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Access to high-priced medicines: inequalities in the organization and the results among Brazilian states

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Abstract *This case study aimed to characterize the Specialized Component of Pharmaceutical Services (CEAF) organization in four Brazilian states from diverse regions of the country. Data were collected with representatives of CEAF management from states in different regions, who answered a 21-question questionnaire on scope, organization, financing, hurdles, and facilitators. This information was complemented with data from national health surveys, DataSUS, the applied resources, and socioeconomic indicators. Differences were observed between states on issues such as the proportion of users and the decentralization of services. These characteristics seem to be related to the level of development concerning the socioeconomic indicators used. Advances in access to medicines were highlighted, despite the difficulties complying with the CEAF's objectives, such as insufficient resources, the qualification of human resources, and the provision of necessary visits and exams. The results point to advances, different forms of organization and highlight the need for more in-depth studies on the clinical and economic outcomes achieved as a strategy to outline solutions to achieve the comprehensive and equal care for users.*

Key words *Pharmaceutical care, Access to health services, High-cost technology, Essential medicines*

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Introduction

Medicines play an important role in health care. However, the increasing costs of therapeutic alternatives incorporated in health systems require strategies to guarantee access and completeness of treatments. This aspect has concerned researchers and managers of health systems, including in developed countries[1-6].

Brazil has implemented different public policies[7-9] to ensure access and rational use of medicines (RUM). Among the strategies for expanding access, the Specialized Component of Pharmaceutical Services (CEAF) was implemented to achieve comprehensive treatment based on lines of care defined in the Clinical Protocols and Therapeutic Guidelines (PCDT/MS), which define the algorithm and treatment and the diagnostic criteria and clinical monitoring mechanisms[8,9]. While Brazil does not adopt a parameter to define allegedly high-cost (as in the English health system) or high-priced medicines[10], the CEAF facilitates the highest mean price of outpatient medicines in the SUS, including the most recently incorporated by CONITEC, such as Ecolizumab[11].

The use of the terms "high-cost medicines" or "high-priced" has not yet been defined internationally and may vary in the same country[12]. Some countries categorize high-cost medicines by the price cap per patient or year to be reimbursed by the public payer. These medicines generally have a monopoly patent and represent a significant financial burden for the public health care system or greater direct expenses for individuals[13].

The financing of CEAF medicines is tripartite. However, those indicated for more complex diseases, with high financial impact and included in actions of the Health Industrial Complex, are acquired centrally by the Ministry of Health or financed by it through the transfer of resources to the states[8,9].

Following the SUS management principles, the underlying steps of CEAF's implementation are decentralized, and the State Health Secretariats (SES) are responsible for organizing services to attend to people, including dispensing medicines. However, some activities can be carried out by the municipal public service network, as long as there is an agreement between the managers[9].

In this context, Rover et al.[14-16] highlight that several factors can influence CEAF's management and that ensuring complete treatments involves access to medication and other care and health services and the articulation between these[14]. The authors argue that the lack of interrelationship of Pharmaceutical Care with other health sectors, which translates, for example, into the mismatch between the demand for CEAF-related services and their offer by the state results in a fragmented care[15,16].

The Federal Government's investments to finance the Component have been on the rise[1,17,18] since CEAF's implementation. However, few studies have been carried out regarding its organization and management, the results achieved, and its coverage in different Brazilian states and regions, considering the known inequalities.

Thus, considering the differences between the structures of pharmaceutical care in the country, people question which aspects still need to be improved to achieve CEAF's objectives. In this sense, this study aimed to characterize the different forms of organization, management, and access to medicines in the CEAF in four states in different regions of the country and their relationship with socioeconomic and health indicators.

Methods

This case study was developed with data collected from 2014 and 2015. Data were retrieved from questionnaires and secondary databases. Participating states were selected by convenience sampling using the managers' availability to respond as a criterion. Invitations to participate in the study were sent by e-mail to six states and the Federal District. Five of them and the Federal District agreed to participate, and four states were included in this study as they showed all the necessary data. Participating managers answered the questionnaires and sent them by e-mail.

The questionnaire was developed from the guidelines provided for in the PCDT and Component's regulations[8,9] and validated through discussions with the research group until reaching a consensus on the most relevant issues for the study. The consensus questionnaire consisted of 20 questions (9 open-ended and 11 closed-ended) related to: scope (e.g., number of users); CEAF's organization (e.g., decentralized, municipalized); financing (e.g., amounts invested); infrastructure (e.g., number of units, reference centers – RC/application poles); logistical and clinical services (e.g., procurement problems and monitoring provided for in the PCDT); open-ended questions about the perception of facilitators and weaknesses in the state's CEAF management.

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The following data were collected from each state: population, Gross Domestic Product (GDP), Municipal Human Development Index (MHDI)[19,20], and SUS Development Index (IDSUS)[21]. The GDP and IDSUS data were categorized into three groups by descending state ranking order: upper tertile (1st to 9th), middle tertile (10th to 18th), lower tertile (19th to 27th). In the case of the MHDI, the classification was as follows: very low = 0-0.499; low = 0.500-0.599; average = 0.600-0.699; high = 0.700-0.799; very high >0.800[20].

Additionally, data were collected from the indicators of access to health services and medicines from the National Health Survey[22] (% of the population that accesses all medicines, % of the population that accesses medical appointments, and % of the population with a private health plan) and DataSUS data[23] (% of resources invested by States EC29 – in health). The amounts invested by the Ministry of Health in CEAF in each state were also considered, per the corresponding ordinances[24-27].

The exchange rate reported by the Central Bank of Brazil (BRL 2.34 per U.S. Dollar) was used for converting BRL to U.S. dollars. The answers to the open questions were analyzed and categorized, following the steps of treatment and analysis of qualitative data by Pope et al.[28]. The Human Research Ethics Committee of the Federal University of Santa Catarina approved this study under Opinion No. 712.031/2014.

Results

The management representatives participating in the survey were pharmacists with statutory employment and with two years or more of experience in the position. The population of the four states together represented approximately 35% of the Brazilian population. Table 1 shows the MHDI, the GDP, the IDSUS, and indicators of access to medicines, appointments, and health plans. We can observe that the analyzed states showed differences in the MHDI, IDSUS, and GDP indicators, which coincided with the data on the indicators of access to medicines and health services.

The states with higher GDP, MHDI, and IDSUS (South and Southeast) also had greater access to medicines, appointments, and private health insurance. Specifically concerning the CEAF, we observed differences in funding, the proportion of users per inhabitant, and the organization of the Component (decentralization of dispensing locations) (Table 2 and 3).

Information on financing for the purchase of medicines showed that the highest (absolute) amounts of resources are transferred by the Federal Government the states with the highest number of users (South and Southeast). In turn, the other two states had the highest proportional expenditure on medicine financing.

The proportion of people served by CEAF was higher in the South and lower in the North. Differences in the degree of decentralization of the Component (understood as a more significant number of dispensing locations) were also highlighted. They were more significant in the states of the South and Southeast. The data showed greater availability of medical centers in the Southeastern state.

The participants said that the implementation of CEAF had weaknesses in different stages, both in the logistical and care processes and in articulation with the municipalities, as categorized in Chart 1. Examples are the lack of information about the first line of care service in some states; the pent-up demand due to the centralized purchase schedule being made without technical reserve; the long time to evaluate requests; weaknesses in the provision of appointments with experts and tests (when required) for access to medicines. Also, according to the participants, there was a need to centralize the purchase of other drugs, mainly due to the economic impact they represented and because the amounts transferred by the Ministry of Health were insufficient. However, strengths were also described, such as the expanded access to medicines, the incorporation of new technologies, and the increased number of clinical conditions for which the public sector provides the treatment. The main weaknesses and strengths described are presented in Chart 1.

It should be noted that the short period of renewal of requests for chronic diseases (quarterly) and the lack of data on the clinical and economic results achieved were also highlighted by the participants.

Discussion

National surveys have identified that access to medicines, including the public and private sectors, has evolved consistently in Brazil[1,29] due to public policies implemented in recent years[8]. In this context, the participants highlighted CEAF's

Table 1. Contextual characteristics of the analyzed states.

Indicador	State (North)	State (South)	State (Northeast)	State (Southeast)
MHDI[a]	Medium	High	Medium	High
IDSUS[b]	Lower tertile	Upper tertile	Lower tertile	Upper tertile
GDP (year)[c]	Medium tertile	Upper tertile	Lower tertile	Upper tertile
% of the resources applied by States EC29 (in health) [d]	13.5	11.2	13.4	12.4
% of the population accessing all medicines [e]	75.8	84.8	80.8	83.1
% of the population accessing the medical appointment [e]	57.5	72.8	66.4	78.4
% of the population with private health insurance [e]	13.7	32.9	13.9	42.1

Sources: [a] Municipal Health Development Index. Brazilian Institute of Geography and Statistics – IBGE, 201420. [b] SUS Development Index 21. [c] Gross Domestic Product 19. [d] DATASUS 23. [e] National Health Survey, 2013 22.

Table 2. Data related to CEAF financing in the four states.

	States			
	North	South	Northeast	Southeast
Total amount invested in medicines - State and Federal Government (in millions *)	21.2	128.2	28.1	890.4
Amount invested by the Federal Government in medicines (in millions *)	15.4	115.6	22.5	719.4
% invested by the state in medicines	27	9.8	19.9	19.2
Mean amount invested per user *	3.023	1.224	2.342	1.644
Investment in Workforce qualification *	-	-	-	-
Investment in structuring services *	64.000	3.418.000	-	-

Source: Federal Investment Data - Ordinances 24-27, the other data were obtained from the interviews.

* Values calculated in US Dollars.

Table 3. Data related to CEAF's coverage and organization in the four states.

	States			
	North	South	Northeast	Southeast
Nº of CEAF users/1,000 inhabitants	0.9	10	3.2	13.2
Nº dispensing locations/100 municipalities	18	75	7	97
Mean number of users per dispensing location	269	347	800	869
Number of Reference Centers/Application Hubs	0	15[a]	2[b]	142

Source: IBGE[19] (number of inhabitants and municipalities by state). The other data were obtained from the interviews.

[a] Administration of Botulinum Toxin, Imiglucerase, and medicines for the treatment of Hepatitis C.
[b] Administration of medicines for the treatment of Hepatitis C and Multiple Sclerosis.

positive results regarding expanding the list, constructing lines of care, and increasing the number of users served as the main strengths. However, the findings of this study show that the results between the states are not homogeneous and that there are still difficulties for the full implementation of the Component.

The heterogeneity observed in the organization for servicing users, and the number of users is related to the contextual differences of the states and management capacity, as the performance of health systems is primarily influenced by the local political, socioeconomic, and cultural characteristics[30,31]. Moreover, access to

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Chart 1. Main weaknesses and strengths pointed out by managers.

Strengths	States
Expanding access to medicines	North/South/Northeast/Southeast
Construction of care lines	South
Decentralization of dispensing in municipalities	South/Southeast
Ministry of Health's centralized purchases of medicines with a more significant financial impact	South/Southeast
Presence of the evaluator and authorizer in service units, providing immediate dispensing	Southeast
Management information system	South
Weaknesses	
Problems in acquisition [a]	North/South/Northeast/Southeast
Insufficient funding [b]	North/South/Northeast/Southeast
Non-implementation of the clinical monitoring provided for in the PCDT	North/South/Northeast
Need to centralize the purchase of other drugs [c]	North/South/Northeast
Need for periodic updating of PCDT and incorporation of other drugs.	North/South/ Northeast/ Southeast
Insufficient workforce	South/Northeast/Southeast
Weak physical structure	Northeast
Few service units (including RC)	North/Northeast/Southeast
Lack of agreement with municipalities for the implementation of CEAF	Southeast
Lack of standardization of implementation steps	Southeast
Computerized systems that do not interoperate	North/South/Northeast/Southeast

[a] Bureaucracy and slow of bidding processes; some items are not quoted in repeated bidding processes; monopolies/duopolies in production; quotation of prices above the reimbursement values by Ministry of Health; interruptions in the production of certain medicines; lack of a database with price registration minutes for all states and a national registry of suppliers.
[b] Delay in the transfer of the Ministry of Health and because the financing of CEAF does not include implementation expenses. Situation aggravated in the Northern state because it could always practice tax exemptions and apply the minimum mandatory discount in acquisition processes.
[c] E.g., Somatropin, Octreotide, Leuprorelin, Dornase Alpha, Botulinum Toxin, Iloprost, Ziprasidone, and Deferasirox.
d E.g., Tiotropium; Insulin analogs; Ranibizumab; Teriparatide; in addition to immunosuppressants for heart transplantation.

Source: Data obtained in interviews.

medicines is highly dependent on the organization and functioning of health systems also at the local level[32].

In this sense, the results of this study indicate that, while the PCDT are national guidelines, the states in the South and Southeast had a higher proportion of users served by CEAF, states with greater availability of economic resources (greater GDP), public services (greater IDSUS), and broader coverage of private health plans. The inverse association between socioeconomic position and underutilization of medications was previously observed in Brazil and corroborates the findings of Luz et al.[33].

Although Penchansky and Thomas[34] believe that service accessibility is determined by the relationship between the volume and type of service available, and the volume and type of user needs, the results corroborate the first statement but do not allow us to state that the lower access to CEAF in the North and Northeast were the result of lesser need since there is no epidemiological data to indicate this hypothesis.

It is also known that, while Brazil has made significant advances regarding access to health services, especially in Primary Health Care, the limited provision of high- and medium-complexity services required to meet the criteria established by the PCDT is still a significant challenge for the public sector of the SUS[1,6,35]. These constraints cause long waiting times, leading to a search for specialized care in the private sector or through the courts, which burdens the state even more[4,14-16,36,37]. Thus, a double standard of access to CEAF medications is established (among those with and those without access to appointments

and tests in the private system), besides informal arrangements (such as mechanisms to overcome the queues)[14].

Buendgens et al.[38] found that, of all users diagnosed with rheumatoid arthritis studied, only one had access to all the health services required for their treatment in the public sector. However, this study also showed that more than 70% of the financing for the treatment of the disease was provided by the public sector. Thus, even with constraints, the public sector has been responsible for most of the financing of these treatments.

This study points out that the most significant proportion of CEAF users is found where there is decentralization to the municipal level of the dispensing units (Southern and Southeastern states), which depends on the articulation capacity with the municipalities and the available resources. Limitations in this regard have already been evidenced in previous studies[39-41], which are barriers to the organization of the service network in municipalities and indicate the need for negotiations between managers[42]. Problems of articulation with municipalities also appear in the non-verification of the supply of the first line of treatment, a fundamental step to ensure effective and complete treatments.

Given that, as mentioned above, access to CEAF medicines is closely related to the availability of dispensing points and access to other services for the diagnosis and monitoring of treatments[14], the results of this study draw attention to the growing need for coordination among health services[44], considering pharmaceutical care as an unequivocal part of system management and not an isolated sector[15]. The results presented here suggest that the real understanding of pharmaceutical care in the planning and decision-making process of the health system is critical to achieving equitable and timely access to treatments.

The results also show differences in the percentages invested in medicines between states. The amounts invested are mainly related to the number of users associated with the level of development and availability of health services. The Ministry of Health's investments for group 1B purchases depend on the request for medicines in each state, which is also determined by the offer of services. However, state procurement management capacity is also a factor that influences the proportionality of investments per user. This situation is even more critical in medicines with a limited number of suppliers due to the monopolies generated by patent protection. Thus, states' exemption expected by the current financing agreement for the highest-priced medicines[8,9] is not adequately achieved.

Also, the states have a smaller population and, thus, lower demand (North and Northeast). They have a lower bargaining capacity vis-à-vis suppliers, which means that acquisition prices are higher; that is, the unit invests proportionally more for the same clinical condition. Thus, the states with lower socioeconomic and development indicators of the SUS will be the most burdened.

Despite the measures adopted to reduce medicine purchase prices, such as the definition of the Maximum Sale Price to the Government[8], the results pointed to the need to strengthen surveillance over the drug market, implement a national price and supplier registration bank, and generate strategies for the joint purchase between states, which can contribute to price regulation[1,45]. Tobar et al.[46] argue that these are alternatives for adopting policies centered on access to medicines.

The data also evidenced the focus of resources on the acquisition of medicines, to the detriment of improving other aspects relevant to achieving the goal of comprehensive care, such as continuous training of the workforce and adequate physical structure. From the participants' perspective, the fact that CEAF's financial transfer is exclusive for the acquisition of medicines burdens the states with the implementing costs, hindering investments in the qualification of services. On the other hand, what is established in the current regulation considers that states are responsible for implementing the CEAF[9].

Another aspect reported by managers was the additional cost of financing drugs not covered by the CEAF but provided as a result of lawsuits. The fact that the medicines requested through the courts, suggested for incorporation by the participants, have already been evaluated by the National Commission for the Incorporation of Technologies in the SUS and the opinion of the majority was unfavorable[47-49], corroborates the evidence collected on the use of judicialization as a mechanism of the pharmaceutical industry to pressure the inclusion of new technologies in the SUS[4,50]. Given this situation, there is a need to develop joint strategies between the Ministry of Health and the states aimed at disseminating independent information on the efficacy and safety of medications and training prescribers for RUM.

The focus on the medicine product is also observed in the development of CEAF-related

activities since activities for the availability of medicines are prioritized. In contrast, the implementation of clinical-assistance activities required for monitoring the treatments (e.g., implementation of RC and monitoring according to the PCDT) are still limited, already reported by other studies[1,16,37,51]. Thus, the lack of data on treatment results translates into the unavailability of information regarding improved people's health status and an effective Component, which is a weakness in health services[52].

Finally, the logistical problems mentioned and the lack of interconnected computerized systems can lead to shortages or delays in the availability of medicines. Specifically concerning information systems, it is essential to highlight that financial and medicine transfers only occur after data transfer to the Ministry of Health. Failures and problems that may occur in this transfer and the impossibility of states requesting technical reserves to serve new users can lead to lack or delays in care, with negative individual and group impacts due to deteriorated health status, use of additional therapies, and services, and higher expenses on treatments[53,54]. Interconnected systems provide agility in transferring information, allowing timely service to users, and deserve special attention from the states and the Ministry of Health.

It should be noted that part of the purchase of medicines demanded by the study participants for the Ministry of Health's acquisition has been centralized in recent years. More recently, through Ordinance No. 13 of January 2020, the Ministry of Health partially solved the issue of short periods for renewal of requests by allowing them to be performed for up to six months of treatment[55]. This measure reduces bureaucracy[1], but if not correctly implemented, it can cause losses for patients whose diseases require more frequent follow-up (e.g., chronic kidney disease patients, transplant recipients, and patients with active inflammatory diseases).

One limitation of this study is the use of some data mentioned by the informants, as the states do not have or do not make publicly available all the data related to the organization and management of the Component. Intentional sampling was adopted, and, therefore, the study cannot be interpreted as an evaluation of the four regions as a whole. However, the results provide an overview of the different conditions of Brazilian states and the different conditions of access to CEAF medicines.

This first approach to the study of the organization of CEAF points out that the Component has contributed to the expanded access to high-priced medicines in Brazil. However, given that access to medicines depends on contextual characteristics and management capacity, the results of this study highlight the need to overcome interstate inequalities in the access to health services to meet the constitutional precepts of universal and comprehensive care.

The results suggest that the country needs to advance in access to drug therapy, ensuring equity and opportunity. Overcoming these challenges requires measures related to the Component's management and more significant interaction between pharmaceutical care managers and the other managers of the SUS to design strategies to strengthen the decentralization process and overcome the shortcomings in the provision of specialized services.

We also observed that the different forms of organization and structuring of CEAF have impacted people's access to medicines. The finding that the states with the worst development indicators invest proportionally more for the same clinical condition is troubling. Finally, the lack of national data on CEAF points to the need for more in-depth studies on the results achieved, which enable the formulation of public policies to streamline the implementation of the CEAF.

Collaborations

MRM Rover: collected the data, analyzed the field findings, and drafted the text; SN Leite helped in the analysis of the results, in the conception and the final writing; EB Faraco collaborated in the analysis of the results and the text drafting; MR Farias assisted in the final text drafting. CM Vargaz-Pelaez collaborated in the analysis of the results and the text drafting; C Colussi collaborated in data analysis and final review of the text; S Storpirtis assisted in the final review of the text.

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