

PHARMACEUTICAL INSPECTION IN TEN DECENTRALIZED BASES OF THE URGENCY MOBILE CARE SERVICE (SAMU) IN SOUTHWEST PARANÁ

ABSTRACT

Abstract: The purpose of storage is to ensure that the pharmacological and physico-chemical properties of the medicinal products are preserved during storage on the shelf, or wherever stored, until the patient's use. **Objective:** This study aimed to establish Pharmaceutical Inspection in the ten decentralized bases of the southwestern region of Paraná, monitoring the storage of medicines in the warehouse and ambulances. **Methods:** A documentary analysis was conducted to evaluate the result of the initiation of the inspections carried out from May 2016 to May 2017. The data from the documents produced in the inspections were tabulated in Excel spreadsheet with the aid of elements of the descriptive statistics and obeying the questions of the inspection script. **Results:** Potential problems were found in relation to medicines, such as the presence of overdue lots in the warehouse and in the medicine cases in the ambulances. **Conclusions:** The study showed the importance of Pharmaceutical Care in the prehospital environment. Studies on the performance of the pharmacist in the prehospital environment are scarce, however, important to guide the activities of this professional.

INTRODUCTION

For the effective realization of Pharmaceutical Assistance in the context of the Unified Health System (SUS), it is essential to have as a basic principle the Pharmacy Assistance Cycle, which is a system consisting of the selection, programming, acquisition, storage, distribution and dispensation stages of medicines.^{1,2}

As in the hospital environment, the prehospital environment also requires Pharmaceutical Assistance to ensure the proper functioning of the activities, and to ensure the quality of care provided to the patient, promoting the safe and rational use of medications and related drugs.²

It is up to Pharmacy to carry out the selection process with the preparation and publication of the list of medicines, to plan and carry out the purchase of medicines considering the needs of the service and the available budget, to manage the different places of storage of medicines, to provide medicines with information support for the professionals who will administer them in emergencies and emergencies. It is this set of activities, which when performed in an appropriate way, enables the medication to fulfill its clinical function.^{3,4}

The purpose of storage is to ensure that the pharmacological and physico-chemical properties of the medicinal products are preserved during storage on the shelf, or wherever stored, until the patient's use. In this sense, care must be taken with temperature and humidity of the environment where they are stored. When improperly stored, the medicines may suffer changes in their properties, which in turn make them unfit for consumption.⁵

SAMU-192 is the main component of the National Policy on Emergency Care, created in Brazil in 2003. It establishes an initiative of the Ministry of Health for prehospital care (HPS) within the scope of the SUS, within the first level of care, aimed at individuals with acute clinical, traumatic or psychiatric conditions, when they occur outside the hospital environment, suffering, sequelae or death.⁶

According to SESA Resolution 358/2015, which "provides for good practices for the operation of public or private prehospital care services, civil and military in the State of Paraná and provides other measures" in Annexes III and IV require the presence of suitcases of medicines and in Annex VIII establishes the minimum criteria for the operation of the Pharmacy. Therefore, in order to ensure quality care, always seeking the patient's well-being, SAMU's Mobile Units of Assistance, have a considerable stock of medicines to support life.⁷

In addition to drug cases, each decentralized base has a stockpile containing a minimum stock of drugs and hospital supplies, enough to supply the demand for care in the region where each Basic and Advanced Support Mobile Unit is located.⁷

Previous research investigating the quality of Hospital Pharmaceutical Care has identified weaknesses in drug storage in both public and private hospitals and at different levels of complexity. These fragilities were more present in the hospitals that adopted as a model of drug supply the collective or the individualized dose, for hospitalized patients, since the method of medication distribution adopted by each hospital is directly related to the quantity and diversity of items that will be under the responsibility of the professionals in the nursing posts.⁸⁻¹¹

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However, we did not find any study in a prehospital environment, whose distribution model is the Collective, reporting problems related to the storage of medications, if we find irregularities in drug storage, mainly regarding their validity.

In this context, the objective of the study was to establish the Pharmaceutical Inspection as the guideline of the SAMU-192 Pharmacy Service in the southwestern region of Paraná and to evaluate the results of the introduction of inspections in the period of one year (May 2016 to May 2017) in the decentralized bases of the SAMU-192, before documentary analysis from pharmaceutical inspections, observing the results in the quality of the storage.

METHODS

A cross-sectional, exploratory-descriptive case study was carried out, with a quantitative approach, where our study target was the Mobile Emergency Care Service (SAMU-192) in the southwest of Paraná.^{12,13} SAMU-192 was implemented in 2012 in the southwestern region of Paraná, and has 10 decentralized bases spread across the 42 municipalities that cover the region, serving about 600 thousand inhabitants, whose staff of professionals that provide assistance in emergency cases is formed by 1 doctor, 1 nurse and 1 life-saving driver in the Advanced Support Units (USA) and 1 nursing technician and 1 life-saving driver in the Basic Support Units (USB).

The process of establishing Pharmaceutical Inspections in the decentralized bases of SAMU-192 in the southwest region was carried out by the pharmaceutical company responsible for the 10 decentralized bases, whose planning was to carry out a monthly visit to each base, from May 2016 to May 2017. Each Pharmaceutical Inspection has completed a form, prepared by the Pharmacy Service, which has 10 issues centered on quality criteria, namely: correct identification of medicines (label, batch, nameplates on the shelves), medicines within the validity period, separation by Brazilian Common Denomination (DCB), cleaning/disinfection and quick access to medicines,⁴ both for the warehouse and ambulances (USA and UBS), aiming at characterizing the inspection process and describing the alterations identified in the storage of medicines, by parameter and by frequency of inspection.¹³

We analyzed the forms from the Pharmaceutical Inspections of the 10 bases, from May 2016 to May 2017, where the data from the documents produced in the inspections were tabulated in an Excel spreadsheet with the aid of elements of the descriptive statistics obeying the questions of the script of inspection.¹³

The project was approved by the Ethics Committee on Research with Human Beings of the International University Center – UNINTER – under Opinion 2.076.273, where the research was conducted in accordance with the provisions of Resolution 466/12 of the National Health Council.

RESULTS AND DISCUSSION

Establishment of the Pharmaceutical Inspection

The process of instituting Pharmaceutical Inspections occurred with the visitation of the responsible pharmacist, according to monthly schedule, in the 10 decentralized bases of the SAMU of the southwestern region of Paraná.

At each inspection, the “Pharmaceutical Inspection Form” was filled out by the responsible pharmacist, with the assistance of the nurse, at the decentralized bases with the presence of an Advanced Support Unit, and with the assistance of the nursing technique, at the decentralized bases with the presence of Basic Support Unit.

The observation of the procedures performed for the inspections of the decentralized bases allowed to know and trace the flow of this activity, as shown in Figure 1.

In the possession of the inspection form, the pharmacist observed the conditions of storage of medicines in the warehouse, verifying the

possible presence of inadequacies such as identification problems, expired expiration dates, not organized by Brazilian Common Denomination (DCB), difficult to access by professionals and/or dirty place.

Following the observation of the medicines in the warehouse, the medication in the ambulance was observed, which should be kept in specific suitcases (medicine bags), which coating is considered ideal for the storage of emergency medications for prehospital use.⁷ When some irregularities were found in the storage of medications, these were discussed with the nursing professionals.

During the inspections, careful attention was given to the date of validity of the medicines available in all the places investigated, since until that moment, many medicines expired and for lack of an inspection routine, they remained in the warehouse of the decentralized base and in the case present in the ambulance. Medications with expired validity were immediately withdrawn, since it has long been known that the use of overdue medications can lead to serious damages with poisoning, poisoning and even death of the users.¹⁴

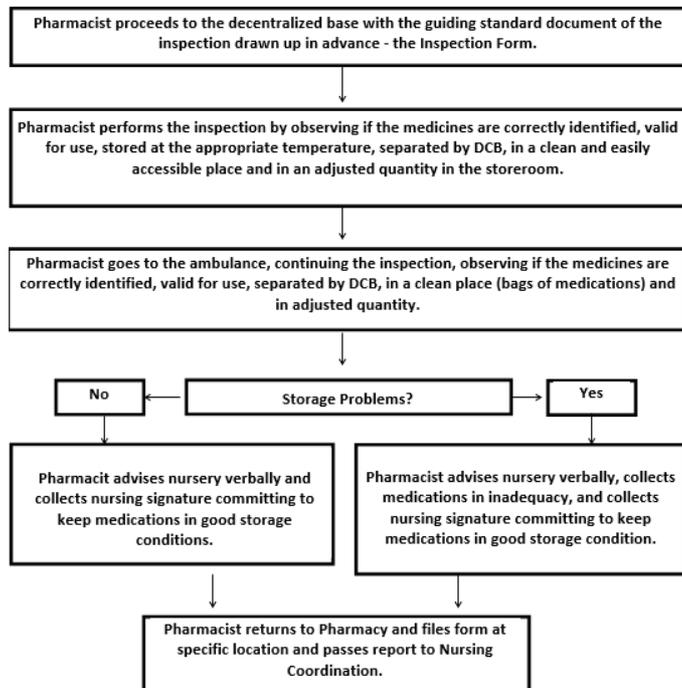


Figure 1. Flowchart of the pharmaceutical inspection process on a decentralized basis focused on the monitoring of drug storage.

Previous studies have shown that the approximation and greater link between nursing professionals and the pharmacist contribute to positive dialogue and significant improvement in pharmaceutical orientation, resulting in an improvement in the quality of storage. What is expected as a product of this approach goes beyond the identification of problems related to the storage of medicines but seeks to establish trust between different professional categories responsible for the activity and continuity of the service.¹⁵⁻¹⁷

According to Reeder & Mutinick¹⁸ and Rosa et al,¹⁹ the pharmacist must have active participation within the hospital community, exercising judiciously the activities necessary for Pharmacy Assistance. The active participation of pharmacists in the Hospital Pharmacy Assistance, while requiring the execution of a list of activities related to access to quality medicines, recognizes that these activities require multiprofessional support.

In this way, it can be affirmed that the introduction of the Pharmaceutical Inspection in the decentralized bases allowed an improvement in the quality of the service, making possible a greater contribution of the pharmaceutical orientation to the promotion of the rational and safe use of medicines.

Results of one year of Pharmaceutical Inspections

We analyzed the documents produced by 99 inspections carried out from May 2016 to May 2017. The item that had the greatest number of storage irregularities was the validity, both in the warehouse, with 28 observations, and in the ambulance, with 26 observations, factor considered because overdue medications lose their efficacy, stability and can cause serious harm to the patient.¹⁴

For the drugs to comply with the expected pharmacological action in their entirety, they must be in appropriate use and within the expiration date. These features are essential for effective treatment and user safety. After the expiration date, overdue drugs should be disposed of and discarded correctly.^{14,20}

Sousa et al., in a study with overdose of acetylsalicylic acid, showed that the drug out of date has changes in its composition, presenting degradation products, which justifies its disuse.²⁰

Table 1 -- Pharmaceutical inspections and the number of inadequacies found in the Warehouse in each decentralized base

Inadequações encontradas no Almoarifado						
	Inspections carried out	Identification	Shelf life	Separation by DCB	Storage conditions	Access
Base 1	12		5			
Base 2	10		5	1		
Base 3	9		4			
Base 4	9		5			
Base 5	11		2			
Base 6	10	1	1	1		1
Base 7	10					
Base 8	10		2			
Base 9	10					
Base 10	8	2	4		2	1
Total	99	3	28	2	2	2

Problems in drug identification were observed 3 times in the warehouse, being 2 times in the same decentralized base, where it lacked standard identification tag in the cabinets. In the ambulances no identification fault was observed. The correct identification of the name and the batch of the medication decreases cases of errors in administration and the replacement of the same in their correct place.²¹

In the ambulance, 1 irregularity was observed in the period of the study, which was like the one observed in the warehouse (Table 2).

The storage conditions in the warehouse were accounted for by 2 inadequacies, which presented with the lack of adequate cleaning of the environment where the medicines were stored, being these on the same decentralized basis (Table 1). While access to medicines, 2 inadequacies were observed on different bases, where it took some time for all professionals to adjust to the standardization of the place where the drugs should be stored (Table 1).

In general, there was an improvement in the quality of drug storage during the months in which the Pharmaceutical Inspections were carried out, mainly to the bases that received the most visits in this period, this shows, as already mentioned, the importance of the active participation of the pharmacist in the Hospital Pharmacy Assistance process and the dialogue among the professionals involved.^{18,19}

Kupas et al, also using a structured process of pharmaceutical inspection, reviewed the transport and storage practices of medications present in advanced support ambulances, assessing possible potential issues to produce harm to patients. They also encountered problems related to expired medications besides labeling problems and different drugs stored in identical bottles.²²

A study carried out in the United Kingdom demonstrated the great benefits that the presence of the pharmacist brings back to the emergency department, such as rationalization of medications at admission, identification of adverse reactions, support with complex drug issues.²³

In Australia, a study also showed how much the pharmacy service in the emergency department is a vital component in the safety contribution of drug use to its patients, with the number of medication errors decreasing by 11% with the presence of Active Pharmaceutical Assistance.²⁴

Table 2 -- Pharmaceutical inspections and the number of inadequacies found in Ambulances in each decentralized base

Inadequações encontradas nas Ambulâncias						
	Inspections carried out	Identification	Shelf life	Separation by DCB	Storage conditions	Access
Base 1	12		5		1	
Base 2	10		6		3	
Base 3	9		3			
Base 4	9		4		1	
Base 5	11		2		5	
Base 6	10				1	
Base 7	10		1		2	
Base 8	10				1	
Base 9	10		2			
Base 10	8		3	1	1	
Total	99		26	1	15	

Another important factor pointed out in the results found in this study was the need for the participation of the pharmacist in the control of hospital infections, because of the 99 visits performed in the 10 bases, in 15 of them the ambulance was presented without performing the routine cleaning and disinfection of the ambulance (Table 2).

It is known that hospital infection is today a serious public health problem, where the hospital and prehospital environment, consisting of air, dust, moisture and inanimate surfaces, may be directly related to the occurrence of hospital infection, after all, microorganisms such as bacteria, fungi and viruses survive in the environment for long periods and the presence of soils may facilitate their proliferation.²⁵

For such microorganisms to be eliminated, it is extremely important to perform the Good Operational Practices related to hospital disinfection, which are described in the SAMU of the Southwest of Paraná, are described in the Technical Operating Standards (NOT) for Cleaning, Disinfection and Sterilization.

The performance of such cleaning processes contributes to Hospital Infection Control, as well as ensuring the health of employees who are in direct and constant contact with this environment.²⁵

CONCLUSION

After this study, it can be affirmed that the introduction of the Pharmaceutical Inspection process was successful and demonstrated the importance of the presence of the pharmacist in the SAMU, contributing for the Pharmaceutical Cycle to occur with quality, consequently contributing to health and preservation of life, which is SAMU's goal vis-à-vis the population.

The study also showed potential safety problems related to drug storage is a very important and complex step and requires the multiprofessional commitment of pharmacy and nursing, as improper storage of medications increases the risk of morbid outcomes for patients due to medication errors.

This study is innovative in the sense of analyzing the prehospital pharmaceutical environment and can be reproduced in other pharmaceutical environments, always seeking to improve the quality of Pharmaceutical Care.

More studies are needed to guide the activity of the pharmaceutical professional in the prehospital environment, which is so scarce in Brazil and in other countries.

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There weren't any financial support.

Conflict of Interests

The authors declare that there are no conflicts of interest

Authors' Contributions

Francieli Molinett was responsible for designing the project, analyzing and interpreting the data, referring it to the ethics committee, writing the article and reviewing the content for final approval of the version to be published.

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PHARMACEUTICAL INSPECTION FORM

Base: _____ Date: __/__/__

Here is an evaluation of the storage conditions of the medicines in the Warehouse:

Correctly identified? YES () NO ()
Valid for use? YES () NO ()
Which ones not? _____
Separated by DCB? YES () NO ()
Stored in a clean place? YES () NO ()
Stored in an easily accessible place? YES () NO ()

Following is an evaluation of the storage conditions of the medicines in the Ambulance:

Correctly identified? YES () NO ()
Valid for use? YES () NO ()
Which ones not? _____
Separated by DCB? YES () NO ()
Stored in an easily accessible place? YES () NO ()

Ambulance cleaning/disinfection conditions:

Performed cleaning/disinfection in the last week? YES () NO ()

Instruction/Suggestion:

Nurse/Tech. Pharmaceutical

Nursing

NOTE: Elaborated by the author