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Technical issues and conservation conditions of medicines in the Primary Care in the Unified Health System in the capitals of Brazil

Situação sanitária dos medicamentos na atenção primária no Sistema Único de Saúde nas capitais do Brasil

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ABSTRACT

Introduction: Pharmacies, within the scope of the Unified Health System (SUS), must comply with health standards, as well as follow the guidelines established by the Ministry of Health to guarantee access to safe, effective and quality medicines. **Objective:** To characterize the technical issues and conservation conditions of medicines of primary care in the Unified Health System, in the capitals of Brazil, grouped by regions, about technical-sanitary requirements, storage and environmental conditions, fire safety and electrical breakdown items, control system of inventory, fractionation, waste management, regulation of advertising/promotion of medicines, actions related to pharmacovigilance and transport. **Method:** Cross-sectional, exploratory study, covering 455 pharmacies in primary care services in the capitals of Brazil, which constitute a subsample of the *Pesquisa Nacional sobre Acesso, Utilização e Promoção do Uso Racional de Medicamentos* (PNAUM). An observation guide and interviews were used with those responsible for pharmaceutical assistance (n = 24) and those responsible for delivering medicines to services (n = 108). **Results:** Non-compliance with technical and sanitary conditions, which can interfere in maintaining stability, quality, efficacy, and safety, indicating management problems, infrastructure and quality of pharmaceutical services were identified, in addition to possible increased costs for the system due to losses. More deficient sanitary conditions in general were found in the capitals of the North and Northeast and better conditions in the capitals of other regions. **Conclusions:** Pharmacies of the SUS primary health network face problems in management, infrastructure, organization, and quality of pharmaceutical services that can compromise the quality of the medicines offered, and increase costs for the system. Improvement of management, investments in infrastructure and in the qualification of human resources, and improvement of inspection and health surveillance are urgently needed for essential medicines and pharmaceutical assistance policies to be effective.

KEYWORDS: Drugs for Primary Health Care; Pharmaceutical Services; Pharmacovigilance; Unified Health System; Health Surveillance

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RESUMO

Introdução: As farmácias, no âmbito do SUS, devem cumprir as normas sanitárias, bem como seguir as diretrizes estabelecidas pelo Ministério da Saúde, a fim de garantir o acesso a medicamentos seguros, efetivos e de qualidade. **Objetivo:** Caracterizar a situação sanitária dos medicamentos na atenção primária no SUS, nas capitais do Brasil, segundo as regiões, no tocante a: requisitos técnico-sanitários, condições de armazenamento, itens de segurança contra incêndio e pane elétrica, condições ambientais, sistema de controle de estoque, fracionamento, gerenciamento de resíduos, regulação da publicidade/promoção de medicamentos, ações relacionadas à farmacovigilância e ao transporte. **Método:** Estudo transversal, exploratório, abarcando 455 farmácias de serviços de

atenção primária das capitais do Brasil que constituem uma subamostra da Pesquisa Nacional sobre Acesso, Utilização e Promoção do Uso Racional de Medicamentos (PNAUM). Utilizou-se um roteiro de observação e entrevistas com os responsáveis pela assistência farmacêutica (n = 24) e responsáveis pela entrega de medicamentos dos serviços (n = 108). **Resultados:** Constatou-se o descumprimento de requisitos técnicos e sanitários que podem interferir na manutenção da sua estabilidade, qualidade, eficácia e segurança, indicando problemas de gestão, infraestrutura e qualidade dos serviços farmacêuticos, além de possível incremento de custos para o sistema devido a perdas. Condições sanitárias mais deficitárias foram encontradas nas capitais do Norte e Nordeste e mais favoráveis nas demais. **Conclusões:** As farmácias enfrentam problemas de gestão, infraestrutura, organização e qualidade dos serviços farmacêuticos que podem comprometer a qualidade dos medicamentos oferecidos e incrementar custos para o sistema. O aprimoramento da gestão, os investimentos em infraestrutura e na qualificação dos recursos humanos e o aprimoramento da fiscalização da Vigilância Sanitária se fazem urgentes para que as políticas de medicamentos e de assistência farmacêutica sejam efetivas.

PALAVRAS-CHAVE: Medicamentos para a Atenção Primária; Assistência Farmacêutica; Farmacovigilância; Sistema Único de Saúde; Vigilância Sanitária

INTRODUCTION

With the 1988 Constitution, Brazil began to recognize and protect the right to health, among other social rights[1]. This was followed by the creation of the Unified Health System (SUS), with the objective of formulating health policies and conducting promotion, protection and recovery actions, in addition to providing integrated care and encouraging preventive actions[2]. Health surveillance and comprehensive therapeutic assistance, including pharmaceutical assistance, are to be provided by SUS.

Established by Resolution n. 338, of May 6, 2004, of the National Health Council, the National Pharmaceutical Assistance Policy (PNAF) is part of the National Health Policy. It determines that pharmaceutical assistance (PA) must guide the formulation of sectoral policies comprising a set of actions aimed at the promotion, protection and recovery of health, both individual and collective. It also rules that medicines are essential supplies that have to be used rationally and to which the population must have access[3]. One of the strategic axes of PNAF is the formulation of a Health Surveillance Policy that ensures the population's access to safe, effective and quality services and products[3].

The health surveillance of medicines is one of the areas of operation of SUS. Fully structured health surveillance is one of the fundamental requirements for the implementation of SUS, given its normative and supervisory power over health services and the therapeutic supplies used in them. Its actions must also take priority over others due to their essentially preventive nature[4], and they are to be performed on both public and private health goods and services.

Medicines are sensitive products created to prevent, diagnose, and cure diseases or control their symptoms. They must be produced, stored and distributed with high technical rigor to ensure their quality, efficacy and safety. They are hybrid scientific objects: essential goods with therapeutic and economic value, and instruments for the accumulation of power and capital. The expected result of their use is to prevent diseases or restore health. However, under certain conditions, they can cause harm and, since they pose such risk, they must be subject to health surveillance[5].

Within the scope of SUS, pharmacies must comply with health standards, follow the guidelines established by the Ministry of Health (MS), and have physical infrastructure, human and material resources that enable the integration of services and the performance of PA actions to ensure medication quality, humanized care and improved healthcare conditions[6].

Ensuring the safety, efficacy and quality of medicines is an important guideline established by the National Policy for Medicines (PNM), published in 1998, and represents a major challenge to regulatory systems around the world. The health control of medicines requires compliance with health regulations and inspection activities for the regular and systematic check of technical and legal requirements of medicine-related activities[3]. With the creation of Brazil's National Health Surveillance Agency (Anvisa) in 1999[7] and according to the guidelines and priority axes of PNM and PNAF, several standards were formulated or updated to enable greater health regulation of medicines. The need to evaluate PNAF led the MS to institute the National Survey on Access, Use and Promotion of the Rational Use of Medicines (*Pesquisa Nacional sobre Acesso, Utilização e Promoção do Uso Racional de Medicamentos* — PNAUM). Conducted in partnership with 11 academic institutions, the survey was organized into two strategies—a population component and a service component—to evaluate aspects related to access, use and promotion of the rational use of medicines.

The service component of PNAUM aimed to characterize the organization of PA services in primary care, with a view to accessing medicines and promoting their rational use, through the selection and investigation of a vast set of characteristics and attributes of practices and procedures within the services. This is a cross-sectional, exploratory, evaluative study, carried out between 2014 and 2015, with a sample of 600 municipalities representing all regions of Brazil and 1,143 primary healthcare services/SUS[8].

The survey produced a large amount of data and information on PA and access to medicines and on pharmaceutical services, through interviews with health secretaries, PA head pharmacists, users, physicians and those responsible for the delivery

of medicines in pharmacies/dispensing units, in addition to the observation of pharmaceutical services in primary care units, according to methodological details in Álvares et al.[8].

In Brazil, research on the health status of medicines in both public and private settings is still scarce. The most comprehensive study[9] was part of PNAUM — Service Component.

This study aimed to characterize the health surveillance situation of medicines in primary care/SUS in the state capitals of Brazil, according to the regions, with regard to: technical-sanitary requirements, storage conditions, safety items against fire and electrical failure, environmental conditions, inventory control system, fractionation, waste management, regulation of medicine advertising/promotion, pharmacovigilance-related actions, and transport conditions.

METHOD

This is a cross-sectional, exploratory study of an evaluative nature, which uses a subsample of PNAUM consisting of the state capitals of Brazil grouped by regions. PNAUM was carried out between 2014 and 2015 and the data were produced through direct observation of pharmaceutical services in a sample of primary care services and through interviews with key respondents. In the verification of pharmacies/medicine dispensing units, and places of storage and delivery of medicines, an observation guide and trained personnel were used to verify technical-sanitary documentation, medicine storage and delivery conditions, activity log, availability of selected medicines, expired medicines, and the place for storing unsuitable medicines. This guide was prepared based on the Guidelines for Structuring Pharmacies within the scope of SUS[6], in compliance with the relevant health standards.

The observer was accompanied by a professional from the healthcare unit, who was familiar with the place, and filled out the fields according to the observation and information provided by the companion. The interviews were carried out by trained personnel who used a specific questionnaire for each category of respondent. They were held in person with the pharmacists responsible for dispensing medicines and over the phone with PA coordinators.

The sanitary conditions of medicines were investigated based on observation data. Data on medicine advertising control, pharmacovigilance, inventory control and waste management were produced through interviews with pharmacists responsible for dispensing medicines, and data on medicine transportation originated from interviews with PA coordinators. SPSS software, version 22, analysis module for complex samples and the Chi-square test for statistical association analysis were used for data analysis, with a significance level of $p < 0.05$.

PNAUM was approved by the National Research Ethics Committee, Opinion n. 398.131/2013. The respondents were clarified as to the research objectives and signed a free and informed consent form (ICF).

RESULTS

A total of 455 pharmacies/medicine dispensing units from the sample of health services in primary care in the 26 state capitals of Brazil were observed, and 108 pharmacists responsible for dispensing medicines and 24 PA coordinators were interviewed.

Table 1 presents the sanitary conditions of medicines in primary care in the capitals and reveals inequalities between regions. In general, there were poorer sanitary conditions in the North and Northeast regions and better conditions in other areas.

Technical-sanitary documentation proved deficient, with significant statistical differences between regions. The lowest percentage of location and operating permits was found in the Center-West (36.4%), and the highest was found in the South (68.8%). This permit is granted by the municipal body responsible for land use planning and control for non-residential use in its territory.

As for health permits, only 12.1% of the pharmacies/medicine dispensing units in the Southeast had them. In the South, 68.8%. This document is issued by the municipal health surveillance body once the fulfillment of technical-sanitary requirements in public or private pharmacies is confirmed. Fire department licenses, a legal requirement for the operation of pharmacies, were found in just over a third (36.1%) of the investigated services: the lowest rate was in the North region (23.9%), and the highest, in the Southeast (65.6%).

The Technical Responsibility Certificate (CRT), issued by the Regional Pharmacy Council and mandatory in pharmacies/dispensing units, which must have a pharmacist in charge of or responsible for technical-pharmaceutical services, was found in only 20.3% of the establishments: the lowest percentage was in the Northeast (9.8%), and the highest, in the South (55.9%). In the capitals as a whole, there were more establishments with location and operating permits (44.3%) than with health permits (21.3%) or CRT (20.3%).

In the capitals, pharmacists are responsible for 59.2% of pharmacies/dispensing units, with a much lower rate in the Northeast (35.9%) and much higher in the Southeast (90.0%), with significant statistical differences. Other healthcare professionals with higher education in this role were identified, at a lower rate in the Southeast (3.0%) and higher in the South (17.2%) and Center-West (17.0%).

In the dimension of “storage area conditions”, significant statistical differences were found between regions in most variables. Medicine storage areas of pharmacies/medicine dispensing units of the primary care network in Northern and Northeastern capitals generally presented the most deficient conditions. Of the establishments investigated, 55.3% had air conditioning: in the Southeast, less than 50.0%, and in the South, less than 25.0%. Of the units that dispense psychotropic drugs, about

Table 1. Sanitary conditions in pharmacies/medicine dispensing units (n = 455) in primary care in the state capitals of Brazil according to the regions.

Regions	North	Northeast	Center-West	Southeast	South	State capitals of Brazil
Dimension/Variable	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**
Technical-sanitary documentation*						
Location and Operation Permit	38.8(28.4-8.7)	43.5(33.7-53.8)	36.4(25.7-48.5)	40.4(31.2-50-3)	68.8(58.7-77.4)	44.3(39.4-49.3)
Health Permit (Visible and valid permit)	17.4(10.7-7.1)	15.2(9.2-24.1)	20.5(11.5-33.6)	12.1(7.0-20.2)	63.4(53.2-72.6)	21.3 (17.7 -25.5)
Fire Department License	23.9(14.8-36.1)	28.3(19.9-38.4)	32.6(23.8-42.9)	65.6(55.4-74.5)	34.3(25.7-44.2)	36.1(31.5-41.0)
Technical Responsibility Certificate	14.1(8.1-23.5)	9.8(5.2-17.8)	21.6(12.5-34.7)	18.2(11.8-27.0)	55.9(45.7-65.6)	20.3(16.7-24.5)
Responsible person for the Pharmacy/Dispensing Unit*						
Pharmacist	41.3(31.4-51.9)	35.9(26.6-46.4)	52.3(41.1-63.3)	90.0(83.4-95.2)	57(46.8-66.7)	59.2(54.3-64.0)
Another healthcare professional with higher education	15.2(24.1-84.8)	12.0(6.7-20.3)	17.0(10.4-26.6)	3.0(1.0-9.0)	17.2(10.8-26.3)	10.6(8.1-13.9)
Storage Area Conditions						
Air conditioning device*	70.7(60.5-79.1)	71.7(61.7-80.0)	63.6(52-6-73.4)	43.4(34.0-53.3)	24.7(17.0-34.5)	55.3(50.3-60.2)
Locker with key for controlled medicines in the units that dispense them*	39.1(29.4-49.8)	37.0(27.6-47.4)	39.8(29.0-51.6)	84.8(76.4-90.7)	47.3(37.4-57.4)	54.9(49.9-59.8)
Exclusive medicine storage refrigerator/fridge*	39.1(29.4-49.8)	67.4(57.1-76.2)	76.1(65.5-84.3)	91.8(84.7-95.9)	82.8(73.7-89.2)	73.3(68.8-77.4)
Medicines in direct contact with the floor or walls	22.8(15.3-32.6)	22.8(15.1-32.9)	17.0(10.4-26.6)	20.2(13.4-29.3)	18.3(11.7-27.5)	20.9(17.1-25.3)
Control of entry and circulation of people*	37.0(27.4-47.6)	84.8(75.9-90.8)	73.9(63.4-82.2)	96.0(89.7-98.5)	84.9(76.2-90.9)	79.3(75.3-82.8)
Shelves or cabinets for product storage (medicines, supplies)*	82.6(73.4-89.1)	89.1(80.9-94.1)	96.6(89.9-98.9)	99.0(93.2-99.9)	96.8(90.5-99.0)	92.9(89.9-95.0)
*Pallets/decks**	15.2(9.2-24.1)	34.8(25.6-45.3)	21.6(13.2-32.2)	88.9(81.0-93.7)	22.6(14.2-32.2)	46.8(41.8-51.9)
Digital thermometer (room temperature)*	18.5(11.8-27.8)	26.1(17.9-36.3)	31.8(21.9-43.7)	76.8(67.4-84.1)	48.4(38.4-58.5)	45.0(40.1-50.1)
Hygrometer (air humidity)*	2.2(0.5-8.3)	12.0(6.4-21.1)	5.7(2.4-13.0)	43.4(34.0-53.3)	26.9(18.9-36.8)	22.2(18.1-26.9)
Refrigerator thermometer*	23.9(15.9-34.4)	48.9(38.8-59.2)	55.7(44.4-66.4)	86.9(78.7-92.2)	63.4(53.2-72.2)	59.6(54.7-64.4)
Bins for medicine storage*	5.4(2.3-12.4)	39.1(29.6-49.6)	33.0(22.6-45.3)	63.6(53.7-72.5)	37.6(28.4-47.9)	40.7(35.8-45.8)
Existence of at least one expired medicine in inventory	18.5(11.8-27.8)	18.5(11.5-18.3)	17(10.4-26.6)	11.8(6.7-20.1)	14.1(8.5-22.5)	16(12.6-20.1)
Fire and electrical failure safety items						
Fire prevention equipment*	13.0(7.5-21.6)	15.2(9.2-24.1)	25.0(15.8-37.2)	43.4(34.0-53.3)	71.0(61.0-79.3)	32.3(27.9-37.2)
Power generator	2.2(0.5-8.3)	1.1(0.2-7.3)	0.0	1.1(2.7-12.9)	2.9(1.5-5.3)	2.9(1.5-5.3)

* $p < 0.05$.
Source: PNAUM Serviços - Brazil, 2015.

50.0% met the legal requirement of a locker with a key; in the Northeast, only 37.0%.

In about 20.0% of the pharmacies/dispensing units, medicines were found in direct contact with the floor or walls, and in 16.0% of them there were expired medicines in inventory, with no statistically significant differences between regions.

As for accident prevention, pharmacies in southern capitals had the highest rate (71.0%) of fire prevention equipment, whereas the lowest rates were concentrated in the North (13.0%) and Northeast (15.2%). Health units with power generators were rare, therefore, most were not compliant with the legislation[19].

Table 2 presents the environmental conditions and medicine fractionation conditions in pharmacies/medicine dispensing units, with more favorable conditions in the Southeast and South. Temperature control was identified in only 47.2% of them, with lower rates in the North (27.2%) and Northeast (23.9%). Humidity control was even lower: in 10.2% in the Center-West, 16.3% in the Northeast, and 17.4% in the North, a

Table 2. Environmental and fractioning conditions in pharmacies/medicine dispensing units (n = 455) in basic care in the state capitals of Brazil according to the regions.

Regions	North	Northeast	Center-West	Southeast	South	State capitals of Brazil
Dimension/Variable	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**
Environmental conditions of the pharmacy/medicine dispensing unit						
[a] Has temperature control*	27.2(18.7-37.8)	23.9(16.1-34.0)	55.7(44.5-66.3)	76.8(67.4-84.1)	44.1(34.4-54.3)	47.2(42.2-52.3)
[a] Has an air circulation system	42.4(32.5-53.0)	32.6(23.6-43.1)	31.8(22.6-42.7)	43.3(34.0-53.3)	33.3(24.5-43.5)	38.0(33.2-43.0)
[a] Has humidity control*	17.4(10.9-26.6)	16.3(9.8-25.9)	10.2(5.4-18.6)	48.5(38.8-58.3)	31.2(22.6-41.3)	28.7(24.3-33.6)
[a] Specific area for storing unsuitable medicines*	25.0(17.2-34.9)	30.4(21.9-40.6)	55.7(44.3-66.5)	67.7(57.9-76.1)	59.1(48.9-68.6)	47.6(42.7-52.7)
[a] Temperature at time of observation:* aUp to 25°C	68.5(58.2-77.2)	28.3(19.8-38.6)	31.8(22.5-42.9)	74.7(65.3-82.3)	51.6(41.5-61.6)	54.2(49.2-59.1)
[b] Between 25°C and 30°C	14.1(8.4-22.9)	17.4(10.9-26.6)	38.6(28.0-50.5)	7.1(3.4-14.1)	9.7(5.1-17.6)	14.0(11.0-17.7)
[b] Above 30°C	1.6(3.7-15.1)	5.4(2.3-12.4)	6.8(3.1-14.4)	-	1.1(0.2-7.3)	3.5(2.2-5.7)
[b] No thermometer/Unable to check temperature	9.8(5.2-17.8)	48.9(38.8-59.1)	22.7(15.0-32.9)	18.2(11.8-27.0)	37.6(28.4-47.9)	28.3(24.0-33.0)
[b] Allows direct sunlight on medicines	5.4(2.3-12.4)	3.3(1.1-9.6)	3.4(1.1-10.1)	4.0(1.5-10.3)	9.7(5.1-17.6)	4.8(3.1-7.3)
[b] Signs of rodents and insects*	19.6(12.4-29.4)	6.5(3.0-13.8)	8.0(3.0-19.6)	6.1(2.7-12.9)	22.6(15.2-32.2)	10.9(8.3-14.2)
[b] Presence of mold or seepage	21.7(14.2-31.8)	21.7(14.4-31.4)	26.1(16.9-38.1)	10.1(5.5-17.8)	18.3(11.7-27.5)	17.7(14.3-21.8)
Environmental conditions of the medicine dispensing area						
[a] Has temperature control*	31.9(22.8-42.6)	28.4(19.9-38.7)	55.2(43.7-66.1)	80.8(71.8-87.4)	51.6(41.5-61.6)	51.9(46.9-57.0)
[a] Has an internal air circulation system	48.4(38.1-58.8)	40.9(31.0-51.6)	33.3(23.9-44.4)	45.5(35.9-55.3)	40.9(31.4-51.1)	43.2(38.2-48.2)
[a] Has humidity control*	17.6(11.0-26.9)	15.9(9.6-25.1)	10.3(5.4-18.8)	46.5(36.9-56.3)	39.8(30.4-50.0)	29.3(24.9-34.2)
[b] Allows direct sunlight on medicines	4.4(1.7-11.2)	4.5(1.7-11.5)	3.4(1.1-10.2)	6.1(2.7-12.9)	10.8(5.9-18.9)	5.8(3.9-8.6)
[b] Signs of rodents and insects*	22.0(14.4-32.1)	6.8(3.1-14.4)	9.2(3.8-20.7)	4.0(1.5-10.3)	25.8(17.9-35.6)	11.3(8.6-14.6)
[b] Presence of mold or seepage	22.0(14.4-32.1)	26.1(18.0-36.3)	21.8(13.8-32.8)	9.1(4.8-16.6)	21.5(14.3-31.0)	18.7(15.1-22.9)
Medicine fractionation conditions						
Specific area for fractioning*	1.7(0.2-11.3)	8.3(3.2-20.2)	29.6(19.1-42.7)	18.9(9.3-34.7)	2.0(0.3-12.9)	11.2(7.5-16.2)
Bench covered with smooth and sturdy material	20.7(12.1-33.1)	10.4(4.4-22.8)	38.0(26.5-51.1)	24.3(13.2-40.5)	6.0(1.9-17.0)	18.7(14.1-24.5)
Packaging and labeling material and equipment*	1.7(0.2-11.3)	4.2(1.0-15.2)	22.5(12.6-37.0)	37.8(23.8-54.2)	10.0(4.2-21.9)	14.8(10.4-20.6)
Sharp instruments	100.0	95.8(84.8-99.0)	93.0(84.1-97.1)	94.6(80.8-98.6)	94.0(83.0-98.1)	95.8(92.2-97.8)

[a] positive aspects; [b] negative aspects.
* $p < 0.05$.
Source: PNAUM Serviços - Brazil, 2015.

region where, additionally, only 25.0% of the establishments had a specific area to store medicines that are no longer suitable for use.

In the Center-West, at the time of observation for data collection, temperatures above 30°C were found in 6.8% of the services. In the Northeast, 48.9% of establishments did not have a thermometer, or measuring the temperature was not possible; in the South, this index was 37.6%. Incidence of direct sunlight on medicines was observed in 4.8% of pharmacies/medicine dispensing units in the capitals of Brazil; the highest percentage was in the South (9.7%), and the lowest, in the Northeast (3.3%). Evidence of rodents and insects was found in 10.9%. This increases to 19.6% in the North and 22.6% in the South. Mold or seepage, which can affect medicine stability, were found in more than 17.0% of the establishments. The lowest index was in the Southeast (10.1%), and the highest, in the Center-West (26.1%).

Environmental conditions specifically in the dispensing area were also deficient. Temperature control was performed in just over half (51.9%) of the establishments, and humidity control,

in less than 30.0%. In this area, more than 5.0% of the sample was affected by direct sunlight, exceeding 10.0% in the South; evidence of rodents and insects in these areas was found in more than 11.0% of the establishments, with the highest percentage in the South (25.8%), and the lowest, in the Southeast (4.0%). Presence of mold or seepage in the dispensing area was found in more than 18.0% of the establishments, with the highest rate in the Northeast region (26.1%), and the lowest, in the Southeast (9.1%).

As for the fractionation of medicines, of the 255 establishments that performed it, only 11.2% had an area for this purpose only, with significant statistical differences between regions. The highest percentage was found in the Center-West (29.6%), and the lowest (1.7%), in the North. There were benches covered with smooth and sturdy material in 18.7% of the investigated services. The highest percentage was in the Center-West (38.0%), and the lowest, in the South (6.0%). Packaging and labeling material and equipment were found in only 14.8% of them, with rates of 37.8% in the Southeast and 1.7% in the North.

Regarding transport problems, according to the participating PA coordinators, in more than half of the capitals there were problems with insufficient and inadequate transport of medicines (Figure).

In the Center-West, transport is totally insufficient and inadequate, whereas in the Southeast this problem has already been addressed. In the South, the big problem is insufficiency (66.7%); in the Northeast, there are problems of insufficiency and/or inadequacy (77.7%); in 50.0% of the capitals of the North there is some inadequacy.

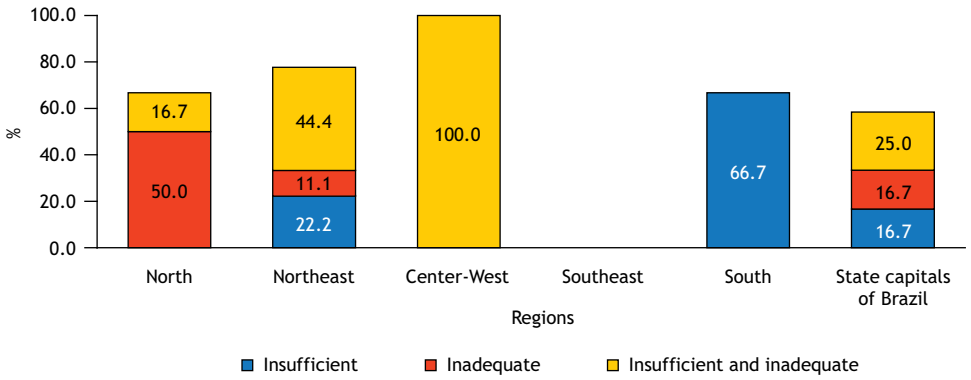
Table 3 shows the findings on medicine advertising regulation, pharmacovigilance initiatives and waste management. The regulation of visits by representatives of pharmaceutical companies and medicine distributors and the entry of advertising materials and free samples into the public network differed between regions. The highest percentages were in the Center-West (90.0%) and Southeast (87.9%); the lowest, in the North (30.0%). Distribution of free samples—which encourages self-medication and can be characterized as abusive promotion—was identified in 43.3% of services in the North and in 30.0% in the Center-West, in contrast with the 1.7 % found in the Southeast.

In the pharmacovigilance item, the existence of mechanisms for reporting medicine-related technical complaints and adverse events were higher in the capitals of the Southeast (84.5%) and South (80.0%) and much lower in the other regions. The reporting of technical complaints/adverse events by pharmacists responsible for dispensing medicines reached 42.5% in Brazil based on data from the Southeast and Northeast regions. There were no references to reporting in the other regions, although the services had mechanisms to perform it. There is some variation in the recipients of the reports among regions, with significant statistical differences. In general, the municipal coordination of PA predominated (35.2%), followed by health surveillance bodies (22.7%). In 12.6% of the capitals, respondents said they do not file any reports of adverse events.

Regarding inventory control systems, significant statistical differences were found between regions. Despite the predominance of computerized control systems (80.5%), in the North and Northeast, many of the services still rely on manual systems (43.2% and 50.0% respectively) and there are services that do not have any control system at all.

Regarding a Health Service Waste Management Plan (PGRSS), significant statistical differences were observed between the regions in most items: the North and Northeast regions are the most deficient, 33.0% have a plan, whereas the Southeast reaches 77.6%.

Regarding the existence of a specific place in compliance with health standards to store unsuitable medicines until they are collected, the lowest rate was observed in the Center-West region (20.0%), and the highest was found in the Southeast (70.7%). Regarding medicine waste collection services, the results were more favorable: in all regions they exceeded 80.0%. Among state capitals, 91.2% have this service, but we could not verify the place of disposal.



Source: PNAUM Serviços - Brazil, 2015.

Figure. Problems in the transport of medicines in the capitals of Brazil, according to the person responsible for pharmaceutical assistance (n = 24).

Table 3. Regulation of medicine advertising, pharmacovigilance and waste management in primary care in Brazilian state capitals, according to pharmacists responsible for the dispensing work (n = 108).

Regions	North	Northeast	Center-West	Southeast	South	State capitals of Brazil
Dimension/Variable	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**	**CI 95%**
Regulation of medicine advertising/promotion*						
Norm to regulate the visit of representatives of laboratories and medicine distributors and medicine advertising material	30.0(15.9-49.3)	41.7(17.4-70.8)	90.0(50.7-98.7)	87.9(76.7-94.2)	60.0(19.9-90.1)	70.7(61-78.8)
Do not know	30.0(14.2-52.6)	-	-	8.6(3.6-19.2)	-	11.2(6.2-19.4)
Distribution of free medicine samples at the health unit	43.3(25.5-63.1)	16.7(4.1-48.6)	30.0(6.7-71.9)	1.7(0.2-11.4)	20.0(2.7-69.4)	12.7(7.7-20.2)
Do not know	3.3(0.5-20.5)	-	10.0(1.3-49.3)	5.2(1.7-14.9)	-	4.2(1.6-10.4)
Pharmacovigilance*						
Mechanism for reporting technical complaints and adverse events	23.3(10.5-44.2)	16.7(4.1-48.6)	20.0(4.3-58.0)	84.5(72.7-91.8)	80.0(30.6-97.3)	62.6(52.8-71.5)
Has already reported a technical complaint or adverse event	-	25.0(8.0-56.3)	-	62.1(49.0-73.6)	-	42.5(33.0-52.6)
Submission of technical complaints and reports of adverse events caused by medicines*						
To the pharmaceutical supply center	10.0(2.3-34.1)	33.3(10.9-67.2)	10.0(1.2-49.8)	12.1(5.8-23.4)	14.4(8.4-23.6)	14.4(8.4-23.6)
To the municipal coordination of pharmaceutical assistance	33.3(17.7-53.8)	16.7(4.0-49.0)	40.0(11.1-78.1)	39.7(27.8-52.9)	35.2(26.3-45.2)	35.2(26.4-45.1)
To the health surveillance body	13.3(4.9-31.3)	8.3(1.1-42.5)	40.0(9.6-80.7)	27.6(17.5-40.6)	22.7(15.4-32.2)	22.7(15.5-32.0)
None	6.7(1.6-23.7)	8.3(1.1-42.5)	-	15.5(8.2-27.4)	20.0(2.6-69.9)	12.6(7.3-20.9)
Other submissions	36.7(20.3-56.9)	33.3(12.3-64.0)	10.0(1.2-49.8)	5.2(1.6-15.1)	20.0(2.7-69.4)	15.1(9.5-23.1)
Inventory control system*						
Manual	43.2(26-62.5)	50.0(32.3-67.7)	21.1(7.6-46.5)	10.8(4.1-25.5)	4.2(1.6-10.7)	18.0(13.3-23.8)
Computerized	51.0(34.5-67.9)	46.7(29.3-64.8)	78.9 (53.5-92.4)	86.5(71.3-94.3)	95.8(89.3-98.4)	80.5(70.7-85.5)
Do not have it	5.4(1.3-19.3)	3.3(0.5-20.3)	-	2.7(0.4-16.9)	-	1.5(0.5-4.1)
Medicine waste management						
The health unit has a Waste Management Plan*	33.3(17.3-54.4)	33.3(11.0-66.8)	50.0(15.8-84.2)	77.6(65.0-86.6)	60.0(19.9-90.1)	62.6(52.8-71.4)
Specific and suitable place for storage of medicine waste in compliance with standards*	30.0(15.9-49.3)	41.7(16.5-72.0)	20.0(4.3-58.0)	70.7(57.7-81.0)	60.0(19.9-90.1)	57.7(47.8-67)
Specific and suitable place for storage of medicine waste without compliance with standards*	23.3(10.5-44.2)	16.7(4.1-48.6)	20.0(2.8-68.8)	12.1(5.8-23.3)	20.0(2.7-69.4)	15.2(9.4-23.5)
There is no specific place*	46.7(28.3-65.9)	41.7(17.4-70.8)	60.0(22.2-88.7)	13.8(7.0-25.3)	20.0(2.7-69.4)	24.9(17.5-34.1)
Medicine waste collection service from the pharmacy/dispensing unit	90.0(72.8-96.8)	83.3(51.4-95.9)	100.0(100.0-100.0)	93.1(82.9-97.4)	80.0(30.6-97.3)	91.2(84.0-95.3)

* $p < 0.05$.
Source: PNAUM Serviços - Brazil, 2015.

DISCUSSION

Overall, the sanitary situation of medicines in Brazil's state capitals has better indicators than those of pharmacies/medicine dispensing units in primary care in Brazil as a whole, according to Costa et al.[9], whose study revealed the inadequate sanitary conditions to which medicines are subject and the noncompliance with essential requirements for the conservation of their quality[9].

Most pharmacies in primary care units in Brazilian state capitals do not comply with sanitary and land use legislation, which may mean that these facilities did not undergo health inspections by competent bodies. It can also mean that municipal health

surveillance bodies do not have the power to enforce the necessary requirements in activities that handle medicines in public healthcare services.

The results corroborate other works on PA in primary care in Brazil with regard to the sanitary conditions of pharmacies/dispensing units. A study by the World Bank[10] found that, of public health units that have their own storage area, 23.0% did not have adequate storage conditions, with problems like lack of space, dust, mold, and inadequate furniture. Medicine logistics management accounted for about 20.0% of health budgets, which can lead to inefficiency and losses; 70.0% of Brazilian municipalities had none or poor inventory control[10]. The study by Barreto and Guimarães[11] evaluated PA management in municipalities in Bahia and revealed that despite some progress, the facilities dedicated to the storage and dispensing of medicines in health units continued to be the smallest in terms of physical area. Moreover, they did not fulfill essential requirements to preserve the quality of medicines.

When investigating the qualification of pharmaceutical services in Brazilian municipalities, Vieira[12] found that in 81.0% of the cases, inventory control was missing or poor, and in 47.0% of the cases the storage conditions were inadequate. Control bodies like the Federal Audit Court (TCU) and the Federal Accountability Office (CGU) have been pointing out several problems related to the management and conservation of medicines in the SUS, at both municipal and state levels. The Operational Audit Report TCU Basic Pharmacy 2011 found inadequate storage conditions and lack of controls over medicine inventories in several municipal Pharmaceutical Supply Centers (CAF). The main problems were lack of temperature and humidity control, exposure to contaminants, dust and environmental pollution, and the entry of insects, birds and rodents, among others[13].

In 2017, CGU published the Government Program Execution Assessment Report n. 71: Financial Support for the Acquisition and Distribution of Medicines from the Specialized Component of Pharmaceutical Assistance (CEAF), which revealed inadequate storage of at least one medicine in 36.0% of the CAFs of the states; discrepancies between the physical inventory and inventory control systems in 56.0% of the CAF; and medication disposal due to expiration or poor storage conditions in 44.0%[14].

In the present study, the question of temperature and humidity control raises concerns: temperatures above 30°C, mainly in the North and Northeast regions, occur for most of the year and, in these regions, temperature control is available in less than 28.0% of the establishments. Humidity control is present in ever fewer of them. Exposing medicines to temperatures above this can destabilize and impair the formulation. In the capitals as a whole, more than 28.0% of the services did not have a thermometer or observing the temperature was not possible, with almost 50.0% of the establishments in the Northeast. This situation proved to be more unfavorable in primary care in Brazil as a whole. According to Costa et al.[9], about 46.0% of pharmacies/dispensing units did not have a thermometer or observing the temperature was not possible, with more than 71.0% of them in the Northeast. Humidity control did not reach 12.0%[9].

Regarding medicine fractioning, which occurs in about half of the pharmacies/dispensing units in the capitals, the conditions proved to be quite deficient. Specific areas for this purpose and benches covered with smooth and sturdy materials exist only in a small percentage of establishments in all regions; material and equipment for labeling and packaging are also rare. The exception was limited to sharp instruments.

Anvisa regulated this activity with resolutions that establish the necessary technical and operational conditions and requirements for the handling of medicines. Medicines can only be fractionated from their original fractionable packaging, and the work must be done by a pharmacist, in an establishment regulated by health surveillance, with human resources, physical infrastructure, equipment and operational procedures that meet the requirements. Only about 59.0% of the pharmacies/dispensing units in the capitals of Brazil have a head pharmacist. If the supply of fractionated medicines promotes rationality and economy, when carried out inappropriately and with medicines in non-fractionable packaging, it exposes the product to storage conditions in packaging in which its stability has not been tested[15]; inadequate fractionation can change the stability of medicines and, as a consequence, pose risks to users' health[16].

Standards to regulate the visit of representatives of pharmaceutical companies and medicine distributors and distribution of advertising are quite frequently followed in some regions, but very rarely in the Northeast and North, one of the regions where the distribution of free medicine samples had a high frequency, along with the Center-West. Marketing strategies are widely adopted to encourage the consumption of medicines, including with the distribution of free samples. By treating health as an object of consumption, medicine advertising encourages self-medication and often the irrational use of medicines[17,18]. Self-medication increases the direct and indirect risks of medication use, inhibits disease prevention behaviors, diverts resources that could support food and housing initiatives, and opposes the concept of rational use of medication[19]. Anvisa did research to monitor medicine advertising, which revealed that more than 90% of the ads contained irregular information and contribute to the misinformation of both professionals and consumers[20].

Regarding pharmacovigilance, the findings indicate the low organization of these actions in primary care. We found mechanisms for reporting technical complaints/adverse events across all regions, but also great diversity in the destination of the reports and relevant percentages of pharmacists who declared they do not report adverse events.

The thalidomide incident in the 1960s, one of the most impactful cases in the history of world health, boosted pharmacovigilance[21]. In Brazil, the creation of Anvisa, in 1999, encouraged

the launch of the National Pharmacovigilance System. However, after 20 years, this system has not yet been consolidated and has recently been redesigned[22]. Considering the importance of this practice in healthcare systems, in 2011 the Pan American Health Organization prepared Technical Document n. 5 on Good Pharmacovigilance Practices for the Americas[23].

Another indicator of this study revealed deficiencies and even the absence of inventory control. High percentages of computerized systems were found in only two regions. Manual inventory control and even the lack of any control are still frequent, which reveals insufficient investment in equipment and infrastructure, which contributes to the increase in medicine costs, since the lack of control increases losses.

The management of health waste also raises concerns, especially in the North and Northeast regions, although in the group of capitals only a little more than 60.0% had a PGRSS, a mandatory item according to the standard[24].

Residues of medicines, cosmetics and health products have been detected in surface water and groundwater, for human consumption and in the soil, with deposition of sewage sludge. Studies on the toxicological effects of environmental exposure to medicines are not yet conclusive, but it is known that these compounds can interfere with the metabolism of aquatic organisms. A study in the United States found that 24 metropolitan areas were supplied with drinking water contaminated by pharmaceuticals like antibiotics, anticonvulsants, mood stabilizers and hormones[25]. Hormonal residues have produced serious environmental effects like the feminization of fish, and antibiotics disposed of in the environment are of great concern because of their potential to increase bacterial resistance[26].

Another relevant issue is the transport of medicines, an important step in the cycle that influences quality. Sanitary standards establish that transport must take into account the characteristics of the medicines and use equipment that ensure the maintenance of requirements of purity, safety and efficacy of the product and the disinfection and hygiene conditions needed for the preservation of health. According to a document from the São Paulo Regional Pharmacy Council, the activity of transporting products is key in the supply chain because of its economic and political importance and for social integration[27].

In more than half of the capitals of Brazil, problems of insufficient and inadequate transportation of medicines were reported. Transport logistics is a major problem because it is a complex system that demands time, personnel training, routing, vehicle fleet sizing and location[28]. A set of factors can directly interfere with the loss of medicine efficacy.

Dimensions investigated in this study are related to the institutionalization of PA, which, in turn, is related to access to medicines. Souza et al.[29] investigated the structure, funding and investment in qualification of PA in the regions, and the results revealed that only 54.8% of those responsible for the PA declared that there had been expenses with the improvement of structures and only 11.9% reported expenses with personnel training.

Barros et al.[30] identified a strong link between aspects of the institutionalization of PA and access to medicines. Full access was greater when there was a computer system for PA management, protocols for storage, distribution and delivery of medicines and some type of qualification or training of PA professionals[30].

This study has some limitations, like the fact that we only investigated pharmacies/dispensing units at the primary level of healthcare, in which medicines from the Basic Component and part of the Strategic Component are offered, like the treatment of tuberculosis, leprosy and toxoplasmosis. The sanitary conditions of medicines in PA and other medicines of the Strategic Component, such as those for HIV/AIDS and hepatitis C, generally offered in pharmacies of reference services, were not investigated. Additionally, we could not study the sanitary situation of medicines in state pharmaceutical centers, important places where supplies from the three components of PA are received, stored and distributed.

Other limitations are related to the exploratory nature of the research. The determinants of the health situation and its shortcomings were not investigated, or how the problems of medicine transportation in the Southeast were equated, nor greater detailing of the initiatives in relation to pharmacovigilance. The exploratory study seeks an approximation to the reality of the object of investigation, on which we do not have much information yet. According to Triviños[31], this type of study enables researchers to increase their experience on a particular problem or phenomenon and contributes to identifying other research questions that can, in turn, drive more accurate research in the future. The purpose of PNAUM was to provide a baseline for future research.

CONCLUSIONS

The findings of this study raise some concern because we may say that they have indirectly evaluated health surveillance work and identified weaknesses in this component of the SUS in primary care services in Brazil. It revealed shortcomings in all dimensions we studied: shortage of pharmaceutical professionals; precarious environmental conditions in pharmacies; incipient adoption of technical procedures for the conservation, handling and distribution of medicines; weaknesses in pharmacovigilance and waste management actions, among others.

The results corroborate other studies that identified gaps between the legally required PA of primary care networks and the real PA in the services, where problems were found ranging from the poor conservation of medicines in the storage process to the shortage of essential medicines, and the absence of guidance for their proper use.

The results of this study indicate that pharmacies/dispensing units face management, infrastructure, organization and quality problems, which can compromise the quality of the supplies

(medicines and health products) offered by SUS, in addition to increasing the cost of to the public system. The variables studied here can support the improvement of health policies related to PA in SUS. The results suggest some progress, although still below what is necessary, especially in the capitals of the North and Northeast regions, which were more deficient. In this sense, management can be improved with investment in the training of human resources and increased funding for programs like the QUALIFAR-SUS, aimed at improving the storage of thermolabile drugs and the computerization of primary care PA, as well as the expansion of programs like "Farmácia de Todos", in Minas Gerais, and "Farmácias da Bahia", which are fundamental to make medication and PA policies more effective.

Anvisa has been playing its role as coordinator of the National Health Surveillance System (SNVS) by preparing and improving the regulation of medicines. However, in public pharmacies of primary care, the current health regulations, designed to prevent unwanted changes in pharmaceutical formulations and thus protect the health of the population, have been disregarded, to a greater or lesser extent, depending on the region analyzed. Additionally, the actions of health surveillance inspection—incumbent on the subnational levels of the SNVS—, which should not distinguish public and private pharmaceutical services, are still not very effective. Knowing the health status of medicines from other levels of care is relevant, both in pharmacies of reference services and in state pharmaceutical centers, which is why further research is recommended.

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Authors' Contribution

Pereira MT, Costa EA – Conception, planning (study design), acquisition, analysis, interpretation of data and writing of the manuscript. All authors approved the final draft of the manuscript.

Disclosures

The authors report that there is no potential conflict of interest with peers and institutions, nor political or financial conflicts in this study.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.