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Serviços de avaliação farmacológica no Brasil: ampliando os resultados da metodologia utilizada pela OMS

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Abstract   *The objective of this paper is to explore and analyze the results of the Diagnosis of the Pharmaceutical Situation in Brazil (DiagAF-Br) from a regional perspective. The study made use of an exploratory approach of multiple cases based on the DiagAF-Br data collected in five Brazilian states. A descriptive analysis of selected indicators was performed in each of the Brazilian states in three pharmaceutical dimensions: access, quality, and rational use of medicines. The mainly results concerning the "percentage of completed prescriptions" varied from 1.1% in the State of Goiás to 98.6% in Espírito Santo; the "percentage of patients who know how to take their medicines" varied from 60.4% in Sergipe to 93.3% in Rio Grande do Sul. Educational level showed to be an important predictor of knowledge on how to use medicines, especially relevant when prescription is completed. The "average number of prescribed medicines", approximately 2.1, did not show any difference between the visited sites. Different levels of management capacity and services organization were identified, suggesting the need for more adequate strategies to improve access, quality and mainly rational use of medicines in Brazil.*

Key words   *Pharmaceutical services, Pharmaceutical services evaluation, Healthcare quality indicators, Rational drug use, Health policy*

Resumo   *O objetivo deste artigo é explorar e analisar os resultados do Diagnóstico da Situação Farmacêutica no Brasil (DiagAF-Br) em uma perspectiva regional. Foi utilizada abordagem exploratória de casos múltiplos, baseada nos dados do DiagAF-Br, que foram coletados em cinco estados brasileiros. Foram realizadas análises descritivas por estado para indicadores selecionados nas três dimensões: acesso, qualidade e uso racional de medicamentos. Entre os achados, destacam-se o percentual de prescrições completas, que variou de 1,1% no estado de Goiás a 98,6% no Espírito Santo; o percentual de pacientes que sabem como tomar os medicamentos, que variou de 60,4% no Sergipe a 93,3% no Rio Grande do Sul. A escolaridade apresentou-se como um importante preditor do conhecimento sobre como tomar os medicamentos, especialmente quando a prescrição está completa. O número médio de medicamentos por prescrição, cerca de 2,1, não mostrou diferenças entre os locais visitados. Foram identificados diferentes níveis de capacidade de gerenciamento e organização dos serviços farmacêuticos, o que sugere a necessidade de estratégias mais adequadas para ampliar o acesso, qualidade e principalmente o uso racional de medicamentos no Brasil.*

Palavras-chave   *Serviços farmacêuticos, Avaliação de serviços farmacêuticos, Indicadores de qualidade do cuidado de saúde, Uso racional de medicamentos, Políticas de saúde*

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Introduction

The main objectives of Brazil's National Medicine Policy are to guarantee the necessary safety, efficacy, and quality of essential medicines and to promote rational use of these products by the population, based on the principles and guidelines of the Unified National Health System (SUS)[1].

One of the guidelines of the National Medicine Policy is to reorient pharmaceutical services organization[2], including a broad and diverse range of activities which involve the supply of medicines in each and every stage, most of which are multidisciplinary and focused jointly on integrating health actions. There is a reasonable consensus in Brazil on dealing with selection, programming, acquisition, storage, distribution and dispensing/utilization of medicines[3,4] as systemically interdependent components of pharmaceutical services. Thus, the absence or precarious quality of one component jeopardizes the quality of the entire process.

Many countries have formally developed and implemented national medicine policies. Others have pursued specific improvements in the quality of pharmaceutical services. Both processes deserve an evaluative approach, which requires the elaboration of instruments and the development of methodologies that allow the effective monitoring of the National Medicine Policy and its components, permitting performance evaluation and review of priorities[5].

The World Health Organization (WHO) has invested in the development of methodologies to analyze the pharmaceutical situation in the countries, including pharmaceutical services, access, quality and rational use of medicines in a country, region, or health unit, using a limited number of objective indicators[6]. The latter should have a feasible operational financial cost and be sufficient to allow planners, administrators, and researchers from the health field to make comparisons between situations in different sites or at different moments[6-11].

Evaluation is the component of the management approach that proposes to conduct a judgment of the merit, value, or significance of the object evaluated, which can be a service, policy, or program[12,13], aimed at backing the decision-making process, as well as correcting the orientation, so as to achieve the objectives. Evaluation and monitoring are recognized as fundamental activities for orienting the Brazilian National Health System (SUS)[14] in general and medicines policy in particular[2].

The Rapid Assessment Method (RAM) was developed as a routine management tool to obtain data to back the performance improvement of programs and thus the quality of care[8]. It was adapted for the assessment of pharmaceutical services by **Management Sciences for Health**[15] and is based on the collection of indicators, allowing tabulation of the data at the international level. It is premised on the greatest possible methodological simplification, but without jeopardizing the quality of the data.

The model currently proposed by the WHO for worldwide monitoring and evaluation of pharmaceutical services divides the evaluative approach into three levels or stages, the first two of which are applied ideally every four years. The first level relates to aspects pertaining to the organizational structure and process of the pharmaceutical sector and was conducted in Brazil in 2003[16]. The second uses outcome indicators of the National Medicines Policy, measured in public and private services and at the household level[16]. The third consists of studies that aim to describe specifically detailed aspects of the pharmaceutical sector's organization[16].

The survey entitled DiagAF-Br (Diagnosis of Pharmaceutical Situation in Brazil) corresponds to the second level. It basically used the RAM as proposed in the manual "WHO Operational Package for Assessing, monitoring and evaluating Country Pharmaceutical Situations: Guide for Coordinators and Data Collectors"[11]. Its pharmaceutical services evaluation component was conducted in Brazil contemplating the three dimensions that, according to the WHO, express the outcome of medicine policies: access, quality, and rational use. For these three dimensions, the WHO analytical proposal contemplates a minimum range of indicators, which can be studied at the national level for countries with different forms of organization of health policy and medicine policy, when the latter exists[16].

The objective of the current article is to explore and analyze, in light of Brazil's regional and national specificities, the results of the Diagnosis of Pharmaceutical Situation in Brazil (DiagAF-Br) from a regional perspective. It is believed that consideration of the country's regional specificities will allow expanding the knowledge of the national reality for pharmaceutical services.

Methodology

This was an exploratory cross-sectional descriptive study of multiple cases, based on the data and instruments from the DiagAF-Br survey, and is not intended to be generalized[17].

The DiagAF-Br study was conducted in the States of Espírito Santo (ES), Goiás (GO), Pará

(PA), Rio Grande do Sul (RS), and Sergipe (SE). Five State-level Pharmaceutical Supply Warehouses (CAF) were visited, or one for each State, in addition to 10 municipal CAFs, 30 health units, and 30 private pharmacies[16].

The DiagAF-Br used, basically, the rapid evaluation assessment (REA), as proposed in the "Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors 1". Data collection was conducted during 10 consecutive working days, from 13 to September 24, 2004 in five Brazilian regions[16].

The selection of states was randomized, one per region and 2 municipalities per state, being one the capital of the state and the other one municipality with Plain Primary Health Care Management status or with no Health Care Management status, located at least 100 km from one municipality with Plain Health System Management status. The capital presents in general a better health care system organizational level and centralizes the medicines distribution basis. The criteria for the second municipality aimed to identify the most distant from big cities and with a less complex health care system[16].

It was chosen the heath care facilities with the biggest volume of appointments, among that ones with ambulatory medicines dispensation, one year prescriptions record, medical records, ambulatory care sheet or any other system that allowed to track tracer diseases of interest[16].

The selection of key medicines was performed considering most import health problems at the primary health care in Brazil. The national essential medicines list (RENAME 2002), the standardized medicines basket for primary health care, as defined by the Decree 16/2000[18]ŷ and specific convenient medicines basket for primary pharmaceutical services were also considered[16].

The 30 persons to the patient exit interview in each public dispensary should be older 18 years and have a prescription to their own use or to someone they were the caregivers[16]. Prescriptions were randomized form the hard copy record until complete 30 in each public dispensary.

This study explores and analyzes the results for the selected indicators from the DiagAF-Br study obtained at the 30 health facilities. The choice to work with the indicators collected at the health units was due to the possibility of performing bivariate analyses, allowing the analysis of the dimensions of access, quality, and rational use, as well as more in-depth analyses in the target regions. Chart 1 shows the selected indicators.

For the continuous variables, tests were performed for difference from the mean (t-test, ANOVA, and Bonferroni), while the categorical variables were tested for association between variables (chi-squared) by State and type of health management modality in the municipalities. At the time of the study, Brazilian municipalities were classified according to criteria pertaining to their local health system management capacity. All of these tests used a 95% significance level. Such tests were only done to indicators calculated based on data from patient interviews and revision of prescriptions.

Associations were investigated with the following variables: gender, complete prescription, knowing how to take the medicines, and schooling.

Schooling, coded in the original study as: illiterate/incomplete primary, complete primary/incomplete secondary, complete secondary/incomplete university, and complete university, was recoded for schooling (yes or no), with schooling defined as having at least a complete primary education. The correlation between "schooling" and "knowing how to take the medicines" was tested, isolating the confounding effect of the variable "complete prescription".

It was necessary to remodel the database from the original study, re-keying-in the data from the data collection forms to obtain some of the variables in disaggregated form[16].

Results

Table 1 shows the values for the 18 selected indicators according to access, quality, and rational use.

In the access dimension, "availability of key medicines" varied from 80.4% in Espírito Santo to 61.2% in Rio Grande do Sul, and the "percentage of prescribed medicines that were dispensed or administered", the national average of which was 67.9 %, varied from 89.6% in Espírito Santo to 52.6 % in Rio Grande do Sul considering the state and from 22.0% to 93.2% considering the individual health units.

For the quality dimension, only one key medicine was found with the date expired, in a single health unit. However, only 31.7% of the health units kept inventory records.

For rational use, the "percentage of medicines prescribed that are on the list of essential medicines" showed a national rate of around 80%, but with important regional differences between Espírito Santo and Goiás and the other three States. The rate varied from 48.4% to 97.4% in the health units.

Chart 1. Dimensions, Indicators, and Criteria.

Dimension	Indicator	Criterion
Access	Availability of principal medicines (%)	Drug availability considering 24 key medicines on the RENAME list, from the minimum mandatory list of medicines negotiated under Brazil's Basic pharmaceutical services policy.
	% of prescribed medicines dispensed or administered	Observed through interviews with patients after receiving assistance at the pharmacy in the public health unit, checking on the prescription order the number of medicines prescribed and the number of medicines actually dispensed or administered.
Quality	Adequate conditions for conservation of medicines (inventory area) (%) and (dispensing area) (%)	Evaluated by means of a checklist with pre-established criteria. Items in the checklist were based on those defined as mandatory in the inspection protocol specified by Brazilian legislation.
	% medicines with date expired	Checked directly by the researcher for all the key medicines.
	Existence of inventory turnover records (%)	Tabulated as positive when there was information for at least 6 of the 12 months provided for in the review.
Rational use of Medicines	Mean number of medicines per prescription (prescription review and patient interviews)	Checked in the health units based on two different sources (prescriptions filed in the pharmacy and interviews with patient after assistance at the pharmacy)
	% of medicines prescribed that are on the essential medicine list	RENAME (the Brazilian National Essential medicine List) was used as the reference medicine list for checking this item (exit interview).
	% of medicines prescribed by generic name (BCD or ICD)	The medical prescriptions from the last 12 months were requisitioned, and a sample of 30 prescriptions was taken. Next, the number of prescriptions by generic name was checked. When access to the complete file was not possible, a selection of the prescriptions was made in the available file.
	% of patients receiving antibiotic prescriptions	All anti-infectious medicines were classified as antibiotics.
	% of patients with prescription of injections	Immunizations and injected contraceptives were excluded
	% of adequately labeled medicines – Brazil criterion	Expressed as a mean value for the percentage of labels with at least the generic name of the medicine, manufacturer, batch, concentration or potency, and expiration date.
	% of adequately labeled medicines – WHO criterion	Expressed as a mean value of the percentage of labels with the name of the medicine and information on the dose/dosing schedule, duration of treatment, and administration route.
	% of patients who know how to take the medicines	Checked whether patients could correctly inform how all the medicines should be used, according to the prescription.
	% of complete prescriptions	Expressed as mean percentage of prescriptions that contained at least dose/ dosing interval, duration of treatment, and administration route for each medicine, recorded as complete only if all the medicines on the prescription met all the criteria.
	Availability of Essential medicine List (%)	Recorded as positive if the list used (national, State, or municipal list of essential medicines) was found anywhere inside the health unit.
	Availability of Standard Treatment Protocol (STP) for tuberculosis (%)	Checked the availability of the tuberculosis treatment protocol anywhere inside the health unit.
	% of tracer cases treated according to protocol/ treatment guidelines	Treatment checked for selected diseases – diarrhea and pneumonia in children under five years and otitis media and fever for any age.

Table 1. Access, Quality, and Rational Use of medicines by State. Brazil, 2004.

Dimension	Indicator	Brazil	ES	GO	PA	RS	SE	p-valor
Access	Availability of principal medicines (%) (A1)	73.0	80.4	78.4	65.7	61.2	75.5	-
	% of prescribed medicines that were dispensed or administered (A2)**	65.7	89.6	74.1	69.5	52.6	54.9	0,000
	Adequate conditions for conservation of medicines (inventory area) (%) (Q1)	61.1	85.0	52.5	63.2	42.9	50.0	-
	Adequate conditions for conservation of medicines (dispensing area) (%) (Q2)	70.1	86.7	52.5	75.4	75.5	63.3	-
Quality	% of medicines with date expired (Q3)	0.3	1.2	0	0	0	0	-
	Existence of inventory turnover records (%) (Q4)	31.7	33.3	0.0	50.0	40.0	16.7	-
	Mean number of medicines per prescription (patient interview) (RU1)**	2.3	2.1	2.6	2.5	2.5	1.8	0,000
	Mean number of medicines per prescription (review of prescriptions) (RU2)**	2.3	2.2	2.4	2.5	2.5	2.1	0,000
Rational use of Medicines	% of medicines prescribed that where on the essential medicine list (RU3)**	78.3	91.1	86.9	67.9	75.7	78.4	0,000
	% of medicines prescribed by generic name (BCD or ICD) (RU4)**	84.2	92.7	83.3	80.6	86.3	87.3	0,000
	% of patients with prescription of antibiotics(RU5)*	40.1	42.2	43.3	45.0	33.3	39.4	0,237
	% of patients with prescription of injections(RU6)*	6.9	8.3	6.1	7.8	4.7	7.2	0,706
	% of adequately labeled medicines – Brazil criterion (RU7)**	95.2	89.0	95.1	97.5	98.7	96.9	0,000
	% of adequately labeled medicines – WHO(RU8)**	6.1	13.8	0.00	0.00	10.4	9.4	0,010
	% of patients who knew how to use the medicines (RU9)*	77.8	75.2	86.1	75.3	93.3	60.5	0,000
	% of complete prescriptions (RU10)*	46.0	98.6	1.1	27.2	29.3	81.9	0,000
	Availability of Essential medicine List (%) (RU11)	70.0	100	0.0	100	83.3	50.0	-
	Availability of Standard Treatment Protocol (STP) for tuberculosis (%) (RU12)	43.3	33.3	33.3	50.0	50.0	50.0	-

*Chi-square **Anova and Bonferroni with necessary

A2 – Bonferroni ESxGO pvalue 0,001; ESxPA, ESxRS, ESxSE,; GOxRS, GOxSE; PAxRS and PAxSE pvalue 0,000
RU1 – Bonferroni ESxGO pvalue 0,003; ESxPA pvalue 0,024; ESxRS pvalue 0,021; GOxSE, PAxSE e RSxSE pvalue 0,000
RU2 – Bonferroni GOxSE – p-valor 0,044; PAxSE pvalue 0,004; RSxSE pvalue 0,002
RU3 – Bonferroni ESxPA, ESxRS e ESxSE pvalue 0,000; GOxPA pvalue 0,005; PAxSE pvalue 0,006
RU4 – Bonferroni ESxGO pvalue 0,006; ESxPA 0,000
RU7 – Bonferroni ESxGO pvalue 0,026; ESxPA, ESxRS and ESxSE pvalue 0,000
RU8 – Bonferroni ESxGO pvalue 0,043 and ESxPA pvalue 0,047

The "percentage of medicines prescribed by generic name (DCB - Brazilian Common Denomination, or INN - International Non Proprietary Name)" varied from 80.6% in Pará to 92.7% in Espírito Santo.

All the States showed good results for the "percentage of adequately labeled medicines – Brazil criterion" (Table 1), with a important difference for the State of Espírito Santo. The adequacy in relation to the Brazil criterion depends on the manufacturer, since most of the products are industrialized. Using the WHO criterion[19], non-adequacy is justified, since it is not required by Brazilian legislation.

As for the "percentage of patients who know how to take the medicines", the figure ranged from 60.5% in Sergipe to 93.3% in Rio Grande do Sul (Table 1).

As for the "percentage of complete prescriptions", 15 health units showed unsatisfactory results and ten showed excellent results, according to the criterion used in the Brazilian study [ÿ16]. Stratification by State showed large regional differences, ranging from 1.1% in Goiás to 98.6% in Espírito Santo (Table 1).

The Essential Medicine List was available in 21 health units (70%), concentrated in the States of

Espírito Santo, Pará, and Rio Grande do Sul (Table 1). The list was not located in any of the health units in Goiás. Only half of the health units visited in Sergipe had the list available. In relation to "availability of standard treatment protocol (STP) for tuberculosis", the figures were even lower. In the States of Pará, Rio Grande do Sul, and Sergipe, the figure was around 50%, and in Goiás and Espírito Santo fewer than half of the health units had the protocol available (Table 1).

Related to "tracer cases treated according to recommended treatment protocol/guide", for uncomplicated pneumonia in children, although the mean value was 63.3% for adherence to the protocol (use of plain amoxicillin), the results varied greatly between States, from 33% in Pará to 91.7% in Espírito Santo.

For treatment of fever in patients of any age, oral dipyrone was widely used, reaching 57% in Goiás (Table 2), despite this medicine is no more in Brazilian EML since 1999.

For dehydration in children under five, oral rehydration therapy (ORT) was prescribed in the majority of cases. However, there was also a high rate of antibiotic use (Table 2). Management of acute otitis media included the prescription of antibiotics for most cases, except in Sergipe.

Table 3 shows the distribution of users according to the retrospective review of medical prescriptions and user interviews.

Table 2. Results of Tracer Cases Treated According to Recommended Protocol/ Treatment Guidelines, by State, Brazil, 2004.

Tracer disease	Indicator	Brazil	ES	GO	PA	RS	SE
Diarrhea in children under five	Total number of cases	231	20	60	60	41	50
	% of prescriptions with ORT	78.4	96.7	90.0	83.3	76.0	54.5
	% of prescriptions with antibiotics	30.3	3.3	20.0	51.7	28.0	34.8
	% of prescriptions with anti-diarrheal medicines and/or antispasmodics	14.7	24.4	20.0	26.7	2.0	3.3
Mild/moderate pneumonia in children under five	Total number of cases	123	13	45	24	36	5
	% of prescriptions with amoxicillin.	63.3	91.7	88.0	33.0	47.0	60.0
	% of prescriptions with more than one antibiotic	15.2	33.3	12.0	0.0	22.0	0.0
Acute otitis media in patients of any age	Total number of cases	206	27	60	30	54	35
	% of prescriptions with antibiotics	83.5	100	95.0	89.4	88.3	46.7
Fever in patients of any age	Total number of cases	255	22	60	59	54	60
	% of prescriptions with dipyrone	30.8	18.1	56.7	31.9	9.2	31.7
	% of prescriptions with paracetamol	46.7	55.7	31.7	48.0	64.2	38.3
	% of prescriptions with ibuprofen	0.4	0.0	1.7	0.0	0.0	0.0
	% of prescriptions with no antipyretics	19.8	16.2	6.7	21.9	22.5	30.0

Table 3. Overall and State-by-State Profile of Users According to Retrospective Review of Medical Prescriptions and Exit Interviews.

Review of Prescriptions	Brazil	ES	GO	PA	RS	SE
Number of prescriptions reviewed	870	180	180	180	150	180
% Women	59.0	60.6	58.9	54.7	56.7	64.4
Exit interview						
Users Interviewed	832	145	180	180	150	177
% Women	61.8	54.5	61.7	63.9	63.3	64.4
Mean age (years)	35.5	37.2	37.6	28.1	46.0	31.3
Schooling						
% Illiterate/ incomplete Primary	55.9	78.6	45.0	51.1	50.7	58.8
% Complete Primary/ Incomplete Secondary	22.8	19.3	27.2	27.3	26.0	14.1
% Complete Secondary/ Incomplete University	19.0	1.4	26.1	20.5	20.7	23.2
% Complete University	2.0	0.7	1.7	1.1	2.7	4.0

Gender was not associated with "mean number of medicines per prescription". Increasing age showed a slight increase in the number of prescribed medicines. The mean number of medicines per prescription was 2.0 for age brackets up to 50 years, 2.5 for 50-60 years, and 2.7 for over 60.

The variable "knowing how to take the medicines" showed a positive association with "schooling" and "complete prescription". By isolating the effect of prescription completeness on "knowing how to take the medicines", the association with "schooling" increased for those with complete prescriptions, while in the group with incomplete prescriptions, schooling showed no effect on the level of understanding of the prescription (Table 4).

No significant difference was found for any of the indicators according to type of management modality in the municipal health system (Brazilian counties are nationally classified according their health system management capacity), suggesting that the differences have more to do with regional characteristics than with the complexity of the management system.

Discussion

Although the methodology adopted here, a multiple case study, does not support either generalization of the data or regional comparison, analysis of the indicators by State showed differences, the results of which should be considered and interpreted at the local level. Considering the decentralization principle underlying the Unified National Health System, based on which each State and it

municipalities are to implement health activities according to their needs, such studies will increase their potential use to support decision-making and policy reorientation if applied locally.

Most of the selected indicators showed non-homogeneous results in the five different States. Important exceptions were "drugs with date expired", "mean number of medicines per prescription", and "percentage of medicines prescribed by generic name", "percentage of patients with antibiotic prescriptions", and "percentage of adequately labeled medicines – Brazil criterion".

For the access dimension, the "availability of key medicines" was lower than in other studies in Brazil, most of which were done at the municipal level. Naves *et al*[20] found a figure of 83.2%. Cunha *et al*. [21] found an availability of 87.2%. Santos *et al*[22] found 98.4%, and Marcondes[23] 87%. Importantly, in addition to differences in the selection of health units included in the studies, differences were identified in the composition of the medicine list, both in the number of medicines included and their content. The current WHO proposal is to define the key medicines based on the important diseases in the context in which the evaluation takes place, which minimizes the problem, since what is verified is the possibility of treating relevant conditions at the primary care level. The verification method proposed by the WHO[11] defines an item as available when there is at least one pill in the inventory, which in many cases does not mean that it is possible to treat a patient.

In other studies, the values found for "percentage of prescribed medicines that were dispensed or administered" varied from 39.7% to 80,7%[3,20-28] and

Table 4. Schooling Versus Knowing How To Take Medicines, according to Completeness of Prescription.

| | | Schooling | | | | | |
| | | Yes | | No | | Total | |
Variables		n	%	n	%	n	%
Does patient know how to take the	Yes	300	85	300	85	300	85
medicines?(complete and incomplete	No	54	15	54	15	54	15
prescriptions) (OR= 2.1, p= 0.00)	Total	354	100	354	100	354	100
Does patient know how to take the medicines?	Yes	120	85	120	85	120	85
(complete prescription) (OR= 2.7, p= 0.00)	No	22	15	22	15	22	15
	Total	142	100	142	100	142	100
Does patient know how to take the medicines?	Yes	180	85	180	85	180	85
(incomplete prescription) (OR=1.4)	No	32	15	32	15	32	15
	Total	212	100	212	100	212	100

in this study it varied from 89.6% to 52,6% in the States and from 22.0% to 93.2% in the health units. According to PAHO[16], one way to refine this analysis is to characterize whether the medicines not dispensed are included on the RENAME, or the local reference list. Naves **et al.**[20] found an overall rate of 61.2% for effective dispensing and showed that among the medicines not dispensed, 60.6% were on the RENAME list.

When analyzed jointly, the variables "availability of key medicines", "percentage of medicines dispensed", and "percentage of medicines prescribed on the RENAME list" highlight the case of Sergipe, where the low rate of medicines dispensed was accompanied by a reasonable level of availability and prescription conformity with the RENAME list. More detailed analyses are needed to better explain the findings, including the trends in prescribing practices.

For "adequate conditions for conservation of the medicines", they were generally better in the dispensing area as compared to the inventory area, considering the time the medicines remained in stock, generally shorter in the dispensing area. This result is worrisome, since the checklist was based on the items that were considered mandatory in routine inspection according to the Brazilian legislation[16].

For rational use of medicines, the values for "mean number of medicines per prescription" according to both methods showed small regional differences but were adequate[8] and similar to those found in other studies in Brazil. Cosendey[24], who analyzed health services in municipalities in five States of Brazil, found a figure of 2.4, while Fegadolli **et al.**[26] found 2.6, Luiza[3] found 2.0, and Naves **et al.**[20] found 2.3. The consistency of these findings suggests that this indicator does not present a discriminatory nature in the country.

The results point to the need for greater discussion on the concept of essential medicines in each specific context. Some municipalities do not use the essential medicine list to orient their purchases[3], which could distort the habitual prescription practices.

Prescription of medicines by generic name is required by law in Brazil[29]. Thus, strategies are needed to strengthen this practice. Other studies have found different results, varying from 30.6% in Santos **et al.**[22] to 84.3% in Cunha **et al.**[21]. Cosendey[24] found a mean value of 69.42% for the five States. These results point to a tendency towards a change in prescribing behavior, with greater adherence to this norm.

In all the States, the result for prescription of injected medicines was less than 20%, which is reasonable according to WHO guidelines[8] and does not differ considerably from the results of other studies, which vary from 7.5%[20] to 12.5%[26]. On the other hand, the antibiotic prescription rate was high, considering that the WHO recommends 30% as acceptable[8]. Still, the rates found in the current study were similar to those in Cosendey[24] (39.2%) and Marcondes[23] (33%).

Brazilian standard treatment protocol for TB is inserted in a general Tb clinical standard guideline[30]. TB treatment is offered only in reference public health facilities. Nevertheless, considering that the objective of the Tuberculosis Control Program is to reduce TB transmission by means of early diagnosis and adequate case treatment[30], the availability of the standard treatment protocol can be considered low, since all health facilities are expected to have information on correct management of TB cases[16].

According to the literature women, children, and the elderly receive more medicines per prescription[31-34]. The data indicate that increasing age is associated with more medicines per prescription, consistent with the findings by Bertoldi **et al.**[32], who found an important increase in the use of medication with age. Studies on use of medication in specific populations of elderly have shown a higher number of medicines than in studies in the overall population, ranging from 2.3 in Coelho **et al.**[33] to 4.0 Mosegui **et al.**[34].

The association between "knowing how to take the medicines" and "complete prescriptions" points to the need to isolate this confounding effect, since the criterion used for "knowing how to take the medicines" was to request that the user express the information verbally, comparing it to the prescription, and it was evident that the less complete the prescription (i.e., the less information), the easier for the user to reproduce the instructions contained on it.

The results for "knowing how to take the medicines" and "schooling" highlight important issues, beginning with the need for adjustments in the methodology and the data collection technique, given the influence of prescription completeness on judgment of the users' knowledge as to correct use of the medicines, verifying knowledge on use only when the patient has a complete prescription, and more importantly, on care required in the clarity of the prescription and instructions on the medicines, particularly for users with less schooling.

Conclusions

The indicators "percentage of complete prescriptions" and "availability of the essential medicine list", which presented the largest differences, suggest that these aspects should be dealt with at the State level, and that they allow differentiating between the regions.

Other indicators point to countrywide problems, as with the "existence of inventory records", considered fundamental information for inventory control to support the programming and procurement stages. Lack of this information has a negative effect on the subsequent stages., the "percentage of antibiotic prescriptions", in which the level exceeded the WHO guidelines, and "availability of the standard treatment protocol for tuberculosis".

For the treatment regimens used for tracer diseases, some deviations from rational use were also observed. These results highlight the need for measures to promote rational prescription.

Educational level showed to be an important predictor of knowledge on how to use medicines, especially relevant when prescription is completed.

Further studies are needed to elucidate regional aspects identified for some indicators. In relation to medicine labeling, this applies to understanding how the inclusion of information on dose scheduling contributed to correct use of the medicines and to identifying which requirements within the "WHO criterion" are not being complied with, and based on this, to devise intervention strategies for improving the quality of the information provided to users.

Caution should be used in comparing these results to those of other studies, considering that the nomenclature and calculation and data collection techniques vary between authors, possibly due to differences in translation and adaptation of the methodology. It is thus necessary to standardize the nomenclature and indicators at the national level in order to minimize errors in monitoring the pharmaceutical situation in different States, municipalities, and health services.

The current study provided an overview of the current situation in the pharmaceutical sector in the sites visited according to the methodology proposed by the WHO to expand knowledge on the national and regional reality of pharmaceutical services, while exploring other possibilities for analysis to complement the existing recommendations. The hope is that this methodology will support local, State, or regional studies in addition to the national study, allowing not only cross-sectional studies, but also the building of a monitoring system as an important management tool.

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Collaboration

ICM Emmerick, VL Luiza and VLE Pepe had equal participation in the conception, outline, analyzis and data interpretation, composition of the article, critical review and approval of the version to be published.

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