PATIENT SAFETY STRATEGY FOR THE NATIONAL HEALTH SYSTEM OF SPAIN

Main achievements: 2005-2007

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National Quality Agency. Spanish Ministry of Health and Consumer Affairs. Spain (SM0H)
SPANISH NATIONAL HEALTH SYSTEM

- 44,108,530 inhabitants
- 17 Health Regions

<table>
<thead>
<tr>
<th>Professionals</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>194,668</td>
</tr>
<tr>
<td>Dentists</td>
<td>21,055</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>57,945</td>
</tr>
<tr>
<td>Nurses</td>
<td>225,487</td>
</tr>
</tbody>
</table>
GENERAL PRINCIPLES

- Social / interterritorial equity
- Integration of all health care networks under the NHS umbrella
- Oriented to the citizens: rights and duties

FUNDAMENTAL FEATURES

- Universal coverage
- Extensive benefits
- Descentralised management
- Public funding
Basic principles

2005

Consolidation

2006

Safe practices

2007

Patients

2008
### Epidemiological studies

<table>
<thead>
<tr>
<th>Country</th>
<th>AUTHOR &amp; Year</th>
<th>Nº HOSPITALS</th>
<th>Nº Patients</th>
<th>% AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ( New York) (Harvard medical practice study)</td>
<td>Brennan 1984</td>
<td>51</td>
<td>30.195</td>
<td>3,8</td>
</tr>
<tr>
<td>USA ( UTAH-COLORADO) (UTCOS)</td>
<td>Thomas 1992</td>
<td>28</td>
<td>14.565</td>
<td>2,9</td>
</tr>
<tr>
<td>FRANCE</td>
<td>Michel 2005</td>
<td>71</td>
<td>8.754</td>
<td>5,1</td>
</tr>
<tr>
<td>NEW ZELAND</td>
<td>Davis 1998</td>
<td>13</td>
<td>6.579</td>
<td>11,3</td>
</tr>
<tr>
<td>SPAIN (ENEAS Study)</td>
<td>Aranaz (MoH) 2006</td>
<td>24</td>
<td>5.624</td>
<td>9,3</td>
</tr>
<tr>
<td>CANADA</td>
<td>Baker 2002</td>
<td>20</td>
<td>3.720</td>
<td>7,5</td>
</tr>
<tr>
<td>DENMARK</td>
<td>Schioler 2002</td>
<td>17</td>
<td>1.097</td>
<td>9</td>
</tr>
<tr>
<td>UK</td>
<td>Vincent 1999</td>
<td>2</td>
<td>1.014</td>
<td>11,7</td>
</tr>
</tbody>
</table>

That means 450,000 adverse events/year in Spain
Spain's National Strategy for PS. Main Components

- Raising Awareness: Information-Sensibilization
- Education-Training: leaders, managers, clinicians, researchers, patients
- Infrastructures and human resources: risk management units
- Safe Practices implementation
- Establishing Networks and Alliances: Professionals, patients, organizations (national and international)
- Information systems / evaluation /measurement
- Research Promotion and capacity building

BUDGET 2005-2007 45 M €
International Conferences, workshops, seminars...

www.msc.es/conferencia-seguridaddelpaciente

www.plandecalidadesns.es
Training in PS for professionals

**MASTER IN PS: 1600 hours**
- Concepts. Epidemiology
- Risk Management. Quality Assurance
- Clinical Practice and EBM
- Medication Errors
- AEs analysis
- Legal aspects
- Communication

**RISK MANAGEMENT: 150 hours**
- Risk Management tools
- Electronic resources for RM
- Epidemiology and Prevention of AE
- EBM

**BASIC CONCEPTS: 30 hours**
- AE, errors, etc.
- Risk Management.
- Notification systems
- Communication
- International Strategies
RESOURCES FOR TRAINING AND EDUCATION

1. e-room, didactic materials & documents

2. Newsletter, blog, interactive resources (WEB 2.0)

3. PS Online training resources

Web based integrated electronic platform
Patient Safety & Adverse Event Prevention:
Training materials for graduate and post-graduate levels

CD and downloadable tutorial
- Resources for Teachers & Students
- Powerpoints
- Case studies
- Quizes and tests
- Bibliographic references and links
ALLIANCES WITH STAKEHOLDERS

QUALITY AGENCY MoH

Agreements

17 Health Regions

Agreements and contracts

COLLABORATION

PROFESSIONALS
140 Scientific Societies supporting PSS.

PATIENTS/CONSUMERS
19 associations supporting PSS

PUBLIC AND PRIVATE ORGANIZATIONS

• Academic and research Institutions and Agencies
• Public Health Schools
• Others
Strategic projects included in the HR contracts with the MoH

<table>
<thead>
<tr>
<th>Years:</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies of Aes in Hospitals (56%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand hygiene (94%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification Systems for hospitalised patients (89%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safe clinical practices (83%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information and Training in Patient Safety (89%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creation of Risk Management Units (94%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perception professionals (33%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aes estudies in PC (89%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safe Practices in PC (89%)</td>
<td></td>
<td></td>
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</tbody>
</table>
PROMOTE SAFE CLINICAL PRACTICES

SAFE PRACTICES

• Anaesthesia-related complications
• Hip fractures in surgical patients
• Pressure ulcers in hospitalized patients
• PTE/ DVT in surgical patients
• Surgical wound infection
• Hand hygiene
• Wrong-site surgery
• Medication errors
• Chronic and palliative care
• Mother and baby care
• Ensure patients´ last wishes
INTERNATIONAL

- IberoAmerican network in PS
- Involvement in WHO global alliance
- Participation in working groups
  - OECD:
  - European Commission
Committed to the WAPS

IBEAS

Research Advisory Council

Delphi
Spanish validation

HR
RESEARCH

National Research Programme (Grants)
- 2006: 1.5 mill € (400 projects, 20 PS)
- 2007: 4.5 mill € (600 projects, 60 PS)
- 2008: 6 mill €

Cochrane Review Group in Patient Safety

Specific studies (Contracts)
- ENEAS (Hospitals): 8.4% (CI, 95%: 7.7 - 9.1)
- APEAS (Primary Care): incident prevalence of 17.93% (CI 95%: 17.09% – 18.77%) composed of near-misses (7.82%) and AE (10.11%).
- Nosocomial infection prevalence
- Medication system: ISMP Questionnaire
- Perception and quality of life studies (patients)
- Professionals perception (AHRQ)
- Complaints and suggestions
- Validation of the NQF indicators
- Cost studies
- Safe practices to prevent AEs

International Studies

- IBEAS
- Blood stream infections
- EUNetPaS
PATIENT’S INVOLVEMENT

Nominal group

- Situation analysis
- Critical issues
- Main actions

22 patients and consumer associations

- 2 Focal groups
  N & L system
- Proposal
  for a national declaration

2007

January  June  November  December
Our national health system is pretty safe but there is still room for further improvement.

The improvement actions should be focused on: medicaments use, technical procedures, health care associated infection and effective communication.

Patients are demanding: information, training, participation and empowerment.

Main obstacles: lack of safety culture, training, communication skills and resistance to change.

Cultural change must reach managers, clinicians, patients and citizens.
NEXT STEPS

- Consolidation of the actions already undertaken
- Implementation of new actions
- Impact measurement
- Communication of results
- Dissemination of the Patient Safety Culture

SETTING PATIENT SAFETY AS AXIS OF:

Health Policy
Clinical practice
SPANISH PATIENT SAFETY STRATEGY FOR THE NHS

Patient Safety Information System

Assessing AHRQ and OCDE PSI in Spain

Terol E. Deputy Director, Quality Agency, SMoH
Objective:

To analyze, at national level, the feasibility and validity of the patient safety indicators (PSI) according to the recommendations of the AHRQ and OECD
Methods:

- In Spain, data for indicators calculation are obtained from the National Minimum Basic Data Set (MBDS) that uses the ICD-9-MC codification system. (It is mandatory for all the public hospitals)

- MBDS and population data were analyzed in order to calculate the indicators according to inclusion and exclusion criteria and feasibility.

- Other secondary sources of data were used for comparability.

- A **validity study** was carried out based on the CMBD data of 12 HRs in the period 2003-04. In addition, the variability of the indicators was also assessed.
Minimum Basic Data Set

Hospital

Data Base Quarterly (MBDS)

Health Region

Data Base validation

Regional Data Base

Discharge records (ICD9-CM) +

Hospital activity

Quality Agency

National Data Base
PSI secondary sources:

- **ICU - ENVIN**: Incidence of HCAI in intensive Care Units

- **EPINE**: National Prevalence Study of HCAI in Hospitals

- **GNEAUPP**: Research Group for the study of pressure ulcers at national level

- **NTSP**: National Transfusion Surveillance Programme
# Patient Safety Indicators Tested 2005

<table>
<thead>
<tr>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection due to medical care</td>
</tr>
<tr>
<td>Decubitus ulcer</td>
</tr>
<tr>
<td>Complications of anesthesia</td>
</tr>
<tr>
<td>Postoperative hip fracture</td>
</tr>
<tr>
<td>Postoperative PE or DVT</td>
</tr>
<tr>
<td>Postoperative sepsis</td>
</tr>
<tr>
<td>Technical difficulty with procedure</td>
</tr>
<tr>
<td>Transfusion reaction</td>
</tr>
<tr>
<td>Foreign body left in during procedure</td>
</tr>
<tr>
<td>Birth trauma - injury to neonate</td>
</tr>
<tr>
<td>Obstetric trauma – vaginal delivery</td>
</tr>
<tr>
<td>Obstetric trauma - caesarean section</td>
</tr>
</tbody>
</table>
## AHRQ - OCDE national PSI results

<table>
<thead>
<tr>
<th>Indicators 2005</th>
<th>MBDS National Rate</th>
<th>VC (providers)</th>
<th>Other Sources</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| Infection due to medical care | 0.1463 % | 0.54 | NCI (EPINE): 8.1 %  
ICU (ENVIN): 14.20 % | MBDS: 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: Underreporting. High inter-hospital variability  
GNEAUPP: specific study of prevalence. Different exclusion and 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 |  | Underreporting. High inter-hospital variability |
| Postoperative sepsis | 0.4181 % | 0.54 | Bacteraemia (EPINE): 5.56 % | MBDS: Underreporting. High inter-hospital variability  
EPINE: Different inclusion criteria |
| Technical difficulty with procedure | 0.1655 % | 1.05 |  | Underreporting. |
| Transfusion reaction | 0.0003 % | 0.17 | NTSP: 0.067 % | MBDS: High inter-hospital variability  
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 |  | Possible underreporting |
| Obstetric trauma – vaginal delivery | 1.1985 % | 0.44 |  | Possible underreporting  
High inter-hospital variability |
| 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
<table>
<thead>
<tr>
<th>Indicators 2005</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection due to medical care</td>
<td>Use of other source of data in parallel</td>
</tr>
<tr>
<td>Decubitus ulcer</td>
<td>Inclusion of the nursing report for codification</td>
</tr>
<tr>
<td>Complications of anesthesia</td>
<td>Inclusion of the anaesthesia report for codification</td>
</tr>
<tr>
<td>Postoperative hip fracture</td>
<td>No problems with the codification. There are problems with the date of the surgery</td>
</tr>
<tr>
<td>Postoperative PE or DVT</td>
<td>It should be necessary to review the clinical record</td>
</tr>
<tr>
<td>Postoperative sepsis</td>
<td>Use of other source of data in parallel</td>
</tr>
<tr>
<td>Technical difficulty with procedure</td>
<td>Inclusion of the surgical report for codification</td>
</tr>
<tr>
<td>Transfusion reaction</td>
<td>Use of other source of data in parallel</td>
</tr>
<tr>
<td>Foreign body left in during procedure</td>
<td>Inclusion of the surgical report for codification</td>
</tr>
<tr>
<td>Birth trauma - injury to neonate</td>
<td>Only clinical records for neonates in some Hospitals. It is necessary to improve clinical records for neonates</td>
</tr>
<tr>
<td>Obstetric trauma – vaginal delivery</td>
<td>Most women deliver in private Hospitals. It is necessary to improve codification in private Hospitals</td>
</tr>
<tr>
<td>Obstetric trauma - caesarean section</td>
<td>Most women deliver in private Hospitals. It is necessary to improve codification in private Hospitals</td>
</tr>
</tbody>
</table>
National Balance scored card

PSI
Good practices
AE Notification

Perception
Training
Costs

Patient safety monitoring tool
BALANCE SCORED CARD FOR PATIENT SAFETY

Quality Agency – MoH

Prioritized Indicators

Reports

Health Regions

Society

OECD Others

HR

MSC

Scientific Associations

Others

HOSPITAL

PRIMARY CARE

MBDS (ICD 9-CM)

Surveillance Transfusion

Patients’ Complaints

Quality Plan NHS

Nosocomial Infections

Intensive Care Units

Pressure Ulcers

Medication System

Good practices (NQF)

AEs Primary Care

Costs

AE - Notification System

Scientific Associations

Health Regions

Society

OECD Others

30
Main conclusions:

- The hospital MBDS allows construction of PS indicators through agreement of standards at national level.

- Common ICD-9-CM codification: high coverage and high expertise in codification in public hospitals are clear advantages of the data set.

- Underreporting and High inter-hospital variability are a common problem (Discharge records and clinical records are frequently incomplet).

- Promotion of use of secondary records (nurses, lab, surgery records etc.) not now used as a source for codification.

- Discharge and clinical records do not usually include adverse events or near misses.

- Complementary sources are necessary in order to achieve more accurate data to assess PS.

- PSI have to be validated and adapted locally.
Patient safety: a long but beautiful road to clinical excellence

Thank You