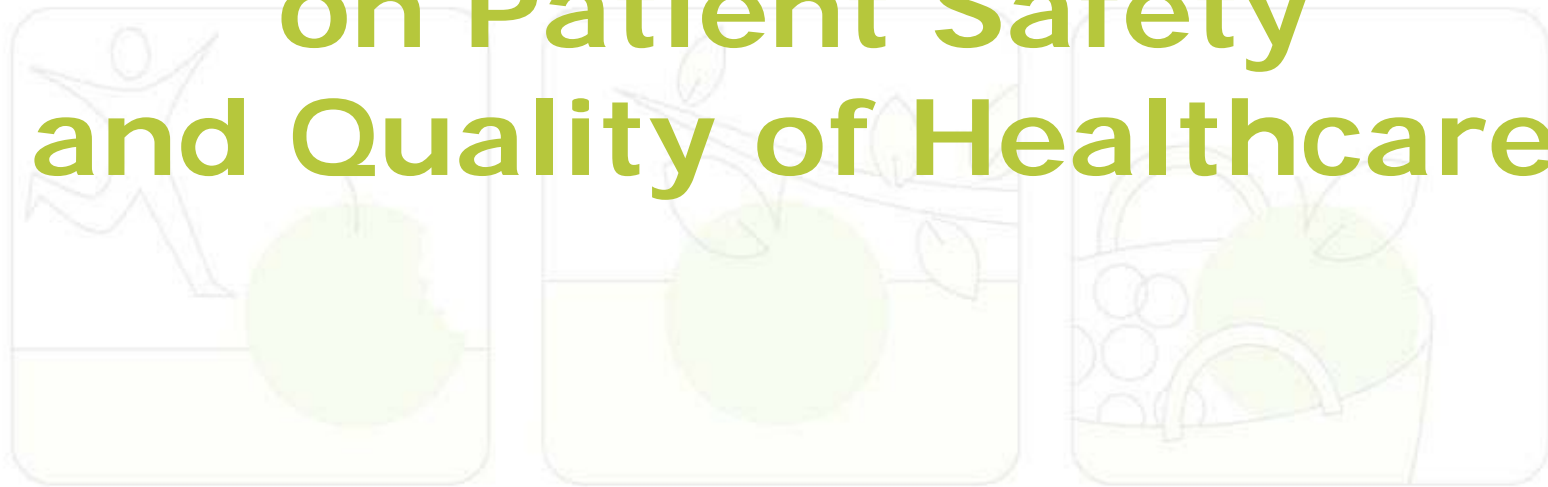# EU Actions on Patient Safety and Quality of Healthcare

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Questions for this presentation

- **Is patient safety a problem in the EU?**
- **Is there EU law for patient safety?**
- **What is the role of the EC?**
- **Just talking or also concrete activities at EU level?**

Why EU action on patient safety?

8 - 12% of patients admitted to hospital in the EU suffer from adverse events whilst receiving healthcare;
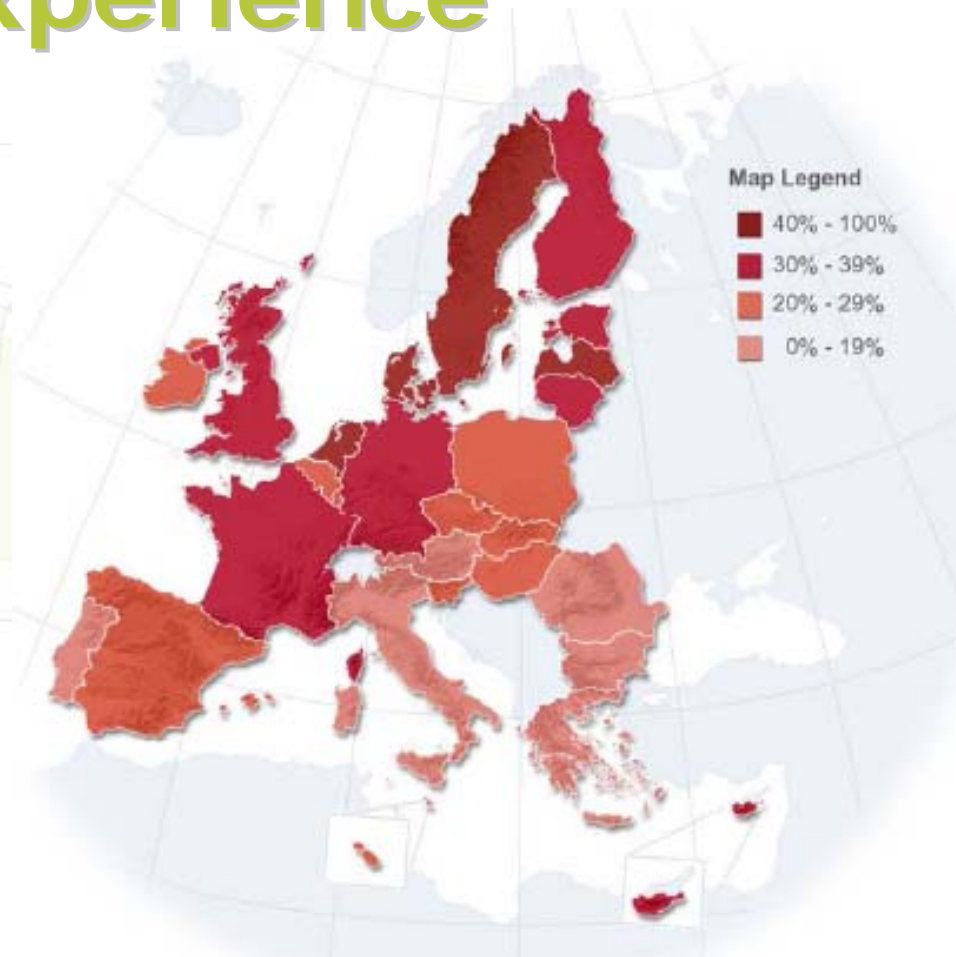
much of the harm to patients is preventable

Healthcare associated infections

Medication-related errors

Surgical errors

Medical devices failures

Errors in diagnoses

Failure to act on the results of tests

Source: European Commission

Patients' experience

25% of respondents to EU survey say they or their family experienced an adverse event with healthcare

Map Legend
- 40% - 100%
- 30% - 39%
- 20% - 29%
- 0% - 19%

Source: Special Eurobarometer 327

State of play

- Over a decade of serious work
- Successes in some topics
- But:
  "safety does not just depend on measurement, practices and rules, nor on specific improvement methods; it depends on achieving a culture of trust, reporting, transparency and discipline" (Leape et al. Qual Safe Health Care 2009)
- Hot topics: education, patient participation, reporting and learning, integration of care

What is the EU response?

EU legal framework of public health

The Treaty on the functioning of the European Union (Lisbon 2009):

➢The Union shall fully respect Member States' responsibilities for health policy, health services, healthcare.

➢The EC will be able to support, coordinate and supplement Member States in the quality and safety domain

➢Hard law for some topics in the quality and safety domain:

   ➢ Human blood and blood components (2002)

   ➢ Donation and procedures around human tissues and cells (2004)

   ➢ Human organs for transplantation (2010)

   ➢ Patients' rights of cross-border healthcare (2011)

   ➢ Pharmacovigliance and falsified medicinal products

Activities of the EC

- **A working group on patient safety and quality of healthcare**
  - EU Member States, EFTA, Council of Europe, WHO, OECD, European associations of patients, doctors, pharmacists, nurses, managers

- **Research projects**
  - e.g. EUNetPaS, EU network on patient safety 2007-2010

- **Legal tools**
  - Council Recommendation on patient safety, including the prevention and control of HCAI (2009)

- **Joint Action on patient safety and quality of healthcare** (EU collaboration on patient safety and quality of healthcare)

Council Recommendation

- **Composed of two parts:**
  - **General patient safety issues (seven recommendations)**
  - **Prevention and control of healthcare associated infections (two recommendations)**

http://ec.europa.eu/health/patient_safety/policy/index_en.htm

Council Recommendation:

- **Activities for Member States:**
  - Patient safety policies, empowerment of patients, reporting and learning, education and training

- **Actions for the EU**
  - Classify, codify patient safety, share knowledge and good practices at EU level, promote research

- **Healthcare associated infections (by ECDC)**
  - Strategy for control and prevention of HCAI, mechanism for implementation

Implementation Report to the Council

- **Progress report from Member States – due June 2011 – based on a questionnaire prepared by the EC**

- **Report by the Commission – due in June 2012** « assessing impact of the Recommendation, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action »

- *Public consultation second half 2012?*

- **Further steps after 2012 if necessary**

Joint Action on Patient Safety and Quality of Healthcare

Joint Action **means a collaboration between the Commission and Member States under co-financing by the Health Programme**

Main objectives of the Joint Action

- **To contribute to the implementation of the Council Recommendation on patient safety**

- **To establish collaboration among Member States on aspects of *quality of healthcare***

- **To promote collaboration among Member States on *patient involvement/empowerment***
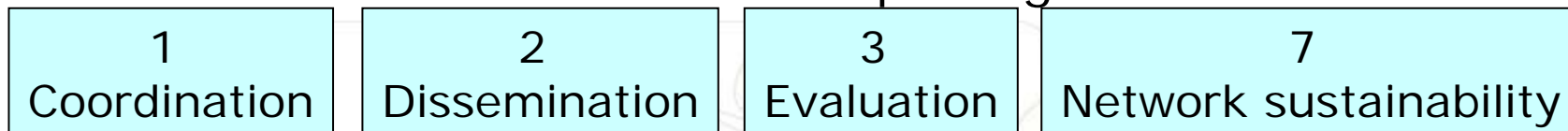
From patient safety to wider quality of healthcare

- **Discussions in the Council Working Party on Public Health at Senior Level under the French and Spanish Presidencies**
- **Reflection paper on healthcare quality developed by the Commission and the working group**
- **Main discussion points:**
  - **Which areas of quality should and could be addressed at EU level?**
  - **How to ensure patient empowerment and involvement of health professionals?**

Joint Action - process

- **Two preparatory meetings held by the Commission in 2010 to define both content and structure (MS, stakeholders, international organisations)**

- **All MSs and many EU stakeholder organisations**

- **Coordination: France (HAS)**

- **Project submission: 27 May 2011**

- **Joint action: *2012-2014***

- ***Sustained collaboration thereafter***

Joint action-work packages

Horizontal work packages

1 Coordination	2 Dissemination	3 Evaluation	7 Network sustainability

Core work packages

4 Patient Safety good clinical practices	5 Patient Safety Initiatives implementation	6 Quality healthcare systems collaboration in the EU

Core work packages in the Joint Action

Aim

- to select and share good practises in patient safety among Member States;

- to contribute to implementing and evaluating a selection of good practices in participating Member States to promote patient safety;

- to collect and share knowledge about quality and safety systems in place in Member States, and to reflect on principles of good quality healthcare.

Methods

➢ Learning by exchange of good practices, including site visits

➢ By implementing selected good practices

➢ By analysing quality management systems

Quality and safety in the cross-border Directive
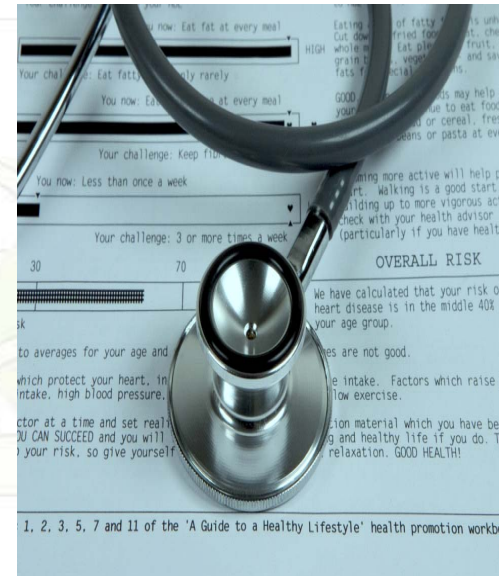
- **Transparency to patients**

  Information about safety and quality regulations available for patients

- **Information about healthcare providers**

  Refusal of prior authorisation if doubts over quality and safety of a healthcare provider

- **Cooperation of Member States**

  On standards and guidelines on quality and safety

To summarise

- **Is patient safety a problem in the EU?**
- **Is there EU law for patient safety**
- **What is the role of the EC?**
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Thank you !