

Patient Safety Strategy for the National Health System

2015-2020 Period

HEALTH 2015

MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

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PRESENTATION

The Ministry of Health, Social Services and Equality (MSSSI) fosters and promotes the Patient Safety Strategy for the National Health System (NHS), which has been being carried out as of 2005 in collaboration with the Health Regions and the Instituto Nacional de Gestión Sanitaria (INGESA), integrating the contributions of the health care professionals and of the patients by way of their organizations.

The objectives of this strategy are initially aimed at promoting and further enhancing patient safety culture in the health care organizations, incorporating health care risk management, training the professionals and patients in basic aspects of patient safety, implementing safe practices and getting patients and citizens actively involved.

After ten years of the Patient Safety Strategy development , this update is being set out for a further five-year period (2015-2020), in order to provide an overview of what has previously been done and to facilitate decision making on the basis of a consensus reached about Patient Safety for the NHS for this new period.

The process of assessing what has already been done entails recognizing that: the established collaboration, with the Health Regions, has worked efficiently Health Regions; the contributions of the professionals and their organization has turned out to be crucial; the scientific societies have played a key role; and that the patients and their organizations have been an innovative element having afforded the possibility of making progress in patient empowerment.

The update presented herein incorporates the strategic lines of action already set out, includes the current international recommendations on the subject of patient safety, incorporates the achievements and strong points attained, proposes objectives and recommendations based on the best available evidence, and proposes an assessment system on the basis of a consensus with the Health RegionsHealth Regions which will make it possible to measure the scope of this new strategy in a standardized manner.

The process of designing this strategy has been made possible thanks to the work of the scientific and technical coordinators of the strategy, the institutional

technical committee of the Health Regions which have assumed the commitment of taking on this update in a rigorous, thorough manner, as well as the professionals, through their scientific societies, and the patients who are taking part with their contributions and commitment and other experts from organizations interested in patient safety.

I would like to express my gratitude to all those who have taken part in the preparation of this document, which will undoubtedly contribute to further enhancing patient safety in the National Health System.

Alfonso Alonso Aranegui

Minister of Health, Social Services and Equality

INTRODUCTION

Further enhancing the quality of the health care provided has always been inherent to the NHS principles, as is inferred from Spain's National Health Law, Title I of which includes, as one of the measures to be carried out by the health care administrations, that of keeping a check on and further enhancing the quality of the health care provided at all levels thereof¹. This law served as the framework of reference on the subject of quality in the health care services, which has been further expanded upon under the laws and regulations of the different Health Regions over the past few years.

It was within this context and under the protection of the 2003 Law on Cohesion and Quality that the MSSSI began developing the NHS Patient Safety strategy in 2005 in collaboration with the Autonomous Community administrations, based on international recommendations and those of Spanish experts². This strategy, included in the 2006 Quality Plan³ has served as a tool and framework of reference for the process of deploying programs and actions which have progressively been being carried out in Spain with regard to patient safety.

One of the most important of this strategy's achievements worthy of special mention are that working networks and alliances created around patient safety with the Health Regions and INGESA, (when the text refers to the Health Regions generically it is understood that the INGESA included), the professionals and their scientific societies, the patients, the academic institutions and other organizations interested in this subject, which has favored patient safety being included in the quality plans of the Health Regions and the dissemination of the safety culture throughout the entire NHS. Projects have additionally been carried out which have afforded the possibility of gaining a better knowledge of the safety-related problems affecting the NHS and the tools for preventing and keeping a check on them.

There is still a great deal as yet to be done toward truly bringing about a change in the culture of the NHS health care organizations and in order for the leaders, the clinics and management organizations to become the driving force behind this change with the actual active involvement of the patients and their caregivers.

The patient safety strategy presented herein continues along the same line as that which has been being carried out to date, retaining the same strategic lines of

action and incorporating new objectives and recommendations regarding aspects pending further development. The process of preparing this strategy has taken into account: the current recommendations of the international organizations, the data available from ten years of having carried out the patient safety strategy, the information and opinions provided by the scientific coordinators for the current strategy, the Health Regions, the health care professionals (through the scientific societies having wished to collaborate), the patients (through the NHS Citizen Health Schools Network) and other experts consulted. This strategy is the consensus on patient safety of those mainly involved in the quality of the care provided by the National Health System.

TECHNICAL NOTE

This document is comprised of eight perfectly well-defined parts.

1. General aspects dealing with the justification of the Patient Safety Strategy, its purposes, the target population and the situation analysis set out by way of the magnitude and impact of the harm associated with the process of health care being provided, in conjunction with the interventions carried out at the national and international level.
2. Strategy lines maintaining the basic principles of the patient safety strategy already in the process of being carried out, incorporating objectives and new recommendations, on the basis of the assessment made as to the process of carrying out the strategy per se, the international recommendations and the opinions of experts, professionals and patients:
 - Line 1: Patient safety culture, human and organizational factors
 - Line 2: Safe clinical practices
 - Line 3: Management of the risk involved and systems for notification and learning from the incidents
 - Line 4: Participation of the patients and citizens for their safety
 - Line 5: Research in patient safety
 - Line 6: International participation
3. Evaluation including a brief description of the components of the evaluation of this strategy which will comprise a separate document.
4. Glossary of the terms used in the text related to the safety and quality of the health care provided.
5. Abbreviations and acronyms
6. List of tables
7. List of figures
8. Bibliography

1. GENERAL ASPECTS

a. Justification

Patient safety, a key dimension of quality of the health care, involves carrying out strategies for reducing all unnecessary harm to patients associated with health care.

The 1999 American Medical Institute report⁴ led to several governments and international health care organizations making patient safety one of their health policy priorities. Hence, the World Health Organization launched the “Alliance for Patient Safety” in 2004, promoting actions, tools and recommendations for further enhancing the safety in all countries worldwide⁵. In 2006, the Council of Europe urged countries to develop policies, strategies and programs for further enhancing patient safety in their health care organizations⁶. In June 2009, the European Council launched the “Council Recommendations on patient safety, particularly preventing and combatting health care-associated infections”⁷.

In keeping with the international recommendations, the MSSSI made the decision in 2005 to carry out a patient safety strategy for the NHS in collaboration with the Health Regions, respecting and further rounding out the actions which are currently being carried out thereby in the exercise of their authorities in the provision of health care services.

The objectives of this strategy have mainly been aimed at further enhancing the patient safety culture and health care risk management, the training of the professionals, the implementation of safe practices, the active involvement of the patients and citizens and international participation.

The epidemiological studies carried out within the framework of this strategy and the data from the evaluation of the programs and actions promoted at the national and regional level afford precise valid knowledge as to the degree of patient safety in the NHS².

After ten years of carrying out this strategy, this update is being set out as a tool for facilitating the process of analyzing, thought being given to and decisions being made on the basis of a consensus reached concerning Patient Safety for the NHS in accordance with the new needs set out and taking the current situation into account.

The strategy presented herein is focused along the same lines as the preceding one, and the strategic lines of action proposed are based on the work previously carried out in the NHS as well as on the current international recommendations and needs detected by the Health Regions and other parties who have an interest in this subject.

b. Purpose of the strategy: mission, vision and overall objective

Vision:

This strategy is aimed at being a reference point element for the further enhancement of patient safety in the NHS, taking into account the evidence available from the recommendations made, the feasibility of their implementation, as well as the equity and sustainability of the system.

Mission:

Setting objectives and making recommendations aimed at minimizing the risks involved in the process of providing health care and reducing health care-related harm.

Overall Objective:

Further enhancing patient safety at all levels in all settings in which care is provided in the National Health System.

c. Target population

This strategy targets all patients and citizens for whom health care is provided within the NHS, the professionals (both clinical and managerial), the health care organizations and providers in the NHS and all those academic institutions and agents involved in further enhancing patient safety in Spain.

d. Situation analysis

i. Magnitude and impact of health care-related harm

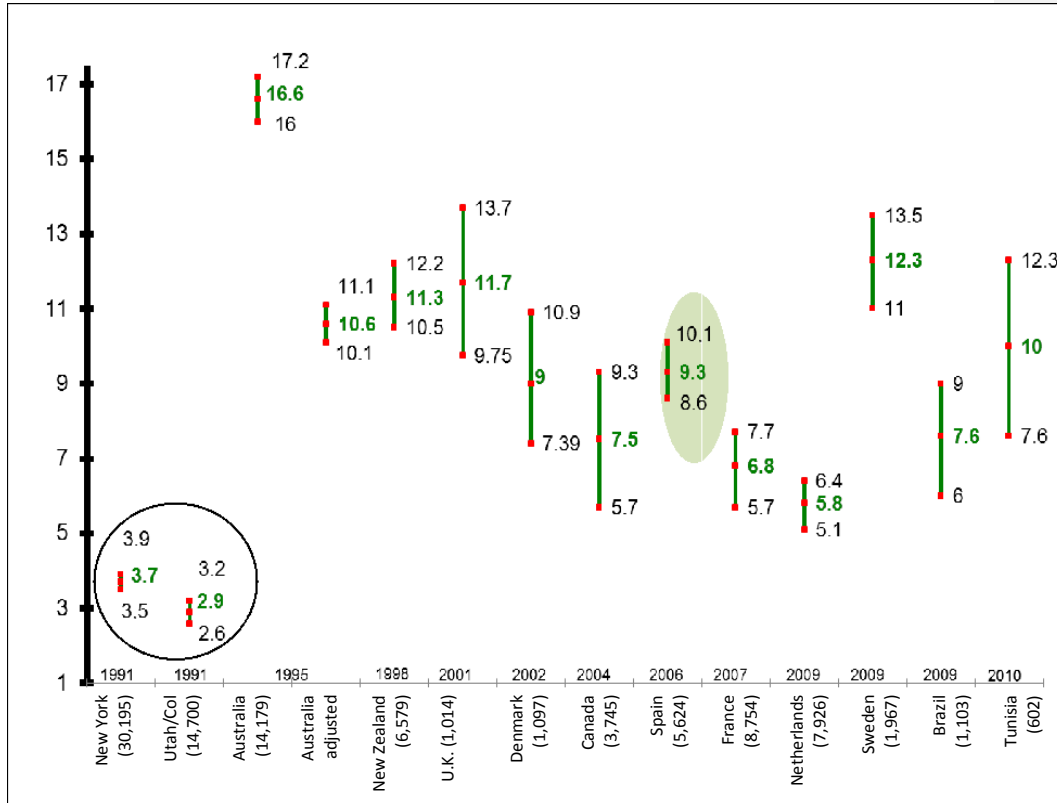
➤ Frequency of adverse events

Different epidemiological studies published as of the 1990's have made a major contribution toward ascertaining the magnitude, impact and characteristics of health care-related adverse events^{8,9,10,11,12,13,14,15,16,17,18,19,20}. The different objectives set and the different methodologies employed in these studies are the reason for the differences found in the frequency of adverse events (Fig. 1).

A systematic review of the year 2008 revealed the average incidence of hospitalization-related adverse events to have been 9.2% (95% CI: 4.6% – 12.4%), a total of 43.5% (95%CI: 39.4% – 49.6 %), of which could have been prevented. A total of 7% of the adverse events identified could lead to a permanent disability, and 7.4% could be directly related to the patient's death²¹. Despite harm apparently being caused infrequently to patients, some experts point out that this data may be underestimated, given that these studies do not include the adverse events following discharge from hospital²². On the other hand, some experts also recommend the need of using different methodologies so as to be able to better detect the occurrence of adverse events²³.

In the European Union, the frequency of adverse events among hospitalized patients is within the 8% - 12% range²⁴, one death being caused for every 100,000 inhabitants per year as a result of said adverse events, meaning around 5,000 deaths per year. Nevertheless, it seems that these figures could also be underestimated, because they are based on data recorded by the professionals²⁵.

Fig. 1. List of studies conducted for the purpose of ascertaining the incidence of adverse events in hospitals



The starting point for ascertaining the magnitude and the determining factors involved in healthcare risk in Spain have been the ENEAS¹⁵, APEAS²⁶, EARCAS²⁷ and SYREC²⁸ studies promoted by the MSSSI. The EVADUR²⁹ study carried out by the Spanish Society for Emergency Medicine has also provided useful information in the field of emergency care.

– **National Study on Hospitalization-Related Adverse Events (ENEAS Study):** A retrospective study of a cohort of 5,624 patients hospitalized at 24 public hospitals in Spain for more than 24 hours and discharged within the June 4-10, 2005 period (all inclusive). A total of 42,714 days of hospital stays were studied. The incidence of patients with adverse events related to the care provided was of 9.3% (525/5,624), (95%CI: 8.6% -10.1%). The incidence density was of 1.2 adverse events per 100 patients/day (95%CI 1.1 – 1.3). The actual incidence of patients with adverse events

related directly to the hospital care (not including those referred from primary care, external offices and caused at another hospital) was of 8.4% (473/5,624), (95%CI: 7.7% - 9.1%). Added to the actual incidence are those cases in which an adverse event had been the reason for admission to hospital in order to offset to some degree the losses for post-discharge adverse events.

A total of 37.4% of all adverse events were related to the medication, whilst nosocomial infections of any type totaled 25.3% and 25% were related to technical problems during a procedure. A total of 45% (n=295) of the adverse events were considered mild, 38.9% (n=255) moderate and 16% (n=105) severe. In all, 42.8% of the adverse events were considered preventable^{15,30,31,32}. (Table 1).

Table 1. Main ENEAS Study Data

Types of adverse events	N	%	Preventable
Care-related	50	7.63	56.0
Pressure ulcer	24	3.66	
Burns, scrapes and contusions (including consequent fractures)	19	2.90	
Acute pulmonary emphysema and Respiratory failure	4	0.61	
Other consequences of extended bedridden situation	3	0.46	
Medication-related	245	37.4	34.8
Nausea, vomiting or diarrhea secondary to medication	32	4.89	
Itching, rash or skin irritations reactive to drugs or bandages	32	4.89	
Other drug side effects	29	4.43	
Uncontrolled glycaemia	19	2.90	
Hemorrhage due to anticoagulation	18	2.75	
Others	104	15.89	
Nosocomial infection-related	166	25.34	56.6
Surgical wound infection	50	7.63	
Nosocomial urinary tract infection	45	6.87	
Other type of nosocomial infection or an unspecified nosocomial infection	22	3.36	
Sepsis and septic shock	19	2.90	
Nosocomial pneumonia	17	2.60	
Device-related bacteremia	13	1.98	
Procedure-related	164	25.04	31.7
Hemorrhage or hematoma related to surgical intervention or procedure	61	9.31	
Injury to an organ during a procedure	20	3.05	
Other complications following surgical intervention or procedure	14	2.14	
Ineffective or incomplete surgical procedure	11	1.68	
Uterine rupture	9	1.37	
Others	49	7.48	
Diagnosis-related	18	2.75	84.2
Delayed diagnosis	10	1.53	
Diagnostic error	8	1.22	
Others	12	1.83	33.4
Pending being specified	7	1.07	
Other adverse events	5	0.76	
Total	655	100.00	42.6

– **Study on patient safety in primary care (APEAS Study):** A prevalence study conducted on an opportunity sample from 48 primary care centers in 16 Health Regions, in which 452 professionals took part. A study was conducted of the 96,047 patients who came in for appointments over the course of a two-week period in June 2007.

The observed prevalence of adverse events was of 11.18‰ of the primary care consultations (95%CI: 10.52 – 11.85). The prevalence of patients having some adverse event was of 10.11‰ (95%CI: 9.48 – 10.74). A total of 6.7% of the patients had more than one adverse event. A total of 54.7% (n=606) of the adverse events were considered mild, 38.0% (n=421) moderate and 7.3% (n=81) severe.

A total of 47.8% of the adverse events (n=530) were medication-related, 8.4% (n=93) involving health care-associated infections of any type, a total of 10.6% (n=118) being related to some procedure and 6.5% (n=72) to the care provided.

The majority of the adverse events (64.3%) were considered preventable, and solely 5.9% were severe, the majority being medication-related^{33,34}.

– **Adverse events at social health centers and nursing homes (EARCAS Study):** A qualitative study conducted in several stages aimed at evaluating an initial approach to patient safety in average-length-of-stay and extended-stay hospitals and social services in Spain, in which more than 950 experts from nearly 100 centers and institutions from all of Spain's Health Regions took part.

According to the study findings, the most common incidents and adverse events are related to the care provided to the patients, the use of medication and health care-associated infections. The most outstanding factors which contribute to the onset of these incidents and adverse events are those related to the patient's vulnerability.

The magnitude of this problem, set out in the study findings, reveals the need for identifying and carrying out strategies for further enhancing patient safety in the social services and medical care settings²⁷.

– **Incidents and adverse events in intensive care medicine. Safety and risk in the critical patient (SYREC Study):** A prospective cohort study conducted on 79 Spanish intensive care units based on the reporting of incidents by the professionals proper. The risk of experiencing a harmless incident as a result of being admitted to an intensive care unit, given as a median figure, was of 73%, and a 40% risk of experiencing an adverse event. The adverse events which occurred most frequently

were those related to care provided and health care-associated infections. A total of 90% of all the harmless incidents and 60% of the adverse events were classified as preventable or possibly preventable³⁵.

– ***Adverse events linked to the care provided in Spain's hospital emergency services (EVADUR Study):*** A prospective study conducted on 21 emergency services within the October – December 2009 period. The health care provided to a sample of 3,854 patients was followed over the course of a seven-day period. At least 12% of the patients for whom care was provided in an emergency service were affected by an incident, and 7.2% experienced an incident involving harm. Evidence was found of improper action in 54.6% of these cases. The factors associated with the incidents were related to the use of medications, delayed diagnosis and breakdown in communication. A total of 70% of the adverse events were considered preventable²⁹.

Table 2 provides a summary of the characteristics and main findings of these studies.

Table 2. Spanish studies on the frequency of adverse events in different health care-providing settings

Study	Year data collected	Type of study	Scope	Total AEs (%patients)	Most frequent AEs	% of AEs preventable
ENEAS ¹⁵	2005	Historic cohorts	24 Hospitals	9.3%	Medication (37.4%) HAIs (25.3%) Procedures (25%)	50%
APEAS ²⁶	2007	Prevalence	48 Primary Care Centers	10.11%	Medication (47.8%) Baseline disorder evolved for the worse (19.9%) Procedures (10.6%)	70%
EARCAS ²⁷	2010- 2011	Qualitative	Social services medical services centers and living facilities	--	Care, Medication HAIs	---
SYREC ²⁸	2007	Prospective cohorts	79 ICUs/ 76 Hospitals	33.1%	Care (26%) HAIs (24%) Medication (12%)	60%
EVADUR ²⁹	2009	Prospective	21 Emergency Services	7.2%	Care-providing process (46.2%), Medication (24.1%) Procedures (11.7%)	70%

- ENEAS: National Study on Hospitalization-Related Adverse Events - APEAS: Study on Adverse Events in Primary Care
- EARCAS: Adverse Events at Social Services Medical Services Centers and Living Facilities - SYREC: Safety and Risk in the Critical Patient
- EVADUR: Adverse Events in Emergency Care -AE: Adverse event. – HAIs: Health care-associated infections

According to the results of these studies, it can be said that the incidence of adverse events related to the care provided and the spread by categories in Spain's hospitals is similar to that of the studies conducted in American and European countries employing a similar methodology. The ENEAS Study served to make following the recommendations based on evidence a strategic priority on the NHS agenda, to disseminate best practices and to put the available knowledge into practice as a guarantee of clinical safety. The APEAS study served the purpose of revealing that, although the frequency of adverse events was low and severe to only a scarce degree at the primary level, the multi-causal etiology, the high probability of prevention and the existing high degree to which primary care is frequented warranted undertaking actions aimed at further enhancing patient safety at this care-providing level.

➤ Citizen opinions

A total of 53% of all European Union citizens are of the opinion that they could be harmed on undergoing hospital care (40% in outpatient care). Additionally, a total of 27% of those surveyed (23% in Spain) stated that either they themselves or their caregivers have been harmed at some time in the process of hospital care³⁶.

In Spain, the Health care Barometer conducted in 2010 revealed that 11.7% of those surveyed reported either they, themselves, or their caregivers having experienced an error during the consultation with the specialist, 11.5% during a hospital stay, 9.6% in a primary care consultation and 8% in the emergency services³⁷.

➤ The cost of adverse events

In view of the difficulty of assessing the cost of the harm involved in providing health care and the savings entailed on implementing patient safety programs, a recent publication suggests several tools for assessing the costs associated with adverse events and the cost-effectiveness of the practices for their prevention³⁸.

In Spain, two articles published are worthy of special mention. The first article estimates that the costs of unsafeness related to medication, nosocomial infection and surgical procedures in hospitalized patients in 2011 has entailed 2.474 million euros for Spain's National Health System³⁹. This article based on the study of costs of unsafeness conducted by the MSSSI in 2008⁴⁰, for which the results as per the hospital revenues and the Consumer Price Index for 2011 were updated. The second article evaluates the economic impact of the incidence of adverse events on hospital care in Spain on the basis of the data at discharge from hospital of patients for whom care has been

provided by means of admission to the hospitals belonging to the Spanish Hospital Costs Network during the January 1, 2008 – December 31, 2010 period. The findings show the total incremental costs of the adverse events to be 88,268,906 €, an additional 6.7% added onto the total health care spending figure⁴¹.

In short, after nearly ten years of working on patient safety in Spain, we can say that:

- a) Sufficient knowledge exists regarding the frequency and distribution of the adverse events, as well as the contributing factors in all areas of health care: acute hospitals, intensive care, emergency care, average-length-of-stay and extended-stay hospitals and primary care.
- b) Around 9-12% of the patients for whom care is provided in hospitals, both in hospitalization and emergency care, and 1.2% of the patients for whom care is provided at primary care centers experience some adverse event related to the care provided. These figures are similar to those found to exist in other countries.
- c) The percentages of preventability, were the available knowledge to be put into practice, are of major importance, ranging from 50% to 70% depending on the type of adverse event and care-providing setting in question.
- d) Moderate to high-quality evidence exists as to the importance and usefulness of implementing safe practices and procedures. Very little research has however been done on the implementation and evaluation of these practices. In other words: we know what should be done, but we don't know if we are doing so to the extent it should be done⁴².
- e) It is estimated that the costs resulting from adverse events and the opportunities missed as a result of not doing what should be done add up to a major percentage of health care spending.
- f) In short, the adverse events related to the health care provided are a public health problem due to their magnitude, far-reaching importance and preventability.

ii. Interventions carried out at the international level

Patient safety has always been a focal point of the attention and efforts of the health care professionals and institutions ⁴³, although the importance thereof was particularly brought to fore as of the report “To Err Is Human: Building a Safer Health care System”, published in 1999 by the U.S. Medical Institute ⁴. This report served as a guide for the main international health care organizations for developing strategies and recommendation for cultivating the control of the preventable harm in health care.

INTERNATIONAL ORGANIZATIONS INTERESTED IN PATIENT SAFETY

Some of the most outstanding international organizations interested in patient safety which have had the greatest influence on Spain’s safety policies in particular are the World Health Organization, the Pan American Health Organization, the Organization for Economic Cooperation and Development, the European Council and the European Union institutions (particularly the European Commission).

- **World Health Organization (WHO)**

In 2004, the World Health Organization launched the World Alliance for Patient Safety, currently referred to as the Patient Safety Program, which includes different challenges and actions for further enhancing patient safety at the worldwide level, some of the most outstanding of which are:

- *Challenges:*

Programs dealing with significant risks for the patients for whom care is provided which are relevant for all of the countries pertaining to the World Health Organization:

- *Clean care is safer care*⁴⁴. Its top-priority objective is to assure that improving hand hygiene is on the agenda of the health care organizations for promoting the prevention of health care-associated infections and their consequences.
- *Safe surgery saves lives*⁴⁵. This program revolves around the surgical checklist as a tool for further enhancing safety in surgery.
- *Combatting antimicrobial resistance*⁴⁶. Third challenge launched by the World Health Organization in 2010 for promoting the reasonable use of antibiotics in humans, in veterinary medicine and agriculture and

promoting research in this field. As of May 2014, the World Health Organization undertook the commitment of developing a global plan for action for meeting the challenge with resistance to antibiotics means for human health⁴⁷.

○ *Main actions:*

Some of the main actions worthy of special mention are:

- Patients for patient safety. Aimed at creating a Patients and Consumers for Patient Safety Network⁴⁸.
- Reporting and learning systems⁴⁹. – Knowledge management⁵⁰.
- Safe clinical practices⁵¹.

In February 2012, the World Health Organization promoted a meeting in Geneva on Safety in Primary Care for the purpose of analyzing the data available on frequency, characteristics and possibilities of prevention and severity of adverse events and to assess the challenges in view of a situation of economic crisis and the possibility of setting up common studies among countries⁵². The participants placed top priority on a number of recommendations for further enhancing patient safety in primary care (Table 3).

Table 3. Top-priority recommendations for further enhancing patient safety in primary care

Top-priority recommendations in primary care
Training the professionals in patient safety
Promoting patient safety studies employing different methodologies
Developing policies for promoting patient safety in primary care
Improving the definitions concerning errors and their classification
Facilitating learning from past errors
Assuring that the systems for further enhancing patient safety in primary care are put into practice

On the road map to be followed, it was considered important to avail of some guidelines on patient safety in primary care by promoting a systematic focus on the same and making suggestions for improvement both in the management as well as the care-providing aspects.

The World Health Organization promoted the study *Prevalence of adverse events in Latin American hospitals (IBEAS Study)* carried out in collaboration with Spain's MSSSI and five countries in the region, being the first study to have been carried out on a large scale in Latin America for measuring the adverse events in the hospitals. The IBEAS study positioned Spain as a benchmark country in patient safety in the Spanish-speaking world^{53,54}.

- **Pan American Health Organization (PAHO)**

The Pan American Health Organization has been carrying out the Care Quality and Patient Safety Program⁵⁵ within the framework of which different projects have been carried out, some of the most noteworthy of which are:

- Systems for reporting incidents in Latin America which take in information on different reporting systems in the region and recommendation for their implementation and development.
- **Adverse Events in patients for whom care is provided in the outpatient care services in Latin America- AMBEAS Study.** The main objective of this research was to assess the feasibility of carrying out this type of studies in the region, as well as ascertaining the frequency, characteristics and preventability of adverse events among the population under study⁵⁶. This study was conducted

in response to the interest of the countries in the region in broadening the knowledge on patient safety and comprising part of the strategy lines set out under Resolution CSP27.R10 of October 5, 2007: “Regional Policy and Strategy for the Guarantee of Quality in Health Care, including patient safety”⁵⁷.

- **Organization for Economic Cooperation and Development (OECD)**

The Organization for Economic Cooperation and Development set up a working subgroup of patient safety indicators in 2007 for the purpose of developing homogeneous indicators on the basis of administrative databases which would make evaluation and comparison among countries possible^{58, 59}.

A study was conducted within the Spanish scope for the purpose of determining the empirical validity of the PS indicators and preventable hospitalization for the evaluation of the quality of the health care providers⁶⁰.

- **Council of Europe**

The Warsaw Declaration for Patient Safety of 2006 recommended including patient safety as a priority on the national and international agendas, cooperating with the Council of Europe⁶¹, the European Commission and the World Health Organization for assuring the implementation of patient safety actions.

It recommended the following strategy lines be carried out:

- Promoting a patient safety culture with a systematic focus
- Setting up incident reporting systems for learning and decision-making
- Getting the patients and citizens actively involved in further enhancing safety

- **European Union (EU)**

- **European Commission.** For the purpose of providing the population with a high degree of health protection⁶² and supporting the Member States in achieving safe health care, the European Commission has carried out different actions, coordinating or supporting the activities and projects in which the Member States, the professionals and patients and most of the organizations and institutions which have an interest in this subject have taken part or are currently taking part.
- **Luxembourg Declaration on Patient Safety.** A Declaration which arose out of a conference organized during Luxembourg’s presidency of the

European Union, with the slogan: “Patient Safety – Making it Happen!” Including specific recommendations on patient safety at the European Union, national and local levels⁶³.

- **Quality and Patient Safety Working Group.** A Group working under the High-Level Group on Health Services and Medical Care and set up by way of a European Commission decision in April 2004. This group contributed considerably to the proposal of the Council of the European Union Recommendations on patient safety and health care-associated infections. This group serves as a platform for sharing information on actions under way, priorities and innovative solutions with a view to the European Union’s patient safety and care quality-related challenges. This group is comprised of representatives from the European Commission, the Member States, the World Health Organization, the Organization for Economic Cooperation and Development and other interested parties⁶⁴.
- **Joint actions of the Member States.** Most of the European Union countries have been working together on two consecutive projects funded by way of the European Union public health program.
 - **European Union Network for Patient Safety: EUNetPaS.** Carried out within the 2008-2010 period for the purpose of promoting networks for collaboration in patient safety for sharing knowledge and experiences at the national and European Union levels⁶⁵.
 - **European Union Network for Patient Safety and Quality of CARE: PaSQ.** Joint action between the European Commission and the European Union countries aimed at promoting the implementation of the Council of the European Union recommendations, promoting the sharing of knowledge and experiences in the field of patient safety and care quality and favoring a sustainable collaboration network in the European Union revolving around care quality and patient safety⁶⁶.

- **Recommendations of the Council of the European Union concerning patient safety, including prevention and control of health care-associated infections of June 2009.**

This Recommendation is comprised of two chapters⁷:

- The first chapter, devoted to patient safety, makes reference to a number of recommendations, including the development of national policies, patient training, setting up adverse effects-related information and learning systems, the promotion of the education and training of health care workers and carrying out research. It also invites the Member States to share patient safety-related best practices and knowledge.
- The second chapter, devoted to health care-associated infections, recommends that the Member States adopt a strategy for the prevention and control of health care-associated infections and that they set up an intersectorial mechanism for the coordinated implementation of this strategy (measures at the national and regional level and at the level of the health institutions: surveillance systems, education and training of professionals and patients, in addition to research).

In 2012, the European Commission published an executive report addressing the Council on the implementation of these recommendations, based on the answers given by the Member States on a standardized questionnaire. The actions recommended had not been fully implemented by all of the countries, a further one-year time frame therefore having been allowed for the implementation thereof.

Spain was one of the countries which had implemented 10-12 of the total 13 patient safety recommendations made⁶⁷. In June 2014, the European Commission made a second consolidated report on the implementation of the Council Recommendations on patient safety public⁶⁸. In view of the findings, the Commission sets forth seven (7) suggested areas at the end of the report for working in collaboration with the Member States (Table 4):

Table 4. Areas for working on patient safety suggested by the Council of the European Union

Areas for working on patient safety suggested by the European Commission
1. Collaborating for developing a common definition regarding care quality and providing greater support for the development of common indicators and terminology in patient safety.
2. Collaborating at the European Union level on the subject of patient safety and care quality for sharing best practices and effective solutions. This could be based on continuing the joint PsSQ action currently under way and extending it to other subjects identified by the Member States and the interested parties.
3. Preparing guidelines as to how to provide patients with care quality-related information
4. Developing a model in conjunction with the Member States concerning standards of care quality and patient safety for the purpose of achieving a better shared understanding of these concepts.
5. Promoting, in conjunction with the Member States, transparent information regarding complaint and compensation systems, as is required under the Directive on patient rights in cross-border health care ⁶⁹ .
6. Cultivating training being carried out for the patients, families and caregivers, employing tools from information technology and periodically updating and disseminating the recommendations on education and training in patient safety for health care professionals ⁷⁰ .
7. Cultivating the reporting process as a tool for disseminating the patient safety culture; periodic updating and dissemination of the recommendations concerning starting up and operating an incident reporting system for learning purposes ⁷¹ .

- **Directive on patient rights in cross-border health care.** This directive is aimed at clearly setting out patient rights on accessing health care in another member state and the refunding thereof; aiding toward making well-informed decisions based on the information provided on quality and safety by the health care providers; and guaranteeing cooperation among the Member States in the patients' interest⁶⁹.

This directive entered into effect in October 2013 and was transposed into the Spanish legal system by way of Royal Decree 81/2014 of February 7, 2014⁷².

- **European Reference Networks.** Within the context of the Cross-border Health Care Directive and with the unanimous support of the Member States, the European Commission approved the legal basis for the implementation of reference networks aimed at further enhancing access and knowledge for managing rare or highly complex diseases, including a wide-ranging list of care

quality and patient safety-related criteria with which the highly-specialized medical services centers in the European Union must comply in order to be approved as members of the network^{73,74}.

- **The Council's conclusions on care quality and patient safety:** In 2014, the Council of the European Union approved some conclusions on this subject, underlining the importance and priority of the patient safety-related policies and setting out the commitment of the countries as to continuing working on said policies, entrusting to the European Commission the organization of a permanent platform for providing sustainability for the joint action and the sharing of best practices among the Member States⁷⁵.

INTERNATIONAL STRATEGIC LINES OF ACTION IN PATIENT SAFETY

The international strategies for patient safety are focused mainly on two major areas: the cultural change of the professionals and the implementation of safe practices.

- **Patient safety culture, human factor and training**

Ascertaining an organization's patient safety culture is the first step toward its further enhancement. The safety culture-related research has been focused mainly on evaluating the safety climate (the safety-related attitudes and perceptions of the professionals) and their association with different clinical outcomes, as well as the satisfaction of both professionals and patients ⁷⁶.

Although no clear-cut evidence currently exists concerning the relationship between the safety culture and the prevention of adverse events, some studies find there to be a correlation between a positive safety climate and a better implementation of safe practices and better clinical outcomes ^{77, 78}.

The organizations committed to the safety culture focus their efforts on four key aspects: cultivating the safety culture at all levels; evaluating and promoting a good safety-related climate; increasing training in patient safety and the so-called human factors or non-technical factors of the professionals; and developing safety elements at the clinical unit level⁷⁹.

The importance of the human factor in further enhancing patient safety has grown over the past few years, there currently being several experts who are recommending training the health care professionals in this aspect and favoring the incorporation of the human factor-related principles into the organization by taking into account physical aspects (design, equipment, etc.), cognitive aspects (the professional's status and situation, communicating skills, teamwork ("from the work team to teamwork") and organizational aspects (the organization's culture)^{80,81,82,83}.

Training in patient safety is the first step toward further enhancing the safety culture and is an indispensable element in order for the health care professionals to understand why the patient safety-related initiatives are necessary and how they can put them into practice. The importance of training the professional in patient safety has been pointed out both by the World Health Organization, which has developed a specific curriculum guide⁸⁴ and by the European Commission, which has recently published some recommendations in this regard⁷¹.

- **Safe practices**

Safe practices are those interventions aimed at preventing or mitigating the necessary harm associated to health care and further enhancing patient safety^{42, 85}. Table 5 provides a brief description of the safe practices recommended by different international agencies and organizations based on the frequency of the most common adverse events and the evidence for their control. The practices which most of the organizations recommend are those which have to do with the prevention of health care-associated infections (especially hand hygiene), safe use of medication, safe surgery and care.

Table 5. Safe practices recommended by different international organizations

AHRQ Evidence for PSP (2013)	NQF PSP for better health care (2010)	JC National PS goals (2014)	WHO Patient safety solutions (2007)
<ul style="list-style-type: none"> • Hand hygiene • Medication reconciliation • High-risk medications • Safe surgery • CRB • Catheter-related UTI • VAP • Safety culture • Medical devices • Care transition • Pressure ulcers • Falls • Active patient/caregiver involvement 	<ul style="list-style-type: none"> • Hand hygiene • High-risk medications • Safe surgery • CRB • Catheter-related UTI • Surgical infection • VAP • Safety culture • Medical devices • Informed consent • Care transition • Antimicrobial (drug) resistance • Pressure ulcers • Falls • Venous thrombosis • Ionizing radiation in pediatrics 	<ul style="list-style-type: none"> • Hand hygiene • Medication reconciliation • Safe surgery • CRB • Catheter-related UTI • Surgical infection • Identification • Communication 	<ul style="list-style-type: none"> • Hand hygiene • Medication reconciliation • High-risk medications (concentrated electrolyte solutions) • Safe surgery • Identification • Care transition • Similarly-named medications

AHRQ: Agency for Health care Research and Quality⁸⁶; National Quality Forum⁸⁷; JC: Joint Commission⁸⁸; WHO: World Health Organization⁸⁹ CRB: catheter-related bacteremia, UTI: urinary tract infection; HRMs: high-risk medications, VAP: ventilator-associated pneumonia, RAM: resistance to antimicrobials, PUs: pressure ulcers

- **Safe medication use**

Special interest has been focused on the importance of medication errors on the part of different international agencies and organizations, which have stressed the need of implementing safe practices which are effective for reducing these errors.

- In 2007, the American Medical Institute published a number of recommendations for all of the players involved in the medication use circuit, after having pointed out that at least 1.5 million preventable medication-related adverse events occur every year in the United States⁹⁰.
- The Council of Europe also published a report which included a thorough review of the studies conducted on medication errors in Europe, as well as recommendations for their prevention addressed to health care authorities, institutions, health care professionals and the pharmaceutical industry⁹¹.
- In 2013, the European Medicines Agency organized a meeting⁹², with the participation of representatives of all of the agents involved in the notification, evaluation and prevention of medication errors for the purpose of facilitating the implementation of new legal provision in Pharmacovigilance in the European Union⁹³.

Numerous safe practices have similarly been proposed for preventing medication errors, especially in the hospital setting. These practices involve some major differences with regard to cost, degree of complexity for implementation, evidence of effectiveness and impact on patient safety, different initiatives therefore having been carried out for selecting the essential practices on which top priority should be placed for their implementation on the part of health care authorities and institutions:

- In May 2007, the *World Health Organization* launched nine measures which have shown themselves to be effective for the purpose of preventing adverse events, the implementation of which is considered a top priority⁸⁹. Several of these measures are practices related to the safe use of medications: prevention of errors due to similar-sounding or similarly-spelled medication names, control of concentrated electrolyte solutions and medication reconciliation at care-providing transitions.
- In 2013, the *Agency for Health care Research and Quality* published an updated report on the evidence of safe practices known to date, considering

the evidence of their effectiveness and the cost and difficulties involved for their implementation⁸⁶. Four of the 22 practices selected have to do with the medication area (setting out a list of abbreviations which must not be used, incorporating clinical pharmacists on the care-providing teams, implementing assisted electronic prescription and reconciling medication).

- In 2010, the *National Quality Forum* published an update of 34 top-priority safety practices for preventing care-providing errors, grouped into 7 functional categories⁸⁷, including several practices related to the prevention of medication errors (incorporating assisted electronic prescription, verifying the verbal prescriptions, limiting the use of abbreviations, medication reconciliation, implementing standardized procedures with the high-risk medications, maintaining risk management programs, etc.)
- The *Joint Commission* set out the *National Patient Safety Goals* as of 2003 which are objectives aimed at promoting the prevention of errors in different areas in the accredited institutions⁸⁸. These objectives are reviewed annually and are maintained or replaced depending on whatever priorities may arise. The objectives related to the system for use of medications have revolved around further enhancing the identification of the patients, standardizing abbreviations, controlling the high-risk medications, reducing medications of similar names being confused with one another, properly labeling all of the medications which are prepared, avoiding free-flow infusion pumps, reconciling medications and fostering the active involvement of the patients in their treatment.

- **Health care-associated infections**

In hospitals, the prevalence of health care-associated infections falls within the 5.7% - 19.1% range, with an overall prevalence of 10.1%. In the developed countries, health care-associated infections affect 5%-15% of all hospitalized patients⁹⁴. In Europe, this prevalence falls within the 3.5% -14.8% range, thus meaning that around 4 million people per year are affected by health care-associated infections during their hospital stay, causing 37,000 deaths, 16 million extra days of hospitalization and approximately seven trillion euros in direct costs^{67,95}.

Health care-associated infections are often difficult to treat due to the involvement of microorganism multiresistant to antibiotics, but the evidence shows that around 50% can be prevented by way of safe practices. Therefore, preventing and combatting these infections and resistance to antibiotics is a key priority for different international organizations such as the World Health Organization, the European Center for Disease Prevention and Control and the European Commission²⁴.

- **The World Health Organization** took upon itself to spearhead the prevention of health care-associated infections by way of its first challenge “Clean care is safe care”⁴⁴ one of the main components of which was its worldwide campaign: «Save Lives: Clean Your Hands”, aimed at further enhancing the hand hygiene practices of health care personnel. A person’s hands are the main means of transmission of the microorganisms causing health care-associated infections, hand hygiene comprising the simplest, cheapest, most highly effective means of reducing these infections. However, according to various studies, this measure is not being followed by more than 40%⁹⁶. The implementation of the multimodal strategy for further enhancing hand hygiene promoted by the World Health Organization is apparently improving compliance with achieving a higher degree of hygiene and reducing the rate of multiresistant microorganisms such as *Methicillin-Resistant Staphylococcus Aureus* (MRSA) and *Clostridium difficile*^{97,98}.

The objective of World Hand Hygiene Day, held every May 5th, is to heighten awareness about the need of health care professionals implementing the hand hygiene practice at the fitting point in time and in the appropriate manner (by following the five moments recommended by the World Health Organization) for the purpose of contributing to reducing the spread of potentially lethal infections at medical services centers.

- **The European Commission** has also become actively involved in combatting HAIs by means of different actions and strategies, some of the most outstanding of which are:
 - The Council of the European Union Recommendation⁷ on patient safety, particularly preventing and combatting health care-associated infections. In this Recommendation, the Member States are asked to adopt and implement a strategy for preventing and combatting health care-associated infections, mention being made of a “Plan for action against the growing threat of bacterial resistances”, which includes twelve actions that must be carried out

by the European Union countries, one of which is the action for “strengthening infection prevention and control in health care settings”.

The latest report published by the European Commission on the implementation of the aforesaid recommendations⁶⁷ invites the Member States to focus their efforts on monitoring the infections, especially surgical site infection and those caused on intensive care units and at social services medical services centers. Mention is also made therein as to the need of preparing national diagnostic guides, setting out actions for continued training of health care professionals, implementing the definitions of health care-associated infections and the further enhancement of the diagnostic capabilities of laboratories. As a priority, it is recommended to assure:

- A sufficient number of trained professionals devoted to the control of health care-associated infections at the medical services centers.
- Capacity for putting precautions into place for isolating hospitalized patients infected who are showing relevant clinical signs and symptoms.
- Standardized surveillance of the consumption of alcohol-based products for hand hygiene.

The Commission has funded several projects on a European scale within the frameworks of the 2003-2008 and 2008-2013 Health Programs, the objectives of which are detailed in Table 6.

Table 6. European Union and ECDC initiatives for combatting HAIs and AMR

Project	Objectives
HELICS	To set up a standardized health care-associated infection surveillance system and databases (surgical site infection and infection on intensive care units) at the European Union level for pinpointing areas for improvement.
IPSE	Reducing the burden of health care-associated infections and the challenge of resistance to antibiotics by developing recommendations, training tools and control indicators.
BURDEN	Generating adequate knowledge and awareness among policymakers and society as a whole concerning the social dimension of health care-associated infections and resistance to antibiotics by providing valid, comparable information on the load of morbidity and the costs attributable to these problems in the European Union.
IMPLEMENT	Identifying strategies at the individual hospital and country level for reducing health care-associated infections and resistance to antibiotics.
PROHIBIT	Analyzing the guidelines and practices currently in effect for the prevention of health care-associated infections, the facilitating factors and barriers for full compliance with the best practices and the effectiveness of the interventions of known effectiveness.

HELICS: Hospital in Europe Link for Infection Control through Surveillance⁹⁹.

IPSE: Improving Patient Safety in Europe¹⁰⁰.

BURDEN: Burden of Resistance and Disease in European Nations¹⁰¹

IMPLEMENT: Implementing Strategic Bundles for Infection Prevention & Management¹⁰²

PROHIBIT: Prevention of Hospital Infections by Intervention and Training¹⁰³

HAIs-. Health care-associated infections

AMR: Antimicrobial resistance

ECDC: European Center for Disease Prevention and Control¹⁰⁴

In 2010, a trans-Atlantic collaboration was carried out between the European Union and the United States aimed at combatting resistance to antibiotics.¹⁰⁵ The recommendations resulting from this collaboration have to do with the need of creating indicators of structure and process for the use of antibiotics, for use in both humans and in veterinary medicine, to develop tools which will aid toward changing habits in their use, improving information on the basis of epidemiological studies, harmonizing the criteria for the interpretation of resistance among the European and American laboratories, reaching a consensus as to the prevention tools for the hospital control programs, preparing a joint inoculation strategy for

preventing health care-associated infections, stimulating the creation of new antimicrobial drugs and, in general, sharing the efforts and know-how in this area.

- **The European Center for Disease Prevention and Control: ECDC** which coordinates European surveillance of surgical infections, infections on intensive care units and the resistance to antimicrobial drugs, developed a protocol in 2009 for studying the prevalence of health care-associated infections and the use of antimicrobial drugs in acute hospitals which was put into practice in the Member States throughout the 2011-2012 period¹⁰⁴. The ECDC additionally supports a European network for health care-associated infection surveillance at the extended stay hospitals¹⁰⁶. The European Center for Disease Prevention and Control sponsors the preparation of guidelines and indicators for the prevention of health care-associated infections and develops guidelines for preventing and combatting infections by *Clostridium difficile* and by carbapenemase-producing enterobacteriaceae.

- **Safe surgery**

The studies conducted for ascertaining the adverse events associated to surgery reveal that 25% of the patients having undergone surgery have experienced complications following surgery (3% - 16% being major complications). In industrialized countries, 3%-22% of the adverse events related to surgery at hospitals lead to disability, involving death rates of 0.4% - 0.8%¹⁰⁸.

Taking this data into account and the fact that at least 50% of the surgery-related adverse events could be prevented by way of safe practices, the World Health Organization launched a second challenge in 2008: **Safe Surgery Saves Lives**⁴⁵. This multimodal program suggests working in four areas: preventing surgical wound infection; preventing the wrong site/wrong patient/wrong procedure; further enhancing the safety of surgical equipment; and safety in handling anesthesia. The results of an international pilot study conducted in 10 countries demonstrated the effectiveness of the measures recommended¹⁰⁹ especially the use of the surgical checklist. This list has also shown a reduction in errors when they are used in simulated crisis situations¹¹⁰.

Despite the efforts made, the implementation of the surgical checklist has been incomplete at the international level. The main barrier detected have been:

considering it to be imposed by the administration; change in the organization of times on surgical lists and possible delays; not being fully convinced of its usefulness; feeling of duplicating tasks; lack of adaptation of the list to the center's circumstance; embarrassment and feeling of ridicule. At different hospitals, greater importance has been placed on the recordkeeping aspect than on compliance, as a result of which the checklist has been completed however carried out inadequately^{111,112} which has led to some experts accentuating the need of coming up with strategies for the correct use of the surgical checklist¹¹³.

As regards anesthesia, the European Council of Anesthesiology, in collaboration with the European Society for Anesthesiology, promoted the ***Helsinki Declaration on Patient Safety in Anesthesiology***, approved in conjunction with the World Health Organization, the International Federation of Anesthesiology Societies and the European Patients' Federation at the Euroanaesthesia meeting held in Helsinki in June 2010. This declaration includes elementary safety –related recommendations which were already being implemented in part ^{114,115,116}.

- **Safe care**

Nursing care encompasses a number of procedures and techniques requiring special precaution being taken, due not only to the intrinsic risk involved in some for patient safety but also due to the volume and scope thereof at all care-providing levels. It is therefore necessary for strategies to be set out for preventing care-related adverse events with a system for ranking by priorities according to their frequency of occurrence, the severity of their consequences and their preventability¹¹⁷.

Historically, nursing has taken care related to the prevention of some adverse events very closely into account, such as falls or pressure ulcers, having reached quite a generalized consensus as to their prevention and the use of and heeding risk assessment scales ¹¹⁸.

- **Patient identification safety**

Approximately 13% of the errors reported in the surgical field and 67% of those related to the transfusion of blood components have to do with erroneous patient identification¹¹⁹. That is why setting out measure for guaranteeing patient identification safety, their samples and all of their information, is one of the top-priority practices recommended by different international organizations (Table 5).

For proper patient identification, it is recommended: to use at least two identifiers (never bed or room number), to promote automated identification, to always check to verify the patient's identity prior to any procedure and to get patients and caregivers actively involved¹²⁰.

- **Reporting and Learning Systems**

The reporting and learning systems make it possible to report the care-providing related incidents and to obtain useful information of the sequence of events having led up to the incident in question having occurred, affording the opportunities to learn lessons for preventing them from reoccurring.

The main limitation of the reporting and learning systems is infra-notification, some of the causes of which include the organization's lack of safety culture and the professionals' fear of finding themselves involved in lawsuits due to a lack of specific law to protect them. This fear has a bearing on the quality of the data obtained from these systems and on the best use being made of the information recorded. These systems have been found to usually achieve a greater deal of active involvement on the part of the professionals when they are voluntary and anonymous.

The reporting and learning systems are explicitly recommended by the World Health Organization¹²¹ and by the Council of the European Union⁷. The World Health Organization is currently carrying out a project in collaboration with the European Commission and the Member States for the purpose of setting out a model of minimal information for reporting on patient safety which will make it possible to set out a common taxonomy and comparisons among countries¹²².

In the report prepared by the European Commission on implementation of the recommendations put forth by the Council of the European Union, it is pointed out that the reporting and learning system is a useful learning tool which favors the dissemination of the patient safety culture, provided that the professionals are properly informed in a timely fashion concerning the problems identified and the measures taken for improvement⁶⁷.

To favor the development of incident reporting systems, the European Commission has recently published a report on findings and recommendations of the European Union patient safety incident reporting systems⁷¹.

- **Patient and caregiver participation**

The change in the profile of the patients and the development of their entitlement to autonomy and decision-making regarding the own health entails both a challenge and an opportunity for the health system. The participation of the patients has been more appreciable in the case of chronic disorders yet has been to a lesser degree in aspects concerning patient safety. Nevertheless, some experts point out that the patients can play an outstanding role in the prevention of incidents¹²³, this being the reason why different international organizations have developed strategies for promoting their participation for the safety.

The need of getting patients actively involved and empowered for their safety has been pointed out by different international organizations:

- The World Health Organization has spearheaded patient participation for their own safety with the program “Patients for Patient Safety”⁴⁸, started in 2005.. This program aims to incorporate the patient, family and community voice into all levels of health care through engagement and empowerment

The World Health Organization recommends to create mechanisms for giving patients the opportunity to take part in the health care policies and in their health process at three levels: macro (by fostering their participation in the patient safety policies), meso (by means of participation on professional committees, taking training, etc.) and micro (being provided with clear information and sharing decisions regarding their health process).¹²⁴.

- The recommendations of the Council of the European Union concerning patient safety urged the Member States to carry out actions for the purpose of:
 - Getting the patients’ organizations actively involved in the development of safety-related policies and programs at all levels.
 - Informing patients on safety standards and measures implemented for reducing or preventing adverse events and facilitating the decision-making process.
 - Getting complaint procedures and compensation systems under way, as well as the terms and conditions for their implementation.

However, the latest European Commission report on the implementation of the aforementioned recommendations reveals that no progress has been made in this

field, and that the term “empowerment” still as yet remains unclear for many countries⁶⁷. Different projects funded by the European Commission are aimed at promoting the sharing of experiences and improving the knowledge on this subject (PaSQ⁶⁵, EMPATHIE¹²⁵, Value+¹²⁶).

Table 7 provides a description of other initiatives carried out by different international agencies for promoting patient participation and empowerment for their safety.

Table 7. Actions carried out by different organization to facilitate patient participation for their safety

Organization	Actions
The Joint Commission http://www.jointcommission.org/	Educational material and specific campaigns such as “Speak Up” for encouraging patients to ask professionals questions and thus help them to take an active role in preventing errors in the health care provided ¹²⁷ .
National Patient Safety Foundation	Resources, information and publications. Annual patient safety awareness week ¹²⁸ .
U.K. National Health Service	Recommendations drafted based on experiences in citizen participation emphasizing the importance of patients as active stakeholders in the process of further enhancing safety, reiterating the need of heightening the levels of basic health knowledge and patient autonomy for managing their own health ¹²⁹ .
Institute for Health Improvement	Actions for facilitating patient participation, including patients and caregivers in the verification of safe practices (identify the patient before taking medication), re-checking a diagnostic test or intervention at the point in time at which the patient or family member so requests; inviting patients and caregivers to take part in multidisciplinary rounds; facilitating patient/caregiver participation on the safety committees ¹³⁰ .
National Patient Safety Foundation's Lucian Leape Institute	Guide with recommendation and tools for favoring the collaboration between professionals and patients for safety ¹³¹ .
Australian Commission on Safety & Quality in Health Care	Programs for fostering clear, transparent information for patients and caregivers when an adverse event occurs for the purpose of further enhancing the quality and safety of the health care provided ¹³² .

The experiences carried out show that when setting out strategies for promoting the participation of the patients for their safety, the patients’ needs and expectations, the opinions of the professionals and the maturity of the organization must be taken into account^{133, 134}.

iii. Interventions carried out in the National Health System

To make reference to the current patient safety situation in Spain, mention must necessarily be made of the actions promoted by the MSSSI which have been being carried out as of 2005 within the framework of the patient safety strategy³, in addition to those carried out by the Health Regions, the healthcare centers, academic institutions and other organizations which have shown an interest in this subject^{2,135}.

The strategy lines included in the National Patient Safety Strategy for the 2005-2013 period were in keeping with the top-priority objectives thereof: fostering the patient safety culture among the professionals and the patients at any level at which health care is provided, training the professional in patient safety, implementing safe practices, research into adverse events and their conditioning factors and getting patients and citizens actively involved.

Deploying the aforementioned strategy entailed both a political and economic commitment with all of the regional services, although this strategy has been implemented to differing degrees from one Autonomous Community to another, and the funding allocated has ceased to exist as a result of the current economic restrictions.

A description is provided in following of the actions carried out within the framework of the Patient Safety Strategy for the 2005-2013 period.

PATIENT SAFETY STRATEGY LINES CARRIED OUT IN THE NATIONAL HEALTH SYSTEM

- Patient **safety culture, human factor and training**

For the purpose of meeting the first objective of Spain's National Health System Quality Plan Strategy Number 8 (to promote and further the patient safety culture and knowledge among the professionals and patients at any level at which health care is provided) the MSSSI has been holding forums, workshops, meetings and conferences at the national and international level, has been disseminating news and recommendations by way of its Website and has been developing training courses in patient safety for professionals.

- **Information and dissemination.** The different Health Regions have echoed these initiatives and have, in turn, carried out seminars, forums, meetings and have disseminated aspects for furthering and implementing the safety culture.

The scientific societies have also been holding forums where the patient safety-related aspects have played a leading role and have also promoted the implementation of safe practices among the professionals. Special mention may also be made in this regard of the work which is being done by the scientific societies, coordinated by the MSSSI, for identifying those aspects of the care provided which do not provide any added value and which may entail a risk or harm for the patient^{136,137,138}.

- **Perception-related studies.** The MSSSI has promoted studies for the purpose of getting to know the patient safety culture in different health care settings:
 - In the field of hospital care, the *Hospital Survey for Patient Safety* developed by the *Agency for Health care Research and Quality* was adapted into the Spanish language and validated, having been used on a random sample of 24 of the acute hospitals in the NHS. The main findings of this study showed that the professionals considered safety to be acceptable and acknowledged weak points with regard to "Staffing", "Teamwork among units and departments", "Perception of safety" and "Hospital Administration support in patient safety". This study additionally stresses that the working pace at many hospitals may have a bearing on patient safety¹³⁹.

- In primary care, the *Medical Office Survey on Patient Safety Culture (MOSPS)* developed by the Agency for Health care Research and Quality was adapted and validated, then having been given nationwide to 4,344 professionals from 215 health centers in 15 Health Regions. The nursing professionals showed higher levels of patient safety culture than the physicians, the physicians having shown, in turn, a higher level than the all of the other professional categories. The administrative staff members are, according to the survey findings, the professional category showing the least degree of patient safety culture. Similarly, the professionals in positions of responsibility or leadership positions showed a greater degree of patient safety culture compared to those not holding leadership positions, those over 40 years of age compared to those younger and the professionals with smaller quotas (1,000 or more health system cards) compared to those who had a greater number. Generally speaking, the perception of patient safety among the primary care professionals is positive on an overall basis according to this study¹⁴⁰.

■ **Training professionals**

After the efforts made over these past years in training health care professionals in patient safety, the following assessment can be made of the current situation:

- It is difficult to assess the impact of the training, not only at the individual level but also the institutional repercussion thereof. In any case, according to the data available from the NHS², there are a major number of professionals possessing training in patient safety who are playing a major role as instructors and promoters of the change in their work settings.
- A snowball effect is being caused, as a result of both the boost provided by the MSSSI and the recommendations from the World Health Organization and from the Council of the European Union and the interest taken on the part of the Health Regions and some universities and institutions of a private nature, who have carried out training initiatives in patient safety at certain times.

- Although attempts have been made to incorporate patient safety as transversal training, the truth of the matter is that it still has not been formally integrated into either the undergraduate degree training or the specialized training in health sciences.

The MSSSI patient safety web¹⁴¹ is the showcase for the production of training resources, reports and experiences of different types which have been promoted and carried out over these past few years. One point worthy of special mention in this regard is the base of projects which have been being progressively carried out as a final study of the successive editions of the master's program and of the risk management course. Those of the latter are available freely on the aforementioned web.

It is necessary for the managers of each institution to set some overall patient safety-related objectives and for them to support the initiatives of the clinical units for the same to be achieved, by facilitating the knowledge and tools appropriate for carrying out these initiatives.

It would additionally be desirable for patient safety to comprise part of the course curricula of the Schools of Health Science and that all of the professionals newly incorporated into the NHS were to undergo basic entry level training on the concepts and practice of care-providing safety.

- **Safe practices**

- **Safe medication use**

In the multicenter studies which have been carried out in Spain as of 2005 for the purpose of making an overall analysis of the frequency and types of adverse events in different health care settings, it has been found that the adverse events related to the use of medications comprise a large percentage of the total number of adverse events which occur in the process of providing health care (Table 8).

Table 8. Frequency of the adverse events due to medications in the multicenter studies conducts at the national level

Study	Total AEs (%patients)	Most frequent AEs	AEs due to medications	
			Percentage of total number	Preventable (%)
ENEAS¹⁵	9.3%	Medication (37.4%). HAIs (25.3%) Procedures (25%).	37.4	34.8
APEAS²⁶	10.11%	Medication (47.8%) Baseline disorder evolving for the worse (19.9%) Procedures (10.6%).	47.8	59.1
EARCAS²⁷	Qualitative study	Care. Medication HAIs	–	–
SYREC²⁸	33.1%	Care (26%) HAIs (24%) Medication (12%)	11.6%	58.9%
EVADUR²⁹	7.2%	Care-providing process (46.2%). Medication (24.1%) Procedures (11.7%).	24.1%	–

- ENEAS: National Study of Adverse Events Related to Hospitalization
- APEAS: Study of Adverse Events in Primary Care
- EARCAS: Adverse Events in Social services medical services centers and Living facilities
- SYREC: Safety and Risk in the Critical Patient
- EVADUR: Adverse Events in Emergency Care
- AE: Adverse Event
- HAIs: Health care-associated Infections

Other studies also conducted in Spain have specifically characterized and analyzed the preventable adverse events due to medications in different health care settings and have estimated the frequency of medication errors in the different processes of the system for the use of medications. Table 9 details the most relevant aspects of the findings of these studies, which show the major degree to which medication errors have an impact on the health care provided.

Table 9. Findings of studies conducted in Spain on medication errors and adverse events related to medications

<p>A total of 1.4% - 5.3% of hospitalized patients experienced adverse events due to medication errors during their hospital stay^{142,143}. The main types of errors which caused these events were failure to have prescribed a necessary medicine, an incorrect dosage or an inappropriate medicine having been prescribed, an insufficient follow-up on the treatment and interactions among medicines.</p>
<p>An average of 17 errors per every 100 hospitalized patients (16% in prescribing, 27% in transcription/validation, 48% in dispensing and 9% in administration) are estimated to occur daily. A total of 85% did not go as far as to reach the patient, and solely 0.35% caused harm. Omission was the most frequent error in all of the processes¹⁴⁴.</p>
<p>According to one multicenter observational study, the error rates in the administration and preparation of medications fall within the 18.2% - 33.4% range (not including errors due to delayed administration),¹⁴⁵.</p>
<p>More than 50% of polymedicated elderly patients may experience reconciliation errors at hospital admission or discharge. The most frequent types of errors are the omission of medicines and the difference in the dosage timing¹⁴⁶.</p>
<p>Medication errors were the cause of 4.7% -5.0% of the hospital admissions to medical units. The main types of errors identified were an inappropriate medicine or too high a dosage having been prescribed, inappropriate follow-up, failure to adhere to the treatment or inappropriate self-medication^{147, 148}.</p>
<p>In 2011, the estimated cost for the NHS of the preventable medication-related adverse events in hospitalized patients, plus those having caused hospital admissions and calls to emergency services totaled approximately 1.779 million euros (which would amount to 2.9% of all NHS health care spending)³⁹.</p>

In 2007, the MSSSI published the “Self-Assessment Questionnaire on the Safety of the System for the Use of Medications at Hospitals”¹⁴⁹, an adaptation of the *Medication Safety Self-Assessment for Hospitals*¹⁵⁰, making it possible to fully evaluate in detail the implementation of safe medication practices. Based on the aforesaid publication, a nationwide study was conducted that same year for the purpose of knowing the baseline situation of Spain’s hospitals with regard to the implementation of safe medication practices¹⁵¹. This same study was repeated in 2011 for evaluating the changes which had taken place within that time frame¹⁵². The information obtained afforded the possibility of ascertaining that progress had been made in the process of implementing safe practices in the systems for the use of medications, however that, despite the progress made, there was still a great deal of room left for improvement.

Table 10 shows the findings for 2007 and 2011 for the evaluation items included on the questionnaire which are best in keeping with the top-priority safe practices recommended by different international organizations. The findings are stated in the form of percentages of the maximum figure possible for each item to be assessed, which reflects their degree of implementation at the participating hospitals. It was objectively found that some practices had been implemented to quite a great degree in the NHS (avoiding verbal prescriptions and dispensing the medicines in individual doses), and others had undergone noticeable increases over the course of the time frame in question (the incorporation of the e-prescription with clinical decision-making support, the setting up of systems for reporting and learning from medication errors). In other cases, changes of a lesser degree were observed (avoiding the use of free-flow pumps and preventing errors in the connection of catheters) or that the practices had been implemented to only a very small degree (validation of all of the prescriptions by a pharmacist and the integration thereof into the clinical teams).

Table 10. Top-priority safe practices related to medications suggested by different organizations and degree to which implemented in Spain according to the studies conducted in 2007 (n= 105 hospitals) and 2011 (n= 165 hospitals) with the “Self-Assessment Questionnaire on Safety in the System for Use of Medications in Hospitals”.

Top-priority safe practices	Suggested by	Main associated assessment items	Findings (% of the maximum figure possible)*	
			2007 Study (n=105)	2011 Study (n=165)
Implementing e-prescription programs with clinical decision-making help systems	AHRQ, NQF	52, 53	32%, 26%	60%, 46%
Avoiding verbal prescriptions and setting up a verification procedure for use in event of emergencies	NQF, JC	58, 59	68%, 85%	70%, 91%
Setting out a list of abbreviations and acronyms which must not be used	AHRQ, NQF, JC	57	17%	30%
Integrations of the clinical pharmacist - Validation of all the prescriptions - Incorporation into the care-providing teams	AHRQ, NQF JC	36 38, 39	44% 34%, 23%	47% 35%, 27%
Practices for further enhancing the safety of high-risk medicines - Identification, maximum dosages, double-checking - Standardizing and limiting the concentrations of medications - Removing concentrated electrolyte solutions - Setting protocols for anticoagulants	NQF, JC OMS	30, 32, 123 y 223 86.1, 86.2 110 -	42%, 33%, 13% y 7% 44%, 50% 14% -	52%, 43%, 26% y 19% 50%, 51% 33% -
Practices for preventing errors due to similar names of medicines	OMS	68, 69, 70	37%, 53%, 26%	46%, 63%, 32%
Dispensing the medications individual doses	NQF	76	77%	83%
Labelling all of the medications and containers/devices containing them	NQF, JC	84, 85	52%, 53%	58%, 59%
Avoiding the use of free-flow pumps	JC	130	46%	64%

Incorporating new technologies in administration – Bar code - Smart infusion pumps	NQF	16 128	8% 41%	14% 42%
Preventing the errors in connecting catheters and devices	OMS	122, 124	32%, 35%	44%, 50%
Medicine reconciliation - Obtaining a full drug therapy record on the patient - Reconciling the medication at admission and discharge - Reconciling the medication on transfers from one unit to another - Providing written information on the medication at discharge	AHRQ, OMS, NQF, JC	21 22 23 173	49% 28% 45% 35%	56% 38% 51% 45%
Educating the patients regarding the medication and fostering their active involvement	NQF, JC	Criterion 16	44%	52%
Maintaining medication reporting and management programs	NQF	Criterion 18	22%	41%

* Findings given in the form of a percentage of the maximum value the item evaluated would have if fully implemented

- AHRQ: Agency for Health care Research and Quality

- JC: Joint Commission

- NQF: National Quality Forum

- WHO: World Health Organization

■ Health care-associated infections

The strategies for the prevention and control of health care-associated infections require agile, robust, sustainable systems of multi-faceted, standardized measures promoting the implementation of safe practices by multidisciplinary teams.

Surveillance system

Epidemiological surveillance, understood as a continued, systematic process of collection, analysis, interpretation and dissemination of data on infectious diseases for taking the appropriate actions¹⁵³ is the basis of the infection control programs. These systems have evolved from global nosocomial infection surveillance into a surveillance focusing on processes related to the prevention and indicators of health care-associated diseases. The comparison of these indicators has been found to be useful for setting out measures for the preventing and curtailing health care-associated infections.

In Spain, the Health Regions are currently using different health care-associated infection surveillance systems. The most widely-used are the Study of Nosocomial Infections in Spain (EPINE)¹⁵⁴ and the National Study of Surveillance of Nosocomial Infection in Intensive Care Medicine Services (ENVIN-HELICS)¹⁵⁵.

- **EPINE** is a prevalence register making it possible to study the health care-associated infections in all of the services throughout the hospital, including the pediatric population. EPINE was promoted by the Spanish Society for Preventive Medicine, Public Health and Hygiene in 1990. In 2012, EPINE was adapted to the European protocol by contributing data to the “Prevalence Point Surveillance (PPS)”. In 2004, a total of 269 hospitals were participating, with some 55,700 patients having been studied. The prevalence of infection was 7.85%, these being percentages progressively on the decline since 2009 (8.59%). A decline has been found to exist in the percentage of infection acquired at hospital admission per se and of the patients who were admitted who already had an infection beforehand, the most outstanding of which was surgical infection. Respiratory infection has become more prevalent in 2014 (21.4%, followed by surgical infection (20.9%), urinary infection (20.1%) and catheter-associated bacteremia (15.3%). The data also shows a discreet decline in the number of patients undergoing antibiotic treatment at the point in time of the study (45.4%)¹⁵⁴.

- **ENVIN-HELICS** is an incidence register developed in 1994 by the Spanish Society for Intensive Care Medicine, Critical Care and Coronary Care Units (SEMICYUC), affording the possibility of studying the device-related infections acquired on intensive care units. This register has been compatible with European surveillance since 2007¹⁵⁶, although the data published in Spain includes the patients hospitalized for longer than 24 hours in April-June, whilst at the European Center for Disease Prevention and Control; all of the data for the year is recorded, but for stays of longer than 48 hours¹⁴⁸.

The control of the main infections in critical patients includes ventilator-associated pneumonia, catheter-related urinary tract infection, primary bacteremia, encompassing the bacteremia of unknown origins plus catheter-associated bacteremia and, lastly, the bacteremia's secondary to other focal points.

The percentage of patients with infections (device-related infections) dropped from 15.5% in 2009 to 5.7% in 2014. This significant drop coincides in time with the period when the Zero Bacteremia and Zero Pneumonia programs were implemented¹⁵⁷. Similarly, the use of antibiotics has decreased on the intensive care units from 122.1 to 113.8 days of antibiotic per 100 stays. Carbapenems are one of the antibiotic groups most used.

- **The National Health System Health Care-Associated Infection Surveillance System.** The MSSSI, in collaboration with the Carlos III Health Institute, the Health Regions and the scientific societies involved, has prepared a proposal regarding which a consensus was reached with Spain's Surveillance Body and which was approved by the Public Health Commission for a national health care-associated infections surveillance systems which will make it possible to avail of systematic, homogeneous information with a standardized methodology for ascertaining the incidence and characteristics of the health care-associated infections and facilitating their prevention and control.

This proposal is in response to a request from Spain's Congress of Deputies for a National Plan for the Control of Health Care-Associated Infections a¹⁵⁸ to be developed and the recommendations from the Council of the European Union⁷ for bolstering the surveillance systems active at the national level for the purpose of evaluating and focusing the infection prevention and control policies on the medical services centers. Similarly, there was a widespread feeling among the

different health authorities in favor of having a health care-associated infection surveillance system for the health care provided by Spain's NHS.

- ***Surgical site infection surveillance.*** The study of surgical site infection incidence is representative to a much lesser degree than the two aforementioned registers. Approximately some 30 hospitals from various Health Regions take part in the surveillance of the surgical processes suggested by the European Center for Disease Prevention and Control. Some Health Regions such as Madrid, Catalunya and the Basque Country has their own individual surgical infection surveillance program (VIRAS¹⁵⁹, VINCAT¹⁶⁰ and INOZ¹⁶¹, respectively).
- ***Outbreaks.*** Although the presence of outbreaks of nosocomial infections should be notified to the Carlos III Health Institute, compliance is rendered to a small degree, the information therefore being obtained mainly by way of scientific publications or presentations.
- ***Antimicrobial resistance.*** Spain's Microbiology laboratories contribute to plotting the map of resistances by way of their data from blood cultures and other safety samples. Through the Carlos III Institute, the information is sent to the European *Antimicrobial resistance interactive database (EARS-Net)* program, currently centralized at the *European Center for Disease Prevention and Control*¹⁶². The findings rank Spain among those countries having the highest level of antimicrobial resistances, especially for gram-negative bacteria, although to a lesser degree than Greece, Italy and Portugal¹⁶³. The latest data is for 2011, the figures provided being lower than the figures shown in the EPINE register for 2014¹⁵⁴.
- ***Antimicrobial consumption.*** Spain provides the consumptions of antibiotics at the extrahospital level, not the data for the consumption at the hospital level, to the program *European Surveillance of Antimicrobial Consumption Network (ESAC-Net)*¹⁶⁴, also coordinated by the *European Center for Disease Prevention and Control*, which has been monitoring the use of antibiotics for years. The national data on use in hospitalized patients is obtained from EPINE and ENVIN-HELICS. In general, the data suggests a high degree of use and a high percentage of treatments in health care-associated infections without any supporting microbiological documentation serving as a basis.

Programs for preventing health care-associated infections promoted by the MSSSI, within the framework of the strategy for patient safety. Some of the most noteworthy of these programs are:

– ***Spanish National Health System Hand Hygiene Program.***

In 2006, Spain joined the World Health Organization “Clean Care is Safe Care” campaign, the main objective of which is to further enhance adherence to Hand Hygiene. The Spanish NHS Hand Hygiene program¹⁶⁵, promoted by the MSSSI, is being carried out in collaboration with all of the Health Regions for the purpose of further enhancing adherence to Hand Hygiene and is currently implemented in more than 80% of the public hospitals and medical services centers. Within the framework of this program, a consensus has been reached concerning basic actions (mainly promoting the World Health Organization’s multimodal strategy and training of the “5 moments” of the process) and evaluation indicators for structure, process and outcome which are evaluated annually.

As of 2009, World Hand Hygiene Day has been being celebrated nationwide in Spain, with specific actions for professionals and patients in the Health Regions and medical services centers, following the recommendations of the World Health Organization for that day.

– ***Patient safety program for critical care patient***

The Zero Bacteremia and Zero Pneumonia projects¹⁵⁷ have made it possible, by way of a multifactorial intervention based on the simultaneous implementation of a package of simple, sustainable measures, not only to significantly reduce the incidence of two of the highest-impact, highest-cost health care-associated infections, but also to favor the networking of many professionals and centers nationwide and to serve as a reference study of what should be a process of putting safe practices into practice at all levels of health care.

– The Zero Bacteremia Project objectives were:

- a) To reduce the incidence-density rates (IDR) of the catheter-related bacteremia to < 4 episodes per 1000 days of central venous catheter.
- b) To document all of the episodes of bacteremia, including the bacteremia’s secondary to other focal points, as well as the etiology and the characteristics of the patients who experience these episodes.
- c) To create working groups with leadership abilities which can follow programs for the prevention of other nosocomial infections.
- d) To bolster the safety culture in the management of critical patients.

Over the course of the 18 months of the study (2009-2010), 192 ICUs from all of the Health Regions contributed cases, a 50% drop in the rate having been achieved in all types of hospitals¹⁶⁶. It was estimated toward the end of 2013 that 384 deaths had been prevented and 159,630.700 € had been saved on hospital stays.

- Zero Pneumonia Project. Following the same setup as for Zero Bacteremia, a specific package of measures and an integral safety program were proposed in agreement with the Health Regions, the Spanish Society for Intensive Care Medicine, Critical Care and Coronary Care Units (SEMICYUC) and the Spanish Society for Intensive Care Nursing and Coronary Care Units (SEEIUC). The main objective was to reduce the IDR of Ventilator-Associated Pneumonia (VAP) to < 9 episodes x 1000 days of mechanical ventilation maintaining the secondary objectives of the Zero Bacteremia Project. More than 240 ICU's (80% of all ICUs in Spain) have taken part in the project, having achieved a rate of less than 7 episodes per 1000 days of mechanical ventilation. It has been estimated that 340 deaths have been prevented and 164 million euros saved¹⁶⁷.
- Programs for the Optimization of In-Hospital Use of Antibiotics (PROA): The Spanish Society for Infectious Diseases and Clinical Microbiology, the Spanish Society of Hospital Pharmacy and the Spanish Society for Preventive Medicine, Public Health and Hygiene have come to an consensus and prepared a program for further enhancing the prescription of antimicrobial drugs for the purpose of reducing the resistances, which has been being carried out successfully in several of the Spanish NHS hospitals¹⁶⁸.
- Strategic plan for action for reducing the risk of selection and dissemination of resistances to antibiotics. Coordinated by the MSSSI through the Spanish Medicines and Medical Products Agency (AEMPS), this Plan covers both human and veterinary medicine, having as its objective that of reducing the risk of selection and dissemination of resistances to antibiotics, also aiming at rendering compliance with the European Commission Communiqué of November 17, 2011, by way of which the member States have been requested to set out a plan for action regarding resistances to antibiotics, as well as the Conclusions of Council of the European Union of June 22nd, urging that a joint approach be taken to this issue¹⁶⁹.

The agencies and institutions which are collaborating in this Plan include: The Spanish Ministry of Health, Social Services and Equality (Spanish Medicines and Medical Products Agency, the Spanish Food Safety and Nutrition Agency and different General Directorates), the Ministry of Agriculture, Food and Environmental Affairs, Ministry of Economy and Competitiveness (Carlos III Health Institute), Complutense University of Madrid, Spanish Antibioqram Committee, Scientific Societies involved and Official Professional Organizations.

- **Surgery**

In Spain, the incidence of adverse events due to surgery is around 10.5% (8.1%-12.5%), a total of 36. 5% of which would be preventable¹⁷⁰.

In the National Patient Safety Strategy for the 2005-2011 period, it was recommended that actions be implemented for promoting Safe Surgery as of January 2008, coinciding with the launching of the World Health Organization's second challenge "Safe Surgery Saves Lives". The basic principles of this challenge were classified into 4 areas (1. The prevention of surgical wound infections 2. The safety of anesthesia 3. The training of safe surgical teams. 4 The measurement of the surgical services) aimed at achieving some top-priority objectives for preventing the adverse events in surgery for which the World Health Organization facilitates as tools the surgery safety checklist and a manual for the implementation thereof⁴⁵.

The Health Regions recommended and contributed initiatives and standards for the implementation of the aforementioned list in their hospital networks. Most of these practices were included as recommendations in the document "Surgical Block Standards and Recommendations"¹⁷¹ published by the MSSSI, which additionally included the adaptation of the list on the part of the Spanish Surgeon's Association. Despite these actions, the process of implementing the safe surgery checklist in Spain's NHS has been difficult, incomplete and highly varying.

The World Health Organization's challenge also proposed a minimum set of uniform indicators ("vital surgical statistics") for the national and international surveillance of surgical care. The information on "vital statistics" is variable at the level of the Health Regions, no register existing for these statistics at the national level.

Some of the other outstanding efforts include the recommendations on the part of the Spanish Society for Anesthesiology and Resuscitation for the Anesthesia services to adopt the principles of the Helsinki Declaration on Patient Safety in Anesthesiology¹¹⁶, which the Spanish Society for Anesthesiology and Resuscitation

subscribed in its launching in June 2010. Also worthy of special mention is the publication of recommendations for the labeling of drugs administered in anesthesiology and the publication of a pre-procedure anesthesia equipment checklist¹⁷².

- **Safe care**

The ENEAS report attributes 7.63% of the adverse events to care-related causes¹⁵. The factors associated with these adverse events comprise useful information for targeting the strategies aimed at further enhancing patient care.

As a result of the decentralized funding of the Health Regions within the framework of the Patient Safety Strategy within the 2005-2011 time frame, it has been encouraged that different projects and best practices be gotten under way in nursing care which have made it possible to further enhance the aspects related to the prevention and treatment of pressure ulcers, fail-safe patient identification, the further enhancement of the prevention of accidental falls, the prevention of infection with the Hand Hygiene strategies, the reduction of catheter-associated bacteremia or ventilator-associated pneumonia, and the safe use of medications.

Nevertheless, the safe care practices have not been implemented in full, and the degree to which implemented has varied greatly nationwide. Some of the possible causes may include the nursing care plans barely existing at all and the scarcity of specific information systems making it possible to evaluate the same.

The reference study on patient safety in regard to the care provided is the project "Standards of Care Quality for Patient Safety in Spain's NHS hospitals, known as the "SENECA" study¹⁷³, funded by the MSSSI, based on which different standards of care quality for Spain's NHS were voluntarily evaluated. This study made it possible to ascertain the quality of the care provided related to patient safety nationwide and to recommend a number of more or less complex practices which were then followed to differing degrees by the Health Regions.

Measures aimed at setting out a crisis plan for the proper management of severe adverse events

According to the Gallagher study, a total of 55% of all Canadian and U.S. physicians acknowledged having made a clinical error¹⁷⁴. In Spain, according to the ENEAS study data, it can be estimated that around 15% of the hospital professionals

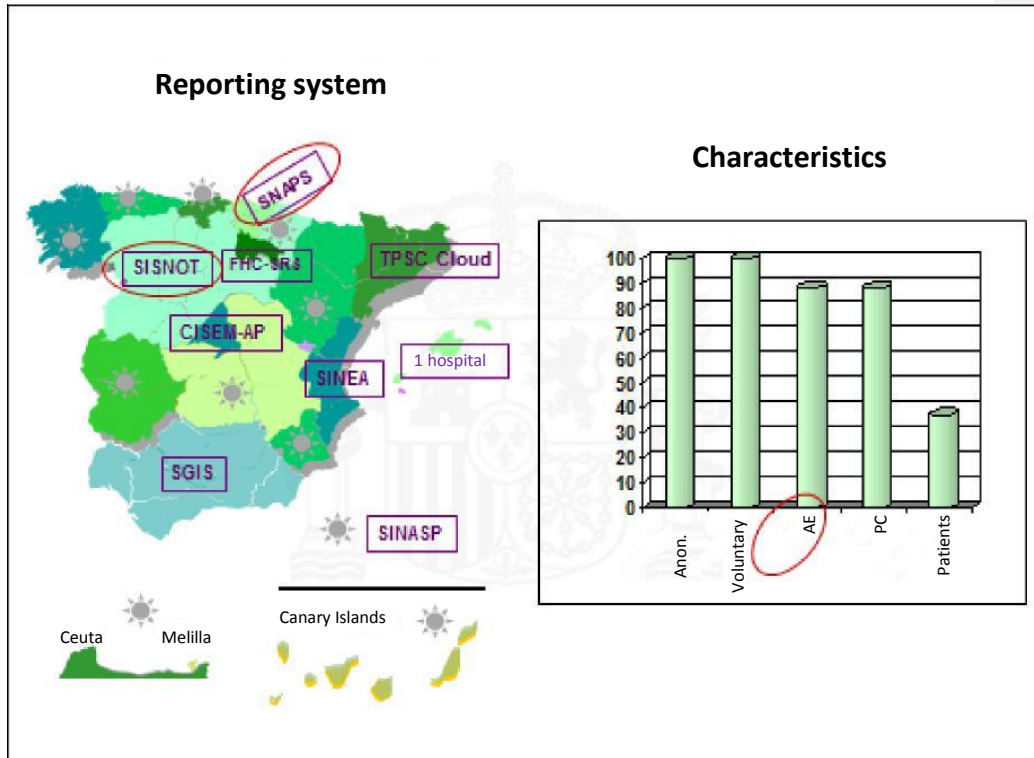
may find themselves involved in an adverse event per year¹⁵, although they be a matter of adverse events without any severe consequences in most cases.

When a severe adverse event occurs, the patient is the main victim, but the professionals involved are the second victims. The repercussions of adverse events on the second victims may go so far as to leave them incapacitated, seriously affecting their carrying out their duties, above all when there is external social pressure¹⁷⁵. In Spain, there are very few studies dealing with the consequences of adverse event on professionals¹⁷⁶, it therefore being necessary to learn from the experiences carried out in other settings¹⁷⁷. It would be desirable for the medical services centers to avail of specific strategies which were to include: what must one do and not do when a severe adverse event occurs; actions for frankly communicating with the patients and caregivers; procedures for supporting the professionals involved in the adverse events; and the approach as to how to manage the communication with the media once they have occurred. The experiences carried out in other countries may be useful for putting into practice in these situations^{178, 179,180,181}. Some Health Regions have developed guidelines for the management of severe adverse events, including the approach for dealing with the second victims in a systematic manner¹⁸².

Reporting and learning systems

The MSSSI has promoted the Reporting and Learning System for Patient Safety (SINASP)¹⁸³ as a reporting system readily available to the health care professionals through their regional health services. A total of nine Health Regions and the National Health care Management Institute for Ceuta and Melilla (INGESA) are currently using this reporting system, whilst all of the other Health Regions have developed their own reporting systems, some prior to the Reporting and Learning System for Patient Safety. Fig. 2 details the incident reporting systems developed in Spain's NHS, in conjunction with their characteristics (anonymous, voluntary, type of incident, setting and accessibility to patients).

Fig.2. Incident reporting systems developed in Spain's NHS and their characteristics



CISEM-AP: Notification of safety-related incidents involving no harm or medication errors in primary care; FHC: Adverse effecting reporting and registry systems; SGIS: Safety-related incident management system; SINASP: Reporting and Learning System for Patient Safety; SINEA: Incident and adverse event reporting system SISNOT: System for reporting incidents not involving any harm; SNASP: System for reporting and learning in patient safety; TPSC: Platform for the management of patient safety; AE: Adverse event; PC: Primary care

The greatest concern expressed by Spanish professionals having to do with the reporting systems is with regard to the lack of legal protection when the adverse events are reported. The legal opinion reports commissioned by the MSSSI suggest the need of introducing legislative changes for guaranteeing the protection of the professionals involved in reporting or analyzing adverse events¹⁸⁴.

- **Patient and caregiver participation**

The active involvement and empowerment of patients and caregivers in their own clinical safety have been taking on growing importance at the national and international level. In this regard, the MSSSI organized a workshop for ascertaining the

opinions, expectations and positioning of experts, representatives of patients' associations, consumers, users and patient advocates in different Health Regions concerning this matter and their possible participation in future actions aimed at preventing risks and proposing patient safety-related solutions. This document and the Citizen Trainers Network developed following the workshop marked a milestone in the change necessary for getting patients and caregivers actively involved in further enhancing clinical safety. Currently, the Citizen Trainers Network has been integrated into Spain's NHS Citizen Health Schools Network promoted by the MSSSI and carried out in collaboration with the Health Regions¹⁸⁶.

Research into patient safety

Safe health care requires employing procedures and practices which have been shown to be effective for reducing the occurrence of mistakes, errors and adverse outcomes and also for generating new knowledge as to the factors which contribute to further enhancing patient safety.

Patient safety and patient safety-related incidents the two opposites sides of one same coin as yet to be minted: the management of the risk involved in providing health care.

The following can be considered as areas for research in patient safety¹⁸⁷:

- Quantifying the magnitude and characteristics of the clinical risk
- Improving the comprehension of the factors which contribute to the occurrence of the incidents related to patient safety.
- Evaluating the impact of the adverse events on the health system.
- Identifying effective, feasible and sustainable solutions for achieving safe health care and preventing adverse events and incidents.

Special mention must be made of the fact that a great number of articles and monographic studies on patient safety have been published in Spanish journals in the field of clinical quality¹⁸⁸. A neither systematic nor completely thorough review of what has been published over the past few years leads one to the conclusion that there has been a major increase in the amount of research on patient safety published at the national and international level in comparison to earlier time frames^{189, 190}. Despite this increase, it still continues to be necessary to generate valid, accurate evidence on the impact of clinical and organizational solutions which will further enhance safety.

Similarly, delving deeper into the epidemiological study of incidents and adverse events will make it possible to better know the risk factors of the patients who are most exposed to experiencing adverse events and will facilitate the implementation of prevention strategies.

DEPLOYING THE PATIENT SAFETY STRATEGY IN THE SPANISH NATIONAL HEALTH SYSTEM

For the purpose of availing of updated information on the deployment of strategies, programs and actions which are being carried out in Spain's NHS with regard to patient safety, sharing information and fostering the sharing of experiences, a questionnaire was sent out to the Health Regions' in which information was requested concerning organization of the patient safety strategy, development of lines of action funded by the MSSSI up to 2012, reporting system, patient participation and deployment in primary care.

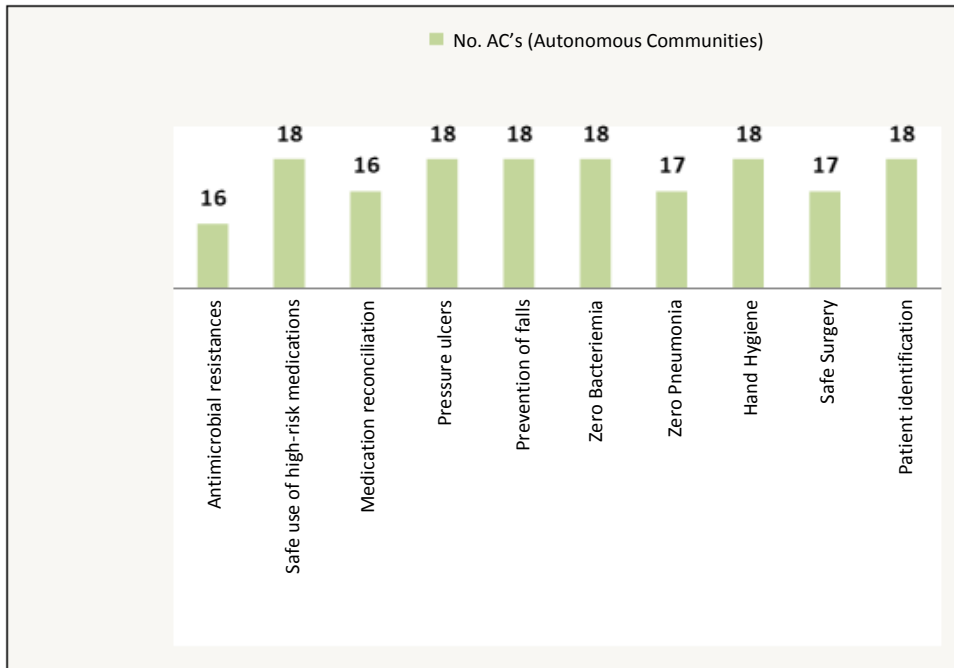
The seventeen Health Regions and INGESA answered the survey.

The findings are detailed in following, summarized by each dimension of the questionnaire:

- Development of the patient safety strategy on the part of the Health Regions with regard to its organization:
 - A total of 13 Health Regions say they have a Patient Safety Strategy (72.2%). The rest say they are going to develop a strategy.
- Actions carried out by the Health Regions for fostering the safety culture:
 - All of the Health Regions are carrying out patient safety training actions, 81% saying they currently have a specific patient safety training program in place for health care professionals.
 - A total of 72.2% of the Health Regions say they are furnishing information to professionals concerning standards, measures for reducing incidents and best practices in patient safety. The rest say they are working on this aspect.
- Safe practices implemented, recommended in the strategy for patient safety carried out in the NHS.
 - Fig. 3 details the information furnished by the Health Regions concerning the implementation of these activities in specialized care and in and in Fig. 4

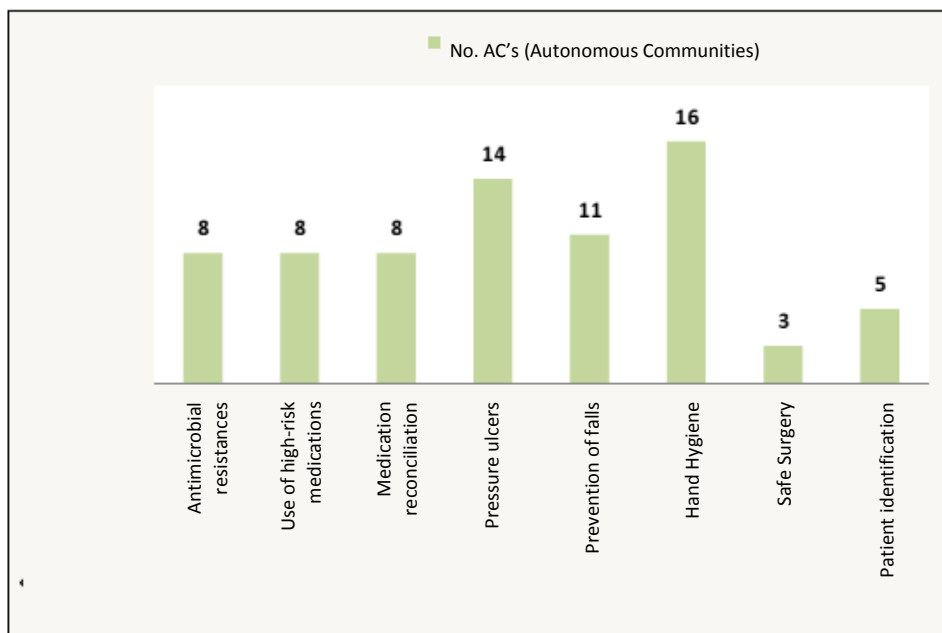
for primary care. These actions are being carried out at all or several centers of the Health Regions.

Fig. 3. Safe practices recommended in the patient safety strategy which are implemented in specialized care in the NHS (including the 17 Health Regions and INGESA)



ACs: Health Regions

Fig. 4. Safe practices recommended in the patient safety strategy implemented in Spain's NHS primary care (including the 17 Health Regions and INGESA)



ACs: Health Regions

A remarkable difference among Health Regions is noted in the implementation of the eight effective practices targeting primary care, solely two Health Regions incorporating all eight of these practices, three incorporating six of the practices and in the lower range, one Autonomous Community with one single practice implemented.

In addition to these practices, the Health Regions implement other safe practices in keeping with the objectives of their strategies.

As far as the implementation of safe practices is concerned, it may also be said that, within the framework of the Joint Action for Patient Safety and Care Quality (PaSQ), twelve Health Regions and 121 medical services centers are taking part in the implementation of the four safe practices recommended: Multimodal strategy for further enhancing Hand Hygiene, surgical checklist, medication reconciliation and scale for the early detection of clinical deterioration in pediatrics¹⁹¹. The evaluation is made by means of a questionnaire and specific indicators.

- All of the Health Regions have some system for reporting incidents related to the health care provided. Due to their frequency, the Reporting and Learning System for Patient Safety is the first-line system. The implementation is mostly in hospitals and primary care, although this has also been extended, in some Health Regions, to social services medical services centers, extrahospital emergency services, psychiatric centers, etc.
- A total of 50% of the Health Regions stated having informed the Patients' Associations in the Community of the strategies or programs being carried out in patient safety, a total of 39% not having done so and 12% not having answered this question.
 - A total of 14 Health Regions answered that there is no stable setup for patient and/or caregiver participation in patient safety; a total of 3 having answered that such a setup does exist and one not having answered at all.
 - Most of the actions carried out have to do with activities involving information and training for patients.
- Deployment of the patient safety strategy within the primary care setting in the Health Regions.
 - Three Health Regions say they have a specific patient safety strategy in place for primary care.
 - A total of seven Health Regions state their organizational chart including a person in charge of patient safety in primary care. In the rest, this is integrated into the overall Patient Safety Strategy.
- Programs/actions carried out by the Health Regions for promoting research into patient safety.
 - A total of six Health Regions fund specific lines of research in patient safety. The rest carry out research projects in patient safety within the framework of general lines of research. Similarly, many of them carry out research projects within the framework of care quality enhancement projects.

Evaluation of the deployment of the patient safety strategy

The Patient Safety Strategy has promoted the creation of elements of safety infrastructure and the implementation of safe practices at the level of the Health Regions. During the time frame throughout which the strategy is being carried out, these elements have been being evaluated by way of a number of indicators which were agreed with the Institutional Committee for the Strategy (representatives from the different Health Regions).

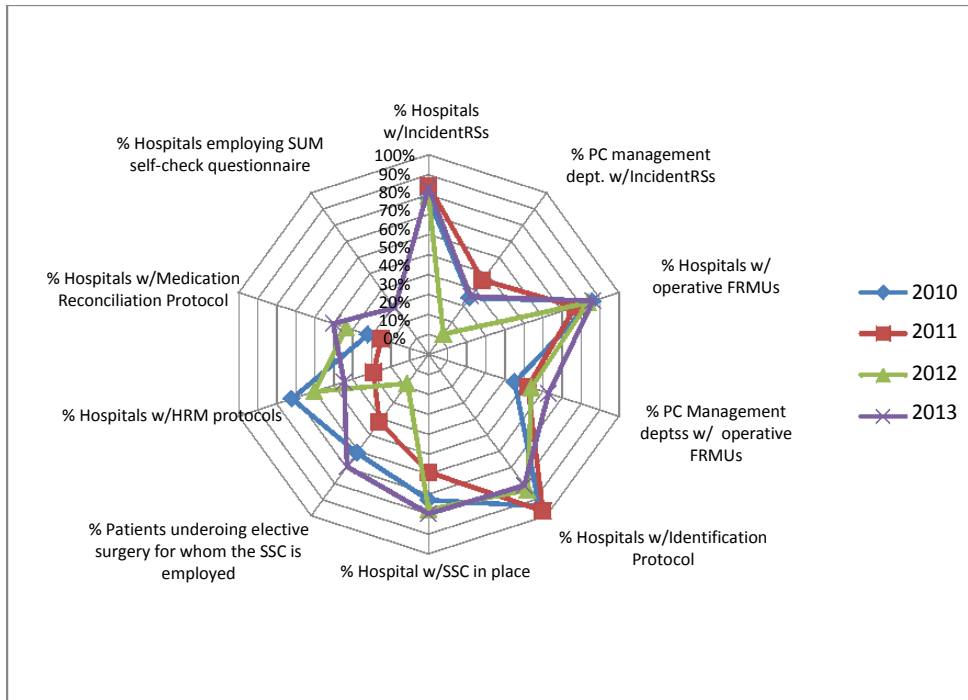
The indicators proposed have been grouped into: patient safety indicators and the Hand Hygiene program indicators

- The **patient safety indicators** make reference to the lines which have been being promoted in the Health Regions and which were funded up to 2011 by way of specific agreements or specifically-allocated funding for the NHS strategies (Table 11).

Table 11. Patient safety strategy indicators for the 2010-2013 time frame

Spain's NHS Patient Safety Indicators
1. % Hospitals having a PS-related Incident Reporting and Learning System
2. % Primary care centers having a PS-related Incident Reporting and Learning System
3. % Hospitals having Functional Risk Management Units which are operative
4. % Primary care management departments having Functional Risk Management Units
5. % Hospitals having a Patient Identification Protocol
6. % Hospitals having the safe surgery checklist implemented
7. % Patients having undergone electric surgery regarding whom the safe surgery checklist is implemented
8. % Hospitals having high-risk medication protocols in place
9. % Hospitals having protocols in place for medication reconciliation at discharge
10. % Hospitals using the self-check safety questionnaire regarding the system for in-hospital medication use

Fig. 5. Results of the evaluation of the patient safety indicators for the 2010-2013 time frame



IncidentRS: Incident reporting systems for learning; FRMUs: functional risk management units; SUM: safe use of medication; HRM: high-risk medication; SSC: safe surgery checklist

The results for these indicators (Fig. 5) show that although the majority of safe practices evaluated having been being carried out properly at the hospital, this not having been the case in primary care.

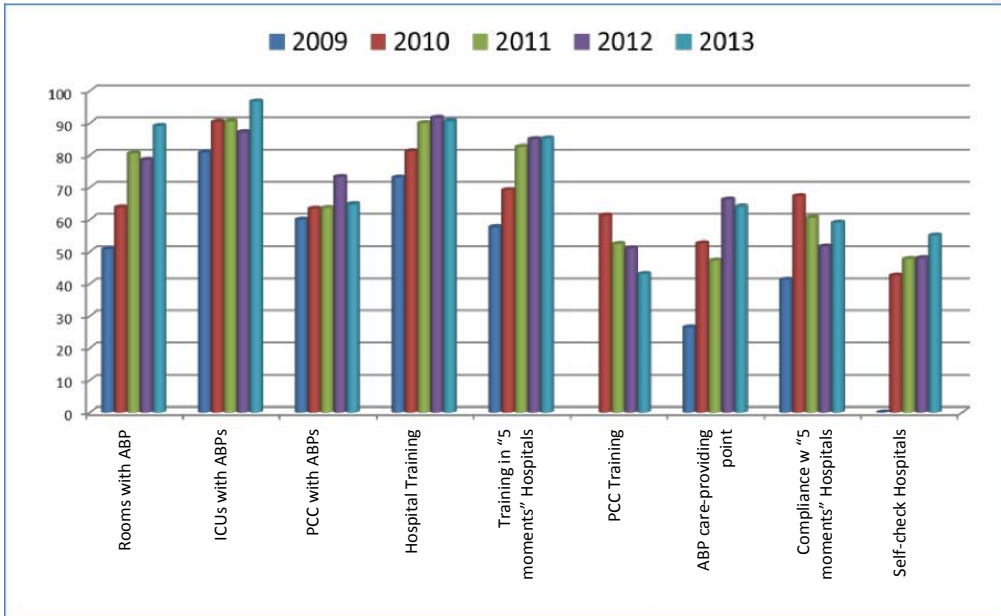
- **Hand Hygiene indicators.** Spain’s NHS Hand Hygiene program has been being carried out since 2008 in collaboration with the Health Regions with whom a consensus has been reached regarding different indicators (Table 12).

Table 12. Spain's NHS Hand Hygiene program indicators

Spain's NHS Hand Hygiene program indicators
1. % Beds with alcohol-based product in the room
2. % Beds on intensive care units with alcohol-based product at care-providing point
3. % Primary care centers with pocket alcohol-based product for home care
4. % Hospitals having training activities in place
5. % Primary care centers having training activities in place
6. Consumption of alcohol-based product hospitalization: liters of alcohol-based produce for every thousand patients per day
7. % Beds with alcohol-based product at care-providing point
8. % Hospitals which observe compliance with the "5 moments"
9. % Hospitals conducting self-check as per the WHO recommendations
10. % Hospitals having training activities in the "5 moments"

The result of the measurement of these indicators shows an improvement over the course of time for all of them except for the aspect having to do with training in Hand Hygiene in primary care.

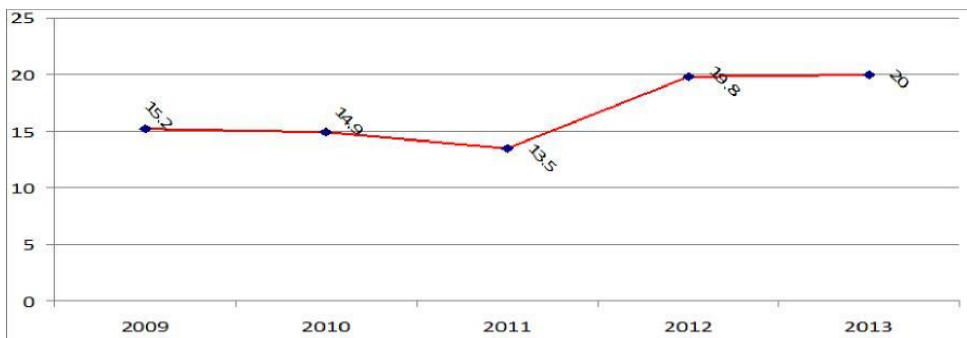
Fig. 6. Results of the evaluation of the NHS Hand Hygiene indicators



ABP: alcohol-based product; ICU: intensive care unit; PCC: primary care center

The consumption of alcohol-based products has been progressively improving over the past few years up to the point of meeting the standards recommended by the World Health Organization (Fig. 7).

Fig. 7. Evolution of the consumption of alcohol-based product in the NHS for the 2009-2013 period



- **Indicators of specific programs**

Evaluations have additionally been being made of indicators of specific programs such as SINASP, Zero Tolerance on the intensive care units, safe use of medication, the results of which are disseminated by way of the MSSSI Patient Safety Web¹⁹².

- **Accreditation**

The periodic evaluation, which is made via the MSSSI, of the hospitals accredited for Specialized Health care Training in Health Sciences has included patient safety criteria which are related to the following clinical practices recommended in the strategy: Hand hygiene, high-risk medications, medication reconciliations, surgical checklist and fail-safe patient identification.

The document furnished by the center proper made it possible for an assessment to have been made in 2012 at the level of development or implementation of these safe practices by employing the criteria included in Table 13.

Table 13. Patient safety criteria evaluated in the accreditation of the NHS teaching hospitals

Point Score	HH	HRM	MedRecon	SSC	PaTIden
0	There is no plan / protocol in place				
1	Protocol: Yes Date: No Person in charge: No Resources: Not specified Training: incomplete Dissemination: exclusively for International HH Day Evaluation: Not specified	Protocol: Yes Consider evaluation, but do not furnish any data			
2	Protocol: Yes Date: No Person in charge: No Resources: Location Training: incomplete Dissemination: exclusively for International HH Day Evaluation: Not specified	Protocol: Yes Consider evaluation, but do not furnish any data			
3	All of the required information is complete				

HH: Hand Hygiene; HRM: high-risk medications; MedRecon: medication reconciliation; SSC: safe surgery checklist; PATIden: patient identification. NHS: National Health System

Table 14. Results of the patient safety criteria evaluated in 2012 in the audits of the NHS teaching hospitals

Total	HH	HRM	MedRecon	SSC	PatIden
0	7 (13%)	8 (15%)	13 (24%)	6 (11%)	1 (2%)
1	11 (20%)	26 (48%)	19 (35%)	18 (33%)	19 (35%)
2	19 (35%)	7 (13%)	7 (13%)	10 (19%)	17 (32%)
3	14 (26%)	4 (7%)	3 (6%)	15 (28%)	9 (17%)
No documentation	3 (6%)	9 (17%)	12 (22%)	5 (9%)	8 (15%)
Total	54 (100%)	54 (100%)	54 (100%)	54 (100%)	54 (100%)

HH: Hand Hygiene; HRM: high-risk medications; MedRecon: medication reconciliation; SSC: safe surgery checklist; PATIden: patient identification.

According to the data furnished by the hospitals, it has been found that no practice evaluated has been fully implemented, especially those having to do with the safe use of medication (Table 14).

Therefore, it can be said that progress has been made over the course of the last ten years in the development of the patient safety infrastructure in the Health Regions, especially in the creation of functional risk management units, incident reporting systems and protocols for the implementation of safe practices. The implementation of safe practices has entailed some clear-cut results in the reduction of health care-associated infection, especially on the critical care units and in the improvement of some aspects of the safe use of medications, as previously discussed. However, room for a major degree of improvement is noted in the implementation of several safe practices, especially in primary care. The need is also noted of working with more highly valid evaluation tools which will make it possible to get a more exact idea as to the impact of the actions carried out.

The data gleaned from the evaluation of the strategy carried out to date has contributed to the proposal of the strategic lines for taking action of the current patient safety strategy.

2. STRATEGIC LINES OF ACTION

- **Strategic line of action 1: Patient safety culture, human and organizational factors, and training**

A positive patient safety-related culture in the health care institutions is an indispensable pre-requisite for preventing and minimizing patient safety-related incidents and being able to learn from past errors in order to reduce the probability of their reoccurring.

For the purpose of further enhancing patient safety culture, it is necessary to continue carrying out actions aimed at measuring and enhancing the safety climate, informing and training all NHS professionals in safety-related aspects, fostering training in effective care, training the working teams in risk management, fostering leadership in safety, reporting and learning from the incidents and keeping the professionals information of the details of the evaluation of their medical services centers, stimulating their active involvement in the enhancements proposed.

General objective 1: Further enhance patient safety culture, human and organizational factors

Specific objectives:

1. Promote the medical services centers availing of a safety plan (their own or institutional) which actively involves all of the professionals and is known by all.
2. Promote the leadership of the professionals for assuring that the patient safety plan objectives will be achieved.
3. Favor the evaluation of the safety climate in the health care organizations and the dissemination of their findings, as an aid in the implementation of safe practices.
4. Foster basic training in patient safety of all of the health care professionals at all levels of their training and development.
5. Disseminate the knowledge and experiences concerning patient safety to all levels of the National Health System.

6. Favor the dissemination of recommendations for the purpose of preventing health care from being provided which is of very little value or is harmful to patients.

Recommendations:

- Set out plans for action in patient safety at the medical services centers with annual objectives, evaluation and planning for dissemination of the results.
- Incorporate clinical leaders who will promote the implementation, development and evaluation of safe clinical practices at the centers/on the units.
- Include patient safety as one of the aspects to be addressed in the plans for taking on new professionals.
- Periodically evaluation, by way of validated tools, the safety climate of the organization as an aid toward knowing the weak points and strong points regarding patient safety.
- Reach a consensus regarding a minimum basic training curriculum in patient safety for the professionals in the NHS which includes concepts on safe clinical practices, communicating, teamwork and health services factors which have a bearing on patient safety.
- Promote the basic training in patient safety of the health care professionals during their undergraduate schooling, specialized training and continued training.
- Identify, disseminate and share at the national, regional and local levels best practices, information and experiences on patient safety by way of different means such as congresses, workshops, conferences, webpages, etc.
- Periodically disseminate the updated recommendations for the purpose of preventing unnecessary health care being provided which is of very little value or which is harmful for the patient.

- **Strategic line of action 2: Safe clinical practices**

Different international organizations have recommended different safe practices on the basis of the frequency of the most frequent adverse events and the existing evidence for their control. Within the framework of the Patient Safety Strategy and in collaboration with the Health Regions, the MSSSI has been promoting different safe practices in keeping with the international recommendations.

The safe practices recommended in this strategy are mainly those aimed at promoting the safe use of medications, preventing health care-associated infections and preventing the harm associated with surgery or patient care procedures, which are the main factors associated with the adverse events according to the different epidemiological studies conducted at the national level^{5,26,27,28,29}. Other practices recommended herein, such as appropriate patient identification, effective communicating or the safe use of ionizing radiation also contribute to preventing avoidable adverse events. The inclusion of recommendation on the adequate management of severe adverse events is in keeping with a widespread feeling in the NHS as to it being necessary to deal with this problem.

General objective 2.1: Promote safe medication use

The activities of pharmacovigilance, training and updating of physicians and nurses in therapeutics and clinical pharmacology or the prevention of errors in the medication circuits are some of the relevant initiatives for further enhancing safety in the use of medications.

The **e-prescription** is useful when associated with supporting clinical decision-making programs for reducing the errors resulting from an incorrect prescription and can also even appreciably enhance the treatments being followed¹⁹³. The computer applications can also provide the information and the instructions necessary for correctly administering the medications.

High-risk medications have a greater probability than other types of medications of being associated with adverse events of severe consequences for the patients. The health care institutions must identify these medications, set out procedures for their safe management in all of the care-providing processes, evaluate the procedures implemented for specific groups of medicines and take specific risk-reducing measures.

Chronic patients, especially polymedicated patients, are more vulnerable to medication errors and must therefore be given special care and require a clinical review being made of the medication regarding both the effectiveness of the treatments and the adherence to the same. One internationally recommended practice aimed at reducing medication errors in care-providing transitions, particularly useful in these patients, is **medication reconciliation**. This is a formal, multidisciplinary process which is aimed at achieving that the information which is conveyed concerning the medication at the points of care-providing transfer will be one in the same, accurate and complete¹⁹⁴. This process must be carried out with the participation of all of the professionals responsible for the patient in question and with the patient and/or caregiver proper, whenever possible. This would also make it possible to evaluate the adherence and/or lack of comprehension of the treatments.

The patients and their caregivers play a fundamental role in medication safety and therefore must be informed so as to be able to assume responsibility for their treatment. The patients must be prepared to serve as a barrier for preventing possible medication errors which occur in other processes, especially for preventing their own errors during the processes of administering the medications in their own homes.

The **analysis and management of the medication errors** detected by the health care professionals in the course of their activity is an essential strategy for further enhancing the quality and safety of the system for the use of medications and a key element for the creation of a safety culture at the local level which must continue being maintained for the purpose of facilitating the sharing of experiences, conveying the lessons learned to the entire NHS and preventing the same errors from once again affecting other patients in the future.

Specific objectives:

1. Promote e-prescriptions assisted with clinical decision-making help systems of proven effectiveness.
2. Foster the implementation of safe practices with high-risk medication.
3. Promote medication reconciliation during the care-providing transitions.
4. Encourage initiatives being taken for further enhancing safety in the use of medication, especially in polymedicated chronic patients and in pediatric patients.

5. Promote the training of health care professionals concerning the safe use of medications.
6. Promote the training of the patients/caregivers concerning the use of medications and their active involvement in the treatments.
7. Promote the reporting of incidents related to the use of medications through the existing reporting systems.
8. Promote the self-evaluation of the safety of the system for the use of medications at the medical services centers.

Recommendations:

- Carry out actions for implementing e-prescription programs which include clinical decision-making help systems which are integrated into the medical services center information systems and are available for all of the professionals involved in the care being provided for the patient in question.
- Set out specific interventions aimed at preventing the most frequent errors involving high-risk medications.
- Standardize the procedures for preparing and administering injectable medicines and parenteral nutrition.
- Systematically review the medication in the polymedicated chronic patients in order to detect or prevent adverse events, guarantee proper medication and further enhance adherence to the treatment.
- Set out recommendations concerning the use of abbreviations, symbols and phrasing used in the process of prescribing and administering medicines.
- Determine specific interventions aimed at preventing medication errors in the care provided for pediatric patients (training, dissemination of guides, etc.).
- Reconcile the medication during care-providing transitions, especially in polymedicated chronic patients and in high-risk patients. This reconciliation must involve the collaboration of all of the people involved (professionals responsible for the patient in question, patient/caregiver, community pharmacy, etc.).
- Carry out training actions offered for the health care professionals concerning the safe use of medications.

- Carry out programs for informing and training the patients/caregivers, especially those polymedicated or those taking high-risk medications, at all of the care-providing levels.
- Maintain and further enhance the reporting of errors and incidents involving medications which occur in the NHS by way of the existing reporting systems, including the analysis and evaluations of the information generated and the dissemination of fitting recommendations.
- Create the necessary collaboration with the pharmacovigilance centers so that the errors involving harm will be notified to the Spanish Pharmacovigilance System.
- Conduct periodic self-checks on the safety of the system for the use of medications by employing standardized tools and setting out recommendation for improvement.
- Increase the surveillance and supervision of the safe use of medications on the part of the pharmacy units and services.

General objective 2.2: Promote safe practices for preventing and controlling health care-associated infections

Health care-associated infections affect 5%-10% of all patients admitted to acute hospitals and involve a high rate of morbimortality in addition to an increase in care-providing costs. The experience gained over the course of the last few years in Spain goes to show that the prevention and control of health care-associated infections is based on the following aspects: an adequate surveillance system, employing standards of care of proven effectiveness and the appropriate, reasonable use of antibiotics.

Likewise, this experience goes to show a need for an interdisciplinary effort including everything from the management and administration of the centers to the professionals who perform their professional duties in all fields of health care.

Health care-associated infections are occasionally related to implantable biomedical devices (catheters, wound vacs, prostheses, implants, etc.), the feasibility and functionality of which is seriously compromised by infection. The mains types of health care-associated infections are related to invasive procedures such as: surgical site infection, catheter-related urinary infection, Central line-associated bloodstream infections (CLABSIs) and ventilator-associated pneumonia.

Employing specific multimodal strategies has shown itself to be useful in preventing these infections, it therefore being necessary to continue promoting the programs which have been gotten under way for their control.

Concerning reporting outbreaks or new resistant pathogens, it is necessary to promote early transmission of information.

The process of combatting antimicrobial resistance must be approached by way of an effective, multifaceted, multidisciplinary strategy actively involving the different sectors and professionals from different specialties.

Specific objectives:

1. Maintain and promote the expansion of the NHS Hand Hygiene program to all medical services centers.
2. Maintain and promote the programs for the prevention health care-associated infections in critical patients and also expanding them to other areas of hospitalization using the surveillance and control systems in place at the medical services centers.
3. Promote a program for the prevention and control of surgical site infection at the NHS level.
4. Promote and implement programs for the rational, optimized use of antimicrobial drugs.
5. Promote the prevention and control of antimicrobial resistances, focusing special attention on the control of the diffusion of multiresistant microorganisms.
6. Favor multidisciplinary strategies for the early detection and treatment of sepsis.
7. Promote programs for the prevention and control of infections within the social service medical services center setting.
8. Promote the systems for the surveillance of health care-associated infections for making the control of their evolution and the comparability of results among centers and services possible.

Recommendations:

- Maintain and consolidate the actions carried out for further enhancing adherence to hand hygiene by professionals and patients/caregivers, in hospitals, primary care and social healthcare services and nursing homes.
- Carry out actions for the appropriate use of antiseptics and disinfections at the medical services centers.
- Set out actions for the proper cleaning, disinfection and sterilization of medical material.
- Carry out a national program in collaboration with the Health Regions for the prevention and control of surgical site infection in selected procedures.
- Maintain the programs carried out for preventing and controlling CLABSIs and ventilator-associated pneumonias on critical care units as well as developing similar programs in other areas of hospitalization adapted to their characteristics.
- Carry out actions for preventing and controlling catheter-related urinary infections on units involving a special risk.
- Maintain and expand the existing programs for the prevention of infection and transmission of multiresistant microorganism to different care-providing units, especially to those which are high-risk (critical care, dialysis, etc.).
- Carry out programs for optimizing antibiotics in keeping with the Strategy Plan for action for reducing the risk of selection and dissemination of resistances to antibiotics.
- Carry out programs for preventing and controlling peripherally-inserted venous catheter-associated phlebitis.
- Set up special programs for controlling and preventing health care-associated infections at social services medical services centers and living facilities.
- Get specific actions under way for the early detection and treatment of patients with sepsis/severe sepsis and septic shock taking into account multidisciplinary involvement.
- Set up teams (multidisciplinary teams, as a priority) at the medical services centers which are specialized in the surveillance and control of health care-

associated infections and which are in keeping with the NHS surveillance programs guidelines.

General objective 2.3: Promote the implementation of safe practices in surgery

The effective implementation of the safe surgery checklist requires specific multimodal and multidisciplinary strategies which include this checklist being appropriately completed and used for detecting incidents revolving around the surgical act. This is a matter of a simple, efficient and effective measure for further enhancing patient safety in the surgical procedure by facilitating full compliance with the universal protocol (right patient, right procedure, right site) and the prevention of surgical site infection. The safe surgery checklist transcends the simple safety enhancement check and improves the communications and teamwork involved and should be completed in full at least in elective surgery.

Full compliance with the Helsinki Declaration on patient safety in Anesthesiology would serve as a stimulus for promoting the use of the Safe Surgery Checklist on being included under Section 4 of said Declaration.

Specific objectives:

1. Promote the implementation and correct use of the Safe Surgery Checklist.
2. Promote the adoption of the recommendations of the Helsinki Declaration on patient safety in anesthesiology.
3. Promote the specific training in non-technical aspects (communication, teamwork, etc.) among the surgical block professionals.
4. Improve communication in the transfer of the patient from the operating rooms to recovery or intensive care unit.

Recommendations:

- Carry out actions at the NHS medical services centers for the implementation, adaptation, appropriate use and evaluation of the Safe Surgery Checklist, both in hospital surgery and extrahospital surgery.
- Promote the marking of the surgical site as a routine practice as well as recommendations to the patients in this regard.
- Disseminate and implement the Helsinki Safety in Anesthesia recommendations.

- Carry out training actions for the surgical block professionals in non-technical aspects (communication, teamwork, etc.).
- Develop and implement a patient status list on transfer from operating room to Recovery or intensive care unit, especially in patients with severe systemic disease.
- Carry out measure for improving the prophylaxis of venous thromboembolism.

General objective 2.4: Promote the implementation of safe practices in patient care

The objectives suggested in this regard have not as yet been fully achieved to date, the degree to which achieved having varied greatly throughout the country. All of this entails the need of systematically promoting procedures for the implementation of safe practices of proven effectiveness in the nursing care provided for the patients.

Specific objectives

1. Foster individualized nursing care plans suited to each patient's needs being carried out.
2. Promote the inclusion of patient safety aspects in the care plan on the patient's medical record and on the discharge report.

Recommendations

- Develop a personalized care plan (in hospitalized patients or homecare patients) which addresses at least the following aspects relevant to patient safety:
 - Preventing falls and related injuries
 - Preventing pressure ulcers
 - Preventing health care-associated infections
 - Safety in physically restraining those patients who so require
 - Preventing malnutrition and dehydration, especially in elderly patients
 - Preventing broncho-aspiration
 - Safely caring for frail patients
 - Preventing and controlling pain the adults and children, tending to the needs and preferences of the patients and their caregivers

- Include actions in the care plan for informing the patients and caregivers regarding the care provided and the risks involved.
- Include in the care plan for the patient's medical record and discharge report the evaluation of the patient's risks due to their clinical situation and the implementation of the care necessary for the prevention and treatment thereof.
- Develop specific care plans which include the integral assessment of the patients in homecare, restrained patients and terminal patients.

General objective 2.5: Promote safer patient identification

The shortcomings in identifying patients entail risks which may lead to incorrect diagnoses, tests being conducted or surgical procedures being performed or medicines or hemoderivatives being administered to the wrong patients.

Safe patient identification of all patients must be guaranteed by means of appropriate methods which make it possible to confirm the patient's identity every time a procedure is performed, especially if it is an invasive procedure¹⁹⁵.

Specific objectives:

1. Promote the safe patient identification of the right patient, right procedure and right site.
2. Promote safe patient identification of the patients who have specific risks.
3. Assure safe patient identification of biological samples, which are determining factors for the diagnosis.
4. Foster the fail-safe identification of the patient's clinical documents.

Recommendations:

- Develop and implement actions for safe patient identification, including:
 - Using at least two unique identifiers for the patient. Preferably using automated means of identification.
 - Checking the patient's identification for each procedure, especially for those which are high-risk.
 - Setting out standardized systems for safe patient identification and those entailing specific risks.

- Training the personnel in the appropriate procedure for identifying patients and the need of verifying their identification, at least in view of any intervention involving a risk.
- Getting the patient/caregiver actively involved in the identification process.
- Making an evaluation and conducting a follow-up on the identification process.
- Assure the safe identification of newborns before they leave the delivery room and that this identification be made in the presence of the mother or a family member, whenever possible.
- Check the identification of documents of each patient during the care-providing process.
- Label the biological samples and imaging tests at the exact point in time at which they are taken.
- Set out actions which assure traceability of both solid and liquid biological samples, whether or not they be replaceable, which are determining factors for the diagnosis, from the very outset of the sample being taken.
- Determine mechanisms at the hospital and ambulatory level of care, for identifying unidentifiable patients and suitably distinguishing among those who have similar identifiers (same name, etc.).

General objective 2.6: Promote communication among professionals

In the course of the care-providing process, it must be assured that the information conveyed among professionals concerning the patient’s clinical situation is accurate, adequate and is provided to the right person.

Conveying clinical information on patients, especially during the transition of care, is a high-risk process in which the key element involved is communication. The breakdowns in communication among professional comprise the factor most often involved in sentinel events causes¹⁹⁶.

The standardization of the communicating procedure during the transitions of care, minimizes the variability of the messages and favors the efficacy of the communication, contributing to all of the professionals involved in the transfer being aware of the patient’s overall situation and the errors being reduced¹⁹⁷.

Specific objectives:

1. Promote standardized communication, both within the units and during the transition of care for guaranteeing safe, continued care for the patients.

Recommendations:

- Carry out actions for the implementation of structured communicating techniques.
- Set out actions for effective communicating in a timely fashion of alert and critical values of diagnostic tests which may be life-threatening for the patient.

General objective 2.7: Promote the design and development of strategies for dealing with severe adverse events at healthcare centers

When an adverse event occurs, especially when it has caused serious harm to the patient, the patients and their family members (first victims) must be provided with support by the organization and must be furnished with the information appropriate for the circumstances in question (open disclosure), as well as the consequences and the actions to be carried out for providing a response to their needs. In turn, the health care professionals involved in an adverse event (second victims) must be able to rely on institutional support so as to be able to openly report what has happened and must be furnished with support for their integration into the care-providing endeavor without any aftereffects.

The health care organizations should take a proactive position which is a step ahead of the situations involving conflicts, availing of protocols and procedures for adequately responding to patients and professionals when a severe adverse event occurs, additionally taking into account actions for maintaining or restoring the organization's (third victim) prestige and the confidence of the organization's users.

Specific objectives:

1. Promote strategies being carried out for managing severe adverse events and supporting the victims thereof.
2. Promote the training of the professionals for the purpose of being able to appropriately carry out said strategies.

Recommendations

- Set out strategies for the appropriate management of severe adverse events which will assure:
 - Providing the patients and caregivers who have experienced a severe adverse event with timely, clear, sincere and fitting information concerning which has happened, as well as a plan for providing support for their needs.
 - Offering support to the health care professionals involved in a severe adverse event.
 - Appropriately managing the process of conveying information to the organization and to the media for the purpose of restoring the confidence in the institution.
- Carry out training actions for the professionals and the managers of the medical services centers concerning aspects of providing care for the patients and professionals involved in severe adverse events.

General objective 2.8: Promote the safe use of ionizing radiation in clinical procedures

The development of technologies employing radiation in the field of medicine has given rise to some major improvements in the diagnosis and treatment of disorders involving a major benefit for patients. The use of these technologies has been increasing over the years in such a way that medical exposures are currently one of the sources of artificial radiation which contribute the most to the population's exposure¹⁹⁸.

Within this context, the international organizations such as the World Health Organization and the International Atomic Energy Agency (IAEA) have promoted Plans for Action for the Radiological Protection of Patients in the health care sector^{199, 200}.

Therefore, at the national level and on the basis of that which is set forth under the Framework Agreement between the MSSSI and the Nuclear Safety Council concerning collaboration on the subjects of medical exposures, lines of patient safety are proposed in this area for the purpose of promoting the safe, controlled use of ionizing radiation in the NHS.

The strategy lines further expand upon that which is set out under the new European Directive on Radiological Protection approved in 2013²⁰¹, as well as the specific national Regulations^{202,203,204,205}.

The above additional reflect the pillars of the radiological protection of patients (above all, those most highly vulnerable, such as pediatric patients) and the heightening of awareness and adaptation, in conjunction with the auditing, which were agreed at the latest International Conference for Radiological Protection of Patients²⁰⁶.

Specific objectives

1. Promote actions for further enhancing the processes justifying the use of ionizing radiation, especially in patients under 18 years of age.
2. Promote Patient Safety in the diagnostic and therapeutic procedures involving the use of ionizing radiation.
3. Promote the detecting and prevention of the adverse events due to ionizing radiation, especial in radiation therapy and in interventional radiology procedures.

Recommendations

- Carry out actions for training and informing the prescribing physicians in the use of procedures involving ionizing radiation, especially in patients under 18 years of age.
- Set out protocols for conducting diagnostic tests and treatments involving ionizing radiation, especially in patients under 18 years of age.
- Set out protocols, taking into account the ALARA criteria for the optimizing of radiological protections and the use of updated reference levels for the process of conducting diagnostic tests and treatments involving ionizing radiation, especially in patients under 18 years of age.
- Make certain that Quality Assurance Programs are carried out in all those services working with ionizing radiation, especially in the radiation therapy services, which include risk analyses and management of the incidents reported.
- Set out protocols to be followed by patients who have been given high doses of radiation in interventional procedures.

- Furnish patients with prior information concerning the risks related to the procedures which employ ionizing radiation.
- Set out and promote the dissemination of a guide as to indications for correctly requesting imaging diagnostic testing.
- Favor the patient's clinical documentation including information being recorded on each one of the procedures which are carried out with ionizing radiation (dose received, activity and route for administration of radiology drugs, description of the technique employed and distribution of doses in radiation therapy and brachytherapy).
- Periodically conduct a review to make certain that the equipment is in proper working order so as to guarantee the least amount of ionizing radiation possible in the diagnostic procedures, as well as optimized distributions in radiation therapy.
- Make certain that the incidents related to radiation therapy are reported and properly managed (at the very least, at the departmental level).

- **Strategic line of action 3: Risk management and reporting and learning systems**

This risk management is focused on the identification and analysis of the health care-associated risks, as well as carrying out plans for action for preventing these risks and informing the professionals concerning the achievements attained. This risk management provides some highly useful tools such as the Root Cause Analysis, which affords the possibility of making an in-depth analysis of the patient safety-related incidents, especially the sentinel events, and of preventing these incidents from recurring.

The medical services centers must carry out specific strategies for the proper management of health care risks.

The reporting systems afford the opportunity of learning from the experiences of others for the purpose of preventing errors. However, the fear and reticences of the professionals with regard to reporting these errors due to possible penalizing consequences have a bearing on the quality of the reporting systems and their being used to the best advantage.

General objective 3.1: Promote risk management at the medical services centers

Specific objectives:

1. Promote the creation of risk management units at healthcare centers which will carry out strategies for the proper management of health care-related risks.

Recommendations:

- Set up (at the individual center or management level) functional health care risk management units or similar units which assume these duties.
- Promote different methods for identifying safety-related risks (analysis of complaints and suggestions, safety rounds, review of medical records, sessions for learning from mistakes made, epidemiological studies, etc.).
- Promote the training of all of the professionals in the management of risks and in the use of the risk assessment tools applicable to their individual field.
- Carry out specific risk management actions, including taking a proactive attitude and the use of a methodology which will make it possible to identify problems, analyze their causes and carry out actions which will prevent or reduce their being repeated.
- Make in-depth, systematized analyses of the sentinel events identified which so require.

General objective 3.2: Promote the implementation and development of systems for reporting health care-related incidents for purposes of learning

Specific objectives:

1. Promote the implementation and development, at healthcare centers, of systems for reporting health care-related incidents focused on lesson learning and problem solving at local level.
2. Promote strategies being carried out for further enhancing and providing incentives for incidents being reported at the medical services centers.
3. Foster agile, timely feedback from the information to the professionals who have taken part in reporting incidents, as well as to the rest of the organization.
4. Foster periodic publication of information related to the safety incidents identified in the NHS.

5. Promote the protection of the professionals taking part in the reporting systems for disciplinary or legal proceedings.

Recommendations:

- Set up a system for reporting health care-related incidents at the medical services centers or units which do not already have such a system in place, which will be voluntary, confidential and non-punitive and which will encourage learning.
- Facilitate those centers which do have this system in place with the use and sustainability thereof for the purpose of further enhancing the safety of the health care provided.
- Carry out training actions for all of the professionals for the proper reporting of health care-related incidents.
- Carry out actions with the managers and professionals which will favor the reporting, analysis and management of incidents related to the health care provided.
- Facilitate the reporting of incidents by patients/caregivers.
- Provide the clinical professionals with timely information as to the incidents identified and the actions taken for their prevention.
- Furnish the clinical professionals with the information on the most frequent safety-related incidents in the NHS and the recommendations for their prevention
- Promote further expansion on the fitting rules and regulations focusing on the protection of those reporting incidents.

- **Strategic line of action 4: Patient and caregiver participation for their safety**

Many reticences still as yet exist both on the part of the managers and on the part of the professionals which are hindering patients being actively involved in the decision-making process and citizen participation at the group level in health care-related decision-making. This participation is based on the right which individuals, as citizens, have for taking part in the decisions affecting them and their freedom of choice within the health system.

There are also cultural reticences on the part of the patients proper to adopt a different profile and role in the health care delivery process.

Despite the above, it is indeed true that the role of patients is changing and that this requires a major cultural change in the professional-patient relationship based on the shared decision-making process.

General objective 4.1: Promote the participation of the patients and their caregivers in patient safety

Specific objectives:

1. Promote the patient/caregiver being furnished with complete, readily comprehensible information concerning their care delivery process and the risks entailed, facilitating a shared decision-making process with the professional/team providing the patient's care.
2. Promote the training of the patients/caregivers concerning the patient's disorder, the care required and the risks entailed in the health care provided and their prevention.
3. Promote the active involvement of the patients / caregivers in patient safety-related aspects in their contacts with the health system.

Recommendations:

- ☐ Have patient receiving plan in place including clear, complete, comprehensible information on their rights and obligations, the health services in which the care will be provided, the risks entailed in the care to be provided and the patient's involvement in the decision-making process.

- Foster specific training programs for patients/caregivers for the purpose of achieving their active involvement in the decision-making and care-providing processes.
- Carry out actions for stimulating the participation of the patients/caregivers in patient safety-related activities (joint patient and professional committees, patients' council, etc.).
- Allow and promote the presence of a companion for the patient, provided that this be possible, in all of the health care settings, especially in the case of pediatric patients or those patients whose cognitive abilities are diminished.
- Assure the correct procedure in obtaining the informed consent of the patients, above all in invasive procedures, as well as in the process of recording living wills, promoting practices which will help the patient to execute a living will in an informed manner.
- Prepare guidelines as to how to provide patients with care quality and patient safety-related information, fostering the transparency of the information.
- Carry out training actions for professionals on techniques for communicating with the patients.

- **Strategic line of action 5: Research into patient safety**

The fields of research into patient safety should include aspects for further enhancing the knowledge concerning: the magnitude and the characteristics of the clinical risk, the comprehension of the factors contributing to patient safety-related incidents occurring, the impact which the adverse events have on the health system and the identification of cost-effective, feasible, sustainable solutions for achieving safer health care.

General objective 5.1: Promote the further enhancement of the knowledge in the prevent of the harm associated with health care

Specific objectives:

1. Promote specific lines of research in patient safety at national and Regional level.
2. Foster the dissemination of the findings of the patient safety research to the entire NHS and to the citizenry.

Recommendations:

- Promote research studies being carried out which will make it possible to:
 - Quantify the magnitude and the characteristics of the clinical risk and the risk trends.
 - Further enhance the comprehension of the factors which contribute to the occurrence of the patient safety-related incidents.
 - Evaluate the economic impact which adverse events have on the health system.
 - Evaluate the impact, effectiveness and sustainability of the practices, procedures and solutions implemented for the purpose of further enhancing patient safety.
- Promote the identification and dissemination of cost-effective, feasible, sustainable solutions for achieving safer health care and preventing incidents harmful to the patients.
- Favor the dissemination of the findings of the research studies conducted concerning patient safety.

- **Strategic line of action 6: International participation**

Spain has been taking active part in the activities carried out by the World Health Organization's Patient Safety Program since the Program first began, as well as in patient safety-oriented actions with the Pan-American Health Organization. Spain is a member of the technical groups in the Organization for Economic Development and Cooperation, and in the European Commission. .

General objective 6.1: Promote international collaboration in patient safety

Specific objectives:

1. Foster collaboration with the World Health Organization's and the Pan American Health Organization's patient safety Program.
2. Promote Spanish participation in international forums related to patient safety.

Recommendations:

- Maintain and bolster the collaboration with the World Health Organization's and the Pan American Health Organization's Patient Safety Program.
- Maintain and bolster the collaboration with the Member States and the European Commission in working groups and joint actions within the framework of the European Union's care quality and patient safety-related actions.
- Collaborate with other international organizations which carry out relevant actions regarding patient safety.

3. EVALUATION

For the evaluation of this strategy, several indicators and criteria are being agreed with the Health Regions and will be included in a separate document currently in the process, titled "Evaluation of the 2015-2020 National Health System Safety Strategy".

4. GLOSSARY

- **Accreditation.** Formal recognition of the independence and technical capacity of a conformance evaluation agency for carrying out its work in accordance with internationally-recognized requirements²⁰⁷.
- **Adverse event:** An incident which causes harm to the patient²¹³.
- **Health Region.** Territorial entity which, within the constitutional body of law of the Kingdom of Spain, is endowed with legislative autonomy and executive authorities, as well as the power of administering themselves by means of their own representatives²¹¹.
- **Quality of care.** The degree to which the health services for the individuals or the population increase the possibility of achieving the desired results and are, at the same time, consistent with current scientific knowledge. The health system must see to further enhancing the following areas of the health care provided: effectiveness, efficiency, accessibility, acceptability (patient-centered care), equity and safety²⁰⁹.
- **Error.** This refers to the fact of not carrying out a planned action or of employing an incorrect plan. Errors can be either errors of commission, if something is done wrong, or errors of omission, if the correct thing is not done²¹³.
- **Safe patient identification.** A procedure affording the possibility of making certain of the patient's identify during the care-providing process on the basis of the identification of details which pertain solely to the patient in question and cannot be shared by other patients¹⁹⁵.
- **Hand hygiene.** A general term for referring to the removal of microorganisms by way of disinfecting agents such as alcohol or soap and water⁸⁶.
- **Harmless incident.** An incident which the patient experiences but which causes no appreciable harm²¹³.
- **Health care-associated infection.** An infection acquired as a result of a health care intervention in any health care setting (hospital, outpatient care setting, living facilities, etc.) and which was not present or being incubated at the point in time at which the care was provided¹⁰⁴.

- **Health care-related harm.** The harm which results from the plans or measures adopted during the process of providing health care or which is associated with the same²¹³.
- **High-risk medications.** Those which have a very great probability of causing severe harm or even death when an error is made in the course of their use. This definition does not indicate that the errors associated with these medications are more frequent, but rather that in the event an error is indeed made, the consequences for the patients are usually more severe²¹⁶.
- **Medication error.** An unintentional error in the process of prescribing, dispensing or administering a medicine under the control of the health care professional or of the citizen who takes the medicine²¹⁴.
- **Medication Reconciliation.** A formal process consisting of obtaining a complete, accurate list of the patient's medication prior to admission to hospital and comparing it to the medication prescribed for that same patient at hospital admission, in the transfers and at discharge from hospital. The discrepancies found must be appropriately recorded and reported to the next health provider and to the patient²¹⁰.
- **National Health System.** Coordinated set of the health services of the Central Government Administration and the health services of the Health Regions which integrates all of the health care benefits and functions which, by law, are the responsibility of the public powers²²⁰.
- **Nosocomial infection.** An infection acquired during a hospital stay which was not present or in the incubation stage at the point in time at which the patient was initially admitted to hospital²¹⁵.
- **Patient participation.** The process allowing the patients, their caregivers or the person to whom they devolve their power to take part in the decisions related to their health condition and in the prevention of health care-related harm, thus contributing to the organization's learning by way of their experience as patients.

The term "public participation" is understood as the extension by way of which the patients or caregivers, through their representative organizations, contribute to shaping the health system by means of their active involvement

in the process of designing the health policies, the preparation of health strategies and the governance of the institutions.⁶⁴

- **Patient safety.** Reduction of the risk of unnecessary harm associated with the process of providing health care up to an acceptable minimum, taking into account the current knowledge at the point in time, the available resources and the context in which the care is provided²¹³.
- **Reporting and learning system.** A system requiring the collection of data and analysis concerning all aspects related to the process of providing care for the patient in which there has been an unanticipated circumstance which could have caused or has caused the patient unnecessary harm, for the purpose of preventing its reoccurrence by way of learning⁶⁵.
- **Patient safety-related incident.** An event or circumstance which has caused or could have caused a patient unnecessary harm²¹³.
- **Patient.** A person who requires health care and is placed under the care of professionals for maintaining and/or restoring his/her health or bringing symptoms under control²¹⁷.
- **Procedure.** Structured method for doing something or performing a task²¹⁸.
- **Risk management.** Clinical, administrative and industrial activities which the organizations employ with a view to identifying, evaluating and reducing the risk of harm to the patients, the personnel and the visitors in addition to the risk of losses for the organization²¹³.
- **Risk.** Likelihood of an incident occurring²¹³.
- **Safe practices.** Interventions, strategies or approaches aimed at preventing or mitigating the unnecessary harm associated with the process of providing patients with health care and further enhancing their safety⁸⁶.
- **Safe surgery.** Set of rules to be followed during the surgical procedure for the purpose of guaranteeing the patient's safety in the prevention of adverse events related to: surgical site infection, wrong site/wrong patient/wrong procedure, the surgical equipment, the anesthesia and the use of the medicines⁴⁵.
- **Safety culture.** An organization's safety culture is the result of the values, attitudes, perceptions, skills and patterns of behavior of individuals and

groups which determine the commitment as well and the style and ability thereof, with regard to the health of the organization and the management of safety²¹².

- **Sentinel event.** An unanticipated incident in which death or severe physical or mental harm or the risk of the same being caused occurs. Severe harm specifically includes the loss of a limb or a function. The phrase “or the risk of the same being caused” encompasses all variations of the process the repetition of which would entail a major probability of a severe adverse outcome. These events are known as “sentinel” events because they alert to the need of an immediate attention and response²¹³.
- **Specialized Care Activity Register- Minimum Basic Data Set (RAE-CMBD in Spanish):** Royal Decree 69/2015 of February 6 governing the Specialized Care Activity Register (RAE in Spanish), based on the current Minimum Basic Data Set (MBDS). This includes the standardized recording of a number of variables related to the patient and to the care-providing episode in question, including the diagnoses and the procedures. This register encompasses both hospitalization as well as the homecare hospitalization, medical day hospital, outpatient surgery, especially complex outpatient procedures and hospital emergencies care-providing modalities²¹⁹.

5. ABBREVIATIONS & ACRONYMS

AEMPS: Spanish Medicines and Medical Products Agency

AHRQ: Agency for Health Care Research and Quality

PC: Primary Care

CRB: Catheter-Related Bacteremia

BURDEN: Burden of Resistance and Disease in European Nations

PCC: Primary Care Center

ACs: Health Regions

CHAFEA: European Commission and Consumers, Health, Agriculture and Food Executive Agency

CISEM-AP: Reporting harmless safety incidents and medication errors in primary care

CISP: Population Health Research Center. MBDS: Minimum Basic Data Set

MedRecon: Medication Reconciliation

AE: Adverse Event

EARCAS: Adverse Events at Social services medical services centers and Living facilities

SYREC: Safety and Risk in the Critical Patient

EARS-Net: Antimicrobial Resistance Interactive Database

ECDC: European Center for Disease Prevention and Control

ENEAS: National Study on Hospitalization-Related Adverse Events

APEAS: Study on Adverse Events in Primary Care

EVADUR: Adverse Events in Emergency Care

FHC: Systems for reporting and recording adverse events

HELICS: Hospital in Europe Link for Infection Control through Surveillance

HH: Hand Hygiene

HAIs: Infection acquired as a result of a health care intervention in any health care setting (hospital, outpatient care, living facilities, etc.) which had not become evident or had been incubating at the point in time at which the care is provided (ECDC).

PATIden: Patient Identification

IMPLEMENT: Implementing Strategic Bundles for Infection Prevention & Management

INGESA: National Health care Management Institute for Ceuta and Melilla

CPI: Consumer Price Index

IPSE: Improving Patient Safety in Europe

UTI: Urinary Tract Infection

JC: Joint Commission

SSC: Safe surgery checklist

HRM: High-Risk Medications

MOSPS: Medical Office Survey On Patient Safety Culture

MRSA: Methicillin-Resistant *Staphylococcus Aureus*

MSSSI: Ministry of Health, Social Services and Equality

NQF: National Quality Forum

VAP: Ventilator-Associated Pneumonia

OECD: Organization for Economic Cooperation and Development

WHO: World Health Organization

PaSQ: Joint action for patient safety and care quality

ABP: Alcohol-Based Product

PROA: Program for Optimization of the Use of Antibiotics in Hospitals

PROHIBIT: Prevention of Hospital Infections by Intervention and Training

AMR: Antimicrobial Resistance

SEEIUC: Spanish Society for Intensive Care Nursing and Coronary Units

SEMICYUC: Spanish Society for Intensive Care Medicine, Critical Care and Coronary Care Units

SGIS: Safety-Related Incident Management System

SINASP: Patient Safety-Related Reporting and Learning System

SINEA: Incident and Adverse Event Reporting System

SISNOT: Harmless Incident Reporting System

SNASP: Patient Safety-Related Reporting and Learning System

IncidentRS: Incident Reporting System for Learning

NHS: National Health System

TPSC: Patient Safety Management Platform

ICU: Intensive Care Unit

FRMU: Functional Risk Management Unit

PU: Pressure ulcers

SMU: Safe Medication Use

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