APEAS Study

Patient Safety in Primary Health Care

REPORTS, STUDIES AND RESEARCH 2008
MINISTRY OF HEALTH AND CONSUMER AFFAIRS

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in Primary Health Care

(Pending review)

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APEAS Study
National Health System Quality Agency
Ministry of Health and Consumer Affairs
Paseo del Prado, 18-20
27071 Madrid

APEAS Project Scientific Director
Dr. Jesús María Aranaz Andrés. Dept. of Public Health, History of Science and Gynaecology. Dept. Preventive Medicine. Hospital Universitari Sant Joan d'Alacant. Miguel Hernández University. Elche, Alicante.

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APEAS Study

Patient Safety
in Primary Health Care

GOVERNMENT OF SPAIN
MINISTRY OF HEALTH & CONSUMER AFFAIRS

National Health System
Quality Plan

Contents

Project Summary

1. Introduction

One of the pivotal points around which health care quality revolves is assuring that the treatment and care provided to patients will not entail any harm, injuries or complications beyond those stemming from the natural evolution of their illness and those necessary and justifiable for properly handling their disease diagnosis, treatment or palliation process.

But providing health care entails risks for the patients and for the professionals who are caring for them, and as the diagnostic and treatment techniques become more highly complex, these risks are logically heightened. Apart from the above, Primary Care (PC)- the first point where patients come into contact with the health system- is the level of care used most by the population, Spain having the highest frequentation figures in Europe. There are thus fortunately controlledly limited times when a patient may sustain some harm or undergo some complication in their evolution without any error necessarily being involved on the part of the professionals.

In technical terms, it is said, in these cases, that the patient has experienced an Adverse Effect, in other words, an unanticipated, unforeseen accident causing them some harm or complication which is a direct result of the care dispensed and not of their illness. Other times, the accident does not go so far as to cause any harm to the patient, this being referred to as an incident (IN) in this case. Adverse effects and incidents are referred to, together, as adverse events (AEs), many of which are unpreventable regardless of how great an effort is made by professionals. However, others can be prevented, if we consider, for example, how certain procedures (catheterization, administering drugs, etc.) are performed. This is the reason why programs are being promoted through the Health Authorities for heightening patients' clinical safety.

In an initial study conducted two years ago, funded by Spain's National Health System Quality Agency, the frequency and types of these AE's in hospitalized patients was analyzed. This research, known as the ENEAS Study[1], has had major repercussions both in Spain and abroad due to its being one of the broadest-scope studies conducted anywhere in the world [2,3,4].

This second research project has taken up the analysis of the frequency and types of AE's in PC. It must be said that this is one of the first studies to deal with this problem at health care centers, encompassing a wide-ranging sample of physician's and nurse's offices.

2. Objectives

General Objectives:

1.Further enhance knowledge in relation to patient safety by way of delving into the magnitude, far-reaching importance and impact of Adverse Effects and analyzing the characteristics of the patients and of the care associated with preventable Adverse Effects arising.

2.Increase the number of professionals actively involved in patient safety.

3.Incorporate objectives and activities aimed at improving patient safety into the PC team agenda.

Specific Objectives:

1. Identify the adverse events stemming from the care provided in PC, including both incidents (no harm is done to the patient) and Adverse Effects (patient is harmed).

2. Estimate the frequency of care-related Adverse Effects at health care centers in different Autonomous Communities in Spain.

3. Identify the characteristics of the patient and of the care in those patients with Adverse Effects related to the care provided.

4. Estimate the impact which health care has on the Adverse Effects in PC, distinguishing between those which are preventable and those which are unpreventable.

5. Describe the types of Adverse Effects associated with the care provided in PC.

6. Analyze the factors contributing to Adverse Effects arising.

7. Identify the Adverse Effects of most far-reaching importance in order to design preventive strategies which will facilitate minimizing Adverse Effects in PC.

3. Hypothesis

Very few studies have been conducted on Adverse Effects in Primary Care. Additionally, the studies previously conducted deal with this subject only in part, given that they focus on the error and not on the Adverse Effect, which is a result not only of the error, but also of the failure of the system[5, 6]. Following a systematic review of the scientific literature, we have not found any study of an epidemiological kind in the strict sense of the word.

Our working hypothesis, after having conducted a pilot study, is that adverse events may affect at least 3% of the subjects for who care is provided in Primary Care and that at least 40% of these adverse events can be prevented[7].

4. Methodology

Study Subjects: All of those patients who are seen, for any reason, by the Primary Care Teams of the Healthcare Centers selected.

Design: Observational, cross-sectional study with analytical components[8].

Study Scope: 48 Primary Care Centers operating in 16 of Spain's Autonomous Communities.

Sample: Opportunistic and voluntary participation comprised of 452 professionals (251 family practitioners, 49 pediatricians and 152 nurses). The Primary Care teams were selected by way of the Patient Safety reference points of the Autonomous Communities, Scientific Societies and Key Informants.

To be included in the study, the participation of at least three Family Practitioners, one Pediatrician and one Nurse from each team would be required.

Outcome variables: Adverse event (Adverse Effect and incident) and preventable Adverse Effect.

Information Sought: Frequency of Adverse Effects. Percentage of Adverse Effects which are preventable.

Procedure: Completion by the professionals of a form prepared for the purpose of being used every tie an Adverse Effect is identified, confidentiality being assured by means of a data-recording system masked for the study management.

Analysis of the data: Description of the variables by means of the statistics most appropriate for the type of variables in question, type and measurement scale. Percentage analysis for the qualitative variables, whilst the quantitative variables will be presented by means of centralization and dispersion measures, as pertinent. For the bivariate analysis, the x^2 test or Fisher's exact test was used for the qualitative variables, and Student's t-test or the Mann-Whitney U test for the quantitative variables (depending on whether or not the normalcy criteria are met), as well as the variance analysis for the comparison of various measures, "p"

values of under 0.05 being considered significant. The association among variables was analyzed by means of logistic regression.

5. Results

Within the time period under study, 96,047 patients visited a Primary Care office at their Healthcare Center. Among 452 Primary Care professionals, 2,059 alerts were identified which were related to 1,932 visits. A total of 63.5% of the visits recorded were seen by family practitioners, 26.5% by qualified nurses and 10% by pediatricians.

The prevalence of adverse events was 18.63‰ (95% CI: 17.78 – 19.49). The prevalence of incidents was 7.45‰ (95% CI: 6.91 – 8.00) and for Adverse Effects, 11.18‰ (95% CI: 10.52-11.85). The prevalence of patients with some Adverse Effect is 10.11‰ (95% CI: 9.48-10.74). A total of 6.7% of the patients had more than one Adverse Effect.

A total of 54.7% (n=606) were considered minor Adverse Effects, 38.0% (n=421) moderate and 7.3% (n=81) serious.

A total of 57.4% of the patients having experienced an adverse event were females, the mean age being age 59, and the average being 53 for both genders. A total of 58.0% of the subjects with an adverse event had some risk factor.

We would like to point out that in 48.2% of the cases, the factors having caused the Adverse Effect were related to the medication; in 25.7%, to the care provided; in 24.6%, to communication; in 13.1% with the diagnosis; in 8.9% with the management; and in 14.4%, other causes.

On considering the consequences (effect) of the Adverse Effects, we found 47.8% of the Adverse Effects (530) to have been related to the medication, the infections associated with the care of any type provided totaling 8.4% (93) of the total Adverse Effects; 10.6% (118) having been associated with some procedure; and 6.5% (72) with the care provided.

Outstanding as the most frequent Adverse Effects were: worse course of evolution of the patient’s baseline disease; nausea, vomiting or diarrhea secondary to medication; pruritus, rash or skin lesions reactive to drugs or bandages; infection of surgical and/or trauma wound and neurological alterations secondary to drugs, which totaled 44% of the adverse effects.

A total of 6.7% (n=74) of the cases were considered to be unpreventable; 23.1% (n=256), slightly unpreventable; 70.2 (n=778), clearly preventable Adverse Effects.

The degree of preventability of an Adverse Effect was related to its severity, such that the preventable Adverse Effects were 65.3% preventable; the moderate Adverse Effects, 75.3% preventable; and the serious Adverse Effects, 80.2% preventable, this difference being statistically significant (p-value<0.001).

By studying the origin of the adverse events, we found 73.5% of the adverse events to have occurred at a Primary Care Center; 25.8%, in Specialized Care – 2.9% of which occurred in their Hospital’s Emergency Department, the other 0.7% having occurred in Pharmacies.

In 23.6% of the cases, the consequence of the Adverse Effect did not affect the care provided; in 33.1%, a higher level of observation and monitoring was required; in the remaining 7.5%, the Adverse Effect required an additional test; and in 17.1%, an additional medical or surgical treatment was performed on the part of PC. In 14.9%, the consequence of the Adverse Effect required another visit or referral to Specialized Care (without hospitalization); and in 5.8%, hospitalization of the patients for some life support treatment having been required.

6. Findings

The results set out in this report reveal the care provided in Primary Care to be reasonably safe; the frequency of Adverse Effects to be low and those of a minor nature to more prevalent.

Despite the above, patient safety is important at the first level of care. The high frequentation of the Primary Care offices in Spain means that although the frequency of Adverse Effects is relatively low, in absolute terms, the large numbers of patients are affected. Were we to extrapolate the results to the overall population as a whole, an average of 7 out of every 100 citizens could be affected per year.

Preventing Adverse Effects in Primary Care is seen as a top-priority strategy, given that 70% of the Adverse Effects are preventable, and the more serious they are, the more preventable they are (up to 80%). This information opens up the way to further improving clinical safety despite the positive findings of this study.

The etiology (cause(s)) of the adverse events is multicausal. Their origins entail factors having to do with the use of drugs, with communication, with management and with the care provided.

The most common consequence is a worse evolution of the patient's baseline illness; and health care-related infections are not uncommon at all in Primary Care.

One fourth of the Adverse Effects did not require any additional care; another fourth had to be referred to specialized care; and half were remedied directly in Primary Care.

7. Study Value

7.1 Contributions to knowledge:

The APEAS Project contributes a methodology for the study of Adverse Effects in Primary Care.

It is a reference point, on being the first epidemiological study involving such a large-scale sample of patients (96,047 visits). This study is a status check for our country and opens up a line of research which will be of some major benefits to patients.

The multiple causes entailed in originating Adverse Effects require a multi-factorial approach for effectively improving Patient Safety.

This study reveals the safeguarding role of the personnel who are the first ones with whom patients come into contact for care and emphasizes those aspects which must be stressed in order to reduce Adverse Effects in PC.

7.2 Contributions to clinical practice:

Given the leading role drugs play both in the origins and in the consequences of Adverse Effects, it is advisable to standardize the presentation of the medication information from the industry to the professionals, and from professionals to patients so that the safe use thereof will be dealt with, even in clinical record-related computer applications. This is a pressing need, as also is the conciliation between Specialized Care and Primary Car treatments.

The procedures and care need to be constantly updated so they will incorporate the safest techniques that scientific advancement progressively makes available.

Special mention may be made of the Adverse Effects related with communication problems. The clinical interview is now a discipline incorporated into the degree training plans and in those specifically of residents in Family and Community Medicine, but requires more and better training in order for communication to really be effective and care safe.

Drafting strategies aimed at improving patient safety in primary care is highly effective, on preventing 70% of all Adverse Effects in general and 80% of the serious Adverse Effects in particular.

8. Summation

This study has been conducted thanks to the collaboration of a non-significant yet highly meaningful sample of PC professionals nationwide, due to their qualification, number and desire for improvement.

The frequency of Adverse Effects in Primary Care should be, at the very least, the same as that found in this study, it being possible to anticipate an increase therein over the next few years. But the interest on the part of the organization and the professionals' motivation will tend to mitigate the impact thereof.

Background

The care provided by any health care organization consists essentially of attempting to successfully cure and relieve the ailments and health problems of the population of its surrounding environment. A large number of goods and services are involved in this exchange, from administration, maintenance and medical material to medical and nursing care. The integration of all these elements into the health care organization must aspire to provide care of the best possible quality, in which patients seeking medical treatment will be guaranteed that a procedure will be performed on them correctly and safely with the aim of achieving the desired outcome. However, the growing complexity of health care systems may favor the proliferation of adverse events as the result of system failures or human errors, and being able to set out the necessary measures for preventing and/or minimizing these failure and errors will depend upon the knowledge possessed with regard thereto.

One of the pivotal points around which health care quality revolves is assuring that the treatment and care patients receive will not entail any harm, injuries or complications beyond those stemming from the natural evolution of their illness and those necessary and justifiable for properly handling their disease diagnosis, treatment or palliation process. Different initiatives have contributed to this interest, such as the publication of the high-impact report "To Err is Human" from the U.S. Institute of Medicine[9], or the setting up, on the part of the WHO, of the World Alliance for Patient Safety"[10].

Numerous studies have been published to date on the frequency of Adverse Effects related to the health care provided, the effect thereof on patients, the potential impact on the health systems and the need for the study thereof [1, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20]. And although the majority of these studies have been conducted in a hospital environment, experiences are now starting to be seen at other levels of care, such as in Primary Care (PC) [21, 22].

Providing health care entails risks for the patients and for the professionals who are caring for them, and as the diagnostic and treatment techniques become more highly complex, these risks logically increase. Apart from the above, Primary Care (PC), the first point where patients come into contact with the health system, is the level of care used most by the population, Spain having the highest frequentation figures in Europe. There are thus fortunately controlled times when a patient may sustain some harm or undergo some complication in their evolution without any error necessarily being involved on the part of the professionals.

In technical terms, it is said, in these cases, that the patient has experienced an Adverse Effect, in other words, an unanticipated, unforeseen accident causing them some harm or complication which is a direct result of the care dispensed and not of their illness. Other times, the accident does not go so far as to cause any harm to the patient, this being referred to as an incident (IN) in this case. Adverse effects and incidents are referred to, together, as adverse events (AEs), many of which are unpreventable regardless of how great an effort is made by professionals. However, others can be prevented, if we consider, for example, how certain procedures (catheterization, administering drugs, etc.) are performed. This is the reason why programs are being promoted through the Health Authorities for heightening patients' clinical safety.

In an initial study conducted two years ago, funded by the National Health System Quality Agency, the frequency and types of these AE's in hospitalized patients was analyzed. This research, known as the ENEAS Study, has had major repercussions both in Spain and abroad due to its being one of the broadest-scope studies conducted anywhere in the world. In the ENEAS study, the incidence of patients experiencing Adverse Effects related directly to the hospital care provided (not including PC, outpatient visits and those having occurred in another hospital) was estimated at 8.4% (95% CI: 7.7%-9.1%). The incidence of patients with Adverse Effects related to the care provided was 9.3% (95% CI: 8.6%-10.1%). The incidence density was 1.4 Adverse Effects per 100 days of patient stay (95% CI: 1.3-1.5). The incidence density of moderate or serious Adverse Effects was 7.3 Adverse Effects per 1000 days of stay (95% CI: 6.5-8.1). A total of 42.8% of the Adverse Effects were considered to be preventable.

Few studies have been conducted to date in the field of Primary Care and have been confined, in most cases, to pilot studies limited to a small number of physicians[23, 24] and based mainly on voluntary reporting systems[6, 25].

Individually, the medical errors (not necessarily Adverse Effects) most frequently found in all of the studies are related to the prescribing of medications, the figures nearing 40% [26]. Of this 40%, up to 20% of the cases could be considered preventable[27].

Diagnosis-related errors are also considered to be a major source of Adverse Effects. The most frequent of all is a wrong diagnosis[28]. The combination of diagnostic errors with prescribing-related effects is responsible for 13.6% of the effects found[29].

Poor communication among professionals and the communication with patients were considered to be a very important contributing factor in several studies. Wilson considers it to be a symptom of organizational problems more than of a true cause of Adverse Effects[30].

One problem when attempting to ascertain the incidence of Adverse Effects in Primary Care is that many of these effects go unnoticed because they have no consequences. In one international study conducted in collaboration with six countries, it was seen how only 31% had consequences for the patient and 3.7% required hospitalization[26]. Additionally, one must bear in mind that many patients who experience an Adverse Effect go directly to hospital emergency rooms without first going through PC.

In order to make progress in Patient Safety, it is necessary to put mechanisms into practice which will make it possible to identify human errors and system failures from two different angles. First of all, from the political standpoint, by developing strategies which will stress the preventive and not the punitive nature of identifying Adverse Effects. Secondly, at the local-health care center level through the development of patient safety programs and the inclusion of suitable technology which will make it possible to detect the problems and implement the solutions.

When a human error or system failure occurs, one should not try to find who was involved therein to find who was at fault, the truly effective approach really being that of analyzing it to identify how and why it has occurred[31]. In other words, it is of interest to know what, how and where the error/failure occurred and to understand why in order to adopt actions which will prevent it from reoccurring[32]. Therefore, the prime objective of an Adverse Effect reporting system must be to learn from experience[33].

The mandatory reporting systems revolve around adverse episodes which cause serious injuries or deaths and on being an incentive for the institutions to prevent safety-related problems which could lead to penalties. The systems of a voluntary type are focused more not so much on finding those responsible, but rather on improving safety. The objective is to identify the system's vulnerable areas and elements and to train the professionals on the basis of what has been learned[34].

The main shortcoming of the reporting systems is the under-reporting. The reasons mentioned for responsible for under-reporting[35] include: no perceived benefits, lack of feedback, increased work load, damage to one's reputation or concern about a possible lawsuit.

There are different strategies which can be carried out for heightening the confidence professionals place in reporting Adverse Effects. These strategies may be: clarifying definitions, simplifying the reporting methods, designating personnel, providing feedback and explaining the nature and purpose of systems of this type[34]. How successful voluntary reporting systems are will depend mainly on the willingness to report on the part of the health care professionals.

The Primary Care services are the gateway to the health system. Their objective is to respond to most of the problems posed by health care system users in coordination with other levels of care and from a perspective oriented toward patients in an overall manner.

According to the Spanish Ministry of Health & Consumer Affairs data, over 247 million non-emergency medical visits were conducted at the Health Centers and Physician's Offices; 88% of the visits having been seen by family practitioners and the other 12% by pediatricians, the need for diagnosis and treatment being the most frequent reason for these visits[36]. If studies conducted in Primary Care are considered, in which an error rate of 75.5/1000 visits[5] has been estimated, one is afforded with an approximate idea of the importance indentifying Adverse Effects has as this level of care.

One of the main characteristics of primary care is based on the continuity of the care provided and on teamwork. Therefore, it is difficult to set up retrospective surveillance systems, given that, unlike at hospitals, the clinical records are not focused on limited episodes, but rather on an integral, integrated endeavor.

Approximately 60% of all Primary Care spending is on drugs[37]. In both primary and specialized care, medication-related Adverse Effects are among the most frequent and are additionally especially important due to their preventability[39]. A total of 22.4% of the drug-related Adverse Effects could have been prevented by proper monitoring[38].

On being the patients' first point of contact with the system most initial diagnoses are made in Primary Care. An error at the start may mean an entire string of unnecessary tests and treatments which may be harmful to the patients. Primary Care is provided within a framework of major uncertainty, the providing of care during the starting stages of the disease where the symptoms are often not clear. To which one must add the associated presence of psychosocial problems, the short length of time allowed for the visits, care load pressure, etc. All this often hinders proper diagnoses being made[39].

The population seen in Primary Care is mainly over age 65 and customarily has more than one ailment. Therefore, this is a population at higher risk of experiencing Adverse Effects[40]. If it is also taken into account that 60% of all drugs are consumed by patients over 65 years of age[41, 42], it is not surprising that the risk of experiencing an Adverse Effect is especially higher among this population.

Most of the tools used for measuring Adverse Effects have been developed for identifying these effects in the hospital environment. Given the differences in the care provided and the organization of one system and the other, it is important that a specific tool be developed for identifying Adverse Effects in Primary Care.

Objectives

General Objectives:

1. Further enhance knowledge in relation to patient safety by way of approaching the magnitude, far-reaching importance and impact of Adverse Effects and analyzing the characteristics of the patients and of the care associated with preventable Adverse Effects arising.
2. Increase the number of professionals actively involved in patient safety.
3. Incorporate objectives and activities aimed at improving patient safety into the PC team agenda.

Specific Objectives:

1. Identify the adverse events stemming from the care provided in PC, including both incidents (no harm is done to the patient) and Adverse Effects (patient is harmed).
2. Estimate the frequency of care-related Adverse Effects at health care centers in different Autonomous Communities in Spain.
3. Identify the characteristics of the patient and of the care in those patients with Adverse Effects related to the care provided.
4. Estimate the impact which health care has on the Adverse Effects in PC, distinguishing between those which are preventable and those which are unpreventable.
5. Describe the types of Adverse Effects associated with the care provided in PC.
6. Analyze the factors contributing to Adverse Effects arising.
7. Identify the Adverse Effects of most far-reaching importance in order to design preventive strategies which will facilitate minimizing Adverse Effects in PC.

Hypothesis

Very few studies have been conducted on Adverse Effects in Primary Care. Additionally, they also deal with this subject only in part, given that they focus the study on the error and not on the Adverse Effect, which is a result not only of the error, but also of the failure of the system[5, 6]. Following a systematic review of the scientific literature, we have not found any study of an epidemiological kind in the strict sense of the word.

Our working hypothesis, after having conducted a pilot study, is that adverse events may affect at least 3% of the subjects for who care is provided in Primary Care and that at least 40% of these adverse events can be prevented[7].

Methodology

Study Subjects: All of those patients who are seen, for any reason, by the Primary Care Teams of the Healthcare Centers selected.

Design: Observational, cross-sectional study with analytical components[43].

Study Scope: Healthcare Centers from Spain's Autonomous Communities as a whole.

Sample: It was planned to screen an opportunistic sample comprised of at least 6 professionals (3 Family Practitioners, 1 Pediatrician and 2 Nurses) from a minimum of 25 Healthcare Centers, selected by way of the Patient Safety reference points of the Autonomous Communities, Scientific Societies and Key Informants, setting as limiting aspects the participation of a maximum of 5 centers per Autonomous Community for a maximum of 50 Healthcare Centers in the study. Thus, calculating 30 visits/professional/day throughout the 10 days of the study, we would be within the 45,000-90,000 patients range and would be within the 150-300 professionals range in the event that only one health care team per center were to take part.

In the end, a total of 48 Primary Care Healthcare Centers pertaining to 16 Autonomous Communities were included. A total of 452 professionals took part, 55.5% (249) of whom were Family Practitioners or Medical Residents (MIR); 33.6% (152) Nurses and 10.8% (49) Pediatricians, a number three times greater than the established minimum sample.

The study was conducted throughout the second and third weeks of June 2007.

Outcome variables: Adverse event (incident and Adverse Effect) and preventable Adverse Effect

0. **Adverse event**: Combination of Incidents and Adverse Effects.
1. **Incident**: Adverse event resulting from the care provided which does not cause any harm to the patient.
2. **Adverse effect**: Any unanticipated, unexpected accident identified at the point in time of the office visit which has caused harm and/or disability and which stems fro the care provided and not from the patient's baseline illness. In order to determine that the adverse event is due to the care provided, the reviewers will score the degree to which they are confident that the Adverse Effect in question was due to the care provided and not to the disease process on a six-point scale (1= no evidence or little evidence; 6= virtually certain evidence). A priori, we considered a cut-off point of ≥ 2 for considering it to be positive.
3. **Preventable Adverse Effect**: To determine that the Adverse Effect is preventable, the reviewers will score on a six-point scale (1= no evidence or little evidence; 6= virtually certain evidence). A priori, we considered a cut-off point of ≥ 4 for considering it to be positive.

Aspects to be established: Adverse effect frequency. Percentage of preventable Adverse Effects

Study Organization:

1. The APEAS form: Questionnaire prepared based on the one used by the University of Washington School of Medicine in its patient safety project and adapted following the findings of the ENEAS Study, under consensus techniques[44].

2. Software application for the management of the data: System for the Monitoring and Control of Adverse Effects in Primary Care. SIVCEA AP 1.0 Database.

Procedure: The professionals are to complete the form every time they identify an Adverse Effect which is prevalent or in sequelae stage independently of which the Adverse Effect in question may have originated and are to enter the information into the computer application and keep the forms for a future quality review, assuring the confidentiality thereof by means of a record-keeping system masked for the study management.

Data analysis: Description of the variables by means of the statistics most appropriate for the type of variables in question, type and measurement scale. Percentage analysis for the qualitative variables, whilst the quantitative variables will be presented by means of centralization and dispersion measures, as pertinent. For the bivariate analysis, the x^2 test or Fisher's exact test was used for the qualitative variables, and Student's t-test or the Mann-Whitney U test for the quantitative variables (depending on whether or not the normalcy criteria are met), as well as the variance analysis for the comparison of various measures, "p" values of under 0.05 being considered significant. For controlling the variables explaining the degree of severity and the preventability of the Adverse Effects from being confused and/or interacting, a multivariate logistic regression calculated by the forward method was used for reasons of credibility.

The statistical analyses were made using the SPSS Version 14.0 statistics program.

Working Definitions
Taxonomy employed and
Working Definitions [45,46,47]

Adverse event: Combination of incidents and Adverse Effects.
Incident: Unanticipated, unexpected random incident related to the care provided which does not cause any harm to the patient. An incident may also be defined as an event which, under different circumstances, could have been an Adverse Effect or as an event which, if not discovered or corrected in time, may entail problems for the patient.
Adverse effect: Any unanticipated, unexpected accident identified at the point in time of the office visit which has caused harm and/or disability, which stems from the care provided and not from the patient's baseline disease. To determine that an adverse event is due to the care provided, the reviewers will score the degree to which they are confident that the Adverse Effect in question was due to the care provided and not to the disease process on a six-point scale (1= no evidence or little evidence; 6= virtually certain evidence). A priori, we considered a cut-off point of ≥ 2 for considering it to be positive.
Preventable Adverse Effect: To determine that the Adverse Effect is preventable, the reviewers will score the degree to which they are confident that the Adverse Effect in question was due to the care provided and not to the disease process on a six-point scale (1= no evidence or little evidence; 6= virtually certain evidence). A priori, we considered a cut-off point of ≥ 4 for considering it to be positive, in accordance with their experience, the information included in the operating manual and the consensus from the training period.
Serious Adverse Effect: Causes death, residual disability at medical release or requires surgical intervention.
Moderate Adverse Effect: If it leads to a hospital stay of at least 1 day (Grade 2). If it requires care in the emergency room or a specialist's office (Grade 1).
Minor Adverse Effect: Harm or complication which causes none of the above.
Medical error: A mistake or omission in the practice of the health care professionals which may contribute to an adverse event occurring.
Medication error: An effect which is preventable or which is caused by an inappropriate use of a medication causing harm to a patient while the medication is under control of the health care personnel, patient or consumer.
Adverse drug reaction: Negative change and/or harm caused when the medications are used inappropriately (virtually unpreventable).
Accidental drug overdose: Intake of potentially toxic products (drugs) accidentally when they exceed the maximum therapeutic dosage, including if they intend to mitigate a symptom and an excessive amount (overdose) is taken for this purpose without the intervention of a health care professional.
Reintervention: Surgical procedure repeated within less than a thirty-day period due to causes related to the previous intervention (i.e. suture dehiscence following pilosebaceous cyst removal).
Nosocomial infection: An infection is considered to be nosocomial is there is no indication of the patient having had it in the clinical stage nor that it was incubating at the point in time that the health care was provided; otherwise being considered a community-acquired infection. Any infection present at the point in time of hospital admission which were to have been acquired during a prior hospital stay (i.e. prosthesis infection) is considered to be a special case of nosocomial infection.
Healthcare-related infection: An infection which develops in a patient for whom care is provided at any of the establishments were health care is provided: health centers (primary care), acute care hospital (nosocomial infection), chronic care hospital, senior citizen living facilities, outpatient clinics, dialysis centers, homecare and which is related to the care in question (it was not in the incubation stage or present at the point in time at which the care was

provided). The case definition criteria set out by the CDC will be applied for the classification of this infection[48, 49, 50].

1. Urinary infection: Must meet one of the following criteria:

1.1 *One of the following:* Fever (> 38ºC), urgent urination, pollakisuria, dysuria or tension in suprapubic region or the urine culture has been positive (more than 100,000 colonies/ml) for a maximum of two different microorganisms.

1.2 *Two of the following:* Fever (> 38ºC), urgent urination, pollakisuria, dysuria or tension in suprapubic region plus any of the following:

- Positive reactive strip in urine for leukocyte esterase and/or nitrates or pyuria or when more than 100 colonies/ml of the same uropathogen have been isolated in urine gram tincture in two urine cultures taken by suprapubic puncture.
- In a patient undergoing correct antibiotic treatment, less than 100,000 colonies/ml of one single uropathogen show up in a urine culture.
- There is a medical diagnosis.
- Prescription on the part of the physician of an appropriate antibiotic treatment.

1.3 *Other urinary tract infections:* Any of the following must apply:

- A microorganism has been isolated in a fluid or tissue culture.
- A clear sign of infection has been noticed in a surgical intervention or in an anatomopathological study.
- Fever (>38ºC), pain or tension in the affected region plus any of the following: pustulent drainage, microorganism isolated in blood culture, X-ray evidence of infection, existence of a medical diagnosis or prescription on the part of the physician of an appropriate antibiotic treatment.

2. **Surgical site infection:**

2.1 *Superficial surgical site infection:* Occurring within the 30 days immediately following the surgery and affecting solely the skin and subcutaneous cell tissue at the incision site. One of the following sub-criteria must also be met:

- Purulent drainage of the superficial incision.
- Isolation of a microorganism in the culture of a fluid or of a tissue taken from the superficial incision.
- Medical diagnosis of superficial infection of the incision.
- Pain or hypersensitivity to touch or pressure.
- Localized inflammation (heat, numbing, erythema) and the incision is deliberately opened by the surgeon.

The following cases are not considered superficial infections: minimal abscess of the suture point, infected burn, incision infection extending toward the fascia and muscle walls.

2.2 *Deep infection of an incision:* Occurring within the 30 days immediately following the surgery if no implant (any foreign body of non-human origin) has been performed or within the first year if an implant has been performed and the infection is related to the surgical procedure and the infection also affects the deep soft tissue of the incision (fascia and muscle walls). One of the following criteria must also be met:

- Purulent drainage from the deep area of the incision but not from the organs or spaces.
- Medical diagnosis of superficial infection of the incision.
- The incision spontaneously opens or is opened by the surgeon for any of these reasons: fever (>38ºC), localized pain, hypersensitivity to touch or pressure.

During a reintervention or direct inspection or histopathological or X-ray study, an abscess or other evidence of infection affecting the deep tissues of the incision is found.

2.3 *Organ or space infection:* Occurring within the 30 days immediately following the surgery if no implant has been performed or within the first year if an implant has been performed, and the infection is related to the surgical procedure and the infection also affects any part of the anatomy opened or manipulated during the operation, other than the incision. One of the following criteria must also be met:

- Purulent fluid collected by means of drain placed in an organ or space (if the area through which the drain penetrates the skin has become infected, the infection will not

be considered surgical but rather a skin or soft tissue infection, depending on the depth of the infection.

- Medical diagnosis of space/organ surgical infection.
- Isolation of microorganisms in samples taken from fluids or tissue from organs or spaces.
- During a reintervention or direct inspection or histopathological or X-ray study, an abscess or other evidence of infection which affects an organ or space is found.

3. Pneumonia: One of the following criteria must be met:

- Auscultation of rales or dullness to percussion during the physical examination of the chest and any of the following: onset of purulent sputum or change in sputum characteristics, a microorganism has been isolated in a blood culture; a microorganism has been isolated in a sample taken by transtrachael aspiration, bronchial brushing or biopsy.
- In chest X-ray, signs of a new infiltrate or the progression of a previous infiltrate or a pleural cavitation, consolidation or leakage and any of the following are found: onset of purulent sputum or change in sputum characteristics; a microorganism has been isolated in a blood culture; a microorganism has been isolated in a sample taken by transtrachael aspiration, bronchial brushing or biopsy; a virus has been isolated or the results of a test for the detection of viral antigens in respiratory secretions has been positive; the specific IgM antibody titration is diagnostic, or the IgG antibodies have quadruples in two successive samples; histopathological diagnosis of pneumonia.

4. **Primary bacteriemia:** One of the following criteria must be met:

- A microorganism unrelated to any other focal point of infection ahs been isolated in a blood culture.
- Fever (>38ºC), chills or hypotension plus any of the following: in two blood cultures which have not been performed simultaneously, the same standard skin contaminant totally unrelated to any other focal point of infection has been isolated; in a blood culture performed on a patient who has an intravascular cannula, a standard skin contaminant has been isolated and the physician has prescribed the pertinent antibiotic treatment; positive result of a test for the detection of blood antigens to an organism unrelated to any other focal point of infection.

5. Sepsis: One of the following criteria must be met if there is no other cause which would explain them:

- Fever (>38ºC), hypotension (systolic pressure of 90 mm Hg or under) or oliguria (<20 ml/h) plus any of the following: no blood culture has been performed or the blood cultures have been negative and the results of the tests for the detection of blood antigens have been negative; no other focal point of infection has been discovered; the physician has prescribed the pertinent antibiotic treatment for a sepsis.

6. Secondary bacteriemia: When the organism isolated in the blood culture is compatible with another health care-related infection.

7. Intravascular device-related bacteriemia:

- When, the catheter culture having been performed, the microorganism isolated in the blood cultures is the same as that isolated from the catheter tip, from the connection or from the infusion fluid.
- When, the catheter culture not having been performed, the blood culture is positive and no focal point of sepsis is recognizable, the most likely origin is the catheter, and the patient improves following the catheter removal.

8. Infectious phlebitis or arteritis: One of the following criteria must be met:

- In the culture of an artery or vein biopsy taken by surgical dissection, a microorganism has been isolated and the blood cultures have been negative or have not been performed.
- During an intervention or in the anatomopathological study, signs of infection of the corresponding vascular area have been detected.
- One of the following: Fever (38ºC), pain, erythema or heat in the affected vascular area; plus two of the following: more than 15 colonies have been isolated from the

intravascular top of the cannula in the semi-quantitative culture; the blood cultures have been negative or have not been performed.

- Purulent drainage from the affected vascular area, and the blood cultures have been negative or have not been performed.
- Any of the following in a patient of 12 months of age or younger: fever (>38ºC), hypothermia (<35ºC), apnea, bradycardia, clouded consciousness, pain, erythema or heat in the affected vascular area plus two of the following: in the semi-quantitative culture of the intravascular tip of the cannula, more than 15 colonies of microorganisms have been isolated; the blood cultures have been negative or have not been performed.

9. Intra-abdominal infection: Including infection of the gallbladder, bile ducts, liver – with the exception of hepatitis -, spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space and that of those intra-abdominal tissues or regions which have not been defined in any other section. One of the following criteria must be met:

- A microorganism has been isolated in the culture of a purulent pathological product obtained in a surgical intervention or by needle aspiration.
- An abscess or another obvious sign of intra-abdominal infection has been observed in a surgical intervention or in an anatomopathological study.
- Two of the following, if there is no other cause explaining them: fever (>38ºC), nausea, vomiting, abdominal pain or ictericia plus any of the following: a microorganism has been isolated in the drainage culture from a tube inserted during an intervention (closed system, open or T-tube, for example); microorganisms have been found in the Gram tincture of a drainage or of a tissue sample taken in a surgical intervention or by needle aspiration**;** a microorganism has been isolated in a blood culture and there is X-ray evidence of abdominal infection.

10. Skin or soft tissue infection: One of the following criteria must be met: Pus formation, pustules, vesicles or furuncles.

Two of the following in the affected area: spontaneous pain to palpation, numbness, erythema or heat plus any of the following: a microorganism has been isolated (if it comprises part of the normal flora of the skin, the culture must be pure and contain only one single microorganism in the culture of an aspirate or of a drainage from the affected area; positive result of a test for the detection of antigens in the affected tissue or in the blood; multinucleate giant cells have been found in the microscopic study of the affected tissue; the type of specific IgM antibodies is diagnostic or the IgG antibodies have quadruples in two successive samples.

Pressure injury: Ischemic necrosis and ulceration of tissues covering a ridge of bone which has been subjected to prolonged pressure as the result of being bed ridden for long period due to the disease having given rise to the hospital admission (provided that it were not present at the point in time of the admission).

Pulmonary thromboembolism: Lodging of a blood clot in a pulmonary artery with the consequent obstruction of the blood flow from the pulmonary parenchyma following long-term bed rest with immobility or due to the postoperative condition as a result of the hospitalization.

Deep vein thrombosis: Blood clot caused by long-term bed rest with immobility or due to the postoperative condition as a result of the hospitalization.

Non-infectious phlebitis or arteritis: Vascular inflammation which may or may not be associated with vascular thrombosis (thrombophlebitis) which does not meet the criteria for being infectious angeitis.

Hemorrhaging or laceration-related complications: Resulting from surgical intervention or treatment procedure (ex.: CVA in dialysis).

Surgical technique-related Adverse Effects: Resulting from a surgical intervention.

Suture dehiscence: Opening of tissues artificially sutured together due to a technical failure which leads to the edges of the suture coming apart and the organic content inside leaking out. This usually has to do with the sutures of the digestive and genitourinary apparatus and entails a surgical complication.

Foreign body or substance left by accident: Totally foreign to the organism proper. Left in the surgical field by oversight during an intervention.

Device, implant or graft-related complication: Resulting from a surgical intervention.
Accidental fall or traumatism: resulting from the health care provided.
Sudden death: Death due to cardiorespiratory arrest unrelated to the natural past history of the primary illness.
Error due to insufficient identification: Including all of the measures taken on a patient for which they were not intended as a result of insufficient identification (i.e. transfusions to the wrong patient, errors in surgical procedures, wrong limb, etc.).
Undernourishment/dehydration: Due to lack of adequate nutritional support during the hospitalization period. Weight los >2% in one week.
Perinatal death: Death which occurs from the 22nd week of pregnancy up to 28 days following birth, if known.
Transfusion reaction: Clumping and massive intravascular hemolysis of RBC's which appears following a blood transfusion.
Delayed care: Caused for reasons due to poor organization and not due to the patient or due to a professional decision.

Working definitions of intrinsic risk factors:

Renal insufficiency: A patient will be considered to have renal insufficiency when it is so stated on their Clinical Record or when the patient has some compatible clinical and analytical findings.
Diabetes: A patient will be considered to have diabetes when it is so stated on the Record or if any of the following diagnostic criteria[51] are met:
- Fasting venous glycemia (for at least 8 hours) $\geq$ 126 mg/dL.
- Random venous glycemia (independently of the length of time since the last food intake) $\geq$ 200 mg/dL, in the presence of symptoms of hyperglycemia (polyuria, polydypsia or unexplained weight loss),
- Venous glycemia $\geq$ 200 mg/dL, at 2 hours following oral overload with 75 g glucose dissolved in water.
Neoplasia: Patients diagnosed with malignant neoplasia over the course of the past five years.
Immunodeficiency: Patients diagnosed with some type of primary or secondary immunodeficiency, which may include, among others: acute and chronic lymphatic leukemias, Hodgkin's or non-Hodgkin's lymphomas, AIDS and the cases which involve HIV+ and have a CD4 of less than 5000.
Chronic pulmonary disease: A patient will be classified with this diagnosis if so stated on the Clinical Record.
Neutropenia: Defined as total blood neutrophills (band and segmented) < 1.5·109/L.
Liver cirrhosis: A patient will be classified as having cirrhosis if so stated on the Clinical Record.
Drug addiction: Regular use of inhaled or injected drugs over the past two years.
Obesity: Diagnosed or defined as BMI>30 (BMI=mass (kg)/height (m).
Hypoalbuminemia: Patients with albumin under 3 g/L.
Pressure ulcer: A patient will be classified with this diagnosis if so stated on the Clinical Record or if can be verified.
Malformations: If so stated on the Clinical Record or if can be verified.
Cardiac insufficiency: A patient will be diagnosed with Cardiac Insufficiency when they have proof of an altered ventricular (systolic and/or diastolic) function, in conjunction with intolerance to exercise, fluid retention or it is so stated on the Clinical Record.
Coronary disease: If a past history of AMI or angina pectoris or angina-like symptoms is stated on the Clinical Record, or the patient is on anti-angina medication.
Hypertension: If more than one record of blood pressure readings showing a systolic arterial pressure (SAP) of 140 or above and/or a diastolic arterial pressure of 90 mmHg or above in adults age 18 or older, and/or the patient has been prescribed antihypertensive medication (in patients with Diabetes Mellitus and/or Renal Insufficiency, lower values of 135/85 will be considered).

Alcoholism: Any deterioration in an individual's physical, mental or social functioning of a nature making it possible to reasonably infer that alcohol is a part of the causal nexus giving rise to such a disorder.
Dyslipemia: If, in a recent analysis, a plasma cholesterol value of 250 mg/dL (6.5 mmol/L) or a triglyceride value >200 mg/dL is found (although one single value solely once does not suffice) or the patient is undergoing drug treatment with hypolipemiants.
Depression: If so specified on the clinical record or if the patient has a disorder in which a key symptom is a depressed mood, loss of energy and/or loss of interest or of the ability to enjoy themselves or to experience pleasure (anhedonia) which affects the person's life for the better part of the day throughout at least a two-week period.
AIDS: Patient infected by the human immunodeficiency virus (HIV), who has opportunistic infections and certain types of tumors as a result of the progressive deterioration of the infected patient's immune system.

Working definitions of intrinsic risk factors:

Open urinary catheter: Presence of urinary catheter with open drainage system (permanent catheter; not entailing irrigations or purely temporary catherizations).
Close urinary catheter: Present of a urinary catheter with closed drainage system. A closed urinary drainage system will be considered to be that which is equipped with a: Non-return valve.
Area specially designed for taking puncture samples.
Bag drainage tube located at the most distal portion.
Enteral nutrition: Enteral nutrition system.
Nasogastric tube: Patient fitted with complete nasogastric tube system.
Tracheostomy: Patient with open tracheostomy independently of when performed.
Immunosuppressive therapy: Patient undergoing treatment, as per clinical record, with corticoids and/or other immunosuppressants.
Colostomy: Patient with open colostomy with temporary or permanent drainage.

Working definitions of intrinsic risk factors:

Pressure ulcer (PU) and worsening of a previously-existing PU: Will always be considered an Adverse Effect. The degree of preventability will depend on the patient's comorbidity.
Drug intolerance: If stated the past history of intolerance is stated on the record and is prescribed even so, this will be considered an incident or Adverse Effect (according to the repercussions on the patient) and will be considered preventable. If prescribed and not administered because notice is received of the intolerance, this is not considered as anything. If prescribed and the intolerance is then realized, this is considered an Adverse Effect or incident depending on the repercussions on the patient and will be considered unpreventable or virtually unpreventable.
Non-administering of treatment (for example: drug not available in pharmacy or medication normally taken not prescribed). This will be considered an incident or Adverse Effect according to the need for the medication for the patient's proper handling.
Prescription of contraindicated drug: This will be considered an incident or Adverse Effect depending on the repercussions on the patient.
Poor pain management: Considered a preventable Adverse Effect.
Diagnostic testing delay: Considered an incident unless a circumstance important for the clinical handling of the patient has not been diagnosed/evaluated, in which case it shall be considered an Adverse Effect. The preventability will depend on the reason for the delay; if due to care pressure (low preventability) or due to misplaced requests (high preventability).

The form questions

Care-related variables:

Type of center: Urban or rural
Professional category: Family practitioner, pediatrician, nurse, resident (MIR)
Professional experience: Less than 1 year, 1-5 years, 5-10 years, 10+ years.

Patient details:

Case: One-to-one patient-visit identification by means of consecutive numbering. A patient who has 1 or more Adverse Effects on the same visit will be encoded with the same case identification number, but on a different form. This field is MANDATORY.
Age: In years
Gender: Male or female
Date reported: (dd/mm/yyyy)
Event date: (dd/mm/yyyy)

Form:

Module 1: Causal factors of the Adverse Effect. Multiple answers allowed. In this section, the investigator may mark as many options as deemed necessary.
Module 2: Summarize what happened and what you believe the cause to have been. Free text field. It is highly advisable to state, among others, the origin of the Adverse Effect (for example, if it originated in the odontology office, in the hospital emergency room, etc.
Module 3: To what extent was the health care provided the cause of the harm. Select one of the options on the pull-down menu.
Module 4: Preventablity of the Adverse Effect. Binary variable (yes/no).
Module 5: Evidence of possibility of prevention. Select one of the options from the pull down menu.
Module 6: Effect caused in the patient. Complete the questionnaire for each effect one same patient may have experienced.
Module 7: What could have been done to prevent this problem? Free text field.
Module 8: Impact on the patient. Select one of the options from the pull down menu.
Module 9: Care provided to the patient as a result of the Adverse Effect. Select one of the options from the pull down menu.
Module 10: Risk factors. Multiple-choice answers. Mark all those the patient has.

Results

1. Characteristics of the population studied

A total of 452 professionals from 48 Healthcare Centers in 16 Autonomous Communities have collaborated in this study.
During the study period, 96,047 patients came in to their Healthcare Center for a Primary Care visit, and 2,059 reports were made related to **1,932** subjects.
In addition to the above, 86 reports were received on the part of 18 professionals regarding which we do not know the number of visits for the period in which the adverse events had occurred. Therefore, they shall not be taken into account for the prevalence calculations. However, they shall be taken into account for the causality, impact and preventability analyses.
A total of 63.5% of the visits encoded were seen by Family Practitioners; 26.5% by Nurses and 10.0% by Pediatricians (Table 1).

Table 1. Visits studied by Professional Category

Professional Category	**N**	**%**
Family Practitioner	61,049	63.5%
Nurse	25,436	26.5%
Pediatrician	9,563	10.0%
Total	**96,047**	**100.0%**

A total of 42.6% of the patients in the study were males and 57.4% females (Table 2).
There were no age differences in terms of the gender of the subjects in the study.
The age and gender characteristics are provided in Table 3.

Table 2. Visits by gender

Gender	**N**	**%**
Males	40,963	42.6%
Females	55,084	57.4%
Total	**96,047**	**100.0%**

Table 3. Age and gender of the patients with Adverse Effect notification

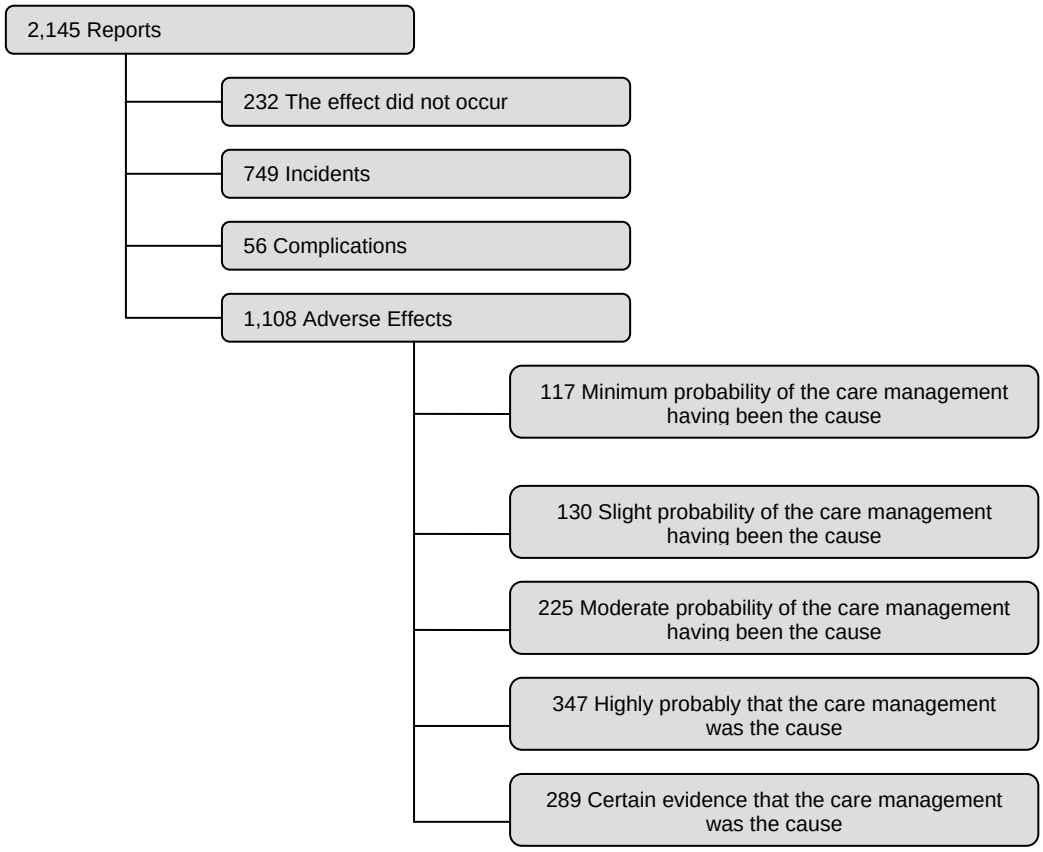
Gender	**Average age (SD)**	**Mean age in yrs (IA)**
Males	52.7 (25.8)	59 (38)
Females	53.5 (25.3)	59 (40)
Total	**53.1 (25.5)**	**59 (39)**

n= 1,932 Patients
SD: Standard deviation
IA: Interquartile amplitude

A total of 2,145 forms were completed, 232 of which did not identify any Adverse Effect or incident, a close call not having caused any harm or complication having arisen in 749, and the

harm or complication identified not having been related to the care provided (no evidence of this relationship) in 56 cases, as a result of which they were not considered to be care-related. And, in the other 1,108 reports, Adverse Effects were identified in accordance with the definition previously stated (Figure 1).

Fig. 1. Reports Submitted



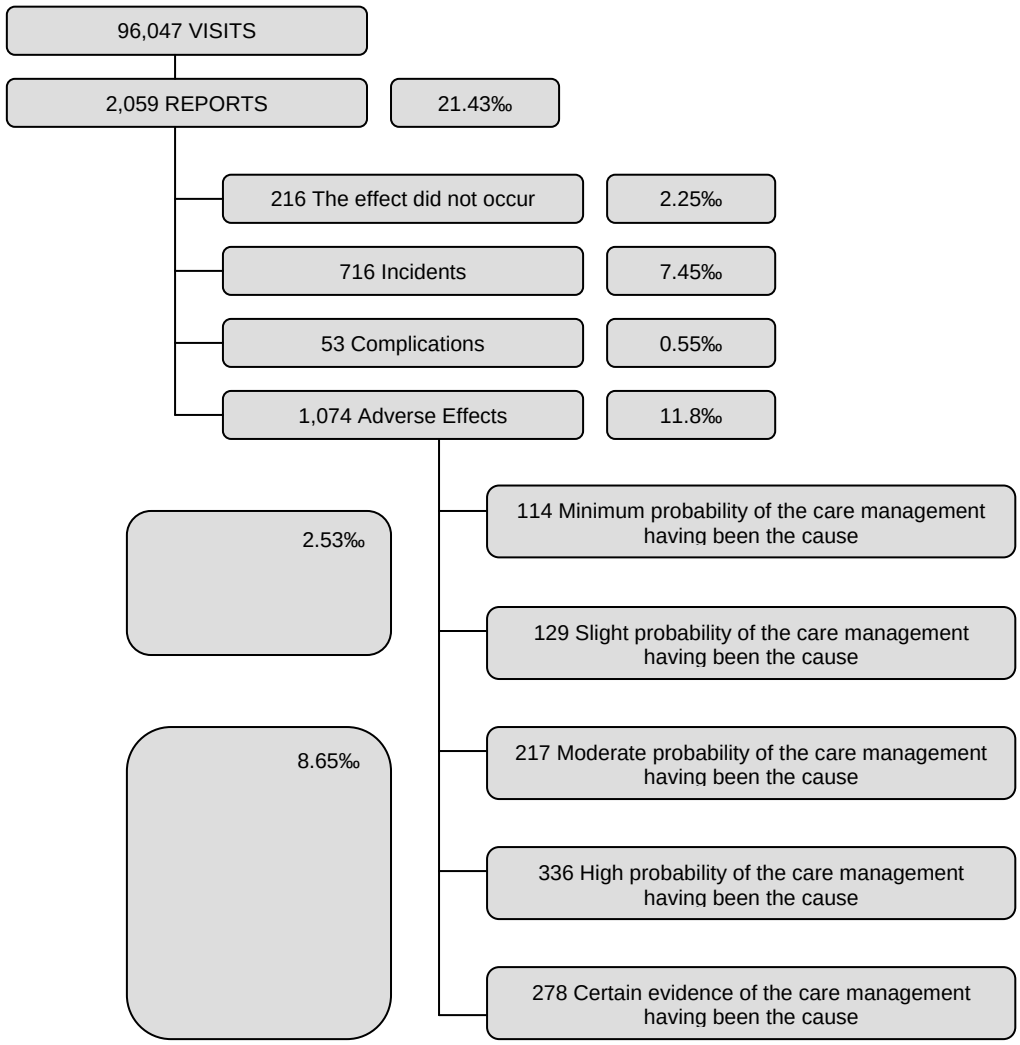
Of the total reports identified as possible Adverse Effects (1,108), in 77.7% of the cases, the harm was considered highly care-related (moderately, highly probable or certain evidence), whist in 22.3% of the cases, it was considered to be of low probability (minimal or slight evidence).

2. Calculation of the prevalence of patients experiencing an Adverse Effect

The reports for which the total number of visits made (denominator for the calculation) were know have been selected. Of the 96,047 visits, the health care professional detected some possible Adverse Effect in 1,932 visits, generating a total of 2,059 reports. A total of 1,074 Adverse Effects were identified corresponding to 971 different patients. In 243 reports, there was a minimal or slight probability of the patient handling or the health care provided having been the origin of the Adverse Effect, as compared to the 831 reports in which there was some Adverse Effect strongly linked to the care provided.

The prevalence of Adverse Effects per visit is on the order of 11.18‰ (1,074/96,047) 95% CI: 10.52‰ - 11.85‰ (Figure 2).

Fig. 2 Reports with denominator



The prevalence of visits which experience some adverse event was 17.93‰ (1,722/96,047) (95%CI: 17.09‰ - 18.77‰), comprised of 7.38‰ (709/96,047) Incidents, 0.44‰ (42/96,047) Complications and 10.11‰ (971/96,047) prevalence of patients with an Adverse Effect.
On reviewing the professional category of the reporting persons, the nurses identified a greater prevalence of Adverse Effects than the rest of the professionals, whilst the pediatricians identified less, the differences being statistically significant (p-value<0.01) as shown in Table 4.

Table 4. Prevalence of Adverse Effects by type of professional

	Patients	Visits	Prevalence‰	95‰ CI
Professional Category				
Family Practitioner	632	61,049	10.35	9.55-11.16
Nurse	293	25,436	11.52	10.21-12.83
Pediatrician	46	9,563	4.81	3.42-6.20
Total	**971**	**96,047**	**10.11**	**9.48-10.74**

3. Characteristics of the subjects with an Adverse Effect

A total of 10.08‰ of the males developed a health care-related adverse effect as compared to the 10.13‰ of the females. The difference as statistically non-significant (p=0.942) (Table 5).

Table 5 Prevalence of Subjects with an Adverse Effect, by gender

Gender	Patients	Visits	Prevalence‰	95‰ CI
Males	413	40,963	10.08	9.11-11.05
Females	558	55,084	10.13	9.29-10.97
Total	**971**	**96,047**	**10.11**	**9.48-10.74**

For all of the other results, we used the total number of reports submitted, 2,145 reports which were for 2,013 patients, a total of 1,002 of who experienced an Adverse Effect.
The distribution of Adverse Effects by professional category and number of Adverse Effects per patient is provided in Table 6.

Table 6. Total number oa Adverse Effects per patient per professional category

Professional Category	Family Practitioner	Nurse	Pediatrician	Total
1 Adverse Effect	621	265	49	933
2 Adverse Effects	29	20	2	51
3 Adverse Effects	2	7	0	9
4 or more Adverse Effects	1	6	0	7

A total of 6.7% of all patients who experienced an Adverse Effect experienced more than one Adverse Effect.
A total of 58.0% of the subjects who experiences Adverse Effects had some risk factor, as compared to the 42.0% of the subjects who had no risk factors (Table 7).

Table 7. Percentage of Subjects with some risk factor

Risk factors	Patients	Percentage
No Risk Factors	421	42.0%
Risk Factors Present	581	58.0%
Total	**995**	**100%**

The presence of intrinsic risk factors was important, especially if one takes into account that there was no age-related limiting aspect in the study, hypertension, diabetes, obesity, hypercholesterolemia and depression being the most frequent (Table 8).

Table 8. Intrinsic risk factors in patients with an Adverse Effect

	Patients	Presence	% Total
Intrinsic Risk Factors	Hypertension	315	31.5%
	Diabetes	175	17.5%
	Obesity	143	14.3%
	Dyslipemia	126	12.6%
	Depression	106	10.6%
	Cardiac Insufficiency	66	6.6%
	Neoplasia	59	5.9%
	Coronary Disease	55	5.5%
	Chronic Pulmonary Disease	44	4.4%
	Renal Insufficiency	38	3.8%
	Pressure Ulcer	23	2.3%
	Alcoholism	11	1.1%
	Liver Cirrhosis	7	0.7%
	Immunodeficiency	4	0.4%
	HIV (AIDS)	4	0.4%
	Drug Addiction	4	0.3%
	Neutropenia	1	0.1%
	Malformations	1	0.1%
	Patients with some intrinsic factors	575	57.4%

However, the extrinsic risk factors are not very frequency in Primary Care, solely 2.4% of the patients having these risk factors, half of these risk factors consisting of being fitted with a urinary catheter (Table 9).

Table 9. Extrinsic risk factors in patients with Adverse Effects

	Patients	Present	% Total
Extrinsic Risk Factors	Closed urinary catheter	11	1.1%
	Immunosuppressive therapy	6	0.6%
	Enteral nutrition	4	0.4%
	Colostomy	2	0.2%
	Open urinary catheter	2	0.2%
	Nasogastric tube	1	0.1%
	Patients with some extrinsic factor	24	2.4%

As an indicator of the degree of seriousness of the Adverse Effect, an analysis was made of the impact which the Adverse Effect in question had on the patient, as well as the care provided to the patient as a result of the Adverse Effect, such that, of the 1,002 patients who experienced an Adverse Effect, the Adverse Effect was considered slight in 57.5% of the patients; moderate in 36.6% and serious in 5.9%.

On exploring the pattern of the degree of seriousness of the Adverse Effect among the patients who has more frequent intrinsic risk factors (diabetes, obesity, hypertension,

hypercholesterolemia and depression) it was found that there does not seem to be any relationship between the more serious Adverse Effects and any risk factor in particular.

Table 10. Seriousness of the Adverse Effects for the most frequent Intrinsic Risk Factors

Intrinsic Risk Factor	Slight		Moderate		Serious	
Hypertension	197	62.5%	102	32.4%	16	5.1%
Diabetes	100	57.1%	65	37.1%	10	5.7%
Obesity	86	60.1%	52	36.4%	5	3.5%
Dyslipemia	76	60.3%	46	36.5%	4	3.2%
Depression	57	53.8%	41	38.7%	8	7.7%

4. Cause-Effect Relationship

Of the 1,108 Adverse Effects detected, in 97.5% of the cases, one or more causal factors may have been involved, which have been grouped into those related to the medication, the communication, the management, the diagnosis, the care provided and others.
As this is a multiple-choice answer, the results grouped by category are not the sum thereof. For example, in the case in point, of the 48.2% of the patients who have experience some Adverse Effect, at least one of the causal factors which has had a bearing thereon is medication-related.
Worthy of special mention here is the fact that in 48.2% of the cases, the causal factors of the Adverse Effect are medication-related; 25.7%, care-related; 24.6%, communication-related; 13.1%, diagnosis-related, 8.9% care management-related and 14.4% other causes (Figure 3, Tables 11, 12, 13, 14, 15 and 16).

Fig. 3 Causal Factors of Adverse Effects

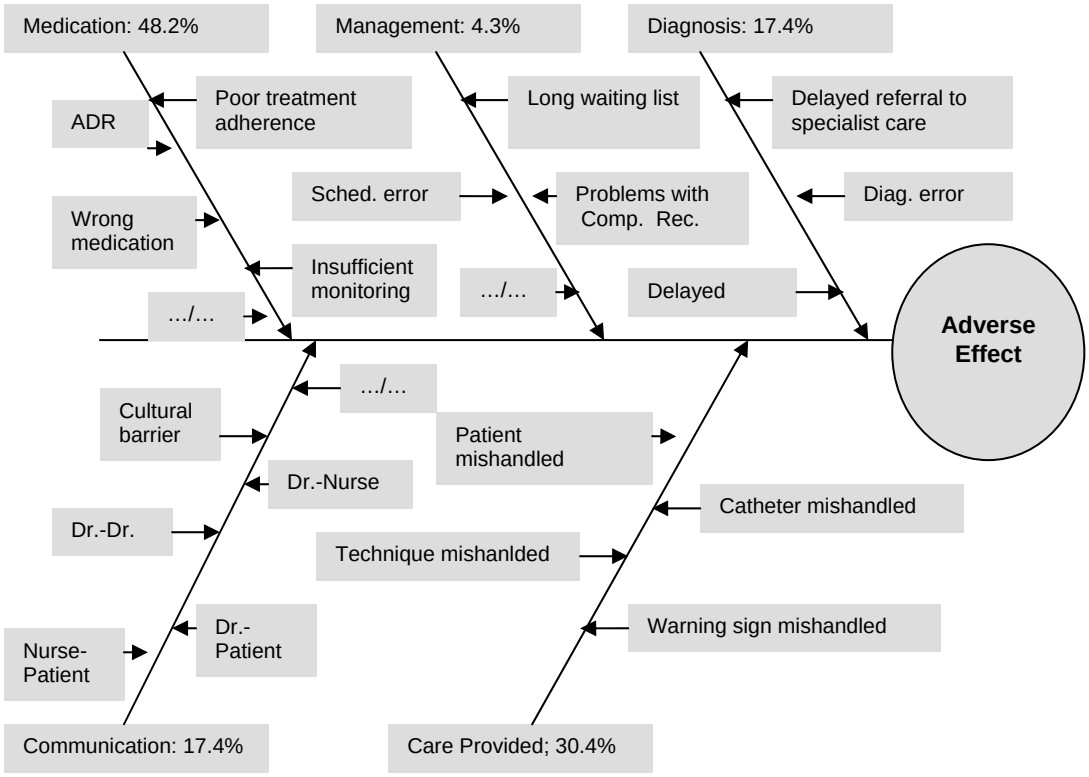


Table 11. Groups of Causal Factors present in giving rise to the Adverse Effect

Adverse Effect Causal Factors	**N**	**%**
Medication-related	534	48.20%
Care-related	285	25.70%
Communication-related	273	24.60%
Other causes	159	14.40%
Diagnosis-related	145	13.10%
Management-related	99	8.90%
Some Causal Factor	1080	97.5%

Table 12. Medication-related causal factors

Medication-related causal factor	**N**	**%**
Medication-related	534	48.20%
ADR	288	26.0%
Incorrect dosage	58	5.2%
Failure to adhere to the treatment	53	4.8%
Missed dose, medication or vaccine	52	4.7%

Wrong medication	43	3.9%
Drug interaction	39	3.5%
Incorrect administration frequency	30	2.7%
Incorrect treatment duration	30	2.7%
Insufficient monitoring	21	1.9%
Wrong patient	14	1.3%
Preparation or handling error	11	1.0%

It will be noted that more medication errors than ADR have been reported. This will be discussed at a further point herein.

Table 13. Care-related causal factors

Care-related causal factors	**n**	**%**
Care-related	285	25.70%
Patient mishandled	136	13.7%
Technique mishandled	103	10.4%
Warning sign mishandled	89	8.9%
Catheter mishandled	6	0.6%

Table 14. Communication-related causal factors

Communication-related causal factors	**n**	**%**
Communication-related	273	24.60%
Physician-patient communication	166	15.0%
Nurse-patient communication	54	4.9%
Physician-physician communication	40	3.6%
Other communication factor	34	3.1%
Cultural barrier	25	2.3%
Language barrier	18	1.6%
Physician-nurse communication	9	0.8%

One of the main problems in this regard still continues to be communication with the patients, including language or cultural barriers. Not to be slighted also is the influence of the communication problems among professionals and among levels of care.

Table 15. Diagnosis-related causal factors

Diagnosis-related causal factors	**n**	**%**
Other Causes	159	14.40%
Delayed diagnosis	83	7.5%
Error in diagnosis	47	4.0%
Delay in referral to specialized care	34	3.0%

Table 16. Management-related causal factors		
Management-related causal factors	**n**	**%**
Management-related	99	8.90%
Long waiting list	59	5.3%
Scheduling error	24	2.2%
Problems with computerized record	12	1.1%
Error in the health information	6	0.5%
Error in the patient identification	3	0.3%

Some of the problems in relation to the management of the scheduling or the health information could be correctable independently of the frequentation in Primary Care.
The distribution of the causal factors of the Adverse Effects by type of professional are provided in Tables 17, 18, 19, 20, 21 and 22.

Table 17. Adverse Effect causal factors, by professional category						
Causal factors of adverse effects	**Family Practitioner**		**Nurse**		**Pediatrician**	
Total Factors	671	97.4%	357	97.5%	52	98.1%
Medication-related	406	58.90%	103	28.10%	25	47.20%
Communication-related	179	26.00%	809	21.90%	14	26.40%
Care-related	102	14.80%	175	47.80%	8	15.10%
Diagnosis-related	100	14.50%	34	9.30%	11	20.80%
Other Causes	71	10.30%	77	21.00%	11	20.80%
Management-related	66	9.60%	31	8.50%	2	3.80%

Table 18. Medication-related causal factors, by professional category						
Adverse effect causal factors	**Family Practitioner**		**Nurse**		**Pediatrician**	
Medication-related	406	58.9%	103	28.1%	25	47.2%
ADR	245	35.6%	30	8.2%	13	24.5%
Incorrect dosage	38	5.5%	14	3.8%	6	11.3%
Failure to adhere to the treatment	26	3.8%	23	6.3%	4	7.5%
Missed dose, medication or vaccine	36	5.2%	16	4.4%	0	0.0%
Drug interaction	33	4.8%	6	1.6%	0	0.0%
Wrong medication	30	4.4%	10	2.7%	3	5.7%
Incorrect administration frequency	22	3.2%	7	1.9%	1	1.9%
Incorrect treatment duration	19	2.8%	9	2.5%	2	3.8%
Insufficient monitoring	19	2.8%	2	0.5%	0	0.0%
Wrong patient	14	2.0%	0	0.0%	0	0.0%
Preparation or handling error	7	1.0%	4	1.1%	0	0.0%

Table 19. Communication-related causal factors, by professional category

Adverse effect causal factors	Family Practitioner		Nurse		Pediatrician	
Communication-related	179	26.0%	80	21.9%	14	26.4%
Physician-patient communication	120	17.4%	40	10.9%	6	11.3%
Nurse-patient communication	19	2.8%	33	9.0%	2	3.8%
Physician-physician communication	36	5.2%	2	0.5%	2	3.8%
Other communication factor	16	2.3%	15	4.1%	3	5.7%
Cultural barrier	18	2.6%	7	1.9%	0	0.0%
Language barrier	14	2.0%	2	0.5%	2	3.8%
Physician-nurse communication	1	0.1%	8	2.2%	0	0.0%

Table 20. Care-related causal factors, by professional category

Adverse effect causal factors	Family Practitioner		Nurse		Pediatrician	
Care-related	102	14.8%	175	47.8%	8	15.1%
Patient mishandled	54	7.8%	76	20.8%	6	11.3%
Technique mishandled	32	4.6%	69	18.9%	2	3.8%
Warning signs mishandled	24	3.5%	64	17.5%	1	1.9%
Catheters mishandled	3	0.4%	3	0.8%	0	0.0%

Table 21. Diagnosis-related causal factors, by professional category

Adverse effect causal factors	Family Practitioner		Nurse		Pediatrician	
Diagnosis-related	100	14.5%	34	9.3%	11	20.8%
Delayed diagnosis	57	8.3%	22	6.0%	4	7.5%
Error in diagnosis	33	4.8%	8	2.2%	6	11.3%
Delay in referral to specialized care	25	3.6%	7	1.9%	2	3.8%

Table 22. Management-related causal factors, by professional category

Adverse effect causal factors	Family Practitioner		Nurse		Pediatrician	
Management-related	66	9.6%	31	8.5%	2	3.8%
Long waiting list	38	5.5%	19	5.2%	2	3.8%
Scheduling error	14	2.0%	9	2.5%	1	1-9%
Problems with computerized record	11	1.6%	1	0.3%	0	0.0%
Error in health information	5	0.7%	1	0.3%	0	0.0%
Error in patient identification	1	0.1%	2	0.5%	0	0.0%

5. Type of the Adverse Effect

A total of 47.8% of the Adverse Effects (520) consisted of medication-related problems; infections of any type having totaled 8.4% (93) of all Adverse Effects; 10.&% (118) entailing complications of some procedure and 6.5% (72) having been care-related. The different types of

Adverse Effects are provided in Tables 23, 24, 25, 26, 27, 28 and 29, exactly as they were distributed in the study.

Table 23. Types of Adverse Effects

Types of Adverse Effects	n	%
Medication-related	530	47.8%
Worse course of evolution of baseline disease	221	19.9%
Procedure-related	118	10.6%
Infection-related	93	8.4%
Others	74	6.7%
Care-related	72	6.5%
Total	1,108	100.0%

Table 24. Medication-related Adverse Effects

Types of Adverse Effects	n	%
Medication-related	530	47.8%
Nausea, vomiting or diarrhea secondary to medication	99	8.9%
Pruritus, rash or skin lesions reactive to drugs or bandages	58	5.2%
Drug-induced neurological changes	56	5.1%
Other drug-related complications (cough, dypsnea, dry mouth)	42	3.8%
Drug-induced upset stomach or stomachache (epigastralgia)	37	3.3%
Systemic allergic reactions	31	2.8%
Poor glycemia control	27	2.4%
Drug-induced hypotension	27	2.4%
Local effects or fever following vaccination or drug admin.	26	2.3%
Poor control of blood pressure	25	2.3%
Drug-induced headache	21	1.9%
Poor pain management	19	1.7%
Functional alteration (renal, liver, thyroid…)	17	1.5%
Upper digestive tract hemorrhage	10	0.9%
Anticoagulation-induced hemorrhage	8	0.7%
Edema, cardiac insufficiency and shock	8	0.7%
Drug-induced change in heart rate or electrical activity	7	0.6%
Electrolyte imbalance	5	0.5%
Constipation	4	0.4%
AMI, CVA, PTE, DVT	3	0.3%

Table 25. Worse course of evolution of the baseline disease and other Adverse Effects		
Types of Adverse Effects	**n**	**%**
Worse course of evolution of the baseline disease	221	19.9%
Others	74	6.7%
Need of repeating procedure or the visit	35	3.2%
Anxiety, stress or depression	25	2.3%
Another Adverse Effect	14	1.3%

Table 26. Procedure-related Adverse Effects		
Types of Adverse Effects	**N**	**%**
Procedure-related	118	10.6%
Hemorrhage or hematoma related to surgical intervention	39	3.5%
Suture dehiscence	35	3.2%
Seromas, abscesses and granulomas	18	1.6%
Other complications due to a procedure	16	1.4%
Circulatory disorder (cast too tight)	5	0.5%
Perforated eardrum	4	0.4%
Catheterization-related hematuria	1	0.1%

Table 27. Infection-related Adverse Effects		
Types of Adverse Effects	**n**	**%**
Infection-related	93	8.4%
Surgical and/or trauma wound infection	56	5.1%
Opportunistic infection due to immunosuppressant or antibiotic	17	1.5%
PU infection	9	0.8%
Catheterization-related UTI	8	0.7%
Aspiration pneumonia	3	0.3%

Table 28. Care-related Adverse Effects		
Types of Adverse Effects	**n**	**%**
Care-related	72	6.5%
PU	38	3.4%
Burns, scrapes, falls and contusions		
(Including resulting fractures)	18	1.6%
Other consequences of long-term immobilization	10	0.9%
Phlebitis	6	0.5%

The most frequent Adverse Effects were: worse course of evolution of the baseline disease, nausea, vomiting or diarrhea secondary to medication, pruritus, rash of skin lesions reactive to drugs or bandages, surgical and/or trauma wound infection and neurological alterations secondary to drugs, which, all combined, totaled 44% of the Adverse Effects. Figure 4 is a

Pareto Diagram on relative frequencies and absolute values of each one of the Adverse Effects. Table 29 provides the equivalents for interpreting the figure.

Table 29. Adverse Effect Codes

1	Worse course of evolution of the baseline disease	21	Burns, scrapes, falls and contusions (including resulting fractures)
2	Nausea, vomiting or diarrhea secondary to medication	22	Opportunistic infection due to immunosuppressant treatment or antibiotics
3	Pruritus, rash or skin lesions reactive a drugs or bandages	23	Functional alteration (renal, liver, thyroid …)
4	Surgical and/or trauma wound infection	24	Other complications due to a procedure
5	Drug-induced neurological alterations	25	Another Adverse Effect
6	Other drug-related complications (cough, dypsnea, dry mouth)	26	Other consequences of long-term immobilization
7	Hemorrhage or hematoma related to surgical intervention	27	Upper digestive tract hemorrhage
8	PU	28	PC-related infection
9	Drug-induced upset stomach or stomachache (epigastralgia)	29	Catheterization-related UTI
10	Suture dehiscence	30	Anticoagulation-induced hemorrhage
11	Need of repeating the procedure or the visit	31	Edema, cardiac insufficiency and shock
12	Systemic allergic reactions	32	Drug-induced change in heart rate or electrical activity
13	Drug-induced hypotension	33	Phlebitis
14	Poor glycemia control	34	Circulatory disorder (cast too tight)
15	Local effects or fever following vaccination or drug administration	35	Electrolyte imbalance
16	Poor blood pressure control	36	Perforated eardrum
17	Anxiety, stress or depression	37	Constipation
18	Drug-induced headache	38	Aspiration pneumonia
19	Poor pain management	39	AMI, CVA, PET, DVT
20	Seromas, abscesses and granulomas	40	Catheterization-related hematuria

Fig. 4. Adverse Effects Pareto Diagram

The Family Practitioners and Pediatricians detected more frequently the medication-related Adverse Effects and those related to a worse course of evolution of the patient's baseline disease, while the care-related, procedure-related and nosocomial infection-related Adverse Effects were detected mainly by the Nursing personnel (Table 30).

Table 30. Type of Adverse Effect, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Medication-related	395	57.3%	109	29.8%	26	49.1%
Worse course of evolution of baseline disease	161	23.4%	43	11.7%	17	32.1%
Procedure-related	44	6.4%	73	19.9%	1	1.9%
Others	37	5.3%	31	8.5%	26	11.3%
Infection-related	35	5.1%	57	15.6%	1	1.9%
Care-related	17	2.5%	53	14.5%	2	3.8%
Total	689		366		53	

Table 31. Medication-related Adverse Effects, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Medication-related	395	57.3%	109	29.8%	26	49.1%
Nausea, vomiting or diarrhea secondary to medication	83	12.0%	9	2.5%	7	13.2%
Drug-induced neurological changes	49	7.1%	6	1.6%	1	1.9%
Other drug-related complications (cough, dypsnea, dry mouth)	39	5.7%	2	0.5%	1	1.9%
Drug-induced upset stomach or stomachache (epigastralgia)	35	5.1%	2	0.5%	0	0.0%
Pruritus, rash or skin lesions reactive to drugs or bandages	34	4.9%	16	4.4%	8	15.1%
Drug-induced hypotension	23	3.3%	4	1.1%	0	0.0%
Systemic allergic reactions	19	2.8%	7	1.9%	5	9.4%
Drug-induced headache	19	2.8%	2	0.5%	0	0.0%
Poor pain management	15	2.2%	3	0.8%	1	1.9%
Poor glycemia control	13	1.9%	14	3.8%	0	0.0%
Functional alteration (renal, liver, thyroid…)	13	1.9%	4	1.1%	0	0.0%
Poor blood pressure control	9	1.3%	16	4.4%	0	0.0%
Upper digestive tract hemorrhage	9	1.3%	1	0.3%	0	0.0%
Anticoagulation-induced hemorrhage	8	1.2%	0	0.0%	0	0.0%
Edema, cardiac insufficiency and shock	7	1.0%	1	0.3%	0	0.0%
Drug-induced change in heart rate or electrical activity	6	0.9%	1	0.3%	0	0.0%
Local effects or fever following vaccination or drug admin.	5	0.7%	18	4.9%	3	5.7%
Constipation	4	0.6%	0	0.0%	0	0.0%
Electrolyte imbalance	3	0.4%	2	0.5%	0	0.0%
AMI, CVA, PTE, DVT	2	0.3%	1	0.3%	0	0.0%

Table 32. Worse course of evolution and other Adverse Effects, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Worse course of evolution of baseline disease	161	23.4%	43	11.7%	17	32.1%
Others	37	5.3%	31	8.5%	26	11.3%
Anxiety, stress or depression	17	2.5%	8	2.2%	0	0.0%
Need of repeating procedure of the visit	12	1.7%	20	5.5%	3	5.7%
Another Adverse Effect	8	1.2%	3	0.8%	3	5.7%

Table 33. Procedure-related Adverse Effects, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Procedure-related	44	6.4%	73	19.9%	1	1.9%
Hemorrhage or hematoma related to surgical intervention	17	2.5%	22	6.0%	0	0.0%
Other procedure-related complications	12	1.7%	4	1.1%	0	0.0%
Seromas, abscesses and granulomas	6	0.9%	12	3.3%	0	0.0%
Suture dehiscence	5	0.7%	30	8.2%	0	0.0%
Circulatory disorder (cast too tight)	2	0.3%	3	0.8%	0	0.0%
Perforated eardrum	2	0.3%	1	0.3%	1	1.9%
Catheterization-related hematuria	0	0.0%	1	0.3%	0	0.0%

Table 34. Infection-related Adverse Effects, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Infection-related	35	5.1%	57	15.6%	1	1.9%
Surgical and/or trauma wound infection	14	2.0%	41	11.2%	1	1.9%
Opportunistic infection due to immunosuppressive or antibiotic treatment	13	1.9%	4	1.1%	0	0.0%
PU-related infection	1	0.1%	8	2.2%	0	0.0%
Catheterization-related UTI	5	0.7%	3	0.8%	0	0.0%
Aspiration pneumonia	2	0.3%	1	0.3%	0	0.0%

Table 35. Care-related Adverse Effects, by professional category

Type of Adverse Effect	Family Practitioner		Nurse		Pediatrician	
Care-related	17	2.5%	53	14.5%	2	3.8%
Burns, scrapes, falls and contusions (including resulting fractures)	7	1.0%	9	2.5%	2	3.8%
Phlebitis	4	0.6%	2	0.5%	0	0.0%
PU	3	0.4%	35	9.6%	0	0.0%
Other consequences of long-term immobilization	3	0.4%	7	1.9%	0	0.0%

The distribution of the different types of Adverse Effects by type of professional is provided in Tables 31, 32, 33, 34 and 35.

Table 36 shows the causal factors of the different types of Adverse Effects in groupings. Special mention must be made here of the fact that the causal factors of infection are most frequently

Table 36. Causal Factor of the Adverse Effect, by Type of Adverse Effect

		Causal Factors											
Type of Adverse Effect	**No.**	Medication		Communication		Management		Diagnosis		Care		Others	
Medication-related	530	404	7.62%	112	21.9%	11	2.1%	20	3.8%	44	8.3%	79	14.9%
Worse evolution of baseline disease	221	66	29.9%	92	41.6%	55	2.49%	81	36.7%	41	18.6%	14	6.3%
Procedure-related	118	14	11.9%	16	13.6%	8	6.8%	11	9,3%	76	64-4%	27	22.9%
Infection-related	93	24	25.8%	12	12.9%	5	5.4%	10	10.8%	53	57.0%	18	19.4%
Others	74	15	20.3%	23	31.1%	18	24.3%	15	20.3%	19	25.7%	11	14.9%
Care-related	72	11	15.3%	18	25.0%	2	2.8%	8	11.1%	52	72.2%	10	13.9%
Total	1,108	534	48.2%	273	24.6%	99	8.9%	145	13.1%	285	25.7%	159	14.4%

care-related, and that a prominent aspect in the medication-related Adverse Effects is precisely communication, and that this group of causal factors is also present when the Adverse Effect is a worse evolution of the baseline disease.

Studying the origin of the Adverse Effects, 73.5% of the Adverse Effects were found to have occurred at a Primary Care Center; 25.8% in Specialized Care (2.9% of these Adverse Effects having occurred in their Hospital Emergency Room); and, lastly, the other 0.7% took place in the Pharmacies (Table 37).

Table 37. Origin of the Adverse Effect, by Types

Type of Adverse Effect	**PC Center**		**Specialized Care**		**Pharmacy**		**Total**	
Medication-related	441	85.0%	74	14.2%	4	0.8%	519	47.7%
Worse course of evolution of patient's baseline disease	139	63.5%	77	35.1%	3	1.4%	219	20.1%
Procedure-related	63	54.3%	53	45.7%	0	0.0%	116	10.7%
Infection-related	58	63.0%	34	37.0%	0	0.0%	92	8.5%
Others	48	66.7%	24	33.3%	0	0.0%	72	6.6%
Care-related	51	72.9%	19	27.1%	0	0.0%	70	6.4%
Total	800	73.5%	281	25.8%	7	0.7%		1,088

6. Adverse Effect Impact

A total of 54.7% of the Adverse Effects (606 Adverse Effects) were considered slight; 38.0% (421) moderate and 7.3% (81) serious.
On exploring the degree of seriousness of the Adverse Effect by the professional category of the health care personnel, statistically significant differences were found among them (p-value=0.005) (Table 38). The Adverse Effects detected by the pediatricians were divided evenly between slight and moderate, not entailing any serious one. The seriousness pattern of the Adverse Effects detected by the physicians and nurses showed a different trend, with a similar frequency of moderate Adverse Effects and a higher frequency of serious Adverse Effects in nurses.

Table 38. Degree of Seriousness of the Adverse Effects, by professional category

Professional category	Slight		Moderate		Serious		Total	
Family Practitioner	393	57.0%	254	36.9%	42	6.1%	689	62.2%
Nurse	186	50.8%	141	38.5%	39	10.7%	366	33.0%
Pediatrician	27	50.9%	26	49.1%	0	0.0%	53	4.8%
Total	606	54.7%	421	38.0%	81	7.3%		1,108

On exploring the degree of seriousness of the Adverse Effect by reclassifying Moderate and Serious Adverse Effect, no statistically-significant differences were found between them (p-value=0.132) (Table 39).

Table 38. Reclassification of Degree of Seriousness of the Adverse Effects, by professional category

Professional category	Slight		Moderate & Serious		Total	
Family Practitioner	393	57.0%	296	43.0%	689	62.2%
Nurse	186	50.8%	180	49.1%	366	33.0%
Pediatrician	27	50.9%	26	49.1%	53	4.8%
Total	606	54.7%	502	45.3%		1,108

When the degree of seriousness of the Adverse Effect is studied by types of Adverse Effects (Table 40), the procedures-related and the medication-related Adverse Events are found to be less serious than the infection-related, care-related and other Adverse Effects.

Table 40. Degree of Seriousness of the Adverse Effects, by type of Adverse Effect

Type of Adverse Effect	Slight		Moderate		Serious		Total	
Medication-related	341	64.3%	159	30.0%	30	5.7%	530	47.8%
Worse course of evolution of the patient's baseline disease	107	48.4%	100	45.2%	14	6.3%	221	20.0%
Procedure-related		57.1%		39.0%		9.3%		10.6%

	61		46		11		118	
Infection-related	34	36.6%	50	53.8%	9	9.7%	93	8.4%
Others	39	52.7%	30	40.5%	5	6.8%	74	6.7%
Care-related	24	33.3%	36	50.0%	12	16.7%	72	6.5%
Total	606	54.7%	421	38.0%	81	7.3%		1,108

The distribution of the Adverse Effects by type and degree of seriousness is provided in Tables 41, 42, 43, 44 and 45.

Table 41. Medication-related Adverse Effects and degree of seriousness

Type of Adverse Effect	Slight		Moderate		Serious	
Medication-related	341	64.3%	159	30.0%	30	5.7%
Nausea, vomiting or diarrhea secondary to medication	81	81.8%	17	17.2%	1	1.0%
Pruritus, rash or skin lesions reactive to drugs or bandages	33	56.9%	25	43.1%	0	0.0%
Drug-induced neurological changes	38	67.9%	13	23.2%	5	8.9%
Other drug-related complications (cough, dypsnea, dry mouth)	30	71.4%	9	21.4%	3	7.1%
Drug-induced upset stomach or stomachache (epigastralgia)	24	64.9%	12	32.4%	1	2.7%
Systemic allergic reactions	11	35.5%	17	54.8%	3	9.7%
Poor glycemia control	18	66.7%	5	18.5%	4	14.8%
Drug-induced hypotension	20	74.1%	7	25.9%	0	0.0%
Local effects or fever following vaccination or drug admin.	20	76.9%	6	23.1%	0	0.0%
Poor blood pressure control	21	84.0%	4	16.0%	0	0,0%
Drug-induced headache	14	66.7%	6	28.6%	1	4.8%
Poor pain management	9	47.4%	8	42.1%	2	10.5%
Functional alteration (renal, liver, thyroid…)	7	41.2%	6	35.3%	4	23.5%
Upper digestive tract hemorrhage	1	10.0%	8	80.0%	1	10.0%
Anticoagulation-induced hemorrhage	1	12.5%	7	87.5%	0	0.0%
Edema, cardiac insufficiency and shock	4	50.0%	4	50.0%	0	0.0%
Drug-induced change in heart rate or electrical activity	5	71.4%	0	0.0%	2	28.6%
Electrolyte imbalance	2	40.0%	2	40.0%	1	20.0%
Constipation	2	50.0%	2	50.0%	0	0.0%
AMI, CVA, PTE, DVT	0	0.0%	1	33.3%	2	66.7%

Table 42. Worse course of evolution and other Adverse Effects and degree of seriousness

Type of Adverse Effect	Slight		Moderate		Serious	
Worse course of evolution of baseline disease	107	48.4%	100	45.2%	14	6.3%
Others	39	52.7%	30	40.5%	5	6.8%
Need of repeating the procedure or the visit	20	57.1%	15	42.9%	0	0.0%
Anxiety, stress or depression	15	60.0%	8	32.0%	2	8.0%
Another Adverse Effect	4	28.6%	7	50.0%	3	21.4%

Table 43. Procedure-related Adverse Effects and degree of seriousness

Type of Adverse Effect	Slight		Moderate		Serious	
Procedure-related	61	51.7%	46	39.0%	11	9.3%
Hemorrhage or hematoma related to surgical intervention	26	66.7%	12	30.8%	1	2.6%
Suture dehiscence	16	45.7%	14	40.0%	5	14.3%
Seromas, abscesses and granulomas	8	44.4%	9	50.0%	1	5.6%
Other complications due to a procedure	7	43.8%	6	37.5%	3	18.8%
Circulatory disorder (cast too tight)	4	80.0%	1	20.0%	0	0.0%
Perforated eardrum	0	0.0%	3	75.0%	1	25.0%
Catheterization-related hematuria	0	0.0%	1	100.0%	0	0.0%

Table 44. Infection-related Adverse Effects and degree of seriousness

Type of Adverse Effect	Slight		Moderate		Serious	
Infection-related	34	36.6%	50	53.8%	9	9.7%
Surgical and/or trauma wound infection	20	35.7%	30	53.6%	6	10.7%
Opportunistic infection due to immunosuppressive or antibiotic treatment	8	47.1%	9	52.9%	0	0.0%
PU-related infection	2	22.2%	6	66.7%	1	11.1%
Catheterization-related UTI	3	37.5%	4	50.0%	1	12.5%
Aspiration pneumonia	1	33.3%	1	33.3%	1	33.3%

Table 45. Care-related Adverse Effects and degree of seriousness

Type of Adverse Effect	Slight		Moderate		Serious	
Care-related	24	33.3%	36	50.0%	12	16.7%
PU	15	39.5%	16	42.1%	7	18.4%
Burns, scrapes, falls and contusions (including resulting fractures)	6	33.3%	9	50.0%	3	16.7%
Other consequences of the long-term immobilization	1	10.0%	7	70.0%	2	20.0%
Phlebitis	2	33.3%	4	66.7%	0	0.0%

In nearly one fourth of the cases studied (23.6%), the consequence of the Adverse Effect did not entail any major health care. Approximately one half were remedied in PC; in 33.1%, a higher level of observation and monitoring was required; in 7.5%, the Adverse Effect required an additional test; and in 17.1%, an additional medical or surgical treatment was performed on the part of PC. In approximately one third of the cases, a referral to Specialized Care was required (in 24.9%, the consequence of the Adverse Effect required an office visit to Specialized Care

without any hospitalization; and in 5.8%, it was necessary for the patient to be hospitalized for some life-support treatment (Table 46).

Table 46. Care dispensed as a result of the Adverse Effect

Care provided as a result of the Adverse Effect	Adverse Effect	%
The care was not affected	262	23.6%
Required a higher level of observation and monitoring in PC	367	33.1%
Required an additional test (X-ray, analysis, etc.) in PC	83	7.5%
Additional medical or surgical treatment in PC (antibiotics, minor surgery, etc.)	190	17.1%
Required a further office visit or referral to Specialized Care or Emergency Service without hospitalization	276	24.9%
Required hospitalization: Life-support treatment (orotrachael intubation, CPR, SI)	64	5.8%

To control the phenomena of confusion and interaction when analyzing the degree of seriousness of the Adverse Effect, a multivariate analysis was made using logistic regression (forward method for reasons of credibility). The causal factor and the type of Adverse Effect were found to be explicative of the degree of seriousness of the Adverse Effect. The model did not take in: the place where the Adverse Effect occurred, the professional category, the gender and the age of the patients. The model is summarized in Table 47.

Table 47. Logistic regression model explicative of the degree of seriousness of the Adverse Effect

Explicative variable	Odds Ratio	95% CI
Causal factor (Communication)[a]	1.5	1.0-2.2
Causal factor (Management)[a]	1.4 n.s.	0.8-2.5
Causal factor (Diagnosis)[a]	4.7	2.4-9.1
Causal factor (Care)[a]	1.5	1.0-2.3
Causal factor (Others)[a]	1.6 n.s.	0.9-2.6
Type (infection)[b]	2.5	1.5-4.1
Type (Care)[b]	2.7	1.5-4.9
Type (Procedure)[b]	1.2 n.s.	0.7-1.9
Type (Worse evolution)[b]	1.2 n.s.	0.8-1.8
Nature (Others)[b]	1.2 n.s.	0.7-2.1

n.s.: Non-significant
a Reference category: Medication-related
b Reference category: Medication-related

The regression is aimed at establishing a model in which the effect of each individual variable is added together to explain the dependent variable, and in the case in which there is an interaction, the effect will be multiplied.

Hence, in relation to the degree of seriousness of the diagnosis-related Adverse Effects, the risk is 4.7 times higher of being serious or moderate than those related to medication; for the care-related and communication-related Adverse Effects, the risk is 1.5 time higher of being serious our moderate than those related to medication. When the type of Adverse Effect is taken into consideration, the infection-related Adverse Effects entail a risk 2.5 times higher than the medication-related Adverse Effects, whilst the care-related ones entail a risk 2.7 times higher than the medication-related Adverse Effects.

7. Preventability

To explore the preventability of the Adverse Effects, the degree of their preventability was scored on a 1-6 scale (1=no evidence of being preventable; 6 = total evidence). A total of 6.7% (74) of the Adverse Effects were considered to be totally unpreventable; 23.1% (256) being preventable to a small degree, being those scored 2 or 3; and 70.2% (778) having been considered preventable, being those scored above 3 on this scale. The distribution of this characteristic is shown in Table 48.

Table 48. Adverse Effect Preventability

Adverse Effect Preventability	N	%
1. No evidence of preventability	74	6.7%
2. Minimal probability of preventability	68	6.1%
3. Slight probability of preventability	188	17.0%
4. Moderate probability of preventability	268	24.2%
5. High probability of preventability	333	30.1%
6. Full evidence of preventability	177	16.0%
Total	1,108	100.0%

Studying the relationship between the degree of preventability of the Adverse Effects and the professional who detected these Adverse Effects, a statistically significant association (p=0.006) has been found to exist, it being worthy of special mention that the 76.5% of the Adverse Effects detected by a Nurse were considered preventable, as compared to the 67.1% and 67.5% of the Adverse Effects detected respectively by Family Practitioners and Pediatricians (Table 49).

Table 49. Adverse Effect Preventability, by professional category

Preventability	Family Practitioner		Nurse		Pediatrician		Total	
Unpreventable	227	32.9%	86	23.5%	17	32.1%	330	29.8%
Preventable	462	67.1%	280	76.5%	36	67.9%	778	70.2%
Total	689		366		53		1,108	

The preventability of the Adverse Effect was related to its degree of seriousness, such that 65.3% of the slight Adverse Effects, 75.3% of the moderate Adverse Effects and 80.2% of the serious Adverse Effects were preventable; the more serious the Adverse Effect, the more preventable they are (Table 50). This difference is statistically significant (p-value<0.001).

Table 50. Adverse Effect Preventability, by degree of seriousness

Preventability	Slight		Moderate		Serious		Total	
Unpreventable	210	34.7%	104	24.7%	16	19.8%	330	29.8%
Preventable	396	65.3%	317	75.3%	65	80.2%	778	70.2%
Total	606		421		81		1,108	

Taking all of the Adverse Effects combined, 79.2% of the procedure-related Adverse Effects, 76.7% of the infection-related Adverse Effects, 77.1% of the care-related Adverse Effects, 58.2% of the medication-related Adverse Effects and 74.6% of the Adverse Effects related to other causes were considered to be unpreventable. The difference among them as regards the degree of preventability was statistically significant (p-value<0.001).
By studying the preventability pattern by professional category, some statistically significant differences are found. Generally speaking, Adverse Events of any type are more preventable in nursing, the procedure-related and medication-related Adverse Effects being the most outstanding (Table 51).

Table 51. Preventability Percentage by Type of Adverse Effect and Professional Category

Type of Adverse Effect	Family Practitioner	Nurse	Pediatrician	Total
Procedure-related	75.0	82.2	100.0	79.7
Infection-related	74.3	82.5	100.0	79.6
Care-related	70.6	73.6	50.0	72.2
Medication-related	58.0	64.2	53.8	59.1
Worse course of evolution of baseline disease	81.4	86.0	88.2	82.8
Others	83.8	87.1	66.7	83.8
Total	67.1	76.5	67.9	70.2
p-value	<0.001	0.007	0.234	<0.001

Tables 52 and 57 show the preventability for each one of the types of Adverse Effects and the preventability of the moderate and serious Adverse Effects combined. In general, the slight Adverse Effects are less preventable, except in the cases of PU-related infection, phlebitis, drug-induced stomach upset or stomachache, poor control of glycemia, drug-induced hypotension, upper digestive tract hemorrhage and anticoagulation-induced hemorrhage.

Table 52. Medication-related Adverse Effect Preventability

Types of Adverse Effects	n	Preventability	Preventability of moderate and serious Adverse Effects
Medication-related	530	59.1%	66.1%
Nausea, vomiting or diarrhea secondary to medication	99	53.5%	61.1%
Pruritus, rash or skin lesions reactive to drugs or bandages	58	51.7%	56.0%
Drug-induced neurological changes	56	67.9%	77,8%
Other drug-related complications (cough, dypsnea, dry mouth)	42	45.2%	50.0%
Drug-induced upset stomach or stomachache (epigastralgia)	37	62.2%	61.5%
Systemic allergic reactions	31	51.6%	60.0%
Poor glycemia control	27	55.6%	44.4%
Drug-induced hypotension	27	77.8%	71.4%
Local effects or fever following vaccination or drug admin.	26	26.9%	50.0%

Poor control of blood pressure	25	80.0%	100.0%
Drug-induced headache	21	38.1%	57.1%
Poor pain management	19	78.9%	80.0%
Functional alteration (renal, liver, thyroid…)	17	76.5%	80.0%
Upper digestive tract hemorrhage	10	70.0%	66.7%
Anticoagulation-induced hemorrhage	8	75.0%	71.4%
Edema, cardiac insufficiency and shock	8	62.5%	100.0%
Drug-induced change in heart rate or electrical activity	7	85.7%	100.0%
Electrolyte imbalance	5	100.0%	100.0%
Constipation	4	100.0%	100.0%
AMI, CVA, PTE, DVT	3	66.7%	66.7%

Table 53. Adverse Effect Preventability

Types of Adverse Effects	n	Preventability	Preventability of moderate and serious Adverse Effects
Medication-related	530	59.1%	66.1%
Worse evolution of baseline disease	221	82.8%	82.5%
Procedure-related	118	79.7%	80.7%
Care-related infection-related	93	79.6%	83.1%
Others	74	83.8%	88.6%
Care-related	72	72.2%	77.1%
Total	1,108	70.2%	76.1%

Table 54. Preventability of the Adverse Effects related to a worse course of evolution of baseline disease and others

Types of Adverse Effects	n	Preventability	Preventability of moderate and serious Adverse Effects
Worse evolution of baseline disease	221	82.8%	82.5%
Others	74	83.8%	88.6%
Need of repeating the procedure or the visit	35	91.4%	100.0%
Anxiety, stress or depression	25	92.0%	100.0%
Other Adverse Effects	14	50.0%	60.0%

Table 55. Preventability Procedure-Related Adverse Effects			
Types of Adverse Effects	**n**	**Preventability**	**Preventability of moderate and serious Adverse Effects**
Procedure-related	118	79.7%	80.7%
Hemorrhage or hematoma related to surgical intervention	39	69.2%	69.2%
Suture dehiscence	35	91.4%	94.7%
Seromas, abscesses and granulomas	18	77.8%	80.0%
Other procedure-related complications	16	93.8%	100.0%
Circulatory disorder (cast too tight)	5	100.0%	100.0%
Perforated eardrum	4	25.0%	25.0%
Catheterization-related hematuria	1	0.0%	0.0%

Table 56. Preventability Care-Related Infection-Related Adverse Effects			
Types of Adverse Effects	**n**	**Preventability**	**Preventability of moderate and serious Adverse Effects**
Infection-related	93	79.6%	83.1%
Surgical and/or trauma wound infection	56	89.3%	91.7%
Opportunistic infection due to immunosuppressive or antibiotic treatment	17	64.7%	66.7%
PU-related infection	9	77.8%	71.4%
Catheterization-related UTI	8	50.0%	60.0%
Aspiration pneumonia	3	66.7%	100.0%

Table 57. Care-Related Infection-Related Adverse Effects			
Types of Adverse Effects	**n**	**Preventability**	**Preventability of moderate and serious Adverse Effects**
Care-related	72	72.2%	77.1%
PU	38	68.4%	73.9%
Burns, scrapes, falls and contusions (including resulting fractures)	18	77.8%	83.3%
Other consequences of long-term immobilization	10	70.0%	77.8%
Phlebitis	6	83.3%	75.0%

In order to control the confusion and interaction phenomena on analyzing the preventability, a multivariate analysis was made by logistic regression (forward method for reasons of credibility). The causal factor, the degree of seriousness of the Adverse Effect and the origin where the Adverse Effect occurred were found to be explicative of the degree of preventability of the Adverse Effects. The model did not take in the type of the Adverse Effect, the professional category, the gender or the age of the patients. A summary of the model is provided in Table 58.

Table 58. Logistic regression model explicative of the degree of seriousness of the Adverse Effect

Explicative variable	Odds Ratio	95% CI
Causal factor (Communication)[a]	3.2	2.1-4.9
Causal factor (Management)[a]	5.7	2.7-11.9
Causal factor (Diagnosis)[a]	6.3	2.6-15.2
Causal factor (Care)[a]	3.1	2.1-4.7
Causal factor (Others)[a]	1.4 n.s.	0.8-2.0
Seriousness (moderate+serious)[b]	1.4	1.0-1.8
Origin of the Adverse Effect (Specialized Care)[c]	1.9	1.3-2.9
Origin of the Adverse Effect (Hospital Emergency Room)[c]	4.3 n.s.	0.9-18.9
Origin of the Adverse Effect (Pharmacy)[c]	2.8 n.s.	0.3-24.0

n.s.: Non-significant
a Reference category: Medication-related
b Reference category: Medication-related
c Reference category: PC Healthcare Center

Thus, the diagnosis-related Adverse Effects are 6.3 times more preventable than the medication-related Adverse Effects; the management-related Adverse Effects being 5.7 times more preventable; whilst the communication-related and the care-related Adverse Effects are respectively 3.2 and 3.1 times more preventable than the medication-related Adverse Effects. If the origin of the Adverse Effects is taken into consideration, the Adverse Effects having originated in Specialized Care are 1.9 times more preventable than those having originated at a health care center. Lastly, the serious or moderate Adverse Effects are 1.4 times more preventable than the slight Adverse Effects.

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Table 59. Causal Factors of a Worse Evolution of the Patient's Baseline Disease

Causal Factors	n	%
Physician-patient communication	56	25.3%
Delay in diagnosis	53	24.0%
Long waiting list	32	14.5%
Improper handling of the patient	28	12.7%
Error in diagnosis	24	10.9%
Failure to adhere to the treatment	22	10.0%
Physician-physician communication	22	10.0%
Delay in referral to specialized care	19	8.6%
Missed dose, medication or vaccine	17	7.7%
Nurse-patient communication	17	7.7%
Improper handling of warning signs	14	6.3%
Other causes	14	6.3%
Scheduling error	13	5.9%
Incorrect administration frequency	12	5.4%
Language barrier	11	5.0%

Cultural barrier	10	4.5%
Incorrect dosage	9	4.1%
Other communication factor	9	4.1%
Problems with computerized record	9	4.1%
Wrong medication	8	3.6%
Wrong patient	8	3.6%
Insufficient monitoring	6	2.7%
Incorrect treatment duration	6	2.7%
ADR	5	2.3%
Improper handling of the technique	5	2.3%
Error in preparation or manipulation	2	0.9%
Error in health information	2	0.9%
Drug interaction	1	0.5%
Physician-nurse communication	1	0.5%
Error in patient identification	1	0.5%

The percentage shown is the Table is related to the number of Adverse Effects entailing the causal factor in question, on this being a multiple-choice question. For the Adverse Effect consisting of nausea, vomiting or diarrhea secondary to medication, the ADR is the most frequent causal factor (62.6% of the cases). Special mention must also be made of the physician-patient communication as an important causal factor (11.1%) (Table 60).

Table 60. Causal Factors of Nausea, Vomiting or Diarrhea Secondary to Medication

Causal Factors	**n**	**%**
ADR	62	62.6%
Physician-patient communication	11	11.1%
Other causes	8	8.1%
Incorrect dosage	7	7.1%
Incorrect administration frequency	7	7.1%
Drug interaction	5	5.1%
Improper handling of the patient	5	5.1%
Incorrect treatment duration	4	4.0%
Another communication factor	4	4.0%
Error in diagnosis	4	4.0%
Missed dose, medication or vaccine	3	3.0%
Wrong medication	2	2.0%
Failure to adhere to the treatment	2	2.0%
Language barrier	2	2.0%
Error in preparation or manipulation	1	1.0%
Insufficient monitoring	1	1.0%
Wrong patient	1	1.0%
Nurse-patient communication	1	1.0%
Cultural barrier	1	1.0%
Improper handling of warning signs	1	1.0%

For the pruritus, rash or skin lesions reactive to drugs, an ADR was one of the causal factors of the Adverse Effect in 53.4% of the cases, other causes totaling 19.0% (Table 61).

Table 61. Causal Factors of Pruritus, Rash or Skin Lesions Reactive to Drugs or Bandages

Causal Factors	**n**	**%**
ADR	31	53.4%
Other Causes	11	19.0%
Wrong medication	6	10.3%
Incorrect dosage	4	6.9%
Physician-patient communication	4	6.9%
Nurse-patient communication	4	6.9%
Incorrect treatment duration	3	5.2%
Other communication factor	3	5.2%
Improper handling of warning signs	3	5.2%
Drug interaction	2	3.4%
Cultural barrier	2	3.4%
Improper handling of the patient	2	3.4%
Improper handling of the technique	2	3.4%
Incorrect administration frequency	1	1.7%
Failure to adhere to the treatment	1	1.7%
Language barrier	1	1.7%
Long waiting list	1	1.7%
Problems with the computerized record	1	1.7%
Delay in the diagnosis	1	1.7%

A total of 60.7% of the drug-induced neurological changes were caused by an ADR; 16.1% having been caused by a drug interaction. Special mention must also be made of the physician-patient communication having been a determining factor in 14.3% of the cases (Table 62).

Table 62. Causal Factors of Drug-Induced Neurological Changes		
Causal Factors	**n**	**%**
ADR	34	60.7%
Drug interaction	9	16.1%
Physician-patient communication	8	14.3%
Other causes	7	12.5%
Incorrect dosage	5	8.9%
Wrong medication	4	7.1%
Missed dose, medication or vaccine	2	3.6%
Insufficient monitoring	2	3.6%
Improper handling of the patient	2	3.6%
Incorrect administration frequency	1	1.8%
Error in preparation or manipulation	1	1.8%
Failure to adhere to the treatment	1	1.8%
Physician-nurse communication	1	1.8%
Physician-physician communication	1	1.8%
Language barrier	1	1.8%
Other communication factor	1	1.8%
Long waiting list	1	1.8%
Error in diagnosis	1	1.8%
Improper handling of the technique	1	1.8%

The surgical and/or trauma wound infections having occurred in patients were due to great part (30.4%) to an improper handling of the warning signs; in 25.0%, to an improper handling of the patient; in 23.2%, to other causes; and in 21.4%, to an improper handling of the technique (Table 63).

Table 63. Causal Factors of Surgical and/or Trauma Wound Infection		
Causal Factors	**n**	**%**
Improper handling of warning signs	17	30.4%
Improper handling of the patient	14	25.0%
Other causes	13	23.2%
Improper handling of the technique	12	21.4%
Delay in the diagnosis	6	10.7%
Physician-patient communication	3	5.4%
Nurse-patient communication	3	5.4%
Long waiting list	3	5.4%
Missed dose, medication or vaccine	2	3.6%
Insufficient monitoring	2	3.6%
Incorrect treatment duration	2	3.6%
Failure to adhere to the treatment	2	3.6%
Incorrect administration frequency	1	1.8%
Error in preparation or manipulation	1	1.8%
Wrong patient	1	1.8%
Other communication factor	1	1.8%
Delay in referral to specialized care	1	1.8%

The impact of the most frequent Adverse Effects was temporary harm (94.3%) (Table 64).

Table 64. Impact on the Patient of the Most Frequent Adverse Effects

Impact on the Patient	(1)		(2)		(3)		(4)		(5)		Total
The incident has occurred and has affected the patient, but the patient has come to no harm	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	0.9%	2	0.4%
The effect has occurred and the patient has been temporarily harmed	98	99.0%	58	100.0%	51	91.1%	50	89.3%	205	92.8%	462	94.3%
The effect has occurred and the patient has been in a critical situation.	0	0.0%	0	0.0%	1	1.8%	0	0.0%	0	0.0%	1	0.2%
The effect has occurred and the patient has suffered permanent injury	1	1.0%	0	0.0%	4	7.1%	5	8.9%	12	5.4%	22	4.5%
The effect has occurred and has resulted in the patient's death	0	0.0%	0	0.0%	0	0.0%	1	1.8%	2	0.9%	3	0.6%
Total	99	20.2%	58	11.8%	56	11.4%	56	11.4%	221	45.1%	490	100.0%

(1) Nausea, vomiting or diarrhea secondary to medication
(2) Pruritus, rash or skin lesions reactive to drugs or bandages
(3) Drug-induced neurological changes
(4) Surgical and/or trauma would infection
(5) Worse course of evolution of baseline disease

The care needed as a result of the most frequent Adverse Effects is summarized in Table 65.

Table 65. Care Dispensed to Patient as a Result of the Most Frequent Adverse Effects

Impact on the Patient	(1)		(2)		(3)		(4)		(5)		Total
The care was not affected.	45	45.5%	21	36.2%	19	33.9%	4	7.1%	33	14.9%	122	24.9%
Required a higher level of observation or monitoring in PC	35	35.4%	12	20.7%	21	37.5%	19	33.9%	78	35.3%	165	33.7%
Required an additional test (X-ray, analysis, …) in PC	2	2.0%	2	3.4%	2	3.6%	2	3.6%	23	10.4%	31	6.3%
Additional medical or surgical treatment (antibiotics, minor surgery) in PC	8	8.1%	16	27.6%	2	3.6%	17	30.4%	29	13.1%	72	14.7%
Required a further office visit or referral to Specialized Care or Emergency Room without hospitalization	9	9.1%	9	15.5%	14	25.0%	15	26.8%	88	39.8%	135	127.6%
Required hospitalization: Life-support treatment (orotrachael intubation, CPR, surgical intervention)	1	1.0%	1	1.7%	1	1.8%	5	8.9%	8	3.6%	16	3.3%
Total	99	20.2%	58	11.8%	56	11.4%	56	11.4%	221	45.1%	490	100.0%

(1) Nausea, vomiting or diarrhea secondary to medication
(2) Pruritus, rash or skin lesions reactive to drugs or bandages
(3) Drug-induced neurological changes
(4) Surgical and/or trauma would infection
(5) Worse course of evolution of baseline disease

9. Most Serious Adverse Effects

The most serious Adverse Effects are taken as being those causing death, residual disability at medical release or which require surgical intervention. On reviewing the types of serious Adverse Effects, special mention must be made of the fact that one third of the most serious Adverse Effects are medication-related (Figure 5).

Fig. 5 Distribution of the Most Serious Adverse Effects

Table 66 Adverse Effect Codes

1	Worse course of evolution of the baseline disease	15	Poor pain management
2	PU	16	Other consequences of long-term immobilization
3	Surgical and/or trauma wound infection	17	Anxiety, stress or depression
4	Drug-induced neurological alterations	18	Nausea, vomiting or diarrhea secondary to medication
5	Suture dehiscence	19	Drug-induced headache
6	Drug-induced hypotension	20	Upper digestive tract hemorrhage
7	Functional alteration (renal, liver, thyroid …)	21	Electrolyte imbalance
8	Burns, scrapes, falls and contusions (including resulting fractures)	22	Catheterization-related UTI
9	Other Adverse Effect	23	PU-related infection
10	Systemic allergic reactions	24	Aspiration pneumonia
11	Other procedure-related complications	25	Hemorrhage or hematoma related to surgical intervention
12	Other drug-related complications (cough, dypsnea, dry mouth)	26	Seromas, abscesses and granulomas
13	AMI, CVA, PET, DVT	27	Perforated eardrum
14	Drug-induced change in heart rate or electrical activity	28	Drug-induced upset stomach or stomachache (epigastralgia)

Figure 6. Pareto of the Most Serious Adverse Effects

When compared by the professionals who detected the Adverse Effects, special mention may be made of the fact that the most serious Adverse Effects most frequently identified by the physicians were medication-related Adverse Effects and those having causes a worse evolution of the patient's disease; whilst those most frequently identified by the nurses were the care-related and medication-related Adverse Effects (Table 67).

Table 67. Percentage of Serious Adverse Effects, by professional category

Type of Adverse Effect	**Physician**		**Nurse**	
Procedure-related	4	9.5%	7	17.9%
Infection-related	2	4.8%	7	17.9%
Care-related	2	4.8%	10	25.6%
Medication-related	20	47.6%	10	25.6%
Worse course of evolution of the baseline disease	11	26.2%	3	7.7%
Others	3	7.1%	2	5.1%
Total	42	51.9%	39	48.1%

Discussion

Patient Safety entails different aspects ranging from preventing harm to improving safety. Primary prevention deals with taking action on the system organization to make clinical practice safer. Secondary prevention deals with early diagnosis of the harm so as to minimize its effect. Tertiary prevention is aimed at repairing the damage caused such as to make it possible to minimize its impact, and quaternary prevention is aimed at identifying the safest practices most acceptable by the patients in order to prevent the overuse of diagnostic tests, unnecessary treatments and dysthanasia, as well as the associated harm.

Implementing safe practices could be understood as the safeguarding of health and the cultural changes affording the possibility of moving from a reactive to a proactive culture [52]. These two aspects comprise the core of promoting safety.

At the point of origin of the harm (adverse effects), human error and the system failure have been identified[53]. It being well-understood that error per se does not mean harm in itself, sometimes entailing potential harm which the patient never experiences and so one must not equate medical error with adverse effect of the care provided. One may be the cause and the other the result. In medical practice, errors may occur due to unnecessary actions, due to the improperly performing necessary maneuvers or due to the omission of beneficial actions. That is to say, due to overuse, misuse or underuse. In other words, due to errors of commission or omission[54, 55, 56, 57]. Similarly, system failures do not always mean harm for patients.

The APEAS Study falls within the framework of secondary and tertiary prevention on being aimed at identifying the harm and its consequences, but it is also a major sources for developing preventive strategies on identifying the characteristics of the subjects (intrinsic risk factors) as well as of the care (contributing factors) and is therefore a support for primary prevention on investigating the causal model.

The studies on Patient Safety in Primary Care conducted to date have gone in two complementary directions, both entailing lines of research basically sharing one same methodology, which is the use of the questionnaire. Apart from this, the interest has been focused on approaching the type of error in order to move forward in the taxonomy. Hence, most of the classifications proposed for Primary Care are causal[23, 24, 25] and not Adverse Effect classifications as such. The second line has been aimed at approaching the frequency by asking the professionals. Perhaps this may be why the frequency found varies within a 2%-76‰ range.

Within this line of research, it has also been pointed out that 39.3% of the errors might entail harm for the patient[59]. However, we have not identified any epidemiological study which explores the frequency of Adverse Effects.

The results of this study lack a framework of reference. The study's objective of identifying the incident and the adverse effect from the epidemiological standpoint has not been dealt with previously in Primary Care. However, the frequency found is plausible with the care model. In all certainty, the orchestrating is conditioned by the frequency being comparatively lower than that found in similar studies in the hospital environment and, also by the percentage of slight Adverse Effects being higher[1].

The characteristics of the subjects under study, who were patients who see physicians at a Healthcare Center, and the absence of age-based exclusion criteria, lead to visits due to illness being included, but also health promotion visits and healthy child visits, and therefore, on there being a lesser exposure to the risk, the Adverse Effect frequency necessarily has to be lower than other more interventionist scenarios.

Nevertheless, the frequency of use of the Primary Care services, as will be noted in Table 68, is so high as to mean that every citizen comes in to the Healthcare Center for a visit to see a Primary Care Physician or Pediatrician on the average of over 7 times a year.

Table 68. Primary Care Activity in the National Health System		
	1994	**2003**
Visits to see a Family Practitioner or Pediatrician (millions)	212.8	309.6
% Family Practitioner visits	89.3%	86.8%
% Pediatrician visits	10.7	13.2
Visits / inhabitant / year	5.4	7.5
Source: Ministry of Health & Consumer Affairs. Regional Health Services and National Health Survey		

Thus, a relatively low frequency of care-related Adverse Effects results in entailing quite a considerable absolute frequency. Hence, one of every 7 citizens in Spain would eventually have a problem of the type with which we are dealing herein. Then, the Adverse Events related to Primary Care are a true Public Health problem, especially if we take into consideration that 70% of the Adverse Effects identified in this study are of a preventable type, that that the more serious the Adverse Event, the greater the degree to which it is preventable.

A total of 25.8% of the Adverse Effects detected in Primary Care had to do with a transfer of the Adverse Effect on the part of specialized care (office visits and hospitalization) and, as such, cannot be attributed directly to the first level of care. This item was discussed in the ENEAS Study on Adverse Effects associated with hospitalization[1].

One must not overlook the fact that, aside from the study design-related problems possibly having underestimated the frequency observed, on clinical surveillance diagnosing the adverse events, one can be led to believe that solely the tip of the iceberg is as yet being seen as regards the problems of patient safety in health care[60].

The epidemiological pattern of the risk factors identified in our study is a carbon copy of the epidemiological pattern of Spain's population[61, 62]. Apart from this, the risk factors of the subjects in our study revealed the disease load in Primary Care to be considerable, and if different studies are taken into account which have established a relationship between comorbidity and Adverse Effects[63, 64], the results of our study uphold to some extent the safeguarding role of Primary Care in a National Health System model.

The Adverse Effect frequency identified by professionals is consistent with the characteristics of clinical practice and the population for which care is dispenses, such that, as was to be anticipated, the Pediatricians identify half the number of Adverse Effects as the Family Practitioners and the Qualified Nurses.

The multi-causality which has been considered in the origin of the Adverse Effects is confirmed in this study, in which an average of 2.3 causal factors were involved in each Adverse Effect. In addition thereto, the pattern of causal factors of Adverse Effects identified is well in keeping with clinical practice in Primary Care and with the professionals' dedication.

The causal factors identified in this study are along the line of the taxonomy for the study of the Adverse Effects in Primary Care proposed in other studies[23, 45, 58].

Among the causal factors of the medication-related Adverse Effects, a total of 50.2% ADRs and 33.2% medication errors have been identified, this justifying the need of suiting the taxonomy and affording the possibility of distinguishing more exactly between ADR and medication errors.

The most frequent communication problems lie in the communication between the health care professional and the patient. This should be changing in view of the new health care paradigm, in which the access to information on the part of the patients and their active involvement in the decision-making process play a prime role. It is necessary to create a climate of confidence and establish an effective dialogue between both sides. This key aspect is currently the target of some improvement programs, and their implementation will be facilitating the health care professionals' work.

As regards care management, there are some aspects where there is room for improvement, independently of the frequentation of the centers. Errors in identifying patients or in appointment scheduling should be reduced to the unavoidable minimum in accordance with a progressively more highly computerized care model.

Within the diagnosis-related problems, some serious thought must be given to the impact the delay in diagnosis or in their referral to Specialized Care may have on patients.

The types of Adverse Effects found were those anticipated: the result of the use of drugs, a worse evolution of the course of the baseline disease, the result of certain procedures, infection and result of the care provided.

The pattern of the types of Adverse Effects is typical of the level of care. Table 69 shows the differences on comparing the type of the Adverse Effect between the study conducted in PC and another on the prevalence of Adverse Effects in Hospitalization (EPIDEA: study of prevalence of Adverse Effects at 22 hospitals in the Autonomous Community of Valencia).

Table 69. Types of Adverse Events prevalent in PC and in Hospitalization

	PC	Hospital
Types of Adverse Effects	**%**	**%**
Medication-related	47.8%	16.3%
Worse course of evolution of baseline disease	19.9%	3.9%
Procedure-related	10.6%	30.1%
Infection-related	8.4%	45.1%
Others	6.7%	1.3%
Care-related	6.5%	3.3%

Given the outstanding role played by drugs in both the origin as well as the consequence of the Adverse Effects, standardizing the presentation of the information on the medication from the industry to the professionals and from the professionals to the patients such that their safe use in taken into account is a pressing need. And perhaps the need of distinguishing more accurately between an Adverse Medication Reaction and a Medication Error is in great need of a clarifying effort. The need of appropriately prescribing medication seems clear, taking into account the interactions and making certain that the patient has understood the dosage and directions for use and the possible ADRs.

The procedures and care need to be continuously updated such that they will incorporate the safest techniques that scientific advancement progressively makes available. It must also be taken into account that 45.7% of the procedure-related Adverse Effects, 37% of the care-related infections, 35% of the Adverse Effects which caused a worse course of the baseline disease and 27% of the care-related Adverse Effects had their origins in specialized care. This upholds the idea that many of the Adverse Effects identified in PC which have to do with handling the patient are due to a transfer from another level of care.

In this regard, there being an 8.4% of infection-related Adverse Effects stands to support the change in nomenclature from nosocomial infection to care-related infection, because these infections are not inherent only to the hospital environment alone. At the same time, we find there to be room for some major improvements. For example. The high incidence rate of urinary tract infections in patients with catheters would make it advisable to disseminate the most clinically safe measures for catheter insertion and care.

Drafting strategies to prevent Adverse Effects in Primary Care is highly effective, on it being possible to prevent 70% of the Adverse Effects in general and 80% of the serious Adverse Effects in particular. In order to carry out this task, it is necessary for the professionals to adopt a clear, unified taxonomy regarding Adverse Effects and the factors contributing to the same, and that the organization to which they belong promote a culture of confidence and

confidentiality which will allow all of the initiatives set out to be able to be carried out calmly. Additionally, a spirit of collaboration among the organizations is indispensable in order to be able to share and learn from these initiatives[64].

The model explaining preventability is congruent with the fact that the Adverse Effects which were not medication-related were more preventable, given that, by definition, ADRs are preventable to a minor degree or are unpreventable, and totaled 50.2% of the contributing factors among the medication-related Adverse Effects.

Primary Health Care is highly effective also in caring for the needs resulting from Adverse Effects. The intervention of Specialized Care was required solely in one third of the cases. Putting Adverse Effect surveillance and control and/or reporting and record-keeping systems into effect would make it possible not only to solve the problem which had previously been caused, but also to learn by sharing the Adverse Effect-related knowledge gained with other colleagues and thus prevent their reoccurrence.

Improving communicating skills shows itself to be a safe and sure approach, if one bears in mind that one out of every four cases in which a worse course of evolution of the baseline disease was caused entails problems in communicating with the patient among their causal factors, which is also present to an outstanding extent when the adverse effect was medication-related.

Perhaps the first yet least important of the limitations of this study may be the representativity-related aspect resulting form its design, on being a non-probabilistic sampling. However, on being so numerically large-scale, representative of the entire country and entailing subjects whose epidemiological pattern is a carbon copy of that of Spain's population, it allows us to be more lenient with regard to considering this study to be valid elsewhere outside of Spain.

An epidemiological study based on voluntary completion can generate a non-response bias. Different reasons may be found in published works explaining a low register, such as, for example not recognizing the Adverse Effects[65, 66], confusion regarding the different working definitions[67, 68], concerns regarding the information in the reporting remaining anonymous and confidential[71], not availing of enough time during working hours[72], and distrust regarding the possible effect the reporting might have[73].

The description of the Adverse Effect was to be provided during the professional's working hours, this being something which could have also led to an underestimation of the prevalence or the data being recorded in less detail, taking into account the length of time allowed for an office visit in Primary Care.

Evaluating causality is a value judgment. Additionally, most times, the participating professional per se is the one responsible for the Adverse Effect having occurred, as a result of which, this combination of facts may also have led to an underestimation of the prevalence. The value judgment concerning the degree of preventability also entails this same problem. One interesting aspect is that the preventability of the Adverse Effects having occurred in PC was 65.3%, whilst the preventability judgment of those which occurred in specialized care was 83.9%. This difference is inherent to the fact of asking a primary care professional to judge the preventability of an Adverse Effect which has occurred at other levels of care, without specific knowledge of the specialty and without having access to the clinical record from outpatient office visits or from the hospitalization episode. Additionally, on comparing the preventability judgment for each type of Adverse Effect, there are glaring differences between the Adverse Effects having originated in specialized care judged by the primary care professionals (83.9%) and that judged by the hospital professionals per se (55.4%) (EPIDEA Study).

Findings

The results provided in this report reveal the care dispensed in Primary Care to be safe. The frequency of Adverse Effects is low, in addition to slight Adverse Effects being predominant.

Despite this, patient safety is important in Primary Care if one takes into account that Adverse Effects may affect 7 out of every 100 citizens in any given year, and that 70% of the Adverse Effects are preventable.

The etiology of the Adverse Effects is multicausal. Their origins lie in drug use-related, communication-related, management-related and care-related factors.

The Adverse Effects (in other words, the effect of the effect") are: a result of the use of drugs, entail a worse course of evolution of the baseline disease, are a result of certain procedures, infection and care.

The ability to dealing with Adverse Effects at the primary care level is outstanding. One fourth of the Adverse Effects required no further care, another fourth having had to be referred to specialized care and half having being remedied directly in Primary Care.

The difficulty entailed in making the value judgments inherent to this type of design requires clearly determining the origin of the Adverse Effect, as well as a borderline in their study for the different levels of care.

The Study's Value

1. Contributions to Knowledge:

The APEAS Study further enhances the knowledge of the Adverse Effects related to the health care provided by focusing, in the study, on the Adverse Effects at the first level of care.

This study is a remarkable point of reference, on being the first epidemiological study with such a large-scale sample of patients (96,047 office visits).

It is a status report for our country and opens up a line of research which will be having some major benefits for patients.

The multi-causality entailed in the origins of Adverse Effects therefore requires a multi-factorial approach in order to effectively improve Patient Safety.

This study reveals the safeguarding role of the personnel with whom patients first come into contact for health care and highlights what aspects must be emphasized in order to reduce the Adverse Effects in PC.

2. Contributions to Clinical Practice:

Given the outstanding role medications play both in the origins as well as the consequences of Adverse Effects, it seems necessary to set out recommendations on the further enhancement of the training of the professionals in the proper handling of medications, to standardize the presentation of the information on the medications from the industry to the professionals and from the professionals to the patients so as to provide for their safe use. Improving communicating/informing patients in order to better their adherence seems to be a pressing need for improving the safety of the health care provided.

The procedures and care need to be continuously updated so that they will incorporate the safest techniques that scientific advancement progressively makes available.

Drafting strategies to prevent Adverse Effects in Primary Care is highly effective, on 70% of all Adverse Effects in general and 80% of the serious Adverse Effects in particular being preventable. At the very least, ascertaining the magnitude and far-reaching importance of Adverse Effects should be the first step toward developing preventive strategies and thus setting out on the cultural change for achieving safer care.

Summation

The frequency of Adverse Effects in PC will at least equal that found in this study and may be anticipated to increase over the next few years. Nevertheless, the organization's interest and the professionals' motivation should be conducive to mitigating their impact.

Professionals having collaborated in this project (APEAS Group)

Executive Committee

Jesús María Aranaz Andrés
Carlos Aibar Remón
Julián Vitaller Burillo
José Joaquín Mira Solves
Domingo Orozco Beltrán
Enrique Terol García
Yolanda Agra Varela

Ministry of Health and Consumer Affairs Monitoring Group

María del Mar Fernández Maíllo	Quality Agency Administration
Eduardo Sierra Pérez	Quality Agency Administration
Jesús Casal Gómez	Quality Agency Administration
María José García Díaz	Quality Agency Administration
Pilar del Peso Hernández	Quality Agency Administration

AUTONOMOUS COMMUNITY REFERENCE POINTS

Autonomous Community	Name
Andalusia	Elvira Fernández de la Mota Pilar Vázquez Garijo
Aragón	Carlos Aibar Remón
Asturias	Joaquín Moris de la Tassa
Basque Country	Marbella García Urbaneja
Canary Islands	Paloma García de Carlos
Cantabria	Trinidad Dierssen Sotos
Castile-La Mancha	Félix Alcázar Casanova Juan Fernández Martín
Castile and Leon	José Miguel García Vela
Catalunya	Lluis Torralba i Novella
Community of Valencia	Ricard Meneu de Guillerna
Extremadura	Juan María Benegas Capote
Galicia	Ana María Clavería Fontán
Madrid	Alberto Pardo Hernández
Murcia	Susan Valbuena Moya
Navarra	Francisco Javier Gost Garde
Rioja	Mercedes Carreras Viñas Eva Martínez Ochoa

HEALTHCARE CENTER COODINATORS

Autonomous Community	Healthcare Center	Name
Andalusia	Abla (Almeria)	Ma Soledad Alonso Humada
Andalusia	Torre del Mar	(Malaga) Maria Botella Romero
Andalusia	Plaza de Toros (Almeria)	Jose Sebastian Perez Martinez
Andalusia	Candelaria (Seville)	Carmen Garcia Vazquez
Andalusia	Gran Capitan (Granada)	Francisco Jose Ferrer Luque
Aragon	Delicias Sur (Zaragoza)	Francisca Gonzalez Rubio
Aragon	Actur Sur (Zaragoza)	Javier Valdeperez Torrubia
Aragon	Torrero (Zaragoza)	Jose Angel Martinez Milian
Aragon	San Pablo (Zaragoza)	Maria Jose Lahoz Mustienes
Asturias	Otero (Oviedo)	Jesus Gonzalez-Nuevo Quinones
Basque County	Rekalde Berri (Bilbao)	Ana Gorronogoitia Iturbe
Basque Country	San Martin (Vitoria)	Ana Fernandez Buergo
Basque Country	Ondarreta (San Sebastian)	Fernando Palacio Lapuente
Basque Country	Parte Vieja (San Sebastian)	Ma Aranzazu Mendiguren Navascues
Canary Islands	La Victoria (Santa Cruz Tenerife)	Ma del Cristo Rivero Martin
Cantabria	Dobra (Torrelavega)	Elena Basabe Blanco
Cantabria	Castilla Hermida (Cantabria)	Carmen Gaisan Tome
Cantabria	Zapaton (Cantabria)	Pilar de la Puebla Cagigas
Castile and Leon	Comuneros (Burgos)	Juan Carlos Verdes-Montenegro
Castile and Leon	Baltanas (Palencia)	Pedro Azaola Rodriguez-Espina
Castile and Leon	Alamedilla (Salamanca)	Pilar Moreno Gonzalez
Castile and Leon	Casa del Barco (Valladolid)	Miguel Angel Diez Garcia
Castile-La Mancha	Puertollano II (Ciudad Real)	Rosa Munoz Camacho
Castile-La Mancha	La Estacion (Talavera)	Jesus Melendez Sanchez
Catalunya	La Mina (Barcelona)	Silvia Calvet Junoy
Catalunya	Area Basica (Vic)	Albert Ledesma Castelltort
C. Valencia	Sant Joan d´Alacant	Carmen Pardo Tomas
C. Valencia	Cabo Huertas (Alicante)	Mavi Hernandis Santamaria
C. Valencia	Mutxamel (Alicante)	Vicente Rodriguez Sempere
C. Valencia	Stma. FAZ-Ayto. (Alicante)	Alejandro Canals Baeza
C. Valencia	Hospital Provincial (Alicante)	Rosario Garcia Santa Fe
C. Valencia	Gerona (Alicante)	Ignacio Antonio Verdu Jorda
C. Valencia	Xixona (Alicante)	Victoriano Borreguero Guerra
Extremadura	Plaza de Argel (Caceres)	Antonio Cruz Macias
Extremadura	Pueblo Nuevo de Guadiana (Caceres)	Augusta Albarran Sanz-Calcedo
Galicia	Tomino (Vigo)	Ana Tapia Gil
Galicia	Bueu (Pontevedra)	Alberto Perez Vazquez
Madrid	Castilla Nueva (Fuenlabrada)	Virginia Rodriguez Coronado
Madrid	Monovar (Madrid)	Manuel Jaraba Mezquida
Madrid	Torrelodones (Madrid)	Aranzazu Luaces Gallan
Madrid	Vicente Soldevilla (Madrid)	Natividad Montalvo Serrano
Madrid	El Soto (Mostoles)	Blanca Gutierrez Teira
Murcia	San Anton (Cartagena)	Alfonso de Miguel Gomez
Murcia	San Andres (Murcia)	Ma Isabel Sanchez Lopez
Navarra	Iturrama (Pamplona)	Ramon Villanueva Moreno
Navarra	San Jorge (Pamplona)	Feli Oses Zudaire
Rioja	Najera (La Rioja)	Jose Tomas Gomez Saenz
Rioja	Alfaro (La Rioja)	Francisco Manuel Adan Gil

HEALTHCARE CENTER COLLABORATORS

Autonomous Community	Healthcare Center	Name
Andalusia	Abla (Almeria)	Francisco Peralta Ortiz
Andalusia	Abla (Almeria)	Carmen Lozano de Cruz
Andalusia	Abla (Almeria)	Jesus Martin Montes
Andalusia	Abla (Almeria)	Jose Manuel Garcia Aparicio
Andalusia	Abla (Almeria)	Maria Jose Bernabe Rodriguez
Andalusia	Abla (Almeria)	Julia Puertas Carretero
Andalusia	Abla (Almeria)	Ma Teresa Martinez Lao
Andalusia	Abla (Almeria)	Encarnacion Quesada Sanchez
Andalusia	Abla (Almeria)	Joaquin Galindo Pelayo
Andalusia	Abla (Almeria)	Gerardo Medina Diaz
Andalusia	Abla (Almeria)	Juana Ma Iribarren Berrade
Andalusia	Abla (Almeria)	Maria Pardo Romero
Andalusia	Abla (Almeria)	Dolores Diaz Trujillo
Andalusia	Abla (Almeria)	Jose Manuel Oliva Oliva
Andalusia	Torre del Mar (Malaga)	Florencio Garcia Molina
Andalusia	Torre del Mar (Malaga)	Antonio Blanco Garcia
Andalusia	Torre del Mar (Malaga)	Paloma Almagro Martin-Lomena
Andalusia	Torre del Mar (Malaga)	Alicia Gonzalez Garcia
Andalusia	Torre del Mar (Malaga)	Soledad Gomez Garcia
Andalusia	Torre del Mar (Malaga)	Rosa Maria Moreno Quiros
Andalusia	Plaza de Toros (Almeria)	Maria Jose Garcia Gonzalez
Andalusia	Plaza de Toros (Almeria)	Emilio Tejera Hurtado
Andalusia	Plaza de Toros (Almeria)	Maria Victoria Rabell Inigo
Andalusia	Plaza de Toros (Almeria)	Luisa Mingorance Sanjuan
Andalusia	Plaza de Toros (Almeria)	Carlos Escobar Molero
Andalusia	Plaza de Toros (Almeria)	Aurelia Perez Gimenez
Andalusia	Plaza de Toros (Almeria)	Casilda Gomez Leon
Andalusia	Plaza de Toros (Almeria)	Alfonsa Cano Rueda
Andalusia	Plaza de Toros (Almeria)	Pilar Gea Velazquez De Castro
Andalusia	Plaza de Toros (Almeria)	Adelaida Perez Navarro
Andalusia	Plaza de Toros (Almeria)	Jose Sebastian Perez Martinez
Andalusia	Candelaria (Seville)	Araceli Perez Rodriguez
Andalusia	Candelaria (Seville)	Carmen Garcia Vazquez
Andalusia	Candelaria (Seville)	Valle Fernandez-Pro Ledesma
Andalusia	Candelaria (Seville)	Marta Requena Albinana
Andalusia	Candelaria (Seville)	Eva Alvarez Perez
Andalusia	Candelaria (Seville)	Josefa Mayoral Sanchez
Andalusia	Candelaria (Seville)	Concepcion Cobano Parraga
Andalusia	Candelaria (Seville)	Assumpta Codina Lanaspa
Andalusia	Candelaria (Seville)	Manuel Praena Crespo
Andalusia	Candelaria (Seville)	Amelia Fdez. Valverde
Andalusia	Candelaria (Seville)	Lidia Rodriguez Pulido
Andalusia	Candelaria (Seville)	Carmen Villalba Zoilo
Andalusia	Candelaria (Seville)	Pureza Mena Bravo
Andalusia	Candelaria (Seville)	Manuel Suarez Garcia
Andalusia	Candelaria (Seville)	Teresa Perez Diaz
Andalusia	Gran Capitan (Granada)	Enrique Vercher Moreno
Andalusia	Gran Capitan (Granada)	Francisco Jose Sanchez Ortiz
Andalusia	Gran Capitan (Granada)	Jose Antonio Huertas Jimenez
Andalusia	Gran Capitan (Granada)	Isabel Ocete Alcalde
Andalusia	Gran Capitan (Granada)	Manuel Mateos Perez
Andalusia	Gran Capitan (Granada)	Francisco Jose Ferrer Luque
Andalusia	Gran Capitan (Granada)	Pilar Barruetabena Alonso
Andalusia	Gran Capitan (Granada)	Francisca Verde Gomez

Andalusia	Gran Capitan (Granada)	Ascension J. Martinez Porcel
Andalusia	Gran Capitan (Granada)	Ma Carmen Pilar Conde Garcia
Aragon	Delicias Sur (Zaragoza)	Francisca Gonzalez Rubio
Aragon	Delicias Sur (Zaragoza)	Oscar Esteban Jimenez
Aragon	Delicias Sur (Zaragoza)	Jose Carlos Perez Villarroya
Aragon	Delicias Sur (Zaragoza)	Lourdes Asensio Asensio
Aragon	Delicias Sur (Zaragoza)	Rosa Sebastian Gallego
Aragon	Delicias Sur (Zaragoza)	Ma Pilar Marcos Calvo
Aragon	Delicias Sur (Zaragoza)	Enrique de la Figuera Von Wichman
Aragon	Delicias Sur (Zaragoza)	Manuel del Castillo Pardo
Aragon	Delicias Sur (Zaragoza)	Jose Luis Cantalapiedra Obis
Aragon	Delicias Sur (Zaragoza)	Ma Jesus Gimeno De la Torre
Aragon	Delicias Sur (Zaragoza)	Beatriz Calvo Sanchez
Aragon	Delicias Sur (Zaragoza)	Pilar Oliveros Gonzalvo
Aragon	Actur Sur (Zaragoza)	Javier Valdeperez Torrubia
Aragon	Actur Sur (Zaragoza)	Carlos Arruga Mombiela
Aragon	Actur Sur (Zaragoza)	Isabel Lostal Gracia
Aragon	Actur Sur (Zaragoza)	Jose Luis Antonio Paniagua
Aragon	Actur Sur (Zaragoza)	Ma Jesus Morales Gregorio
Aragon	Actur Sur (Zaragoza)	Ma Carmen Martin Sola
Aragon	Torrero (Zaragoza)	Jose Angel Martinez Milian
Aragon	Torrero (Zaragoza)	Fernando Martin Moreno
Aragon	Torrero (Zaragoza)	Rafael Vargas Arevalo
Aragon	Torrero (Zaragoza)	Ma Jose Rodriguez Fabre
Aragon	Torrero (Zaragoza)	Jesus Romeo Ladrero
Aragon	Torrero (Zaragoza)	Juana Loscos Morato
Aragon	Torrero (Zaragoza)	Jose Fernando Pina
Aragon	Torrero (Zaragoza)	Jose Manuel Millaruelo Trillo
Aragon	Torrero (Zaragoza)	Ana Carmen Ferrer Gazol
Aragon	Torrero (Zaragoza)	Esther Arroyo Ramos
Aragon	San Pablo (Zaragoza)	Maria Jose Lahoz Mustienes
Aragon	San Pablo (Zaragoza)	Selma Valverde Aranda
Aragon	San Pablo (Zaragoza)	Natividad Castro Pinedo
Aragon	San Pablo (Zaragoza)	Mercedes Eguiluz Lopez
Aragon	San Pablo (Zaragoza)	Maria Eugenia Vargas Royo
Aragon	San Pablo (Zaragoza)	Rosa Medrano Gonzalo
Aragon	San Pablo (Zaragoza)	Carmen Postigo Gascon
Aragon	San Pablo (Zaragoza)	Azahara Carbonel Tabuenca
Asturias	Otero (Oviedo)	Ma Teresa Pascual Alperi
Asturias	Otero (Oviedo)	Victoria Sanchez Marques
Asturias	Otero (Oviedo)	Julia Fernandez Diaz
Asturias	Otero (Oviedo)	Isabel Pardo Gonzalez
Asturias	Otero (Oviedo)	Jesus Pablo Glez-Nuevo Quinones
Asturias	Otero (Oviedo)	Marcelino Becerro Perez
Basque Country	Rekalde Berri (Bilbao)	Ana Gorronogoitia Iturbe
Basque Country	Rekalde Berri (Bilbao)	Henar de Benito Valencia
Basque Country	Rekalde Berri (Bilbao)	Begona Toscano Pardo
Basque Country	Rekalde Berri (Bilbao)	Miren Aizpuru Barandiaran
Basque Country	Rekalde Berri (Bilbao)	Inigo Alquiza Basanez
Basque Country	Rekalde Berri (Bilbao)	Leticia Irazabal Olabarrieta
Basque Country	Rekalde Berri (Bilbao)	Rosa Gutierrez Martinez-Campanon
Basque Country	Rekalde Berri (Bilbao)	Itziar Mintegui Maiz
Basque Country	Rekalde Berri (Bilbao)	Ma Jose Fernandez Hernandez
Basque Country	Rekalde Berri (Bilbao)	Leonor Gonzalez Calvo
Basque Country	Rekalde Berri (Bilbao)	Ma Carmen Garcia Rada
Basque Country	Rekalde Berri (Bilbao)	Ma Jose Lorenzo Hernandez
Basque Country	San Martin (Vitoria)	Ana Fernandez Buergo

Basque Country	San Martin (Vitoria)	Lucia Pereda Lopez
Basque Country	San Martin (Vitoria)	Ana Luisa Arrieta Insausti
Basque Country	San Martin (Vitoria)	Maria Jesus Serna Sagarminaga
Basque Country	San Martin (Vitoria)	Felix Ricarte Senosiain
Basque Country	San Martin (Vitoria)	Jesus Ordono Bolinaga
Basque Country	San Martin (Vitoria)	Inaki Aguirrezabal Bazterrika
Basque Country	San Martin (Vitoria)	Rosa Esquisabel Martinez
Basque Country	San Martin (Vitoria)	Teresa Gomez Merino
Basque Country	San Martin (Vitoria)	Aurora del Campo Deustua
Basque Country	San Martin (Vitoria)	Carolina Ocio Aracama
Basque Country	San Martin (Vitoria)	Ana Blanca Arana Ortiz
Basque Country	Ondarreta (San Sebastian)	Ma Victoria Albisu Aparicio
Basque Country	Ondarreta (San Sebastian)	Rafaela Argamasilla Civico
Basque Country	Ondarreta (San Sebastian)	Victor Irigoyen Murua
Basque Country	Ondarreta (San Sebastian)	Juan Luis Mendia Gorostidi
Basque Country	Ondarreta (San Sebastian)	Ma Luisa Herrero Mateos
Basque Country	Ondarreta (San Sebastian)	Fernando Palacio Lapuente
Basque Country	Ondarreta (San Sebastian)	Ma Victoria Manrique Iturrioz
Basque Country	Ondarreta (San Sebastian)	Garbine Sukia Armendariz
Basque Country	Ondarreta (San Sebastian)	Xabier Sanz Cascante
Basque Country	Parte Vieja (San Sebastian)	Jose Miguel Yetano Laguna
Basque Country	Parte Vieja (San Sebastian)	Angel Gutierrez Manzanas
Basque Country	Parte Vieja (San Sebastian)	Isabel Aguirre Odriozola
Basque Country	Parte Vieja (San Sebastian)	Milagros Arriola Muguerza
Basque Country	Parte Vieja (San Sebastian)	Beatriz Laviada Pardo
Basque Country	Parte Vieja (San Sebastian)	Ma Aranzazu Mendiguren Navascues
Canary Islands	La Victoria (Santa Cruz Tenerife)	Jose Angel Fernandez Hernandez
Canary Islands	La Victoria (Santa Cruz Tenerife)	Miguel Gutierrez Almarza
Canary Islands	La Victoria (Santa Cruz Tenerife)	Matilde Fernandez Castro
Cantabria	Dobra (Torrelavega)	Elena Basabe Blanco
Cantabria	Dobra (Torrelavega)	Fernando Alonso Lopez
Cantabria	Dobra (Torrelavega)	Rosa Alvaro Martinez
Cantabria	Dobra (Torrelavega)	Ramon Martinez Bretones
Cantabria	Dobra (Torrelavega)	Ma Isabel Priede Diaz
Cantabria	Dobra (Torrelavega)	Teodoro Gutierrez Landeras
Cantabria	Dobra (Torrelavega)	Juan Carlos Vecin Justo
Cantabria	Dobra (Torrelavega)	Yolanda Cuerno Rios
Cantabria	Dobra (Torrelavega)	Carmen Toribio Gonzalez
Cantabria	Dobra (Torrelavega)	Rosa Esparza Escayola
Cantabria	Dobra (Torrelavega)	Juan Carlos Santos Sanchez
Cantabria	Dobra (Torrelavega)	Luis Unceta Barrenechea-Aguirre
Cantabria	Dobra (Torrelavega)	Ma Dolores Garcia Gonzalez
Cantabria	Dobra (Torrelavega)	Ma Dolores Marin Ortega
Cantabria	Dobra (Torrelavega)	Yolanda Laguillon Estebanez
Cantabria	Dobra (Torrelavega)	Sagrario Perez Sanchez
Cantabria	Dobra (Torrelavega)	Ma Josefa Diez Lamadrid
Cantabria	Dobra (Torrelavega)	Elena Medel Toledano
Cantabria	Castilla Hermida (Cantabria)	Carmen Gaisan Tome
Cantabria	Castilla Hermida (Cantabria)	Fernando Salas Herrera
Cantabria	Castilla Hermida (Cantabria)	L. Alberto Vara Gonzalez
Cantabria	Castilla Hermida (Cantabria)	Rosa Gonzalez Garcia
Cantabria	Castilla Hermida (Cantabria)	Ma Jesus Lopez Rivera
Cantabria	Castilla Hermida (Cantabria)	Angelica Saiz Berzosa
Cantabria	Castilla Hermida (Cantabria)	Luis Diego Barquin
Cantabria	Castilla Hermida (Cantabria)	Ana Galvan Manso
Cantabria	Castilla Hermida (Cantabria)	Monserrat Serradell Cabra
Cantabria	Castilla Hermida (Cantabria)	Rosa Callejas Herrera

Cantabria	Castilla Hermida (Cantabria)	Rosa Callejas Herrera
Cantabria	Castilla Hermida (Cantabria)	Angela Perez Nicolas
Cantabria	Castilla Hermida (Cantabria)	Yolanda Llarenda Lopez
Cantabria	Castilla Hermida (Cantabria)	Emilia Gimeno Beser
Cantabria	Castilla Hermida (Cantabria)	Elena Aragoncillo Bailon
Cantabria	Castilla Hermida (Cantabria)	Gurutze Hornilla Saiz
Cantabria	Castilla Hermida (Cantabria)	Soledad Merino Serna
Cantabria	Castilla Hermida (Cantabria)	Valentin de Benito
Cantabria	Castilla Hermida (Cantabria)	Jose F. Mantecon Artasanchez
Cantabria	Zapaton (Cantabria)	Pilar de la Puebla Cagigas
Cantabria	Zapaton (Cantabria)	Begona Bermejo Garcia
Cantabria	Zapaton (Cantabria)	Carmen Feijoo Monasterio
Cantabria	Zapaton (Cantabria)	Elena Sellers Asensio
Cantabria	Zapaton (Cantabria)	German Castellano Barca
Cantabria	Zapaton (Cantabria)	Jose Hernandez Urculo
Cantabria	Zapaton (Cantabria)	Jose Manuel Gutierrez Pellon
Cantabria	Zapaton (Cantabria)	Maria Antonia Martin Macazaga
Cantabria	Zapaton (Cantabria)	Ricardo Sanchez Villar
Cantabria	Zapaton (Cantabria)	Maria Luisa Millan Sagaste
Cantabria	Zapaton (Cantabria)	Maria Teresa Alonso Lopez
Cantabria	Zapaton (Cantabria)	Teresa Sobrino Lopez
Cantabria	Zapaton (Cantabria)	Maria Antonia Gandara Revuelta
Cantabria	Zapaton (Cantabria)	Carmen Barez Gomez
Castile and Leon	Comuneros (Burgos)	Ma Teresa Anton Nuno
Castile and Leon	Comuneros (Burgos)	Estrella Trabada Guijarro
Castille and Leon	Comuneros (Burgos)	Jose Herrero Roa
Castile and Leon	Comuneros (Burgos)	Juan C. Verdes-Montenegro Atalaya
Castile and Leon	Comuneros (Burgos)	Ma Victoria Castillo Carrasco
Castile and Leon	Comuneros (Burgos)	Nieves Saiz Alonso
Castile and Leon	Baltanas (Palencia)	Pedro Azaola Rodriguez-Espina
Castile and Leon	Baltanas (Palencia)	Felisa Juarez Doyague
Castile and Leon	Baltanas (Palencia)	Montserrat Fraile Prieto
Castile and Leon	Baltanas (Palencia)	Jesus Miguel Gonzalez Rodriguez
Castile and Leon	Baltanas (Palencia)	Jose Maria Herrero Quijano
Castile and Leon	Baltanas (Palencia)	Margarita Gonzalez Fernandez
Castile and Leon	Baltanas (Palencia)	Lourdes Triana Sanchez
Castile and Leon	Baltanas (Palencia)	Alejandro Plaza Gutierrez
Castile and Leon	Baltanas (Palencia)	Nieves Maestro Lopez
Castile and Leon	Baltanas (Palencia)	Encarnacion Cantera Aguado
Castile and Leon	Baltanas (Palencia)	Maria Carmen Jimenez Santiago
Castile and Leon	Baltanas (Palencia)	Isabel Carpintero Martin
Castile and Leon	Alamedilla (Salamanca)	Pilar Moreno Gonzalez
Castile and Leon	Alamedilla (Salamanca)	Ma Angeles Polo Sanchez
Castile and Leon	Alamedilla (Salamanca)	Concepcion Hernandez Garcia
Castile and Leon	Alamedilla (Salamanca)	Emilio Ramos Delgado
Castile and Leon	Alamedilla (Salamanca)	Luz Ma Martinez Martinez
Castile and Leon	Alamedilla (Salamanca)	Consuelo Gil Rodriguez
Castile and Leon	Alamedilla (Salamanca)	Ma Angeles Campo de la Torre
Castile and Leon	Alamedilla (Salamanca)	Mo Dolores Garcia Garcia
Castile and Leon	Casa del Barco (Valladolid)	Amparo Gomez Arranz
Castile and Leon	Casa del Barco (Valladolid)	Ruperto Sanz Cantalapiedra
Castile and Leon	Casa del Barco (Valladolid)	Miguel Angel Diez Garcia
Castile and Leon	Casa del Barco (Valladolid)	Aventina de la Cal de la Fuente
Castile and Leon	Casa del Barco (Valladolid)	Julia Santos Gonzalez
Castile and Leon	Casa del Barco (Valladolid)	Angel Sanchez Martin
Castile and Leon	Casa del Barco (Valladolid)	Marta Gonzalez Touya
Castile and Leon	Casa del Barco (Valladolid)	Ma Concepcion Hernandez San Jose

Castile and Leon	Casa del Barco (Valladolid)	Ma del Mar Caceres Hernandez
Castile and Leon	Casa del Barco (Valladolid)	Casto Fernandez Cuadrillero
Castile and Leon	Casa del Barco (Valladolid)	Luis M. Quintero Gonzalez
Castile and Leon	Casa del Barco (Valladolid)	Marta Mendez Liron
Castile-La Mancha	Puertollano II (Ciudad Real)	Virginia Moreno Hinojosa
Castile-La Mancha	Puertollano II (Ciudad Real)	Carmen Gallego Iniesta
Castile-La Mancha	Puertollano II (Ciudad Real)	Ines Benitez Rueda
Castile-La Mancha	Puertollano II (Ciudad Real)	Rosa Munoz Camacho
Castile-La Mancha	Puertollano II (Ciudad Real)	Concepcion Cardona Chacon
Castile-La Mancha	Puertollano II (Ciudad Real)	Isabel Ruiz-Zorrilla
Castile-La Mancha	Puertollano II (Ciudad Real)	Emma Ruiz Garcia
Castile-La Mancha	Puertollano II (Ciudad Real)	Luis Gargallo Garcia
Castile-La Mancha	La Estacion (Talavera)	Jesus Melendez Sanchez
Castile-La Mancha	La Estacion (Talavera)	Miguel Angel Sanchez Libran
Castile-La Mancha	La Estacion (Talavera)	Maria Auxiliadora Sanchez Benitez
Castile-La Mancha	La Estacion (Talavera)	Jose Enrique Magana Loarte
Castile-La Mancha	La Estacion (Talavera)	Maria del Carmen Carmona Arance
Castile-La Mancha	La Estacion (Talavera)	Manuela Mingo Blanco
Castile-La Mancha	La Estacion (Talavera)	Luis Alberto Gomez Alonso
Catalunya	La Mina (Barcelona)	Silvia Calvet Junoy
Catalunya	La Mina (Barcelona)	Ernest Vinyoles Bargallo
Catalunya	La Mina (Barcelona)	Alberto Ramos Fuertes
Catalunya	La Mina (Barcelona)	Laura Ruiz Balestra
Catalunya	La Mina (Barcelona)	Albert Brau Tarrida
Catalunya	La Mina (Barcelona)	Carme Espel Masferrer
Catalunya	La Mina (Barcelona)	Joan Pericas Bosch
Catalunya	La Mina (Barcelona)	Miquel Puente Capdevila
Catalunya	La Mina (Barcelona)	Magda Delgado Ayza
Catalunya	La Mina (Barcelona)	Isabel Bobe Molina
Catalunya	La Mina (Barcelona)	Concha Royo Pastor
Catalunya	La Mina (Barcelona)	Marta Tafalla Eustaquio
Catalunya	La Mina (Barcelona)	Cristina Murillo Anzano
Catalunya	La Mina (Barcelona)	Dolores Alejandro Hibernon
Catalunya	Area Basica (Vic)	Albert Ledesma Castelltort
Catalunya	Area Basica (Vic)	Pilar Aguila Pujols
Catalunya	Area Basica (Vic)	Lidia Busquets Poblet
Catalunya	Area Basica (Vic)	Pilar Santamaria vilaro
Catalunya	Area Basica (Vic)	Angels Moleiro Oliva
Catalunya	Area Basica (Vic)	Xavier Farres Fabre
Catalunya	Area Basica (Vic)	Lidia Aulet Molist
Catalunya	Area Basica (Vic)	Elisabeth Reig Nuri
Catalunya	Area Basica (Vic)	Mireia Galles Muntada
Catalunya	Area Basica (Vic)	Eli Marce Almellon
Catalunya	Area Basica (Vic)	Griselda Trullas Ortiz
C. Valencia	Sant Joan d´Alacant	Carmen Pardo Tomas
C. Valencia	Sant Joan d´Alacant	Lucas Jimenez Cruzado
C. Valencia	Sant Joan d´Alacant	Juan Garcia de Quinis Chacon
C. Valencia	Sant Joan d´Alacant	Mercedes Garcia Fernandez
C. Valencia	Cabo Huertas (Alicante)	Mavi Hernandis Santamaria
C. Valencia	Cabo Huertas (Alicante)	Salvador Pertusa Martinez
C. Valencia	Cabo Huertas (Alicante)	Blas Cloquell Rodrigo
C. Valencia	Cabo Huertas (Alicante)	Syra Gimenez Pastor
C. Valencia	Cabo Huertas (Alicante)	Ana Amado Corrales
C. Valencia	Cabo Huertas (Alicante)	Antonio Tosao Sanchez
C. Valencia	Cabo Huertas (Alicante)	Jose Antonio Agote Andres
C. Valencia	Cabo Huertas (Alicante)	Lucia Reus Lopez
C. Valencia	Cabo Huertas (Alicante)	Veronica Lacaba Sanz

C. Valencia	Cabo Huertas (Alicante)	Inmaculada de Scal Jimenez
C. Valencia	Cabo Huertas (Alicante)	Ester Santoro Sanchez
C. Valencia	Cabo Huertas (Alicante)	Francisco Milan Galvan
C. Valencia	Mutxamel (Alicante)	Vicente Rodriguez Sempere
C. Valencia	Mutxamel (Alicante)	Joaquin Paredes Pardo
C. Valencia	Mutxamel (Alicante)	Alberto Asensio Aznar
C. Valencia	Mutxamel (Alicante)	Carlos Lozano Quijada
C. Valencia	Mutxamel (Alicante)	Antonio Cutillas Herrero
C. Valencia	Mutxamel (Alicante)	Jose Luis Berenguer Blay
C. Valencia	Stma. FAZ-Ayto. (Alicante)	Jose Vicente Mas Ferrer
C. Valencia	Stma. FAZ-Ayto. (Alicante)	Sabina Jover Perez
C. Valencia	Stma. FAZ-Ayto. (Alicante)	Emma Oliver Lloret
C. Valencia	Hospital Provincial (Alicante)	Rosario Garcia Santa Fe
C. Valencia	Hospital Provincial (Alicante)	Jose Luis Lopez Blasco
C. Valencia	Hospital Provincial (Alicante)	Juan Chico Asensi
C. Valencia	Hospital Provincial (Alicante)	Nieves Gomez Moreno
C. Valencia	Hospital Provincial (Alicante)	Ma Carmen Sirvent Mayor
C. Valencia	Hospital Provincial (Alicante)	Ma Jose Fernandez Tari
C. Valencia	Hospital Provincial (Alicante)	Ma Luisa Alvarez Cristobal
C. Valencia	Hospital Provincial (Alicante)	Ma Jose Gutierrez Villarias
C. Valencia	Hospital Provincial (Alicante)	Marta Arana Hidalgo
C. Valencia	Gerona (Alicante)	Paz Ortega Ruiz
C. Valencia	Gerona (Alicante)	Ignacio Antonio Verdu Jorda
C. Valencia	Gerona (Alicante)	Susana Romero Gotor
C. Valencia	Xixona (Alicante)	Victoriano Borreguero Guerra
C. Valencia	Xixona (Alicante)	Rosario Oliver Ros
C. Valencia	Xixona (Alicante)	Eva Ma San Nicolas Manogil
Extremadura	Plaza de Argel (Caceres)	Antonio Cruz Macias
Extremadura	Plaza de Argel (Caceres)	Jose Ma Villanueva Rebollo
Extremadura	Plaza de Argel (Caceres)	Carlos Rubio Villega
Extremadura	Plaza de Argel (Caceres)	Vicente Caballero Pajares
Extremadura	Plaza de Argel (Caceres)	Catalina Duran Iglesias
Extremadura	Plaza de Argel (Caceres)	Julio Diaz Sanguino
Extremadura	Plaza de Argel (Caceres)	Dolores Corrales Nevado
Extremadura	Pueblo Nuevo Guadiana	Augusta Albarran Sanz-Calcedo
Extremadura	Pueblo Nuevo Guadiana	Antonio Peinado Rodriguez
Extremadura	Pueblo Nuevo Guadiana	Concepcion Brito Lobon
Extremadura	Pueblo Nuevo Guadiana	Ma Carmen Gragera Villafaina
Extremadura	Pueblo Nuevo Guadiana	Mario de Felipe Felipe
Extremadura	Pueblo Nuevo Guadiana	Ma Angeles Gordon Cuenda
Extremadura	Pueblo Nuevo Guadiana	Rosa Donoso Fernandez Henestrosa
Extremadura	Pueblo Nuevo Guadiana	Rosario Trinidad Ramos
Extremadura	Pueblo Nuevo Guadiana	Carmen Matilla Alvarez
Extremadura	Pueblo Nuevo Guadiana	Beatriz Pardo Diaz de Entresoto
Extremadura	Pueblo Nuevo Guadiana	Eva Fernandez Calderon
Extremadura	Pueblo Nuevo Guadiana	Miguel Escobar Fernandez
Galicia	Tomino (Vigo)	Ana Tapia Gil
Galicia	Tomino (Vigo)	Concepcion Curto Perez
Galicia	Tomino (Vigo)	Evangelina Filloy Miguez
Galicia	Tomino (Vigo)	Jose Carlos Varela Alonso
Galicia	Tomino (Vigo)	Nieves Turienzo del Rio
Galicia	Tomino (Vigo)	Clara Gonzalez Formoso
Galicia	Tomino (Vigo)	Ma Dolores Cardalda Freire
Galicia	Tomino (Vigo)	Ana Nieto Jacome
Galicia	Tomino (Vigo)	Jose Antonio Sangabriel Villar
Galicia	Tomino (Vigo)	Francisca Vazquez Couso
Galicia	Bueu (Pontevedra)	Cesar Gil Cons

Galicia	Bueu (Pontevedra)	Jose Manuel Goimil Martinez
Galicia	Bueu (Pontevedra)	Jose Antonio Reimundez Campos
Galicia	Bueu (Pontevedra)	Jose Ruiz Almendro
Galicia	Bueu (Pontevedra)	Alberto Perez Vazquez
Galicia	Bueu (Pontevedra)	Josefa Ares Alvarez
Galicia	Bueu (Pontevedra	Cristina Velasco Martinez
Galicia	Bueu (Pontevedra)	Carmen Garcia Pons
Madrid	Castilla Nueva (Fuenlabrada)	Virginia Rodriguez Coronado
Madrid	Castilla Nueva (Fuenlabrada)	Carlos Diaz Gomez-Calcerrada
Madrid	Castilla Nueva (Fuenlabrada)	Javier Roldan San Juan
Madrid	Castilla Nueva (Fuenlabrada)	Montserrat Jurado Sueiro
Madrid	Monovar (Madrid)	Manuel Jaraba Mezquida
Madrid	Monovar (Madrid)	Esther Vaquero Lucas
Madrid	Monovar (Madrid)	Carmen Martin Madrazo
Madrid	Monovar (Madrid)	Ana Belen Bonilla Rodriguez
Madrid	Monovar (Madrid)	Pilar del Dedo Torre
Madrid	Monovar (Madrid)	Sagrario Munoz Quiros
Madrid	Torrelodones (Madrid)	Fatima Bermejo Fernandez
Madrid	Torrelodones (Madrid)	Santiago Alvarez Montero
Madrid	Torrelodones (Madrid)	Ma Auxiliadora Fernandez Perez
Madrid	Torrelodones (Madrid)	Aranzazu Luances Gayan
Madrid	Torrelodones (Madrid)	Cristina Ciria de Pablo
Madrid	Torrelodones (Madrid)	Ana Isabel Perez Hernandez
Madrid	Torrelodones (Madrid)	Pilar Gallego Casado
Madrid	Torrelodones (Madrid)	Teresa Herrero Lopez
Madrid	Vicente Soldevilla (Madrid)	Juan Antonio Salcedo Mata
Madrid	Vicente Soldevilla (Madrid)	Rocio Olivera Garcia
Madrid	Vicente Soldevilla (Madrid)	Eliseo Morales Rodriguez
Madrid	Vicente Soldevilla (Madrid)	Gema Lizcano Navas
Madrid	Vicente Soldevilla (Madrid)	Juan Luis Ruiz Gimenez
Madrid	Vicente Soldevilla (Madrid)	Pilar Sanz Velasco
Madrid	Vicente Soldevilla (Madrid)	Ma Teresa Martin Palacios
Madrid	Vicente Soldevilla (Madrid)	Beatriz Calleja Nunez
Madrid	Vicente Soldevilla (Madrid)	Malik Najjar Batal
Madrid	Vicente Soldevilla (Madrid)	Jesus Jordan Martinez
Madrid	Vicente Soldevilla (Madrid)	Natividad Montalvo Serrano
Madrid	Vicente Soldevilla (Madrid)	Ludwin Hernandez Fuertes
Madrid	Vicente Soldevilla (Madrid)	Carmen Raquejo Grado
Madrid	Vicente Soldevilla (Madrid)	Elena Olias Egea
Madrid	Vicente Soldevilla (Madrid)	Ma Jose Garcia Berral
Madrid	Vicente Soldevilla (Madrid)	Ana Garcia Garcia
Madrid	Vicente Soldevilla (Madrid)	Laura Catalina Rodriguez Samaniego
Madrid	El Soto (Mostoles)	Myriam Gari Meseguer
Madrid	El Soto (Mostoles)	Lucia Carbonel Munoz
Madrid	El Soto (Mostoles)	Juan Carlos Munoz Garcia
Madrid	El Soto (Mostoles)	Ma Almudena Garcia Sanchez
Madrid	El Soto (Mostoles)	Ma Rosario Fernandez Lago
Madrid	El Soto (Mostoles)	Rosario Blanco Escudero
Madrid	El Soto (Mostoles)	Blanca Gutierrez Teira
Murcia	San Anton (Cartagena)	Jose Antonio Pena Doncel-Moriano
Murcia	San Anton (Cartagena)	Alfonso de Miguel Gomez
Murcia	San Anton (Cartagena)	Carmen Perez-Crespo Gomez
Murcia	San Anton (Cartagena)	Carmen Botias Martinez
Murcia	San Anton (Cartagena)	Carmen Imbernon Garcia
Murcia	San Anton (Cartagena)	Xania de Casas Fernandez
Murcia	San Anton (Cartagena)	Lucia Garcia Guerrero
Murcia	San Anton (Cartagena)	Maria Jose Sanchez de las Matas

Murcia	San Anton (Cartagena)	Aida Flores Fernandez
Murcia	San Anton (Cartagena)	Silvia Navarro Sanchez
Murcia	San Anton (Cartagena)	Paz Ortuno del Moral
Murcia	San Anton (Cartagena)	Elena Roca Pegalajar
Murcia	San Anton (Cartagena)	Jose Luis Murcia Legaz
Murcia	San Anton (Cartagena)	Charo Cobo Gonzalez
Murcia	San Anton (Cartagena)	Ma Angeles Bocanegra Baleriola
Murcia	San Anton (Cartagena)	Pedro Conesa Madrid
Murcia	San Anton (Cartagena)	Puri Caja Romero
Murcia	San Anton (Cartagena)	Maria del Puy Munarriz Noguera
Murcia	San Anton (Cartagena)	Isabel Cayuela Sanchez
Murcia	San Anton (Cartagena)	Lola Carrillo Garcia
Murcia	San Anton (Cartagena)	Jose Garcia Denia
Murcia	San Andres (Murcia)	Ma Isabel Sanchez Lopez
Murcia	San Andres (Murcia)	Ma Jose Martinez Villalba
Murcia	San Andres (Murcia)	Carmen Alfonso Cano
Murcia	San Andres (Murcia)	Ma Carmen Sandoval Saura
Murcia	San Andres (Murcia)	Mariano Leal Hernandez
Murcia	San Andres (Murcia)	Francisco Carrillo Navarro
Murcia	San Andres (Murcia)	Emilio Ruiz Castillo
Murcia	San Andres (Murcia)	Francisca Hernandez Lapaz
Navarra	Iturrama (Pamplona)	Ana Blanca Sola Larraza
Navarra	Iturrama (Pamplona)	Cruz Bartolome Moreno
Navarra	Iturrama (Pamplona)	Ma Jose Echarri Montano
Navarra	Iturrama (Pamplona)	Ramon Villanueva Moreno
Navarra	Iturrama (Pamplona)	Carmen Lizarraga Urruela
Navarra	Iturrama (Pamplona)	Ma Teresa Salinas Vidondo
Navarra	Iturrama (Pamplona)	Inmaculada Iragui Subiza
Navarra	Iturrama (Pamplona)	Araceli Martinez de Zuniga Sanchez
Navarra	Iturrama (Pamplona)	Ma Jesus Esain Nicuesa
Navarra	Iturrama (Pamplona)	Marta Gonzalez Villar
Navarra	Iturrama (Pamplona)	Raquel Azcona Vidaurre
Navarra	Iturrama (Pamplona)	Jose Antonio Diaz Benito
Navarra	Iturrama (Pamplona)	Maite Velasco Garcia
Navarra	Iturrama (Pamplona)	Ma Consolacion Barace Garces
Navarra	San Jorge (Pamplona)	Feli Oses Zudaire
Navarra	San Jorge (Pamplona)	Elena Santamaria Martinez
Navarra	San Jorge (Pamplona)	Amaia Linero Alduan
Navarra	San Jorge (Pamplona)	Ma Dolores Lezaun Burgui
Navarra	San Jorge (Pamplona)	Maite Calvo Yanguas
Navarra	San Jorge (Pamplona)	Clemente Bernues Gambarte
Rioja	Najera (Rioja)	Rafael Tremps Garcia
Rioja	Najera (Rioja)	Inmaculada Garcia Rioja
Rioja	Najera (Rioja)	Jose Tomas Gomez Saenz
Rioja	Najera (Rioja)	Esteban Gracia Gil
Rioja	Najera (Rioja)	Ma Jesus Martinez Saenz
Rioja	Najera (Rioja)	Ma Carmen Leon Duarte
Rioja	Najera (Rioja)	Arturo Martinez Larios
Rioja	Najera (Rioja)	Isabel Martinez Pascual
Rioja	Najera (Rioja)	Angel Martinez Ceballos
Rioja	Najera (Rioja)	Javier Santamaria Marin
Rioja	Najera (Rioja)	Sonia Calvo Garcia
Rioja	Najera (Rioja)	Juan Jose Garcia Diez
Rioja	Najera (Rioja)	Elena Jimenez Saez
Rioja	Najera (Rioja)	Elena Muro Ovejas
Rioja	Najera (Rioja)	Ma Isabel Iruzubieta Marca
Rioja	Alfaro (Rioja)	Francisco Manuel Adan Gil

Rioja	Alfaro (Rioja)	Teofilo Javier Barron Bazo
Rioja	Alfaro (Rioja)	Cesar Mateos Gil
Rioja	Alfaro (Rioja)	Jose Manuel Orive Abos
Rioja	Alfaro (Rioja)	Isabel Ibarrondo Fernandez-Ladreda
Rioja	Alfaro (Rioja)	Belen Abengochea Cotaina
Rioja	Alfaro (Rioja)	Eresvita Tobias Tobias
Rioja	Alfaro (Rioja)	Roberto Alonso Marin
Rioja	Alfaro (Rioja)	Villar Torres Ladron de Guevara
Rioja	Alfaro (La Rioja)	Maria Rosario Arribas Orradre
Rioja	Alfaro (La Rioja)	Isabel Rubal Zarraluqui

COMPUTER AND STATISTICS TECHNICAL SUPPORT

Alicante	Hospital Sant Joan d´Alacant	Ma Teresa Gea Velazquez de Castro
Alicante	Hospital Sant Joan d´Alacant	Juana Requena Puche
Alicante	Hospital Sant Joan d´Alacant	Ramon Limon Ramirez
Alicante	Hospital Sant Joan d´Alacant	Ma Andrea Ricci Suzzara
Alicante	Hospital Sant Joan d´Alacant	Milagros Rey Talens
Alicante	Hospital Sant Joan d´Alacant	Milagros Rey Talens
Alicante	Hospital Sant Joan d´Alacant	Paloma Masso Guijarro
Alicante	Hospital Sant Joan d´Alacant	Daniel Gallardo Martinez
Alicante	Hospital Sant Joan d´Alacant	Mireya Martinez Fernandez
Alicante	Univ. Miguel Hernandez	Juan Jose Miralles Bueno
Alicante	Univ. Miguel Hernandez	Roberto Garcia Miguel
Alicante	Univ. Miguel Hernandez	Fabiola Perez Chacon
Alicante	Univ. Miguel Hernandez	Marina Vitaller Baguena
Alicante	Univ. Miguel Hernandez	Veronica Aranaz Ostariz
Alicante	Univ. Miguel Hernandez	Ana Ma Baeza Plaza
Alicante	Univ. Miguel Hernandez	Clara Vitaller Baguena
Zaragoza	Hospital Clinico Universitario Lozano Blesa	Elena Altarribas Bolsa
Zaragoza	Hospital Clinico Universitario Lozano Blesa	Silvia Castan Ruiz
Zaragoza	Hospital Clinico Universitario Lozano Blesa	Cristina Navarro Gistau

Annex 1

Reset form

Print form

ENEAS II
Primary Care

Incident and Adverse Effect Report Questionnaire

Center details
Type of center

☐ Urban ☐ Rural

Professional category
☐ Family Practitioner
☐ Pediatrician
☐ Nurse
☐ Resident (MIR)

Work experience:
☐ Less than 1 yr.
☐ 1-5 yrs.
☐ 5-10 yrs.
☐ 10+ years

Patient details:
Case:

Age:

☐ Male ☐ Female
Date of report:
Date of event:

1. Mark all of the causal factors of the adverse effect

Medication-related
☐ ADR
Medication-related errors
☐ Wrong medication
☐ Incorrect dose
☐ Missed dose, medication or vaccine
☐ Incorrect frequency of administration
☐ Error in preparation or handling
☐ Insufficient monitoring
☐ Dispensing error
☐ Wrong patient
☐ Incorrect duration of treatment
☐ Failure to adhere to treatment
☐ Drug interaction

Communication-related
☐ Physician-patient communication
☐ Physician-nurse communication
☐ Nurse-patient communication
☐ Physician-physician communication
☐ Language barrier
☐ Another different from the above

Management-related
☐ Clinical record duplicated
☐ Lost documents
☐ Mistake in the health information (Other patients' test results)
☐ Error in patient identification
☐ Long waiting list
☐ Problems with the computerized record
☐ Scheduling error

Diagnosis-related
☐ Error in diagnosis
☐ Delay in referral to specialized care
☐ Delay in the diagnosis

Care-related
☐ Improper handling of the patient
☐ Improper handling of the warning signs
☐ Improper handling of the technique
☐ Improper catheter care

Others
☐ Other causes

2. Summarize what happened and what you believe to be the cause (Also state where originated):

3. To what extent has the care provided been the cause of the harm?
☐ 1. No evidence of the incident being due to how the patient was handled
☐ 2. Minimal probability of the how patient was handled having been the cause
☐ 3. Slight probability of how the patient was handled having been the cause
☐ 4. Moderate probability of how the patient was handled having been the cause
☐ 5. Highly probable that the handling was the cause
☐ 6. Full evidence of how the patient was handled having been the cause of the incident/adverse effect

4. In your judgment, is there any evidence of it having been possible for the Adverse Effect to have been prevented? ☐ Yes ☐ No

5. Score the evidence of the possibility of prevention on a 1-6 point scale
☐ 1. No evidence of preventability
☐ 2. Minimal possibility of having been prevented
☐ 3. Slight possibility of having been prevented
☐ 4. Moderate possibility of having been prevented
☐ 5. Highly possible to have been prevented
☐ 6. Full evidence of preventability

Annex 2

Form modified following the experience gained by way of the study:

APEAS

Form for the identification of Incidents and Adverse Effects in Primary Care

Center details
Type of center
☐ Urban ☐ Rural

Patient details:
Case: _____
Age: _____

Professional Category
☐ Family Practitioner
☐ Pediatrician
☐ Nurse
☐ Resident (MIR)

Work Experience
☐ Less than 1 yr.
☐ 1-5 yrs.
☐ 5-10 yrs.
☐ 10+ years

☐ Male ☐ Female
Date of report: ____ / ____ / ____
Date of event: ____ / ____ / ____
dd mm yyyy

1. Please mark all of the following risk factors of the patient in question.

INTRINSIC R.F.

☐ Renal insufficiency
☐ Diabetes
☐ Neoplasia
☐ Immune deficiency
☐ Chronic pulmonary disease
☐ Neutropenia
☐ Liver cirrhosis
☐ Drug addiction
☐ Obesity
☐ Hypoalbuminemia
☐ Pressure ulcer
☐ Malformations
☐ Cardiac insufficiency
☐ Coronary disease
☐ Hypertension
☐ Alcoholism
☐ Hypercholesterolemia
☐ Depression
☐ HIV
☐ Malaria

EXTRINSIC R.F.

☐ Open urinary catheter
☐ Closed urinary catheter
☐ Enteral nutrition
☐ Tracheotomy
☐ Immunosuppressive therapy
☐ Colostomy
☐ Nasogastric tube

3. Please state briefly what happened and what you believe to be the cause:

_____

_____

3. At which level of care did the problem occur?

☐ Emergency care in Primary Care
☐ Office visits in Primary Care
☐ Primary Care nursing visits
☐ Hospital Emergency Room
☐ Prior hospital stay
☐ Specialized Care office visits
☐ Pharmacy
☐ Others (herbalist's, physical therapy…)

4. Which of these statements best describes the impact on the patient?

- ☐ No effect occurred, but close to occurring
- ☐ The incident occurred but was detected before having affected the patient
- ☐ The incident occurred and has affected the patient, but the patient has come to no harm
- ☐ The effect occurred, and the patient has come to temporary harm
- ☐ The effect occurred, and the patient has been in a critical situation (ex. Cardiac arrest)
- ☐ The effect occurred, and the patient has sustained permanent injury
- ☐ The effect occurred had resulted in the patient's death

5. Please mark all of the effects caused to the patient:

Procedure-related
- ☐ Hemorrhage or hematoma related to surgical intervention or procedure.
- ☐ Catheterization-related hematuria
- ☐ Circulatory disorder (cast too tight)
- ☐ Suture dehiscence
- ☐ Seromas, abscesses or granulomas
- ☐ Perforated eardrum
- ☐ Other procedure-related complications

Nosocomial infection-related
- ☐ Surgical and/or trauma wound infection
- ☐ Catheterization-related UTI
- ☐ Device-related bacteriemia
- ☐ Opportunistic infection due to immunosuppressive or antibiotic treatment
- ☐ Pressure ulcer-related infection
- ☐ Aspiration pneumonia

Care-related
- ☐ Phlebitis
- ☐ Pressure ulcer
- ☐ Burns, scrapes, falls and contusions (including resulting fractures)
- ☐ Injectable-induced sciatic nerve damage
- ☐ Other consequences of the care provided

General
- ☐ Worse course of evolution of the baseline disease
- ☐ Need of repeating the procedure or the visit
- ☐ Anxiety, stress or depression

Medication-related
- ☐ Nausea, vomiting or diarrhea secondary to medication.
- ☐ Upset stomach or stomachache (epigastralgia)
- ☐ Pruritus, rash or skin lesions reactive to drugs or bandages
- ☐ Systemic allergic reactions
- ☐ Drug-induced headache
- ☐ Drug-induced neurological changes
- ☐ Constipation
- ☐ Other secondary effects (cough, dyspnea, dry mouth…)
- ☐ Drug-induced hypotension
- ☐ Poor blood pressure control
- ☐ Upper digestive tract hemorrhage
- ☐ Anticoagulation-related hemorrhage
- ☐ AMI, CVA, PET, DVT
- ☐ Electrolyte imbalance
- ☐ Edema, cardiac insufficiency and shock
- ☐ Drug-induced change in heart rate of electrical activity
- ☐ Functional change (renal, hepatic, thyroid, …)
- ☐ Poor control of glycemia
- ☐ Neutropenia
- ☐ Local effects or fever after vaccine or drug
- ☐ Poor pain management

Others
- ☐ Other consequence

- ☐ **No effect**

6. What care was dispensed to the patient as a result of the adverse effect?
- ☐ The care was not affected.
- ☐ Required a higher level of observation and monitoring in PC
- ☐ Required an additional test (X-ray, analysis, …) in PC
- ☐ Additional medical or surgical treatment (antibiotics, minor surgery, …) in PC
- ☐ Required a further office visit or referral to Specialized Care or the Emergency Room without hospitalization
- ☐ Requires hospitalization. Life-support treatment (orotrachael intubation, CPR, surgical intervention).

7. Please mark all of the causal factors of the adverse effect

Medication-related
- ☐ ADR

Medication-related errors
- ☐ Wrong medication
- ☐ Incorrect dose
- ☐ Missed dose, medication or vaccine
- ☐ Incorrect frequency of administration
- ☐ Error in preparation or handling
- ☐ Insufficient monitoring
- ☐ Dispensing error
- ☐ Wrong patient
- ☐ Incorrect duration of treatment
- ☐ Failure to adhere to treatment
- ☐ Drug interaction

Management-related
- ☐ Clinical record duplicated
- ☐ Lost documents
- ☐ Mistake in the health information (Other patients'' test results)
- ☐ Error in patient identification
- ☐ Long waiting list
- ☐ Problems with the computerized record
- ☐ Scheduling error

Diagnosis-related
- ☐ Error in diagnosis
- ☐ Delay in referral to specialized care
- ☐ Delay in the diagnosis

Communication-related
- ☐ Physician-patient communication
- ☐ Physician-nurse communication
- ☐ Nurse-patient communication
- ☐ Physician-physician communication
- ☐ Language barrier
- ☐ Another different from the above

Care-related
- ☐ Improper handling of the patient
- ☐ Improper handling of the warning signs
- ☐ Improper handling of the technique
- ☐ Improper catheter care

Others
- ☐ Other causes

8. To what extent has the care provided been the cause of the harm?
- ☐ 1. No evidence of the incident being due to how the patient was handled
  The harm is due completely to the patient's disease
- ☐ 2. Minimal probability of the how patient was handled having been the cause
- ☐ 3. Slight probability of how the patient was handled having been the cause
- ☐ 4. Moderate probability of how the patient was handled having been the cause
- ☐ 5. Highly probable that the handling was the cause
- ☐ 6. Full evidence of how the patient was handled having been the cause of the incident/adverse effect

9. In your judgment, is there any evidence of it having been possible for the Adverse Effect to have been prevented? ☐ Yes ☐ No

10. Please score the evidence of the possibility of prevention on a 1-6 point scale
- ☐ 1. No evidence of preventability
- ☐ 2. Minimal possibility of having been prevented
- ☐ 3. Slight possibility of having been prevented
- ☐ 4. Moderate possibility of having been prevented
- ☐ 5. Highly possible to have been prevented
- ☐ 6. Full evidence of preventability

11. What could have been done to prevent this problem?

_____ _____

Annex 3

User's Manual:
APEAS Database Version 1.0

System Requirements

Windows 95/98/NT4/2000/ME/XP
.Net Framework 2.0
MDAC 2.8
Crystal Report for Net 2.0

Installation

To install APEAS:
Insert the CD
The installation process will start automatically.
When the system asks if you want to install the application, select "install".
The program will then be installed and will start automatically.

To uninstall APEAS:

Click on the “Start” button
Select “Configuration” > “Control Panel”
Double click on “Add / Remove Programs”
Click on “Change / Remove”
Check to be certain that the “Remove the program from this System” is marked and select “OK”.

To Start using the program, go to “Start → Programs → Galysoft → APEAS

New Case:

By default, when the program starts up, it is ready for entering the data for a new case.

Next, complete the “General” tab information.

To go from one control to another, you may use the TAB key on your keyboard. Once you have completed all of the data you consider pertinent for this tab, go on to the next tab. To go to the next tab, either click on the tab or on the “Page Up” button. As before, complete the date for all of the other tabs, until the 10 questions have been answered. It is recommended that you not forget to save the data every now and again using the buttons you may find either on the toolbar or on the “File” menu so as not to lose any data due either to a program error or any other problem with your PC.

Once you have entered all the data you consider pertinent for one case, you may then go on to entering the data for another case by selecting the “New Case” button.

Edit an existing questionnaire

You can navigate through the data of each case by using the navigator control scroll buttons.

As you go through the cases, their data will be progressively updated on the corresponding controls.

If you have any trouble finding a case, you can use the “Select Case” button.

Then, a new window will open up with a grid, where you will be able to see the general data of the different cases you have saved.

To put the cases in order by some of the available fields, just click on the header of the column in question.

After you have found the case you were looking for, select the corresponding record by clicking on it and selecting “Open”. Now, the file sheet for the case in question will open and you can read / edit the data.

Remember to save whatever changes you make.

Preview a Case printout

If you would like to see how the information for a case will look on hard copy before printing it, you can open the preview window by pressing the button located at the bottom.

A window will then open up where you will be able to see how the data will look when it is printed.

Preview the printout of a Case

If you would like to print the information for a case, just open the file for the case in question and press the button located at the bottom, next to the navigator control.

The Windows dialogue when then be displayed, where you will be able to select the printer you wish to use for printing the case. Select the printer from the list and then press “Okay”.

Export questionnaire data

If, for any reason, you need to retrieve the data for a case from the program, you can convert the information into the following formats:

Portable Document (PDF)
Crystal Report
Microsoft Word
Microsoft Excel
RTF

To do so, open the case preview and press the button located to the left.

In the next window, select the location of the file and the type of format.

Send results

Once you have all of the information entered into the program, you can send it to us by exporting the data and e-mailing it to us as the address stated on the documentation provided with the CD.

To send the data, open the “File” menus and either select the “Export” option or press “CTRL +E”.

Next, select the file location and the name of the file to which the data is going to be exported. Then, press “Okay”.

The next step will be to send this file you have just generated by attaching it to an e-mail message using your usual program.

Annex 4. Literature Review

Patient Safety – Adverse Effect
Primary Care

Contents

Aspects comprising the research

The care quality, clinical safety and health care-related adverse event prevention areas have undergone remarkable bibliography-related growth over the past few years. This Annex presents the results of a systematic bibliographic search which has been used as a script by the 10th Unit of "Aibar C. Aranaz JM, Seguridad del paciente y prevención de efectos adversos [Patient Safety and Preventing Adverse Effects] (CD-ROM). Madrid: Ministry of Health and Consumer Affairs; 2007". Reference texts, journals which usually publish articles on this subject or which have monographic studies, series or collections of articles on this topic and databases: PubMed, LILACS and IME have been consulted.
The terms used were: Patient safety, Adverse Effect and Primary Care. These terms were entered in the search using natural language, with the Thesaurus descriptors (MeSH; controlled vocabulary) and with a combination of these two methods.

Selection of the databases and sources consulted

Reference Journals

British Medical Journal

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- **Advanced search throughout entire BMJ**, using a natural language to enter the different concepts. The search strategy was: “patient safety” AND “adverse events” AND “ambulatory care”]
Results:

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- Special search on reducing errors and improving safety. BMJ 2000 Mar 18; 320(7237):759-763.
Results:

(página 115)

- Special search on patient-focused care. BMJ 2003 Jun 14:326 (7402).
The search strategy was: “patient safety” AND “adverse events” AND “ambulatory care”]
No related article.

- Special search on Risk Reporting. BMJ 2003 Sep 27;327(7417).
The search strategy was: “patient safety” AND “adverse events” AND “ambulatory care”]
Results:

- Special search on injuries and benefits of medical care. BMJ 2004 Jul 3; 329 (7456).
No related article.

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New England Journal of Medicine

Search strategy: “ambulatory care “patient safety”.
Results:

Search strategy: “ambulatory care “adverse events”.
Results:

Search strategy: “primary care” “medical errors”.
Results:

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JAMA

Search strategy: Patient Safety and Ambulatory care.
Results:

Search strategy: Patient Safety and Primary care.
Results:

Search strategy: Medical errors.
Results:

Search strategy: medical errors and ambulatory care
Results:

(página 117)

Revista de Calidad Asistencial (Care Quality Journal)

Search strategy: Adverse events and Ambulatory care.
Results:

Search strategy: atención primaria y seguridad del paciente (primary care and patient safety)
Results:

Quality and Safety in Health Care

Search strategy: ambulatory and care adverse events
Results:

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Search strategy: Primary care adverse events.
Results:

Search strategy: errors and general practice.
Results:

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Medline

Selection of the descriptor terms and their combinations and analysis of the findings.
As this is an in-depth search, the aim was to retrieve all of the articles found on using the different combinations in the search strategy. This fact has led to a high percentage of duplicated articles, the articles having been singled out therefore being presented in the last section (Summary of the findings). In said results, those more specifically related to the components of the search initially set out are highlighted in bold face print. The search was conducted in natural language, with the descriptors of the Thesaurus (MeSH; controlled vocabulary) and with a combination of the two methods.

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Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Safety management and ambulatory care, respectively.

Search strategy:
"Safety Management" [Mesh] AND "Ambulatory Care"[Mesh].
Results: 47 articles (unlimited).
Results limited by language (English, French, German, Italian, Spanish) of the article: 44 articles.

(página 122)

Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Risk management and ambulatory care, respectively.
Results: 400 articles.
Restricting by patient safety with the following search strategy:
"Safety Management"[Mesh] AND "Ambulatory Care"[Mesh] AND "Risk Management" [Mesh]
Results: 47 articles (unlimited).
Restricting my language (Spanish, English; French, German, Italian): 44 articles.

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Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Safety management and ambulatory care facilities, respectively.
Search strategy: “Ambulatory Care Facilities” [Mesh] AND “Safety Management” [Mesh].
Results: 63 articles.
Restricting by language: 61 articles.

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Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Risk management and ambulatory care facilities, respectively.
Search strategy: “Ambulatory Care Facilities” [Mesh] AND “Risk Management” [Mesh].
Restricting by language: 375 articles (articles).

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Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Safety management and outpatient clinics, respectively.
Search strategy: “Safety Management” [Mesh] AND “Outpatient Clinics, Hospital”[Mesh].
Results: 9 articles.
Restricting by language: 7 articles

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Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Risk management and outpatient clinics, respectively.
Search strategy: “Risk Management” [Mesh] AND “Outpatient Clinics, Hospital”[Mesh].
Results: 105 articles.
Restricting by language: 103 articles

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Search terms: Adverse events, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse events” AND “ambulatory care” AND “patient safety”.
Restricting by language: 9 articles

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Search terms: Medical errors, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “medical errors” AND “ambulatory care” AND “patient safety”.
Results: 22 articles

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Search terms: medical error (sing.), ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “medical error” AND “ambulatory care” AND “patient safety”.
Results: 2 articles (limits by language)

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Search terms: Adverse event (sing.), Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse event” AND “ambulatory care” AND “patient safety”.
Results: 3 articles (limit by language)

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Search terms: Adverse events, Primary care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse events” AND “ambulatory care” AND “patient safety”.
Results: 9 articles (limiting language)

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Search terms: Adverse event (sing.), Primary care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse event” AND “primary care” AND “patient safety”.
Results: 2 articles (limiting language)

(página 140)

Search terms: Malpractice, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “malpractice” AND “ambulatory care” AND “patient safety”.
Results: 2 articles (limits by language)

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Search terms: Negligence, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “negligence” AND “ambulatory care” AND “patient safety”.
Results: 1 article (limiting language)

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Search terms: diagnostic errors, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “diagnostic errors” AND “ambulatory care” AND “patient safety”.
Results: 3 articles (limiting language)

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Search terms: medication errors, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “medication errors” AND “ambulatory care” AND “patient safety”.
Results: 15 articles (limiting language)

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Search terms: prescribing errors, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “prescribing errors” AND “ambulatory care” AND “patient safety”.
Results: 0 articles (limiting language)

(página 143)

Search terms: iatrogenic disease, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “iatrogenic disease” AND “ambulatory care” AND “patient safety”.
Results: 3 articles (limits by language)

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Search terms: adverse effects, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse effects” AND “ambulatory care” AND “patient safety”.
Results: 10 articles (limiting language)

(página 144)

Search terms: adverse drug reaction reporting systems, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “adverse drug reaction reporting systems” AND “ambulatory care” AND “patient safety”.
Results: 7 articles (limits by language)

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Search terms: drug interactions, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “drug interactions” AND “ambulatory care” AND “patient safety”.
Results: 3 articles (limiting language)

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Search terms: postoperative complications, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “postoperative complications” AND “ambulatory care” AND “patient safety”.
Results: 1 article (limits by language)

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Search terms: clinical competence, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “clinical competence” AND “ambulatory care” AND “patient safety”.
Results: 1 article (limits by language)

(página 145-146)

Search terms: health services research, Ambulatory care and Patient safety

Without using controlled vocabulary.
Search strategy: “health services research” AND “ambulatory care” AND “patient safety”.
Results: 7 articles (limiting by language)

(página 146)

Search terms: Adverse events and Ambulatory care

Using the controlled vocabulary: Safety Management and domiciliary care, respectively
Search strategy: “Safety Management” [Mesh] AND domiciliary care.
Restricting by language: 100 articles.
Results: 7 articles (limiting by language)

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Search terms: culture, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “culture” AND “ambulatory care” AND “patient safety”.
Results: 11 articles (limit by language)

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Search terms: organisational culture, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “organisational culture” AND “ambulatory care” AND “patient safety”.
Results: 0 articles (limits by language)

(página 153)

Search terms: culture of safety, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “culture of safety” AND “ambulatory care” AND “patient safety”.
Results: 0 articles (limits by language) the same 11 as using culture of safety.

(página 153)

Search terms: health care quality, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “health care quality” AND “ambulatory care” AND “patient safety”.
Results: 1 article (limiting language).

(página 153)

Search terms: quality improvement, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “quality improvement” AND “ambulatory care” AND “patient safety”.

Results: 7 articles (limit by language).

(página 154)

Search terms: risk analysis, Ambulatory care and Patient safety.

Without using controlled vocabulary.
Search strategy: “risk analysis” AND “ambulatory care” AND “patient safety”.
Results: 0 articles (limiting language).
Without using controlled vocabulary.
Search strategy: “health services research” AND “ambulatory care” AND “patient safety”.
Results: 7 articles (limit by language).

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Epidemiological Studies on Patient Safety in Primary Care

Search strategy: “adverse events” AND (incidence OR prevalence OR frequency) AND (primary care OR ambulatory care).
Results:

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Search strategy: “error” AND (incidence OR prevalence OR frequency) AND (ambulatory care OR ambulatory care facilities OR ambulatory care information systems OR out patient clinics hospital OR general practice OR primary care).
Results: 126 articles.

(página 157)

Search strategy: “adverse event” AND (incidence OR prevalence OR frequency) AND (ambulatory care OR ambulatory care facilities OR ambulatory care information systems OR out patient clinics hospital OR general practice OR primary care).
Results: 56 articles.

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Search strategy: “patient safety” AND (incidence OR prevalence OR frequency) AND (ambulatory care OR ambulatory care facilities OR ambulatory care information systems OR out patient clinics hospital OR general practice OR primary care).
Results: 39 articles.

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Search strategy: “medical errors” AND (incidence OR prevalence OR frequency) AND (ambulatory care OR ambulatory care facilities OR ambulatory care information systems OR out patient clinics hospital OR general practice OR primary care).
Results: 43 articles.

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Articles on Adverse Effects Related to the Prescribing of Medications in Primary Care:

(página 160)

Articles on Adverse Effects Related to the Prescribing of Medications in Primary Care:

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LILACS

Search strategy: efectos AND adversos AND atencion AND paciente

Results: 6 articles

Search strategy: errores AND diagnosticos

Results: 26 articles

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ÍNDICE MÉDICO ESPAÑOL (SPANISH MEDICAL INDEX)

Results:

(página 163)
Search strategy: efectos adversos and Atención ambulatoria = 0; efectos adversos and seguridad del paciente = 1
Search terms: efectos adversos and atención primaria.
Results: 18 articles

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Search strategy: Atención primaria and error diagnóstico = 4 articles

(página 163)
Search strategy: "seguridad del paciente" in the title.
Results: 11 articles.

(página 164)
Search strategy: "calidad asistencial" in the title.
Results: 177 articles.

(página 164)
Summary of the findings.

1: **Woods DM, Thomas EJ, Holl JL, Weiss KB, Brennan TA. Ambulatory care adverse events and preventable adverse events leading to a hospital admission. Qual Saf Health Care. 2007;16(2):127-31.**
- Review journal Quality and Safety in Health Care.

2: **Borrell-Carrió F, Páez Regadera C, Suñol Sala R, Orrego Villagan C, Gil Terrón N, Martí Nogués M. Errores clínicos y eventos adversos: percepción de los médicos de atención primaria. Aten primaria. 2006;38(1):25-32.**
-"Atención primaria" and "error diagnostico" in Índice Médico Españoñ.

3: **Rubin G, George A, Chinn DJ, Richardson C. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Qual Saf Health Care 2003;12(6):443-7.**
- Review journal Quality and Safety in Health Care.

Annex 5

Research Ethics Committee Approval

AUTONOMOUS COMMUNITY
GOVERNMENT OF ARAGON
Department of Health and Consumer Affairs

COMITÉ ÉTICO DE INVESTIGACIÓN
CLINICA DE ARAGON (CEICA)
Avda. Gómez Laguna, 25 planta 3
50009 Zaragoza

I, María González Hinjos, the Secretary of the Clinical Research Ethics Committee of Aragón,

DO HEREBY CERTIFY

That the research project titled "National Study on Patient Safety in Primary Health Care (Apeas-Eneas-2 Study)"

Principal Investigator: Dr. Jesús María Aranaz Andreés

Has been evaluated by this Committee and, following the review of the documentation submitted, this CREC resolves to render a FAVORABLE OPINION concerning the conducting of the study in question, as is stated in the Meeting Minutes 20/2007 of November 28, 2007 and so informs the principal investigator of the project in this regard.

To which I set my hand in Zaragoza on this the 5th day of December of 2007.

María González Hinjos

AUTONOMOUS COMMUNITY
GOVERNMENT OF ARAGON
Department of Health and Consumer Affairs

COMITÉ ÉTICO DE INVESTIGACIÓN
CLINICA DE ARAGON (CEICA)
Avda. Gómez Laguna, 25 planta 3
50009 Zaragoza

COMPOSITION OF THE CLINICAL RESEARCH ETHICS COMMITTEE OF ARAGON

I, Dr. María González Hinjos, the Secretary of the Clinical Research Ethics Committee of Aragón,

DO HEREBY CERTIFY

1. At the meeting held on November 28, 2007, Meeting Minutes No. **20/2007,** the requirements set forth under the laws in force – Royal Decree 223/2004 and Autonomous Community Government of Aragon Decree 26/2003, amended by Decree 292/2005, were met in order for the decision of the aforesaid CREC to be valid.

3. The CREC of Aragón meets the GCP standards regarding both the composition and the SWP thereof.

4. The composition of the CREC of Aragón on the aforesaid date was as follows:

- **Chairman:** Cesar Loris Pablo, M.D. Pediatrics Department. Miguel Servet University Hospital. Representing the Research Commission.
- **Deputy-Chairman:** Carlos Aibar Remón, M.D. Preventive Medicine and Public Health Department. Hospital Clínico Universitario Lozano Blesa. Medical Professional expert in clinical epidemiology.
- **Secretary:** María González Hinjos. Pharmacist.
- Pilar Comet Cortés. Nurse. Combined Research Department. Hospital Clínico Universitario Lozano Blesa.
- Marina Heredia Ríos. Representing the Consumer and User Organizations.
- Gabriel Hernández Delgado, M.D. Radiology Department. Miguel Servet University Hospital. Representing the Research Commission.
- Angela Idolpe Tomás. Pharmacist. Pharmacy Department. Miguel Servet University Hospital. Hospital Pharmacist.
- María Jesús Lallana Álvarez. Primary Care Pharmacist. Zaragoza District III.
- Jesús Magdalena Bello, M.D. Azuara Healthcare Center. Practicing physician, representing the Healthcare Ethics Committee of Primary Care Districts II and V.
- Esteban de Manuel Keenoy, M.D. Aragon Health Sciences Institute. Representing the Aragon Health Sciences Institute.
- Mariano Mateo Arrizabalaga, M.D. Clinical Pharmacology Department. Hospital Clínico Universitario Lozano Blesa.
- Javier Perfecto Ejarque, M.D. Arrabal Healthcare Center. Practicing physician.
- Alexandra Prados Torres, M.D. Aragon Health Sciences Institute. Representing the Research Commission.
- José Puzo Foncillas, M.D. Biochemistry Department. San Jorge General Hospital. Representing the Research Commission.
- Susana Torrente Fari. Attorney. Center for Social Studies. Law Degree. Unrelated to the health care profession.

For the record wherever befitting, at the request of the sponsor,

Zaragoza – November 28, 2007

Signature: María González Hinjos

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Primary Care (PC), the gateway to the health care system for patients, is the level of care used most by the population, the highest frequentation figures in Europe being in Spain.

The APEAS Study has undertaken the analysis of the frequency and type of Adverse Effects in Primary Care. Special mention must be made as to this being one of the first studies to deal with this problem at health care centers, taking in a wide-ranging sample of medical and nursing office visits.

The findings provided in this report reveal clinical practice in Primary Care to be reasonably safe, the frequency of Adverse Effects to be low and those Adverse Effects of a minor type to be predominant.

Preventing Adverse Effects in Primary Care reveals itself to be a top-priority strategy, given that 70% of the Adverse Effects are preventable, and the more serious the Adverse Effects, the more preventable (by up to 80%) they are.

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