– PATIENT SAFETY

Plan de Calidad para el Sistema Nacional de Salud

National Study on Hospitalisation-Related Adverse Events. ENEAS 2005.

Report. February 2006

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Quality Plan
for the National Health
System

This study has been conducted through an arrangement between the Miguel Hernández University and the Ministry of Health and Consumer Affairs.

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CONTENTS

SUMMARY

Main objectives:

- Determine the incidence rate of Adverse Events (AE's) and patients with AE's at the hospitals throughout Spain.
- Determine the percentage of AE's which occur during the prehospitalisation period.
- Describe the immediate causes of AE's.
- Define the preventable AE's.
- Ascertain what impact AE's have in terms of disability, *death* and/or extended hospital stays.

Design:

Retrospective cohort study.

Study Scope:

Sample of 24 hospitals: 6 small-sized (under 200 beds), 13 medium-sized (200-499 beds) and 5 large-sized (500 beds or more). 451 discharges in small-sized hospitals, 2,885 discharges in medium-sized hospitals and 2,288 discharges in large-sized hospitals, for a total of 5,624 case records.

Study Subjects:

Hospitalised patients, under hospitalisation for more than 24 hours at the selected hospitals who have a case record at said hospitals and who have been discharged within the June 4-10, 2005 period (all inclusive).

Instrumentalisation:

For the identification of possible AE's, the Screening Guide from the Adverse event Identification Project (IDEA), a questionnaire prepared based on prior research of a list of conditions similar to that of the New York, Utah and Colorado studies were used under consensus techniques. The case records having met at least one of the 19 criteria set out in the Screening Guide were then reviewed in detail for a precise typing of the AE using the Modular Review form (MRF2).

Determinations:

Nursing and medical professionals from each hospital reviewed all case records selected in search of any of the conditions alerting AE's. Subsequently, teams comprised of a staff physician from the medical area and another from the surgical area, trained for this purpose, visited the hospitals to confirm the AE by means of a detailed review of the episode in question in the case record (external evaluations).

Work Schedule:

The initial review of the case records by the nursing professionals was conducted during the first two weeks of June.

The review by the external evaluators was conducted throughout July 2005.

MAIN FINDINGS

A total of 1,755 (32%) of the 5,624 patients were screened as possible AE's, 3,869 of whom were ruled out due to their not meeting the requirements of any of the screening guide alerts. On reviewing the patients screened as positive, 501 false positives and 191 patients showing solely incidents were found.

The positive predicting value (positive alerts which were confirmed as AE's or incidents) of the screening guide for detecting some type of adverse event (accident and/or incident) was 71.5% (95% CI: 69.3% - 73.6%), considering all types of AE's, that is to say, also those unpreventable and/or due to the disease.

A total of 1,063 patients with AE's during hospitalisation were detected, the incidence of patients with healthcare-related AS's being 9.3% (525/5,624); 95% CI: 8.6% - 10.1%. The incidence of patients with AE's related directly to hospital care (excluding those from primary care, out-patient treatment and those caused at another hospital) was 8.4% (473/5,624); 95% CI: 7.7% - 9.1%.

A total of 17.7% of the patients with AE's had more than one AE. Among a total of 105 (22.2%) of the 473 patients with hospitalisation-related AE's, the AE was the cause of the hospital admission (re-admission).

The patients having intrinsic risk factors had 1.6 times more probabilities of having AE's.

Those over age 65 with extrinsic risk factors had 2.5 times greater risk than those under age 65 without these factors.

There was a total of 655 AE's, 45% (295 AE's) of which were considered minor, 39% (255 AE's) moderate and 16% (105 AE's) severe. The degree of severity of the AE's was not related to the ASA (American Society of Anaesthesiologists) patient risk (p=0.170), but the more severe the patients' condition, the less often were major AE's found to exist. However, the degree of severity of the AE's is related to the prognosis of the primary illness according to the probability of the patient recovering their baseline condition (p=0.012).

The incidence density as 1.4 AE's/100 days hospital stay/patient (95% CI: 1.3-1.5). The incidence density of moderate or major AE's was 7.3 AE's for every 1000 days of hospital stay (95% CI: 6.5 - 8.1).

A total of 37.4% of the AE's were related to the medication, nosocomial infections of any type totalling 25.3% of all AE's, a total of 25.5% being related to technical problems during a procedure.

A total of 31.4% of the AE's resulted in a extended hospital stay, the AE having conditioned admission in 24.4% (some patients re-admitted due to AE had more than one AE) the entire hospital stay having therefore been due thereto. This load entailed an average 4-day stay for those AE's having extended the hospital stay and an average 7-day stay for those having led to a re-admission. Thus, a total of 3,200 additional stays (6.1 additional stays/patient) were caused by healthcare-related AE's, 1,157 of which entailed avoidable AE's (2.2 additional avoidable stays/patient).

A total of 66.3% of all AE's required performing additional procedures (ex. Radiodiagnosis testing), 69.9% having required additional treatments (ex. Medication, rehabilitation or surgery).

A total of 42.8% of the AE's were considered to be preventable in terms of the pre-established criteria. The degree of severity of the AE's was also related to their preventability, a total of 43.8% of the minor AE's, 42.0% of the moderate AE's and 41.9% of the major AE's having been preventable, although these differences were not statistically significant (p=0.889).

OBJECTIVES

1. Overall Objectives

Determine AE incidence at Spanish hospitals.

1. Determine the percentage of AE's which occur in the prehospitalisation period.
2. Identify and describe the immediate causes of the AE's.
3. Evaluate the preventability of these AE's.
4. Estimate the impact AE's have in terms of disability, *death* and/or extending hospital stays.

2. Specific Objectives

1. Assess the incidence of adverse events, unforeseeable accidents leading to injury, patient disability or extended stays resulting from the care provided as stated in the case records at Spanish hospitals.
2. Quantify the percentage of adverse events, unforeseeable accidents leading to injury, patient disability or extended hospital stay resulting from the care provided which occur within the period prior to hospitalisation at Spanish hospitals as sated in the patients case records.
3. Describe the immediate causes of AE's by means of reviewing the case records.
4. Evaluate the preventability of the AE's by means of the expert judgement of the evaluators.
5. Estimate the impact AE's have in terms of disability, death and/or extending hospital stays according to the clinical evaluator's criteria.

WARRANTING

Clinical safety is an essential aspect of healthcare quality, bearing in mind the complexity of both clinical practice and the organisation thereof. Safe clinical practice requires achieving three major objectives: 1) Identifying which clinical diagnostic and treatment procedures are the safest and most effective 2) Ensuring that they are applied to those who need them and 3) Performing them correctly without mistakes.[1]

The measurement of the risk related to hospital care is a matter of maximum importance to the health system, both in its healthcare and its economic, legal, social and even media-related dimension. In the healthcare and public health field, the term "risk" entails some particularly unique aspects, conventionally linked to the study of the cause-effect relationship[2] and the probability of events related to health or its loss thereof occurring, such as death, disease, worsening, accident, full recovery, improvement, etc.[3]

Interest in healthcare-related risks, although a matter of great current importance, is not something new. Unwanted effects of medications, nosocomial infections, complications involved in clinical treatments and diagnosis and treatment mistakes are part of the healthcare professionals concerns[4]. In 1955, Barr[5] saw them as being the price to be paid because of the modern diagnosis and therapy methods, and in 1956, Moser[6] termed them as being "Diseases of Medical Progress".

In 1964, Schimmel [7,8] called attention to the fact that 20% of the patients admitted to a university hospital experiences some iatrogeny, and that one fifth were severe cases. In 1981, Steel et al[9] established the figure as being 36%, one fourth of which were severe, being the main cause in both studies the error in medication.

The Adverse events (AE) rate at hospitals has been estimated at 4%-17%, around fifty percent of which have been considered preventable[10]. These studies have been conducted in the U.S. [11, 12, 13] , Australia[14], United Kingdom[15], Denmark[16], New Zealand[17] and Canada[18, 19] . All of these studies shared the working definition of an AE as the unintentional harm caused by a medical act more than by the nosological process per se. All of these were retrospective cohort studies with a similar methodology by means of the review of case records, at first by nursing personnel, who detected possible alerts in patients who might have had an AE. Subsequently, in a second stage, those patients who had been detected by the Screening Guide were reassessed by physicians in order to assess whether or not an AE was actually involved[13].

The reference study was that which was conducted in New York in 1984, known as the Harvard Medical Practice (HMPS)[11] study, which estimated a 3.7% AE incidence in the 30,121 patient case records. Among seventy percent (70%) of these patients, the adverse event led to minor or temporary disabilities, the disabilities having been permanent in 3% of the cases and having contributed to the patient's death in 14% of the cases. The reason for this review was to determine the degree of negligence entailed in these AE's occurring and not to gauge the possibility of the prevention thereof. Reactions to medications comprised the most frequent AE (19%), followed by surgical wound nosocomial infections (14%) and technical complications (13%). The specialties showing the greatest number of adverse events were the surgical specialties, particularly Vascular Surgery (16.1%), whilst the medical specialties were those showing the lowest frequency (3.6%). The patients over 65 years of age had more double adverse events than patients under age 65, and most of the cases of negligence were due to diagnostic problems and therapeutic errors.

In 1992, employing similar methods to those in Harvard Medical Practice Study, a study in the states of Utah and Colorado(13) found an annual 2.9% incidence of adverse events among the 15,000 records reviewed. Just as in the Harvard study, information is provided on solely one AE per patient and, in the case in which a patient has more than one AE, solely that which caused greater disability to the patient was taken into account. Additionally, as in the previous study, preventable AE's are not measured, and the review was made from a medical-legal standpoint (not for the purpose of attempting to prevent the AE as such, but rather to ascertain the frequency thereof).

The adverse event rate in both of these studies contrasts with those found in other studies employing a similar methodology (retrospective cohort study based on the review of medical records) although based on different motivations: to infer federal policies for improving the safety of the country's healthcare through a knowledge of the errors and the degree of severity and importance thereof. Hence, in the Quality Australian Health-care Study (QAHCS), a study conducted at 28 hospitals in southern Australian and New South Wales, a 16.6% AE rate was found, 51% of which were preventable. The specialties in which the greatest

number of AE's occurred were: general surgery (13.8%), orthopaedic surgery (12.4%) and internal medicine (6.5%). The highly preventable events were related to those entailing a greater degree of disability.

The reasons which might stand to explain the differences found in the rates between the New York and Australian studies could be as follows: a) different AE definition. In the HMPS, the AE was considered only once (whether discovered prior to or during the hospitalisation under study) while in the QAHCS the AE was included as many times as the admissions to which it gave rise. B) The reasons for the studies differed. C) Both of these studies were conducted based on the information stated in the medical records (retrospective studies) however having been conducted in very different time periods.

In the study conducted by Vincent et al[15] at two London hospitals, a 10.8% AE incidence rate was found among 1,014 patients hospitalised within the 1999-2000 period, 48% of which were preventable. The specialty found to have the most AE's was General Surgery, with 16.2% of patients having AE's.

In the 1995 study conducted in New Zealand by Davis et al.[17] and in the Baker et al.[18] study in Canada in 2000, 12.9% and 7.5% AE rates were respectively found, being the Surgery Unit the one responsible for giving rise to the highest percentage of AE's.

The study which have shown the highest rates is the Healey[20] study, conducted in Vermont in 2000-2001 on 4,743 patients followed prospectively, finding 31.5% AE's (48.6% preventable). They justify such high figures findings (4-6 times higher) due to the fact of exclusively surgery patients having been studied as a result of employing a broader definition of what was considered to be complications (having included minor complications), and because, in addition to the patient complications rate, the total complication rate was analysed, and lastly because the study was integrated within the hospital policy, which provided a continued improvement culture, facilitating carrying out suggestions for quality improvement and providing a forum for continued medical training which would ensure optimum healthcare quality.

A pilot study was conducted in France in 2002, co-ordinated by the "Comité de Coordination de l'Evaluation Clinique et de la Qualité in Aquitaine[21] (CCECQA)" for setting the bases of the national ENEIS study under way currently, headed by the "Comité de Coordination de l'Evaluation Clinique et de la Qualité in Aquitaine", commissioned by the *Ministère des Affaires Sociales, du Travail et de la Solidarité*, by the *Ministère de la Famile et des Persones Handicapéés* and by the *Direction de la Recherche, des Études, de l'Evaluation et des Statistiques* (DREES)[22] .

In Spain, a multi-center study [23,24] - IDEA (Identification of Adverse events) Project - financed by the Spanish Healthcare Research Fund (HRF) is currently under way and it was useful as a pilot study for this national study, on having adapted the materials, databases, etc. thereof.

All studies have estimated the incidence of AE's, the percentage of preventable AE's, evaluating the impact in terms of the patients' disability or death and/or extending of the hospital stay. Some have analysed the percentage of AE's linked to medical negligence and others even to the cost. In some case, the relationship between AE's and *death* has been estimated, although not too well-founded, given that information stemmed from methodological designs not highly well-suited to analysing this type of relationship.

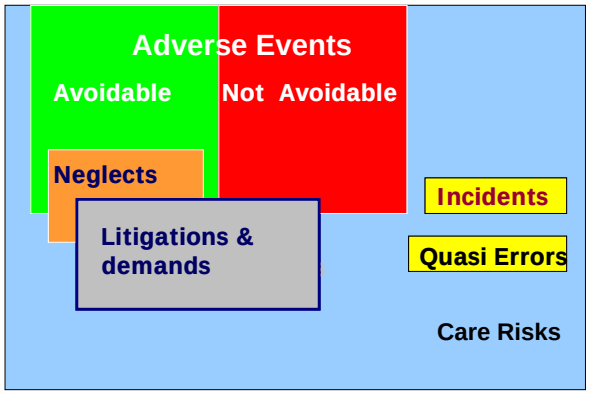
The limitations of the studies are considerable, starting from the lack of consensus with regard to the taxonomy of the AE's, which have made it necessary to set out *ad hoc* working definitions[25, 26, 27, 28, 29], being difficult to compare results. The degree of severity of the AE's requires value judgements in absence of appropriate tools to make an objective assessment, the same reason with regard to the preventability thereof, and, lastly, all of these studies have provided an insufficient analysis of causes.

These studies have conditioned a joint professional awareness, have stimulated a study thereof and even the getting under way of programs with the ultimate objective of reducing the risk in order to ensure patient safety within the healthcare system.

Theoretical model:
The technical model of the ENEAS Study takes that developed in the IDEA (Identification of Adverse events) Project as its point of reference, attempt to be explanatory, reveal the thin line which separates preventable adverse events from those not preventable, such that it is difficult to distinguish between those AE's linked to the healthcare of those who are conditioned by the characteristics of comorbidity and/or intrinsic patient risk factors[30, 31]. On the other hand, in the course of healthcare, incidents and near-incidents which have no

consequences in themselves occur but, as precursors of the accidents, are essential to be studied. Additionally, from a medical-legal standpoint, this model includes the cases of negligence, which, by definition, are always preventable, although they not always result in harm to the patient. Lastly, consideration must be given to the *lawsuits*[32] which may arise both when the adverse event is preventable and when it is not, independently of whether or not harm[33] has been caused (Fig. 1).

Fig. 1 Theoretical model diagram



To select the most appropriate epidemiological model for studying AE's is not a trivial matter. Different studies have analysed this item, and their conclusions could be summarised by saying that the method must be selected in terms of the study objectives by attempting to combine both the minimisation of biases and the validity of the identification of AE's with the reproducibility of the value judgement on the iatrogenic nature thereof and/or the preventability thereof[34, 36, 36,37].

As our objective was to make a situation diagnostic for Spain, we opted for a retrospective cohort study - related to the analysis of the complete hospitalisation of the subjects discharged within a one-week period- on a representative sample of the patients hospitalised in Spain, taking into account the size of the hospitals, in order to estimate the incidence rate and impact of the AE's and the preventability thereof.

With the epidemiology knowledge of adverse events we could afford to develop prevention strategies to prevent them or, wherever applicable, to minimise their consequences if it has not been possible to prevent them[38] .

It is necessary to get mechanisms under way to identify human errors and system faults from two different aspects: Firstly from the policy standpoint by developing policies which will have a bearing on the preventive and not punitive nature of the identification of adverse events and risk management and, secondly, at the local hospital level, by means of carrying out suitable risk management and technology implementation programs which will make it possible to detect these problems before they have any consequences[39] .

MATERIALS AND METHODS

Design:
Retrospective cohort study.

Study scope:
Patients discharged from hospital during the week of June 4-10, all inclusive, on a sample of 24 hospitals, 6 small-sized (under 200 beds), 13 medium-sized (200-499 beds) and 5 large-sized (500 beds or more). A list of the hospitals which took part in the study and the number of beds of each one thereof is provided in Table 1. A total of 740 discharges at small-sized hospitals, 2,018 discharges at medium-sized hospitals and 3,742 discharges at large-sized hospitals were estimated, therefore totalling 6,500 case records.

Follow-up period:
The study have comprised the patients discharged during the second week of June 2005
A follow-up was made of all the days of hospital stay of the hospitalisation process caused by each one of the patients, from their admission up to their discharge, to identify the adverse events which occurred during this hospitalisation period or those resulting from a previous hospitalisation at the same hospital, or resulting from the healthcare provided thereto prior to the prehospitalisation period related to the admission in question.

Table 1. Participating hospitals and Number of beds

Hospital	Beds
H.U. Miguel Servet	1309
C.A. Salamanca	918
H.U. San Cecilio	655
H.U. Getafe	640
H. Navarra	501
H. Del Mar	424
H. Do Meixoeiro	418
H. De l'Hospitalet	385
C.H. La Mancha Centro	368
H.U. Sant Joan d'Alacant	361
H. San Agustín Avilés	350
H. Vega Baja	330
H. Don Benito	282
H. Ntra. Sra. Del Prado	268
H. San Agustín Linares	264
H. Verge de la Cinta	237
H. Infanta Margarita	236
H. Rafael Méndez	230
H. Hellín	126
H. Ernest Lluch	122
H.C. Mora d'Ebre	120
H. San Eloy	118
H. Fundación Calahorra	83
H. Malva Rosa	50

Case definition:
In view of the non-existence of any universally-accepted AE taxonomy, the term "case" is defined for this study as any accident or incident included in the Case record which has caused harm to the patient or might have caused harm thereto, linked to the conditions of the healthcare provided and not to the patient's baseline illness.

The accident may give rise to a longer hospital stay,sequela at time of discharge from the hospital, death or any combination thereof. An "incident" does not cause any injury or harm, but may facilitate them.

Adverse event: Any unforeseen or unexpected accident included in the case record which has caused an injury and/or disability and/or extended hospital stay and/or *death*, which stems from the healthcare and not the patient's baseline illness.

To determine that an AE is due to the healthcare provided, the reviewers used a six-point scale (1= no evidence or slight evidence; 6 = practically certain evidence) to scoring the certainty they had the AE might have been due to the healthcare and not to the pathological process. A score of $\geq$ 4 was required to be considered positive.

Preventable Adverse event:
To determine the adverse event was preventable, the reviewers used a six-point scale (1= no evidence or minimal evidence; 6= practically certain evidence), for scoring the confidence they had the AE was preventable. A score of $\geq$ was required to be considered positive.

Incident: An event which could have caused harm or complication in some circumstances or which may favour the onset of an adverse event.

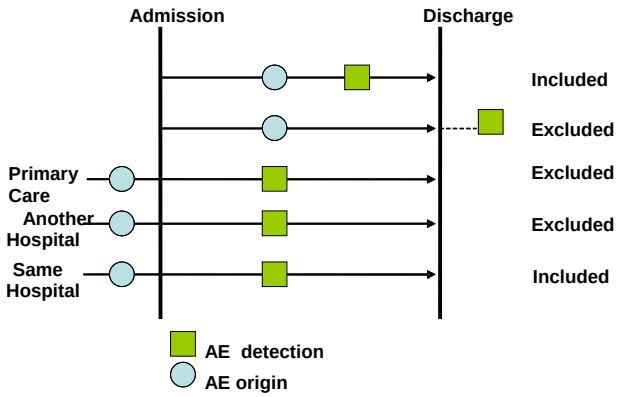
Criteria for inclusion in the study:
Patients admitted to the hospitals selected, whose stay were longer than 24 hours, who had a case record at the same and who had been discharged during the second week of June 2005.

Criteria for exclusion:
Patient hospitalised for less than 24 hours or in emergency and observation areas or short-stay units. Patient whose hospitalisation episode under study was not available in the case record. Patient whose case record was not available.

For healthy new-borns, only the mother's hospitalisation episode was studied.

Those AE's detected during the hospitalisation and those which were a result of episodes of prior hospitalisation at the same hospital were included. Those adverse events which occurred in Primary Care and Outpatient Clinics and were detected in the hospitalisation and those which occurred during hospitalisation and were detected following discharge were excluded in the calculation of the incidence of hospitalisation-related adverse events. Those which occurred during a prior hospitalisation in a different hospital have not been included in the study (Fig. 2). However, all thereof were taken into account, some for the incidence calculation and others for the percentage of adverse events prior to hospitalisation, although they were excluded from the impact and preventability analysis due not to have access to the information for the study (prior Case record).

Fig. 2. AE detection and their inclusion in the study



Determinations:
1. Adverse event Alert: Identified by the Screening Guide[23] in the Case record.

2. Adverse events: Identified by the Modular Review Form (MRF2)[41] in the Case record.

3. Incidents: Identified by the MRF2 form in the Case record.

Sample:
After consulting the information furnished by the Ministry of Health related to the Healthcare indicators for Spanish hospitals, was estimated that the minimum anticipated discharges annually was approximately 4,500,000. Due the study was going to be conducted during a week of the year chosen at random, the number of discharges to be studied for that week would be ninety thousand (90,000) according to the diagram in Table 2.

Table 2. Annual discharges and estimated discharges per week

	Minimum	Maximum
Nº. discharges annually	4,500,000	4,800,000
Nº. weekly discharges (approx.)	87,000	92,000

For efficiency and feasibility purposes, it was decided to rule out those hospitals which had less than 50 beds. These hospitals would contribute a significant percentage of patients is a large number thereof were to be samples (ex. For obtaining 1500 patients at hospitals having less than 200 beds, 21 hospitals would be required, but if only those hospitals having 50-200 beds are considered, it would be only necessary to sample 7 hospitals). On eliminating these hospitals from the population subject to be selected, the number of discharges was reconsidered to 83,000 discharges (always assuming that the incidence of the Adverse events does not depend on the size of the hospital).

The sample selected was random layered by hospital size, in which the hospitals to take part in the study were chosen at random according to the sample size required to compiling all of the discharges for the study period which met the criteria for inclusion.

For an expected 20% Adverse events incidence rate with the 83,000 aforementioned discharges, as shown in Table 3, a sample size ranging according to the accuracy would be required.

Table 3. Statistical accuracy according to sample size

Sample Size	Accuracy (%)
5,500	1.445
6,000	1.379
6,500	1.320
7,000	1.268

In Accord to the variances found, this accuracy fell within 1.1% - 1.5% range due to the effect design.

The type of sampling was layered by the number of beds of the hospitals (by selecting a number of hospitals from each layer), using the information about the hospital catalogue available on the Spanish Ministry of Health webpage. The layers were: < 200 beds (79 hospitals), 200-499 beds (163 hospitals) and 500 or more beds (64 hospitals). All the patients were selected from among those hospitals which met the criteria for inclusion.

There were substitution units for all of the layers in the event of a hospital deciding not to take part in the study. In that case, the hospital selected would be replaced by another with similar characteristics selected at random. This situation occurred only in one case of the medium-sized hospitals group.

As shown in Table 4, the layers and the number of records to be samples, were calculated based on all this data.

Table 4. Sampling by hospital size

	< 200	200 - 499	≥ 500
Nº. 5,500	627	1,708	3,166
Hospital	5	11	4
Nº. 6,000	683	1,863	3,454
Hospital	6	12	5

Nº. 6,500 Hospital	740 6	2,018 13	3,742 5
Nº. 7,000 Hospital	797 7	2,173 14	4,029 5

If the sample exceeds 6,500 discharges, efficiency of the study is less, given that not so much is gained in accuracy despite increasing the sample size.

The design selected was that which has the selection of 24 hospitals distributed among: 740 discharges at 6 hospitals having fewer than 200 beds; 2,018 discharges at 13 hospitals having 200-499 beds and 3,742 discharges at 5 hospitals having more than 500 beds, in order to thus obtain a total of 6,500 records. The selection of these records within each hospital was made by means of a systematic sampling.

Variables studied:

1. Healthcare-related variables:
   - 1.1 Hospitalisation unit
   - 1.2 Type of admission (scheduled or emergency)
   - 1.3 Stay in number of days
   - 1.4 Extrinsic risk factors (open urinary drainage system, closed urinary drainage system, peripheral venous catheter, central catheter, peripherally-inserted venous catheter, central venous catheter, parenteral nutrition, enteral nutrition, nasogastric tube, percutaneous esophagogastric tube, tracheotomy, mechanical ventilation, immunosuppressive therapy).

2. Variables related to the disease or procedure:
   - 2.1 Primary diagnosis (literal or ICD-9-CM code, International Disease Classification, Ninth Revision, Clinical Modification).
   - 2.2 Surgical procedure (literal or ICD-9-CM code).
   - 2.3 ASA[40] Risk. Prognosis classification drafted by the American Society of Anaesthesiologists:
     1. A normal healthy patient.
     2. A patient with systemic disease, but which does not result in limitation of activity.
     3. A patient with severe systemic disease, with clear functional limitation.
     4. A patient with severe systemic disease, functional limitation and constant potential threat to life.
     5. A patient who is at substantial risk of death within 24 hours.

3. Subject-related variables:
   - 3.1 Age
   - 3.2 Sex
   - 3.3 Intrinsic risk factors (coma, renal insufficiency, diabetes, neoplasia, COPD, immunodeficiency, neutropenia, hepatic cirrhosis, drug addiction, obesity, desnutrition, pressure ulcer, malformations, cardiac insufficiency, coronary disease, hypertension).

4. Impact-related variables:
   - 4.1 Stay caused by adverse event
   - 4.2 Procedures and treatments added as a result of the AE.
   - 4.3 Disability.

Instrumentalisation:

1. Forms used in the study of adverse events at the hospital:
   - 1.1 Adverse event screening guide, adapted from the Harvard[11] study.
   - 1.2 Spanish version of the Modular Form for retrospective case review, MRF2[41]. This form is comprised of 5 stages.

     Stage A: Identifies the Adverse event.

     Stage B: Describes the injury and its effects.

     Stage C: Circumstances (point in time) of the hospitalisation at which the effect occurred.

     (C0: Prior to admission; C1: ward Admission; C2: Procedures, instrumentalisation; C3: Immediate postoperative, ICU- Intensive Care Unit; C4: General ward care; C5: Assessment at discharge).

Stage D:: Main problems at the process care.
(D1: Diagnostic error; D2: In relation to patient's overall condition; D3: Supervision and care; D4: Nosocomial infection; D5: Surgical procedure; D6: Medication; D7: Resuscitation procedure)
Stage E: Causative factors and preventability.

Each patient may have had one or more AE's, and all thereof have been taken into account for the evaluation of their relationship with the care, their preventabilty and their impact. They may have occurred, in turn, during the prehospitalisation period or under any of the circumstances involved in hospitalisation described in Stage C. Similarly, at each one of these points in time, one or more problems may have arisen in the process of care in accordance with the Stage D classification.

2. IDEA (Identification of Adverse events) Project database. For processing the data compiled on the forms, an information system (IDEA) has been developed and put into practice which is capable of managing multiple AE's in one single subject and multiple causes for each AE.
This system provides for easy data input and mining by means of a client-server application under a Windows environment developed at Power-Builder Enterprise 7.0 against the relational database management system Sybase Adaptive Server Anywhere 6.0.

Procedure:
Nursing professionals and, in some cases, physicians who had been previously trained for this purpose, completed the Screening Guide for all of the discharges included in the study.

When the Screening Guide had a box marked "Yes" on the case record Summary Form (positive screening Guide), the completion of the MRF2 Form (Spanish version) had to be undertaken. This was done at each hospital by two reviewers: A trained medical specialist for the medical cases and another trained in surgical specialties for the surgical cases.

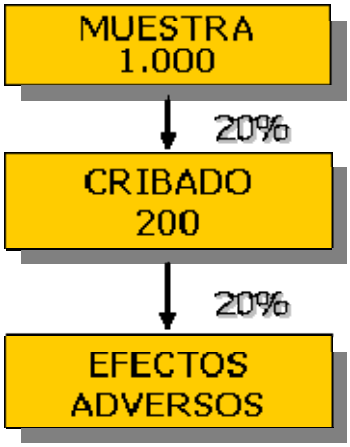
The dubious cases were re-analysed by the Management Committee.

Surveyors
One/two nurses or physicians for each hospital trained to complete the Screening Guide.

Six expert physicians were trained to complete the MRF2 form and in the management of the IDEA Project database.

To calculate the work loads, a sample of 1000 patients who met the criteria for inclusion in the study was assumed. It was anticipated to find 20% thereof to have some affirmative answer on the case history Summary Form on the Screening Guide. Only 20% of the 200 for whom the Stage A on the MRF2 form have to be completed would true AE's, hence, in the end, the MRF2 form would have to be completed in full for only 40 of the 1000 patients included in the study (Fig. 3).

Fig. 3. Estimated AE frequency



SAMPLE
1,000
20%
SCREENING
2,000
20%
ADVERSE EVENTS

Data collection quality control:
Those of the IDEA Project proper, aimed at maintaining the integrity of the information gathered.

All forms were reviewed by the Management Committee. Those which included problems were discussed at a joint meeting for deciding as to their inclusion.

During the entire data collection process, the management team was in contact with the reviewers for the purpose of answering queries and facilitating anything they may have needed.

Reviewer Agreement Analysis:
Prior to the field work, a study was made about the degree of agreement among the reviewers to evaluate the training in the identification and typing of the AE's and to discover any possible errors, differing opinions and defects in the description thereof. For this purpose, 5 reviewers studied 48 case records selected from internal medicine and another 5 reviewers studies 22 surgical case records, all of which were records revealing some sort of problem.

The number of events (adverse events and incidents) found are summarised in Table 5.

Table 5. No. of AE's and incidents by unit type.

	Unit Type	
Events	**Internal Medicine**	**General Surgery**
Adverse events	19	13
Incidents	22	4
No adverse event or incident	7	5

As there is no gold standard for the identification and typing of adverse events, a list was made of all of the possible events and their effect, impact and preventability were established by means of a consensus among the reviewers and the group co-ordinating the study.

Preventability was explored by means of a 1-6 scale (1: no evidence of preventability; 6: total evidence of preventability). By taking the adverse events as hardly preventable or absolutely not preventable if they had been assessed with a low score (1-3) and preventable or highly preventable with a high score (4-6). Table 6 provides the percentage of preventable and unpreventable events in each unit by type of event.

Table 6. Gold Standard Event preventability

		Events	Adverse events
Unit Type	Internal Medicine	Preventable	17
		Unpreventable	2
	General Surgery	Preventable	11
		Unpreventable	2

The degree of agreement among the reviewers and the consensus when identifying adverse events, incidents and their preventability was studied by means of the kappa agreement measurement (Table 7). Tables 8 and 9 summarise the agreement study conducted.

Table 7. Degree of agreement according to kappa figure

Kappa	Degree of agreement
< 0.20	Poor
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Substantial
0.81 - 1.00	Almost perfect

Table 8. Kappa. Study of degree of agreement in Internal Medicine

	Internal Medicine	
Reviewers	Adverse events	Preventability
1	0.652	0.841
2	0.819	0.413
3	0.868	0.552
4	0.722	*
5	0.772	0.836

* The reviewer did not complete this MRF2 stage.

Table 9. Study of degree of agreement in General Surgery

	General Surgery	
Reviewers	Adverse events	Preventability
1	0.510	*
2	0.784	*
3	0.488	0.354
4	0.431	*
5	0.488	0.276

* The reviewer did not complete this MRF2 stage.

The degree of agreement found in internal medicine for AE identification was substantial to almost perfect, whilst there was not such a high degree of agreement when assessing preventability. In general surgery, A lesser degree of agreement was found, ranging from moderate to substantial.

The gold standard was constructed based on an agreement among the reviewers and the management team, consulting specialists when necessary.

Following the completion of the study of the degree of agreement, all of the interpretations which conditioned the study disagreement results were discussed in order to come to a consensus as to the criteria to be followed during the field study. The agreements reached for be applied during the ENEAS study were:

- Extravasations:
  Considered to be incidents (requiring another insertion).
  They are preventable for the most part (e.g. if the line has been in place for some time...), but may be considered preventable if the extravasation occurs when inserting the needle.

- Line change due to malfunctioning:
  Considered an incident (requiring another insertion).
  They are not very preventable (2 or 3).

- Line change due to pain:
  Considered to be an incident.

- Phlebitis:
  Considered minor AE's.
  They are considered to require additional treatment (line change and local dressing) even though nothing be specified on the record.
  They are preventable (4-6) according to the baseline pathology.

  Given that the populational studies to date have not considered phlebitis to be an AE, it shall not be considered as such in this study either in order to facilitate international comparison, but shall be taken into account for calculating the extended incidence (including phlebitis in all its aspects, even when it arises as a single AE).

- Phlebitis + extravasation:
  Solely the phlebitis will be described.

- Drainage system pulled out (vesical drainage, peripheral pathway ...
  Considered an incident or an AE if it has repercussions on the patient (e.g. hematuria).
  Considered preventable according to the evaluation made of the patient, if the patient is nervous, upset, if the patient collaborates, is aware of the situation at hand... and if the necessary measures had been taken in terms of said evaluation.

- Pressure ulcers and worsening of a pre-existing pressure ulcer:
  Always considered an AE.
  Preventability will depend upon the patient's comorbidity.

- Vaginal tear and childbirth:
  Considered an AE when there has been prior episiotomy, being indicated and, even so, having not been prevented. In any other case, it will be considered a complication due solely to the birthing process.

  When considered an AE, it will be considered preventable.

- Drug intolerance:
  If a past history of intolerance is noted on the record and the drug is prescribed even so, it is considered an incident or AE, depending upon the repercussions on the patient and will be considered preventable.

  If the drug is prescribed and is not administered because the intolerance is alerted, it is not counted as anything.

  If the drug is prescribed and the intolerance subsequently found to exist, it is considered an AE or incident, depending upon the repercussions on the patient and will be considered unpreventable or not very preventable.

- Non-administering of treatment (e.g. drug not available at the pharmacy, regular medication not scheduled...):
  Will be considered an incident or AE, depending upon the need for the medication for the appropriate management of the patient.

- Contraindicated drug prescribed:
  Will be considered an incident or AE, depending upon the repercussions on the patient.

- Improper approach to the pain:
  Will be considered a preventable AE.

- Delay in diagnostic tests:
  Will be considered an incident unless a major situation for clinically management the patient has not be diagnosed / assessed, in which case it will be considered an AE.

  The preventability will depend upon the reason for the delay, whether it is due to care load pressure (not very preventable) or due to misplaced requests (highly preventable).

- Suspension of surgical procedure:
  Will be considered an AE, when the cause having given rise thereto is not related to the process of the disease (concurring infection, unanticipated complication...), it is preventable.

  The preventability depends upon the cause giving rise thereto. It is not very preventable is it is due to care pressure (unforeseen emergency interventions) and preventable in those cases in which the patient is not adequately prepared in scheduled interventions (no suspension of the anticoagulant treatment...).

- Surgical wound infection:
  Will always be considered an AE.

  The degree of preventability will depend upon the characteristics of the surgery, the degree of contamination, the proper antibiotic prophylaxis, ...

Data analysis:

1. **Description of the AE's.** Overall and by layer (by type of hospital and by type of medical and surgical units)
   - Description of the sample: number of patients included/excluded, those lost will be explained.
   - Description of the variables studied.
   - Description of the alerts detected by the Screening Guide.
   - Description of the confirmed cases of AE's.

2. **Calculation of Incidences:** In estimating the incidence rate, solely the AE's caused and detected in the hospitalisation process under study were taken into consideration. The cumulative incidence and the incidence density were calculated.

Cumulative incidence of patients with AE: Number of patients with AE among the total number of patients.

Cumulative incidence of AE's: Number of AE's among the total number of patients.

Incidence density: Number of among the total number of patients.

The percentage of patients who were readmitted for an AE and the percentage of AE's which occurred during the prehosptialisation period out of the total number of patients (Primary Care, Out-patient treatment and prior hospital admission) were calculated. The percentage of preventable AE's was calculated by layer and hospital unit.

3. **Cause-effect analysis:** Based on the description of the results of MRF2 form Stages C and D and the qualitative analysis of the summary of the AE description on the same form.

4. **Analysis of the AE's during the prehosptialisation period.** Description of the results of MRF2 form Stage C0.

5. **Analysis of the AE's leading to readmission.** Description of the results of MRF2 form Stage C0.

6. **Analysis of the impact of the AE's.** Description of the consequences of the AE's and their preventability.

Statistical analysis: A univariate analysis was made for the description of the sample (average, mean, standard deviation and interquartile spread for continuous variables and frequencies for categorical variables), and a bivariate analysis for establishing relationships between the variables (by means of the Mann-Whitney U Test for comparing averages and the Chi Square - x^2 - for comparing percentages) and a step forward logic regression model for reasons of veracity for controlling the confusion and/or interaction thereof. The hypotheses were compared on a two-way basis, with a 0.05 significance level, except the logical regression model, in which a p-value lower than 0.05 was used for inclusion and under 0.10 for the exclusion thereof. The statistical analyses were made using the SPSS Version 12.0 statistics program.

Confidentiality and ethical aspects

This study was conducted following the recommendations of the WHO (World Health Organisation) and the Spanish NHS[42] (National Health System) Cohesion Law.

The Study Director established the necessary conditions for ensuring full compliance with the Spanish Personal Data Protection Act (Ley Orgánica 15/1999 de Protección de Datos de Carácter Personal.

The data was initially collected on a name basis, but individual identifications were kept exclusively until the Database Quality checks were passed. As of that point in time, a Database managed solely by the Study Director afforded the possibility of linking the data to the patients.

All of those taking part in the study were placed under the obligation of guarding secrecy concerning the information to which they had access throughout the study just as in any other of their professional activities.

The data has always been displayed in aggregate from, so that it has not been possible to go so far as to identity a patient based on the dissemination of data in any case.

The study was submitted to the consideration of the Ethics and Clinical Research Committee of Aragon.

WORKING DEFINITIONS

General definitions

Adverse event (AE)
Defined for this study as any accident or incident included in the patient's Clinical Record which has caused or may have caused injury to the patient, linked, above all, to the conditions of the care provided. The accident may lead to a extending of the hospitalisation time, a sequela at the point in time of discharge, death or any combination thereof. The incident causes no injury or harm, but may facilitate the same.

To meet this requirement, an injury or complication, extending of the stay, subsequent treatment, disability at discharge or *death* must be involved as a result of the healthcare provided out of moderate probability that the management were to have been the fully evident cause.

Preventable adverse event
That which, there being any possibility of prevent, shows moderate to total evidence of preventability.

Major Adverse event
That which leads to *death* or residual disability at discharge from the hospital or which required surgical intervention.

Moderate Adverse event
That which causes the extending of the hospital stay by at least one day.

Minor Adverse event
That which causes an injury or complication without extending the hospital stay.

Accident
Random unforeseen or unexpected event which either causes injury to the patient or material or any other type of losses.

Incident
Random unforeseen or unexpected event which does not cause injury to the patient or material or any other type of losses. An incident may also be defined as an event which might have been an accident under other circumstances, or as an event which, if not discovered or correct in time, may entail problems for the patient.

Medical Error
Act of commission or omission in the practice of the healthcare professionals which might have contributed to the occurrence of an adverse event[43,44]. In this regard, some authors have stressed the need of improving the pinpointing of their existence by means of a pair evaluation at the point of time at which they occur[45] .

Near-error (Close Call /Near Miss)
A poorly defined category which includes events such as: case in which the accident has been prevented by a bare margin[46] any situation in which a continuous chain of effects was halted, preventing potential consequences from arising, an event in which, under other circumstances, could have had serious consequences; a dangerous event which has not causes personal injuries but has caused material damage and which serves as a sentinel event regarding possible adverse event accidents per se).

Medication error

Effect which can be prevented and which is caused by an inappropriate use of a medication, causing injury to a patient while the medication is under the control of the healthcare personnel, patient or consumer[47] .

Adverse drug reaction
Alteration and/or injury caused when the drugs are inappropriately used (hardly preventable).

Negligence

Hardly justifiable error caused by laziness, carelessness, apathy, insufficient study, lack of diligence, omission of due precautions or carelessness in the application of the knowledge which a qualified professional should possess and utilise.

Malpractice
Deficient clinical practice which has caused an injury to the patient, understood as such when the results are clearly worse than those which other professionals of similar qualifications would have foreseeably achieved under identical circumstances.

Lawsuit
Dispute prosecuted before a court which may be motivated by a disagreement with the care provided or with the undesirable effects thereof, relatively frequently not due to the existence of prior events.

Specific definitions

0. *Death*
Unnecessarily early death preventable from the healthcare standpoint, provided that it is not related to the natural history of the disease and is indeed related to any other of the adverse events defined. Neither the patient's prognosis nor the degree of severity nor the age of the patient having made this foreseeable.

1. Reintervention
Surgical procedure repeated within less than a thirty-day period due to causes related to the previous intervention (e.g. evisceration following colon surgery, subphrenic abscess following pelvic surgery, etc. ...)

2. Readmission
Further hospitalisation within less than a six-month period related to the immediately previous admission.

3. Nosocomial infection
An infection is considered nosocomial is there are no indications of the patient having this infection in clinical phase or incubating at the point in time of the admission; it shall otherwise being considered of the community-acquired type. Any infection present at the point in time of the admission which were to have been acquired on a prior admission (e.g. prosthesis infection) is considered Nosocomial Infection as an individual case.

For their classification, the case definition criteria of the PREVINE[48] (Programa Específico para la Vigilancia de la Infección Nosocomial en Hospitales Españoles) study prepared by the CDC's[49,50] (Centers for Disease Control and Prevention) will be used.

3.1 Symptomatic urinary tract infection: Must meet at lease one of the following criteria:

3.1 Patient has at least one of the following: fever (>38ºC), urgency, frequency, dysuria or suprapubic tenderness and patient has a positive urine culture ($\geq 10^5$ micro-organisms per cm^3 of urine with no more than two species of micro-organisms.

3.1.2 Patient has at least two of the following signs or symptoms: fever (>38ºC), urgency, frequency, dysuria or suprapubic tenderness and at least one of the following: positive dipstick for leukocyte esterase and/or nitrate, pyuria, organisms seen on Gram stain, at least two urine cultures taken by suprapubic aspiration in which more than 100 colonies per ml of the same uropathogen have been repeatedly isolated. In a patient undergoing proper antibiotic treatment, the isolation of a uroculture of less than one hundred thousand colonies per ml of one same uropathogen; physician diagnosis or urinary tract infection; physician institutes appropriate therapy for a urinary tract infection.

3.1.3 Other infections of the urinary tract: Must meet at least one of the following criteria: Patient has organisms isolated from culture of fluid or tissue in which a micro-organism has been isolated; a clear sign of infection has been found during a surgical operation or during a histopathological study; Patient has at least two of the following: fever (>38ºC), localised pain or tenderness at the involved site and at least one of the following: purulent drainage from affected site, organisms cultured from blood that are compatible with suspected site of infection; radiographic evidence of infection; physician diagnosis of infection or physician institutes appropriate antibiotic therapy.

3.2 Surgical site infection:

3.2.1 *Surgical site infection (superficial incisional):* Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision. And patient has at least

one of the following: Purulent drainage from the superficial incision; Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; Medical diagnosis of superficial incisional infection; Pain or tenderness, localised inflammation (heat, tumefaction, erythema) and the incision is deliberately opened by the surgeon.

(The following cases are not considered superficial infections: minimal abscess of suture point, infected burn, incisional infection which extends toward fascia and muscle walls.)

3.2.2 *Surgical site infection (deep incisional).* Infection occurs within 30 days after the operative procedure if no implant (any foreign body of non-human origins) if left in place or within 1 year if the implant is in place and the infection appears to be related to the operative procedure and, additionally, the infection involves deep soft tissues (fascia and muscle walls) and the patient has at least one of the following: Purulent drainage from the deep incision but not from the organ/space component of the surgical site; Medical diagnosis of a deep incisional infection; The incision spontaneously dehisces or it is opened by the surgeon when the patient has at least one of the following signs or symptoms: fever (>38ºC), localised pain, tenderness to touch or pressure; An abscess or other evidence of infection involving the deep tissues of the incision is found during reoperation, during direct examination or by histopathologic or radiologic examination.

3.2.3 *Surgical site infection (organ/space).*Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure and, additionally, the infection involves any part of the anatomy opened or manipulated during the operative procedure other than the incision. Patient has at least one of the following: Purulent drainage from a drain placed in an organ or space (if the area through which the drainage tube is inserted through the skin has become infected, this infection shall not be considered surgical, but rather a skin or soft tissue infection, depending upon the depth involved); Medical diagnosis of surgical organ/space infection. Isolation of micro-organisms in samples taken from fluids or tissues from organs or spaces; An abscess or other evidence of infection involving an organ or space is found during a reoperation, during a direct examination or histopathologic or radiologic examination.

3.3 Pneumonia: Must meet at least one of the following criteria:

3.4 Laboratory-confirmed bloodstream infection: Must meet at least one of the following criteria:

Patient has a recognised pathogen cultures form one or more blood cultures which is not related to an infection at another site.

Patient has at least one of the following signs or symptoms: fever (≥38ºC), chills, hypotension and any of the following: Common skin contaminant unrelated to any other site of infection is cultured from two blood cultures drawn on separate occasions. Common skin contaminant is cultured from at least one blood culture from a patient with an intravascular line and the physician institutes appropriate antimicrobial therapy; Positive antigen test on blood on an organism unrelated to any other site of infection.

3.5 Clinical sepsis: Must meet at least one of the following criteria: Patient has at least one of the following signs or symptoms with no other recognised cause:

Fever (>38ºC), hypotension (systolic pressure ≤ 90 mm Hg) or oliguria (≤ ml/hr) and at least one of the following: Blood culture not done or no organisms or antigen detected in blood; no apparent infection detected at another site; Physician has instituted appropriate antibiotic treatment for sepsis.

3.6 Laboratory-confirmed bloodstream infection: when the micro-organism isolated in the blood culture is compatible with another nosocomial infection.

3.7 Bloodstream infection related to intravascular device: When the catheter has been cultured.

Common micro-organism isolated in the blood culture and on the catheter tip, the connection or the infusion fluid. When the catheter has not been cultured. Positive blood culture, no type of site of sepsis can be recognised, the most probable origin being the catheter and the patient improves following the removal thereof.

3.8 Arterial or venous infection: Must meet at least one of the following criteria:

A micro-organism isolated in the culture of an arterial or venous biopsy by surgical dissection and the blood cultures have been negative or no blood culture done.

Signs of infection in the vascular area involved found during a surgical procedure or in the histopathological examination.

Patient has at least one of the following: fever (>38ºC), pain, erythema or heat in the vascular area involved and at least two of the following: More than 15 colonies isolated in the semi-quantitative culture of the intravascular cannula tip; Blood cultures negative or blood cultures not done.

Purulent draining in the vascular area involved, and blood cultures negative or blood cultures not done.

Any of the following in a patient aged 12 months or less: Fever (<38ºC), hypothermia (<37ºC), apnea, bradycardia, obnubilation, pain, erythema or heat in the vascular area involved, and at least two of the following: More than 15 colonies isolated in the semi-quantitative culture of the intravascular cannula tip. Blood cultures negative or blood cultures not done.

3.9 Intraabdominal infection: (including that of gallbladder, bile ducts, liver - except hepatitis-, spleen, pancreas, peritoneum, subphrenic or sub-diaphragmatic space, and that of those intraabdominal tissues areas not defined under any other section). Must meet at least one of the following criteria:

Patient has organisms isolated from a culture a purulent material from intraabdominal space during a surgical operation or needle aspiration.

Patient has abscess or other evidence of intraabdominal infection seen during a surgical operation or a histopathological examination.

Patient has at least two of the following with no not other recognised cause: fever (>38ºC), nausea, vomiting, abdominal pain or jaundice and at least one of the following: organisms cultured from drainage surgically placed drain (e.g. closed suction drainage system, open drain or T-tube drain). Organisms seen on Gram stain of drainage or tissue obtained during a surgical operation or needle aspiration; Organisms cultured from blood culture and radiographic evidence of abdominal infection.

3.10 Skin or soft tissue infection: Must meet at least one of the following criteria:

Patient has purulent drainage, pustules, vesicles or boils.

Patient has at least two of the following in the area involved: Spontaneous pain to palpation, tumefaction, erythema or heat and at least one of the following: Organisms cultured from aspirate or drainage from affected site if organisms are normal skin flora, they must be a pure culture Positive antigen test performed on infected tissue or blood; Multinucleate giant cells seen on microscopic examination of affected tissue; Diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen.

4. Pressure ulcer

Ischemic necrosis and ulceration of tissues covering a bony protuberance which has been subjected to long-term pressure due to patient being bedridden for a lengthy period of time due to the illness having given rise to the admission (provided that the same were not to be present at the point in time of admission). Skin abrasions and irritations which are not posture-related are excluded.

5. Pulmonary thromboembolism

Blood clot lodged in pulmonary artery with subsequent obstruction of blood flow to the pulmonary parenchyma following long-term bed rest with immobility or due to the postoperative condition as a result of hospitalisation.

6. Deep vein thrombosis

Blood clot caused by long-term bed rest with immobility or by the postoperative condition as a result of hospitalisation.

7. Non-infectious arterial or venous inflammation

Vascular inflammation related or unrelated to vascular thrombosis (thrombophlebitis) which does not meet the criteria as infectious angeitis.

8. Haemorrhage-related complications and lacerations

Resulting from a surgical operation or therapeutic procedure (e.g. cerebrovascular accident in dialysis).

9. Surgical technique-related adverse events
Resulting from a surgical operation. Including immediate injuries (e.g. injury to urethra in surgical operation) and later injuries (post-biopsy haemorrhage).

10. Suture dehiscence

11. Foreign body or substance left by accident unrelated to the organism proper
Inadvertently left in the surgical field as the result of a surgical operation.

12. Device, implant or graft complication: Resulting from surgical operation.

13. Acute Myocardial Infarction complicating surgery
That which occurs following a non-cardiac surgery operation, independently of whether or not the patient has cardiovascular risk factors.

14. Acute Myocardial Infarction complicating hospitalisation
That which unexpectedly occurs in the course of hospitalisation, independently of whether or not the patient has cardiovascular risk factors.

15. Traumatism, accident or accidental fall
During hospitalisation. Including the burns as a result of procedures.

16. Sudden death
Death due to cardio-respiratory arrest unrelated to the natural history of the primary illness, during hospitalisation or within the 24 hours immediately following discharge, if a record exists thereof.

17. Prior hospitalisation among those under age 65
During the last year the patient is under age 65, due to the primary diagnosis per se and unforeseeable as a result of the natural history of the disease. The scheduled hospitalisation for secondary procedures or for treatment of chronic disease and the hospitalisation unrelated to prior hospitalisation is therefore excluded.

18. Prior hospitalisation among those over age 65
During the last 6 months when the patient is over age 65, for the same primary diagnosis and unexpectedly as a result of the natural history of the disease. The scheduled hospitalisation for secondary procedures or for treatment of chronic disease and the hospitalisation unrelated to prior hospitalisation is therefore excluded.

19. Medication Errors
An event which can be avoided and is caused by an inappropriate use of a medication causing injury to a patient while the medication is under control of healthcare personnel.

20. Adverse drug reaction
Related to alterations and/or injuries caused when the drugs are used appropriately, which are hardly preventable.

21. Accidental drug overdose
Intake of potentially toxic products (drugs) accidentally when they exceed the maximum therapeutic doses, including if they are intended to mitigate a symptom and an excessive amount (overdose) is ingested for this purpose without the involvement of healthcare personnel.

22. Toxic drug dose
If they have no consequences, they will be incidents; and if they do, they will be AE's (e.g. convulsions due to an overdose of theophyllin).

23. Error due to mistaken identification
Including all those actions taken by a patient for which aimed as a result of a mistaken identification (e.g. transfusions to wrong patient, surgical procedure errors, wrong member, etc.)

24. Desnutrition / dehydration
Due to lack of nutritional support during the period admitted. Weight loss >2% within one week's time.

25. Delayed surgery
Cause for reasons depending on poor organisation and not for reasons having to do with the patient or physician's decision.

26. Suicide
Action by which a subject takes his/her own life voluntarily or intentionally.

27. Obstetric trauma
Injuries to the new-born caused during childbirth.

28. Vaginal tears
Considered an AE solely if episiotomy is indicated and has been performed and, even so, has not be prevented.

29. Low Apgar score
Score below 8 at the one-minute test or at the five-minute test.

30. Perinatal death
Death which occurs from week 22 of pregnancy up to 28 days immediately following birth, if there is a record thereof.

31. Transfusion-related reaction

Massive clumping and intravascular hemolysis of the red blood cells which occur following a blood transfusion.

32. Anaesthesia-related complications
Undesirable phenomena which occur as a result of the anaesthesia.

33. New neurological deficit at the point in time of discharge.
Including sense, motor deficit, confusion and agitation.

TYPES OF AE's

In a multifactorial AE occurrence model, all of the elements involved co-ordinate favouring the occurrence of the AE according to cause-effect sequence which is not always correlative yet is analysable from the cause-effect chain, for example:

> The hospitalised patient sustains a hip fracture as a result of falling out of bed, which is caused by a deficient monitoring of a patient who has had an acute cerebrovascular accident and this has occurred because the healthcare personnel have not properly recognised the patient's vulnerability. There being no protecting bars on the bed and the nurse call button being out of the patient's reach may have contributed to the fall, all of these situations being favoured if this occurs at night and the person staying with the patient is asleep.

Another example related to the activity of the surgical units would be as follows:

> The patient has a surgical wound infection most probably related to failure to strictly follow the patient cleanliness preparation protocol and a lack of surgical antibiotic prophylaxis. This deficiency is due to the surgery not having been scheduled and having to have been performed in the emergency surgery at night. Additionally, the post-surgery control and the wound dressing processes were done on the internal medicine ward, given that the patient was not able to be admitted to the surgery ward due to a lack of beds.

For it to be possible for an injury or complication to be considered an AE, a relation must be established between the care due to the healthcare provided, which is not always easy, given that the age, the severity of the patient's primary illness and co-morbidities and certain situations may favour the occurrence of these types of complications. Hence, all of these factors must be taken into consideration for assessing the involvement of the care provided in the occurrence of an AE. Two examples are provided below:

> The infection of a surgical wound is always related to the care provided, but also depends upon the patient's vulnerability (age, co-morbidities, other risk factors), the type of surgery (clean, contaminated, clean-contaminated or dirty), the circumstances of the surgical operation, the proper surgical technique, the clean preparation of the patient and the perioperatory antibiotic chemoprophylaxis[51, 52] . In the case of a 16 year-old patient, following the performing of an appendectomy for phlegmonose appendicitis, the relationship of the AE to the management of the patient is more evident than in the case of an 85 year-old male on whom surgery has been performed for appendicular peritonitis.
>
> Pressure ulcers are always related to the care provided, but the occurrence thereof depends upon intrinsic risk factors such as age, comorbidity, nutritional condition, mobility, dependency for daily living activities, etc., the length of the hospital stay, the proper management of the patient (position changes), an appropriate assessment of the risk involved and the taking of preventive measures in keeping with the risk (pressure ulcer-preventing mattress, protective patches, etc.)[53] . There is greater evidence of the management being related to the occurrence of pressure ulcers in a 70 year-old male on whom surgery has been performed for a full hip prosthesis and with an improper assessment of the risk involved or the preventive measures not being taken for the case of an 85 year-old male with a long-term hospital stay affected by a cerebrovascular accident who is dependent for everyday living activities following a proper risk assessment and the taking of appropriate preventive measures to minimise said risk.

This assessment has been made based on a 1-6 scale (1 = no evidence of relationship with the management of the patient; 6 = full evidence.

The possibility of preventing the AE is defined on a scale similar to the aforementioned, in which 1 means no evidence of preventability and 6 full evidence. These are examples of preventable AE's[54] (discussed on three other occasions hereinabove).

> Patient who develops congestive heart failure after halting diuretic treatment.

Upper digestive tract haemorrhage caused by NSAI's (Nonsteroidal anti-inflammatory medications) in a patient over 65 years of age without any gastric protection prophylaxis.

AE's may be grouped into different types:

1. Diagnosis or diagnostic testing-related AE's

1. Error in clinical diagnosis (including Emergency Room)
2. Delay in the diagnosis due to lack of pertinent tests
3. Lack of attention to the anamnesis
4. Error in patient identification
5. Error in identifying labels on hemogram vials
6. Incorrect conveyance of the microbiology results
7. Contamination of the blood in the laboratory
8. Expired reagents
9. Suspension of the examination due to insufficient patient preparation (no food intake)
10. Equipment improperly calibrated

2. AE's related to an assessment of the patient's overall condition:

1. Incorrect assessment of the patient's condition due to paying little attention to the case history notes
2. Dangerous delay in being seen in Emergency Room
3. Patient discharged too soon
4. Suicide
5. Reacutization of COPD (chronic obstructive pulmonary disease) during time admitted
6. Lack of psychological support during hospitalisation

3. AE's related to the monitoring of the patient or the care required thereby:

1. Pressure ulcers
2. Failure to confirm "strange" orders
3. Improperly inserted catheters
4. Bronchopulmonary aspiration in elderly person suffering from dementia
5. Phlebitis
6. Hematuria with pulling out of drainage system
7. Patient's cognitive impairment
8. No scheduling of respiratory physiotherapy exercises
9. Recent onset of neurological deficit
10. Monitoring system alarm mechanism fault

4. Nosocomial infection-related AE's

1. Surgical site infection
2. URI (urinary tract infection) in patient with drainage system
3. Catheter-related bloodstream infection.
4. Clinical sepsis
5. Pneumonia
6. Prosthesis infection
7. Conjunctivitis
8. Food poisoning
9. Diarrhoea caused by *clostridium dificile*
10. Nosocomial Legionnaire's disease

5. Surgical operation and procedure-related AE's:

1. Anaesthesia-related complications
2. Haemorrhages or hematomas during a procedure
3. Wrong-site surgery
4. Suture dehiscence
5. Foreign body following surgical operation

6. Post-operative hypocalcaemia
7. Injury to urethra
8. Intestinal fistula
9. Hematic fluid leakage following lumbar punction
10. Surgical burns
11. Change in surgery scheduling (delay)
12. Surgical reintervention
13. Obstetric trauma
14. Hematuria following vesical drainage system insertion
15. Suspension of a procedure due to insufficient patient preparation

6. Medication or water balance-related AE's:

1. Delays in treatment
2. Overtreatment with antibiotics
3. Adverse drug reaction
4. Urine retention following epidural anaesthesia
5. Digitalis poisoning
6. Kidney failure
7. Omission of prophylaxis with gastric protection
8. Acute myocardial infarct, cerebrovascular accident or pulmonary thromboembolism due to inadequate anticoagulant control
9. Glycaemia not kept under control during hospitalisation
10. Allergic reaction (exanthema)
11. Drug intolerance
12. Non-administering of necessary schedule medication
13. Administering of contraindicated medication
14. Poor approach to pain
15. Diarrhoea caused by *clostridium dificile*

7. Postoperative recovery procedure-related AE's:

1. Burns following resuscitation procedures
2. The defibrillator was not available, res8usitation being delayed for 5 minutes
3. *Death* due to heart failure treated in emergency room by an unsupervised resident

8. Miscellaneous AE's:

1. Accidental fall in vulnerable patient
2. Case record mix-up
3. Breach of confidentiality
4. Illegible writing on discharge report
5. Deficient information on post-discharge treatment
6. Lawsuits and complaints

RESULTS

1. Characteristics of the population under study

A total population of approximately 6,500 patients had been estimated for study. The population finally placed under study in the end, comprised of the discharges for the week in question who met the criteria for inclusion, totalled 5,908 in number. A total of 103 case records were not located for the study, given that they were not in the records department at the point in time at which the field work was done. The resulting sample was of 5,805 patients. It was only necessary to substitute one hospital in the medium-sized hospital group, which refused participation in the study and was substituted in accordance with the study planning.

A total of 181 patients of the 5,805 subjects studied were excluded due to losses in the follow-up who had been screened positive in the Screening Guide and for whom the records were not available in the records department during the visit made to the hospital by the reviewers, the final sample for the study therefore having been comprised of **5,824 subjects**.

Less than 10% of the patients were lost in the follow-up.

The sample was distributed by hospital type as shown in Table 10.

Table 10. Sampling and subjects studied by hospital size

Hospitals	No.	Estimated no. patients	Actual no. patients
Large-sized	5	3,742	2,288
Medium-sized	13	2,018	2,885
Small-sized	6	740	451
Total	24	6,500	5,624

The distribution of the patients under study by hospital size and unit type is shown in Table 11.

Table 11. Subjects studied by hospital size and unit type

Hospitals	No.	Medical units	Surgical units
Large-sized	5	996	1,292
Medium-sized	13	1,304	1,581
Small-sized	6	150	301
Total	24	2,450	3,174

The total of 42,714 days of hospital stay were caused by the subjects under study. The average overall hospital stay was of 7.6 days (standard deviation [sd]: 11.3); 8.5 days (sd: 10.8) for the large-sized hospitals; 7.3 days (sd: 11.7) for the medium-sized hospitals; and 5.6 days (sd: 10.4) for the small-sized hospitals. In turn, the hospital stays totalled 9.3 days (sd: 13.2) for the medical units and 6.3 days (sd: 9.4) for the surgical units.

A total of 45.5% of the subjects in the study were males and 54.5% females. The mean age was 53.5 years of age (sd: 24.9), the median age being 59 and the mode 72 years of age. The mean stay was 7.6 days (sd: 11.3);the median, 5 days; and the mode, 2 days.

The age and length of stay-related characteristics by hospital size are shown in Table 12.

Table 12. Age and length of stay by hospital size

	Large	Medium	Small
Mean age (sd)	52.7 (25.2)	53.6 (24.9)	56.6 (23.6)
Median age	57	59	63
Stay (sd)	8.5 (10.8)	7.3 (11.7)	5.6 (10.4)
Median stay	5	5	3

2. Calculation of the incidence rate of patients having AE's

A total of 1,755 of the 5,624 patients were screened as possible AE's, 3,869 of whom were ruled out as a result of not meeting the requirements of the screening guide alerts. On reviewing those patients screened as positive, a total of 501 false positives (the AE or incident having been identified after completing the MRF2 form) were found, solely 191 patients having incidents.

The positive predictive value (positive alerts which were confirmed as being AE's or incidents) of the screening guide for detecting some type of adverse event (accident and/or incident) was 71.5% (95% CI: 69.3% - 73.6%), considering all types of AE's, in other words, also those preventable and/or due to the disease in question.

A total of 1,063 patients were found to have AE's, a total of 276 thereof having AE's due to the disease process and 787 due to the care provided, 262 patients of whom showed minimal or slight probability of the management of the patient or the care provided having been the initial cause of the AE. Therefore, a total of 525 patients remained having AE's linked to the care provided, cumulatively adding up to a total of 655 AE's (Table 13).

Table 13. AE distribution and subtypes

	No.	%	95% CI
Illness-related	276	26.0%	23.3%-28.6%
Linked to the care provided	787	74.0%	71.4-76.7%
Minimal or slight probability	262	24.6%	22.1-27.2
Moderate or high probability	**525**	49.4%	46.4-52.4
TOTAL	1,063	100%	

In a total of 131 (25.0%) of these 526 patients with AE's, the AE occurred within the prehosptialisation period: 13 in Emergency Room, 27 in primary care, 17 in specialised care out-patient treatment, 47 in preliminary care provided in the same unit, 17 in preliminary care provided in a different unit, 8 at another hospital and 2 regarding whom no data was compiled.

The distribution of the AE's by hospital size is shown in Table 14.

Table 14. AE's per patient by hospital size

	Large-sized	Medium-sized	Small-sized	Total
0	2046 (89.4%)	2654 (92.0%)	399 (88.5%)	5099 (90.7%)
1	190 (8.3%)	201 (7.2%)	41 (9.1%)	432 (7.9%)
2	34 (1.5%)	26 (0.9%)	6 (1.3%)	66 (1.2%)
3	13 (0.6%)	4 (0.1%)	3 (0.7%)	20 (0.4%)
4 or more	5 (0.2%)	0 (0.0%)	2 (0.4%)	7 (0.1%)

A total of 17.7% of the patients having AE's had more than one AE.

The incidence rate of patients with AE's related to the care provided was 9.3% (525/5,624); 95% CI: 8.6% - 10.1%. The incidence rate of patients with AE's related directly to the hospital care (excluding those from primary care, out-patient treatment and those caused at a different hospital) was 8.4% (473/5,624): 95% CI: 7.7% - 9.1%.

The AE incidence rate was the highest at the small-sized hospitals, that of the large-sized hospitals ranking in between, and the lowest rate being at the medium-sized hospitals. In turn, this rate was higher in the medical units than in the surgical units.

The incidence rate by hospital type and by unit type is shown in Table 15.

Table 15. AE incidence rate by layers

	Patients	Incidence rate	95% CI
Large-sized hospitals	221	9.66%	8.45-10.9
Medium-sized hospitals	206	7.14%	6.20-8.08
Small-sized hospitals	46	10.2%	7.41-13.0
Medical units	217	8.86%	7.73-10.0
Surgical units	256	8.07%	7.12-9.01
OVERALL	473	8.41%	7.69-9.14

A total of 105 (22.2%) of the 473 patients having hospitalisation-related AE's gave rise to readmission. The distribution thereof by hospital size and unit type is shown in Table 16.

Table 16. AE's leading to readmission by layer

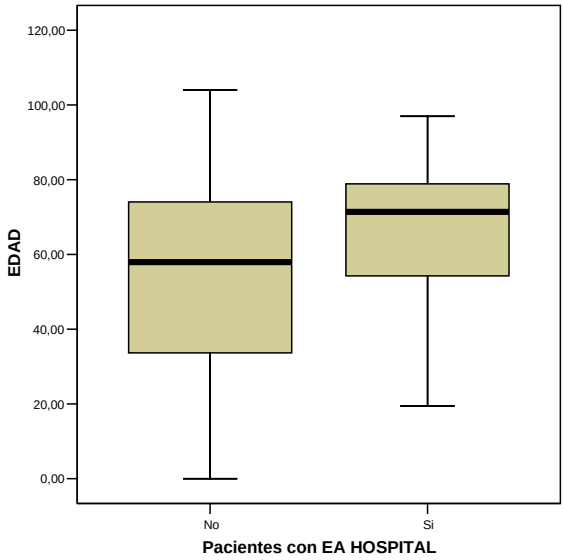
	AE's	Readmissions	95% CI
Large-sized hospitals	52	24.9%	19.0-30.7
Medium-sized hospitals	42	20.8%	15.2-26.4
Small-sized hospitals	11	24.4%	12.9-39.5
Medical units	43	20.5%	15.0-25.9
Surgical units	62	25.2%	19.8-30.6
OVERALL	105	22.2%	18.5-25.9

3. Characteristics of the subjects

The ages of the subjects who developed AE's during hospitalisation was a mean of 64.3% years of age (sd: 20.5), with a median age of 71 years of age, as compared to the mean 52.5 years of age (sd: 25.0) with a median age of 57 years of age for the subjects having no AE (Fig. 4). These differences were statistically significant (p<0.001).

The patients over 65 years of age showed a higher frequency of AE's than those under age 65(12.4% vs. 5.4%). This difference was statistically significant (p<0.001), such that the risk of developing an AE among those over age 65 is more than double that of those below age 65 (RR: 2.5 95% CI: 2.0-3.0).

Fig. 4 Ages of patients with and without AE's



AGE

Patients with HOSPITAL AE

A total of 9.1% of the males developed a hospitalisation-related AE as compared to 7.8% of the females. This difference was not statistically significant (p=0.088).

Total of 13.2% of the subjects having some intrinsic risk factor (co-morbidities and other risk characteristics of the patient) developed an AE as compared to the 5.2% of the subject who had no risk factors. This difference was statistically significant (p<0.001) a dose-response effect being found such that the subject with an intrinsic risk factor had an AE in 10.5 of all cases, which rose to 15.1% when there were 2 risk factors involved and to 22.9% when there were 3 or more risk factors. This difference was statistically significant (p<0.001).

A total of 4648 patients (82.6%) had some extrinsic risk factor (invasive devices, such as, for example, peripheral venous catheter or urinary drainage system). The extrinsic risk factors cumulatively totalled 7235 in number. A total of 80.2% of the patients had a peripheral venous catheter and, if those patients who has some risk factor are considered, the peripheral venous catheter was present in 97.2% of these cases, which gives an idea as to the frequency of this extrinsic risk factor.

A total of 9.5% of the subjects who had some extrinsic risk factor developed an AE as compared to the 3.4% of the subjects who had no risk factors. This difference was statistically significant (p<0.001). Given that there is a high percentage of subjects who had a peripheral pathway inserted, even in absence of clinical need thereof, we repeated the analysis ruling out this situation as a risk, and the effect held true. Also found in this case was a dose-response effect such that 5.6% of the subjects without any extrinsic risk factor has an AE, this figure rising to 11.4% when there was one risk factor, to 14.2% when there were 2 risk factors and to 33.5% when there were 3 or more risk factors. This difference was statistically significant (p<0.001).

The subjects having AE's had a median 11-day stay with an interquartile spread of 14, whilst those subjects who did not develop AE's had a median 4-day stay with an interquartile spread of 6, the difference being statistically significant (p<0.001). At the large-sized hospitals, the median stay of patients without any AE was 5 days (interquartile spread: 6) as compared to a mean of 11 days (interquartile spread: 13) when an AE had occurred.

The relationship between the length of the stay and the development of AE's was explored as follows: An analysis was made as to whether or not any differences existed between the spread of the stay among those patients whose AE did not extend their stay and all of the other patients (including those without any AE) and among those whose stay was extended and all of the others for the purpose of exploring whether the length of the stay (extending) was a cause or effect.

The median stays of those AE's which did not extend the stay was of 10 days (interquartile spread 9), whilst for all of the other patients it was 5 (interquartile spread: 7), this difference being statistically significant (p<0.001), which means that the extending of the stay is a risk factor for developing an AE.

In turn, the median stay of those AE's which extended the stay was of 18 days (interquartile spread 21), whilst for all of the other patients it was 5 days (interquartile spread 7), this difference also being statistically significant (p<0.001), thus meaning that the development of an AE extends the length of the hospital stay.

For controlling mix-up and interaction phenomenon, a multivariate analysis was made by logic regression (forward method for reasons of verisimilitude). We found that the age, the length of the hospital stay, the size of the hospital, the unit type and the number of both intrinsic and extrinsic risk factors explained the occurrence of AE's. Sex was not included in the model, which means that sex has no bearing on the development of an AE. This model is summarised in Table 17.

Table 17. Explanatory logic regression model

Explanatory variable	Odds Ratio	95% CI
Unit category* (Med.)	1.23 n.s.	0.89-1.72
Hospital size (medium)*	0.81	0.66-0.99
Hospital size (small)*	1.44	1.02-2.03
Age*	1.98	1.48-2.63

Hospital stay*	**5.07**	**3.80-6.76**
No. intrinsic factors*	**1.57**	**1.27-1.94**
No. extrinsic factors*	**2.30**	**1.68-3.17**
Age* No. extrinsic factors	**0.58**	**0.37-0.82**
Unit Category* Stays	**0.56**	**0.38-0.83**

n.s.: not significant

* Reference category: Surgical Units

***** Comparing the small and medium-sized hospitals to the large-sized hospitals (reference category)

* Reference category: Under 65 years of age

* Reference category: Less than one week

* Reference category: No intrinsic risk factors

* Reference category: No extrinsic risk factors

This regression is aimed at establishing a model in which the effect of each independent variable is added to the others in order to explain a dependent variable, and in the event that an interaction exists, the effect is multiplied.

Thus, those patients admitted to a small-sized hospital had 1.4 times more risk of having an AE than those who were admitted to a large-sized hospital. Those who had intrinsic risk factors, 1.6 times more risk than those who did not. Those under 65 years of age who had extrinsic risk factors, 2.3 times more risk than those who had none. Those over age 65 who had not extrinsic risk factors, twice the risk, and those over age 65 with extrinsic risk factors, 2.5 times more risk (Table 18)). Similarly, those who were admitted to a medical unit, 1.2 times more risk than those who were admitted to a surgical unit (no significant difference), those who were hospitalised for more than one week in a surgical unit, 5.0 times more risk, and those who were hospitalised for longer than one week in a medical unit, 3.43 times more risk (Table 19).

Table 18. Risk (OR) related to the age and extrinsic risk factors:

	No extrinsic risk factors	**Extrinsic risk factors involved**
< age 65	1	2.30
> age 65	1.98	1.98* 2.30* 0.58 =2.55

Table 19. Risk (OR) related to the unit type and the length of stay:

	Surgical	**Medical**
< 1 week	1	1.23 (n.s.)
> 1 week	5.07	1.23* 5.07* 0.56 = 3.43

As an indicator of the severity of the original normal condition of those patients who had AE's linked to the care provided, the ASA (American Society of Anaesthesiologists) risk was analysed in 446 patients, in which it was distributed such that 13.7% of the patients were healthy, 26.7% had a minor disease, 49.8% a functional limitation and 9.9% a life-threatening condition.

The severity of the AE's was not related to the patients' ASA risk (p=0.170) as shown in Table 20.

Table 20. Relationship between ASA Risk and AE severity

Severity ASA	**No.**	**Slight%**	**Moderate%**	**Severe%**
Healthy	61	45.9	31.1	23.0
Minor disease	119	36.1	41.2	22.7
Functional limit.	222	45.0	40.5	14.4
Life-threatening	44	50.0	27.3	22.7

On taking the ASA risk from the dichotomy of being both healthy or with a slight illness and, on the other hand, functional limitation or life-threatening condition and exploring the relationship between the degree of severity of the AE's, the differences in the spread were not statistically significant (p=0.146) either.

On evaluating the prognosis of the primary illness not conditioned by the AE, 72.2% of the subjects having an AE would recover their original normal condition, 17.4% would recover health maintaining a residual disability, and 10.4% had a terminal illness.

The severity of the AE's was related to the prognosis of the primary illness, being statistically significant (p=0.012) such that, in cases of residual permanent disability, the percentage of severe AE's was greater. The pattern of the other two groups is similar (Table 21).

Table 21. Relationship between prognosis of the primary illness and degree of severity of the AE

Prognosis	No.	Slight AE's	Moderate AE's	Severe AE's
Complete recovery to the original normal condition	455	44.0	40.4	15.6
Recovery with residual permanent disability	127	53.5	26.0	20.5
Terminal disease	65	40.0	49.2	10.8

Both the presence or absence of co-morbidities (p=0.007) (Table 22) as well as the total number thereof (p=0.008) was associated to the severity of the AE's.

Table 22. Relationship between comorbidity and degree of severity of the AE

Co-morbidities	No.	Slight %	Moderate %	Severe%
No	70	10.2	7.8	19.0
Yes	585	89.8	92.2	81.0
Total	655	100	100	100

4. AE Incidence Density

The density of AE incidence was 1.41 AE's for every 100 patient-days of hospital stay (95%CI: 1.29 - 1.52 for every 100 patient-days). In the large-sized hospitals, 1.55 AE's for every 100 days of stay; in the middle-sized hospitals, 1.14 AES for every 100 days of stay; and at the small-sized hospitals, 2.58 AE's for every 100 days of stay. By type of unit, the incidence density was 1.20 AE's for every 100 days of stay in the medical units and 1.64 AE's for every 100 days of stay in the surgical units (Table 23).

Table 23. Incidence density by layer

	AE's	Incidence density	95% CI
Large-sized hospitals	297	1.55/100 days	1.37-1.72/100 days
Medium-sized hospitals	239	1.14/100 days	0.99-1.28/100 days
Large-sized hospitals	65	2.58/100 days	1.95/3.21/100 days
Medical units	273	1.20/100 days	1.06-1.35/100 days
Surgical units	328	1.64/100 days	1.46-1.81/100 days
Total	601	1.41/100 days	1.29-1.52/100 days

The incidence density of moderate or severe AE's was 7.28 (95% CI: 6.5 -8.1 for every 1000 patients-day). AE's for every 1000 days of stay. At the large-sized hospitals, 7.34 AE's for every 1000 days of stay; at the medium-sized hospitals, 6.6 AE's for every 1000 days of stay; and at the small-sized hospitals, 12.3 AES' for every 1000 days of stay. By unit type, the incidence density was 5.3 AE's for every 1000 days of stay at the medical units, and 9.5 AE's for every 1000 days of stay at the surgical units (Table 24).

Table 24. Incidence density of moderate or severe AE's by layer

	AE's	Incidence density	95% CI
Large-sized hospitals	141	7.34/10^3 days	6.13-8.55/10^3 days
Medium-sized hospitals	139	6.63/10^3 days	5.52-7.73/10^3 days
Large-sized hospitals	31	12.3/10^3 days	7.97-16.63/10^3 days
Medical units	120	5.29/10^3 days	4.35-6.24/10^3 days
Surgical units	191	9.53/10^3 days	8.18-10.88/10^3 days
Total	311	7.28/10^3 days	6.47-8.09/10^3 days

5. Cause-Effect Relationship

The AE's may have initially arisen during the prehosptialisation period (C0), at admission to a ward (C1), during a procedure (C2), during a resuscitation process or during ICU care (C3), during the ward care (C4) or during advisory on discharge (C5).

The total AE's identified (excluding phlebitis) independently of the point in time, in other words, prior to or during hospitalisation and/or as cause of readmission was 655.

A total of 135 AE's (20.6%) were caused during the prehosptialisation period, 13 AE's (9.6%) of which occurred in the Emergency Room, 28 (20.7%) in primary care, 17 (12.6%) in out-patient treatment, 48 (35.6%) in the same unit during prior care, 17 (12.6%) in another unit at the same hospital during prior care provided, 9 (6.7%) at a different hospital and 3 (2.2%) unidentified.

A total of 8 AE's (1.2%) were caused during the ward admission period, 3 (37.5%) of which occurred in the emergency room, 3 (37.5%) during preoperative evaluation and 2 (25.0%) during arrival on the ward.

A total of 171 AE's (26.1%) were caused during a procedure, 95 (55.6%) of which occurred during the surgical operation, 7 (4.1%) during an endoscopy procedure, 7 (4.1%) in the administering of anaesthesia, 5 (2.9%) during a catherisation process, 5 (2.9%) in performing a vesical catherisation, 4 (2.3%) during the taking of a biopsy, 3 (1.7%) in the drainage of body cavity fluids, 2 (1.2%) in an IV insertion procedure, 1 (0.6%) in the manipulation of a fracture, 1 (0.6%) in interventionist radiology, 1 (0.6%) in the insertion of a nasogastric drainage system, 35 (20.3%) other procedures and 5(2.9%) unidentified.

A total of 42 (6.4%) AE's occurred in ICU or recovery, 23 (54.8%) of which occurred in ICU, 4 (9.5%) in recovery, on awakening, 11(26.2%) and 2 (4.8%) unidentified. A total of 286 AE's (43.7%) occurred during care on the unit, 9 AE's (1.4%) during the discharge advisory (recommendations) and 4 (0.6%) for which the source of the AE is not stated.

The nature of the principal problem may have been an error in diagnosis, a problem in the overall assessment, in the supervision and care, of nosocomial infection, a surgical procedure-related problem, related to the use of the medication or another type of problem.

A total of 37.4% of the AE's (245) were related to the medication, nosocomial infections of any type totalling 25.3% (166) of all of the AE's, 25% (164) having been related to technical problems during a procedure. The different types of AE's precisely as spread in the study are shown in Table 25.

Table 25. Types of AE's

Types of AE's	No.	%
Related to the care provided	**50**	**7.63**
Pressure ulcer	24	3.66
Burns, scrapes and contusions (including resulting fractures)	19	2.90
Acute Pulmonary Edema and respiratory failure	4	0.61
Other consequences of long-term immobilisation	3	0.46
Medication-related	**245**	**37.4**
Nausea, vomiting or diarrhoea secondary to medication	32	4.89
Pruritus, rash or skin lesions reactive to drugs or dressings	32	4.89
Other secondary effects of drugs	29	4.43
Poorly controlled glycaemia	19	2.90
Haemorrhage due to anticoagulation	18	2.75
Worsening of renal function	13	1.98
Upper digestive tract haemorrhage	13	1.98
Delay in treatment	11	1.68
Heart failure and shock	10	1.53
AMI, CVA, PTE	9	1.37
Neutropenia	9	1.37
Drug-related neurological alterations	9	1.37
Drug-related alteration in heart rate or electrical activity	9	1.37
Drug-related hypotension	7	1.07
Opportunist infection due to immunosuppressing treatment	6	0.92
Electrolyte imbalance	6	0.92
Drug-related headache	5	0.76
Ineffective medical treatment	5	0.76
Adverse reactions to anaesthetic agents	3	0.46
Nosocomial infection-related	**166**	**25.34**
Surgical wound infection	50	7.63
Nosocomial UTI	45	6.87
Other type of nosocomial infection or unspecified nosocomial infection	22	3.36
Sepsis and septic shock	19	2.90
Nosocomial pneumonia	17	2.60
Device-related bloodstream infection	13	1.98
Procedure-related	**164**	**25.04**
Haemorrhage or hematoma related to surgical operation or procedure	61	9.31
Injury to an organ during a procedure	20	3.05
Other complications following surgical operation or procedure	14	2.14
Ineffective or incomplete surgical operation	11	1.68
Uterine tear	9	1.37
Pneumothorax	7	1.07
Suspension of surgical operation	6	0.92
Urine retention	6	0.92
Eventration o evisceration	6	0.92
Suture dehiscence	5	0.76
Hematuria	5	0.76
Local radiation therapy-related complications	4	0.61
Seroma	5	0.76
Adhesions or functional alterations following surgical operation	3	0.46
Childbirth-related complications in new-born	2	0.31
Diagnosis-related	**18**	**2.75**
Delay in diagnosis	10	1.53
Diagnostic error	8	1.22

Others	**12**	**1.83**
Pending specifying	7	1.07
Other AE's	5	0.76
Total	**655**	**100.00**

A total of 4% (227) of the patients studies had some medication-related AE (245 AE's).

A total of 2.8% (156) of the patients studied had some type of nosocomial infection (166 AE's).

A total of 0.3% (18) of the patients studied has pressure ulcer (24 AE's).

Table 26 shows the different types of AE's by hospital size.

Table 26. Types of AE's by hospital size

Types of AE's by hospital size						
	Large-sized		Medium-sized		Small-sized	
	AE's	%	AE's	%	AE's	%
Healthcare-related	**28**	**8.78**	**14**	**5.28**	**8**	**11.27**
Pressure ulcer	11	3.45	8	3.02	5	7.04
Burns, scrapes and contusions (including resulting fractures)	11	3.45	5	1.89	3	4.23
Acute Pulmonary Edema and respiratory failure	3	0.94	1	0.38	0	0.00
Other consequences of long-term immobilisation	3	0.94	0	0.00	0	0.00
Medication-related	119	37.30	93	35.09	32	45.07
Nausea, vomiting or diarrhoea secondary to medication	18	5.64	6	2.26	8	11.27
Pruritus, rash or skin lesions reactive to drugs or dressings	12	3.76	18	6.79	2	2.82
Other secondary effects of drugs	16	5.02	11	4.15	2	2.82
Poorly controlled glycaemia	11	3.45	6	2.26	2	2.82
Haemorrhage due to anticoagulation	13	4.08	4	1.51	1	1.41
Worsening of renal function	6	1.88	6	2.26	1	1.41
Upper digestive tract haemorrhage	5	1.57	6	2.26	2	2.82
Delay in treatment	5	1.57	4	1.51	1	1.41
Heart failure and shock	5	1.57	4	1.51	1	1.41
AMI, CVA, PTE	6	1.88	2	0.75	1	1.41
Neutropenia	3	0.94	6	2.26	0	0.00
Drug-related neurological alterations	4	1.25	5	1.89	0	0.00
Drug-related alteration in heart rate or electrical activity	2	0.63	5	1.89	2	2.82
Drug-related hypotension	3	0.94	1	0.38	3	4.23
Opportunist infection due to immunosuppressing treatment	1	0.31	2	0.75	3	4.23
Electrolyte imbalance	1	0.31	3	1.13	2	2.82
Drug-related headache	5	1.57	0	0.00	0	0.00
Ineffective medical treatment	2	0.63	2	0.75	1	1.41
Adverse reactions to anaesthetic agents	1	0.31	2	0.75	0	0.00
Nosocomial infection-related	63	19.75	83	31.32	20	28.17
Surgical wound infection	19	5.96	28	10.57	3	4.23
Nosocomial UTI	17	5.33	20	7.55	8	11.27
Other type of nosocomial infection or unspecified nosocomial infection	10	3.13	8	3.02	4	5.63
Sepsis and septic shock	10	3.13	7	2.64	2	2.82
Nosocomial pneumonia	5	1.57	10	3.77	2	2.82
Device-related bloodstream infection	2	0.63	10	3.77	1	1.41
Procedure-related	88	27.59	68	25.66	8	11.27
Haemorrhage or hematoma related to surgical operation or procedure	31	9.72	24	9.06	6	8.45
Injury to an organ during a procedure	10	3.13	10	3.77	0	0.00

Other complications following surgical operation or procedure	11	3.45	3	1.13	0	0.00
Ineffective or incomplete surgical operation	7	2.19	3	1.13	1	1.41
Uterine tear	7	2.19	2	0.75	0	0.00
Pneumothorax	3	0.94	4	1.51	0	0.00
Suspension of surgical operation	1	0.31	4	1.51	1	1.41
Urine retention	2	0.63	4	1.51	0	0.00
Eventration o evisceration	3	0.94	3	1.13	0	0.00
Suture dehiscence	5	1.57	0	0.00	0	0.00
Hematuria	4	1.25	1	0.38	0	0.00
Local radiation therapy-related complications	2	0.63	2	0.75	0	0.00
Seroma	1	0.31	4	1.51	0	0.00
Adhesions or functional alterations following surgical operation	1	0.31	2	0.75	0	0.00
Childbirth-related complications in new-born	0	0.00	2	0.75	0	0.00
Diagnosis-related	10	3.13	6	2.26	3	4.23
Delay in diagnosis	6	1.88	4	1.51	1	1.41
Diagnostic error	4	1.25	2	0.75	2	2.82
Others	11	3.45	1	0.38	0	0.00
Pending specifying	6	1.88	1	0.38	0	0.00
Other AE's	5	1.57	0	0.00	0	0.00
Total	319	100.0	265	100.0	71	100.0

As can be seen, there is a similar pattern, although differences can be found in the comparison among the hospitals by size in the regard that all of the groups of AE's have a higher percentage in the small-sized hospitals than in all of the hospitals as a whole, except in the group of procedure-related AE's. The higher percentage of nosocomial infection-related AE's in the medium-sized hospital grouping is of special note.

Table 27 shows the different types of AE's by hospital unit.

Table 27. Types of AE's by hospital unit type.

Types of AE's by Hospital Unit Type				
	Medical Unit		**Surgical Unit**	
	AE's	**%**	**AE's**	**%**
Healthcare-related	27	8.7	23	6.7
Pressure ulcer	9	2.9	15	4.4
Burns, scrapes and contusions (including resulting fractures)	14	4.5	5	1.5
Acute Pulmonary Edema and respiratory failure	2	0.6	2	0.6
Other consequences of long-term immobilisation	2	0.6	1	0.3
Medication-related	168	53.8	76	22.2
Nausea, vomiting or diarrhoea secondary to medication	23	7.4	9	2.6
Pruritus, rash or skin lesions reactive to drugs or dressings	13	4.2	19	5.5
Other secondary effects of drugs	22	7.1	7	2.0
Poorly controlled glycaemia	18	5.8	1	0.3
Haemorrhage due to anticoagulation	12	3.8	6	1.7

Worsening of renal function	8	2.6	5	1.5
Upper digestive tract haemorrhage	9	2.9	4	1.2
Delay in treatment	7	2.2	3	0.9
Heart failure and shock	6	1.9	4	1.2
AMI, CVA, PTE	5	1.6	4	1.2
Neutropenia	9	2.9	0	0.0
Drug-related neurological alterations	5	1.6	4	1.2
Drug-related alteration in heart rate or electrical activity	8	2.6	1	0.3
Drug-related hypotension	3	1.0	4	1.2
Opportunist infection due to immunosuppressing treatment	6	1.9	0	0.0
Electrolyte imbalance	6	1.9	0	0.0
Drug-related headache	4	1.3	1	0.3
Ineffective medical treatment	4	1.3	1	0.3
Adverse reactions to anaesthetic agents	0	0.0	3	0.9
Nosocomial infection-related	66	21.2	100	29.2
Surgical wound infection	3	1.0	47	13.7
Nosocomial UTI	25	8.0	20	5.8
Other type of nosocomial infection or unspecified nosocomial infection	12	3.8	10	2.9
Sepsis and septic shock	8	2.6	11	3.2
Nosocomial pneumonia	10	3.2	7	2.0
Device-related bloodstream infection	6	2.6	5	1.5
Procedure-related	35	11.2	129	37.6
Haemorrhage or hematoma related to surgical operation or procedure	12	3.8	49	14.3
Injury to an organ during a procedure	2	0.6	18	5.2
Other complications following surgical operation or procedure	5	1.6	9	2.6
Ineffective or incomplete surgical operation	1	0.3	10	2.9
Uterine tear	0	0.0	9	2.6
Pneumothorax	5	1.6	2	0.6
Suspension of surgical operation	1	0.3	5	1.5
Urine retention	2	0.6	4	1.2
Eventration o evisceration	1	0.3	5	1.5
Suture dehiscence	1	0.3	4	1.2
Hematuria	2	0.6	3	0.9
Local radiation therapy-related complications	3	1.0	1	0.3
Seroma	0	0.0	5	1.5
Adhesions or functional alterations following surgical operation	0	0.0	3	0.9
Childbirth-related complications in new-born	0	0.0	2	0.6
Diagnosis-related	9	2.9	10	2.9
Delay in diagnosis	6	1.9	5	1.5
Diagnostic error	3	1.0	5	1.5
Others	7	2.2	5	1.5
Pending specifying	4	1.3	3	0.9
Other AE's	3	1.0	2	0.6
Total	312	100.0	343	100.0

As can be seen above, the pattern, as anticipated, differs on taking the type of hospital unit into consideration. The infection and procedure-related AE's were more frequent (three times greater) in the surgical units, whilst the medication-related AE's were more frequent in the medical units (more than double).

6. AE's in the prehosptialisation period

A total of 45.8% of the 135 patients whose AE had occurred during the prehosptialisation period were admitted to a large-sized hospital, 43.5% to a medium-sized hospital and 10.7% to a small-sized hospital. A total of 58% of the cases were admitted to a medical unit, whilst 42% were admitted to a surgical unit.

A total of 56.6% were females and 43.4% males; these patients averaging 72 years of age.

The nature of the principal problem was an error in diagnosis in 8.1%, a problem with the overall evaluation in 8.9%, the supervision and care in 3.7%, nosocomial infection in 17.8%, a surgical procedure-related problem in 17.8%, a problem related to the use of medications in 34.8% and related to another type of problem in 8.1% of the cases.

7. AE's resulting in hospital admissions

Of the 473 patients who has hospital healthcare-related AE's, the AE result in readmission in 105 patients, whilst is led to hospital admission in 46 of the patients whose AE occurred in the prehosptialisation period or at a different hospital. Thus, of the 151 patients whose AE involved admission, 47% were admitted to a large-sized hospital, 41.7% to a medium-sized hospital and 11.3% to a small-sized hospital. A total of 51.7% of the patients were readmitted to a medical unit, while 48.3% were readmitted to a surgical unit. A total of 49.7% were females and 50.3% males, these patients averaging 71 years of age. However, the percentage of AE's having resulted in readmission by hospital size was practically tallies exactly with these figures (Table 28).

Table 28. Percentage of AE's resulting in readmission

	AE's	% resulting in readmission
Large-sized hospitals	319	22.9
Medium-sized hospitals	265	23.8
Small-sized hospitals	71	23.9
Medical units	312	25.0
Surgical units	343	21.9
Total	655	23.4

The nature of the principal problem was an error in diagnosis in 6.66%, a problem in the overall evaluation in 7.9%, the supervision and care in 3.3%, nosocomial infection in 19.9%, a surgical procedure-related problem in 25.2%, a problem related to the use of the medication in 29.8% and related to another type of problem in 7.9% of the cases.

8. Impact of the AE's

A total of 45% (295 AE's) were considered slight, 38.9% (255) moderate and 16% (105) severe.

At the large-sized hospitals, 49.5% were slight, 35.4% moderate and 15% severe. At the medium-sized hospitals, 38.9% were slight, 43.4% moderate and 17.7% severe. At the small-sized hospitals, 47.9% were slight, 38% moderate and 14.1% severe. The differences found were not statistically significant (p=0.125).

In the medical units, 50% were slight, 42.9% moderate and 7.1% severe, whilst in the surgical units, 40.5% were slight, 35.3% moderate and 24.2% severe. The spread differentials were statistically significant (p<0.001).

A total 31.4% of the AE's resulted in a extended hospital stay, and 24.4% of the AE's conditioned admission (some patients who were readmitted for AE's had more than one AE), the full hospitalisation therefore being due thereto. This load involved a median 4 days for the AE's which extended the hospital stay and 7 days for those resulting in readmission. Thus, the total additional stays caused by AE's totalled 3,200 (6.1 additional stays per patient), a total of 1,157 of which were preventable AE's (2.2 preventable stays per patient).

A total of 66.3% of all AE's required additional procedures being performed (e.g. radiodiagnosis tests) and additional treatments in 69.9% (e.g. medication, rehabilitation or surgery).

A total of 102 of the 5,624 patients followed up were studied due the criteria of **death** being involved in the Screening Guide, and 10 who were followed up for other reasons (a different screening criterion) were also *death*. Of these 112 patients (2.0% of the total number of patients), 23 had an AE (20.5% of the *death* and 0.41% of the total number of patients). As a result thereof, the *death* incidence rate among subjects who had

AE's was 4.4% (95%CI 2.8 - 6.5). In 15 of these patients (13.4% of the *death* and 0.2% of the total number of patients), a relationship exists between the AE and the *death*, 7 AE's being considered to be the direct causes of the *death*. Solely in one case was the AE which caused the *death* considered preventable. Half of the 8 AE's which were related were considered preventable.

9. Preventability

To mine the preventability of the AE's, the possibility of their being prevented was scored on a 1-6 scale(1 = no evidence of preventability; 6= total evidence). Those AE's score within the 1-3 range were considered unpreventable or hardly preventable, those scoring higher than 3 on this scale being considered preventable. The spread of this characteristics is shown in Table 29.

Scale	No.	%
1. No evidence	206	31.5
2. Minimal probability	54	8.2
3. Slight probability	114	17.4
4. Moderate probability	209	31.9
5. Highly probable	61	9.3
6. Total evidence	8	1.2
Losses	3	0.4
Total	655	100.0

A total of 42.6% (278/652) of the AE's were preventable, whilst 57.4% (374/652) thereof were unpreventable.

No associations were found between the degree of preventability and the type of hospital unit, but were however indeed found with regard to the size of the hospital. A total 40.0% of the AE's of patients hospitalised in a large-size hospital were preventable. Likewise preventable were the 39.8% of those who were hospitalised in a medium-sized hospital, whilst 64.8% of the AE's of patients in small-sized hospitals were preventable.

The preventability of the AE's was not related to their severity, such that 43.8% of the slight AE's, 42.0% of the moderate AE's and 41.9% of the severe AE's were preventable, although, as was to be expected, the slight AE's entail a greater degree of preventability (Table 30).

Table 30. AE Severity and Preventability

	Unpreventable	Preventable
Slight %	55.8	43.8
Moderate %	58.0	42.0
Severe %	58.1	41.9

Considering all of the AE's, 84.2% of the diagnosis-related AE's, 55.4% of the nosocomial infection-related AE's and 52.0% of the healthcare-related AE's were considered preventable (Table 31).

Table 31. AE Type and Preventability

TYPE	Med.	Surg.	Total	Preventable
Procedure-related	11.2	37.6	25.0	31.7
Nosocomial infection-related	21.2	29.2	25.3	56.6
Medication-related	53.8	22.2	37.4	34.8
Healthcare-related	8.7	6.7	7.6	56.0
Diagnosis-related	2.9	2.9	2.7	84.2
Others	2.2	1.5	1.8	33.3
Total	312	343	655	278 (42.6%)

The preventability pattern shows no major differences by hospital units, although the nosocomial infection-related AE's are more preventable in the medical units, whilst the diagnosis-related AE's are more preventable in the surgical units (Tables 32 and 33).

Table 32. AE Type and Preventability. Medical Units

TYPE OF PROBLEM	Medical (%)	Preventable (%)
Procedure-related	11.2	34.3
Nosocomial infection-related	21.2	60.6
Medication-related	53.8	36.3
Healthcare-related	8.7	55.6
Diagnosis-related	2.9	77.8
Others	2.2	33.3
Total	312	137 (44.1%)

Table 33. AE Type and Preventability. Surgical Units

TYPE OF PROBLEM	Surgical (%)	Preventable (%)
Procedure-related	37.6	31.0
Nosocomial infection-related	29.2	54.0
Medication-related	22.2	31.6
Healthcare-related	6.7	56.5
Diagnosis-related	2.9	90.0
Others	1.5	33.3
Total	343	141 (41.3%)

10. *Expanded Incidence Rate*: Including all phlebitis cases
A total of 182 patients who has phlebitis as their sole AE, must be added to the 525 patients having healthcare related-AE's, totalling 707 patients having AE's.

The expanded incidence rate of patients having healthcare-related AE's was 12.6% (707/5,624); 95%CI: 11.7% - 13.4%. The extended incidence rate of patients with AE's directly related to the hospital care provided (excluding those in primary care, out-patient treatment and those caused in a different hospital) was 11.6% (655/5,624); 95% CI: 10.8% -12.5%.

The expanded incidence rate of AE's was higher at the small-sized hospitals, was lower at the large-sized hospitals and lowest at the medium-sized hospitals. In turn, this incidence rate was higher in the medical units than in the surgical units.

The expanded incidence rate by hospital type and by hospital unit is shown in Table 34.

Table 34. Expanded incidence rate by layer

	Patients	Incidence Rate	95% CI
Large-sized hospitals	284	12.4%	11.1-13.8
Medium-sized hospitals	308	10.7%	9.6-11.8
Small-sized hospitals	63	14.0%	10.8-17.2
Medical units	332	13.6%	12.2-14.9
Surgical units	323	10.2%	9.1-11.2
OVERALL	655	11.6%	10.8-12.5

These 655 patients cumulatively totalled 876 hospital care-related AE's.

11. *Extended Incidence density*: including all phlebitis cases
The extended AE incidence density was 2.05 AE's for every 100 days of hospital stay. At the large-sized hospitals, 2.1 AE's for every 100 days of stay; at the medium-sized hospitals, 1.8 AE's for every 100 days of stay; and at the small-sized hospitals, 3.8 AE's for every 100 days of stay. By type of hospital unit, the extended incidence density was 2.0 AE's for every 100 days of stay in the medical units and 2.1 AE's for every 100 days of stay in the surgical units (Table 35).

Table 35. Extended Incidence density by layer

	AE's	Incidence density	95% CI
Large-sized hospitals	405	2.11/100 days	1.90-2.31/100 days
Medium-sized hospitals	376	1.79/100 days	1.61-1.97/100 days
Small-sized hospitals	95	3.77/100 days	3.01-4.53/100 days
Medical units	450	1.99/100 days	1.80-2.17/100 days
Surgical units	426	2.13/100 days	1.92-2.33/100 days
OVERALL	876	2.05/100 days	1.92-2.19/100 days

12. *Extended Incidence Rate* Impact

A total of 61.3% (570 AE's) were considered slight, 27.4% (255) moderate and 11.3% (105) severe.

At the large-sized hospitals, 62.3% were slight, 26.5% moderate and 11.2% severe. At the medium-sized hospitals, 59.7% were slight, 28.6% moderate and 11.7% severe. At the small-sized hospitals, 63.4% were slight, 26.7% moderate and 9.9% severe. The differences were not statistically significant (p= 0.924).

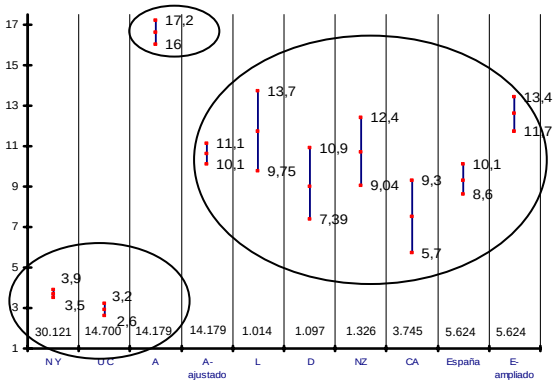
In the medical units, 68.1% were slight, 27.4% moderate and 4.5% severe; whilst in the surgical units, 53.7% were slight, 27.4% moderate and 18.8% severe. The differences in the spread were statistically significant (p<0.001).

INTERPREATION OF RESULTS

The national study on the adverse events related to hospitalisation (ENEAS) is frameworked within a set of studies conducted with the objective of quality improvement. Hence, al pursuing a maximum degree of knowledge as to prospects of improving healthcare quality, the methodology employed takes in the possibility of a subject having more than one adverse event during an episode of hospitalisation, including in the analysis of the AE's which may be caused during the per-hospitalisation period which are detected during their hospital stay, as well as those which have occurred during a previous hospitalisation which are the cause of readmission to the hospital. Sever, moderate and slights AE's are additionally included.

The incidence rates for patients having hospital care-related AE's [8.4% (95% CI: 7.7-9.1)] and healthcare-related AE's [9.3% (95% CI: 8.6%-10.1%)] fall within the rates found in the set of quality improvement-oriented studies, no differences being found between the values of the Adjusted Australian, London, Danish, New Zealand and Canadian studies and much higher than the U.S. rates but lower that the unadjusted Australian study, even on considering the extended incidence rate, which includes phlebitis as an adverse event (Fig. 5). These results are closely in keeping with the methodology employed.

Fig. 5. AE incidence rate of the main studies



NY: New York, UC: Utah and Colorado; A: Australia, L: London (UK), D: Denmark, NZ: New Zealand, CA: Canada, Spain and E-extended: Extended Spain

The patients having AE's average 12 years older than those having no AE's. This result is congruent with that found in most of the studies. The risk of developing an AE among those over 65 years of age is double that of those under age 65 (RR: 2 95% CI: 1.5-2.6) tallying with the results of the HMPS[11] in our study; and just as in the other studies, we found no differences for reasons of sex. This may be due to a general analysis having been made which prevents inferences at this level. In order to be able to properly explore whether or not any association exists between sex and AE's, it should be controlled by the diagnostic complexity, given that most of the females within the 25-45 age range are discharged at the hospital with a diagnosis of childbirth without any complications, and this factor could be causing some mix-up in the results obtained. In order to be able to properly answer the question as to whether any sex-AE relationship exists, subsequent studies should be conducted taking into account the primary diagnosis or the Diagnosis-Related Group (DRG) of the hospitalisation episode in question.

On exploring the incidence rate of patients having an AE and the factors which may have been related thereof, it has not been possible to analyse the association with the patient's degree of severity, given that there was no variable available which would explicitly furnish this information. However, we have approximated this assessment on exploring the association with age, the length of the hospital stay and both the intrinsic and extrinsic risk factors, which may be indirect indicators of the degree of severity.

This study reveals the degree of vulnerability on the part of the patients to be a decisive factor solely noted to date in the occurrence of healthcare-related AE's on having been able to measure both the intrinsic and extrinsic risk factors of all of the patients included in the study as a whole, regardless of whether or not they had AE's. Thus, the greater the number of risk factors, the higher the risk of having an AE. Even more interesting is the result obtained in regard to the occurrence of AE's and the presence of extrinsic risk

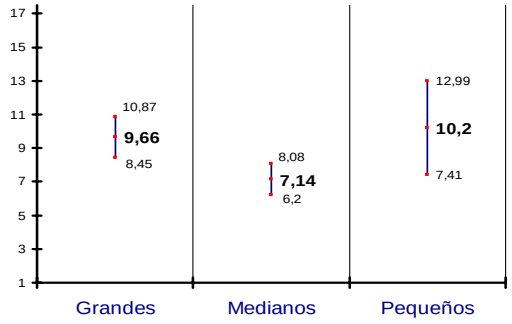
factors, since although it is difficult to take action on the intrinsic risk factors, given that they are factors not greatly lending themselves to change, action can indeed be taken on the extrinsic risk factors. Reducing them to the lowest degree possible in each patient would considerably minimise the risk of AE's occurring.

One further factor in favour of the relationship between the patient's degree of vulnerability and the risk of having an AE is the result that 17.7% of those patients having AE's have more than one AE. The prognosis (primary illness with possible residual permanent disability) as well as the presence of co-morbidities, are related to the degree of severity of the AE's, although not linearly. These results are similar to those found in the study conducted by Michel et al.[55] in France.

We have found differences in the incidence rate depending upon the hospital size, being higher at the small-sized hospitals and lower at the medium-sized hospitals, in both cases related to the large-sized ones. This result differs slightly to that found by Baker et al.[18] in a study of 20 hospitals in Canada. In the case thereof, the larger the size of the hospital, the higher the incidence rate. Our result may be conditioned by the number of patients followed up, which, on being proportionally smaller in the case of the small-sized hospitals, leads to the confidence interval for the estimated incidence rate to being quite broad, which may also be influence by other variables conditioning the AE which have not been taken into account.

As a illustration of that which has been commented upon up to this point, the AE incidence rate and the confidence intervals thereof are provided in Fig. 6 below. As can be seen therein, the estimate for the case of the small-sized hospitals is not very accurate, on showing a broader confidence interval, in addition to the difference being quite close to zero (OR: 1.44; 95% CI: 1.02-2.02), due to the sample size of the small-sized hospitals differing substantially from that which had been estimated.

Fig. 6. AE incidence rate by hospital size



Large-sized	Medium-sized	Small-sized

This study makes it possible to establish the hospital stay-AE relationship, such that it is, on one hand, clearly a risk factor (adjusted by all of the other variables) - the longer the stay, the greater the risk of AE - and, on the other hand, is also a clear-cut result of the AE, given that the AE prolongs the hospital stay.

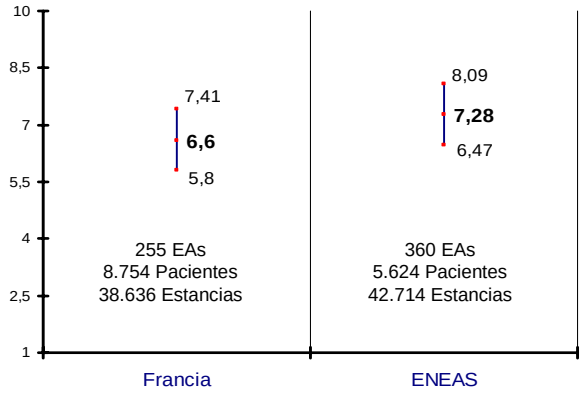
The highest incidence density for the small-sized hospitals may be conditioned by the shorter average length of stay at these hospitals, which makes the denominator noticeably proportionally lower. This result might also be explained by a possible bias of information, due to differences in completing the case record and due to the characteristics of the patients. In any event, this result must be considered with a great deal of caution, because the estimate is not highly accurate and is therefore an aspect to be studied specifically at some point in the future.

The large-sized hospitals have an incidence density higher than the medium-sized hospitals, possible conditioned by the higher complexity of the clinical practice.

Perhaps the hospital size may not currently be an appropriate characteristics for classifying the hospitals, such that seeking a combination between the available technology and the complexity of clinical practice may be interesting for grouping the different types of hospitals thinking about the patient's clinical safety and the care-related AE's.

The only study which provides information on incidence density is the French study, but in the case thereof solely the severe adverse affects[55] are studied. The results b adjusting the methodology of both studies are absolutely comparable (Fig. 7). In our case, we additionally found that the rate for the surgical units practically doubles that of the medical units, just as was to be expected in view of the different invasive technique and instrumentalisation load.

Fig. 7. Moderate or severe AE incidence density



255 AE's 8,754 Patients 38,636 Stays France	360 AE's 5,624 Patients 42,714 Stays ENEAS

Although lower than the percentage found in the Canadian study conducted by Baker et al.[18] , the percentage of AE's which occur in the prehosptialisation period (20.6% vs. 31%) which are detected during the hospital stay is far from negligible. This fact is particularly important in a National Health System such as ours, which as a high degree of accessibility and a highly-developed Primary Care. Three problems: nosocomial infection, the surgical procedures and the problems related to the use of medications, explain 70.4% of all AE's which occur within the prehosptialisation period, those related to the use of medications, which total 34.8%, being of outstanding importance.

It would be of interest to delve deeper into the study of the AE's linked to Primary Care, not only those which lead to hospitalisation, but all those which have their origins therein, taking into account such a high degree of frequentation as our healthcare system shows. Something similar could be said concerning the AE's linked to the Emergency Care Units[56] . Although this study was not designed for such a purpose, it has already advanced some items of date making it possible to recommend this analysis strategy. A total of 9.6% of the AE's within the prehosptialisation period occur in Emergency Care Units during some care prior to that which gives rise to the hospitalisation, and also some AE's which occurred within the ward admission period have their origins in the Emergency Care Unit (37.5%).

Regarding the type of problems giving rise to AE's, this study identifies prospects for improvement heretofore not objectivated to any major degree. That far from negligible 7.6% of AE's related to the care provided in the wards, which is ranked fourth in frequency following those related to the use of medications, nosocomial infection and surgical techniques, and the incidence of which is perhaps underestimated, moves up to the top-ranked position when phlebitis is also considered as being an AE. On the other hand, for all these AE's, there are designed strategies or proven effectiveness. The challenge seemingly lies in the practical implementation thereof.

Although this is not a study specifically designed for the analysis of the adverse events linked to the use of medications, it has proven itself to be highly effective for this purpose. This group is that showing the highest frequency among the different types of AE's. Additionally, it makes it possible to identify that 4.1% of the hospitalised patients studied have at least one AE related to the use of the medication involved, a result which doubles that found by Bates et al.[57] , although it be lower than that found by Otero et al.[58] . This result is of special importance in the case of the medical units, as is revealed by Alcalde et al.[59] .

The use of the medication in the process of providing patient care is a complex system in which the expertise of the professionals, the precision of the teamwork and the patient's individual susceptibility interact, hence management by processes, which makes it possible to establish the components of the process, their relations and the activities are ensuring success with safety for the patient, is an appropriate answer to quality improvement[60] .

The adverse events related to the use of medication can be approached from an individual standpoint aimed at establishing the cause-effect relationship, the human errors and the faults in the system[61] , or from a collective standpoint affording the possibility of identifying the risk factors as well as the characteristics related to the adverse events in a group of patients. This study has been conducted along the lines of the latter of these two groups.

The problems of the AE's which give rise to hospital admissions or readmissions are nosocomial infection, surgical procedures and the problems related to the sue of medications, which explain 74.9 % of the readmissions.

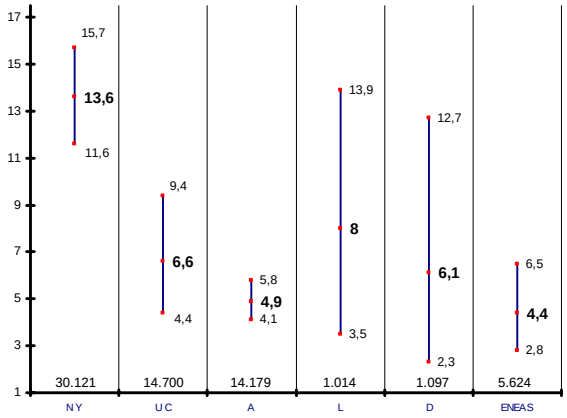
The impact pattern of the AE's according to their degree of severity is congruent with that stated in all of the studies conducted as a whole. A total of 16% were considered severe, and the death related to the AE occurred in 17 patients (1.9%) of those included in the study. No differences in pattern are found either by hospital size, although differences have been found by type of unit, such that a higher number of severe AE's were found in the surgical units.

The death rate of the subjects having AE's was lower than that found in other studies, although the difference is not statistically significant with the exception of the HMPS, with which all of the other studies show differences, as can be seen in Table 36 and in Fig 8 below.

Table 36. Incidence of *death* in patients having AE's in the main studies

Study	Incidence rate (%)	95% CI
Harvard Medical Practice Study	13.6	11.6 - 15.7
Utah and Colorado	6.6	4.4 - 9.4
Quality in Australian Healthcare Study	4.9	4.1 - 5.8
London	8.0	3.5 - 13.9
Denmark	6.1	2.3 - 12.7
ENEAS	4.4	2.8 - 6.5

Fig. 8. Death incidence rate in the main studies



NY. New York; UC: Utah and Colorado; A: Australia; L: London (UK); D. Denmark; NZ: New Zealand; CA: Canada; Spain and E-extended: Extended Spain. The value shown on the "X" axis in each study is the number of subjects studied.

Additionally, according to the data furnished by the Spanish National Institute of Statistics, the death rate in Spain is 8.71 / 1000 inhabitants, and the death rate at the hospital is 3.8% deaths related to the total number of hospital discharges, taking into account that a subject may be provided with care at a hospital several times (the readmissions rate has been estimated at approximately 20%), which means that this statistic may be underestimating the actual hospital death rate. In fact, form example, the Autonomous Community of Valencia MBDS for 2002 recorded a total of 395,486 discharges (episodes of hospitalisation) and a total of 315,127 subjects hospitalised, with a total *death* of 13,418, the death rate on the total number of discharges therefore being 3.4% and the death rate on hospitalised subjects 4.3%.

Although there are no statistically significant difference between the overall hospital death rate and that found among the subjects having AE's, the differences may also be explained because, firstly, the study was not designed to study this relationship, so that those patients who did not remain hospitalised for more than one day were excluded, and the Screening Guide death criterion was reserved for those cases in which the death occurred unexpectedly, in those which neither the prognosis nor the degree of severity of the illness, nor the patient's condition, nor the patient's age made it foreseeable, it therefore being necessary to take this indirect measurement of the death rate cautiously.

Regarding the degree of preventability, no association has been found in our study between the degree of preventability and the degree of severity of the AE's. This result tallies with that found in the Canadian study which states preventability as being independent of severity[19] .

Limitations of the study

The AE's have been identified by means of the information included in the medical records. The poor quality thereof may have led us to underestimate the AE incidence rate.

With regard to the quality of the notes on the medical records, the reviewers have considered the AE-related information furnished thereby to have been inadequate or barely adequate in 19.0% of the cases.

The spread by hospital size and hospital unit type is summarised in Tables 37 and 38.

Table 37. Assessment of the medical record quality by hospital size

Hospital size	Inadequate or barely adequate information	Adequate or highly adequate information
Large-sized	19.78	80.22
Medium-sized	15.91	84.09
Small-sized	29.17	70.83

Table 39. Assessment of the medical record quality by hospital unit type

Hospital unit type	Inadequate or barely adequate information	Adequate or highly adequate information
Medical unit	17.05	82.95
Surgical unit	20.86	79.14

The typing of AE's resulting form the care more than from the nosological process per se is a value judgement on the part of the reviewer and, thus, in order to increase the degree of confidence as to this being so, the surveyors were asked to score the degree of probability that it was due to the care on a 1-6 scale, a figure of ≥ 4 being required to be considered as such. This same criterion has been employed for assessing the adverse event as being preventable, for the sake of improving the objectivity of the value judgement.

The Screening Guide has been used in the cohort studies conducted in the U.S.[11, 12, 13] , Australia[14] and in different European countries[15] . This Guide has a high degree of sensitivity (84%) for detecting AE's, we thus assuming that the number of false negatives must be minor, although the number of false positives has been calculated with the revision of the second questionnaire (MRF2), a predictive value of 71.5% (95% CI: 69.3% - 73.6%) having been found. This figure is far above the figure estimated (20%) in other studies[13] which served for calculating the work loads of the reviewers.

The screening criteria have not be applied the same throughout all of the hospitals, hence the *death* criterion required a number of characteristics which led them to take it into consideration if it resulted positive, such as unexpected death related to a procedure, etc. not taken into account by some reviewers which may modify the calculated positive predictive value. Even so, a value much higher than that calculated in other studies[19] has been found.

The Spanish version of the Stage Questionnaire for case review MRF2, has been adapted to our country for carrying out the IDEA Project, being a questionnaire on which the researcher must make some value judgements, as a result of which the researcher must be a person who is an expert on the subject and who is capable of detecting the adverse events by means of criteria which is most often implicit, and the specificity of the medical or surgical process may have hindered the exhaustive typing of the adverse event at times. To this end, the concordance analysis and training has been carried out, which has found values higher than those published by the U.S. and European studies. The degree of reliability of the questionnaire assessed in other studies as been typed as moderate[62], having been moderate to good in our study.

We believe the participation of those involved in the processes in the identification and typing of the AE's to be fundamental, so that in those circumstances in which there may be some sort of controversy, they may aid in clearing up the matter. Although, a priori, this entails a major limitation, it may be useful for the expert to become involved and take part in the problem analysis process and, a posterior, to collaborate in suggesting preventive measures.

The external reviewers were experts (internal medicine physicians and surgeons) in no way related to the unit under study and therefore not familiar with the characteristics concerning the type of work, task organisation, unit organisation, whether or not working protocols or clinical practice guides existed, etc., which often made it difficult to ascertain the circumstances which had ultimately given rise to the adverse event and therefore the potential preventability thereof, items which are included in Stage E and which have rarely been exhaustively assessed. Stage E must be answered by reviewers who know the unique aspects and working system of the unit being researched.

On the contrary, the instructional training specifically in AE assessment along with the impartiality of the assessment on being external professionals has its advantages and reduces the screening bias (incorrect identification of the cases) thus heightening the internal validity of the study.

VALUE OF THE STUDY

1.- The study objective-related findings:

1. At Spanish hospitals, adverse events were found to have a 9.3% healthcare-related incidence, with an 8.4% hospital care-related EA incidence, being similar to those found in the studies conducted in North American, Central American, South American and European countries employing a similar methodology.

The Spanish National Health System's efforts and the technical training of its professionals have made it possible for our country to be positioned among those showing the greatest concern for ensuring patient clinical safety, the AE's identified having been found to be similar in frequency and distribution to those conducted in other countries.

2. A total of 20.6% of all AE's occurred during the prehosptialisation period, the principal problem involved entailing the use of the medication (34.8%), nosocomial infection (17.8%) and surgical procedure-related (17.8%).

The frequency of AE's having not initially occurred during hospitalisation makes it advisable for new studies to be designed affording the possibility of a baseline analysis in other fields of care, such as Primary Care and both Hospital and Extrahospital Emergency Care.

3. The three immediate causes related to the AE's associated with healthcare at Spanish hospitals were, by order of frequency: medication-related causes, nosocomial infections and surgical procedure-related technical problem causes.

These results serve as a guide aiding in setting the priorities for ensuring Patient Clinical Safety through Clinical Management.

4. Similarly to others, our study has identified nearly half (42.8%) of the care-related AE's as being preventable.

The heightened awareness of well-informed professionals will facilitate preventing the readily avoidable, not doing that which is inappropriate or unnecessary plus being risky, and making that which is hardly avoidable more highly improbable.

It is necessary to continue researching the efficacy and effectiveness of the measures for preventing the AE's which are top priority due to their frequency or impact.

The dissemination of the clinical practice guides, recommendations founded on evidence and good practices must be a top-priority line of strategy in healthcare policy and the implementation thereof in clinical practice a responsibility of the healthcare professionals. Putting the available knowledge into practice is a guarantee for clinical safety.

5. The more universal and more highly complex healthcare is and the more vulnerable the patients are, the greater the impact care-related AE's have. In our study, 54.9% of the AE's were considered moderate or serious. A total of 31.4% of the AE's resulted in a longer hospital stay, the AE having conditioned admission in 24.4% of the cases. There was a 4.4% incidence of death among subjects having AE's.

Until quite recently, the health-related, social and economic impact of AE's has been a silent epidemic in our country, making the need for the study thereof a top Public Health priority. Among other aspects, we must leave the guilt-based culture behind to adopt the knowledge-based culture.

2. Other findings of the study:

6. This is the fifth most high-powered study - by number of subjects studied - ever conducted to date anywhere world-wide.

7. This study shows the Spanish National Health System to be a safe one, the results thereof being similar to those of the most highly-advanced countries.

8. Patient vulnerability has been identified therein as playing a major role in generating healthcare-related AE's.

9. The global nature of the study does not in any way lessen its discriminability in comparison to other more specific studies (e.g. medication error studies) for identifying both AE's as well as the points in time at which or the circumstances under which these effects occur during the care process.

10. This study has afforded the possibility of developing a specific AE study methodology by improving the way in which the professionals perceive AE, thus eliminating one of the main barriers to patient clinical safety.

11. There are still as yet questions remaining to be answered which a more detailed analysis of the available information will allow us to tackle, such as which Diagnosis-Related Groups total most AE's or studying AE's not by hospital size, but rather by diagnosis-treatment complexity, in addition to the economic repercussion thereof.

12. The baseline analysis made brings us to the need for a cultural change among healthcare professionals which will facilitate the promotion of the proactive culture for patient safety. Healthcare mesomanagement (hospital management teams) and healthcare macromanagement or policy must also be involved in contributing to this culture.

13. Availing of a baseline analysis makes it possible to be one step ahead of a problem of growing social repercussion and concern. The available results afford the possibility of informing the public at large, patients and media honestly, openly and transparently as to the healthcare-related risks and the measures which can be taken to avoid them.

Seeking collaboration with the population and the involvement of the social structures thereof is going to be a determining factor for this cultural change necessary for making headway in patient clinical safety.

14. Lastly, special mention must be made of the fact that this study would be useless were it not to serve for setting goals for improvements in care quality and in researching the appropriateness, effectiveness and efficiency of the healthcare provided.

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DIRECCIÓN GENERAL DE LA AGENCIA DE CALIDAD DEL SISTEMA NACIONAL DE SALUD

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Jesús María Aranaz Andrés

January 2006-06-04

HOSPITALIZATION-LINKED ADVERSE EVENTS

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HOSPITALIZATION-LINKED ADVERSE EVENTS

FORM

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HOSPITALIZATION-RELATED ADVERSE EVENTS

TABLES

Table 1. Statistical accuracy, by sample size	
Sample size	**Accuracy (%)**
5,500	1.445
6,000	1.379
6,500	1,320
7,000	1,268

Table 2. Sample, by hospital size			
Beds	**100-199**	**200-499**	**≥ 500**
N : 5,500	627	1,708	3,166
Hospital	5	11	4
N : 6,000	683	1,863	3,454
Hospital	6	12	5
N : 6,500	740	2,018	3,742
Hospital	6	13	5
N : 7,000	797	2,173	4,029
Hospital	7	14	5

Table 3. No. AE's and incidents by hospital unit type for the agreement analysis		
	Hospital unit type	
Events	**Internal medicine**	**General surgery**
Adverse events	19	13
Incidents	22	4
No adverse event or incident	7	5

Table 4. Event preventability, by Gold Standard		
	Events	**Adverse events**
Internal medicine	**Preventable**	17
	Unpreventable	2
General surgery	**Preventable**	11
	Unpreventable	2

Table 5. Degree of agreement, by kappa	
Kappa	**Degree of agreement**
< 0.20	**Poor**
0.21 - 0.40	**Fair**
0.41 - 0.60	**Moderate**
0.61 - 0.80	**Substantial**
0.81 - 1.00	**Almost perfect**

Table 6. Kappa. Study of degree of agreement in Internal Medicine		
	Internal Medicine	
Reviewers	**Adverse events**	**Preventability**
1	0.652	0.841
2	0.819	0.413
3	0.868	0.552
4	0.722	*
5	0.772	0.836

Table 7. Study of degree of agreement in General Surgery		
	General Surgery	
Reviewers	Adverse events	Preventability
1	0.510	*
2	0.784	*
3	0.488	0.354
4	0.431	*
5	0.488	0.276

Table 8. Screening guide results					
		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	Positive screening	1755	30.2	31.2	31.2
	Negative screening	3869	66.6	66.8	100.0
	Total	5624	96.9	100.0	
Lost	System	181	3.1		
Total		5805	100.0		

Table 9. Patients, by hospital type			
Hospitals	No.	Estimated no. patients	Actual no. patients
Large-sized	5	3742	2288
Medium-sized	13	2018	2885
Small-sized	6	740	451
Total	24	6500	5624

Table 10. Sample, by hospital type and hospital unit type			
Hospitals	**No.**	**Medical units**	**Surgical units**
Large-sized	5	996	1292
Medium-sized	13	1304	1581
Small-sized	6	150	301
Total	24	2450	3174

Table 11. Type of hospital stay in days		
		Hospital stay
No.	**Valid**	5609
	Lost	15
Mean		7.7
Median		5
Mode		2
Standard deviation		11.3
Total		42714

Table 12. Ages of the subjects under study		
		Age
No.	**Valid**	5509
	Lost	115
Mean		53.5
Median		59
Mode		72
Standard deviation		24.9
Total		294613.42

Table 13. Ages and length of stay in days caused by the subjects			
	Large	**Medium**	**Small**
Mean age (sd)	53.19 (24.3)	54.20 (23.9)	56.55 (23.6)
Median age	57	59	64
Stay (sd)	8.5 (10.8)	7.3 (11.7)	5.6 (10.4)
Median stay	5	5	3

Table 14. Sex of the subjects under study					
		Frequency	**Percentage**	**Valid percentage**	**Cumulative percentage**
Valid	**Female**	3031	53.9	54.5	54.5
	Male	2529	45.0	45.5	100.0
	Total	5560	98.9	100.0	
Lost		64	1.1		
Total		5624	100.0		

Table 15. False positives and incidents in Positive Screenings					
		Frequency	**Percentage**	**Valid percentage**	**Cumulative percentage**
Valid	**Patients w/AE's**	1063	60.6	60.6	60.6
	Patient only w/incidents	191	10.9	10.9	71.5
	False positives	501	28.5	28.5	100.0
Total		1755	100.0	100.0	

Table 16. Patients having illness-related and healthcare-related AE's			
Patients w/AE's	**No.**	**%**	**95% CI**
Illness-related	276	26.0%	23.3-28.6
Healthcare-related	787	74.0%	71.4-76.7
Minimal or slight probability	262	24.6%	22.1-27.2
Moderate or high probability	525	49.4%	46.4-52.4

Table 17. AE patients according to the situation of the principal care-related problem					
		Frequency	**Percentage**	**Valid percentage**	**Cumulative percentage**
Valid	**Prior to admission**	131	25.0	25.1	25.1
	At ward admission	8	1.5	1.5	26.7
	During a procedure	140	26.7	26.9	53.6
	Following a procedure	28	5.3	5.4	58.9
	In general ward	206	39.2	39.5	98.5
	At end of admission and discharge	8	1.5	1.5	100.0
	Total	521	99.2	100.0	
Lost		4	0.8		
Total		525	100.0		

Table 18. Location of occurrence of prehosptialisation period-related AE's					
		Frequency	**Percentage**	**Valid percentage**	**Cumulative percentage**
Valid	**In emergency room**	13	9.9	10.1	10.1
	In primary care	27	20.6	20.9	31
	In out-patient treatment	17	13	13.3	44.2
	In same unit, in primary care provided	47	35,9	36.4	80.6
	In a different unit in same hospital	17	13	13.2	93.8
	In a different hospital	8	6.1	6.1	100.0
	Total	129	98,5	100.0	
Lost		2	1.5		
Total		131	100.0		

Table 19. AE's per patient, by hospital type				
	Large-sized	**Medium-sized**	**Small-sized**	**Total**
0	2046 (89.4%)	2654 (92.0%)	399 (88.5%)	5099 (90.7%)
1	190 (8.3%)	201 (7.2%)	41 (9.1%)	432 (7.9%)
2	34 (1.5%)	26 (0.9%)	6 (1.3%)	66 (1.2%)
3	13 (0.6%)	4 (0.1%)	3 (0.7%)	20 (0.4%)
4 or more	5 (0.2%)	0 (0.0%)	2 (0.4%)	7 (0.1%)

Table 20. Patient healthcare-related AE incidence rate, by hospital and hospital unit type			
	Patients	**Incidence rate**	**95% CI**
Large-sized hospitals	221	9.66%	8.45-10.9
Medium-sized hospitals	206	7.14%	6.20-8.08
Small-sized hospitals	46	10.2%	7.41-13.0
Medical units	217	8.86%	7.73-10.0
Surgical units	256	8.07%	7.12-9.01
OVERALL	473	8.41%	7.69-9.14

Table 21. Patient incidence rate for hospitalisation-related AE's causing readmission			
	AE's	**Readmissions**	**95% CI**
Large-sized hospitals	52	24.9%	19.0-30.7
Medium-sized hospitals	42	20.8%	15.2-26.4
Small-sized hospitals	11	24.4%	12.9-39.5
Medical units	43	20.5%	15.0-25.9
Surgical units	62	25.2%	19.8-30.6
OVERALL	105	22.2%	18.5-25.9

Table 22. Ages of the subjects having developed AE during hospitalisation			
	Patients with Hospital AE		Statistic
AGE	With AE	Mean	64.3
		Median	71
		Standard deviation	20.5
	Without AE	Mean	52.5
		Median	57
		Standard deviation	25.0

Statistically significant (p<0.001)

Table 23. Patients having AE's over age 65 and under age 65					
			Patients		Total
			Over age 65	Under age 65	
AE	With AE	Number	328	186	514
		%AE's	63.8%	36.2%	100.0%
	Without AE	Number	2004	2991	4995
		% AE's	40.1	59.9	100.0%
Total		Number	**2332**	**3177**	5509
		% AE's	**42.3%**	**57.7%**	100.0%

Statistically significant (p<0.001)

Table 24. Patients with Hospital AE, by sex					
			Patients		Total
			Without hospital AE	Whit hospital AE	
Sex	Females	Number	2794	237	3031
		%Sex	92.2%	7.8%	100.0%
	Males	Number	2299	230	2529
		% Sex	90.9%	9.1%	100.0%
Total		Number	5093	467	5560
		% Sex	91.4%	8.4%	100.0%

Table 25. Patients with/without an intrinsic risk factor, by AE's					
			Patients		Patients
			Without hospital AE	With hospital AE	
Intrinsic risk factors	No risk factor	Number	3181	174	3355
		% of intrinsic risk factors	94.8%	5.2%	100.0%
	Have risk factor	Number	1970	299	2269
		% of intrinsic risk factors	86.8%	13.2%	100.0%
Total		Number	5151	473	5624
		% of intrinsic risk factors	91.6%	8.4%	100.0%

Statistically significant (p<0.001)

Table 26. Patients, by number of intrinsic risk factors and AE's					
			Patients		Patients
			No hospital AE	With hospital AE	
Intrinsic risk factors	0	Number	3181	174	335
		% of intrinsic risk factors	94.8%	5.2%	100.0%
	1	Number	1254	147	1401
		% of intrinsic risk factors	89.5%	10.5%	100.0%
	2	Number	507	90	597
		% of intrinsic risk factors	84.9%	15.1%	100.0%
	3	Number	209	62	271
		% of intrinsic risk factors	77.1%	22.9%	100.0%
Total		Number	5151	473	5624
		% of intrinsic risk factors	91.6%	8.4%	100.0%

Table 27. Patients with/without an extrinsic risk factor, by AE's					
			Patients		Patients
			Without hospital AE	With hospital AE	
Extrinsic risk factors	No risk factor	Number	943	33	976
		% of extrinsic risk factors	96.6%	3.4%	100.0%
	Have risk factor	Number	4208	440	4648
		% of extrinsic risk factors	90.5%	9.5%	100.0%
Total		Number	5151	473	5624
		% of extrinsic risk factors	91.6%	8.4%	100.0%

Statistically significant (p<0.001)

Table 28. Patients, by number of extrinsic risk factors and AE's					
			Patients		Patients
			No hospital AE	With hospital AE	
Extrinsic risk factors	0	Number	943	33	976
		% of extrinsic risk factors	96.6%	3.4%	100.0%
	1	Number	2707	183	2890
		% of extrinsic risk factors	93.7%	6.3%	100.0%
	2	Number	1156	155	1311
		% of extrinsic risk factors	88.2%	11.8%	100.0%
	3	Number	345	102	447
		% of extrinsic risk factors	77.2%	22.8%	100.0%
Total		Number	5151	473	5624
		% of intrinsic risk factors	91.6%	8.4%	100.0%

Table 29. Patients with/without an extrinsic risk factor without peripheral venous catheter, by AE's					
			Patients		Patients
			Without hospital AE	With hospital AE	
Extrinsic risk factors without peripheral venous catheter	No risk factor	Number	3586	211	3797
		% of extrinsic risk factors w/o peripheral venous catheter	94.4%	5.6%	100.0%
	Have risk factor	Number	1565	262	1827
		% of extrinsic risk factors w/o peripheral venous catheter	85.7%	14.3%	100.0%
Total		Number	5151	473	5624
		% of extrinsic risk factors w/o peripheral venous catheter	91.6%	8.4%	100.0%

Statistically significant (p<0.001)

Table 30. Patients, by number of extrinsic risk factors without peripheral venous catheter					
			Patients		Patients
			No hospital AE	With hospital AE	
Extrinsic risk factors without peripheral venous catheter	0	Number	3586	211	3797
		% of extrinsic risk factors w/o peripheral venous catheter	94.4%	5.6%	100.0%
	1	Number	1194	153	1347
		% of extrinsic risk factors w/o peripheral venous catheter	88.6%	11.4%	100.0%
	2	Number	230	38	268
		% of extrinsic risk factors w/o peripheral venous catheter	85.8%	14.2%	100.0%
	3	Number	141	71	212
		% of extrinsic risk factors w/o peripheral venous catheter	66.5%	33.5%	100.0%
Total		Number	5151	473	5624
		% of intrinsic risk factors w/o peripheral venous catheter	91.6%	8.4%	100.0%

Table 31. Length of hospital stay among the subjects who developed and AE during hospitalisation			
			Statistic
Hospital stay	Patients without any Hospital AE	Median	4
		Interquartile spread	6
	Patients with Hospital AE	Median	11
		Interquartile spread	14

Table 32. Length of hospital stay of the subjects who developed AE's, by hospital				
		Hospital size		Statistic
Hospital stay	Patients without Hospital AE	Large-sized hospital	Median	5
			Interquartile spread	6
		Medium-sized hospital	Median	4
			Interquartile spread	6
		Small-sized hospital	Median	3
			Interquartile spread	4
	Patients with Hospital AE	Large-sized hospital	Median	11
			Interquartile spread	13
		Medium-sized hospital	Median	12
			Interquartile spread	12.25
		Small-sized hospital	Median	8.5
			Interquartile spread	13

Table 33. Hospital stay of the subjects whose AE did not extend the stay			
	The AE extended the hospital stay		Statistic
Hospital stay	No	Median	5
		Interquartile spread	7
	Yes	Median	10
		Interquartile spread	9

Statistically Significant (p<0,001)

Table 34. Hospital stay of the subjects whose AE extended the stay			
	The AE extended the hospital stay		Statistic
Hospital stay	No	Median	5
		Interquartile spread	7
	Yes	Median	18
		Interquartile spread	21

Statistically Significant (p<0,001)

Table 35. Summary of logic regression model best explaining the AE response variable (Yes/No)		
Unit category* (Medical)	1.24 n.s.	0.89-1.72
Hospital size (medium)*	0.81	0.66-0.99
Hospital size (small)*	1.44	1.02-2.03
Age*	1.98	1.48-2.64
Hospital stay*	5.07	3.80-6.76
No. intrinsic factors*	1.57	1.27-1.94
No. extrinsic factors*	2.30	1.68-3.17
Age* No. extrinsic factors	0.58	0.37-0.82
Unit Category* Stays	0.56	0.38-0.83

n.s.: not significant

* Reference category: Surgical Units

***** Comparing the small and medium-sized hospitals to the large-sized hospitals (reference category)

* Reference category: Under 65 years of age

* Reference category: Less than one week

* Reference category: No intrinsic risk factors

* Reference category: No extrinsic risk factors

Table 36. Risk (OR) related to the age and extrinsic risk factors		
	No extrinsic risk factors	**Extrinsic risk factors involved**
< age 65	1	2.30
> age 65	1.98	1.98* 2.30* 0.56 =2.55

Table 37. Risk (OR) related to the unit type and the length of stay		
	Surgical	**Medical**
< 1 week	1	1.23 (n.s.)
> 1 week	5.07	1.23* 5.07* 0.55= 3.43

Table 38. ASA Risk for patients having AE's		
		Total
ASA Risk	**Healthy**	13.7%
	Minor disease	26.7%
	Functional limitation	49.8%
	Life-threatening	9.9%

Table 39. Patient ASA risk, by degree of AE severity			
Severity ASA	Slight%	Moderate%	Severe%
Healthy	45.9	31.1	23.0
Minor disease	36.1	41.2	22.7
Functional limit.	45.0	40.5	14.4
Life-threatening	50.0	27.3	22.7

Not statistically significant difference (p=0.170)

Table 40. ASA risk Distribution and AE's severity			
Severity ASA	Slight%	Moderate%	Severe%
Healthy or Minor disease	39.4%	37.8%	22.8%
Functional limitation or life-threatening	45.9%	38.3%	15.8%

Not statistically significant difference (p=0.146)

Table 41. Patient ASA risk					
		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	Complete recovery to original normal condition	374	71.2	72.2	72.2
	Recovery with residual permanent disability	90	17.1	17.4	89.6
	Terminal illness	54	10.3	10.4	100.0
	Total	518	98.7	100.0	
Losses		3	1.3		
Total		525	100.0		

Table 42. Patient disease prognosis spread, by degree of AE severity						
			Severity			Total
			Slight	Moderate	Severe	
Illness type	Complete recovery to original normal condition	Number	3200	184	71	455
		% illness type	44.0%	40.4%	15.6%	100.0%
	Recovery with residual permanent disability	Number	68	33	26	127
		% illness type	53.5%	26.0%	20.5%	100.0%
	Terminal illness	Number	26	32	7	65
		% illness type	40.0%	49.2%	10.8%	100.0%
Total		Number	294	249	104	647
		% illness type	45.4%	38.5%	16.1%	

Statistically significant difference (p=0.012)

Table 43. Co-morbidities involved /not involved, by degree of AE severity						
			Severity			Total
			Slight	Moderate	Severe	
Co-morbidities involved/not involved	No co-morbidities involved	Number	30	20	20	70
		% co-morbidities involved/not involved	42.9%	28.6%	28.6%	100%
		% severity	10.2%	7.8%	19.0%	10.7%
	Co-morbidities involved	Number	265	235	85	585
		% co-morbidities involved/not involved	45.3%	40.2%	14.5%	100%
		% severity	89.8%	92.0%	81.0%	89.3%
Total			100%	100%	100%	100%

Statistically significant difference (p=0.007)

Table 44. AE incidence density			
	AE's	Incidence density	95% CI
Large-sized hospitals	297	1.55/100 days	1.37-1.72/100 days
Medium-sized hospitals	239	1.14/100 days	0.99-1.28/100 days
Small-sized hospitals	65	2.58/100 days	1.95/3.21/100 days
Medical units	273	1.20/100 days	1.06-1.35/100 days
Surgical units	328	1.64/100 days	1.46-1.81/100 days
Total	601	1.41/100 days	1.29-1.52/100 days

Table 45. Moderate or severe AE incidence density			
	AE's	Incidence rate	95% CI
Large-sized hospitals	141	7.34/10^3 days	6.13-8.55/10^3 days
Medium-sized hospitals	139	6.63/10^3 days	5.52-7.73/10^3 days
Small-sized hospitals	31	12.3/10^3 days	7.97-16.63/10^3 days
Medical units	120	5.29/10^3 days	4.35-6.24/10^3 days
Surgical units	191	9.53/10^3 days	8.18-10.88/10^3 days
Total	311	7.28/10^3 days	6.47-8.09/10^3 days

Table. 46. AE origins spread					
		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	**Prior to admission**	135	20.6	20.7	20.7
	At ward admission	8	1.2	1.2	22.0
	During a procedure	171	26.1	26.3	48.2
	Following a procedure	42	6.4	6.5	54.7
	In general ward	286	43.7	43.9	98.6
	At the end of admission and discharge	9	1.4	1.4	100.0
	Total	651	99.4	100.0	
Lost		4	0.6		
Total		655	100.0		

Table 47. Prehosptialisation period-related AE spread			
			Total
The AE occurred	**In Emergency Room**	**Number**	13
		% when AE occurred	9.6%
	In primary care	**Number**	28
		% when AE occurred	20.7%
	In out-patient treatment	**Number**	17
		% when AE occurred	12.6%
	In same hospital unit, in prior care provided	**Number**	48
		% when AE occurred	35.6%
	In a different unit in the same hospital	**Number**	17
		% when AE occurred	12.6%
	At a different hospital	**Number**	9
		% when AE occurred	6.7%
	Unidentified	**Number**	3
		% when AE occurred	2.2%
Total		**Number**	135
		% when AE occurred	100.0%

Table 48. Ward admission-related AE's			
			Total
The AE occurred	In Emergency Room, prior to admission	Number	3
		% when AE occurred	37.5%
	During preoperative assessment	Number	3
		% when AE occurred	37.5%
	During arrival to ward	Number	2
		% when AE occurred	25.0%
	Number and % when AE occurred	Number	8
		% when AE occurred	100%

Table 49. AE's caused during procedure			
			Total
Which of the following procedure was related to the AE?	Anaesthesia administration	Number	7
		% when AE occurred	4,1%
	Surgical operation	Number	95
		% when AE occurred	55,6%
	Manipulation of fracture	Number	1
		% when AE occurred	0,6%
	Endoscopy procedure	Number	7
		% when AE occurred	4,1%
	Biopsy	Number	4
		% when AE occurred	2.3%
	Catherisation	Number	5
		% when AE occurred	2.9%
	Interventionist radiology	Number	1
		% when AE occurred	0.6%
	Intravenous injection	Number	2
		% when AE occurred	1.2%
	Vesical catheterisation	Number	5
		% when AE occurred	2.9%
	Body cavity fluid drainage	Number	3
		% when AE occurred	1.7%
	Nasogastric tube insertion	Number	1
		% when AE occurred	0.6%
	Other procedures	Number	35
		% when AE occurred	20.3%
	Unidentified	Number	5
		% when AE occurred	2.9%
	Total	Number	171
		% when AE occurred	100.0%

Table 50. Spread of the AE's caused in ICU and recovery			
			Total
When did the principal problem occur?	During the care on awakening	Number	11
		% when AE occurred	26.2%
	During the care in recovery	Number	4
		% when AE occurred	9.5%
	During the care in the ICU	Number	23
		% when AE occurred	54.8%
	Unidentified	Number	2
		% when AE occurred	4.8%
	Total	Number	42
		% when AE occurred	100.0%

Table 51. Types of AE's

Table 51. Type of principal problem which caused the AE		
	AE's	**%**
Related to the care provided	**50**	**7.63**
Pressure ulcer	24	3.66
Burns, scrapes and contusions (including resulting fractures)	19	2.90
Acute Pulmonary Edema and respiratory failure	3	0.46
Other consequences of long-term immobilisation	4	0.61
Medication-related	**245**	**37.4**
Nausea, vomiting or diarrhoea secondary to medication	32	4.89
Pruritus, rash or skin lesions reactive to drugs or dressings	32	4.89
Other secondary effects of drugs	29	4.43
Poorly controlled glycaemia	19	2.90
Haemorrhage due to anticoagulation	18	2.75
Worsening of renal function	13	1.98
Upper digestive tract haemorrhage	13	1.98
Delay in treatment	11	1.68
Heart failure and shock	10	1.53
AMI, CVA, PTE	9	1.37
Neutropenia	9	1.37
Drug-related neurological alterations	9	1.37
Drug-related alteration in heart rate or electrical activity	9	1.37
Drug-related hypotension	7	1.07
Opportunist infection due to immunosuppressing treatment	6	0.92
Electrolyte imbalance	6	0.92
Drug-related headache	5	0.76
Ineffective medical treatment	5	0.76
Adverse reactions to anaesthetic agents	3	0.46
Nosocomial infection-related	**166**	**25.34**
Surgical wound infection	50	7.63
Nosocomial UTI	45	6.87
Other type of nosocomial infection or unspecified nosocomial infection	22	3.36
Sepsis and septic shock	19	2.90
Nosocomial pneumonia	17	2.60
Device-related bloodstream infection	13	1.98

Procedure-related	**164**	**25.04**
Haemorrhage or hematoma related to surgical operation or procedure	61	9.31
Injury to an organ during a procedure	20	3.05
Other complications following surgical operation or procedure	14	2.14
Ineffective or incomplete surgical operation	11	1.68
Uterine tear	9	1.37
Pneumothorax	7	1.07
Suspension of surgical operation	6	0.92
Urine retention	6	0.92
Eventration o evisceration	6	0.92
Suture dehiscence	5	0.76
Hematuria	5	0.76
Local radiation therapy-related complications	4	0.61
Seroma	5	0.76
Adhesions or functional alterations following surgical operation	3	0.46
Childbirth-related complications in new-born	2	0.31
Diagnosis-related	**18**	**2.75**
Delay in diagnosis	10	1.53
Diagnostic error	8	1.22
Others	**12**	**1.83**
Pending specifying	7	1.07
Other AE's	5	0.76
Total	**655**	**100.00**

Table 52. Types of AE's by hospital size

Table 52. Type of principal problem causing AE, by hospital size						
	Large-sized		Medium-sized		Small-sized	
	AE's	%	AE's	%	AE's	%
Healthcare-related	28	8.78	14	5.28	8	11.27
Pressure ulcer	11	3.45	8	3.02	5	7.04
Burns, scrapes and contusions (including resulting fractures)	11	3.45	5	1.89	3	4.23
Acute Pulmonary Edema and respiratory failure	3	0.94	1	0.38	0	0.00
Other consequences of long-term immobilisation	3	0.94	0	0.00	0	0.00
Medication-related	119	37.30	93	35.09	32	45.07
Nausea, vomiting or diarrhoea secondary to medication	18	5.64	6	2.26	8	11.27
Pruritus, rash or skin lesions reactive to drugs or dressings	12	3.76	18	6.79	2	2.82
Other secondary effects of drugs	16	5.02	11	4.15	2	2.82
Poorly controlled glycaemia	11	3.45	6	2.26	2	2.82
Haemorrhage due to anticoagulation	13	4.08	4	1.51	1	1.41
Worsening of renal function	6	1.88	6	2.26	1	1.41
Upper digestive tract haemorrhage	5	1.57	6	2.26	2	2.82
Delay in treatment	5	1.57	4	1.51	1	1.41
Heart failure and shock	5	1.57	4	1.51	1	1.41
AMI, CVA, PTE	6	1.88	2	0.75	1	1.41
Neutropenia	3	0.94	6	2.26	0	0.00
Drug-related neurological alterations	4	1.25	5	1.89	0	0.00
Drug-related alteration in heart rate or electrical activity	2	0.63	5	1.89	2	2.82
Drug-related hypotension	3	0.94	1	0.38	3	4.23
Opportunist infection due to immunosuppressing treatment	1	0.31	2	0.75	3	4.23
Electrolyte imbalance	1	0.31	3	1.13	2	2.82
Drug-related headache	5	1.57	0	0.00	0	0.00
Ineffective medical treatment	2	0.63	2	0.75	1	1.41
Adverse reactions to anaesthetic agents	1	0.31	2	0.75	0	0.00
Nosocomial infection-related	63	19.75	83	31.32	20	28.17
Surgical wound infection	19	5.96	28	10.57	3	4.23
Nosocomial UTI	17	5.33	20	7.55	8	11.27
Other type of nosocomial infection or unspecified nosocomial infection	10	3.13	8	3.02	4	5.63
Sepsis and septic shock	10	3.13	7	2.64	2	2.82
Nosocomial pneumonia	5	1.57	10	3.77	2	2.82
Device-related bloodstream infection	2	0.63	10	3.77	1	1.41

Procedure-related	88	27.59	68	25.66	8	11.27
Haemorrhage or hematoma related to surgical operation or procedure	31	9.72	24	9.06	6	8.45
Injury to an organ during a procedure	10	3.13	10	3.77	0	0.00
Other complications following surgical operation or procedure	11	3.45	3	1.13	0	0.00
Ineffective or incomplete surgical operation	7	2.19	3	1.13	1	1.41
Uterine tear	7	2.19	2	0.75	0	0.00
Pneumothorax	3	0.94	4	1.51	0	0.00
Suspension of surgical operation	1	0.31	4	1.51	1	1.41
Urine retention	2	0.63	4	1.51	0	0.00
Eventration o evisceration	3	0.94	3	1.13	0	0.00
Suture dehiscence	5	1.57	0	0.00	0	0.00
Hematuria	4	1.25	1	0.38	0	0.00
Local radiation therapy-related complications	2	0.63	2	0.75	0	0.00
Seroma	1	0.31	4	1.51	0	0.00
Adhesions or functional alterations following surgical operation	1	0.31	2	0.75	0	0.00
Childbirth-related complications in new-born	0	0.00	2	0.75	0	0.00
Diagnosis-related	10	3.13	6	2.26	3	4.23
Delay in diagnosis	6	1.88	4	1.51	1	1.41
Diagnostic error	4	1.25	2	0.75	2	2.82
Others	11	3.45	1	0.38	0	0.00
Pending specifying	6	1.88	1	0.38	0	0.00
Other AE's	5	1.57	0	0.00	0	0.00
Total	319		265		71	

Table 53. Type of principal problem causing the AE, by Hospital Unit Type				
	Medical Unit		Surgical Unit	
	AE's	%	AE's	%
Healthcare-related	27	8.7	23	6.7
Pressure ulcer	9	2.9	15	4.4
Burns, scrapes and contusions (including resulting fractures)	14	4.5	5	1.5
Acute Pulmonary Edema and respiratory failure	2	0.6	2	0.6
Other consequences of long-term immobilisation	2	0.6	1	0.3
Medication-related	168	53.8	76	22.2
Nausea, vomiting or diarrhoea secondary to medication	23	7.4	9	2.6
Pruritus, rash or skin lesions reactive to drugs or dressings	13	4.2	19	5.5
Other secondary effects of drugs	22	7.1	7	2.0
Poorly controlled glycaemia	18	5.8	1	0.3
Haemorrhage due to anticoagulation	12	3.8	6	1.7
Worsening of renal function	8	2.6	5	1.5
Upper digestive tract haemorrhage	9	2.9	4	1.2
Delay in treatment	7	2.2	3	0.9
Heart failure and shock	6	1.9	4	1.2
AMI, CVA, PTE	5	1.6	4	1.2
Neutropenia	9	2.9	0	0.0
Drug-related neurological alterations	5	1.6	4	1.2
Drug-related alteration in heart rate or electrical activity	8	2.6	1	0.3
Drug-related hypotension	3	1.0	4	1.2
Opportunist infection due to immunosuppressing treatment	6	1.9	0	0.0
Electrolyte imbalance	6	1.9	0	0.0
Drug-related headache	4	1.3	1	0.3
Ineffective medical treatment	4	1.3	1	0.3
Adverse reactions to anaesthetic agents	0	0.0	3	0.9
Nosocomial infection-related	66	21.2	100	29.2
Surgical wound infection	3	1.0	47	13.7
Nosocomial UTI	25	8.0	20	5.8
Other type of nosocomial infection or unspecified nosocomial infection	12	3.8	10	2.9
Sepsis and septic shock	8	2.6	11	3.2
Nosocomial pneumonia	10	3.2	7	2.0
Device-related bloodstream infection	8	2.6	5	1.5

Procedure-related	35	11.2	129	37.6
Haemorrhage or hematoma related to surgical operation or procedure	12	3.8	49	14.3
Injury to an organ during a procedure	2	0.6	18	5.2
Other complications following surgical operation or procedure	5	1.6	9	2.6
Ineffective or incomplete surgical operation	1	0.3	10	2.9
Uterine tear	0	0.0	9	2.6
Pneumothorax	5	1.6	2	0.6
Suspension of surgical operation	1	0.3	5	1.5
Urine retention	2	0.6	4	1.2
Eventration o evisceration	1	0.3	5	1.5
Suture dehiscence	1	0.3	4	1.2
Hematuria	2	0.6	3	0.9
Local radiation therapy-related complications	3	1.0	1	0.3
Seroma	0	0.0	5	1.5
Adhesions or functional alterations following surgical operation	0	0.0	3	0.9
Childbirth-related complications in new-born	0	0.0	2	0.6
Diagnosis-related	9	2.9	10	2.9
Delay in diagnosis	6	1.9	5	1.5
Diagnostic error	3	1.0	5	1.5
Others	7	2.2	5	1.5
Pending specifying	4	1.3	3	0.9
Other AE's	3	1.0	2	0.6
Total	312		343	

Table 54. Patients having prehosptialisation period-related AE's		
	Cases	**%**
Large-sized hospitals	60	45.8
Medium-sized hospitals	57	43.5
Small-sized hospitals	14	10.7
Medical units	76	58.0
Surgical units	55	42.0
Lost through sistem	4	-
Overall	131	100.0%

Table 55. Type of principal problem causing the AE in patients		
	AE's	%
Care-related	11	3.70
Medication-related	45	34.8
Nosocomial infection-related	20	17.8
Procedure-related	21	17.8
Overall assessment-related	11	8.9
Diagnosis-related	11	8.2
Others	11	8.2

Table 56. Patients having AE's leading to readmissions		
	Cases	**%**
Large-sized hospitals	72	47.0
Medium-sized hospitals	58	41.7
Small-sized hospitals	17	11.3
Medical units	76	51.7
Surgical units	71	48.3
Unidentified	4	1.97
Overall	151	100.0%

Table 57. AE's leading to readmissions		
	Cases	**%**
Large-sized hospitals	319	22.9
Medium-sized hospitals	265	23.8
Small-sized hospitals	71	23.9
Medical units	312	25.0
Surgical units	343	21.9
Overall	655	23.4

Table 58. Type of principal problem causing the readmission		
	AE's	%
Care-related	5	3.3
Medication-related	43	29.8
Nosocomial infection-related	30	19.9
Procedure-related	36	25.2
Overall assessment-related	11	7.9
Diagnosis-related	10	6.6
Others	12	7.9
Total	147	100.0

Table 59. AE impact		
	Cases	%
Slight AE's	295	45.0
Moderate AE's	255	38.9
Severe AE's	105	16.0
Overall	655	100

Table 60. AE impact by hospital size

			Severity			Total
			Slight	Moderate	Severe	
Hospital size	Large-sized hospital	Number	158	113	48	319
		% hospital size	49.5%	35.4%	15.0%	100.0%
	Medium-sized hospital	Number	103	115	47	265
		% hospital size	38.9%	43.4%	17.7%	100.0%
	Small-sized hospital	Number	34	27	10	71
		% hospital size	47.9%	38.0%	14.1%	100.0%
Total		Number	285	255	105	655
		% hospital size	45.0%	38.9%	16.0%	100.0%

Table 61. AE impact by hospital unit type						
			Severity			Total
			Slight	Moderate	Severe	
Hospital unit type	Medical specialty	Number	158	134	22	312
		Unit % hospital admissions	50.0%	42.9%	7.1%	100.0%
	Surgical specialty	Number	139	121	83	343
		Unit % hospital admissions	40.5%	35.3%	24.2%	100.0%
Total		Number	295	255	105	655
		Unit % hospital admissions	45.0%	38.9%	16.0%	100.0%

Table 62. AE's which resulted in Extended stay		
	Extended stay	Led to readmission
AE's	31.4%	24.4%
Median	4	7

Table 63. AE's having required additional procedures					
		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	No	206	31.5	31.5	31.5
	Yes	434	66.3	66.3	97.8
Lost		15	2.3	2.3	100.0
Total		655	100.0	100.0	

Table 64. AE's having required additional treatments					
		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	No	182	27.8	27.8	27.8
	Yes	458	69.9	69.9	97.7
Lost		15	2.3	2.3	100.0
Total		655	100.0	100.0	

Table 65. AE's resulting in death		
	Frequency	Percentage
Death	112	2.05%
Deaths which were AE's	23	0.42%
Death-AE relationship	15	0.22
Total cases	5,476	100%

Table 66. AE preventability		
	AE's	%
No evidence	206	31.5
Minimal probability	54	8.2
Slight possibility	114	17.4
Moderate possibility	209	31.9
Major possibility	61	9.3
Total evidence	8	1.2
Lost through system	3	0.4
Total	655	100.0

Table 67. Degree of AE preventability, by hospital size					
			AE's		Total
			Preventable	Unpreventable	
Hospital size	Large	Number	192	125	317
		% hospital size	40.0%	60.0%	100.0%
		%	51.1%	45.4%	48.6%
	Medium	Number	157	107	264
		% hospital size	39.8%	40.2%	100.0%
		%	42.2%	38.2%	40.5%
	Small	Number	25	46	71
		% hospital size	64.8%	35.2%	100.0%
		%	6.7%	16.4%	10.9%
Total		Number	374	278	652
		% hospital size	42.6%	57.4%	100.0%

Table 68. Degree of AE severity related to AE preventability					
			AE's		Total
			Preventable	Unpreventable	
Severity	Slight	Number	165	127	292
		% severity	43.8%	56.2%	100.0%
		%	43.8%	46.1%	44.8%
	Moderate	Number	148	107	256
		% severity	42.0%	58.0%	100.0%
		%	39.8%	38.2%	39.1%
	Severe	Number	61	44	105
		% severity	41.9%	58.1%	100.0%
		%	16.4%	15.7%	16.1%
Total		Number	374	278	652
		% severity	57.1%	42.9%	100.0%
		%	100.0%	100.0%	100.0%

Table 69. AE type and preventability				
	Medical	Surgical	Total	Preventable
Procedure-related	11.2%	37.6%	25.0%	31.7%
Nosocomial infection-related	21.2%	29.2%	25.3%	56.6%
Medication-related	53.8%	22.2%	37.4%	34.8%
Care-related	8.7%	6.7%	7.6%	56.0%
Diagnosis-related	2.9%	2.9%	2.7%	84.2%
Others	2.2%	1.5%	1.8%	33.3%
Total	312	343	655	278(42.6%)

Table 70. AE type and preventability in the medical units		
	Medical	Total
Procedure-related	11.2%	34.3%
Nosocomial infection-related	21.2%	60.6%
Medication-related	53.8%	36.3%
Care-related	8.7%	55,6%
Diagnosis-related	2.9%	77.8%
Others	2.2%	33.3%
Total	312	137 (44.1%)

Table 71. AE type and preventability in the surgical units		
	Surgical	Total
Procedure-related	37.6%	31.0%
Nosocomial infection-related	29.2%	54.0%
Medication-related	22.2%	31.6%
Care-related	6.7%	56.5%
Diagnosis-related	2.9%	90.0%
Others	1.5%	33.3%
Total	343	141 (41.3%)

Table 72. Extended Incidence Rate, including all cases of phlebitis, by hospital size and hospital unit type			
	AE's	Extended incidence	95% CI
Large-sized hospitals	284	12.4%	11.1-13.8
Medium-sized hospitals	308	10.7%	9.6-11.8
Small-sized hospitals	63	14.0%	10.8-17.2
Medical units	332	13.6%	12.2-14.9
Surgical units	323	10.2%	9.1-11.2
Overall	655	11.6%	10.8-12.5

Table 73. Extended Incidence density, including all cases of phlebitis, by hospital size and hospital unit type			
	AE's	Extended incidence density	95% CI
Large-sized hospitals	405	2.11/100 days	1.90-2.31/100 days
Medium-sized hospitals	376	1.79/100 days	1.61-1.97/100 days
Small-sized hospitals	95	3.77/100 days	3.01-4.54/100 days
Medical units	450	1.99/100 days	1.80-2.17/100 days
Surgical units	426	2.13/100 days	1.92-2.33/100 days
Overall	876	2.05/100 days	1.92-2.19/100 days

Table 74. Extended Incidence Rate impact, by hospital size						
			Severity			Total
			Slight	Moderate	Severe	
Hospital size	Large-sized hospital	Number	266	113	48	427
		% hospital size	62.3%	26.5%	11.2%	100.0%
	Medium-sized hospital	Number	240	115	47	402
		% hospital size	59.7%	28.6%	11.7%	100.0%
	Small-sized hospital	Number	64	27	10	101
		% hospital size	63.4%	26.7%	9.9%	100.0%
Total		Number	570	255	105	930
		% hospital size	61.3%	27.4%	11.3%	100.0%

Table 75. Extended Incidence Rate impact, by hospital unit type						
			Severity			Total
			Slight	Moderate	Severe	
Hospital unit type	Medical specialty	Number	333	134	22	489
		Unit % hospital admissions	68.1%	27.4%	4.5%	100.0%
	Surgical specialty	Number	237	121	83	441
		Unit % hospital admissions	53.7%	27.4%	18.8%	100.0%
Total		Number	570	255	105	930
		Unit % hospital admissions	61.3%	27.4%	11.3%	100.0%

Table 76. Studies including mortality rate indexes for patients having AE's		
	Incidence rate (%)	95% CI
Harvard Medical Practice Study	13.6	11.6 - 15.7
Utah and Colorado	6.6	4.4 – 9.4
Quality in Australian Healthcare Study	4.9	4.1 – 5.8
London	8.0	3.5 – 13.9
Denmark	6.1	2.3 – 12.7
ENEAS	4.8	3.1 – 6.9

Table 77. Assessment of the medical record quality, by hospital size		
Hospital size	**Inadequate or barely adequate information**	**Adequate or highly adequate information**
Large-sized	19.78	80.22
Medium-sized	15.91	84.09
Small-sized	29.17	70.83

Table 78. Assessment of the medical record quality, by hospital unit type		
Hospital unit type	**Inadequate or barely adequate information**	**Adequate or highly adequate information**
Medical unit	17.05	82.95
Surgical unit	20.86	79.14

MINISTERIO DE SANIDAD Y CONSUMO

SECRETARÍA GENERAL DE SANIDAD

DIRECCIÓN GENERAL DE LA AGENCIA DE CALIDAD DEL SISTEMA NACIONAL DE SALUD

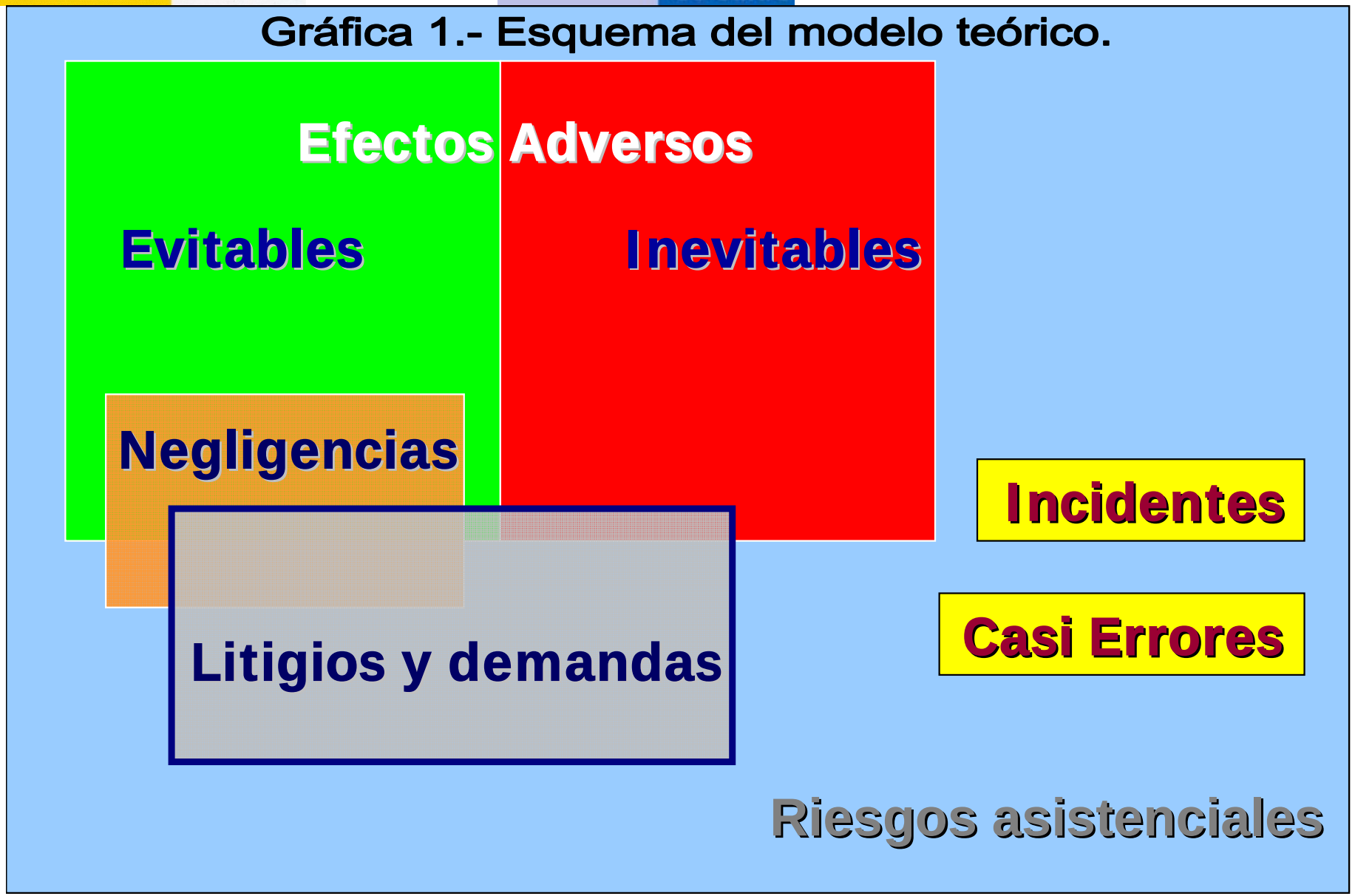
Plan de Calidad para el Sistema Nacional de Salud

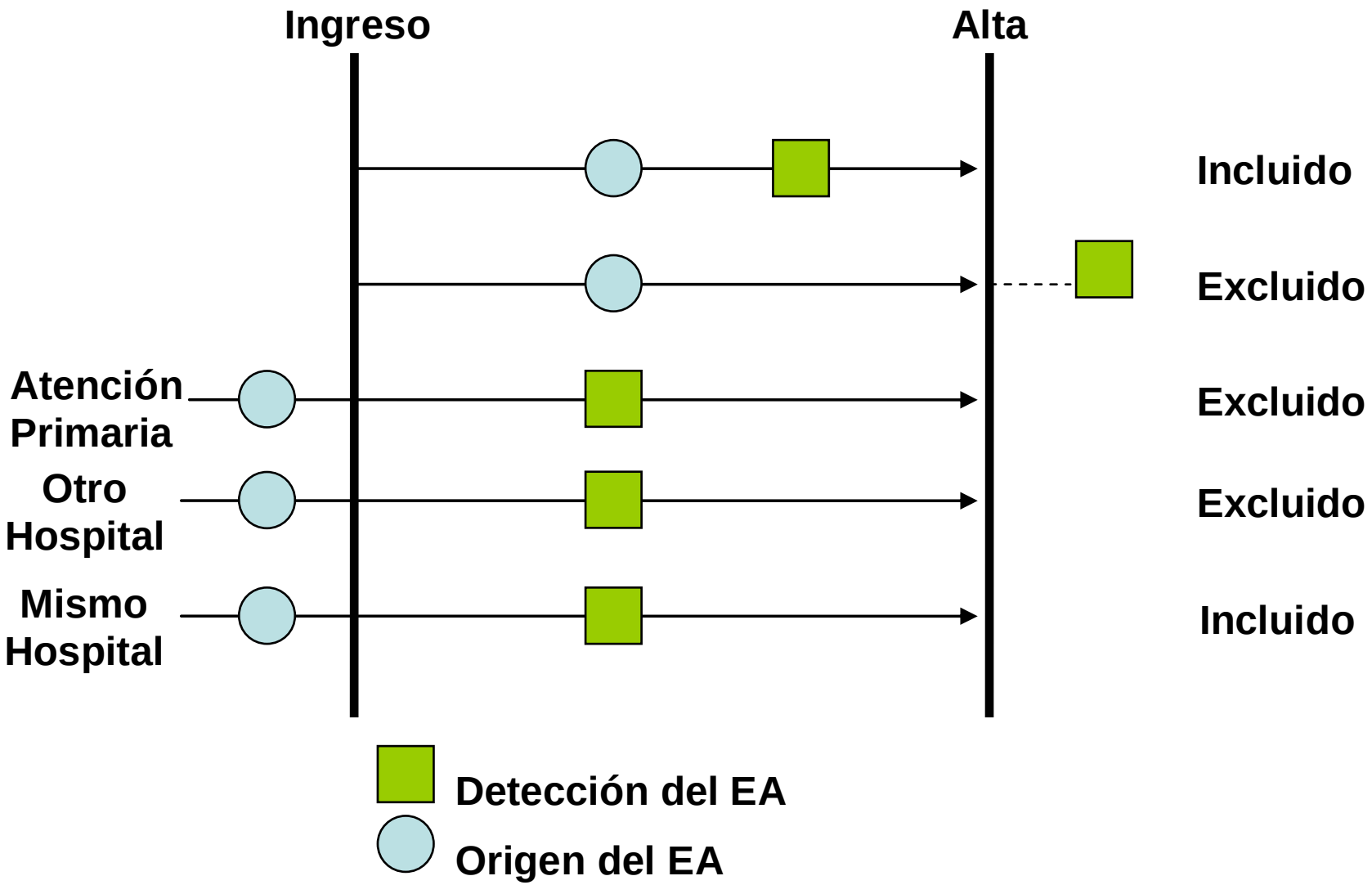
NATIONAL STUDY ON HOSPITALISATION-RELATED ADVERSE EVENTS

ENEAS 2005

APPENDIX
Graphs

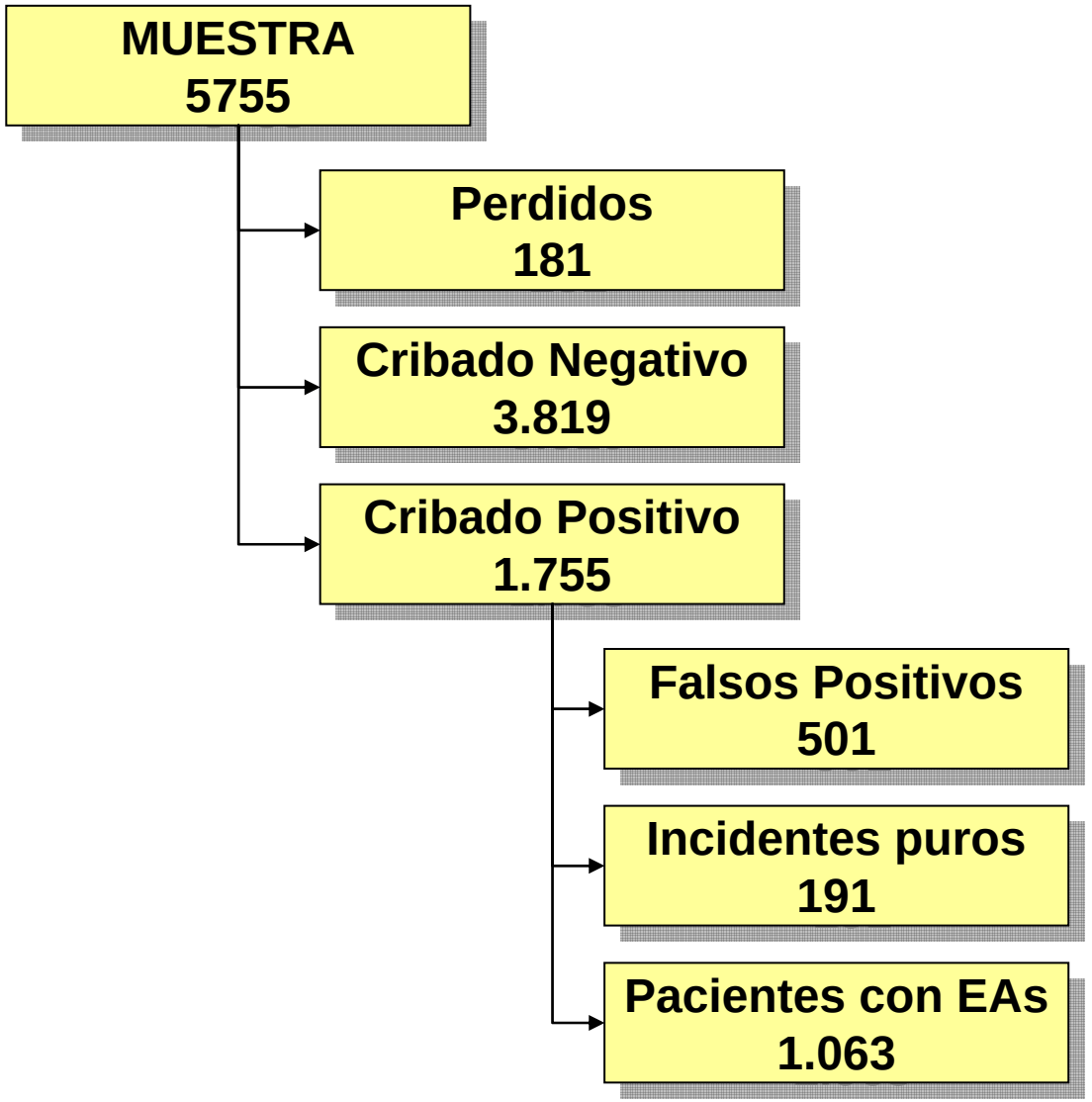
Gráfica 1.- Esquema del modelo teórico.



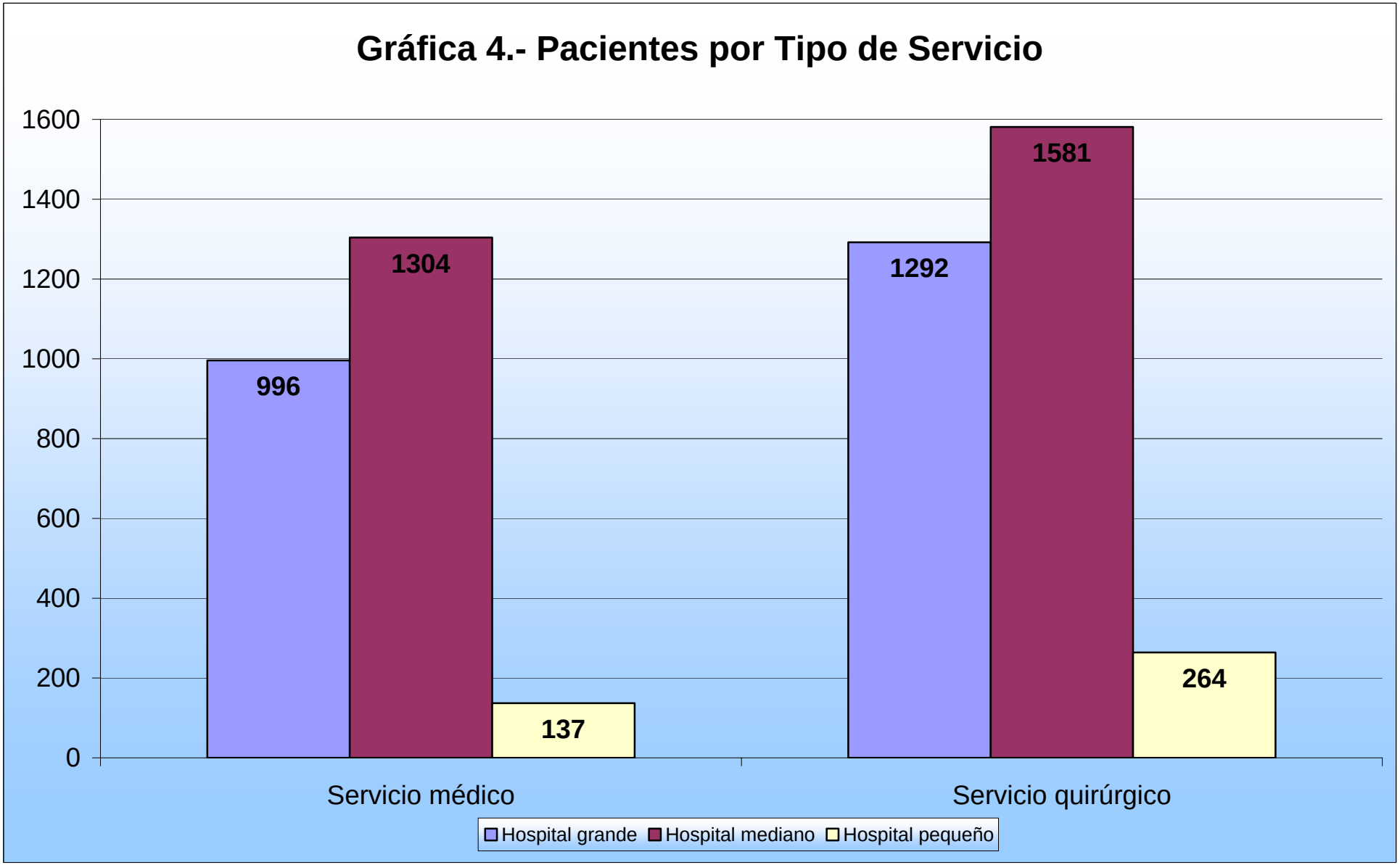


Gráfica 2.- Detección de EAs y su inclusión en el estudio.

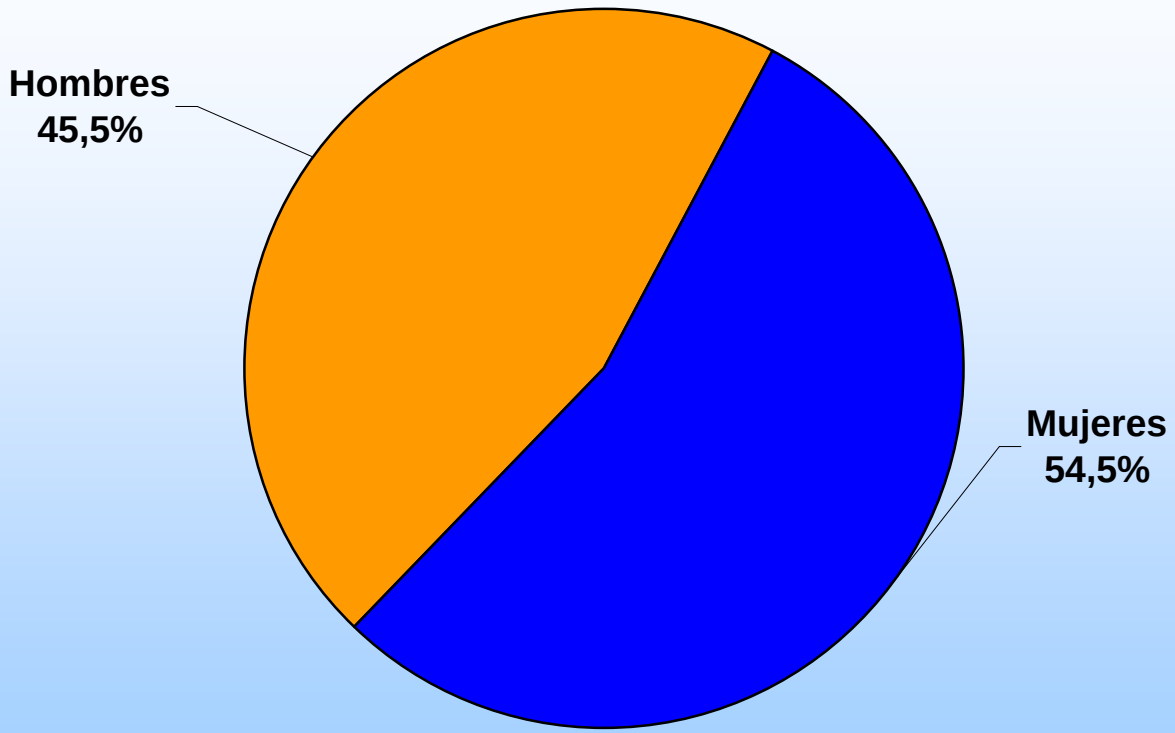
Gráfica 3.- Descripción de la muestra a estudio y del cribado.

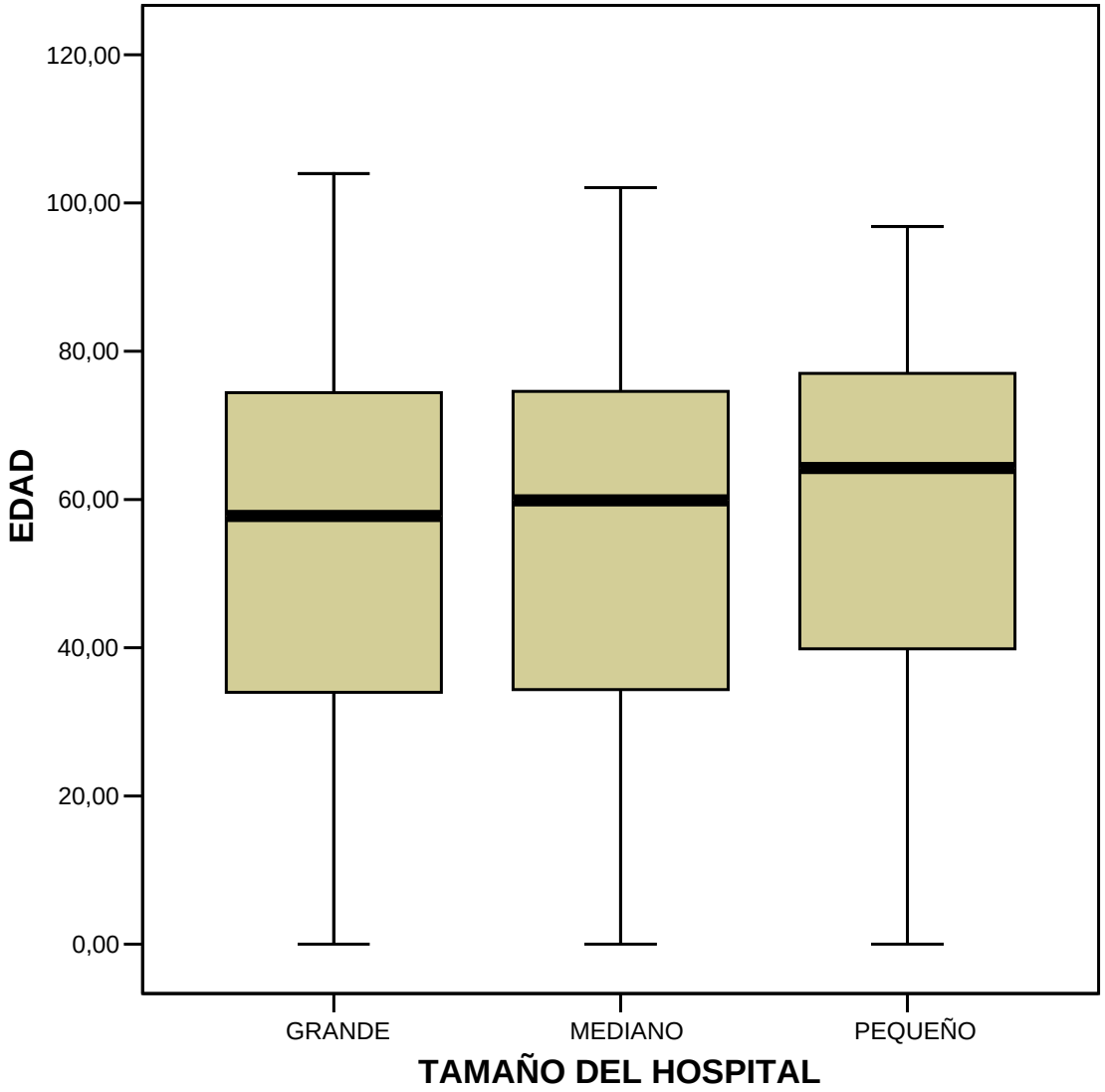


Gráfica 4.- Pacientes por Tipo de Servicio



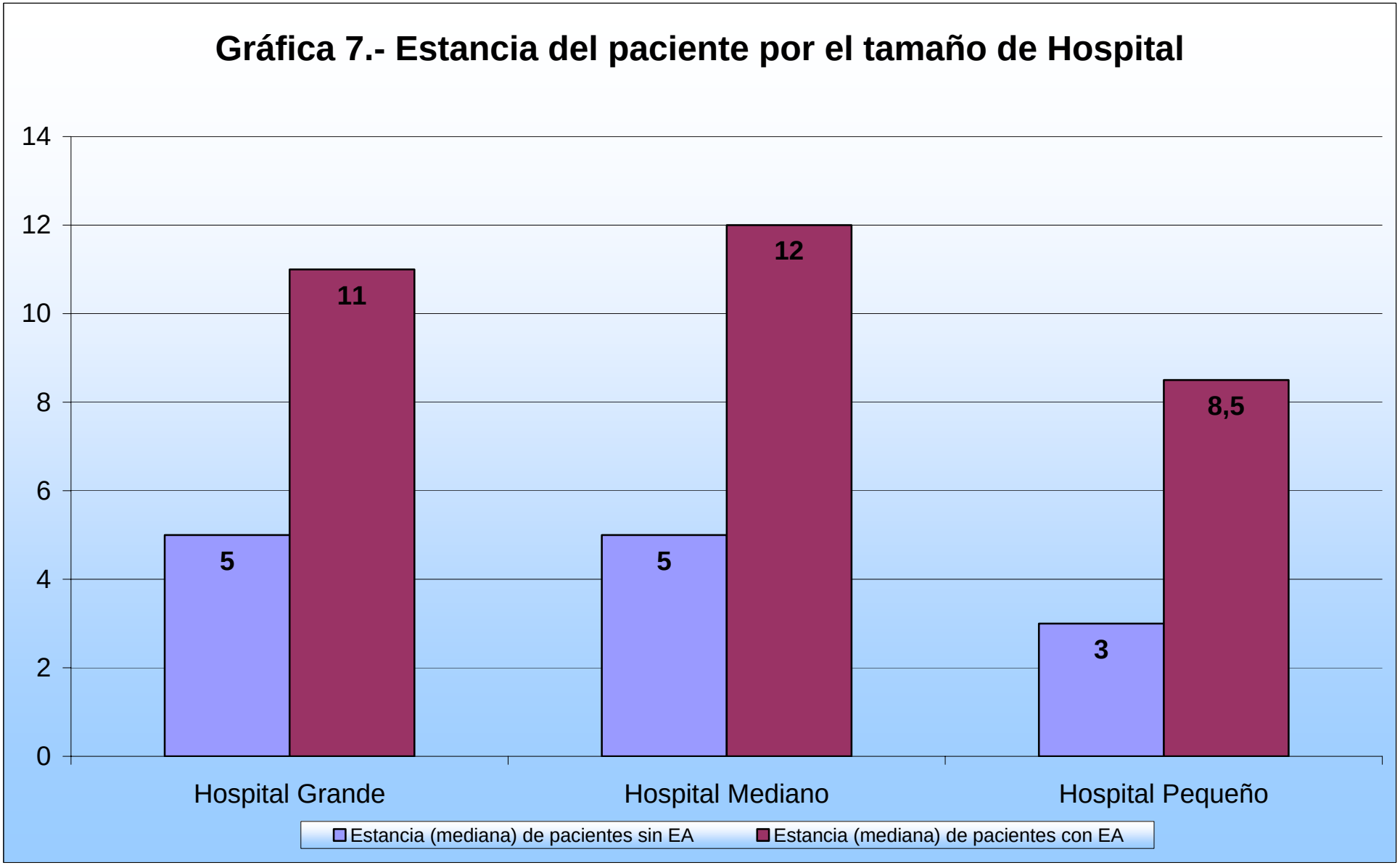
Gráfica 5.- Distribución muestral por Sexo



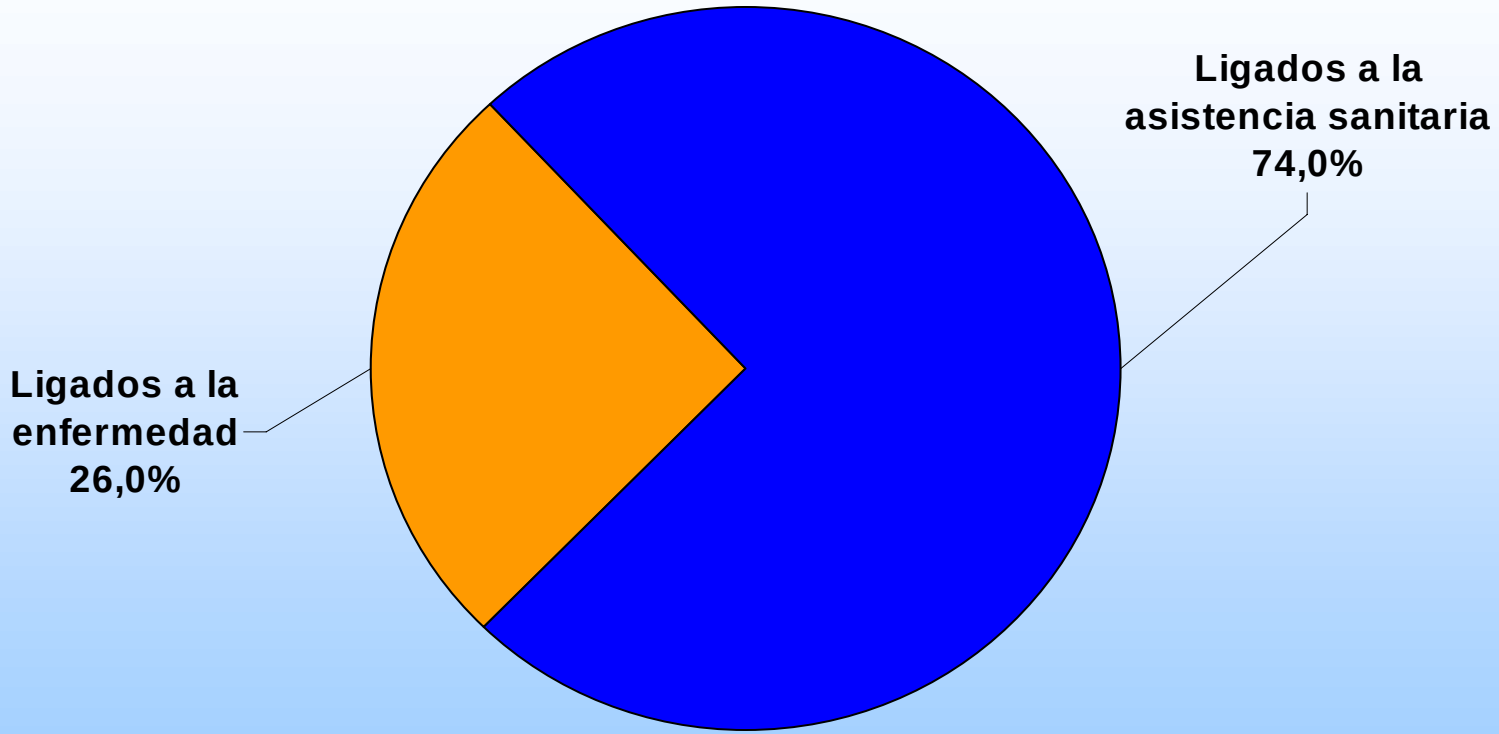


Gráfica 6.- Edad media del paciente por tamaño de Hospital

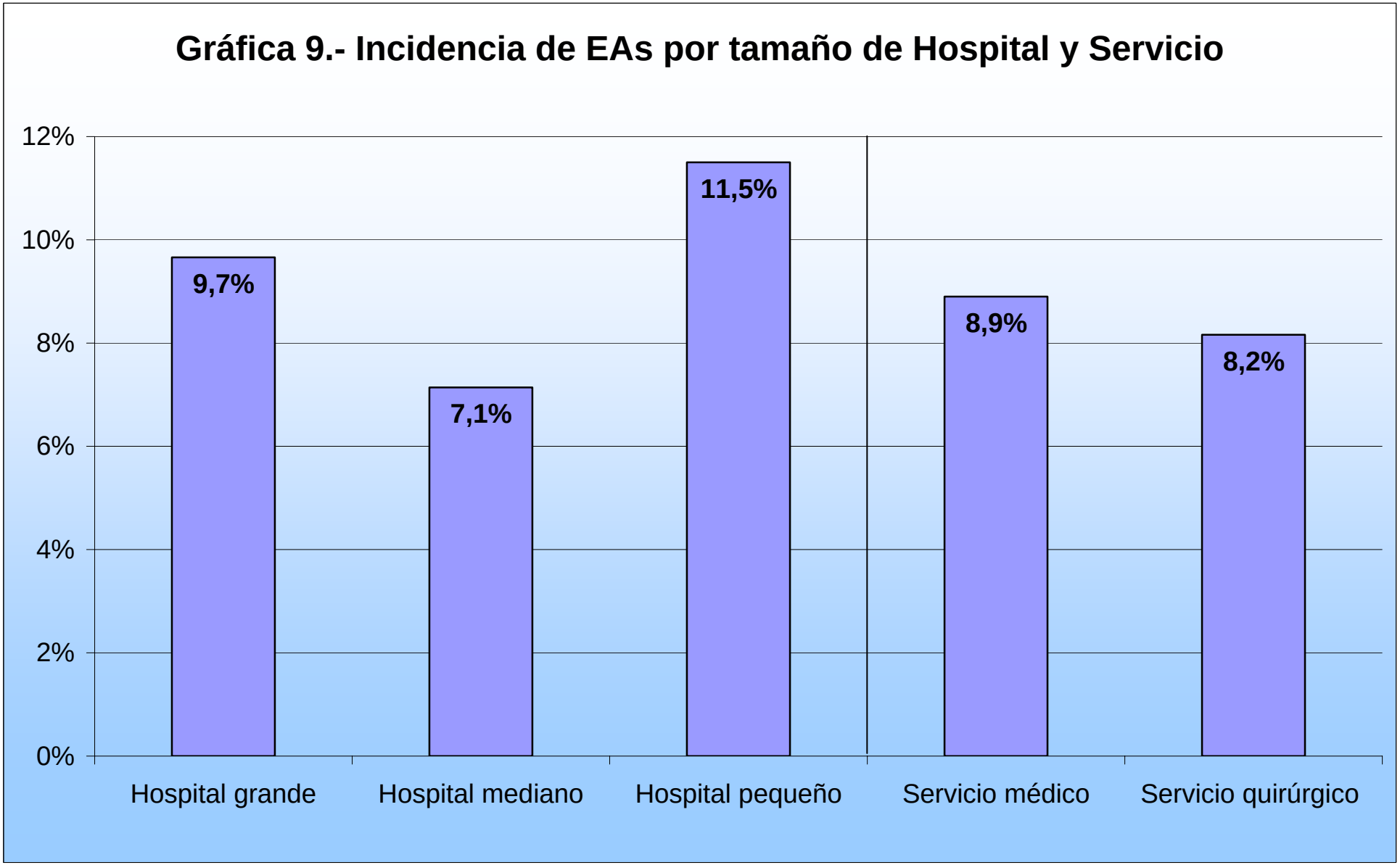
Gráfica 7.- Estancia del paciente por el tamaño de Hospital



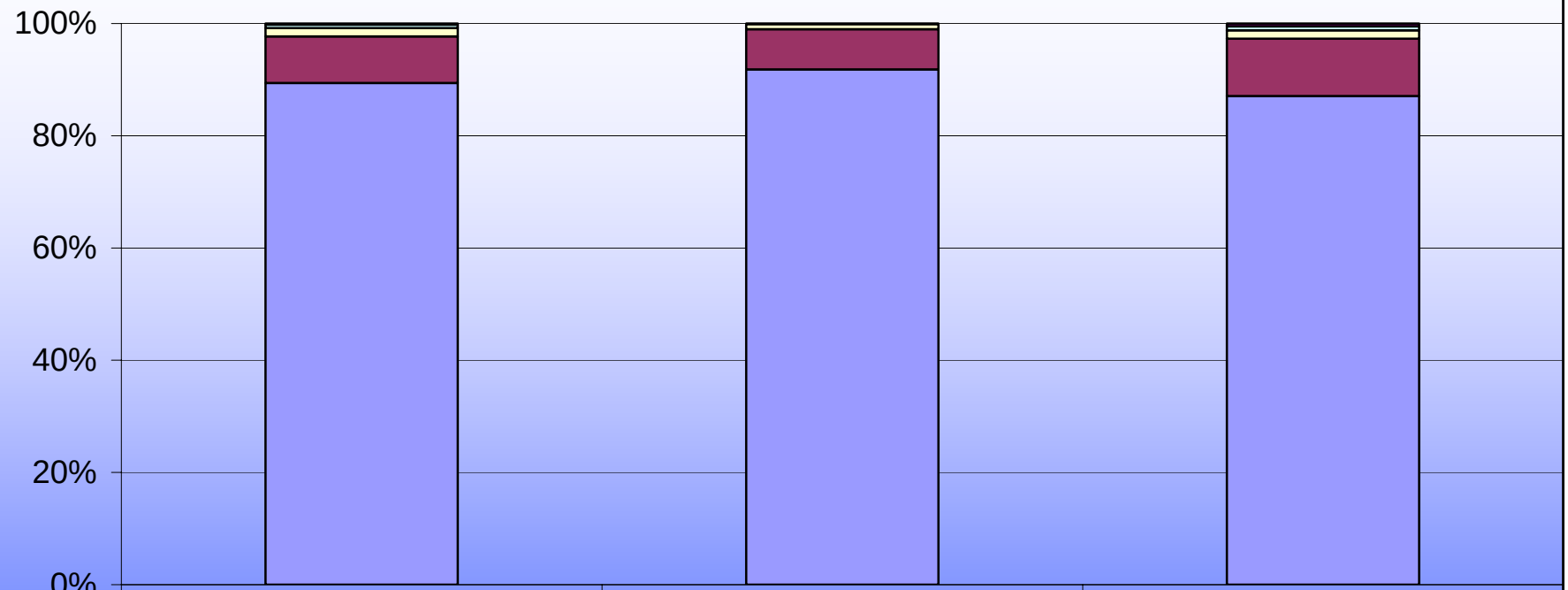
Gráfica 8.- EAs ligados a la Enfermedad y a la Asistencia Sanitaria



Gráfica 9.- Incidencia de EAs por tamaño de Hospital y Servicio

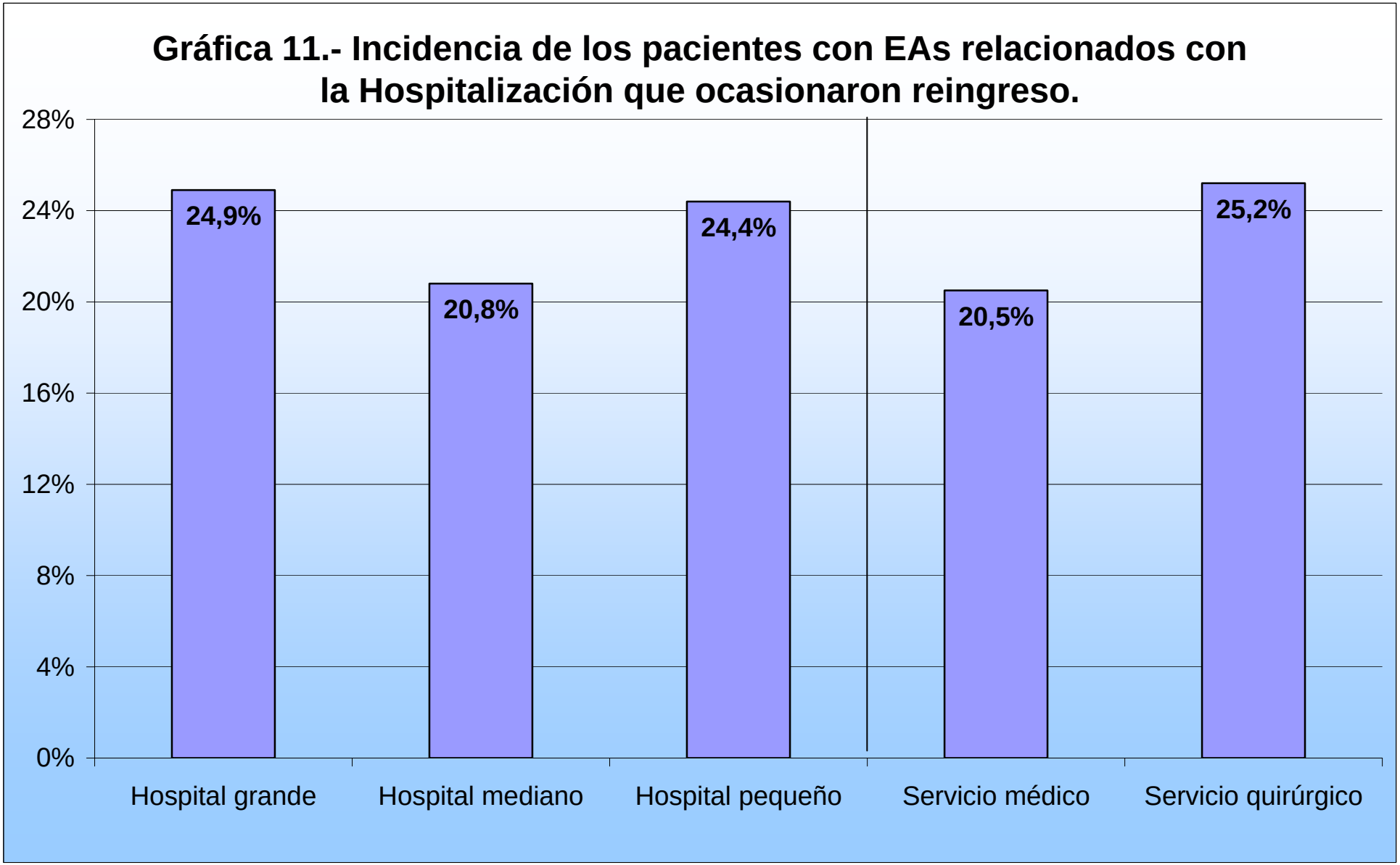


Gráfica 10.- Porcentaje de EAs por paciente y tamaño de Hospital

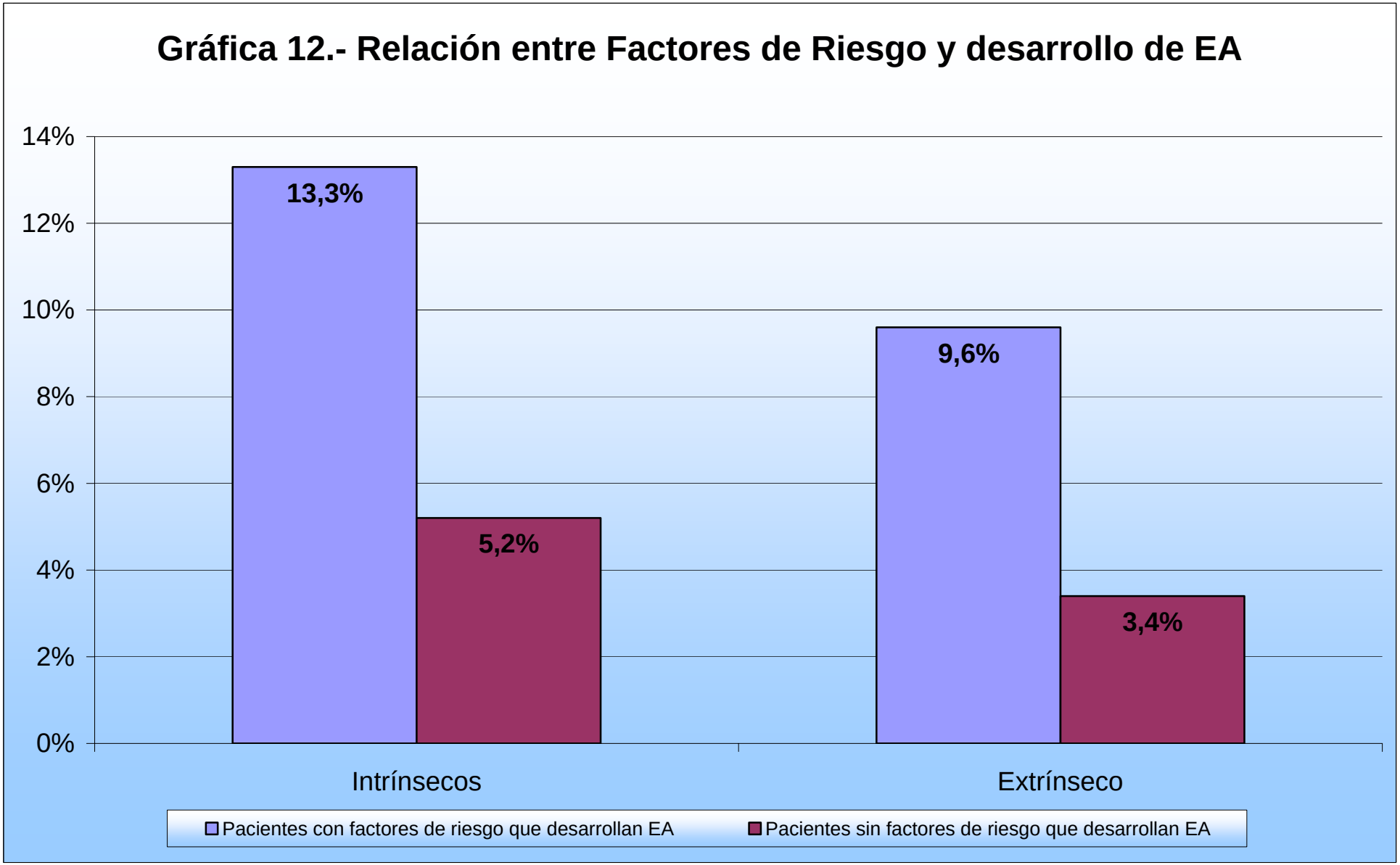


	Hospital grande	Hospital mediano	Hospital pequeño
4 o más EAs	0,2%	0,0%	0,5%
Tres EAs	0,6%	0,1%	0,7%
Dos Eas	1,5%	0,9%	1,5%
Un EA	8,3%	7,2%	10,2%
Ningún EAs	89,4%	92,0%	87,0%

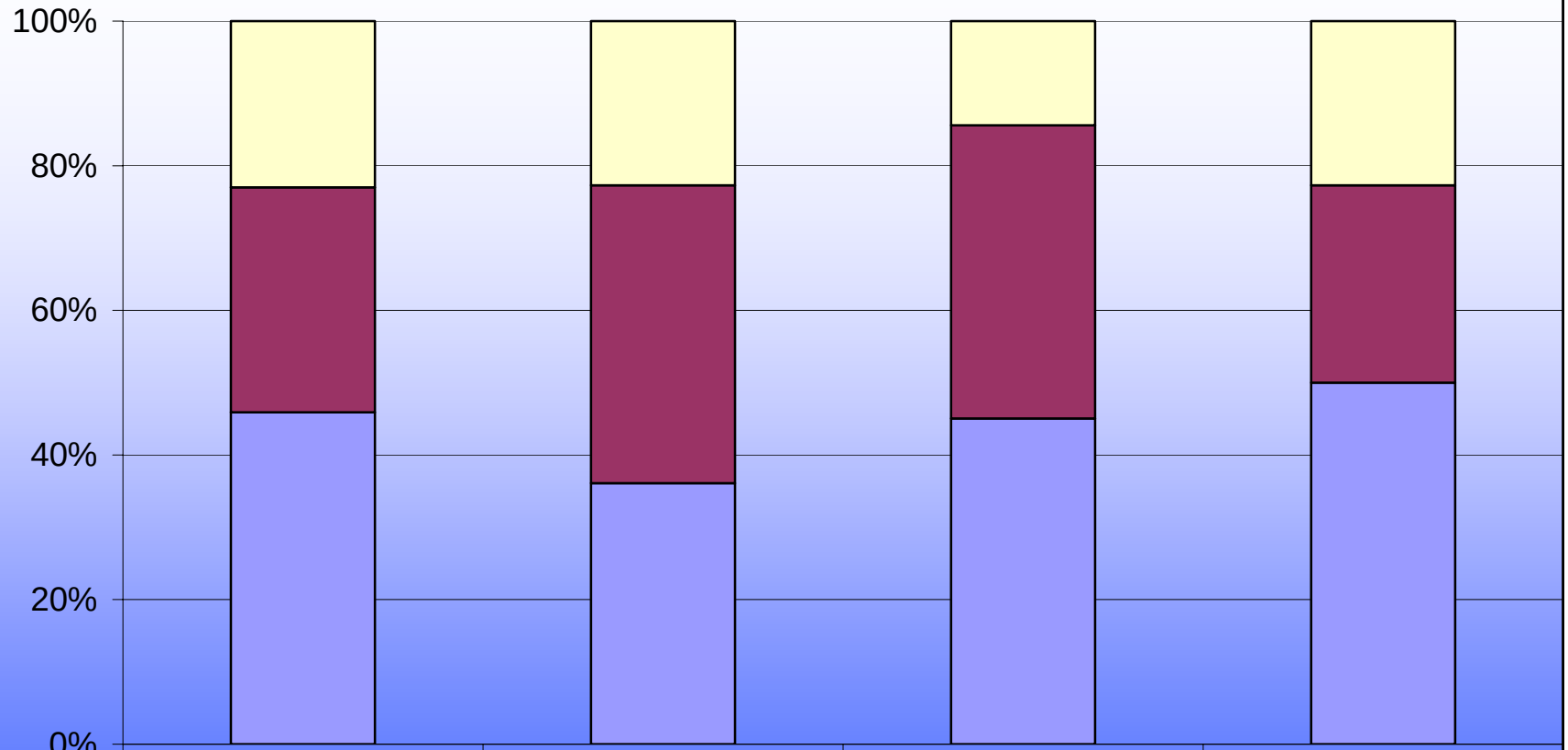
Gráfica 11.- Incidencia de los pacientes con EAs relacionados con la Hospitalización que ocasionaron reingreso.



Gráfica 12.- Relación entre Factores de Riesgo y desarrollo de EA

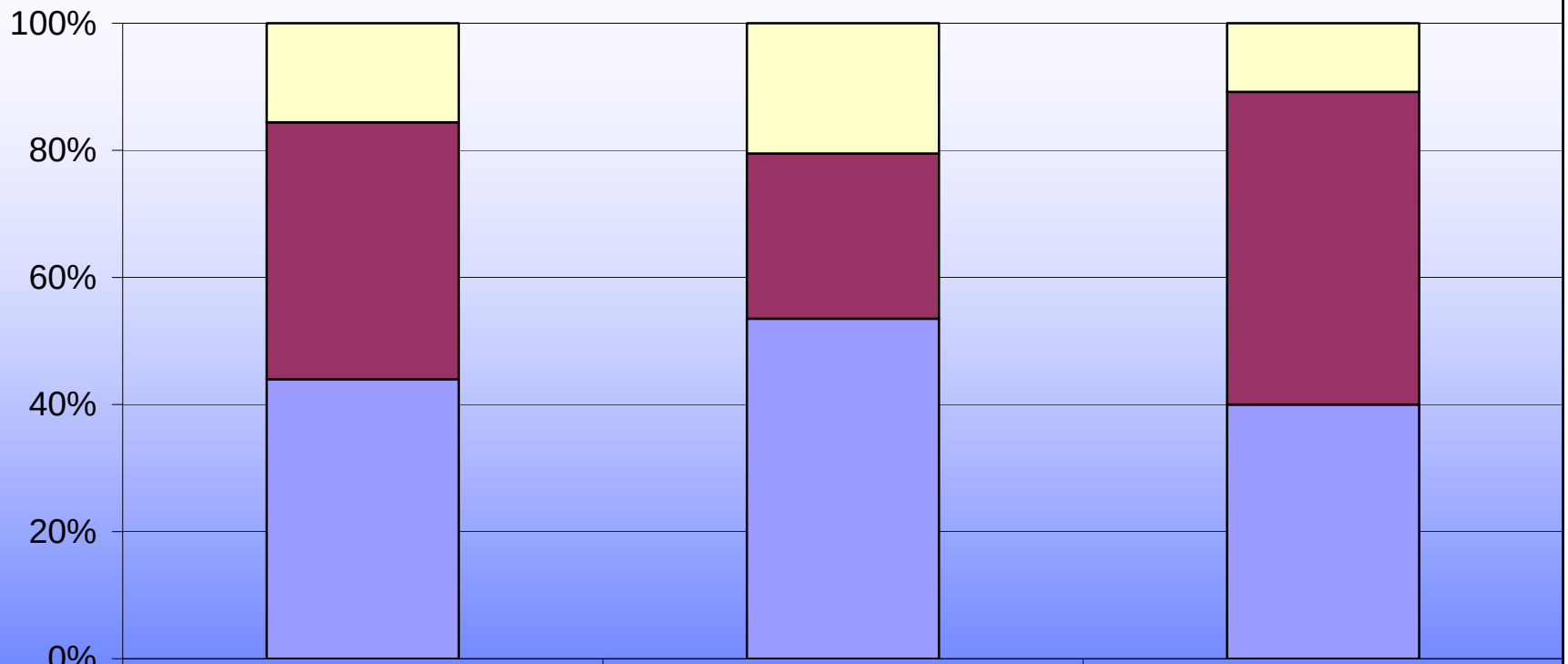


Gráfica 13.- Relación de EAs y Riesgo ASA



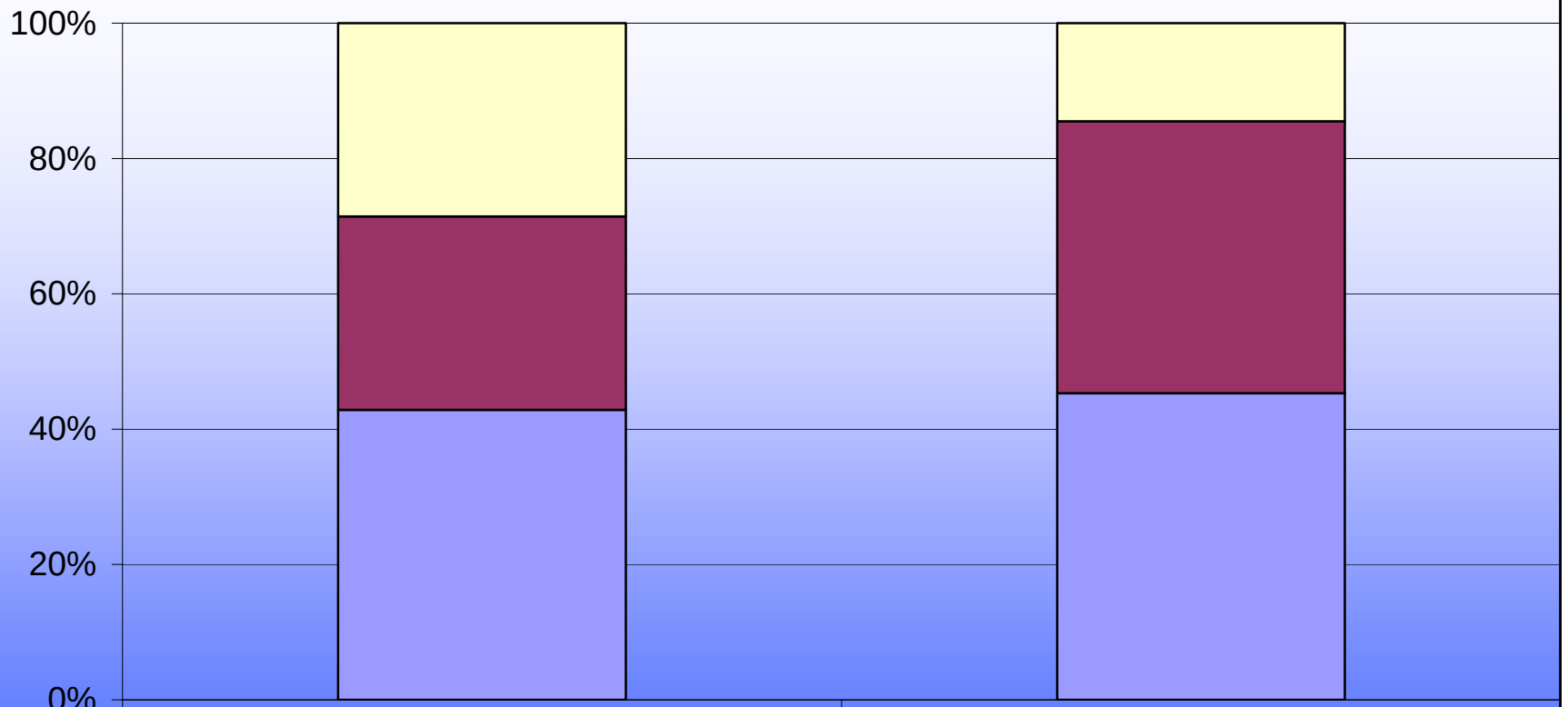
	Sano	Enf. Leve	Lim. Funcional	Amenaza de muerte
EAs Graves	23,0%	22,7%	14,4%	22,7%
EAs Moderados	31,1%	41,2%	40,5%	27,3%
EAs Leves	45,9%	36,1%	45,0%	50,0%

Gráfica 14.- Pronóstico de la Enfermedad Principal y EAs



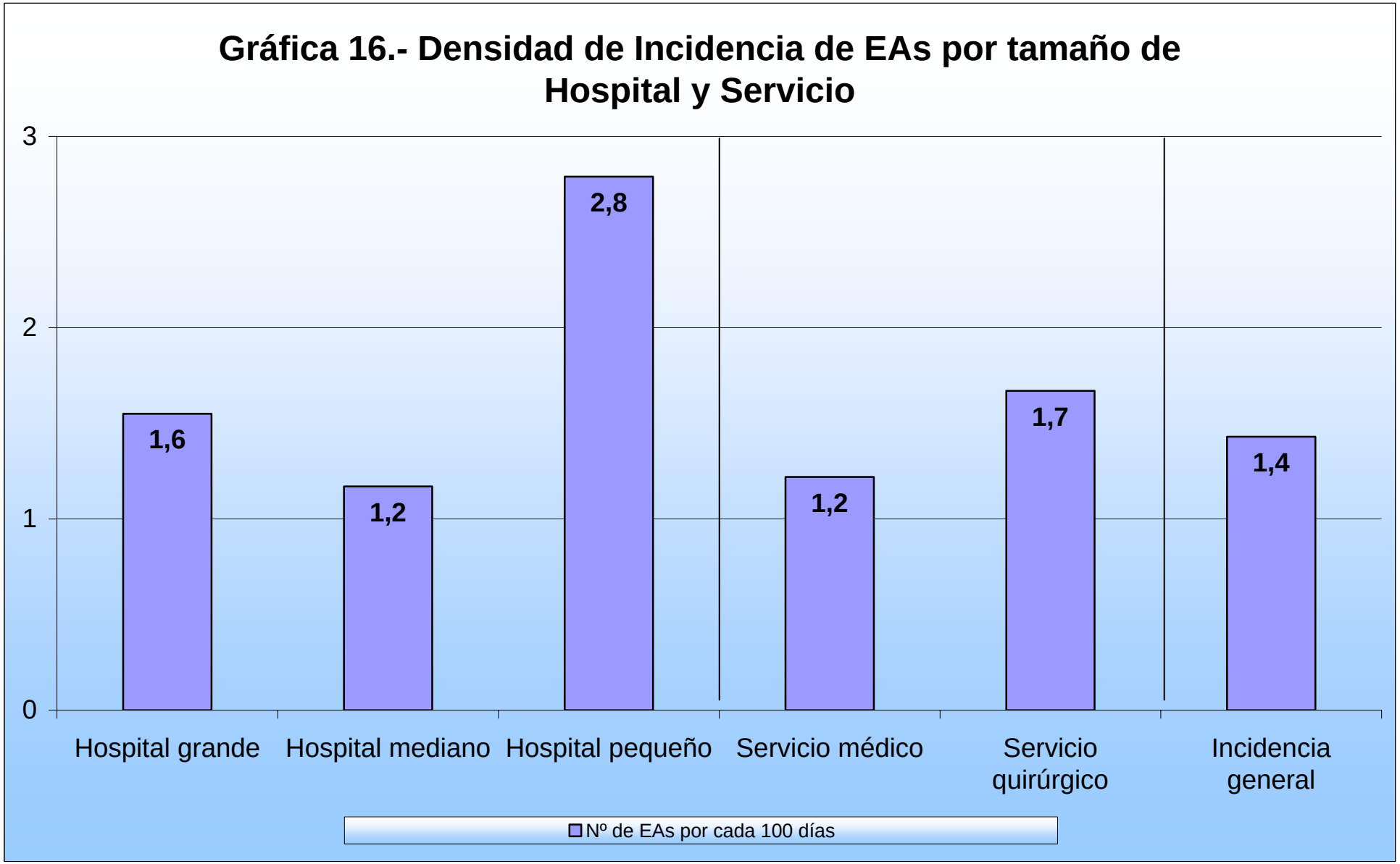
	Recuperación completa al estado de salud basal	Recuperación con invalidez residual	Enfermedad terminal
EAs Graves	15,6%	20,5%	10,8%
EAs Moderados	40,4%	26,0%	49,2%
EAs Leves	44,0%	53,5%	40,0%

Gráfica 15.- Asociación de Comorbilidades con la Gravedad del EA

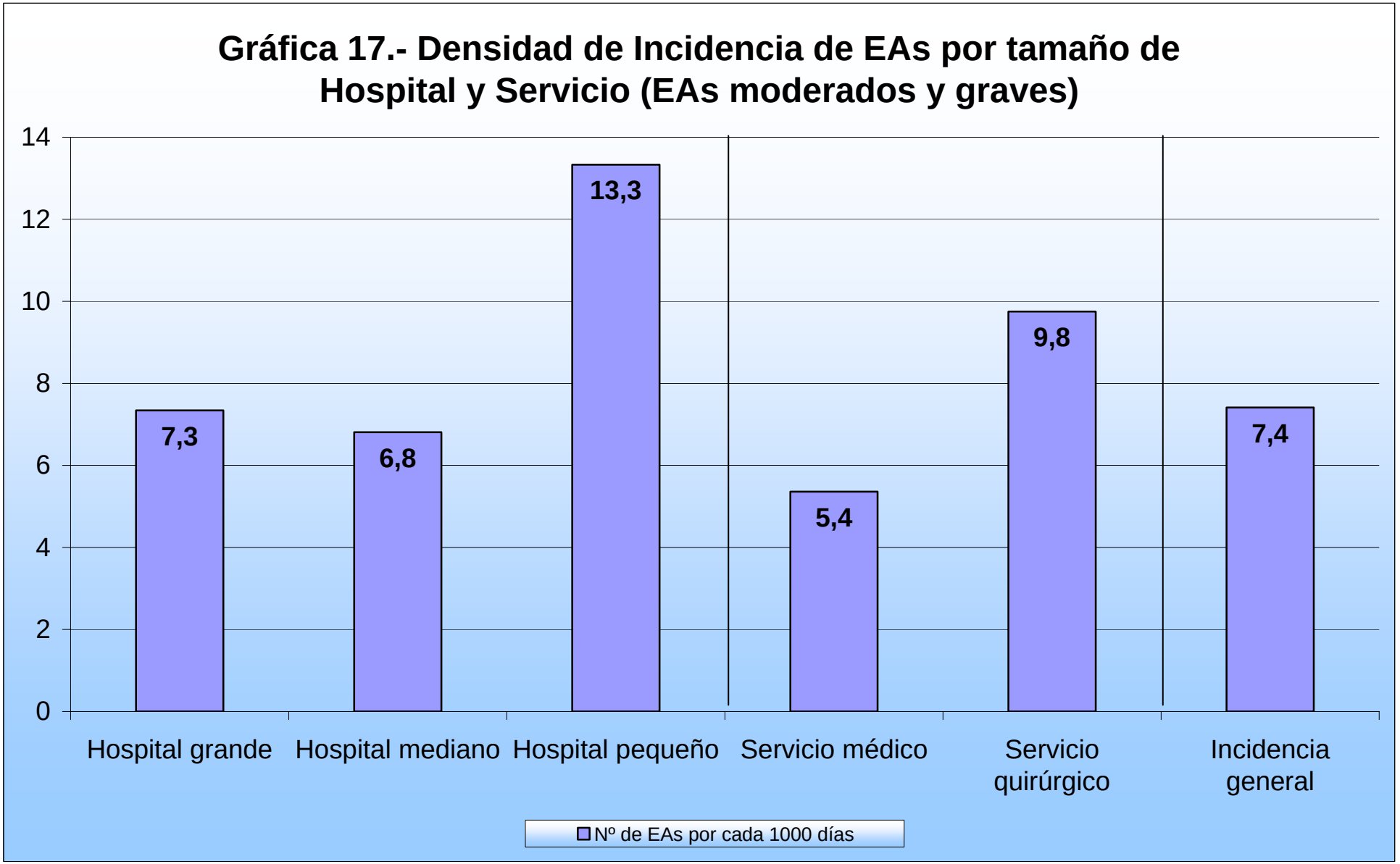


	Ausencia de comorbilidades	Presencia de comorbilidades
EAs Graves	28,6%	14,5%
EAs Moderados	28,6%	40,2%
EAs Leves	42,9%	45,3%

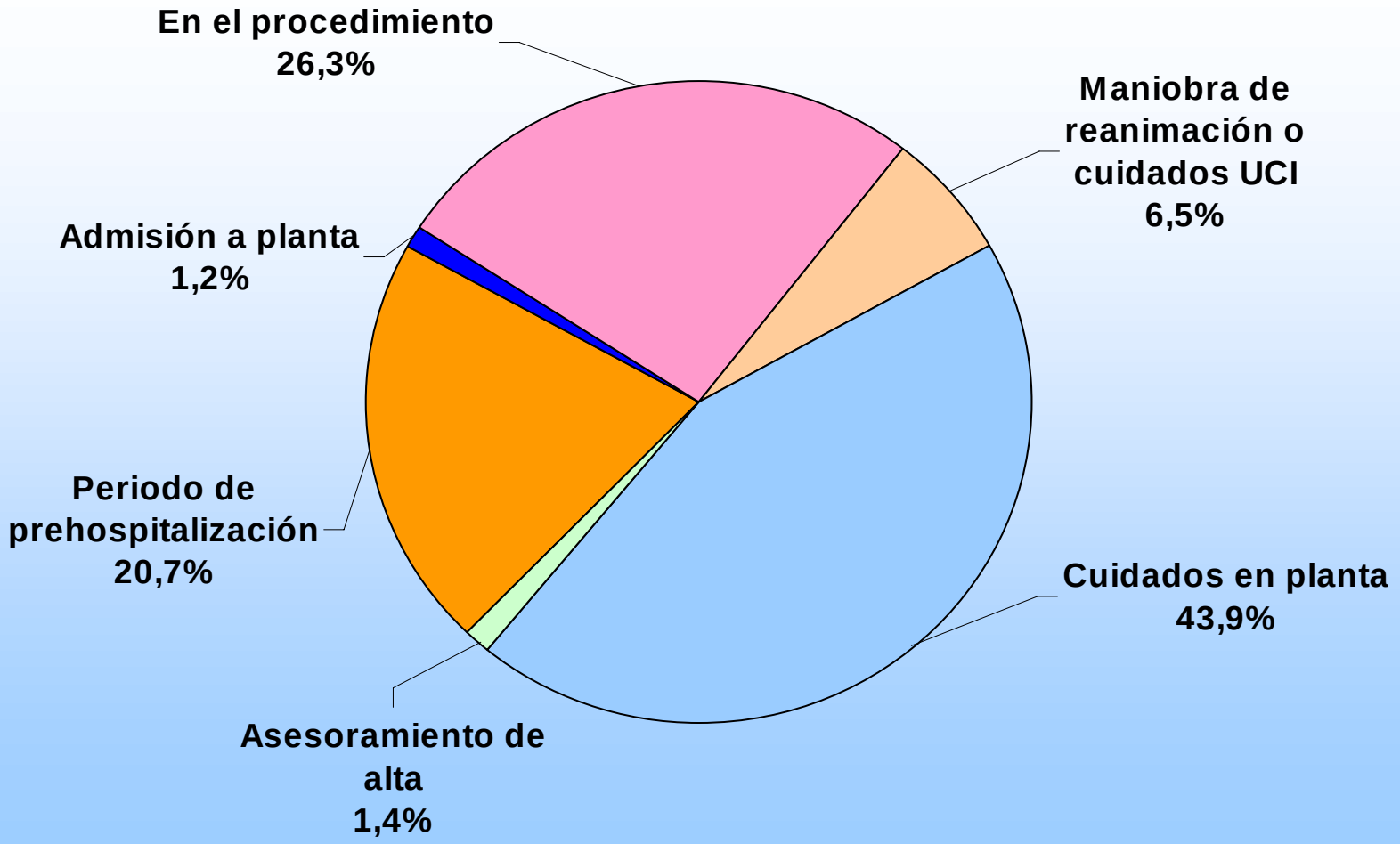
Gráfica 16.- Densidad de Incidencia de EAs por tamaño de Hospital y Servicio



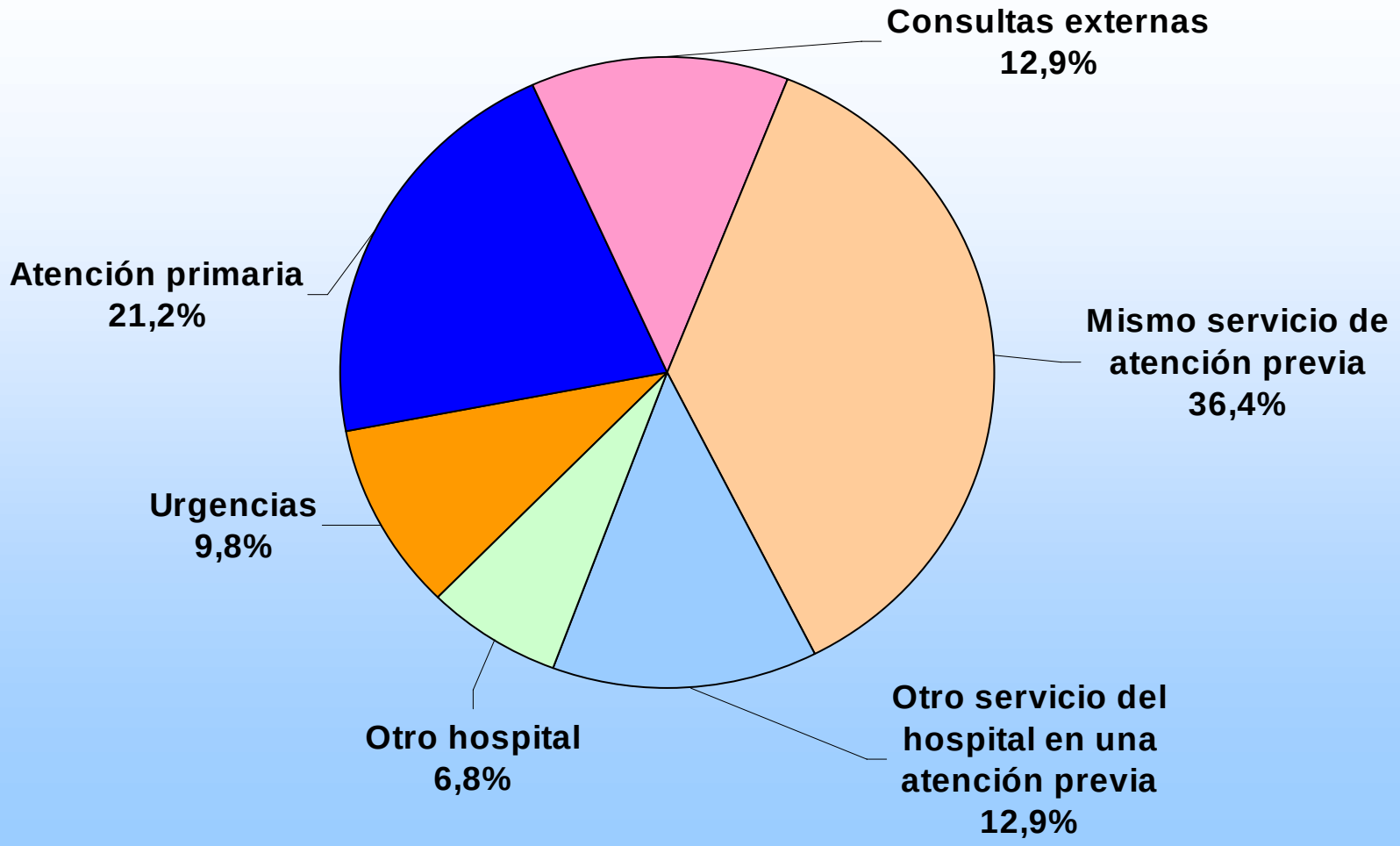
Gráfica 17.- Densidad de Incidencia de EAs por tamaño de Hospital y Servicio (EAs moderados y graves)



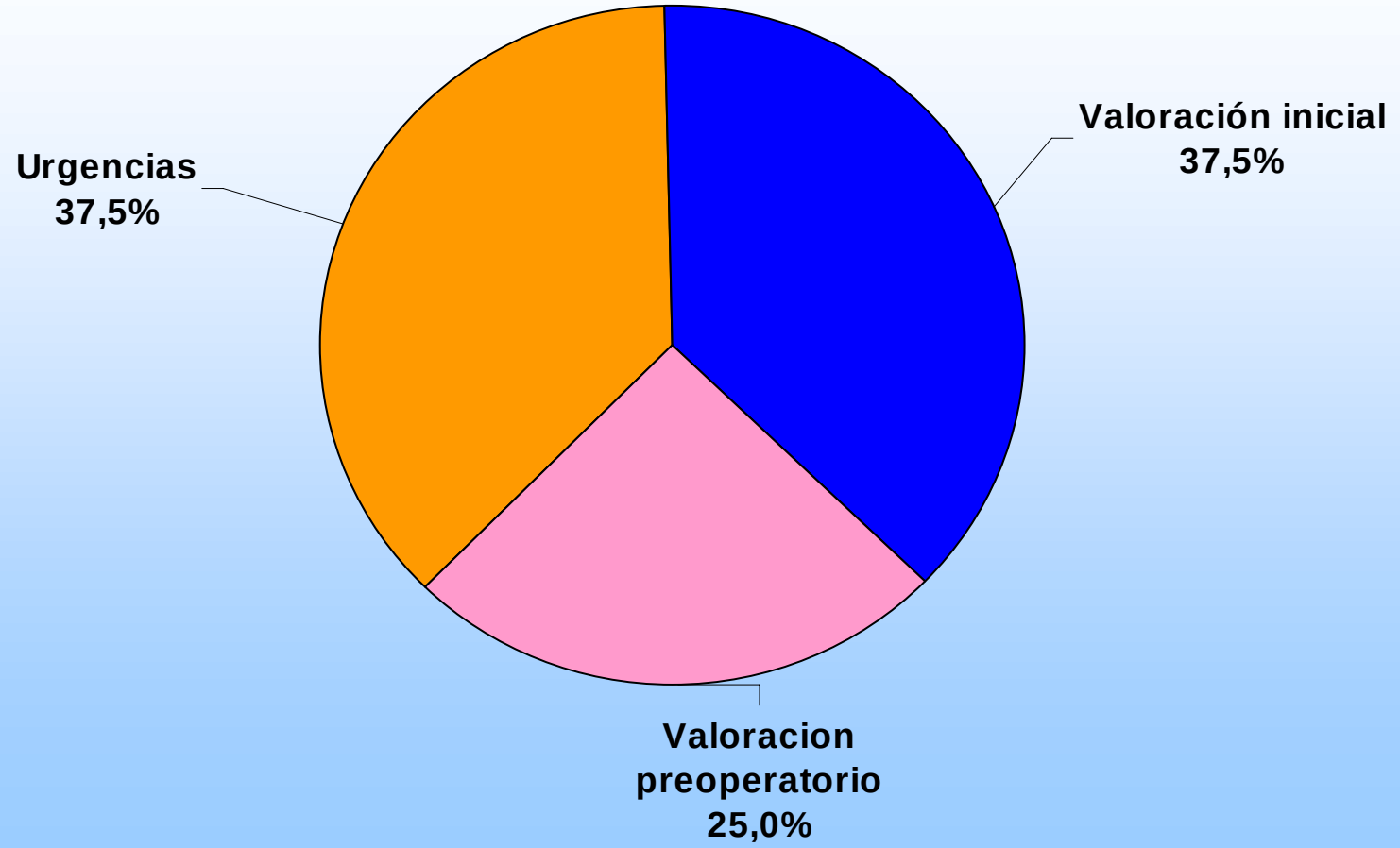
Gráfica 18.- Causalidad de los EAs



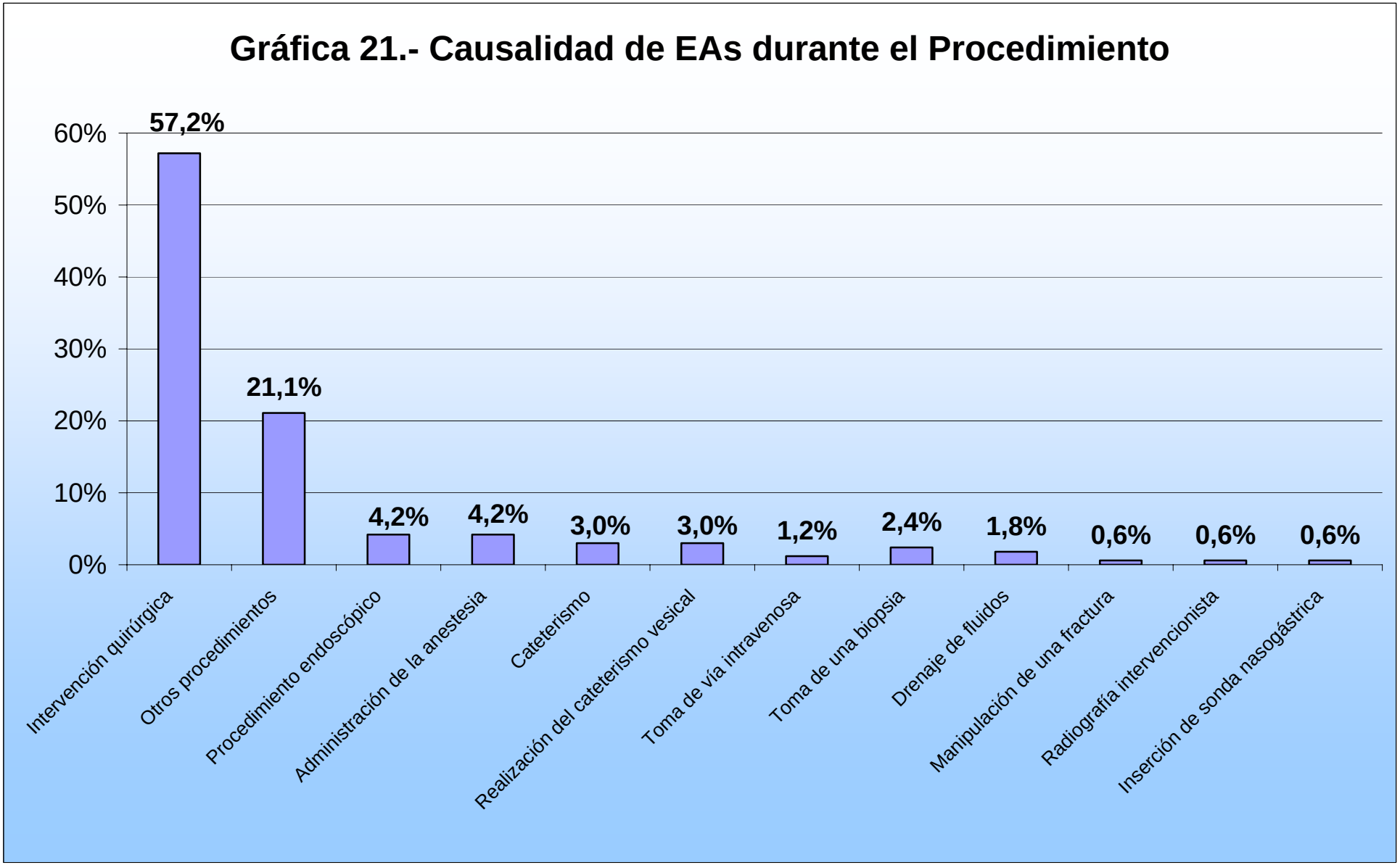
Gráfica 19.- Causalidad de los EAs en el periodo de Prehospitalización



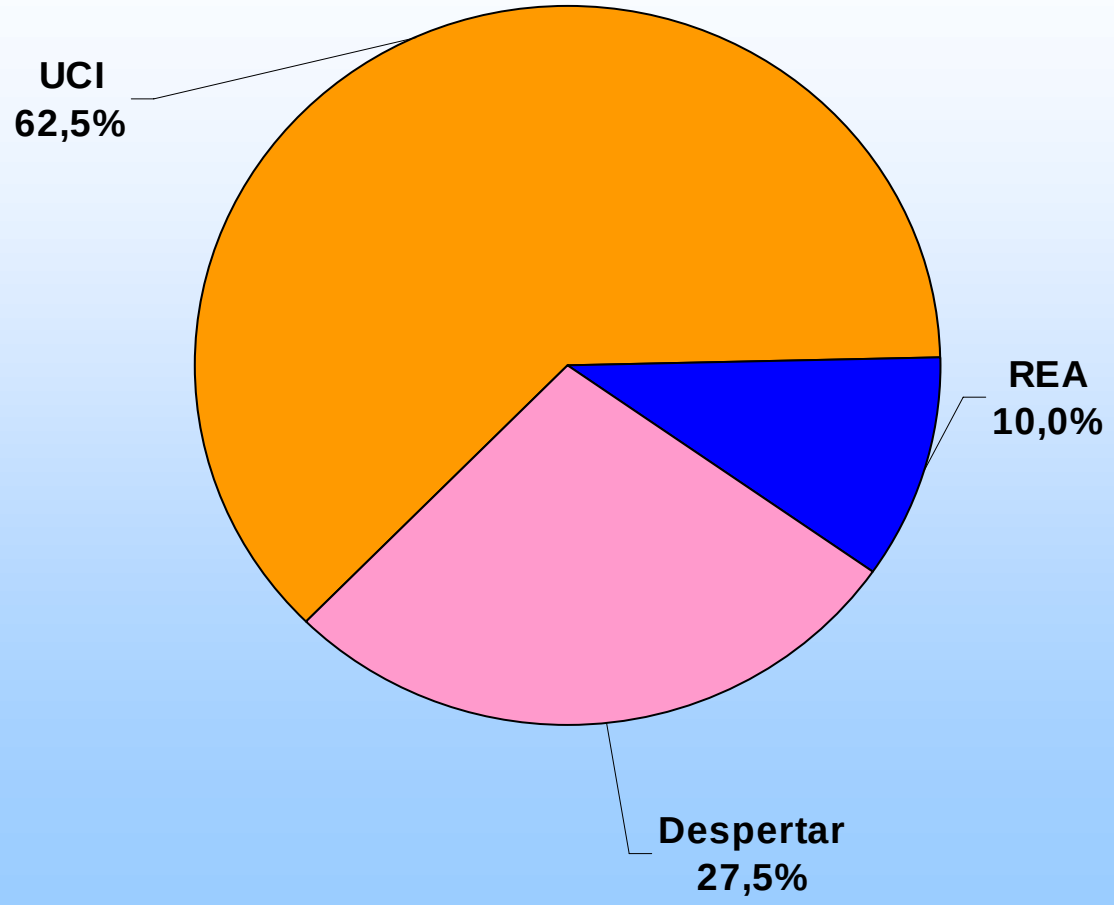
Gráfica 20.- Causalidad de los EAs en el periodo de Admisión a Planta



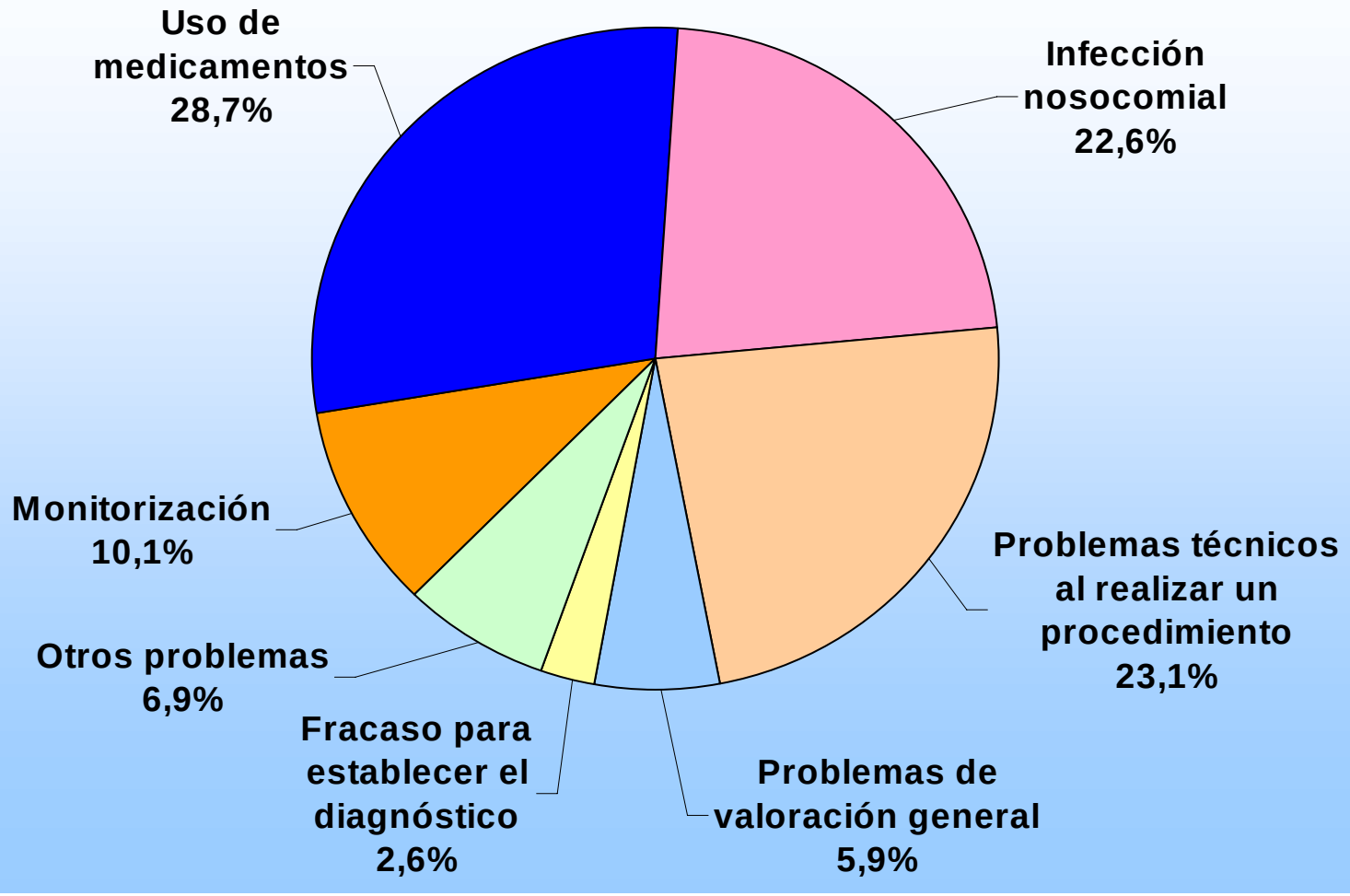
Gráfica 21.- Causalidad de EAs durante el Procedimiento



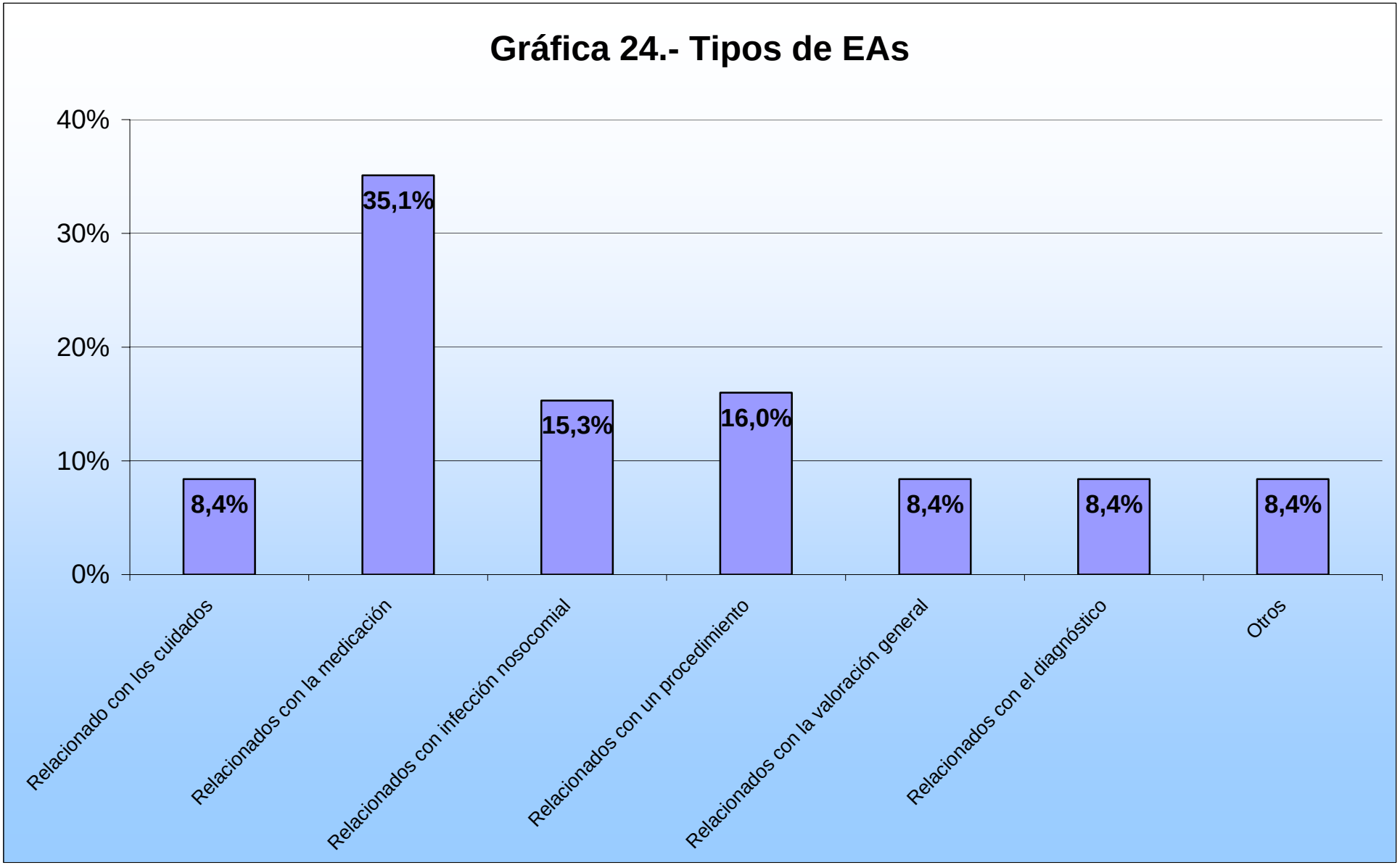
Gráfica 22.- Causalidad de EAs en UCI o Reanimación



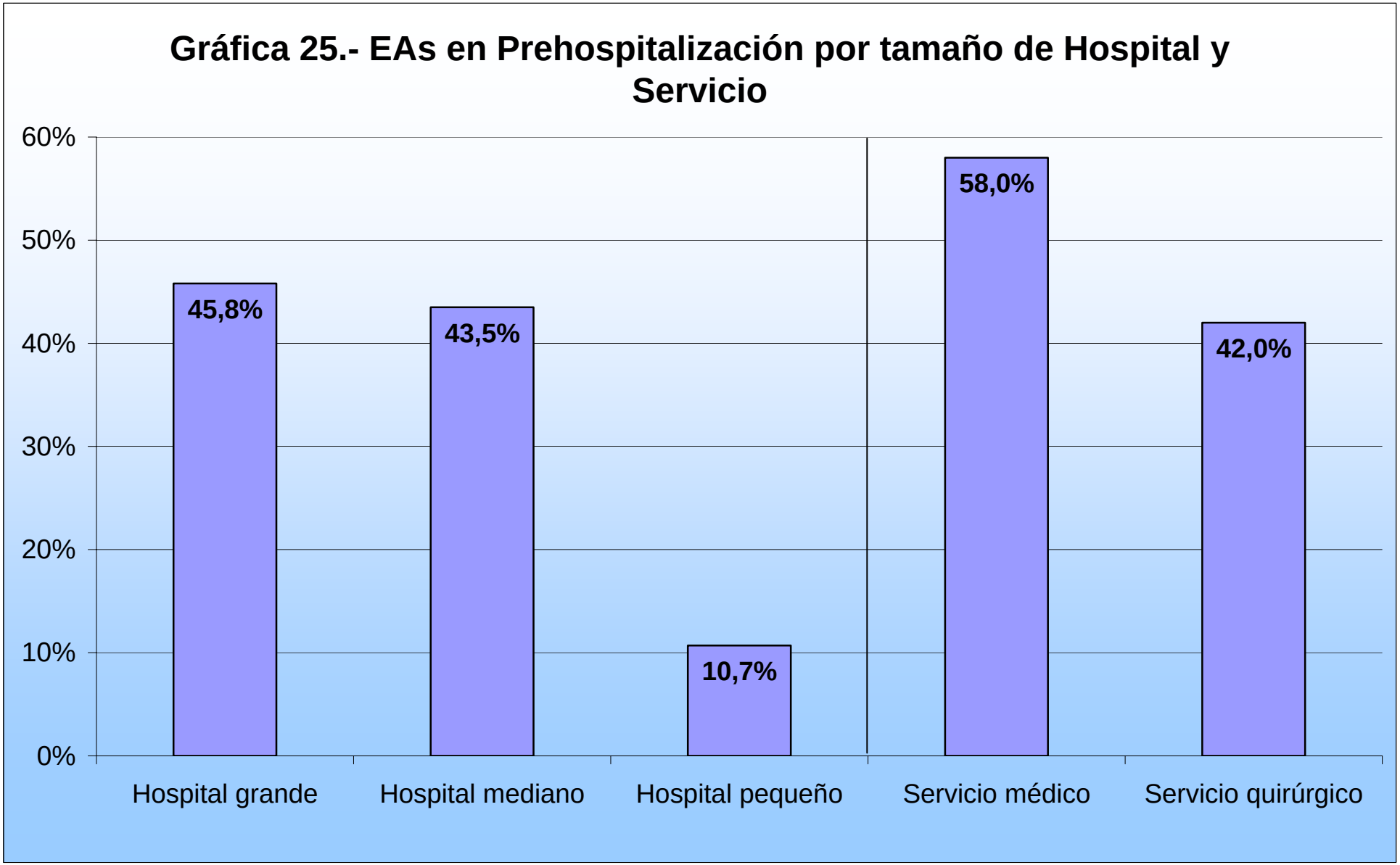
Gráfica 23.- Naturaleza del problema principal del EA



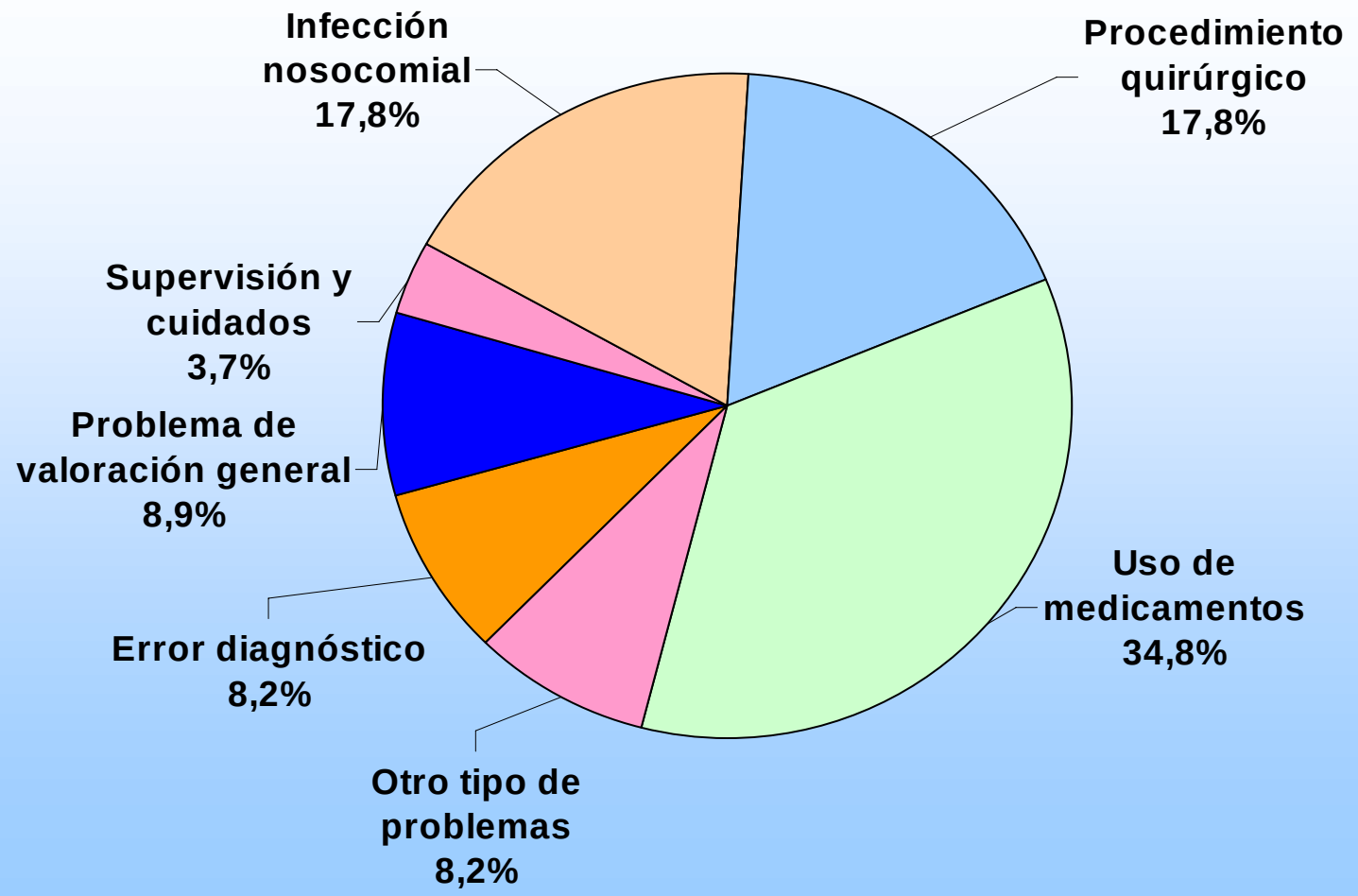
Gráfica 24.- Tipos de EAs



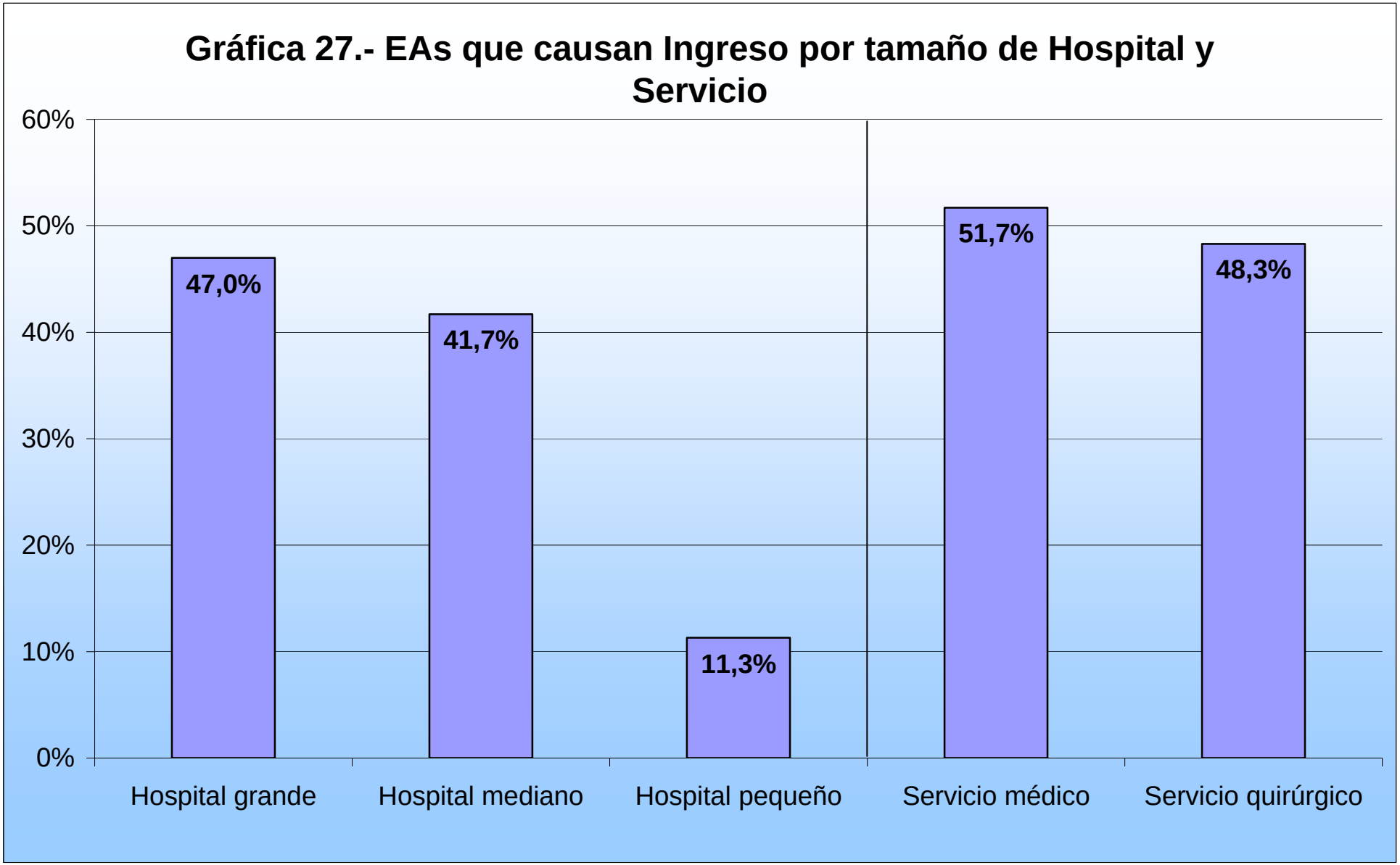
Gráfica 25.- EAs en Prehospitalización por tamaño de Hospital y Servicio



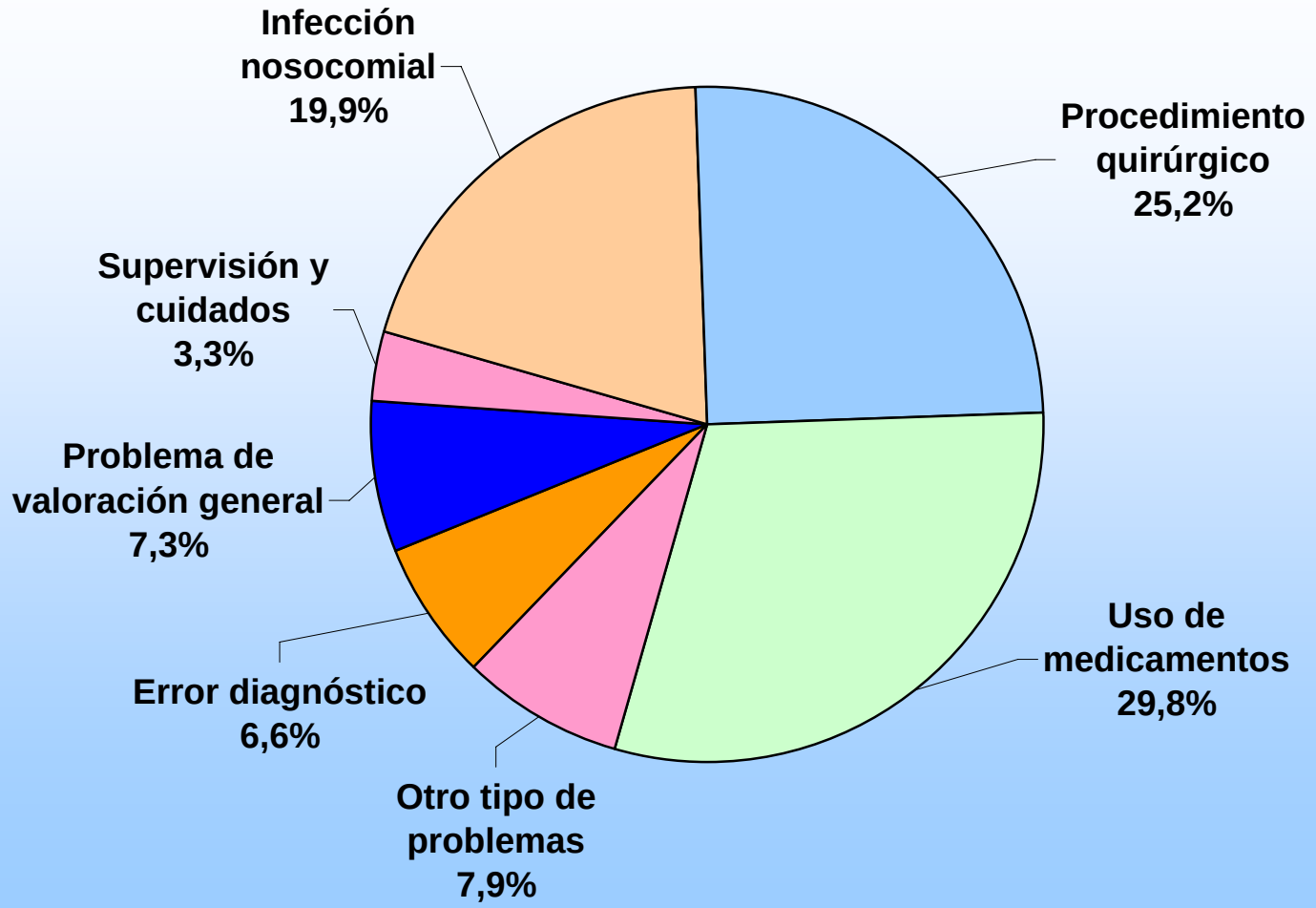
Gráfica 26.- Tipos EAs del periodo de Prehospitalización



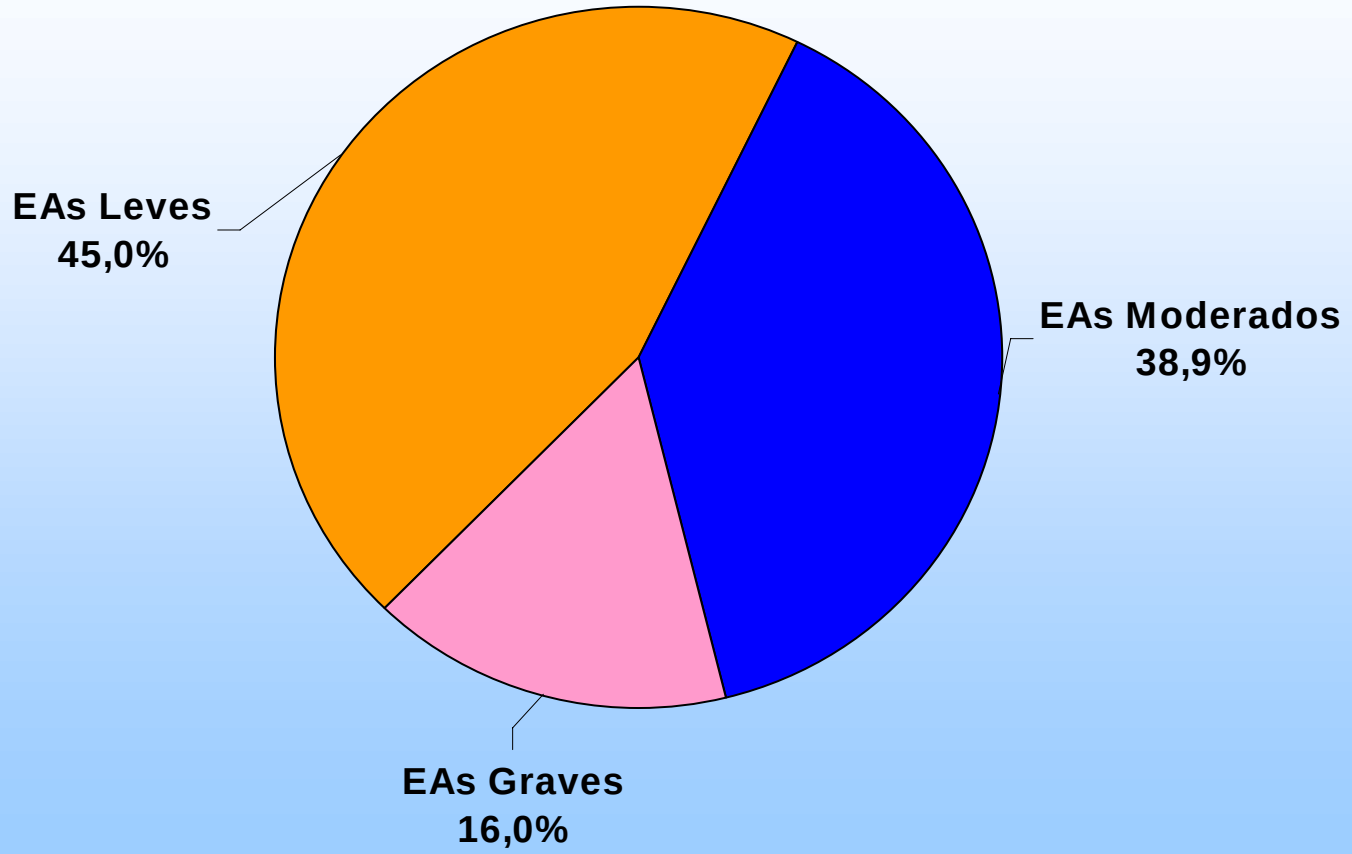
Gráfica 27.- EAs que causan Ingreso por tamaño de Hospital y Servicio



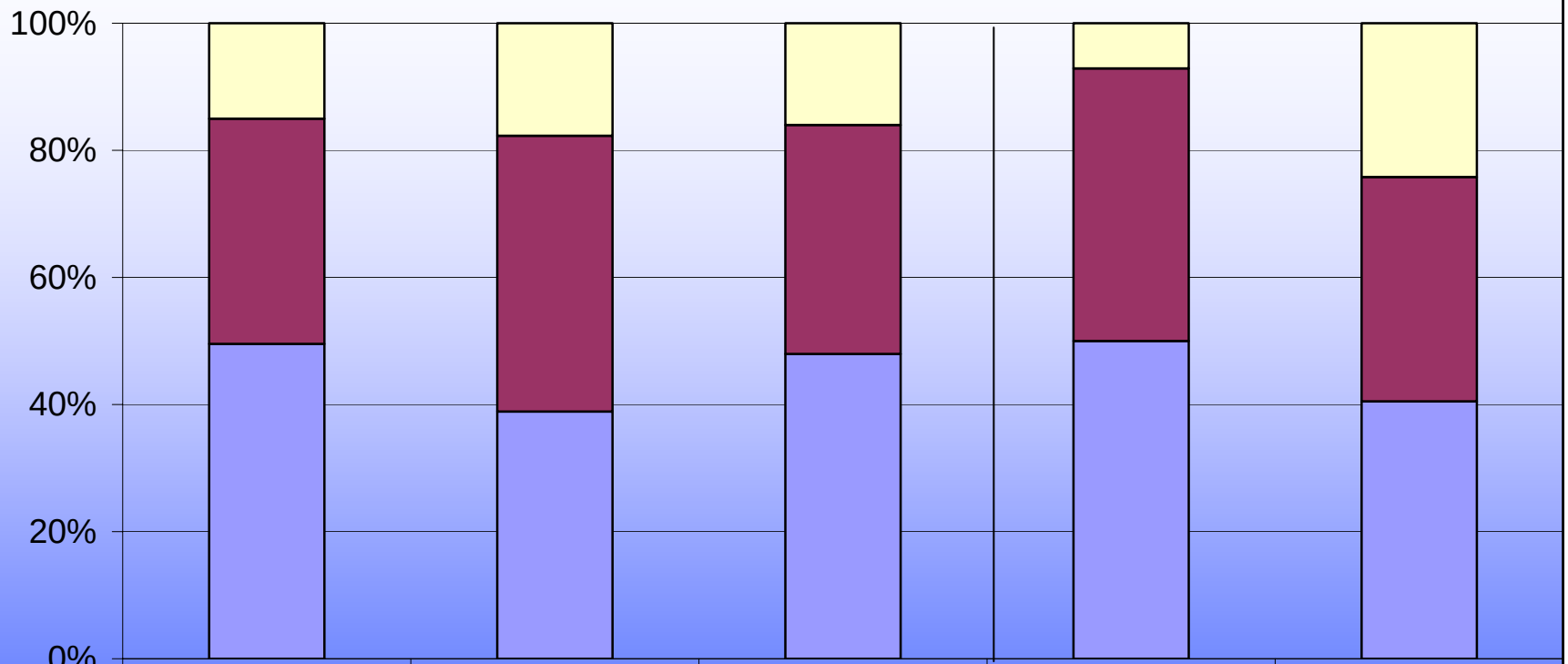
Gráfica 28.- Tipos de EAs que causan Ingreso Hospitalario



Gráfica 29.- Impacto de los EAs

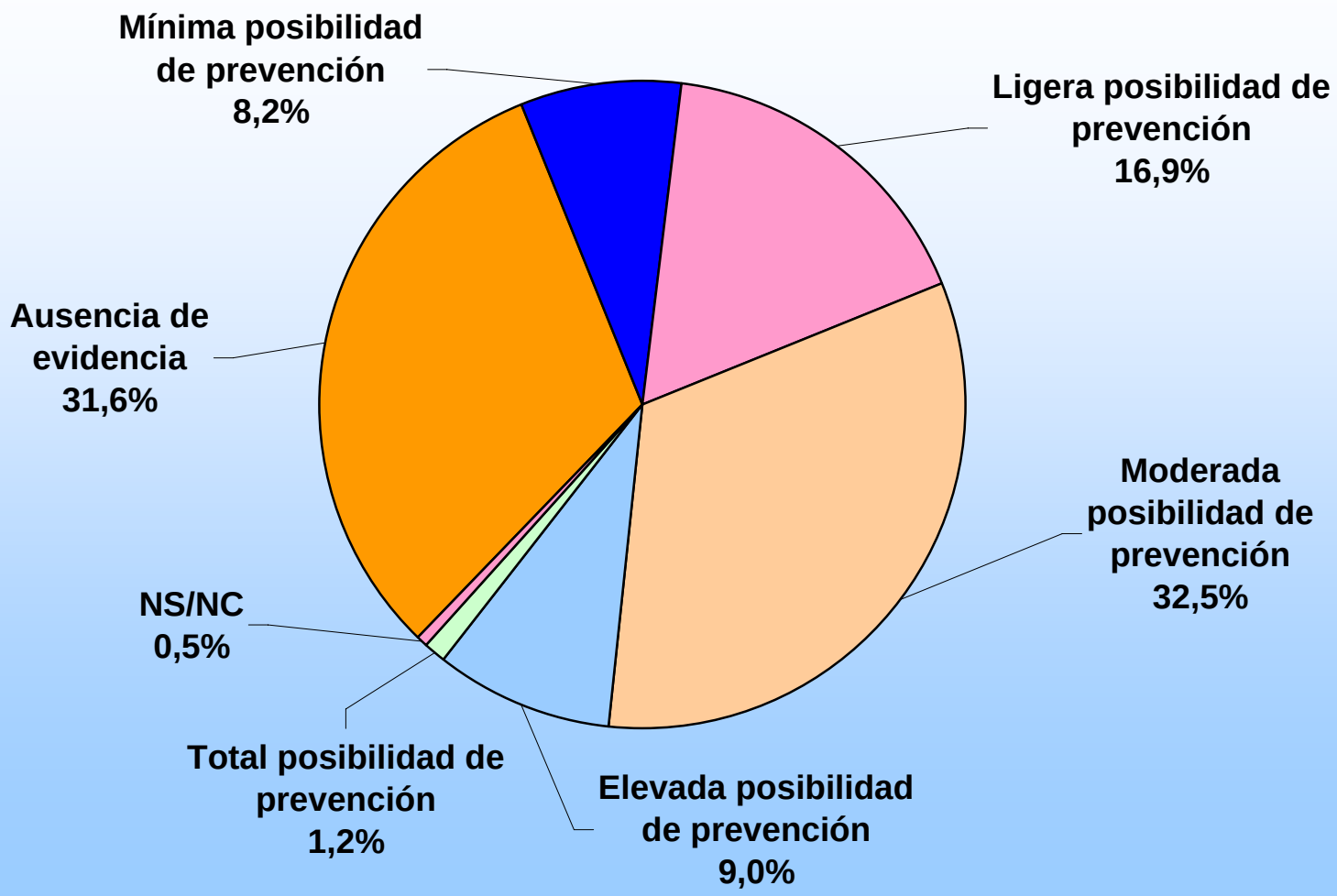


Gráfica 30.- Impacto de EAs por el tamaño de Hospital y Servicio

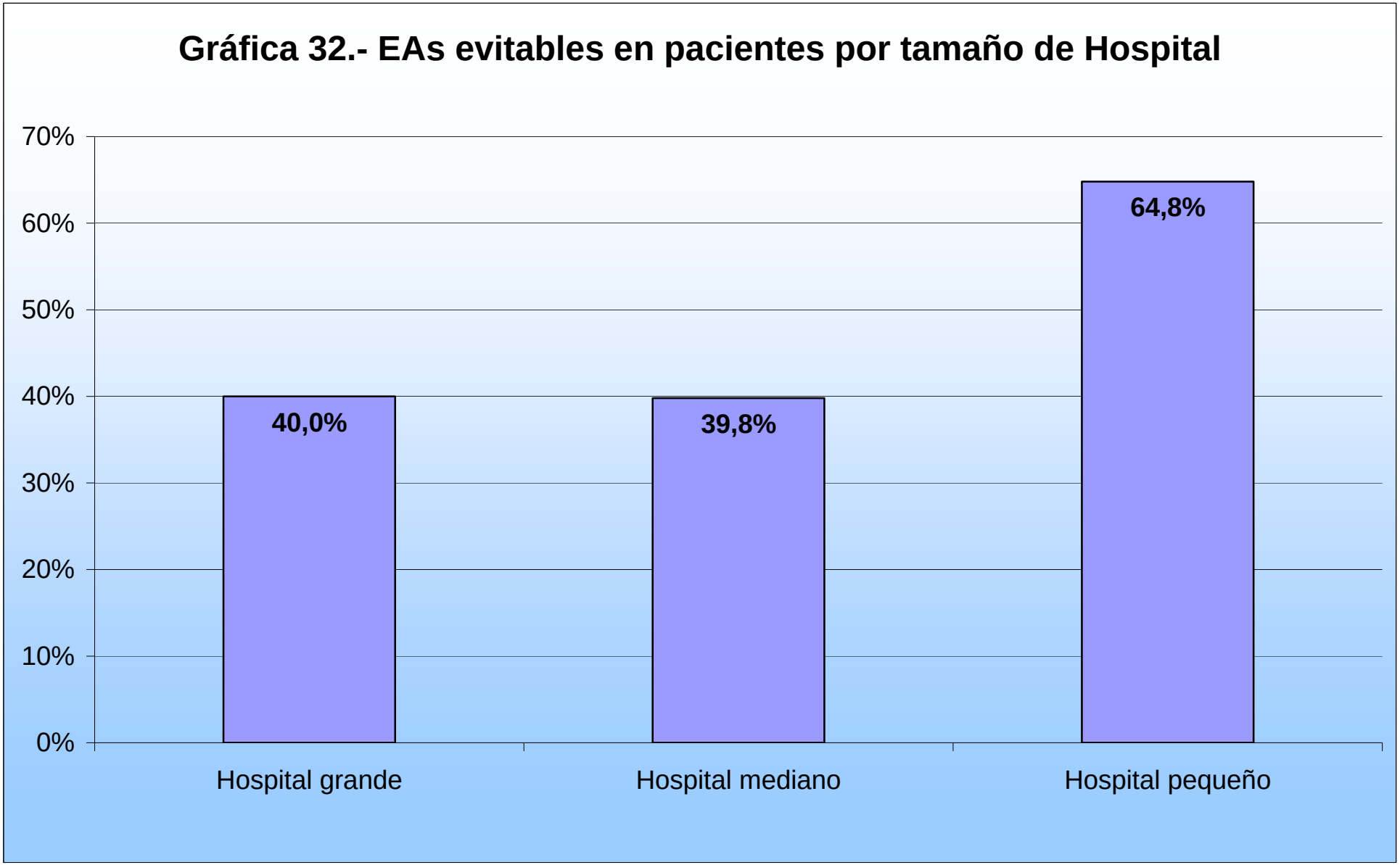


	Hospital grande	Hospital mediano	Hospital pequeño	Servicio médico	Servicio quirúrgico
EAs Graves	15,0%	17,7%	16,0%	7,1%	24,2%
EAs Moderados	35,4%	43,4%	36,0%	42,9%	35,3%
EAs Leves	49,5%	38,9%	47,9%	50,0%	40,5%

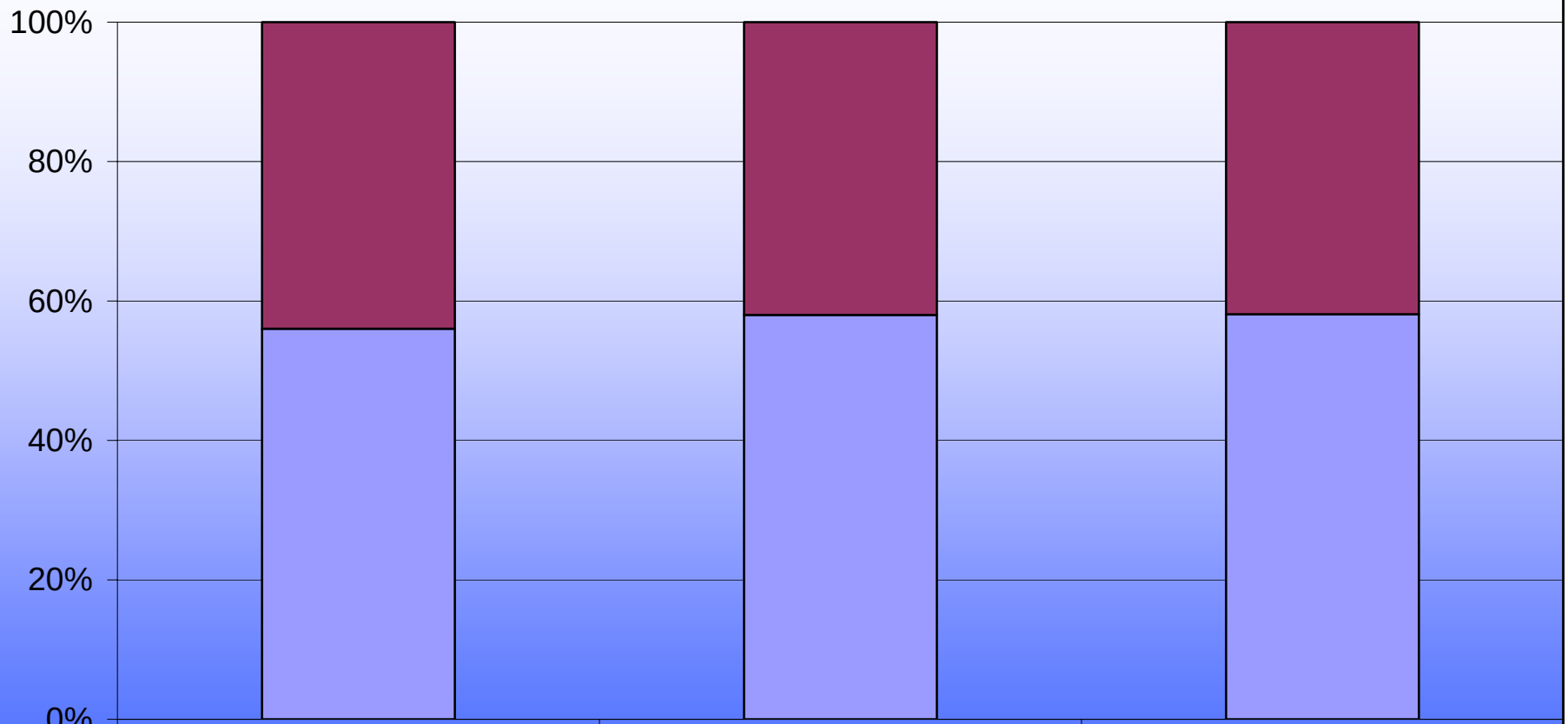
Gráfica 31.- Evitabilidad de EAs



Gráfica 32.- EAs evitables en pacientes por tamaño de Hospital

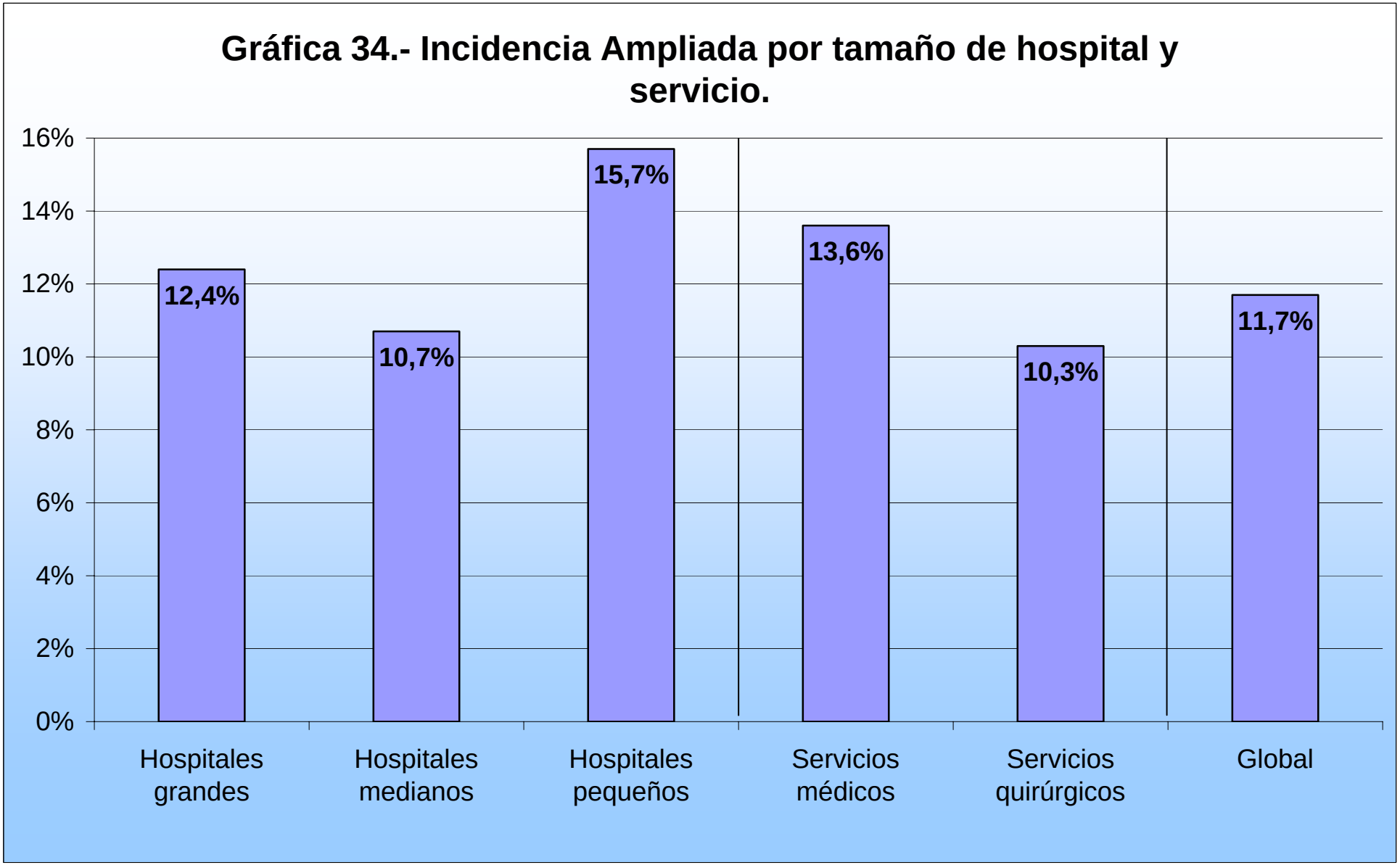


Gráfica 33.- Gravedad de los EAs considerando su evitabilidad

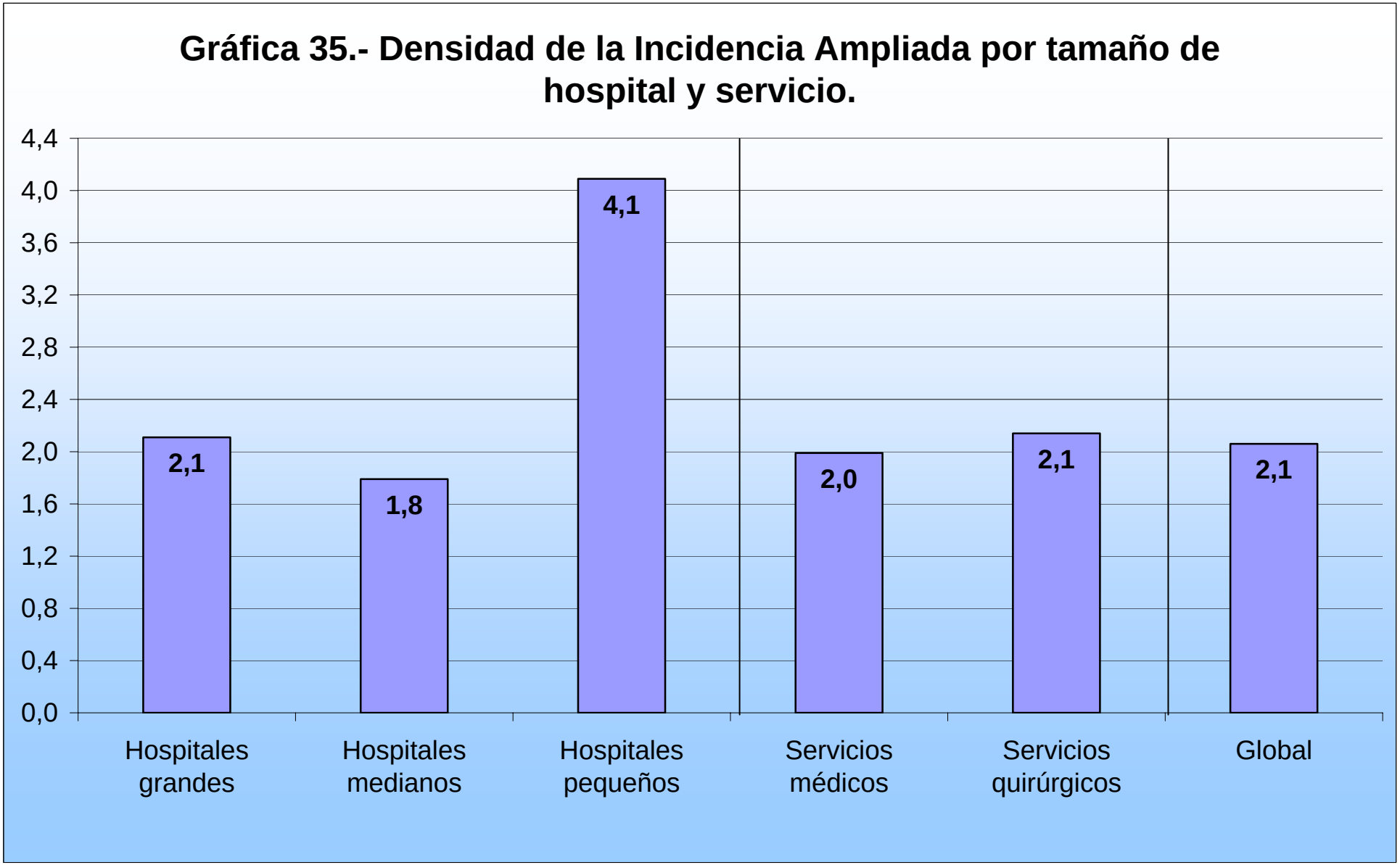


	EAs Leves	EAs Moderados	EAs Graves
Evitable	43,8%	42,0%	41,9%
No evitable	55,8%	58,0%	58,1%

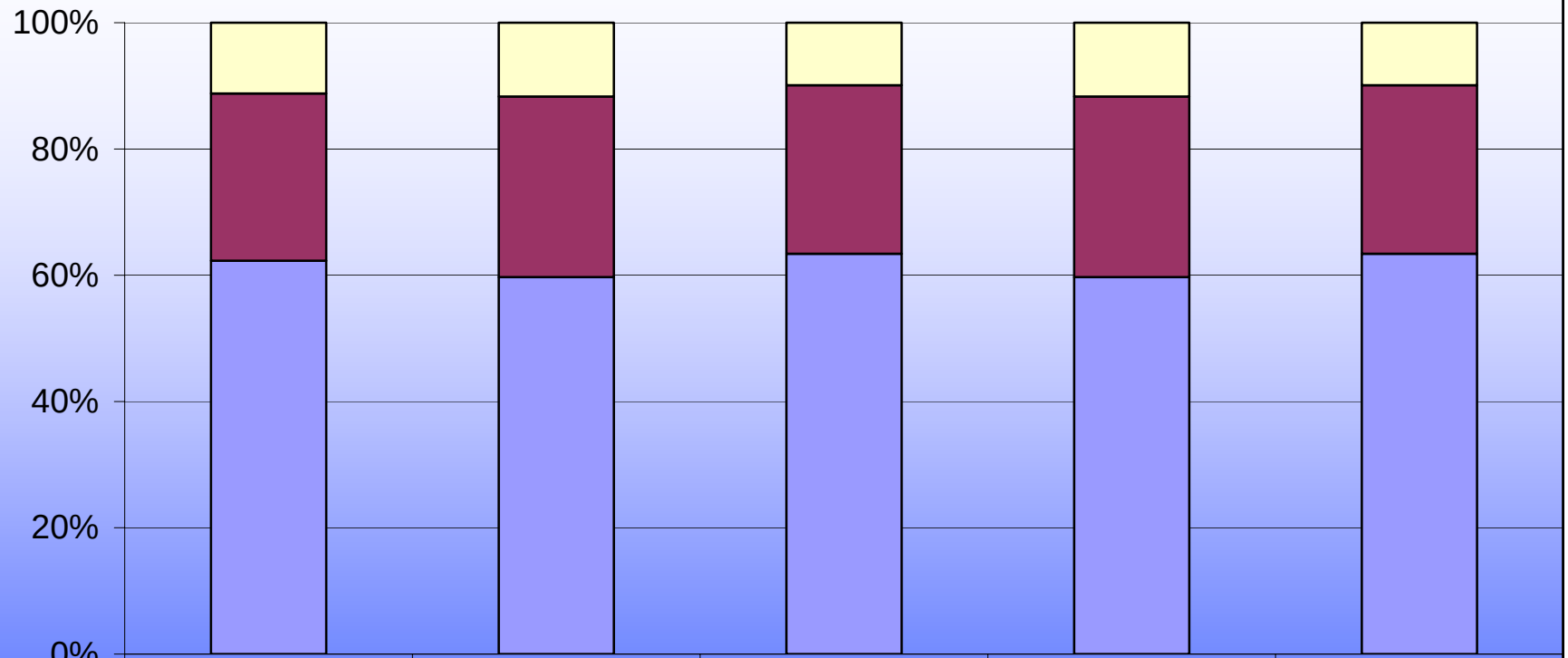
Gráfica 34.- Incidencia Ampliada por tamaño de hospital y servicio.



Gráfica 35.- Densidad de la Incidencia Ampliada por tamaño de hospital y servicio.

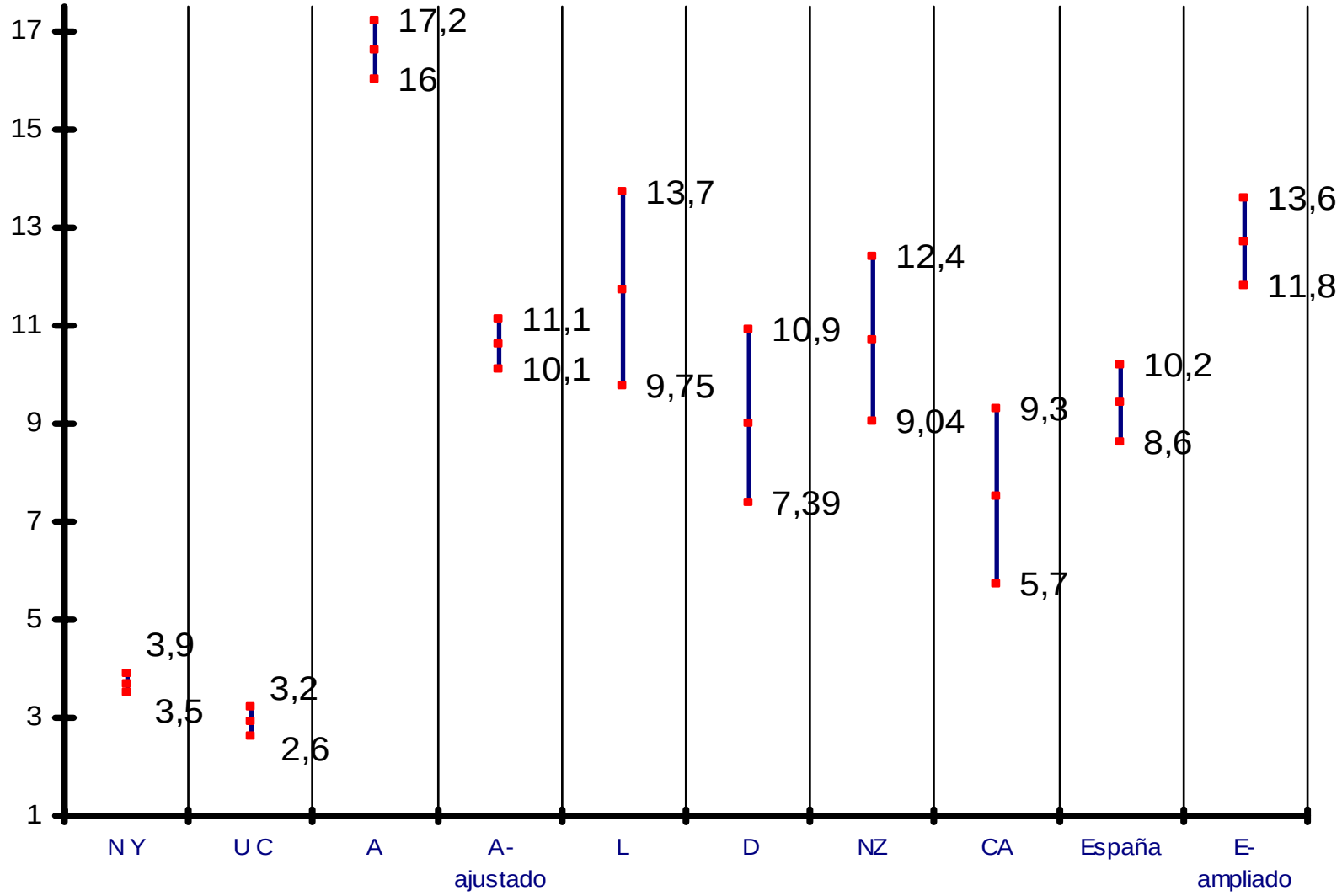


Gráfica 36.- Impacto de la Incidencia Ampliada por tamaño de hospital y servicio



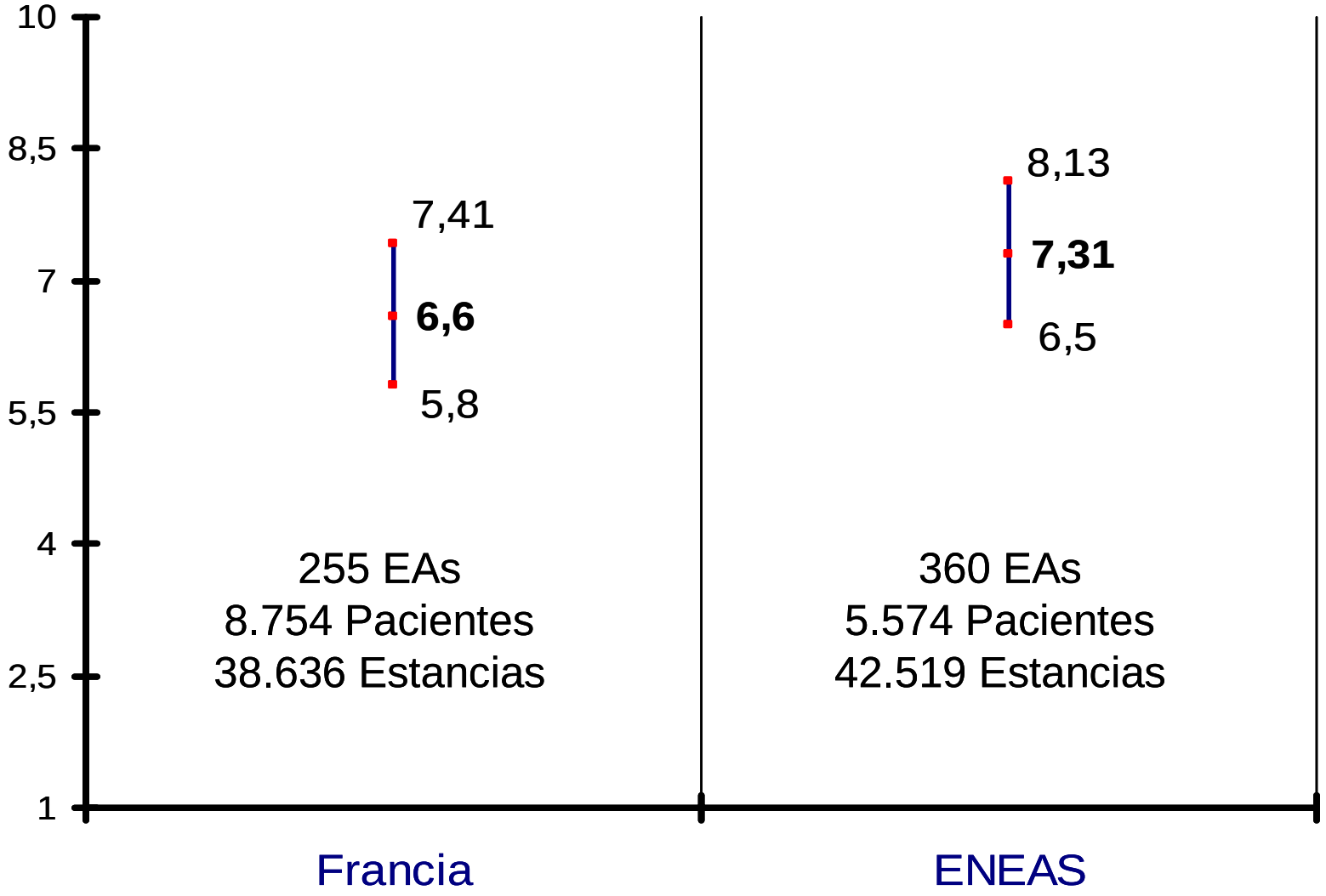
	Hospital grande	Hospital mediano	Hospital pequeño	Servicio médico	Servicio quirúrgico
Eas Graves	11,2%	11,7%	9,9%	11,7%	9,9%
Eas Moderados	26,5%	28,6%	26,7%	28,6%	26,7%
Eas Leves	62,3%	59,7%	63,4%	59,7%	63,4%

Gráfica 37.- Distribución de la Incidencia de pacientes con EAs, relacionados con la asistencia sanitaria.

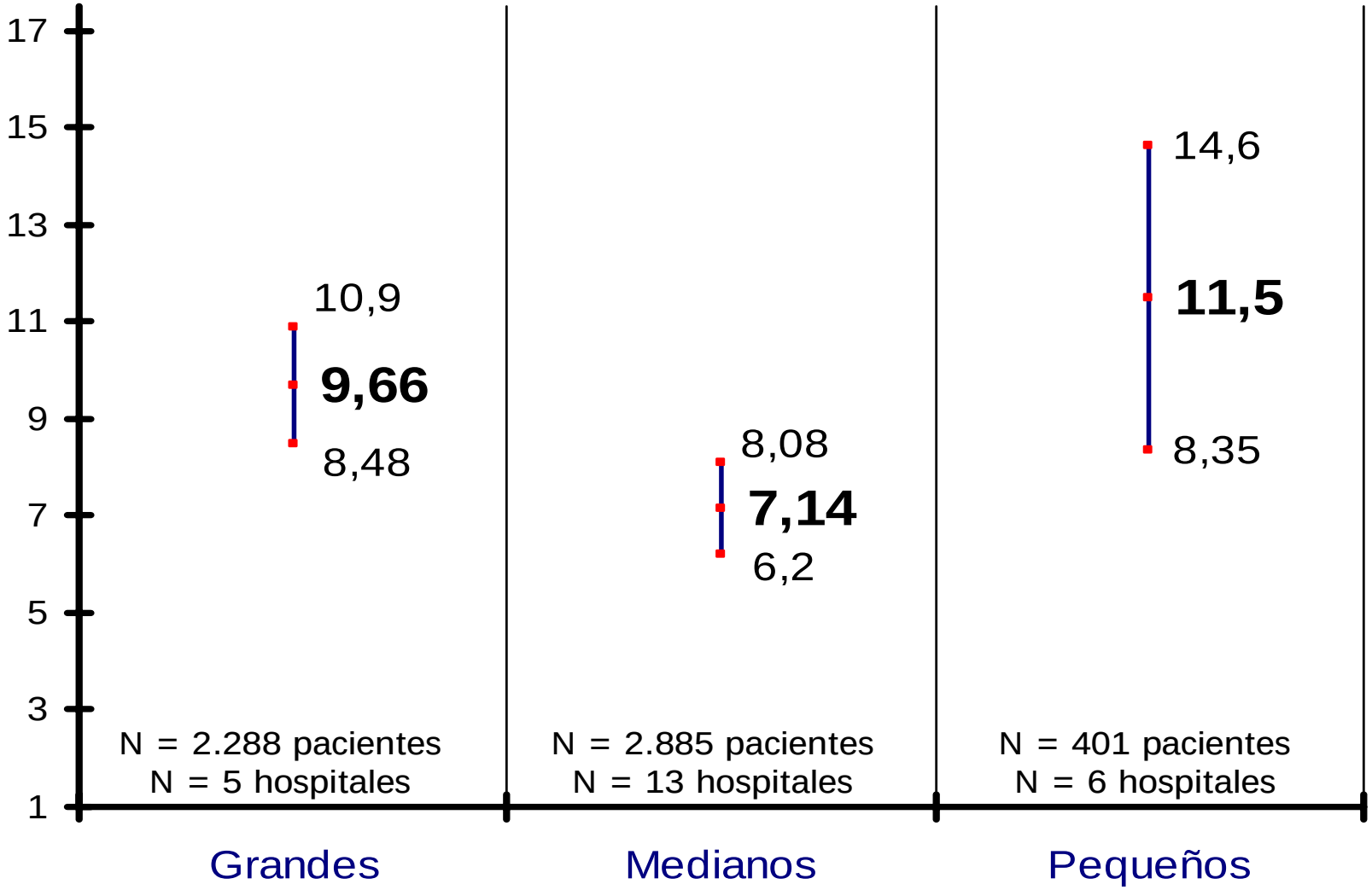


NY: Nueva York; UC: Utah y Colorado; A: Australia; L: Londres (Reino Unido); D: Dinamarca; NZ: Nueva Zelanda; CA: Canadá; España y E-ampliado: España ampliado.

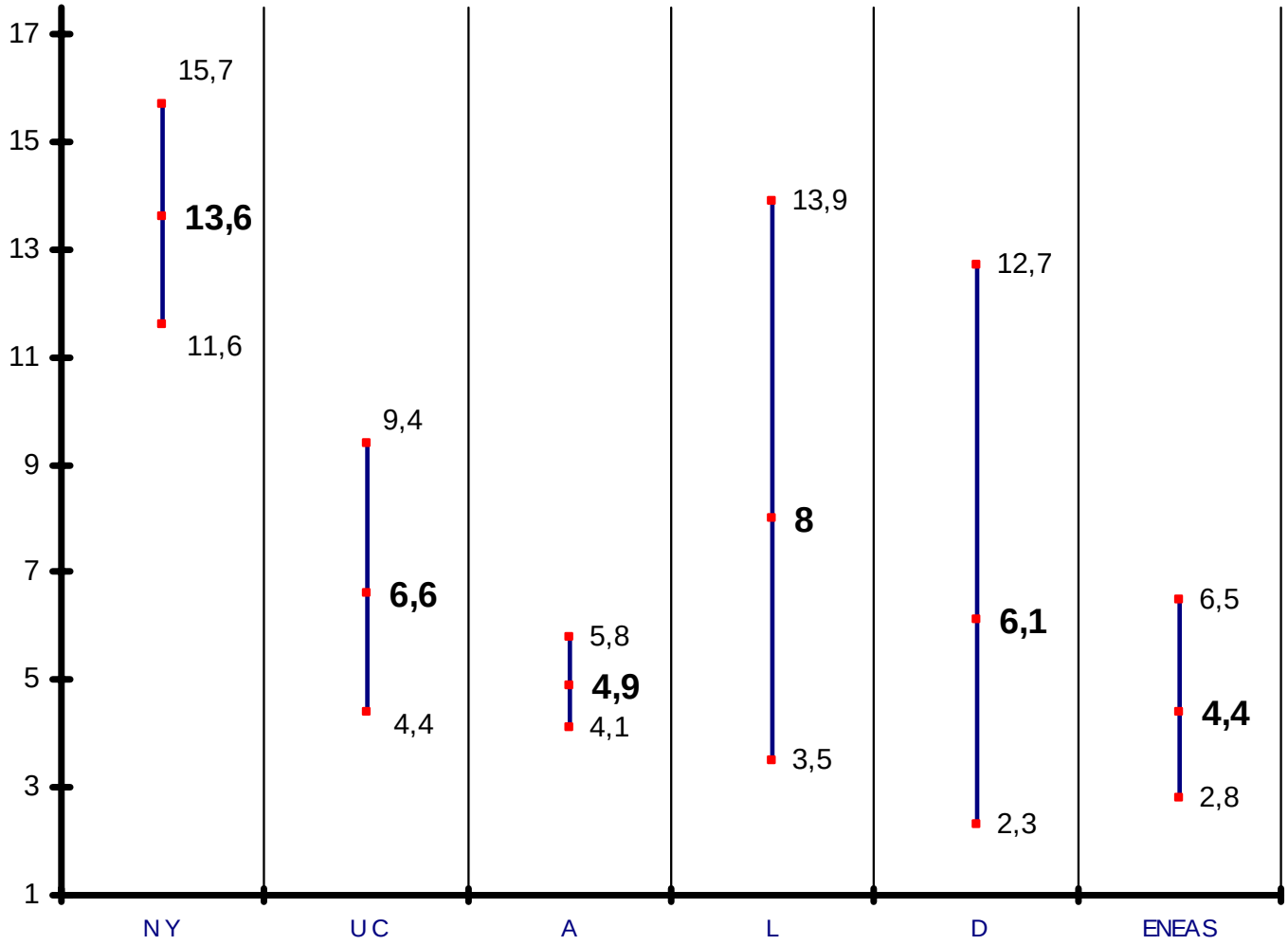
Gráfica 38.- Distribución de la Densidad de Incidencia de EAs moderados o graves.



Gráfica 39.- Distribución de la Incidencia acumulada de pacientes con EAs por tamaño de hospital.



Gráfica 40.- Distribución de la Incidencia de mortalidad encontrada en los principales estudios.



NY: Nueva York; UC: Utah y Colorado; A: Australia; L: Londres (Reino Unido); D: Dinamarca; España

NATIONALE STUDY ON THE HOSPITALISATION-RELATED ADVERSE EVENTS

ENEAS 2005

APPENDIX
Form

"IDEA" ADVERSE EVENT IDENTIFICATION PROJECT

ADVERSE EVENT SCREENING GUIDE

Reviewer: .....

Case No.: Medical Record (MR) No.:

Hospital: Hospital Unit:

Date admitted: Date discharged:

Full name: .....
(Fill in only if stated on the Medical Record)

Date of birth: ..... / ..... / ..... Sex: Male ..... Female .....

Primary diagnosis: _____
"DGR" Diagnosis Group: (Do not look up on medical record) _____
Disease-ICD: (Do not look up on medical record) _____
Operation-ICD: (Do not look up on medical record) _____ Date of operation: ..... / ..... /.....
Charison Index: (Do not look up on medical record) _____

RISK FACTORS (RF's)
Indicate whether the patients has any of the following risk factors by placing an "X" in the pertinent box.

	INTRINSIC R.F	**Yes**	**No**		**EXTRINSIC R.F.**	**Yes**	**No**
1	Coma			1	Open urinary drainage		
2	Renal insufficiency			2	Closed urinary drainage		
3	Diabetes			3	Peripheral venous catheter		
4	Neoplasia			4	Arterial catheter		
5	Immunodeficiency			5	Peripherally-inserted central catheter		
6	Chronic pulmonary disease						
7	Neutropenia			6	Central venous catheter		
8	Hepatic cirrhosis			7	Umbilical catheter (vein)		
9	Drug addiction			8	Umbilical catheter (artery)		
10	Obesity			9	Parenteral nutrition		
11	Hypoalbuminemia			10	Enteral nutrition		
12	Pressure ulcer			11	Nasogastric tube		
13	Malformations			12	Tracheotomy		
14	Cardiac insufficiency			13	Mechanical ventilation		
15	Coronary disease			14	Immunosuppressing therapy		
16	Hypertension						

STUDY OF HOSPITAL CARE-RELATED ADVERSE EVENTS

"IDEA" ADVERSE EVENT IDENTIFICATION PROJECT

CASE HISTORY SUMMARY FORM

Place an "X" in the pertinent box located beside the correct answer.

	Yes	No
1. Prior hospitalisation within the last year in patient under age 65 or prior hospitalisation within the last 6 months in patient age 65 or older.		
2. Antineoplastic treatment within the 6 months immediately prior to the hospitalisation.		
3. Traumatism, accident or fall during hospitalisation.		
4. Adverse Drug Reaction (ADR) during hospitalisation.		
5. Fever over 38.3ºC on the day immediately prior to discharge from the hospital.		
6. Moved from a general ward to a special-care ward.		
7. Moved to a different acute-care hospital.		
8. Second surgical operation during this hospitalisation.		
9. Following an invasive procedure having been performed, an injury was caused to an organ or system having involved the indication of surgical operation or treatment.		
10. New neurological deficit at the point in time of discharge from the hospital.		
11. AMI (acute myocardial infarction), ACVA (acute cerebrovascular accident) or PTE (pulmonary thromboembolism) during or following an invasive procedure.		
12. Cardio-respiratory arrest.		
13. Injury or complication related to miscarriage, amniocentesis, childbirth or post-delivery.		
14. Death.		
15. Unscheduled open surgery operation or admission (for surgery) following scheduled outpatient surgery, whether laparoscopy or open surgery.		
16. Any injury or complication related to outpatient surgery or to an invasive procedure resulting in the patient being admitted to hospital or assessment in emergency care unit.		
17. Any other Adverse event (AE).		
18. Letters or medical record notes (including patrimonial claims) related to the care provided which might give rise to a lawsuit.		
19. Any type of nosocomial infection.		

IF YOU HAVE ANSWERED "YES" TO ANY OF THE QUESTIONS ABOVE, COMPLETE THE MRF2 MODULAR RETROSPECTIVE CASE RECORD REVIEW QUESTIONNAIRE.

STAGE A: PATIENT INFORMATION AND BACKGROUND TO ADVERSE EVENT

A1 REVIEWER INFORMATION Date of Review ☐☐☐☐☐☐
d d m m y y

Reviewer ID Number ☐☐☐ Case No. ☐☐☐☐ MRN ☐☐☐☐☐☐☐☐

A2 PATIENT INFORMATION Date of birth ☐☐☐☐☐☐☐☐ Sex: M/F ☐ Pregnancy: Yes/No ☐

Date of admission: ☐☐☐☐☐☐☐☐ Degree of emergency at time of admission:

Date of discharge or date of death: ☐☐☐☐☐☐☐☐ ☐ Urgent (emergency) ☐ Routine (non-urgent)
d d m m y y y y

A3 NATURE OF ILLNESS **Primary Diagnosis** _____

Prognosis from the primary illness: To answer, tick relevant "Yes" or "No" responses to 3A, 3B and 3C.

3A. Complete recovery back to patient's normal health Yes ☐ No ☐ If "yes", then complete recovery is: ☐ 1. Probable ☐ 2. More likely than not ☐ 3. Possible ☐ 4. Unlikely	**3B**. Recovery with residual disability Yes ☐ No ☐ If "yes", then recovery is: ☐ 1. Non-progressive ☐ 2. Slowly progressive ☐ 3. Rapidly progressive	**3C.** Terminal illness Yes ☐ No ☐ If "yes", the prognosis is: ☐ 1. Likely to die this admission ☐ 2. Likely to die within3 month ☐ 3. Expected to survive > 3 month

ASA Risk: ☐ Healthy ☐ Slight disease ☐ Functional limitation ☐ Life-threatening ☐ Dying

A4 CO-MORBIDITIES

Please tick all of the following co-morbidities that apply to this patient or No co-morbidities ☐
No known co-morbidities ☐

Cardiovascular
- ☐ Coronary artery disease
- ☐ Peripheral vascular disease (varicose veins)
- ☐ Cardiac insufficiency or dysrhythmia
- ☐ Hypertension

Respiratory
- ☐ Asthma
- ☐ COPD (chronic obstructive pulmonary disease)
- ☐ Other serious lung problem (e.g. scarring)
- ☐ Alveolar tuberculosis, osteotuberculosis (specify)

Gastro-intestinal
- ☐ Chronic or recurrent dyspepsia
- ☐ Inflammatory bowel disease (Crohn's and colitis)
- ☐ Chronic liver disorder

Endocrine
- ☐ Diabetes
- ☐ Endocrine disorders (thyroid, adrenal)
- ☐ Parkinson's
- ☐ Dementia
- ☐ Other serious neurological disorders (e.g. MS, MND) (Specify): _____

Renal
- ☐ Chronic renal disease

Haematological
- ☐ Anaemia
- ☐ Leukaemia
- ☐ Lymphoma
- ☐ Other (specify): _____

Existing cancer
- ☐ Specify: _____

Bone/joint Disorders
- ☐ Osteoporosis
- ☐ Severe rheumatoid arthritis
- ☐ Severe osteoarthrosis

Disability
- ☐ Wheel chair bound
- ☐ Blind
- ☐ Deaf
- ☐ Learning difficulty
- ☐ Other (specify): _____

Psychiatric
- ☐ Schizophrenia
- ☐ Affective disorder
- ☐ Other (specify): _____

Psychosocial
- ☐ Alcoholism
- ☐ Drug abuse
- ☐ Smoker
- ☐ Homeless
- ☐ Other (specify): _____

Infection
- ☐ AIDS
- ☐ Chronic infection (e.g. Hep C, MRSA) (specify): _____

Trauma
- ☐ Multiple traumas (traffic accidents)

Nutritional condition
- ☐ Obese
- ☐ Cachetic
- ☐ Other (specify): _____

Other co-morbidity
- ☐ Specify: _____

Allergies
- ☐ Specify: _____

A6. SPECIALTY/UNIT TO WHICH THE PATIENT HAS BEEN ADMITTED

SURGERY	☐ 1. Anaesthesiology-Recovery	☐ 7. Orthopaedic Surgery & Traumatology	☐ 12. Urological Surgery
	☐ 2. Cardiac Surgery	☐ 8. Paediatric Surgery	☐ 13. ENT Surgery
	☐ 3. General and digestive surgery	☐ 9. Plastic Surgery	☐ 14. Eye Surgery
	☐ 4. Gynaecology	☐ 10. Thoracic Surgery	☐ 15. Dermatology
	☐ 5. Obstetrics	☐ 11. Vascular Surgery	☐ 16. Others (specify)
	☐ 6. Neurosurgery		
MEDICINE	☐ 16. Cardiology	☐ 24. Infectious Disease Unit	☐ 31. Pulmonary disease
	☐ 17. Hemodynamics	☐ 25. Medical Oncology	☐ 32. Radiation Therapy
	☐ 18. Endocrinology	☐ 26. Neonatology	☐ 33. Rehabilitation
	☐ 19. Gastroenterology	☐ 27. Nephrology	☐ 34. Rheumatology
	☐ 20. Geriatrics (elderly care)	☐ 28. Neurology	☐ 35. Neurophysiology
	☐ 21. Haematology	☐ 29. Paediatrics	☐ 36. Others (specify)
	☐ 22. Immunology and Allergy	☐ 30. Psychiatry	
	☐ 23. Internal Medicine		

A6. IDENTIFYING MAIN FEATURES OF THE ADVERSE EVENT

a) INJURY or COMPLICATION **Was there a patient injury or complication?** ☐ Yes ☐ No

b) DISABILITY /EXTENDED STAY

Did the injury or complication result in disability at the time of discharge and/or a prolonged hospital stay (or re-admission or out-patient treatment) or death?

1. Disability at discharge	☐ Yes ☐ No
2. Prolonged/subsequent stay or treatment	☐ Yes ☐ No
3. Death	☐ Yes ☐ No

c) INCIDENT

Was there any adverse event without an injury or extending of the hospital stay? (e.g. patient having had a fall without any consequences)? ☐ Yes ☐ No

If so, please explain in detail: _____

d) CAUSE OF THE INJURY OR COMPLICATION

The injury or complication was due to:

☐ 1. Healthcare provided
☐ 2. Due solely to the process of the disease
☐ 3. Don't know/ no answer

After consideration of the clinical details of the patient's management, irrespective of preventability**, what level of confidence do you have that the CARE PROVIDED IS THE CAUSE OF THE INJURY?**

☐ 1 Virtually no evidence for management causation
Injury entirely due to the patient's pathology (no AE, then STOP).
☐ 2. Minimal probability of management causation.
☐ 3. Slight probability of management causation
☐ 4. Moderate probability of management causation.
☐ 5. Highly probable evidence for management causation.
☐ 6. Virtually certain evidence for management causation.

If no injury or other complications have been caused (Question A6, Sections a, b and c), there is no AE.
If an incident has occurred (Question A6, Section C) go directly to Stage E.
If the injury has not been due to the process of the disease or there is no evidence of the management having been the cause of the injury or complication (Question A6, Section d), there is no AE.

A7 AE SUMMARY

Date of the AE ☐☐☐☐☐☐
d d m m y y

Describe AE in context of overall illness

Describe the AE. Provide details of the injury or complications caused by the AE.

_____

Describe the principal problem in the care of the patient which led to the AE (e.g. an error in diagnosis, technical problem, lack of monitoring, etc. was involved).

_____

_____

Give details of contributory events leading up to the AE

_____

_____

Give details of any other problem that played a significant part in the causation of the AE

_____

Give any other details relevant to the AE (e.g. point in time of the event, if known)

_____

Within the clinical context, indicate the degree of probability of the Adverse event having occurred:

☐ 1. Very rarely
☐ 2. Rarely
☐ 3. Occasionally
☐ 4. Frequently

Specify the circumstances related to the principal problems in the care provided.

Mark all those items which may be applicable to the principal problem.
This will identify the section which must be completed in Stage C.

☐ **C0.** Care prior to the admission (including care in emergency, primary care, another hospital or other unit)
☐ **C1.** Care on admission to a ward (including surgery and anaesthesia)
☐ **C2.** Care during a procedure (including surgery and anaesthesia)
☐ **C3.** Post-operative care or post-procedure (Recovery or ITU)
☐ **C4.** General ward care (after operation; or after full assessment and commencement of medical care)
☐ **C5.** End of admission assessment and discharge care.

Was there any error in handling the AE? ☐ Yes ☐ No ☐ Not clear

If so, please describe the error in question.

_____

_____

A8. ADEQUACY OF RECORDS FOR JUDGEMENT OF

Does the medical record provide enough information for assessing the AE?

☐ 1. No, the information is inadequate.
☐ 2. No, the information is not highly adequate.
☐ 3. Yes, the information is adequate.
☐ 4. Yes, the information is highly adequate.

STAGE B: THE INJURY AND ITS EFFECTS

B1. DISABILITY CAUSED BY ADVERSE EVENT

Describe the impact of the adverse event on the patient (e.g. increased pain and suffering for "x" days, delayed recovery from the primary illness; patient not given adequate care and support; contributed or caused death).

_____

_____

Assessment of the degree of disability

Physical impairment

- ☐ 0 No disability (still an AE if hospital stay was prolonged)
- ☐ 1 Minor social handicap
- ☐ 2 Severe social handicap and/or slight occupational disability
- ☐ 3 Severe occupational disability
- ☐ 4 Total occupational disability
- ☐ 5 Disability for walking without the help of others
- ☐ 6 Bedridden
- ☐ 7 Unconscious
- ☐ 8 Death (specify the relationship with the AE)
  - ☐ 8.1 Death unrelated to AE
  - ☐ 8.2 Resulting from the hospital stay
  - ☐ 8.3 Death entirely due to AE

Pain:

- ☐ 0 No pain
- ☐ 1 Slight pain
- ☐ 2 Moderate pain
- ☐ 3 Severe pain

Emotional trauma

- ☐ 0. No emotional trauma
- ☐ 1. Minimal emotional trauma and/or recovery within one month
- ☐ 2. Moderate trauma, recovery in one to six months
- ☐ 3. Moderate trauma, recovery in six months to a year
- ☐ 4. Severe trauma effects lasting longer than a year
- ☐ 5. Cannot reasonably judge

B2 REPERCUSSION OF THE AE'S ON THE HOSPITALIZATION

Was part or all of the hospitalisation due to the AE? (including transfer to another hospital)

- ☐ 1. Did not extend the stay
- ☐ 2. Resulting from the stay
- ☐ 3. Caused readmission (the following stay in its entirety or the hospitalisation being assessed was caused by a previous AE).

Estimate how many additional days the patient stayed in the hospital because of the AE: ____ days
How many of these days did the patient stay in the ICU? _____ days

B3 ADDTIONAL TREATMENT AS A RESULT OF THE AE

Did the patient require additional *procedures*? ☐ Yes ☐ No

If so, please specify:

_____

_____

Did the patient require additional *treatments*? ☐ Yes ☐ No

If so, please specify:

_____

_____

_____

STAGE C: PERIOD OF HOSPITALIZATION DURING WHICH THE AE OCCURRED:

C0. AE PRIOR TO ADMISSION

(Including Emergency care, Primary Care, other units and different hospitals)

The AE occurred:

- ☐ 1. In Emergency Care Unit
- ☐ 2. In Primary Care
- ☐ 3. In outpatient specialist care
- ☐ 4. In the same hospital unit, during prior care provided
- ☐ 5. In a different hospital unit, in the same hospital
- ☐ 6. At a different hospital

The person responsible for the initial care was:

- ☐ 1. A specialist
- ☐ 2. A resident - MIR-
- ☐ 3. Nursing personnel
- ☐ 4. Other (specify): _____

If the principal problem was the care with which the patient was provided, it was due to:

(Mark all those options you consider pertinent)

- ☐ 1. An error in the medical care provided
- ☐ 2. An error in the nursing care
- ☐ 3. Others (specify)

What type of principal problem was involved at this stage of the healthcare provided?

Mark all those options you consider pertinent)

- ☐ 1. Failure to diagnose primary condition correctly → D1
- ☐ 2. Overall Assessment (including preoperative assessment) → D2
- ☐ 3. Management /monitoring including nursing/ ancillary care → D3
- ☐ 4. Procedure-related infection → D4
- ☐ 5. Procedure-related technical problem (e.g. intubation; equipment failure; monitoring during procedure) → D5
- ☐ 6. Drugs (including anaesthetic agents / fluids / blood) → D6
- ☐ 7. Resuscitation → D7
- ☐ 8. Other. Please specify: _____

Were there any other problems during this period / section of care not covered by the above? ☐ Yes ☐ No

If so, please specify:

_____

_____

_____

_____

Faltan C1 y C2

C3 PRINCIPAL PROBLEM DURING IMMEDIATE POST-PROCEDURAL, HIGH DEPENDENCY CARE or ICU CARE

When did the principal problem occur?

- ☐ 1. During the immediate post-procedural care (whilst in the recovery area)
- ☐ 2. During recovery, high dependency care
- ☐ 3. During care in the intensive care unit

Who was responsible for the post-procedural, HDU or ICU care?

- ☐ 1. Specialist
- ☐ 2. Resident - MIR-
- ☐ 3. Nursing personnel
- ☐ 4. Other (specify)

What type of principal problem was involved?

(Mark all those options you consider pertinent)

- ☐ 1. Diagnosis → D1
- ☐ 2. Overall Assessment → D2
- ☐ 3. Management /monitoring including nursing or ancillary care. → D3
  (e.g. Not taking action after learning the results of a test or other findings. Failure to get monitoring under way. Failure to provide protective care. Failure to provide high dependency intensive care)
- ☐ 4. Nosocomial infection -related → D4
- ☐ 5. Procedure-related technical problems → D5
- ☐ 6. Drugs (including anaesthetic agents) / fluids / blood → D6
- ☐ 7. Resuscitation → D7
- ☐ 8. Other. Specify: _____

Were there any other problems during this period / section of care not covered by the above? ☐ Yes ☐ No

If so, please specify:

_____

_____

C4 PRINCIPAL PROBLEM RELATED TO WARD CARE

(Including errors in the clinical management)

If the principal problem was in ward care, it was due to:

(Tick all that apply)

- ☐ 1. A failure in medical care
- ☐ 2. A failure nursing care
- ☐ 3. Other (specify)

Describe the principal problem:

_____
_____
_____
_____
_____

Who was responsible for the care provided following the procedure, in recovery or in the intensive care unit?

- ☐ 1. Specialist
- ☐ 2. Resident - MIR-
- ☐ 3. Nursing personnel
- ☐ 4. Other (specify)

What was the nature of principal problem?

(Tick all that apply)

- ☐ 1. Diagnosis → D1
- ☐ 2. Overall Assessment → D2
- ☐ 3. Management /monitoring including nursing or ancillary care. → D3
- ☐ 4. Nosocomial infection -related → D4
- ☐ 5. Procedure-related technical problems → D5
- ☐ 6. Drugs / fluids / blood → D6
- ☐ 7. Resuscitation after collapse → D7
- ☐ 8. Other. Please specify: _____

Were there any other problems during this period / section of care not covered by the above? ☐ Yes ☐ No

If so, please specify:

_____
_____
_____
_____

C5. FAILURE TO ADVISE ADEQUATELY AT THE TIME OF DISCHARGE

Which doctor was directly responsible for advising the patient before discharge?

- ☐ 1. Specialist
- ☐ 2. Resident - MIR-
- ☐ 3. Other (specify) _____

What is the nature of the principal problem?

(Tick all that apply)

- ☐ 1. Diagnosis ➔ D1
- ☐ 2. Overall Assessment ➔ D2
- ☐ 3. Management /monitoring including nursing or ancillary care. ➔ D3
  (e.g. Clinical condition not under good control; Patient not well enough to be discharged, e.g. mobilised; Failure to teach patient about their condition; Failure to communicate adequately with services in community care, including GP)
- ☐ 4. Nosocomial infection -related ➔ D4
- ☐ 5. Procedure-related technical problems ➔ D5
- ☐ 6. Drugs (Medications not appropriate) / fluids / blood ➔ D6
- ☐ 7. Resuscitation ➔ D7
- ☐ 8. Other. Please specify: _____

Were there any other problems during this period / section of care not covered by the above? ☐ Yes ☐ No

If so, please specify:

_____

_____

_____

Complete the pertinent section on Stage D
as many times as has been stipulated in Sections C1 - C5.

STAGE D: PRINCIPAL PROBLEMS IN THE HEALTHCARE PROCESS

D1 AE RELATED TO DIAGNOSTIC OR ASSESSMENT ERROR

Was the AE the result of diagnostic error? ☐ Yes ☐ No

If "yes", give details

_____

Was the AE the result of a delay in diagnosis? ☐ Yes ☐ No

_____

_____

The person responsible for the diagnostic assessment was:

- ☐ 1. Specialist
- ☐ 2. Resident - MIR-
- ☐ 3. Other (specify) _____

Factors contributing to the diagnostic error (tick as many as apply).

- ☐ 1. Failure to take an adequate history and/or to perform a satisfactory physical examination
- ☐ 2. Failure or delay to employ indicated test
- ☐ 3. Test was incorrectly performed
- ☐ 4. Test was incorrectly reported
- ☐ 5. Failure or delay to receive report
- ☐ 6. Failure or delay to act upon results of tests or findings
- ☐ 7. Failure to draw reasonable / sensible conclusions or make a differential diagnosis
- ☐ 8. Failure or delay to get expert opinion from:
- ☐ 9. Expert opinion incorrect
- ☐ 10. Other (specify) _____

How did these factors contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any problems related to diagnostic assessment? ☐ Yes ☐ No

If "yes", give details.

D2 AE FROM FAILURE TO APPRECIATE PATEINT'S OVERALL CONDITION

The person responsible for the assessment was:

- ☐ 1. Specialist
- ☐ 2. Resident - MIR-
- ☐ 3. Other (specify) _____

In what respect was the overall assessment inadequate?

- ☐ 1. Failure to take a full clinical history
- ☐ 2. Failure to examine carefully
- ☐ 3. Failure to take account of co-morbidity
- ☐ 4. Failure to monitor adequately
- ☐ 5. Failure to record
- ☐ 6. Failure to communicate to the rest of the team (clinical and multi-disciplinary)
- ☐ 7. Failure to assess the supplementary tests
- ☐ 8. Failure to make the ASA risk assessment
- ☐ 9. Other (specify) _____

How did this contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any other problems related to the assessment or care of the patient's overall condition? ☐ Yes ☐ No

If "yes", give details.

_____

_____

STUDY ON THE INCIDENCE OF ADVERSE EVENTS IN HOSPITAL CARE - PROJECT FIS P1021078

Based on the "Modular Adverse Events Review Form"

Clinical Safety Research Unit, Imperial College, London

D3 AE ARISING FROM A FAILURE IN CLINICAL SUPERVISION / CARE

(Including DISCHARGE ARRANGEMENTS, NURSING /ANCILLARY CARE SERVICES)

Was the AE the result of problems in the monitoring / observation of this patient? ☐ Yes ☐ No

If "yes", give details

_____

_____

Was the AE the result of failure in overall management of the patient (acting on observations) of the patient? ☐ Yes ☐ No

If so, what was the problem in management?

_____

_____

Was the AE the result of failure to ensure condition stable before handover to other areas? ☐ Yes ☐ No

If "yes", give details

_____

Indicate if the patient was:

☐ 1. Postoperative (including post-delivery, postmanipulation of fracture)
☐ 2. Undergoing medical (non-surgical) treatment
☐ 3. Undergoing rehabilitation
☐ 4. Other (specify) _____

the responsible person.?

Was the inadequate monitoring/management related to failure to recognise:

☐ 1. Abnormal vital signs (including neurological status)
☐ 2. Problems with fluids / electrolytes (including renal function)
☐ 3. Side-effects of medication
☐ 4. Cardio-pulmonary dysfunction
☐ 5. Damage to skin and pressure areas
☐ 6. Adequate mobilisation
☐ 7. Infection
☐ 8. Poor progress in healing (e.g. checking gut function after abdominal operation; care of wounds/ canular sites)
☐ 9. Changes to the patient's general condition (e.g. patient develops a medical condition, e.g. CHF)
☐ 10. Other (specify) _____

D3 (cont'd)

In what respects was the clinical management unsatisfactory?

- ☐ 1. Failure to take note of routine observations (e.g. TPR charts, neurological assessment, fluid balance (check if charts completed)
- ☐ 2. Delay in noting lab / test results
- ☐ 3. Not aware of significance of lab / test results
- ☐ 4. Failure to act appropriately on lab / test results
- ☐ 5. Poor note-keeping
- ☐ 6. Inadequate handover
- ☐ 7. Lack of liaison with other staff
- ☐ 8. Inadequate "out-of-hours" cover/working practice
- ☐ 9. Guideline / protocol failure (either not available or not followed
  (specify) _____
- ☐ 10. Apparent failure to recognise deterioration.
- ☐ 11. Deterioration recognised but additional care not provided
  (specify indicated care) _____
- ☐ Failure to recruit help
  - ☐ 12. Medical help
  - ☐ 13. Nursing help
  - ☐ 14. Ancillary help
- ☐ 15. Other (specify) _____

Was there any failure in discharge procedure? ☐ Yes ☐ No

If "yes", indicate which of the following apply to this patient and provide details.

☐ 1. Failure to educate the patient, including use of protocols
(e.g. for asthma, diabetes, post MI)

_____

☐ 2. Failure to show evidence that discharge status was appropriate to home conditions (e.g. careplan)

_____

☐ 3. Failure to liaise adequately with community care (e.g. GP, district nurse, social worker)

_____

☐ 4. Other (specify)

_____

How did these factors contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any other problems related to monitoring or care, including the handover and discharge? ☐ Yes ☐ No

If "yes", give details

_____

_____

STUDY ON THE INCIDENCE OF ADVERSE EVENTS IN HOSPITAL CARE - PROJECT FIS P1021078
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D4 AE'S IN RELATION TO FAILRUE TO PREVENT/CONTROL INFECTION

What was the site of the infection / infection related to?

- ☐ 1. Surgical wound
- ☐ 2. Internal invasive procedure
- ☐ 3. Urinary tract
- ☐ 4. Respiratory tract
- ☐ 5. Blood
- ☐ 6. Other (specify) _____

What was the nature of the infection?

- ☐ 1. Contaminated wound

Side-effect of drugs (specify type):

- ☐ 2. Antibiotic-induced (C. Difficile)
- ☐ 3. Yeast infection
- ☐ 4. Immuno-suppressive drugs
- ☐ 5. Other (specify)

Cross-infection (specify type):

- ☐ 6. MRSA (describe): _____
- ☐ 7. Salmonella
- ☐ 8. Other (specify) _____

Foreign body (specify type):

- ☐ 9. Urinary drainage
- ☐ 10. Intravenous catheter
- ☐ 11. Swab
- ☐ 12. Drainage tube
- ☐ 13. Shunt
- ☐ 14. Other (specify): _____

Stasis (specify type):

- ☐ 15. Respiratory depression
- ☐ 16. Urinary retention
- ☐ 17. Other (specify): _____
- ☐ 18. Other type of infection (specify) _____

The person responsible for the prevention / control of the infection was:

- ☐ 1. Specialist
- ☐ 2. Resident
- ☐ 3. Other (specify)

What were the errors in managing AE due to infection? Give full details

- ☐ 1. Failure to drain pus or remove necrotic material _____
- ☐ 2. Failure to give appropriate antibiotic treatment (including overuse) _____
- ☐ 3. Failure to give appropriate physiotherapy (e.g. chest) _____
- ☐ 4. Failure to maintain care of catheters / canulas / drains / wounds_____
- ☐ 5. Other (specify): _____

How did this contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Was there any other problems related to the management of infection ☐ Yes ☐ No

If "yes", give details.

_____

_____

D5 AE DIRECTLY RELATED TO A PROBLEM WITH AN OPERATIOR OR PROCEDURE

Was the procedure performed:

- ☐ 1. In the general ward
- ☐ 2. In the operating theatre suite
- ☐ 3. Elsewhere (e.g. radiology; specify) _____

The person responsible for performing the procedure was:

- ☐ 1. A specialist
- ☐ 2. A resident - MIR-
- ☐ 3. Other (specify): _____

Choose one of the following that best describes the nature of the AE (give details where possible)

- ☐ 1. Avoidable delay in undertaking procedure _____
- ☐ 2. Inappropriate procedure - specify alternative _____
- ☐ 3. Inadequate preparation before procedure (specify) _____

Anaesthetic incident:

- ☐ 4. Intubation (specify) _____
- ☐ 5. Anaesthetic agent _____
- ☐ 6. Equipment failure _____
- ☐ 7. Monitoring during the procedure (e.g. oxygenation, CO_2, airway pressure) _____
- ☐ 8. Other (specify) _____

Operation/procedure incident:

- ☐ 9. Difficulty in defining anatomy _____
- ☐ 10. Inadvertent organ damage (specify) _____
- ☐ 11. Bleeding (specify. E.g. from slipped ligature; from vascular puncture) _____
- ☐ 12. Perforation (specify nature) _____
- ☐ 13. Anastomotic breakdown (specify contributing factors) _____
- ☐ 14. Wound problem (e.g. dehiscence((specify)_____
- ☐ 15. Siting prosthesis _____
- ☐ 16. Equipment failure _____
- ☐ 17. Other (specify)_____
- ☐ 18. Inadequate monitoring during procedure (specify) _____

Infection-related:

- ☐ 19. Wound (including trip-related cellulitis) _____
- ☐ 20. Internal infection (e.g. abscess, specify) _____
- ☐ 21. Others (e.g. cholangitis, specify) _____
- ☐ 22**. Drainage-related**
- ☐ 23. Others, including inefficacious result (specify) _____

How did these factors contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any other problems related to procedures? ☐ Yes ☐ No

If "yes", give details.

_____

_____

How long was any EXTENDED operation time as a result of the AE? _____ minutes
(for the same intervention)

How long was any *additional* operation time as a result of the AE? _____ minutes
(for successive additional interventions)

How long was the hospitalisation time prolonged as a result of the AE? _____ days

STUDY ON THE INCIDENCE OF ADVERSE EVENTS IN HOSPITAL CARE - PROJECT FIS P1021078

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Clinical Safety Research Unit, Imperial College, London

D6 AE REALTION TO PRESCRIBING, ADMINISTRATION OR MONITORING OF DRUGS OR FLUIDS (including BLOOD)

Was there an error in the *prescription / preparation* of drugs, iv fluids or blood? ☐ Yes ☐ No
If so, specify

_____

_____

Was there an error in *administering* of drugs, iv fluids or blood? ☐ Yes ☐ No
If so, specify

_____

_____

Was there an error in *monitoring* of the drug action / toxicity or of the fluid balance? ☐ Yes ☐ No
If so, specify

_____

_____

How was the medication / fluid administered?

☐ 1. Intravenous ☐ 4. Orally ☐ 7. Topical
☐ 2. Intra-muscular ☐ 5. Sublingual ☐ 8. Rectal
☐ 3. Subcutaneous ☐ 6. Intrathecal ☐ 9. Other (specify) _____

What medication was used?

☐ 1. Antibiotic ☐ 7. Sedative or hypnotic ☐ 13. Potassium
☐ 2. Antineoplastic ☐ 8. Peptic ulcer medication ☐ 14. NSAID
☐ 3. Anti-seizure ☐ 9. Antihypertension ☐ 15. Narcotic (e.g. morphine/pethidine)
☐ 4. Anti-diabetes ☐ 10. Antidepressant ☐ 16. Diuretics
☐ 5. Cardiovascular ☐ 11. Antipsychotic ☐ 17. Others (specify) _____
☐ 6. Antiasthmatic ☐ 12. Anticoagulant

Name of drug: _____

What was the nature of the drug-related injury?

☐ 1. Drug less effective than expected (e.g. as a result of delayed treatment, dose too little)
☐ 2. Side-effect of drug (specify)_____
☐ 3. Effect of high dose for this patient in this circumstance _____
☐ 4. Idiosyncratic (allergic) re-action
☐ 5. Drug-drug interaction
☐ 6. Other (specify) _____

The person responsible for management the therapeutic regimen was:

☐ 1. A specialist
☐ 5. Resident - MIR-
☐ 6. Other (specify) _____

Would a doctor using reasonable medical judgement, prescribe the drug even with knowledge beforehand that this AE could occur? ☐ Yes ☐ No

D6 (cont'd)

What was the cause of the drug-related injury?

- ☐ 1. No underlying cause (other than the patient's response)
- ☐ 2. Delay in the prescribing (specify)
- ☐ 3. Delay in administering (after prescribing)
- ☐ 4. Wrong drug prescribed (specify)
- ☐ 5. Right drug but wrong dose or length of treatment
- ☐ 6. Right drug but wrong route (specify)
- ☐ 7. Error in administration (describe)
- ☐ 8. Inadequate monitoring (describe)
- ☐ 9. Other (specify) _____

How did these factors contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any other problems related to the management of iv fluids / blood? ☐ Yes ☐ No

If so, specify

D7 AE ARISING FROM A RESUSCITATION PROCEDURE

What was the condition which led to the need for resuscitation?

- ☐ 1. Cardiac arrest (cause)
- ☐ 2. Respiratory Failure /arrest (cause)
- ☐ 3. Coma (specify) _____
- ☐ 4. Fits
- ☐ 5. Bleeding (specify)
- ☐ 6. Multiple trauma
- ☐ 7. Metabolic disorder (e.g. Hypoglycaemia) (Specify) _____
- ☐ 8. Overwhelming infection (specify) _____
- ☐ 9. Other (specify)

The person responsible for caring for the patient during the resuscitation was:

- ☐ 1. A specialist
- ☐ 5. Resident - MIR-
- ☐ 6. Other (specify) _____

Was there delay in dealing with the problem? ☐ Yes ☐ No

Is "yes", what was the reason?

- ☐ 1. Staff not available
- ☐ 2. Staff not competent
- ☐ 3. Equipment not available
- ☐ 4. Lack of suitable or needed drugs
- ☐ 5. Lack of control (management)
- ☐ 6. Other (specify) _____

Was there confusion regarding correct action to take?

If so, what was the reason?

- ☐ 1. Inappropriate action
- ☐ 5. Failure to obtain appropriate analyses / tests
- ☐ 6. Other (specify) _____

How did this contribute to the AE?

- ☐ 1. Led to in inappropriate or inadequate treatment
- ☐ 2. Risk / benefit ratio of the treatment was not assessed / appreciated
- ☐ 3. Patient's degree of vulnerability was not recognised
- ☐ 4. Other (specify)

Were there any other problems related to the management of the patient during resuscitation? ☐ Yes ☐ No

If "yes", give details.

_____

_____

STAGE E: CAUSATIVE / CONTRIBUTORY FACTORS and PREVENTABILITY OF AE

E1 CAUSATIVE FACTORS

The occurrence of an AE and the actions or omissions of those involved may be influenced by many contributing factors. Many of these contributing factors can only be satisfactorily assessed by interviewing the staff involved in the care of the patient. Please indicate, where possible, likely causative factors.

Please rate each of the following factors according to its importance in the occurrence of this particular adverse event.

Totally unimportant	Slightly important	Important	Very important
0	1	2	3

		0	1 2 3
1.	**Patient characteristics**		
1.1	Patient was not able to understand /communicate with the clinical/nursing team (e.g. deaf, stroke, language difficulties in absence of interpreter or cultural differences)	☐	☐☐☐
1.2	Personality or social factors	☐	☐☐☐
1.3	Comorbidity	☐	☐☐☐
1.4	Other patient characteristics (specify) _____	☐	☐☐☐
2.	**Task factors**	0	1 2 3
2.1	New, untested or difficult task or procedure	☐	☐☐☐
2.2	Evidence of lack of guidelines / protocols or their use	☐	☐☐☐
2.3	Test results unavailable, difficult to interpret or inaccurate	☐	☐☐☐
2.4	Poor task design / structure	☐	☐☐☐
2.5	Other task factors (specify) _____	☐	☐☐☐
3.	**Individual factors**	0	1 2 3
3.1	Staff working outside their expertise	☐	☐☐☐
3.2	Lack of knowledge of individuals	☐	☐☐☐
3.3	Lack of skill of individuals	☐	☐☐☐
3.4	Attitude / motivation problem	☐	☐☐☐
3.5	Long shift / under pressure	☐	☐☐☐
3.6	Other individual staff factors (specify) _____	☐	☐☐☐
4.	**Team factors**	0	1 2 3
4.1	Poor teamwork	☐	☐☐☐
4.2	Inadequate supervision	☐	☐☐☐
4.3	Poor verbal communication	☐	☐☐☐
4.4	Inadequate handover	☐	☐☐☐
4.5	Poor written communication (e.g. defects notes)	☐	☐☐☐
4.6	Other team factors (specify) _____	☐	☐☐☐
5.	**Work environment**	0	1 2 3
5.1	Defective or unavailable equipment	☐	☐☐☐
5.2	Problems with provision of (theatre list, lab tests, x-rays)	☐	☐☐☐
5.3	Inadequate functioning of hospital support services (e.g. pharmacy, blood bank, housekeeping)	☐	☐☐☐
5.4	Inadequate staffing at the time of the AE	☐	☐☐☐
5.5	Out of hours (time of day/day of week) factors	☐	☐☐☐
5.6	Other work environment factors (specify) _____		
		0	1 2 3
6.	**Organisational / Management factors**	☐	☐☐☐
6.1	Lack of essential resources (E.g. ICU beds)	☐	☐☐☐
6.2	Poor co-ordination of overall services	☐	☐☐☐
6.3	Inadequate senior leadership	☐	☐☐☐
6.4	Other organisational / management factors (specify) _____		

E2 GIVE DETAILS ON THE MOST IMPORTANT CONTRIBUTORY FACTORS TO THIS AE

(ANSWER ACCORDING TO CAUSAL CASCADE: 1: CAUSE OF AE, 2: CAUSES OF 1. CAUSES OF 2)

1. _____
_____

2. _____
_____
_____

3. _____
_____
_____

E3 ASSESS THE DEGREE OF PREVENTABILTY OF THIS AE

In your judgement, is there some evidence that this AE was preventable? ☐ Yes ☐ No

Rate on a 6-point scale the strength of evidence for preventability.

☐ 1. No evidence
☐ 2. Minimal probability
☐ 3. Slight probability
☐ 4. Moderate probability
☐ 5. Highly probable
☐ 6. Total evidence of preventability

If you ticked 2-6, answer the following questions:

Describe briefly the manner in which the AE could have been prevented. _____
_____
_____
_____

Can you identify any reason(s) for the failure to prevent this AE? _____
_____
_____

EXPERTISE OF REVIEWER

Is the reviewer's judgement limited or hampered by a lack of knowledge of the specialty? ☐ Yes ☐ No

Mark "Yes" it you think a specialist's review is necessary and indicate which specialty or discipline (e.g. pharmacy), listing as many as necessary.

_____ _____ _____
_____ _____ _____

Describe the judgement which is limited or hampered by the lack of knowledge of the specialty and the clinical question which should be posed to a specialist.

_____
_____

Describe the resolution of the question(s) posed following the consultation with a specialist.

_____
_____

Specialist's ID Number: ☐☐☐

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