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Preventability and Impact of Adverse Events in Spanish public hospitals

Introduction
In the last years, they have been carried out several epidemic studies in diverse countries .That Epidemiological studies have estimated an AE related to hospital care rate of between 4% and 17%, and have considered 50% of them ace preventable.

All the studies estimate both AE incidence and preventable AE ratio and at the same time, evaluate impact in terms of patient disability or death and/or hospitalisation stay prolongation, and association between AE and death. Among the factors contributing to an increase in AE risk, the following stand out: introduction of new techniques and procedures, fatigue and lack of experience of professionals, severity of the process, the need for emergency care and the length of hospital stay.

The aim of this study is to define preventable AE and determine the impact in terms of disability, death and/or prolongation of hospital stay of AE associated with medical care in Spanish public hospitals.

Methods
Retrospective cohort study by means of the review of 5,624 medical records in 24 hospitals selected by random sampling stratified. We used the screening guide and the MRF2 form. We were able to identify 525 patients suffering Adverse Events(AE) associated with medical care, who accumulated 655 AE. Of these, 42.8% were considered as preventable. Most frequent preventable AEs were found in those related to diagnosis (84.2%), to nosocomial infections (56.6%) and to care (56%).

As for the severity of the EA, 45% were considered slight, 39% you control and 16% severe. There were no significant differences between AE severity and hospital size, but there were according to service type. Some 31.4% of AEs resulted in a longer stay and 23.4% led to hospital admission. AE associated with medical care caused 6.1 additional stays per patient. Of the patients, 66.3% required additional procedures and 69.9% required additional treatments. Incidence of death in patients with AE was 4.4% . We observed 13.2% of preventable AE in patients with intrinsic risk factors and 5.2% in

patients without ($p<0.001$). Similarly, 9.5% of preventable AE were observed in patients with extrinsic risk factors and 3.4% in patients without ($p<0.001$). Age over 65 was associated with a higher incidence of preventable AE.

Discussion

The most frequent causes of AE resulting in admission or readmission are nosocomial infections, problems during surgical procedure and problems associated with the use of medication. These causes explain 74.9% of these admitted cases. AE associated with health care cause a high sanitary (distress, disability and, in isolated cases, even death), social (increasing hospital stay) and economic impact (consumption of additional resources). Some 16% of AE were considered severe and in 15 patients (0.3%) included in the study, death was associated with AE

Fortunately a high percentage of them can be prevented by improving medical care. We have not found an association between preventability and severity of AE.

The information from the clinical record, a poor quality of these clinical records could lead us to underestimate the incidence of AE. With regard to the quality of the notes in the clinical record, the reviewers considered that the information on the AE in the record was inadequate or not very adequate in 19% of the cases.

To know the impact and preventability of AE, contributes to improvements in the patient's safety.

Incidence of adverse events related to health care in Spain.

Aranaz Andres,JM[1]; Limón Ramirez,R[1]; Gea Velazquez de Castro,MT[1]; Requena Puche,J[1]; Aibar Remón,C[2]; Terol García,E[3].

[1]Miguel Hernández University of Elche. Spain. [2]University of Zaragoza. Spain. [3]Spanish Ministry of Health and Consumer Affairs.

Introduction:

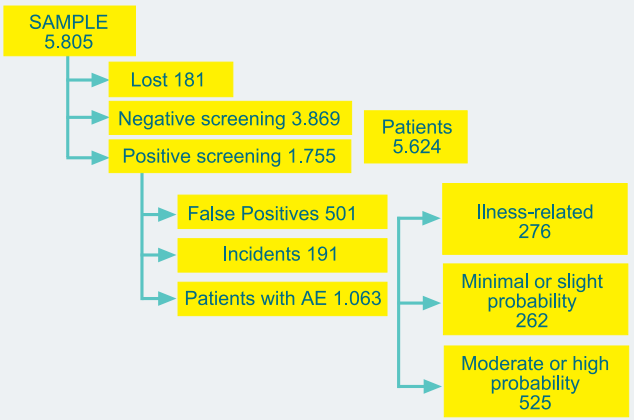
A safe clinical practice requires the achievement of three main objectives: to identify the safest and most efficient diagnostic and therapeutic clinical procedures, to guarantee their implementation for those requiring them and to conduct them correctly and without errors.

Objectives:

Our objective was to make a diagnosis of the situation in Spain.

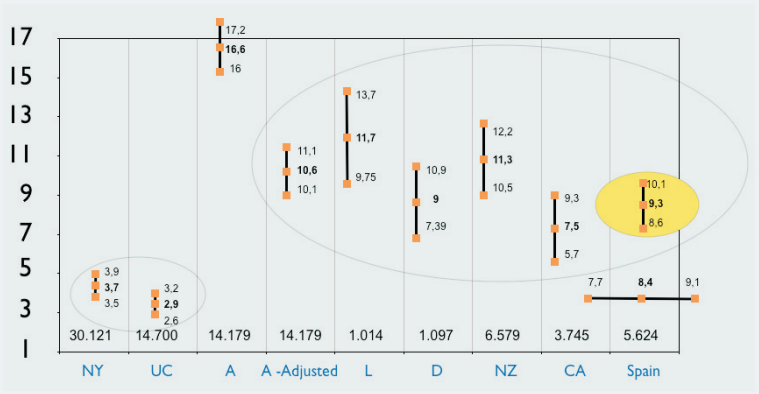
Methodology:

Retrospective cohort study.

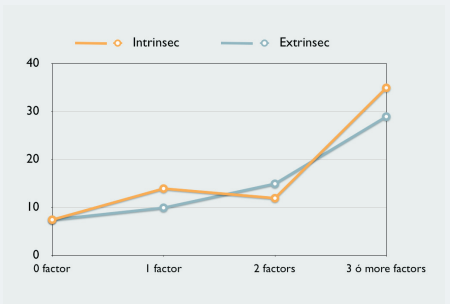


Results:

Incidence



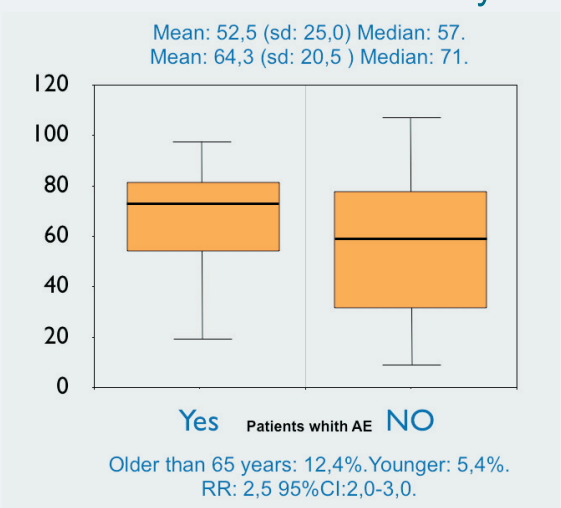
Patient vulnerability



		ADVERSE EVENT		
		Absence	Presence	TOTAL
INTRINSIC RISK FACTORS	Absence	3.181 94.8%	174 **5.2%**	3.355
	Presence	1.970 86.8%	299 **13.2%**	2.269
	TOTAL	5.151 91.6%	3.181 94.8%	5.624

		ADVERSE EVENT		
		Absence	Presence	TOTAL
EXTRINSIC RISK FACTORS	Absence	943 96.6%	33 **3.4%**	976
	Presence	4.208 90.5%	440 **9.5%**	4.648
	TOTAL	5.151 91.6%	473 8.4%	5.624

Patient vulnerability



Older than 65 years: 12,4%.Younger: 5,4%.
RR: 2,5 95%CI:2,0-3,0.

Types of AE

Problem nature	Total (%)	Avoidable (%)
Procedure-related	25.0	31.7
Nosocomial infection-related	25.3	56.6
Medication-related	37.4	34.8
Related to the care provided	7.6	56.0
Diagnosis-related	2.7	84.2
Others	1.8	33.4
Total	655(100%)	278(42.6%)

Conclusions:

The incidence of patients with AE related to medical assistance in Spanish hospitals was similar to that found in the studies conducted in American and European countries using a similar methodology. Patient vulnerability has been identified therein as playing a major role in generating healthcare-related AE. Preventability was not related to severity. The health-related, social and economic impact of AE, until quite recently a silent epidemic in our country, makes their study a Public Health priority.

Plan de Calidad para el Sistema Nacional de Salud

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO

Preventability and impact of adverse events in Spanish public hospitals.

Aranaz Andres,JM[1]; Requena Puche,J[1]; Gea Velázquez de Castro,MT[1]; Limón Ramirez,R[1]; Aibar Remón,C[2]; Agra Varela,Y[3].

[1]Miguel Hernández University of Elche. Spain. [2]University of Zaragoza. Spain. [3]Spanish Ministry of Health and Consumer Affairs.

Introduction:

Epidemic studies in several countries have estimated a rate of AE related to hospital care between 4% and 17%, and have considered 50% of them as preventable.

Objectives:

To define preventable AE and to determine the impact of AE associated to medical care in terms of disability, death and/or prolongation of hospital stay in Spanish public hospitals.

Methodology:

Retrospective cohort study. 5,624 medical records from 24 hospitals were reviewed. Hospitals were selected by stratified random sampling.

Results:

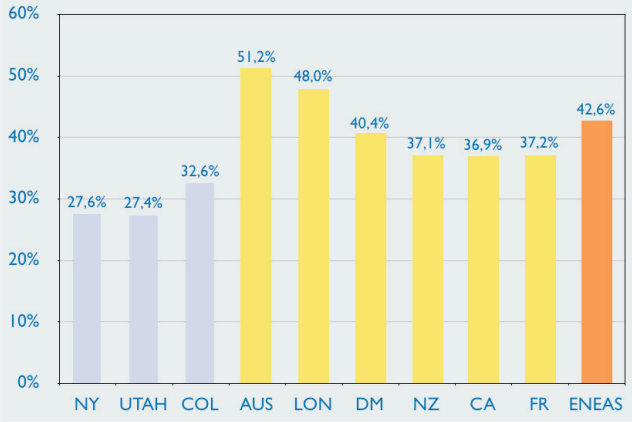
Severity and preventability of AE

TYPE	N	%	Avoidable (%)
Slight	295	45	43.5
Moderate	255	39	42.0
Severe	105	16	41.9
TOTAL	655	100	42.6

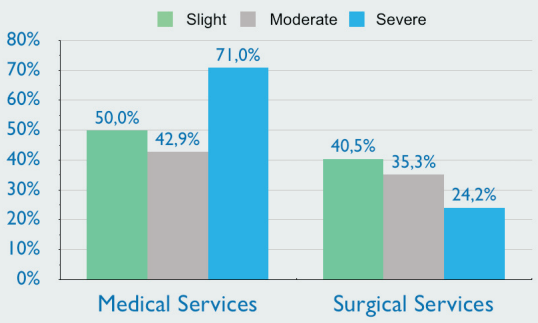
Severity of AE

ENEAS	N	%	Avoidable (%)
Non severe	550	84	42.8
Severe	105	16	41.9
TOTAL	655	100	42.6

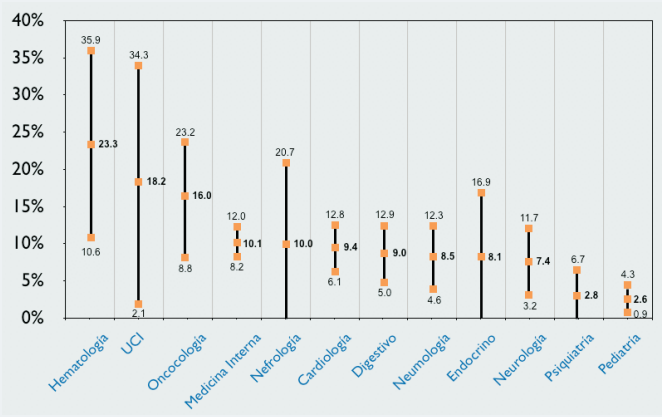
Preventability of AE



Severity of AE by Service type



Incidence of AE to service



Impact of AE

Impact on the hospitalization	%
Extended stay	31.4
Readmission	25

Impact on the hospitalization	days
Additional stays/patient with AE	6
Additional stays	3.200
Avoidable additional stays	1.153

Conclusions:

AE related to health care cause a high individual (distress, disability and exceptionally, death), social (increased hospital stay) and economic (consumption of additional resources) impact. 16% of AE were considered severe and death was associated with AE in 15 patients (0.3%) included in the study. A high percentage of AE can be prevented by improving medical care. We have not found an association between preventability and severity of AE.

Plan de Calidad para el Sistema Nacional de Salud

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO

Assessing Patient Safety Indicators, recommended by OECD, in Spain.

Agra Y, Gogorcena M, Fernández MM, Mataix R, López O, Terol E.
National Quality Agency. Spanish Ministry of Health and Consumer Affairs

Introduction:

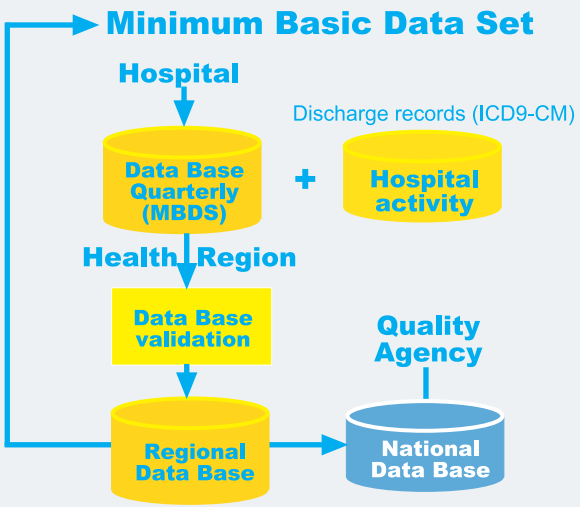
Patient safety (PS) is one of five priority areas identified by the OECD in the development of the Health Care Quality Indicators Project.

Objectives:

To analyze, at national level, the feasibility and reliability of PS indicators according to OECD.

Methodology:

The indicators were obtained from the National Minimum Basic Data Set (ICD-9-MC). Other sources of data were also used for comparability.



Results:

Indicators were obtained for 3,541,107 discharges from 262 public general hospitals. Some of them suffer from possible underreporting due to local coding rules.

Indicators 2005	MBDS National Rate	VC (providers)	Other Sources / other series	Remarks
Infection due to medical care	0.1463%	0.54	NCI (EPINE): 8.1 % ICU (ENVIN): 14.20%	**MBDS**: Possible underreporting **ICU**: Specific study of incidence in 105 Units (97 Hospitals, 11,684 patients) **EPINE**: Specific study of prevalence.
Decubitus ulcer	0.7956%	0.46	GNEAUPP:8.24 (95% CI: 7.67-8.85)	**MBDS**: Possible underreporting **GNEAUPP**: specific study of prevalence. Different exclusions. Different inclusion criteria
Complications of anaesthesia	0.0089%	0.33		Difficulty reporting E codes
Postoperative hip fracture	0.0048%	0.23		Adequate data
Postoperative PE or DVT	0.2614%	0.54		
Postoperative sepsis	0.4181%	0.54	Bacteraemia (EPINE): 5.56 %	**EPINE**: Different inclusion criteria
Technical difficulty with procedure	0.1655%	1.05		High variability among Hospitals
Transfusion reaction	0.0003%	0.17	NTSP: 0.067%	**NTSP**: Specific programme. Different denominator (175 Hospitals)
Foreign body left in during procedure	0.0049%	0.51		Possible underreporting
Birth trauma - injury to neonate	0.5209%	0.80		Similar variable results High variability among Hospitals
Obstetric trauma – vaginal delivery	1.1985%	0.44		Different criteria
Obstetric trauma - caesarean section	0.2806%	0.49		Possible underreporting

VC: Variation Coefficient; **ICU**: Intensive Care Unit; **NCI**: Nosocomial Infection; **EPINE**: National Prevalence Study of Nosocomial Infection; **GNEAUPP**: Research Group for the study of pressure ulcers at national level; **NTSP:** National Transfusion Surveillance Programme.

According to these findings some recommendations could be made to improve the quality of the indicators.

Indicators 2005	Recommendations
Infection due to medical care	Parallel use of other source of data
Decubitus ulcer	Inclusion of nursing reports for codification
Complications of anesthesia	Inclusion of anesthesia reports for codification
Postoperative hip fracture	Increase recording of date of the surgery
Postoperative PE or DVT	It should be necessary to review the clinical record
Postoperative sepsis	Parallel use of other source of data
Technical difficulty with procedure	Inclusion of surgical reports for codification
Transfusion reaction	Increase reporting
Foreign body left in during procedure	Inclusion of surgical reports for codification
Birth trauma - injury to neonate	To establish standards for clinical records in neonates
Obstetric trauma – vaginal delivery	Only public hospitals included. It is necessary to improve codification in private Hospitals
Obstetric trauma - caesarean section	Only public hospitals included. It is necessary to improve codification in private Hospitals

Conclusions:

- MBDS is a good source of data to study hospital morbidity and permits to obtain PS indicators through agreement of standards at national level .The variability presented is similar in other countries using administrative data.
- Administrative data could be incomplete for some clinical conditions (present at the moment of admission).
- Data audit should include a specific study at national level in order to assess the validity of the PS indicators.
- Take actions in order to improve professional awareness to increase AE register should be necessary.
- Complementary sources of data could be necessary in some indicators to achieve more accurate results.

Plan de Calidad para el Sistema Nacional de Salud
GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO

Spanish Patient Safety Strategy: 2004-2007 Results.

Terol E, Agra Y, Fernández MM, Sierra E, García MJ, Infante A.
National Quality Agency. Spanish Ministry of Health and Consumer Affairs

Introduction:

Patient Safety is a priority for the Spanish National Health System (SNHS).
It is included as a strategy in the Quality Plan for the SNHS.

Objectives:

To describe the methods and results of the Spanish Strategy in Patient Safety (SSPS) from 2004 to 2007.

Methodology:

A formal network of representative members from each Health Region was established in order to agree the terms of the strategy.The budget allocated for the strategy was 45 million €

Spanish Patient Safety Network

Results:

The main results are described according to the strategic lines developed.

CULTURE AND AWARENESS

Information
- 3 International Conferences held
- Declaration on PS signed by 120 Scientific Professional Associations
- Ministry of Health supported the World Alliance on PS (WHO)

Perception Studies

Professionals:
- National survey on PS culture in hospitals and primary care (2000 professionals)

Patient associations and leaders:
- Qualitative study
- PS workshop (20 national associations)

Teaching Program
- Basic training
- Risk management on-line
- Medication and PS
- PS for managers
- Clinical practice guidelines
- PS and adverse events prevention
- Master on Quality and PS

2005-2007: 4200 professionals

SAFE PRACTICES

Percentage of HR involved in the implementation of best practices

Year:	2005	2006	2007
Budget:	(6,000,000€)	(9,846,029€)	(12,962,689€)
Adverse event studies (55.6%)			
Safe practices in health care (83.3%)			
Hand Hygiene (94.4%)			
Patient identification in hospitals (88.9%)			
Culture and awareness 88.9%)			
Risk Management Units (94.4%)			
Professionals culture surveys (33.3%)			
AEs studies in Primary care (88.9%)			
Safe practices in PC (66.7%)			

HR: Health Regions
Budget: assigned by the Ministry of Health

INFORMATION AND NOTIFICATION SYSTEM

HOSPITAL / PRIMARY CARE

- HR: MBDS (IDC 9-CM); Transfusion Safety S.; Patients' Complaints
- MoH: Quality Plan NHS
- Scientific Associations: Nosocomial Infections; Intensive care; Pressure Ulcers
- Others: Variability Analysis; Good practices (NQF); AEs Primary Care; Medication Not System; AEs Notification System

Balance Scored Card

Quality Agency-MoH → Prioritized Indicators, Reports → Health Regions, Society, OECD, Others

HR: Health regions, MoH: Ministry of Health and Consumer Affairs, MBDS: Minimum Base Data System

RESEARCH

2006-2007: 80 projects submitted on PS

- Specific budget for the National Research Plan
- Cochrane Review Group on PS
- Participation in international research forums
- National and international projects

-ENEAS (AEs incidence = 9,3%)
-AEs prevalence in Primary Care
-AEs prevalence in Latin America
-Medication-Safety in Hospitals
-Nosocomial infection
-EUNetPas
-Costs and adverse events studies
-Others

EC
ISQUA
WHO
PAHO
Others

Conclusions:

The development of the strategy was possible because of the policy determination, the funds dedicated to it and the agreements among all the stakeholders.

Plan de Calidad para el Sistema Nacional de Salud

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO

Patient safety initiatives developed in a 800-beds hospital of Gran Canaria (Spain)

Alvarez-Leon, EE. Molina-Cabrillana, J. Garcia-de-Carlos, P. Gonzalez-Santana, MD. Deniz-Rodriguez, MJ. Garcia-Garcia, J.
Complejo Hospitalario Universitario Insular Materno-Infantil. Gran Canaria. Servicio Canario de la Salud.

In Spain, patient safety has been promoted in last years by central and local health authorities. The National Quality Agency of the Spanish Health Ministry has developed the National Quality Plan, with 12 strategies. One of the Strategies is "To Improve safety of patients attending Sanitary Centers of the National Health System". This Strategy include the implantation of proyects that impulse and evaluate safety practices in 8 specific areas, trough agreements with local health authorities. Two of this areas are "To prevent nosocomial infection and surgery infection" and "To prevent wrong-site surgery". This work presents the patient safety initiatives developed by the Preventive Medicine Service and the Patient Safety Commission in a 800-beds hospital of the Canary Islands Community (Complejo Hospitalario Universitario Insular-Materno Infantil, CHUIMI).

Five strategies to promote patient safety were developed in the CHUIMI. (1) Basic course of patient safety for health professionals. (2) Creation of a Patient Safety Commission in the CHUIMI conformed by 5 doctors and 2 nurses. The Commission was supported by the CHUIMI direction team. (3) Creation of a Work Group for a Root Cause Analisys of a wrong-patient surgery incident detected before surgery. One of the identified root causes was the insufficient implantation of identification bracelets in CHUIMI. (4) Development of a proyect to prevent wrong-site surgery throught patient identification bracelets, financied with 30.000€. A Failure Mode and Effect Analysis and surveys with key persons were done to identify improvements areas in patient identification process. Five different trade bracelets were evaluated in order to select the more efficient one. Health professional and patient opinions were considered. (5) Development of a proyect to prevent nosocomial infections promoting hand hygiene with hidroalcoholic solution by the Preventive Medicine Service, financied with 54.000€. Baseline hand hygiene compliance rate was 29,7%. Intervention consisted in feedback on compliance rates, availability of hidroalcoholic solution, and educational sessions about appropiate use. Post-intervention compliance rate was 41,4% ($p<0,001$)

Spanish health authorityes are promoting patient safety at central level and at local levels. In Canary Islands some initiatives are being developed in recent years. Health professionals interest in patient safety is growing. The Complejo Hospitalario Insular-Materno Infantil is a pioneering center in this area. Future works and evaluations are guaranteed.

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Transforming patient Care at the Bedside

Introduction

Improving patient safety requires a transformation in how we currently care for patients. Not only healthcare organizations must adopt a new paradigm of care that holds patient safety as a core value and practice, but health personnel have to change their believes and knowledge.

To be able to learn from errors, it is important to consider all adverse events, also those that do not cause patient injury. It is important that health care workers understand why and how they should report.

Medication errors are an important problem in paediatrics, and effective strategies for preventing them are needed. Most resulted from errors at the ordering stage, but many also occur at the administration stage, many administration errors that were not detected undoubtedly occur. In the process of medication, nursing work has a critical and direct impact on patient safety. The administration has almost no barriers to avoid the harm.

Experts in risk management explain system failures and system-driven errors over direct human error, and accentuate the crucial role that organizational method has in ensuring safety.

At our institution, during 2005-2006, we have conducted a survey of global safety climate and culture. Based on these results we design a patient safety program specially oriented towards nurses and young paediatric doctors.

Methods

Over a period one year we project to train hospital personnel who primarily work with hospitalized patients. The target sample is 100% nurses working on the wards, 100% of residents and a 10% random sample of all other hospital staff, like technicians or pharmacists. The core skills paediatric workshop is divided into two modules focusing on situation of risk, teamwork, potential adverse events, medication related errors and decision-making. Preventable adverse events and near misses can only be found if they are sought out. The workshop will include an introductory part how medical errors are classified, and how errors evolve in complex working domains. The second section will include the development of generic problem-solving skills incorporating the extensive use of realistic

simulators whenever possible. Focusing on potentially risky situation like: drug administration, route of administration and adverse events and specially with uncommon drugs.

Out of this course, we hope to be able to propose an institutional auditing of patient safety by design rules and procedures within the hospital. The goal is to get ability and skills to improve patient safety based on experienced personnel. Quantitative and qualitative measures of the efficiency of training will be applied

Discussion

Patient safety has become an international priority. The challenge is how to organize efforts that will produce health care more safe for patients. Despite the best efforts of health care practitioners, medical errors are inevitable. Healthcare is increasingly complex, fragmented and unsafe. No single method can be universally applied to avoid errors in practice. Medical knowledge and technology are expanding at an incredible rate, making it difficult for the healthcare providers to keep pace with advancing knowledge.

Hospitals and other health-care providers today are being pressed more than ever to use technologies for reducing medical errors.

Simplification and standardization are desirable design principles, since they can contribute significantly to the prevention of adverse events. Strategies that have been found to be effective in reducing medication errors include the use of computerized physician order entry systems, preprinted order forms, and color-coded systems. The implementation of theses strategies have a limited success not only by the economic costs but of the possibility of human and system errors in the delivery of care.

We designed a plan focus in work environment and integration of information, to the following years to reduce risk. Thus, the knowledge skills learned during this programme also spill over into emergencies practice. We hypothesize based on literature that medical students, nurses, residents, every health worker in contact with patients need more knowledge about patient safety. We envision coping with adverse event on the healthcare process.

AUTHORS

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(1). Andalusian School of Public Health

(2) Spanish Ministry Of Health and Consumer Affairs

TITLE

The expectations and stance of patients, patient associations and the general public on Patient Safety in the Spanish National Health Service

INTRODUCTION

The policy framework on ***Patient Safety in the Spanish National Health Service*** has identified the need to be aware of the opinions, expectations and the stance of patients, patient associations and key elements of citizenry on this theme, and likewise on their participation in future actions directed towards risk prevention and on proposed solutions linked to Patient Safety. To achieve this, the Spanish Ministry Of Health and Consumer Affairs and the Andalusian School of Public Health have conducted research where these aspects may be analysed with the view that the information and knowledge obtained from this special perspective – that of sick people and their carers – could be seen as expert, which in turn could help both the early identification of risk and bring about viable and realistic solutions to problems.

METHODS/RESULTS

A qualitative methodology based on focal groups and in-depth interviews has been designed for this study. The profiles of the people interviewed are as follows:

- Patients and family members

  Two variables were considered:

  - The severity of the pathology
  - Awareness of having suffered from any incident in their experience with the Health Service (Yes/No)
- Patient associations with the greatest social penetration

- citizenry key players.

Among the most significant results, a difference has been found which depends on the type of the illness. While people with chronic illnesses associate safety with the quality and continuity of assistance, people with acute illnesses understand safety as the absence of error, the appropriateness of treatment and a rapid response by the Health Service.

According to some of the interviewed key players the concept of safety is perceived erroneously within the Spanish context, being perceived more as a concept of confidence. From the professionals' point of view the manner of tackling safety in health culture would be through a good professional-patient relationship.

As for patients, some of the demands which have arisen from all the focal groups are based on clear information, admission of mistakes and the offer of apologies from professionals.

ARGUEMENT

The response by both individual interviewees and groups alike can be characterized by the lack of culture on safety in the field of health. With the exception of concrete cases, such as people affected by an allergy to latex for example, it has been difficult to focus on and begin the development of the patient safety issue. Nevertheless, once set in motion, all participants in the study have brought concrete examples and have provided interesting arguments to the issue in question.

We believe that these arguments are of high interest and that the citizenry should get involved with and assist the Health Service Administration in elaborating strategies of communication and planning health policy on themes of safety.

Iniciativas de la Comunidad Autónoma de Madrid para fomentar un uso seguro de los medicamentos y los productos sanitarios

Dirección General de Farmacia y Productos Sanitarios

Consejería de Sanidad de la Comunidad de Madrid. España.

E-mail:seguridadmedicamento@salud.madrid.org

Web: https//www.seguridadmedicamento.sanidadmadrid.org

SaludMadrid

Dirección General de Farmacia y Productos Sanitarios

Comunidad de Madrid

La Administración Autonómica coordina un proyecto en el que se **integran** los profesionales sanitarios que trabajan en el ámbito de la **atención primaria**, en los **hospitales** y en las **oficinas de farmacia** cuyo objetivo es minimizar la yatrogenia producida por los medicamentos

La participación de los farmacéuticos de oficina de farmacia se realiza mediante la creación de una “**Red de Farmacias Centinela, RFC**”

SaludMadrid

Dirección General de Farmacia y Productos Sanitarios

Comunidad de Madrid

Se cuenta con la participación de todos los profesionales sanitarios que trabajan en atención primaria y hospitalaria, liderados a través de unas unidades específicas de vigilancia de riesgos creadas en cada hospital y gerencia de atención primaria.

SaludMadrid
Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

IDENTIFICACIÓN DE PROBLEMAS:

Los profesionales sanitarios comunican incidentes con medicamentos y productos sanitarios, tanto prevenibles (considerados errores de medicación), como los considerados reacciones adversas a medicamentos (RAM) a la Dirección General de Farmacia y Productos Sanitarios de la Comunidad de Madrid. Se hace un análisis de los mismos y se proponen las actuaciones encaminadas a minimizarlos.

Actuaciones realizadas en materia de seguridad de medicamentos y productos sanitarios

SaludMadrid

Dirección General de Farmacia y Productos Sanitarios

Comunidad de Madrid

Formación a los profesionales sanitarios

• Se organizan cursos de seguridad de medicamentos dirigidos a profesionales sanitarios (año 2006: 4 cursos, 200 participantes)

•Se favorece la autoformación mediante el acceso a material educativo desde el portal "Uso Seguro de Medicamentos y Productos Sanitarios"

Se puede obtener material docente

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https://www.seguridadmedicamento.sanidadmadrid.org/

SaludMadrid Portal de Salud de la COMUNIDAD DE MADRID

Dirección General de Farmacia y Productos Sanitarios
Consejería de Sanidad

Comunidad de Madrid
La Suma de Todos

Uso Seguro de Medicamentos y Productos Sanitarios

Sugerencias | Enlaces de interés | Ayuda | Cerrar sesión

Errores de medicación
- Información general
- Notificar

Reacciones adversas a medicamentos (RAM)
- Información general
- Notificar

Vigilancia de productos sanitarios
- Información general
- Notificar

Alertas
- Medicamentos y Productos Sanitarios

Información de Seguridad de Medicamentos
- Boletines y Memorias
- Material Docente

Estadísticas
- Errores de Medicación y RAM

Inicio

Bienvenida

Bienvenido a la página Uso Seguro de Medicamentos y Productos Sanitarios de la Comunidad de Madrid. Esta iniciativa forma parte del Plan Estratégico de Política Farmacéutica, desarrollado por la Consejería de Sanidad a través de la Dirección General de Farmacia y Productos Sanitarios y cuyo propósito es fomentar el uso seguro de los medicamentos y productos sanitarios como medio para conseguir la mejor asistencia farmacoterapéutica para los pacientes.

Esta página dirigido a profesionales sanitarios, pretende conseguir un enfoque global de la seguridad integrando las actividades de farmacovigilancia, con la notificación de errores de medicación e incidentes con productos sanitarios, no sólo para la identificación y cuantificación de riesgos, sino para la comunicación efectiva de riesgos a los profesionales y la prevención de los mismos. La página también permite consultar documentos de apoyo sobre seguridad, selección de web, estadísticas de las notificaciones recibidas y noticias de interés.

Se ha integrado la notificación de problemas relacionados con los medicamentos en las actividades de vigilancia que se llevan a cabo desde las *unidades funcionales para la gestión de riesgos* de atención primaria y atención especializada. Esta página constituye un espacio compartido de trabajo para los profesionales de los servicios públicos y los farmacéuticos de oficina de farmacia de la *Red de Farmacias Centinela* de la Comunidad de Madrid.

Desde esta cultura de la seguridad de medicamentos, solicitamos la colaboración de todos para hacer de esta página una herramienta útil que redunde en la mejora de nuestro servicio sanitario a la población.

Acceso usuarios

Usuario

Clave

Entrar

PIROXICAM: ACTUALIZACIÓN DE INFORMACIÓN SOBRE SU P...

Más Novedades

Creación de un “Portal de seguridad de medicamentos”*

* Con la colaboración de la Dirección General de Informática.

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Uso Seguro de Medicamentos y Productos Sanitarios

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Errores de medicación
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Reacciones adversas a medicamentos (RAM)

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Servicios que ofrece el portal

“Uso Seguro de Medicamentos”

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PIROXICAM: ACTUALIZACIÓN DE INFORMACIÓN SOBRE SU P...

Más Novedades

Miércoles 19 de Septiembre de 2007

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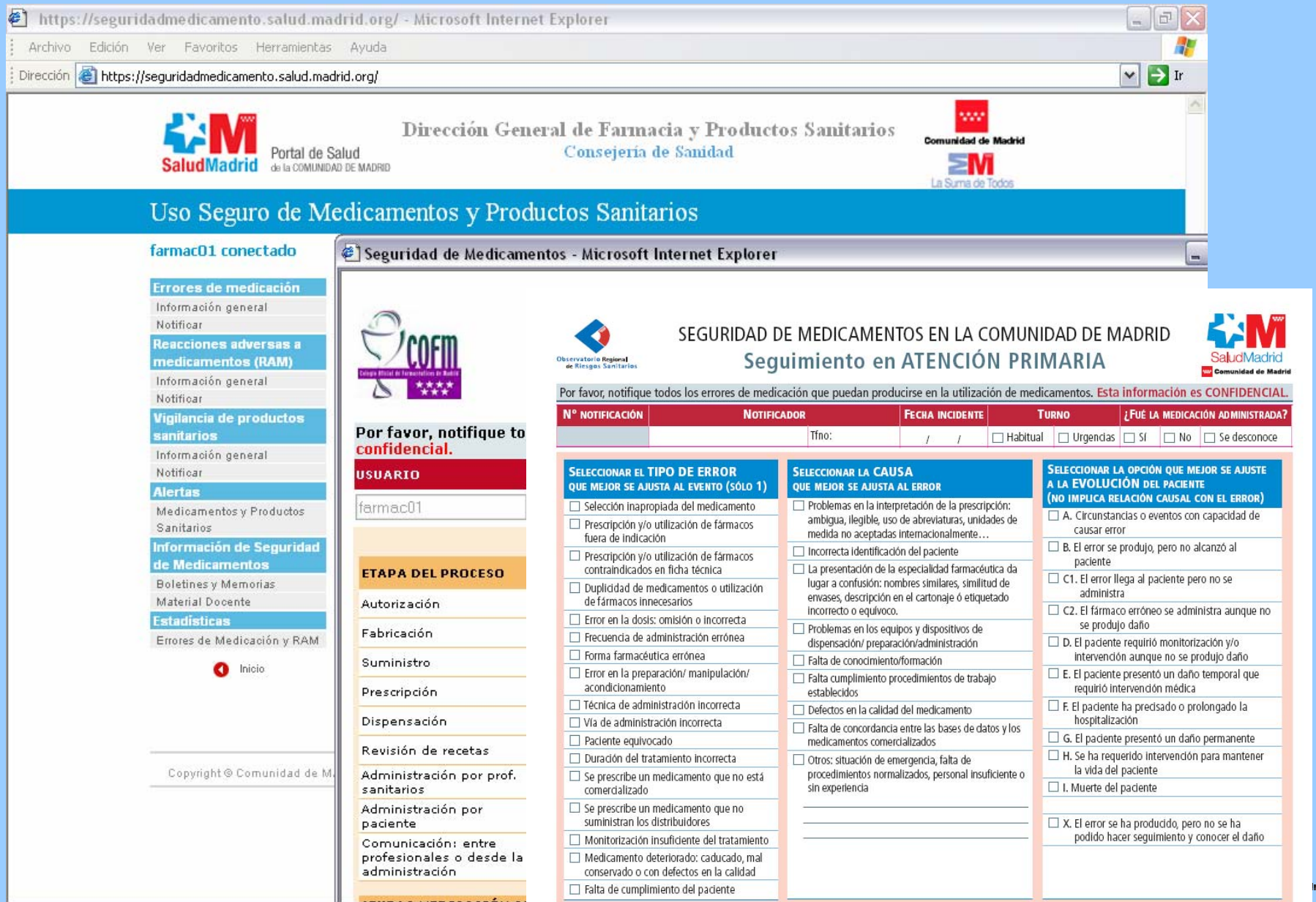
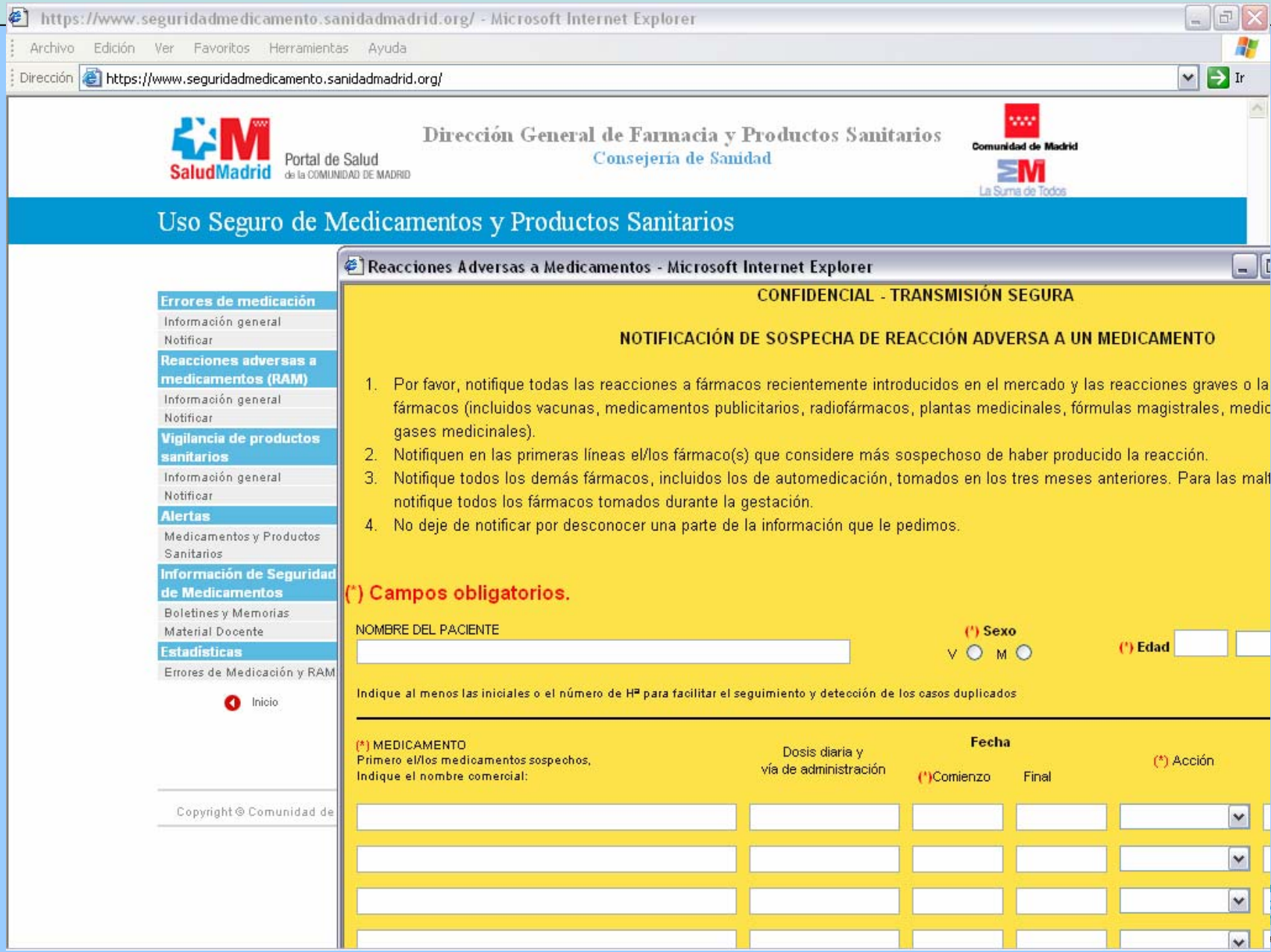
Comunidad de Madrid

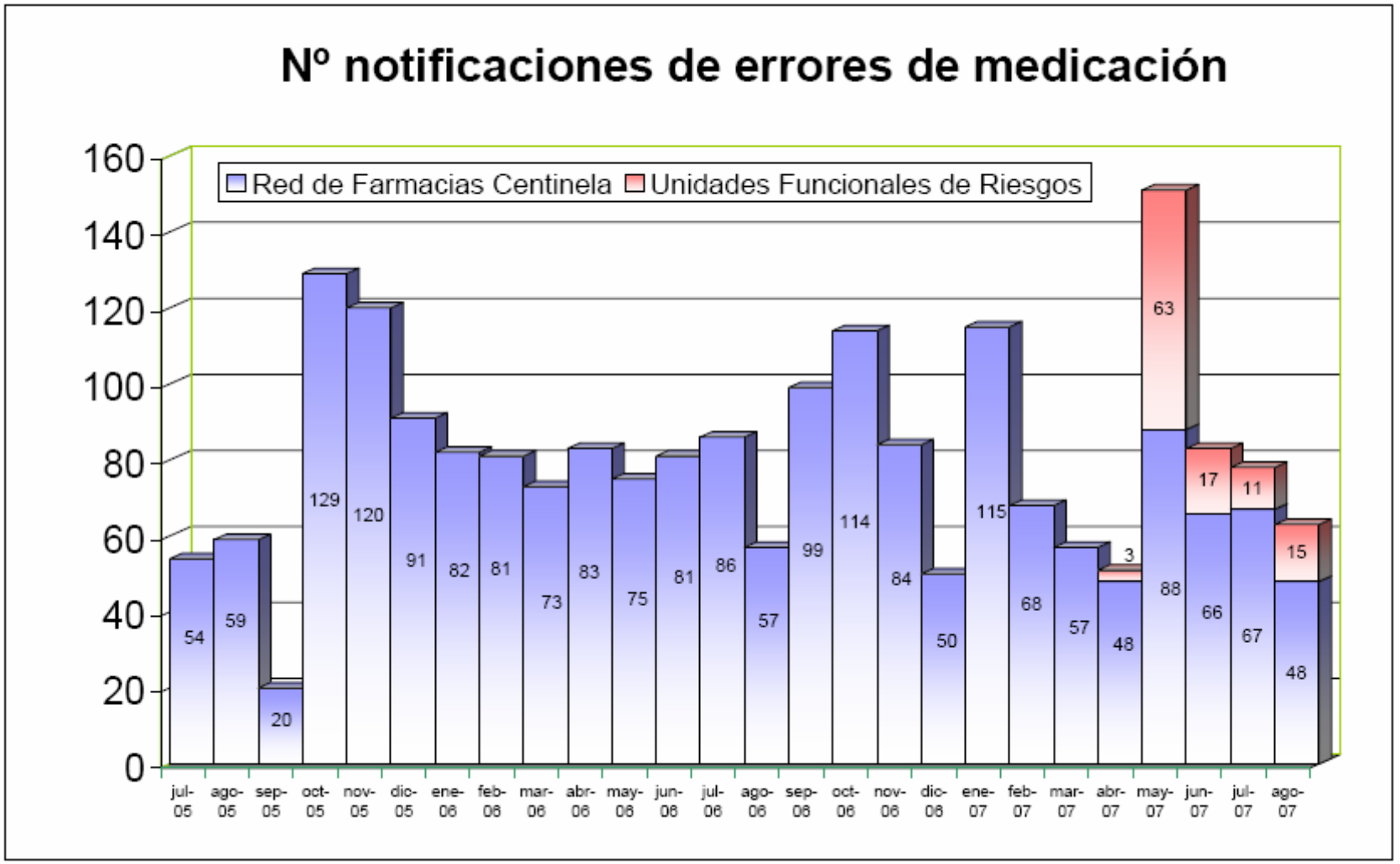
Notificación on-line de incidentes con medicamentos: Formulario específico para el ámbito de primaria, hospitales y oficinas de farmacia



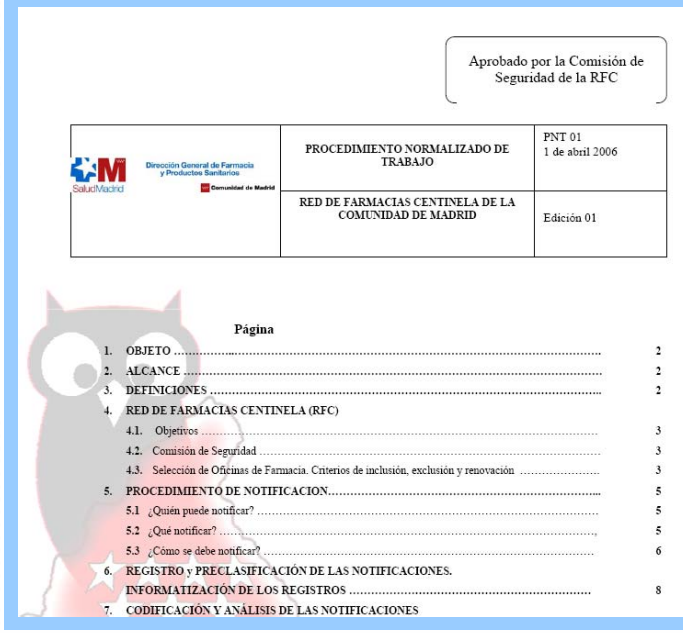
Notificación on-line de sospechas de Reacciones Adversas a Medicamentos (RAM)



Estadísticas de errores de medicación y sospechas de RAM



Acceso a documentos de seguridad: boletines, memorias, recomendaciones a profesionales…



BOLETINES RFC

- Nº 6 de Julio 2007
- Nº 5 de Abril 2007
- Nº 4 de Diciembre 2006
- Nº 3 de Marzo 2006
- Nº 2 de Enero 2006
- Nº 1 de Julio-Octubre 2005
- Nº 0 Presentación 2005

Acceso a alertas sanitarias en materia de seguridad y recomendaciones de sitios web

Comunicación de los riesgos

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Comunidad de Madrid

Plan de comunicación de riesgos a profesionales

Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

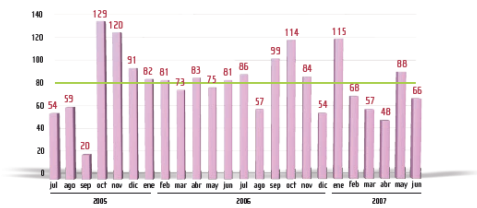
COFM

RFC

Nº6-JULIO 2007

RED DE FARMACIAS CENTINELA DE LA COMUNIDAD DE MADRID

Evolución mensual del número de notificaciones



Nº DE NOTIFICACIONES DE ERRORES DE MEDICACIÓN RECIBIDAS A TRAVÉS DE LA RFC — Promedio mensual

ACUMULADO DESDE EL INICIO DE LA RFC 1.884 NOTIFICACIONES

En estos dos años, se mantiene el promedio de 79 notificaciones mensuales. El descenso observado en los meses de marzo y abril de 2007, es atribuible al inicio de la notificación on-line.

Noticias de interés

Precauciones en la prescripción, dispensación y administración de METOTREXATO.

- **Oral:** Se han descrito varios casos de errores de medicación relacionados con la posología en la administración de **metotrexato oral.** El metotrexato es un antimetabolito utilizado como antineoplásico y como inmunomodulador en el tratamiento de artritis reumatoide y de psoriasis. En estos últimos casos, el esquema de dosificación es **semanal. Es imprescindible por tanto asegurarse de que el paciente conoce la dosis, frecuencia de administración y duración de tratamiento.**
- **Parenteral:** Se han notificado 5 incidencias en la dispensación del medicamento **Metoject® 10 mg/ml** originadas por problemas en la **interpretación de la prescripción.**

  La descripción del medicamento, en todos los casos, empieza por Metoject® 10 mg/ml seguido de la dosis total de la jeringa [Ejemplo Metoject® 10mg/ml 1 jer precarg 2,5 ml/25 mg]. Por tanto **es importante leer la descripción completa del medicamento, especialmente la última parte** que es la que hace referencia a las diferentes dosificaciones de Metoject®.

  La Comisión de Seguridad de Medicamentos de la Comunidad de Madrid ha propuesto a la Dirección General de Farmacia y Productos Sanitarios del Ministerio de Sanidad y Consumo que se modifiquen las descripciones utilizadas en el nomenclátor oficial para este medicamento con el fin de evitar estos errores.

SEGURIDAD DE MEDICAMENTOS DE LA COMUNIDAD DE MADRID
SMCM

Comunicación de incidencias en la prescripción a los profesionales

Incidencia: 7/2007
Fecha comunicación: 16/07/2007

MEDICAMENTO(S) IMPLICADO (S)

METOTREXATO

CARACTERÍSTICAS DEL ERROR

Errores en la prescripción, dispensación y administración de metotrexato:

- **Oral:** Se han descrito varios casos de errores de medicación relacionados con la posología en la administración de metotrexato oral. El metotrexato es un antimetabolito utilizado como antineoplásico y como inmunomodulador en el tratamiento de artritis reumatoide y de psoriasis. En estos últimos casos, el esquema de dosificación es **semanal.** Es imprescindible asegurarse de que el paciente la dosis, frecuencia de administración y duración del tratamiento, con el fin de evitar una potencial sobredosificacion que puede conducir a problemas hematológicos graves.
  La Agencia Española de Medicamentos y Productos Sanitarios emitió una alerta al respecto en el año 2004 que puede ser consultada en la siguiente dirección:
  http://www.agemed.es/actividad/alertas/usoHumano/seguridad/metotrexato.htm
- **Parenteral:** Se han notificado 5 incidencias en la dispensación del medicamento Metoject® 10 mg/ml originadas por problemas en la interpretación de la prescripción.
  La descripción del medicamento en todos los casos empieza por Metoject® 10 mg, cuando en realidad la prescripción puede corresponder a 10, 15, 20 o 25 mg, dependiendo de los mililitros de la presentación. La Comisión de Seguridad de Medicamentos de la Comunidad de Madrid ha propuesto a la Dirección General de Farmacia y Productos Sanitarios del Ministerio de Sanidad y Consumo que se modifiquen las descripciones utilizadas en el nomenclátor oficial para este medicamento. Así mismo se ha comunicado a las farmacias esta situación con el fin de que extremen la precaución en la dispensación de estos medicamentos.

RECOMENDACIONES EN CUANTO A LA PRESCRIPCIÓN

- Extremar la precaución al establecer dosis y frecuencia de administración de la forma oral y asegurarse de que el paciente está correctamente informado de las mismas. Sería conveniente, detallarlas por escrito, especificando incluso, los días de la semana en que se tomará el medicamento.
- Asegurarse, en prescripciones informatizadas, que la receta de metotrexato parenteral coincide con la dosis deseada.

Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

SUBDIRECCIÓN GENERAL DE PRESTACIÓN FARMACÉUTICA
Paseo Recoletos 14, 3ª planta, 28001-Madrid
Teléfono: 91 426 90 18
e-mail: seguridad.medicamento@salud.madrid.org

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Dirección General de Farmacia y Productos Sanitarios
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Comunicación a la **Administración competente** y a los laboratorios farmacéuticos implicados

Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

SEGURIDAD DE MEDICAMENTOS Y PRODUCTOS SANITARIOS DE LA COMUNIDAD DE MADRID

Comunicación de incidencias a la **AEMPS**
Nº 18/2007
Fecha 12/07/07

ESPECIALIDAD(s) FARMACÉUTICA(s) IMPLICADA(s)

Metotrexato oral

PROBLEMA DETECTADO

Se ha recibido, a través de la Red de Farmacias Centinela y de las Unidades Funcionales para la Gestión de Riesgos de Atención Especializada de la Comunidad de Madrid, 6 notificaciones de errores de medicación relacionados con la utilización de metotrexato oral.

CONSECUENCIAS

En alguno de los casos comunicados, la actuación profesional de los farmacéuticos, evitó que al paciente se le administrara la dosis errónea del medicamento. Sin embargo en dos casos, se han documentado cuadros graves de pancitopenia, con leucopia, trombopenia y anemia que requirieron la administración de ácido fólico, factor estimulante de colonias granulocíticas y trasfusiones de hematíes y plaquetas.

PROPUESTAS DE LA COMISIÓN DE SEGURIDAD DE LA COMUNIDAD DE MADRID

La Comisión de Seguridad de Medicamentos de la Comunidad de Madrid ha informado específicamente a los profesionales sanitarios de las precauciones a seguir en la prescripción y administración de este medicamento.

Se plantea que dada la frecuencia con la que se están produciendo episodios graves asociados a la sobredosificación de este medicamento, sería conveniente disponer en el mercado español de una presentación específica semanal, similar a la existente para otros medicamentos. Por tanto se propone que la AEMPS traslade esta situación al laboratorio fabricante de metotrexato. Por parte de la Dirección General de Farmacia y Productos Sanitarios de la Comunidad de Madrid, se va a proceder a trasladar esta información a dicho laboratorio.

Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

SEGURIDAD DE MEDICAMENTOS Y PRODUCTOS SANITARIOS DE LA COMUNIDAD DE MADRID

Comunicación de incidencias a la **DGFyPS**
Nº4/2007
Fecha 7/06/07

ESPECIALIDAD(s) FARMACÉUTICA(s) IMPLICADA(s)

METOJECT® 10 MG/ML

PROBLEMA DETECTADO

Se han notificado, a través de la Red de Farmacias Centinela de la Comunidad de Madrid, cuatro incidencias en la dispensación del medicamento METOJECT® 10 MG/ML originadas por problemas en la interpretación de la prescripción.

La descripción de las distintas presentaciones que figura en la base de datos del nomenclátor Digitalis del Ministerio de Sanidad y Consumo del mes de marzo, en el campo NESPECIFICO, es la siguiente:

		CODNACK	NESPECIFICO
	+	730812	METOJECT 10MG/ML 1 JER CON AGUJA 1,5ML/15MG SOL IN
	+	729665	METOJECT 10MG/ML 1 JER CON AGUJA 1ML/10MG SOL INYE
	+	731299	METOJECT 10MG/ML 1 JER CON AGUJA 2,5ML/25MG SOL IN
	+	730838	METOJECT 10MG/ML 1 JER CON AGUJA 2ML/20MG SOL INYE
	+	866848	METOJECT 10MG/ML 1 JER PREC 1,5ML/15MG SOL INYECTA
	+	865790	METOJECT 10MG/ML 1 JER PREC 1ML/10MG SOL INYECTABL
	+	870170	METOJECT 10MG/ML 1 JER PREC 2ML/20MG SOL INYECTABL
	+	866889	METOJECT 10MG/ML 1 JER PRECAR 2,5ML/25MG SOL INY

Al leer la receta el farmacéutico interpreta que se refiere a Metoject® 10 mg en todos los casos, cuando en realidad la prescripción puede corresponder a 10, 15, 20 o 25 mg, dependiendo de los mililitros de la presentación.

CONSECUENCIAS

Teniendo en cuenta que el nombre que consta en el nomenclátor del MSC es el que se incorpora al programa OMI-AP, estas descripciones pueden dar lugar a confusiones tanto en la prescripción como en la dispensación del medicamento.

PROPUESTAS DE LA COMISIÓN DE SEGURIDAD DE LA RFC

La Comisión de Seguridad de Medicamentos de la Comunidad de Madrid propone que se modifiquen las descripciones utilizadas en el nomenclátor oficial indicándose en primer lugar, tras el nombre del medicamento, la concentración correspondiente a cada envase, por ejemplo Metoject® 20 mg/2ml, o bien solamente los miligramos contenidos, así: Metoject® 10 mg, Metoject® 20 mg, etc…

Resultados de la gestión de errores de medicación

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Dirección General de Farmacia y Productos Sanitarios
Comunidad de Madrid

SEGURIDAD DE MEDICAMENTOS DE LA COMUNIDAD DE MADRID
SMCM

Estadísticas de la gestión de las notificaciones de errores de medicación.

Período: julio 2005-septiembre 2007

42 notificaciones a la Agencia Española de Medicamentos y Productos Sanitarios, comunicando errores derivados de la denominación del medicamento, solicitando cambio de cartonaje, revisión de fichas técnicas o prospectos.... así como notificando problemas de calidad. A raíz de estas notificaciones:

- Se han producido 5 casos de retirada de lote por medicamentos defectuosos
- En 2 casos la AEMPS ha hecho recomendaciones específicas al laboratorio sobre medidas para mejorar la presentación de esos dos medicamentos
- En 2 medicamentos se ha cambiado la ficha técnica
- En el año 2007, en 20 casos se ha trasladado la solicitud de cambio al laboratorio titular del medicamento, teniendo constancia que en 2 de estos casos se va a proceder a un cambio de cartonaje de los medicamentos.

9 notificaciones a la Dirección General de Farmacia y Productos Sanitarios del Ministerio de Sanidad y Consumo, solicitando la corrección de la base de datos del nomenclátor así como la revisión de la situación de medicamentos que están autorizados desde hace más de 5 años y no han llegado a comercializarse.

Elaboración y difusión de 9 recomendaciones específicas dirigidas a profesionales sanitarios alertándoles de incidencias que están ocurriendo en la prescripción de medicamentos

Notificación a las Subdirecciones de la Dirección General de Farmacia y Productos Sanitarios de la Consejería de Sanidad de la Comunidad de Madrid, de aquellas situaciones relacionadas con errores de medicación y que están en el ámbito de sus competencias: 12 notificaciones a la SG de Asistencia Farmacéutica y 70 notificaciones a la SG de Control Farmacéutico y Productos Sanitarios.

Seguridad de Medicamentos y Productos Sanitarios de la Comunidad de Madrid

e-mail: seguridadmedicamento@salud.madrid.org

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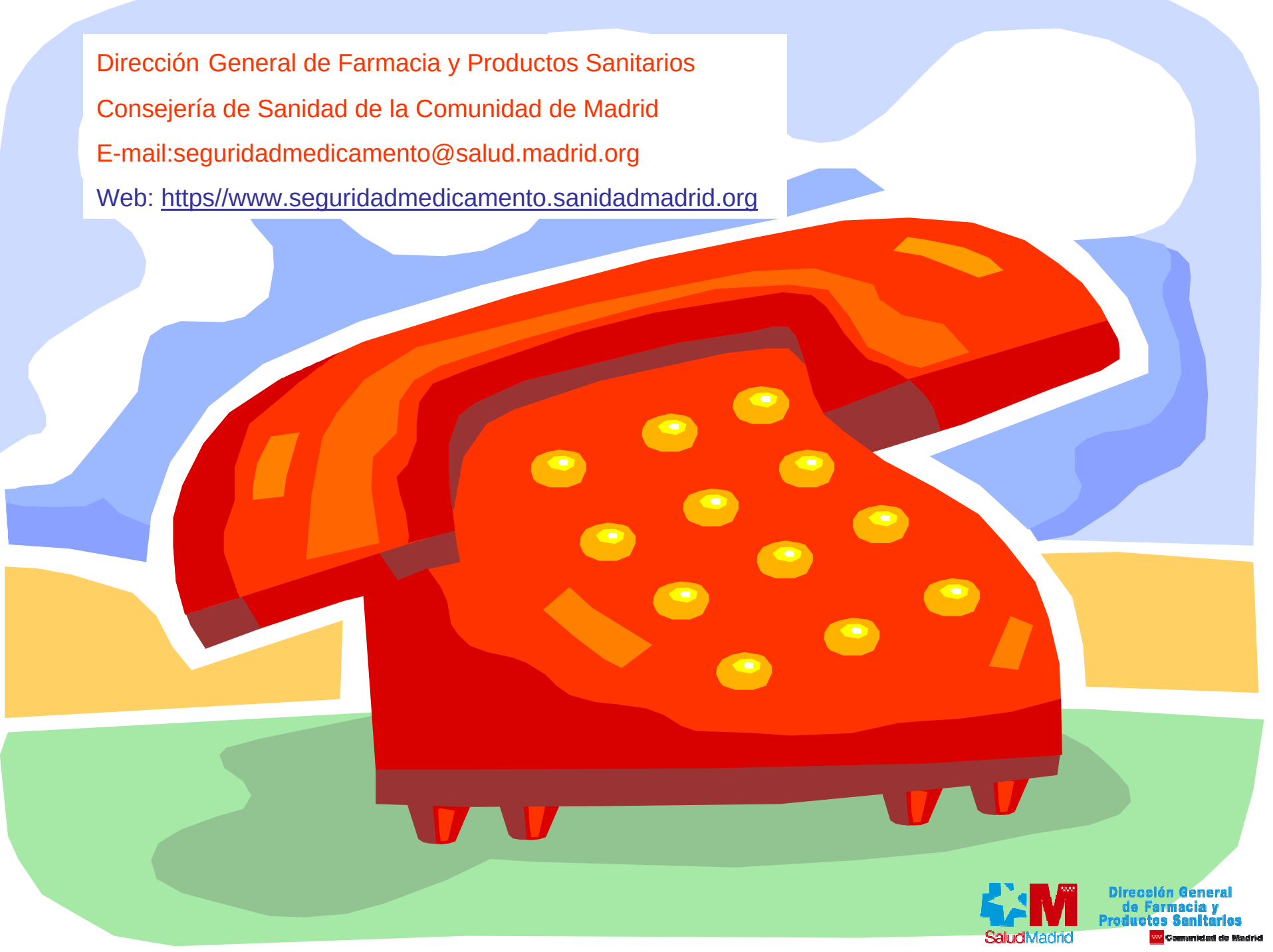

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AUTHORS

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(1). Andalusian School of Public Health

(2) Spanish Ministry Of Health and Consumer Affairs

TITLE

The expectations and stance of patients, patient associations and the general public on Patient Safety in the Spanish National Health Service

INTRODUCTION

The policy framework on ***Patient Safety in the Spanish National Health Service*** has identified the need to be aware of the opinions, expectations and the stance of patients, patient associations and key elements of citizenry on this theme, and likewise on their participation in future actions directed towards risk prevention and on proposed solutions linked to Patient Safety. To achieve this, the Spanish Ministry Of Health and Consumer Affairs and the Andalusian School of Public Health have conducted research where these aspects may be analysed with the view that the information and knowledge obtained from this special perspective – that of sick people and their carers – could be seen as expert, which in turn could help both the early identification of risk and bring about viable and realistic solutions to problems.

METHODS/RESULTS

A qualitative methodology based on focal groups and in-depth interviews has been designed for this study. The profiles of the people interviewed are as follows:

- Patients and family members

  Two variables were considered:

  - The severity of the pathology
  - Awareness of having suffered from any incident in their experience with the Health Service (Yes/No)
- Patient associations with the greatest social penetration

- citizenry key players.

Among the most significant results, a difference has been found which depends on the type of the illness. While people with chronic illnesses associate safety with the quality and continuity of assistance, people with acute illnesses understand safety as the absence of error, the appropriateness of treatment and a rapid response by the Health Service.

According to some of the interviewed key players the concept of safety is perceived erroneously within the Spanish context, being perceived more as a concept of confidence. From the professionals' point of view the manner of tackling safety in health culture would be through a good professional-patient relationship.

As for patients, some of the demands which have arisen from all the focal groups are based on clear information, admission of mistakes and the offer of apologies from professionals.

ARGUEMENT

The response by both individual interviewees and groups alike can be characterized by the lack of culture on safety in the field of health. With the exception of concrete cases, such as people affected by an allergy to latex for example, it has been difficult to focus on and begin the development of the patient safety issue. Nevertheless, once set in motion, all participants in the study have brought concrete examples and have provided interesting arguments to the issue in question.

We believe that these arguments are of high interest and that the citizenry should get involved with and assist the Health Service Administration in elaborating strategies of communication and planning health policy on themes of safety.

MEDICATION ERRORS IN A NEONATAL INTENSIVE CARE UNIT (NICU).

Campino Villegas A., López Herrera M., López de Heredia y Goya J., García Franco M., and Valls-i-Soler A.
Neonatal Intensive Care Unit, Department. of Paediatrics, Cruces Hospital, University of the Basque Country, Barakaldo-Bilbao, Bizkaia, Spain

Aim

To evaluate the impact of a comprehensive educational preventive strategy on the drug error rate in a level III regional NICU.

Background

To err is human, but medical errors should be considered as system errors.

The incidence of medical errors in NICUs might be high because it is a complex environment.

There are many health care processes to be checked to improve patient safety, but medication management should be highlighted because of its complexity.

It must be stressed that medication errors are preventable and although potentially dangerous, but usually do not harm patients.

Knowledge about these errors and their causes, are essential to implement preventive interventions to decrease the medication error rate.

Methods

. DESIGN. This prospective observational study was performed in a level III regional NICU in a university-affiliated hospital.

. MEASUREMENTS. All drug orders written on randomly selected days were evaluated, excluding those related to enteral feedings, parenteral nutrition and blood-derived products. Deviations from drug use related to legibility, dose, units, route of administration and dosing intervals were registered. Data was retrieved from hand-written doctor's orders and corresponding nursing transcriptions and introduced at bed-side in an specifically designed database, by the use of a laptop computer.

PHASES: The study was planed in three successive steps:

a) **Pilot phase,** drug prescriptions and transcriptions were registered (n=122), to estimate feasibility and sample size.

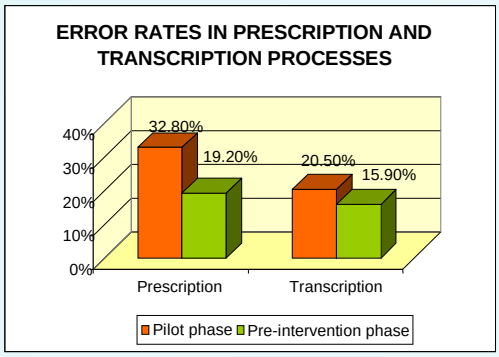
b) **Full pre-intervention phase,** it ran before any intervention was implemented (n=4,182).

c) **Final phase,** One year after the pre-intervention phase ended, the final phase started to check if error rates varied after a comprehensive, educational, multidisciplinary preventive strategy we implemented, along with a standaritation of all drug-related processes.

to measure the effect of the educational preventive intervention on the drug error rate (n=1,648).

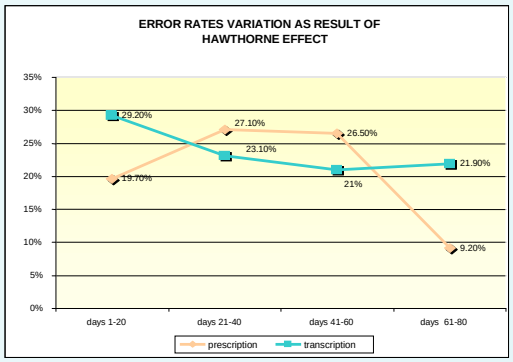
STATISTICS. Values are given as percentages. Two-tails X^2 test was done. $p<0.05$ accepted as significant.

Results



1) We observed that the simple act of reviewing and registering data about the medication process by itself reduced the drug error rate.

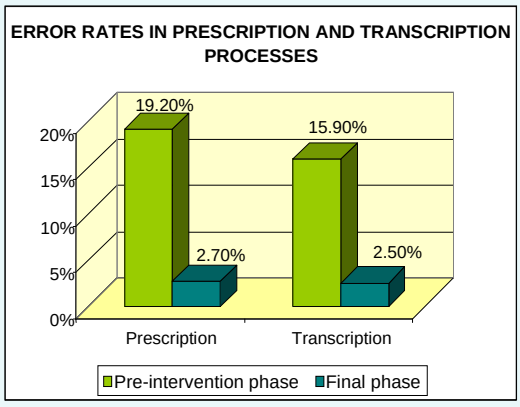
Physicians and nurses seem to have changed their behavior when they were aware of being observed and evaluated. This effect is known under the name of **Hawthorne effect**.

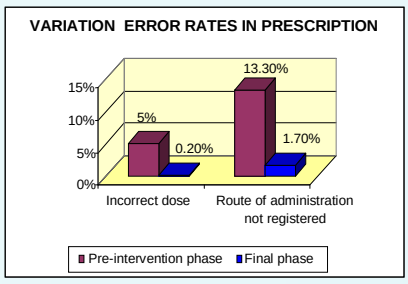


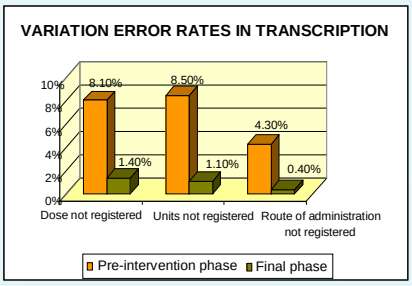
2) In the post-intervention phase a significant reduction in both, prescription and transcription errors rates were observed.

. In the prescription process, a decrease in the use of incorrect doses as well as lack of route of administration was registered (p< 0.001).

. In the transcription process, non registration of units, dose and route of administration also showed a significant decreased (p<0.001)







Conclusions

1) We showed that the presence in the NICU of a person reviewing and registering at the bed-side the drug prescription and transcription process, by itself had a positive impact on the overall drug administration error rate. This might have been related to the so-called **Hawthorne effect**, and that should be taken in consideration when designing and evaluating the efficacy of specific interventions to prevent medication or other type of errors.

2) We showed that after the preventive strategies was fully implemented there was a significant decreases in the drug error rate.

Which are the adverse events in an Acute Geriatric Hospital?

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OBJECTIVE:

Adverse events in healthcare occur more often in older people, and they are more vulnerable to the effects of these adverse events. Despite this, there are few studies that focus specifically on reducing adverse events in this group of patients in acute hospitals. The aim of this study was to show the safety patient culture and the adverse events, and the interventions, to reduce them in our organization.

DESIGN, SETTING, PARTICIPANTS, INTERVENTIONS :

D: Internal sources of adverse events through voluntary notification of incident report (IR2) system used in the National Health Service in UK as the primary tool; active searching of adverse events by the Risk Clinical Managers in the wards and mandatory notification of patient falls. OECD and PSA indicators. Prevalence of nosocomial infection (Spanish National Study of Prevalence –EPINE).

S: Monte Naranco Hospital (Oviedo, Spain), an associated University Hospital with 200- beds (with acute geriatric patients)

P: All 1279 inpatients in a geriatric ward of our hospital during the year 2006.

I: Leadership of Head of the Hospital, training in patient safety, incident report and analysis, and interventions to reduce the adverse events.

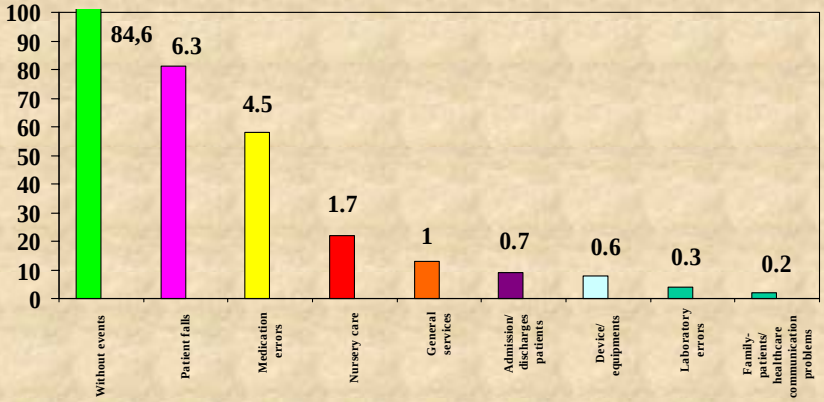
RESULTS:

The mean age of the 1279 patients admitted to the Hospital was 83.96 (± SD 6.91) years during the period of study and the lengths of stay rate of 8.62 days.

A total of 197 incidents and adverse events (15.4% of the patients) were reported by nursing staff (92.6%), medical staff (3.2%), and allied health professionals (4.2%).

The category of incidents and adverse events (and indicators), was as follow (Figure and Table): a) Patient falls 81 (6.3%); b) Medication errors 58 (4.5%); c) Nursery care 22 (1.7%); d) General services 13 (1%); e) Admission and discharges of patients 9 (0.7%); f) Device and equipments adverse events 8 (0.6%); g) Laboratory errors 4 (0.3%) and h) Family- patients/ healthcare workers communication problems 2 (0.2%).

The prevalence of nosocomial infection in the hospital was 4.1%.



Indicator measure	Value (%)
General indicators:	
No. of adverse events and near miss per patient -day	0.15
No. of adverse events and near miss per 1000 patients –day	0.40
No. of adverse events	193 (98)
No. of near miss	4 (2)
No. of adverse events with red code	17 (8.6)
No. of deaths following an adverse event	1 (0.08)
Falls indicators:	
General falls rate	0.06
No. of falls/ bed days of care x 1000 BDOC	0.2
Injury rate	5.2
Medication errors:	58
Dispensation	29(50)
Prescription	5(8.6)
Transcription	4(6.9)
Administration	20(71.4)
Nursery care:	22
Patients without or mistakes in the identification	5.9%
Decubitus ulcers	0.5%
Diaper dermatitis	0
Other nursery activities	0,9%

CONCLUSIONS AND MAINLY MEASURES:

1) This is one of a few reports in geriatric patients (in our case with the oldest patients of the series)

2) We have a full time clinical risk manager using voluntary notification and walkrounds in the wards since 2006

3) The most frequent adverse events in elderly patients were patient falls and medication errors

4) The aggregate reports were used to select a small number of areas on which to focus ward-level quality improvement activities: a) new beds and procedures to fall prevention, b) redesign the medication procedure, c) Nursery care and the prevention of adverse events was a priority in our organization, d) This activities are support for a strong training and education in patient safety including the handwashing compliance through an induction plans and workshops and seminars to the healthcare workers.

Evaluation of a program of update of the recommendations about Hand Hygiene.

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Servicio de Medicina Preventiva. Hospital General Universitario de Alicante. Spain

Background:

The most common and serious problems with the safety of the patients are the infections associated with healthcare. The evaluation about the effectiveness and efficiency of programs of prevention and control of that type of infections is necessary. The Hand Hygiene (HH) is the most important measurement to prevention this type of infections.

Objective:

The objective of this work is to evaluate the program of update of recommendations about HH introduced on a general hospital.

Methods:

- It have been realized two interventions: The first one from march to october of 2005 and it had consist in the realisation of sessions of update about when and how realize the HH (315 persons had assisted), the second one have been make up in May of 2006 and it consisted of the distribution of an informative three-part document to all the workers of the center (approximately 3000) where it was reporting of when and how must they realized the HH and the compliance with of that recommendations in the first evaluation that have been realized.
- For evaluate this program we have use:
  - ✓ The level of knowledge measured with a questionnaire of five questions that have been given to the pupils before and after de sessions and to consider the answers inadequate when three or more aren't well done.
  - ✓ The consumption of alcoholic solutions on ml/stay is group in semesters from 2004 since 2006.
  - ✓ The compliance of the recommendations about HH was measured by directly observation (it have been realized two evaluations, the first one in december of 2005 and in February of 2006 –n=3957 episodes that was indicated the HM-, and the second one in October and November of 2006 –n=1162-).
  - ✓ Prevalence of infections and patients with infection (EPINE studies of the years 2004-2005-2006).

Results:

The frequency of inadequate answers to the questionnaires to evaluate the level of knowledge's has gone on from 57.5 % before the session to 18.9 % later (p <0.001), Table 1. The consumption of alcoholic solutions for the HH has passed from 3 ml/stay in 2 º semester from 2004 to 17 ml/stay in 2 º semester of 2006 (p <0.001), Table 2. The compliance of the recommendations about the HH has happened from 31.0 % of the 1 ª evaluation to 55.6 % of 2 ª evaluation (p <0.001), Table 3. The prevalence of nosocomial infections and of patients with nosocomial infection has happened from 11.4 % and 9.6 % respectively in 2004 to 9,4 % and 8,9 % in 2006 (N.S.), Table 4.

Table 1. Frecuency of "answers inadequate".

	Total n=228	Stand-in n=57	Staff n=171	p
Before	57,5%	68,4%	53,8%	<0,05
After	18,9%	5,3%	23,4%	<0,01
p	<0,001	<0,001	<0,001	

Table 2. Evolution consum alcoholic solution for Hand Hygiene.

	Total Consum		Stay days
	Liters	ml/stay	
2ºSemester 2004	381	3,1	124341
1ºSemester 2005	842	6,6	127185
2ºSemester 2005	975	8,5	114697
1ºSemester 2006	1294	10,6	121705
2ºSemester 2006	1979	17,4	113851

Table 3. Compliance of the recommendations about Hand Hygiene for activity type.

	1ªEval.	2ªEval.	p
Any activity	31,0%(1227/3957)	55,6%(646/1162)	<0.001
Before contact	12,4% (183/1476)	48,8%(248/508)	<0.001
After contact	42,1%(1044/2481)	68,9%(398/654)	<0.001

1ªEval.: First Evaluation. 2ªEval.: Second Evaluation.

Table 4. Evolution of Nosocomial Infections Prevalence and Nosocomial Patients with Infection Prevalence in the period 2004-2006.

	Infections Prevalence		Prevalence patients with infection			
	%	(n)	%(CI95%)	(n)	OR(CI95%)	p
Year 2004 (n=625)	11,4%(71)		9,6%(7,4-12,2)(60)		1	N.S.
Year 2005 (n=625)	10,6%(66)		9,1%(7,0-11,7)(57)		0,94(0,65-1,38)	
Year 2006 (n=609)	9,4%(57)		8,9%(6,7-11,4)(54)		0,92(0,62-1,35)	

Conclusion:

The program is obtaining in a progressive way theirs objectives because the three indicators of process (level of knowledge, consumption of alcoholic solutions, and compliance) have improve of way statistically significativa, and the indicator of results (frequency of the nosocomial infections), have improve but without reaching the statistic signification.

Supported by Grants: Dirección General de Calidad de la Conselleria de Sanitat de la Generalitat Valenciana. Nº Expte: 12-2004 and Ministerio de Sanidad – Fondo de Investigaciones Sanitarias. Nº Expte: PI0542075

PORTO 2007

Patient Safety Research
shaping the European agenda
24-26 September 2007: Porto, Portugal

Patient safety initiatives developed in a 800-beds hospital of Gran Canaria (Spain)

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1. Introduction & Aim

In Spain, patient safety has been promoted in last years by central and local health authorities.

The National Quality Agency of the Spanish Health Ministry has developed the National Quality Plan, with 12 strategies.

One of the Strategies is "To Improve safety of patients attending Sanitary Centers of the National Health System".

This Strategy include the implantation of proyects that impulse and evaluate safety practices in 8 specific areas, trough agreements with local health authorities.

Two of this areas are "To prevent nosocomial infection and surgery infection" and "To prevent wrong-site surgery".

This work presents the patient safety initiatives developed by the Preventive Medicine Service and the Patient Safety Commission in a 800-beds hospital of the Canary Islands Community (Complejo Hospitalario Insular-Materno Infantil, CHUIMI)

2. Methods & procedures

Five strategies to promote patient safety were developed in the CHUIMI:
(1) Basic course of patient safety for health professionals.
(2) Creation of a Patient Safety Commission in the CHUIMI
(3) Creation of a Work Group for a Root Cause Analisys
(4) Development of a proyect to prevent wrong-site surgery throught patient identification bracelets
(5) Development of a proyect to prevent nosocomial infections promoting hand hygiene with hidroalcoholic solution

3. Results

1)Three **Basic courses** of patient safety for health professionals were performed until now.

2)The **Patient Safety Commission** was conformed by 5 doctors and 2 nurses. It was supported by the CHUIMI direction team.

3)A **Root Cause Analisys** of a wrong-patient surgery incident detected before surgery was done. One of the identified root causes was the **insufficient implantation of identification bracelets** in CHUIMI.

4)A proyect to prevent wrong-site surgery throught patient identification bracelets was financied with 30.000€. A **Failure Mode and Effect Analysis** and surveys with key persons were done to identify improvements areas in patient identification process. Five different trade bracelets were **evaluated** in order to select the more efficient one. Health professional and patient opinions were considered.

5)A Proyect to prevent nosocomial infections **promoting hand hygiene with hidroalcoholic solution** was financied with 54.000€ (developed by the Preventive Medicine Service). Baseline hand hygiene compliance rate was 29,7%. Intervention consisted in:

- Feedback on compliance rates
- Availability of hidroalcoholic solution
- Educational sessions about appropiate use.
- **Compliance rates increases** from 29,7% (basal) to 41,4% (post-intervention), p<0,001

4. CONCLUSION: Spanish health authorityes are promoting patient safety at central level and at local levels. In Canary Islands some initiatives are being developed in recent years. Health professionals interest in patient safety is growing. The Complejo Hospitalario Insular-Materno Infantil is a pioneering center in this area. Future works and evaluations are guaranteed.

Incidence of adverse events related to health care in Spain

Aranaz Andres, JM [1]; Limón Ramirez, R[1]; Gea Velazquez de Castro, MT[1]; Requena Puche, J[1]; Aibar Remón, C[2]; Terol García ,E.[3]

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2Department of Microbiology, Preventive Medicine and Public Health. University of Zaragoza. Spain.
3National Quality Agency. Spanish Ministry of Health and Consumer Affairs

Introduction

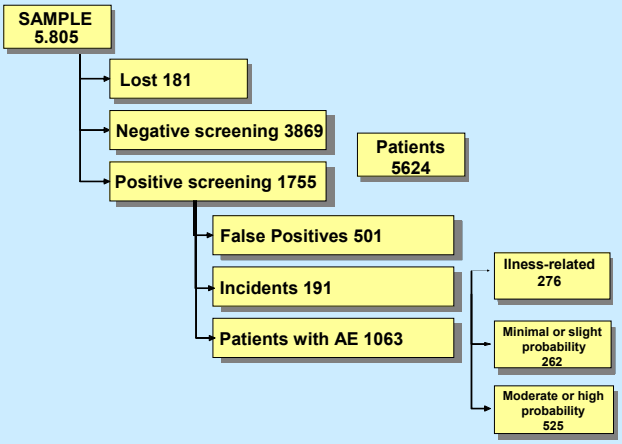
A safe clinical practice requires the achievement of three main objectives: to identify the safest and most efficient diagnostic and therapeutic clinical procedures, to guarantee their implementation for those requiring them and to conduct them correctly and without errors.

Objectives

Our objective was to make a diagnosis of the situation in Spain.

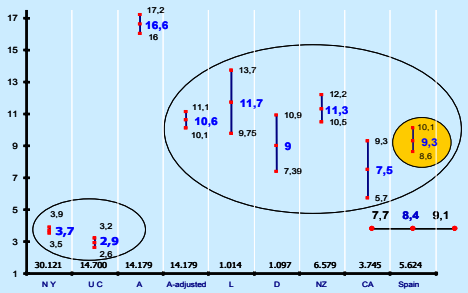
Methodology

Retrospective cohort study

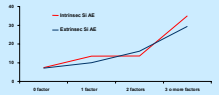


Results

Incidence



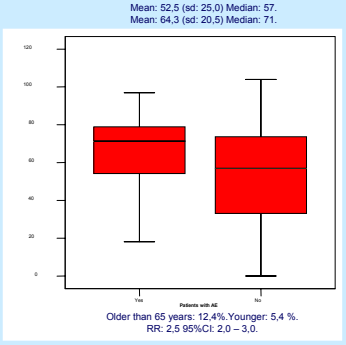
Patient vulnerability



		ADVERSE EVENT		
		Absence	Presence	TOTAL
INTRINSIC RISK FACTORS	Absence	3.181 94,8 %	174 5,2 %	3.355
	Presence	1.970 86,8 %	299 13,2 %	2.269
	TOTAL	5.151 91,6 %	473 8,4 %	5.624

		ADVERSE EVENTS		
		Absence	Presence	TOTAL
EXTRINSIC RISK FACTORS	Absence	943 96,6 %	33 3,4 %	976
	Presence	4.208 90,5 %	440 9,5 %	4.648
	TOTAL	5.151 91,6 %	473 8,4 %	5.624

Patient vulnerability



Types of AE

Problem nature	Total (%)	Avoidable (%)
Procedure-related	25,0	31,7
Nosocomial infection-related	25,3	56,6
Medication-related	37,4	34,8
Related to the care provided	7,6	56,0
Diagnosis-related	2,7	84,2
Others	1,8	33,4
Total	**655 (100%)**	**278 (42,6%)**

Conclusions

The incidence of patients with AEs related to medical assistance in Spanish hospitals was similar to that found in the studies conducted in American and European countries using a similar methodology. Patient vulnerability has been identified therein as playing a major role in generating healthcare-related AEs. Preventability was not related to severity. The health-related, social and economic impact of AEs, makes their study a Public Health priority.

Preventability and impact of adverse events in Spanish public hospitals

Aranaz Andres, JM[1]; Requena Puche, J[1]; Gea Velazquez de Castro, MT[1]; Limón Ramirez, R[1]; Aibar Remón, C[2]; Agra Varela, Y.[3]

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Introduction

Epidemic studies in several countries have estimated a rate of AE related to hospital care between 4% and 17%, and have considered 50% of them as preventable.

Objectives

To define preventable AE and to determine the impact of AE associated to medical care in terms of disability, death and/or prolongation of hospital stay in Spanish public hospitals.

Methodology

Retrospective cohort study. 5,624 medical records from 24 hospitals were reviewed. Hospitals were selected by stratified random sampling.

Results

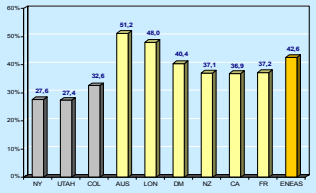
Severity and preventability of AE

TIPO	N	%	Avoidable (%)
Slight	295	45	43,5
Moderate	255	39	42,0
Severe	105	16	41,9
TOTAL	655	100	42,6

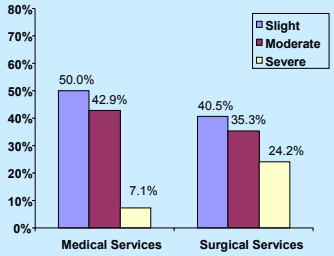
Severity of AE

ENEAS	N	%	Avoidable (%)
Non severe	550	84	42,8
Severe	105	16	41,9
TOTAL	655	100	42,6

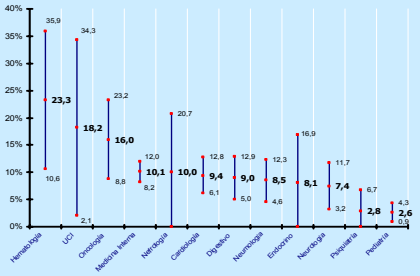
Preventability of AE



Severity of AE by service type



Incidence of AE to Service



Impact of AE

Impact on the hospitalisation	%
Extended stay	31,4
Readmission	25

Impact on the hospitalisation	days
Additional stays / patients with AE	6
Additional stays	3.200
Avoidable additional stays	1.153

Conclusions

AE related to health care cause a high individual (distress, disability and exceptionally, death), social (increased hospital stay) and economic (consumption of additional resources) impact. 16% of AE were considered severe and death was associated with AE in 15 patients (0.3%) included in the study.

A high percentage of AE can be prevented by improving medical care. We have not found an association between preventability and severity of AE.

Expectativas y posicionamiento de pacientes, asociaciones y ciudadanía sobre la seguridad del paciente en el SNS

A. Ruiz Azarola, A. Suess, MA. Prieto Rodríguez. JC. March Cerdá, E. Terol García, J. Casal Gómez
Escuela Andaluza de Salud Pública

Objetivos

✔Conocer las opiniones, expectativas y posicionamiento de pacientes, asociaciones y ciudadanía sobre la seguridad del paciente y su participación en futuras acciones.

Métodos

✔Para la realización de este estudio se ha utilizado una metodología cualitativa basada en grupos focales y entrevistas en profundidad.

Perfiles

- Pacientes
- Asociaciones de pacientes
- Ciudadanía (personas claves y líderes de opinión)

Resultados

PACIENTES

1.- El grado de severidad de la enfermedad de una persona influye en su concepto de seguridad.

- Personas que sufren **enfermedades crónicas** asocian la seguridad a la **calidad y la continuidad asistencial.**
- Personas afectadas por **enfermedades agudas** entienden la seguridad como la **ausencia de errores, la adecuación del tratamiento y la respuesta rápida** por parte del sistema sanitario.

2.- En todos los grupos focales aparecen demandas que se basan en información clara, admisión de la equivocación y el ofrecimiento de disculpas por parte de los/las profesionales.

EXPERTOS/AS

3.- Los/as expertos/as entrevistados/as dan preferencia al concepto de confianza sobre los términos de seguridad o error.

ASOCIACIONES

4.- Desde las asociaciones se demanda una mayor participación en las decisiones que intervengan en una mejora de la seguridad del paciente, puesto que piensan que las medidas, a menudo, no se adecuan a sus necesidades.

Conclusiones

1.- En un principio, tanto pacientes como asociaciones, no perciben la seguridad del paciente como un tema sobre el que puedan opinar y participar. Sin embargo, todas las personas entrevistadas aportan experiencias concretas y propuestas de mejora.

2.- Expertos/as y agentes clave de la ciudadanía destacan la necesidad de pasar de una cultura de la “culpa” a una cultura del reconocimiento del error y el fomento de la confianza.

JUNTA DE ANDALUCIA
Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD
MINISTERIO DE SANIDAD Y CONSUMO
Plan de Calidad para el Sistema Nacional de Salud

DETERMINATION OF MEDICAL ERRORS AMONG TRAUMA PATIENTS USING ADMINISTRATIVE DATABASES (ICD 9-CM)

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Introduction

Trauma patients represent a significant number of patients admitted to hospitals around the world. The rate of adverse events and medical errors (AE/ME) among these patients and the risk factors associated with such events are unknown.
Hospital Discharge Data using the International Classification of Disease, 9th Revision, Clinical Modification (ICD9-CM) cover 90% of all discharges occurring in private and public hospitals in Spain. In this study, we decided to investigate whether the use of hospital discharge data (ICD9-CM) allows for identification and characterization of adverse events and medical errors among this patient population.

Aim

• Determine adverse events and medical errors rates among trauma patients.
• Establish risk factors associated with personal or injury characteristics.
• Investigate if the use of hospital discharge data allows for identification and characterization of adverse events and medical errors among trauma patient.

Methods

Population-based cross sectional design using hospital 4,682,165 discharge data from Spain that included approximately 90% of all hospital discharge data for the year 2004.

Univariate and multivariate analyses were conducted to identify the crude and adjusted incidence rates of AE/ME. Personal (age and gender), injury (severity as measured by ISS, nature of injury), health care (type of admission, readmission, length of stay) were investigated as possible risk factors.

We used up to 14 diagnostic fields available for each record and discharges identified as belonging to one of 3 categories:

- non-trauma,
- trauma,
- patients presenting with any AE/ME.

Trauma is defined as anyone presenting to the hospital and having a discharge code with at least one 800-999 or an E800-E999 codes.
Using previously published literature we identified discharge codes consistent with AE/ME: E850-E858, E870-E876, E878-E879, E930-E949 or E349.0, E415.11, E512.1, E518.4, E664, E668.0-2, .8-9, E669.9, E674.9, E707.0, E968, E995.0,.2,.4, E997.1-.6 and .9, E998.1-.9 or E999.4-8).

Results

▪ Of a total of 4,682,165 discharges for 2004, 484,657 (10%) met the ICD 9-CM definition of injury (i.e, trauma and/or adverse effects).

Of those, 306,577 (63%) were patients with traumatic injuries, and 12,054 of them (3.9%) were identified as having adverse effects in addition to their traumatic injuries.

The remaining 178,080 (37%) patients were patietns solely presenting with adverse effects (i.e., no trauma injuries)

▪ Using univariate analysis males, older patients, admitted urgently, or readmitted, those with longer length of say and patients with higher ISS scores were identied as risk factors more likely associated to AE/ME.

Conclusions

• Using ICD9-CM coding the prevalence rate we found a rate of AE/ME which is consistent with that of the other studies.

• We found that AE/ME are more likely to be found on men, older patients, more severely injured, and patients admitted urgently or readmitted.

• Trauma patients are no exempted from suffering adverse events and medical errors, although they seem to presenting them at rates comparable to those of oother types of patient.

Patient Safety Research, 24-26 September 2007; Porto, Portugal

DIFFERENT SYSTEMS OF DETECTING NURSING MEDICATION ADMINISTRATION ERRORS

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***University Clinic of Navarra, Spain. Johns Hopkins University, Baltimore, USA**.**
University of Navarra, Spain***

Introduction

It is generally agreed that medication errors are one of the most important causes of medical errors in health systems and they cause morbidity and mortality with high costs. Such errors are considered a major contribution to adverse events and it is estimated that adverse drug events is a cause of death only surpassed by heart disease, cancer and stroke. Among medication errors, drug administration errors are the most difficult to address, and they are considered one of the riskiest nursing activities. Usually, it is taken for granted that nurses who undertake drug administration are adequately trained for it. However, it is now clear that there are many contributing factors to staff member's failure. Identifying the frequency and characteristics of these errors is an essential step to develop preventive measures.

Aims

- To demonstrate that the frequency and distribution of medication errors are different depending on the system chosen to detect them.
- To investigate the similarities and differences of data collected through 3 of these systems: questionnaires, direct observation and notification reporting system.
- To explore the practical implications of the found differences (if any) in regards to updating the training of nurse students and nurses and to changing systems at organizational level.

Method

Cross sectional study in a 300 bed university teaching hospital in Spain with nurses with medication administration duties.

The three data sources used were:

1. Questionnaires to know the beliefs, knowledge and attitudes of nurses on medication errors.
2. Direct blind one-way observation to the nursing medication administration.
3. Medication error notification system. A computerized medication notification system was implemented.

Results

Errors and potential errors using three different data sources

	Questionnaire				Direct blind observation		Incident Reporting System	
	Multiple choice question		Open ended question					
	n=310		n=185		n=17 or 88 or 171 (see text)		n=15	
	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Incorrect doses	96.7	94.1 – 98.4	13.5	8.9 – 19.3	4.2	2.0-7.5	31.0	11.0 - 58.7
Incorrect label	86.4	82.1 – 90.1	2.7	0.9 – 6.2	0		0	
Wrong dosage form	0		7.5	4.2 – 12.4	0		6.2	0.2 - 30.2
Deteriorated drug	85.1	80.7 – 88.9	0		0		0	
Wrong drug	98.3	96.3 – 99.5	9.1	5.4 – 14.3	40.6	36.7–44.7	12.5	1.6 -38.4
Insufficient monitorisation	50.9	45.3 – 56.7	3.7	1.5 – 7.6	14.7	11.1–19.0	0	
Similar drug names	0		0		0		0	
Dose or Drug omitted	88.0	83.9 – 91.5	6.4	3.4 – 11.1	58.3	49.0–67.3	6.2	0.2 - 30.2
Wrong patient/wrong side	94.5	91.4 – 96.8	25.0	19.3 – 32.3	28.3	24.0–33.0	31.0	11.0 - 58.7
Similar containers	0		0.5	0.01 – 3.0	0		6.2	0.2 - 30.2
Wrong administration technique	94.1	91.0 – 96.5	6.4	0.03 – 0.1	13.1	8.8-18-7	0	
Other	N/A		25.2		N/A		N/A	

Conclusions

- The three systems show different percentages of medication administration errors.
- This conclusion is relevant because organizations usually rely on the notification system to detect medication errors.
- As improvement depends on valid information, it is important to maintain these studies periodically to have a real picture of medication administration errors.
- These findings will be useful to set the objectives for continuing education in this field.

Acknowledgment
The Health Department of the Government of Navarra (Spain) partially supported the study.

Patient Safety Research, 24-26 September 2007; Porto, Portugal

The IBEAS Project

Carlos Aibar, on behalf of IBEAS working team

IBEAS Project: the origins

- A perceived need:
  - 2 courses: Sta Cruz de la Sierra (2005) and Cartagena de Indias (2006)
- ENEAS study, june 2005
- First International Conference in Patient Safety. Madrid, nov 2006
- WHO World_Alliance Patient Safety, PAHO and Spanish Minister of Health Affairs: interest and support

IBEAS Project: the aims

- To improve knowledge of patient safety matters
- To identify patient safety priority areas and problems, to facilitate and encourage prevention processes.
- To increase the number of healthcare professionals involved in patient safety.
- To put goals and activities for the enhancement of patient safety on all the countries agendas, at the different organizational and care levels.

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IBEAS Project: the study

- **Design:** cross-sectional study
- **Scope of study:** 35 hospitals in five countries.
- **Subjects of study:** All patients hospitalized at the time of the study.
- **Sample:** More than 1,500 patients per country and 10,000 patients in all, will be included in the prevalence study.
- **Tools:**
  - 1) Adverse event screening guide and 2) Spanish version of the modular review form MRF2
  - Application for data handling: Adverse Event Monitoring and Control System. SVCEA 1.0 – IDEA 4.0 database.

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IBEAS: Organizational levels

Steering Comitte
I Larizgoitia- PS Alliance
J Gonseth-PAHO
E Terol-MoH Spain
Y Agra-MoH Spain

Country teams leaders
A Amarilla, Argentina
F Raúl, Colombia
O Urroz, Costa Rica
Santivañez A, Peru
R. Inga, Peru

& **Country technical teams**

Technical leadership
JM Aranaz
C. Aibar

Hospital teams

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IBEAS Project: the study

PORTO 2007

IBEAS Project: Milestones and timetable planned

nov,2006	To arise the idea, Begining of conversations, Agreements
jan-feb,2007	Study design and protocol
mars,2007	Country teams training workshop, Buenos Aires Project agreement with country leaders Design of final protocol
april-may,2007	Improvement of reviewers, Design of national protocols, hospitals sampling, and Review by ethics committee
may-june,2007	Reviewers workshop by country teams
june-july,2007	Doubts solving, agreement study between reviewers Reinforcement of training and setting consensus if disagreement
sept,2007	Field work: All hospitalized patients in one week
oct,2007	Follow up until discharge Review of medical records (1month from begining of study)
nov-dec,2007	Data entry in database on line
jan,2008	Preliminary data analysis
april, 2008	Final report

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IBEAS Project: Tools for networking

- E-mail
  - One-to-one
    - With Country leaders
  - One-to-group
    - With Country-Teams
- PAHO-website
  - http://ecs.edgeof.net/patientsafetyresearch/IBEAS/:
  - Contibutions, files, discussions,..
- Phone
  - One-to-one
  - Group (1/month) with Country-Executive Director Teams
  - Video-conference with country teams (sometimes more than 80 people)

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IBEAS Project: learned lessons

- The study has a great added value:
  - Growth of critical mass of health providers worried for PS
  - Continuos learning opportunities for all stakeholders

- Limitations:
  - The geographical distance is a problem
  - Some communication problems for the group
    - Acces to website (speed of internet at local levels)
    - Phone-group (organizational problems: too much number of people)
  - We have created expectations, maybe too many
  - Schedule excessively optimistic
  - Different concepts and language forms:
    - It has been necessary an important agreement effort

Networking for Patient Safety

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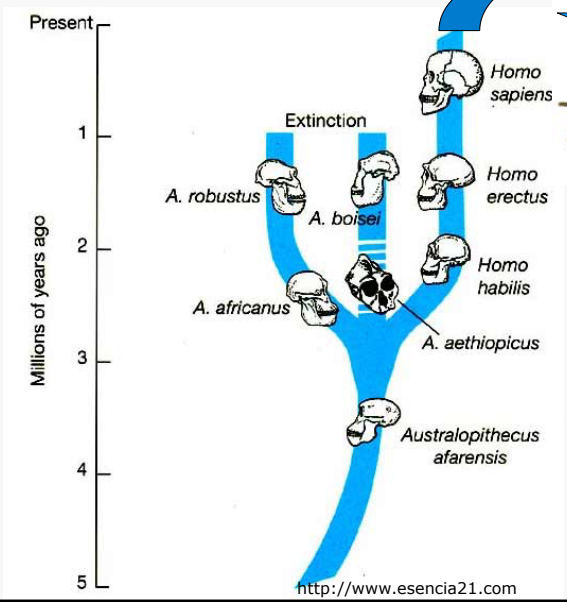
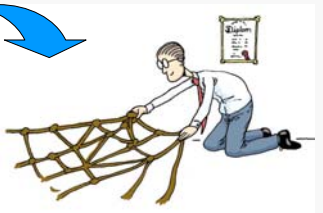
To improve, we need... the *homo networker*





We are learning!

Networking for Patient Safety

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