing legislation guarantees the fundamental rights of the elderly, particularly those aged 80 years and over[6], it is not always effective, that is, it is not always applied as intended.

Law and public health are closely linked, shaping the way people interact and experience the world around them. Laws can contribute to the improvement of communities, especially in public health actions, and it is essential to understand their repercussions on the collective[7].

Thus, the objective of this article is to evaluate the effectiveness of the law on priority for the elderly in relation to the procedural processing of health claims filed in the Lower Courts of Justice of the judicial district of the Rio de Janeiro State Capital (TJRJ).

Methodology

This is an observational, cross-sectional descriptive study, about the health claims filed in the Lower Courts of the Capital of Rio de Janeiro State (TJRJ). The cases were extracted from the TJRJ website, of cases assigned in the period of 2018-2019. The lawsuits were accessed by the name of the defendant, considering the two private health plans with the greatest number of beneficiaries (Amil and Unimed) effective in the municipality of Rio de Janeiro[8], filed in civil courts. Cases in which the plaintiff was under 40 years of age and whose claims were not related to health care were excluded, as well as cases that were not digitalized and only listed in the system as physical records.

Regarding the characteristics of the elderly, the following variables were assessed: age group (40 to 59 years, 60 to 79 years and ≥ 80 years), gender (male and female), marital status (married or consensual union, single, widowed, divorced, ignored), nationality, retired, municipality of residence (capital and other municipalities). With regard to the characteristics of the lawsuit, the following variables were evaluated: representative (lawyer, public defender); defendant (Amil, Unimed); assignment of the action to the duty court; type of lawsuit (complaint or interlocutory relief, an application made before the lawsuit is filed); court to which the case was assigned; preliminary injunction, that is, an urgent and well-founded claim, considered by the judge at the start of the process, without hearing the adverse party, (granted and complied with, granted and not complied with, dismissed, not requested), cause of death related to the claim, outcome of the suit (granted, dismissed, case not judged or merit not judged), cause of death not judged (agreement between the parties, settled administratively, withdrawal, abandonment, death, procedural error), type of procedural error (transfer of jurisdiction, with referral to the court of competent jurisdiction, non-payment of costs; absence of procedural prerequisite, that is, lacking the legal requirements for filing of the action). As for the type of action, health care-related claims were included, such as, for example, hospitalization, supply

of drugs, performance of exams, supply of health inputs, performance of surgery, and home care. The requested drugs were also classified according to whether they were registered with the National Health Surveillance Agency (ANVISA), on the list published by the National Health Agency (ANS) and if they were for off-label use (treatment of diseases not recorded on the medication package insert[9]).

The percentage of each category of the variables studied was calculated, stratified by age group; with mature adults (40 to 59 years) compared to the elderly (≥ 60 years), and people aged 80 years and over compared to the remaining elderly (60 to 79 years). Pearson's chi-square test was calculated to assess the existence of a statistically significant difference ($p \leq 0.05$) between strata, with Yates's correction where necessary.

Additionally, the median time of proceedings was calculated (between assignment and judicial decision and between judicial decision and publication) using the Kaplan Meier method, for non-parametric estimate of the time of occurrence[9]. In this analysis, procedural errors were excluded (document produced in a different manner to that requested, change of the author's name in the sentence etc.). The outcomes of interest were the judicial decision and the publication of the judicial decision, censoring the cases on the date on which the agreement between the parties occurred (consensual agreement with subsequent ratification by the judge), administrative resolution (the plaintiff's request granted in the administrative sphere), withdrawal (formally informed in the judicial process), abandonment of the action, or death prior to the judicial decision. Cases not judged by 31 December 2020 were censored. Curves were plotted to reflect the time taken to process the case, stratified by age group. Log-rank test was calculated to compare the time curves, being considered different when the respective p value was ≤ 0.05[9].

The legal effectiveness of the law was identified when the representative requested that the case be expedited based on the law, or if it was considered by the judge on his own initiative, without any request presented by the representative. It was considered as socially effective, i.e., having an impact on society, when the time taken to process cases was shorter for people aged 80 years and over than for other elderly people (60 to 79 years); and for elderly people (≥ 60 years) than for mature adults (40 to 59 years).

Data were stored in Excel® version 2013 and analysed in the R statistical program version 3.4.3.

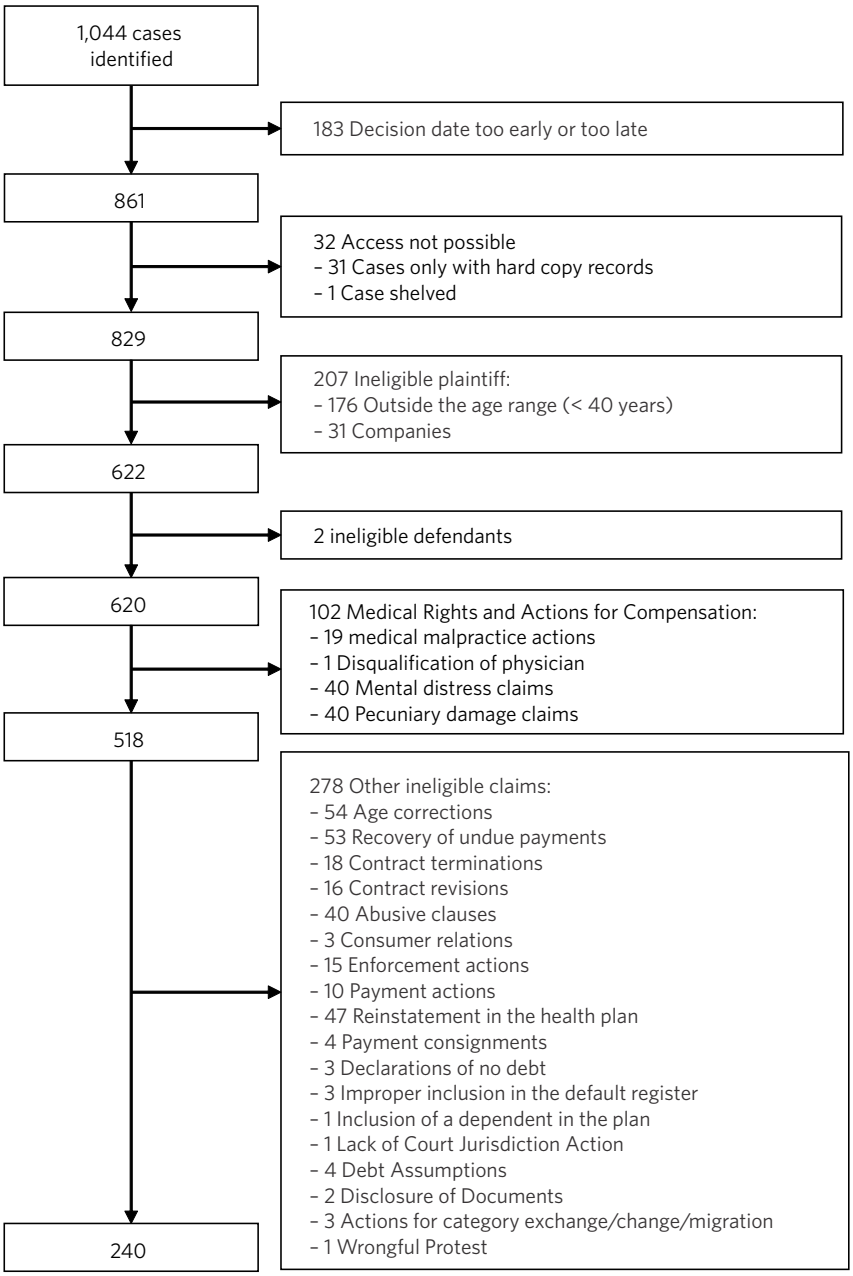
In relation to the judicial decisions, the results were interpreted based on the Health Plans Law, on the normative resolutions and attributions of the ANS, on the consumer relationship in light of the Consumer Defence Code, on the fundamental rights provided for in the Constitution and on the decisions of the Brazilian Courts on actions against health plans, as well as precedents and case law.

The study was exempted from ethical review by the Research Ethics Committee of the Escola Nacional de Saúde Pública Sergio Arouca/Fundação Oswaldo Cruz (CEP/ENSP/FIOCRUZ), number 04/2020.

Results

A total of 1,044 court cases were identified (*figure 1*). Of these, only 240 cases (23%) were eligible for the study. There were 196 elderly (≥ 60 years) plaintiffs (81.7%), 75 (31.3%) of whom were aged 80 years or older (*table 1*). Among the elderly, there was a higher percentage of widowers, retirees and Brazilians in relation to mature adults ($p \leq 0.045$), with prominent presence of those aged 80 years or more who included an even higher percentage of widowers and retirees than the other elderly people ($p \leq 0.008$).

Figure 1. Diagram of the procedure for identifying court cases related to the health of mature adults and elderly people in the Lower Courts of Justice of the State of Rio de Janeiro, in the period from 2018 to 2019



Source: Developed by the authors.

Table 1. Distribution of sociodemographic characteristics by age group of the plaintiffs in lawsuits filed at the Lower Courts of Justice of the State of Rio de Janeiro, in the period from 2018 to 2019

	Total		40 to 59 y.o		60 and over			60 to 79 y.o		80 and over		
Characteristics	**N**	**%**	**N**	**%**	**N**	**%**	**p value**	**N**	**%**	**N**	**%**	**p value**
Gender												
Male	107	44.6	16	36.4	91	46.4	0.296	62	51.2	29	38.7	0.116
Female	133	55.4	28	63.6	105	53.6		59	48.8	46	61.3	
Municipality of residence												
Capital:	218	90.8	36	81.8	182	92.9	**0.045**	111	91.7	71	94.7	0.624
Others	22	9.2	8	18.2	14	7.1		10	8.3	4	5.3	
Marital Status												
Single	41	17.1	15	34.1	26	13.3	**0.005**	17	14.0	9	12.0	**<0.001**
Married or consensual union	101	42.0	17	38.6	84	42.9		61	50.4	23	30.7	
Divorced	31	12.9	6	13.6	25	12.8		19	15.7	6	8.0	
Widower	51	21.3	3	6.8	48	24.5		19	15.7	29	38.7	
Ignored	5	2.1	3	6.8	13	6.6		5	4.1	8	10.7	
Retired												
Yes	187	77.9	16	36.4	171	87.2	**<0.001**	99	81.8	72	96.0	**0.008**
No	53	22.1	28	63.6	25	12.8		22	18.2	3	8.3	
Nationality												
Brazilian	225	93.8	43	97.7	182	92.9	0.389	116	95.9	66	88.0	0.073
Foreigner	15	6.3	1	2.3	14	7.1		5	4.1	9	12.0	

Source: Developed by the authors.

Mature adults filed a higher percentage of lawsuits against Amil than elderly people (p = 0.049) (*table 2*). Only 17.5% of the cases were brought by the public defender's office. The duty court service, which serves urgent requests outside office hours, received 35.8% of the judicial requests. The most used procedural document was the Complaint (96.7%). Most cases were granted (45.4%), but the proportion of settlement or administrative resolution was higher among mature adults (18.2%) than among elderly people (6.6%), while non-trial cases (23%) and deaths before court decision (12.8%) were proportionately higher among elderly people than mature adults (13.6% and 4.5% respectively) but was not statistically significant (p = 0.118), probably due to the small sample size in some categories. Furthermore, death before trial was proportionally higher among people aged 80 years or over (20%) than among the other elderly (8.3%), although also not to a statistically significant degree (p = 0.134).

Table 2. Distribution of the characteristics of the lawsuits by age group of the plaintiffs filed at the Lower Courts of Justice of the State of Rio de Janeiro, in the period from 2018 to 2019

	Total		40 to 59 y.o		60 and over			60 to 79 y.o		80 and over		
Characteristics	**N**	**%**	**N**	**%**	**N**	**%**	**p valor**	**N**	**%**	**N**	**%**	**p valor**
Defendant (Private Health Plan)												
Amil	140	58.3	31	70.5	109	55.6	**0.049**	72	59.5	37	49.3	0.213
Unimed Rio	100	41.7	13	29.5	87	44.4		49	40.5	38	50.7	
Representative												
Attorney	198	82.5	37	84.1	161	82.1	0.93	99	81.8	62	82.7	1.00
Public Defender's Office	42	17.5	7	15.9	35	17.9		22	18.2	13	17.3	
Duty Court												
Yes	86	35.8	17	38.6	69	35.2	0.799	44	36.4	25	33.3	0.781
No	154	64.2	27	61.4	127	64.8		77	63.6	50	66.7	
Type of Action												
Complaint	232	96.7	42	95.5	190	96.9	0.975	117	96.7	73	97.3	1.00
Interlocutory relief*	8	3.3	2	4.5	6	3.1		4	3.3	2	2.7	
Outcome of the case												
Granted	109	45.4	20	45.5	89	45.4	0.118	59	48.8	30	40.0	0.134
Rejected	9	3.8	2	4.5	7	3.6		3	2.5	4	5.3	
Merit not judged due to settlement or resolved administratively	21	8.8	8	**18.2**	13	6.6		11	9.1	2	2.7	
Merit not judged due to withdrawal or abandonment	16	6.7	4	9.1	12	6.1		7	5.8	5	6.7	
Merit not judged due to death.	27	11.3	2	4.5	25	**12.8**		10	8.3	15	**20.0**	
Merit not judged due to procedural error.	7	2.9	2	4.5	5	2.6		3	2.5	2	2.7	
Not judged	51	21.3	6	13.6	45	**23.0**		28	23.1	17	22.7	

Source: Developed by the authors.

* Urgent request before the action is brought. If granted, the plaintiff must amend such petition within 15 days or longer period as determined by the judge. If not performed within such deadline, the case is dismissed.

One 75-year-old plaintiff did not apply for an injunction because he obtained an administrative agreement for the surgery to be performed. There were also two withdrawals of lawsuits before the injunction decision among mature adults: one concerned the request for hospital transfer, and the other, the performance of examinations. Two injunctions of elderly plaintiffs were suspended: in one, the plaintiff committed fraud against the institution, and was criminally charged; and the other, the judicial expert report proved that there was no need for the provision of home care. There were also three deaths of elderly people before the injunction decision, but they were not related to the procedural claims.

Among the 232 injunctions that were assessed, the majority were granted and complied with (66.8%), and there was no statistically significant difference between age groups ($p \geq 0.583$). Of the injunctions granted and not complied with, the claims were mainly related to hospitalization or home care (38.9%); and those denied, to surgery (24.9%) and hospitalization or home care (24.9%).

Of the 191 injunctions that were granted, the health plans appealed 79 (41.4%), while of the 41 injunctions that were denied, the plaintiffs appealed 20 actions (48.8%); filing an interlocutory appeal, which serves to claim the

groundlessness and, consequently, dismissal of the injunction.

The main claim was for hospitalization or home care services (26.3%), followed by requests for surgery (19.2%) and medication (17.5%) *(table 3*). Among mature adults, requests for medication (25%) and surgery (15.9%) were the most common; among the elderly aged 80 years or over, the request for hospitalization or home care predominated (54.7%); and among the other elderly, medication (23.1%) and surgery (21.5%).

Table 3. Distribution of the health claims by age group of the plaintiffs filed at the Lower Courts of Justice of the State of Rio de Janeiro, in the period from 2018 to 2019

	Total		40 to 59 y.o		60 to 79 y.o		80 and over	
Claim	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Hospitalisation	22	9.2	5	11.4	11	9.1	6	8.0
Medication	42	17.5	11	25.0	28	23.1	3	4.0
Surgery	46	19.2	7	15.9	26	21.5	13	17.3
Transplant	9	3.8	2	4.5	6	5.0	1	1.3
Performance of examinations	12	5.0	5	11.4	6	5.0	1	1.3
Hospital Transfer	4	1.7	2	4.5	1	0.8	1	1.3
Hospital at home or home care	63	26.3	4	9.1	18	14.9	41	54.7
Supply of inputs	6	2.5	1	2.3	3	2.5	2	2.7
Chemotherapy, radiotherapy or haemodialysis	7	2.9	0	0.0	5	4.1	2	2.7
Services	7	2.9	1	2.3	4	3.3	2	2.7
Medical treatment	22	9.2	6	13.6	13	10.7	3	4.0
Total	**240**	**100.0**	**44**	**100.0**	**121**	**100.0**	**75**	**100.0**

Source: Developed by the authors.

Most of the claims were either granted (45.4%) or have not yet been judged (21.3%). Of the nine rejected actions, three were requests for hospitalization services or home care for elderly people aged 80 or over, two for electroconvulsive therapy and physiotherapy, one for elective surgery for breast reconstruction and excision of breast lesion guided by stereotactic marking, and one for a drug not registered with ANVISA.

In relation to surgery, 56.5% were granted, and 13% were resolved through an agreement between the parties or administrative resolution with the health plan operator itself, but 17.4% were still awaiting a judicial decision. None of the nine requests for transplants were denied, although three deaths occurred before the court decision and two were still awaiting a decision.

Of the 42 drugs requested, 10 (22.8%) were registered with ANVISA and belonged to the ANS list, 1 was for off-label use and was obtained through agreement with the health plan. Twenty-six drugs (61.9%) were not on the ANS list, 5 of which were for off-label use, four 4 were granted and in one 1 case the plaintiff died before the judicial decision. Six (14.3%) were not registered with ANVISA, but 3 of these were granted.

Of the 21 drugs with ANVISA registration but not yet ANS-listed, most refer to new drugs indicated for the treatment of cancer, such as

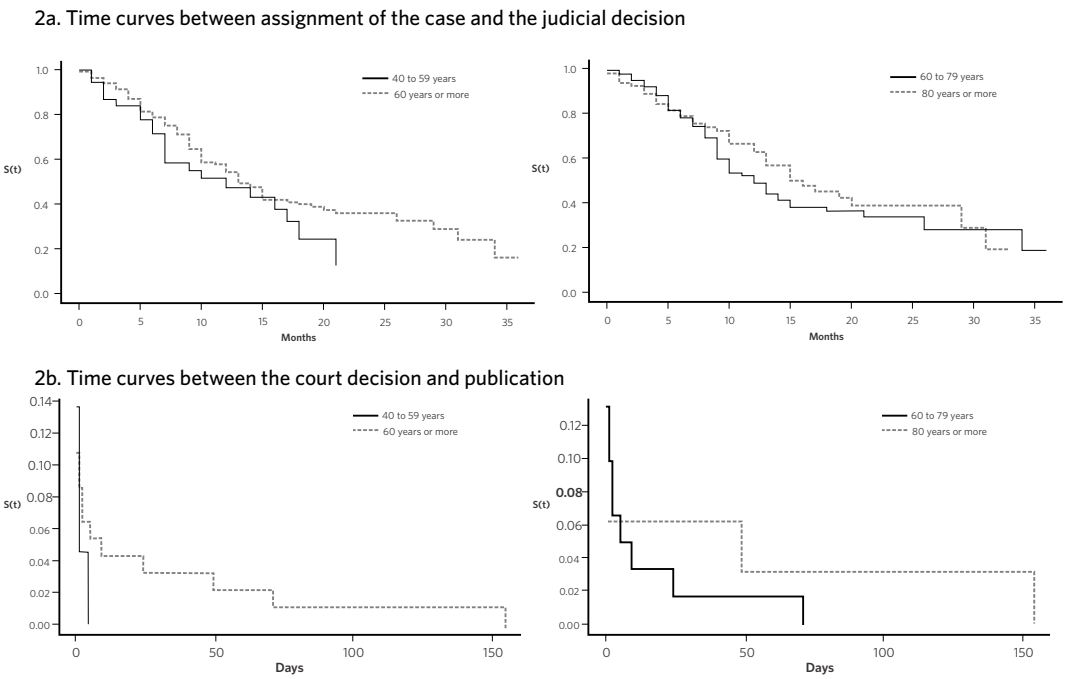
Ibrance® (Palbociclibe) used for advanced or metastatic breast cancer, alectinib (Alecensa®) and pemetrexed (Alimta®) for lung cancer, and regorafenib (Stivarga®) for metastatic or non-resectable gastrointestinal stromal tumours (GIST), hepatocellular carcinoma (HCC) and metastatic colorectal cancer (CRC).

The legal effectiveness of the law on priority for older people was high: 86% for the 60 to 79 age group and 97.3% for the special priority of those aged 80 and over. Furthermore, in six cases in which the lawyer did not request priority, the judge granted it on his own initiative, five of which were in the 60 to 79 age group, and one was a 95 year-old, increasing the effectiveness to 90.1% and 98.7% respectively.

Regarding the time it took to process the case, the median was 13 months between assignment and the judicial decision, with it being shorter for mature adults than for the elderly (p = 0.020), but there was no statistically significant difference between people aged 80 years or more and other elderly people (p = 0.400) (*figure 2a*).

Of the 118 judicial decisions in the period, most were published on the same day (86.4%). Time to publication, however, was higher among older people than mature adults (p = 0.500) and among people aged 80 years and over than other elderly people (p = 0.700), although the differences were not statistically significant, probably due to the small sample size (*figure 2b*). There was no statistically significant difference in relation to the time between the assignment of the case and the injunction decision, both for mature adults and elderly people (p = 0.200) and between people aged 80 years and over and other elderly people (p = 0.600).

Figure 2. Time curves between the assignment of the case and the court decision (a and b) and between the court decision and publication (c and d) by age group in the Lower Courts of Justice of the State of Rio de Janeiro, in the period 2018 to 2019



Source: Developed by the authors.

Discussion

This study identified 1,044 lawsuits in the Lower Courts of the Rio de Janeiro State capital, but only 240 were eligible (23%). The identification procedure makes it impossible to restrict characteristics and exclude aspects of no interest to the research, making the process more complex and time-consuming. Elderly people constituted 81.7% of the plaintiffs, but there was no statistically significant difference between age groups for the procedural and socioeconomic characteristics studied, except for those related to age, such as retirement, widowhood and death while the case was ongoing.

The study found that the law on priority for the elderly was effective (90.1%), as was the law on special priority for the elderly aged 80 years and over (98.7%), but there was no social effectiveness. Legal practitioners have complied with the legal rule, however, the objective of the rule, which is to give procedural priority to the elderly, making it speedier, has not been achieved. In this study, mature adults enjoyed a speedier processing time than the elderly. In a previous study[10], based on cases in the Higher Courts, neither legal nor social effectiveness in the law of special priority for the elderly aged 80 years or more was observed. The authors emphasized that the result was probably due to the short time for which the law had been in force and to the fact that, during the research period, the TJRJ system only offered priority service to the elderly when the lawsuit was being filed, without making any distinction between the elderly age groups.

The right of the elderly aged 80 years or more to priority is well defined in the Statute of the Elderly[6,11], but the way in which it should be exercised is found in the Code of Civil Procedure[12], which presents distinct interpretations. For some jurists[13], it should be interpreted in a simple way, that is, simply attaching a document that proves the age of the plaintiff should automatically gain him/her the right to priority. For others, the right to priority must be requested by the defendant and granted by the magistrate after proving that he/she is entitled to such benefit. In practice, most of the attorneys usually request priority, including grounds for the request, in the body of their complaint filed in the procedural process.

In addition to these grounds, it is also very common to find reference to this right at the start of the action. Therefore, it can be assumed that if the right to priority was determined only by the simple attachment of the plaintiff's identification document, there would not be this insistence shown by the representatives, so eager to achieve such priority for the elderly. This behaviour is not exclusive to lawyers; it is also found in the procedural documents of the Public Defender's Office with the same format of request. Currently, the TJRJ system already supports request for priority during registration of the procedural action by means of informing the date of birth, as well as attaching documents required for filing the lawsuit. However, it does not provide any transparency on how the cases involving the elderly are processed and whether priority is really being exercised.

The effectiveness of the law on priority, known as super-priority, engaged in health lawsuits, proved to be totally artificial, since it was not borne out in society; despite existing and being valid, it failed to achieve the social purpose for which it was produced. The law should be created in the image of its society, revealing its values and hopes[14], therefore, the creation of a rule, which, even after a period of social adaptation, is unable to uphold its objective, is shown to be a mere theoretical and abstract creation[15]. Society is therefore required to monitor the situation and apply pressure to ensure the effectiveness of the law.

A limitation of the study was the fact that it was impossible to stratify the processing time by type of claim, procedural outcomes and urgent and emergency situations (despite this being appreciated in the preliminary

injunctions) due to an insufficient sample size. A higher percentage of agreement between the parties or administrative settlement was reached by mature adults than by elderly people, which, in a way, reduces the time of the procedural process.

Hospitalization or home care service was the main claim (26.3%) and was higher among the elderly aged 80 years or over (54.7%). Perhaps this claim is more evident among users of private health care plans, since the law that provides for private health plans and insurance[16] does not include health care in the home environment among the mandatory coverage, only guaranteeing the provision of some services, products and specific medication. Patients who need this service also face the obstacle of its exclusion from the ANS list of compulsory coverage, as well as the fact that some health plans exclude the right to coverage of this procedure from their contracts. The ANS has regulated this service, determining that if the health plan operator offers a hospital at home service as a substitute for hospitalization, whether contractually provided for or not, it must comply with the ANVISA requirements[17] and the provisions of the Health Plans Law[16]. Furthermore, when there is a direct request for home care assistance but not as a substitute for hospital admission, such assistance must comply with the contractual provision or negotiation between the parties.

Despite these obstacles, the lawsuits filed with this claim have been mostly successful when there is express indication of the assistant doctor. In this study, only three were rejected. The courts generally tend to follow the doctor's request regarding the health plan operator's refusal to provide the service. Additionally, the São Paulo Court of Appeals has been a reference for all other courts in the country to support the request[18]. The legal representatives have also used the financial argument, that is, the costs of maintaining a patient under hospital at home care are considerably lower than those of a hospital admission, demonstrating that it is more economically advantageous for the health plan itself.

The second most frequent claim was for surgery (19.2%). One aspect to be considered is the grace period stipulated in the contract, since for each surgical procedure there is a minimum time established before it can be performed. Elective surgeries can usually only be performed 180 days after contract is signed. In the case of urgent or emergency surgery, the grace period is normally 24 hours or immediately, when there is a risk of death[16], but these are maximum deadlines and the health plan operator may reduce or extinguish them to its own discretion, which is usually used as a market strategy[19]. Precedent 597 of the Superior Court of Justice (STJ)[20] also considers contracts abusive if they stipulate a grace period that exceeds 24 hours for assistance in emergency or urgent cases to be provided. However, some bills are currently being considered in the House of Deputies that seek to alter the Health Plans Law with the objective of exempting the beneficiary from complying with grace periods in urgent and emergency cases, and to reduce the grace period for hospitalization to 120 days[21].

Surgeries requested due to pre-existing injuries and/or diseases follow another criterion, as currently the operator conducts a medical assessment before a health form is completed, with it being the individual's obligation to inform the operator of any pre-existing disease or injury; this does not preclude requests for surgeries, but the grace time for their performance will be longer, generally 24 months. However, there are surgeries that are not covered at all, such as purely aesthetic, experimental surgeries, treatments and interventions, invasive or not, without scientific backing.

Regarding transplants, the ANS determines the coverage of some types (kidney, cornea and medulla) for plans that offer hospital assistance, which are also obliged to cover all related expenses[22], which extend far beyond the surgical operation itself. Furthermore, any candidate patient for a kidney or cornea

transplant from a deceased donor must be enrolled at one of the Centres for Notification, Capture and Distribution of Organs (CNCDO), which form the single national waiting list, coordinated by the National Transplant System (SNT)[23].

Claims for drugs corresponded to 17.5% of the requests. The compulsory supply of drugs by health plans is still widely discussed by scholars, especially medications that are not included on the ANS list and for off-label use. In Brazil, for any medicine to be manufactured and sold, it must be registered with ANVISA, and to be approved, tests and analyses are carried out to demonstrate its quality, efficacy and safety, ensuring that the treatment has a positive impact on the population's health[24]. The ANS presents a list of health procedures and events, updated every two years, with a mandatory list of consultations, exams, surgeries and other procedures that must be offered to beneficiaries. This list is destined for the insured covered by new plans, that is, plans contracted as of 1 January 1999 or adapted to the law; otherwise, the coverage will be as determined in the contract, and the beneficiary may adapt or migrate to another plan at any time, to be covered under the rules of the new plans[19]. In the latest published list[22], there were significant additions, such as, for example, eight oral drugs for cancer treatment.

The discussion on the use of off-label drugs has been a relevant topic for both public and supplementary health. Off-label drugs are prevalent in certain clinical situations, such as oncology and in certain groups, such as the elderly, pregnant women and children, due to the difficulty and/or impossibility of conducting clinical trials among these groups[25]. The issue, however, is when the request for medication is denied by the health plan, due to distinct degrees of complexity among these types of claims. Obtaining an ANVISA-registered and ANS-listed drug will not be as difficult as obtaining others, since it fits within the legal criteria established for its request. No request for this type of drug was refused. A drug registered with ANVISA but not listed by the ANS could be interpreted as a demand with a higher degree of difficulty to obtain, but, on this issue, we encountered different understandings in the courts.

Some deem that the health plan has a legal duty to treat the illnesses provided for in the contract, even without ANS or ANVISA recognition. Others, in turn, understand that the ANS list is merely exemplary, and not exhaustive, and does not constitute suitable grounds for denying coverage. In an attempt to pacify the matter, the fourth panel of the STJ adopted the understanding that the ANS list is not merely exemplary, but is a mandatory minimum for health plan operators[26]. Although the third panel of the same Court has taken the opposite view, i.e., that the ANS list is merely exemplary, the fact that a procedure is not included in the list does not relieve the plan of the obligation to pay for it if it is indicated by the doctor to treat the illness provided for in the contract.

With regard to the legality of the medical practice of prescribing off-label use of drugs, there is no legislative or deontological rule that authorises or expressly prohibits these practices nationwide[27]. ANVISA itself presents a relativized position regarding off-label prescriptions, informing that their use is the responsibility of the prescribing physician, and that it may result in a medical error, but it recognizes that there are off-label prescriptions that are essentially correct, which have not yet been duly approved. It also adds that it appreciates the importance of these prescriptions in rare diseases, because there may never be indications of such diseases on the drug package insert, since they will never be studied by clinical trials[17,22] due to the insufficient sample size to support a study.

The fourth panel of the STJ decided that plans must cover off-label use of medicines registered with ANVISA[28]. This decision unifies the court's understanding on the issue, since the third panel had taken a similar stance, that is, a lack of specific indication on the package

insert is not a reason for denying coverage of the treatment. The justices understood that off label corresponds to the essentially correct use of a drug approved in clinical trials and produced under state control, only not yet approved for a certain treatment[28].

Regarding the professional responsible for prescribing off-label use of drugs, the reporting Justice Luis Felipe Salomão ratified that the authority to publish rules that define when a medical treatment is experimental comes under the exclusive responsibility of the Federal Council of Medicine, which is why neither the ANS nor health insurance providers may claim this authority for themselves. It should be noted, however, that drugs for experimental use must be included in an REC-approved study, and all inputs are the responsibility of the study sponsor.

For drugs not registered with ANVISA, the disputes are accentuated. The study identified six applications, one granted, one rejected, and the others had not yet been judged. In general, neither the State nor private health care operators are obliged to provide medicines not registered with ANVISA, since such registration constitutes public health protection, attesting to the efficacy, safety and quality of drugs marketed in the country. This public health registration cannot be considered a merely bureaucratic and dispensable procedure, but rather an essential process for protecting the universal right to health. For Justice Barroso, court decisions that order the provision of drugs that lack the proper sanitary registration, especially when they have not been subjected to the minimum technical tests and criteria required, represent a serious risk to public health[29]. Faced with the absence of information and scientific knowledge about the possible adverse effects of a substance, allied to a lack of ANVISA certification as to the safety and efficacy of a drug, the judicial decision should never be to authorise its consumption[30]. A majority vote decision by the Federal Supreme Court (STF) granted exceptional concession when there is a delay by ANVISA in considering the application, for a period longer than that provided by law[29], and the drug is registered with renowned agencies abroad, and there is no substitute medication in Brazil[29]. On the other hand, the STJ has determined that the health plan operators are not obliged to supply medicines not registered by ANVISA[31,32].

Furthermore, among the various marketeering practices that the pharmaceutical industry uses to make profit, without doubt, the use of the medical professional is the key to success, not least because it is forbidden to freely advertise drugs in Brazil to the lay public. Therefore, this professional group inevitably ends up leveraging, directly or indirectly, the financial growth of this market, since they hold the power to prescribe drugs. The pharmaceutical industry therefore seeks out medical professionals to persuade them to prescribe a certain drug, and in return may offer some advantages. Obviously, one can find professionals who succumb to these advantages and thus start prescribing medicines despite the existence of alternatives of similar use or effect or appropriate cost[33,34].

Final considerations

Brazil is still considered a young country, but it has a significant population that is undergoing an accelerated ageing process. This ageing population brings with it some implications in the socio-economic spheres of the country, especially in the health system, both public and private, because although ageing is not synonymous with illness, the process may bring about some weaknesses and diseases. Thus it is of utmost importance that laws are created that can effectively correspond to society's real wishes; a law that is merely a theoretical creation will not correspond to the social will.

The laws aimed at the elderly, especially the priority law, are extremely important, and cannot be simply a fantasy law, but rather an instrument of protection aimed at

this population group. The elderly need the guaranteed right to priority that has been enshrined in law, as they are in a phase of life in which the issue of time issue is of fundamental weight, and further aggravated when they present a health-related problem. The introduction of laws that establish specific rights seek to level social inequalities so common in society, hence the importance of their legal and social effectiveness being duly materialised.

Despite the limitations cited, the study contributed to a better understanding of the effectiveness of the law, because research that carries out this type of evaluation so relevant to society is rare. The academia can fulfil this social role and, in a way, disseminate the behaviour of the law in society, thus contributing to its improvement and enforcement. For now, the results of this research reinforce the need for further analysis to understand the effect produced by the rules, because although the priority law is an important victory in the fight for the rights of the elderly, in a society dominated by ageist and prejudiced ideology, there are still misunderstandings on the subject.

Collaborators

Azevedo AA (0000-0002-3957-1551)* study design, preparation of the work, data analysis and interpretation, writing of the first version and approval of the final version of the paper. Girianelli VR (0000-0002-8690-9893)* data analysis and interpretation, critical review of the content and approval of the final version of the paper. Bonfatti RJ (0000-0002-0924-5149)* data analysis and interpretation, critical review of the content and approval of the final version of the paper. ■

*Orcid (Open Researcher and Contributor ID).

References

1. United Nations. Department of Economic and Social Affairs. Population Division. World Population Prospects 2019: Highlights (ST/ESA/SER.A/423). New York: DESA; 2019.

2. Organización Mundial de la Salud. Informe mundial sobre el envejecimiento y la salud. Ginebra: OMS; 2015.

3. Instituto Brasileiro de Geografia e Estatística. Pesquisa Nacional por Amostra de Domicílios Contínua. Características gerais dos domicílios e dos moradores 2019. [acesso em 2021 out 17]. Disponível em: https://sidra.ibge.gov.br/tabela/6407#resultado.

4. Simões CCS. Relações entre as alterações históricas na dinâmica demográfica brasileira e os impactos decorrentes do processo de envelhecimento da população. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2016.

5. Efing AC, organizador. Direitos dos idosos: tutela jurídica do idoso no Brasil. São Paulo: LTr; 2014.

6. Brasil. Lei nº 13.466, de 12 de julho de 2017. Altera os arts. 3º, 15 e 71 da Lei nº 10.741, de 1o de outubro de 2003, que dispõe sobre o Estatuto do Idoso e dá outras providências. Diário Oficial da União. 13 Jul 2017.

7. Burris S, Ashe M, Levin D, et al. A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology. Annu Rev Public Health. 2016; (37):135-48.

8. Brasil. Agência Nacional de Saúde. Dados e Indicadores do Setor. Beneficiário por municípios. [acesso em 2020 jan 18]. Disponível em: http://www.ans.gov.br/perfil-do-setor/dados-e-indicadores-do-setor.

9. Carvalho MS, Andreozzi VL, Codeço CT, et al. Estimação não paramétrica: estimador de Kaplan-Meier. In: Carvalho MS, Andreozzi VL, Codeço CT, editores. Análise de Sobrevida: teoria e aplicações em saúde. Rio de Janeiro: Ed. Fiocruz; 2005. p. 93-152.

10. Azevedo AA, Girianelli VR, Bonfatti RJ. A efetividade da lei de prioridade especial quanto às demandas judiciais de saúde na 2ª. Instância do Tribunal de Justiça do Estado do Rio de Janeiro. Rev. Bras. Geriatr. Gerontol. 2020; 23(4):e200212.

11. Brasil. Lei nº 10.741, de 1º de outubro de 2003. Dispõe sobre o Estatuto do Idoso e dá outras providências. Diário Oficial da União. 3 Out 2003.

12. Brasil. Lei nº 13.105, de 16 de março de 2015. Código de Processo Civil. Diário Oficial da União. 17 Mar 2015.

13. Neves DAA. Novo Código de Processo Civil: comentado artigo por artigo. Salvador: JusPodivm; 2016.

14. Venosa SS. Introdução ao estudo do direito. 6. ed. São Paulo: Atlas; 2019.

15. Nader P. Introdução ao estudo do Direito. 36. rev. ed. Rio de Janeiro: Forense; 2014.

16. Brasil. Lei nº 9.656, de 03 de junho de 1998. Dispõe sobre os planos e seguros privados de assistência à saúde. Diário Oficial da União. 4 Jun 1998.

17. Brasil. Agência Nacional de Saúde. Parecer Técnico nº 05/GEAS/GGRAS/DIPRO/2021. Cobertura: Assistência domiciliar (*home care*, assistência domiciliar, internação domiciliar, assistência farmacêutica domiciliar). [acesso em 2021 out 18]. Disponível em: https://www.gov.br/ans/pt-br/arquivos/acesso-a-informacao/transparencia-institucional/pareceres-tecnicos-da-ans/2020/parecer_tecnico_no_05_2021_atencao_domiciliar_-_home_care.pdf.

18. São Paulo. Tribunal de Justiça do estado de São Paulo. Súmulas. 2021. [acesso em 2021 jan 18]. Disponível em: https://www.tjsp.jus.br/Download/Portal/Biblioteca/Biblioteca/Legislacao/SumulasTJSP.pdf.

19. Brasil. Agência Nacional de Saúde. Carência: período para começar a usar o plano. 2021. [acesso em 2021 out 18]. Disponível em: https://www.ans.gov.

br/planos-de-saude-e-operadoras/espaco-do-consumidor/carencia.

20. Brasil. Supremo Tribunal de Justiça. Súmulas Anotadas. Súmula 597. Diário da Justiça Eletrônico. 20 Nov 2017.

21. Brasil. Câmara dos Deputados. Projeto de Lei nº 3.657/2019. Altera a Lei nº 9.656, de 03 de junho de 1998 (Lei dos Planos de Saúde), para isentar o beneficiário do cumprimento de períodos de carência nos casos de urgência e emergência e para reduzir para cento e vinte dias o período de carência nas internações hospitalares. [acesso em 2021 out 18]. Disponível em: https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=2208826.

22. Brasil. Agência Nacional de Saúde. Resolução normativa nº 428, de 07 de novembro de 2017. Atualiza o Rol de Procedimentos e Eventos em Saúde, que constitui a referência básica para cobertura assistencial mínima nos planos privados de assistência à saúde, contratados a partir de 1º de janeiro de 1999; fixa as diretrizes de atenção à saúde; e revoga as Resoluções Normativas nº 387, de 28 de outubro de 2015, e RN nº 407, de 3 de junho de 2016. Diário Oficial da União. 8 Nov 2017.

23. Brasil. Ministério da Saúde. Decreto nº 9.175, de 18 de outubro de 2017. Regulamenta a Lei nº 9.434, de 4 de fevereiro de 1997, para tratar da disposição de órgãos, tecidos, células e partes do corpo humano para fins de transplante e tratamento. Diário Oficial da União. 19 Out 2017.

24. Brasil. Lei nº 6.360, de 23 de setembro de 1976. Dispõe sobre a Vigilância Sanitária a que ficam sujeitos os Medicamentos, as Drogas, os Insumos Farmacêuticos e Correlatos, Cosméticos, Saneantes e Outros Produtos, e dá outras Providências. Diário Oficial da União. 24 Set 1976.

25. Brasil. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Uso *off label*: erro ou necessidade?. Rev. Saúde Pública. 2012; 46(2):395-397.

26. Brasil. Supremo Tribunal de Justiça. REsp 1733013/PR. Relator Min. Marco Aurélio Belize. Quarta Turma. Diário da Justiça Eletrônico. 20 Fev 2020.

27. Sá MFF, Ferreira PHM. A prescrição *off label* de medicamentos: análise do entendimento do Superior Tribunal de Justiça por ocasião do julgamento dos recursos especiais nº 1.721.705/SP e nº 1.729.566/SP. Rev Bras. Direito Civil. 2019; (21):147-161.

28. Brasil. Supremo Tribunal de Justiça. REsp nº 1729566 SP 2017/ 0333668-7. Relator Min. Luis Felipe Salomão. Quarta Turma. Diário da Justiça Eletrônico. 30 Out 2018. [acesso em 2022 nov 5]. Disponível em: https://www.jusbrasil.com.br/jurisprudencia/stj/643679514/inteiro-teor-643679519.

29. Brasil. Supremo Tribunal Federal. AgR RE 657718 / MG. Relator do Acórdão Min. Roberto Barroso. Diário da Justiça Eletrônico. 25 Out 2019.

30. Barroso AS, Hoyos A, Silva HS, et al, organizadores. Diálogos Interdisciplinares do Envelhecimento. São Paulo: Edições Hipótese; 2019.

31. Brasil. Supremo Tribunal de Justiça. REsp nº 1726563 / SP (2017/0120185-3). Relator Min. Moura Ribeiro. Segunda Seção. Diário da Justiça Eletrônico. 19 Mar 2018.

32. Brasil. Supremo Tribunal de Justiça. REsp nº 1712163 / SP (2017/0182916-7). Relator Min. Moura Ribeiro. Segunda Seção. Diário da Justiça Eletrônico. 26 Nov 2018.

33. Gøtzsche PC. Medicamentos mortais e crime organizado: como a indústria farmacêutica corrompeu a assistência médica. Porto Alegre: Bookman; 2016.

34. Peres G, Job JRPP. Médicos e indústria farmacêutica: percepções éticas de estudantes de medicina. Rev. Bras. Educ. Méd. 2010; 34(4):515-524.

Received on 10/26/2021
Approved on 09/20/2022
Conflict of interests: non-existent
Financial support: This article was developed with financial support from of the Stricto Sensu Post-Graduation Program in Public Health PPG-SP/ENSP/FIOCRUZ in the translation of language from portuguese to english