

Analysis of right-to-health litigation involving high-cost medicines in Brazil: a scoping review protocol

Análise dos processos judiciais envolvendo medicamentos de alto custo no Brasil: protocolo de revisão de escopo

Análisis de juicios por medicamentos de alto costo en Brasil: un protocolo de revisión del alcance

Received: 11/07/2022 | Revised: 11/18/2022 | Accepted: 11/19/2022 | Published: 11/26/2022

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Abstract

Many studies investigating right to health litigation involving medicines mention “high-cost medicines”. However, detailed data on the characteristics of legal claims for these drugs and their share in terms of volume and spending in right to health litigation involving medicines is scarce. This paper presents a protocol for a scoping review that seeks to determine the profile of legal claims for high-cost medicines in Brazil and calculate the volume of purchases and amount spent on these drugs as a share of overall volume and spending related to right to health litigation involving medicines. Structured following the PRISMA-P checklist, this protocol describes the stages of the methodological framework for conducting the review. Guided by the PCC mnemonic (Population, Concept and Context), we searched for articles and other academic research reports published from 2000 to the present date using the MEDLINE, Embase, LILACS, Scopus, and Web of Science databases and the Brazilian Digital Library of Theses and Dissertations, respectively. Study selection will be performed in two stages (reading of titles and abstracts and assessment of the full-text version of the articles) by two independent reviewers. Any disagreements will be resolved by a third reviewer. We will perform a qualitative and quantitative analysis of the results, which will be presented in a descriptive format using figures, tables, and diagrams. The final review report will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Scoping Reviews (PRISMA-ScR) checklist. This protocol is registered with the Open Science Framework (DOI: [10.17605/OSF.IO/8PXUB](https://doi.org/10.17605/OSF.IO/8PXUB)).

Keywords: Scoping review; Health's Judicialization; Health litigation for access to medicines; Medicines.

Resumo

Nos estudos sobre a judicialização da saúde, sobretudo a judicialização de medicamentos, é frequentemente mencionado o papel dos ‘medicamentos de alto custo’. Entretanto, não há dados mais detalhados na literatura sobre essa participação, em termos de volume, gastos ou características. Este artigo apresenta um protocolo de revisão de escopo que tem como objetivos examinar a participação dos medicamentos de alto custo na judicialização de medicamentos no Brasil e seu perfil. O protocolo objetiva documentar os processos envolvidos no planejamento metodológico e execução de uma revisão de escopo abrangente, tendo sido desenvolvido a partir do PRISMA-Protocols (PRISMA-P) 2015 Checklist. A estratégia P(opulação), C(onceito) e C(contexto) sistematizou a busca por estudos publicados nas bases bibliográficas Medline, Lilacs, Scopus, Embase e Web of Science e por produtos acadêmicos na Biblioteca Digital de Teses e Dissertações, cobrindo o período de janeiro de 2000 até os dias atuais. A

seleção dos artigos será realizada em duas etapas (títulos e resumos, seguida da avaliação do texto completo dos artigos), por dois avaliadores independentes, com resolução das divergências realizadas por um terceiro revisor. Os resultados serão analisados qualitativa e quantitativamente e apresentados em síntese descritiva acompanhada de tabelas e diagramas. O relatório final da revisão obedecerá ao checklist presente no Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR). O protocolo foi registrado no Open Science Framework (doi: 10.17605/OSF.IO/8PXUB).

Palavras-chave: Revisão de escopo; Judicialização da Saúde; Judicialização do acesso a medicamentos; Medicamentos.

Resumen

En los estudios sobre la judicialización de la salud, en especial la judicialización de medicamentos, es frecuentemente mencionado el papel de los ‘medicamentos de alto costo’. Sin embargo, no existen datos detallados en la literatura sobre esa participación, en términos de volumen, gastos o características. Este artículo presenta un protocolo de revisión de finalidades que tienen como objetivos examinar la participación de los medicamentos de alto costo en la judicialización de medicamentos en el Brasil y su perfil. El protocolo objetiva documentar los procesos involucrados en la planeación metodológica e ejecución de una revisión de alcances extensos, que fue desarrollado a partir do PRISMA-Protocols (PRISMA-P) 2015 Checklist. La estrategia Población, Concepto y Contexto sistematizó la búsqueda por estudios publicados en las bases bibliográficas Medline, Lilacs, Scopus, Embase y Web of Science y por productos académicos en la Biblioteca Digital de Tesis y Disertaciones, cubriendo el período de enero del 2000 hasta los días actuales. La selección de los artículos será realizada en dos etapas (títulos y resúmenes, seguida de la evaluación del texto completo de los artículos), por dos evaluadores independientes, con resolución de las divergencias realizadas por un tercero revisor. Los resultados serán analizados cuali-cuantitativamente y presentados en síntesis descriptiva acompañada de tablas y diagramas. El reporte final de la revisión obedecerá al checklist presente en el Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR). El protocolo fue registrado en el Open Science Framework (doi: 10.17605/OSF.IO/8PXUB).

Palabras clave: Revisión de alcances; Judicialización de la salud; Medicamentos.

1. Introduction

The Brazilian judiciary has played an increasing role in ensuring access to medicines since the enactment of the 1988 Federal Constitution, which recognizes health as a “right for all and duty of the State” and provides that citizens should enjoy universal and equitable access to health services (Brazil, 1988).

The constitutional enshrinement of the right to health was accompanied by the creation of the country's public health system, the *Sistema Único de Saúde* (SUS) or Unified Health System, strengthening the role of the courts in ensuring access to health goods and services not made available on the health system (Freitas et al., 2020). This role was strengthened even further in the 1990s, when legal claims for antiretroviral medicines reached their peak (Pepe et al., 2010).

This process is referred to as the “judicialization” of health, or right to health litigation, and the increase in legal claims for the provision of healthcare and medicines is a major concern due to the high cost of complying with court orders (Zago et al., 2016). There is much debate about right to health litigation because, while it can encourage more and better delivery of health services (Kavanagh, 2016) and help bring about changes in policy that strengthen health technology assessment (Borges, 2018), it may also worsen existing health inequalities by transferring already scarce funding from one area to another (Ferraz, 2009), raising doubts about its role in achieving health equity (Andia & Lamprea, 2019).

Medicines are one of the main drivers of right to health litigation in Brazil (Lopes et al., 2021). This is due to, among other factors, poor medicines management, stock shortages, overpricing of drugs by pharmaceutical companies, and the absence of certain medicines from the official SUS drug list (Chieffi et al., 2017), with many legal claims requesting access to drugs that are not included in SUS programs and protocols. Right to health litigation tends to privilege individuals who have access to the justice system over the rest of the population and can have a significant impact on the health budget, potentially compromising health equity (Chieffi & Barradas, 2009).

Boing et al. (2013) highlight that right to health litigation accounts for a large share of spending on pharmaceutical services in the SUS, with legal claims for drugs alone representing approximately 26% (R\$21 million) of the R\$80 million

spent on services in 2006. The list of pharmaceutical products requested includes biotech drugs for the treatment of chronic or rare diseases. The cost of these medicines is high and the purchase of these drugs by court order undermines the bargaining power of public procuring entities, inflating purchase prices (Andia & Lamprea, 2019).

The share of SUS spending on successful claims for drugs has grown exponentially over the last two decades and the impact of this expenditure on the health budget has drawn the attention of researchers. Lopes et al. (2019) reported that federal spending on successful claims for drugs increased by 1,006% between 2008 and 2015. The Ministry of Health alone spent more than R\$2.7 billion on medicines purchased in compliance with court orders between 2010 and 2015, with 54% of this amount being spent on just three high-cost medicines that are not registered in the country and a large share of total spending going to products that are not incorporated into the SUS (TCU, 2017).

The upward trend in right to health litigation is worrying as the financial resources allocated to purchases are not included in the government budget and therefore compromise public health policy (Silva et al., 2017). Chagas & Santos (2018) draw the same conclusion, suggesting that right to health litigation worsens health inequities and compromises the management of the SUS.

Various studies and literature reviews of right to health litigation involving medicines include “high-cost medicines” (Catanheide, Lisboa & Souza, 2016; Freitas, Fonseca & Queluz, 2020). However, the definition of high-cost medicine is not fully clear. These medicines tend to be defined either from a regulatory standpoint, focusing on the high cost of these drugs to the health system, or from a broader perspective encompassing the complexity of certain diseases and conditions, duration of treatment, and ability to pay. Several elements therefore converge to form the characteristics of these types of medicines. In general, these drugs represent a high financial burden for the population and the public health system and are the only treatment option for diseases with a profound social impact and/or high risk of mortality or used to treat extremely rare diseases (Organização Pan-Americana da Saúde, 2009; Dana et al., 2017).

In Brazil, there is also no clear consensus on the definition of high-cost medicines and the financial parameters and limits used in such definitions. Moreover, the country does not have a national list of potentially high-cost medicines used in the SUS (Souza et al., 2010; Libanore, 2020). This makes it difficult to determine the profile of legal claims for high-cost medicines and obtain an accurate picture of the volume of purchases and amount spent on the latter as a share of overall volume and spending related to right to health litigation involving medicines, hampering the formulation and implementation of public health policies for these drugs.

In light of the above, we propose to undertake a systematic appraisal of available research evidence in the form of a scoping review aimed at synthesizing current literature on right to health litigation against the State involving high-cost medicines.

2. Methodology

2.1 Study design

This protocol describes the stages of the methodological framework for conducting a scoping review of studies addressing right to health litigation involving high-cost medicines in Brazil. By using transparent and standardized selection criteria, the framework aims to reduce bias in the study search and selection process (Silveira et al., 2020).

The scoping review approach was chosen because, unlike systematic reviews, in which the research question is clearly defined and structured, the review question is much broader and tends to focus on the nature, number, and characteristics of studies, and not necessarily on the synthesis of findings (Arksey & O'Malley (2005). Furthermore, a scoping review is recommended when the main purpose is to identify knowledge gaps and deficiencies in the area, describe research designs, and clarify concepts (Daudt et al., 2013; Munn, et al., 2018). When the literature is complex and heterogeneous, scoping reviews

can help identify and clarify concepts and definitions within a field, enabling the mapping or discussion of characteristics and providing an indication of the volume of literature and studies available as well as an overview of their focus (Peters et al., 2020).

A search of protocols registered in the Open Science Framework (OSF) and International Prospective Register of Systematic Reviews (PROSPERO) performed in August 2022 did not identify any published or ongoing scoping or systematic review protocols addressing health litigation involving high-cost medicines.

The present review will follow the methodology proposed by the Joanna Briggs Institute Manual for Evidence Synthesis (Aromataris & Munn, 2020), Chapter 11 (Peters et al., 2020), using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Scoping Reviews (PRISMA-ScR) checklist (Tricco et al., 2018). This review protocol was structured following the PRISMA-P checklist (Shamseer et al., 2015).

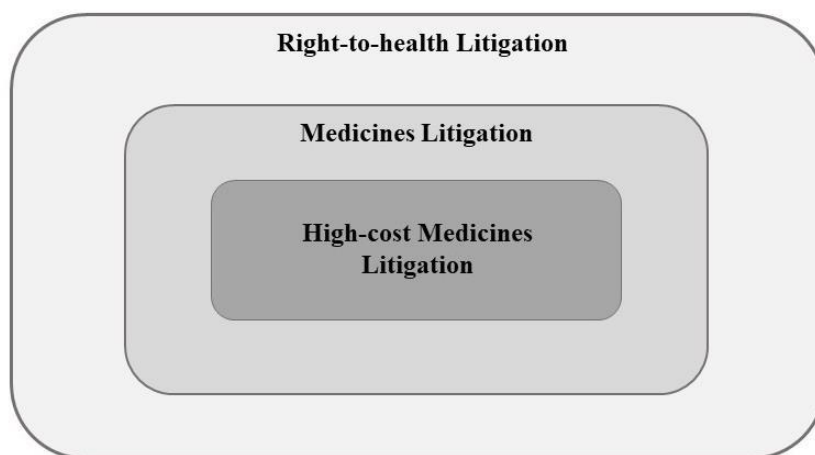
To ensure transparency, this protocol is registered with the Open Science Framework (doi: 10.17605/OSF.IO/8PXUB).

The scoping review will follow the five-stage framework proposed by Arksey & O'Malley (2005) detailed below.

2.2 Identification of the research question

The review intends to map and synthesize the literature on right to health litigation involving high-cost medicines in Brazil (Figure 1), aiming to understand the specific characteristics of legal claims for high-cost medicines and calculate the volume of purchases and amount spent on the latter as a share of overall volume and spending related to claims for drugs.

Figure 1 - Judicialization of access to high-cost medicines.



Source: Authors (2022).

As mentioned above, there is no clear consensus on the definition of high-cost medicines in the literature in Brazil. For the purposes of the study we will therefore adopt the following preliminary operational definition: medicines that present a high unit cost for the public health system or families and individuals; medicines that present a high total cost for the treatment of diseases with a profound social impact and/or a high risk of mortality; highly complex medicines that are challenging to administer and require monitoring to assess patient progress or high precision administration; and novel drugs under patent or monopoly.

Based on the rationale in figure 1, the research questions guiding the investigation, analysis, and consolidation of the evidence are:

- a) How are high-cost medicines defined in legal claims for drugs in Brazil?
- b) What is the share of high-cost medicines in terms of volume and spending in right to health litigation involving medicines in Brazil?
- c) What is the profile (case, medical/health, and political/administrative characteristics) of legal claims for high-cost medicines?

The research questions were structured using the PCC mnemonic (Population, Concept and Context) as shown in Table 1 below, which guided the search and refinement of the inclusion and exclusion criteria that will be adopted in the scoping review.

Table 1 - PCC mnemonic used in the scoping review.

Criterion	Description
Population	Studies addressing right to health litigation involving medicines in Brazil
Concept	Characteristics of legal claims against federal, state, or municipal governments for high-cost medicines registered or not registered with ANVISA.
Context	Judicialization of access to high-cost medicines in Brazil

Legend: ANVISA – National Health Surveillance Agency. Source: Authors (2022).

2.3 Identification of relevant studies

The following bibliographic databases: MEDLINE (via PubMed), Embase, LILACS (via BVS), Scopus, and Web of Science. The search strategies were developed by the reviewers with the help of a qualified librarian using health descriptors (MeSH, DeCS, and Emtree) when available and specific terms related to the judicialization of health and medicines identified in article titles and abstracts. The search terms were connected using the Boolean operators AND or OR, depending on the database. Language restrictions were not applied in this stage.

The time period covered by the review was from January 1st, 2000 to the database search date, October 14th, 2022. Where possible, database alerts were set up to receive notifications of the publication of new articles after the search date. These alerts will be updated towards the end of the search process to ensure the inclusion of new studies.

The search strategies are shown in Table 2 below.

Table 2 - Search strategies and number of references generated by each bibliographic databases.

Database	Search strategies	Number of references retrieved
Medline (via PubMed)	((("jurisprudence"[MeSH Terms] OR "medical jurisprudence"[Title/Abstract] OR ("judicialization"[Title/Abstract] OR "judicialization of health"[Title/Abstract] OR "judicialization of health care"[Title/Abstract] OR "judicialization of healthcare"[Title/Abstract] OR "judicialization of right to health"[Title/Abstract] OR "judicialization of"[Title/Abstract]) OR "judicial decisions"[Title/Abstract] OR "right to health"[Title/Abstract] OR "litigation*"[Title/Abstract] OR "lawsuit*"[Title/Abstract] OR "legal demand"[Title/Abstract] OR "health litigation"[Title/Abstract] OR "health judicialization"[Title/Abstract] OR "judicialisation"[Title/Abstract] OR "law suit*"[Title/Abstract]) AND ("pharmaceutical preparations"[MeSH Terms] OR "pharmaceutical preparations"[Title/Abstract] OR "medicine*"[Title/Abstract] OR "medication*"[Title/Abstract] OR "drug*"[Title/Abstract] OR "treatment*"[Title/Abstract] OR "pharmacoterap*"[Title/Abstract] OR "pharmaceutical product*"[Title/Abstract] OR "pharmaceutical*"[Title/Abstract] OR "access to medicine*"[Title/Abstract]) AND ("Brazil"[MeSH Terms] OR "Brazil"[Title/Abstract] OR "brasil*"[Title/Abstract] OR "brazil*"[Title/Abstract])) AND (2000:2022[pdat])	319

Lilacs (via BVS regional)	((Brasil*) OR (Brazil*)) AND ((Preparações farmacêuticas) OR (Drogas) OR (Fármaco) OR (Fármacos) OR (Lista de Medicamentos) OR (Medicamento) OR (Medicamentos) OR (Preparação Farmacêutica) OR (Produto Farmacêutico) OR (Produtos Farmacêuticos) OR (Quimioterápico) OR (Quimioterápicos) OR (Remédio) OR (Remédios) OR (Medicamento* órfão*) OR (Medicamentos do Componente Especializado da Assistência Farmacêutica) OR (Medicamento Excepcional) OR (Medicamento do Componente Especializado da Assistência Farmacêutica) OR (Medicamentos Excepcionais) OR (Medicamentos de Dispensação Excepcional) OR (Medicamentos de Dispensação em Caráter Excepcional) OR (Medicamentos para Doenças Raras) OR (CEAF)) AND ((Judicialização da Saúde) OR (Judicialização da Assistência Farmacêutica) OR (Judicialização da Política de Assistência Farmacêutica) OR (Judicialização da Prescrição Medicamentosa) OR (Judicialização da Saúde Pública) OR (Judicialização das Políticas de Saúde) OR (Judicialização do Acesso a Medicamentos) OR (Judicialização do Acesso aos Serviços de Saúde) OR (Judicialização do Acesso à Saúde) OR (Judicialização do Direito à Saúde) OR (Judicialização em Saúde) OR (Judicialização na Obtenção de Medicamentos) OR (Judicialização na Saúde) OR (Juridicização da Saúde) OR (Demanda* judícia*) OR (Aç* judícia*))	438
Embase	'jurisprudence'/exp OR 'medical jurisprudence':ab,ti OR 'judicialization':ab,ti OR 'judicialization of health':ab,ti OR 'judicialization of health care':ab,ti OR 'judicialization of healthcare':ab,ti OR 'judicialization of right to health':ab,ti OR 'judicialization of':ab,ti OR 'judicial decision*':ab,ti OR 'right to health':ab,ti OR 'litigation*':ab,ti OR 'law suit':ab,ti OR 'lawsuit*':ab,ti OR 'legal demand':ab,ti OR 'health litigation':ab,ti OR 'health judicialization':ab,ti OR 'judicialisation':ab,ti OR 'judicialisation of health':ab,ti OR 'judicialisation of health care':ab,ti OR 'judicialisation of healthcare':ab,ti OR 'judicialisation of right to health':ab,ti OR 'health judicialisation':ab,ti AND 'pharmaceutical preparations'/exp OR 'pharmaceutical preparations':ab,ti OR 'medicine*':ab,ti OR 'medication*':ab,ti OR 'drug':ab,ti OR 'treatment*':ab,ti OR 'pharmacoterap*':ab,ti OR 'pharmaceutical product*':ab,ti OR 'pharmaceutical*':ab,ti OR 'access to medicine':ab,ti AND 'brazil'/exp OR 'brazilian'/exp OR 'brazil*':ab,ti OR 'brazilian*':ab,ti OR 'brasil*':ab,ti	194
Scopus	(TITLE-ABS-KEY (("jurisprudence" OR "medical jurisprudence" OR "judicialization" OR "judicialization of health" OR "judicialization of health care" OR "judicialization of healthcare" OR "judicialization of right to health" OR "judicialization" OR "judicial decisions" OR "right to health" OR "litigation*" OR "lawsuit*" OR "legal demand" OR "health litigation" OR "health judicialization" OR "judicialisation" OR "law suit*")) AND TITLE-ABS-KEY (("pharmaceutical preparations" OR "pharmaceutical preparations" OR "medicine*" OR "medication*" OR "drug*" OR "treatment*" OR "pharmacoterap*" OR "pharmaceutical product*" OR "pharmaceutical*" OR "access to medicine*")) AND TITLE-ABS-KEY (("Brazil" OR "Brazil" OR "brasil*" OR "brazil*")) AND (LIMIT-TO (PUBYEAR , 2022) OR LIMIT-TO (PUBYEAR , 2021) OR LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR , 2010) OR LIMIT-TO (PUBYEAR , 2009) OR LIMIT-TO (PUBYEAR , 2008) OR LIMIT-TO (PUBYEAR , 2007) OR LIMIT-TO (PUBYEAR , 2006) OR LIMIT-TO (PUBYEAR , 2004) OR LIMIT-TO (PUBYEAR , 2003) OR LIMIT-TO (PUBYEAR , 2002) OR LIMIT-TO (PUBYEAR , 2001) OR LIMIT-TO (PUBYEAR , 2000))	519
Web of Science	("jurisprudence" OR "medical jurisprudence" OR "judicialization" OR "judicialization of health" OR "judicialization of health care" OR "judicialization of healthcare" OR "judicialization of right to health" OR "judicialization" OR "judicial decisions" OR "right to health" OR "litigation*" OR "lawsuit*" OR "legal demand" OR "health litigation" OR "health judicialization" OR "judicialization" OR "law suit*") (Tópico) and ("pharmaceutical preparations" OR "pharmaceutical preparations" OR "medicine*" OR "medication*" OR "drug*" OR "treatment*" OR "pharmacoterap*" OR "pharmaceutical product*" OR "pharmaceutical*" OR "access to medicine*") (Tópico) and ("Brazil" OR "Brazil" OR "brasil*" OR "brazil*") (Tópico)	269
Total		1739

Source: Authors (2022).

Grey literature was also searched to identify dissertations and theses, given that an important part of the literature on judicialization of access to medicines in Brazil includes academic research reports. To this end, using the same terms

mentioned above, we performed a search of the Brazilian Digital Library of Theses and Dissertations, an information and search engine for electronic theses and dissertations produced in Brazil's teaching and research institutions. The search was performed using the advanced search tool (<https://bdtd.ibict.br/vufind/>), adapting the terms mentioned above as and when necessary.

Additional searches for relevant articles will be performed using the reference lists of literature reviews and the studies included in the review, ensuring that the search is as comprehensive as possible.

The studies generated by the searches will be inputted into a bibliographic citation management software (EndNote version XI) to identify and remove duplicate references.

2.4 Eligibility criteria

Relevant studies will be selected using specific inclusion and exclusion criteria based on the components of the PCC mnemonic, as suggested by Peters et al. (2020).

2.4.1 Inclusion criteria

Original studies providing data on legal claims against federal, state, or municipal governments for high-cost medicines.

There will be no restrictions on study design, as long as the study focuses on claims filed in Brazil, addresses the research question, and meets the stipulated inclusion criteria.

Finally, articles focusing on the judicialization of health may be included if they contain relevant data on the judicialization of medicines, including data on claims for high-cost medicines.

2.4.2 Exclusion criteria

Abstracts, reports, congress proceedings, literature reviews, and articles discussing legal arguments will not be included. Studies mentioning high-cost medicines that do not provide sufficient data pertinent to study question will also be excluded.

Manuscripts that are duplicates of dissertations and theses will be excluded based on the assumption that the latter contain more data.

Finally, studies published in languages other than English, Spanish, and Portuguese will be excluded, but will be recorded to identify potential language bias.

2.5 Study selection

The selection of articles after the removal of duplicates will be performed independently by two researchers in two stages. Any disagreements will be resolved by a third reviewer.

Different forms containing detailed instructions will be created using Google Forms to standardize and document the two stages of the study selection process.

In the first stage of screening, the titles and abstracts will be assessed to determine whether they meet the above inclusion criteria. The full-text version of the articles, including those where it is not clear from the title and abstract whether they meet the inclusion criteria, will then be read to determine whether they meet the eligibility criteria. The reasons for excluding an article after reviewing the full-text version will be documented.

The study selection process, including the number of articles identified, selected, and included in the review will be summarized using the PRISMA flow diagram (Page et al., 2021).

2.6 Charting the data

Two reviewers will independently chart the data from the articles included in the review. Any disagreements will be resolved by a third reviewer.

The data will be inputted into a standardized electronic form created using Google Forms and previously tested on a set of studies included in the review to determine whether the approach and content are consistent with the research question and aim of the review.

The authors of the selected studies may be contacted for clarification or to request additional data using a maximum of two attempts.

All definitions of high-cost medicines proposed by the authors of the studies included in the review will be documented and compared with the operational definition established by the researchers mentioned above.

Data on other medicines and high-cost medicines will be charted separately to determine the volume of and expenditure on the latter as a share of overall volume and expenditure.

The specific characteristics of claims for this group of medicines will be analyzed using a preliminary set of preselected items and subitems based on the Manual of Indicators for the Evaluation and Monitoring of Legal Claims for Drugs (Pepe et al., 2011), as shown in Table 3.

Table 3 - Data extraction items and subitems.

Study identification
Study ID
Author(s)
Year of publication
Journal
Language (Portuguese, English, Spanish)
Funding source (when mentioned)
Study location (when mentioned)
Is the study an academic research report (dissertation, thesis)?
Complete reference of the academic research report
Study characteristics
Object of study
Study objectives
Region/state/municipality
Study design
Study period
Data sources: databases/administrative data belonging to federal agencies; databases belonging to the institutions that make up the justice system (including the Prosecutor General's Office, district attorney/federal prosecutor's/public defender's offices, and state, regional and federal courts of justice).
Concept of high-cost medicines
Does the study provide a definition of high-cost medicines? If so, what?
Which components of the operational definition of high-cost medicines were used by the studies? List for each study
Characteristics of legal claims for medicines
Overall number of legal claims for medicines
Total spending (currency and year) on overall legal claims for medicines
Number (and %) of legal claims for high-cost medicines
Spending (amount and %) on legal claims for high-cost medicines

Number (or proportion) by defendant (federal, state, or municipal government)
Number (or proportion) of representatives bringing the claim (private or appointed attorney, public defender's office, public prosecutor's office, attorney general)
Number (or proportion) of individual claims
Number (or proportion) of collective claims
Number (or proportion) of successful claims
Number (or proportion) of out-of-court settlements
Sex of claimants of high-cost medicines
Age of claimants of high-cost medicines
Income of claimants of high-cost medicines
Occupation of claimants of high-cost medicines
Number (or proportion) of high-cost medicines requested by therapeutic/pharmacological/chemical subgroup (ATC Classification)
Number (or proportion) of high-cost medicines requested by main diagnoses or by major diagnostic category
Number (or proportion) of requested high-cost medicines on essential medicines lists
Number (or proportion) of requested high-cost medicines not registered with ANVISA
Number (or proportion) of requested high-cost medicines for off-label use
Number (or proportion) of requested high-cost medicines not included in the components of the pharmaceutical services funding block
Number (or proportion) of requested medicines included in the Specialized Component of Pharmaceutical Services
Does the study mention strategies for dealing with legal claims? Is so, which? Include all strategies based on the typology adapted from Yamauti et al. (2020): (i) Technical support for the judiciary; (ii) State health committees; (iii) Service organization; (iv) Compliance with legal orders; (v) Computerized information systems; (vi) Administrative proceedings; (vii) Public defense; (viii) Pharmacy and Therapeutics Committee; and (ix) Alternative dispute resolution.
Additional observations
Study limitations mentioned by the authors
Any other characteristic(s) considered relevant to the study
Other additional observations

Legend: ANVISA – National Health Surveillance Agency; ATC - Anatomic Therapeutic Chemical. Source: Authors (2022).

2.7 Assessment of methodological quality

There is considerable debate in the literature regarding the need to assess the methodological quality of original studies in scoping reviews, particularly because the latter seek to provide a broad spectrum of knowledge and types of evidence available on a topic, clarifying important concepts or attempting to gain a comprehensive understanding of emerging concepts (Khalil et al., 2016; Munn et al., 2018).

Given its scope and purpose and the fact that restrictions on study design will not be imposed, the present review does not intend to assess methodological quality.

2.8 Analysis and synthesis of results

We will perform a quantitative analysis of the results using absolute and relative frequencies. The results will be presented in a descriptive format using figures, tables, and diagrams to synthesize the findings.

The qualitative element is to be explored as a synthesis of relevant information from the literature, through thematic content analysis (Bardin, 1977). Analytical categories that have been identified by means of in-depth reading of the retrieved literature will structure the synthesis. Common content elements and key expressions will be identified to lead content into appropriate categories to be discussed and interpreted (Oliveira et al., 2008).

3. Ethical Aspects

This protocol refers to a scoping review that will use open access publications and academic research reports that do not identify the claimants or other interested parties involved in bringing the legal claims. The study therefore does not require prior ethical approval. The results of this review will be made available in an article published in a peer-reviewed journal.

The review is part of a larger study titled “Analysis of legal claims for medicines against the federal government and mapping of strategies for the out-of-court settlement of disputes over medicines”, developed by the Oswaldo Cruz Foundation (Fiocruz) and coordinated by Vera Lúcia Edais Pepe, Miriam Ventura da Silva, and Thais Jerônimo Vidal.

4. Final Considerations

In Brazil, there is no clear consensus on the definition of high-cost medicines and the financial parameters or limits used in such definitions. Moreover, the country does not have a national list of potentially high-cost medicines used in the SUS. This makes it difficult to determine the profile of legal claims for high-cost medicines and obtain an accurate picture of the volume of purchases and amount spent on these drugs as a share of overall volume and spending related to right to health litigation involving medicines.

These gaps in knowledge and the lack of research in this area warrant further investigation. To this end, the present scoping review aims to map the literature on right to health litigation involving high-cost medicines in Brazil, seeking to understand the profile of legal claims for these medicines and calculate the share of this group of drugs in terms of overall volume and spending related to right to health litigation involving medicines.

This is a scoping study protocol. As such it is a descriptive tool to assess the future results of the scoping review that is under way. The proposed review will make a valuable contribution to existing knowledge on this topic and provide important inputs to inform the development of specific policies and strategies to mitigate the problem of judicialization of high-cost medicines in Brazil. The protocol may also inform future reviews in the area of health litigation, specifically on litigation for access to medicines.

Acknowledgements and funding

The authors are grateful to Gizele da Rocha Ribeiro, librarian at the Oswaldo Cruz Foundation, for her support in developing the search strategies. This review received funding from the Oswaldo Cruz Foundation/Ministry of Health (TED 01/2022).

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