Utilization of parenteral drugs in vials at a pediatric unit of a university hospital

UTILIZAÇÃO DE MEDICAMENTOS PARENTERAIS EM FRASCOS-AMPOLA EM UMA UNIDADE PEDIÁTRICA DE UM HOSPITAL UNIVERSITÁRIO

USO DE MEDICAMENTOS PARENTERALES EN FRASCOS-AMPOLLA EN UN SERVICIO PEDIÁTRICA DE UN HOSPITAL UNIVERSITARIO

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ABSTRACT

This observational study aimed to determine the frequency of utilization of vials containing parenteral medications in a pediatric unit, and to identify nursing team actions related to their preparation and administration. Data were collected from prescription forms and by checking these drugs in the refrigerator and stocks at the unit. Vials were prescribed to 30.8% of patients. Aspects such as: reconstitution, storage, temperature and drug label were observed. Only 6.8% of the drugs had all the information researched in order to evaluate the process of preparation and administration. The correct identification of vials is important for the safe use of medication. Training programs for the healthcare team and the adoption of intravenous therapy guidelines are essential tools to optimize the utilization of parenteral medication.

KEY WORDS

Pharmaceutical preparations. Infusions, parenteral. Nursing, team.

RESUMO

Este estudo observacional determinou a fregüência de utilização de medicamentos parenterais em frascos-ampola em uma unidade pediátrica, e identificou as ações da equipe de enfermagem associadas ao preparo e administração desses medicamentos. Os dados foram coletados por meio da prescrição médica e observação direta dos medicamentos nas geladeiras e armários da unidade. A apresentação em frascos-ampola foi prescrita para 30,8% dos pacientes. Foram observados aspectos quanto à reconstituição, ao armazenamento, à temperatura e à rotulagem dos medicamentos, fatores importantes para utilização segura dos mesmos. As informações pesquisadas para avaliar o processo de preparo e de administração estavam todas presentes em apenas 6,8% dos medicamentos. A identificação correta dos frascosampola é importante para o uso seguro dos medicamentos. O treinamento da equipe de saúde e a adoção de diretrizes de terapia endovenosa são instrumentos essenciais para otimizar o processo de utilização de medicamentos parenterais.

DESCRITORES

Preparações farmacêuticas. Infusões parenterais. Equipe de enfermagem.

RESUMEN

Este estudio de observación determinó la frecuencia para utilizar medicamentos parenterales en frascos-ampolla en una unidad pediátrica, identificando las acciones del equipo de enfermería con respecto a su preparación y administración. Para la recolección de datos se utilizó la prescripción médica y la observación directa de los medicamentos en los frigideres y estantes del servicio. La presentación en frascosampolla fue prescripta en 30.8% de los pacientes. Se observó la reconstitución, el almacenamiento, la temperatura y los rótulos de los medicamentos, factores importantes para asegurar su administración. Las informaciones investigadas para evaluar el proceso de preparación y administración estuvieron presentes en apenas 6.8% de los medicamentos. La correcta identificación de los frascos-ampolla es importante para su administración. El entrenamiento del equipo de salud y la adopción de directrices sobre tratamiento endovenoso son instrumentos esenciales para optimizar la utilización del medicamento parenteral.

DESCRIPTORES

Preparaciones farmacéuticas. Infusiones parenterales. Grupo de enfermería.

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INTRODUCTION

The reutilization of parenteral medication stored in vials is a frequent practice in healthcare services. Professionals usually adopt this practice as an alternative to avoid wasting products, especially due to the high costs of pharmacotherapy⁽¹⁻²⁾.

Medication stored in vials can be destined to single- or multiple-dose applications. The denomination of multipledose vials is only applicable to drugs whose formulations includes preservatives and the manufacturer recommends the reutilization⁽¹⁻²⁾. However, the term multiple-utilization vial is widely used in clinical practice to refer to any vial, provided that it can be used more than once and stored for reutilization. This attitude of healthcare professionals occurs because the pharmaceutical industry does not specify the classification of parenteral drugs stored in vials(1).

The risk of contamination, when a dose is removed from a vial, is influenced by factors like: type of vial, characteristics of the needle or other puncturing device used to retrieve the dose, number of punctures in the stopper, physi-

cal characteristics of the stopper, aseptic technique used by the physician or nursing professional, injection of air in the vial and efficiency of the preservatives (3-4).

The Centers for Disease Control and Pre- without the observation vention – CDC guidelines for infection prevention related to vascular access inform that the extrinsic risk of contamination of multiple dose vials is minimal, but that the consequences of the contamination can result in an infection that can threaten the individual's life. This document notes that preservativefree vials can present a contamination risk if they are punctured several times⁽⁵⁾.

The reutilization of drugs stored in vials without the observation of good administration practices can jeopardize the quality and safety of the parenteral medication usage process. The nursing team should know the differences between single-dose and multiple-dose vials, and the risks associated to inadequate usage⁽⁶⁾.

This study was developed to discover the dimension of the medication reutilization practice in a pediatric unit of a university hospital, and also to identify the actions of the nursing team related to the preparation and application process of vial-administered drugs. The pediatric unit was selected for this investigation due to the importance of intravenous pharmacotherapy to treat chronic and acute diseases in hospitalized children, which can result in wider utilization of parenteral medication in vials.

OBJECTIVES

Determine the frequency of parenteral medication prescription in vials in a pediatric unit and identify the actions of the nursing team associated to the reutilization of these drugs.

METHOD

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usage process.

This is an observational, descriptive, cross-sectional study, which analyzed the utilization of parenteral medication stored in vials in the pediatric inpatient unit of a university hospital.

The pharmaceutical forms of the drugs used in the pediatric unit from September, 2004 to August, 2005 were identified by researching the computerized material management system of the hospital pharmacy.

A pilot study was carried out to test the data collection instrument used to analyze parenteral medication prescriptions. After the pilot test, some adaptations were made. Collection was performed on three days, with a seven-day interval between them. Data collection occurred in September, 2005. Any patient hospitalized on the three collection days was considered as a single patient, grouping the information from the three days for the sake of analysis. The sample was non-probabilistic, covering all prescriptions for

> patients in pharmacotherapy during the research period.

> Patients using pharmacotherapy were identified through the individual distribution system of the hospital pharmacy. The variables related to the parenteral drugs prescribed were collected from copies of the prescriptions. Data related to the process of medication preparation and application was collected from the medical prescriptions available at the pharmacy and through observation in refrigerators and cabinets of the inpatient unit. The drugs were not submitted to any laboratory analy-

sis, and the professionals responsible for their preparation were not identified. Patients were neither interviewed nor identified. Aspects related to the reconstitution, storage, temperature and labeling of the drugs were analyzed. The study was authorized by the institution and approved by the Ethics Committee of the University.

Small-volume parenteral drugs in vials (less than 100 ml) were analyzed for the presence of preservatives. In order to identify the presence of preservatives, the package inserts of the pharmaceutical specialties stored at the hospital's pharmaceutical supply center were consulted. Identification was performed by looking at the section information about the formulation of the package inserts.

Data were inserted into an Excel v.2000 spreadsheet and descriptive statistical analysis was performed, determining absolute and relative frequencies through SPSS 10.0 software.

RESULTS

The pharmaceutical forms of the drugs used at the pediatric unit were solid oral drugs (34.7%), small-volume



parenteral drugs (33.1%), liquid oral drugs (18.1%), semisolid external drugs (4.2%), large-volume parenteral drugs (3.9%) and others (6.0%).

The presentation frequency of prescribed parenteral drugs in the study period was: 111 (49.6%) in ampoules, 69

(30.8%) in vials and 44 (19.6%) in large-volume parenteral bottles.

When observing parenteral drugs in refrigerators, 44 drugs were detected. Table 1 shows the parenteral drugs found in the refrigerators of the pediatric inpatient unit.

Table 1 – Parenteral drugs found in the refrigerators of the pediatric inpatient unit - Belo Horizonte, 2005

Drugs	Frequency	(%)
Ampicillin 500mg Vial	1.0	2.3
Amphotericin B 50mg Vial	3.0	6.8
Cefazolin 1g Vial	1.0	2.3
Cefepime 1g Vial	2.0	4.5
Cefotaxime 1g Vial	5.0	11.4
Ceftriaxone 1g Vial	6.0	13.6
Dexamethasone 10mg Vial	2.0	4.5
Erythropoietin 1000UI Vial	1.0	2.3
Hydrocortisone 100mg Vial	5.0	11.4
NPH Human Insulin 100 UI Vial	2.0	4.5
Regular Human Insulin 100 UI Vial	2.0	4.5
Meropenem 500mg Vial	3.0	6.8
Methylprednisolone 125mg Vial	1.0	2.3
Oxacilin 500mg Vial	2.0	4.5
Penicilin 5.000.000 UI Vial	1.0	2.3
Teicoplanin 200mg Vial	1.0	2.3
Vancomycin 500mg Vial	6.0	13.6
Total	44.0	100.0

Heparin and dexamethasone were the only drugs found being stored at room temperature after the bottles had been opened.

To evaluate the preparation and application process of parenteral medication in vials, the medication to be reutilized

was checked for the following data: identification of the person responsible for the dilution, time of reconstitution, liquid used for reconstitution, volume and date of reconstitution. Only three (6.8%) drugs had all researched data. Table 2 presents the distribution of inadequacy factors related with the preparation of parenteral medication in vials, found in the 41 irregular bottles.

Table 2 - Inadequacies related to the preparation of parenteral medication in vials - Belo Horizonte - 2005

Inadequacy Factor	Frequency	(%)
Absence of the person responsible for the reconstitution	40.0	97.6
Absence of the time of reconstitution	20.0	48.8
Absence of the liquid used for reconstitution	11.0	41.5
Absence of the date of reconstitution	7.0	17.1
Absence of the identification of the volume and liquid for reconstitution.	1.0	26.8

The presence of preservatives was identified in 29.9% of the instructions of small-volume parenteral drugs, while 76.1% did not have the preservative explicitly informed. Of the preservatives found, 68.8% had methylparaben; 18.8% had benzilic alcohol; and 6.2% each for benzethonium chloride and the methylparaben/propylparaben association.

DISCUSSION

In the study, it was observed that the drugs used in the pediatric inpatient unit were presented more often in the parenteral and solid-for-oral-use forms. Parenteral drug administration presents a significant potential for increased risk of iatrogenic diseases, especially bacteremias and

candidemias⁽⁷⁾. In view of the clinical relevance of using parenteral forms, evidenced in different studies, it is essential that they be administered adequately. A tool that contributes to this goal is the adoption of good intravenous therapy practices in healthcare services, in accordance with the recommendations of the National Health Surveillance Agency – *Agência Nacional de Vigilância Sanitária* – *ANVISA*⁽⁸⁾. At the pediatric inpatient unit of the investigated hospital, written procedures were not available to orient the administration of parenteral drugs, as recommended by ANVISA practices. However, there is a manual at the unit with guidelines about the reconstitution, dilution, incompatibilities, physical-chemical and microbiological stability of parenteral drugs. The manual was written by pharmacists in partnership with nurses. It covers a significant num-



ber of drugs and is an adequate instrument for the orientation of parenteral drug preparation and application. A multidisciplinary approach of the medication administration process in the hospital environment is important to evidence and support vulnerable spots, improving healthcare quality and patient safety⁽⁹⁾.

When choosing the drug administration route, the adequacy of the patient's clinical state should be taken into consideration, as well as the pharmacokinetic characteristics of the drug. Oral administration depends on the existence of a pediatric presentation, possibility of absorption through the gastro-intestinal tract that may be hampered and on the clinical situation in which the use of the oral way becomes impossible. If it is not possible to administer drugs orally, these can be administered parenterally⁽¹⁰⁾.

In the analysis of medication presentation, it was identified that vials ranked second, corresponding to 30.8% of the parenteral drugs. Due to the particularities of pediatric pharmacotherapy and the frequency of vial utilization, reutilization tends to be common in pediatric units.

The lack of parenteral medication in adequate presentations is one of the factors that contribute to the reutilization of these drugs, and also to the increasing healthcare costs, especially in pediatric units.

In the pharmaceutical market, most parenteral drugs are not adequate for the pediatric age range. A descriptive study in a pediatric hospital in São Paulo identified that the lack of pediatric presentations increased healthcare costs. None of the 41 drugs found in the prescriptions had pediatric presenta-

tion, incurring in more manipulation and preparation time, number of calculations, risk of contamination and loss of stability $^{(10)}$.

It is considered that the lack of formulations and presentations of drugs directed specifically to the pediatric age range, in addition to being concerning, constitutes a challenge in the quest for quality healthcare for children. The nursing, pharmacist, physician and service management teams should make efforts to change this scenario.

In some hospitals, a strategy created to decrease the impact of this problem refers to the implantation of intravenous mixture preparation centers. The centralization of preparation promotes a more rational utilization of drugs in hospitals.

The practice of reutilizing parenteral drugs in vials is evidenced by the number of drugs found in the refrigerator at the unit, according to Table 1. A North-American study about risks for patient safety notes that the reutilization of parenteral drugs in vials is a common practice in hospitals,

often employed as a strategy to economize and prevent medication waste, but also that the risks inherent to this practice can incur in higher costs. The study emphasizes the relevance of making the healthcare team aware of the risks of transmitting infections with the reutilization of vials, and warns that the risk is increased when the vial is not the multiple-dose type⁽⁶⁾.

Table 2 presents the irregularities detected in the identification process of drugs for reutilization. The presence of the register of all identification items on the bottle labels was rare, found only in three of them, which shows the need for training and making the nursing team aware of the importance of correctly identifying the bottles, assuring the safety of their reutilization. The absence of the following data: time of reconstitution, liquid used for reconstitution, volume and date of reconstitution on the vials destined for reutilization can cause administration errors. This information is also essential for nursing professionals to verify whether the medication is within the time of physical-chemical and microbiological stability⁽¹¹⁾. The nursing team should be informed about the consequences for the

patient and the increase of institutional costs due to the risk of acquiring infections, prolonging the hospitalization time or even incurring in therapeutic failure.

Insulin was found in the refrigerator without adequate identification. The lack of identification of the date the bottle was first opened does not allow for the verification of whether the drug is within the valid dates for utilization. The recommendation of the national manufacturers and the American Diabetes Association is to use the drug for up to

30 days after the bottle was first opened. This period corresponds to the guarantee of efficiency of the preservative system and the preservation of the pharmacological properties⁽¹²⁾.

Heparin and dexamethasone vials were found at room temperature. The manufacturers do not recommend cold storage for these drugs. It should be noted that products stored at room temperature present a higher risk of contamination. Refrigeration can inhibit microbial multiplication. However, depending on the type of medication, the manufacturers can recommend room temperature storage, possibly in order to preserve physical-chemical stability.

The main infection outbreaks in healthcare services related to the utilization of multiple-dose vials published from 1983 to 2002 were identified in a comprehensive and careful literature review⁽¹⁾. A synthesis of the identified outbreaks is presented in Table 3. The analysis of this table yields three journals reporting outbreaks involving heparin, which shows the need for greater surveillance when using this medication in vials in hospital settings.

In the pharmaceutical market, most parenteral drugs are not adequate for the pediatric age range.



Tabela 3 - Infection outbreaks related with the use of multiple-dose vials identified from 1983 to 2002 in a literature review (1) – Belo Horizonte - 2005

Medication	Pathogen	Infection	Patients	Deaths	Evidence
Propofol	E.cloacae	BSI	4	2	Epidemiologic, molecular biology
Propofol	S. marcescens	BSI, wound infection	7	2	Epidemiologic, molecular biology
Propofol	S. aureus	Wound infection	5		Molecular biology
Propofol	S. aureus	BSI	5		Epidemiologic, molecular biology
Propofol	S. aureus, C. albicans, Moraxella, E. agglo merans, S. marcescens	Nosocomial Infection	62		Epidemiologic, molecular biology
Propofol	K. pneumoniae	BSI	4		Microbiologic
Propofol	HCV	Hepatitis C	5		Epidemiologic, molecular biology
Saline	HCV	Hepatitis C	17		Epidemiologic, molecular biology
Saline	A. xylosoxidans	*	7		Microbiologic
Saline	HCV	Hepatitis	2		Molecular biology
Saline/ anesthetic	S. aureus	BSI, abcess	7		Molecular biology
Saline	HBV	Hepatitis	30		Molecular biology
Epoetin alfa	S. liquefaciens	BSI	15		Molecular biology
DT Vaccine	Streptococci, group A	Abcess	2		Microbiologic
DTP Vaccine	Streptococci, group A	Abcess	9		Microbiologic
Heparin	B. cepacia	BSI	14		Epidemiologic, molecular biology
Heparin	Plasmodium falciparum	Malaria	1		Epidemiologic
Heparin/saline solution	HCV	Hepatitis	11		Epidemiologic, molecular biology
Dextrose	E. cloacae / P.aeruginosa	BSI	6	2	Epidemiologic, molecular biology
TPN	C.albicans	BSI	8	3	Molecular biology
Anesthetic	HBV	Hepatitis	2		Epidemiologic, molecular biology
Distilled water	P. pickettii	BSI	7		Microbiologic
Bupivacaine	HBV	Hepatitis	10		Epidemiologic, serotype
Methylpredinisone	S.marcescens	Artritis	10		Microbiologic
Lomeprol	P.aeruginosa	Meningitis	5	2	Molecular biology

BSI = Bloodstream Infection; DT = Diphtheria/Tetanus; DTP = Diphtheria, Tetanus, Pertussis; HBV = Hepatitis B virus; HCV = Hepatitis C virus; NICU = Neonatal Intensive Care Unit; TPN = Total Parenteral Nutrition.

A significant association between the use of multi-dose heparine vials and infections related to vascular access is described in a study about risk factors for bacteremia, with a predominance of gram-negative microorganisms and absence of phlebitis. The patients included in the study had a peripheral intravenous route as the only risk factor⁽¹³⁾. The same study also shows the need to reevaluate the process or reutilization of heparin vials in healthcare services so as to guarantee safe usage.

In the universe of parenteral medication in vials available at the hospital, the presence of preservatives was observed in only 23.9% of the package inserts. For the remaining ones, the information was not explicit. This information is biased, because the preservative may not be present on the package insert but included in the formulation, or have side effects for that specific formulation. The limits of this study could not yield a more in-depth analysis, but it is evident that information about single-use and presence of preservatives is important for adequate and safe utilization of the medication in healthcare services and by patients at home. This information should be clear on the drug label and package insert.

In the orientations for pharmacotechnical development of multiple-dose parenteral drugs, the United States Pharmacopeia recommends that one or more adequate substances be added to drugs stored in multiple-dose bottles in order to prevent the proliferation of microorganisms, regardless of the type of sterilization used. These substances

are named preservatives, and their purpose is to maintain the microbiological stability of the drugs. The absence of preservatives is accepted by the American pharmacopeia when the drug presents antimicrobial activity or its trials recommend against it⁽¹⁴⁾.

The European Pharmacopeia also establishes the addition of preservatives to the formulation of drugs in multiple-dose bottles, and states that it is essential to provide orientations about the necessary precautions for administration and storage, especially after successive retrievals⁽¹⁴⁾.

According to the Brazilian Pharmacopeia, fourth edition (F. BRAS IV), the multiple-dose bottles are made of glass with resistant walls, which, after being filled with either liquid preparations or solid substances for dissolution or suspension, are sealed with a stopper made of another material. The content of these bottles can be removed in a single or in several doses. Differently from other pharmaceutical codes, F. BRAS IV does not regulate the presence of preservatives in the formulation; it only addresses the characteristics of the bottling material (15).

The preservative needs to maintain its antimicrobial activity in the presence of other inputs of the formula; may not decompose during thermal sterilization; and needs to present, preferably, biocide action. The probability of a preservative meeting all these requisites is low. Consequently, the pharmacist developing parenteral drugs is faced with the difficulty to select one or more inputs that can become an effective preservative system along with the components of the formula⁽¹⁶⁾.



The primary objective of the preservative system is the elimination of all microorganisms that can alter the drug stability or may cause infection. In addition to the preservative capabilities, the system cannot present toxic or irritant characteristics⁽¹⁶⁾.

The test of preservative efficiency, stated by the pharmacopeias, is essential to assure the safety of multipledose drugs and evaluate the preservatives' antimicrobial efficiency. It is important to note that, for multi-dose sterile drugs, the preservative shouldt have self-sterilizing capabilities, because the violation of bottle sterility is admitted in function of the opening of the bottle⁽¹⁶⁾.

Multiple-dose bottles need to be capped with rubber stoppers to allow needles to puncture it without destroying or removing the stopper. After the needle is removed from the bottle, the stopper is again sealed, protecting the contents from airborne contamination. The needle can be inserted to retrieve part of the solution for immediate use or to introduce a vehicle or solvent into a powder destined for injection. In any case, sterility should be maintained⁽¹⁴⁾.

Therefore, it is essential that explicit and objective information about the multiple-dose classification be present on the medication label. On the national pharmaceutical market, with the exception of a few immuno-biological drugs and a few types of insulin, most manufacturers do not inform the total number of doses in the bottle. According to international pharmacopeias, the presence of a preservative in the formulation is necessary in order to have the drug considered as multiple-dose. However, in hospital practice, the fact of bottling drugs in vials effectively turns them into multiple-dose bottles. This attitude aims at reducing costs with the reutilization of medication. In pediatric healthcare, due to absence of presentations of specific drugs for this age range, the reutilization practice is more frequent.

Administering parenteral medication is important in the context of infection control actions, especially considering the risk of infection transmission associated with the use of multiple-dose vials. As a strategy to assure safe administering of parenteral drugs, the elaboration of regulations and training on intravenous therapy for healthcare institution professionals is recommended⁽¹⁷⁾.

Training for nursing teams should be based on CDC recommendations for preventing and controlling infections related to vascular access and directly linked to the utilization of parenteral drugs. The following measures are recommended: preparing parenteral fluid medication regularly at the pharmacy, using laminar flow and aseptic techniques; not using turbid solutions, with leaks, cracks, particles or after the valid dates; choosing single-dose drugs; not reutilizing single-dose vial leftovers; storing multiple-dose bottles in the refrigerator if either literature or the manufacturer recommends it; disinfecting the diaphragms of multiple-dose bottles with 70%-alcohol before puncturing; using sterile devices to access the multiple-dose bottle contents and

avoiding touching the diaphragm during the penetration; and finally, discarding the multiple-dose vial if sterility has been jeopardized⁽⁵⁾.

Orientations for the prevention of medication contamination and their importance for infection control and prevention actions are also part of a technical journal of the American Society of Anesthesiology, published in 2004. This institution presents various orientations, several of them based on CDC recommendations: the need to identify the single-dose parenteral drugs without preservatives; prepare medication at the moment of administration, and discard the unused part soon thereafter; always use sterilized syringes and needles; not administer medication from the same syringe into multiple patients, even if the needles are replaced; observe the requisites for the maintenance of the physical-chemical stability of the drugs; discard drugs 24 after preparation, since microorganisms start their exponential stage of microbial growth: follow the manufacturer's recommendations to define the dates for utilization of multiple-dose bottle medications(18).

FINAL CONSIDERATIONS

In this study, most of the drugs destined for reutilization did not have the necessary information about the safety of the preparation and administration of vials, which is important to guarantee the preservation of the therapeutic activity of the drug and reduce the risk of contamination. Although the risk described in literature is small, the consequences for morbidity and mortality can be significant, especially in a population as vulnerable as pediatric patients. In the studied hospital, the importance of this risk is greater in function of the significant prevalence of parenteral drug prescriptions. Therefore, reutilization needs to be performed according to well-established standards. Recommendations by the CDC, American Society of Anesthesiology and ANVISA should serve as references (5,8,18).

Information about the presence of preservatives is essential to support the reutilization of vials. The pharmaceutical industry is another important element to increase the safety in the utilization of such drugs. It should improve the quality of the technical information related to the preparation and administration of parenteral drugs, especially making it clear whether the drug is intended for multipledose usage or not.

Regarding the actions of the nursing team related to the reutilization of drugs in vials, there is an evident need for educational measures and revision of the work processes to make professionals aware of the risks and measures to minimize them. Due to the inadequacies related to the adequate preparation of these drugs found in the studied hospital, adequate labeling and storage are important for safe utilization. Therefore, training the healthcare team, the adoption of CDC recommendations (2002) and good prac-



tices of intravenous therapy utilization in healthcare services are essential instruments to optimize the quality and safety of the parenteral drugs usage process. A better integration among the pharmacy professionals and the nursing team would contribute to optimize the process of using parenteral drugs in hospitals.

Despite its relevance, this study presents methodological limitations, especially related to sample size, restricting the generalization of the results. Therefore this research needs to be replicated in other hospitals with different complexities and regions of the country, so as to discover the magnitude of the problem in the Brazilian reality.

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