MEDICATION SAFETY IN NEONATOLOGY: NURSING IN THE PERSPECTIVE OF THE ECOLOGICAL RESTORATIVE APPROACH

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ABSTRACT
Objective: to analyze the factors that interfere in the medication safety process in a neonatal intensive care unit (NICU).
Method: An exploratory study with a qualitative approach. The collection took place from December 2014 to March 2015, using focus groups and photography walkabouts, in the perspective of the ecological restorative approach, with 12 nursing professionals from the neonatal ICU of a public hospital in the Southern Region of Brazil. The information was organized using the NVivo 10 software and was submitted to thematic content analysis.
Results: the following thematic categories emerged from the analysis: Individualized approach and medication error punishment culture; Safety factors related to the physical structure of the medications in the neonatal ICU; Safety factors related to routines and protocols; and Nursing as a barrier to the occurrence of medical prescription errors.
Conclusion: the study demonstrates the complexity of the medication process in neonatology and highlights critical points that can cause errors and adverse events, as well as proposals to prevent errors. The role of the nursing team in the detection of medication prescription errors is highlighted, functioning as the last barrier to the prevention and reduction of errors associated with medication.

SEGURIDAD DE LA TERAPIA MEDICAMENTOSA EN LA NEONATOLOGÍA: UNA MIRADA DE LA ENFERMERÍA EN LA PERSPECTIVA DEL PENSAMIENTO ECOLÓGICO RESTAURATIVO

RESUMEN
Objetivo: analizar los factores que interfieren en la seguridad en el proceso de medicación, en una unidad de terapia intensiva (UTI) neonatal.
Método: estudio exploratorio y con un abordaje cualitativo. La obtención de datos se dio entre Diciembre del 2014 y Marzo del 2015 a través de grupos de enfoque y caminada fotográfica, en la perspectiva del pensamiento ecológico restaurativo, con 12 profesionales de enfermería de la UTI neonatal de un hospital público de la Región Sur del Brasil. Las informaciones fueron organizadas a través del software Nvivo 10 y sometidas al análisis del contenido temático.
Resultados: a partir del análisis emergieron las siguientes categorías temáticas: Abordaje individualizado y cultura de pujíción de los errores de medicación, Factores de (in)seguridad relacionados con la estructura física de los medicamentos en la UTI neonatal, Factores de (in)seguridad relacionados con las rutinas y protocolos y La enfermería como barrera para la ocurrencia de fallas de prescripción médica.
Conclusión: el estudio demuestra la complejidad del proceso de medicación en la neonatología y destaca puntos críticos, en el mismo, que pueden ocasionar fallas y eventos adversos, así como propuestas de mejoras para prevenir los errores. Se destaca el papel del equipo de enfermería en la detección de errores de la prescripción médica, funcionando como la última barrera para la prevención y reducción de los errores asociados con la medicación.


INTRODUCTION
The complexity of the health system has risen dramatically. The increase in technologies associated with nursing care and treatment is constantly changing. Although these advances mean benefits in several aspects, we still have a fragile care process with security risks, triggering undesirable effects on the care provided.1

Undesired effects may result in harm to the patient as a result of intentional or unintentional actions of health professionals.2-4 Incidents that cause harm to the patient are called adverse events (AEs), some of which are the result of errors.1,5 Errors are understood as execution problems when a planned action is not performed, or a planning problem when a wrong plan is applied, when avoidable.1,5

The medication process is comprised of three stages: prescription, dispensing, or dispensing and administering medications.9 Despite the division of responsibilities between different professional categories, among them, doctors, pharmacists and nursing staff, it is known that, in practice, the professional activities happen in an interdependent way, and their synchronism directly affects patient safety.

Adverse mediation-related errors and events are among the most common incidents that can affect a patient in health services, this fact was made known in the 1999 US Institute of Medicine report, and remains a reality.5,7

One in seven adult hospitalized patients experience at least one adverse event related to nursing care during their hospitalization, and medication administration errors are among the most frequent errors,8 estimating that the probability of errors with potential to cause harm is three times higher in children than in hospitalized adults.9 A prospective systematic observation study conducted at a pediatric unit in Rio de Janeiro revealed a rate of preparation error in about 67% of medications and 87% in the administration phase.10

Premature infants less than 30 weeks of gestation and weighing less than 1500g are the most prone to adverse events because they are critically ill and therefore require longer hospitalization periods and a greater number of interventions for their recovery.11-14 Medication errors, which are already frequent in inpatients, are eight times more likely to occur in neonatal ICUs than in other inpatient population.15,15

A recent systematic review had the objective to identify the occurrence of incidents with or without injury occurring in a neonatal ICU described in the literature.1 A survey based on 16 articles, two dissertations and one thesis, showed that the most frequent incidents in this area are related to problems in the use of medications, mainly related to incorrect or inappropriate dosages (mean 38%), omission of administration or lack of prescription of necessary medications, administration technique error and wrong administration route.1

A recent integrative review indicates the lack of studies with strong levels of evidence in the Brazilian scenario in relation to this theme.10 In addition, the absence of research that gives a better understanding on the phenomenon under study is observed, indicating the existence of gaps in this area of knowledge.

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In view of these arguments and the complexity of the medication process, especially in newborns, it is understood that the adoption of the assumptions of ecological restorative approach offers resources to comprehensively and exhaustively explore the socio-technical care systems, with careful attention to the local factors and systemic aspects of this care environment. In light of the above, the objective of this research is to analyze the factors that interfere in the safety of the medication process in a neonatal intensive care unit.

METHOD

An exploratory study, with a qualitative approach based on the perspective of the ecological restorative approach. The origin of the ecological restorative approach is in the interchanges between the biological/natural and human sciences and was adapted to the area of health and patient safety by Canadian researchers. This approach provides a comprehensive view of the processes involved in the complex health system through the engagement of professionals who explore, rethink, critique and propose improvements both in their practices and in their work environment. The use of photographic methods in this perspective helps professionals to participate collaboratively in the identification of risks and to propose methods that can strengthen patient safety.

The four pillars of this approach are considered: (i) the ethics of the environment - the integrated work with the members of the community in order to understand its history, culture and practices; (ii) citizen science - the use of participatory research methods such as field observation and photographic methods; (iii) engaged practice - the adoption of restorative practices, self-monitoring and a daily work guide in order to improve environmental conditions; and (iv) adaptive learning - using everyday findings to re-imagine and recreate better ways of living among the individuals involved and the shared context.

The study was carried out at the neonatal ICU of a public hospital, specialized in maternal and child health, in Southern Brazil. The sample was intentional and comprised of one nurse and 11 nursing technicians who were working during the period of data collection and who also expressed an interest in discussing the topic and in participating in the study by signing the informed consent form. The inclusion criterion was: to be a professional of the nursing team at the neonatal ICU at the study site. Exclusion criteria for the participation of the research were: being a nursing manager of the sector at the time of data collection, professionals who act as relief staff (were not exclusive to neonatology), or who were on a temporary contract, with less than 6 months in the department.

Data collection was performed between December 2014 and March 2015, through two focus groups and the participatory photographic method, collection techniques which are aligned with the ecological restorative approach. Twelve nursing professionals participated in the study, 11 of them in the first focus group, two of them participated in the photography walkabout, and four of them in the second focus group. In the second focus group, a new participant was added due to the withdrawal of the seven professionals who were in the first meeting.

A total of 11 professionals participated in the first focus group, one nurse and 10 nursing technicians. The objectives of the research were presented and guiding questions were raised for the discussion based on the descriptive data of the adverse events reported by the professionals of the unit, made available by the institution’s risk management team. The guiding questions were related to the group’s opinion regarding the medication process in the neonatal ICU, on the practice of intravenous drug dilution and administration in the unit, among others. After this focus group, the discussions were transcribed and analyzed using the Nvivo 10 program, in order to create an itinerary for the photography walkabout, which aimed to capture the safety-related factors in the use of medication in neonatology which were brought up by participants in the first focus group.

Before the photography walkabout, the itinerary was validated by three participants from the first focus group. Validation was performed by consensus among the participants, on the pertinence and relevance of the points highlighted in the itinerary, which portrayed the discussions of the first focus group and indicated critical points of the medication process in the unit. They were invited to participate in the photography walkabout, only one participant refused because they already had a prior scheduled commitment on the same day as the walk. The participants of the photography walkabout had the function of narrating the photos that were being taken, as well as to proceed to the recording of all the dialogues that happened during the route. The main researcher (study guide, guiding the taking of photos), the master student (taking the photos), researcher (taking notes - making field notes and the digital photos form),
nurse technician and nurse (who led the group to the unit and pointed out the aspects listed in the script), participated in the photography walkabout, which constituted a group of five members.

After the photography walkabout, the narratives were transcribed and analyzed, and the photographs were selected and organized by the researcher using the NVivo 10 program. Both the participants who had their statements recorded and those who were photographed confirmed their participation by signing of a specific informed consent form for this stage of the research.

The photographic walk resulted in 50 photographs of which 16 were selected by the researcher, based on the objective of the study in order to analyze the main factors that interfered in the safety of the medication process in the place where the participants worked, as a source of discussion of the second focus group, in which the participants could express their opinions about the obtained images. In addition, this focus group aimed at surveying the prevention measures of medication errors in neonatology which were highlighted by the participants of this meeting.

The same participants of the first group were invited to the second focus group. However, seven participants were unable to attend, with four participants from the first meeting, and one member was replaced by one alternative participant from the list of participants in the second focus group, giving a total of five participants in the second meeting. The number of participants in the focus groups followed the guidelines of studies that refer to six to 15 people as recommended, however smaller sizes of five to seven participants can also be used to deepen certain aspects.22-23

The material from the focus groups and photography walkabout was organized through the NVivo 10 program and analyzed through thematic content analysis.19 This analysis method consists in the discovery of the nuclei of meaning that compose a communication, whose presence or frequency responds to the objectives of the proposed research.24 The organization of the data in the NVivo 10 program served to ratify and complement the categorization proposed by the researcher, giving consistency to the data analysis.

The study was approved by the Research Ethics Committee under Protocol number 14.164, CAAE 34641714.7.0000.5530 and was in compliance with the recommendations of Resolution 466/12 of the National Health Council on research with human beings. The research was presented and authorized by the managers of the institution after approval from the ethics committee, and the participants were asked to sign an informed consent form at each stage of the research. In the transcription of the speeches, the letter P followed by the number referring to their order of participation in the meetings, as well as GF1, GF2 or CF, was used to identify the subjects and also to maintain confidentiality, distinguishing which of the moments of the research the same happened, focal group 1, focal group 2 or photographic walk, respectively.

RESULTS

The categories that emerged from the thematic content analysis were organized in order to better understand the information: “Individualized approach and punishment culture for medication errors”, “Safety factors related to the physical structure of medications in the Neonatal ICU”, “Safety factors related to routines and protocols” and “Nursing as a barrier to the occurrence of medical prescription errors”.

Individualized approach and punishment culture for medication errors

In the first focus group, it was discussed how punitive measures are taken when medication errors occur. Participants understood that punishments were made differently depending on the category of those involved, according to the following statement: I think it depends on who has to be punished. I think if it’s a doctor, things do not happen. But, if you are a nursing technician... (P7, GF1).

During the discussion on the subject they commented that, in situations in which the nursing technician committed an error, a disciplinary administrative proceeding was opened and the professional was dismissed. However, they reported on occasions in which no administrative referral had been made when physicians had committed errors.

The errors were not seen systemically, but rather individualized, as described in the following reports on an adverse event suffered by a baby in 2013, where an enteral diet was administered parenterally: this was an isolated case that occurred with the feeding, a colleague had just put the feeding solution into a venous access (P4, GF2).

In reporting this situation, participants stated that the professional involved in the error was re-
turning from an extended health leave and was not able to fully assume the nursing activities in a neonatal intensive care unit. This individualized approach to error was verbalized by only one participant of the second focal group, but the other participants shared this perception.

(Un)safety factors related to the physical structure of medications in the Neonatal ICU

Participants discussed factors related to the physical structure that contributes to patient safety, such as the segregation of high risk medication, and which predispose them to unsafe assistance, such as the storage of a particular medications mixed with another type of medication, as shown in Figure 1.

Figure 1 - Photo 35: storage cabinet for oral, injectable medicine and medical supplies

Where are you going to put it? That is the patient’s, we do not share with the others, not even the medications that are in the health clinic. But where will I put it? (P1, GF2).

Figure 1 identifies the packaging of oral and injectable drugs together with medical materials and topical medication. In addition, medications that are not routinely used, and are not stocked in the unit, but are prescribed for a patient, are at risk of being lost because there is no specific place for their storage.

In contrast, the controlled medication, which according to the routine of the unit should be locked away, are kept open, because other medications that do not belong to that category are stored with the controlled medication. Figure 2 shows the photograph of the controlled drug drawer of the unit under study.

But there are other medications together that are not controlled (P4, CF).

The risk related to the multiple medication stored in the controlled medication drawer, according to Figure 2, was raised by the photography walkabout participants and, although not discussed in the first focal group, photographs were taken of the same. In the second focus group the participants reported changes that had occurred in the controlled medication drawer, which the nursing team professionals themselves had done, during the course of the research. Now the controlled are only with the controlled and are divided, each has an item, and the medication is now in smaller divisions (P2, GF2).

(Un)safety factors related to routines and protocols

Early in the first focus group, participants highlighted the medication dilution chart as an effective tool for medication safety. However, they reported that this was incomplete for use in neonatology, since the dilution for this population is dependent on the weight and other characteristics of the newborn, as shown in Figure 3.

Figure 3 demonstrates that the medication dilution chart used in the study period contained four columns, which included, the name of the drug, the volume and diluting agent used for reconstitution, the storage conditions and the stability time, and some observation pertinent to the medication. It is observed that there is no dilution column or maximum concentration that guides the nursing technician to do it according to the weight of the patient.
For redilution we do not have a routine. [...] And for a baby you will take off 0.2 of the medication, how much more will you put? The baby is small, the baby is big, what weight is it? (P2, GF2). Medications that had a stability of a few hours were diluted, identified and left on a tray at the nursing station for common use. However, the participants reported that this routine was not always followed, and that bottles and ampoules were often opened in this place, which could result in contamination of their contents and consequent harm to the patient. Figure 4 demonstrates the above.

Participants in the first focus group talked extensively about the “big tray” and how there wasn’t a standardization for the provision of these drugs that could be used in multiple patients, as can be seen in Figure 4. When the photograph was presented in the second group focal, their disapproval to what they were seeing was evident. The participants reported that they did not use the already opened ampoules, nor the syringes with diluted drugs, according to the established routine in the sector because they did not seem safe.

**Nursing as a barrier to the occurrence of medical prescription errors**

In this topic, the participants’ statements were organized regarding the role of the nursing team as the last barrier of errors effecting the patient, especially regarding questioning the medical prescription. In the following report, the nursing technicians involved were surprised by the prescribed doses, and questioned the medical staff about their prescriptions.

This often happens. IVs with very high amounts of electrolytes, we look, but the baby is very small, it can not be. We go to the nurse, the nurse goes to the doctor: ‘No, it’s wrong, it’s good that you saw it’ This happens very often (P6, GF1).

The report demonstrates the concern of nursing technicians when doses that are not common to their daily practice appear in the medical prescriptions. It is emphasized that the nurse seems to exert this liaison role, taking the observations of the nursing technicians and questioning the medical team.

In another similar reported case, the nursing technician emphasized the importance of nursing team autonomy in double checking the items that are prescribed, and especially the freedom to be able to discuss the prescriptions with the medical team as a way to prevent unnecessary harm to the patient.

I went to the resident and I spoke with her: ‘Please check this here, see if that’s correct.’ And she had the humility to check and see: ‘No, really, it’s three times more, it’s very high, I was wrong’ and she rewrote the prescription. I did not give the medication before, I went, I was not going to administer it, I went to question her. I think this is important that we have this autonomy, this openness to be able to check (P9, GF1).

However, one participant expressed concern about assuming this responsibility due to...
the high number of tasks included in the nursing work process.

It’s just, in addition to our workload getting heavier because of several different factors, we still have to pay attention if the doctor correctly prescribes. There are some things that are really obvious [...]. That we look like this: no, this is not possible here, this is not the right thing to do. And then we always go and question, but it should not be like that, right (P1, GF2).

According to the information described and documented in photographs, the participants’ statements highlighted several potential risks to patient safety in neonatology.

DISCUSSION

The assumptions of the ecological restorative approach and participatory photographic methods contributed to the mobilization of the professionals involved in the medication processes and this provided a prime opportunity for them to rethink their practices and to identify potential sources of risks to the safety of neonates. These aspects were also highlighted in other studies that highlight the participatory nature of this methodology, which, in addition to modifying the practice environments, contribute to sustaining the desired changes, through professional engagement.17-20

The study participants reported that the different professional categories were treated differently when an adverse event occurred, and that nursing professionals often suffered punishment, such as administrative referral due to their errors. This perception is confirmed in a study that identified the persistence of the punishment culture regarding medication errors in nursing staff.25

In the participant’s statements we can perceive the institution’s reactive attitude to the adverse events that occurred, and the lack of an institutional policy that prevents the occurrence of such errors. The third pillar of ecological restorative thinking proposes that, through engaged practice, the workers themselves create ways to improve the environment conditions.21 A beginning of this engaged team attitude is observed when, after the analysis of an error, barrier measures for the prevention of faulty airways were implemented by establishing a double checking routine.

The individualized approach to error, which seeks to blame, for the most part, those who are in direct care, does not account for reducing health care errors. Other areas of complex activities, such as aviation and industry,26 already use a systemic approach to understand error, from the understanding that errors are inherent in human activity, aiming to create systems that anticipate errors and prevent or capture them before they cause harm or damage.27

Nursing acts in the last stage of the medication process, through the preparation and administration of drugs. Therefore, it has the opportunity to play a fundamental role in detecting errors in the prescription and dispensing phases, acting as a barrier to medication-related adverse events.27,29 This was clearly identified by the research participants, as they reported a number of episodes in which they had the opportunity to question inadequate medical prescriptions and in turn, prevent errors from reaching patients.

However, some authors have identified lack of experience as a risk factor for the occurrence of medication-related incidents.27,29,30 Resident physicians, nurses and nursing technicians who are unfamiliar with prescriptions, especially in relation to drug dosages prescribed for neonates in intensive care are less likely to recognize an error.

In addition, data from the present study demonstrated that the unit’s method of medication storage, loss of non-daily replacement drugs, inadequate dilution, and packaging for use in more than one patient, both in refrigeration and on the counter (“the big tray”), make the process unsafe, and predispose the occurrences of incidents in newborns. These findings, which depict aspects of local ethics, were also found in a systematic review,31 as other studies included in the study identified medication stocks as a risk factor for their exchange and loss.

Due to its specificity, neonatology requires routines directed at the needs of newborns, therefore, protocols for adult use do not respond to the care demands of this population.32 Participants reported that the drug dilution chart, although very useful for the reconstitution of lyophilized medication, does not meet the need for standardization of redilution for the administration of very small doses, such as those used by neonatology patients.

The weaknesses and complexity of the medication preparation and administration processes are intrinsically related to the work processes of the nursing team. There is a need to deepen this area of knowledge, especially in the area of neonatology, with a view to contributing to the construction of a safety culture in the practice scenario.33,34

The ecological restorative research method envisages that participants engage in a practice which is engaged in the results they construct in a participatory manner, and adaptive learning, gener-
This was perceived throughout the study, as upon identifying that the controlled drugs were stored together with other drugs in the first focus group and in the photographic walk, the team reorganized the space that contained these medications and started to keep the drawer closed. In addition, the routine of segregation and control of high risk medication was identified as a point of improvement already implemented for safety in the use of medication in the unit, which can be referred to as a process of continuing education.

Despite the relevance of the findings of this study, due to the complexity of the theme and the methodology used, its limitations must be considered. Conducting the research in a limited period of time and in a single institution restricts comparison with other investigations. In addition, the reduced participation of nurses and the fact that they have worked as a professional category restricts the results obtained to a specific reality.

Despite these limitations, the results present innovations and contributions to the understanding of the phenomenon, as well as indicatives of actions to prevent risks in the use of medication in neonatology. In addition, the possibility of further investigations exploring the subject in different contexts and among different professional categories is envisaged, since the medication process also includes medical and pharmaceutical professionals. Another aspect to be considered in future studies is the challenging inclusion of users (patients and family members) as active elements of security in the health services scenario.

CONCLUSIONS

The study of safety in the medication process in neonatology from the perspective of the nursing team through a restorative ecological approach was presented as an opportunity for researchers and professionals think critically about this process in a collaborative way. By realizing the autonomy that the team acquired in order to propose and implement changes in their daily practice, it was possible to ratify the importance of research focused on engaged practice and its rewards to the researcher in seeing his or her research in real reality.

The findings highlight the need to review institutional policies and practices in order not to focus the errors on individual accountability without assessing the systemic causes that lead to the error. In addition, the participants highlighted the role of the nursing team in the detection of medical prescription errors, functioning as the last barrier in the prevention of errors in the medication process.

The study also showed that there are numerous risk factors for incidents in the medication process in neonatology, such as the medication-related physical structure, and the lack or incompatibility of routines and protocols. Among the factors related to physical structure are the poor storage conditions of the medications and the storage of numerous medication together with those controlled by the unit. Regarding the routines and protocols, the participants reported that there was a lack of procedure standardization and that some protocols, such as the medication dilution chart, were based on adult dosages, and their lack of specificity does not account for the demands of the care for newborns.

Therefore, the study also highlights methods for training health professionals, and emphasizing safety in the medication process as a fundamental issue. It is also envisaged that the implementation of restorative ecological approach, as a management tool, can support the managers and leaders of health services in the construction of policies that enable the construction of a patient safety culture, supporting workers throughout the institution.

REFERENCES


Medication safety in neonatology: nursing in the perspective...


