

# Patient safety – Clinical risk management systems

## Analysis of international practices

Support for improving quality of healthcare and patient safety in Slovenia

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## Glossary

A list with the abbreviations that will appear in this documents is presented below:

- **AHPEQS:** Australian Hospital Patient Experience Question Set
- **AQuAS:** Catalan Agency for Health Quality and Evaluation
- **CRM:** Clinical Risk Management
- **DDKM:** Danish Healthcare Quality Programme
- **DHW:** Department of Health and Wellbeing
- **DPSD:** Danish Patient Safety Database
- **GDP:** Gross Domestic Product
- **GRC:** Centre for Clinical Risk Management and Patient Safety
- **HIQA:** Health Information and Quality Authority
- **HSA:** Health and Safety Authority
- **IKAS:** Danish Institute for Quality and Accreditation in Healthcare
- **IRS:** Incident-reporting systems
- **ISO:** International Organization for Standardization
- **IT:** Information Technology
- **MEM:** Major Emergency Management
- **MoH:** Ministry of Health
- **NHQRS:** National Healthcare Quality Reporting System
- **NPSO:** National Patient Safety Office
- **NSQHS:** National Safety and Quality Health Service
- **OECD:** Organisation for Economic Co-operation and Development
- **PS:** Patient Safety
- **QoC:** Quality of Care
- **SLS:** Safety Learning System
- **SRSP:** Structural Reform Support Programme
- **TRI:** Thematic Research Index
- **WHO:** World Health Organization
- **XHUP:** Public hospital network



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**01/ Objectives, expected results  
and phases of the project**

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## 01/ Objectives, expected results and phases of the project

General and specific objectives of the project



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### General objective

To contribute to **institutional, administrative and growth-sustaining structural reforms** in Slovenia, in line with **Article 4 of the SRSP Regulation**

### Specific objectives



To support the initiatives of **national authorities** to design their reforms **according to their priorities**, taking into account **initial conditions** and **expected socioeconomic impacts**



To support the national authorities:  
(1) in **enhancing their capacity** to formulate, develop and implement reform policies and strategies  
(2) in **pursuing an integrated approach**, ensuring **consistency between goals and means** across sectors



In Slovenia, to support the **Slovenian Ministry of Health (MoH)** in capacity building to develop a National strategy on Quality of Care, Clinical Risk Management and Patient Safety, and a legal framework of non fault compensation model

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## 01/ Objectives, expected results and phases of the project

Expected results of the project



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### Direct results

Over the longer-term, to **contribute towards improving the quality of care and patient safety in Slovenia**

### Indirect results

- **Improved knowledge** of challenges and opportunities in **patient safety and quality of care**
- Strengthened **patient safety culture** and **patient risk management**
- Improved **strategic planning and governance** of the quality of healthcare system
- **Revised set of indicators for quality of care for hospitals, specialist outpatient care and primary care** available, tested and communicated

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**01/ Objectives, expected results and phases of the project**  
 Phases of the project

The phases of the project will be approached around the following **dimensions**:

The diagram shows three circular icons arranged horizontally, connected by a thin line. The first icon is green and contains a white silhouette of hands holding a cluster of people. The second icon is grey and contains a white silhouette of a person with a checkmark and a warning sign. The third icon is purple and contains a white silhouette of a house, a person, and a dollar sign.

- Quality of Care (QoC)**
- Patient Safety (PS) and Clinical Risk Management (CRM)**
- No-fault patient compensation model (claim regulation procedures)**

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**01/ Objectives, expected results and phases of the project**  
 Phase 3 of the project

The diagram shows a sequence of 11 project phases, each represented by a chevron-shaped box pointing to the right. Phase 3 is highlighted in blue, while the others are grey. A magnifying glass icon is positioned over Phase 3. The phases are arranged in two rows: the first row contains Phases 1 through 6, and the second row contains Phases 7 through 11.

- Phase 1**: Kick-off meeting and inception report
- Phase 2**: Situation analysis of the national context of PS & patient RM, patient compensation and QoC
- Phase 3**: Patient CRM framework and action plan
- Phase 4**: Improve PS and safety culture
- Phase 5 \***: No-fault compensation model
- Phase 6**: National strategy for the QoC
- Phase 7**: Governance of the QoC system model
- Phase 8**: Quality indicators
- Phase 9**: IT functional specifications
- Phase 10**: Continuous quality improvement
- Phase 11**: Communication plan

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## 01/ Objectives, expected results and phases of the project

Phase 3 of the project



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Phase 3  
Patient RM  
framework and  
action plan

### Objective of the phase



- To assist in the development of comprehensive clinical risk management system of PS
- To analyze the system focusing on prevention and early intervention to mitigate safety risks

T 3.2: Conduct a **comparative analysis** of risk management systems of PS used in other countries: Denmark, Catalonia (Spain), Tuscany (Italy), Ireland, Australia

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## 02/ Methodology - Phase 3

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## 02/ Methodology - Phase 3

### Methodological process summary



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An analysis of clinical risk management systems of PS used in other countries will be carried out using different methodologies. This analysis entails:



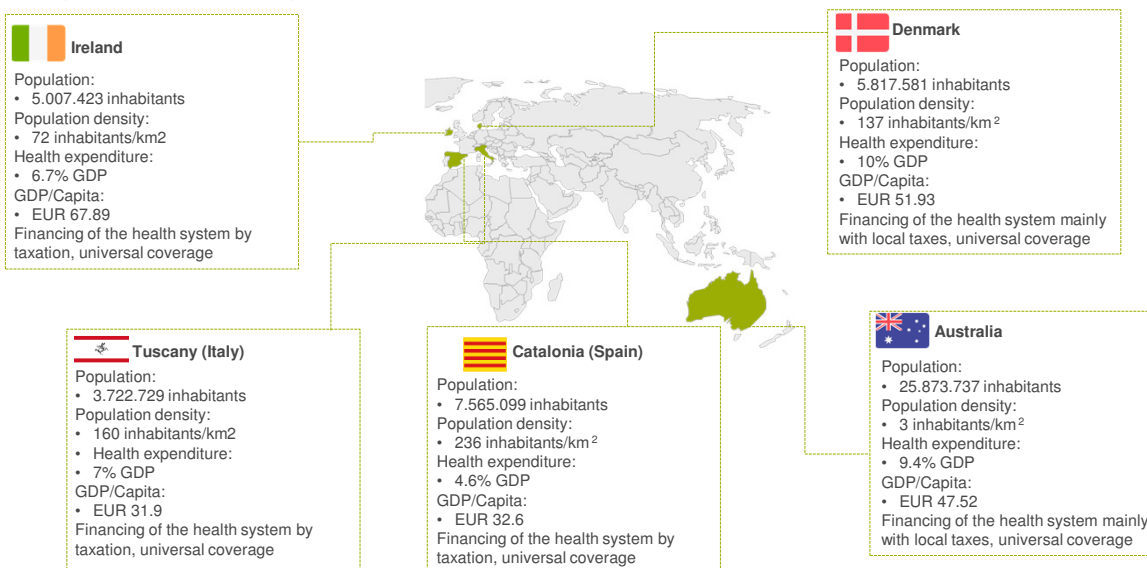
1. **Country selection\*** for conducting the analysis
2. Research **protocol elaboration** with a thematic research index (TRI)
3. Desk research and **non-exhaustive literature review**
4. Review of the information and **critical reading**
5. **Elaboration of the report** on the comparative analysis

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## 02/ Methodology - Phase 3

### Country selection

Countries/regions with great development in the field of QoC and PS, with a wide spectrum of processes and mechanisms to ensure the quality of care and safety of patients have been selected:



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## 02/ Methodology - Phase 3

### Research protocol elaboration

A research protocol was drawn up for the development of this phase of the project:



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## 02/ Methodology - Phase 3

### TRI elaboration

To analyse the country/regions case studies, comparative elements of each of the axes were standardized. **TRI's themes** have been structured around the **following topics**:



#### Patient Safety

- QoC and PS **Agencies**
- QoC and PS **plans**
- **Maturity** of the Healthcare System
- **Compensation** schemes
- **Accreditation/audits/guidelines**
- Regular **monitoring indicators of CRM**
- Quality and safety **processes and mechanisms**
- **Safety culture**
- PS **legislation**
- PS **measurement**
- PS **training**



#### Clinical Risk Management

- Clinical risk classification
- Clinical risk **assessment**
- **Mitigation** strategies
- Clinical risk management **training**
- **Roles**

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## 02/ Methodology - Phase 3

### Desk research and non-exhaustive literature review



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To guide the search for information and to carry out structured analysis, a **Thematic Research Index (TRI)** has been developed with key issues to be identified in each of the selected regions/countries.



#### Review of literature according TRI and critical reading of information

- Critical Reading according to TRI
- Synthesis of information found

#### Official information sources consulted (non-exhaustive list)

Country sources	<ul style="list-style-type: none"> <li>• Health Service of Tuscany</li> <li>• Centre for Clinical Risk Management and Patient Safety of Tuscany Region (GRC)</li> </ul>	<ul style="list-style-type: none"> <li>• Health Service Executive (HSE)</li> <li>• Irish Department of Health (Government of Ireland)</li> <li>• National Patient Safety Office</li> <li>• Health and Safety Authority (HSA)</li> </ul>	<ul style="list-style-type: none"> <li>• Government of Catalonia (gencat)</li> <li>• Health Department of Catalonia</li> <li>• Catalan Agency for Health Quality and Evaluation (AQuAS)</li> </ul>	<ul style="list-style-type: none"> <li>• Australian Commission on Safety and Quality in Health Care</li> <li>• Australian Institute of Health and Welfare (Australian Government)</li> </ul>	<ul style="list-style-type: none"> <li>• Danish Patient Safety Authority</li> <li>• Danish Ministry of Health</li> <li>• Danish Society for Patient Safety</li> <li>• Danish Digitization Agency</li> </ul>
Transversal sources	World Health Organisation (WHO) // Eurostat // Organisation for Economic Co-operation and Development (OECD)				

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## 03/ Results - Phase 3

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### 03/ Results- Phase 3

#### Overview



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The following slides aim at characterising the main highlights of each of the selected countries regarding **PS** and **CRM**:

1. Health System organisation
2. Governance structures
3. Plans and strategies
4. Clinical risk management
5. Patient safety

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## Tuscany



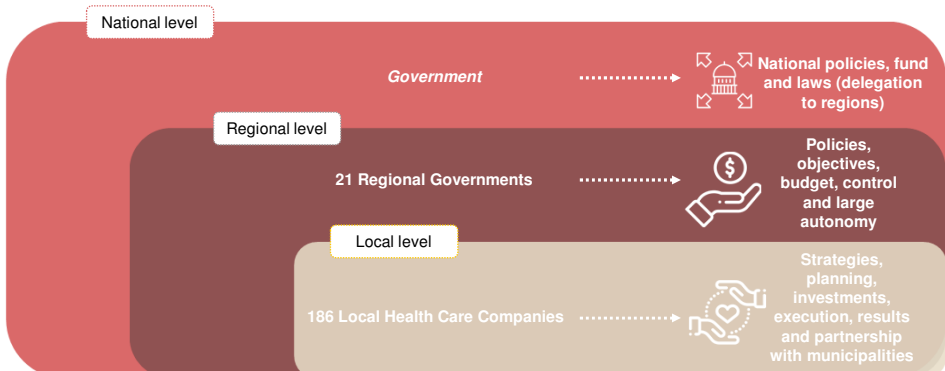
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**Italian health system**  
Health system organisation



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The health system in Italy is decentralised on 3 levels: central, regional and local.



**National level**  
Government → National policies, fund and laws (delegation to regions)

**Regional level**  
21 Regional Governments → Policies, objectives, budget, control and large autonomy

**Local level**  
186 Local Health Care Companies → Strategies, planning, investments, execution, results and partnership with municipalities


**+** Instead of analysing Italy, we will analyse **the Tuscany Region**, a Regional Authority strongly committed to foster patient safety and to promote European practices for patient safety culture that organizes the system through several entities that cover the whole regional territory. This region is composed by:

- 12 Local Health Care Agencies
- 4 University Clinical Centres – Teaching Hospitals
- 3 Service Companies

All of them are divided in 3 Clusters and the Local Health Authorities Companies work in partnership with Municipalities.

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**PS and CRM**  
Governance structures



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The institution in charge of QoC and PS in the Tuscany Region of Italy is presented as follows:

**Governance structure and organization of QoC and PS**

Governance (I)	Key objectives
 <p>The <b>CRM and PS Centre (GRC)</b> is a clinical governance structure instituted in 2003 by the Tuscan regional council. The GRC enrolls professionals of different disciplines (public health, <b>clinical risk management</b>, industrial design, human factors, organization studies, communication science, law, psychology, international relations) and since the beginning of the activity, is connected to a scientific committee.</p>	<p>GRC promotes the <b>safety culture</b> through the active and cross disciplinary learning from adverse events and errors. The GRC aims to construct a <b>shared vision for safety</b> through the sharing of experiences and the development of collaborative projects for <b>PS</b>. The centre proposes standards for the operational contexts and supports the effective measurement of critical process and measures.</p> <p>The GRC has organized a series of <b>initiatives to involve citizens in PS's policy and practice</b>. The GRC centre Management and WHO Collaborating Centre (GRC Centre-Centro Gestione Rischio Clinico e Sicurezza del Paziente) aims at developing and promoting practices for safety, awareness raising and the analysis of adverse events for the constant improvement of care delivery.</p>
 <p><b>Department for Health of the Tuscany Region</b> The Tuscan health service counts on over 50,000 people including doctors, nurses and technicians who work daily in the 40 hospitals in Tuscany, in the structures and health services of the territory. It is precisely to these that the specialist, operational and more in-depth contents of the Tuscan Health Service pages are aimed.</p>	<p>The aim of the Department of Health is to provide information (in the foreground, opportunities, rankings and events) and regional indications (authorization and accreditation) aimed at supporting the activities to <b>improve the services and health of citizens together</b>.</p>

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**PS and CRM**  
*Plans and strategies*

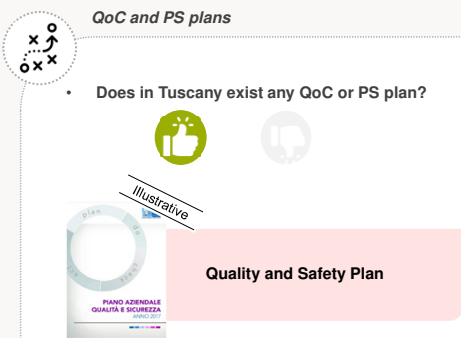


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Quality and Safety Plan and its main strategic lines is presented below:

**QoC and PS plans**

- Does in Tuscany exist any QoC or PS plan?




This plan undertakes to guarantee a structured path of **quality, safety and process improvement** in compliance with national and regional guidelines. The improvement actions that will arise from this path will be consistent with the general company processes, in particular with the planning and management control processes and budget objectives, quality, permanent staff training, insertion of newly acquired personnel, diagnostic paths, prevention of risks / unwanted events.

The strategic lines and actions on which the plan is committed are:

- Build a **clear and branched system of quality and safety governance**
- Support the **self-assessment by professionals** and therefore the processes of accreditation and **continuous improvement**
- Promote the **appropriateness** and adoption of **evidence-based** technical professional tools at all levels
- Enhance the **user experience** in improving services
- Encourage, disseminate and support the **culture of reporting** and transparency
- Oversee adverse events, promote their analysis and monitor the resulting **improvement actions**
- Supporting operators at all levels through **continuous training** and coherent enhancement and **evaluation systems**
- Analyze, reorganize, standardize and monitor corporate macro processes with a view to **quality and safety**

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**PS and CRM**  
*Clinical risk management*



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Reported systems and indicators of CRM in the Tuscany region are detailed below:

**Reporting Systems & Monitoring indicators**

Goals for CRM are divided into a mid-term action plan for CRM; and short-term PS campaigns and laboratories for PS. Mid-term action plan is devoted to develop a participatory process in order to create a local CRM system, connected with the regional network. Short-term campaigns focus on specific problems for an immediate answer to well known risks, demonstrating the institutional commitment for PS.

**Incident-reporting systems (IRS)** are tools that allow front-line healthcare workers to voluntarily report adverse events and near misses. The WHO has released guidelines that outline the basic principles on how to design and implement successful IRS in healthcare organizations. A written survey was administered with an assisted self-assessment technique to a representative sample of healthcare workers in Italian hospitals with and without IRS. Data were collected using two different 16-item questionnaires. The questionnaires targeted two issues:

1. Workers' experience of PS incidents
2. Workers' expectations on incident reporting

0% of respondents confirmed involvement in a PS incident, but only 40% utilized an IRS to formally report the event. The data indicate that information regarding PS incidents is not communicated throughout the entire organization. So, the conclusion is that research findings are consistent with the available evidence on healthcare workers' experience of PS incidents.

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**PS and CRM**  
*Clinical risk management*



The CRM process and how clinical risk mitigation works in Tuscany region is described below:

**CRM process**

The building of the system is based on the cycle of CRM: identification through reporting, analysis by means of peer review, prevention and control with improvement plans. CRM system is a process of three steps:

- 1. Identification of clinical risks:** is done by using different sources such as public data, as the patients' claims and complaints, and the invisible data concerning near misses and accidents without damages for the patients.
- 2. Analysis of clinical risks and safety management:** methods used are CRM clinical audit as well as mortality and morbidity review. At the end of the analysis, an alert report is issued. It contains the analysis of the event and the related action plan for safety improvement. The alert report is then highlighted on the intranet and specifically sent to all those units that may draw advice. It is also sent to the CRM centre and added to the regional data base.
- 3. Promoting campaigns:** the campaigns focus on well-known risks for PS. Evidence shows that many incidents occur because of the same latent falls, and we also know there are effective solutions for some kinds of adverse events. We only need to benchmark the solutions and push the system in the proper direction.

**Clinical risk mitigation**

Management of clinical risk is a proactive activity, and it is what should happen at all times, not only when there is an incident. It implies the acceptance of risk rather than the desire to eliminate risk, and constant mitigation will decrease the potential for harm.


Clinical risk control consists of the **implementation of prevention procedures** and strategies that lead to the creation of a specific **clinical risk prevention/mitigation**. The control focuses on the training of employees in terms of information, consent, accurate compilation of a medical record, hospital discharge sheets, and reporting of unwanted events. It should also concentrate on the development of protocols, procedures, and/or control measures that can improve the safety of the assisted person and on the efficiency of the CRM units understood as monitoring capacity, interpretation of the causes of unwanted events, and identification of clinical corrective factors.

Various strategies\* can be taken to mitigate inherent risks in high-risk situations. Mitigation of this clinical risk entails conduct of error checking at each stage of the preparation.

\* The specific actions that are put in place for clinical risk mitigation have not been found.

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**PS and CRM**  
*Patient safety*



In Tuscany, they have training programmes to promote safety culture and it works as follow:

**Safety culture**

**Training programmes**

Training program based on ergonomics and human factors for clinical risk managers, the CRM team, facilitators and healthcare workers has been designed in order to prepare the human resources for this effort.

CRM regional centre organized 3 editions of the **course** for CRM teams members, with the aim to train those who promote **PS** initiative at the agency level. A master course for certified CRM was organized together with the most authoritative academic institutions in Tuscany. Training programs have been delivered for facilitators and for operators, beginning from high risk clinical areas.

The main objective of the training program is to promote a **new safety culture** based on the cognitive approach to the human error and the systemic approach to clinical risk

and PS. In order to create reporting culture where the operators feel free to talk about their errors without being blamed, the training courses have been based on the discussion of adverse events presented by participants.

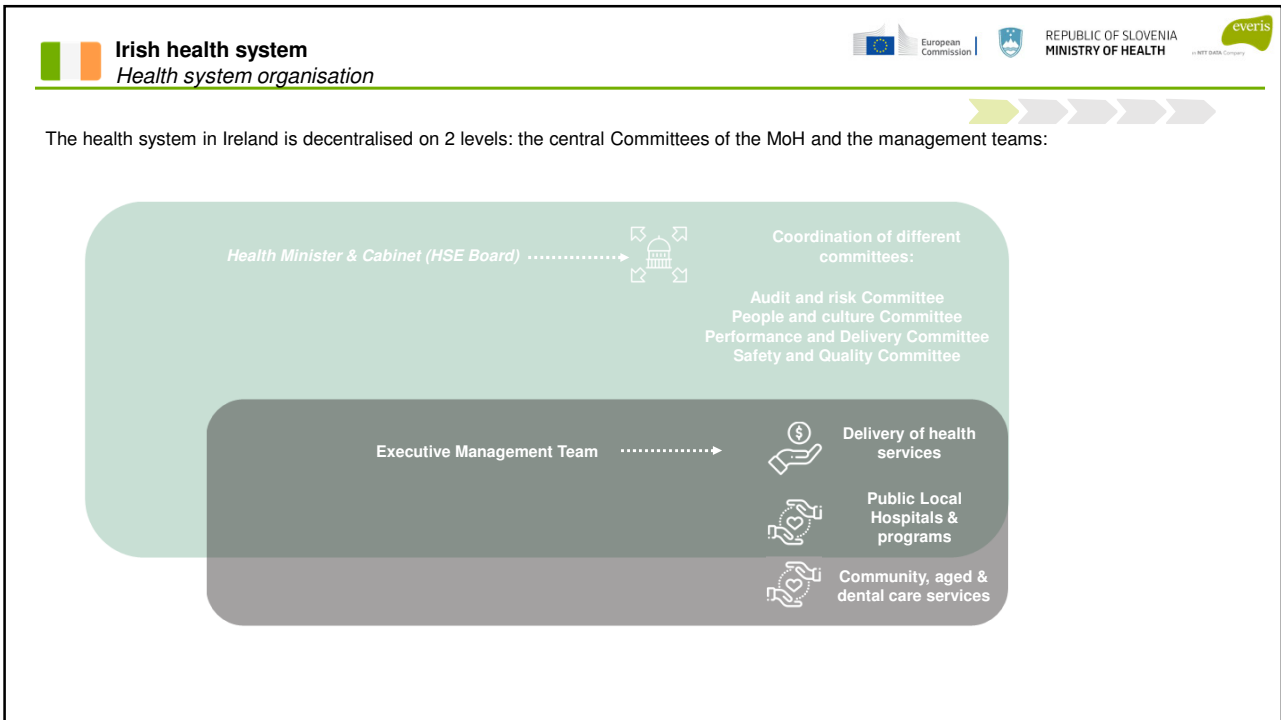
All the operators of the clinical areas where the problem of adverse events is more relevant (emergency department, orthopaedics, intensive care unit, surgery,...) have been involved in a basic course about CRM.

The CRM centre also designed and is delivering a training program for the forensic medical doctors and the operators of the offices for public relation with the citizens. It will be also activated the **simulation laboratories** for emergency teams and an anesthesia and critical care teams with the aim of fostering the communication skills and the ability of the team to manage the unexpected.

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**PS and CRM**  
Governance structures

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The QoC and PS in Ireland is organized as follows:

**Governance structure and organization of QoC and PS (I)**

**Governance (I)**

- There is a **Quality and PS Directorate** established in order to ensure that high quality safe services are designed and delivered to patients and clients. This directorate is committed to a multi-agency approach, and it is focused on the development and implementation of safe quality healthcare
- Recently, the health service has placed an important emphasis on quality and service user safety by developing an infrastructure for integrated QoC, PS and CRM.
- Governance for quality involves having the necessary structures, processes, standards and oversight in place to ensure that safe, person-centred and effective services are delivered. Good governance supports strong relationships between frontline staff, service users and leaders within any organization.
- In Ireland, quality in healthcare is defined by the four domains set out in the **HIQA National Standards for Safer Better Healthcare** (Health Information and Quality Authority, 2012): **person centred, effective, safe and better health and well-being.**

**Key objectives**

- The overall goal of the HSE Quality and PS Enablement Programme as outlined in the HSE Code of Governance (2015) is underpinned by four key objectives:
  - 1 Services must subscribe to a set of **clear quality standards** that are based on international best practices
  - 2 Services must be **safe** and there must be a robust level of both quality improvement and quality assurance
  - 3 Services must be **relevant** to the needs of the population
  - 4 Patients must be appropriately **empowered** to interact with the service delivery system.
- In 2016, the HSE launched the **Framework for Improving Quality in our Health Service** which outlines six critical success factors:
 

1. Leadership for Quality	4. Use of improvement methods
2. Personal and Family Engagement	5. Measurement for Quality
3. Staff Engagement	6. Governance for Quality

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**PS and CRM**  
Governance structures

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The QoC and PS in Ireland is organized with different types of Boards, described below:

**Governance structure and organization of QoC and PS (II)**

**Governance (II)**

**Types of Boards in Ireland**

- Currently in Ireland there are an estimated 500 people participating on **healthcare boards**. The governing board leads the organization using authority to direct and control provided by the owner and the legal act of formation (where applicable). They set initial direction and have the authority to act in the service user and services best interest. Governing boards function at arm's length from the operational organization. They focus on the big picture, future-oriented and act as a single entity.
- There are a number of key policy documents and resources applicable to boards and executives within healthcare in Ireland. When services do not have boards the CEO/General Manager and executive team take on this responsibility. There are different types of boards within HSE funded healthcare services which operate within the HSE Performance Accountability Frameworks. These include:

Hospital Group Boards

Voluntary Healthcare Provider Board of Directors

Advisory Boards

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There are two national plans regarding QoC and PS in Ireland, and the first one is presented as follows:

**QoC and PS plans (I)**

- Does in Ireland exist any QoC or PS plan?

**Illustrative**

**1. National Quality Improvement Team working in partnership to lead innovation and lasting quality improvement to achieve better and safer care**

**Illustrative**

**2. Patient Safety Strategy 2019 - 2024**

**1. National Quality Improvement Team working in partnership to lead innovation and lasting quality improvement to achieve better and safer care**

**Aims**

- Partner with people who use and work in our health and social care services to achieve measurable and sustainable improvements in quality.
- Proactively enable a culture of person centredness within our health and social care services that continually improve QoC, practice and experience.
- Promote learning and development through education, research and continual evaluation of improvement work.
- Make connections between those interested in and trained in QI.

The National QI Team has **7 programmes of work** to support front- line teams in improving quality:

- |                                       |   |
|---------------------------------------|---|
| 1. Sustainable QI Programme           | 5. Partnering with people who use health services Programme |
| 2. School of QI Programme             | 6. Global Health Programme                                  |
| 3. QI Connections Programme           | 7. Clinical Directorate Programme                           |
| 4. Evidence for Improvement Programme |   |

There are two national plans regarding QoC and PS in Ireland, and the second one is presented as follows:

**QoC and PS plans (II)**

- Does in Ireland exist any QoC or PS plan?

**Illustrative**

**1. National Quality Improvement Team working in partnership to lead innovation and lasting quality improvement to achieve better and safer care**

**Illustrative**

**2. Patient Safety Strategy 2019 - 2024**

**2. Patient Safety Strategy 2019 – 2024**

The objective of this strategy plan is to improve the safety of all patients by identifying and reducing preventable harm within the health and social care system.

To support and monitor the implementation of the Strategy, a PS Programme and Team have been established.

**Aims**

- Ensure patients are partners in their care
- Promote an open and transparent culture of PS
- Learn from near misses and errors
- Identify and address the common causes of harm

This strategy has **6 commitments**:

- Empowering and Engaging Patients to Improve PS
- Empowering and Engaging Staff to Improve PS
- Anticipating and Responding to Risks to PS
- Reducing Common Causes of Harm
- Using Information to Improve PS
- Leadership and Governance to Improve PS

**PS and CRM**  
Clinical risk management

In this case, below it is presented the Reporting Systems and Monitoring indicators specifically for Ireland and the International Standard ISO 31000 in which Ireland holds:

**Reporting System & Monitoring indicators**

In Ireland, the National Patient Safety Office (NPSO) has a health indicator framework named the **National Healthcare Quality Reporting System (NHQRS)**. An indicator is a measurement or value of an item and often used with the prefix performance, quality or health and used to provide comparable information and to track progress and performance over time. Since 2014 the NHQRS has produced an annual report that is published on the Department of Health website. In this 2020 report there are a total of 52 indicators, from 11 data sources, across five key domains:

Key domain	Data sources
1. Helping people to stay health and well	<ul style="list-style-type: none"> <li>Immunisation rates</li> <li>Cancer screening rates</li> </ul>
2. Supporting people with long term conditions	<ul style="list-style-type: none"> <li>Ambulatory care sensitive conditions</li> </ul>
3. Helping people when they are being treated and cared for in our health services	<ul style="list-style-type: none"> <li>Cancel survival rates</li> <li>Cancer surgery</li> <li>Acute hospital care</li> </ul>
4. Supporting people to have positive experiences of healthcare	<ul style="list-style-type: none"> <li>National In-Patient Experience Survey</li> <li>National Maternity Experience Survey</li> </ul>
5. Treating and caring for people in a safe environment	<ul style="list-style-type: none"> <li>Healthcare associated infection rates</li> <li>Antibiotic consumption rates</li> <li>Medication Safety</li> </ul>

The **International Standard ISO 31000** is intended to meet the needs of a wide range of stakeholders, including:

- Those responsible for developing CRM policy within their organization
- Those accountable for ensuring that risk is effectively managed within the organization as a whole or within specific area, project or activity
- Those who need to evaluate an organization's effectiveness in managing clinical risk
- Developers of standards, guides, procedures and codes of practice that, in whole or in part, set out how clinical risk is to be managed within the specific context of these documents

The primary objective of the NHQRS is to provide publicly available information on the quality of healthcare. This in turn should inform and support decision-making by patients, policy makers and service providers.

**PS and CRM**  
Clinical risk management

The CRM process, clinical risk assessment and clinical risk mitigation in Ireland is described below:

**CRM process**

The following figure presents the relationships between the CRM process:

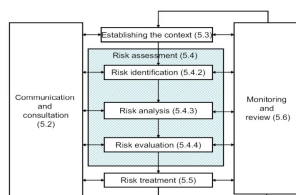


Figure 1: CRM process

The principals regarding CRM are:

- a) Creates value
- b) Integral part of organizational processes
- c) Part of decision making
- d) Explicitly addresses uncertainty
- e) Systematic, structured and timely
- f) Based on the best available information
- g) Tailored
- h) Takes human and cultural factors into account
- i) Transparent and inclusive
- j) Dynamic, iterative and responsive to change
- k) Facilitates continual improvement and enhancement of the organization

**Clinical risk assessment and mitigation**

There is a **National Risk Assessment** for Ireland produced by the Government of Ireland that acts as a guideline regarding risk.

In it, there is a Framework for Major Emergency Management (MEM) chaired by the National Steering Group on MEM. This Framework adopt an all hazards approach to emergency management, which advocates a system approach based on the following **Five-Stage Emergency Management Paradigm**:



Figure 2: Five-Stage Emergency Management Paradigm

Moreover, **mitigation** as a risk treatment process involves reducing or eliminating the likelihood and/or the impact of an identified clinical risk. Legislative controls are in place in relation to a number of significant risks. These legal controls are enforced by regulatory authorities or agencies overseen by the relevant Lead Government Departments. Decisions regarding prioritizing and resourcing of appropriate mitigation measures are the responsibility of the relevant Department and/or relevant bodies under its aegis. This process informs the allocation of additional resources, if necessary, at all levels up to central Government funding. Progress on mitigation, i.e., risk reduction, is monitored and reported internally by each Lead Government Department.



The safety culture of Ireland and the measurement process is presented as follows:


**Safety culture**
**Governance**

The **HSA** has the overall responsibility for the administration and enforcement of health and safety at work in Ireland. They promote the benefits of creating a positive safety culture and defend that directors and officers of undertakings who authorize and direct work activities are responsible for ensuring good safety and health as part of their corporate governance role. Regarding patient safety, the **Commission on PS and Quality Assurance strongly supports the prioritization of education, training and research on patient safety**. The Commission recommends:

- All bodies responsible for the training and continuing development of healthcare workers should review their curricula to ensure that both technical and human factors in relation to PS and QoC are incorporated into their education modules. Education and training suites and modules on PS need to be developed and implemented in collaboration with professional training bodies, the HSE and the Health Research Board (HRB).

**Measurement process**

The organization should measure, monitor and evaluate safety and health performance. Performance can be measured against agreed standards to reveal when and where improvement is needed. Active self-monitoring reveals how effectively the safety and health management system is functioning. Self-monitoring looks at both hardware (premises, plant and substances) and software (people, procedures and systems, including individual behavior and performance). If controls fail, reactive monitoring should find out why they failed, by investigating the accidents, ill health or incidents, which could have caused harm or loss.

Moreover, the Commission recognizes the need for specific education and training requirements and supports for healthcare managers. It also recommends to create an specific vocational management **training programme** aimed not only at producing high quality managers but also a enhancing the management capability of health professionals at all levels of the health system; this programme would also include **specific modules on PS and QoC**.

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**Catalan health system**  
Health system organisation

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The health system in Spain is decentralised on 3 levels: central, autonomic and municipal.

Instead of analyzing Spain, we will analyze Catalonia, one of the Autonomous Communities in Spain which has its own Health Department.

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**PS and CRM**  
Governance structures

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The different organizations related to QoC and PS in Catalonia are presented as follows:

**Governance structure and organization of QoC and PS**

**Governance**

**Key Objectives**

The **Health Department of the Government of Catalonia** has its own **PS department** and the **Alliance for PS in Catalonia**. Within the framework of the Alliance, multicentre projects in PS have been promoted and various initiatives have been carried out which have made it possible to achieve quite significant results in the areas that have been improved.

Moreover, in Catalonia there is the **AQuAS**. This is the agency that promotes the evaluation of technologies and health services and the analysis of the social impact of research, among others.

Their key objectives is to **promote PS** in Catalonia through the development and **improvement of systems** for the detection and prevention of healthcare safety problems and the coordination of the different initiatives, and contribute to the involvement of citizens, professionals, centres and the administration so that society can address these issues in a positive way.

The key objective and mission of AQuAS is to generate knowledge through the evaluation and analysis of data for decision-making in order to contribute to the improvement of the health of the citizens and to the sustainability of the health system of Catalonia.

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The general health plan and the specific plan for PS in Catalonia are presented as follows:

### QoC and PS plans

- Does in Catalonia exist any QoC or PS plan?



#### 1. Health Plan for Catalonia 2016 - 2020



#### 2. Strategic plan for Patient Safety in Catalonia 2014 - 2018

#### 1. Health Plan for Catalonia 2016 - 2020

This plan is a general plan for health, and it includes target goals for QoC and PS:

- To carry out healthcare activities with a high level of QoC and PS and ensure the satisfaction of people using the health system.
- The QoC and PS are elements that must be maximized and guaranteed to the citizen. The challenge for healthcare organizations and professionals will be to promote excellence and the quality of healthcare in Catalonia as a benchmark of trust for the citizen.

#### 2. Strategic plan for Patient Safety in Catalonia 2014 - 2018

- The mission of this plan is to facilitate personalized, comprehensive and quality care, which leads to a reduction for patients to suffer an unnecessary risk related to health care to an acceptable minimum.
- The vision of this plan is commitment, patient orientation and the desire for continuous improvement with safe healthcare for all citizens.
- The strategic lines are: promotion of Safety Culture for patients, promotion of best practices through specific projects about PS, evaluation and improvement of PS strategy, communication about PS with all healthcare stakeholders, training to all healthcare stakeholders and participation of patients in QoC and PS improvement.

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The reporting system carried out in Catalonia is described below:

### Reporting System & Monitoring indicators



In Catalonia, in 2012, a PS model in the **Quality and Bioethics Promotion Service** was driven. The aim of this model was to achieve excellence in PS and minimize the risk of unnecessary damage associated with the care provided. This Service is the one which prepares a report where it analyzes incidents in the public hospital network (XHUP) and consortia and in primary care related to PS.

The aim is to **collect incidents** that allow them to be **analysed and solutions** sought in order to reduce their number and frequency in order to increase PS during healthcare.



The system used to report these incidents is **TPSC-Cloud™**, (the online platform of the PS Company), which began to be implemented in Catalonia at the end of 2013. In this system all types of incidents related to PS can be reported, voluntarily, confidentially, anonymous and not punitively.

The principal functionalities of this system are:



#### Notification

Allows notification in a structured way, based on different types of questionnaires depending on the type of incident being reported (medication, falls, etc.)



#### Management

Allows proactive management through tools (risk matrix, cause-effect analysis, barrier analysis, process analysis, AMFE (modal analysis of falls and their effects)) integrated in the platform



#### Analysis and reporting

Allows to analyze incidents to identify risks in a systematic way and prevent errors



#### Improvement actions

Allows to define, plan and monitor improvement actions, preventive measures or changes in the organization.

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The CRM process and how risk is classified in Catalonia is presented below:



#### CRM process

The ISO 31000 Risk Management Standard helps manage risk through a Risk Management Plan. It is therefore a very good tool for CRM in accordance with the ISO 9001 quality certification and the ISO 14001 environmental management certification. In Catalonia, in order to implement the Risk Management process according to ISO, the following steps must be followed:



#### Clinical risk classification

In Catalonia, they classify incidents depending on the following aspects:

- Gravity
- Probability
- Type of clinical risk

And regarding the type of clinical risk, this is classified by:

- **Very low clinical risk:** verification of possible presentation trends throughout the hospital
- **Low clinical risk:** verification of possible presentation trends in the affected area / service
- **Moderate clinical risk:** assessment and monitoring of possible presentation trends in the affected area / service
- **High clinical risk:** detailed analysis and adoption of measures to be disseminated in the affected area / service
- **Extreme clinical risk:** detailed analysis and adoption of immediate measures to be disseminated throughout the hospital

In Catalonia, the most usual incidents are falls and then medication errors.

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The PS culture is promoted in Catalonia with a strategy presented as follows:



#### Safety culture

##### Patient Safety Culture

The patient's safety culture is based on learning from adverse events, developing preventive strategies to prevent their occurrence and recognizing and accompanying those who have suffered unnecessary and involuntary harm resulting from the health care received.

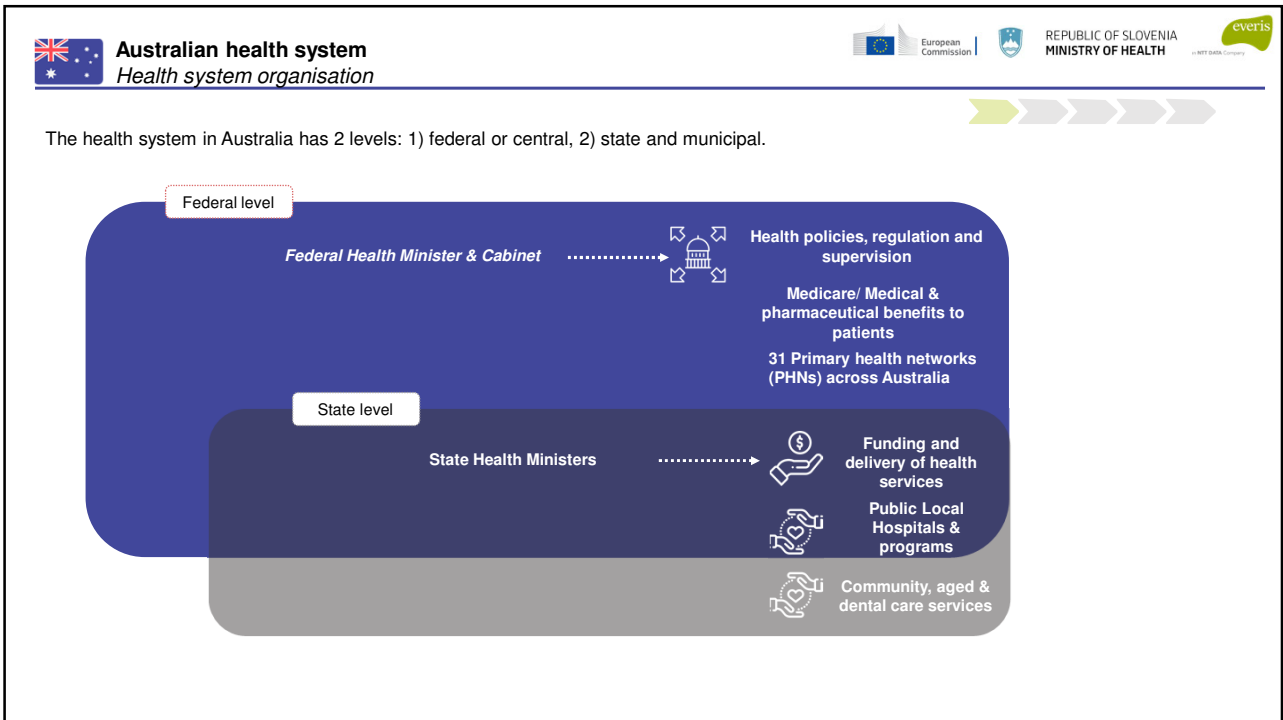
This is the reason why in Catalonia, the **culture of PS has been promoted** since 2008 through the Department of Health and, specially since 2012, the "Functional Patient Safety Units" have been implemented in health centres with the following strategy:

- 1 Create a quality and PS committee
- 2 Identify those responsible and leaders who must **drive, promote and implement** the PS strategy in the centres
- 3 Identify and prioritize **areas of greatest risk** in health centres
- 4 Implement an **incident notification system**
- 5 **Patient safety training** for healthcare professionals
- 6 **Dissemination of PS** through the News PS newsletter and the PS channel
- 7 Evaluate the **PS strategy** by implementing the dashboard in acute care and primary care hospitals
- 8 **Involve patients and citizens** by transmitting useful and interesting information about their safety as patients and how to make their care safer
- 9 Establish **communication forums** by conducting PS Conferences (14 conferences to date).

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**QoC, PS and CRM**  
*Governance structures*

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The main organizations in Australia regarding QoC, PS and CRM is presented as follows:

**Governance structure and organization of QoC and PS (I)**

Governance	Key Objectives
<p><b>Australian Commission on Safety and Quality in Health Care</b> The Australian Commission on Safety and Quality in Health Care to lead and coordinate national improvements in the safety and quality of health care. The Commission commenced as an independent statutory authority on 1 July 2011, funded jointly by the Australian Government and state and territory governments.</p> <p><b>Department of Health and Wellbeing (DHW)</b> has used the Safety Learning System (SLS) since 2011. This is an incident management system that allows healthcare staff to report incidents and near misses.</p> <p><b>Medicare Easyclaim</b> is a stand-alone process via an integrated feature of the practice management software products. It is used for Medicare bulk billing and patient claiming.</p>	<p>Key objectives of the Commission include <b>developing national safety and quality standards</b>, developing clinical care standards to improve the implementation of evidence-based health care, coordinating work in specific areas to improve outcomes for patients, and providing information, publications and resources about safety and quality. The Commission works in four priority areas: 1) PS, 2) Partnering with patients, consumers and communities, 3) Quality, cost and value, 4) Supporting health professionals to provide care that is informed, supported and organized to deliver safe and high-quality care.</p> <p>Their key objectives is to have SLS reviewed, escalated where appropriate, analysed and investigated in an attempt to prevent their occurrence in the future. The SLS is a "state-wide" system which allows healthcare professionals access to report incidents in all SA public health services and related agencies such as ambulance.</p> <p>Medicare Easyclaim has the objective of giving patients the option to claim their Medicare benefit and have it paid into their bank account through the practice's EFTPOS terminal.</p>

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**QoC, PS and CRM**  
*Governance structures*

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In Australia, there are a concrete standards that guide QoC and PS, which are described below:




**Governance structure and organization of QoC and PS (II)**

**NSQHS STANDARDS** The National Safety and Quality Health Service (NSQHS) Standards provide a nationally consistent statement of the level of care consumers can expect from health service organizations. The NSQHS Standards were developed by the Commission in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, patients and carers. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision. The eight NSQHS Standards provide a nationally consistent statement about the level of care consumers can expect from health services.

<p><b>Clinical Governance</b> Leaders of a health service organization have a responsibility to the community for continuous improvement of the safety and quality of their services, and ensuring that they are patient centred, safe and effective.</p>	<p><b>Partnering with Consumers</b> Leaders of a health service organization develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement and evaluation of care. The workforce uses these systems to partner with consumers.</p>	<p><b>Preventing and Controlling Infections</b> Leaders of a health service organization aims to improve infection prevention and control measures to help prevent infections, and the spread of antimicrobial resistance through the appropriate prescribing and use of antimicrobials.</p>	<p><b>Medication Safety</b> Leaders of a health service organization describe, implement and monitor systems to reduce the occurrence of medication incidents, and improve the safety and quality of medicines use. The workforce uses these systems.</p>
<p><b>Comprehensive Care</b> Leaders of a health service organization establish and maintain systems and processes to support clinicians to deliver comprehensive care, and establish and maintain systems to prevent and manage specific risks of harm to patients during the delivery of health care.</p>	<p><b>Communicating for Safety</b> Leaders of a health service organization set up and maintain systems and processes to support effective communication with patients, carers and families; between multidisciplinary teams and clinicians; and across health service organizations.</p>	<p><b>Blood Management</b> Leaders of a health service organization describe, implement and monitor systems to ensure the safe, appropriate, efficient and effective care of patients' own blood, as well as other blood and blood products. The workforce uses the blood product safety systems.</p>	<p><b>Recognizing and Responding to Acute Deterioration</b> Leaders of a health service organization set up and maintain systems for recognizing and responding to acute deterioration. The workforce uses the recognition and response systems.</p>

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 **QoC, PS and CRM**  
*Plans and strategies*

Both the Work Plan and the National Framework for QoC and PS in Australia are presented as follows:

**QoC and PS plans**


- Does in Australia exist any QoC or PS plan?




**1. Safety and Quality Work Plan 2017-2019**  
This plan identifies the priorities to improve the safety and QoC provided to consumers. It identifies 6 priority areas:

- 1) PS
- 2) Partnering with patients, consumers and community
- 3) Quality cost and value
- 4) Supporting health professionals to provide safe and high quality care
- 5) SLS
- 6) Communication strategy to support safety and quality.

**2. Australian Safety and Quality Framework for Health Care**  
Australian Health Ministers endorsed the Australian Safety and Quality Framework for Health Care in 2010. The Framework describes a vision for safe and high-quality care for all Australians and sets out the actions needed to achieve this vision. The Framework specifies three core principles for safe and high-quality care: **care is consumer centred, driven by information, and organized for safety.** This Framework is used as the basis for strategic and operational safety and quality plans, provide a mechanism for refocusing current safety and quality improvement activities and designing goals for health service improvement

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 **QoC, PS and CRMC**  
*Clinical risk management*

Indicators for Reporting Systems in Australia are classified as follows:

**Reporting System & Monitoring indicators**

In Australia, Indicators for Reporting Systems are classified in five indicators sets:

- 1 Patient experience question set:** the Australian Hospital Patient Experience Question Set (AHPEQS) is a questionnaire with response options.
- 2 Sentinel events:** A sentinel event is a particular type of serious incident that is preventable and has caused serious harm to, or death of, a patient. In Australia, reporting of sentinel events, against a nationally endorsed and agreed sentinel event list (endorsed by all Australian Health Ministers in 2002), has been mandatory since 2007. Since 2017, public hospitals receive no Australian Government funding for an episode of care in which a patient experiences or suffers from a sentinel event.
- 3 Clinical incidents:** Australia has implemented a mandated reporting system where clinical incidents, their causes and any relevant contextual information are systematically recorded in a central repository. The information is then analysed and deployed to improve deficient processes where relevant, share lessons across related settings, improve safety for patients and prevent similar incidents from happening again.
- 4 Hospital-acquired complications:** Hospital-acquired complications (HACs) are a sub-set of adverse healthcare events that have been identified as originating during the patient's hospital stay and are not present when the patient is admitted. A HAC refers to a complication for which clinical risk mitigation strategies may reduce (but not necessarily eliminate) the risk of that complication occurring. The Commission has developed a list of 16 high-priority HACs.
- 5 Avoidable hospital readmissions:** avoidable hospital readmissions are costly, and rates remain relatively steady. However, action is being taken to improve data collection which can be used to inform local quality improvement

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**PS and CRM**  
*Clinical risk management*



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The CRM process and how risk is evaluated in Australia is described below:



**CRM process**

The following figure presents an overview of the **structured and systematic risk management process** as detailed by the Australian/New Zealand Standard AS/NZS ISO 31000:2018 Risk Management. The risk management process outlined is intended to be an integral part of any organization's practices and be applicable to all contexts. As such, clinical risks can be managed using the 5 steps shown in the figure. Additionally, the overall processes of "Communication and consultation" and "Monitor and Review" should be included during all the stages of the CRM process. All organizations should record their clinical risks and management activities in a Risk Register.

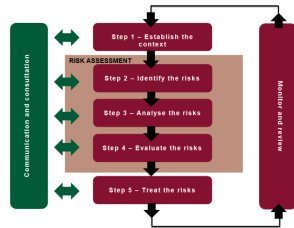


Figure 3: CRM process in Australia



**Clinical risk evaluation**

**Evaluating treatment options**

Each of the treatment options should be evaluated on the basis of the extent of clinical risk reduction, and the benefits or opportunities created. Following an evaluation process, health services may apply the alternative treatment options either individually or in combination. Selection of the most appropriate treatment option will require health service providers to evaluate the cost of implementing each option against the benefits that may be derived from it. Risk evaluation and prioritization involves comparing the level of risk found during the analysis step with previously established risk criteria and developing a prioritized list of risks for further action. A decision should be made for **treatment options**:

- Avoiding the activity/event associated with the unacceptable risk
- Reduce the risk by improving controls
- Transferring the clinical risks
- Retaining the clinical risks

The **clinical quality registries** use clinical data to identify benchmarks and variation in clinical outcomes and feedback essential risk-adjusted clinical information. The following figure shows the clinical outcome feedback loop:



Figure 4: Clinical Quality Feedback Loop



**QoC and PS**  
*Safety culture*



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The PS Culture and the measurement process is presented below:



**Safety culture**

**Patient Safety Culture**

The Commission uses the term 'patient safety culture' as their work focuses on the aspects of culture that relate to patient safety.

Positive patient safety cultures have **strong leadership** that drive and **prioritize safety**. Commitment from leaders and managers is important, their actions and attitudes influence the perceptions, attitudes and behaviors of the wider workforce. Other important aspects of positive PS culture include:

- Shared perceptions of the importance of safety
- Constructive communication
- Mutual trust
- A workforce that is engaged and always aware that things can go wrong
- Acknowledgement at all levels that mistakes occur
- Ability to recognize, respond to, give feedback about, and learn from, adverse events.



To support local monitoring of PS culture in Australian hospitals, the Commission is **developing a toolkit** which will include a short validated survey for regular monitoring, along with an implementation guide. The guide will provide advice on options for more detailed examination of PS culture, and advice on how to use this information to **improve care**.

**Measurement process**

Measurement of PS culture enables the identification of **strengths and areas for improvement**. This information can be used to develop appropriate interventions. PS culture measures can also be used to evaluate new safety programs by comparing results before and after implementation. It can be **measured through surveys of hospital staff, qualitative measurement (focus groups, interviews), ethnographic investigation or a combination of these**. **Surveys of hospital staff are the most common way of measuring PS culture**. Hospital staff are often the first to notice patterns of unsafe practice and the conditions which increase or decrease the likelihood of such practice.

**PS culture forms one component of a comprehensive measurement and improvement system; it should be measured alongside other indicators of safety and quality, such as, complications acquired while in hospital, accreditation outcomes, mortality, patient-reported measures and serious in-hospital incidents.**





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**Danish health system**  
Health system organization

The health system in Denmark operates across three political and administrative levels: national, regional and local.

**Determination of national standards of care:**

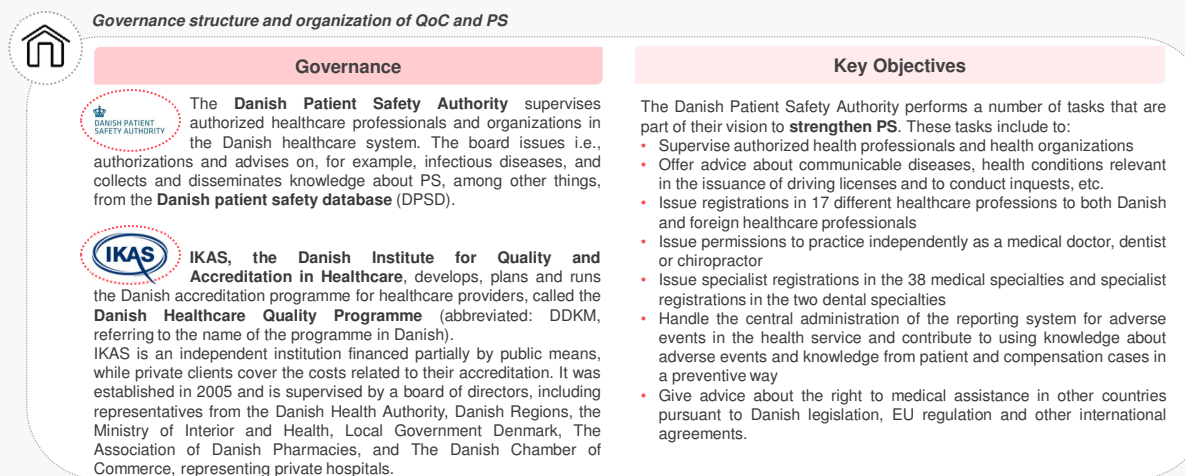
- *The Danish Healthcare Quality Programme is a national system intended to support a continuous quality improvement of the Danish healthcare service as a whole. It is a method to generate persistent quality development across the entire healthcare sector in Denmark.*

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## QoC, PS and CRM

### Governance structures

The agency in Denmark regarding QoC, PS and CRM is presented as follows:

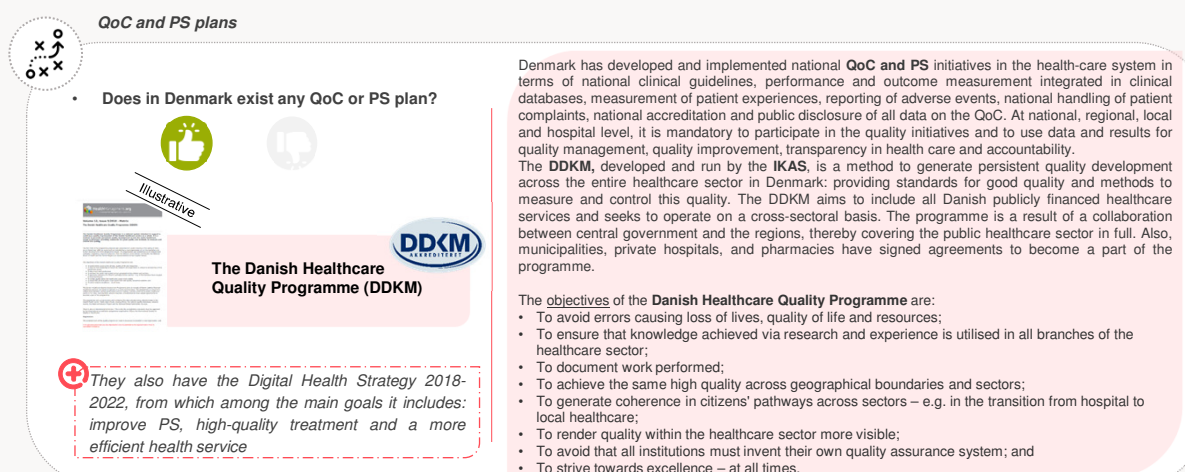


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## QoC, PS and CRM

### Plans and strategies

The Danish Programme regarding QoC and PS is explained below:



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Danish recommendations regarding Reporting Systems are presented as follows:

**Reporting System & Monitoring indicators**



In 2001, a study named *Danish Adverse Event Study* found out that 9% of discharged patients had experienced an adverse event. From that moment, they start to act on PS by implementing a **Reporting System** that could teach how to do it. The reporting system for adverse events is an important tool for ensuring knowledge about what is going wrong in the healthcare system. Since the reporting system was established, there has been a great deal of focus on the system and reporting itself. A culture of reporting has been created in all sectors and among healthcare professionals, patients and relatives. But at the same time, it has become clear that the reporting system as a whole is too bureaucratic and that there is too much focus on reporting and too little focus on acting and improving the systems as a result of the reports. In order to optimize the system, they have established eight recommendations for an optimized reporting system that can support improvements in the healthcare system for the benefit of PS. The eight recommendations can be summarized under the following headings:

**The original spirit of the reporting system must be preserved**

The perspective and reactions to unintended events can be divided into individual perspective and a system perspective. The reporting system is thought of and should still be too anchored in a system perspective alone. This is entirely in line with the available knowledge that in the vast majority of cases it is inappropriate systems that are the cause of unintended events - and not the negligence or negligence of individuals.

**It must be reported the important and anchor the system locally**

The working group recommends that in future, healthcare professionals should only report what is important - in contrast to now, where you are obliged to report all unintended events. It must also be made easier to report, and the reports must, as far as possible, be used locally.

**The reporting system must be considered together with the quality program**

Incidents cannot stand alone and reporting itself does not lead to improvements, there is a need to think about the reporting system together with a national quality program. Adverse events should not be prevented in a separate context, but should be used everywhere to motivate improvements in the quality Health system that is being established and where each unit Works systematically towards local goals related to the overall quality goals.

**The reporting system must support a legitimate and transparent healthcare system**

The reporting system must contribute to a transparent public system. There are international experiences about the publication of anonymous incidents, which the working group recommends that you study and possibly pilot tests. Finally, systems must be established to ensure that the reporter receives feedback on how the system has improved after reporting.

CRM process and how risk is assessed are described as follows:

**CRM process**



The risk management process in Denmark consists of several main activities which are fundamental to the overall process. Risk management is a cross-organizational process, and involves many stakeholders with different tasks and areas of responsibility. Planning, coordination and communication are therefore always a backdrop in the risk management process, both before and after the implementation of the main activities. Management anchoring is crucial for a successful risk management process.

What is crucial for risk management is the following 3 activities:

- Preparation of a risk management plan
- Management anchoring of risk management plan
- Implementation of risk management plan

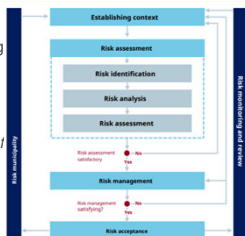


Figure 5: CRM process in Denmark

**Risk assessment**



The risk assessment is the foundation of the risk management process. This is where risks need to be:

- Identified and described (risk identification)
- Analysed and measured (risk analysis)
- Evaluated in relation to the risk tolerance (risk evaluation)

The risk assessment should always be carried out on the basis of an established method. The individual activities in the risk assessment are elaborated below. There is no method requirement in ISO 27001 for how the risk assessment is carried out. Choice of method can i.e. depend on the size and complexity of the organization. However, an assessment must always be made of the risk of loss of confidentiality, integrity and availability. How the risk assessment is carried out in practice must be stated in a process and method description, so that the risk assessment is systematic and the results comparable. Several of the activities will advantageously be carried out simultaneously. For example, many risks can be both identified and analysed by the same people.

Safety Culture in Denmark and its proactive approach are presented below:



**Safety culture**

**Governance**

In the Patient Safety Strategy for 2019-2024 promoted by HSE, they specify ways to improve **patient safety culture** by implementing a new way of organizational learning which actively promotes, captures, shares, spreads and implements learning to improve patient safety at every level of organization.

**Background**

The Danish Act on Patient Safety was introduced in 2004, but already in 2002, the importance of a supportive culture for a high level of patient safety, and the active role of the line management in creating such a culture, was emphasized. In 2006 the first Danish PhD thesis on PS culture was published. This thesis addressed topics such as experiences with reporting of adverse events, ethics in patient safety, apologising after adverse events, and the relationship between safety culture, occupational health and patient safety. With this thesis, a validated instrument for measuring PS culture and a manual of how to do was introduced and from 2016 onwards there has been more and more focus on PS culture. The Danish Society for Patient Safety has emphasised the importance of PS culture as a lever for better patient safety, and they have addressed the issue of cultural changes in their improvement projects.

**Measurement process**

In Denmark, the **Danish Patient Safety Culture Questionnaire** was developed, which is based on an extensive development process with field testing and validation. It has different stages: a developmental process, testing, validation and general use.

Individual units and organizations e.g. nursing homes and hospital departments have worked with **measuring and improving PS culture as part of quality improvement**. Also, PS culture was used as an outcome measure in a large in-situ simulation intervention study across hospitals. In two of the five Danish regions accountable for hospital care, pilots of a PS culture measurement have been made to **qualify the political strategic decision** of a regional measure and plan the execution of the measurement and follow up activities respectively. A measurement has been performed across all hospitals in the Capital Region of Copenhagen, it involved answers from more than 15,000 health care professionals, and it was motivated by a serious breach in patient safety. The **measurement was called PLUS**, it was performed, and results fed back to the hospitals in the spring of 2019.

**04/ Conclusions**

## 04/ Conclusions

The following are the main conclusions of the comparative analysis on QoC, PS and CRM systems:

### ● Health-system organization

1. In all analysed countries, health expenditure ranges between 5 and 10% of GDP, and all of them follow the Beveridge healthcare model, except for Australia who owns a mixed model.

### ● Governance structures

2. All analysed countries own governance structures (public organizations or institutions) responsible for overseeing QoC and PS issues (except for the Tuscany region whom institution focuses on CRM and PS).
  - 2.1. Each of the analysed countries adequate its governance structure to its specific characteristics and all of them depend on their respectively MoH.
    - In Tuscany, the Clinical Risk Management and Patient Safety Centre is directly instituted by the Tuscany region council. This organization is also observed in Catalonia, where the different stakeholders for quality and patient safety governance (the Patient Safety department, the Alliance for Patient Safety and the Agency for Quality and Sanitary Evaluation) are competencies of the local government.
    - In Ireland and Denmark, the directorates in QoC and PS directly depend on the MoH.
    - In Australia, the Commission on Safety and Quality in Health Care is an independent institution despite the funding of the Australian and territorial government.

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## 04/ Conclusions

The following are the main conclusions of the comparative analysis on QoC, PS and CRM systems:

### ● Plans and strategies

3. All analysed countries have one or more strategic plans specifically about Quality and Patient Safety.
  - The period for the development of the work plans ranges between 2 and 5 years.
  - In Ireland, they have two separated plans: one for Quality improvement and another one for patient safety.
  - In Australia, there is a global framework for Safety and Quality and a specific 2-years work plan.
  - In Denmark, the QoC and PS are addressed through a specific Quality Programme.
4. All the strategic plans pursue similar key objectives, even though each country shares the vision of those goals with a different approach. All plans emphasize:
  - 4.1. Importance of **continuous quality** improvement to achieve better QoC
  - 4.2. Improvement based on **patient-centred** culture and patient experience
  - 4.3. Promotion of **safety culture** through the oversee, identification, and prevention of **adverse events**
  - 4.4. Support to health professionals through patient safety **education/training programmes**
  - 4.5. Establishment of a **patient safety strategy** and development of a **communication plan**

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## 04/ Conclusions

The following are the main conclusions of the comparative analysis on QoC, PS and CRM systems:

### ● Clinical Risk Management

5. In terms of CRM, the five studied countries follow the **ISO 31000 Risk Management Standards**, which clearly defines the CRM process.
  - 5.1. Regarding Reporting Systems, each country has established specific reporting systems: some countries have more standardized and systematized reporting, based on the gathering of multiple quality indicators through medical records, while others use particular tools/platforms to register and report events manually and not systematically.
    - In Tuscany, a tool that allows front-line healthcare workers for voluntary reporting is used. Similarly, in Catalonia, a reporting system is used to inform about any type of incident related to patient safety in the public hospital network.
    - Ireland and Australia utilise monitoring indicators. In Ireland, the National Healthcare Quality Reporting System (NHQRS) is based on 52 indicators for 5 key domains; while in Australia, indicators for reporting systems are classified in 5 indicators sets.
    - Denmark does not offer specific information about the reporting system and emphasize the importance of working on the improvement actions rather than in the reporting
  - 5.2. Concerning risk mitigation, countries are less specific in terms of the procedures applied to compensate for risks. Only Ireland provides information about the general framework for risk mitigation.
    - In Ireland, there is a National Risk Assessment which acts as a guide for risk. The Lead Government Department decides about prioritizing and resourcing of appropriate mitigation measures and monitors and reports internally the progress on mitigation. They establish a five-stages procedure for risk assessment.

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## 04/ Conclusions

The following are the main conclusions of the comparative analysis on QoC, PS and CRM systems:

### ● Patient Safety

6. All analyzed countries implement a **patient safety culture** prioritizing **education, training, and research** on patient safety to healthcare professionals, making the special focus on Managers and Directors capacitation.
  - 6.1. Particular strategies differ among countries, but they pursue these goals through initiatives like specific training programs, masters, forums, newsletters, etc.
    - In Tuscany and Ireland, the promotion of safety culture is supported through training programmes, including certified master's courses taught by regional CRM centres or the Executive Health Service to promote a new safety culture, with a special focus on manager training.
    - In Catalonia, the Department of Health has implemented the Functional Patient Safety Units to promote patient safety in the medical centres. These units work in the promotion and implementation of patient safety strategies and measures in their centre.
    - Australia also emphasises the measurement of the patient safety process and, the Commission is developing a toolkit that includes a short validated survey and an implementation guide for regular patient safety qualitative monitoring.

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