Comprehensiveness and universality of the pharmaceutical assistance in times of judicialization of health care

Integralidade e universalidade da assistência farmacêutica em tempos de judicialização da saúde

Luciana de Melo Nunes Lopes[a]
https://orcid.org/0000-0001-5520-6813
E-mail: lucianamnlopes@gmail.com

Tiago Lopes Coelho[a]
https://orcid.org/0000-0002-1740-2482
E-mail: tiagolopes.adv@gmail.com

Semíramis Domingues Diniz[a]
https://orcid.org/0000-0001-7767-5936
E-mail: semirinhadomingues@hotmail.com

Eli Iola Gurgel de Andrade[a]
https://orcid.org/0000-0002-0206-2462
E-mail: iola@medicina.ufmg.br

[a]Universidade Federal de Minas Gerais. Faculdade de Medicina. Grupo de Pesquisa em Economia da Saúde. Belo Horizonte, MG, Brasil.

Abstract

Law no. 12,401/2011 and Decree no. 7,508/2011 are celebrated, among other reasons, for introducing new rules for the pharmaceutical assistance policy that would have the potential to streamline the judicialization of health care in Brazil. This study aims to analyze the effects of the universal access to the comprehensive pharmaceutical assistance established by these legislations considering the judicialization of medicines in the state of Minas Gerais from 1999 to 2009. This is a retrospective study that analyzes the legal disputes deferred against Minas Gerais during the period. If the criteria established in 2011 were normalized and respected by the Judiciary in this interval, between 68.84% and 85.77% of the medicines judicialized in Minas Gerais would have been rejected. However, despite having the potential to streamline the judicialization, the legislations do not seem to have influenced the judicial decisions permanently.

Keywords: Judicialization of Health; Pharmaceutical Assistance; Brazilian National Health System; Health Policy.

Correspondence
Luciana de Melo Nunes Lopes
Universidade Federal de Minas Gerais. Av. Alfredo Balena, 190, 7 andar, Santa Efigênia. Belo Horizonte, MG, Brasil. CEP 30130-100.

Resumo

A Lei nº 12.401/2011 e o Decreto nº 7.508/2011 são celebrados, entre outros motivos, por introduzir regras inéditas para a política de assistência farmacêutica que teriam o potencial de racionalizar a judicialização da saúde no Brasil. Este estudo visa analisar qual seria o impacto da observância dos critérios de acesso universal à assistência farmacêutica integral, delimitados pelos marcos normativos, no cenário da judicialização de medicamentos em Minas Gerais de 1999 a 2009. Trata-se de um estudo retrospectivo que analisa os litígios judiciais deferidos contra o estado no período. Se os critérios instituídos em 2011 estivessem normalizados e fossem acatados pelo Judiciário no intervalo em pauta, entre 68,84% e 85,77% dos medicamentos judicializados em Minas Gerais teriam sido indeferidos. Contudo, apesar de demonstrar potencial para racionalizar a judicialização, as normativas ainda não parecerem ter influenciado as decisões em saúde de forma determinante.

Palavras-chave: Judicialização da Saúde; Assistência Farmacêutica; Sistema Único de Saúde; Política de Saúde.

Introduction

The medicines are the main object of legal disputes in health care in Brazil (Aumentam..., 2017). Among the main acclaimed arguments for their judicialization, universality and comprehensiveness of the constitutional right to health care stand out (Balestra Neto, 2015). The difficulty in delimiting the specific outlines of these principles, as well as the consolidation of a judicial interpretation unable to situate them in a more coherent and harmonious way with the development process of all the structures of the Brazilian National Health System (SUS) were key elements for the exacerbated growth in the judicialization of health care in the country (Aith et al., 2014; Bittencourt, 2016).

The significant volume of disputes over health care at the end of the 2000s and its financial impact showed some of the contradictions of judicialization and the consequent need for interventions in order to streamline it and detain its expansion (Balestra Neto, 2015).

One of the institutional initiatives in this direction was the creation of a new legislation for the pharmaceutical assistance of SUS, arising from changes promoted by Law no. 12,401, of April 28, 2011, and by Decree no. 7,508, of June 28 of the same year (Brasil, 2011a, 2011b). These legislations were created after the Public Hearing no. 4 held by the Supreme Court in 2009 and renewed structures and central criteria to ensure the pharmaceutical assistance in the country. After delimiting the scope of comprehensiveness (Aith et al., 2014; Balestra Neto, 2015) and the conditions for the universal and equitable access to the pharmaceutical assistance within SUS (Siqueira, 2015), the legislations were announced with the aim to focus on the dynamics of the judicialization of health care.

Law no. 12,401/2011 created the National Commission for Health Technology Incorporation of SUS (Conitec) and defined in its article 1, which includes article 19-M in Law no. 8,080/1990, that the comprehensive therapeutic assistance includes the "dispensation of medicines and products of interest for health care, whose prescription is in accordance with the guidelines defined in the therapeutic clinical protocol" and the supply of therapeutic

procedures selected by the federal manager of SUS. The legislation establishes that, in the absence of a clinical protocol, the relation of medicines defined nationally (National Relation of Essential Medicines – Rename) must be observed, as well as the relation defined by states or by municipalities (Brasil, 2011a).

Decree no. 7,508/2011 instituted Health Care Networks as a model for organization of SUS and established cumulative criteria that require universal and equal access to the pharmaceutical assistance, namely:

> I – the patient must be assisted by health actions and services provided by SUS; II – the medicine must have been prescribed by health professionals in the regular exercise of their functions in SUS; III – the prescription must be in accordance with Rename and Clinical Protocols and Therapeutic Guidelines or with the state, district or municipal complementary specific relation of medicines; and IV – the dispensation must have occurred in units indicated by the directors of SUS. (Brasil, 2011b, art. 28)

The clarification of parameters about the organization of the public health policy and the principles of SUS would theoretically ensure greater streamlining for judicial activities (Ramos; Diniz; Madureira, 2015). But at a time of debate about the judicialization of the right to health care in the country, when a large amount of actions and the prominence of the Judiciary is observed (Guimarães, 2014), would these norms have the ability to streamline the judicialization of health?

In order to contribute to the debate, this study verified the potential to streamline the criteria of universal access to comprehensive pharmaceutical assistance, established by Law no. 12,401/2011 and by Decree no. 7,508/2011, in the judicialization of health after analyzing its impact on the first decade of the judicialization of the access to medicines in Minas Gerais, between 1999 and 2009.

Methods

This is a retrospective and descriptive study based on the records of the 6,112 legal proceedings in health deferred against the State Secretariat of Health of Minas Gerais (SES/MG) between October 1999 and October 2009. The database containing such records was created by the Research Group on Health Economics at the Universidade Federal de Minas Gerais (EPG/UFMG) from documentation of legal proceedings provided by SES/MG. The database contains variables with information about the legal aspect of the proceeding, the beneficiary, the author, the legal representative, the defendant, the service, the medicine and the possible proceedings, materials and inputs.

To conduct the analysis of this study, we selected variables that contained information about the clinical care (presence of logo of SUS in the prescription, nature of the service organization and professional record of the prescriber) and the medicine (year of the process, medicine, active ingredient, classification – if medicine, cosmeceutical, nutritional support or another – and inclusion into Rename 2013). The medicines with undefined active ingredients and those classified as cosmeceuticals, nutritional support or other were excluded.

The variables selected for the study were confronted with the criteria for access to the pharmaceutical assistance imposed in 2011 as follows: when the care was provided in an establishment of public nature, it was considered that the patient was assisted by health actions and services within SUS (criterion I); in the case of prescription with the logo of SUS, we understood that the medicine was prescribed by a health professional in the regular exercise of his/her functions in SUS (criterion II); when the medicine demanded was in Rename, it was considered that the limitation period was in accordance with the Clinical Protocols and Therapeutic Guidelines (PCDT) and/or Rename (criterion III), since the legislations require compliance with the Relation in the absence of clinical protocols, and few of them had been adopted/updated until 2010 (Pepe, 2011). As judicialization precedes the dispensation of medicines, the IV criterion, "the dispensation must have occurred in units indicated by the directors of SUS" was disregarded.

When there was not enough information about the care and prescription that originated the dispensation of a drug, Rename 2013 was considered a reference for conducting the analysis, since this information was available to all medicines selected for this study.

Considering the possibility of hiring private services within SUS, the classification adopted in this study according to the suitability of the criteria defined by the Decree no. 7,508/2011, together with Law no. 12,401/2011 was set as shown in Chart 1. From this classification, the absolute and relative frequencies of distribution of judicialized medicines were calculated among the groups of defined criteria.

Chart 1 – Classification adopted to assess the adequacy of judicialized medicines to the criteria for the access to the pharmaceutical assistance

Classification	Criterion I – the patient must be assisted by health actions and services of SUS	Criterion II – the medicine must have been prescribed by health professionals in the regular exercise of their functions in SUS	Criterion III – the prescription must be in accordance with PCDT and/or Rename
Adequate (1)	Organization of public, non-informed or private nature	Prescription with logo of SUS	Medicine included in Rename
Adequate (2)	Organization of public nature	No information about the logo of SUS or prescription without logo of SUS	Medicine included in Rename
Impossible to classify	Organization of non-informed or private nature	No information about the logo of SUS	Medicine included in Rename
Inadequate (1)	Organization of non-informed or private nature	Prescription with logo of SUS	Medicine included in Rename
Inadequate (2)	Organization of public, non-informed or private nature	Prescription without or with the logo of SUS or without information about its existence	Medicine NOT included in Rename

The limitations of the study include: the lack of assessment of PCDT, since it is not always a medicine that is present in Rename will be judicialized for use according to clinical protocols (off label use); the lack of assessment of the inclusion of medicines in the Relation to Medicines of the State of Minas Gerais and in the Municipal Relations of Essential Medicines of the municipalities of Minas Gerais, which were supportive defendants of the state of Minas Gerais, since, according to the legislations, the prescription must be in compliance with one of these three official lists of medicines; the assessment of the inclusion criterion in Rename having as reference the Relation of 2013 and not that into force on the date of the court order; and the possibility of misuse of the prescription of SUS to patients treated in private institutions that were not hired by the public health system.

This study was conducted as part of the master's thesis of the first author, supported by Capes. In addition, it integrates the projects "Impact of lawsuits on the national pharmaceutical assistance policy: clinical management and medicalization of justice" (CNPq/EPG/FM/UFMG) and "Budget impact analysis in the Brazilian National Health System (SUS) of the most demanded medicines by judicial means in Pharmaceutical Assistance Programs "(Fapemig no. 14/2013, Research Program for SUS (PPSUS MS/CNPq Fapemig/SES)), whose approval by the Research Ethics Committee of UFMG was obtained by Opinion no. Etic 292/08.

Results

Of the 11,507 items deferred as pharmaceuticals in lawsuits against the SES/MG from October 1999 to October 2009, 10,051 medicines were selected for the study. Among these, 773 (7.69%) medicines were classified as adequate and 6,919 (68.84%) as inadequate to the criteria for access to the

pharmaceutical assistance imposed in 2011. Table 1 shows the distribution of medicines according to the classification proposed.

Table 1 – Distribution of 10,051 judicialized medicines according to the classification of adequacy to the criteria for access to the pharmaceutical assistance, Minas Gerais, 1999-2009

Classification	Number of medicines	Percentage (%)
Adequate (1)	406	7.69
Adequate (2)	367	
Impossible to classify	2,359	23.47
Inadequate (1)	1,985	68.84
Inadequate (2)	4,934	
TOTAL	10,051	100.00

Source: Banco de Dados Judicialização, GPES/UFMG, 2018

Of the 10,051 medicines, 5,580 (55.52%) were related to at least one information about the nature of the establishment or existence of the logo of SUS in the prescription, then we opted for the additional analysis of this group of drugs, so the classification was not based on data related only to the criterion III. According to these parameters, the inadequacy to the criteria increased to 85.77% regarding medicines, while adequacy increased to 13.85%.

The classification was also applied to each year of the period to investigate differences, similarities and trends. Between 1999 and 2002, the number of legal proceedings deferred against the state of Minas Gerais was lower than 100, so we chose to consider the period from 2003 to 2009 for the analysis of temporal trend. Table 2 shows the result of the classification adopted and the number of judicialized medicines for each year studied.

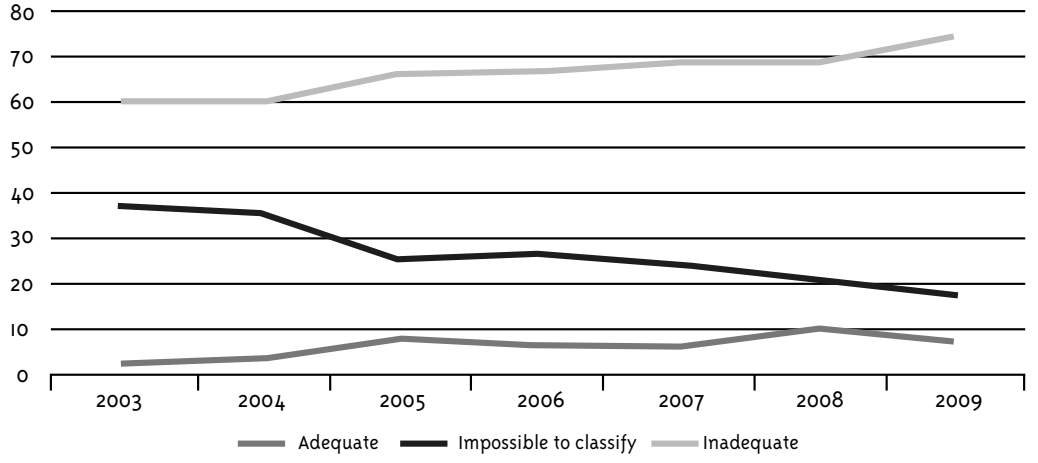
The proportion of medicines adequate to the criteria for access to the pharmaceutical assistance increased randomly between 2003 and 2009, against a steady increase in the proportion of medicines classified as inadequate to the criteria. In addition, we observed an inverse decreasing trend of the lack of information about health care over the years. Figure 1 shows the behavior almost mirrored the curves relating to the classifications "Impossible to classify" and "inadequate."

Table 2 – Distribution of 10,051 medicines deferred in legal proceedings against the state, per year, according to the classification of adequacy to the criteria for access to the pharmaceutical assistance, Minas Gerais, 1999-2009

Year	Quantity of judicialized medicines	Proportion of medicines adequate to the criteria (%)	Proportion of medicines impossible to classify (%)	Proportion of medicines inadequate to the criteria (%)
1999	2	50.00	0.00	50.00
2000	15	20.00	33.33	46.67
2001	3	33.33	66.67	0.00
2002	54	1.85	59.26	38.89
2003	113	2.65	37.17	60.18
2004	315	3.81	35.87	60.32
2005	835	7.90	25.75	66.35
2006	1,614	6.38	26.83	66.79
2007	2,489	6.39	24.59	69.02
2008	2,929	10.07	20.76	69.17
2009	1,682	7.67	17.66	74.67

Source: Banco de Dados Judicialização, GPES/UFMG, 2018

Figure 1 – Proportion of judicialized medicines, per year, according to the classification of adequacy to the criteria for access to the pharmaceutical assistance, Minas Gerais, 2003-2009



Source: Banco de Dados Judicialização, GPES/UFMG, 2018

Discussion

The results of this study show that the definition of the outlines of comprehensiveness by Law no. 12,401/2011 and universal and equal access to the pharmaceutical assistance by Decree no. 7,508/2011 could lead to a significant reduction in the judicialization of health care, if the Judiciary guided its actions based on the criteria set out in such legislations. If, between 1999 and 2009, such parameters were respected by the Judiciary, at least 68.84% of the judicialized medicines in Minas Gerais would have been deferred. The temporal analysis from 2003 to 2009 shows the possibility of increasing this proportion when more information is available. By analyzing only the medicines to which it was possible to assign at least one information about their prescription, the percentage of inadequacy to the criteria increased to 85.77%, confirming the importance of having detailed information about the judicialization of health care for its deep knowledge.

Due to the lack of national data that can offer a Brazilian overview for judicialization, we believe that the results in Minas Gerais, the second state with more lawsuits in health care (Aumentam..., 2017), may reflect the relevance of the impact generated by the observance of Law no. 12,401/2011 and Decree no. 7,508/2011 by the Judiciary.

However, we do not know to what extent the parameters established in 2011 were incorporated by the legal practitioners, and further research with updated data need to be conducted. Recent studies indicate that decisions in disagreement with public policies are still being made (Asensi; Pinheiro, 2016; Guimarães, 2014; Siqueira, 2015), which suggests that the legislations addressed in this study did not influence a decisive judicial action. In 2015, after evaluating legal proceedings complied by the State Secretariat of Health of São Paulo, Siqueira (2015) found that 69% of the prescriptions in the processes came from the private health network. In addition, the author showed that, although Rename 2013 includes 884 medicines offered to meet the needs for 99% of diseases, 93% of the judicialized medicines in the state were not covered by SUS and the 7% covered were not in compliance with PCDT (Siqueira, 2015).

For Guimarães (2014), one of the possible explanations for the failure to comply with the legislations by the Judiciary is the dubiousness of the conclusions issued by the final report of the Public Hearing of 2009, which recognizes the legitimacy and accountability of SUS to decide what will be offered and under what conditions, but at the same time, it assumes the prerogative of Judicial decisions against the guidelines of public health policy. The author suspects that there is no big "doctrinal and

pedagogical" effort for the proper dissemination of Law no. 12,401/2011, including the managers of SUS.

Also, the historic moment of the prominence of the Judiciary must be considered (Guimarães, 2014), which, according to Asensi and Pinheiro (2016), is more similar to a health policy. Guimarães (2014) highlights an increasing trend to transfer political decisions to the legal sphere, including the scope of the evaluation and incorporation of health technologies. When discussing the challenges of political incorporation of technologies in SUS, the author indicates that, according to the international experience, the success of agencies of health technology assessment (ATS) such as Conitec, created by Law no. 12,401/2011, depends significantly on its public recognition and prestige, such as what happens with the National Institute for Health and Care Excellence (Nice) in England. In Brazil, however, despite Conitec being a national reference agency in ATS, the National Justice Council (CNJ) has a parallel project financially supported by the Ministry of Health, regarding the creation of a database of technical notes on health drawn up by Technical Support Centers to subsidize judicial decisions only (CNJ..., 2016).

In this context, we should consider that, although the creation of Conitec means a breakthrough for health policy in Brazil, it has not yet achieved the "methodological development and broad scientific legitimacy and potential for comprehensive political action" (Novaes; Soárez, 2016, p. S11). For institutional strengthening, Conitec needs funds for the maintenance of a technical framework of stable and qualified human resources; greater transparency in the processes and decisions, including prioritization criteria of evaluations; promotion of greater involvement and clarification of civil society and greater independence; as well as the development of more rigorous research (Guimarães, 2014; Novaes; Soárez, 2016).

Final considerations

Once the importance of a robust policy of ATS in a context of intense judicialization and technology imperative is recognized (Andrade et al., 2008; Guimarães, 2014), a question needs to be answered: instead of creating and supporting a parallel network of health technology analysis centered on CNJ, would it not be more appropriate for such efforts to focus on the improvement and strengthening of the policy of ATS of SUS itself, such as Conitec?

In this scenario of prominence of the Judiciary, the decisions taken by the Justice System for the confrontation of judicialization can find more supporters than the decisions taken by the parliamentary system, as is the case of the legislations in question.

Bittencourt (2016, p. 107) indicates that, currently, the judicialization of health represents "not only a conflict, but also a sociopolitical phenomenon," and all its complexity, its impact, as well as the responses of institutional powers (whether the Judiciary or Parliamentary systems) should be carefully analyzed. In this context, the results of this study indicate the Law no. 12,401/2011 and Decree no. 7,508/2011 as potential tools for streamlining the judicialization of health in the country.

However, to streamline judicialization does not automatically approach the State to the implementation of the right to health in the constitutional provisions. The streamlining potential of the criteria established in 2011 for universal access and comprehensive pharmaceutical assistance goes through definitions of the principles of SUS that can, at some extent, drive the health policy away from the constitutional landmark. Thus, a thorough reflection should be made about the impacts of defining the judicial activity in health care by such criteria, and further studies must be carried out on the subject.

References

AITH, F. et al. Os princípios da universalidade e integralidade do SUS sob a perspectiva da política de doenças raras e da incorporação tecnológica. *Revista de Direito Sanitário*, São Paulo, v. 15, n. 1, p. 10-39, 2014. Disponível em: <https://bit.ly/2U345IM>. Acesso em: 23 set. 2016.

ANDRADE, E. I. G. et al. A judicialização da saúde e a política nacional de assistência farmacêutica no Brasil: gestão da clínica e medicalização da justiça. *Revista Médica de Minas Gerais*, Belo Horizonte, v. 18, n. 4, p. 46-50, 2008. Suplemento 4.

Disponível em: <https://bit.ly/2FKY3DU>. Acesso em: 14 out. 2016.

ASENSI, F. D.; PINHEIRO, R. Judicialização da saúde no Brasil: dados quantitativos sobre saúde pública. Rio de Janeiro: UERJ, 2016. Disponível em: <https://bit.ly/2V3qORf>. Acesso em: 14 out. 2016.

AUMENTAM os gastos públicos com judicialização da saúde. *Tribunal de Contas da União*, Brasília, DF, 23 ago. 2017. Notícias. Disponível em: <https://bit.ly/2V5dI6a>. Acesso em: 9 dez. 2017.

BALESTRA NETO, O. A jurisprudência dos Tribunais Superiores e o Direito à Saúde: evolução rumo à racionalidade. *Revista de Direito Sanitário*, São Paulo, v. 16, n. 1, p. 87-111, 2015. Disponível em: <https://bit.ly/2U31bnp>. Acesso em: 23 set. 2016.

BITTENCOURT, G. B. O "estado da arte" da produção acadêmica sobre o fenômeno da judicialização da saúde no Brasil. *Cadernos Ibero-Americano de Direito Sanitário*, Brasília, DF, v. 5, n. 1, p. 102-121, 2016. Disponível em: <https://bit.ly/2JPwEVr>. Acesso em: 23 set. 2016.

BRASIL. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. *Diário Oficial da União*, Brasília, DF, 28 abr. 2011a. Disponível em: <https://bit.ly/2JPrSHr>. Acesso em: 14 out. 2016.

BRASIL. Decreto nº 7.508, de 28 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde - SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. *Diário Oficial da União*, Brasília, DF, 28 jun. 2011b. Disponível em: <https://bit.ly/2lFZNoB>. Acesso: em 14 out. 2016.

CNJ e Ministério da Saúde firmam acordo para criação de banco de dados. *Conselho Nacional de Justiça*, Brasília, DF, 23 ago. 2016. Notícias. Disponível em: <https://bit.ly/2OvOziz>. Acesso em: 23 set. 2016.

GUIMARÃES, R. Incorporação tecnológica no SUS: o problema e seus desafios. *Ciência & Saúde Coletiva*, Rio de Janeiro, v. 19, n. 12, p. 4899-4908, 2014. Disponível em: <https://bit.ly/2CEpHAr>. Acesso em: 23 set. 2017.

NOVAES, H. M. D.; SOÁREZ, P. C. Organizações de avaliação de tecnologias em saúde (ATS): dimensões do arcabouço institucional e político. *Cadernos de Saúde Pública*, Rio de Janeiro, v. 32, p. S1-S14, 2016. Suplemento 2. Disponível em: <https://bit.ly/2Oy29Sx>. Acesso em: 15 jan. 2018.

PEPE, V. L. E. O formulário terapêutico nacional, os protocolos clínicos e diretrizes terapêuticas: extensões da seleção de medicamentos. *Escola Nacional de Saúde Pública Sergio Arouca*, Rio de Janeiro, 2011. Disponível em: <https://bit.ly/2GXL6nz>. Acesso em: 15 jan. 2018.

RAMOS, E. M. B.; DINIZ, I. M.; MADUREIRA, A. S. O Conselho Nacional de Justiça: o Fórum da Saúde e o excesso de judicialização. *Cadernos Ibero-Americanos de Direito Sanitário*, Brasília, DF, v. 4, n. 4, p. 81-89, 2015. Disponível em: <https://bit.ly/2UhtoYh>. Acesso em: 23 set. 2016.

SIQUEIRA, P. S. F. A judicialização da saúde no estado de São Paulo. In: CONASS - CONSELHO NACIONAL DE SECRETÁRIOS DE SAÚDE. *Direito à saúde*. Brasília, DF, 2015. p. 1-15. (Coleção Para Entender a Gestão do SUS: 2015). Disponível em: <https://bit.ly/2CJhoTL>. Acesso em: 14 out. 2016.

Authors' contribution

Lopes designed the study, collected and analyzed the data and wrote the article. Diniz, Coelho and Andrade have contributed to the discussion of the project and with the data and revised the manuscript. All authors approved the final version of the article.

Received: 21/11/2018
Approved: 28/02/2019.