Impact and preventability of adverse events in Spanish public hospitals: results of the Spanish National Study of Adverse Events (ENEAS)

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Abstract

Objective. To determine the impact and preventability of adverse events (AEs) associated with health care in Spanish hospitals.

Design. Retrospective cohort study.

Setting. Twenty-four Spanish hospitals.

Participants. Patients of any age with a clinical record indicating an inpatient stay of >24 h and a discharge between 4 and 10 June 2005 (n = 5908).

Intervention. None.

Main Outcome Measures. Percentage of AEs considered preventable.

Results. We were able to identify 525 patients suffering AEs associated directly with medical care, who accumulated 655 AEs with 43% of these AEs considered preventable. Overall, 45% (295 AEs) were considered minor, 39% (255 AEs) moderate and 16% (105 AEs) severe. There were no significant differences in AE severity by hospital size, but AEs associated with surgical services were more likely to be severe than those associated with medical services. Some 31.4% of AEs resulted in a longer stay and 23.4% led to hospital admission. AEs associated with medical care caused 6.1 additional days per patient. Of the patients, 66.3% required additional procedures and 69.9% required additional treatments. Incidence of death in patients with AEs was 4.4% (CI 95%: 2.8–6.5). Age over 65 was associated with a higher incidence of preventable AEs. The highest percentages of preventable AEs were related to diagnosis (84.2%), to nosocomial infections (56.6%) and to care (56%).

Conclusions. In Spanish hospitals, AEs associated with health care cause distress, disability, death, lengthen hospital stay and cause increased consumption of health-care resources. A relatively high percentage of AEs in Spain may be preventable with improvements in medical care.

Keywords: adverse events, medical errors, clinical safety, quality of care, patient safety

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Introduction

Health care has been considered a high-risk activity due to the likelihood of harm to patients as a result of care [1, 2]. Risk has been defined as the probability that an incident will occur, and a patient safety incident as any event or circumstance which could have resulted, or did result, in unnecessary harm to a patient [3]. Harm includes injury, disease, suffering, disability and death [3]. A comprehensive study of patient safety includes incidents [near misses and adverse events (AEs)], errors and system failures as antecedents, and disability and lawsuits (with negligence) as consequences.

The technical model developed in the IDEA (Identification of Adverse Events) Project [4] attempted to discriminate between extrinsic (health care system-based) and intrinsic (patient-based) contributory factors in order to assess causality and determine whether an AE or an illness complication occurred. It was also designed to discriminate between preventable and non-preventable AEs.

An AE is defined as any incident which caused health care-associated harm to a patient and an error is defined as a failure to carry out a planned action as intended or application of an incorrect plan [3]. Medical error may involve commission or omission [5–8]. Risk analysis can be conducted a priori, before any harm is produced, by means of techniques such as failure mode and effects analysis (FMEA) [9, 10] or a posteriori by analysing variables associated with harm.

AEs can be studied individually, by means of techniques such as root cause analysis to determine causal cascades and latent failures, or collectively, by means of epidemiological studies to characterize consequences and identify contributing factors. Root cause analysis has been recommended by the Joint Commission on Accreditation of Healthcare Organisations in all the cases where a serious AE or key incident has occurred [11]. Epidemiological studies have, on the other hand, been recommended by the WHO World Alliance for Patient Safety [12] and by the Quality Office of the Spanish National Health System [13].

Epidemiology has contributed to the understanding of risks and hazards in health care [14]. Patient safety epidemiological studies, to date, have involved review of medical records and have been done from a medico-legal perspective, by looking for negligence, as in studies from the USA, or from a quality improvement perspective, looking for preventability, to inform national policies to improve the safety of health systems. Epidemiological studies conducted in the USA [15–17], Australia [18], Great Britain [19], Denmark [20], New Zealand [21], Canada [22, 23], France [24] and Spain [25] have estimated AE rates of between 4% and 17% and have judged ~50% to be preventable [26].

These studies have variously estimated the frequency of all AEs, the fraction judged preventable (most non-US studies), the proportion of AEs associated with temporary or permanent disability (most studies), the extent of prolongation of hospital stay (most studies), the fraction judged to be due to negligence (US studies) and associated costs [27, 28]. Questions have been raised about the extent to which the various outcomes, including death, can legitimately be attributed to AEs, given the inherent limitations of the methods used [29–33].

At the end, the goal is to develop strategies to control AEs. In prioritizing these strategies, the frequency of the AEs, their potential impact on the patient or the organization, and the ability of health-care system to prevent AEs should all be taken into account. These three dimensions of AEs (their frequency, severity and impact, and preventability) are the keys to guiding organizations in the design of the most efficient strategies for the improvement of patient safety.

The aim of this study was to identify AEs, to estimate the fraction of AEs considered preventable, and to determine their impact in terms of disability, death and/or prolongation of stay in Spanish public hospitals.

Methods

This retrospective cohort study involved a two-stage sampling approach. The required sample size was estimated at 6500 discharges with a precision of 1.32 and a design effect of 2. We stratified by hospital size and then selected hospitals at random until reaching the target sample size, using a count of all discharges between the 7th and 13th of May 2005 to establish the sampling algorithm. To generate the study sample, the number of discharges needed in each stratum was proportional to the number of discharges in the base population that week. Patients of all ages were included if they stayed >24 h in one of the selected hospitals and had a clinical record suggesting they had been discharged between the 4th and the 10th of June 2005 (inclusive). On the basis of these criteria, the sample comprised 24 hospitals: 6 small hospitals (fewer than 200 beds) with 451 discharges, 13 medium-sized (between 200 and 499 beds) with 2885 discharges and 5 large (500 or more beds) with 2288 discharges.

An AE was defined as any health care-associated incident which caused harm, with a causation score of at least 4. Causation was scored by reviewers using a 6-point scale, with 1 being no or minimal evidence and 6 practically certain evidence of health care-related contributory factors causing the harm. A score of ≥4 was considered positive. The same method was used to assess preventability score.

We studied variables linked to health care (hospital service, stay in days and extrinsic risk factors); those linked to the main diagnosis or procedure and American Society of Anaesthesiology (ASA) score [34]; those linked to the patient (intrinsic factors) and those linked to AE impact (where the hospital stay was caused by the AEs, additional procedures and treatments as a consequence of AEs, disability or death). An AE was defined as severe when it was related to patient death or required surgery (due to the risk involved) and as moderate if it caused re-admission or prolonged hospital stay.

Data were collected by means of the screening guide of the IDEA project [4], a questionnaire elaborated using
consensus techniques based on a previous investigation. This project provided a list of criteria similar to the one used in the New York, Utah and Colorado studies and this was used to identify records with a potential for AEs. Clinical records that fulfilled at least 1 of the 19 criteria of the screening guide were reviewed in detail to further characterize the AEs by completing the modular revision form (MRF2) [35]. Nursing staff or physicians at each hospital examined all selected clinical records. After screening, criteria-positive records went forward for second-stage review and an MRF2 (Spanish version) was completed; a physician was used for medical and a surgeon was used for surgical cases. The uncertain cases were re-analysed by the executive committee.

The initial study sample consisted of 5908 discharges from 24 hospitals. On conducting the screening guide, hospital staff found that 103 clinical records were missing. When the external reviewers prepared to complete the MRF2, they found that the clinical information from 181 cases could not be retrieved and therefore the total number of patients studied was 5624.

We calculated the percentage of preventable AEs per hospital size and service type. A univariate analysis was conducted to describe the sample. A bivariate analysis was performed to state the relationships among the variables (using the $\chi^2$ to compare ratios) and an stepwise logistic regression model using likelihood ratio test to control the confusion and/or the interaction among them. The hypothesis contrasts were bilateral with a 0.05 significance level except for the logistic regression model in which we used a $P$-value $<0.05$ for inclusion and $<0.10$ for exclusion. The dependent variable was preventable (1) or non-preventable (0). The statistical analysis was conducted using the statistical programme SPSS version 12.0.

**Results**

On screening the study sample of 5624 patients, 1755 (32%) were identified as potentially having AEs. Among those with potential AEs, reviewers detected 1063 patients with harm during hospitalization period. Among these 1063 patients, 525 patients had AEs associated directly with medical care and these patients experienced 655 AEs based on a causation score $\geq 4$. Among the 525 patients with AEs, 17.7% suffered more than one AE. Of these 525 patients, 473 suffered an AE related to hospital care with 105 of these cases (22.2%) associated with a hospital re-admission. Forty-six patients out of 52 with AEs occurring in a non-hospital service were admitted to hospital because of the AEs. Of the 151 patients (105 + 46) whose AE was related to hospital admission, 47% were admitted to a large hospital, 41% to a medium-sized one and 11.3% to a small one. In addition, 51.7% of these patients were admitted to a medical service and 48.3% to a surgical service. Nevertheless, the percentage of AEs associated with re-admissions did not differ substantially by hospital size or service type (Table 1).

Out of 5624 patients, 112 patients had died (102 of these patients were identified at the screening stage and 10 patients were identified based on another screening criterion. Among these 112 patients (2% of total patients), 23 reported AEs (20.5% of patients who died or 0.41% of all of the study patients). Thus, incidence of death in patients with AEs was 4.4% (CI 95% 2.8–6.5). In 15 cases (13.4% of patients who died and 0.2% of total of patients), there was an association between the AEs and the death, with seven AEs considered to be a direct cause of death. Among the seven AEs that were a direct cause of death, only one was considered preventable. Among the 8 AEs related to patient death, half were considered preventable.

Of these 655 AEs, 45% (295) were considered minor, 39% (255) moderate and 16% (105) severe. Although differences in the distribution of the severity of the AEs per hospital size were found (Fig. 1), they did not reach statistical significance ($P = 0.125$). Among patients admitted to medical services, 50% of AEs were minor, 42.9% moderate and 7.1% severe, whereas among patients admitted to surgical services, 40.5% were minor, 35.3% moderate and 24.2% severe. These differences were statistically significant ($P < 0.001$).

Severity of AEs was not associated with ASA score of patients ($P = 0.170$), although severe AEs were less frequent among patients with higher ASA scores. Severity of AEs was associated with the prognosis for the primary diagnosis and this reached statistical significance ($P = 0.012$). In cases expecting recovery with residual disability, percentage of severe AEs was higher. The pattern was similar in those

### Table 1 AEs and percentage resulting in re-admission

<table>
<thead>
<tr>
<th>AEs</th>
<th>% resulting in re-admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital size</td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>319</td>
</tr>
<tr>
<td>Medium</td>
<td>265</td>
</tr>
<tr>
<td>Small</td>
<td>71</td>
</tr>
<tr>
<td>Services</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>312</td>
</tr>
<tr>
<td>Surgical</td>
<td>343</td>
</tr>
<tr>
<td>Total</td>
<td>655</td>
</tr>
</tbody>
</table>

**Figure 1** Impact (severity) of AEs according to hospital size.
cases with a total recovery to the basal state of health prog-
nosis and in patients with terminal disease.

Among AEs, 31.4% resulted in a longer stay and 23.4% led to hospital admission (some patients re-admitted due to an AE had more than one AE). AEs leading to longer stay added a median of 4 hospital days whereas AEs leading to re-admission added a median of 7 hospital days. Consequently, an estimated 3200 additional days were attributable to AEs associated with medical care (6.1 additional stays per patient) and 1157 of these were due to preventable AEs (2.2 additional days per patient). Among the AEs, 66.3% required additional procedures (e.g. radiologic procedures) and 69.9% required additional treatments (e.g. medication, rehabilitation or surgery).

Some 42.6% (278/655) of AEs were considered preventable (rated as having at least moderate evidence of preventabil-
ity and hospital size. AEs detected in small hospitals were more often preventable (64.8%) than those detected in large and medium-sized hospitals (40.1% and 39.8%, respectively) ($P < 0.0001$). Preventability of AEs was not associated with severity: 43.8% of minor, 42.0% of moderate and 41.9% of severe AEs were preventable. Among AEs, the percentage judged preventable varied by type with 84.2% of those associated with diagnosis judged preventable, whereas 55.4% of those associated with nosocomial infections and 52.0% of those associated with medical care were judged preventable (Table 2). The overall preventability did not differ significantly according to service type, although AEs related to nosocomial infections were more frequently preventable for medical services, whereas those associated with diagnosis were more frequently preventable for surgical services.

Multivariable analysis showed that the presence of intrinsic risk factors, hospital size and the nature of the AEs were associated with preventability. AEs in small hospitals were 2.5 times more likely to be judged preventable than AEs in large hospi-
tals. Using AEs related to the use of medication as the reference category, those associated with diagnosis were 11.4 times more preventable, those associated with nosocomial infection 2.5 times, and those associated with care 2.3 times (Table 3).

### Table 2 Characteristics of AEs and their preventability

<table>
<thead>
<tr>
<th>Nature</th>
<th>Medical ($n = 312$)</th>
<th>Surgical ($n = 343$)</th>
<th>ALL ($n = 655$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per cent of AEs</td>
<td>Per cent preventable</td>
<td>Per cent of AEs</td>
</tr>
<tr>
<td>Associated with a procedure</td>
<td>11.2</td>
<td>34.3</td>
<td>37.6</td>
</tr>
<tr>
<td>Associated with nosocomial infection</td>
<td>21.2</td>
<td>60.6</td>
<td>29.2</td>
</tr>
<tr>
<td>Associated with medication use</td>
<td>53.8</td>
<td>36.3</td>
<td>22.1</td>
</tr>
<tr>
<td>Associated with care</td>
<td>8.7</td>
<td>55.6</td>
<td>6.7</td>
</tr>
<tr>
<td>Associated with diagnosis</td>
<td>2.9</td>
<td>77.8</td>
<td>2.9</td>
</tr>
<tr>
<td>Other</td>
<td>2.2</td>
<td>33.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>44.1</td>
<td>100</td>
</tr>
</tbody>
</table>

### Discussion

The Spanish National Study of Adverse Events (ENEAS) is one of a group of studies whose objective is to improve health-care quality by examining patient safety. To identify the maximum number of improvement opportunities, the methodology allows that a patient could suffer several AEs during hospitalization, including AEs that occurred in the pre-hospitalization period and those detected during the hospital stay as well as those suffered in a previous admission and that were associated with re-admission. Results about contributory factors (patient and health care related), nature (type) and care process associated with AEs and the severity of AEs have been published elsewhere [36, 22]. The severity of the AEs in this study is congruent with that stated in other studies. A total of 16% of AEs were considered severe. No differences in pattern are found either by hospital size, although differences have been found by type of unit with a higher proportion of severe AEs found in surgical units.

Until recently, the health-related, social and economic impact of AEs has been a silent epidemic in Spain. Our results suggest that the impact of AEs appears to be associated with the complexity of health-care services and the vulnerability of patients. In our study, nearly two-thirds of the AEs were considered moderate or serious and nearly one-third resulted in a longer hospital stay. The estimated 4.4% incidence of death among subjects having AEs was not trivial.

Until recently, the impact of AEs had not been studied in Europe with the exception of a recent study of serious AEs in France. In some countries like the USA, Australia, Canada and New Zealand, the impact of the AEs has been studied from a population perspective. Data on the frequency and preventability of AEs have otherwise not been available previously in Spain. Although AEs have been studied from the legal perspective in Europe, ours is among the first studies in Europe to study AEs for the purpose the improvement of the quality and among the first to identify predictive factors for AE preventability.

Hospital size was associated with preventability of AEs, but not with the severity of AEs. However, the severity of AEs was associated with service type with a higher...
The incidence of ‘death’ among hospitalized patients who experienced AEs in six major published studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Incidence rate (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvard Medical Practice Study</td>
<td>13.6</td>
<td>11.6–15.7</td>
</tr>
<tr>
<td>Utah and Colorado</td>
<td>6.6</td>
<td>4.4–6.4</td>
</tr>
<tr>
<td>Quality in Australian Healthcare Study</td>
<td>4.9</td>
<td>4.1–5.8</td>
</tr>
<tr>
<td>London</td>
<td>8.0</td>
<td>3.5–13.9</td>
</tr>
<tr>
<td>Denmark</td>
<td>6.1</td>
<td>2.3–12.7</td>
</tr>
<tr>
<td>ENEAS</td>
<td>4.4</td>
<td>2.8–6.5</td>
</tr>
</tbody>
</table>

*aSee reference list.

The proportion of severe AEs on surgical services, probably because surgery involves added intrinsic risk. Table 4 shows that in ENEAS, mortality in patients with AEs (4.4%) was lower than that found in other studies (range 4.4–13.6%). According to the ‘Instituto Nacional de Estadística’ (Spanish National Institute of Statistics), the mortality rate in Spain is 8.71/1000 inhabitants per year and the mortality rate in hospital is 3.8% among all hospital discharges. The comparison of mortality rates based on hospital discharges is challenging because a patient can be admitted to the same hospital several times (re-admission rate has been approximately estimated at 20%) making this statistic an underestimate of the patient mortality rate in hospitals. Preventability in our study is within the contributed values from literature (range 27.4–51.2%) [37]. We have not found an association between preventability and severity of AEs. This result fits in with the findings of the Canadian study that states that preventability is independent of severity [23].

Not surprisingly, as the number of both intrinsic and extrinsic risk factors increases, the probability of AEs increases as well. This fact suggests that a strategy that adapts practice to high-risk patients and avoids subjecting them to additional risks. Knowing that nosocomial infection is among the most avoidable types of AEs, hospitals could develop strategies, like hand hygiene, and the implementation of clinical guides and protocols, to avoid the occurrence of such infections.

Our study had limitations. Because AEs were identified by means of the information from the clinical record, poor quality of these clinical records could lead us to underestimate the incidence of AEs. With regard to the quality of the notes in the clinical record, the reviewers considered that the information on the AEs in the record was inadequate or not very adequate in 19% of the cases. On the other hand, the degree of agreement among the reviewers and the consensus when identifying AEs, incidents and their preventability was studied by means of the kappa agreement measurement. The

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**Appendix**

**ENEAS work group**

The study was approved by the Ethics and Clinical Research Committee of Aragón.

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Confidentiality and ethical aspects

This study was conducted following the recommendations of the WHO (World Health Organization) and the Cohesion Law of the SNS [38] (Spanish National Health System). The necessary conditions to guarantee the enforcement of the Organic Law 15/1999 of Personal Data Protection were established. The initial data collection was nominal but the individual identification was exclusively maintained until the quality controls of the database were passed. From this point on, a database under the exclusive control of the director of the study allowed a link between the data and the patients. All the participants in this study were obliged to maintain the confidentiality of the information they had access to during the study, as well as in any other professional activity. The data were presented in such a way that no patient could be identified from the diffusion of the results.

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