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ORIGINAL ARTICLE

THE ROOT CAUSE ANALYSIS METHOD FOR THE INVESTIGATION OF ADVERSE EVENTS

O MÉTODO DE ANÁLISE DE CAUSA RAIZ PARA A INVESTIGAÇÃO DE EVENTOS ADVERSOS EL MÉTODO DE ANÁLISIS DE CAUSA RAIZ PARA INVESTIGACIÓN DE EVENTOS ADVERSOS

Mileide Moraes Pena¹, Marta Maria Melleiro²

ABSTRACT

Objectives: to identify adverse drug error, phlebitis, fall and pressure injury events and analyze their root causes by proposing interventions. **Method:** quantitative, exploratory and descriptive study, with retrospective data collection, in a university hospital, using a sample of 263 events. The analysis employed descriptive statistics and specific tests. **Results:** 39.9% corresponded to phlebitis; 32.7%, to medication errors; 16% to pressure injuries and 11.4% to falls. Most of the events occurred in the morning, in the Intensive Care Units, and involved Nursing assistants/technicians, followed by the nurse and the doctor. In 66.5%, the predominant root cause was the professional's failure, mainly, in the communication process in the care transitions. Interventions were proposed and implemented. **Conclusion:** evidenced the prevalence of phlebitis, followed by medication errors. Most of the events had their cause attributed to the professionals, identified the need for improvement in the process of communication between the teams, resulting in interventions in the care practice. **Descriptors:** Quality of Health Care Patient Safety; Patient Safety; Safety Management; Risk Management; Nursing.

RESUMO

Objetivos: identificar os eventos adversos erro de medicação, flebite, queda e lesão por pressão e analisar suas causas raízes, propondo intervenções. **Método:** estudo quantitativo, exploratório e descritivo, com coleta retrospectiva dos dados, em hospital universitário, utilizando-se uma amostra de 263 eventos. A análise empregou estatística descritiva e testes específicos. **Resultados:** 39,9% correspondem a flebitis; 32,7%, a erros de medicação; 16%, a lesões por pressão e 11,4%, a quedas. A maioria dos eventos ocorreu no período da manhã, nas Unidades de Terapia Intensiva, e envolveu auxiliares/técnicos de Enfermagem, seguidos pelo enfermeiro e o médico. Em 66,5%, a causa raiz predominante foi a falha do profissional, principalmente, no processo de comunicação nas transições do cuidado. Foram propostas e implantadas intervenções. **Conclusão:** evidenciada a prevalência das flebitis, seguidas pelos erros de medicação. A maioria dos eventos teve sua causa atribuída aos profissionais, identificada a necessidade de melhoria no processo de comunicação entre as equipes, resultando em intervenções na prática assistencial. **Descritores:** Qualidade da Assistência à Saúde; Segurança do Paciente; Gerenciamento de Segurança; Gestão de Riscos; Enfermagem.

RESUMEN

Objetivos: identificar los eventos adversos error de medicación, flebitis, caída y lesión por presión y analizar sus raíces, proponiendo intervenciones. **Método:** estudio cuantitativo, exploratorio y descriptivo, con recolección retrospectiva de los datos, en hospital universitario, utilizando una muestra de 263 eventos. El análisis empleó estadística descriptiva y pruebas específicas. **Resultados:** 39,9% corresponden a flebitis; 32,7%, a errores de medicación; 16%, a lesiones por presión y 11,4% a la caídas. La mayoría de los eventos ocurrieron en el período de la mañana, en las Unidades de Terapia Intensiva, e involucró al auxiliares / técnicos de Enfermería, seguidos por el enfermero y el médico. En el 66,5% la causa raíz predominante fue la falla del profesional, principalmente, en el proceso de comunicación en las transiciones del cuidado. Se han propuesto e implantado intervenciones. **Conclusión:** evidenciada la prevalencia de las flebitis, seguidas por los errores de medicación. La mayoría de los eventos tuvieron su causa atribuida a los profesionales, identificada la necesidad de mejora en el proceso de comunicación entre los equipos, resultando en intervenciones en la práctica asistencial. **Descriptor:** Calidad de la Atención de Salud; Seguridad del Paciente; Gestión de la Seguridad; Gestión de Riesgos; Enfermería.

¹Nurse, PhD, PUC-Campinas Hospital. Campinas (SP), Brazil. E-mail: mileidempena@gmail.com; ²Nurse, Associate Professor, University of São Paulo. São Paulo (SP), Brazil. E-mail: melleiro@usp.br

INTRODUCTION

International studies show that 3% to 17% of admissions are associated with Adverse Event (AE), resulting in prolonged hospitalization, disability or death. Half of these events are considered preventable.¹

In Brazil, in 2011, there were 11,117,837 hospitalizations, with an estimated 844,875 (7.6%) AE. Of these, 563,575 (66.7%) were considered avoidable and evolved to death in 40% of cases.² This proportion expresses the relevance of the problem and the urgency for actions that act on unnecessary harm to patients.

The deficiencies of the care system in its conception, organization and functioning are pointed as the main factors for the occurrence of AE. The premise is that human beings make mistakes, so mistakes are expected and considered consequences and not causes. Although the human condition cannot be changed, it is possible to act by creating defenses or barriers in the system.³

However, in practice of assistance, there is still a punitive culture, creating obstacles to notifications; especially in cases that result in harm, missing out on important learning opportunities. Understanding AE and analyzing it carefully, in a multidisciplinary way, is the best way to correct the practice. The concern with patient safety is to provide instruments for professionals to take power over preventive measures, approaching the event in a constructive way, in the search for the root cause and decrease of occurrences.

The methodology of Root Cause Analysis consists of a retrospective evaluation used to identify the root causes of near misses and events with or without damage.⁴ Several tools have been used for root cause analysis: Barrier Analysis, Analysis of Changes, Diagram of Ishikawa, among others, elaborating the causal chain.

Systematic review reviewed studies from the United States, United Kingdom, Australia and Canada, which identified active failures (errors and violations) as contributing factors for incidents. Individual factors, communication, equipment and supplies were the most reported.⁵

In the United Kingdom, root cause analysis identified factors related to in-patient deaths. The most common were the difficulty to recognize signs of deterioration (23%), patient retraction (10%), healthcare-associated infections (10%), unexpected intraoperative death (6%), and failures in the handover process (5%).⁶

In the Brazilian reality, the academic production on the subject is still scarce. In addition to a few studies, until now there is no research with a broad geographical scope, which would be important, considering the great variability of the characteristics of Brazilian hospitals.⁴

Some AEs have drawn attention to how often they occur: medication errors, phlebitis, falls, and pressure injuries. Such events, for the most part, are preventable and, usually cause temporary or even permanent damage.⁷⁻⁹

Given this scenario, it is extremely important to analyze these events in depth, in search of the root cause, so that effective risk management measures can be implemented to prevent new events.

Given the scarcity of studies in Brazil about the root cause analysis of AD and the relevance of the topic to patient safety, it is considered relevant to develop this work.

The objectives of this study were:

- To identify the AE medication error, phlebitis, fall and pressure lesion.
- To analyze the root causes of events and propose interventions.

METHOD

A quantitative, exploratory and descriptive study, with retrospective data collection, consisting of 263 EA of medication error, phlebitis, fall and pressure injury that occurred in a large, tertiary private university hospital in the interior of the state of São Paulo, Brazil.

Data collection took place in 2014. The sample was calculated considering the total of 831 events occurred in the last triennium, with a sampling error of 5% for more or less and a 95% confidence interval. This interval is justified because the institution received its first quality certification (Level 1) in 2010. Such certification is issued by the National Accreditation Organization (ONA), a non-governmental and non-profit entity that certifies the quality of services in Brazil, focusing on patient safety. Level 1 corresponds to the institutions that meet patient safety criteria in all areas of activity, including structural and care aspects.

The data were extracted through documental analysis of event notification reports and structured instrument. The event notification reports were systematically selected by statistical recommendation and analyzed individually.

The following variables were analyzed: event types, date, time, patient's age, unit

where the event occurred or was notified, professionals involved in the event and root cause.

The involvement of the professionals was considered from the participation in the occurrence or notification of the event, in the mitigation actions until the investigation and the elaboration of the action plan.

The Ishikawa Diagram¹⁰ was used to identify the factors that caused the events, divided into six classes:

- Method - how the process is carried out, organization of information and work;
- Raw materia - characteristics of the inputs needed for the process;
- Labor - human resources;
- Machines - equipment and systems (computers, telecommunications, etc.) used to carry out the work;
- Measurement - how the result is measured, process supervision;
- Environment - physical characteristics of the work environment (temperature, noise, lighting, etc.) and people relation (motivation, remuneration, relationship between hierarchical levels).

The data were stored in Excel Spreadsheet, processed in the Microsoft Excel system and statistical software Statistical Package for Social Science (SPSS 22). Descriptive statistics

were used, applying the specific tests of Welch, ANOVA and Chi-square for the crossing of variables.

The research project was approved by the Research Ethics Committee (REC) of the university, under opinion nº 447.736.

RESULTS

The events were distributed in 105 (39.9%) phlebitis, 86 (32.7%) medication errors, 42 (16%) pressure injuries and 30 (11.4%) falls.

The mean age was 52.04 years (standard deviation, SD = 25.17). The Welch test compared the means of age among the people of the groups formed by the type of event, which were considered statistically different ($p < 0.001$). Medication errors and phlebitis were identified in patients from zero year. For falls and pressure injuries, the minimum age was 25 and 26 years, respectively. The patient with the highest age of the sample (101 years) suffered a fall.

The AEs occurred predominantly at the morning shift, except for the falls, distributed equally in all three work shifts. There was no statistical relationship between time and occurrence of AD ($p = 0.903$) (Table 1).

Table 1. Distribution of events by turn of occurrence. Interior of São Paulo (SP), Brazil, 2014.

Shift	Medication error		Phlebitis		Fall		Pressure lesion	
	N	%	N	%	N	%	N	%
Morning	35	40.7	42	40.0	10	33.3	17	40.5
Afternoon	31	36.1	34	32.4	10	33.3	13	31.0
Night	18	20.9	27	25.7	10	33.3	12	28.5
Not informed	2	2.3	2	1.9	0	0.0	0	0.0
Total	86	100.0	103	100.0	30	100.0	42	100.0

$p = 0.903$ (Chi-square test, statistically significant difference if $p\text{-value} \leq 0.05$)

Table 2 shows a greater number of medication errors and pressure lesions in the Intensive Care Units (ICU); phlebitis, in the

Hospitalization Units and falls, in the Emergency and Emergency Units ($p\text{-value} < 0.001$).

Table 2. Distribution of events by service in which they occurred or were reported. Interior of São Paulo (SP), Brazil, 2014.

Services	Medication error		Phlebitis		Fall		Pressure lesion	
	N	%	N	%	N	%	N	%
Outpatient center	0	0.0	0	0.0	2	6.7	0	0.0
Urgency / Emergency	17	19.8	32	30.5	15	50.0	2	4.8
Intensive care unit	34	39.5	27	25.7	2	6.7	24	57.1
Inpatient unit	26	30.2	39	37.1	10	33.3	9	21.4
Home care	3	3.5	1	1.0	1	3.3	7	16.7
Surgery Center	5	5.8	1	1.0	0	0.0	0	0.0
Hemodialysis	1	1.2	0	0.0	0	0.0	0	0.0
Chemotherapy	0	0.0	5	4.7	0	0.0	0	0.0
Total	86	100.0	103	100.0	30	100.0	42	100.0

$p\text{-value} < 0.001$ (Chi-square test, statistically significant difference if $p\text{-value} \leq 0.05$)

In the majority of the events, more than one professional was involved, however, the highest participation was by the assistant /

Nursing technician, followed by the nurse and the doctor (Table 3).

Table 3. Distribution of events by professional involved in the event. Interior of São Paulo (SP), Brazil, 2014.

Professional	Medication error		Phlebitis		Fall		Pressure lesion		p-value*
	N	%	N	%	N	%	N	%	
Assistant / Nursing Technician	74	86.0	99	94.3	28	93.3	41	97.6	0.08
Pharmacy technician	24	27.9	4	3.8	0	0.0	0	0.0	<0.001
Nurse	56	65.1	94	89.5	25	83.3	40	95.2	
Pharmaceutical	30	34.9	77	73.3	0	0.0	5	11.9	<0.001
Physiotherapist	0	0.0	0	0.0	1	3.3	6	14.3	<0.001
Doctor	47	54.7	72	68.6	22	73.3	10	23.8	
Nutritionist	2	2.3	1	1.0	0	0.0	10	23.8	<0.001
Others	2	2.3	0	0.0	3	10.0	0	0.0	0.004

*p-value obtained by Chi-square test, statistically significant difference if p-value ≤ 0.05

According to the data in table 4, most of the events presented more than one cause, predominating the root cause related to the

workforce (professional failures), except in the phlebitis, related to the raw material.

Table 4. Prevalence of root causes by event. Interior of São Paulo (SP), Brazil, 2014.

Root cause	Medication error		Phlebitis		Fall		Pressure lesion		p-value*
	N	%	N	%	N	%	N	%	
Method	32	37.2	20	19	11	36.7	16	38.1	0.018
Raw material	5	5.8	90	85.7	4	13.3	16	38.1	<0.001
Workforce (professionals)	82	95.3	39	37.1	20	66.7	34	81	<0.001
Machines	4	4.7	5	4.8	10	33.3	6	14.3	<0.001
Measurement	0	0	0	0	2	6.7	9	21.4	<0.001
Environment	20	23.3	8	7.6	16	53.3	19	45.2	<0.001

*p-value obtained by Chi-square test, statistically significant difference if p-value ≤ 0.05

The causal factors prevalent in each category of root cause are described in table 5. 175 (66.5%) events, with root cause related to the workforce, report verbal and written

communication failures as the main causal factors, particularly in the process care transition.

Tabela 5. Detalhamento dos fatores causais dos eventos por causa raiz. Interior de São Paulo (SP), Brasil, 2014.

Root cause	Detailing of causes	N	%
Method	Absence of standardization of the ducts in the transition process of care; absence / fragility of the description of the work process and prevention guidelines; difficulty in accessing the operating rules and procedures described.	79	30.0
Raw material	Potential irritant of drugs; quality of materials / inputs used in care and / or prevention.	11	43.7
Workforce (professionals)	Failure of verbal and written communication in the shift, on the transfer of the patient and on the performance of the procedure; absence of record in medical records; incomplete prescription; absence of checking; failure to identify risks; Incomplete event notification report; number of pharmacists.	17	66.5
Machines	Absence of information regarding the irritant potential of drugs and the time and speed of infusion in the electronic prescription system; equipment without preventive maintenance.	25	9.5
Measurement	Absence of monitoring / supervision of the result.	11	4.2
Environment	Furniture / equipment in bad conditions of use and / or without evidence of preventive maintenance; interruptions; over crowded; work overload.	63	23.9

DISCUSSION

In other studies, infections and falls were the most frequent events.¹¹⁻² There are indications of prevalence of AD at night shift.¹³⁻¹⁴ It is important to consider that the

Nursing staff dimensioning at this institution does not contemplate the reduction of professionals in the night period . In addition, because it is a university hospital, there is a greater concentration of professionals and procedures in the morning.

The ICU is an unhealthy environment, a place of constant tensions, where professionals experience harrowing experiences. In a cumulative and progressive way, stress can lead to psychological distress, compromising the organization of work, and may result in AD, as we can see in the results of this research, highlighting the occurrence of medication errors and pressure injuries in these units.

Although ICUs present a higher rate of medication error, this did not reflect the occurrence of phlebitis, which may be considered a consequence of the application of some medication. It can be inferred that the design of ICUs favors the supervision of venous access conditions, whereas, in the hospitalization units, the number of professionals is relatively smaller.

One factor impacting the prevalence of falls in emergency and emergency units is overcrowding. With an occupancy rate of 258%, unsafe conditions emerge: stretchers in the corridor, insufficient sizing, increased workload, among others.

The hallmark of Nursing, which is the patient's presence in the 24 hours of the day, makes this category present in most events. On the other hand, it shows that these professionals are in a privileged position in the prevention of AD, detecting the complications early and performing actions to minimize damages.¹⁵

Phlebitis had greater medical involvement due to incorrect dilution prescriptions and / or incorrect infusion time for drugs with high irritant power. Secondly, medication errors, due to prescriptions failures, making it difficult for Nursing and pharmacy professionals to understand, causing errors in dispensing, dilution and administration.

Historically, there is a difficulty in understanding medical prescriptions due to spelling. These difficulties have been minimized with the insertion of electronic prescription, even in the institution studied. However, other problems arise from this practice, such as the prescription of wrong dose and route and dilution. When using the computerized system, doctors select the wrong item and do not conference before or after printing.

In the situations mentioned above, the intervention of the clinical pharmacist could prevent its occurrence by conducting a second prescription conference before dispensing, and may discuss with the physician dilutions and drug interactions.

Although the pharmacist's role permeated the most diverse stages of care, it was found that his involvement in the analysis of events was restricted to AE phlebitis, drug analysis and its irritant potential.

In medication errors, the pharmacist restricted himself to investigating events involving specific processes of the Pharmacy Service, such as dispensing medications. This fact demonstrates the dichotomy between the work processes of the different professionals, which can lead to the failure of the actions implemented by the fragmentation of activities.

Approximately 86% of medication errors can be intercepted by nurses and pharmacists and knowledge upgrading is a strong ally in prevention.¹⁶

EAs are caused by faulty systems and, often, have common causes that can be generalized and corrected. Although each case is unique, there is a likelihood of similarities and patterns of risk factors that may go undetected when events are not reported and analyzed.²

When deepening the analysis, it was verified that the professionals' failures were mainly related to the process of communication between the teams in the transitions of care, suggesting the need for improvement in this process.

The implementation of a care transition program, associated with improvements in communication, reduced in 30% the preventable AEs in nine hospitals in the United States and Canada.¹⁷

In the opinion of Nursing professionals, the lack of communication between Nursing staff and medical staff is a strong reason for the occurrence of AD, suggesting that safe care depends on accurate and effective communication.¹⁸

Failure of verbal communication between the Nursing team and between the patient and the patient, together with failure of the records, was considered the second cause of occurrence of falls in a general hospital.⁴

It should be emphasized that the adequate number of professionals is an indispensable prerequisite for safe care, and it is an institutional responsibility to provide human resources. The quantitative adequacy of professionals, according to the needs of patients, reduces the risk to patients and the incidence of health problems for professionals.¹⁹

Constant surveillance is a key factor in preventing falls. There is evidence that adequate Nursing staffing contributes to

improved care outcomes and reduced falls in hospitalized patients.²⁰

In this study, most phlebitis was classified as chemical phlebitis due to the drug's irritant potential, reflected in the root cause analysis, the predominant factor being the raw material. In a part of these events, the absence of information regarding the irritating potential of the administered medication was verified, as well as the lack of orientation regarding the time and infusion rate, in an easy-to-see place for the Nursing team.

A study that translated, adapted and evaluated the psychometric properties of Phlebitis Scale for the Portuguese population, observed an incidence of 35.5%. The variable administration of drugs or solutions with risk characteristics for complications showed a statistically significant distribution.²¹

In the AE whose root cause was the method, it was found that the work process and the orientations related to that event were not well defined or described. The care transition process was not defined and aligned in all its aspects: shift change; transport and transposition of patients; unit transfers; referrals for exams or discharges, disregarding the particularities and complexity of each patient.

The definition of a process goes through several stages and one of them would be the description of the process, the registration and the orientation of the team involved. These steps are closely linked to written and verbal communication. The description and implementation of prevention protocols bring the focus of therapeutic action into daily practice for the development of improvements and contribute to patients' quality of life.²²

The four EA related in this study presented environmental failures, either to a greater or lesser extent, evidencing the need to prioritize investments for physical and structural adaptations in the institution.

UTI professionals suggest actions aimed at improving quantity, quality and maintenance of materials and equipment, as well as improving the physical structure of the work environment.²³ In this direction, it is possible to verify the concern with the issues related to the environment and their influence on the occurrence of the AE.

Interventions

The events were discussed at a monthly meeting held at the institution, where the prevalent EAs were presented and which included the Directorates, the Middle

Management and the multiprofessional care team.

Considering that most of the events were related to the root cause of the workforce (professional failures) and that, in the unfolding of causal factors, there were communication failures between the teams in the transition process of care, the following improvements were proposed and implemented: elaboration / revision of protocols for the standardization of the ducts in the transition process of care (shift, shift and transposition of patients, unit transfers, referrals for exams or discharge); use of the Situation-Background-Assessment-Recommendation (SBAR) tool 24 for patient transfer between units and establishment of admission flows and patient care in the transition processes of care.

Thus, a review of the protocols was initiated, under the coordination of Nursing managements, and jointly with the multiprofessional team. Interactions between the multiprofessional teams and support teams were made, aligning patient admission flows in the care units and in the diagnostic and therapeutic support units, ensuring the registration in the medical records.

The pharmacist was involved in all analyzes of medication errors, regardless of the stage of the drug chain in which the failure occurred, in order to incorporate the multi-causality of events and interdisciplinarity.

In addition, a plan was drawn up for the purchase of wheelchairs, cradles and transport gurneys with grids and patient transfer boards, as well as a preventive maintenance schedule by the Engineering Service, to ensure safety in the use of the same.

CONCLUSION

The prevalence of phlebitis was evidenced, followed by medication errors. Most of the events were attributed to professional failures, suggesting the need for important reflection and understanding, on the part of these professionals and the board, that most of the AEs result from systemic rather than individual failures and that their vision should be expanded during this analysis, avoiding the culpability of the professional and strengthening a just culture.

In the deepening of the analysis of this root cause, it was possible to identify the need for improvement in the communication process between the teams, generating a movement of engagement in the analysis and discussion

of events, action planning and interventions in the care practice.

Retrospective analysis of data was limited to this study, since the consultation of the notification reports did not always provide all the detailed information about the occurrence of the event, restricting the analysis to the information contained in those documents.

It is concluded that the improvement of the safety culture, the incentive to the notification of the events, the analysis and discussion of its causes are important measures for the transformation of the scenario in the health institutions.

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Corresponding Address

Mileide Moraes Pena

Rua Irmã Maria Inês, 84, Torre 2, Ap. 102
Bairro Jardim Chapadão

CEP: 13070-030 – Campinas (SP), Brazil