



## ADMINISTRACIÓN – GESTIÓN – CALIDAD

### Adverse events arising from nursing care: phlebitis, pressure ulcers and falls

Eventos adversos derivados del cuidado de enfermería: flebitis, úlceras por presión y caídas

\*R.N., Magister in Nursing. University Teacher. E-mail: [doraiparra@yahoo.com](mailto:doraiparra@yahoo.com) \*\*R.N., Magister in Epidemiology. University Teacher, \*\*\* R.N., Magister in Pediatrics. University Teacher, Escuela de Enfermería. Universidad Industrial de Santander, Bucaramanga. Colombia.

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#### ABSTRACT

**Introduction:** adverse events have great impact on patients' health, in institutional costs and professional practice; it is necessary to know how often they occur in health institutions, especially those events related to nursing care.

**Objective:** to describe the incidence of some adverse events related to nursing interventions in an institution of tertiary health care.

**Materials and methods:** pilot testing of a concurrent cohort study of adverse events related to nursing care in a health institution of tertiary care in the city of Bucaramanga, Colombia. 198 patients were included who had entered the institution for emergency care, with stays between 6 to 24 hours and older than 18 years. On admission and throughout hospitalization, an instrument was applied to assess possible risk factors and occurrence of each adverse event: pressure ulcers, falls, phlebitis and withdrawal/loss of therapeutic devices. A descriptive analysis of participants was performed and the incidence of adverse events was estimated with confidence intervals of 95%.

**Results:** the incidence of adverse events during the pilot study was 16.16% (n = 32, 95% CI = 11.32 - 22.04). Patients undergoing 65.63% of adverse events (n = 21) presented an event, 25% (n = 8) two events, and 9.38% (n = 3) three events. Among all reported adverse events the most frequent was pressure ulcers.

**Conclusions:** we report a significant number of adverse events figures are consistent with the literature. Knowing the epidemiology will help establish measures for their prevention and control.

#### RESUMEN

**Introducción:** Los eventos adversos tienen gran impacto en la salud de las personas, en los costos institucionales y en el ejercicio profesional, es por ello que es necesario conocer el comportamiento de

éstos en las instituciones de salud y especialmente aquellos relacionados con el cuidado de enfermería.

**Objetivo:** Describir la incidencia de algunos eventos adversos relacionados con las acciones de Enfermería en una institución de salud de tercer nivel de atención.

**Materiales y métodos:** Prueba piloto de un estudio de cohorte concurrente sobre eventos adversos relacionados con el cuidado de enfermería en una institución de salud de tercer nivel de atención de la ciudad de Bucaramanga, Colombia. Fueron incluidos 198 pacientes que habían ingresado por urgencias, con permanencia entre 6 hasta 24 horas y mayores de 18 años de edad. Fue aplicado al ingreso y durante toda la hospitalización un instrumento general que evaluaba posibles factores de riesgo y la ocurrencia para cada evento adverso: úlceras por presión, caídas, flebitis y retiros de dispositivos terapéuticos.

**Resultados:** La incidencia de eventos adversos durante la prueba piloto del estudio fue de 16.16% (n=32, IC95%= 11.32 – 22.04). De los pacientes que realizaron eventos adversos el 65.63% (n=21) presentó un evento; el 25% (n=8) dos eventos y el 9.38% (n=3) tres eventos. Entre todos los eventos adversos presentados el evento más frecuente fueron las úlceras por presión.

**Conclusiones:** Se reporta una incidencia importante de eventos adversos, cifras consistentes con la literatura. El conocer su epidemiología ayudará a establecer medidas para su prevención y control.

## INTRODUCTION

In response to the report "To Err is Human: Building a Safer Health System", which <sup>(1)</sup> examines medical errors in the U.S. and calls for providing safer health care for patients, many health systems are beginning to take action and establish regulations. International bodies like the World Health Organization (WHO) have initiated campaigns for patient safety, such as the Global Alliance (2002), which proposes a series of indicators to assess and monitor the performance of health systems and standardize security in Health Service Providers Institutions (called IPS in Colombia, similar to HMOs in the US) to attain safer treatments and fewer errors <sup>(2-3)</sup>.

In Colombia, the Mandatory Health Care Quality System <sup>(4)</sup> establishes security as a desirable feature, which was converted in 2008 into a national policy, whose primary objective is to prevent the occurrence of situations compromising the patients' safety, decrease and where possible eliminate the occurrence of adverse events <sup>(5-6)</sup>.

Adverse events (AE) are defined as "unintended injuries or complications that occur in the course of health care, that are more attributable to it rather than to the underlying disease and that can lead to death, disability or deterioration in the state of patient's health, delay discharge, cause extended hospital length stays and increased costs" <sup>(7)</sup>.

Additionally, adverse events not only impact the patient and his family, given the physical injury or psychological damages they produce, but also generate "post-traumatic stress, depression, defensive attitudes in the practice of care, increased, and also affects health professionals good name; economic and financial are increased by the additional care costs (between 17 and 29 billion year) and finally affects the credibility given by the society at large to the quality of health care services once these situations are made public <sup>(8-9-10)</sup>.

Regarding the incidence of adverse events found in several studies <sup>(11-17)</sup> based primarily on medical records reviews, it has been found to be in the range between 2.9% to 16.6%; the most prominent of these studies in account of the large number of

hospitals involved are the Harvard Medical Practice study, studies Utah and Colorado and the Quality in Australian Health Care study <sup>(18)</sup>. These three studies provided the guidelines that generated another series of investigations used the methodological criteria that were used by them. However in the last few years, research on this subject have made use of most often of observational designs and prospective cohort <sup>(19-20)</sup>, due to the limitations in retrospective studies based on clinical history because of underreporting of adverse events

It should be noted that patient safety is central to nursing and health care quality <sup>(21)</sup> and as some authors believe, nurses are most interested on this subject <sup>(22)</sup>, as they stay longer with patients and can easily detect adverse events related to the care provided by themselves or by other health professionals. This is the reason for which this study objective was to describe and determine the incidence of some adverse events arising from the actions of nursing care such as pressure ulcers, falls, and phlebitis and withdraw of therapeutic devices in an institution of tertiary health care.

## **MATERIALS AND METHODS**

### **Study Design**

A pilot study of a concurrent cohort study during 15 days of August 2010 in a health institution of high complexity in the city of Bucaramanga, Colombia. The institution has a capacity of 371 beds, serving mainly a poor and vulnerable population. It cares for 17,027 patients a year, with an average stay of 7.0 days stay and a 89.8% occupancy, according to data provided by the internal Statistics Office for the year 2010.

### **Participants**

The recruited study population was over 18 years, admitted to the emergency room, with stays between 6 and 24 hours in the hospital. The sample was selected non-probabilistically: during the recruitment period all patients who met the above criteria were included in the study.

### **Track**

Procurement of information followed these steps: a first group of researchers applied an instrument to patients who met the criteria and conducted the first evaluation, asked for informed consent, then registered medical records data such as co-morbidities, pre-existing conditions, medical laboratory results and drugs prescribed. Once these data was taken, patients were evaluated and additional information added if it had not been recorded in the first step. Average time for filling out this instrument was 25 minutes.

The second group of researchers was led by two audit quality nurses with experience in the subject of adverse events, conducting daily monitoring of patients who were enrolled in the study to identify the presence of adverse events such as phlebitis, Pressure Ulcers (PU), falls, lacerations from failures and withdrawal of therapeutic devices if this some kind of damage and / or additional cost. Once detected the event, researchers from the project together with the quality nurses verified it and confirmed it, filling out a form for each. Neither group knew the other group collected information. All of those involved had received prior training on the procedures, tools and instructions designed to collect the information and how to control data quality.

## Adverse Event

The working definition of adverse event was the one defined in the official patient safety policy for Colombia<sup>(2)</sup>. Adverse events observed in this study were pressure ulcers, defined as those lesions of the skin or underlying tissue usually over bony prominences as a result of pressure<sup>(23)</sup>; Phlebitis<sup>(24)</sup> defined as the presence of at least two of the following signs or symptoms upon examination of catheter insertion sites: redness, swelling, palpable venous cord, tenderness or pain; Falls, defined as the result of any event that precipitates the individual into the ground against his will<sup>(25)</sup>.

The criterion for inclusion of the event was that it was generated after the initial assessment. If it was caused by previous treatment in another institution or had developed prior to the initial assessment, it was considered as pre-existing and not included. If a patient developed the same type of event more than once, each was considered separately and was recorded in a the respective form, depending on the event, and whether different events unfolded at the same time or during the stay

For the evaluation of the event severity the extended stay and the procedures required to repair the damage. Severity was defined as mild, if the injury did not prolong hospital stay, moderate when stay was prolonged at least a for day and serious if death or a serious disability was caused requiring surgical intervention

## Instrument

The evaluation questionnaire applied to patients upon inclusion in the study consisted of four parts: the first was an overview of the patient's location, dates of entry and discharge, code; secondary patient information, including demographic aspects, current illness, vital signs, co-morbidities, and in the third, information on the contributing factors of the patient, of the health personnel, and of the environment. This part of the questionnaire included scales such as Barthel's<sup>(26)</sup> and Katz's<sup>(27)</sup>, to determine the degree of patient dependency in carrying out daily routine activities; the Morse Falls Scale<sup>(28)</sup> to determine the fall risk ; Braden and Norton Scales<sup>(29)</sup>, to determine the risk of pressure ulcers. Finally, the fourth part included aspects of events and preventive measures given to the patient at the time. This article reports some results of the demographics, current illness, comorbidities, factors related to health personnel and the events of interest.

## Data analysis

Forms were entered in duplicate in databases built and validated in Epi Data 3.1. Data analysis was performed in Stata 10.1<sup>(19)</sup>. Descriptive analysis was performed providing continuous variables with the corresponding measures of central tendency and dispersion, and categorical variables with absolute and relative frequencies. Because there was a possibility that a person suffered more than one adverse event during the follow-up period and the current study recorded all events presented by the patients, two calculations were performed to describe the frequency of adverse events in the pilot study of the cohort: the first a cumulative incidence for submitting the adverse event where the numerator was the number of patients experiencing adverse events and where the denominator was the total number of patients in the study, with accompanying calculation of confidence intervals 95% (95%). The other calculation was performed for all adverse events reported in the study, which estimated a ratio of

the total number of reported adverse events and the total number of patients studied; the latter analysis was also performed for each individual adverse events.

## Ethical Considerations

To ensure the anonymity of the information each user was assigned a numeric code which identified him/her in the study and remained until discharge. The study complied with the ethical principles in accordance with national and international standards for research involving human subjects. The research protocol was approved by the ethics committee of the Faculty of Health of the Industrial University of Santander. Precious to participation in the study all patients gave their informed consent. If the patient was not able to do so it was obtained from a relative.

## RESULTS

### Overview of the population

Included in the study were 198 people, where 74.62% (n = 147) of the patients were referred, of which 45.07% (n = 64) were from the primary care level and 35.21% (n = 50) of second, the 61.7% (n = 121) were male with an average age of 55.1 years (STD 19.8), 55.2% (n = 100) was being treated for internal medicine consultation. Causes for consultation were 16.24% (n = 32) for respiratory diseases, cardiovascular related 15.23% (n = 30) and trauma related (9.14% (n = 18), 4.55% (n = 9) had had surgical procedures and 31.31% (n = 62) had a hemoglobin of less than 9gr/dl.

Incidence and overview of adverse events of the 198 patients accompanied 32 adverse events and in total there were 46 adverse events. Thus, the cumulative incidence of adverse events of interest during the pilot study was 16.16% (n = 32, 95% CI = 11.32 - 22.04) and the ratio of reported adverse events for patients was 46/198 = 0.23, i.e. 23 adverse events per 100 patients followed.

In conducting the same analysis for each of the adverse events we have evaluated the cumulative incidence of phlebitis present at least once during the study was 8.6% (n = 17, 95% CI = 5.1 - 13.4) and the ratio of phlebitis presented by patients was 20/198 = 0.10, phlebitis or 10 per 100 patients followed. For the cumulative incidence of pressure ulcers, those that presented at least one PU during the study, it was 8.1% (n = 16, 95% CI = 4.7 - 12.8) and the ratio of PU per patient was 24/198 = 0.12, i.e. 12 PU per 100 patients followed, for the cumulative incidence of falls, at least one fall during the study, it was 1.01% (n = 2, 95% CI = 0.12 - 3.6) and the rate of falls per patient was 2/198 = 0.01 i.e. 1 drop per 100 patients. During the study period no removal of therapeutic devices was performed.

Of patients experiencing adverse events, (n=32), 65.63% (n=21) presented an event, 25% (8) two events and 9.38% (n= 3) three events for a total of 46 adverse events. For all adverse events that occurred during follow-up of the 198 patients Table 1 shows the distribution by type of event, which shows that the PU was the most frequent.

**Table 1. Type of Adverse Event**

Event	N° de events (n = 46)	Frecuency
PU	24	52.2%
Phlebitis	20	43.5%
Falls	2	4.3%
Withdraw of Therapeutic Devices	0	-

In 81.25% (n = 26) of patients with adverse events, severity of the event was moderate, in 18.75% (n = 6) events were mild. As for the service where the events originated, surgical specialties was the one who had the highest frequency with 75% of the events (n = 24), as shown in Table No. 2.

**Table 2. Distribution of the hospital services where adverse events occurred**

Service	Number (n=32)	Frecuency
Surgery Specialities	n=24	75%
Internal Medicine	n=4	12.50%
Operating Rooms	n=2	6.25%
Gineco-Obstretics	n=1	3.13%
Surgery (general)	n=1	3.13%

With regard to notification, 32% (n = 28) of patients with these events were not reported and where this took place (n = 5), the person who performed was the nurse in the 100% of cases. Additionally, it was found that information regarding adverse events was not written on the patients' records adequately in 40.63% (n = 13) of the cases (see Table 3).

**Table 3. Notification on patient records**

Aspect	Number (n=32)	Frecuency
Inadequate	n=13	40.63 %
Adequate and complete, no need for additional information	n=10	31.25%
Not adequate , required additional information from other sources	n=9	28.13%

## DISCUSSION

Pressure ulcers, phlebitis, and falls are frequent events that occur during nursing interventions, however large studies of adverse events (11 to 15.18) do not take them into account. Despite this, it is known that these events produce impacts on the health of patients, ranging from mild effects to death. PUs may prolong hospital stay<sup>(30)</sup>, due to medical and surgical treatments that they generate. As for phlebitis, the most serious complications referred in the literature are purulent thrombophlebitis, sepsis and thrombosis formation, leading to a longer hospital stays, need for antibiotics and surgery are possibilities<sup>(31)</sup>, leading to high morbidity and mortality which are often

underestimated<sup>(32)</sup>. For its part, falls, have effects on the welfare and quality of life of older persons and their families and caregivers<sup>(33)</sup>.

In Colombia there are few studies on the behavior of overall adverse events and even rarer for the types of adverse events considered in this study; however the literature refers UPP frequencies between 7 to 22%<sup>(34-36)</sup>, phlebitis 12.9%<sup>(37)</sup> and fall between 14%<sup>(38)</sup> to 29.7%<sup>(39)</sup>. In this study, the overall frequency of each event with respect to the observed population was less than these studies indicate, which can be explained since the population was relatively young for the case of some events such as falls and pressure ulcers<sup>(34-35)</sup>, which have been associated with aging.

Among the socio-demographic variables related to adverse events in general, no relationship was found between age, gender and race, however there have been found statistically significant differences between age groups, especially among young patients and those older than 65 years<sup>(40)</sup>. A study, conducted in three Colombian health institutions<sup>(41)</sup>, found a higher frequency of adverse events in persons 49 years or older in surgical specialties, whereas in the present study the majority of patients were internal medicine patients but more frequent events happened in surgical services.

Additionally, in that study<sup>(41)</sup> 22% of patients had two or more events and 4% had three or more events, figures similar to the current investigation, although the events of interest were specific and related to care nursing

With regards to the complications generated to the adverse events, the New York study found that 70.5% of events caused disabilities for at least 6 months and 2.6% caused permanent disability, while in Utah and Colorado the latter occurred in 9% of the case. In the Australian study, disability occurred in 77.1% of the cases for at least 12 months, and 13.7% of those were permanent<sup>(40)</sup>. In the present study, complications caused were moderate severity leading to stays no longer than one day.

In relation to the culture of adverse event reporting, underreporting still persists, as shown in this study results. It is the reason why the first related investigations whose designs were based on retrospective review of medical records, reported some limitations. Given this limitation, in the current study, follow-up was performed until patient discharges, so that to monitor for any events and restrict under-reporting. This explains the overall rates presented in this pilot.

## **CONCLUSIONS**

The results provide an approach to the understanding of the reality of the issue of adverse events in health institutions, which may result in the course of nursing care. In most of the cases they are indicative of the quality of care provided, therefore it is important to continue observational designs for determining not only the incidence of, but also factors related to their occurrence, in order to originate actions towards a reduction of incidence and resulting disabilities.

### **Conflict of interest**

The authors do not report conflict of interest.

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