

# ORIGINAL ARTICLE

# ANALYSIS OF NOTIFIABLE CIRCUMSTANCES: INCIDENTS THAT MAY COMPROMISE PATIENT SAFETY

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#### **ABSTRACT**

Objective: To identify incidents defined as notifiable circumstances that occurred in a teaching hospital in Goiás.

Method: Descriptive cross-sectional study that uses retrospective analysis of reports made by the nursing team of a general medicine unit made in the January 2010-December 2015 period. Data was collected and recorded in a semi-structured instrument and descriptive analysis was performed. Results: There were 2,718 notifiable circumstances, of which 1,100 (40.5%) were related to Resources/ Organizational Management, 844 (31.1%) to Medical Devices/Equipment, 270 (9.9%) to Documentation, 262 (9.6%) to Infrastructure/Facilities, 109 (4.0%) to Behavior, 80 (3.0%) to Medications/Intravenous Fluids, 28 (1.0%) to Blood/Blood derivatives, 17 (0.6%) to Diet/Food. Conclusion: The present study showed that situations with the potential to cause harm to hospitalized patients were very common, exposing organizational and care weaknesses that must be discussed by the management, so that improvements are implemented in the health care process and incidents are prevented.

**DESCRIPTORS:** Patient safety; Risk management; Health Care quality; Quality management; Nursing care.

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# ARTIGO ORIGINAL / ARTÍCULO ORIGINAL I

# ANÁLISE DE CIRCUNSTÂNCIAS NOTIFICÁVEIS: INCIDENTES QUE PODEM COMPROMETER A SEGURANÇA DOS PACIENTES

#### **RESUMO**

Objetivo: identificar os incidentes do tipo circunstância notificável ocorridos em um hospital de ensino de Goiás.

Método: estudo descritivo, transversal, de análise retrospectiva de relatórios da equipe de enfermagem da unidade de clínica médica, entre janeiro de 2010 e dezembro de 2015. Os dados foram coletados e registrados em instrumento semiestruturado e procedeu-se à análise descritiva.

Resultados: foram encontradas 2.718 circunstâncias notificáveis, das quais 1.100 (40,5%) estavam relacionadas a Recursos/Gestão Organizacional, 844 (31,1%) a Dispositivos/ Equipamentos Médicos, 270 (9,9%) a Documentação, 262 (9,6%) a Infraestrutura/Instalações, 109 (4,0%) a Comportamento, 80 (3,0%) a Medicações/Fluidos Endovenosos, 28 (1,0%) a Sangue/Hemoderivados, 17 (0,6%) a Dieta/Alimentação.

Conclusão: o estudo permitiu identificar alta frequência de situações com potencial para gerar danos aos pacientes internados, demonstrando fragilidades organizacionais e assistenciais que precisam ser discutidas pela gestão, de modo a promover melhorias no processo de cuidado e prevenção da ocorrência de incidentes.

DESCRITORES: Segurança do Paciente; Gestão de Riscos; Qualidade da Assistência à Saúde; Gestão da Qualidade; Cuidados de Enfermagem.

# ANÁLISIS DE CIRCUNSTANCIAS NOTIFICABLES: INCIDENTES QUE PUEDEN COMPROMETER LA SEGURIDAD DE LOS PACIENTES

#### **RESUMEN**

Objetivo: identificar los incidentes del tipo circunstancia notificable que ocurrieron en un hospital de enseñanza de Goiás.

Método: estudio descriptivo, trasversal, de análisis retrospectivo de informes del equipo de enfermería de la unidad de clínica médica, hecho entre enero de 2010 y diciembre de 2015. Se obtuvieron los datos y estos se registraron por medio de instrumento semi estructurado, procediéndose al análisis descriptivo.

Resultados: se apuntaron 2.718 circunstancias notificables, de las cuales 1.100 (40,5%) se relacionaban a Recursos/Gestión Organizacional, 844 (31,1%) a Dispositivos/Equipos Médicos, 270 (9,9%) a Documentación, 262 (9,6%) a Infraestructura/Instalaciones, 109 (4,0%) a Comportamiento, 80 (3,0%) a Medicaciones/Fluidos Endovenosos, 28 (1,0%) a Sangre/Hemoderivados, 17 (0,6%) a Dieta/Alimentación.

Conclusión: el estudio posibilitó identificar alta frecuencia de situaciones con potencial para generar daños a los pacientes ingresados, lo que muestra fragilidades organizacionales y asistenciales que se necesitan discutir por la gestión, de manera que se promuevan mejorías en el proceso de cuidado y prevención de la ocurrencia de incidentes.

DESCRIPTORES: Seguridad del Paciente; Gestión de Riegos; Calidad de la Asistencia a la Salud; Gestión de la calidad; Cuidados de Enfermería.

# INTRODUCTION

Health care problems have received great attention due to the high incidence of harm caused to users, and are considered serious public health issues globally. It is estimated that there are 421 million hospitalizations in the world annually, and approximately 42.7 million adverse events occur in patients during these hospitalizations<sup>(1)</sup>.

An analysis of the notification of incidents in health care settings in 26 states of the United States and Washington, D.C., between 2004 and 2015 identified 9,581 sentinel events, with the highest incidence (67%) in hospital services. Most of these incidents are of voluntary reporting, and it is believed that they represent only a small percentage of the events that actually occur<sup>(2)</sup>.

Incidents are events or circumstances that may result in unnecessary harm to the patient, may result from intentional acts or not, and include four types: notifiable circumstance (NC), near-miss, incident without harm, and adverse event<sup>(3)</sup>.

The notifiable circumstance is characterized as an event, situation or process that has significant potential to cause harm but in which no associated error occurred<sup>(3)</sup>. These include situations such as lack of human resources, problems related to equipment maintenance and communication failures that deserve attention, as they compromise care safety and may lead to the occurrence of an adverse event.

Near-miss is an incident that did not reach the patient because it was detected in advance. In turn, a no harm incident is an incident that reaches the patient but does not cause harm. Finally, adverse events are incidents that occur during care provision that result in harm to the patient, which can be physical, social, or psychological<sup>(3)</sup>.

From June 2014 to June 2016, 63,933 adverse events were reported in Brazil. Of these, 96.9% were notified by hospitals and 0.6% resulted in death<sup>(4)</sup>. Adverse events may originate from notifiable circumstances that have turned into latent failures in the health institution because their risks were not identified, their causes were not analyzed and their prevalence rates were not stopped by improvement measures and barriers to prevention of these incidents. Therefore, the identification of notifiable circumstances is essential, as it is a prerequisite for the elaboration of strategies and actions to prevent patient harm from occurring<sup>(5)</sup>.

Of the most prevalent notifiable circumstances, the working conditions of the nursing team deserve mention, mostly due to inadequate sizing of personnel and work overload factors that jeopardize the quality of care<sup>(5)</sup>. These incidents may occur in any health care setting. However, in hospitalization units such as general medicine units where professionals from several medical specialties and different backgrounds provide care to the patients, the environment becomes highly susceptible to the occurrence of incidents.

A study carried out in Minas Gerais found that the highest percentages (21.1%) of notifications of incidents occurred in the admission units<sup>(6)</sup>. In the southern region of Brazil, admission units were also the most frequent sites (64.8%) of incident reporting<sup>(7)</sup>. A study carried out in a general medicine admission unit showed an incidence of adverse events per 100 admitted patients of 10.2<sup>(8)</sup>. In Brazil, most adverse events with deaths occur in hospital admission sectors<sup>(4)</sup>.

Nursing professionals are the largest part of the healthcare workforce and are in more direct contact with patients than other professionals, either in direct care activities or in the management of the services provided. Thus, they are a potential source of information about incidents. Moreover, there is a direct relationship between this professional occupation and the theme patient safety and its strategies for the prevention of errors and reduction of failures in health care<sup>(9)</sup>.

It should be noted that studies related to incidents - notifiable circumstances, in

particular - are still scarce in Brazil. Therefore, the guiding question of this study was, as follows: which notifiable circumstances are most prevalent in a teaching hospital?

The identification of these types of incidents will provide knowledge about the main care delivery-related problems, making it possible to promote a planned and proactive action, without waiting for errors and harm to be caused to patients to intervene and propose improvements. Due to the importance of nurses in the healthcare segment, they should actively seek actions that change this scenario<sup>(10)</sup> and promote a culture of patient safety.

The present study intends to collaborate with discussions related to the prevention of the occurrence of adverse events and patient safety. Thus, its purpose was to identify incidents defined as notifiable circumstances occurred in a teaching hospital in Goiás.

# **METHOD**

Descriptive cross-sectional study conducted in the general medicine unit of a teaching hospital in Goiânia – Goiás. The general medicine unit had 59 beds divided into 13 wards, two of which were designed to isolate patients with infectious diseases. The unit is responsible for the delivery of care to adult patients in the following medical specialties: cardiology, endocrinology, gastroenterology, hematology, immunology, nephrology, oncology, pneumology and rheumatology. The nursing team was composed of seven nurses, as follows: one in a managerial position and the others with direct care responsibilities. Also, 56 nursing technicians worked 30 hours a week.

Data was extracted from nursing records for the January 2010-December 2015 period. This period preceded the establishment of the Institution's Patient Safety Nucleus. Thus, there was no incident reporting system or culture.

Nursing records were carried out in diaries kept for this purpose and included general information about the work process of the nursing team, such as handover, internal communications, requests and notes related to incidents. In 2012, only the January-July period was analyzed, since the other diaries were missing. Seventeen (17) diaries containing 400 pages each were analyzed.

The records were read for the identification of the incidents defined as notifiable circumstances. The notifiable circumstances detected, if any, were fully transcribed in a semi-structured data collection instrument consisting of items that included information about date, time of record and occurrence of the event, number of notifiable circumstances identified in each record and categories of notifiable circumstances, according to the process and its respective problem.

The Notifiable Circumstances were classified and divided into nine categories, based on the International Classification for Patient Safety (ICPS)<sup>(3)</sup>, described below:

#### 1. Documentation

Process (documents involved): Requests, requisitions, medical records /evaluation/consultation, checklist, forms/certificates, instructions/information / procedures/policies, tags/identification wristbands, communication log, reports /outcomes.

Problems: Missing/unavailable documentation, untimely documentation, wrong patient/wrong document/, incomplete/illegible/ ambiguous document information.

# 2. Medication/intravenous fluids (IV)

Process: Prescription, preparation/ dispensing, presentation, delivery, administration, supply / order, storage, monitoring.

Problems: Wrong patient, wrong medication, wrong frequency, wrong presentation/

formulation, wrong route, wrong dose, contraindication, improper storage, missed dose, overdue medication, adverse reaction.

# 3. Blood/Blood derivatives

Process: prescription, preparation / dispensing, presentation, delivery, administration, supply/order, storage, monitoring.

Problems: Wrong patient, wrong product, wrong frequency, wrong dose, wrong label/instructions, contraindication, wrong storage, missed dose, overdue product, adverse reaction.

# 4. Diet/Eating

Process: Prescription/ requisition, preparation/production, supply/order, presentation, dispensing, administration, storage.

Problems: wrong patient, wrong diet, wrong amount, wrong frequency, wrong consistency, wrong storage.

# 5. Medical devices/equipment

The ICPS does not specify the items that should be classified into this category. Thus, for categorization purposes, all materials and equipment essential to direct or indirect health hospital care were considered, and clothing-related products (sheets and clothes) were also included.

Problems: Improper packing/package, stock-out (stock shortage), item not fit for the specified purpose, dirty/unsterilized, failure/malfunction, missing/insufficient quantity in the unit, not found/loss of connections.

#### 6. Behavior

Process: Uncooperative, uncaring/rude/hostile/inconvenient, daring/reckless/dangerous professionals, patients and companions/relatives.

Problems: Substance use/abuse, harassment, discrimination, inconsistent/absent, self-inflicted/suicidal, verbal/physical/sexual assault, property damage, death threat.

# 7. Exposure

A concept associated to patients' vulnerability, i.e. patients exposed to external threats because of their health status.

Problems: Mechanical stress, thermal mechanism, risk of respiratory distress, chemical exposure, another specific mechanism of injury (e.g. animals).

#### 8. Infrastructure/Facilities

Process: Type of structure/building/installation (electrical installation, hydraulic installation, lack of energy, lack of water, leakage in the gas distribution network, elevators unavailable, telephone installation problems and structural problems such as lining, walls etc.). Problems: nonexistent, inadequate, damaged.

# 9. Resources/Organizational management

Process: Excessive workload, adequacy/availability of beds, suitability/availability of services, adequacy/availability of nursing human resources, organization of staff/ services, suitability/availability of protocols.

Problems: nonexistent, inadequate, excessive.

Data analysis was performed in two phases. In the first phase, the researcher analyzed the contents of the records, identified the occurrence of potential notifiable circumstances and classified them. In the second phase, the records with potential notifiable circumstances were independently analyzed by two external reviewers with expertise in patient safety for confirmation of the occurrence classified as notifiable circumstance when both experts

agreed with the researcher. As for the classification in a given category, the decision was made by majority vote. The data collected was typed, stored and analyzed using the Statistical Package for The Social Science (SPSS), version 19.0 for Windows, and the absolute and relative frequencies were presented.

The present study is part of the project "Analysis of occurrences of adverse events in a sentinel hospital in the Center-Western Region of Brazil", approved by the Ethics Committee on Medical Human and Animal Research of the institution, under protocol no. 064/2008.

# **RESULTS**

The data collected allowed the identification of 2,718 notifiable circumstances, an average of 453 per year or 37.7 per month, occurring in the general medicine unit.

The historical record series showed a decrease in the number of notifiable circumstances in 2012, but it should be noted that in that particular year the diaries corresponding to the August-December period were not analyzed. The calculations of proportions for that year shows increase in the number of notifiable circumstances to 475 in 12 months. Therefore, nursing documentation has been improving since 2013, particularly in 2015 when the number of incidents recorded by nurses was higher than the ones recorded in the remaining years), as shown in Figure 1.

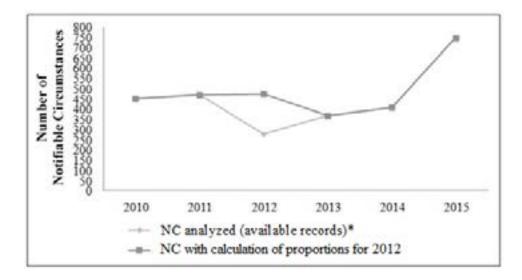


Figure 1 – Distribution of the records of notifiable circumstances, according to the year of occurrence. Goiânia, GO, Brazil, 2016

The notifiable circumstances are presented according to the category and year of occurrence in Table 1. It should be noted that one record might include more than one notifiable circumstance.

<sup>\*</sup>In 2012 only 7 months were analyzed.

Table 1 – Distribution of notifiable circumstances occurring in the general medicine unit of a teaching hospital, according to the category and year of occurrence. Goiânia, GO, Brazil, 2016

Category	Year						Total	
	2010	2011	2012	2013	2014	2015	N	%
Resources/Organizational management	206	155	148	141	167	283	1.100	40.5
Medical devices/Equipment	152	191	63	120	151	167	844	31.1
Documentation	35	27	26	32	23	127	270	9.9
Infrastructure/Facilities	30	62	32	42	42	54	262	9.6
Behavior	21	27	5	11	6	39	109	4
Medication/IV fluids	4	1	3	12	5	55	80	3
Blood /Blood derivatives	1	2	_	5	10	10	28	1
Diet/Nutrition	_	3	-	3	2	9	17	0.6
Exposure	2	1	_	-	2	3	8	0.3
TOTAL	451	469	277	366	408	747	2.718	100

Most frequent categories of notifiable circumstances were related to "Organizational Resources/Management" (40.5%) and "Medical Devices/Equipment" (31.1%). The notifiable circumstances of the category "Resources/Organizational Management" were analyzed according to the type and their distribution in the period (Table 2).

Table 2 – Notifiable circumstances related to "Resources/Organizational Management" that occurred in the general medicine unit of a teaching hospital, according to type and year of occurrence. Goiânia, GO, Brazil, 2016

Resources/Organizational management	Year						Total	
	2010	2011	2012	2013	2014	2015	N	%
Unavailability of nursing human resources	78	70	91	81	88	106	514	46.7
inadequate service organization	63	26	26	25	20	54	214	19.5
Unavailability of beds	32	22	14	15	22	53	158	14.3
Unavailability of services	19	25	4	12	17	52	129	11.7
Excessive workload	14	12	13	8	20	18	85	7.7
TOTAL	206	155	148	141	167	283	1.100	100

The most frequent incidents related to "Organizational Resources/Management" concerned the poor availability of personnel in the nursing team (46.7%), caused by unexcused absences, medical certificates, leaves, late arrivals and early departures from work, which resulted in understaffing.

Regarding the inadequacy of the organization of services (19.5%), recurrent communication failure between team members and between different services deserves mention.

The low availability of beds (14.3%) was frequent, especially for patient transfer, with emphasis on Intensive Care Units (ICUs). Thus, intensive care to critically ill patients, which should be provided in a specialized setting, was delivered in the general medicine unit.

Regarding the unavailability of services (11.7%), it should be stressed that sanitation services, when untimely performed, result in the delay of procedures and increase the incidence of infections, as well as other problems. The unavailability of computer systems (to enter admissions/medical discharges, for example) was also a circumstance identified.

As for the category "Medical Devices", 844 occurrences were recorded, corresponding to 31.1% of the total notifiable circumstances described in Table 3.

Table 3 – Notifiable circumstances of the type "Medical Devices/Equipment" that occurred in the general medicine unit of a teaching hospital, according to type and year of occurrence. Goiânia, GO, Brazil, 2016

Medical Devices/Equipment	Year						Total	
	2010	2011	2012	2013	2014	2015	N	%
Missing/Insufficient quantity in the unit	103	107	40	72	99	87	508	60.2
Failure/malfunction	35	61	22	39	42	58	257	30.4
Not found/ loss of connections	8	14	1	6	3	11	43	5.1
Stock-out (stock shortage)	5	8	_	1	7	6	27	3.2
Item not fit for the specified purpose	1	1	-	2	-	4	8	0.9
Dirty/Unsterilized	-	-	-	-	-	1	1	0.1
TOTAL	152	191	63	120	151	167	844	100

The results indicated that the most frequently identified event was lack and / or insufficient medical devices/equipment. The medical devices/equipment included multi parameter monitor, oximeter, X-ray machine, CT equipment, electrocardiograph machine, ultrasound machine, glucometer, aspirator, mechanical ventilator, defibrillator, sphygmomanometer, stethoscope, nebulizer kit, bag-valve-mask unit, sterile and procedure gloves, syringes, bandages, gauzes, clothes, sheets, capes, bed, stretcher, among others.

# DISCUSSION

The high number of NC identified in this study is a matter of concern, particularly because of the understanding that incidents are underreported and any adverse event is related to a circumstance whose potential for harm was not controlled. Patient safety goals aim at recognizing dangerous situations before the occurrence of harm.

The results obtained corroborate similar studies that reported the great incidence

of notifiable circumstances. A study conducted in a surgical clinic unit with the purpose of examining the incidents that occurred in 750 hospitalizations, identified 1,291 CN in 635 (84.7%) hospitalizations<sup>(11)</sup>.

Regarding the category "Resources/ Organizational Management", the low availability of nursing professionals was the main notifiable circumstance identified. However, the implementation of safe practices that reduce risks to patient safety is directly impacted by the sizing of the nursing personnel and the training/qualification of the team<sup>(12)</sup>.

A study conducted in Mexico found that disparity between the number of professionals, the number of patients and excessive workload are work-related factors that favor the occurrence of adverse events<sup>(13)</sup>. Another study about nursing team's conceptions about the risks to patient safety showed that excessive workload and inadequate sizing of nursing staff were major risks<sup>(14)</sup>.

The lack of human resources can contribute to raise the rate of absenteeism due to unexpected absences, leading to greater work overload. Moreover, the dimensioning of nursing professionals must take into consideration the characteristics of health services, nursing services and patients<sup>(15)</sup>.

As for the category "Medical Devices/Equipment", poor management of materials flow and materials shortage cause interruption in health care, generating stressful situations for patients, families and health professionals. Moreover, the purchase of new materials involves complex bureaucratic procedures, which also impacts the quality of care<sup>(16)</sup>.

Lack of maintenance of equipment also impacts the quality of care since the corrective maintenance process is slower than the preventive maintenance process. Also, nurses should participate in the process of materials control because their close involvement in care activities allows them to more accurately identify local needs<sup>(16)</sup>.

Over the years, particularly in 2015, there has been an increase in the number of reported incidents, and most concerned the following types of notifiable circumstances: "Documentation" and" Medication/IV Fluids". This may be an indicator that nurses, attentive and concerned with complex issues that occur in health care, have decided to record the recurring incidents of the referred types.

Nursing professionals play a key role in the promotion of a safety culture, given the characteristics of their activities that involve the operationalization of patient's direct care and hence can disrupt the cycle of circumstances that lead to harm.

Regarding the other categories of notifiable circumstances identified, although less prevalent, the need for intervention in the processes that cause such incidents is recognized, so that patient safety is fully achieved.

Patient safety studies have shifted the focus of analysis from an exclusive concern with the harm generated by incidents to the identification and control of situations that can cause such incidents. The main strategy for the implementation of a safety culture is the identification of risks<sup>(17)</sup>. Incident reporting improves organizational learning, which would be more effective if the risks posed to patient safety were also reported<sup>(16)</sup>, changing a reactive risk management into a proactive one.

Moreover, rather than devoting themselves to the solution of an isolated problem, which may be overlooked, health professionals should be able to perceive it as part of a system that results in harm and report this incident. Notifying situations of risk to patient safety show the willingness of these professionals to solve them as soon as possible and allows reflecting on the causes of these events, collaborating to a change in attitude in the organization and paving the ground for the establishment of a culture of safety. However, to ensure the effectiveness of these changes, notifications of incidents should not be perceived as documents to be filed: they must be analyzed and contribute to the elaboration of prevention strategies<sup>(16)</sup>.

"Common errors" should not be underestimated and perceived as part of the routine of healthcare, and practitioners should be encouraged to report them. The reporting of situations of risk can be an obstacle, as it involves complex bureaucratic procedures to be performed by health professionals, to the detriment of care activities. However, it is part of the organizational culture that must be encouraged and mastered by health professionals<sup>(18)</sup>.

The present study had the limitations of studies that use retrospective analysis of data, namely the poor quality of the records, since many did not include detailed information about the circumstances, making it difficult to perform a more in-depth investigation and resulted in incomplete information about the causes and consequences of the incidents and the management attitudes toward the incidents, among others. Despite such limitations, the data analyzed revealed an alarming situation, as many notifiable circumstances had a high potential to cause harm to patients.

# CONCLUSION

The present study made it possible to identify the high frequency of notifiable circumstances in patients admitted to the general medicine unit that have been persisting for several years. The most prevalent categories were those related to "Organizational Resources/Management" and "Medical Devices/Equipment". These circumstances are uncontrolled risks that may impair the safety and quality of care, revealing organizational and care weaknesses that must be addressed by the management, so that improvements are made in health care and in the prevention of incidents.

Nursing reports are not instruments for notification of incidents to the relevant bodies. However, they provide evidence that shed light on daily issues experienced by nursing professionals that may go unnoticed. Therefore, nursing reports are instruments that contain valuable information that can support the planning of actions targeted to patient safety.

The present study provides knowledge about situations of risk often handled as everyday problems faced by professionals of many health institutions. These situations must be analyzed by health professionals and managers, with focus on risk prevention, which go beyond those risks inherent in health care and on the implementation of interventions that improve health care structure and processes. We suggest the development of further studies on notifiable circumstances that investigate each type of circumstance, their contributing factors and consequences, for a better understanding of the impact of these incidents on care quality and safety.

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Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - MRS, AEBCS, JCL, ALQB, NNC, MRGS, FREG