# An evaluation of governance capacity of the specialized component of pharmaceutical services in Brazil

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> Abstract This paper presents application of an indicator protocol to assessment of current levels of governance capacity of the Specialized Component of Pharmaceutical Services (CEAF) in a state of the South of Brazil. We chose the theoretical referential of 'governance capacity' proposed by Carlos Matus, which reflects in the concepts of management capacity and pharmaceutical service management, due to the perception of a need to overcome the fragmentation and technicist reductionism that we believe has been imposed on the area of pharmaceutical services. Data was collected using the protocol in 74 municipal or state units. The results of the analysis indicate that the currently existing governance capacity needs improvement in all three dimensions that were evaluated, principally in relation to the aspects that seek sustainability of the governance. The model and the protocol used indicate a way forward for governance of pharmaceutical service by proposing a change from the technicist-logistical focus to an emphasis on strategic and political actions, or ones which foster greater participation and autonomy. With these results in hand, it will be possible to develop strategies for improvement of access to medicines in the SUS, in the sense that the CEAF becomes able to guarantee integrality of medicines treatments.

**Key words** Health evaluation, Health management, Brazilian National Pharmaceutical Services, Specialized Component of Pharmaceutical Services

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#### Introduction

Health technologies, which include medicines, are one of the factors in the increase in spending on health in most countries<sup>1</sup>. This growth can be attributed to the change in epidemiological profiles, the pressure for incorporation of new technologies in public services, and expansion of access to health systems<sup>2</sup>.

To ensure access to Rational Use of Medicines (RUM), Brazil has put various public policies in place since 1998<sup>3,4</sup>. Adoption of the concept of the Specialized Component of Pharmaceutical Services (*Componente Especializado da Assistência Farmacêutica*, or CEAF) is a strategy that aims to create full access to high costs medicines to ensure integrality of treatments, based on paths of care expressed in *Clinical Protocols and Therapeutic Guidelines* (PCDT) published by the Ministry of Health <sup>5</sup>.

CEAF is a significant strategy in that it is the only means of access to some medicines, especially those with higher price. In 2014, of the R\$ 12.4 billion invested in medicines by the Ministry of Health, 4.9 billion was allocated to financing of CEAF<sup>6</sup>

In spite of the major emphasis on the financial aspects, various challenges exist, in a complex context that needs to be administered by the managers of the SUS, to ensure full and universal access to medicines. One of these challenges is the decentralization of action, under which states and municipalities began to assume the direct responsibility for healthcare, including the actions related to pharmaceutical service. According to Solla<sup>7</sup>, decentralization by itself is not enough to support viability of the principles and guidelines of the SUS, which rather depends on strengthening of institutions, governance capacity, and democratization of the health institutions.

To respond to these challenges, investigation of health policies and services plays a fundamental role by making it possible to identify significant problems and provide reliable information, constituting an important tool for improvement of the quality of services<sup>8</sup>.

Although many countries have developed systems of monitoring and evaluation of programs and policies, few have produced regular information on their continuity and on the benefits expected. According to Kruk and Freedman though studies evaluating the performance of health systems include indicators related to the factors continuity of care, opportunity for access, equity and patient satisfaction, some of these are

still little developed worldwide. Thus there is a need to build evaluation models that make it possible to detect the difficulties, and to produce recommendations that help in the correction of directions being taken, and dissemination of lessons and learning with a view to improvement of the policies' performance<sup>11</sup>.

In the case of pharmaceutical policy and services, the evaluations carried out usually focus on technical and logistical aspects, not taking into account the political and social aspects that influence the implementation of public policies<sup>12</sup>. Some advances in the concept of management and evaluation of pharmaceutical service have been presented by Guimarães<sup>13</sup>, Barreto<sup>14</sup> and Barreto and Guimarães<sup>15</sup> in Bahia, and Manzini and Leite<sup>16</sup> and Mendes and Leite<sup>17</sup> in Santa Catarina. These evaluations of the governance of Basic Component of Pharmaceutical Policy ('CBAF') adopted the theoretical referential of governance capacity proposed by Matus<sup>18</sup>, adapting it to the political context and to the particularities of the Brazilian health system in each one of the states studied. This conception of governance gives increased value not only to the result but also to the process; and it gives a position of importance to discussion on the social aspects, on power, and its legitimacy. Also, they considered that management and governance should be oriented by the principles of the SUS, and that evaluation, as a governance instrument, should also follow these precepts.

That is the context of this present study, which seeks to evaluate the governance capacity of CEAF, in a state in the South of Brazil, in terms of three distinct dimensions: organization, operation, and sustainability.

# Method

This is a cross-sectional evaluation study, carried out externally to the subject organization. The indicator protocol applied was built on the basis of the studies of Guimarães<sup>13</sup>, Barreto<sup>14</sup> and Barreto and Guimarães<sup>15</sup>, and on the results of exploratory studies on CEAF<sup>19-21</sup>. The indicator protocol was validated through a consensus workshop which was attended by researchers of the area, managers and other players involved, and which, as well as a description of the indicators, included the measures, calculations and parameters, and the instruments for collection of data<sup>22</sup>. The 25 indicators are divided into three dimensions: 8 in the organizational dimension;

11 in the operational dimension; and 6 in the sustainability dimension<sup>22</sup>.

### Application of the protocol

# Study population; selection of the sample of municipalities

The study population was taken to be all the units that operate in CEAF in the state. Contact with 143 units was obtained from the State Health Department, including municipal and state units. Invitations to participate in the survey were sent by email to all of them. For 10% of the participants, data was collected in person, and in all other cases online. Those units in which the pharmacist responsible agreed to take part in the survey were included in the sample, plus: one representative of the state's Pharmaceutical Service Board; a referral service; and the Pharmaceutical Supply Center.

Municipalities included were characterized by population size according to Veber et al.<sup>23</sup>: 'Conglomerate A' – up to 9,999 population; 'Conglomerate B', 10,000 to 49,999; and 'Conglomerate C' – municipalities with population over 50,000. Units were included from all the health macro-regions of the state.

#### Collection of data

The field work took place over February–May 2016. Data was collected using triangulation of methods<sup>24</sup>, including review of documents, and both *in loco* and remote application of questionnaires. Qualitative studies that were part of the project for an evaluation study were presented in complementary articles and were used as input for discussions on the results presented here<sup>20,21</sup>.

The review of documents included items such as the organization document of the state Health Department; the decisions of the Bipartite Inter-managers Commission ('CIB'); min-

utes of the meetings of the State Health Council; the Multi-year Planning Program ('PPA'), the records of the Health Prices Databank, the State Health Plan, records of ombudsman departments, and data from the computerized systems.

For the *in loco* data collection the questionnaires used (one, specific for pharmacists of the municipal units; another for the state units; and one for the manager of the SES) contained open and closed questions for ascertaining aspects relating to each indicator. Further, check-list-type forms were applied by the researcher on the day of the visit, to evaluate the logistical conditions of the units comprising the CEAF function.

For the remote data collection – the remaining units – the link of the online questionnaires was sent to the units via email. These instruments were adapted from the checklist questionnaires and forms of the *in loco* data collection, and validated after verification of concordance, using the Kappa factor<sup>22,25</sup>.

# Analysis of the data; calculation of the indicators

Data collected was processed, and the indicators calculated, using Microsoft Excel\*. Scores for the indicators were calculated based on agglomeration of the data obtained from the participating units, following the measures and parameters established in the evaluation protocol for each indicator<sup>22</sup>.

Subsequently, for each indicator, a value judgement was attributed and converted into one of four colors, chosen during the design of the protocol, to facilitate visualization of results<sup>13-15</sup> (Chart 1). The judgement is formed when the discoveries and interpretations are compared with one or more parameters selected for evaluation<sup>26</sup>.

Based on the sums of the scores for the indicators, a score per dimension was obtained,

Chart 1. Criteria for judgements: score ranges, the color scale, meanings.

Color	Score*	What the score indicates		
Green	76 to 100% of maximum	Maintain (or improve): Indicators in accordance with the target image which it is sought to build.		
Yellow	50 to 75% of maximum	Caution: Shows progress, but still a need for improvement.		
Orange	25 to 49% of maximum	Warning: Indicators that need to be improved.		
Red	0 to 24% of maximum	Urgent attention: Indicators that need to be given priority.		

<sup>\*</sup> Calculated from the maximum score of the indicator. Compilation: Author.

Chart 2. Protocol of assessment indicators and results, with the value judgement for each indicator and dimension.

Indicator	What does the indicator measure?	indicator measure? Maximum score Data collected		Score	Color
	Organizatio	nal dimensi	on		
Participation	1-Management participation in social participation bodies. 2-Existence of instances enabling participation of actors involved.	10	1- CES, CIB, State Health Conference and PES meetings. 2- None.	5	Yellow
Transparency	1-Publication of information about medicines shortages. 2-Publication of prices paid in acquisition of medicines.	10	1– None. 2– Yes, in the Health Prices Database.	5	Yellow
Planning	1-Inclusion of CEAF actions in the PES, PPA and the Management Report. 2-Existence of meetings specifically for planning.	10	1– Yes. 2– None.	5	Yellow
Monitoring and evaluation of actions	Existence of indicators and use of monitoring of them for planning of actions.	10	There are no indicators.	0	Red
Partnerships	Partnerships with other institutions for carrying out CEAF activities.	10	Yes, with municipalities (CIB 398/2014).	10	Green
Regulation	1-Existence of regulated flows for evaluation of requests. 2-Existence of guidelines on work processes in the units.	10	1- Yes - flows and ministerial orders. 2- Yes, in 41 units.	7.5	Yellow
Institutionalization	Existence of an institutionalized instance responsible for all the activities of CEAF.		Yes, but CAF and tenders are responsibilities of another directorate.	5	Yellow
Decentralized access	Service of users in their municipalities of residence.	10	Yes, in 100% of the municipalities.	10	Green
	TOTAL, DIMENSION	80		<b>47.5</b> (59.37 %)	Yellow

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to which a color was also attributed, as a way of summarizing the results.

### **Ethical aspects**

The survey was approved by the Human Research Ethics Committee of the Federal University of Santa Catarina. Confidentiality was guaranteed in relation to identification of the participants, in accordance with the informed consent form signed by all interviewees.

## Results

Of the 143 units invited, 76 replied agreeing to take part in the survey. One unit withdrew from

*in situ* participation, and one online response was not included because it was sent after the end of the data collection period. Thus a total of 74 units were included in the study: 13 with in-person data collection, and 61 with collection via emailed form.

The units of the state administration participating were: Central Pharmaceutical Service management; 8 decentralized units; 1 Referral Service ('RS'), and the Pharmaceutical Supply Center (CAF). Data was collected from 63 municipal units in varying municipalities.

Population of municipalities by size: 22 of the participating municipalities are classified as Conglomerate A, 26 as Conglomerate B, and 16 as C.

The participating units served 36,823 users of CEAF (approximately 40% of CEAF users in

Chart 2. continuation

Indicator	What does the indicator measure?	Maximum score	Data collected	Score	Color
	Operation	al dimensio	n		
Communication	Communication between the units.	10	Good or very good according to 77% of the units, mainly by email.	10	Green
Complementarity	Concern with compliance with lines of care.	10	100% of the listing in Group 3 is agreed in CIB (501/2013) and production of APAC is regulated for Group 2.	10	Green
Normative conditions	Units with legal and health- regulation conditions for exercise of the activity.	10	- There is no PGRSS 66.2% of the units have Health Operational Licenses and 88.7% have updated RT certificates 38% reported control by the state.	0	Red
Infrastructure	Existence of investments and minimum infrastructure conditions in the units.	10	-77.78% of the state units received investments 75% of the state units and 50.8% of the municipal units meet at least 75% of the minimal conditions.	8.5	Green
RS/Application centers	Existence of RS in various regions of the state.	10	Concentrated in the capital city of the state.	5	Yellow
Information systems	Existence of integrated information systems for carrying out of the activities.	10	Yes, although they do not feed the national database and they do not interoperate with other systems of the healthcare network.	3	Orange
Human resources	1-Availability of HR. 2-Concern with continuous training of HR.	10	1- 55.55% of the units of the state have a sufficient number of pharmacists. 2- 22.86% of the pharmacists report training taking place at least once a year.	2.5	Orange

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the state), involving the work of 427 professional staff. The majority of the units (90%) also served other components of pharmaceutical services and/or programs other than CEAF: the most frequent are the CBAF and the demands required by court order.

Table 1 shows the protocol of indicators and the results of the evaluation.

Of the three dimensions evaluated, none was in accordance with the target image. The dimension that scored lowest was *sustainability*: none

of the indicators evaluated reached the highest score band. That is to say, all the aspects analyzed need to be improved – the most critical being *social control* and *relationship with users*.

In the *organizational* dimension, the highest scores were for *partnerships*, and *decentralized access*; while *monitoring of actions* appeared as a factor needing priority.

Finally, in the *operational* dimension, the main strengths were in *infrastructure*, *complementarity* and *communication*; and the greatest

Chart 2. continuation

Indicator	What does the indicator measure?	Maximum score	Data collected	Score	Color
Financing	1-Capacity to apply the strategies for maintaining financial equilibrium. 2-Availability of funds. 3-Funds lost by omitted APACs.	10	1- Yes – CAP and tax reliefs. 2- There is budget planning, but shortage of funds. 3- < 5% of the APACs are	6.25	Yellow
Logistics management	1-Existence of mechanisms that qualify the programming. 2-Existence of mechanisms that quality the acquisition.	10	omitted.  1- There is an established method.  2- Only mechanisms for punishment of suppliers who do not meet the established criteria.	6	Yellow
Good logistics practices	1-Existence of mechanisms that qualify the distribution. 2-Existence of periodic control of stock of medicines.	10	1- There are no rules for good transport practices, but there is a distribution timetable. 2- 80% of the state units and 70.5% of the municipal units carry out monthly stock control.	6.5	Yellow
Availability of medicines	Concern with timely service to users.	10	There is evaluation for selection of the state listing, but there were shortages of medicines due to shortage of funds and delays in dispensing in 15.7% of the units.	3	Orange
	TOTAL, DIMENSION	110		<b>60.75</b> (55.23%)	Yellow

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weaknesses were in *regulatory conditions*, that is to say, there were weaknesses in the legal and health conditions for the exercise of the activities in the units.

# Discussion

The large number of units evaluated made it possible to make inferences on the governance of this component of healthcare at a state level, and indicated interest and commitment to development of pharmaceutical service.

Overall, the evaluation expresses the need for investments in qualification of the state-level governance of CEAF in all the dimensions, but especially in the dimension of *sustainability*.

The *sustainability* dimension aimed to evaluate: the potential of the governance to sustain the actions and results of CEAF, which is dependent on the interrelationship of pharmaceutical service with other sectors of health; users' satisfaction with the quality of the services; and the degree of social participation<sup>15,27</sup>. The low score in this dimension and the fact that no indicator reached the level seen as consistent with the target image reflected the fact that sustainability of actions is indeed a theme that is little evaluated in the area of pharmaceutical service<sup>17</sup>.

The main strengths in this dimension were in the indicators *manager profile* and *clinical aspects*. In the *manager profile* indicator, training and experience in the pharmaceutical area stood out, as did the formal existence of the position in the

Chart 2. continuation

Indicator	What does the indicator measure?	Maximum score	Data collected	Score	Color
	Sustainabil	ity dimensio	on		
Social control	Inclusion of the CEAF issues in the agenda of the State Health Council's meetings in 2015	10	There are no agendas in the minutes of 2015.	0	Red
Profile of the manager	1-Condition of existence of the position of coordinator of pharmaceutical service, formally instituted, responsible for management of CEAF. 2- Qualification of the manager.	10	1- Formal job position, but not responsible for all the activities of the CEAF. 2- 9 years' experience and specialist in management of pharmaceutical service.	7.5	Yellow
Accessibility	1-Deadline for serving users. 2-Existence of court demand and mechanisms for avoiding actions.	10	1- On average 50 days for first appointment in the pharmacy. 2- No information on % of actions, but there is a committee to provide legal support.	3.75	Orange
Relation between services	1-Existence of actions to monitor and periodically pass on orientations to the units. 2-Relationship of management with the other sectors of the healthcare network.	10	1– Manager - yes for both; pharmacists 67.14% answered that there are periodic orientations, but only 11.43% said there is monitoring.  2- Does not collect figures on the demands for discussion with other sectors.	3	Orange
Clinical aspects	1-Existence of monitoring of the treatments. 2-First consultation carried out by the pharmacist.	10	1- 32.3% carry out the monitoring. 2- Occurs in 67.7% of the units.	6.25	Yellow
Relationship with the users	Concern of management with satisfaction of users, through evaluations and ombudsmen function.	10	- 4.9% of units said they have at one time carried out a satisfaction surveyThere is an ombudsman's department, but the data are not used in the planning of actions	0	Red
	TOTAL, DIMENSION	60		<b>20.5</b> (34.17%)	Orange
,	TOTAL SCORE IN THE PROTOCOL	250		128.75 (	51.5 %)

Key: CES: State Health Council; CIB: Bipartite Inter-managers Commission; CEAF: Specialized Component of Pharmaceutical Policy; PES: State Health Plan; HR: Human Resources; PPA: Multi-year Programming; PGRSS: Health Services Wastes Management Program. RS: Referral Services; CAF: Pharmaceutical Supply Center; APAC: Authorization for High Cost Procedure.

Source: Compilation – Author.

State Health Department, a factor that was considered to indicate progress in terms of the institutionality of the SUS<sup>28</sup>. The weakness found was in fragmentation, and problems for the manager in coordinating/articulating with other areas of the State Health Department that are responsible for part of the functions relating to the working of CEAF.

Within clinical aspects one aspect that stood out was the participation of the pharmacists in primary care (dispensing) for users of CEAF in a large part of the units, which indicated the existence of the minimum conditions for promotion of rational use of medicines29, and achievement of the CEAF objectives. However, there is a need for improvement in the implementation and registry of activities of monitoring of the treatments proposed in the PCDT<sup>30</sup>. Records of monitoring are rich sources of information for management in relation to identification of failings in the services and in planning of actions<sup>16,30</sup>; but they were found in only just over one-third of the units. To overcome this limitation, measures are needed such as expansion of the staff of pharmacists, and development of training activities focused on "change in the philosophical, organizational and functional focus of the pharmacy, increasing its level of responsibility and that of the pharmaceutical professional"31.

The warning on the *accessibility* indicator was related to the waiting time up to first dispensation of medicines, and the existence of court demands for medications supplied by CEAF. These show the need for creation of fast and less bureaucratic flows, to provide appropriate service to users<sup>21</sup>, which will result in sustainability of the government due to the satisfaction of the users' needs.

Similarly, the *warning* level attributed to the indicator *relationship between services* showed the need for information about the demand for services related to CEAF and their supply by the state. This information could be obtained both by actions to monitor the units of CEAF, and also through improvement of the interaction with other sectors of the health network, in the planning for provision of care. These measures are vitally needed for overcoming the limitations in supply described in a previous study, made with users, doctors and pharmacists<sup>21</sup>.

The most critical aspects of the *sustainability* dimension, and which need to be given priority, were the indicators *social control* and *relationship with users*. The distant relationship of management with users described by the participants in this study corroborates the report of Lima-Della-

mora et al.<sup>31</sup>. These results show the need to bring management closer to 'state of the art', and the need for the manager in his/her role as leader to establish efficient channels of communication, aiming to transform the reality of the organization and of the social relationships in production of care, so that they facilitate identification and opportune solution of users' needs<sup>22</sup>.

Some useful alternatives for resolving these weaknesses would include: institutionalization of satisfaction surveys with users of CEAF; and monitoring of the data recorded by the ombudsman function for planning of actions in this component of healthcare. These processes could create a favorable environment for sustaining decisions, resulting in building of a positive image that would increase the viability of the governance at the state level.

In relation to *Social control*, the absence of agenda items on CEAF at the meetings of the State Health Council show the lack of value attributed by management to social participation. Considering the strategic and essential nature of social participation for governance of programs and public policies<sup>15</sup>, it is suggested that these spaces should be used for discussion of aspects such as availability and organization of services that can hinder access to the medicines of CEAF<sup>22</sup>.

In the *organizational* dimension, it was observed that only two indicators – *partnerships* and *decentralized access* – were in accordance with the target image aimed for. The two are related, since *partnership* with other institutions for carrying out CEAF activities *was* indeed established between the state and the municipalities through agreements in the CIB<sup>32</sup>. As one result of this, users began to be served in their municipalities of residence, making it possible to widen access to the medicines of the Component by increasing accessibility to pharmaceutical services – as put forward by Penchansky and Thomas<sup>33</sup>.

The indicators *participation*, *transparency*, *planning*, *institutionalization* and *regulation* showed progress, but a need for enhancement. This group of indicators showed that the capacity for planning and deciding in a participative and transparent manner needs to be improved<sup>28</sup>. To improve *participation*, strategies or instances could be created such as planning meetings, public consultations and activities with associations of patients, for engagement of those involved in CEAF (patients, prescribers, pharmacists) in its management and development, with co-accountability<sup>15</sup>. The creation of such strategies would indicate sharing and transparency in the

decision process, adding to the capacity for decisions to be taken in a democratic environment.

Although the state records the prices charged, in the Health Prices Database<sup>34</sup> the absence of publication of information about shortages of medicines showed that management did not comply with the legal principles of transparency. This also causes users to have to return repeatedly to the dispensing units.

The existence of state-wide guidelines on the process of work in the units (defined as a responsibility of the state management in CIB 398/2014<sup>32</sup>) showed the interest and the commitment of management to the establishment of flows and rules that make the organization of CEAF-related activities legitimate and viable, but it was clear from the results that there is a need to improve the channels of publication to the units, since only just over half of the participating pharmacists knew the guidelines, which could hinder their appropriate implementation.

In spite of the inclusion of CEAF actions in the PES, in the PPA and in the Management Report, no actions to incentivate the process of planning (e.g. strategic planning meetings) were found. The indicator *monitoring and evaluation of actions* was considered to be in the *urgent* category and needing priority attention. Both planning and monitoring, and evaluation, contribute to continuous enhancement of management, in that they are an important mechanism for determining the quality of services offered, identifying weaknesses (as to both why and how they occur) and implementing the necessary enhancements<sup>35,36</sup>.

In the *operational* dimension three indicators were evaluated as being in accordance with the target image: *communication*, *complementarity* and *infrastructure*. However, the scope given in the evaluation of these indicators was limited, and in spite of the positive results some aspects that need to be improved were detected. In the case of *communication*, although a greater part of the participating pharmacists said they succeeded in communicating with the regional/central management in good time to solve problems, there were still problems in the speed of communication – which in some cases can hinder immediate resolution of problems and/or questions, and can result in the patient having to return to the unit.

The *complementarity* indicator aimed to identify the governance capacity of the state to provide mechanisms to ensure service in all the lines of care, with agreement at the CIB that the municipalities are responsible for the first line of

care. However, it was not evaluated whether in practice these mechanisms ensure integrality of medicines treatments.

For the infrastructure indicator, the majority of the units involved with CEAF had the minimum infrastructure conditions called for showing progress in this indicator in relation to the study by Blatt and Farias<sup>37</sup>, and better results than those of Lima-Dellamora et al.31 in health services Rio de Janeiro. This result expressed the investments in the state units in recent years<sup>32</sup>. At the same time, although the decentralization of CEAF benefits users, it was observed that some municipalities do not have the capacity to ensure the organization of the service, physical structure and staff with the qualification that CEAF demands. Thus, it is important that the state management should permanently evaluate the physical structure, the installed capacity and the equipment necessary for structuring g of the services<sup>37,38</sup> and collaborate with the municipalities in structuring and qualification of AF<sup>16</sup>.

The availability in the state of *Referral Services* (*RS*) recommended by the PCDT for some clinical situations was an important advance in<sup>30</sup> implementation of CEAF<sup>39</sup>. However, the results revealed the concentration of the RS in the capital and the non-existence of centers for application of medicines in all the regions. Application centers are vital for ensuring application, conservation, sharing of doses and even for appropriate disposal of the materials, due to the environmental and biological risk. Thus, there is still the need for expansion of these services, with a view to improving the quality of the service provided.

In relation to *financing*, according to the information provided by the manager, the state applied the strategies (coefficient of adaptation of prices and removal of tax burden), to maintain financial equilibrium. These strategies aim to get the most advantageous proposal for the public administration, and their application shows execution capacity in this regard. On the other hand the insufficiency of funds for acquisition of medicines has hindered the management's execution capacity, thus hindering provision of the line of care that is under the responsibility of the state manager.

In relation to *Management of logistics* there were no strategies in the state to face the problems in acquisitions, and this could also be one of the causes of shortages, which hinder access to medicines at the needed time<sup>37,39</sup>. On the other hand the existence of a defined and applied method in programming and mechanisms of

punishment for suppliers that do not comply with the criteria established in tenders were positive for governance, because they aim for availability of medicines of quality and in the appropriate quantities<sup>38</sup>.

The regularity of the distribution also showed management's interest in ensuring prompt access. In the same way, the monthly control of inventory enables regular obtaining of information about the quantities in the units, thus avoiding shortages or loss of medicines due to expiry of validity. Both these criteria analyzed add up to *good logistics practices*. The criterion that hindered governance capacity, in this indicator, was the absence of rules governing good medicines transport practices, for the purpose of supplying the units' demands with attested quality<sup>40</sup>. This activity was carried out by the municipalities, although it is a responsibility of the state<sup>32</sup>.

Although there were *information systems* in the state for management of the CEAF activities, these are not connected to the nationwide base and do not inter-operate with other systems of the healthcare network. This fact hindered governance capacity, because it generates additional work and makes errors possible. Further, it makes it impossible for the professionals responsible for care of the user (doctors and pharmacists) of other health units to access information on the treatments carried out in the CEAF, hindering interaction of the various health services and compromising the integrality of care.

As to the number of pharmacists necessary for carrying out the CEAF's activities, just over half of the units stated that they had a sufficient number of pharmacists. At this moment it is appropriate to discuss that, although the presence of the pharmacist during all the period of functioning of pharmacies is mandatory<sup>41,42</sup>, the number of professionals is short of the needs. Both Blatt and Farias<sup>37</sup> and Lima-Dellamora et al.<sup>31</sup> had already observed this deficiency in carrying out the activities of CEAF.

In relation to the management's responsibility for development, training and qualification of personnel, only a small percentage of pharmacists reported an annual offer of training<sup>3,4</sup>. Among the needs for training mentioned by the pharmacists were: on the PCDT; on clinical monitoring; and on the information system used. Thus, it was seen that qualification of professionals for some activities was only incipient, in spite of the increase of qualification opportunities in recent years, such as, for example, certain federal initiatives.

It is important to highlight that, under Ministerial Order N1554 of 2013<sup>43</sup>, it is not obligatory that all the standardized medicines should be made available, but the selection cannot be allowed to hinder the lines of care. Absence of *medicines being made available* hinders integrality of the treatment and causes financial imbalance<sup>43,44</sup>. According to the data collected, the shortages of medicines, the delays in dispensation due to lack of funds, and problems of infrastructure and personnel hindered availability of medicines. These situations adversely affect users' health, in other words, they hinder execution capacity.

The only indicator in the operational dimension with a red color, regulatory conditions, was evaluated in terms of the existence of legal conditions for exercise of the activities in the units. This involved checking: the Health Services Wastes Management Program (PGRSS)45, Health Operation Licenses<sup>46</sup> and Technical Regularity (RT)<sup>47</sup>. Although the Health Operation License and the RT certificate are the responsibility of the pharmacists of the municipalities (in the municipal units), verification of these requirements indicates the management's concern with the health conditions of the pharmacies where CEAF activities take place. In the study by Mendes and Leite<sup>17</sup> on pharmaceutical police in basic healthcare, less than half of the municipal health units analyzed had a pharmacist, and in many cases when there was a pharmacist, he/she was simultaneously involved in various activities such as coordination of pharmaceutical service and medicines access and the Family Health Support Center. Thus, the fact that the state does not have PGRSS, and monitors the Health Operation Licenses and the RT certificates of less than half of the units, indicates that governance needs to improve in these aspects.

A limitation of this study is the inclusion only of CEAF units whose pharmacists agreed to take part in the survey. We note that the qualitative methodology (interviews and focus groups), which is important for consolidation of the results of the evaluation, has not been described in this paper, but it has been used<sup>21,22</sup> for discussion of the quantitative results of the indicators presented in the text.

# Final considerations of the evaluation

This study has provided, for the first time, application of indicators for evaluation of a state's governance capacity in CEAF, looking from the

point of view of the various actors involved and taking into consideration the policy and the specificities of organization of pharmaceutical service in the state.

It can be noted that the indicators used in this evaluation, by covering aspects that have been neglected in the area for a long time, such as social participation, clinical aspects and relation between services, brings forward new elements for the field of pharmaceutical service and its management.

The final evaluation, in this Brazilian state, expresses the need for investments in qualification of the governance of CEAF in all the dimensions, but especially in the dimension of *sustainability*. There is a fundamental need for progress, so that capacity for decision, execution and sustainability of the results can ensure integrality of medicines treatment and the best possible results for the health of the population.

For this, there is a need for clear and agreed projects, planning and evaluation that will guide and direct toward achieving and maintaining of the operational, technical and human resources able to provide opportune, integral and continuous care. Thus, there is no individual element that will be most essential for the taking of decisions and achievement of results, but rather the group of resources, services, abilities, actions in the political field and social relationships.

The problems in the articulation of management with patients, professionals and other sectors of the public administration, and their reflections in terms of supply of services, are enabling factors that restrict access, as well as hindering the sustainability of the governance project itself.

Thus, considering the importance of the process of implementation of a health policy and its programs, in the perspective of consolidation of the SUS, studies like this are essential for accompanying and evaluating this process.

### **Collaborations**

MRM Rover: conception of the work, data collection, data analysis and interpretation, and drafting the article. SN Leite: conception of the work, data analysis and interpretation, critical revision of the article. CMV Peláez: data analysis and interpretation, drafting and critical revision of the article; EB Faraco: drafting the paper and critical revision. MR Farias: Critical revision of the article.

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