







## **COMPLIANCE TO SAFETY BARRIERS IN THE MEDICATION ADMINISTRATION PROCESS IN PEDIATRICS**

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### **ABSTRACT**

**Objective:** to investigate the compliance to safety barriers adopted in the preparation and administration of intravenous drugs in Pediatric and Pediatric Intensive Care Units.

**Method:** exploratory, observational descriptive study, conducted with the nursing team of a pediatric intensive care unit and a pediatric clinic of a large public hospital in Belo Horizonte, from August to November 2017.

**Results:** the sample consisted of 334 opportunities to observe the preparation and administration of medications in pediatric patients. Most of the actions were performed by female professionals, nursing technicians and civil servants. The professionals did not perform all the necessary safety barriers in any of the procedures. The hygiene of the preparation site, disinfection of the ampoule, connection, conference of the drug/dose/route administered with the prescription and double checking of the drugs were those that had the lowest compliance.

**Conclusion:** the study highlights the fragility regarding compliance to safety barriers in the preparation and administration of medicines, resulting in a risk to the safety of hospitalized children. Continued education based on good practice is believed to be an important strategy for security.

**DESCRIPTORS:** Patient safety. Medication systems in the hospital. Pediatrics. Pediatric Nursing. Nursing care. Quality of health care.

**HOW CITED:** Vória JO, Padula BLD, Abreu MNS, Correa AR, Rocha PK Manzo BF. Compliance to safety barriers in the medication administration process in pediatrics. *Texto Contexto Enferm* [Internet]. 2020 [cited YEAR MONTH DAY]; 29:e20180358. Available from: <https://doi.org/10.1590/1980-265X-TCE-2018-0358>

# ADESÃO ÀS BARREIRAS DE SEGURANÇA NO PROCESSO DE ADMINISTRAÇÃO DE MEDICAMENTOS NA PEDIATRIA

## RESUMO

**Objetivo:** investigar a adesão das barreiras de segurança adotadas no preparo e na administração de medicamentos endovenosos em unidades de Pediatria e Terapia Intensiva Pediátrica.

**Método:** estudo descritivo exploratório, observacional, realizado com a equipe de enfermagem de uma Unidade de Terapia Intensiva Pediátrica e uma clínica pediátrica de um hospital público de grande porte de Belo Horizonte, no período de agosto a novembro de 2017.

**Resultados:** a amostra foi constituída por 334 oportunidades de observação do preparo e administração de medicamentos em pacientes pediátricos. A maior parte das ações foi realizada por profissionais do sexo feminino, técnicos de enfermagem e concursados. Em nenhum dos procedimentos o profissional executou todas as barreiras de segurança necessárias. As ações de higienização do local do preparo, desinfecção da ampola, conexão, conferência do medicamento/dose/via administrada com a prescrição e checagem dupla dos medicamentos foram as que tiveram menor adesão.

**Conclusão:** o estudo aponta para a fragilidade quanto à adesão das barreiras de segurança no preparo e na administração de medicamentos, resultando em risco para a segurança das crianças hospitalizadas. Acredita-se que a educação continuada pautada nas boas práticas seja uma estratégia importante para a segurança.

**DESCRITORES:** Segurança do paciente. Sistemas de medicação no hospital. Pediatria. Enfermagem pediátrica. Cuidados de enfermagem. Qualidade da assistência à saúde.

# ADHERENCIA A LAS BARRERAS DE SEGURIDAD EN EL PROCESO DE ADMINISTRACIÓN DE MEDICAMENTOS EN PEDIATRÍA

## RESUMEN

**Objetivo:** investigar la adherencia a las barreras de seguridad adoptadas en la preparación y administración de fármacos intravenosos en unidades de cuidados intensivos pediátricos y pediátricos.

**Método:** estudio exploratorio, observacional, descriptivo realizado con el equipo de enfermería de una Unidad de Cuidados Intensivos Pediátricos y una clínica pediátrica en un gran hospital público de Belo Horizonte, en el período de agosto del nuevo 2017.

**Resultados:** la muestra consistió en 334 oportunidades para observar la preparación y administración de medicamentos en pacientes pediátricos. La mayoría de las acciones fueron realizadas por mujeres profesionales, técnicas de enfermería y candidatas. En ninguno de los procedimientos el profesional realizó todas las barreras de seguridad necesarias. Las acciones de higiene del sitio de preparación, desinfección de la ampolla, conexión, control del medicamento / dosis / vía administrada con la prescripción y doble control de los medicamentos fueron los que tuvieron menor adherencia.

**Conclusión:** el estudio apunta a la fragilidad en la adherencia a las barreras de seguridad en la preparación y administración de medicamentos, lo que se traduce en un riesgo para la seguridad de los niños hospitalizados. Se cree que la educación continua basada en buenas prácticas es una estrategia importante para la seguridad.

**DESCRITORES:** Seguridad del paciente. Sistemas de medicación en el hospital. Pediatria. Enfermería pediátrica. Cuidado de enfermería. Calidad de la asistencia sanitaria.

## INTRODUCTION

The occurrence of adverse events (AEs) in the pediatric professional environment significantly impacts the life of patients and their families, and results in increased morbidity and mortality, hospitalization time and costs for the health system. Among the main AEs are medication errors, defined as a preventable adverse event which occurs at any stage of medication administration, causing harm to the patient. The damage is understood by structural or functional impairment of the body, including disease, injury, suffering, death, disability or dysfunction<sup>1</sup>. Such events may be related to the working conditions and technical-scientific knowledge of professionals<sup>2</sup>.

In order to strengthen patient safety, the World Health Organization (WHO) created the six international goals, including medication administration safety. In Brazil, basic protocols were developed for patient safety, including the safety protocol in the prescription, use and administration of medications, aiming to promote safe practices in the use of medications and minimize the occurrence of medication errors and consequently AEs<sup>3</sup>. Medication errors can be classified as: prescription error, dispensing, omission, schedule, use of unauthorized or deteriorated medications, dosage, presentation, preparation, administration and monitoring<sup>2</sup>.

In this process, the nursing team constitutes an important barrier to error prevention, since it is responsible for the preparation and administration of medications, and may be involved in risk situations at all times. When it comes to the administration of medicines in pediatrics, this situation becomes even more complex, since most of the drug formulations were developed for adults, implying the need to calculate the individual dosage of the child based on their body weight and organ maturity, in addition to having to consider metabolism and excretion, increasing the possibility of errors<sup>4</sup>.

Studies show that the rate of incidents with medication in pediatrics is varied<sup>5</sup>, and that this rate is higher in neonates and most of these incidents can be considered preventable<sup>6</sup>. In this process, most failures occur in the administration stage, with dose, time and omission errors<sup>7-8</sup> being more common. Among the main causes that contribute to the error are ineffective communication, workload and distraction of the nursing team<sup>8</sup>.

During the care of hospitalized pediatric patients, intravenous medications such as sedatives, anesthetics, opioids and antibiotics are frequent, which require continuous surveillance and monitoring to ensure the safety of the preparation and administration of medications. However, what is observed in practice is that, even with the implementation of protocols, some safety barriers in the process of drug administration seem to be neglected by professionals, and may harm the patient, family members, professionals and the health service<sup>9</sup>.

In view of the above, it is denoted that the process of drug administration is fundamentally important for the safety of pediatric patients. Thus, the present study aimed to investigate the support of safety barriers adopted by the team in the preparation and administration of intravenous drugs in Pediatric and Pediatric Intensive Care (PICU) units.

This study may contribute to the identification of potentialities and weaknesses of the process of preparation and administration of medicines in pediatrics, in order to develop strategies to improve care practice and making it safer.

## METHOD

This is an exploratory and observational descriptive study conducted with the nursing team of a PICU and a pediatric hospitalization unit of a large public hospital in Belo Horizonte, Minas Gerais, Brazil. Data collection was performed from August to November 2017. The PICU has ten beds and a ratio of one nursing technician to two beds. While the inpatient unit has 25 beds and the relationship of a nursing technician to five beds. It is important to mention that both units of the study have small spaces exclusively for the preparation of medications, but there is a large flow of people in these places during this time, causing excessive noise and inevitable interruptions.

The study included professionals who, during data collection, had at least three months of experience and prepared and/or administered intravenous drugs in the PICU or in the pediatric hospitalization unit. Observations were excluded in which these activities were not completed, and no observations were made on the preparation and administration of medications in urgent situations or by verbal prescription.

The sample was calculated considering the number of monthly hospitalizations and the number of intravenous drug administrations in pediatric patients daily, in both sectors. An average of sixty intravenous drug administrations per day were found, 20 in pediatrics and forty in PICU. This data was released in the computerized statistical analysis program Open Epi (version 3.01), with a confidence level of 95%. Thus, the sample consisted of 334 observations regarding the preparation and administration of medications, 111 in pediatrics and 223 in the PICU.

The 334 observations of the preparation and administration of intravenous drugs were non-participants, direct and systematic, and performed during day and night shifts during the collection period. The times for the observations were defined considering the periods in which the largest number of procedures were performed. Thus, the observations occurred in three distinct periods: from 8am to 11am, from 2pm to 5pm and from 7pm to 10pm. Data were collected by three trained researchers, using a checklist instrument based on the document of safe practices for medication use<sup>9</sup> and the catheter-related infection prevention guidelines<sup>10</sup>.

The instrument variables were distributed into three groups: sociodemographic characterization of the participants, items related to safety barriers in the preparation and administration of medications.

The sociodemographic characterization of the participants included the following variables: gender (female or male), age (in years), professional category (nursing technician or registered nurse), complementary training (none, complete superior, incomplete superior or specialization), institutional contract status (contract or civil servant), employment sector (PICU or Pediatric Hospitalization Unit), work shift (morning: 7am-1pm, afternoon: 1pm-7pm, daytime: 7am-7pm or night: 7pm-7am), time of operation in the unit (in years), and other employment ties (yes or no). At this stage, the variable participation in training on the preparation and administration of medicines in the last twelve months (yes or no) was inserted.

The variables of safety barriers in preparation were: transcription of the prescription on an identification label of the drug, confirmation of the drug/dose/route with the prescription, hygiene of the place, hands and vials or ampoules, double check in the preparation and interruption of the professional during preparation.

Regarding administration, the following safety items were established: verification of patient data in the prescription with the wristband/bed identification, verification of the drug/dose/route administered with the prescription, identification and disinfection of the connection, verification of the devices from the puncture place to the corresponding infusion pump, checking the patient and guiding the companion on the purpose of the medication, checking the medication in the medical records after administration (considering appropriate when less than five minutes). It was verified if

there was delay in the administration of the drug, for this variable, a delay was considered when the drugs were administered thirty minutes after the prescribed time.

It is important to highlight that for each action observed there were three alternatives: “performed”, “did not perform” and “does not apply”, which should be indicated by the researchers at the time of observation of the procedure.

It is noteworthy that the instrument was analyzed by four nursing assistants with a master’s degree and with experience in the areas of child safety and health regarding the relevance, clarity and agreement of the items, which suggested changes in relation to the clarity of the items. After assuring the adequacy of the instrument, a pilot test was performed with ten observations of the team regarding the preparation and administration of medications, in order to evaluate the applicability of the instrument, thus, the level of agreement among the evaluators was considered higher than 90%.

Regarding the descriptive analysis of the study, absolute and relative frequencies were used for the qualitative variables. Concerning the quantitative variables, after verifying the asymmetry by means of the Shapiro-Wilk test, the data were presented by mean and standard deviation. The software used in the analyses was R (version 3.4.3).

The research complied with the Regulatory Guidelines and Norms for Research Involving Human Beings of the National Health Council (Resolution CNS 466/2012).

## RESULTS

A total of 334 procedures related to the preparation and administration of medications were observed in pediatric patients, performed by 97 nursing team professionals. Among these, the female gender predominated (99.0%) and the mean age was 42.34 years ( $\pm 9.68$ ). More than half work in the PICU (58.8%) and the time of operation in the units had an average of 8.51 years ( $\pm 7.82$ ). The other characteristics are presented in Table 1.

**Table 1** – Characterization of nursing professionals according to sociodemographic variables. Belo Horizonte, Minas Gerais, Brazil, 2017. (n=97)

Variables	n (%)
Sex	
Female	96(99.0)
Male	1(1.0)
Professional category	
Registered nurse	11(11.3)
Nursing technician	86(88.7)
Additional training	
No	57(58.8)
Specialization	10(10.3)
Complete higher	22(22.7)
Incomplete higher	8(8.2)
Institutional contract status	
Civil service examination	30(30.9)
Contract	67(69.1)
Sector	
Pediatric Intensive Care Unit	57(58.8)
Pediatric inpatient unit	40(41.2)

**Table 1 – Cont.**

<b>Variables</b>	<b>n (%)</b>
Work shift	
Morning	4(4.1)
Afternoon	6(6.2)
Daytime	47(48.5)
Night	40(41.2)
Another employment relationship	
No	60(61.9)
Yes	37(38.1)
Training on drug administration in the last 12 months	
No	69 (67.0)
Yes	28(33.0)

Among the 334 procedures related to the preparation and administration of medications in pediatric patients, the majority occurred in the Utip (n = 223; 67.0%) and, regarding the class of medications, antibiotics predominated (n= 160; 47.9%), followed by anesthetics (n= 38; 11.4%), sedatives (n= 36; 10.8%) and analgesics/antipyretics (n= 22; 6.6%).

The study found that 100% of the observations had at least one safety barrier broken with regard to the complete process, including the stages of preparation and administration of the drug. Regarding medication preparation, when evaluated separately, the barriers were not complied with in 81.4% (n=272) of the observations, as shown in Table 2.

**Table 2 – Observation data during the preparation of medications.  
Belo Horizonte, Minas Gerais, Brazil, 2017. (n=334)**

<b>Variables</b>	<b>n (%)</b>
Transcript of the prescription on label	
Did not perform	193(57.8)
Performed	121(36.2)
Medication performed in bolus	21(6.0)
Hygiene of the site of the preparation of medication	
Did not perform	272 (81.4)
Performed	62 (18.6)
Hand hygiene before medication preparation	
Did not perform	153 (45.8)
Performed	181 (54.2)
Drug/dose/route confirmation with prescription data	
Did not perform	42(12.6)
Performed	292(87.4)
Ampoule/bottle disinfection	
Did not perform	214(64.0)
Performed	120(36.0)
Interruption of the professional during the preparation of the medication	
Did not occur	210(62.8)
Occurred	124(37.2)

It is highlighted that during the preparation and administration of medications, no double check was performed. In the administration stage of the medication, barriers were not complied with in 76.3% (n=255) of the observations.

As for the verifying the drug in the prescription immediately after administration (less than five minutes after administration), this was not performed in 54.2% of the observations (n=181). Regarding the time to perform the medications, most were administered without delay, considering administration up to thirty minutes after the prescribed time (n=190; 56.9%), while the medications that suffered a delay totaled 24.3% of the observations (n=81) and the other medications (n=63; 18.9%) were prescribed at medical discretion, so they did not apply to this question. The other data from the observation of the drug administration stage are presented in Table 3.

**Table 3** – Observation data during medication administration.  
Belo Horizonte, Minas Gerais, Brazil, 2017. (n=334)

Variables	n (%)
Patient data confirmation on prescription with wristband/bed identification	
Did not perform	90(26.9)
Performed	239(71.6)
There was no bracelet/bed identification	5(1.5)
Drug/dose/route administered confirmed with prescription	
Did not perform	78(23.4)
Performed	256(76.6)
Checking the patient's name with the companion	
Did not perform	200(59.9)
Performed	6(1.8)
There was no companion	128(38.3)
Guidance given to the patient and companion on the purpose of the drug	
Did not perform	140(41.9)
Performed	67(20.1)
There was no companion	127(38.0)
The connection shows identification of the medicinal product	
Did not perform	255(76.3)
Performed	54(16.2)
There was no connection or the connection was already identified	25(7.5)
Connection disinfection	
Did not perform	211(63.2)
Performed	121(36.2)
There was no connection	2(0.6)
Checking the devices from the administration site to the corresponding infusion pump	
It did not occur	48(14.4)
Occurred	242 (72.5)
Bolus-infused medication	44 (13.1)

## DISCUSSION

Nursing professionals represent the professional category with greater involvement in the medicine preparation and administration process and, consequently, present greater performance in the prevention of complications<sup>11</sup>. Thus, corroborating other studies, it was verified that most procedures were performed by nursing technicians, and females were predominant<sup>12-15</sup>. In this context, it is inferable that even with the recommendation of the Federal Nursing Council on the supervision of registered nurses in relation to these activities by nursing technicians, this procedure has often been delegated to the professional with a technical level of education without any follow-up, which may impair patient safety. Regarding the employment relationship of the professionals evaluated, the findings reinforce another study whose objective was to evaluate the safety culture in three public hospitals in the state of Ceará, which observed that the contracted professionals present the best perception of the safety culture compared to statutory professionals<sup>16</sup>.

The results showed that there was a breach of at least one of the safety barriers in all observation opportunities, with 81.4% of the actions observed during the preparation phase and 76.3% of the time at the time of administration. To avoid or minimize possible errors, the nursing team must pay attention to detect and correct existing flaws regarding the prescription and dispensing of medications, in addition to fully implementing the safety barriers related to these activities<sup>13</sup>. The data showed divergences regarding other studies, which revealed rates of support greater than 80% in care practices developed by the nursing team, justified by a solid safety culture<sup>14-15</sup>. In this sense, a study points out that, to the extent that all health professionals improve the idea of collective responsibility, it will be possible to move towards a more consistent patient safety culture<sup>17</sup>.

Problems with incorrect filling out or non-existence of medication labels were also found in another study in pediatrics, in which 310 (94.9%) observations had non-conformities<sup>18</sup>. In contrast, in the same sector in a hospital in southern Brazil, transcription was performed 173 (90.6%) times, however, the verification of the complete filling of the label was not made clear in the study<sup>19</sup>. The transcription stage contributes to the preparation and administration of medication not only by memorization, predisposing to errors, but as a moment of verification and possible identification of inconsistencies<sup>19</sup>. It is noteworthy that the Brazilian Health Regulatory Agency (ANVISA) recommends considering the "seven correct steps in the administration of medicines", five of which should be described on the label – right patient, right medication, right route, right time and right dose<sup>3</sup>.

The barriers regarding the hygiene of the preparation site of the medication and the disinfection of the ampoule/vial and connections were frequently broken, corroborating an observational study in a pediatric hospital in northeastern Brazil, which showed that 28.4% of the professionals performed previous cleaning of the countertops and 5.8% performed the disinfection of ampoules and vials<sup>18</sup>. An observational study in Malaysia identified 311 (91.2%) errors in the pre-preparation phase, which includes the organization and hygiene of the environment, with the non-hygiene of the site occurring 29 (9.2%) times and the non-disinfection of the vial/ampoule occurred in 307 (98.7%) observations<sup>20</sup>. However, an Australian study aimed at monitoring compliance with disinfection of injectors found a compliance of 60%<sup>21</sup>. The recommendation to use 70% alcohol as a low-cost disinfectant, easy to apply and with a reduction in the microbial load proven even without prior cleaning is highlighted<sup>22</sup>.

Although hand hygiene (HH) was performed in just over half of the observations, its low compliance can be considered, as it is a simple and effective measure to avoid infections, but still neglected by professionals. An observational study in intensive care units in Germany identified adherence of 43% and determined that in twelve hours, for each patient, there are on average 134 opportunities for HH, and the time spent to perform them is 58 minutes<sup>23</sup>. The rationalization of time is a challenge for professionals, however, low compliance to HH cannot continue to be justified



by systemic failures, since it constitutes a fundamental care action and has ethical implications in relation to professional responsibility<sup>24</sup>. Thus, the increase in the association of professionals to this procedure becomes a great challenge for the control of infections related to health care in the various institutions<sup>12</sup>. In this context, one study highlights the importance of implementing actions such as the bloodstream infection prevention bundle related to the central venous catheter in the pediatric and neonatology units, which consists of hand hygiene, maximum barrier precautions, skin preparation with 2% chlorhexidine, insertion site selection and daily review of the need for the catheter. This strategy aims to mitigate the risks of contamination and, consequently, of hospital infection associated with the use of intravenous devices<sup>25</sup>.

During the preparation, it was evidenced that the double check was not performed at any observation opportunity. This data contradicts a study that compared the performance of the double check at various stages of the medication process, in which the rate of participation ranged from 67 to 99%, except during the dose calculation, in which the double check occurred in 30% of the times<sup>26</sup>. Double checking is essential in the medication process, however more studies are needed to evaluate the team's understanding of this theme<sup>5</sup>. Therefore, the training of these professionals and measures such as the use of checklist, protocols for dosing management, flowchart in the administration of medications and potentiating the safety culture are cited as strategies to promote safe medication without dosage errors<sup>27</sup>.

The identification of the connections and infusion equipment of the medications was another problem found in this study. It is emphasized that this barrier is important to avoid errors regarding infusion pathways or drop errors due to incorrect sequences of medications in the venous line. In addition, rapid infusion rates are associated with pain, phlebitis and device loss<sup>20</sup>. An observational study found a higher frequency of errors (23.5%) related to incorrect administration techniques, which include errors in speed and route<sup>28</sup>.

Before administration it is essential to check the name of the drug and explain the purpose of the drug to the companion, since this moment is considered the final safety barrier before the patient has contact with the drug. A study identified as the second and third most common errors the administration of incorrect medication and the wrong patient, respectively. Such failures can be avoided if the professional confirms the patient's name and explains the purpose of the drug to be administered previously to the companion<sup>29</sup>. The involvement of the family/companion in the care provided to the patient is essential, as it makes them allies in the prevention of AE, since, when they are informed, they can alert the professional of some nonconformity<sup>30</sup>. In the case of children, this recommendation is even greater, considering the vulnerability of these patients. It is noteworthy that when the companion is not present, the patient's conference with the data on the identification bracelet is an important strategy for error prevention, considering that correct identification is the first international goal of patient safety<sup>29</sup>.

At the end of the medication administration, the professional must check the procedure performed in the prescription and document it in the medical record. Failure to observe this barrier was also significant in other studies<sup>26,28,30</sup>, which shows that this problem poses a risk for double administration of the same medication and consequently a danger to patient safety.

The findings presented are directly related to the specificities of the evaluated scenario, a fact that limits generalization. In contrast, it was observed that the findings of this study do not differ from most studies found. Therefore, it is necessary that professionals seek good strategies in the preparation and administration of medications, ensuring safe patient care.

## CONCLUSION

The study identified the weakness regarding the compliance of safety barriers in the medicine preparation and administration in the pediatric area, resulting in a risk to children. It is important to highlight that no professional performed all the necessary barriers to ensure the safety of the pediatric patient. The hygiene of the preparation site, disinfection of the ampoule, connection, conference of the drug/dose/route administered with the prescription and double checking of the drugs were those that had the lowest compliance.

In view of the above, the relevance of the results presented is evident, as the training of the nursing team becomes indispensable for the adoption of good practices and, consequently, for patient safety in the medication administration process in pediatric units.

In addition, it is expected that the results will help to motivate the development of studies through the production of scientific evidence that enable best care practices of the nursing team, since there are no national studies with the same theme in pediatrics, as well as for the construction of a safety culture, thus favoring policies and programs in the area of patient safety.

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## **NOTES**

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### **APPROVAL OF ETHICS COMMITTEE IN RESEARCH**

Approved by the Research Ethics Committee of the Municipal Hospital Odilon Behrens-MG, Opinion Nº.1,363,357. Certificate of presentation for ethical assessment CAAE: 47994215.9.0000.5129

### **CONFLICT OF INTEREST**

There is no conflict of interest

### **HISTORICAL**

Received: October 4, 2018

Approved: April 29, 2019

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