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Pharmaceutical supply centers of Rio Grande do Sul

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Abstract

Objectives: The objective of this study is to depict the Pharmaceutical Supply Centers (PSCs) of municipalities in Rio Grande do Sul, regarding the structure, the processes carried out and the results obtained. **Methods**: The sample consists of a total of 29 municipalities. Data collection took place through visits to the PSC of these municipalities and on-site interviews, document analysis, direct observation, and the use of a questionnaire developed with questions drawn from the literature review. **Results:** The results showed that the daily control of temperature and humidity is recorded in 84.6% and 76.9% of the PSCs, respectively, and all those that have a refrigerator for thermolabile, control these parameters. Most centers that store controlled drugs (Portaria 344/98) use a separate room with a key (75.0%). Upon receipt of the medicines, an inspection is carried out regarding the validity and necessary documentation (invoice, for example) in 92.3% of the places. All PSCs used a computerized system for stock control, in six (23.1%) there was an accumulation of stock resulting from overestimated demand, resources used from the previous year, excess purchases or seasonality and 88.5% carry inventory. For them to function legally, some documentation is needed, such as a health permit, which only 26.9% of the PSCs claimed to have. **Conclusion:** In the evaluation of the quality of the storage stage of the AF, through the components: structure, processes, and results, partially positive results were observed about the technical and administrative recommendations for the PSCs, requiring improvements in some aspects.

Keywords: pharmaceutical services, pharmaceutical supply centers, evaluation

Centrais de Abastecimento Farmacêutico do Rio Grande do Sul

Resumo

Objetivos: O objetivo deste estudo foi descrever as Centrais de Abastecimento Farmacêutico (CAFs) de municípios do Rio Grande do Sul, quanto à estrutura, aos processos realizados e os resultados obtidos. **Métodos:** Trata-se de um estudo de caráter transversal e descritivo cuja coleta de dados deu-se por visitas às CAFs de 29 municípios. Além de entrevistas *in loco,* utilizando um questionário elaborado a partir da revisão da literatura, realizou-se análise de documentos e observação direta da estrutura e das condições de armazenamento. **Resultados:** Os resultados mostram que o registro do controle diário de temperatura e umidade era realizado em 84,6% e 76,9% das CAFs respectivamente e todas aquelas que possuíam refrigerador para os termolábeis, realizavam o controle destes parâmetros. A maioria das centrais que armazenavam medicamentos sujeitos a controle especial utilizavam uma sala separada e com chave (75,0%). No recebimento dos medicamentos, era realizada a inspeção referente à validade e documentações necessárias (nota fiscal, por exemplo) em 92,3% dos locais. Todas as CAFs utilizavam sistema informatizado para controle de estoque, em seis (23,1%) havia um acúmulo de estoque resultante de demanda superestimada, de recursos aproveitados do ano anterior, excesso de compra ou sazonalidade e 88,5% realizavam inventário. Para que funcionem dentro da legalidade são necessárias algumas documentações como alvará sanitário, que apenas 26,9% das CAFs afirmaram possuir. **Conclusão:** Na avaliação da etapa de armazenamento da AF, por meio dos componentes: estrutura, processos e resultados, observou-se resultados parcialmente positivos em relação às recomendações técnicas e administrativas para as CAFs, necessitando de melhorias em alguns quesitos.

Palavras-chave: assistência farmacêutica, centrais de abastecimento farmacêutico, avaliação

Introduction

Through the National Medications Policy (*Política Nacional de Medicamentos*, PNM) and the National Pharmaceutical Assistance Policy (*Política Nacional de Assistência Farmacêutica*, PNAF), it is understood that Pharmaceutical Assistance (PhA) is a set of actions regarding disease prevention and health recovery, promotion and protection, having medications as essential ingredients. PhA is systemic and should work through a cycle, consisting in the stages of selection, scheduling, acquisition, storage, distribution and use, which includes dispensing and prescription. This cycle is continuous and only considered complete if the previous stage is carried out with excellence[1,2].

Functionality of the stages in this cycle should happen harmoniously, as incorrect or unplanned performance of any stage will harm the next. For example, nonexistence or deficiency of stock scheduling and control might compromise the subsequent stages, as it was carried out without the use of parameters that make it possible to measure the real need of the population. In this case, medications are purchased either in amounts greater than necessary, leading to the disposal of those with an expired validity date, or in smaller amounts, resulting in shortages. As a consequence, public agencies will have high health-related expenses and the population will be neglected and/or at risk. Another situation that can lead to loss of medications is failures in the storage stage: inadequate conditions and absent or deficient inventory control, reflecting the non-investment in infrastructure and human resources at the Pharmaceutical Supply Centers (PSCs)[3].

The PSC is responsible for the storage, stock and distribution of medications, and should ensure their quality through care with parameters related to stability. In Brazil, this nomenclature is used to differentiate terms such as depositories, storerooms and warehouses that are used for the storage of other materials and are not suitable when it comes to medications[4]. Through resolutions such as RDC No. 304, of September 17th, 2019, the Ministry of Health imposes requirements for these places, such as offering environmental conditions that will guarantee temperature, humidity, luminosity, ventilation within standard pre-established values and strict hygiene, as the area should be free of dust and dirt and the physical facilities must also be made of specific materials[5].

When analyzing data from research studies that evaluated PSCs regarding infrastructure and storage, it is noticed that there is almost no studies dealing exclusively with these topics; the majority evaluate the PhA in general. Such studies show that Brazilian municipalities are far from meeting the requirements imposed by the legislation and are not able to provide the necessary safety, efficacy and quality to medications, reinforcing the idea that PhA is not a priority[6,7].

A study that analyzed MERCOSUR medication policies shows a waste of around 70% of spending on drugs, related to inadequate prices, quality/storage and expired validity dates, among others[8]. Vieira (2008) observed deficiencies in pharmaceutical services in 90% of the municipalities participating in the research, with absent or deficient stock control and inadequate storage conditions as the categories that presented the highest frequencies, 71% and 39% respectively, finding expired medications in 13%[3]. These problems persist over the years, as evidenced by the 2017 report by the Comptroller General of the Union (CGU), which estimated a waste of 16 million reais due to expired validity and incorrect storage of medications[9].

The results of the National Survey on Access, Use and Promotion of Rational Medication Use (*Pesquisa Nacional sobre Acesso, Utilização e Promoção do Uso Racional de Medicamentos*, PNAUM), carried out in 2015, corroborate the previous studies already mentioned and demonstrate the need for investment in the PhA stages, with emphasis on storage. The data related to the storage conditions are worrying due to the climate in the country, with high temperature and humidity in most of the territory. Quality and effectiveness of a medication are directly related to its stability, which must be guaranteed through proper storage and handling[10].

Considering the data presented above and the importance of the storage stage being carried out correctly and with adequate infrastructure, this paper aimed at describing the PSCs from the municipalities of the state of Rio Grande do Sul, with regard to structure, process and result.

Methods

This is a cross-sectional and descriptive study that used data from the project entitled "Evaluation of the Organization of Pharmaceutical Assistance in Primary Care in municipalities of the state of Rio Grande do Sul: Structure, Process and Result", funded by PPSUS 2017 Public Notice. Details of the project methodology can be accessed in another publication by the research group[11].

To comprise the sample, 18 municipalities where the regional health coordination offices of the Rio Grande do Sul State Health Department and those with more than 100,000 inhabitants were considered, resulting in 29 municipalities and representing more than 50% of the state's population.

Data collection was carried out through on-site interviews, in addition to documentary analysis and direct observation of the structure and storage conditions. The questionnaire used in the interview was prepared based on a literature review and structured by grouping questions about structure, processes and results, as in the study carried out by the Ministry of Health and the Pan American Health Organization[12].

In the interviews, the Epicollect app was used, which allows capturing data through text-entry forms, photographs and videos, and allows exporting the database to an Excel file. The interviews took place after a prior appointment, made through telephone contact and/or email with those responsible for pharmaceutical assistance in each municipality, and were carried out in person by an outsourced company.

Data collection took place from January to March of 2020 and all participants signed the free and informed consent form. The research was approved by the Ethics Committee of the Council for Research, Teaching and Extension of the Federal University of Rio Grande do Sul (*Universidade Federal do Rio Grande do Sul*, UFRGS) through opinion number 2,437,516.

Results

Of the 29 municipalities visited, those that had a Pharmaceutical Supply Center (PSC) totaled 26.

Some of the data related to structure, process and results are presented in Table 1. In relation to the disposition of medications in the PSCs, 96.1% (25) state that they are away from the floor, in 88.5% (23) away from the wall, and 92.3% (24) have pallets for storage. As for the maximum box stacking recommended by the manufacturer, only four (15.4%) centers do not comply with the recommendation. In relation to the arrangement of medications on the shelves, in 80.7% (21) of these places it is in alphabetical order and, in 11.54% (3), by pharmaceutical form. To keep the rooms adequately heated, 88.5% (23) of the centers had air conditioning, 61.5% (16) used windows and/or 19.2% (5) resorted to fans. Daily temperature and humidity control was performed in 84.6% (22) and 76.9% (20) of the PSCs, respectively. Those that stored thermolabile products also carried out daily temperature control of the equipment used to store them.

Most of the centers that stored medications subjected to special control used a separate locked room (75.0%), and all those had an exclusive place for this purpose had a pharmacist in charge of the sector. To ensure security and prevent theft and burglary, the PSCs had alarm systems, a watchman, locked storage locations, security cameras or access control for employees and visitors.

As for the structure made available to the employees, 73.1% pf the PSCs offered exclusive toilets, 53.8% had drinking fountains, and 88.5% the PSCs answered that they had a place for meals and another for the storage of belongings.

In order for a medication to be properly received, it is indispensable to guarantee good quality transportation. Fifteen PSCs (57.6%) validated the vehicles that arrived with the products before receiving them. In 23 PSCs (88.5%), receiving medications is the pharmacist's responsibility. At this moment, a physical inspection should be carried out regarding the amount, quality, validity and documentation of the materials. In 100% of the locations, medications and supplies were counted upon receipt; only in one of the places was the macroscopic quality check not performed. As for the inspection regarding validity and necessary documentation (invoice, for example), they were carried out in 92.3%. If there were discrepancies in the amounts to be received, 46.1% of the PSCs did not receive them.

In addition to the processes shown in Table 1, 42.3% (11) of the PSCs worked with a pre-established date for receiving medications. Considering the last three months, the PSCs suffered from delays in delivery of the medications by suppliers/distributors and the waiting time for receiving these materials is very unstable, varying from 7 days to 60 months. In 23.1% (6) of the PSCs there was accumulation of inventory resulting from overestimated demand, resources used from the previous year, excess purchases or seasonality. So that items do not have their validity dates expired on the shelves, all locations had a computerized system for inventory control and used the "First Expiring, First Out (FEFO)" rule.

Carrying out the inventory is the pharmacist's responsibility in 73.9% (17) of the centers. In the majority, performance periodicity is annual and, when divergences were found, only 4.3% (1) did not justify the error. In case of technical complaints such as broken, missing, damp or opened packages, 69.2% (18) record these events; 57.7% (15) notify the quality deviation directly to the industry (26.9%; 7) and/or through the ANVISA notification system (34.6%; 9). For the correct disposal of unusable medications, 57.7% (15) of the PSCs had a waste management plan.

For the PSCs to function within legal standards, some documents are required by the surveillance agencies. The health permit issued by health surveillance was present in 26.9% (7), the fire protection permit in 42.3% (11) and the location permit/license in 26.9% (7) of the PSCs. All PSCs had a regularity certificate issued by the Regional Pharmacy Council. Standard Operating Procedures (SOPs) were present in 73.1% (19) of the PSCs, whereas the Good Storage Practices Manual was present in 42.3% (11) of them.

Discussion

For PSCs to perform their function of safeguarding medication efficacy, safety and quality, it is necessary that the PhA stages be carried out efficiently, and they should meet the normative requirements established by the supervisory bodies and some basic criteria regarding ambience conditions, hygiene, equipment and security. This study showed that more than 50% of the municipalities included in the research sample were in accordance with the recommendations set forth by the health surveillance bodies and the Good Storage Practices.

Losses of medications due to expired validity dates or their deterioration can be a consequence of the municipalities' difficulty implementing good storage practices (GSPs), or even to non-standardization of processes carried out in the PSCs[13]. Castro (2014), in a study carried out in the municipality of Aracaju in Sergipe[14], and Perez Junior (2018) in the Vale do Jurumin region in São Paulo[15], evaluated the restructuring and analysis of PhA management, respectively, contributing positive data related to the storage stage, such as adequate conditions for it, unlike most studies, which showed weaknesses in this stage.

Table 1. Evaluation of Pharmaceutical Supply Centers in municipalities from RS in terms of structure, processes carried out and results obtained (N = 26).

Structure	N (%)	Process	N (%)	Results	N (%)
Exclusive place to store thermolabile products	17 (65.4)	Performs inventory	23 (88.5)	Delay in receiving medications	25 (96.1)
Exclusive place to store controlled medications (Ord. No. 344/98)	20 (76.9)	Conducts a survey of expired. broken/ leaked medications	24 (92.3)	Lack of medications	22 (84.6)
Exclusive place to store expired. broken/ leaked medications	22 (84.6)	Performs validity inspection upon receipt	24 (92.3)	-	-
Power generator	3 (11.5)	-	-	-	-
Air conditioning	22 (88.5)	-	-	-	-
Protection from direct sunlight exposure on medications	26 (100)	-	-	-	-

High temperature and humidity can accelerate chemical, biological and physical reactions, causing the decomposition of products, altering their stability and, consequently, their shelf life, in addition to changes in consistency, flavor and odor, among others. Hence the importance of keeping the products in the conditions recommended by the manufacturers, making it necessary to have thermo-hygrometers in the storage areas, to carry out daily controls and recording of these parameters, in addition to allowing the correction of possible irregularities in them[16].

The findings of this study regarding the recording and daily control of temperature and humidity are positive. Absence of these records was observed in a study carried out in a PSC from a municipality in Rio Grande do Norte[16]. In another, which evaluated the sanitary situation of medications in the Basic Health Units (BHUs) from municipalities throughout Brazil, it was found that only 26.4% and 10.3% of the BHUs had thermometers and hygrometers, respectively, for daily controls[10]. It is to be expected that, in the PSCs, the structure and processes related to the storage of medications are more adequate than in BHUs, due to the specificity of the activities carried out.

The form of ventilation chosen for the storage area is also important to maintain ideal environmental conditions. In this regard, the use of air conditioning is recommended[17]. In a study that evaluated the storage conditions of medications in BHU pharmacies and in a PSC from the Belo Horizonte Northeast Health District, absence of air conditioning was noticed. Only 7 sites out of 20 analyzed had windows that provided good ventilation[18]. Of the 23 primary health care units evaluated in a municipality from Bahia, only 3 had temperature control equipment[6]. When analyzing the results of this paper regarding the chosen form of ventilation, it is notable that the majority (88.5%) complies with what is recommended by the GSPs, as they have air conditioning.

Through the data presented, it is possible to observe that, in relation to the structure and processes carried out, the PSCs present good results. For example, all the PSCs analyzed have a computerized system for inventory control and use the "FEFO" rule.

When qualifying the pharmaceutical services of 597 Brazilian municipalities, Vieira (2008) observed that inventory control was deficient or absent in 71.4% and that 13% had medications with expired validity dates[3]. However, this data is from thirteen years ago. Since then, PhA has been advancing in Brazil due to public policies. In addition to that, the study sample only included those with less than 500,000 inhabitants. There may be a mismatch between more or less developed municipalities, as those with larger populations have a more complex network of health and PhA services, and become a reference for small and medium-sized municipalities.

In a study carried out in 2014[19] when evaluating PhA in the 15th Paraná Health Region, Volpato and Padial found that there was stock control in 96% of the places, that this control was computerized in 73.9% and that 43.5% of the municipalities did not have medications with their validity dates expiring in the month when the research was carried out.

Souza et al. (2020)[20] show the importance of stock control, as the success of the other PhA stages such as scheduling, acquisition and distribution is guaranteed through this action. Absence or deficiency of control increases the probability of a stock overlap and/or shortage; therefore, its performance avoids lack or waste/loss of medications. The data found in the aforementioned studies confirm the importance of carrying out this control.

Inventory control is carried out to verify the amounts of products in stock, in order to verify that the physical count coincides with the one recorded in the inventory control systems[4]; therefore, it is of major importance for an efficient stock control, as it allows verifying divergences in it. Most of the papers found in the literature only show whether the locations had inventory control, but do not detail how inventory is made in this control. A study carried out in Fortaleza, Ceará, evaluated the quality of PhA in the public network and, regarding the performance inventory controls in the pharmacies included in the study, a mean variation percentage of 90.6% was found in the amounts recorded in the system for the physical count, showing that, although the locations have inventory control, it is inefficient[21]. Of the 26 PSCs evaluated in the current study, 23 claimed to carry out an inventory; however, this finding does not guarantee that inventory control is efficient in these locations, as efficiency was not an evaluated parameter.

As for the Results section, it is possible to observe the high percentage of PSCs that suffered from a delay in receiving the medications and, consequently, the shortage for the population. Most of the times, a consequence of lack of financial resources, lack of raw material in the manufacturing laboratories, delay in delivery by suppliers or even due to the long period between the scheduling, purchase and delivery stages to be carried out. The shortage time suffered by the PSCs in this study was very variable. A study that evaluated five Brazilian states showed that municipal and state PSCs also suffered from lack of medication during a mean period of 74 and 128 days, respectively[12]. Another study carried out in the state of Ceará showed that the municipal PSC of Fortaleza was out of stock for a mean time of 55 days: in that same PSC, unavailability of 13.0% of the medications contained in the municipal list was observed[21].

The storage stage can be divided into several smaller activity stages, in addition to depending on other processes that precede it. Therefore, the preparation and availability of SOPs to those responsible for carrying out the activities guarantees their standardization, assisting in their execution so that the stage objectives are achieved[22]. Among the centers evaluated in this study, 73.1% claimed to use SOPs for this purpose. This data can be associated with the good results found in the other evaluated items. A study that diagnosed PhA in the municipalities of the 31st Regional Health Board of Bahia reports that there were no norms or SOPs in the storage locations and that 44% of the municipalities did not have a suitable place for this purpose[23].

Expired, contaminated or interdicted products present a potential risk to public health and the environment; these products are usually the result of inappropriate PhA management (inadequate storage, erroneous scheduling and acquisition, etc.)[24]. The correct destination of these products can be guaranteed through the Health Waste Management Plan (*Plano de Gerenciamento de Resíduos de Saúde*, PGRSS). Of the places observed in this study, almost 60% asserted having this plan. In Currais Novos, Rio Grande do Norte, the PSC assessed had PGRSS, where periodically a responsible company carried out waste collection; however, the place devoted to unusable products was not correctly identified, allowing for the occurrence of medication errors[16]. On the contrary, 84.6% of the places visited in this study contained a unique and identified place. In turn, the PNAUM evidences that less than 50% of the BHUs that stored medications contained a PGRSS and an exclusive place for the storage of these products[10].

Among the study limitations, we can mention that most of the municipalities included were characterized as medium and large and that the questionnaire emphasized the Structure and Process components to the detriment of the Results.

Conclusion

The evaluation of the PhA storage stage, through the components of structure, processes and results allowed observing advances in relation to the panorama of the PSCs presented by other studies. However, the results were partially positive regarding technical and administrative recommendations for the PSCs. For example, the low frequency of performing inventory controls and the absence of certificates from the health and safety control body draw the attentions, items necessary to guarantee services with due effectiveness, safety and quality to the population.

This paper contributes to better understanding the PSCs in Rio Grande do Sul and can be used as a reference for future studies.

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Collaborators

JWV, DP, RAB, SMG and IH: conception, design, data collection and relevant critical review of the intellectual content.

EAR, TAA and IH: data analysis and interpretation, writing of the article and relevant critical review of the intellectual content.

Conflict Of Interest Statement

The authors declare no conflicts of interest in relation to this article.

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