DOI: 10.1590/1413-812320212611.00842021

Challenges in the management of high-priced drugs in the SUS: evaluation of Pharmaceutical Policy in São Paulo, Brazil

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Abstract *The aim of this study is to evaluate the management capacity of the Specialized Component of Pharmaceutical Services (CEAF, in Portuguese) in the state of São Paulo (SP), according to the organizational, operational and sustainability aspects. The study was designed as an evaluative investigation, with the adoption of a theoretical model and protocol of indicators developed for application at the national level and validated (Nominal Group and Traditional Committee) for application in the reality of the SP. The data collection in the 35 CEAF units was carried out in 2017 and 2018, and covered all technical areas that participate in the management/execution of CEAF, in both its central and regional scopes. The assessment of management capacity was based on a critical analysis of the obtained results, analyzing their strengths and weaknesses. After collecting data from 35 CEAF units, it was found that the management capacity was positive in the operational dimension with challenges concentrated in the other dimensions. The results showed greater investments and development in the technical aspects of pharmaceutical services, but deficiencies in such areas as the monitoring of clinical results, infrastructure, regulation, and communication with the actors involved.*

Key words *Health Services Research, Population Health Management, Pharmaceutical Services, High-cost drugs*

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Introduction

In Brazil, access to high-cost medicine depends on actions and connections which involve the three levels of government. From the three components of pharmaceutical care - which are, Basic Component of Pharmaceutical Care (BCPC), Strategic (StCPA) and Specialized (CEAF) – the CEAF is that which covers high-cost medicine provided by the Brazilian Unified Health System (SUS, in Portuguese). It is defined as a strategy of access to medicine which guarantees treatment integrality, with its care lines defined in Clinical Protocols and Therapeutic Guidelines. At its level, what can be most commomly verified is the tension among increases in spending, pressures of demand, and commercial competition in terms of medicine[1-3].

The acquisition of medicine represents an important part of the total expenses with health care, and availability of high-cost medicine has great social impact and therapeutic relevance; moreover, this kind of medicine requires specialized services in order to be effective[3-5].

Although there is a clear emphasis in Brazilian literature and among the managers concerning the financial aspects of CEAF, there are several challenges that constitute a complex context for its management in order to provide full and universal access to medicine[3,6]. One of the challenges is the decentralization of actions, in the sense that states and municipalities take over direct responsibility for health care, including the actions related to pharmaceutical care[6].

The management of CEAF imposes important challenges in terms of providing for user needs, in terms of the other health services, as well as in terms of infrastructure and the process of services[3,4,6] . To overcome these challenges, the investigation of health policies and services plays a key role, allowing for the identification of relevant issues and the provision of reliable information, thus becoming an important tool to guide management and to improve the quality of the services rendered[7].

In the area of pharmaceutical care, expanded management suggestions and assessments were presented by Barreto[8] and Barreto and by Guimarães[9]. Based on the reference by Carlos Matus[10] and Guimarães et al.[11], they argue that management is a technical, political, and social process capable of producing results, and that management capability is *the capability of an organization, to decide, with autonomy, flexibility and transparence, mobilizing resources and building sustainability of the results of management*[11] (p. 1646). Considering such concepts, assessments of the management capability of pharmaceutical care were developed at the municipal and state levels in a broad perspective, beyond structures and technical processes[6,8,12].

Based on these references, management capability is assessed through three independent dimensions: organizational, operational, and sustainability. The operational dimension shows the ability of maintaining and expanding the logistic and managerial resources. The sustainability dimension reveals the ability of supporting the management results, considering aspects related to the institutionalization of systems and strategies which can expand and/or consolidate support and alliances capable of favoring sustainability in decisions and results planned by the management[9].

The state of São Paulo, which has 21% of the Brazilian population, also faces challenges in the management of pharmaceutical care[13]. This is one of the areas with the most financial impact for CEAF, with projections of increasing even further[13] In 2015, the investment in medicine by CEAF exceeded R$1.5 billion, of which R$ 150 million were financed by the state[14-16].

In this context, it is increasingly more important to make progress in management in order to overcome adversities and respond properly to the needs of the population. Moreover, it is important to remember that the development of assessment studies about the CEAF is quite recent[6].

Therefore, this study aimed to assess the management ability of the CEAF in São Paulo, seeking subsidies to qualify pharmaceutical care and expanding the data on accessibility of high-cost medicine.

Methodology

This is an evaluation study, which took place from June 2016 to February 2018. Both a logical and a theoretical model were used, as well as the indicator protocol and the forms for data collection developed by Rover et al.[6,1718], after adaptation. The indicator protocol is made up of 8 organizational (80 points), 11 operational (110 points), and 6 sustainability (60 points) indicators[6,18].

Ciência & Saúde Coletiva, 26(11):5481-5498, 2021

Place of study and subjects of the survey

This project was developed at the Health Secretariat of the State of São Paulo (SES/SP, in Portuguese), at its central level (CEAF directors) and at its regional level (Central Warehouse and Specialized Medicine Pharmacies [FME, in Portuguese]).

The subjects of the survey (hereinafter referred to as the 'team of specialists'), were selected by convenience, for each phase, according to the following criteria:

Validation of the theoretical model and indicator protocol: professionals with deep knowledge and experience with pharmaceutical care from the state of São Paulo, involved in research, teaching, management, and/or care, with direct or indirect involvement with CEAF; availability to participate in the two phases of the study: validation of online tools and participation in the consensus workshop (in-house).

Appearance validation of the data collection forms and in the phase of their use: professionals responsible (or co-responsible) for the FME and for the Central Warehouse of the SES/SP and manager (central level) of the Components of Pharmaceutical Care and of the CEAF from the SES/SP; availability of response of the data collection form.

Figure 1 shows, for each phase of the survey, the quantity and involvement of the subjects described above.

Adaptation of the survey tools

Adaptation and validation of the theoretical model and the indicator protocol

It was necessary to adapt the theoretical model and indicator protocol, developed by Rover et al.[6,18], considering the functional variables of the CEAF in the state of São Paulo. The adaptation of the indicator protocol took into consideration that the indicator is only valid in the specific context in which the evaluation is performed[19]. The indicators were adapted according to their question, measure, punctuation, parameters, source of data, and weight.

For content validation, the following techniques were used: Nominal Group Technique (NGT) and Traditional Committee. The following phases were followed:

Phase I – NGT – online phase:

The specialists received the theoretical model and the adapted indicators, as well as the theoretical foundation, which led to its elaboration. The documents were organized in forms and made available through an online address, counting on the support of the Google® - Google Forms app and exported to the Microsoft Excel® software for the analyses. The created forms were divided into four parts. The 1st form represented the adapted theoretical model analysis, according to its "relevance"[20]. In the 2nd, 3rd, and 4th forms, the specialists evaluated the quality of the adapted indicators in relation to their question, measure, parameter, data source, and punctuation, using the following attributes: Clarity; Validity/Effectiveness; Accessibility/Measurability[20,21]. For punctuation, a 5-point Likert scale was used[22]. In addition, open fields were included, for justification (when the score given by the specialist was below 3 points) and for improvement answers (regardless of the score given).

Once the data was tabulated, the average of points given was calculated, considering as approved those which received 4 or more points. The indicators which, on average, had a score of 3.9 or below, in any of the attributes, were chosen for discussion at the consensus workshop (phase II).

The suggestions for improvement proposed by the specialists to improve the theoretical model and indicators, regardless of the average score, were evaluated and, whenever relevant, were accepted and incorporated.

Those that had a significant impact on the model or indicator, regardless of having been approved in Phase I, were brought for discussion in Phase II.

Phase II – Traditional Committee Technique:

An in-house, 8-hour workshop was held, according to the "Traditional Committee" consensus technique. First, the theoretical concepts which are the foundation of the indicator[23] protocol, were reviewed. Second, the indicators which had scores of 3.9 and below were presented, as were those that were approved but received suggestions for improvement which impacted their content. The specialists discussed the questions presented until they reached a consensus on keeping (with or without adjustments) or on excluding the indicators. In the third moment, the parameters and weights of all the indicators were reanalyzed, and adjustments and adaptations were made.

After all the adjustments had been implemented, the specialists received the validated versions.

RESEARCH DEVELOPMENT PHASES	RESEARCH SUBJECTS	
	Quantity	**Position**
Bibliographic Research	-	-
Adaptation of the theoretical model of evaluation and the indicators protocol	01	Technical Director of the Components of Pharmaceutical Assistance of the State of São Paulo
Validation of the theoretical model's content and indicator protocol	12	Professionals with ample knowledge and experience in Pharmaceutical Care in the State of São Paulo, who work in teaching, research, management, and/or healthcare, involved in CEAF directly or indirectly (State and Municipal connection)
Adaptation and apparent validation of the data collection tools	05	Sampling of target population for the filling in of data collection forms, acting pharmacists from the Specialized Medication Pharmacies, (03), Central Warehouse (01) and CEAF manager - central level (01) From the Health Secretary of the State of São Paulo
Application of the data collection tools	40	Pharmacists working at the Specialized Medication Pharmacies (37), Central Warehouse (01), Technical Director of the Components of Pharmaceutical Care (01) and CEAF's manager(01) from the Health Secretariat of the State of São Paulo
Evaluation CEAF's management capability in the State of São Paulo	-	-
Return and publication of the results of the survey	-	-

Figure 1. Phases of development of the research and subjects involved in each one of the phases.

Source: Authors' elaboration.

Adaptation and apparent validation of the data collection tools

The initial adaptation of the data collection tools was performed by the author (first author) of this research, based on the documents validated in the previous phase.

The adapted tools are: (a) Data collection form with the MANAGER (central level); (b) Data collection form with PHARMACIES (regional level); (c) Data collection form with the SES/SP CENTRAL WAREHOUSE. The tool (a) was produced using Microsoft Word® software, and tools (b) and (c) were organized in forms with Google® - Google Forms.

After adaptation, the tools were presented to the CEAF - SES/SP management team, who validated the content by consensus and issued the permission for the start of the apparent validation (layout and form comprehension) and for data collection afterwards.

The author and the CEAF - SES/SP management team defined that the apparent validation of the data collection tools would be done with:

The CEAF manager (central level) - advisor responsible for CEAF;

The responsible pharmacists from three specialized medicine pharmacies (FME) - one in the state capital and of large size (management by Social Health Organization); one in the metropolitan area of the state capital, of smaller size (indirect management); and another from the countryside, of large size (management by Social Health Organization);

The pharmacist responsible for the Central Warehouse.

This phase was the last phase of the traditional Committee.

Use of the data collection tools

Data collection was conducted from December/2017 to January/2018 and covered every area which participates in the management/execution of CEAF, connected to SES/SP, at central level (CEAF direction) and regional level (Central Warehouse and 37 FME).

The data collection form for the MANAGER was sent via e-mail, and the data collection forms for the PHARMACIES and CENTRAL WAREHOUSE were made available at an Internet site, with the support of Google® - Google Forms app.

Assessment of the CEAF management capability in the State of São Paulo

With the information collected, it was possible to fill in the validated indicator protocol (Chart 1). The assessment of the CEAF management capability in the state of São Paulo was based on a critical analysis of the results, looking into the strengths and weaknesses of the development of CEAF's state level management.

The attribution of a value judgement for each dimension was based on the parameters validated by the team of specialists and was converted into a color scheme, which helped visualize the obtained results, as presented in Chart 2[23].

Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
Organizational Dimension					
1. Participation	Managers participate in social participation departments and there are instances which allow participation of all parts involved	10	Participated in 3 or more instances: CES, CIB, meetings for creation/ monitoring of PES, technical meetings at CONASS	7.5	Green
			State management developed strategies or created instances for the participation of all parts involved with CEAF: a strategy with association of patients		
2. Transparency	Information is published about medication out of stock and the prices paid for medication	10	State-level management developed strategies or created instances for the participation of all those involved with CEAF: a strategy with association of patients	5.0	Yellow
			The prices paid by the State for CEAF medication (group 1B and 2), are disclosed and made available for the population through the Farmanet digital system (online)		
3. Planning	Inclusion of CEAF actions in PES. Existence of planning meetings specific for CEAF	10	In PES, there are specific actions related to pharmaceutical care that involve matters related to CEAF	5.0	Yellow
			CEAF managers do not hold strategic planning meetings		
4.Monitoring and evaluation of actions	There are indicators and their monitoring is used for planning actions	10	Indicators for monitoring actions related to CEAF are not used for planning actions or there are no indications of monitoring	0.0	Red

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Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
5.Partnerships	Partnerships with other institutions for the development of CEAF activities	10	There are partnerships with other institutions to decentralize care for the patients, and some partnerships are not formalized	5.0	Yellow
6. Regulamentation	There are regulated flows for the evaluation of requests and guidelines on the processes of work in the units	10	In the state, there is no established flow (documented) for the evaluation of CEAF medication requests	0.0	Red
			There are established guidelines (documented) for work processes only for one execution phase, at the units which develop CEAF activities		
7. Institutionalization	There is an institutionalized instance responsible for all the CEAF activities	10	In the administrative structure of the SES, there is an institutionalized instance (and formalized by means of publication) related to pharmaceutical care, and its competence involves only technical issues related to CEAF management. Administrative issues are handled by another coordination department.	5.0	Yellow
8.Decentralized access	Users receive care in the town where they reside	10	CEAF activities related to care for the users (requests, renewals, delivery) are decentralized for 95% of the State's municipalities, so users can receive care in the town where they reside (state units or municipal units)	10.0	Green
Results of the dimension		-	37.5	Orange	Laranja

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The survey was approved by the Research Ethics Committee from School of Pharmaceutical Sciences at the University of São Paulo (CEP/FCF/USP, in Portuguese), logged under Decision number 1,744,740, on September 26, 2016.

Results

The theoretical model, adapted and validated for the context of the state of São Paulo, is presented in Figure 2.

The indicator protocol validated for the state of São Paulo had few changes in comparison to the protocol used as a reference. The most significant adaptations were made in the measurements so that they could better represent the reality of the state of São Paulo.

The adjustments in the measurements were categorized as "temporality" - to limit a measurement within a given time frame; "question writing" - adjustments in the writing of the question on measurement, aimed at providing more clarity and understanding of what is being measured and/or semantic adjustments; "parameter" - altering, expanding, or reducing the parameters used to attribute points to the measurement; "measurement" - adjustments or alterations of the measurement of the indicators; "data collection" - alteration, expansion, or reduction of the sources of data collection to be consulted for the application of the measurement. There was also a

Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
Operational Dimension					
1. Communication	Communication between units	10	53% of the units - FME and Central Warehouse consider the communication with the central team good or very good. (score of 4 or 5)	5.0	Yellow
2. Complementarity	Concern with addressing the lines of care	10	There is no agreement on key medication (minimum list of CEAF Group 3) for the first line of care	5.0	Yellow
			Formalization in APAC is done for the delivery of Group 2 medication		
3.Normative conditions	Units have legal and sanitary conditions to perform their activities	10	50% of the units (FME and Central Warehouse) have a current sanitary permit	1.8	Red
			State management does not monitor updating of sanitary permits for the units which handle CEAF medication		
			44% of the units (FME and Central Warehouse) have a current PGRSS		
			State management does not monitor the updating of the PGRSS of the units that handle CEAF medication		
			68% of the units (FME and Central Warehouse) have a current technical regularity certification issued by the CRF		
			State management does not monitor the updating of the technical regularity certification issued by the CRF for the units which handle CEAF medication		
4. Infrastructure	There is investment in the units, and they have the minimum infrastructure conditions	10	The current PPA does not include investment in infrastructure of the pharmacies (which includes those which deliver CEAF medication	1.3	Red
			35% of the units (FME and Central Warehouse) declare having 75% or more of the necessary infrastructure items		
5. Centers for application of medication/SR	There are SR in several places in the State	10	64% of the units declare having 75% or more of the SR of centers for application of medication researched	5.0	Yellow

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repositioning of a measurement of the indicator "Financing" into the indicator "Programing/Acquisition of Medicine", given the understanding that the practice of tax exemption or the application of the coefficient of price adjustment mostly impacts the capacity to acquire the medicine with a discount, than effectively in the capacity to guarantee the financing for CEAF.

Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
6.Information systems	There are information systems for the development of activities	10	The informatized system(s) cover every activity: logistics, patient requests and management archives, except for clinical activities.	5.0	Yellow
			The system(s) used for registering CEAF activities feeds the national databank		
			The system(s) does/do not interface with other systems at municipal level (ex., prescription, case files, CBAF distribution		
7. Human Resources	There are Human Resources, and there is interest in continuous capacitation	10	Has capacitation training twice a year or more for pharmacists and once a year for professionals other than pharmacists who work with CEAF	5.0	Yellow
8. Financing	Capacity to apply strategies for financial balance and availability of resources	10	The state has budget planning and financial availability to cover CEAF's acquisition needs	10.0	Green
			CEAF's state management has a rate of 0.21% of failed purchases of APAC, in relation to the totality of APAC generated by the state management of CEAF		
			The state management monitors the transfer of federal funds, referring to Group 1B, in relation to the accountability generated		
9. Programing/ Acquisition of Medicines	There are systems which qualify programming and acquisition of medicines	10	There is an established tool/method for the process of programing CEAF medication (of purchases centralized by the Ministry of Health and of purchases by state management)	10.0	Green
			The State always succeeds in creating tax exemptions (ICMS) for the acquisition of CEAF medication		
			The State always succeeds in applying the CAP for the acquisition of CEAF medication		
			There are systems of penalization, established in official publications and/or contracts for the providers who do not fulfill the established criteria, and they are always applied.		
			State management develops formal and informal strategies to deal with problems in the process of acquisition of CEAF medication.		

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Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
10. Best Practices in Logistics	There are systems which qualify the distribution and control of the supply of medication	10	State management provides guidelines for the Central Warehouse, aimed at achieving best practices in transportation of medication to the units which develop CEAF activities	9.0	Green
			There is an established chronogram for supplying medication for the units and extra flow chronogram		
			Central Warehouse does periodic physical inventories		
			94% of the FME do periodic physical inventories		
11. Availability of Medication	There is interest in providing opportune care for the users	10	37.4% of the medication from Group 1B and 2 were missing for more than a month out of the year	6.5	Yellow
			The State has strategic stock in the units which develop execution activities for CEAF of the Central Warehouse		
			There is no evaluation by a Pharmacy Council to select CEAF medication by line of care, aimed at producing/updating the state's list		
			76% of the FME do not detect delays in medication distribution due to HR fault and/or infrastructure deficiencies in caring for the users (in case there is medication available)		
Results of the dimension		110	-	63.5	Yellow

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Of all the adjustments done in the indicator protocol, 84 were performed in the operational dimension, 28 in the organizational dimension, and 25 in the sustainability dimension. The most frequent kind of adjustment was *Adjustment in writing to achieve more clarity and objectivity*[24].

The number of FME represented in the data collection according to the Regional Health Department (RHD) is presented in Figure 3.

Only four of the 37 FME did not send the data; therefore, the collection included a final sample of 35 units (33 FME, 1 from the CEAF Directory, 1 from the Central Warehouse). The results of the evaluation by indicator and dimension are presented in Chart 1. The situation found in the evaluated dimensions differs in many aspects. The dimension which had the lowest score was sustainability, with emphasis on the indicators of social control, relation between services, and clinical aspects being the most critical. In that dimension the indicators with the best scores were the manager's profile and accessibility. In the organizational dimension, participation and decentralized access had the best performance, while the monitoring of the actions and regulation appeared as factors which needed the most attention.

Finally, in the dimension which presented the best evaluation, the operational dimension, the main strengths were those related to best logistic practices, financing, and programing/acquisition. The main weaknesses were in normative

Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
Sustainability dimension					
1.Social Control	Inclusion of CEAF in CES discussions	10	During the last year, CEAF matters were not brought to CES for discussion. The team attended the CES only to clarify information	0.0	Red
2. Manager's profile	There is a manager of pharmaceutical assistance position, formally instituted, responsible for the management of CEAF, who receives qualification	10	There is the position of coordinator/director/manager of pharmaceutical care, who is formally appointed; however, he/she is not responsible for full CEAF management (in technical and administrative terms)	7.5	Green
			The coordinator/director/manager of pharmaceutical care is educated in the area of management and has experience in pharmaceutical care		
3 Accessibility	Time required to provide the needs of the users, existence of litigation, and systems for avoiding litigations	10	Only 13.5% of the patients who sought the "Acessa SUS" program in the last year were eligible for the CEAF	9.0	Green
			The average time lapse between registering the process and the first delivery (of medication) for the 10 most frequent diseases in the State is 6 to 20 days		
			91% of the patients registered in the last year received care		
4.Relationship between services	Actions of follow-up at the units, periodical provision of orientation, and relationship between management and other areas of the healthcare network	10	Manager (central level): considers that he/she provides orientation, regarding CEAF execution, and does follow-up actions at the units. FME: 91% reported having received orientation from the central CEAF manager on execution and only 9% reported having received an in-house, technical, follow-up visit	3.5	Orange
			State management does not discuss CEAF demands (consultations, exams, absences, basic care) with other services of the healthcare network		

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conditions and infrastructure; therefore, deficiencies were found in both the legal and sanitary conditions, which hampered activities of medicine distribution by CEAF.

Discussion

This study enabled us to evaluate the management capacity of CEAF in the state of São Paulo. The adaptations done in the protocol developed by Rover et al.[6] considered the weighted definitions in the literature[11,27], concerning the importance of the adaptation of the indicators in

Chart 1. Evaluation results of the management capability of the Specialized Component of Pharmaceutical Care in the State of São Paulo, according to indicator and dimension.

Indicators	Meaning of indicators	Maximum score	Results of evaluation	Points achieved	Color of indicator
5. Clinical Aspects	There is treatment follow-up and provision of first care by pharmacist	10	In only 21% of the units, the first distribution (of every medication or for Hepatitis C and other specific pathologies) to the patient is done by a pharmacist	0.0	Red
			0.7% of the clinical aspects dealt with by the PCDT are registered in an information system		
6. Relationship with the users	Management shows concern with the users' satisfaction, through evaluations and Ombudsman services	10	30% of the FME did surveys of customer satisfaction in the last year	3.8	Orange
			27% of the FME used data obtained from customer satisfaction surveys to improve their services		
			There are Ombudsman services, which receive patient opinions concerning the services provided by CEAF state-level management; however, the management does not use the information obtained for planning purposes		
Results of the dimension		60	-	23.8	Orange
Total score for the protocol		250	-	125	-

Key: CES: State Health Council; CIB: Intermanager Bipart Commission; CEAF: Specialized Component of Pharmaceutical Care; AF: Pharmaceutical Care; PES: State Health Plan; PPA: Pluriannual Program; RH: Human Resources; SR: Reference Service; APAC: High Cost Procedure Authorization; PGRSS: Health Services Residue Management Program; CFT: Pharmacy and Therapeutics Commission; CBAF: Basic Component of Pharmaceutical Care; PCDT: Clinical Protocols and Therapeutic Guidelines; CRF: Regional Pharmaceutical Council; FME: Specialized Medicine Pharmacies; ICMS: Merchandise Circulation Operations and Provision of Services (of interstate and intermunicipal transportation and communication) Tax; CAP: Price Adjustment Coefficient. Source: the authors.

Source: Authors' elaboration.

a participative manner so that they would reflect the local context. In addition to the adaptation to the reality of the state of São Paulo, the consensus workshops made contributions to pharmaceutical care, thanks to the discussions that took place in the process of this study, bringing together the professionals in this sector.

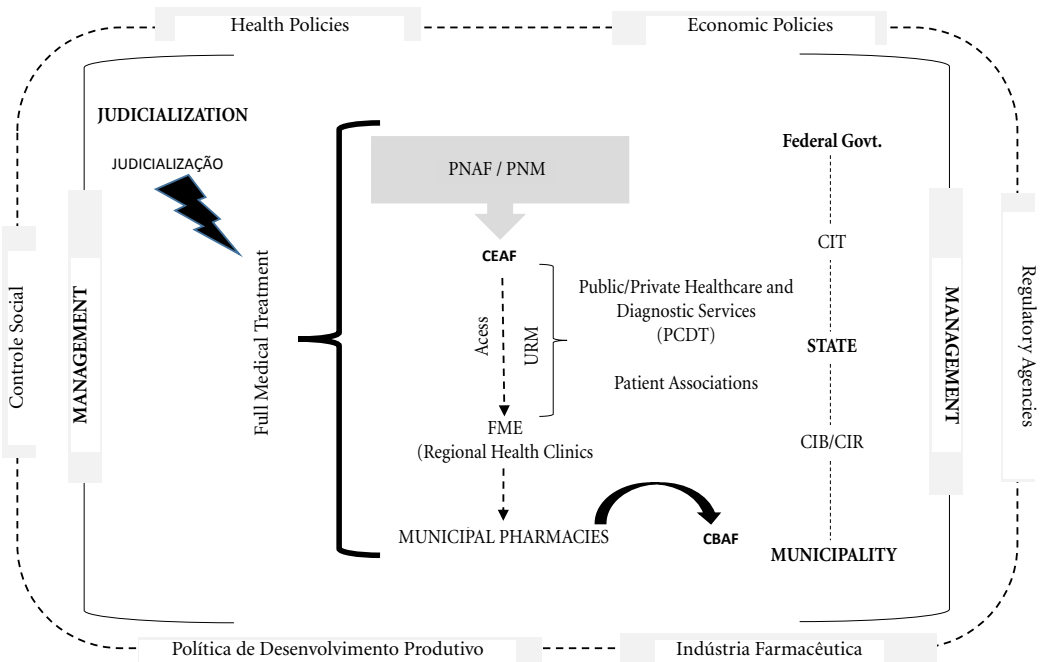
The evaluation demonstrated that issues related to the operational dimension, in other words, process and technical operations, are much more developed and structured. This result, already verified in other studies[6,9,12], demonstrates the strong technical development of pharmaceutical care in recent decades. From the beginning of the 2000s, the decentralization of actions and financing of pharmaceutical care demanded theoretical-methodological definitions and the development of services at the health secretariats[28]. Therefore, operational aspects, like financing, programing/acquisition, and best practices in logistics, were evaluated as "fair". These are aspects considerably regulated and defined nationally for states and municipalities (according to each element of the federation), and are therefore more objective in the sense that there are well-established procedures and rules for their execution. We should emphasize the importance of the state level management to maintain and improve those indicators, which are essential for the quality of the medicine, and particularly, to guarantee the safety and the access of the patients[29].

In terms of financing, the positive results are related to annual budget planning and to financial availability capable of supplying the acqui-

Chart 2. Judgement criteria for indicators and dimensions, considering the score brackets of indicators, the color scheme, and its meaning.

Judgement Criteria	Color	Scoring	Meaning
Indicators	Green	75% to 100% of the points	Maintain/Improve - represents the indicators which meet the parameters considered acceptable by experts
	Yellow	50% to 74% of the points	Needs Care - represents the indicators which had improvements but still need to be perfected
	Orange	25% to 49% of the points	Warning - represents indicators that must be improved
	Red	0% to 24% of the points dos pontos	Urgent - represents indicators which must be prioritized
Dimensões	Green	75% to 100% of the points	The situation found in the dimension is in accordance with what is expected of the management capacity of CEAF
	Yellow	50% to 74% of the points	There have been improvements in the situation found, but there is need for improvement in management capability
	Orange	25% to 49% of the points	Management capability must be improved
	Red	0% to 24% of the points	The situation found is critical and compromises management capability of CEAF, indicating a priority for management

Source: Adapted from Rover MRM et al.[23].



Legend: CBAF – Basic Component of Pharmaceutical Care; CEAF – Specialized Component of Pharmaceutical Care; CIB – Bipart Inter-managerial Commission; CIR – Regional Inter-managerial Commission; CIT – Tripart Inter-managerial Commission; FME – Specialized Medicine Pharmacy; PNAF – National Policy of Pharmaceutical Care; PNM – National Medication Policy; URM – Rational Use of Medication.

Figure 2. Theoretical Model: management capability of the Specialized Component if Pharmaceutical Care in the State of São Paulo.

Source: Authors' elaboration.

Figure 3. Number of Specialized Medication Pharmacies represented in the data collection for the evaluation of management capability of the Specialized Component of Pharmaceutical Care from the State of Sao Paulo by the Regional Health Department.

Source: Authors' elaboration

sition needs. Other outstanding points were the refused purchases (below 0.3%) and the monitoring of national fund transfers. However, the state manager indicated that judicial and administrative litigation resulted in the relocation of resources and compromised the balance, with risk of affecting financial availability. According to Medeiros[30], from the total amount spent with health in the state of São Paulo, 9.86% was used in the acquisition of medicine, and the annual budget laws provided resources for the acquisition, production, and distribution of medicine.

Considering that medicine programming *is fundamental in order to guarantee availability in large amounts and in an adequate time frame, corresponding to the needs of the users, and avoiding wasting* (p. 14), it is important that the SES/SP maintain and improve the methods in use[31]. Concerning the acquisition of medicine, the SES/SP, as well as the Health Secretariat of the state of Santa Catarina[6], have been able to achieve favorable proposals for public administration by applying the Price Adjustment Coefficient (PAC) and tax exemptions to the purchasing of CEAF medicine. Moreover, formal and informal strategies were used to deal with problems related to the process of acquisition, for example, price registration.

Although SES/SP does formalize the billing of medicine (for instance, atorvastatin, fenoterol and cyclosporine) which are part of Group 2 of CEAF, showing its involvement in the financing of the component and respecting the lines of care established by the Clinical Protocols and Therapeutic Directives (PCDT, in Portuguese), there is still a need to improve its execution capacity in terms of complementarity, since to date, there is no agreement on a basic list of medicine between the municipal administrations at the CIB (Bi-party Management Commission) to address the first-line care (Group 3). This indicator is also related to identified weaknesses in communication with the municipalities. The organization of pharmaceutical care, by components, with distinctive rules and financing, increases the challenges for the managers in terms of achieving integral access

to medicine. Therefore, it is extremely important to search for strategies which can lead to this integrality, following the example of the state of Santa Catarina, where there is a basic list of Group 3 medicine agreed upon with CIB[6,32].

In this realm, two indicators - normative conditions and infrastructure - did not reach the defined parameters, requiring priority attention by management. Although there has been investment in the infrastructure of pharmacies, in the informalization of the network from 2013 to 2016, and in the development of initiatives to expand the storage capability of the SES Central Warehouse[30], the data obtained show the need to invest more in units which distribute medicine. The adaptation of the infrastructure in compliance with sanitary norms seeks to improve the quality of the services, ensuring medicine quality and safety for the patients. It is important to highlight that both the direct and the indirect management units (by OSS - Social Health Organization) - showed infrastructural weaknesses. Hence, even though the units managed by OSS receive financing for investment in their units, the infrastructure difficulties call attention to the growing need for the evaluation of public-private contracts[33].

When evaluating the management capacity, in terms of the organizational dimension, we identified that the indicators "monitoring and evaluation of actions" and "regulation" must be prioritized by state-level management. These indicate the weakness in strategies of the permanent evaluation of the services and public policies, which are required in order to make decisions in real time, acting upon evidence. We do understand, however, that the evaluation practices at SUS are not completely institutionalized[34]. Concerning regulation at the moment of the evaluation, there was a regulated procedure only for the phase of solicitation and renewal of treatment continuity. The creation of a best practices manual is needed, which can formalize and harmonize the actions of the central and regional teams in terms of the phases of evaluation, authorization, and distribution. For Rover[32], regulations are the first step toward develop institutionalized activities and demonstrate the degree of interest and commitment with the establishment of procedures and norms which legitimize and make feasible the organization of CEAF activities.

However, up to the moment of this evaluation, there was no list of medicine out of stock that was easily available and accessible to the population of the state of São Paulo. During data collection, the managers informed us that they send such information weekly to the FME and the municipalities, and that the information was not passed to the population. Therefore, to improve the information flow and to provide more transparency to the management of CEAF, an online website is being created, which will allow the patients, individually, to access information on the availability of medicine and justification in case it is not available. In this sense, only the indicator participation and decentralized access stood out positively, achieving results that should be maintained and perfected. We observed that management had participated in many formal instances (CIB, CES, meetings for the creation of the PES); however, there are weaknesses in terms of involving the participants of CEAF (patients, doctors, among others) in the formulation of policies and directives for this component. We highlight that the creation of new strategies is needed in order to boost the creation of policies in a more participative and transparent manner. In terms of decentralized access, the SES/SP stands out for ramifying access to CEAF medicine to 95% of the municipalities, through FME and municipal pharmacies. The state of São Paulo is the third most populous administrative unit in South America[13]; therefore, decentralization is essential to facilitate patient access to medicine and to adjust the organization of services to local realities. However, according to Medeiros[30], the proportion of the population reached by the FME and the population registered in the Regional Health Departments (RHD) is still heterogeneous, ranging from 0.4 (RHD 11, Presidente Prudente) to 10.1 (RHD 4 - Baixada Santista), meaning that, although there are accessible places in most towns, there are still different access proportions in the regions.

From six indicators evaluated in the sustainability dimension, only the manager's profile and accessibility reached the expected levels. For the 10 most common diseases in the state, there was an average time lapse of 6 to 20 days between requesting medicine and the first delivery. In a similar study done in the state of Santa Catarina, the time lapse was 50 days[32]. Possibly, the difference in time happens because in the state of Santa Catarina, evaluation and authorization of medicine requests are done in the same provision unit, and the time lapse refers to the time it takes to distribute the medicine, from the state units (FME) to the municipal units of the region.

It is known that the delays in response are one of the causes of litigation for these medicines[35].

In the state of Minas Gerais, just the average time lapse between the document registration phase for Alzheimer medication (at the regional level), until the feedback from an analyst (at central level), can be between 20 and 87 days. Therefore, the authors of this study conclude that the manager must have *a better control over administrative time lapse, to make the process faster and less bureaucratic*[35] (p. 11).

It is also relevant to mention that accessibility of CEAF medicine depends on access to the healthcare network, which depends on diagnoses, specific examinations, appointments with specialists, and so forth. This issue, combined with the local needs and realities, must be considered due to the incorporation of the medicine, which is aimed at improving and democratizing the relevant policies[9,36]. These findings indicate that more agile flow systems are needed in order to achieve more opportune care for the patients, resulting in a more sustainable management that addresses patient needs and helps reduce judicialzation[37].

Only 30% of the units that distribute CEAF medicine conduct satisfaction surveys among the users. Moreover, data obtained by the Ombudsman's offices was not used in the planning of actions. Therefore, there is a clear need to improve the relationship with users and to use the information obtained with this relationship to plan and improve services. These results reveal that there is a need to bring together the management and the client, and that the managers must create efficient communication channels which can facilitate the identification of barriers and help to overcome them, creating opportunities and a favorable environment to support decision-making[6,38].

Finally, in this realm, two indicators must be prioritized by management, since both - social control and clinical aspects - did not receive any points in the evaluation, indicating an urgent need for attention. The social control indicator showed that, in the previous year, matters related to CEAF were not listed for discussion at the State Health Council, and that every time the team attended the meetings, it was solely for the purpose of providing clarification. It is fundamentally important that CEAF matters are discussed at that management level, since strategies agreed upon at that level will be monitored by its representatives. In the State Health Council, managers can also understand demands, present projects, and seek social and political support, thus achieving sustainability and contributing to improvements in management capacity[30,39].

In relation to clinical aspects, only 0.7% of the users had a registration of treatment monitoring in the SES/SP information technology system. Therefore, there was limited capacity of evaluation and of follow-up in clinical-care information and of the impacts of CEAF on health results. Something which may contribute to solving this issue is the release of the Pharmaceutical Care Program by the Brazilian Health Ministry, in the beginning of 2018. This project is aimed at following up on the treatment (initially) of the patients with hepatitis and rheumatoid arthritis, through means of pharmaceutical appointments, which must be registered in order to continue treatment[40].

It is worth mentioning that the methodology adopted for this study did not have the purpose of reaching a conclusion if the management capability in the state of São Paulo is "good" or "poor", but instead, analyze it as a process which is in different stages of evolution, with the perspective of providing directions for the improvement of this process, indicating which points can be corrected, which investments are needed, and what is the urgency[11].

As an alternative to the problems identified, we suggest the planning of actions which can improve CEAF management, making it a tool which helps to clarify, monitor, and evaluate the established aims[41-43]. In doing so, the system can evolve from action plans to actually overcome the obstacles identified in the indicators with poorer results.

There is a need to formalize the relationship between the pharmacies, which are part of the execution phase and other health services[6]. Considering that the Regional Managers Commission is the forum for negotiation and agreements concerning the regional planning of actions, services, and the distribution of an array of medicine, it is extremely important for the CEAF's state-level management to create or reinforce strategies of participation at that management level actively working in favor of demands that involve other managers[44]. The planning and provision of resources for SUS management is also necessary to improve the infrastructure of the units that execute CEAF activities so as to meet sanitary and legal requirements, thereby contributing to the quality of the services rendered[3,45].

The improvement in the ability to identify user needs, creating ways in which this information subsidizes strategies of managerial action, as well as more social participation in the design of policies at the state level, is essential[9,42,46]. Finally,

there is a need to prioritize clinical aspects, also directing the pharmacists towards care issues and improving actions of pharmaceutical care at CEAF[6]. To overcome this limitation, there is a need for such measures as the development of capacitation activities focused on organizational and functional issues of the pharmacies, providing the pharmacist with a higher level of responsibility[38].

The collection of information for this research did not include the municipal pharmacies, since those do not participate in all activities executed by the CEAF, and the activities they do execute are not formally established at the state level. However, pharmacists who are involved in pharmaceutical care were included in the validation phase of this study, in such a way that the evaluation instrument is also validated for application at that level, and the SES/SP might include, when viable, the municipal pharmacies. This study has, as a limitation, the fact that it used data referred by the people surveyed, since the units do not have or do not make the data related to the organization and management available to the general public.

Final considerations

This study demonstrates the use of indicators to evaluate the management capacity of the CEAF, taking into consideration the specificities of the organization of pharmaceutical care in the state. Considering the relevance of the issue in the national context, this study provides important information to enable and encourage the regular evaluation processes, as well as to monitor pharmaceutical care in every situation, contributing for better access and a more rational use of medicine and health resources.

The final assessment, in this state, shows the need for investments in the qualification of CEAF management in all dimensions, especially in the sustainability dimension. Improvement is fundamental in order to guarantee the integrality of medicine treatment and better health results for the population.

To achieve that, there is a need for clear and agreed upon actions, planning and evaluation which may direct the operational, technical, and human resources, making them accessible to the general population, providing more opportune, integral, and continuous care. The infrastructure problems, the absence of a pharmacist's services to promote a better use of medicine, and the deficient relationship between management and users, as well as health professionals and other sectors of public administration, are factors that restrict access and compromise therapeutic results and the very sustainability of management.

We highlight that there are favorable points in CEAF management in the state of São Paulo, which should be maintained: its active participation in the different managerial levels of SUS, the high ramification of the distribution of medicine, the efficient management of financing, the presence of well-established methods of programing and acquisition, improvements in achieving best practices in logistics, and the existence of the position of a Pharmaceutical Care Manager.

This study provides subsidies for management qualification and access to high-cost medicine through SUS, for both managerial decision making and the improvement of services. Given the importance of CEAF to pharmaceutical care, as it covers the most expensive medicines and enables access to medicines recently incorporated at SUS, and considering the complexity of management and of the diseases involved, continual improvement in management is required, and the evaluation stage is fundamental in order to achieve this desired result.

Collaborations

The authors participated equally in every phase of the production of this article.

Financing

This research was financed by the Science and Technology Department/SCTIE from the Ministério da Saúde, through CNPq, with the support of Fundação de Amparo à Pesquisa do Estado de Santa Catarina (FAPESC).

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Article submitted 21/07/2020
Approved 06/05/2021
Final version submitted 08/05/2021

Chief editors: Romeu Gomes, Antônio Augusto Moura da Silva