

## CONSTRUCT OF THE GLOBAL PATIENT SAFETY CHALLENGE “MEDICATION WITHOUT HARM” IN PEDIATRICS

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**Highlights:** (1) The construct was formed by two dimensions. (2) The dimensions are: checking, registration and information, and reports from patients and family members (3) Professional domains and medications were not included (4) The lack of clarity in the medical prescription was a point of weakness.

PRE-PROOF

(as accepted)

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**ABSTRACT**

This study objective was to define the construct of health professionals working in the pediatric ward, regarding the Global Patient Safety Challenge (DGSP) “Medication without Harm”. This is a cross-sectional and observational study, which included 48 health professionals who work in pediatrics at a university hospital located in the state of São Paulo, Brazil. A questionnaire was applied, which included the characteristics of professionals and the four DGSP domains: Professionals, Medications, Patients and public, Systems, and practices. Factor analysis was performed, with rotation using the *Varimax* method, and *Cronbach's* alpha was calculated. The results revealed the median age of health professionals was 39 years old, with 89.6% being female at birth. Two dimensions were identified: (1) checking, registration, and information; and (2) reports from patients and family members, with *Cronbach's* alpha of 0.8598. It was concluded that health professionals consider it important to inform patients and family members, check solutions labels, understand reports from children and family members, and check the medication dispensed by the pharmacy. The construct did not include the domains of professionals and medications, which may represent weaknesses in the medication process in the pediatric ward studied. These weaknesses refer to training, communication failures, knowledge about previously occurring adverse events, discrepancies between prescriptions, labels, packaging, and keeping medications that are not being used by the patient at the bedside. The clarity of medical prescriptions was also not included in the construct, and its improvement is another important opportunity for improvement.

**Keywords:** Patient safety; pediatrics; factor analysis; medication errors.

**INTRODUCTION**

Patient Safety is one of the six pillars of quality of care and has acquired great importance worldwide for patients, families, managers, and health professionals. In Brazil, the National Patient Safety Program has the objective of contributing to qualifying healthcare in all national health institutions <sup>1</sup>.

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In 2004, the World Health Organization (WHO) launched the Global Alliance for Patient Safety, increasing interest in this issue. This group was the precursor to the WHO Safety and Risk Management Unit, which established the Global Patient Safety Challenge (DGSP), whose objective was to identify “areas of significant risk to patient safety and foster the development of tools and damage prevention strategies”<sup>2</sup>.

Incidents related to healthcare constitute a public health problem and the high risk related to the use of medications must be emphasized. Medication errors cause harm, high costs, and preventable deaths. Given this scenario, the DGSP was established in 2017 with the theme “Medication without Harm”. The goal of this challenge was to reduce serious and preventable harm related to medication use by 50% over the next five years, through the development of safer and more efficient healthcare systems<sup>3</sup>.

Children are particularly vulnerable to events associated with the use of medication, due to several factors, such as varying body weight, different degrees of development, and their level of understanding, among others. Pediatric care is complex, which creates multiple opportunities for failures to occur. Therefore, the safe administration of medication in pediatrics requires differentiated care<sup>4</sup>. This way, mapping barriers, professionals' perceptions, and the creation of a safe environment for this care should be encouraged<sup>5</sup>.

The occurrence of incidents related to healthcare in pediatrics is frequent. In Brazil, the analysis of incidents in the Notivisa system in the year 2023 revealed that the global number of notifications in children under one year of age was comparable to that observed in adults aged 46 to 55 years, demonstrating the relevance of these incidents in the pediatric group<sup>6</sup>. Cooperation between patients, family members, and healthcare professionals can contribute to mitigating incidents and adverse events, which reinforces the importance of teamwork and attention to different perceptions. It is important to highlight that communication failures are often related to security incidents

<sup>7</sup>. The existence of safety protocols mitigates, but does not guarantee, that incidents will not occur, and it is important to investigate other possible associated factors. In this sense, the perception of health professionals working in pediatrics regarding patient safety, which can be identified through a construct obtained by factor analysis, has not been investigated. Factor analysis is a multivariate method that contributes to the identification

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of patterns that summarize a set of observations, simultaneously, through the extraction of factors or dimensions, which are combinations of variables<sup>8</sup>. The identification of this construct can contribute to the knowledge of the factors that, jointly, influence the attitudes and practices of health professionals. In this way, considering that pediatrics has its particularities, knowledge about this construct about safety in the use of medications can contribute to actions aimed at improving patient safety in the pediatric context at the local level, also contributing to public health policies, and can offer elements of comparison for future local and international studies.

This study aimed to define the construct of health professionals working in the pediatric ward, regarding the Global Patient Safety Challenge “Medication without Harm”.

## **MATERIALS AND METHODS**

This is a cross-sectional, quantitative study, with a non-probabilistic sample of health professionals who are permanent staff of a university hospital, located in São Carlos, São Paulo, Brazil. Data collection took place from May 11<sup>th</sup> to September 19<sup>th</sup>, 2023. The hospital admits medium and high complexity. In pediatrics, the profile is of patients with acute conditions, with the majority of hospitalizations being respiratory causes and the prescription system is electronic.

The number of health professionals was provided by the head of the unit, resulting in a target population of 52 professionals. To calculate the minimum non-probability sample size, considering differences between frequencies of 50%, an acceptable error of 0.05, and confidence of 95%, it would be necessary to include at least 43 health professionals.

The inclusion criteria were being a health professional (doctors, nurses, and nursing technicians) and working in the pediatric ward. Health professionals were invited to participate in the study in person, by two researchers, who explained the objective of the study and the time to answer the questionnaire, during the work shift. All shifts and days of the week were covered. The exclusion criteria were those not participating in the medication process in pediatrics.

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A self-answered questionnaire was administered, in person and individually, by two researchers. If participants had any doubts, they were clarified by the researchers. The questionnaire was administered using a tablet. Data collection and management were carried out with the help of the *REDCap* platform. After applying the questionnaire, the data was exported for analysis.

The questionnaire was created by a multidisciplinary team of health professionals with training and experience in patient safety, including two pharmacists, a quality nurse manager, a medical student, and a doctor specializing in pediatrics. Periodic meetings were held to discuss the questions prepared, as recommended in the Delphi methodology, and decisions were taken by consensus<sup>9</sup>. The questionnaire was created based on the DGSP domains and included health professionals' characteristics (age, sex at birth, area of activity, the highest level of training, work and shift schedule, other employment relationships, and length of experience in pediatrics). The questionnaire analyzed four domains: Medications, Patients and public, Systems and practices, and Professionals. Before data collection began, tests were carried out among researchers on the *REDCap* platform, estimating response time and question flow, with adjustments made before the beginning of data collection.

Descriptive statistics were performed, calculating frequencies, medians, and interquartile ranges (IIQ). To analyze the DGSP construct, a factor analysis was conducted, a multivariate method that results in the reduction of a group of variables to a smaller number of factors, which represent the dimension of the latent structure<sup>10</sup>. Initially, components with a correlation greater than 0.3 were tested in the analysis. The number of participants and variables included was observed, obtaining a 6:1 ratio, considered adequate. The *Bartlett* test was applied and then the *Kaiser-Meyer-Olkin* (KMO) test was performed to evaluate the common variance. Factor extraction was performed using the principal components' method, to identify the best combination of variables that explained most of the observed variance. The eigenvalues (*Eigenvalue*) were observed, and the *Scree* graph was analyzed, using the Kaiser criterion, including only factors with *Eigenvalue* values greater than 1.0. The rotation of factors to adjust the loads was carried out using the *Varimax* method. The model was built with parsimony,

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and variables associated with the factors and with a specificity lower than 0.5 were considered. The rotated factor loadings of each variable included were identified, organized from highest to lowest, and shown in the figure. Internal consistency was assessed by estimating Cronbach's alpha for the dimensions found, with values greater than 0.70<sup>11</sup> being considered satisfactory. Data analysis was carried out using the *Stata* version 18.0 program (<https://www.stata.com>).

This research was approved on April 14, 2023, by the institution's Research Ethics Committee (CAAE 67010023.0.0000.5504). The writing of this study followed the Strengthening of the Reporting of OBServational studies in Epidemiology (STROBE) form, for observational studies<sup>12</sup>.

## RESULTS

The questionnaire applied was composed of a set of 22 components or variables. The answers were prepared on a five-level *Likert* scale, with responses being positive (1-totally disagree, 5-totally agree), as shown in Table 1.

Table 1 - Components of Professionals, Medications, Systems and practices, and Patients and public domains

| Components   | 1 | 2 | 3 | 4 | 5 |
|--|---|---|---|---|---|
| <b>DOMAIN PROFESSIONALS</b>  |   |   |   |   |   |
| Have you received any training related to medication safety in the last 12 months?   |   |   |   |   |   |
| In my work environment, I believe that there may be communication failures that could compromise safety with the use of medications. |   |   |   |   |   |
| My work team is committed to safety protocols related to drug therapy, which can prevent harm to patients                            |   |   |   |   |   |

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|  |  |  |  |  |  |
|--|--|--|--|--|--|
| I feel fully competent to carry out my activities related to the preparation and administration of medications   |  |  |  |  |  |
| <b>DOMAIN MEDICATIONS</b>  |  |  |  |  |  |
| It is important to check the name of the medication, label, and packaging when the medication is administered  |  |  |  |  |  |
| When there is a discrepancy in the name of the medication that I am going to administer with what is prescribed, or in the label or packaging, the medication should not be administered before checking with the prescriber/dispenser |  |  |  |  |  |
| Only medications that are currently being used by the same patient should remain on the patient's bed  |  |  |  |  |  |
| <b>DOMAIN SYSTEMS AND PRACTICES</b>  |  |  |  |  |  |
| Medical prescriptions are easy to understand   |  |  |  |  |  |
| Medications must be taken for administration to patients individually (one patient at a time)  |  |  |  |  |  |
| The medication dispensed by the pharmacy must be checked against what is prescribed for the patient, before administering it   |  |  |  |  |  |
| When administering medications, it is essential to check the patient's identification with two identifiers   |  |  |  |  |  |

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|   |  |  |  |  |  |
|---|--|--|--|--|--|
| When the patient has several medications to be administered by different routes (for example, by tube and intravenously), I believe there is some danger related to administration by the wrong route |  |  |  |  |  |
| After administration of a medication, the patient should be evaluated for possible reactions to what was administered   |  |  |  |  |  |
| In infusions with solutions, it is important to check the items and make the label, which is attached to the bottle, with the patient's identification  |  |  |  |  |  |
| It is important to record the medications administered in the medical record immediately after administration   |  |  |  |  |  |
| <b>DOMAIN PATIENTS AND PUBLIC</b>   |  |  |  |  |  |
| I try to understand what children report while under drug therapy   |  |  |  |  |  |
| I try to understand what the family reports about the child's drug therapy  |  |  |  |  |  |
| I allow children in my care when they can understand, to take an active role in drug therapy  |  |  |  |  |  |
| I allow those responsible for my patients to take an active role in drug therapy  |  |  |  |  |  |
| It is essential to inform patients, when they understand, which medication(s) are being administered  |  |  |  |  |  |



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|   |  |  |  |  |  |
|---|--|--|--|--|--|
| It is essential to inform the patients' legal guardians which medication(s) are being administered  |  |  |  |  |  |
| I try to educate my patients, when they understand, about the correct way to take medications, as well as their effects, adverse reactions, and warning signs |  |  |  |  |  |

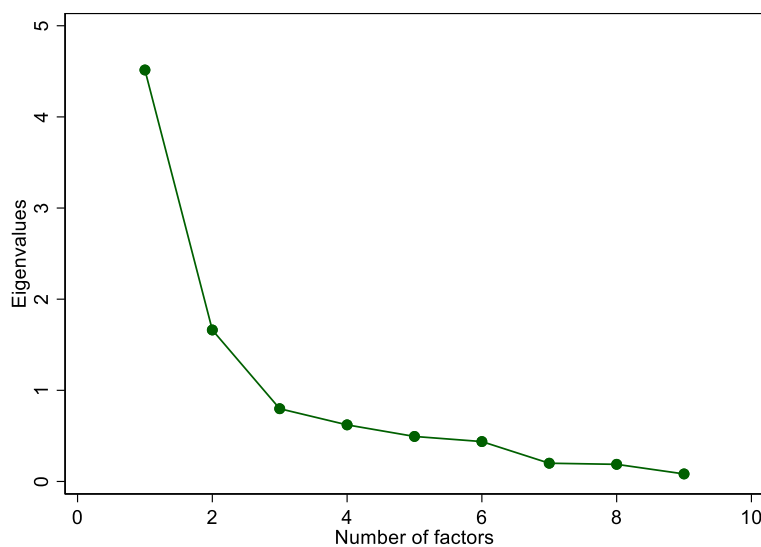
1-completely disagree, 2-partially disagree, 3-neither agree nor disagree, 4-partially agree, 5-completely agree

Source: Prepared by the authors.

In the present study, of the 52 health professionals in the unit, 51 were invited to participate and three refused, with the sample consisting of 48 health professionals. The median age was 39 years (IQR 33.0-43.2 years), 43 of whom were female (89.6%). Regarding the area of activity, 10 nurses (20.8%), 20 nursing technicians (41.7%) and 18 doctors (37.5%) participated. Of these, 11 reported higher education (22.9%), 18 lato sensu postgraduate studies (37.5%) and 5 stricto sensu postgraduate studies (10.4%). When asked about their work regime, 44 (91.7%) of the health professionals stated that they were on duty, while 4 (8.3%) were daily laborers. The majority were on the day shift (68.8%) and 27 (56.3%) said they did not have another job. Regarding clinical experience in the pediatric area, 22 (45.8%) stated that they worked in the area for less than two years, 17 (35.4%) worked for between two and ten years, and 9 (18.8%) worked for more than 10 years.

The analyzed correlation matrix resulted in a moderate KMO value (0.79). The Bartlett test (chi-square 251.09;  $p < 0.001$ ) indicated that the correlational matrix was not an identity matrix, and factorization was appropriate. The *Eigenvalues* analysis suggested two factors, which were confirmed by the *Scree* graph (Graph 1).

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Graph 1 – *Scree* graph.

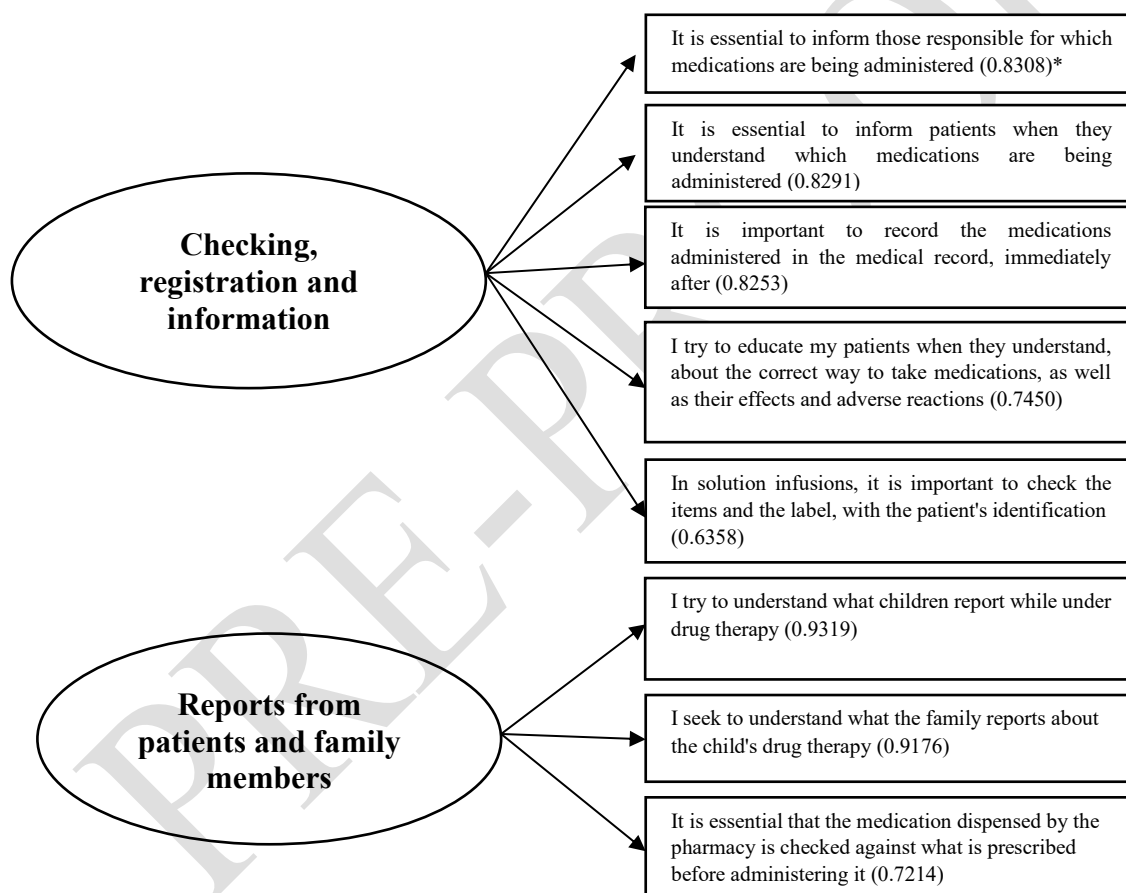
These two factors comprised eight components, extracted from the factor analysis. These components belong to the Patients and public and Systems and practices domains:

1. In solution infusions it is important to check the items and the label, with the patient's identification
2. It is essential that the medication dispensed by the pharmacy is checked against what is prescribed, before administration
3. It is important to record the medications administered in the medical record, immediately after
4. I seek to understand what children report while under drug therapy
5. I seek to understand what the family reports about the child's drug therapy
6. It is essential to inform patients when they understand which medications are being administered
7. It is essential to inform those responsible for which medications are being administered

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8. I try to educate my patients when they understand the correct way to take medications, as well as their effects and adverse reactions

The two factors were named according to the factors obtained. The first factor refers to Checking, registration, and information and the second refers to Reports from patients and family members, as shown in Figure 1. The components included represented the domains of Patients and public and Systems and practices. No component of the Professionals and Medications domains was included in the multivariate model.



\*rotated factor loading

Figure 1 - Model resulting from the factor analysis of the Global Patient Safety Challenge  
 “Medication without Harm” in pediatric health professionals

Source: Prepared by the authors.

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These two factors were responsible for most of the structure observed in the analyzed questionnaires and explained 73.97% of all observed variance. *Varimax* rotation was performed, and the rotated loads were obtained, as shown in Table 1.

Table 1 - Results of the factorial solution of the domains of the Global Patient Safety Challenge “Medication without Harm” in pediatric health professionals

| Variable                | Factor 1 | Factor 2 | Specificity  |
|-------------------------|----------|----------|--------------|
| 1                       |          | 0.7214   | 0.3581       |
| 2                       | 0.6358   |          | 0.3641       |
| 3                       | 0.8253   |          | 0.3159       |
| 4                       |          | 0.9319   | 0.1973       |
| 5                       |          | 0.9176   | 0.1317       |
| 6                       | 0.8291   |          | 0.1603       |
| 7                       | 0.8308   |          | 0.2016       |
| 8                       | 0.7450   |          | 0.4432       |
| <i>Eigenvalue</i>       | 4.50     | 1.41     |              |
| % explained variance    | 0.3988   | 0.3409   | Total=73,97% |
| Number of variables     | 5        | 3        |              |
| <i>Cronbach's alpha</i> | 0.85     | 0.84     | Total=0.8598 |

Source: The authors.

## DISCUSSION

The presented results demonstrate that the construct was formed by two factors, named Checking, registration, and information and Reports from patients and families, representing the domains Systems and practices and Patients and public, of the DGSP “Medication without Harm”. Considering that the DGSP is broad, globally oriented, and its components are complementary<sup>3</sup>, we understand that the domains not included deserve to be carefully evaluated in the unit and should be strengthened.

The importance of providing information to guardians and patients, when they understand it, was included in the first factor of this study, with a high factorial load, revealing that the team attaches importance to these issues. This importance is

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unquestionable and was the basis of Patient for Patient Safety, a program promoted by the WHO that advocates that the patient's voice should be at the center of the movement for their health<sup>1</sup>. In Brazil, in 2012, ANVISA launched the Patients for Patient Safety in Health Services project, to strengthen their participation, in a broad way. There is a need to promote patient participation in improving the safety of healthcare, however, most of the studies are with adult patients and not with children and, even in adults, there is room for improvement<sup>13-15</sup>.

Still, in the first factor, the immediate recording of administered medications in the medical record also had a high factor loading. This item is part of the Nine Certainties in Medication Administration (Right Registration), recommended by ANVISA<sup>16</sup>. The observation of adherence to this item, in practice, in an intensive care unit in Sergipe, showed that the general adherence rate for the correct registration was 33.3 per 100 observation opportunities, being classified as poor assistance, which could improve<sup>15</sup>. It is important to highlight that the setting of the present study was a ward, which is quite different from the reality of intensive care units, which may explain the difference found. It is therefore possible that, in a lower-risk environment such as the ward, this immediate registration occurs more appropriately.

Patient education, when they understand it, is fundamental to their safety, and this education should not exclude pediatric patients. It is important to highlight this aspect in pediatrics, as, in general, the approach is that of the family, leaving the child on a secondary level and this reality needs to change<sup>17</sup>. For children using chemotherapy drugs at home for cancer treatment, for example, this education is imperative to mitigate the potential risks of this treatment, and efforts must be made to eliminate barriers to this education, especially effective communication<sup>18</sup>. It is worth noting that the global agenda of priorities for research related to medication safety includes priority strategies to increase patient literacy and involvement in medication use, especially in low-income settings<sup>19</sup>. Furthermore, for patients to become drivers of their health, they must be aware of their health condition, which is influenced by their level of engagement, defined as facilitating and strengthening patients as co-producers of health<sup>20</sup>. Children can and

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should be co-producers of their health, and it was interesting to observe that, in the pediatric ward scenario, this education found a fertile environment to occur.

The correct identification of solution infusions, which includes the identification of the patient and the medication (dose and dilution), refers to several items of medication safety, such as the right patient, the right route, and the right medication, and was important in the analyzed construct. These parenteral infusions represent a risk, and it is known that adherence to safety mechanisms that mitigate these risks remains less than desirable<sup>15</sup>, with the correct labeling of the medications being administered being essential for patient safety<sup>21</sup>. It is worth highlighting that, even with technological advances, the use of barcodes, the standardization of practices, and the development of high-precision infusion pumps, the medication process does not exempt the human factor, such as preparation, identification, and programming of infusion pumps, which are critical steps in this process<sup>22</sup>.

The reports of children and families must be considered, especially due to the occurrence of underreporting incidents, which can be significant. In a study carried out in pediatrics, which involved family members immediately before discharge, it was observed that they reported adverse events that were not registered in the patient's medical record, and it is suggested that parents' reports be included in patient safety systems<sup>23</sup>. These reports are influenced by the moment they are collected, given the patient's vulnerability and the fear associated with the reports. Furthermore, issues related to the perception of the quality of care provided may have safety implications and must be valued. It is worth noting that the perceptions of family members of hospitalized children with complex conditions involve the use of medication, nutrition, and care in general<sup>24</sup>. Furthermore, patients' experiences concerning care interfere with the feeling of security related to this care<sup>25</sup>. This opportunity to value these reports was also observed in the pediatric environment, suggesting a close relationship between professionals, the patient, and the family.

Checking the medication dispensed with what is prescribed is a fundamental safety barrier and includes the right route, right dose, and right medication. In the present study,

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health professionals valued this component. In agreement, Giron et al., in a descriptive study, observed that, about checking the medication dispensed and prescribed, the percentage of positive responses was high<sup>26</sup>. On the other hand, Vória et al. analyzed 334 procedures in a pediatric ward and a pediatric intensive care unit and observed that checking the medication/dose/route administered with the prescription and double-checking the medications showed adherence in 76,6%<sup>27</sup>. The results of these studies reveal that this practice is inconsistent in pediatrics, and the results may also be influenced by the level of complexity studied.

Furthermore, it is worth highlighting that the Professional and Medication domains were not included in the construct. This result is in line with the literature and points to the weaknesses that exist in the processes related to these domains, which include issues such as patient safety training, communication, and teamwork, knowledge about adverse events related to the use of medication that occurred in the unit and keeping medications that are not being used by the patient at the patient's bedside. Patient safety training was highlighted by professionals as an important safety strategy in a general and university hospital in Rio de Janeiro<sup>26</sup>. Notification, in turn, is essential for identifying the profile of these incidents and for creating improvement plans. This result, found in the present study, may point to the presence of underreporting incidents. In the literature, the factors identified for the occurrence of underreporting are the lack of feedback, the punitive culture, and difficulties in reporting<sup>28</sup>.

Importantly, it is worth highlighting that the clarity of medical prescriptions, although present in the Systems and practices domain, was not included in the model, revealing weaknesses in this stage of the medication process, which could be improved. The frequent fragility of medical prescriptions in pediatrics has previously been highlighted in the literature, even in units with an electronic prescription system, revealing that this system does not guarantee, in itself, clarity<sup>29,30</sup>. It is worth remembering that most of these electronic systems are approved for adults, requiring adaptation and adjustments to the reality of the pediatric population.

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It is believed that the main limitation of this study is that it was conducted in a single center, which makes it difficult to generalize its results. On the other hand, using a multivariate analysis method enabled the definition of the construct of this group of health professionals concerning the DGSP, which could contribute to the future validation of a questionnaire on the DGSP, in addition to indicating points for improvement. To our knowledge, this is the first study on the safety of medication use in pediatrics in Brazil, with an emphasis on the DGSP “Medication without Harm”, where factor analysis was used.

## **CONCLUSION**

The construct identified in this study, based on the DGSP, can be understood as checking, registration, and information and reporting of patients and family members. This construct revealed that health professionals consider information from patients and family members, checking serum labels, understanding reports from children and family members, and checking the medication dispensed by the pharmacy to be relevant in pediatrics. These results reveal that professional domains and medications were not represented in this construct, which may represent weaknesses in the medication process in the pediatric ward studied. These weaknesses refer to training and communication failures, knowledge about previously occurring adverse events, discrepancies between prescriptions, labels, and packaging, and medications not being used by the patient remaining at the bedside. Furthermore, it was observed that the clarity of medical prescriptions was not included in the construct, revealing another important opportunity for improvement.

It is expected that these results will support the multidisciplinary pediatric team, the professionals from the patient safety center, and the unit management, in order to develop strategies to strengthen patient safety in the medication administration process in pediatrics. Future discussions and new research can contribute to these issues. It is



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important to map the medication process locally and share the scientific information found, which could contribute to improving patient safety in other healthcare institutions.

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