



# Legal action for access to resources inefficiently made available in health care systems in Brazil: a case study on obstructive sleep apnea

Daniela V Pachito<sup>1</sup>, Beny Finkelstein<sup>2</sup>, Claudia Albertini<sup>2</sup>, Antonio Gaspar<sup>3</sup>, Carolina Pereira<sup>3</sup>, Paulo Vaz<sup>3</sup>, Alan Luiz Eckeli<sup>4</sup>, Luciano F Drager<sup>5,6</sup>

1. Prossono – Centro de Diagnóstico e Medicina do Sono, Ribeirão Preto (SP) Brasil.
2. ResMed Brasil, São Paulo (SP) Brasil.
3. Heads in Health, São Paulo (SP) Brasil.
4. Departamento de Neurociências e Ciências do Comportamento, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto (SP) Brasil.
5. Unidades de Hipertensão, Instituto do Coração – InCor – e Disciplina de Nefrologia, Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, São Paulo (SP) Brasil.
6. Centro de Cardiologia, Hospital Sírio-Libanês, São Paulo (SP) Brasil.

Submitted: 20 March 2022.

Accepted: 6 December 2022.

Study carried out in the Departamento de Neurociências e Ciências do Comportamento, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto (SP) Brasil.

## ABSTRACT

**Objective:** Obstructive sleep apnea (OSA) is a highly prevalent chronic disease, associated with morbidity and mortality. Although effective treatment for OSA is commercially available, their provision is not guaranteed by lines of care throughout Brazil, making legal action necessary. This study aimed at presenting data related to the volume of legal proceedings regarding the access to diagnosis and treatment of OSA in Brazil. **Methods:** This was a descriptive study of national scope, evaluating the period between January of 2016 and December of 2020. The number of lawsuits was analyzed according to the object of the demand (diagnosis or treatment). Projections of total expenses were carried out according to the number of lawsuits. **Results:** We identified 1,462 legal proceedings (17.6% and 82.4% related to diagnosis and treatment, respectively). The projection of expenditure for OSA diagnosis in the public and private spheres were R\$575,227 and R\$188,002, respectively. The projection of expenditure for OSA treatment in the public and private spheres were R\$2,656,696 and R\$253,050, respectively. There was a reduction in the number of lawsuits between 2017 and 2019. **Conclusions:** Legal action as a strategy for accessing diagnostic and therapeutic resources related to OSA is a recurrent practice, resulting in inefficiency and inequity. The reduction in the number of lawsuits between 2017 and 2019 might be explained by the expansion of local health care policies or by barriers in the journey of patients with OSA, such as difficulties in being referred to specialized health care and low availability of diagnostic resources.

**Keywords:** Sleep apnea, obstructive; Continuous positive airway pressure; Polysomnography; Health services accessibility.

## INTRODUCTION

Access to health care is a right granted to the Brazilian citizen by the Federal Constitution of 1988.<sup>(1)</sup> Article 196 reads "Health is a right for all and a duty of the State, guaranteed through social and economic policies." In this sense, Brazilian National Ministry of Health/Health Minister's Office Ordinance no. GM 4,279/2010, which establishes guidelines for the organization of the Brazilian Health Care Network within the scope of the *Sistema Único de Saúde* (SUS, Unified Health Care System), aims to promote the systemic integration of health actions and services, ensuring the provision of continuous, comprehensive, responsible, humanized, and high-quality care.<sup>(2)</sup>

The process of incorporating technologies in the SUS is carried out by an agency of the Brazilian National Ministry of Health called the *Comissão Nacional de Incorporação de Tecnologias no SUS* (Conitec, Brazilian National Commission for the Incorporation of Technologies in the SUS). Conitec carries out the evaluation for incorporation of health technologies by assessing effectiveness, safety,

cost-effectiveness, and budgetary impact. Technologies incorporated after the evaluation process become part of the National List of Medications or the National List of Equipment and Permanent Fundable Materials for the SUS. Together, the list of these products and services are made available to SUS users in compliance with the recommendations on specific lines of care, presented in the Brazilian Clinical Protocols of Therapeutic Guidelines.

Obstructive sleep apnea (OSA) is a highly prevalent chronic disease. OSA is characterized by partial or complete obstruction of the upper airways during sleep, contributing to fragmented, poor-quality sleep.<sup>(3)</sup> In Brazil, it is estimated that OSA affects 50 million inhabitants.<sup>(4)</sup> This condition promotes a negative impact on quality of life<sup>(5)</sup> and is associated with clinical conditions such as systemic arterial hypertension,<sup>(6)</sup> acute myocardial infarction,<sup>(7)</sup> atrial fibrillation,<sup>(8)</sup> stroke,<sup>(9)</sup> diabetes mellitus,<sup>(10)</sup> motor vehicle crashes,<sup>(11)</sup> and work-related accidents.<sup>(12)</sup> Despite its high prevalence of OSA and the association of OSA with morbidity and mortality, assistance to patients with OSA is neither included in

### Correspondence to:

Daniela Vianna Pachito. Rua Itacolomi, 149, Ribeirão Preto, CEP 14025-250, SP, Brasil.

Tel.: 55 16 3610-0735. E-mail: pachito@uol.com.br

Financial support: This study received financial support from ResMed Brasil.

health care protocols nor guaranteed by lines of care or networks nationally established in Brazil.

Legal action is a strategy that users of health care systems in Brazil have employed as a way to gain access to incorporated diagnostic and therapeutic procedures that are not effectively available, as well as to non-incorporated technologies. According to data from the Brazilian National Council of Justice, between 2008 and 2017, there were 498,715 health-related lawsuits in the first instance.<sup>(13)</sup> Among these lawsuits, 55.6%, 47.1%, and 33.1%, respectively, were related to access to diagnostic technologies, procedures, and supplies or materials. The temporal analysis of the volume of legal actions showed an increase of approximately 130% in the number of health-related legal proceedings between 2008 to 2017.<sup>(13)</sup>

Positive airway pressure (PAP) devices are considered the most effective technology for treating moderate to severe cases of OSA. Although this technology has officially been incorporated by Conitec, with provision for dispensation by the states and the Federal District, the effective provision of the technology depends on local terms of cooperation with responsible bodies. In this scenario, legal action is expressed as a strategy for obtaining specialized assistance. This study aimed at presenting data related to the volume of legal proceedings regarding the access to diagnosis and treatment of OSA in Brazil.

## METHODS

This was a descriptive study of secondary data collected nationwide between January of 2016 and December of 2020. The identification and evaluation of legal proceedings related to access to diagnosis and/or treatment of OSA were conducted in four phases (Chart 1).

During phase 1, two search strategies were developed. Search terms for the diagnosis of OSA were "Polysomnography", "Polysomnogram", "PSG", and "Sleep Apnea Diagnosis," whereas those for the treatment of OSA were "CPAP", "CEPAP", "BILEVEL", "BIPAP", and "Positive Pressure." Sources of information were first and second instances courts of justice at the national, state, and Federal District levels in Brazil.

Phase 2 involved conducting searches in the databases of the courts of justice within the period defined for the analysis. Data from lawsuits potentially related to the diagnosis and/or treatment of OSA were retrieved for further analysis and consolidation.

During phase 3, information related to legal proceedings was manually extracted and consolidated, and then entered into Microsoft Excel software spreadsheets. The compiled variables included date,

court of origin, geographic region, medical board registration number of the prescribing physician, incurred monetary value, object of the demand (diagnosis or treatment), and type of device demanded.

Phase 4 involved the analysis of information obtained from the Information Technology Department of the SUS: geographic region (of the plaintiff and of the court of justice), presence of regional protocols and/or guidelines for the provision of CPAP, and registration number at the National Registry of Health Establishments of the health care facility (defendant). Data from the Federal Council of Medicine were also collected about the prescribing physicians with regard to their being registered as specialists in sleep medicine in the Brazilian Medical Association.

The number of lawsuits was presented as absolute and relative frequencies by geographic region. Data referring to the amounts incurred in the legal proceedings were presented according to the type of health care system (public or private) using measures of central tendency and dispersion. For the estimate of total expenses associated with legal proceedings, including those with no report on the expenses incurred, a projection was made by using the median value of the known expenses. Additionally, a best-case deterministic sensitivity analysis was performed, using the first quartile for the projection of total expenditure, as was a worst-case deterministic sensitivity analysis, using the third quartile for the projection of total expenditure.

## RESULTS

The present study identified a total of 1,462 cases of legal proceedings related to OSA, 258 (17.6%) of which regarding diagnosis and 1,204 (82.4%) of which regarding treatment. In total, only 59.4% of the records had reported the monetary values incurred. Of these, 36.4% were related to the diagnosis and 64.4% were related to the treatment of OSA (Figure 1). Over the period analyzed, there was a downward trend in the number of lawsuits related to OSA treatment and diagnosis, with a reduction of more than 50% in the number of lawsuits in 2019 in comparison with that in 2017. The distribution of lawsuits among the geographic regions of Brazil is presented in Table 1.

The analysis of the distribution of legal proceedings by state and the Federal District showed a concentration of proceedings in São Paulo (n = 780; 53%); Minas Gerais (n = 263; 18%); Rio Grande do Sul (n = 171; 12%); Rio de Janeiro (n = 77; 5%); and the Federal District (n = 30; 2%). They accounted for 91% of the total number of cases during the study period. When considering the number of lawsuits per million

**Chart 1.** Steps for identifying lawsuits related to obstructive sleep apnea.

Phase 1: Search planning, and defining keywords, information sources, and study period
Phase 2: Execution of the search in pre-defined information sources
Phase 3: Data consolidation
Phase 4: Analysis of variables and comparison of information obtained from other public databases

population, the rate in the Southeast region was 1.8 times greater than that in the whole country (10.6 per million population vs. 5.7 per million population).

Of the 1,462 lawsuits, 1,383 (94%) were against governments, 70 (5%) were against private health care providers, and 9 (1%) were kept confidential. Of the lawsuits against governments, 720 (52%), 654 (47%), and 9 (1%), respectively, were at the municipal, state, and federal levels.

**Analysis of legal proceedings related to the diagnosis of OSA**

The analysis of the legal proceedings related to the diagnosis of OSA showed that the state of Minas Gerais ranked first (n = 102; 40%), followed by São Paulo (n = 57; 22%), Rio Grande do Sul (n = 22; 9%), Rio de Janeiro (n = 20; 8%), and Goiás (n = 9; 3%).

Polysomnography is the diagnostic procedure for OSA and is identified in the Management System of the Table of Procedures, Medications, Orthoses, Prostheses, and Special Materials of the SUS (SIGTAP). The analysis showed that 87 legal proceedings (34%) originated from municipalities where the procedure is available in public or private health care services, whereas 171 (66%) originated from municipalities where this procedure is not offered to SUS users.

In 94 legal proceedings (36.4%), it was possible to identify the expenses associated with the requested resource. The monetary value was analyzed separately according to the type of defendant in question (public or private). Legal action was taken against the public and private sphere in 83 and 11 lawsuits, respectively. For lawsuits involving public entities, corresponding to 78 (89%) of the records, the projected expenses

related to all lawsuits, calculated after the imputation of the median value for lawsuits with no reference to the expense incurred, was R\$575,227 for the base case. Sensitivity analysis showed expenses ranging from R\$542,747 to R\$1,031,227 in the best and worst case scenarios. In the private health care system, the total expenditure was estimated at R\$188,002, and sensitivity analyzes ranged from R\$168,906 to R\$202,330 (Table 2).

**Analysis of legal proceedings related to the treatment of OSA**

**Profile of the physician responsible for prescribing treatment**

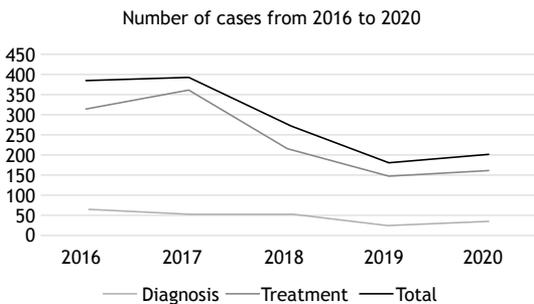
It was possible to identify the physician prescribing treatment in 424 lawsuits (29.0%). Of these, 104 requesting physicians (24.6%) were considered specialists in sleep medicine by the Brazilian Medical Association, whereas 320 had no specialization in that area. We were able to identify the specialties of 297 physicians. The most common ones were ear, nose, throat, in 28.3%; pulmonology, in 18.2%; and neurology, in 13.1%. There were also cardiologists (2.7%), general practitioners (2.7%), psychiatrists (1.7%), and occupational physicians (1.3%).

**Types of PAP devices requested and expenses incurred**

CPAP and BiPAP devices were demanded in 1,117 (95.8%) and 36 (3.0%) of the lawsuits, respectively. It was not possible to identify the type of device requested in 1.2% of cases. Approximately 64% of the lawsuits presented the amounts of expenses incurred.

The expenses associated with CPAP, both in the public and private spheres, were classified as expenses with the purchase or lease of equipment. In the public sphere, 210 of the 624 lawsuits (34%) were related to purchase, while 414 (66%) were related to leasing.

For cases involving public entities, the projected value related to the acquisition of the devices, with the imputation of the median for cases with no reference to the expense incurred, was R\$1,340,781; sensitivity analyzes ranged from R\$1,284,769 to R\$1,443,229. Regarding equipment leasing, the total expenses incurred were estimated at R\$574,525. Including the projection of the lawsuits in which the type of arrangement was not mentioned (i.e., purchase or



**Figure 1.** Number of lawsuits related to obstructive sleep apnea from 2016 to 2020.

**Table 1.** Number of lawsuits related to the diagnosis and treatment of obstructive sleep apnea, stratified by geographic regions of Brazil, during the study period.

Region	Type of resource			%	TP	Per million population		
	Diagnosis	Treatment	Total			Diagnosis	Treatment	Total
Southeast	180	943	1,123	76.8	89	2.0	10.6	12.6
South	28	164	192	13.1	30	0.9	5.4	6.4
Central-west	28	63	91	6.2	17	1.7	3.8	5.5
Northeast	20	3	53	3.6	57	0.3	0.6	0.9
North	2	1	3	0.2	19	0.1	0.1	0.2
Total	258	1,204	1,462	100	212	1.2	5.7	6.9

TP: total population in millions.

leasing), according to the proportions observed in the lawsuits in which this information was present, we found a total expense of R\$2,656,696, and the sensitivity analysis ranged from R\$2,503,032 to R\$2,937,754.

In the private health care system, the total expenditure on lawsuits related to the treatment of OSA was estimated at R\$253,050, and the sensitivity analyzes ranged from R\$211,191 to R\$349,763 (Table 3).

## DISCUSSION

Our findings demonstrate that legal action as a way of accessing diagnostic and therapeutic resources for OSA is a common practice, both in the public and private spheres. Treatment with a PAP device is considered the first line of treatment for moderate to severe cases, in addition to being considered cost-effective.<sup>(14)</sup> The absence of well-defined lines of care and national public guidelines for a highly prevalent condition, potentially treatable, and with a significantly associated burden is a demonstration of the restriction of an integral health care system, one of the basic principles of the SUS.

Legal action regarding health care has become an increasingly common practice to obtain access to health

care in Brazil. In a study conducted in the state of Minas Gerais, most lawsuits were related to legalized high-cost medications, approved by the Brazilian Health Regulatory Agency, for more advanced lines of treatment for clinical conditions such as rheumatoid arthritis and ankylosing spondylitis.<sup>(15)</sup> In the same study, approximately 5% of the technologies demanded were not registered by the Brazilian Health Regulatory Agency, which denotes the emerging nature of these technologies.<sup>(15)</sup> Similar findings were found in a study conducted in the state of Rio Grande do Norte which showed a predominance of claims related to antineoplastic agents and immunomodulators.<sup>(16)</sup> Approximately 13% of the lawsuits in the state of Rio Grande do Norte involved at least one off-label drug.<sup>(17)</sup> Additionally, a systematic review of descriptive studies evaluating lawsuits in Brazil showed that the proportion of therapeutic technologies being requested that could potentially be replaceable by technologies available in the SUS ranged from 41.7% to 80.0%.<sup>(18)</sup>

The present study identified a total of 1,462 cases of legal action related to OSA, 17.6% and 82.4% of which related to the diagnosis and treatment of this condition, respectively. Data from the Brazilian National Council of Justice<sup>(19)</sup> revealed that the proportion of lawsuits requesting access to diagnosis of any condition was 55.6%, and our results showed that 17.6% were

**Table 2.** Expenses associated with legal proceedings regarding diagnosis of obstructive sleep apnea in Brazil during the study period.

Sphere	Lawsuits indicating costs, n	Costs indicated in the lawsuits, R\$			Lawsuits, N	Total projected value, R\$		
		Total	Median (IQR)	Mean		Base case	Best case scenario	Worst case scenario
Public	83	415,227	1,000 (797-3,850)	5,002.73	243	575,227	542,747	1,031,227
Private	11	140,906	11,774 (7,000-15,356)	12,809.63	15	188,002	168,906	202,330
Total	94	556,133	1,000 (899-5,975)	5,916.31	258	763,229	711,653	1,233,557

R\$: Brazilian reais.

**Table 3.** Expenses associated with legal proceedings regarding treatment of obstructive sleep apnea in Brazil during the study period.<sup>a</sup>

Sphere	Lawsuits indicating costs, n	Costs indicated in the lawsuits, R\$			Lawsuits, N	Total projected value, R\$		
		Total	Median (IQR)	Mean		Median	Best case scenario (Q1)	Worst case scenario (Q3)
Public	624	1,589,754	1,000 (1,000-3,000)	2,708.53	1,140	2,656,696	2,503,032	2,937,754
Purchase	212	1,063,229	3,652 (2,915-5,000)	5,138.70	288	1,340,781	1,284,769	1,443,229
Lease	414	526,525	1,000 (1,000-1,000)	2,783.30	462	574,525	574,525	574,525
Unspecified	0				390	741,390	643,737	920,000
Private	21	140,619	5,000 (1,000-10,000)	2,703.59	55	253,050	211,191	349,763
Purchase	12	113,353	10,000 (5,000-12,000)	9,525.19	16	153,353	133,353	161,353
Lease	9	27,267	1,000 (1,000-4,000)	2,783.30	30	48,267	48,267	111,267
Unspecified	0				9	51,430	29,571	77,143
Total	645	1,730,373	1,000 (1,000-3,400)	2,838.66	1,204	2,909,746	2,714,223	3,287,517

R\$: Brazilian reais; Q1: first quartile; and Q3: third quartile. <sup>a</sup>For lawsuits with no specification of the demand (purchase or lease), the proportion of purchase and lease observed in the lawsuits in which such information was available was considered, as were the summary measures of these lawsuits.

related to the diagnosis of OSA alone. Regarding treatment-related lawsuits, the Brazilian National Council of Justice reported an overall proportion of 33.1%, whereas we found a much greater proportion (82.9%) considering the treatment of OSA alone. This difference may indicate that it is more difficult to have access to OSA treatment than to treatment for other conditions. In this sense, legal action as a form of access to the diagnosis and treatment of OSA differs in relation to the prevailing demands in the national scene. The use of CPAP is considered the first line of treatment for moderate to severe OSA cases. The use of intraoral appliances as an alternative treatment for OSA, usually effective for milder cases,<sup>(20)</sup> is not covered by the SUS either, which means that the only treatment alternatives offered are airway surgical procedures.

Legal action in this scenario can, therefore, be explained by the inexistence of a line of care for these patients, the high prevalence of the disease, and the scarcity of allocated resources, such as hospital beds for polysomnography, which is necessary for diagnosis. Polysomnography is a mandatory procedure to be provided by the SUS, either in the hospital or in the outpatient clinic environment. According to SIGTAP, polysomnography costs in an outpatient clinic or in a hospital were R\$125.00 and R\$170.00, respectively, in 2020.<sup>(21)</sup> Considering that this is a specialized procedure that takes a long time and needs continuous technical supervision, the monetary value presented in the SIGTAP is lower than the real cost of the test, which represents a barrier to the opening and maintenance of sleep laboratories accredited by the SUS.

The median of expenditure incurred in lawsuits related to the diagnosis of OSA in the SUS was R\$1,000 during the study period. According to the SIGTAP, the cost for performing a polysomnography in a hospital environment was R\$170.00, that is, five users of the public health care system could have undergone to a polysomnography at that cost, which demonstrates the harmful effects of legal action on the efficiency and sustainability of the SUS.

Although there is not an official protocol or national guidelines from the Brazilian National Ministry of Health to define the line of care for patients with OSA, Conitec recommends an expense of R\$3,000 for the acquisition of a CPAP device. The average amount incurred in the analyzed lawsuits involving the public health care system was R\$3,652, representing a 21.7% surplus of the value recommended by the Conitec. Such discrepancies can be justified by the lack of implementing bidding processes for the acquisition of equipment and by missing opportunities to negotiate prices for high-volume purchases.

The negative impact on health care system efficiency also occurs from the perspective of private health care systems. Polysomnography is part of a set of mandatory procedures. The reference value to be paid depends on negotiations between each service provider and the paying source. The *Classificação*

*Brasileira Hierarquizada de Procedimentos Médicos* (CBHPM, Brazilian Hierarchical Classification of Medical Procedures) table provides the reference value to be used for initial negotiations. The 2016 CBHPM projected for 2018 stipulated that polysomnography had an initial trading value of R\$797.00.<sup>(22)</sup> Dividing the median of expenses incurred with lawsuits in the private sphere related to the diagnosis of OSA (R\$11,774) by that initial value, it is observed that 14 private health care users could have been served by the value proposed by the CBHPM table.

Over the period analyzed, there was a reduction in the absolute number of lawsuits between 2017 and 2019. This fact could be explained by the expansion of local policies allowing access to the diagnosis and treatment of OSA in some localities that introduced administrative processes for the treatment of OSA with CPAP. Alternatively, it may reflect the presence of barriers in patient care, such as the lack of diagnosis and reduced supply of specialized services. However, these arguments are speculative since there is no organized literature review evidencing it. National public guidelines have been proven to be effective to reduce legal action. In 1999, HIV infection was a well-established case of government response to reduce legal action and address health care needs. Between 1991 and 1998, 90% of the legal proceedings were related to the HIV infection. In 1999, with the creation of a national public health program to fight the condition, such lawsuits decreased to 16.7%.<sup>(23)</sup> Other possibilities are the existing barriers during the journey of the patient with OSA, such as the difficulty of being referred to a specialist and the low availability of polysomnography. According to the Brazilian legislation, the diagnosis and treatment of OSA can be performed by any physician. In clinical practice, however, board-certified physicians in sleep medicine are more prone to diagnose and treat patients with OSA.

The methodology used to identify lawsuits is a strong point of the current study. In order to portray the national scenario of legal action related to the care of patients with OSA, research was carried out in the electronic databases of 21 Brazilian Courts of Justice, 4 Superior Courts of Justice or Federal Regional Courts, and the Federal Supreme Court, using descriptive terms for identifying lawsuits related to the topic. The period analyzed encompassed the past 5 years. The projection of total expenses was carried out, with the imputation of the median values for the lawsuits that did not report expenses incurred, as well as deterministic sensitivity analyzes of the best and worst case scenarios, imputing the values of the first and third quartiles, respectively. This procedure allowed a more complete estimate of the total expenses incurred, in addition to considering the uncertainties in relation to the assigned amounts. It is noteworthy that the median was used and that the use of means would have led to more expressive expenditure estimates.

Despite the careful methodology adopted, this study has limitations. It is not possible to rule out the possibility of the existence of legal proceedings in which nonstandard terms describing the requested technologies have been used and which, therefore, might not have been identified, leading to an underestimation of the total universe of legal proceedings related to OSA. Additionally, the identification of specialists in sleep medicine among the prescribing physicians was carried out at the time of the analysis, and not at the time of the execution of the lawsuits, which might have led to an overestimation of the proportion of cases originated by such physicians. Similarly, the identification of health care facilities where the polysomnography procedure was available was performed at the time of analysis.

Although it is public knowledge that there are municipalities that have an organized administrative process, with public sleep centers to offer diagnoses and treatments, there are no systematized public data that allow these municipalities to be evaluated and compared. The present study offers a possibility to understand the volume of legal proceedings related to access to diagnosis and treatment of OSA in Brazil. It is therefore recommended that studies in this area should be conducted.

In conclusion, the high volume of legal proceedings related to the care of patients with OSA in Brazil might be due to the lack of a national public policy

that coordinates and guarantees the line of care of a prevalent, treatable condition associated with morbidity and mortality.

## AUTHOR CONTRIBUTIONS

DVP: conceptualization; methodology; formal analysis; drafting of the manuscript; and approval of the final version of the manuscript. BF: conceptualization; data curation; funding acquisition; project administration; methodology; formal analysis; drafting of the manuscript; and approval of the final version of the manuscript. CA: funding acquisition; review and editing the manuscript; and approval of the final version of the manuscript. AG, CP, and PV: investigation; data curation; resources; and approval of the final version of the manuscript. ALE and LFD: conceptualization; methodology; drafting and review of the manuscript; and approval of the final version of the manuscript.

## CONFLICT OF INTEREST

DVP, ALE, and LFD: consultancy activities for ResMed Brasil for this and other projects. BF: employee at ResMed Brasil during study conduction. CA: current employee at ResMed Brasil. AG, CP, and PV: consultancy activities for ResMed Brasil for this project.

## REFERENCES

1. Brasil. Constituição da República Federativa do Brasil. Brasília, DF: Senado Federal; 1988.
2. Brasil. Ministério da Saúde. Portaria n. 4.279, de 30 de dezembro de 2010. Diário Oficial da União. Brasília, DF; 31 dezembro 2010; Seção 1; p. 88.
3. Gottlieb DJ, Punjabi NM. Diagnosis and Management of Obstructive Sleep Apnea: A Review. *JAMA*. 2020;323(14):1389-1400. <https://doi.org/10.1001/jama.2020.3514>
4. Benjafield AV, Ayas NT, Eastwood PR, Heinzer R, Ip MSM, Morrell MJ, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med*. 2019;7(8):687-698. [https://doi.org/10.1016/S2213-2600\(19\)30198-5](https://doi.org/10.1016/S2213-2600(19)30198-5)
5. Moyer CA, Sonnad SS, Garetz SL, Helman JI, Chervin RD. Quality of life in obstructive sleep apnea: a systematic review of the literature. *Sleep Med*. 2001;2(6):477-491. [https://doi.org/10.1016/S1389-9457\(01\)00072-7](https://doi.org/10.1016/S1389-9457(01)00072-7)
6. Hou H, Zhao Y, Yu W, Dong H, Xue X, Ding J, Xing W, et al. Association of obstructive sleep apnea with hypertension: A systematic review and meta-analysis. *J Glob Health*. 2018;8(1):010405. <https://doi.org/10.7189/jogh.08.010405>
7. Loke YK, Brown JW, Kwok CS, Niruban A, Myint PK. Association of obstructive sleep apnea with risk of serious cardiovascular events: a systematic review and meta-analysis. *Circ Cardiovasc Qual Outcomes*. 2012;5(5):720-728. <https://doi.org/10.1161/CIRCOUTCOMES.111.964783>
8. Youssef I, Kamran H, Yacoub M, Patel N, Goulbourne C, Kumar S, et al. Obstructive Sleep Apnea as a Risk Factor for Atrial Fibrillation: A Meta-Analysis. *J Sleep Disord Ther*. 2018;7(1):282. <https://doi.org/10.4172/2167-0277.1000282>
9. Bassetti CLA, Randerath W, Vignatelli L, Ferini-Strambi L, Brill AK, Bonsignore MR, et al. EAN/ERS/ESO/ESRS statement on the impact of sleep disorders on risk and outcome of stroke. *Eur Respir J*. 2020;55(4):1901104. <https://doi.org/10.1183/13993003.01104-2019>
10. Qie R, Zhang D, Liu L, Ren Y, Zhao Y, Liu D, et al. Obstructive sleep apnea and risk of type 2 diabetes mellitus: A systematic review and dose-response meta-analysis of cohort studies. *J Diabetes*. 2020;12(6):455-464. <https://doi.org/10.1111/1753-0407.13017>
11. Tregear S, Reston J, Schoelles K, Phillips B. Obstructive sleep apnea and risk of motor vehicle crash: systematic review and meta-analysis. *J Clin Sleep Med*. 2009 Dec 15;5(6):573-81. <https://doi.org/10.5664/jcsm.27662>
12. Garbarino S, Guglielmi O, Sanna A, Mancardi GL, Magnavita N. Risk of Occupational Accidents in Workers with Obstructive Sleep Apnea: Systematic Review and Meta-analysis. *Sleep*. 2016;39(6):1211-1218. <https://doi.org/10.5665/sleep.5834>
13. Instituto de Ensino e Pesquisa (INSPER). Judicialização da Saúde: Perfil das Demandas, Causas e Propostas de Solução. Brasília, DF: Conselho Nacional de Justiça; 2019.
14. Pachito DV, Bagattini ÂM, Drager LF, Eckeli AL, Rocha A. Economic evaluation of CPAP therapy for obstructive sleep apnea: a scoping review and evidence map. *Sleep Breath*. 2022;26(1):17-30. <https://doi.org/10.1007/s11325-021-02362-8>
15. Machado MA, Acurcio Fde A, Brandão CM, Faleiros DR, Guerra AA Jr, Cherchiglia ML, et al. Judicialization of access to medicines in Minas Gerais state, Southeastern Brazil. *Rev Saude Publica*. 2011;45(3):590-598. <https://doi.org/10.1590/S0034-89102011005000015>
16. Oliveira YMDC, Braga BSF, Farias AD, Vasconcelos CM, Ferreira MAF. Judicialization of access to medicines: analysis of lawsuits in the state of Rio Grande do Norte, Brazil [Article in Portuguese]. *Cad Saude Publica*. 2021;37(1):e00174619. <https://doi.org/10.1590/0102-311x00174619>
17. Oliveira YMDC, Braga BSF, Farias AD, Pereira SPD, Ferreira MAF. Judicialization of medicines: effectiveness of rights or break in

- public policies?. *Rev Saude Publica*. 2020;54:130. <https://doi.org/10.11606/s1518-8787.2020054002301>
18. Catanheide ID, Lisboa ES, de Souza LEPF. Characteristics of the judicialization of access to medicines in Brazil: a systematic review. *Physis: Rev Saude Coletiva*. 2016;26(4):1335-1356. <https://doi.org/10.1590/s0103-73312016000400014>
  19. Instituto de Ensino e Pesquisa (INSPER). *Judicialização da Saúde: Perfil das Demandas, Causas e Propostas de Solução*. Brasília, DF: Conselho Nacional de Justiça; 2019.
  20. Jordan AS, McSharry DG, Malhotra A. Adult obstructive sleep apnoea. *Lancet*. 2014;383(9918):736-747. [https://doi.org/10.1016/S0140-6736\(13\)60734-5](https://doi.org/10.1016/S0140-6736(13)60734-5)
  21. Brasil. Ministério da Saúde. *Tecnologia da Informação a Serviço do SUS (DATASUS)* [homepage on the Internet]. Brasília: Ministério da Saúde [cited 2020 Dec 2]. SIGTAP - Sistema de Gerenciamento da Tabela de Procedimentos, Medicamentos e OPM do SUS. Available from: <http://sigtap.datasus.gov.br/tabela-unificada/app/sec/inicio.jsp>
  22. Associação Médica Brasileira. *Classificação Brasileira Hierarquizada de Procedimentos Médicos*. Barueri, SP: Manole; 2016. p. 210.
  23. Messeder AM, Osorio-de-Castro CG, Luiza VL. Can court injunctions guarantee access to medicines in the public sector? The experience in the State of Rio de Janeiro, Brazil]. *Cad Saude Publica*. 2005;21(2):525-534. <https://doi.org/10.1590/S0102-311X2005000200019>