

High-alert medication administration errors in a neonatal unit

Errores de administración de medicamentos de alta alerta en una unidad neonatal

Luis Del-Valle Quintana^{a,b,d}, María Caterina Milone^{b,c}, Silvia Regina Secoli^{b,e}

^aFacultad de Enfermería y Obstetricia, Universidad de Los Andes, Chile.

^bEscola de Enfermagem, Universidade de São Paulo. Sao Paulo, Brasil.

^cCarrera de Medicina, Universidad Nacional de la Patagonia San Juan Bosco. Comodoro Rivadavia, Argentina.

^dMatrón.

^eEnfermera.

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What do we know about the subject matter of this study?

High-alert medications account for a large percentage of medication errors in pediatrics. However, evidence of their use and the presence of errors in neonatology in Latin America is scarce.

What does this study contribute to what is already known?

This study highlights errors with high-alert medications in neonatology. The most frequent error was incorrect infusion rate, attributed to lack of attention and improper use of infusion pumps. Technology does not eliminate errors. Ensuring patient safety requires awareness and ongoing training.

Abstract

Medication errors (MEs) are a frequent and preventable cause of harm, with a high clinical and economic impact, especially when they involve high-alert medications (HAMs). These drugs are generally used in hospitalized neonates, who, due to their physiological immaturity, are at higher risk of suffering from MEs. **Objective:** To analyze MEs during the intravenous administration of HAMs in a neonatal critical care unit. **Patients and Method:** Cross-sectional, retrospective study conducted in a neonatal critical care unit of a high-complexity public hospital. Reports of MEs during intravenous administration of HAMs in hospitalized newborns between 2020 and 2024 were included. Records with incomplete information were excluded. Results are presented using absolute and relative frequencies, median, and interquartile range (IQR: p25–p75). **Results:** A total of 34 MEs were reported, 15/34 (44%) involved HAMs in patients with a median gestational age of 30.0 weeks (IQR: 26.3–36.3); and a median hospital stay of 9 days (IQR: 6.0–21.0). In 5/15 (33%) cases, it was due to wrong infusion rate, lack of care, and misuse of infusion pumps; 10/15 (67%) of MEs did not harm the patient, and 13/15 (87%) were reported by nursing staff. The most frequent HAMs were parenteral nutrition 5/15 (33%) and adrenergic agonists 5/15 (33%).

Keywords:

Medication Errors;
Intensive Care Units;
Neonatology;
Patient Safety

Conclusions: MEs included essential HAMs in intensive care units, whose intravenous infusion was compromised by inappropriate rates attributed to human factors. Thus, it is necessary to strengthen the culture of safety, implement rigorous protocols, and promote ongoing training of the healthcare team, especially in the use of technologies.

Introduction

Medication errors (MEs) are preventable events that compromise patient safety. These errors have negative impacts on different actors in the health system and can affect patients, professionals, institutions, or the whole system¹. MEs can be defined as a “failure in the treatment process that causes or has the potential to cause harm to the patient” and can occur at any stage of the process, i.e., during prescribing, dispensing, preparation, administration, or monitoring².

MEs are a frequent cause of preventable harm and are associated with unnecessary costs to the healthcare system and society^{3,4}. In Europe, MEs are estimated to cost the UK healthcare system £98,462,582 per year, consume 181,626 bed days, and contribute to 1,708 deaths annually⁵. In Canada, MEs are estimated to prolong the average hospital stay by 4.6 days, increasing healthcare costs⁶. The impact of MEs can be even more severe in vulnerable populations, especially in developing countries, where the consequences can be twice as severe^{1,7}.

Within the general population, patients in the first stage of life are three times more likely to be affected by MEs than adults⁸. Studies indicate that prescription and administration errors are the most common MEs, which are related to incorrect dosing, use of inappropriate administration techniques or rates, and even the selection of medications that are not suitable for newborns⁹⁻¹¹. These problems can be even greater in neonatal intensive care units (NICUs).

NICUs have been identified by the World Health Organization (WHO) as one of the priority areas for significantly reducing medication-related harm¹. Clinical severity and instability, combined with the immaturity of organs and homeostatic mechanisms dependent on gestational age, are determining factors in the effects of MEs^{12,13}. In addition to a limited number of venous accesses and the complexity of the therapeutic regimen, the co-administration of medications, especially high-alert medications or high-risk medications, contributes to greater susceptibility to MEs¹⁴.

High-alert medications (HAMs) are drugs associated with a high risk of causing significant harm if used incorrectly¹⁵. Evidence suggests that HAMs represent one of the main risks to medication safety in hospitals. The Institute for Safe Medication Practices (ISMP) report highlighted that these groups of drugs increase

the risk of causing harm to patients, with rates ranging from 0.24 to 89.6 errors per 100 prescriptions¹⁶.

Half of MEs are related to parenteral preparations, and one-third are associated with HAMs (anticoagulants, electrolytes, vasoactive agents, sedatives, and analgesics)¹⁷. In a pediatric hospital, 34.8% of reported MEs involved HAMs, which were associated with greater potential harm to the patient and higher levels of risk¹⁸. In Sweden, a national analysis of incidents related to the use of pediatric medications showed that 80% of reports occurred in the 0-6 age group and that there was twice the prevalence of incidents involving HAMs compared to those without¹⁹.

In Latin America, evidence indicates that the rate of MEs in hospitals in Chile and Brazil, determined by direct observation, ranged from 9% to 64%, and the most commonly used HAMs were heparin, tramadol, and insulin. However, the studies included in the review do not report errors associated with the use of HAMs in neonatology²⁰. Furthermore, most of the available research comes from developed countries, which shows regional underrepresentation^{11,18}.

At the local level, the labeling policy for high-risk medications has been in force since 2024 and promoted by the Chilean Institute of Public Health was driven by voluntary reports of adverse events compiled by the National Center for Pharmacovigilance. Between 2012 and 2018, 1,129 medication errors were recorded in the general population, 78% of which caused harm to the patient, mainly related to parenteral administration and drugs requiring special monitoring²¹.

The frequent use of HAMs in pediatric and neonatal units worldwide highlights the urgency of adopting specific strategies to prevent errors in this vulnerable group. However, despite its clinical importance, international evidence remains limited, and in the Chilean context, no studies have yet been identified that analyze MEs or the causes of this problem in this population.

The objective of this research was to analyze MEs in the intravenous administration of HAMs in a neonatal unit.

Patients and Method

Cross-sectional, retrospective study, part of a larger project corresponding to a doctoral thesis called “Use

of the Design Thinking method for the prevention of errors in the administration of intravenous medications in a neonatal unit of a Chilean public hospital.” The writing and structure of the article were guided by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations²².

The study setting was the Neonatology Service of the *Hospital Franco Ravera Zunino*, located in Rancagua, in the Libertador General Bernardo O’Higgins Region, Chile. It is a public tertiary care facility of high complexity and a regional referral center, serving a population of approximately 780,627 inhabitants. The service, focused on critical neonatal care, has a total of 42 beds, including 12 neonatal intensive care unit (NICU) beds and 30 neonatal intermediate care beds. Nursing staffing corresponded to a 1:3 nurse-to-patient ratio in the NICU and a 1:6 ratio in neonatal intermediate care.

In this service, medication is prescribed electronically and sent to the pharmacy for dispensing, with validation by the pharmacist. Medical treatment is delivered in printed form to the nursing staff, who manually record it in the medical record. The preparation and administration of intravenous drugs is carried out exclusively by nurses or midwives, following local protocols.

MEs are reported to management and documented as adverse events using a digital form, which is sent to the hospital’s Quality and Infection Department for analysis and follow-up.

The population consisted of newborns hospitalized in the NICU or the neonatal intermediate care service during the period 2020-2024 who experienced IV-related MEs. This period was determined by the availability of clinical records. MEs that occurred during the administration stage involving HAMs, reported using the adverse event form and containing detailed clinical information on both the patient and the event, were included. Reports with incomplete records or inconsistent data were excluded.

MEs were collected directly from the quarterly reports issued by the Quality Department to the Neonatology Service and from filed notification forms. The respective analyses and improvement plans were also reviewed. Demographic data on the neonates (gestational age, days of life, sex, and discharge status) and details of the adverse event (date, time, patient unit, medication, type of vascular access, reporting staff, and summary description) were collected.

HAMs were grouped according to the ISMP list¹⁵, while the ME type and the severity of the harm were classified according to the operational definitions of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (Table 1)²³.

The statistical analysis was descriptive. Absolute and relative frequencies were calculated for categorical variables, and measures of central tendency and dispersion for continuous variables, specifically median and interquartile range (IQR: p25-75). A descriptive analysis of the notification reports was performed, grouping the causes mentioned according to their thematic content.

The larger project in which this study is included was approved by the Ethics Committee of the South East Metropolitan Service on June 4, 2024. The research complies with the ethical principles established in the Declaration of Helsinki, as well as with current local and international regulations for the protection of participants.

Results

During the study period, 3,953 newborns were admitted to the service, with 34 cases of IV-related MEs reported. Of these, 15/34 (44%) involved HAMs, which mainly affected premature newborns, with a median gestational age of 30.0 weeks (IQR: 26.3–36.3), predominantly male (11/34; 73%). The median length of hospital stay was 9.0 days (IQR: 6.0–21.0), and most events occurred in the NICU.

Central venous access was the most frequent (13/15; 87%), which included both umbilical catheters (3/15; 20%) and peripheral accesses (10/15; 67%). These errors were mostly committed during the day (9/15; 60%) and were reported by nursing professionals in most cases (13/15; 87%). Table 2 reports these findings.

Table 3 shows errors related to incorrect rates (5/15; 33%). According to the reports analyzed, the main cause of these errors was a lack of attention on the part of the nursing professional, as well as failures in the use of technology, specifically in the programming of the continuous infusion pump. The latter cause also contributed to other types of errors (2/15; 13%).

Incorrect treatment duration, which in all cases resulted in prolonged therapy time, was another of the most frequent errors (3/15; 20%), all of which were related to parenteral nutrition. Regarding the causes obtained from the reports, they were attributed to distractions or oversights by the healthcare professional involved.

Errors due to incorrect technique occurred during the preparation of the drugs, resulting in an exchange of solution labels (2/15; 13%).

Figure 1 shows the severity of harm of HAMs errors, focusing on no-harm errors according to NCC MERP, all of which reached the patients. Of these, 10/15 (67%) were no-harm errors, classified as catego-

Table 1. Classification of medication error type and severity of harm according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)²³

| | Operational definition |
|-----------------------------|--|
| Type of medication error | <ul style="list-style-type: none"> - Wrong dose: Amount administered higher or lower than prescribed - Wrong patient: Medication administered to a patient other than the one prescribed - Wrong rate: Medication administered at a rate different from that prescribed - Wrong duration: Total administration time longer or shorter than indicated - Wrong technique: Administration procedure not compliant with the established protocol - Other: Error not classified by NCC MERP |
| Severity of harm categories | <p>Without error</p> <ul style="list-style-type: none"> - Category A: Circumstances with the potential for error, but no error occurred <p>Error without damage</p> <ul style="list-style-type: none"> - Category B: An error occurred but did not reach the patient - Category C: An error reached the patient but did not cause harm <p>Error with damage</p> <ul style="list-style-type: none"> - Category D: An error reached the patient and required additional monitoring, without clinical consequences - Category E: An error caused temporary harm requiring intervention |

ry C. On the other hand, errors classified as category D, which required further follow-up, affected 3/15 (20%) of patients.

In relation to the ISMP's list of HAMs, errors were mainly concentrated in at least five drug groups (Figure 2). Parenteral nutrition and adrenergic agonists accounted for 10/15 (67%) of the reported errors. Among agonists, dopamine and epinephrine administered via central catheter were the most frequently reported (5/15, 33%). Fentanyl was the most common sedative agent (3/15, 20%), while milrinone and calcium gluconate were mentioned in isolation.

Discussion

This Chilean study appears to be the first in Latin America to analyze MEs involving HAMs in neonatology. These MEs included drugs commonly used in NICUs and occurred mainly in premature patients with prolonged hospital stays. The MEs were predominantly reported by nursing professionals and were related to administration times, due to both a lack of attention and difficulties in using infusion pumps. In most cases, the errors reached patients without causing obvious clinical harm.

In this public hospital's neonatology department, despite the low reporting of IV-related MEs, in the last 5 years, HAMs were involved in almost half of the reports. This finding is consistent with previous studies that showed that HAMs account for approximately one-third of MEs in pediatric patients^{18,19,24}. Regardless of epidemiology, HAMs represent a risk factor for MEs in pediatrics, especially in the context of intensive care^{25,26}.

Table 2. General characteristics of patients who experienced high-alert medication errors in the Neonatology Service of Hospital Franco Ravera Zunino, Rancagua, Chile, 2020-2024 (n = 15)

| Variable | n (%) |
|--|-------------|
| Sex | |
| Male | 11/15 (73%) |
| Female | 4/15 (27%) |
| Unit | |
| Neonatal Intensive Care Unit | 14/15 (93%) |
| Intermediate Neonatal Care Unit | 1/15 (7%) |
| Vascular access | |
| Peripherally inserted central catheter | 10/15 (67%) |
| Umbilical venous catheter | 3/15 (20%) |
| Peripheral catheter | 2/15 (13%) |
| Work shift | |
| Day | 9/15 (60%) |
| Night | 6/15 (40%) |
| Reporting professional | |
| Nurse / Midwife | 13/15 (87%) |
| Physician | 2/15 (13%) |
| Discharge status | |
| Alive | 13/15 (87%) |
| Deceased | 2/15 (13%) |

The low number of MEs reported during the period analyzed suggests significant underreporting, especially considering that the service registers approximately 1,000 admissions annually. Reported errors represent only the tip of the iceberg of the phenomenon under investigation and can be attributed to factors such as the normalization of errors or near misses, as well as fear of institutional sanctions or reprisals, among others^{1,9}.

The use of medications is an essential component in NICUs. The occurrence of MEs in the process of using this basic input can compromise overall safety, affecting not only patients but also the healthcare team and the institution, who become “second” and “third” victims²⁷. Thus, identifying the type of MEs can contribute to the promotion of educational strategies.

In this study, the most frequently reported type of error was an incorrect administration rate of HAMs, most likely in adrenergic agonists and parenteral nutrition. Adrenergic agonists are dose-dependent drugs with a short half-life, whose inadequate infusion rate can affect their efficacy²⁸. Rapid infusion of dopamine, for example, can put a newborn at risk due to their

particular physiology, which depends on factors such as weight, gestational age, and the maturity of organs sensitive to medication^{12,13}.

In agreement with other authors, parenteral nutrition represented one of the most frequent HAMs in pediatric MEs^{18,19,25}. Due to its complex nature (osmolarity, presence of electrolytes and minerals), parenteral nutrition presents a high risk of harm during administration, with the possibility of solution contamination, complications related to intravenous access, and metabolic imbalance, among others²⁹. Additionally, the infusion of concentrated electrolytes, such as potassium chloride, magnesium, calcium, and phosphate preparations, may pose a safety risk, reaffirming the need for

Table 3. Distribution of high-alert medication error types according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) and adverse event report narratives. Neonatology Service, Hospital Franco Ravera Zunino, Rancagua, Chile, 2020–2024 (n = 15)

| Type of error | n/N (%) | Main cause | Report narratives |
|-----------------|------------|---|--|
| Wrong rate | 5/15 (33%) | Inattention / improper use of infusion pump | Label interchange; lack of verification; incorrect infusion pump programming. |
| Wrong duration | 3/15 (20%) | Forgetfulness / protocol failure | Infusion not replaced after 24 h; infusion not removed in a timely manner. |
| Wrong technique | 2/15 (13%) | Lack of verification | Label interchange; infusion circuit remained closed. |
| Wrong dose | 2/15 (13%) | Transcription error / lack of knowledge | Tenfold dose error during transcription; overdose due to verbal order. |
| Other | 2/15 (13%) | Equipment / logistics failure | Infusion pump turned off without alarm; accidental bolus due to disconnection. |
| Wrong patient | 1/15 (7%) | Inattention | Similar surnames. |

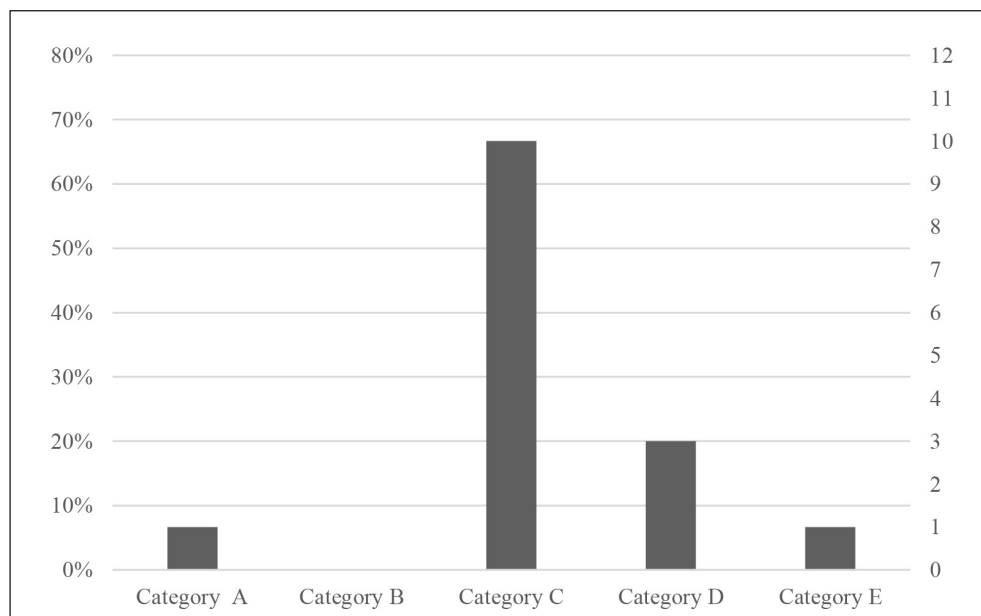


Figure 1. Distribution of severity of harm associated with high-alert medication errors according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Neonatology Service, Hospital Franco Ravera Zunino, Rancagua, Chile, 2020–2024 (n = 15).

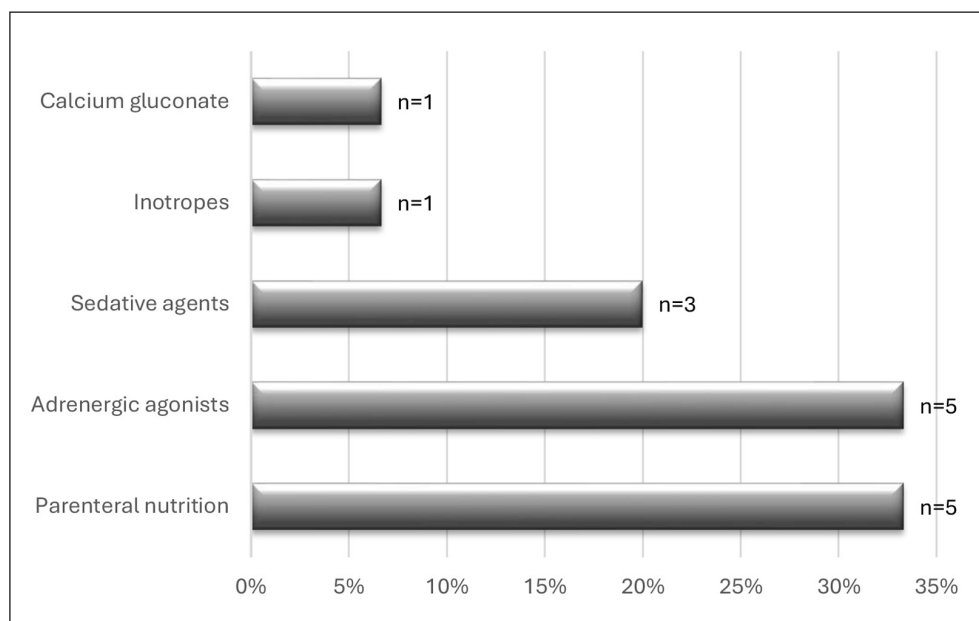


Figure 2. Distribution of high-alert medications involved in medication errors according to the Institute for Safe Medication Practices (ISMP) list. Neonatology Service, Hospital Franco Ravera Zunino, Rancagua, Chile, 2020–2024 (n = 15).

infusion at an appropriate rate³⁰.

A critical aspect identified in parenteral nutrition is the occurrence of MEs associated with pump malfunction and incorrect infusion rate, which has also been documented in another study³¹. However, up to 44% of hospitals do not monitor incidents related to this infusion^{32,33}.

MEs were identified more frequently in newborns hospitalized in the NICU for more than a week. These errors, regardless of their severity, can significantly impact neonatal safety and increase healthcare costs^{18,34}. HAMs carry a higher risk of causing serious harm when administered incorrectly, requiring additional treatments and increasing the length of hospital stays²⁰. Likewise, admission and length of stay in hospitals are associated with a higher risk of MEs, especially in vulnerable populations such as newborns⁷.

Critical patients who spend more time in the hospital are exposed to a greater number of procedures and therapeutic interventions that increase the likelihood of MEs^{35,36}. The complexity of the care required by these patients can contribute to the occurrence of errors, where HAMs are often used^{10,11,14}.

The causes attributed to MEs involving HAMs were mainly human factors and problems with the use of infusion pumps, despite the adequate staffing of nurses in the service. These causes can be explained both by the intrinsic characteristics of the staff and by the influence of the work environment on them^{19,37,38}.

Lack of knowledge, along with distractions resulting from work overload or interruptions, are common causes of MEs. These contributing factors have

been identified in both this study and previous research^{20,39–42}.

Despite the presence of smart pumps in the service, errors in the infusion rate of HAMs occurred. This highlights that the presence of these devices does not guarantee the elimination of errors, as healthcare teams tend to underestimate their functionalities⁴³. Smart pumps are effective in preventing administration errors, which can account for up to 40% of reports in pediatrics^{38,44}.

Thus, MEs related to HAMs in the neonatal setting appear to be multifactorial, highlighting the need for a comprehensive approach that includes educational strategies, improvements in communication, the incorporation of safe technologies with adequate training in their use, and institutional reforms that strengthen patient safety⁴⁵.

67% of HAMs errors were classified in category C, according to NCC MERP. Although these errors did not cause harm to neonates, they may indicate the existence of a systemic problem. HAMs are a key indicator of healthcare quality, and each one, regardless of its severity, represents a learning opportunity. Continuous monitoring can detect patterns in healthcare practice that require improvement or the implementation of preventive measures⁴⁶.

The findings regarding the category of error coincide with those reported in the ICU on HAMs errors, where approximately 1% of these events have serious consequences^{16,45}. This may be due to the inappropriate management of these drugs, as well as the stressful nature of these units and the fact that patients are com-

pletely dependent on the care provided by healthcare personnel.

Nursing professionals were the ones who most frequently reported MEs related to HAMs, which is consistent with their proximity to the patient and their commitment to safety^{47,48}. Their direct contact and continuous monitoring allow them to identify any errors during the process on time. Since the administration of medications is a nursing task, errors occurring in this final phase must be detected and corrected before reaching the patient^{41,49}.

In the current context, nursing professionals are trained to detect and prevent MEs and are made aware of the importance of reporting them. In addition, many institutions encourage them to report errors to improve the safety and quality of care, contributing to a culture of transparency and continuous learning⁵⁰.

In this study, reporting of MEs by physicians was low, which is consistent with previous findings reported in the literature⁵¹. It has been suggested that physicians tend to report mainly events associated with relevant clinical consequences, such as those involving harm to the patient. In such cases, especially in events classified in the E-I categories, their role in therapeutic management could motivate reporting.

Regarding the limitations of the study, it should be noted that the source of information consisted of self-reported MEs, which may be associated with the risk of underreporting by healthcare personnel, suggesting that the available data reflect only a fraction of the actual problem. In addition, subsequent analyses by the quality team to identify the cause or contributing factors of MEs were not always complete and depended on the severity of the error, which limited the information available.

Another limitation of the study is that it was not possible to calculate an accurate rate of MEs, as only the total number of newborns admitted during the period was available. The lack of access to more specific indicators, such as the total number of intravenous administrations or days of catheter use, limits the possibility of comparing the findings with similar studies that use clinically more robust denominators compatible with international literature.

Despite its limitations, this study provides local evidence to guide the implementation of specific measures regarding the preparation, administration, and monitoring of HAMs in neonatal patients. Measuring MEs allows for the evaluation of the effectiveness of safety protocols used in services and for adjustments to be made to ensure a safer care environment.

The study provides insights that are in line with the WHO, emphasizing the need to identify unsafe or high-risk practices in order to develop strategies that reduce MEs and improve patient safety¹. In addition,

this research can help increase the confidence of patients and their families, improving institutional credibility. When a hospital demonstrates that it monitors its MEs, a key indicator of quality, and seeks continuous improvement through research, it conveys confidence and professionalism and strengthens its image in the community.

To mitigate the impacts of MEs involving HAMs, it is crucial to invest in information technology, ongoing training, and more rigorous safety protocols that involve healthcare personnel in a comprehensive and participatory manner, both in the search for solutions and in training, to achieve a non-punitive error reporting system with periodic academic, educational, and corrective audits. Likewise, findings about the causes can support educational strategies aimed at the healthcare team and the strengthening of a culture of safety at both the service and hospital levels.

Future studies should focus on economic analysis, considering that MEs require additional treatments, increase the length of hospital stays, and raise hospital costs.

Conclusion

Local evidence on MEs in the neonatal population, which is the most vulnerable within the healthcare system, indicates that these errors mainly involve HAMs, which are essential in therapeutic management in intensive care units. IV-related MEs were largely due to inappropriate rates influenced by lack of attention and incorrect use of infusion pumps. To ensure safety, it is essential to strengthen the organizational culture, implement rigorous protocols, and promote continuous training of healthcare staff, especially in the proper use of technologies.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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