REVIEW ARTICLE

ANALYSIS OF THE IMPLEMENTATION OF THE NATIONAL PHARMACEUTICAL ASSISTANCE POLICY IN THE BRAZILIAN UNIFIED HEALTH SYSTEM (SUS): ACHIEVEMENTS AND CHALLENGES

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Highlight: (1) National Pharmaceutical Assistance Policy faces policy and management challenges. (2) Availability of medicines, funding, and pharmacists on site are advances. (3) Strengthening pharmaceutical assistance guarantees quality services and right to health.

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ABSTRACT

Pharmaceutical Assistance plays a crucial role in achieving the goals of the 2030 Agenda for Sustainable Development, especially with regard to promoting health and well-being for all. Despite the achievements resulting from decades of implementation of the National Pharmaceutical Assistance Policy in Brazil, numerous challenges are still reported. Understanding these elements is fundamental to strengthening health systems, contributing to the construction of healthier and more resilient societies. Therefore, the objective of this study was to describe the achievements and challenges of the National Pharmaceutical Assistance Policy in the Unified Health System (SUS). A systematic literature review was conducted, including 17 studies. The results show that several actions have progressed positively, reflecting across all fields of Pharmaceutical Assistance. However, several aspects to be included, reorganized, and improved were also identified, especially in relation to Public Policies and Management, highlighting deficiencies in service management as one of the main challenges. In conclusion, the results demonstrate the diversity of conceptions found in Pharmaceutical Assistance, reflecting the ongoing movement in the process of reorienting its implementation. The critical and integrated analysis of these results contributes to addressing the prevalent challenges in primary health care, including access to medicines and pharmaceutical care in Brazil. This research provides relevant evidence to improve the policy and management of Pharmaceutical Assistance, aiming to enhance the quality of services provided and, consequently, the health of the population benefited by the Unified Health System.

Keywords: Pharmaceutical Assistance, Unified Health System, Public Policies.

INTRODUCTION

The implementation of the Unified Health System (SUS) in Brazil has generated several national experiences resulting from attempts to ensure the availability of medicines in its health units within a pharmaceutical assistance process. This practice is essential for Brazilian public health policies to guarantee comprehensive healthcare[1]. However, it was after a decade of struggles and advances, in 1998, that the National Medicines Policy (PNM) was approved under

Ordinance No. 3,916/98 published by the Ministry of Health[2], with the purpose of guaranteeing the safety, efficacy and quality of medicines, as well as promoting the rational use and access by the population to those considered essential[3,4].

Pharmaceutical Assistance, within the scope of the SUS, specifically regarding the National Pharmaceutical Assistance Policy (PNAF), acts to guarantee the access of medicines for the entire population in a safe and rational way, being structured around its five pillars: universality, equity, comprehensiveness, regionalization and hierarchization[5]. These pillars are achieved through research into the development and production of medicines and supplies, their selection, programming, procurement, distribution, dispensing, quality assurance of products and services, all this in addition to monitoring and evaluating their use, always with a view to obtaining concrete results and improving the quality of life of the population[6].

The actions of the PNAF (National Pharmaceutical Assistance Policy) involve those inherent to Pharmaceutical Care, considering attitudes, ethical values, behaviors, skills, commitments, and co-responsibilities in disease prevention, health promotion and recovery, based on the integration of the pharmacist into multidisciplinary health teams, which include doctors, nurses, and other professionals, with a view to ensuring the rational use of medicines and achieving defined and measurable results. These actions are carried out in an interprofessional manner, respecting the biopsychosocial specificities of users, always with the aim of improving quality of life[7].

It is worth noting that with this policy, pharmaceutical care has become a major challenge for this group of professionals, and it has begun to reorient the focus of attention and professional practice, through the encouragement of a cooperative relationship network between the pharmaceutical professional and the patient, with a view to meeting all their therapeutic needs[8].

In this context, the incorporation of the perspectives of the PNAF (National Pharmaceutical Assistance Policy) is still gradual and heterogeneous, far short of social needs, both quantitatively and qualitatively, especially in relation to the issue of the rational use of medicines, which aims at the well-being of the population and the reduction of unnecessary expenses from public coffers. Furthermore, it is still necessary to develop studies that analyze

the results available in the scientific literature and identify existing gaps; such studies provide valuable data for the formulation of more effective and targeted public policies. This critical approach not only strengthens the health system but also contributes directly to the achievement of the goal of the 2030 Agenda for Sustainable Development.

Understanding the challenges faced by pharmaceutical assistance drives concrete and sustainable actions to ensure that everyone has access to essential medicines, reducing disparities and promoting health as a fundamental human right; thus promoting progress towards a more inclusive, resilient, and sustainable health system. Therefore, the objective of this work was to describe the achievements and challenges of the National Pharmaceutical Assistance Policy within the Brazilian Unified Health System (SUS).

METHOD

A systematic review of the scientific literature was conducted, based on the following guiding research question: What are the achievements and challenges of the National Pharmaceutical Assistance Policy in the Unified Health System?

The search process for articles in the scientific literature was carried out following the criteria established by the PRISMA 2020 protocol for systematic reviews[9]. Original, open-access, available in full, published in English or Portuguese between 2004 and 2021, in which the authors discuss the achievements and challenges of the National Pharmaceutical Assistance Policy and the Unified Health System, were included in the study.

The exclusion criteria for the articles were rigorously defined to ensure the relevance and quality of the evidence included in the review. Duplicate articles, literature reviews, and studies that did not have a direct relationship with the research question were excluded, that is, those that did not explicitly address the challenges and achievements of the National Pharmaceutical Assistance Policy in the Unified Health System. In addition, articles published outside the period from 2004 to 2021 were excluded, as well as those that, despite mentioning the SUS or Pharmaceutical Assistance, did not present robust qualitative or quantitative data, or that did not specifically address the implementation of the PNAF.

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In order to identify potentially relevant literature, searches were carried out in the following databases: the thesis and dissertation database of the Coordination for the Improvement of Higher Education Personnel (CAPES), the Virtual Health Library (BVS), the Scientific Electronic Library Online (SCIELO) and the PubMed database.

The search strategy was developed using pre-determined descriptors, taking into account the object of the research and its location. The boolean operator "AND" was used, as well as quotation marks (" ") when necessary. In this review, descriptors validated in the DeCS (Descriptors in Health Sciences) databases were used, in Portuguese and English: Política Nacional de Assistência Farmacêutica, Sistema Único de Saúde, National Pharmaceutical Assistance Policy, and Unified Health System.

The works obtained through the search strategy were selected based on inclusion and exclusion criteria, firstly by reading the titles, in which those that referred to the topic were selected; the second stage was reading the abstract, excluding studies that deviated from the proposed topic; and the third stage was reading all the selected studies in full, performing a filtering and content check, ensuring greater accuracy of the information.

The works considered suitable were tabulated, and the following information was extracted: author, year of publication of the study, title, objective of the study, type of study, main result, challenges and achievements reported, and database in which it was published. Thus, it was possible to map and characterize in the scientific literature the main challenges that still arise after the implementation of the National Pharmaceutical Assistance Policy, regarding its performance in the SUS, as well as its achievements.

A total of 17 articles were included in this literature review and analyzed in detail and critically, allowing the presentation of data and analysis based on relevant theoretical frameworks.

RESULTS

A total of 145 articles were found in the searched databases. Of these, 29 articles were excluded as duplicates, and 99 were excluded for not addressing the proposed theme, resulting in 17 articles included in this review, as illustrated in Figure 1.

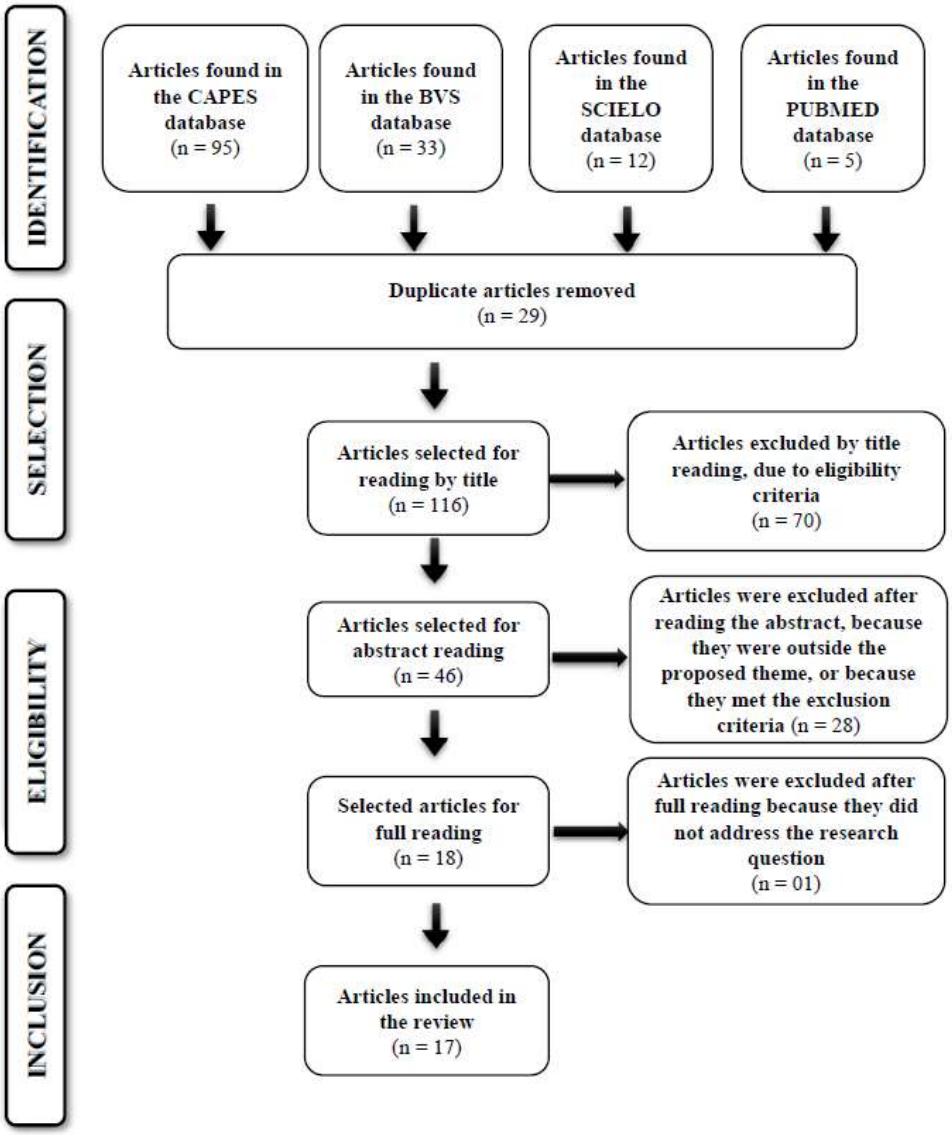

Figure 1. Flowchart of the article search and selection strategy.

(Source: The authors)

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The characterization of the selected studies was described in Table 1.

Table 1 - Characterization of the selected studies regarding year of publication, objectives, type of study and main results.

Author and year	Objectives	Type of study	Main results
VIEIRA, 2008[10]	To highlight unresolved aspects of the Unified Health System agenda related to the qualification of pharmaceutical services.	Cross-sectional study	The municipalities presented problems in the management of resources or services; absence or deficiency in programming and inventory control; losses and waste of public resources; lack of structural investment; and lack of professional training.
MARQUES et al., 2011[11]	To investigate the knowledge and acceptance of integrative and complementary therapies and pharmaceutical care among users of primary health care units.	Cross-sectional study	Users consider greater involvement of the pharmacist to be important, and most patients have no knowledge about the subject.
BRUNS et al., 2014[12]	To verify the performance of different aspects of Pharmaceutical Assistance in municipalities of Paraíba.	Cross-sectional study	Most municipalities presented at least one problem in the management of resources and/or pharmaceutical services; in inventory control; in the acquisition of medicines; diversion of resources and program-related fraud; and lack of basic medicines.
MAGARINOS-TORRES et al., 2014[13]	To describe the profile of state and municipal Pharmaceutical Assistance managers working within the Unified Health System and to discuss their perceptions regarding the implementation of the selection process by states and municipalities.	Cross-sectional study	There are weaknesses in the selection process and in the use of RENAME (National List of Essential Medicines). Barriers identified include the lack of formalization of Pharmaceutical Assistance, difficulties regarding the pharmacy and therapeutics committee, and problems with medications.
NAKATA;SILVA, 2014[14]	To evaluate access to essential medicines within the Unified Health System in a municipality where there were records of initiatives to implement the aforementioned policy, using an evaluation matrix validated by expert consensus.	Case Study	The policy was implemented incipiently, with problems identified in all components of the Pharmaceutical Assistance cycle. Only geographic accessibility was classified as advanced.
ÁLVARES et al., 2017[15]	To evaluate access to medicines in Primary Health Care within the Unified Health System from the user's perspective.	Cross-sectional study	Access to medications remains a challenge as it is still heavily compromised by the low availability of essential medicines in public health units. Privacy during consultations was below satisfactory.
BARROS et al., 2017[16]	To analyze the relationships between access to medicines by the population and the institutionalization of Pharmaceutical Assistance in primary care.	Cross-sectional study	Total access to medicines was higher when professionals reported the presence of aspects related to the following dimensions: "management tools," "participation and social control," "financing," and "staff structure," with significant associations observed in the bivariate analysis.

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COSTA et al., 2017[17]	To identify and discuss the conceptions of Pharmaceutical Assistance according to different actors in Primary Health Care in Brazil.	Cross-sectional study	The findings reveal a tendency to shift from a medicine-centered approach to a broader conception that includes the user and their needs as the final recipients of these actions. Evidence of slow change was observed.
GERLACK et al., 2017[18]	To identify the factors influencing the management of pharmaceutical care in primary care within the Unified Health System.	Cross-sectional study	There is an absence of Pharmaceutical Assistance in the organizational chart of the health department and in the health plan, lack of financial autonomy and knowledge of available funds, and lack of adoption of operational procedures for selection, programming, and procurement.
KARNIKOWSKI et al., 2017[19]	To characterize the drug selection process in primary health care in Brazilian regions.	Cross-sectional study	Those responsible for Pharmaceutical Assistance reported that, in most cases, there was no formally established Pharmacy and Therapeutics Committee. Among the professionals interviewed who performed medicine dispensing, only a minority were pharmacists.
LEITE et al., 2017[20]	To characterize medication dispensing services in the primary care network in Brazil and in different regions, with a view to access and promotion of the rational use of medicines.	Cross-sectional study	There was a predominance of inadequate space for medicine dispensing; some facilities had bars or barriers between users and the dispenser, and few had computerized systems.
LUZ et al., 2017[21]	To investigate the structural and organizational characteristics of Pharmaceutical Care in Primary Health Care (PHC) from the perspective of users and pharmacists.	Cross-sectional study	Users were concerned about the availability of medicines and improvements related to convenience and staffing. Pharmacists pointed out problems related to storage infrastructure, and none reported participating in medicine dispensing activities.
NASCIMENTO et al., 2017[22]	To characterize the physical availability of essential medicines in pharmaceutical care services within the primary care of the Brazilian Unified Health System (SUS).	Cross-sectional study	The average availability of essential medicines in primary health care was less than half. Inadequate availability of medicines for the treatment of chronic diseases and for epidemiologically important diseases, such as tuberculosis and congenital syphilis, was observed.
SOUZA et al., 2017[23]	To characterize the current stage of the institutionalization of Pharmaceutical Assistance in Brazilian municipalities.	Cross-sectional study	There is a heterogeneous and partial process of institutionalization of Pharmaceutical Assistance in Brazil, with an advanced degree observed in formal structures, such as municipal health plans and the existence of standardized medicine lists. Management showed a partial degree of institutionalization, positively revealing the existence of computerized systems, and discrepant results regarding autonomy in the management of financial resources.
SANTOS et al., 2018[24]	To analyze the preliminary results of the implementation and clinical services performed by pharmacists	Cross-sectional study	It was observed that most patients assisted were referred by the health team, and some were identified through active case finding. Of

	in primary health care in a region of the city of São Paulo.		the total workload of services provided, only a small portion was dedicated to pharmaceutical consultations and home visits.
SANTOS et al., 2019[25]	Analyze the positive and negative aspects of the service provided in the municipality of Agudo in Rio Grande do Sul.	Case Study	Most users were satisfied with pharmacy services; however, dissatisfaction was identified regarding the availability of medicines and the commitment of staff to resolving this problem.
SILVA e FEGADOLLI, 2020[26]	To evaluate the implementation of outpatient pharmacy services for the elderly at the Paulista Institute of Geriatrics and Gerontology .	Case Study	The implementation of clinical pharmaceutical services is difficult, mainly due to the insufficient number of pharmacists and the prioritization of actions related to the organization and dispensing of medicines, with limited involvement in care-related activities and, consequently, lower professional recognition of the pharmacist as a member of the health care team.

(Source: The authors)

It was found that most studies were cross-sectional (n=14) and published in 2017 (n=9). The literature findings predominantly indicated a need for improvements in issues related to pharmacists, public policies, structural issues and/or management, as described in Table 1.

All articles (n=17) illustrated the challenges that still arise after the implementation of the PNAF regarding its performance in the SUS (Table 2).

Table 2 – Main challenges that still arise after the implementation of the PNAF regarding its performance in the SUS, organized by analytical axes.

Analytical axes	Main challenges
CHALLENGES RELATED TO PUBLIC POLICIES AND MANAGEMENT	- Service Management[10, 12, 13, 16-18, 22, 23] - Resource Management[10, 12, 16, 18, 22, 23] - Inventory Control[10, 12, 14, 16] - Storage[10, 12] - Physical Structure[10, 14, 16, 20, 21] - Qualification and Training[10, 16, 23] - Availability of Medications[12, 15, 18, 22] - Selection, Programming and Acquisition[12-14, 18, 19, 22] - National List of Essential Medicines - RENAME[13, 19] - Pharmacy and Therapeutics Committee[13, 18, 19]
CHALLENGES RELATED TO PHARMACISTS	- Pharmaceutical Care/ Pharmaceutical Attention/ Therapeutic Assistance[11,15,17,20-26] - Absence of the Pharmacist[14,16,19,21,26] - Interaction of the Pharmacist with the health team[17,23,26]
USER-RELATED CHALLENGES	- Questions about pharmacotherapy[11,20,23,25] - Access to medication[15,23,25] - Privacy in care[15,20]

(Source: The authors)

When mapping the main achievements achieved through the implementation of the PNAF in the SUS (Table 3), it was observed that the most frequently cited achievements were related to the "pharmaceutical professional" axis, with a gradual change in Pharmaceutical Care actions and in the presence of the pharmacist (Table 3).

Table 3 – Main achievements achieved after the implementation of the National Pharmaceutical Assistance Policy regarding its performance in the SUS (Brazilian Unified Health System).

Axes	Main achievements
PUBLIC POLICIES AND MANAGEMENT	- Management of Pharmaceutical Assistance Actions[21] - Financing of Pharmaceutical Assistance[20]
PHARMACIST	- Pharmaceutical Care[17,20,24,26] - Presence of a Pharmaceutical Professional[23]
USERS	- Geographic Accessibility[15] - Quality of Service[15,17]

(Source: The authors).

DISCUSSION

Even decades after the implementation of the National Pharmaceutical Assistance Policy (PNAF), numerous challenges still need to be overcome to strengthen the program. These are directly related to public policies and management, pharmacists, and users. Few achievements are reported in these areas, highlighting the need for studies that can strengthen the role of Pharmaceutical Assistance in the SUS.

The PNAF has gone through several political, economic, and social changes, generating barriers to its implementation in the SUS throughout its history. In this sense, many challenges are faced, and one of the factors most addressed in the selected studies was the deficiencies in service management, which includes a lack of planning and strategy, thus harming the entire Pharmaceutical Assistance cycle and causing harm to public health. This highlights that the absence of effective management compromises the implementation of appropriate actions[10,12,13,15-18,22,23].

Deficiencies in resource management were also addressed, as it is a point of fundamental importance in the supply chain and actions that require financing. BRUNS et al.[12] pointed out that 98.1% of the municipalities that participated in their study presented at least one resource management problem. Also, as shown by GERLACK et al.[18], 81.7% of managers did not know how to report the municipality's expenditure on Pharmaceutical Assistance.

Simply increasing funding for the acquisition of more medicines does not solve the problem, but rather the allocation of financial resources for management qualification, so that efficient resource management is obtained which, along with other factors, in addition to preventing the lack of medicines, also ensures the reduction of losses, optimizing the use of public money[10,12,16,18,22,23].

Another factor found, also resulting from insufficient management, is the inadequate storage conditions[10,12,20] generating poor conservation of medicines and supplies, thus causing supply shortages and financial losses[28].

The setting of pharmacy services also needs to be restructured in order to enable the humanization of care and better working conditions for professionals[10,14,21].

Regarding staff qualification and training, it was noted that their absence or insufficiency has caused great losses and compromised the quality of the entire Pharmaceutical Assistance cycle, since studies indicate that these losses may be occurring due to non-compliance with standards and the lack of training of personnel involved in technical execution, as well as their managers[10,23].

Another important factor is related to the low availability of essential medicines as well as non-compliance with standards for the acquisition of medicines, and the absence of financial counterpart funding[12,22]. On the other hand, there were also reports that there is an expansion of the population's access to essential medicines in addition to the structuring of Pharmaceutical Assistance in municipalities, thus pointing to a major achievement in progress[27,28].

With regard to the National List of Essential Medicines (RENAME), the results indicate weaknesses in the method of its use. The technical quality of RENAME was recognized by managers; however, what mattered to them was its usefulness as an instrument for receiving federal funding and not as a national guiding list, showing a structural deficiency in the management locus1[3,19]. However, the adoption of RENAME is a considerable achievement since the medicines on this list are selected based on criteria of efficacy, safety and cost-effectiveness, making it possible for some dimensions of rational use to be achieved[29].

Other challenges include the stages of the Pharmaceutical Assistance cycle of selection, programming and acquisition of medicines, which have proven to be still incipient[18].

According to those responsible for municipal pharmaceutical assistance, one of the main reasons that justified the occurrence of shortages in the year prior to the survey was, among others, the disorganization of the local purchasing sector. The medicine selection process, within the context of the pharmaceutical care logistics cycle, is a fundamental and understudied step that can influence the promotion of safer drug use and is directly linked to management actions and the conscious use of RENAME[12-14,19,22].

Another factor that contributes to this scenario is the difficulty in forming a Pharmacy and Therapeutics Committee (PTC), which prevents the critical incorporation of medicines into the list of essential medicines[13], or even the absence of a formalized PTC, or lack of periodic meetings[18].

Regarding the challenges related to the Pharmaceutical professional in the SUS, it is observed that in many Brazilian municipalities the dispensing activities are being carried out by unqualified workers[14,16,19,21,26]. This happens, even though in Brazil, on average, 90% of pharmacies/medicine dispensing units have a responsible pharmacist, a fact that constitutes a significant achievement already present in Public Health[23].

The lack of qualified professionals and pharmaceutical care leads to a lack of effective guidance for the user regarding the correct use of medicines, which contributes to polypharmacy (use of five or more medicines). This is a reality in the population served by the SUS and may be related to the excessive or inappropriate use of medications, as the pharmaceutical service remains linked to the curative model, centered on medical consultation and emergency care, in such a way that the pharmacy only meets these demands, making the activity of providing guidance to users almost impractical[11,15,17,20,23,24,30].

It is noteworthy that the studies included in this review were carried out in places where pharmacists were present in primary care, representing a limitation of the study, as it is possible that most medications dispensed in primary care are done without the presence of a pharmacist. This suggests that pharmaceutical care may not be reaching everyone. Furthermore, few studies have cited the integration of the Pharmacist into the multidisciplinary team as a challenge[17,23,26], this fact illustrates that interprofessionalism, which involves collaboration between different professional categories, should be promoted as a means of ensuring comprehensive care for the user, expanding the impact of pharmaceutical actions and improvements in the PNAF.

Another important factor that hinders pharmaceutical care actions is the low implementation of drug information centers in the SUS, since they have the role of guaranteeing access to technical and scientific information and assist in each stage of the Pharmaceutical Assistance cycle of the Pharmaceutical Care cycle[31].

The implementation of Pharmaceutical Care/Pharmaceutical Assistance services has proven to be a relevant challenge, mainly due to the insufficient number of pharmacists and the prioritization of actions related to the organization and dispensing of medications. As a result, there is limited involvement in care actions and a lack of a conducive environment for dialogue and personalized care aimed at identifying and controlling the most prevalent health conditions

and monitoring therapeutic outcomes associated with medication use, which implies risks to users' health[22,25,26].

Despite the challenges observed, a gradual change is seen in relation to Pharmaceutical Assistance actions, which are strongly situated in the field of health promotion and disease prevention. Thus, it is observed that the experience of implementing a pharmaceutical care service alters the vision of primary health care professionals regarding the work of the pharmacist, where a technical and supervisory role has been replaced by the vision of a professional who cares about and takes responsibility for the user[27].

In the study by SANTOS et al.[24], 6,882 pharmaceutical interventions were carried out, reinforcing the importance of clinical pharmaceutical services. The pharmacist is highly recognized by patient for activities related to promoting adherence to treatment, resolving problems related to the efficacy and safety of medications, as well as analyzing and monitoring polypharmacy[26].

LEITE et al.[20] point out in their study that among those responsible for dispensing, 87.4% stated that they always or repeatedly inform about the method of use of medications. The situation found is already the result of a period of incentives from legal instruments that encouraged municipalities to structure pharmaceutical services and primary care[17].

Within the context of Pharmaceutical Assistance in Brazil, there is a trend of shifting from a focus on medication to a broader conception that includes the user and their needs as the ultimate recipient of these actions[17].

In the global context, policy advances in promoting improvements in pharmaceutical care focus on increasing access to medicines, integrating technology, and reforming policies to ensure equitable health care. The shift to a patient-centered model in pharmaceutical care emphasizes the role of pharmacists in optimizing drug therapy and collaborating with healthcare professionals[32]. Initiatives such as the COVAX (Global Access to COVID-19 Vaccines) program highlight the importance of global health diplomacy in addressing disparities in access to medicines, particularly in low- and middle-income countries[33]. In addition, public policies are crucial for promoting advances in pharmaceutical care; intervention strategies need to encompass a comprehensive approach to address the challenges

faced by health systems, highlighting the need for integrated policies and global partnerships to improve pharmaceutical care services.

There is still a need for systematized analyses of pharmacists' experiences in primary health care. Studies that enable the identification of developed actions, as well as an understanding of professional choices within their practice contexts, are recommended to enhance visibility of this professional role and to support the strengthening of Pharmaceutical Assistance in the SUS.

CONCLUSION

The National Pharmaceutical Assistance Policy in the Unified Health System still faces numerous challenges, especially related to public policies and management (such as problems with service and resource management, physical structure, qualification and training, availability of medicines, the National List of Essential Medicines (RENAME), and the Pharmacy and Therapeutics Committee), pharmaceutical professionals (such as deficiencies in pharmaceutical care, absence of pharmacists, and interaction with the multidisciplinary team), and users (such as doubts about pharmacotherapy, lack of access to medicines, and lack of privacy in care). However, advances in all these fields have also been achieved over the years, including the availability of medicines, improvements in Pharmaceutical Assistance management, increased funding for this field, the requirement of a pharmacist on site, better geographical accessibility, and improved quality of care, which were the main achievements identified in the literature.

The results presented in this study provide evidence to support the improvement of public Pharmaceutical Assistance, aiming to improve the quality of services and health indicators, in order to guarantee the right to health for the population.

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