

Concepts and dimensions of access to medicines in the Unified Health System: scope review protocol*Conceptos y dimensiones del acceso a medicamentos en el Sistema Único de Salud: protocolo de revisión de alcances**Conceitos e dimensões sobre acesso a medicamentos no Sistema Único de Saúde: protocolo de revisão de escopo***Paloma Oliveira dos Santos¹**

ORCID: 0000-0001-9671-5286

Tatiane de Oliveira Silva Alencar¹

ORCID: 0000-0001-6257-5633

¹Universidade Estadual de Feira de Santana. Bahia, Brazil.**How to cite this article:**

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Corresponding author:

Paloma Oliveira dos Santos

E-mail:

palomaoliveira.farma@gmail.com

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The aim is to map the scientific productions (year of publication, methodological approach, collection instruments) on access to medicines in Brazil published between 2011 and 2022 and; identify the concepts and dimensions of access used in studies on access to medicines in Brazil. The scope review will be prepared according to the steps of the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR), and will follow the steps recommended by the Joanna Briggs Institute. The documents will be identified by two independent reviewers, in the PubMed, BVS and SciELO databases. Studies that answer the research question, presented in any language, will be considered. The selection of studies will be done blindly and independently, by two reviewers, using the Rayyan Intelligent Systematic Review software. Divergences will be appreciated by a third reviewer. A narrative summary will accompany the results, which will be expressed through figures, tables, charts, graphs, diagrams, and will describe the relationship with the objective and question of the review.

Descriptors: Access to Health Services; Access to Medicines; Pharmaceutical Care; Pharmaceutical Policies; Unified Health System.

Resumen

El objetivo es mapear las producciones científicas (año de publicación, abordaje metodológico, instrumentos de recolección) sobre acceso a medicamentos en Brasil publicadas entre 2011 y 2022 y; identificar los conceptos y dimensiones de acceso utilizados en estudios sobre acceso a medicamentos en Brasil. La revisión del alcance se preparará de acuerdo con los pasos de Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR), y seguirá los pasos recomendados por el Instituto Joanna Briggs. Los documentos serán identificados por dos revisores independientes, en las bases de datos PubMed, BVS y SciELO. Se considerarán estudios que respondan a la pregunta de investigación, presentados en cualquier idioma. La selección de estudios se realizará de forma ciega e independiente, por dos revisores, utilizando el software Rayyan Intelligent Systematic Review. Las divergencias serán apreciadas por un tercer revisor. Un resumen narrativo acompañará los resultados, los cuales se expresarán a través de figuras, tablas, cuadros, gráficos, diagramas, y describirá la relación con el objetivo y pregunta de la revisión.

Descriptorios: Acceso a los Servicios de Salud; Acceso a Medicamentos; Cuidado Farmacéutico; Políticas Farmacéuticas; Sistema Único de Salud.

Resumo

Objetiva-se mapear as produções científicas (ano de publicação, abordagem metodológica, instrumentos de coleta) sobre acesso a medicamentos no Brasil publicadas entre 2011 e 2022 e; identificar os conceitos e dimensões de acesso utilizadas nos estudos sobre acesso a medicamentos no Brasil. A revisão de escopo será elaborada conforme as etapas do *Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews* (PRISMA-ScR), e seguirá as etapas preconizadas pelo *Joanna Briggs Institute*. Os documentos serão identificados por dois revisores independentes, nas bases de dados PubMed, BVS e SciELO. Serão considerados estudos que respondam à pergunta de pesquisa, apresentados em qualquer idioma. A seleção dos estudos será feita de forma cega e independente, por dois revisores, por meio do *software Rayyan Intelligent Systematic Review*. Divergências serão apreciadas por um terceiro revisor. Um resumo narrativo acompanhará os resultados, que serão expressados por meio de figuras, tabelas, quadros, gráficos, diagramas, e descreverá a relação com o objetivo e a questão da revisão.

Descriptorios: Acesso aos Serviços de Saúde; Acesso aos Medicamentos; Assistência Farmacêutica; Políticas Farmacéuticas; Sistema Único de Saúde.



Introduction

The medicine is an essential input in health, since many interventions involve its use. Incorporates the technical, economic, health, ideological, symbolic and political dimensions¹ making it a highly complex health product. In this sense, the analysis of access to medication – understood as a fundamental human right to health, also serving as an indicator of the quality and resolution of health systems² – it becomes equally complex.

Ensuring access to medication in a universal, equal and equitable manner is, therefore, a challenge. Therefore, the World Health Organization³ has emphasized the importance of formulating national drug policies, also considering evaluation and monitoring as important tools for knowing the progress of policy implementation.

In Brazil, the National Drug Policy (PNM)⁴, and the National Pharmaceutical Assistance Policy (PNAF)⁵ follow the guidelines of the Unified Health System (SUS) to more specifically regulate actions to guarantee access to safe and effective medicines, universally and free of charge.

Therefore, it is up to Pharmaceutical Assistance to support the Health Care Network (RAS) through technical-managerial activities (selection, programming, acquisition, storage and distribution of medicines and supplies), in order to supply the product, but also make available, at the different RAS care points, the pharmacist aiming at health promotion, from the perspective of the needs of individuals, family, community and health team⁶. It is clear, therefore, that Pharmaceutical Assistance involves the services and clinical activities of the professional and not just guaranteeing the availability of the medication.

It is important to highlight that the simple availability of a service or product does not constitute access, which is achieved with the use of the service or product⁷. Therefore, in order to analyze access to medicines, it is necessary to understand a phenomenon resulting from the interaction between multiple dimensions that are permeated both by characteristics of the health system and by characteristics of the user.

It is also important to consider that the medicine, although it is a health input, is also considered a commodity, and can be used autonomously by the user, either by self-medication or by not following the instructions given by health professionals, whether by their own will or by misunderstanding. Difficulty accessing health services and lack of time for consultations with professionals are listed as reasons for self-medication, which is also influenced by cultural factors and social conditions that allow greater ease of access to medicines⁸. It is understood, therefore, that access to medicines requires the provision of health services with the supply of a product with rational use and user satisfaction.

In the international literature, it is identified that, although some authors^{9,10} recognize the influence of user characteristics (demand), as well as characteristics of access providers, many place more emphasis on the characteristics of health resources that influence the use of services (supply), acting as a mediating factor between the ability to produce services and your consumption. Access was also

seen as an attribute of health services, noting how services can be accessed or used by those requiring health care¹¹.

Penchansky and Thomas¹² managed to broaden the definition of access taking into account the characteristics of health services and customer expectations. These authors claim that in order to be able to cover the needs of users and the characteristics of health services, access must include specific dimensions, namely: availability, geographic accessibility, suitability, purchasing power and acceptability.

Such dimensions continue to be used in the most recent studies on access, in international scenarios^{13–16} and Brazilian^{2,17} in studies that evaluate access to medicines. It is noticed, however, that the term access is often used in an imprecise and unclear way in its relationship with the use of health services. It is a complex concept that varies between authors and that changes over time and according to the context.¹⁸

This lack of standardization on the concept of access, particularly in studies on access to medicines, becomes evident when consulting scientific databases, as several studies still focus primarily on the dimension of geographic availability or accessibility, which concern the ability of the service to provide a particular service or product¹², but it does not take into account user satisfaction. That is, the analysis of access is restricted, since it does not consider all the aspects that result in the guarantee of the rational use of medicines, which is the primary purpose of pharmaceutical assistance.

Thus, with the mapping of the concept of access to medication, it will be possible to provide a basis for understanding this phenomenon, in addition to contributing as a guide for analysis to guide future research on access to medication. This mapping will be obtained from carrying out the scope review, which is being widely used in the area of health sciences with the purpose of synthesizing and disseminating the results of studies on a subject, clarifying concepts and definitions, identifying characteristics or factors related to concepts; and identify and analyze knowledge gaps. Requires a rigorous and transparent method, providing a descriptive view of the reviewed studies, without summarizing evidence from different investigations, as in a systematic review.^{19–21}

A preliminary search was conducted in the PROSPERO, PubMed, OSF and Cochrane databases. Until May 31, 2022, no scope or systematic reviews were found in progress or completed that addressed aspects related to the topic of interest. This alone justifies conducting a scoping review.

Aiming at an investigation that addresses this knowledge gap, the guiding question is: What conceptions and dimensions of access are present in studies on access to medicines within the scope of the Unified Health System? Considering this questioning, this study aims to: map the scientific production on access to medicines in Brazil published between 2011 and 2022; and identify the concepts and dimensions of access used in studies on access to medicines in Brazil.



Methodology

The scope review will be conducted in accordance with the methodology of the JBI Manual for evidence synthesis²². To ensure rigor, the elaboration of this protocol was based on the principles contained in the Preferred

Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR)²³. The review protocol is registered on the Open Science Framework platform and can be accessed at: <https://osf.io/gm85e>.

Figure 1. PCC strategy applied in the scope review. Feira de Santana, BA, Brazil, 2022

Question: What conceptions and dimensions of access to medication are present in studies on access to medication within the Unified Health System?	
POPULATION	Studies carried out in Brazil and published between 2011 and 2022 will be considered.
CONCEPT	Studies that explore factors related to access to medicines will be considered.
CONTEXT	Studies carried out within the scope of the SUS, including Primary Health Care, the Popular Pharmacy Program in Brazil and the specialized component of Pharmaceutical Assistance will be considered.

Review Question

The formulation of the guiding question was based on the PCC mnemonic (Population, Concept and Context), as shown in Figure 1.

Participants

Estudos publicados nos últimos dez anos (2011 a 2022), em qualquer idioma, realizado no Brasil, sobre análise do acesso a medicamentos no SUS.

Concept

Studies that address access to medicines in the SUS will be included. In this research, access is understood as the relationship between the use of health services (evaluated by performance, service provision and adequacy of these to the health needs of the population), and the beliefs (perceptions and perspectives) of those who seek them^{9,12}

within a context with multiple factors (social, economic, cultural and market), whose analysis needs to cover different dimensions, including not only those that facilitate, but also the obstacles, impediments and difficulties²⁴, taking into account political, economic, social, organizational, technical and symbolic aspects of access¹.

Context

This review will consider all studies carried out in public health services, including Primary Care, the specialized component of Pharmaceutical Assistance and the Popular Pharmacy Program in Brazil.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria are summarized in Figure 2.

Figure 2. Presentation of eligibility and exclusion criteria for studies. Feira de Santana, BA, Brazil, 2022

	Criterion	Rationality
Inclusion criteria	Original studies (quantitative or qualitative) that address aspects related to access to medicines (concept) within the scope of the SUS.	Allows to meet the purpose of the review.
	Articles published between 2011 and 2022.	Allows a coherent (pharmaceutical policy context) and recent approach to studies.
	Publications in any language.	Allows for a broader range of studies.
	Electronically available in full-text.	Allows greater knowledge of the results of the studies and concepts addressed.
Exclusion criteria	Studies that address access to medicines in other countries, even if comparatively to Brazil.	Not restricted to the context of the Brazilian health system.
	Studies that analyze access to medicines in hospitals, prisons or pharmaceutical companies.	These contexts are, in general, restrictive in terms of addressing access to medication or do not address the scope of the SUS.
	Studies that address access to medication from the perspective of judicialization.	Such studies bring a restrictive conception of the dimensions of access to medicines, limiting it to the perspective of the right to health.
	Publications in review, editorial, opinion article, commentary, thesis or dissertation format.	These publications (review, editorial, opinion article and commentary) do not bring a comprehensive perspective that allows achieving the proposed objectives. The others (theses and dissertations) were excluded to prioritize periodical publications.
	Studies whose full text is not available.	Only complete studies will allow for a deeper and more consistent analysis with the objectives of the proposed review.

Evidence Sources

This scope review will consider as sources of evidence complete texts of primary studies available in health databases, published in any language, from 2011 to 2022. Quantitative or qualitative studies that use primary or secondary data may be included.

Databases to be searched include: PubMed, BVS and SciELO. The search for literature will not include: review studies, opinion articles, dissertations, theses, documents and books.



Research Strategy

The search strategy will aim to find primary studies in various databases and will be organized in stages:

1. Definition of descriptors and synonyms from the VHL and MeSH for the elaboration of the search strategy.

Figure 3. Boolean descriptors and operators for searching databases. Feira de Santana, BA, Brazil, 2022

Database: BVS and PubMed		
Mnemonic	Descriptor	Identified keywords
P	Brazil	-
C	Health Services Accessibility	Access to Medications; Access to Medication; Medication Access; Medication Accesses; Access to Health Services; Accessibility of Health Services; Health Services Accessibility.
C	Pharmaceutical Services	Pharmaceutical services, Pharmaceutical Service, Pharmaceutic Services, Pharmaceutic Service, Pharmacy Services, Pharmacy Service.
Database: SciELO		
Mnemonic	Descriptor	Identified keywords
P	Brasil	-
C	Acesso aos Serviços de Saúde	Acesso a medicamentos; acesso ao medicamento; acesso aos medicamentos; acesso à medicação; acesso aos Serviços de Saúde; Acessibilidade aos serviços de saúde.
C	Assistência Farmacêutica	Serviços de Assistência Farmacêutica.
Base strategy Defined with Boolean operators Data base: BVS and PubMed (Access to Health Services OR Accessibility of Health Services OR Health Services Accessibility OR Access to Medications OR Access to Medication OR Medication Access OR Medication Accesses) AND (Pharmaceutical services OR Pharmaceutical Service OR Pharmaceutic Services OR Pharmaceutic Service OR Pharmacy Services OR Pharmacy Service) AND (Brazil) SciELO (acesso a medicamentos OR acesso ao medicamento OR acesso aos medicamentos OR acesso à medicação OR Acesso aos Serviços de Saúde OR Acessibilidade aos serviços de saúde) AND (Assistência Farmacêutica OR Serviços de Assistência Farmacêutica) AND Brasil		

2. The search strategy will be applied in VHL, SciELO and in the PubMed Portal, applying year filters (2011 to 2022) and full text.

Figure 4. Complete search strategy performed for the databases. Feira de Santana, BA, Brazil, 2022

Source of Information	Search Strategy
BVS	(access TO medication*) OR (access TO medicine) AND (pharmaceutical service) AND (primary health care) AND (fulltext:("1")) AND (year_cluster:[2011 TO 2022])
PubMed	((("health services accessibility"[MeSH Terms] OR ("health"[All Fields] AND "services"[All Fields] AND "accessibility"[All Fields]) OR "health services accessibility"[All Fields] OR ("access"[All Fields] AND "medication"[All Fields]) OR "access to medication"[All Fields] OR ("health services accessibility"[MeSH Terms] OR ("health"[All Fields] AND "services"[All Fields] AND "accessibility"[All Fields]) OR "access to medicine"[All Fields]) OR "access"[All Fields] AND "medicine"[All Fields]) OR "access to medicine"[All Fields])) AND "loattrfull text"[Filter] AND ((("pharmaceutical services"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "services"[All Fields]) OR "pharmaceutical services"[All Fields] OR ("pharmaceutical"[All Fields] AND "service"[All Fields]) OR "pharmaceutic service"[All Fields]) AND "loattrfull text"[Filter]) AND ((("primary health care"[MeSH Terms] OR ("primary"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "primary health care"[All Fields]) AND "loattrfull text"[Filter])) AND ((ft[Filter] AND (2011:2022[pdat]))
SciELO	(acesso a medicamentos) ou (acesso aos medicamentos) e (assistência farmacêutica) e (atenção primária à saúde) AND year_cluster:("2017" OR "2014" OR "2019" OR "2011" OR "2015" OR "2021" OR "2022")

Selection of Studies

After searching the databases, the results found will be sent to Zotero® for identification and removal of duplicates. To manage the selection and evaluation of the sample studies, the Rayyan Intelligent Systematic Review® software will be used. The reading and selection of titles and abstracts will be carried out by two reviewers, blindly and independently, based on the inclusion and exclusion criteria prepared. Subsequently, the full text will be read and the reasons for excluding the productions will be justified. Differences in this selection can be resolved through consensus between the two reviewers or through the

decision of a third reviewer. The entire study selection process will be recorded in a PRISMA - ScR flowchart²².

Data Extraction

Data will be extracted from the spreadsheet built in Microsoft Excel 2016® and will include details of the population, concept, context, study methods and main results (concepts and dimensions of access). The instrument developed by the reviewers will be used, based on the JBI manual model and outlined in Figure 4.

Data extraction will be performed independently by two reviewers. At the end, the results found and points of



divergence will be analyzed by a third reviewer. If, during the process, you realize the need to add information, this

instrument will undergo changes that will be recorded in the scope review report.

Figure 5. Data extraction tool. Feira de Santana, BA, Brazil, 2022

Characterization of the study										
Title	Authors	Journal	Year	Place of performance	Methods used	Keywords	Objective	Access concept	Access concept reference	Access dimensions analyzed

Data Analysis and Presentation

The format for presenting the results will provide an overview of the concept and dimensions of access to medication present in the analyzed studies. For this, a summary will be elaborated containing the main results found with the subsequent discussion of the findings. Figures, tables, charts, graphs, diagrams will be constructed to portray the findings and meet the objectives of the review. The research results will be presented according to the PRISMA-ScR and prepared in the form of a scope review.

This scope review seeks to identify and summarize the results of previously published studies on access to medicines.

Expected Results

There are no ethical issues of concern, dispensing with review by an ethics committee. The expected results are the mapping of scientific productions on access to medicines in Brazil, published between 2011 and 2022; and the identification of concepts and dimensions of access used in studies on access to medicines in Brazil. Such results may support a critical analysis of access to medication in the Brazilian context, as well as subsidize other investigations on the subject, the development of new concepts and approaches for studies on access to medication.

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