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ORIGINALES

Use of the Conceptual Framework of the International Classification on Patient Safety in Nursing Ethical-Disciplinary Processes

Uso da estrutura conceitual da classificação internacional sobre segurança do paciente nos processos ético-disciplinares em enfermagem

Uso de la estructura conceptual de la clasificación internacional sobre seguridad del paciente en los procesos ético-disciplinarios en enfermería

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ABSTRACT:

The use of the conceptual structure of the international classification on the patient safety in the nursing ethical disciplinary processes.

Objective: To classify the denounced procedures in the ethical disciplinary processes according to the conceptual structure of the international classification on patient safety.

Method: This is a descriptive research with a quantitative approach and a documental and retrospective character which has analyzed the ethical disciplinary processes of the nursing professionals. It has been previously approved according to the CEP of the Federal University of São Paulo under the Number 110.390 and has not involved any human beings.

Results: The research has highlighted that the most recurrent incident has been related to "medication/IV fluid" with 21,3%. However, this percentage was not significantly different from the 20,2% of the "process/clinical procedure", of the 19,1% of the "resources/organizational management". The analyzed data in the ethical disciplinary processes has allowed to infer that in spite of the ideas to improve patient's safety, the errors in medication are still very common. Furthermore, the other incidents investigated have shown the necessity to pay attention to the professionals. It is very important to have better sources of information to better understand the complex events, and a deeper study to find out the real sources of risk related to assisting nursing professionals.

Conclusion: This research has enabled the classification of procedures that motivated the denunciation and implantation of the ethical disciplinary processes against nursing professionals. The use of one single classification has permitted to better identify the possible sources of risk to the safety of the patient, which is very valuable to the management of assistential risk.

Keywords: Nursing, Risk Management, Quality Management and Damage Liability.

RESUMO:

Objetivo: Classificar os procedimentos denunciados nos processos ético-disciplinares de acordo com a Estrutura Conceitual de Classificação Internacional sobre Segurança do Paciente.
Método: Trata-se de uma pesquisa descritiva de abordagem quantitativa, com caráter documental e retrospectiva, que analisou os processo ético-disciplinares dos profissionais de enfermagem, sendo aprovada preliminarmente pelo CEP da Universidade Federal de São Paulo sob o Parecer Número 110.390 e não envolveu seres humanos.
Resultados: A pesquisa evidenciou que o tipo de incidente mais recorrente foi relacionado a "Medicação/Fluido IV" com 21,3%. Porém este percentual não foi significativamente diferente dos 20,2% de "Processo/ Procedimento Clínico", dos 19,1% de "Recursos/Gestão Organizacional". Os dados analisados nos processos ético-disciplinares permitem inferir que apesar das iniciativas para melhorar a segurança do paciente, o erro de medicação ainda é um evento comum. Não obstante, os demais incidentes levantados demonstram a necessidade de se voltar a atenção para os profissionais. É latente a necessidade de melhores fontes de informações para a compreensão dos eventos adversos e melhor aprofundamento dos estudos para a descoberta das reais fontes de riscos relacionadas à assistência de enfermagem.
Conclusão: Esta pesquisa possibilitou a classificação dos procedimentos que motivaram as denúncias e a instauração dos processos ético-disciplinares contra profissionais de enfermagem. A utilização de uma classificação única permitiu identificar melhor as possíveis fontes de risco à segurança do paciente sendo de grande valia para a gestão do risco assistencial.

Palavras chaves: Enfermagem, Gestão de Riscos, Gestão da Qualidade, Responsabilidade Civil.

RESUMEN:

Objetivo: Clasificar los procedimientos denunciados en los procesos éticos y disciplinarios de acuerdo con el Marco Conceptual de la Clasificación Internacional para la Seguridad del Paciente.
Método: Se trata de una investigación descriptiva con enfoque cuantitativo, carácter documental y retrospectivo que examinó los procesos ético-disciplinarios de los profesionales de enfermería, preliminarmente aprobada por el CEP de la Universidad Federal de São Paulo previo dictamen n. 110 390, y que no involucra a seres humanos.
Resultados: La investigación mostró que el tipo más frecuente de incidente estaba relacionado con "medicamentos fluídos / IV", con 21,3%. Pero este porcentaje no fue significativamente diferente de los 20,2% del "Proceso / Procedimiento clínico" y de los 19,1% de los "Recursos / Gestión Organizacional". Los datos analizados en los procedimientos éticos y disciplinarios permiten inferir que a pesar de las iniciativas para mejorar la seguridad del paciente, los errores de medicación todavía son un evento común. No obstante, los demás incidentes demuestran la necesidad de poner especial atención a los profesionales. Es latente la necesidad de mejores fuentes de información para la comprensión de los eventos adversos y la profundización de los estudios para el descubrimiento de las verdaderas fuentes de los riesgos relacionados con los cuidados de enfermería.
Conclusión: Esta investigación permitió la clasificación de los procedimientos que motivaron las denuncias y el establecimiento de los procedimientos éticos y disciplinarios contra profesionales de enfermería. El uso de una sola clasificación permite identificar mejor las posibles fuentes de riesgo para la seguridad del paciente, siendo de gran valor para la gestión del riesgo asistencial.

Palabras clave: Enfermería, Gestión de Riesgos, Gestión de la Calidad y Responsabilidad Civil

INTRODUCTION

At the beginning of the 21st century, a publication by the Institute of Medicine of the National Academy of Scientists of the United States of America, called *To err is human: Building a safer care system*, brought up a subject that, although often discussed in health studies, needs constant dedication.[(1)]

The report presented data on the quality and safety of health services, which had a major impact and caused society to pay more attention to the issue.

Investigations on adverse events have highlighted the need to improve patient safety[2]. To this end, several global initiatives have been discussed and implemented by governments, companies, entities and the World Health Organization.

On the other hand, several organizations have pointed to the lack of research on patient safety[3,4]. Errors, in the area of health or any other, have a range of study possibilities, and their analysis must consider the context in which the error occurred[5]. In the field of health, identifying institutional risks - those that happen due to management failures - is of fundamental importance for good internal management. The risk for patients is directly related to the quality of care, civil liability and the burden of damages[6].

With the development of worldwide actions to mitigate the risks related to patient safety, it became necessary to standardize the language and some concepts applied to the subject. Thus, in 2009, the World Health Organization launched the Conceptual Framework for the International Classification for Patient Safety, Version 1.1[7], which categorizes the types of incidents involving patient care.

The Conceptual Framework for the Classification for Patient Safety consists of ten (10) categories and aims to "enable the categorization of information regarding patient safety using a set of standardized concepts with agreed-upon definitions, with their own terminology and relationships between them, based on a common ontology (for example, patient safety)"[7]. The categories are: Type of Incident (1), Consequences for the Patient (2), Characteristics of the Patient (3), Characteristics of the Incident (4), Risk Factors (5), Consequences for the Organization (6), Detection (7), Mitigation Factors (8), Actions for Improvement (9) and Actions for Risk Reduction (10).

Along with the development by specialists of studies related to patient safety, the subject also became part of the agenda of major communication vehicles (newspapers, magazines, television programs), mainly due to the interest of society. This interest eventually gave some importance to the discussion, promoting changes in the structures of health system management, with some of these changes occurring in issues regarding legislation and ethics of health professionals.

In this context, the nursing staff is also sensitive to the problem. As part of the health care system, it is often blamed for errors that eventually occur[5]. This blame can be verified in article 12 of Chapter I of Resolution/Cofen 311 of February 8, 2007, which establishes the Code of Ethics in Nursing, addressing the responsibilities and duties of professionals and says: "To ensure to the person, family and community nursing care free of damages resulting from malpractice, negligence or recklessness".[8]

Thus, it is also considered that the nursing staff must be aware of the complexity of their challenges and discourse, which emphasizes their willingness to assume leadership for the safety of health care, with evidence-based practice and research as essential elements of their training.[9] The Conceptual Framework for the Classification for Patient Safety should contribute to this purpose by assisting in the development of research and the search for evidence of improvement in care practice.

OBJECTIVES

To classify the procedures reported in the ethical-disciplinary processes according to the Conceptual Framework for the Classification for Patient Safety;

To identify the types of incidents related to the assistance procedures reported in the processes;

To analyze the types of incidents reported in the ethical-disciplinary processes.

METHOD

This was a descriptive research with a quantitative approach, with a documentary character and retrospective that was carried out at the Supervision Body of the professional practice of Nursing in the State of São Paulo, through the analysis of Ethical and Disciplinary Processes judged in the first and second instance, from January 2008 to December 2011.

During this period, 100 cases judged under the custody of the Regional Nursing Council of São Paulo were analyzed. The research sample consisted of 55 ethical-disciplinary processes.

The research was approved by the Ethical Committee of the Federal University of São Paulo under n. 110.390, and it did not involve human beings.

For the treatment of the data, the *Estrutura Conceitual da Classificação Internacional de Segurança do Paciente* (ECCIP) was used, adapted from the original Conceptual Framework for the International Classification for Patient Safety (ICPS), Version 1.1[7], which categorizes the types of incidents involving the professionals who were reported.

ICPS was used because it offers the possibility of organizing, grouping and relating the data of the ethical and disciplinary processes related to the reported procedures, to facilitate the analysis. Also, it is a validated international classification.

The research paid attention to the types of incidents and the contributing factors, that is, potential risk factors reported in ethical processes, however, it avoided discussing issues related to the characteristics of the incidents and their detection, since this information is not always present in the documents of the ethical proceedings.

In addition, the variables were collected according to the information available in the proceedings, mainly in the initial complaint, in the report of the Reporting Member and in the Trial Minutes. The 55 processes that comprised the sample involved 89 professionals who were reported. The research analyzed characteristics such as time since graduation, age, professional category, among others. Of these 89 professionals, 32 were found guilty of violating the Code of Ethics.

Parametric tests were performed for the statistical analysis, since the data were quantitative and continuous. In addition, the sample had more than 30 subjects, which, according to the Central limit theorem, guarantees the probability of a normal distribution. Thus, there was no need to test the normality of the data, allowing the direct application of the parametric tests.

RESULTS

The research analyzed 55 ethical-disciplinary proceedings from the Regional Nursing Council of São Paulo which took place from January 2008 to December 2011.

Chart 1 shows the distribution of the facts that were grounds for the complaint, which were classified according to the Conceptual Framework for the International Classification for Patient Safety. The factors presented in Table 1 were described in the terms presented in the reports.

Chart 1 - Indicative classification of the grounds for complaint. São Paulo (SP), 2014.

Reported Facts	Factors	Classification
Medication error:	Administering the wrong vaccine	Medication/ IV Fluid
	Administering the wrong medicine	
	Administration through the wrong way	
	Administration without prescription	
	Not administering the prescribed medicine	
	Medicine prescribed by non-qualified professional.	
Damage to the patient:	With sharp materials	Accident with the patient
	With hot water	
	Falling	
	Development of pressure ulcer due to negligence.	
Lack of professional supervision	Resources/Organization Management	
Illegally exercising the profession		
Non-compliance with legal/fiscalization requirements		
Distance shift		
Problems related to the Nursing Scale		
Lack of systematization of nursing care		
Occurrence during Patient Transport	Process/Clinical Procedure	
Loss/Disposal of Laboratory Material		
Occurrence During Bedside Containment		
Occurrence during application of Fleet Enema		
Occurrence during the Probe Passage		
Occurrence during Hand Hygiene		
Occurrence during Oximeter Manipulation		

Occurrence during Patient Care Guidance	
Occurrence During Venous Puncture	
Patient Abandonment	Clinical Administration
Lack of care	
Physical and verbal aggression	Behavior
Attempted rape	
Leaving the shift	
Professional refused to take care of the patient	
Error in diet administration	Diet/Food
Falsification of SAE files	Documents
Not filling in medical records	
Infusion of erythrocyte concentrate in wrong patient	Blood and Hemoderivatives

The facts related to the adverse events that motivated the reports are varied.

Table 1, below, shows the distribution of the type of incident reported with the respective statistics, considering P-value <0.001.

Table 1 - Distribution of Type of Reported Incident. São Paulo (SP), 2014.

Type of reported incident	N	%	P-value
1. Medication/IV Fluid	19	21.3%	Ref.
2. Process/Clinical Procedure	18	20.2%	0.853
3. Resources/Organizational Management	17	19.1%	0.709
4. Accident with the Patient	13	14.7%	0.242
5. Clinical Administration	8	9.0%	0.022
6. Behavior	6	6.7%	0.005
7. Diet/Food	3	3.4%	<0.001
8. Documents	3	3.4%	<0.001
9. Blood/Hemoderivatives	2	2.2%	<0.001

Of the 9 types of reported incidents, 19 (21.3%) were derived from adverse events with medication and/or IV fluid, followed by clinical procedures related to work processes, 18 (20.2%), and organizational management related to general human resources, 17 (19.1%).

Table 2, below, shows the distribution of the type of incident related to the professional category.

Table 2 - **Distribution of the type of incident reported by professional framework of the ethical-disciplinary process. P-value <0.001. São Paulo (SP), 2014.**

	QI			QII			QIII		
Professional Category	**N**	**%**	P-value	**N**	**%**	P-value	**N**	**%**	P-value
Accident with the Patient	6	12.24%	0.027	3	60%	Ref.	6	17.14%	0.169
Clinical Administration	6	12.24%	0.027	0	0.00%	0.051	1	2.86%	0.006
Behavior	0	0.00%	<0.001	0	0.00%	0.051	6	17.14%	0.169
Diet/Food	1	2.04%	<0.001	0	0.00%	0.237	0	0.00%	<0.001
Documents	2	4.08%	<0.001	0	0.00%	0.051	0	0.00%	<0.001
Medication/IV Fluid	8	16.33%	0.095	1	20.00%	0.237	11	31.43%	Ref.
Process/Clinical Procedure	10	20.41%	0.247	1	20.00%	0.237	8	22.86%	0.427
Resources / Organizational Management	15	30.61%	Ref.	0	0.00%	0.051	3	8.57%	0.018
Blood / Hemoderivatives	1	2.04%	<0.001	0	0.00%	0.237	0	0.00%	<0.001

Caption: QI – Nurses QII- Nurse Technician and QIII- Nursing assistant

DISCUSSION

Chart 1, which shows the grounds for the complaints, presents a list of facts and procedures that motivated the report made to the Nursing Council, classified according to the Conceptual Framework for the International Classification for Patient Safety.[7] The procedures were grouped so as not to specify the quantity or technical details, in order to maintain the privacy of the reported professionals.

For the analysis of Table 1, on the distribution of type of incident reported, the Equality of Proportions test was used in order to analyze the distribution of the relative frequency of the procedures according to the classification based on the ICPS. The last column presents the p-values of the comparison of each type of incident, always in relation to the most prevalent one that is as a Reference (Ref.). Thus, the most frequent type of incident was "Medication/IV Fluid", with 21.3% (19). However, this percentage is not significantly different from the category "Process/Clinical Procedure", 20.2% (18), and of "Resources/Organizational Management", 19.1% (17), and also “Accident with the Patient" 14.6% (13).

Drug-related errors are a worldwide concern; however, the difficulty in reporting them is still one of the major obstacles to patient health and safety, since underreporting of these events hampers the assessment of the type, frequency and volume of these errors.[5,10,11] In this study, there were cases related to errors in prescription, administration of medication, among other situations; however, the technical analysis of the events that triggered the error was not the object of this study. Therefore, it is suggested that these events be analyzed with the knowledge of a multidisciplinary team.

What can be perceived by the data analyzed in the ethical-disciplinary proceedings is that despite all initiatives to improve patient safety, when it comes to errors in medication, there is still much work to be done so that the impact of this error on the care given to patients is as small as possible for both the patients and the nursing professionals.

The reason for centralizing safety actions in the professionals is mainly the fact that medicating patients depends on human activity, and errors are part of human nature. Thus, one might speculate, for example, that working long hours might impact on the severity, volume or type of error committed.[12]

It should be noted that there is still much to be improved regarding health care to avoid medication errors, and health professionals can use the ethical-disciplinary proceedings as a source of information to advance studies to mitigate these errors.

Issues related to health care processes and clinical procedures are closely linked to the natural risk involved in the activity of nursing professionals, according to the point of view adopted by the law[13], and all health professionals and institutions are included in this professional and legal context [14].

Iatrogeny is an example of the risk involved in this professional activity. One of the consequences of iatrogenic events is hospital infection. It is estimated that, in Brazil, about 720,000 people are infected in hospitals each year, and, of these, 144,000 end up dying.[15]

The proceedings that comprised the sample of this research contained, for example, complaints that were related to lack of hand hygiene, a measure that is recommended in several international and national infection prevention programs. With this fact, it is possible to infer that although institutions and the government create informative campaigns and pamphlets, these measures need to be understood and assumed as part of the professionals' work ethic. However, putting these measures into practice in order to raise awareness among professionals is a more complex and difficult task[16], and nursing professionals' failure to observe this need can cause the facts that generate reports and, consequently, ethical-disciplinary processes.

The third most frequently reported type of incident relates to resources and organizational management, that is, matters regarding the ability of organizations to manage their staff. In this research, some cases of illegal exercise of the profession were found, in which the professionals pretended to be nurses and/or doctors; this was also one of the major reasons for complaints in the Nursing Council of the state of Santa Catarina[13]. This allows us to infer that although the institutions identify these cases and refer them to the authorities – such as the Police, Public Prosecution or Class Council –, the process of accreditation of these professionals within health institutions is flawed, otherwise, these situations would be detected, avoiding their contracting and their contact with patients, which exposes patients to risk due to the lack of qualification for professional practice.

Accreditation of the team is an extremely important measure for the management of patient risk and safety, since it allows the professional to prove his/her competencies.[17] This is a measure that can be taken to mitigate risks, and other issues related to it, such as the size of the nursing team, are also relevant, and should be discussed in new studies.

Table 2, which shows the distribution of the type of reported incident according to professional category of the ethical-disciplinary process, the same analysis of the previous table was carried out, but now for each professional category related to nursing, noting that N = 89, since it is about the reported nursing professionals. It is possible to verify that the distribution of incidents related to Resources/Organizational Management and Process/Clinical Procedure represent 51% of the reports made against Nurses (QI); for Nursing Technicians (QII), most complaints were related to Accidents With the Patient; and the complaints made against Nursing Assistants (QIII) were mostly related to Medication/IV Fluid and Process/Clinical Procedure.

Nurses are responsible for the management and organization of the work process, according to the duties established by the Nursing Professional Law, which corroborates the statistics found in this research. The fact that reports of medication and fluids were the most common (31.4%) to the Assistants, reveals an interesting fact that should be studies further, since medications are vital to the patient. Considering the data found, it is pertinent to discuss and rethink the permanence or not of three categories for the Nursing team, and to reflect if intra muscular and intravenous medication should be administered exclusively by Nurses.

Finally, in order to obtain more reliable data, it is proposed that a single method of risk classification should be adopted in Brazil. To this end, governments and health institutions should prioritize the Conceptual Framework for the International Classification for Patient Safety as a methodology for classifying health care related events, providing a vast database for research that could later be used to create risk management models[18] more appropriate to the diversity of each region.

CONCLUSION

This research made it possible to classify procedures that motivated reports regarding ethical-disciplinary processes at the Regional Council of Nursing of São Paulo against 89 nursing professionals. These procedures were classified according to the Conceptual Framework for the International Classification for Patient Safety. The research found that the most prevalent incidents related to the exercise of professional nursing activity relate to errors om Medication/IV Fluid (21.3%), Clinical procedures (20.2%), Resources and organizational management (19.01%) and Accidents with the patient (14.7%).

The analysis allowed the conclusion that despite the numerous initiatives related to drug safety and the establishment of technical procedures in health care protocols, the most recurrent ethical infractions are still related to these factors, which suggests the need to further studies, with the inclusion of new sources of information, such as ethical-disciplinary processes or even open hearings at health institutions for clarifying adverse events.

It is suggested that the Conceptual Framework for the International Classification for Patient Safety be used in a systematic and systemic manner in health care, mainly by the control departments, so that it is possible to gather information in a wide and trustworthy database at a regional, national and international level, which could be used for research and subsidize public health policies.

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