

ANALYSIS OF ADVERSE EVENT REPORTING AT ACCREDITED HOSPITALS*

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ABSTRACT: The objective was to analyze the reporting of adverse events at accredited hospitals in the interior of the state of São Paulo from the nursing team's perspective. Descriptive and cross-sectional survey with a quantitative approach, undertaken at three accredited hospitals in the interior of the state of São Paulo, with a sample of 61 nurses and 250 nursing technicians and auxiliary nurses. The data were collected between November 2014 and April 2015. It was demonstrated that 126 (75.4%) participants were knowledgeable to report adverse events, but only 109 (65.3%) reported being authorized to do so. The participants appointed the nurses as responsible for this action. In the total group of participants, 76 (45.5%) affirmed that the event reporting entails punitive measures for the professionals involved. Nevertheless, 62 (37.1%) did not highlight fear of punishment as a hindering factor. The institution should prioritize the learning and the safety culture, focused on improving the quality of care.

DESCRIPTORS: Quality of health care; Health services evaluation; Patient safety; Hospital accreditation; Nursing.

ANÁLISE DA NOTIFICAÇÃO DE EVENTOS ADVERSOS EM HOSPITAIS ACREDITADOS

RESUMO: Objetivou-se analisar a notificação de eventos adversos em hospitais acreditados do interior de São Paulo, sob a perspectiva da equipe de enfermagem. Estudo descritivo, tipo *survey*, transversal, com abordagem quantitativa, realizado em três hospitais acreditados do interior do estado de São Paulo, com amostra de 61 enfermeiros e 250 técnicos e auxiliares de enfermagem. A coleta de dados ocorreu entre novembro de 2014 e abril de 2015. Demonstrou-se que 126 (75,4%) participantes possuíam conhecimento para realizar notificação de eventos adversos, mas apenas 109 (65,3%) relataram ter autorização para realizá-las, sendo os enfermeiros apontados pelos participantes como responsáveis por esta ação. Do total de participantes, 76 (45,5%) afirmaram que a notificação dos eventos gera medidas punitivas para os profissionais envolvidos. Apesar disso, 62 (37,1%) não destacaram medo de punição como fator dificultador. A instituição deve priorizar o aprendizado e a cultura de segurança, focada na melhoria da qualidade do atendimento.

DESCRIPTORIOS: Qualidade da assistência à saúde; Avaliação de serviços de saúde; Segurança do paciente; Acreditação hospitalar; Enfermagem.

ANÁLISIS DE LA NOTIFICACIÓN DE EVENTOS ADVERSOS EN HOSPITALES ACREDITADOS

RESUMEN: La finalidad fue analizar la notificación de eventos adversos en hospitales acreditados del interior del estado de São Paulo, bajo la perspectiva del equipo de enfermería. Estudio descriptivo, tipo *survey*, transversal, con aproximación cuantitativa, desarrollado en tres hospitales acreditados del interior del estado de São Paulo, con muestra de 61 enfermeros y 250 técnicos y auxiliares de enfermería. Los datos fueron recolectados entre noviembre del 2014 y abril del 2015. Se demostró que 126 (75,4%) participantes poseían conocimiento para notificar eventos adversos, pero solamente 109 (65,3%) relataron contar con la autorización para efectuarlas, siendo los enfermeros apuntados por los participantes como responsables por esta acción. Del total de participantes, 76 (45,5%) afirmaron que la notificación de los eventos genera medidas punitivas para los profesionales involucrados. Aunque así, 62 (37,1%) no destacaron miedo de punición como factor dificultador. La institución debe priorizar el aprendizaje y la cultura de seguridad, con foco en la mejora de la calidad de la atención.

DESCRIPTORIOS: Calidad de la atención de salud; Evaluación de servicios de salud; Seguridad del paciente; Acreditación de hospitales; Enfermería.

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● INTRODUCTION

The global patient safety movement and the creation of programs to guarantee the quality of care have contributed to the increasing interest in the theme adverse event (AE) reporting and prevention in health systems.

Despite the advances, human error stands out in the episodes that involve risks for patient safety and is widely disseminated by the press and media, entailing social concerns⁽¹⁾. The lack of understanding about error arouses negative feelings in the professionals and, in addition to the still existing punitive culture, entails omission on their part⁽¹⁾.

AE are known as negative health outcomes, incidents or circumstances that can cause damage to the patients. These outcomes can also be an error, defined as the inability to perform a planned action as intended or the incorrect application of a plan. Error is by definition unintentional and may cause an AE or not. By reducing the errors, the chances of AE will be minimized⁽²⁾.

The incidents can be: incidents without damages, incidents with damages (adverse events) or near misses (almost errors), characterized when an incident can affect the patient, causing damage or not, but was intercepted before its actual occurrence⁽²⁾.

In Brazil, health services have been obliged to report AE since 2013, when the National Patient Safety Program (PNSP) was created⁽³⁾. In the Brazilian context, the computer system NOTIVISA by the National Health Surveillance Agency (Anvisa) stands out, used to register problems related to the use of technologies and care processes, by monitoring the occurrence of technical complaints on drugs and health products, care incidents and AE⁽⁴⁾.

Further efforts are needed to construct robust and efficient reporting system and to train professionals who are qualified, attentive and capable of identifying possible errors and events, with a view to contributing to a safer and damage-free environment. The accountability for the safety in the work environment should be shared among the educational and health institutions, as the theme crosses both areas and still lacks multidisciplinary actions to change the scenario.

Despite the relevance of the theme, knowledge gaps remain in the field, mainly in less developed countries. The lack of resources, infrastructure and computerization limits those countries' ability to collect and systemize information, to develop research projects in the field and, in addition, the reports and occurrence rates of AE may be underestimated, so that they do not picture the true extension and the actual damage caused⁽⁵⁻⁶⁾.

What AE reporting is concerned, the nurse's role should be emphasized with a view to improving the risk identification process of these events, being the professional who is technically responsible for the other nursing team members. Therefore, the nurse should exercise the important function of educator, promoting mobilization to bring down the AE.

Nursing is the profession that spends more time with the patient, being apt to promote AE prevent and patient safety promotion strategies⁽⁷⁾.

It is important to establish national strategies to encourage improvements in the health services' processes and, consequently, the continuing improvement of the population's health. In addition to these strategies, a robust quality assessment system is needed.

In view of that need, institutions with accreditation programs stand out with regard to the theme health care quality, as their actions should be capable of minimizing the AE in health services.

Accreditation is an assessment and promotion process of quality improvements, undertaken voluntary and periodically based on pre-established standards, culminating in transformations in the habits, values and behaviors of the individuals within the adherent institutions, which contributes to qualified and safe care in favor of excellence⁽⁸⁻⁹⁾. Nevertheless, this process also requires that health establishments comply with technical and legal requisites and hold a license validated by Anvisa.

In view of the above, the objective in this study was to analyze AE reporting at accredited hospitals in the interior of the state of São Paulo (SP) from the perspective of the nursing team.

METHOD

Descriptive and cross-sectional survey with a quantitative approach. The study was undertaken intentionally at three institutions located in the interior of the state of São Paulo, which are certified by the Brazilian National Accreditation Organization (ONA). As they use the accreditation tool, we consider that they already possess formal AE reporting and analysis systems and are therefore considered suitable scenarios to achieve the research objectives, which justifies the intentional choice of the scenarios.

The nurses, nursing technicians and auxiliary nurses (N=697) from three hospitals in an interior city in the state of São Paulo were chosen, accredited by ONA, intentionally chosen because, as they use the accreditation tool, they already need to possess formal AE reporting and analysis systems, as the certifying authority prescribes this strategy in its manuals.

Being a nursing professional who deliver direct care to the patient was used as the inclusion criterion, and having worked at the institution less than six months was adopted as the exclusion criterion.

To calculate the sample, the following formulae were used: $n = \frac{z_{\alpha/2}^2 P(1-P)}{\epsilon^2}$ and $n_h = n \frac{N_h}{N}$. In the first, P= prevalence of the event, α =significance level and ϵ =tolerable error and, in the second, N_h= total of each stratum per hospital; h=stratum per hospital and N=population. A sampling loss of 0.2, 5% significance level and 10% relative error were established. For this analysis, the statistician used the software R version 3.0.2. After calculating the sample, it was randomized by means of Statistical Package for the Social Sciences (SPSS) 16.0.

Institution A, a general hospital with clinical and surgical care, offers 94 beds and is accredited at level III. Institution B is a specialized hospital with 21 beds that is accredited at level I. Institution C is a general hospital that offers clinical and surgical care and is accredited at level II. All hospitals have been accredited at the levels described by ONA.

To collect the data, which took place between November 2014 and April 2015, a questionnaire was used elaborated by the researchers. It consisted of 19 closed and two open-ended questions on the reporting of adverse events, besides data to characterize the respondents.

In part of the closed questions, an agreement scale was adopted, which consists of several items that express a viewpoint on a topic. The participants are instructed to mark the extent to which they agree with or disagree from the opinion the assertion expresses⁽¹⁰⁾.

For the face and content validity of the questionnaire, a judgment-based method was used by selecting a group of three experts who work in and/or are references in teaching and/or research on patient safety and nursing.

Three experts were chosen to avoid unclear inquiries and eliminate the risk of a tie in the evaluation. They received the questionnaire, analyzed it and proposed adjustments, as well as the inclusion and exclusion of terms.

The tool contains dimensions related to the improvement of patient safety, characteristics of the reported events, punitive or non-punitive actions and difficulties and potentials for reporting.

The data were analyzed descriptively in SPSS 16.0 to construct the database, manage and treat the data and execute the descriptive statistical analyses and reliability calculations. To elaborate the graphs, Microsoft Excel® was used.

Each item in the questionnaire was assessed according to the percentage of positive answers, obtained by calculating the combination of the two highest answer categories (I totally agree and I agree). The questions referred to patient safety improvement activities and positive factors in the reporting of adverse events. For item number 12, which inquires about the application of punishment after the professional has reported an adverse event, the percentage of positive answers resulted from the combination of the two lowest answer categories (I disagree and I totally disagree).

Approval for the study was obtained from the Research Ethics Committee at the University of São

● RESULTS

The participants' distribution by professional category has been described in Table 1.

Table 1 - Number of participants by professional category per institution. Ribeirão Preto, SP, Brazil, 2015

Institution	Nurses		Nursing Technicians/Auxiliary Nurses	
	N*	N	N*	n
A	92	325	41	145
B	11	48	5	21
C	34	187	15	84
Total	137	560	61	250

* Data provided by participating institutions' Human Resources departments and sample calculation.

The participants' characteristics are displayed in Table 2. The predominant age range was between 20 and 40 years older, with a minimum age of 20 and a maximum of 58 years old, revealing predominantly young adult professionals. Most participants possess between one and 15 years of experience in nursing. The total number of nursing technicians corresponded to 84 (50.3%) participants. Among the participants, 96 (57.5%) answered that they only work at the investigated institution.

Table 2 – Characteristics of research participants according to sociodemographic variables. Ribeirão Preto, SP, Brazil, 2015

Sociodemographic variables		n	%
Function at the institution	Auxiliary nurse	50	29.9
	Nursing technician	84	50.3
	Nurse	33	19.8
Length of experience in nursing	< 1 year	3	1.8
	1 - 15 years	133	79.6
	16 - 30years	24	14.4
	> 30 years	1	0.6
	Missing	6	3.6
Length of experience at the institution	< 1 year	39	23.4
	1 – 15 years	113	67.7
	16 – 30 years	8	4.8
	Missing	7	4.1

In the analysis of the questions related to the AE, it was verified that 126 (75.4%) participants referred knowledge about the institutions' reporting system. Separately, 30 (91%) nurses indicated knowledge on the reporting system.

Although the nurse's role as the main reporting professional is highlighted, a significant number of reporting authorizations were found (n=109; 65.3%), with 22 (67%) nurses and 79 (47.3%) nursing technicians and auxiliary nurses referring knowledge on the reporting flow.

The means indicated to report adverse events were: online in 104 (62.3%) cases, followed by a

specific form in 48 (28.7%) cases, a written report in 30 (18%), and eight (4.8%) participants informed other means.

Paradoxically, although 126 (75.4%) participants appointed the existence of training for reporting purposes, 24 (19%) indicated not knowing the reporting system. It is emphasized that 27 (81.8%) nurses agree that the institution promotes or has promoted training to use the system and report the AE.

The data demonstrated that 102 (61.1%) participants affirmed that the events are reported anonymous and/or voluntarily. The assertion was applied in the same question.

Although the participants, i.e. 225 (72.5%) appointed that the AE reporting system of the institutions where they work is easy to use, 21 (17.4%) appointed difficulties with the system as the main problem to report the AE.

As for the reasons not to report, the nursing technicians, auxiliary nurses and nurses highlighted the lack of time. The answers revealed 72 (43.1%) and 17 (51.5%), respectively, for the categories. It should be highlighted that, among the nurses, the fear of punishment was also appointed in the item in 13 (21.2%) cases. In addition, nine (27.3%) nurses reported that the institutions applied punitive measures in case of AE, as demonstrated in Table 3.

Table 3 – Comparison between nurses and nursing technicians/auxiliary nurses regarding the understanding about the occurrence of punitive measures, feedback to reporting professional and discussion about causes. Ribeirão Preto, SP, Brazil, 2015

Answers	Nurses		Nursing technicians/ auxiliary nurses	
	n	%	n	%
Agree that punitive measures are taken	9	27.3	67	50.0
Agree that the reporting professional and/or sector receives feedback on the report	18	54.5	90	67.2
Agree that possible causes of the reported events and how to avoid them are discussed	22	66.7	96	71.6

The participants agreed that the events entail positive changes in terms of safety, with 132 (79.1%), and that prevention strategies are discussed to avoid that these events reoccur with 128 (76.7%).

Concerning the tools to analyze the AE reports, the nurses mentioned: quality committee, fishbone, indicators, root cause analysis and risk classification. The nursing technicians and auxiliary nurses emphasized: training, meetings, quality management, discussions, protocol, the ONA itself, graphs, specific form/internal protocol, hospital infection committee, specific on-line tool.

The existence of activities to improve patient safety at the institution was appointed by 284 (91.6%) participants, who highlighted: the use of the safe surgery checklist, patient identification wristband, different wristband color for allergic patients, identification and use of bedrails, training, implementation of protocols, prevention of pressure ulcer/position change, the reporting itself of events, use of labels on high-risk drugs and continuing education.

● DISCUSSION

The preponderance of nursing technicians among the professionals studied supports the data from the Federal Nursing Council (COFEN) for the Brazilian context, demonstrating that, in March 2010, 287,119 (19.8%) nurses, 625,863 (43.2%) nursing technicians and 533,422 (36.8%) auxiliary nurses were registered, with a slight increase in the technical category⁽¹¹⁾.

When considering the insecurity of nursing work in the country, resulting from different reasons,

such as deregulation, absence of rights, extensive work journeys, complexity of labor conditions and low wages, appointed as possible causes of diverse bonds⁽¹²⁻¹³⁾, the work burden is unavoidable.

The increased risk of patient death and the occurrence of adverse events are closely related with the work burden of the nursing team. The team managers are responsible for participating in the staff management to reduce the burden and increase the patient safety⁽¹⁴⁾.

What patient safety is concerning, adverse event reporting is an essential tool as it supports care management⁽¹⁵⁾. In this study, it was noticed that the nurses know the reporting system and are the main reporting professionals, but should play their role as team leaders better, disseminating and informing actions in favor of the reporting, as well as the results of the report analyses.

It should be highlighted that all care team workers at the institutions should know the reporting system, particularly in the nursing team. The lack of knowledge on what an AE is, how it is identified and how it is notified in health care data can be higher than the official figures disseminated⁽¹⁶⁾.

Despite the nursing team's fragmented view on patient safety, the AE reporting and accountability should be cross-sectional, in that all team members should be sensitized and engaged to perform it and to outline strategies to prevent damages and prevent new events⁽¹⁷⁻¹⁸⁾.

It should be highlighted that, at accredited hospital, patient safety and, consequently, AE reporting is one of the pillars of the quality system. Through the reports, besides other tools, information is obtained to avoid and reduce health damage and to improve the health system from the patient and the worker's perspective.

The professionals are insecure in reporting when they are unfamiliar with its flow, supporting the understanding that the entire team should know the flow and dynamics of the processes, highlighting the need to adopt a reliable method, supported by effective tools and which permits the achievement of preset objectives⁽¹⁹⁻²⁰⁾.

The institutions should critically reflect on the role the leaders are to perform, as their strategic decisions include personnel management with a view to training the teams to improve the safety⁽⁷⁾. Therefore, the scope on training policies on the system and the reporting flow should be institutional, instead of being an initiative restricted to a category or sector.

The process to prevent the event derives from cultural changes and increased AE reports. In that sense, it is essential for the leadership and management to believe in a non-punitive culture and a systematic approach of the event, welcoming and supporting the professional involved so that the errors do not happen again⁽¹⁷⁾.

To protect the professionals involved in the AE reporting process, in view of a still punitive culture, in order to contribute to the identification of the risk situations and their management, the reporting should happen preferably in an anonymous and confidential manner and not be used as a tool to accuse professionals⁽²¹⁾.

Despite the discussion on the application of punitive measures to the professional in response to the AE, it was verified that the nursing technicians and auxiliary nurses did not appoint the "fear of punishment" as the main hindering factor of reporting.

In that context, the nurses and institutional heads should support the professionals at the frontline of care, providing them with learning and safety to perform their activities and encouraging the reporting through less punitive and more educative conducts.

As regards the positive posture towards AE, these study results are in line with a similar Brazilian study, in which 89.8% of the nurse coordinators agreed that discussing the events has led to positive changes⁽⁷⁾.

Granting feedback about the report to the professional can establish a communication channel that allows the institution to provide an opinion on his/her conduct, advice, information about the strategy to solve the problem and the need for reassessment⁽¹⁵⁾. The discussions deriving from the results of AE analyses can serve as the base for decision making and for planning patient safety, based on the analysis, monitoring, minimization and prevention of incidents that can cause AE⁽²²⁾.

Due to its importance, according to the PNSP, the language used in the event reporting system should be adapted and friendly, with a view to promoting the different professionals' participation⁽³⁾.

Monitoring the incidents is important to guarantee the patient safety and depends on efforts to identify the events before they cause damage, that is, the risks should be identified in time to implement improvements that avoid the negative outcome, and this process should be continuous as the risks are inherent.

One limitation in this study is the application of questionnaires completed by the nursing team only, as all professionals working at these institutions should engage in the AE reporting process. Another limitation is the data collection through a questionnaire only, without observing the participating professionals' daily practice.

● FINAL CONSIDERATIONS

This study contributed to the assessment of weaknesses and strengths of the AE reporting systems at the investigated accredited institutions. Most participants know the event reporting system at the institution, but are unfamiliar with the flow of the reporting system used. The institutions' reporting system is anonymous and voluntary, a factor that is considered important to avoid underreporting and to encourage the team to report without fear of punishment.

The participants characterize the lack of time as the main hindering factor of the reporting, and most of them do not agree that punitive measures exist at the institutions.

Several positive and relevant points were observed in the event reporting at the investigated hospitals, as well as some weak points the managers and leaders should analyze, permitting the enhancement of the work processes, the improvement of the care quality and of the care safety provided.

Among the weaknesses, the importance of enhancing the nursing team's knowledge about AE reporting is highlighted, motivating the team so that all members act as active participants in this activity.

In addition, the health institutions need to invest further in the reporting systems, so that the entire health team reports and is knowledgeable about the dynamics of the AE reporting process, independently of the degree of severity.

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