Formación acreditada

SPECIAL ARTICLE

Design and implementation of a patient safety program for a hospital emergency department: how to do it

MARTÍN TEJEDOR FERNÁNDEZ[1], FRANCISCO JAVIER MONTERO-PÉREZ[2], ROSA MIÑARRO DEL MORAL[1], FRANCISCO GRACIA GARCÍA[2], JUAN JOSÉ ROIG GARCÍA[2], ANA MARÍA GARCÍA MOYANO[2]

[1]Servicio de Calidad y Documentación Clínica, [2]Unidad de Gestión Clínica de Urgencias, Hospital Universitario Reina Sofía, Córdoba, Spain.

CORRESPONDENCE:
F. Javier Montero-Pérez
C/ Gutiérrez de los Ríos, 26
14002 Córdoba, Spain
E-mail:
javiermonteroperez@wanadoo.es

RECEIVED:
5-3-2012

ACCEPTED:
4-7-2012

CONFLICT OF INTEREST:
The authors declare no conflict of interest in relation with the present article.

This paper describes the design of a patient safety program for the emergency department of a highly complex tertiary care university hospital. The program comprises a broad set of preventive measures for reducing the risk of identified adverse events. An expert working group within the emergency department undertook the following steps to create the program: 1) brainstorming to identify the potential adverse events that occur in the emergency department as well as the errors and contributing factors responsible for them, 2) ranking of the adverse events according to a risk priority index by means of failure mode and effect analysis, 3) listing recommendations for risk reduction, and 4) mapping risks onto the overall emergency care process. The working group identified 43 adverse events, 65 types of error, 86 causes, and 207 ameliorating actions. Each adverse event generated between 1 and 21 ameliorating actions. Problems with the clinical care process accounted for 46.51% of the total, medication incidents for 13.95%, the diagnostic process for 6.97%, procedures for 6.97%, and infections for 2.32%. Other types of incidents accounted for 23.26% of the total. Our experience underlines the importance of creating a patient safety culture is of great importance in an emergency department. Such a culture can be created by first analyzing and ranking adverse events according to level of risk and then planning ameliorating actions that reduce risk. [Emergencias 2013;25:218-227]

Keywords: Emergency health services. Adverse events. Patient safety.

Introduction and aims

The principle *primum non nocere* has regulated the thought and actions of health professionals since time immemorial[1], and this is even more relevant today when attendance is considerably more complex and involves greater risk. However, references to patient safety have traditionally been limited to mere analysis of sporadic incidents, sometimes published as a paradigm of errors of teaching value, without generating useful knowledge with learning potential and avoidance of their repetition[2]. In general, the various initiatives to improve patient safety and quality of healthcare presuppose knowledge and acceptance of these problems without necessarily quantifying them. In Spain, on the initiative of the Ministry of Health, two descriptive studies have been carried out to characterize and measure the frequency of adverse events (AE), one in inpatient hospital units - the ENAES study[3] - and the other in primary healthcare - the APAES project[4].

Healthcare in a hospital emergency department (ED) is'' unlimited'' in the sense that it is the only hospital department that can attend and maintain any number of patients, for it is the only point of attention in the hospital considered "infinitely expandable''[5]. The fact of simultaneously attending a large number of patients, generally unknown to the ED professionals, with scarce clinical information, using a vast number of processes and no limits on the type of problems or conditions, under time pressure, means increased risk of AE[5].

The EVADUR[6] study, sponsored by the Spanish Society of Emergency Medicine (SEMES) focused attention on patient safety in our hospital EDs, revealing an AE rate of 12%, events that are often avoidable (70%); many are common to other areas of healthcare while others are more ED-specif-

ic. The clinical significance of these AE is extraordinary, since more than half of the AE identified (7.2%) caused harm to the patient and if we extrapolate the mortality rate found in that study to all urgent attendance in Spain, AE may account for 12,650 deaths each year.

Implementation of a patient safety plan in any clinical area is an accepted ethical obligation, a necessity and a priority in order to achieve the best possible results. It is an essential component of the quality of care[6]. But how can it be put into practice in an ED? Effective implementation of systematic measures to prevent and reduce AE involves methodological and organizational difficulties. The aim of this article is to describe our experience with the design and implementation of a patient safety plan the ED of a high complexity level III university hospital.

Method

Hospital Universitario Reina Sofia, Cordoba, has 1,319 beds and serves an area with 788,287 inhabitants. The general ED for adults (≥ 14 years, not obstetric-gynecological patients) attends approximately 125,000 emergency visits per year. Structurally and functionally, it comprises a consulting area, with 4 care circuits (banal, critical, medical-surgical and trauma), and an observation area with 32 beds and 20 chairs. Medical history is almost entirely digitized in an application of the Andalusian public health system called "DIRAYA-Urgencias®, although paper documentation remains in use in the observation area. Administratively, the application for admissions is that of the hospital, called Averroes®, which coexists with the previous one. The ED records any AE using the model designed and recommended by the Central Commission for Quality and Patient Safety of the center.

In order to effectively apply a patient safety plan in the Clinical Management Unit (UGC in Spanish) of our ED, we established a working group composed of eight professionals (all with more than 10 years of experience in urgent care) from all the disciplines involved (doctors, nurses, assistants, orderlies and administrative staff) and 2 physician members of the Clinical Quality and Documentation department who coordinated the plan, providing methodological and logistic support. Only UGC professionals were voters in the sessions.

As a first step, we conducted a literature search using the Virtual Library of Andalusia and the search engine GERION to search health databases CINAHL, EMBASE, ERIC (USDE), EMI-Biomedicine, MEDLINE, PubMed and SciELO (Scientific Electronic Library Online), employing keywords in Spanish and English: emergencies, adverse events, patient safety, without time limits. All the study participants were given copies of the EVADUR study, published in EMERGENCIAS[6].

For the design of the plan, the working group needed three 2 h sessions. Refining the proposals, calculating the risk priority index (RPI) etc was done by a small group of members of the Quality Service and the ED UGC.

In the first session, we identified the AE that may occur in the ED, as well as the failures and reasons for them, by brainstorming[7], and then constructed a risk map of AE, prepared by expert members of the group. Each AE was assigned an ordinal numerical code. Likewise, each preventive action was coded using the reference AE code as the first digit.

An AE was defined as harm caused to the patient as a result of medical practice, products, processes or systems, as opposed to harm caused by the underlying illness or medical condition[8]. An AE is unfortunate and generally unexpected, associated with the care or service provided in a hospital or primary care center[8].

To standardize the key concepts we used the taxonomy of the WHO International Classification for Patient Safety[9]. The key concepts were:

– Incident related with patient safety: event or circumstance that caused or could have caused unnecessary harm to a patient.

– Quasi-incident: an incident not directly affecting the patient.

– Harmless Incident: incident involves the patient, but does not cause appreciable harm.

– AE: an incident that causes harm to the patient.

– Harm: structural or functional alteration of the body or any deleterious effect. This includes diseases, injury, suffering, disability or death, and can be physical, social or psychological.

– Disease: physiological or psychological dysfunction.

– Injury: harm to tissues by an agent or circumstance.

– Suffering: experience of something subjectively unpleasant, including pain, discomfort, general malaise, nausea, depression, agitation, alarm, fear or grief.

– Disability: any structural or functional alteration of the body, limiting or restricting social activity or participation in society, associated with

Table 1. Rating the severity of the adverse event according to repercussion on the patient

Value	Clinical severity	Perceived or objective consequences for the patient
1-2	None Imperceptible repercussion	No perceived or objective symptoms and no treatment required.
3-4	Mild Repercussion irrelevant. barely perceptible	The result for the patient is symptomatic. the symptoms are mild; minimal or moderate functional loss or damage. but short-lived; no need to intervene or necessary intervention is minimal (eg. close observation necessary, solicit lab tests, ask for evidence, perform a physical exam or administer treatment of minor importance).
5-7	Moderate Of relative importance	The result for the patient is symptomatic and requires action (eg another surgical intervention, supplementary treatment) or extension of stay, or cause long-lasting or permanent damage / loss of function.
8-9	Severe	The result for the patient is symptomatic and requires life-saving action or major surgery, reduces life expectancy, or causes significant permanent or long lasting harm or loss of function.
10	Death	Weighing the odds, the incident caused or led to short term death.

*Conceptual Framework for the International Classification for Patient Safety. Version 1.1. Final Technical Report. January 2009. WHO. Available at: http://www.who.int/about/copyright/es/index.html.

past or present harm.

Then we proceeded to prioritize the AE and obtain risk priority index (RPI), using the failure mode and effects analysis (FMEA)[8,9]. For the RPI, the AE were weighted according to severity, frequency of occurrence and degree of possible prior identification or detectability (D) of their causes.

Clinical severity (CS) measures the perceived or expected physical or psychological harm (AE) for the patient (Table 1). To assess CS, we used the WHO scale for AE[9]. The weighting scales we used for frequency (F) and D were designed by the Clinical Quality and Documentation department and previously applied in nine other UGC of the same hospital (Tables 2 and 3). Their validity was confirmed in previous pilot experiments with experts from medical and surgical departments.

Weighting was expressed as whole numbers on a scale of 1 to 10. F was estimated according to historical or statistical data from an AE registry or from experience. D indicates the likelihood that the cause of the AE or failure mode causing the AE can be detected in advance, enabling harm control or avoidance. The RPI was calculated using the formula D x CS x F.

Critical AE were treated as a dichotomous variable and identified with an "X" in the FMEA spreadsheet. The group members were instructed to weight all those failures on which they could give an opinion, whatever their specialty, area of responsibility or ED UGC status.

The weighting of the AE as well as the criticality rating were individually performed. Data processing was performed by the clinical quality and documentation department; the results were analyzed together by the group in a second session.

Once the group had elaborated the catalog of AE, the failures and causes, and RPI value, their task was to propose what preventive actions could be carried out to decrease risk. In a third group session, a final list was drawn up of preventive actions. As in the reference studies ENAES[3], IBAES[6] and EVADUR[12], the AE were prioritized from a clinical perspective, considering the harm caused, which is equivalent to the definition of "patient outcomes" in the WHO classification[9]. AE were classified as relating to: 1) diagnosis (DG), 2) medication (M), 3) care (C), 4) infections (IN), 5) the implementation of a procedure (P) and 6) other (O), which included mere discomfort, not considered as an AE but as a simple safety incident without patient harm. Given the large number of preventive measures proposed, they were grouped according to homogeneity to enable practical application.

Statistical analysis was performed using Microsoft Office Excel® 2003. For each AE we collected scores for G, F and D and calculated the resulting RPI. For each AE we calculated the number of participants who participated in AE assessment, the mean of the ratings (G, F, D and RPI) and the standard deviation (DE). To further analyze score variability, we also calculated the range of scores, percentiles 25, 50 and 75 (quartiles) and the coefficient of variation. In the case of criticality we counted the number of participants who considered each AE as critical or not (Figure 1).

Results

We identified a total of 43 different AE, 65 types of failure, 86 causes and 207 preventive actions. Each AE generated between 1 and 21 preventive actions. As an example of the group's production and the working document used, Table 4 contains a series of 10 AE identified with their failures and their causes, as well as preventive actions considered by the expert group.

The distribution of the 43 AE cataloged according to the classification used in the reference studies ENAES[3], EVADUR[6] and IBAES[12] was as fol-

Table 2. Rating the frequency / probability of an adverse event

Value	Frequency/probability	Criterion
1	Very Low (≤ 1 in 10.000)	No failure has been associated with almost identical processes of care, ever, but it is conceivable that it may appear.
2-3	Low (1 in 10.000-1.000)	Occasional failures occur in similar or almost identical processes. It is reasonably expected to occur once in any professional practice, although unlikely.
4-6	Moderate (1 in 1.000-100) (1‰-1%)	Failure occasionally appearing in similar care processes or previously known (from the bibliography or experience of the evaluator). Probably appears at some points of the working life of every professional.
7-8	High (2-5 in 100) (2-5%)	Failure repeatedly appearing in similar care processes or cases attended by the health team or professional. Previously documented and on a registry.
9-10	Very high (1 in 20) (>5%)	Highly likely failure. It is certain that the failure will occur frequently. Common adverse event.

lows: AE related with Diagnosis 3 (6.97%), with Medication 6 (13.95%), with care 20 (46.51%), with infections 1 (2.32%), with performance of a procedure 3 (6.97%) and other aspects 10 (23.26%).

Table 5 presents all the AE in decreasing order of mean weighted RPI, and mean values of CS, F and A. The five AE with highest mean scores for CS were: death of the patient in the radiology area (10 points, SD = 0.00), death in the waiting room (10, SD = 0.00), harm due to misdiagnosis or delayed admission (8.1, SD = 1.35), medication or dosage error (8.0, SD = 0.82) and sentinel event awaiting triage (7.9, SD = 1,57). The five AE with greatest mean weight were: patient sleeplessness or stress in the observation room due to noise and voices (6.9 points, SD = 2.54), delay in admission (6.7, SD = 1.58), lack of material (6.3, SD = 1.86), patient stress for the delay in admission (6.0, SD = 2.06) and inadequate food according to type of patient and pathology (6.0, SD = 2,94). Finally, for D, the five most common AE were loss of personal items (5.9, SD = 1.96), uncertainty, stress and fear (5.0, SD = 3.02), contagious infection due to direct contact for the patient or professional (4.7, SD = 3.15), effect of medication or dosage error (4.4, SD = 2.76) and medical error (4.3, SD = 1,38).

The ten AE considered most critical are shown in Figure 1, with the number of experts who supported them. All the AE and their RPI are shown, but for the sake of brevity we only show a limited number (ten) of the failures, causes and preventive actions. The risk map was constructed according to the main activities of the care process to provide information on the particular ED area where AE might originate (Figure 2). After refining the group's proposals, 207 preventive measures were obtained, grouped into 8 sections, as shown in Table 6.

Discussion

This study outlines a real experience on how to implement a patient safety plan, specifically in the ED. In our review of the literature we only found one similar experience in the field of emergency medicine, that by Redfern et al[13] in 2009, on the communication process in the ED. The method we used follows the recommendations of the tutorial published by the Ministry of Health in 2007[14] adapted for ED application and already used in other works[15]. As for idea generation, we employed brainstorming, a tool conventionally used in processes of quality improvement[7,16].

Table 3. Assessing the probability / ease of failure detection

Value	Probability/ ease	Criterion
1	Very high	Failure generating the adverse event is obvious. It is very unlikely that it is not detected by existing controls. Controls almost certainly detect the failure in 95% of cases or more.
2-3	High	The failure, although obvious and easily detectable, could be undetected initially, but would certainly be detected afterwards. Existing controls will normally detect the failure in 80 - 95% of cases.
4-6	Moderate	The failure is detectable and may not be discernible by the patient. It is likely to be detected in the later stages of the care process. Existing controls will detect the fault 40 - 80% of the time.
7-8	Low	The failure is such that it is difficult to detect with the procedures established so far. Existing controls only detect the error 5 - 40% of the time.
9-10	Very Low / Zero	The failure is almost certain to be perceived by the patient. There are no controls for this, or they are ineffective, or the failure cannot be previously detected. Only detected in 0 - 5% of cases.

Table 4. Example of the top 10 adverse events identified in the working group sessions (brainstorming) and the risk priority index obtained for each adverse event, failures, causes and proposed preventive actions to reduce risk

N°	Adverse events (RPI)	Failures	Causes	Preventive actions
1	Hypo- or hyperglycemia in diabetics (98.3)	Erroneous insulin dose administered	Use of micro-drip instead of perfusion pump	1.1. Avoid using micro-drip / always use pump 1.2. Increase surveillance 1.3. Have a specific consultation 1.4. The unit must always have a sufficient number of infusion pumps for use
2	Patient uncertainty, stress, fear (91.9)	Lack of information. delay in attention	Lack of information. delay in attention	2.1. Informing the client 2.2. Training course on attention and communication and conflict management 2.3. Do not give information only once, but repeatedly 2.4. Make guidelines on patient information- communication 2.5. There should be a specific personnel responsible for mediation with the patient and family.
3	Patient falls (76.1)	Lack of handrails	Stretchers in poor condition	3.1. Provide adequate staffing 3.2. SOP periodic review and rail / equipment renewal 3.3. Assign a person responsible for maintaining beds and stretchers 3.4. Always accompany patients susceptible to falls
		Poor risk assessment	Poor staff preparation	3.5. Risk of risk of falling detected by nurses and orderlies 3.6. Training courses 3.7. Inform and involve the family in patient care
		Wet Floor	Absence of Wet Floor signs	3.8. Signaling wet floors mandatory 3.9. Cleaning should be done in times of least use, avoid cleaning in visiting hours
4	Iatrogenic harm (73.1)	Erroneous patient identification	Administrative staff inexperience Excessive staff rotation	4.1. Confirm Identification at each step of the process 4.2. Training Courses 4.3. Have qualified and stable administrative staff in the emergency department 4.4. Welcome plan for new staff (2 days minimum) 4.5. Incentivize the admission staff 4.6. Change in management staff policy
5	Harm caused during patient transfer (24.5)	Poor condition of transfer material	Poor maintenance of transfer material and use of such material	5.1. SOP periodic review and renewal of transfer material including rails 5.2. Increase provision of transport equipmente 5.3. Daily inspection of the provision of stretchers / trolleys
6	Patient distress due to loss of belongings (38.6)	Inadequate information Failure to safeguard belongings Failure to correctly identify belongings	Staff stress and performance urgency	6.1. Inform staff of existing SOP custody rules 6.2. Identify all belongings 6.3. Hand in all belongings to security staff. or to family members when present 6.4. Inform family members or accompanying person of their co-responsibility 6.5. Include the information in the user's welcome pamphlet

(Continued on next page)

The systematic technique for failure analysis FMEA was initially used by NASA, airlines and other high-risk industries during more than 40 years to determine the potential causes of system and equipment failure[9,17,18]. It is currently emerging as a useful tool in healthcare[19] and is becoming more widely used. This technique systematically evaluates a complex process, identifies risk areas, the probability and consequences of failures and provides the basis for the design of preventive interventions and actions to minimize AE, with staff involvement in both tasks[11]. Like all qualitative methods, its main contribution is to facilitate decision-making. The ordering of AE weight from high to low (the RPI) provides a first approximation of importance. By consensus, the group considered that AE with a RPI value below 100 require no intervention, unless the improvement was easy to introduce. However, when AE severity and detectability is > 4, preventive measures should be considered regardless of the RPI value, given the possible clinical consequences. Hence, when the FMEA incorporates special attention for critical (C) effects, as in our case, the method is known as FMCEA20.

The results obtained in our experience in relation to the severity, frequency and detectability of the AE were largely expected, considering previous publications[3,4,6,21,22] although initially one could be surprised how such AE can occur in ED practice. Despite widespread reluctance to publically discuss this type of problem, one of the lessons we learnt was: if we really want to prevent AE, they must be notified, talked about and, after analysis, action for improvement implemented.

It has been estimated that about 50% of the

Tabla 4. (Continued)

Nº	Adverse events (RPI)	Failures	Causes	Preventive actions
7	Invasion of privacy (45.7)	Failure to close curtains on washing patients	Lack of curtains or non-use by staff	7.1. Staff themselves should intervene 7.2. Ensure curtains are in good state 7.3. Have partitions available 7.4. Staff training 7.5. Ensure curtains exist for all bays / beds 7.6. Staff awareness of the problem 7.7. Replace curtains with folding partitions
8	Complications of the disease due to delayed treatment (44.3)	Delay in initiating treatment	Poor inter-agent coordination	8.1. Improve inter-dept communication 8.2. Hold inter-dept meetings at least once a month 8.3. Specific staff training on team-work Staff training on existing SOP for patient treatment
9	Adverse effect of medication / dosage error in the observation area (90.1)	Misidentification of patient	The patient has been assigned another bed and staff are uninformed	9.1. Always confirm identity before administering drugs 9.2. Notify changes as they occur 9.3. The list of patients in observation beds should be updated periodically 9.4. Avoid placing similar-looking pills in adjacent boxes
		Poor risk assessment	Similar-looking pills	9.5. Label medication boxes by active ingredient 9.6. Refresher courses on Pharmacology 9.7. Write down the medication and dosage in treatment orders
		Indicaciones verbales	Non-written treatment orders	9.8. More experienced well-trained staff
		Administración de medicación sin diluir en pacientes críticos. con indicación verbal	Staff inexperience Hurry No feed-back	9.9. Only qualified staff 9.10. Courses on team-work, in the ED with physicians. nurses and auxiliary staff 9.11. Unify dilution criteria
		Diluciones incorrectas	Lack of inter-dept communication	
10	Psychological stress for the patient (41.5)	Lack of physical barriers between patients	Not planned in the structural design	10.1. Ensure physical barriers exist 10.2. Group patients according to disease and age 10.3. Ensure patient privacy

SOP = standard operating procedure; RPI = Risk Priority Index.

AE that occur as a consequence of the healthcare actions are highly or very highly susceptible to preventive measures, and in the field of emergency medicine this rises to 70%[6,23-27]. In our case, the working group generated a high number of preventive actions, all applicable, although they varied considerably in terms of the difficulty of implementing them.

The first important conclusion was that most preventive actions, almost 80%, could be applied practically without additional resources, only organizing them differently. The most important group of preventive actions was that related with the modification of resource availability and the process of care delivery. About 14% of the actions referred to insisting that professionals apply their particular clinical competencies, as a large number of AE are caused by poor clinical practice. As in other experiences, new protocols and procedures or application of existing ones can help avoid many AE. Finally, we would highlight the breadth of the preventive action category organizational changes (Table 6), confirming the importance of these changes in AE prevention.

As with any tool, the technique of brainstorming has its positive aspects (participation, expert opinion, speed, low cost) and its limitations (for example, the initial catalog of AE was not exhaustive, based only on the views and professional experience of the group participants).

Although we followed the guidance given in the conceptual framework of the International Classification of Patient Safety9 and because there is no standardized glossary of AE, a limitation of the FMEA method was the difficulty of determining whether participant proposals were actually AE or failures that occurred. Only when they reached unanimous agreement on the group of AE was it included in the catalog. In addition, despite our categorization of AE according to previous studies[3,6,12], there were some difficulties in grouping some categories of AE since many are not completely mutually exclusive.

As stated before, on using a qualitative method for the construction of the list of AE, types of faults and causes, the result was not exhaustive and we decided to allow for further inclusions after implementation of the safety plan, based on future experience of real events in the ED.

Table 5. Safety incidents. with mean values of clinical severity (CS), frequency of occurrence (F), detectability (D), listed in descending order according to mean value of the risk priority index (RPI) assigned by weighting performed by the group*

Code	Adverse Event*	CS**	F**	D**	RPI**
39	(DG) Harm caused by medical error in the diagnosis and subsequent treatment	7.13	4.29	4.14	104.25
31	(DG) Harm caused by misdiagnosis or delayed diagnosis	8.14	3.38	3.43	101.00
1	(M) Hypo- or hyperglycemia in diabetic patients	7.29	4.14	3.50	98.30
37	(O) Patient suffering due to slow proves of admission	4.75	6.67	2.63	96.50
2	(O) Uncertainty, stress, fear of the patient due to lack of information	4.13	5.22	5.00	91.90
29	(IN) Contagion due to direct contact with the patient	6.43	3.63	4.17	91.43
9	(M) Side effect of medication or dosage error in the observation area	8.00	2.29	4.43	90.14
38	(DG) Suffering due to Inadequate admission after misdiagnosis	7.50	3.17	3.43	77.3
3	(CU) Patient fall	5.86	3.13	3.43	76.14
24	(CU) Self-harm and harm done to others	7.00	4.14	2.83	75.00
4	(P) Erroneous medical actions	5.88	2.71	4.29	73.13
35	(CU) Inadequate food supplied to the patient	2.86	6.00	2.57	71.30
41	(P) Harm caused by malpractice or erroneous procedure	6.83	3.57	2.67	65.17
13	(M) Harm due to medication error or medical treatment in the consultation area	7.00	2.57	4.00	62.86
21	(O) Patient alarm caused by inadequate billing and legal aspects	4.38	3.33	3.71	60.38
20	(M) Complications due to poor medication maintenance	6.00	2.67	3.00	59.17
17	(O) Anxiety in patients and relatives	4.29	5.13	3.14	58.86
16	(CU) Harm caused during postural changes and poor hygiene	6.14	4.38	2.43	57.71
42	(CU) Neglect of patient attention	6.00	4.14	2.50	57.57
18	(CU) Sentinel event while awaiting triage	7.86	2.63	3.00	56.86
28	(CU) Sacro-coccygeal area injuries due to deficient attention	6.14	2.63	3.29	56.00
23	(O) Harm due to lack of technical equipment	4.40	6.33	2.60	55.60
30	(M) Harm by administering drugs to which the patient is allergic	7.50	1.86	4.14	54.50
8	(CU) Preventable complications of the disease	6.63	3.71	2.29	49.63
32	(CU) Harm due to non-attendance in waiting room	6.40	3.17	2.33	48.80
25	(CU) Death of a severe trauma patient in the radiography room	10.00	2.17	2.17	46.00
7	(CU) Invasion of privacy	4.00	5.14	2.38	45.71
11	(P) Skin lesions caused by masks, CPAP or BIPAP	5.25	2.86	3.29	44.90
34	(O) Suffering due to delay in patient care	5.57	4.13	2.14	44.86
15	(CU) Harm from normative mechanical restraint of the patient (without justification)	5.67	6.14	4.38	44.33
40	(CU) Inopportune treatment administered	6.00	3.00	3.29	44.25
43	(O) Harm due to overly lengthy assistance time	7.67	2.86	2.50	44.17
10	(O) Psychological aggression	4.33	4.29	2.67	41.50
22	(CU) Sleeplessness / stress in the patient under observation due to staff noises and voices	4.14	6.86	1.63	41.30
6	(O) Patient alarm for loss of personal items	3.00	2.56	5.88	38.63
36	(M) Double dose drug treatment due to failure to reconcile medication	6.71	2.25	3.29	35.60
26	(CU) Harm due to deficient attention of a patient under observation	5.50	2.83	2.50	33.00
14	(CU) Worsening condition of the patient due to failure to solicit diagnostic tests	4.43	2.71	3.86	32.30
12	(CU) Death of patient alone in the waiting room	10.00	1.40	3.20	32.00
19	(O) Suffering due to incorrect admission	5.25	2.29	3.43	30.00
27	(CU) Erroneous discharge of a dropout patient with high health risk	6.29	2.00	2.67	28.86
5	(CU) Harm caused in patient transport	5.00	2.43	2.57	24.50
33	(CU) Fall in the area immediately outside the emergency department	3.71	2.00	3.71	13.90

*Abbreviations in brackets refer to the categories of the adverse event according to the studies ENEAS[3], EVADUR[6] and IBEAS[12]: DG = diagnosis, M = medication, CU = care, IN = infection, P = procedures, O = Other. **The values in columns CS, F, D and RPI are the mean of the individual values of each item. Therefore, the mean values of RPI shown in the table are not the product resulting from CS x F x D.

Obviously, the FMEA tool is most useful when used in simple processes, but has its limitations when applied to such a complex process as a large ED. However, our experience showed that it was compatible and useful for an initial approach and subsequent application to simpler processes or sub-processes for an ED UGC. It is therefore a good start to implementing a patient safety plan in an ED that does not have a previously established culture in this regard.

The order used in FMEA completion of first identifying the AE, then the failures and finally the causes, is not usually employed. But for health professionals this a more logical approach for addressing these problems.

Regarding the extrapolation of this experience to other EDs, the method has been successfully applied in other UGC in our hospital, suggesting its probable usefulness in other EDs, but this requires confirmation. We believe that this work may be of interest to others who are considering an ED patient safety plan and how to start one, to improving the quality of healthcare in this area. The aim of this work was not to assess the clinical impact of AE in the ED.

Finally, the general methodology[13], adapted to local conditions as described in this article, has allowed us to implement an effective plan of patient safety, currently in operation. Assigning responsibility to each group of preventive measures

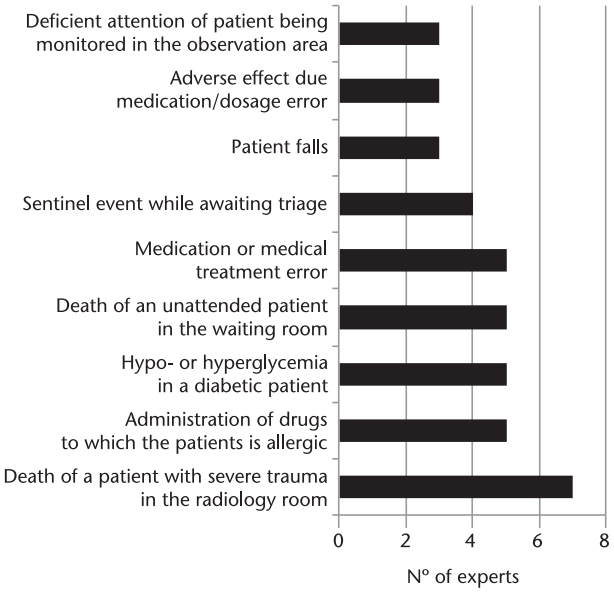

Figure 1. The ten adverse events considered most critical by the experts.

Table 6. Grouping of preventive actions

Preventive actions	Nº (%)
Changes and improvements in the care process	53 (25.60)
Management:	47 (22.70)
Material resources	19
Human resources	16
Structural changes	12
Adequate clinical management	28 (13.52)
Protocols / procedures	27 (13.04)
Training activities	21 (10.14)
Checklist	14 (6.76)
Information/communication between professionals	11 (5.34)
Patient and family member information	6 (2.90)
Total	**207 (100)**

and especially their implementation is what will really help to improve the safety for our patients. This requires maintenance and long-term evaluation of the plan in order to estimate its clinical impact on the incidence of AE in the UGC of our ED, Hospital Emergency Reina Sofía.

The results of similar studies, preferably multicenter initiatives, will allow comparison and information on the consistency of the method and of the tools used in our work.

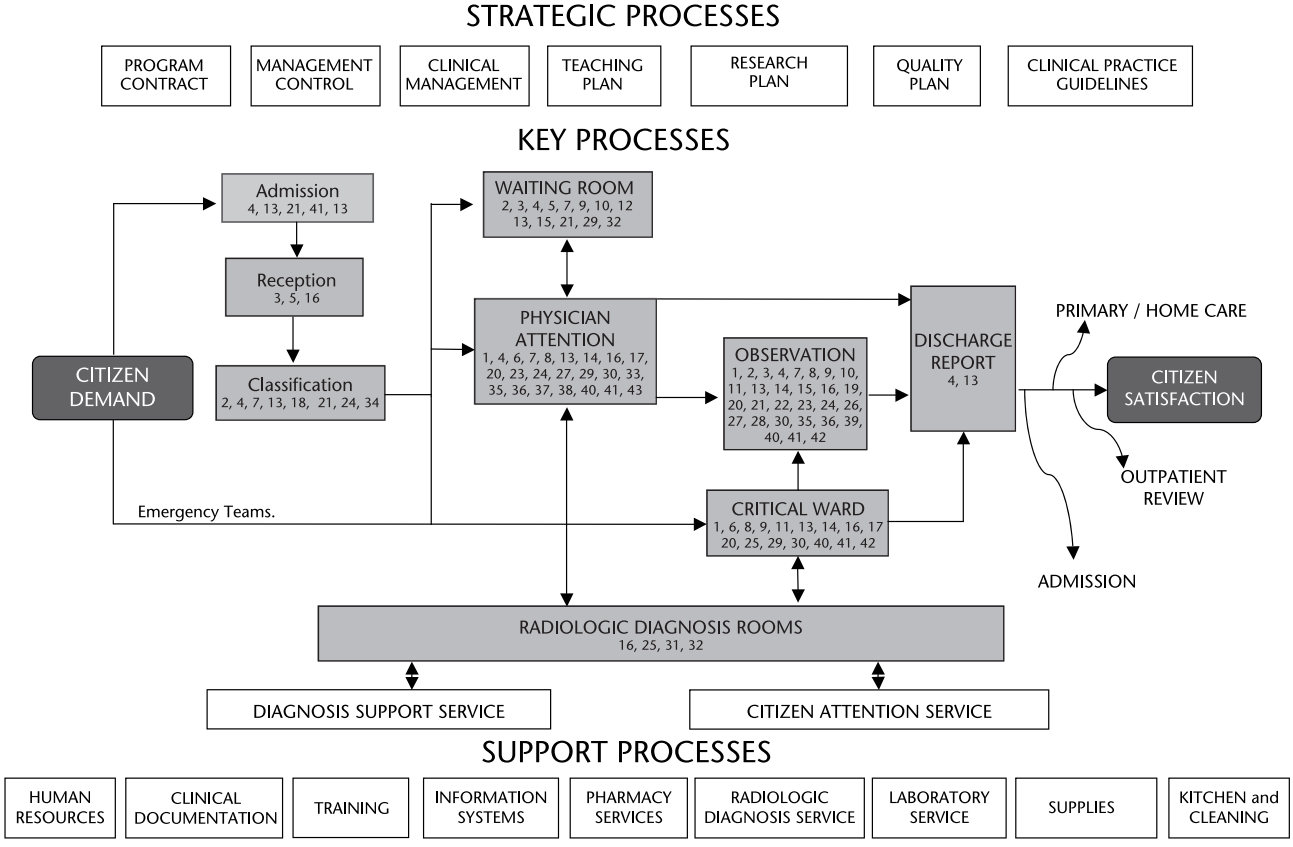

Figure 2. Risk map of the Emergency Department of the Hospital Universitario Reina Sofia, Cordoba. The numbers in the boxes correspond to the codes assigned to adverse events in Table 4.

References

1 Smith CMJ. Origin and Uses of Primum non nocere, Above all, do no harm! Clin Pharmacol. 2005;45:3717.
2 Consejería de Salud de la Junta de Andalucía. Estrategia para la seguridad del paciente. Sevilla: Consejería de Salud. Junta de Andalucía; 2006.
3 Aranaz JM, Aibar C, Vitaller J, Ruiz P. Estudio Nacional sobre los Eventos Adversos ligados a la Hospitalización. ENEAS, 2005. Madrid: Ministerio de Sanidad y Consumo; 2006.
4 Ministerio de Sanidad y Consumo. Estudio APEAS. Estudio sobre la seguridad de los pacientes en atención primaria de la salud. Madrid: Ministerio de Sanidad y Consumo; 2007.
5 Redfern E, Brown R, Vincent CA. Identifying vulnerabilities in communication in the emergency department. Emerg Med J. 2009;26:653-7.
6 Tomás S, Chanovas M, Roquetas F, Alcaraz J, Toranzo T y Grupo de Trabajo EVADUR-SEMES. EVADUR: eventos adversos ligados a la asistencia en los Servicios de urgencias de hospitales españoles. Emergencias. 2010;22:415-28.
7 Palom Izquierdo FJ. "Círculos de calidad. Teoría y práctica". Barcelona: Marcombo Boixareu; 1987.
8 Consejería de Salud de la Junta de Andalucía. Estrategia para la Seguridad del Paciente. Sevilla: Consejería de Salud. Servicio Sanitario Público de Andalucía; 2006.
9 World Health Organization. Marco Conceptual de la Clasificación Internacional para la Seguridad del Paciente. Versión 1.1. Informe Técnico Definitivo. WHO. (Consultado 10 Enero 2009). Disponible en: http://www.who.int/patientsafety/implementation/icps/icps_full_report_es.pdf. Consultado el 15 de Noviembre de 2011.
10 Institute for Healthcare Improvement. Failures Modes and Effects Analysis (FMEA). 2004. (Consultado 2 Noviembre 2011). Disponible en: http://www.ihi.org/knowledge/Knowledge%20Center%20Assets/Tools%20-%20FailureModesandEffectsAnalysisFMEATool_3fd4e6fd-b819-4f14-89ba-fb3563dd4e2d/FailureModesandEffectsAnalysis_IHI.pdf.
11 Orrego Villagran C. Análisis de la seguridad clínica y herramientas de evaluación proactiva. Monografías Emergencias. 2007;3:18-21.
12 Ministerio de Sanidad, Política Social e Igualdad. Estudio IBEAS. Prevalencia de efectos adversos en hospitales de Latinoamérica. Madrid: Ministerio de Sanidad, Política Social e Igualdad; 2010.
13 Redfern E, Brown R, Vincent CA. Improving communication in the emergency department. Emerg Med J. 2009;26:658-61.
14 Gestión de riesgos y mejora de la seguridad del paciente. Tutorial y herramientas de apoyo. Madrid: Ministerio de Sanidad y Consumo, 2007.
15 Tejedor Fernández M, Gálvez Mateos R y grupo de trabajo. Programas de seguridad del paciente en las unidades de tratamiento del dolor. Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, 2011. (Consultado 8 Mayo 2012). Disponible en: http://www.juntadeandalucia.es/salud/servicios/contenidos/nuevaaetsa/up/AETSA_2009-11_Seguridad_Pacientes.pdf.
16 Osborn, AF. Applied imagination: Principles and procedures of creative problem solving (Third Revised Edition). Nueva York: Charles Scribner's Sons; 1963.
17 Ashley L, Armitage G, Neary M, Hollingsworth G. A Practical Guide to Failure Mode and Effects Analysis in Health Care: Making the Most of the Team and Its Meetings. Comm J Qual Patient Saf. 2010;36:351-8.
18 Derosier H, Stalhandskem E, Bagian JP, Nudell T, Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System. The Joint Commission J Qual Improv. 2002;27:248-67.
19 Soluciones iniciales (de la OMS) para la seguridad del paciente. (Consultado 20 Mayo 2012). Disponible en: http://www.who.int/patientsafety/solutions/patientsafety/en/.
20 Bestratén M, Orriols RM, Mata C. Análisis modal de fallos y efectos. AMFE. Instituto Nacional de Seguridad e Higiene en el trabajo. Nota Técnica de Prevención 679. Barcelona. (Consultado 15 Noviembre 2011). Disponible en: http://www.insht.es/InshtWeb/Contenidos/Documentacion/FichasTecnicas/NTP/Ficheros/601a700/ntp_679.pdf.
21 Ott LK, Hoffman LA, Hravnak M. Intrahospital Transport to the Radiology Department: Risk for Adverse Events, Nursing Surveillance, Utilization of a MET, and Practice Implications. J Radiol Nurs. 2011;30:49-54.
22 Hall KK, Schenkel SM, Hirshon JM, Xiao Y, Noskin GA. Incidence and types of non-ideal care events in an emergency department. Quality & Safety in Health Care. 2010;19:i20-i25.
23 Bañeres J. La seguridad en los servicios de urgencias. Emergencias. 2010;22:81-2.
24 Calder LA, Forster A, Nelson M, Leclair J, Perry J, Vaillancourt C, et al. Adverse events among patients registered in high-acuity areas of the emergency department: a prospective cohort study. Canadian J Emer Med Care. 2010;12:421-30.
25 Tomás S. Introducción a la seguridad clínica del paciente. Monografías Emergencias. 2007;3:1-6.
26 Chanovas Borràs M, Campodarve I, Tomás Vecina S. Eventos adversos en los Servicios de urgencias: ¿El servicio de urgencias como sinónimo de inseguridad clínica para el paciente? Monografías Emergencias. 2007;3:7-13.
27 Roqueta F, Tomás S, Chanovas M. Indicadores de seguridad/riesgo en los Servicios de urgencias. Monografías Emergencias. 2007;3:14-7.

Diseño e implantación de un plan de seguridad del paciente en un servicio de urgencias de hospital: ¿cómo hacerlo?

Tejedor Fernández M, Montero-Pérez FJ, Miñarro del Moral R, Gracia García F, Roig García JJ, García Moyano AM

Se describe cómo se ha diseñado un plan de seguridad del paciente en un servicio de urgencias hospitalario de un centro universitario de alta complejidad. El plan contiene una amplia serie de acciones preventivas para minimizar el riesgo de aparición de los eventos adversos identificados. Para ello, se realizó por parte de un grupo de expertos en urgencias la: 1) identificación de los eventos adversos que pueden producirse en el servicio de urgencias hospitalario, así como los fallos y causas que los producen, mediante la técnica de generación de ideas o *brainstorming,* 2) priorización de los eventos adversos y obtención del índice de prioridad de riesgos, mediante el análisis modal de fallos y efectos, 3) propuesta de acciones preventivas, y 4) elaboración de un mapa de riesgos del macroproceso asistencial de urgencias. Se identificaron un total de 43 eventos adversos distintos, 65 tipos de fallos, 86 causas y 207 acciones preventivas. Cada eventos adversos generó entre 1 y 21 acciones preventivas. El 6,97% de los eventos adversos estuvieron relacionados con el diagnóstico, de 13,95% con la medicación, el 46,51% con los cuidados, el 2,32% con infecciones, el 6,97% con la realización de un procedimiento y el 23,26% con otros aspectos. Nuestra experiencia enfatiza la importancia de crear una cultura de seguridad del paciente en un servicio de urgencias hospitalario a través de la implantación de un plan de seguridad que incluya un análisis de los eventos adversos, su priorización y la planificación de acciones preventivas para disminuir su incidencia. [Emergencias 2013;25:218-227]

Palabras clave: Urgencias. Eventos adversos. Seguridad paciente.