SYREC STUDY
Executive Summary
Safety and risk factors for critically ill patients

Adverse incidents and events in Intensive Care Medicine.

REPORTS, STUDIES AND RESEARCH 2009
MINISTRY OF HEALTH AND SOCIAL POLICY

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Study prepared through the collaboration agreement singed by the Ministry of Health and Social Policy and the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC).

(Pending review)

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL

Plan de Calidad para el Sistema Nacional de Salud

SEMICYUC
LOS PROFESIONALES DEL ENFERMO CRÍTICO

Executive Summary

1 Introduction

The goal of health care is to benefit the patient, but the growing complexity of the healthcare processes involves a risk[1] that becomes particularly evident in Intensive Care Services (ICS). The studies carried out in the field of Intensive Care Medicine suggest that the severity of the patient's illness and the complexity of the therapeutic and diagnostic procedures are related to the increased presence of adverse events (AE) in comparison to that shown in studies carried out in other areas of the hospital[2-14].

To date, three multicenter studies have been published in this field. The Australian Incident Monitoring Study in Intensive Care Units (AIMS-ICU) [15] and the ICU Incident Safety Reporting System (ICUSRS) [16] are studies based on anonymous systems of voluntary AI declaration. They are national initiatives undertaken in Australia and US respectively with the common objective of not performing an epidemiological study, but rather to provide the professionals with a tool to identify safety problems and ascertain the main "risk factors" in the intensive care environment. The third study is by the European Society of Intensive Care Medicine, the Sentinel Events Evaluation Project (SEE)[17], a one day cross sectional International multicenter study on parenteral medication errors in Intensive Care, which detected AE in 20,8% of the patients admitted to the participating ICUs.

In our country, the National Study on the Adverse Effects linked to hospitalisation (AENEAS), carried out in 2005 among 24 hospitals and 1,063 patients, identified 655 AE, which equals an incident rate of 1.4 AE per 100 patient days, with being 42.8% of the cases being considered as avoidable. Of all of the AE detected, 23 occurred in ICUs[18].

The different organization model of the Spanish ICUs[19, 20], with the the physical presence of intensive care specialists 24 hours a day, has an impact on mortality and length of stay in Intensive Care Units (ICU)[21, 22]. It is also possible that the presence of the intensive care specialist has an influence on the frequency and types of events detected.

These differences together with the lack of studies on critical patient safety in Spain gives rise to a need for a multicenter study that allows us to know the epidemiology of AE in Spanish ICUs.

Aware of this need, the National Health System Quality Agency and the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC) designed and launched a study to estimate the frequency and impact of AE and no-harm events (NHE), evaluate the consequences and avoidability of the incidents and to identify the factors that facilitate their occurrence.

2 Objectives

1. Estimate the frequency of AE and NHE in the ICUs of the participating hospitals.
2. Estimates the number of patients affected by AE and NHE in the ICUs.
3. Analyse the causes of AE and NHE and identify the phase of the healthcare process in which they were produced.
4. Analyse the proportion of avoidable AE and NHE.
5. Estimate the severity of the AE and the NHE.
6. Analyze the factors that contribute to the occurrence of NHE and AE.
7. Quantify and characterize the proportion of NHE and AE that are communicated to patients and family.

3 Methodology

3.1. Design

One day, observational multicenter study of prospective cohorts running from 08:00 hours on 22 March to 08:00 hours on 23 March 2007.

3.2. Scope

All of the invited ICUs that decide to participate in this study.

3.3. Definitions

Given the current lack of any universally accepted terminology and taxonomy, and until the approval of the WHO International Classification for Patient Safety, the Following Definitions Will Be Used in the Study:

3.3.1. Case or incident: All NHE or AE detected and declared by the medical professionals.

3.3.2. No-harm events (NHE): Incident that does not cause harm to the patient either because it was rejected or, having been accepted, did not have harmful consequences.

3.3.3. Adverse events (AE): Any unexpected or unplanned incident notified by the medical professionals that caused injury and/or disability and/or extension of the hospital stay and/or death as a result of the care given and not related to the evolution or possible complications of the underlying illness or injury of the patient.

3.3.4. Avoidable NHE and AE: The determination of whether or not the incidents were avoidable takes into account the assessment of the observer. incidents are classified into four categories: totally avoidable, possibly avoidable, possibly unavoidable, totally unavoidable.

3.4. Criteria for participation in the study

The study included all of the patients in the intensive care unit of the participating hospitals during the period of observation, including those admitted, released or deceased during the one-day study. This included all of the no-harm events and adverse events that occurred, were detected and notified during the period of observation in the units, as well as those occurring outside of the unit but representing the cause of admittance to intensive care.

3.5. Variables studied

3.5.1. Variables related to the hospital and the ICU: number of beds in the hospital in 2006, number of beds in the unit during 2006, type of unit (medical, surgical, coronary, trauma, mixed, paediatric, other), number of patients admitted in the hospital in 2006, number patients admitted to the ICU during 2006, physician-patient and nurse-patient ratios, Nine Equivalents of Nursing Manpower Use (NEMS) per shift, and number of active beds.

3.5.2. Patient-related variables: Age, sex, date of and time of admission, date and time of discharge, readmission.

3.5.3. Illness-related variables: Type of patient (medical, coronary, surgical, traumatic, septic, paediatric, other), diagnostic group.

3.5.4. Notifying person-related variables: Notifying person (physician, registered nurse (RN), nurses' aid (NA), resident, other).

3.5.5. Variables related to the moment/place of the incident and information to the family: Time period? (8:00h to 15:00h; 15:00h to 22:00h; 22:00h to 8:00h), Family informed?

3.5.6. Variables related to the class of NHE and AE: The incidents were classified into 11 classes, each with one or more subclasses: medication, blood transfusions and by-products, airway and mechanical respiration, vascular access, probes, tubes, drainage or sensors, failure of medical devices or equipment, diagnostic error, diagnostic tests, nursing care, procedures, nosocomial infection, and surgery-related incidents.

3.5.7. Situation-related variables: Category A: Circumstances or situations with the capacity to produce an incident but that do not due to being discovered and solved before affecting the patient. Category B: The incident reached the patient but did no harm. Did not require monitoring or intervention. Category C: The incident reached the patient and did no harm but needed monitoring and/or intervention to verify the absence of harm. Category D: The incident caused indeterminable harm. Category E: The incident contributed or caused temporary harm to the patient and required intervention. Category F: The incident contributed or caused temporary harm to the patient and required or extended hospitalisation. Category G: The incident contributed or caused permanent harm to the patient. Category H: The incident compromised the life of the patient and intervention was needed to maintain life. Category I: The incident contributed or caused the death of the patient.

3.5.8. Avoidability: Totally avoidable, possibly avoidable, possibly unavoidable, totally unavoidable.

3.5.9. Variables that contributed to the NHE and AE: Individual factors of the professional involved in the NHE or AE, team and social factors, communication factors, task-related factors, training and education-related factors, equipment and resource-related factors, work conditions, and patient factors.

3.6. Procedure

After confirming the acceptance to participate in the study, each unit designated two coordinators, a physician and a registered nurse, who were provided with the design and instructions for the study in order to standardise the collection criteria, as well as support and training material which we recommend be distributed among all of the professionals in the units prior to the start of the study.

For the collection of the data, a questionnaire was provided in paper format. On the day of the study, all physicians, RNs and nurses aides completed the corresponding voluntary and anonymous questionnaires. The coordinators of each centre verified

the correct completion of the printed questionnaires and digitalised them for sending by e-mail to the research team.

3.7. Quality control in the collection of data

All the incidents communicated were reviewed individually by the main researchers. Subsequently, a consensus meeting was held to review any discrepancies and decide on their inclusion or exclusion, as well as for the reclassification of any that were incorrectly classified.

3.8. Statistical analysis

in order to process the data collected on the questionnaires, a Microsoft Access database was used for subsequent statistical data mining using the programme SPSS version 15.0.

For each of the incidents, NHE or AE, the following indicators were calculated: risk (aggregate incidence) and rate (density of incident) by centre.

The qualitative variables are presented with the distribution of frequencies and their association is contrasted with the chi-squared test. The quantitative variables by average and standard deviation (SD) or as medians and interquartile ranges (IQR), in the case of asymmetric distributions. The difference in averages is contrasted using the Student-t test for independent samples or the analysis of the variance for more than two averages when the variables are distributed normally and subject to prior study of the uniformity of variances. In the case of asymmetrical distribution, the median test is used for hypothesis testing. Null hypotheses are rejected with values of $p < 0.05$.

The calculation of the specific and global indicators is summarised in median and IQR (percentile 25 - percentile 75).

3.9. Confidentiality and ethical aspects

This study was carried out following the recommendations of the WHO and the Spanish National Health System Cohesion Act. The necessary conditions were established to guarantee compliance with Organic Law 15/1999, on the protection of data of a personal nature.

All data provided was a non-MS, both for patients and medical personnel, and was strictly confidential within the participating hospitals. The data files do not contain any identifying information on patients. The results were presented in aggregate so that no breakdown could lead to the identification of a patient.

Given the observational and anonymous nature, and the lack of interventions, informed consent was not considered necessary.

4 Main results

4.1. Description of the participating ICUs

79 ICUs from 76 participating hospitals were included in the study. Hospital size is classified by: Small hospitals (200 beds or less), medium hospitals (between 201-499 beds) and large hospitals (500 beds for more). Most of the participating ICUs corresponded to medium-sized hospitals (43%) and large hospitals (41%).

The median occupation of the ICUs on the day of study was 80% (IQR 64.06% - 98.96%). There were no significant differences regarding occupation levels in hospital size.

Using the NEMS scale as reflection of the nursing work load, we find statistically significant differences between the average NEMS and the size of the hospital ($p = 0.005$), with the large hospitals having higher workloads (NEMS 29.12, SD 4.29) Van small (NEMS 23.96, SD 4.41), ($p = 0.006$).

Taking into account the occupation level I the day of study, the median of patients attended by each RN was 1.96 (IQR 1.51 – 2.24), with there being no significant differentiation in the number of patients attended by each during the three standard nursing shifts.

4.2. Description of sample

On the day of the study, a total of 1017 patients were admitted at some point during the day in the participating ICUs. Of them, 591 (58.1%) presented one or more incidents. The percentage of patients with incidents was similar for the three sizes of hospital. In 4 units (5%) no incident was notified.

Of the 591 patients that presented some type of incident, 381 (64.5%) were men and 210 (35.5%) women. The overall average age was 61.63 (SD 16.72) years, for the men 61.52 (SD 16.38) years and for the women 61.84 (SD 17.35) years.

4.3. Description of the incidents

The incidents were classified according to whether they produced harm (AE) or not (NHE). 1424 valid incidents were reported affecting 591 patients, of the total 943 were NHE and 481 AE (table 1).

Table 1. No. of participating units by Hospital size and no. of cases reported.

Hospital sides (beds)	Total patients day of study (n=1017)	Patients with NHE and/or AE (n=591)	Patients with NHE and AE (n=1424)	Number of NHE (n=943)	Number of AE (n=481)	Incidents per patient. Median (IQR)	NHE/AE Median (IQR)
<200	88	45	115	85	30	0.83 (0.20-2.00)	1.56 (0.80-3.00)
200-499	367	219	513	341	172	1.24 (0.67-2.33)	1.88 (1.00-2.71)
≥500	562	327	796	517	279	1.27 (0.78-1.82)	1.42 (0.85-3.71)

The Hospital size is not associated with a number of incidents reported per patient (p=0.34) or with the ratio of NHE and AE (p=0.57).

4.3.1. Frequency of the incidents

Risk: Expressed as the median, the risk of suffering a no-harm event due to admittance in the ICU was 73%, while for an AE it was 40%. There were 1.22 incidents per patient (table 2).

Table 2. Risk of incidents, NHE and AE.

	Median	Percentile 25	Percentile 75
Incidents/patient rate	1.22	0.50	2.17
Risk of NHE for 100 patients	72.73	28.57	140.91*
Risk of AE for 100 patients	40.00	15.38	71.43

*This value should be expressed as a rate, since the risk exceeds 100%, therefore, all the patients will be affected at the rate of 1.41 NHE per patient.

The probability that a patient suffers at least 1 incident was 61.90%, at least 1 NHE45.45% and at least 1 EA was 29.17%, expressed as a median (table 3).

Table 3. Individual patient risk of incidents, NHE and AE.

	Median	Percentile 25	Percentile 75
Risk of at least one incident per 100 patients	61.90	43.75	80.00
Risk of at least one NHE per 100 patients	45.45	28.57	63.64
Risk of at least one AE per 100 patients	29.17	15.38	50.00

incident rate: Expressed as the median, the incident rate was of 5.89 for 100 patients per hour of ICU stay, that of a NHE of 3.47 for 100 patients per hour and that of AE was 2.04 per 100 patients per hour of stay in ICU (table 4).

Table 4. Incident rate, NHE and AE.

	Median	Percentile 25	Percentile 75
Incident rate per 100 patients*hour	5.89	2.35	10.66
NHE rate per 100 patients*hour	3.47	1.77	8.59
AE rate per 100 patients*hour	2.04	0.84	3.60

4.3.2. Classification of the incidents The incidents were classified into 11 classes as shown in table 5. 74% of the incidents reported were in relation

to medication, devices, care, vascular accesses and probes, airways and mechanical respiration.

Table 5. Number o NHE and AE per class

	NHE			AE			Total		
	Count	% row	% column	Count	% row	% column	Count	% row	% column
Medication	294	84.0%	31.2%	56	16.0%	11.6%	350	100%	24.6%
Transfusion	4	80.0%	0.4%	1	20.0%	0.2%	5	100%	0.4%
Airway and mechanical respiration	107	74.3%	11.3%	37	25.7%	7.7%	144	100%	10.1%
Vascular accesses, probes	133	89.9%	14.1%	15	10.1%	3.1%	148	100%	10.4%
Devices	207	94.5%	22.0%	12	5.5%	2.5%	219	100%	15.4%
Diagnostic error	5	31.3%	0.5%	11	68.8%	2.3%	16	100%	1.1%
Diagnostic tests	82	80.4%	8.7%	20	19.6%	4.2%	102	100%	7.2%
Care given	81	39.1%	8.6%	126	60.9%	26.2%	207	100%	14.5%
Procedures	29	41.4%	3.1%	41	58.6%	8.5%	70	100%	4.9%
Nosocomial infection	0	0.0%	0.0%	116	100.0%	24.1%	116	100%	8.1%
Surgery	1	2.1%	0.1%	46	97.9%	9.6%	47	100%	3.3%
Total	943			481			1424		

The incidents related to medication, airway and mechanical respiration, vascular accesses, probes and drainage, devices and diagnostic tests were chiefly NHE ($p<0.05$); while those related to diagnostic error, caregiving, procedures and surgery were primarily AE ($p<0.05$). The nosocomial infections are all by definition AE.

4.3.3. Severity of the incidents Based on the harm caused to the patient, the incidents were classified into 9 categories, defined in the methodology section. The first three do not cause harm to the patient and are, therefore, NHE, the other 6 cause variable harm and are all AE. 66% of incidents reported were NHE and the remaining 34% were AE; 29.50% caused temporary harm and 4.28%, caused permanent harm, compromised the life of the patient or contributed to their deaths.

The number of incidents reported in each category is shown in table 6.

Table 6. Number of incidents per category

	n	Rate	Percentage NHE and AE
Category A	168	11.80%	66.22%
Category B	596	41.85%	
Category C:	179	12.57%	
Category D:	115	8.08%	
Category E	185	12.99%	33.78%
Category F	120	8.43%	
Category G	2	0.14%	
Category H	50	3.51%	
Category I	9	0.63%	
	1424	100.00%	

EA contributed to or caused the death of the patient in 9 cases, which implies, for the total hours at risk, a rate of 4.38 per ten thousand patients-hour of monitoring and for the 1017 patients that were admitted, a risk of 8.8 per thousand patients admitted.

The distribution by sex of the deceased was similar, 5 men and 4 women; as well as the type of patient, 4 medical and 5 surgical.

The type of incident, the reason for admission and cause of death are shown on table 7.

Table 7. Characteristics of deceased patients.

Reason for admission	Type of incident	Cause of death
Postoperative abdominal abscess.	Surgery	Abdominal abscess after gastrectomy due to neoplasia. Multiple organ failure.
Postoperative intestinal occlusion by flange.	Surgery	--
Postoperative aortoiliac bypass.	Surgery	Colon perforation.
Postoperative for aortic cardiac prostheses.	Medication	Massive hemoptysis in patient on anticoagulation.
Mediastinitis.	Surgery	Postoperative on cardiac neoplasia Opening of sutures. Mediastinitis.
Cardiac arrest.	Diagnostic error	Delay in ER care with cardiac arrest.
Cardiac plugging.	Procedure	Cardiac plugging during percutaneous mitral valvuloplasty.
Respiratory failure.	Procedure	Radio frequency on pulmonary tumour. Bronchospasm.
Global respiratory failure. Severe asthma.	Nosocomial infection	Nosocomial pneumonia.

Of the 9 AE-related deaths, 2 were considered as avoidable or potentially avoidable.

4.3.4. Avoidability of the incidents The incidents reported were classified according to the potential degree of avoidability as"Totally avoidable", "Possibly avoidable", "Possibly unavoidable" and "Totally unavoidable" according to the criterion of the notifier. According to this classification, 90% of the NHE and 60% of the AE were considered "Totally avoidable" or "Possibly avoidable" (table 8).

Table 8. Avoidability of the incident

	NHE			EA		
	Count	% row	% column	Count	% row	% column
Totally avoidable	618	86.3%	65.5%	98	13.7%	20.4%
Possibly avoidable	225	53.6%	23.9%	195	46.4%	40.5%
Possibly unavoidable	77	33.2%	8.2%	155	66.8%	32.2%
Totally unavoidable	23	41.1%	2.4%	33	58.9%	6.9%

The NHE were considered as avoidable or possibly avoidable more often than the AE, this difference reaching statistical significance, $p<0.05$. Similarly, the EA were considered as unavoidable or possibly unavoidable more often than the NHE, with this difference reaching statistical significance.

4.3.5. Information given to the patient and/or the family: The patient or the family were not informed in 93% of the NHE and 46% of the AE (table 9).

Table 9. Communication to relatives according to incident class

	Information given to the patient and/or the family:								
	NHE			EA			Total		
	Count	% row	% column	Count	% row	% column	Count	% row	% column
No	878	79.89%	93.21%	221	20.11%	45.95%	1099	100.00%	77.23%
Yes	64	19.75%	6.79%	260	80.25%	54.05%	324	100.00%	22.77%

The information to the patient and/or the family was more frequent when the incidents were AE than when no-harm was caused, $p<0.05$. The patient and/or the family were not informed of the incident in those cases that were considered "Totally avoidable", while they were informed in the remainder of the categories. These comparisons reached statistical significance, $p<0.05$.

4.3.6. Analysis of the contributing factors (CF): To study the factors that contributed to the occurrence of incidents we applied the classification of the National Patient Safety Agency (NPSA) adapted to our study. We established 8 groups of contributing factors: individual factors of the professional, team and social factors, communication factors, task-related factors, training and education-related factors, equipment and resource-related factors, work conditions, and patient factors.

Of the 1424 incidents notified, 1247, 87.57% of the total, reported 1 or more CF. In 177 incidents, 12.43% of the total, no contributing factors were found. 2965 converting factors were reported, for a median of 2.00 cf. per incident reported (IQR 1.00-3.00). 1729 (58.31%) were reported for NHE and 1236 (41.69%) in AE. The 1729 CF reported for NHE were on 943 NHE, which implies a median of 1.00 CF per each NHE (IQR 1.00-2.00). The 1236 CF reported for AE were on 481 AE, which implies a median of 2.00 CF per each AE (IQR 1.00-3.00). The difference in favour of greater notification of CF in the AE, reaches statistical significance, $p < 0.001$. In the comparison of medians across all the classes of incident reported, we have found that the incidents related to care and nosocomial infection, reported a higher number of CF than the rest of the incidents, achieving statistical significance, $p<0.001$.

The distribution of CF in the 8 groups included in the study is shown in table 10.

Table 10. No. of NHE and AE in which at least one CF per group of factors.

	NHE			EA			Total incidents		
	Count	% row	% column	Count	% row	% column	Count	% row	% column
Of the professional	364	80.89%	28.04%	86	19.11%	10.94%	450	100.00%	21.59%
Of the team	24	63.16%	1.85%	14	36.84%	1.78%	38	100.00%	1.82%
Of communications	98	81.67%	7.55%	22	18.33%	2.80%	120	100.00%	5.76%
Task-related	101	45.70%	7.78%	120	54.30%	15.27%	221	100.00%	10.60%
Training and education	178	61.59%	13.71%	111	38.41%	14.12%	289	100.00%	13.87%
Equipment and resources	169	83.66%	13.02%	33	16.34%	4.20%	202	100.00%	9.69%
Work conditions	223	64.45%	17.18%	123	35.55%	15.65%	346	100.00%	16.60%
Of the patient	141	33.73%	10.86%	277	66.27%	35.24%	418	100.00%	20.06%
TOTALS	1298			786			2084		

globally, for the no-harm events, the ones that reported the highest number of contributing factors were related to the professional and specifically to cognitive factors, 12.20% (including lack of attention, distraction, preoccupation, work overload, boredom) and with stress, 8.04%. Next, the incorrect operation of devices (equipment and resources), 7.06%; and the

excessive workloads (working conditions), 7.00%. The also highlighted a lack of experience, 4.74%, a lack of appropriate supervision (both linked to training and education), 4.74%, time pressures (working conditions), 4.05% and the complexity of the patient (factors of the patient), 5.55%.

Among the EA, the most reported CF were related to the patient, specifically complexity and severity, with both factors being notified in 17.15% of the AE. Next in importance were the excessive workload, 6.80%, the lack of experience, 4.21%, the lack of adequate supervision, 5.18%, and cognitive factors 4.37%. Any new CF in this group was failure to adhere to protocols (task-related factors), 6.15%.

The conclusions of the CF study and there relation with the incident class, severity and avoid ability are included in table 11.

Table 11. Characteristics of the CF distributed by groups.

	Frequency	Most notified factors	Most related incidents	Severity	Avoidability
Of the professional	21.59%	• Cognitive factors • Stress • Lack of motivation	• Medication • Diagnostic tests	Minor	Avoidable
Of the team	1.82%	• Undefined roles • Lack of leadership	• Airway and MR • Diagnostic tests • Procedures	For all categories:	For all categories:
Of communications	5.76%	• Ambiguous verbal orders • Orders badly directed • Lack of understanding	• Medication • Diagnostic error • Diagnostic tests	Minor	Avoidable
Task-related	10.60%	• Absence of protocols • Non-adherence to protocols • Protocols not up to date	• Nosocomial infection • Care given • Procedures • Diagnostic tests	Less serious	Avoidable
Training and education	13.87%	• Lack of supervision • Lack of training • Lack of knowledge and skills	• Procedures • Diagnostic error • Vascular access	For all categories:	Avoidable
Equipment and resources	9.69%	• Incorrect operation • Incorrect maintenance	• Devices	Minor	Not avoidable
Work conditions	16.60%	• Related to excess workloads • Related to new personnel	• Care given • Diagnostic error • Medication	For all categories:	Avoidable
Of the patient	20.06%	• Complexity • Severity	• Surgery • Nosocomial infection • Care given	Severe	Not avoidable

MR = mechanical respiration.
All the comparisons are statistically significant.

5 Limitations

The under-reporting inherent in anonymous and voluntary reporting systems is a recognised limitation in this type of studies. Despite the fact, some design factors, such as the selection of participating hospitals (not random), the specific participation of coordinators in each centre, the basic training prior to the launch of the project, and the short term of the observation period, may have favoured the notification of incidents.

Also, we cannot rule out the Hawthorne effect, consisting of the application of safer practices on the day of the study due to the feeling of being watched.

One of the main limitations of the study was the high percentage of modifications that the inspectors carried out in the classification of the incidents (40.2%). Despite the fact that the methodology included the description of the incident, the difficulty of fitting specific cases, the high number of reporting parties, and the subjective nature of concepts such as avoid ability, and the difficulty of the design of the study in specifying the final product produced, may be behind this fact. The adoption of a universal classification system such as that proposed by the WHO (International Classification for Patient Safety, ICPS) adapted two critical patients, may contribute to reducing this bias.

The characteristics of the Units included in the study, the percentage of participation and the professional-patient ratios, reflects the reality of the operation and organisation of the Spanish national health care system. This, together with the wide variety in the taxonomy and the methodology employed by PC being studies may pose a barrier to the comparison of our work with previous studies.

The main classes of incidents reported were influenced by the methodology used, and in some cases, such as in nosocomial infection or stress-related ulcers can complicate the appraisal of the results obtained when including in, - given the difficulty in establishing a diagnosis of the safety and the exact time of its appearance-, both those diagnosed during the observation period and those that were actively treated it on the day of the study.

Also the severity of the incidents reported is limited by the tool used, which favors the notification of less serious incidents in comparison with others, such as the review of medical records. Also the short duration of the study does not allow for including all of the cases of final harm to a patient or the detection of the adverse event on subsequent days, with obvious consequences.

Although the percentage of incident notification to patients and family members is in line with other studies, and particularly high in severe AE, the results do not allow us to exhaustively verify the information provided.

As for the CF, the types notify can be related to the intrinsic characteristics of the critical patient (complexity and severity), although we cannot rule out that is also laying to the difficulty of the medical professionals to recognize causal factors linked to their own actions or to the system and not to the characteristics of the patient or the proximity to the classification used

6 Conclusions

One

The probability of suffering at least one safety-related incident for the mere fact of being admitted to and Intensive Care Unit is 62%. On the day of study 1.22 incidents were reported for each patient admitted. The incident occurrence rate in our study was 5.89 incidents per100 patients and hour (results expressed as medians).

The participation of almost 33% of Spain's ICUs and the large number of professionals participating in this study, reflects the motivation and concern of the leaders of our patient safety services, and leads us to believe that, in recent years, there has been improvement in the patient safety culture in our field.

Two

The most frequently reported incidents were those relating to medication, followed by devices, care-related, vascular catheters and probes, and those related to the airway and mechanical respiration. Although these incidents were not the most serious, given that many did not cause harm to the patient, highlights that the main risk factors involve the care of critical patients.

The adverse events that appeared with the most frequency were related to the care given and nosocomial infection.

Three

90% of all incidents and 60% of the AE were classified as avoidable or possibly avoidable. The recognition of the professionals of the possibility to prevent or to avoid the occurrence of an incident is the first step to establishing measures that help to reduce the risk faced by critical patients.

The incorporation scientific evidence into healthcare practice through clinical practice guides and the use of protocols that include proven measures to reduce the risk of adverse events must be considered as a priority. The use of safety indicators that help to evaluate compliance with such measures will be constitute warning signs and will allow for the establishment, when needed, of strategies to improve the quality of healthcare.

Four

The percentage of adverse events detected among the total number of incidents was 33.8%, with almost 21.5% involving moderate harm (temporary harm or extension of the stay) and 3.65% with severe harm (permanent harm or compromised life). For 9 patients out of every thousand, the death relates to the presence of an adverse event.

Five

Contributing factors were reported in 87.57% of the incidents, with the average being 2 factors for each each incident with notified factors. Excluding the factors of complexity and severity of the ICU patients, which, although influential in the origin of the incidents, are intrinsic to ours patients and, therefore not modifiable, the most reported individual factors related to people: stress, lack of attention, distractions, lack of experience, little supervision, and to the the work environment: excessive workloads, incorrect operation of devices and failure to adhere to protocols.

Six

The percentage of no-harm events and adverse events communicated to patients and relatives was 6.8% and 54%, respectively. Although these figures are still well below the patient's expectations, they translate into the common practice of most of the professionals.

Seven

This study is the most extensive one carried out in our environment and allows for a diagnosis of situation of a majority of the Intensive Care Units in our country.

Eight

The results of our study provides us with real information that should contribute to improving our health care practices and to create a turning point in the safety of critical patients.

The clinical research in this field and the training of the professionals involved are, without doubt, the key to improving the culture of safety and make our intensive care units much more safer.

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