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

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)
  - Pharmacovigilance 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)

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

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Thank you!