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Reportable hospital events: incidence and contributing factors in the surgery service of a high complexity hospital in Bogotá, Colombia, 2017

Eventos reportables hospitalarios: incidencia y factores contribuyentes en el servicio de cirugía de un hospital de alta complejidad en Bogotá, Colombia, 2017

Keywords: Incidence, Patient Safety, Health Surveillance, Adverse Effects, Safety Management

Palabras clave: Incidencia, Seguridad del Paciente, Vigilancia Sanitaria, Eventos Adversos, Gestión de la Seguridad

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Abstract

Introduction: Patient safety includes monitoring, analysis, and proposed actions for the prevention of reportable events with unwanted effects (REUE).

Objective: To estimate the incidence, preventability, severity, and contributing factors of REUEs in patients admitted to the surgery service.

Materials and methods: Prospective cohort study in patients with at least 12 hours of hospitalization in the surgical services of a university hospital in Bogotá, Colombia. Random sampling was

used and the sample size was 200 subjects. Sociodemographic and baseline clinical variables were evaluated. We estimated the presence of REUE detection events, their preventability and severity. The analysis of the contributing factors was done using the London protocol.

Results: A total of 106 women (52.47%) and 96 men (47.53%) were included; the median age was 51.93 years (range 18–93); 60% had at least 1 comorbidity measured by the Charlson index and 25.74% had 3 or more. Of the participants, 28.21% presented at least 1 detection event, the incidence of REUEs was 11.8%, and 75% of them were classified as preventable while 75% were serious

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events. The main contributing factors were: patient-related 58.33%, related to scheduled tasks and clinical context 50.00%, and work team-related factors 37.50%.

Conclusion: The incidence, preventability, and severity of REUE are similar to those reported in the literature. The analysis of the contributing factors shows areas that are susceptible to intervention and can be considered as opportunities for improvement.

Resumen

Introducción: La seguridad del paciente incluye la vigilancia, análisis y la propuesta de acciones para la prevención de eventos reportables con efectos no deseados (EREND).

Objetivo: Estimar la incidencia, preventibilidad, severidad y factores contribuyentes de los EREND en pacientes hospitalizados en el servicio de cirugía.

Materiales y métodos: Estudio de cohorte prospectiva en pacientes con al menos 12 horas de hospitalización en los servicios quirúrgicos de un hospital universitario en Bogotá, Colombia. Muestreo aleatorio. Tamaño muestral: 200 sujetos. Se evaluaron las variables sociodemográficas y clínicas basales. Se estimó la presencia de eventos de detección, de EREND, si eran prevenibles y su severidad. El análisis de los factores contribuyentes se hizo mediante el protocolo de Londres.

Resultados: Se incluyeron 106 mujeres (52.47%) y 96 hombres (47.53%); la edad mediana fue 51.93 años (rango 18–93). El 60% tuvo al menos una comorbilidad medida por el índice de Charlson y el 25.74% tuvo 3 o más. El 28.21% de los participantes presentaron al menos un evento de detección, la incidencia de EREND fue 11.8% y el 75% de estos fueron calificados como prevenibles y 75% fueron eventos serios. Los principales factores contribuyentes fueron: del paciente 58.33%, relacionados con tareas programadas y contexto clínico 50.00% y factores del equipo de trabajo 37.50%.

Conclusiones: La incidencia, evitabilidad y severidad de los EREND del estudio se encuentran dentro de las reportadas en la literatura, el análisis los factores contribuyentes presenta elementos que son susceptibles de intervención y pueden ser considerados como oportunidades de mejora.

Introduction

Over the past few years, there has been a growing interest on the part of international and government agencies, as well as local healthcare organizations, in improving inpatient and outpatient safety.^{1,2} The goal is to prevent adverse events defined as unintentional harm to the patient during care or as a result of it,³ as well as to mitigate their impact on the patient.^{1,2} Adverse events have also been called reportable events (REs).⁴ This latter designation is embraced by the authors of this study in an attempt at reducing the punitive and stigmatizing connotations associated with the term “adverse”, and also with the aim of encouraging reporting so that analysis of the events may be conducted under a modified perspective of RE with unwanted effects (REUE).

The frequency of REUE ranges between 2.8% and 32.2%, depending on the service where they are measured,⁵ the type of institution,⁶ the specialty (more frequent in surgical services),⁵ and the measurement methodology.^{7,8} Of this percentage, 30% to 70% are preventable and 4% to 21% contribute to patient death.^{3,5-6,9-14} It has been described that REs are more frequent in individuals over 45 years of age (odds ratio 1.5; 95% confidence intervals [CI] 1.4–1.7),¹⁵ during non-elective surgical procedures,¹⁶ in patients with comorbidities,¹⁷ and in high-complexity institutions. However, there is controversy regarding whether the frequency of REUEs is higher in teaching hospitals as compared to other institutions,⁶ based on the argument that these hospitals receive patients with more complex conditions or greater systemic compromise. Likewise, the issue of age as an independent risk factor is also controversial.^{15,17}

International institutional performance indicators include effective patient safety goals¹⁸ which measure the frequency of REs associated with healthcare provision in the hospital, including transfusions, medication administration, and healthcare-associated infections. Hence, the importance of continuously measuring the frequency of REUEs, particularly preventable ones, in order to comply with the international performance goals.

On the other hand, recognizing factors that contribute to REUEs does not only contribute to the understanding of the context and circumstances in which they occur but also helps develop improvement plans for their prevention, which is a patient safety goal. In accordance with this background, the objective of this study was to estimate the incidence and preventability of REUEs and to identify contributing factors in the surgical services of a university hospital in the city of Bogotá D.C., Colombia.

Methods

Study design and location

Prospective cohort of patients hospitalized at least 12 hours in the surgery service (taken or not to a surgical procedure) of a university hospital in the city of Bogotá that provides care to patients of the contributive regime of the social security system in Colombia. Patients who had experienced the unwanted RE in a different institution were excluded.

Sample size and sampling

Based on an expected 10% incidence of REUEs, a 3% margin of error, a 95% CI and a universe of 1200 subjects (data derived from average patient care instances in the surgery service during the previous year), the calculated sample size was 200 patients. Probabilistic, systematic sampling was used, taking the list of hospitalized patients as a basis. Sampling was performed every other day.

Table 1. Detection event screening tool.

Detection event	Yes	No	NA
Unplanned readmission as a result of general care provided to the patient			
Unplanned referral to the intensive care unit or other special care area			
Unplanned transfer or readmission to the operating room			
Unexpected death			
Unexpected cardiorespiratory arrest			
Development of neurological deficit not present at the time of admission (including changes in the level of consciousness or delirium)			
Nosocomial or hospital-acquired infection			
In-hospital patient accident or injury			
Adverse reaction to medications/supplies documented in the clinical record or in the report on adverse reactions to medications/supplies (including blood products)			
Any other outcome not covered by the previous criteria			

Source: Authors.

Procedure

The study was divided into 4 phases: event identification; event classification; REUE analysis using the London protocol; and out-of-hospital follow-up.

- (1) *Detection event identification*: A duly trained nurse reviewed the clinical records of the patients selected by sampling, and inclusion and exclusion criteria were verified. Subjects who did not meet the selection criteria were replaced following the generated random sequence. After verification, the subjects were explained the objectives and asked to sign the informed consent for voluntary participation in the study. Data on sociodemographic and baseline clinical variables, and the application of the screening tools for detection events (Table 1) were based on the clinical record in order to identify situations suggesting the presence of REUE.¹¹
- (2) *Event classification*: "Detection" events were submitted to a committee of specialist physicians (surgeons and experts in patient safety research). The committee was given information on events happening to the patient from the moment of admission, in chronological order according to their occurrence, as well as detailed information documented in the clinical record. This information was provided by a previously trained general practitioner. Data provided included time of admission, transfers, arrival at the operating theatre, assessments by specialists, and important case-defining decisions.

The committee, for its work of classifying the events, used a tool that allows to determine if there was a REUE, its preventability, severity, potential failures related to performance, prevention, diagnosis, drug treatments, and systems.^{6,11} The event and its preventability were rated using the methodology previously described by Gaitán-Duarte et al.¹¹

- (3) *REUE analysis using the London protocol*: The recommendations of the London protocol developers were used for this application.¹⁹ Various sources of information were used, the most notable being interviews with the hospital staff directly involved in the REUE, and with experts from the surgical service of the study institution, as well as document reviews including clinical records, patient transfer records, surgery and anaesthesia records, institutional protocols, and evidence-based management guidelines (national and international). Contributing factors were identified.
- (4) *Out-of-hospital follow-up*: REUEs may occur during hospitalization or afterwards²⁰; consequently, all the patients in the cohort were followed after discharge from the hospital. The patients in the cohort were followed from the moment they were included, during hospitalization, and by telephone call 15 and 30 days after discharge from the institution, with the aim of identifying REUEs. For this stage, a semi-structured questionnaire with questions designed to recognize detection events was used (Annex 1).

The following variables were assessed: age, gender, type of health insurance, comorbidity on admission, Charlson

comorbidity index,²⁰ diagnosis leading to hospitalization, surgical procedure performed, detection event, source of information of the REUE. Regarding the REUE, the following data were documented: name of the REUE, preventability, timing, type, and setting where it arose, severity, responding service, prolonged length of stay as a result of the event (additional length of stay was determined based on the difference between effective diagnosis-related hospitalization time, and total length of stay following the REUE), resulting disability, type of discharge, associated mortality, and characteristics of the care team. In terms of underlying failures, the assessment included failures related to prevention, diagnosis, treatment, and systems (defined as failure or absence of hospital structure, systems, or processes for in-hospital and out-of-hospital monitoring).

Based on the London protocol, contributing factors were identified, including those related to the patient, the clinical context, scheduled tasks, the environment and the work team, individual factors (affecting care providers), and factors related to the institution or underlying systems.

Analysis

The Stata 14 software package (Stata 14, licence: Universidad Nacional de Colombia, Sciences faculty, Statistic department, Bogotá, Colombia) was used for the analysis. According to the types of variables, a descriptive analysis was carried out using absolute and relative frequencies, and central trend and scatter measurements. In addition, the proportion of detection events, the cumulative incidence and the proportion of preventability and severity of REUEs were estimated. All the results were presented with their respective 95% CI.

Time to the first REUE was calculated, defined as the time between admission to the institution and REUE occurrence for the purpose of this study. In those cases in which the REUE resulted in readmission, time was calculated starting with the record of the previous hospitalization.

The analysis of the results derived from the application of the London protocol was made in descriptive form.

Ethical considerations

The protocol was approved by the ethics committee of the National University of Colombia School of Medicine, as recorded in Minutes 021-260-16 of November 24, 2016. The principles of confidentiality in relation to patients and healthcare workers interviewed were respected. The informed consent of the participants was obtained in all cases.

Results

A total of 1246 patients were admitted to the surgery services between May 1 and July 30, 2017; of them,

236 were randomized, 33 did not meet the inclusion criteria, and 1 declined to participate in the study, for a final sample of 202 patients. Of the participants, 52.47% (n=106) were women, the mean age was 51.93 years (range: 18–93 years), 43.5% (n=88) of the participants were older than 60 years of age. On the other hand, 80.7% (n=163) of the participants were referred from a different institution, 60% had at least 1 comorbidity measured with the Charlson index, and 25.74% had 3 or more comorbidities.

A surgical procedure was performed in 67.49% (n=137) and the remaining percentage of patients, despite having a condition requiring surgery, did not need a surgical procedure during hospitalization. Regarding scheduling of surgical procedures, 54.74% of the subjects (n=75) required emergency procedures while the remaining 45.25% were taken to elective surgery (Table 2). The specialty associated with the largest number of procedures was general surgery with 31.2% (n=63), followed by urology 8.91% (n=18), gastroenterology 6.4% (n=13), orthopaedics 5.94% (n=12), and neurosurgery 2.47% (n=5). The remaining entries were spread among other services, including plastic, vascular, chest, head and neck, and maxillofacial surgery; 32.1% were patients seen by more than 1 surgical specialty.

A total of 57 subjects (28.21%) had detection events (104); of the total number of subjects, 28 (49.13%) had 2 or more detection events. Of the detection events, 60 were identified during hospitalization in 37 subjects (18.31%), and 44 in 27 subjects (13.36%) during follow-up.

REUE analysis

A total of 24 subjects had at least 1 RE, corresponding to a cumulative incidence of 11.88% (95% CI [7.76%; 17.16%]); of these, 75% were classified as preventable (cumulative incidence: 8.91%, 95% CI [5.36; 13.71]). In the group of patients taken to emergency surgery (unscheduled), the incidence of REUE was 31.57% (95% CI [21.38; 43.25]).

In terms of the settings of REUE occurrence, 45.83% were found to occur on the wards, and 33.33% in the operating rooms. On the other hand, associated mortality was 4.16% (1 death out of 24 events) (95% CI 0.10; 21.1), the same as the incidence of disability secondary to REUE. It is important to clarify that, in both instances, these outcomes were associated with non-preventable REs.

Regarding the impact of REs in this study, they resulted in an additional 420 days of hospitalization, with an average of 17.5 days per subject with REUE. In terms of time to the first REUE, the median was 3 days (range 0–31).

The expert committee analysis found that the main factors associated with REUE occurrence were failures related to systems (62.50%), prevention (58.33%) and performance (54.17%). In contrast, non-preventable REUEs were drug-related in 100% of cases, including idiosyncratic reactions (Table 3).

Table 2. Characteristics of the subjects included in the study.

Variable	n (%)
Sex	
Women	106 (52.47)
Men	96 (47.53)
Age*	
18–40 years	45 (22.3)
40–60 years	69 (34.1)
>60 years	88 (43.5)
Type of admission	
Referral	163 (80.7)
Scheduled consultation	29 (14.35)
Non-scheduled consultation	10 (4.95)
Surgical procedure	
Yes	137 (67.49)
Emergency procedure	
Yes	75 (54.74) [†]
Comorbidities by Charlson Index	
No comorbidities	81 (40.10)
1–2 comorbidities	69 (34.15)
3–4 comorbidities	36 (17.82)
5 or more comorbidities	16 (7.92)

*Median and ranges.

[†]Number of emergency surgeries over the total number of patients in the study taken to surgery during hospitalization.

Source: Authors.

The main contributing factors identified as a result of the analysis using the London protocol were: patient-related factors (complexity of the treated diseases, number of comorbidities, advanced age) (58.33%); clinical context-related factors (main health issue of the patient) (50.00%); factors related to scheduled tasks (absence of guidelines and protocols) (50.00%); team-related factors (problems of communication among the healthcare teams, team structure) (37.50%); workplace-related factors (workload) (33.33%); and, finally, individual factors (29.16%), including inadequate or no training (Table 3).

The analysis of preventable REUEs showed that 77.78% occurred in patients over 60 years of age, 83.3% were

associated with a Charlson comorbidity index of 1 or higher, and close to 78% happened during the afternoon and night shifts. Of the preventable events, 61.1% occurred while the patients were in the hospital and were detected during the same hospitalization. Of the preventable REs, 83.33% were serious events (Table 4).

Discussion

The *Harvard Medical Practice Study* is one of the first documents published in the scientific literature that reported an incidence of REUE of 3.7%. This result prompted further publications of relevant studies and methods for REUE detection, which have shown an increase in the incidence values over those initially published.²¹

This study found an incidence of REUEs of 11.88%, similar to the one reported in other countries such as Spain in 2006 (8.4%),²² New Zealand (12.9%),¹² London (10.8%), and specifically in a surgery service in London (16.2%).⁵ It is important to highlight that, compared to studies published recently in the United States and Norway (32%),^{13,14} incidence is lower.

This variability in incidence values is due to the changeability in the definitions and methods used for REUE classification and analysis. The characteristics of the institutions and of the patients receiving care in those institutions are among other factors that may explain this wide range of values.

This study revealed particular characteristics of the sample considered as risk factors for REUE. These include age over 40 years (77.6%), comorbidities measured with the Charlson index in up to 60% (3 or more comorbidities in 25.74%), and other findings such as increased degree of care complexity.

The participants included in this study were only surgical patients, which in itself is a factor associated with high incidence values considering that, according to the reports in the literature, surgery services account for 51% to 77% of all REs in healthcare institutions.¹⁴

Another important finding of this study which is consistent with the reports of the literature is the additional risk in patients undergoing emergency surgical procedures (unscheduled). Our study found that, in the group of patients taken to a surgical procedure, 54.74% underwent unscheduled surgery because of the severity of their condition which required emergent intervention. The cumulative incidence of REs in this group of patients was 31.57% (95% CI 95% [21.38; 43.25]). The study by Guevara et al¹⁶ in 2013 in patients taken to emergency surgery concluded that the risk of reintervention and mortality is greater in this population and this, in turn, favors the REUE occurrence.

As far as preventability is concerned, the incidence of preventable REUEs was 8.91% (95% CI [5.36; 13.71]), representing 75% of the total number of REUEs. In previous

Table 3. Characterization of reportable events with unwanted effects—REUE.

Characteristics of REUEs (n = 24)	
Emergency procedure	Frequency (%)
Yes	21 (87.50)
REUE timing	
Happened during hospitalization and detected during the same admission	17 (70.83)
Happened during hospitalization and detected during readmission	7 (29.16)
Setting of REUE occurrence	
Inpatient service	11 (45.83)
Operating room	8 (33.3)
Intensive Care Unit	3 (12.50)
Recovery room	1 (4.17)
Outpatient clinic	1 (4.17)
REUE Classification	
Serious	18 (75.0)
Non-serious	6 (25.0)
Preventability level	
Preventable	18 (75.00)
Non-preventable	6 (25.00)
Causes of the REUE (n = 24) (expert committee)	Frequency (%)
Related to systems and others	15 (62.50)
Failures in prevention	14 (58.33)
Failures in performance	13 (54.17)
Diagnostic-related failures	11 (45.83)
Treatment selection/institution-related failures	9 (37.50)
Medication-related failures	6 (33.33)
Factors contributing to the occurrence of REUEs (n = 24) (London protocol)	Frequency (%)
Clinical context	12 (50.00)
Patient-related factors	14 (58.33)
Team-related factors	9 (37.5)
Individual factors	7 (29.16)
Factors related with scheduled tasks	12 (50.00)
Workplace-related factors	8 (33.33)

REUE = reportable events with unwanted effect.

Source: Authors.

Table 4. Characterization of preventable and non-preventable REUEs according to work shifts and type of admission.

Shifts	Type of REUE	6AM–12M	12M–6PM	6PM–6AM
	Non-preventable REUEs	1	2	3
	Preventable REUEs	5	6	7
	Total (%)	6 (25%)	8 (33.33%)	10 (41.67%)
Type of admission	Type of REUE	Scheduled consultation	Priority consultation	Interinstitutional transfer
	Non-preventable REUEs	2	0	4
	Preventable REUEs	4	1	13
	Total (%)	6 (25%)	1 (4.16%)	17 (70.84%)

REUE=reportable events with unwanted effect.

Source: Authors.

studies conducted by the same group of researchers of this study,¹¹ a 61% incidence of preventable REUEs was reported in 3 Colombian institutions. On the other hand, other references such as the Canadian study by Baker,⁶ Zegers,¹⁴ or the study by Healey et al,²³ conducted specifically in surgical patients, reported a proportion of preventable REUEs between 36.9% and 46.8%. The degree of preventability of REUEs points to the fact that, despite advances in their identification and analysis, risk management, and prevention strategies appear to be insufficient or not very effective. Consequently, proposals for risk prevention are needed within the framework of risk management systems of proven effectiveness, and further studies are a priority.

Mortality associated with REs in our study was 4.16% (1/24) (95% CI [0.10; 21.1]), similar to the incidence of disability secondary to REs. In both cases, these outcomes occurred as a result of non-preventable REs. In the IBEAS study (Prevalence of adverse effects in Latin American hospitals),⁹ the reported mortality range was 3.3% to 13.5%, while the reported range for disability was 5.2% to 36.8%, showing similar values.

Regarding the analysis of REUE performed by means of the application of the London protocol, the following contributing factors were identified: patient-related factors (58.33%), clinical context-related factors and factors related to scheduled tasks (50.00%). There is a correlation between these factors and the complexity of the conditions seen at the institution, comorbidities, and factors previously described, such as age. In terms of human factors, particularly communication failures, the data are found to correlate with those in the literature, reported at 65%.¹⁴ It is important to mention that communication refers to information that is conveyed accurately and consistently as a result of comprehension.²⁴

Along the same lines, communication errors involved in the occurrence of REUE may be associated with social

structures and organization factors.²⁵ Another result which is consistent with the above is the report by *Joint Commission on Accreditation of Healthcare Organizations*, which documented that poor communication was responsible for 60% of medical errors, 75% of which resulted in death.¹⁸

Being a prospective cohort, this study allowed to create opportunities for real-time impact on the consequences for patients who experienced a RE of unwanted effects. Another important consideration is the 30-day prospective follow-up after discharge from the institution, which is interesting in that it allowed to recognize an important number of healthcare-related REUEs occurring beyond tight control from healthcare providers. This result must also give rise to a judicious reflection about the need for adequate follow-up of patients beyond the walls of the institution and to keep them under remote responsibility of the treating physicians. It also leads to the reflection that care responsibilities do not exist only while the patient is in the hospital or any other healthcare institution, and that all decisions made may result in an REUE within the short, medium or long term.

A limitation of this work is the source of information, mainly the clinical records, which means that the results depend on the quality of the documentation.

Conclusion

The results of this study show REUE incidence, preventability and contributing factors in surgical services within the frequency ranges reported in the international literature. The high frequency of preventable REUEs is an opportunity for improvement by means of the implementation of clinical risk management systems. Moreover, patient-related factors such as the condition leading to admission, age and comorbidities appear to be related with a higher number of REUEs, but further studies are required in order to measure the degree of association.

The study provides relevant information regarding REUEs in the surgery service, characteristics of the patients in whom they occurred, and data regarding the circumstances in which the events occurred. This characterization of the site, time to REUE and contributing factors identified with the London protocol allows this study to not just report figures, but to be used as input for risk management plans in healthcare institutions of similar characteristics as those of the institution studied.

Ethical responsibilities

Human and animal protection: The authors declare that no experiments were conducted in humans or animals for this research.

Data confidentiality: The authors declare having followed the protocols of their institution regarding patient data disclosure.

Right to privacy and informed consent: The authors declare that no patient data appear in this article.

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Conflict of interest

The authors declare having no conflict of interest.

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Annex 1

Out-of-hospital screening questionnaire		
Telephone follow-up screening of events for institutional quality improvement		
Description of events of interest		
The case represents an event of interest	Yes (P7)	No (P21)
P-7 Name of the event of interest		
P-8 Detailed description of the facts related to the event of interest		
P-9 Required care in a healthcare institution due to the event of interest	Yes (P10)	No (P11)
P-10 If yes, name the institution		
P-11 Does the case present another event of interest	Yes (P12)	No (P16)
P-12 Name of the event of interest		
P-13 Detailed description of the facts related to the event of interest		
P-14 Required care in a healthcare institution due to the event of interest	Yes (P15)	No (P16)
P-15 If yes, name the institution		
P-16 Does the case present another event of interest	Yes (P17)	No (P21)
P-17 Name of the event of interest		
P-18 Detailed description of the facts related to the event of interest		
P-19 Required care in a healthcare institution due to the event of interest	Yes (P20)	No (P21)
P-20 If yes, name the institution		
Source of information and observation		
P-21 Source of information for completing this form	Clinical record	Book—entry
	Database	Other: which?
P-17 Observations regarding this form		
P-18 Did the person responsible sign?	Yes	No
P-19 Name of the person responsible for collection		
P-20 Did the reviewer sign?	Yes	No
P-21 Name of the reviewer		

Source: Authors.