**LEGISLATIVE VERSUS NON LEGISLATIVE QUALITY POLICY IN HEALTH CARE**

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**Unsafe health care, Pirjo Pennanen MD, NAMA (Chairman of EU working party)**

- About 10% of patients will experience a harm related to their care
- About 1% will experience a serious harm
- Great deal of harms are related to medication
- Great deal of harms can be prevented
- The safety risks will be realized when “quality systems” fail

**National Authority for Medicolegal Affairs**
**MANY PATIENT SAFETY PROGRAMS IN EU COUNTRIES**

**Health care professionals - clinical autonomy - transparency - GM - variation of outcomes and processes - patient safety**

- “Hospitals are very complex institutions (enterprises), where the quality of care depends on a lot of possible tensions created through the degree of autonomy of the medical professionals, doctors, nurses etc. and the necessary organization of the institution.”
- “In several European health care systems the lawmakers and health care managers feel the tension created by the necessity of national uniformity of health care and the diversity of needs of the different patients. In the Common Market the need for uniformity is enshrined in the Lisbon Treaty. This means a need for state intervention to ensure quality.”
- “In The Netherlands QM is required by law and health care is organized at national level. In Finland, QM is not required by law and the responsibilities for organizing health care are delegated to the municipalities.”
- “The hospitals should organise (also legally) and organise their relations with the healthcare professionals in such a way that they can both cooperate and assume their professional responsibility for the treatment of health of their patients in the medical and realistic way. The practice before health education and preceptorship will be able to provide the best education for patients through correct information. The patient will be able to do very basic work which will have to be done nationally and/or internationally.”

**EXAMPLES OF POOR PROCESS MANAGEMENT**

- 3.7% of hospitalized patients suffer from a harm caused by their treatment - 1/2 preventable, 1/6 lead to death
- 6.7% of hospitalized patients receive false, potentially harmful medication, during their hospital stay
- estimate - 150000 patients die annually in US hospitals due to a preventable harm caused by their treatment
- similar findings in other industrialized countries

**PROCESS MANAGEMENT IN HEALTH CARE ACCREDITATION USA - 50 YEARS**

**The Quality of Health Care / Hospital Activities**

- Published 1999, SCOPE STILL RELEVANT, DETAILS SHOULD BE UPDATED
- AVAILABLE IN ENGLISH, FRENCH, RUSSIAN AND SPANISH FREE OF CHARGE

**The impact of legislative versus non-legislative quality policy in health care: a comparison between two countries**

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Clinical auditing focuses particularly on the following aspects:

- Variations between quality management approaches between EU countries and within countries
- Governments are the key players - lack of vision and leadership
- Most of the EU countries have legislation about HC quality - this is an important incentive
- Leadership for quality improvement requires strong commitment of the professionals (as well as the top management of the organisation) who need training to do it
- The organisations that have "a QM system" do better than the ones who do not have it.

The European Committee for Standardization (CEN) is a business facilitator of Europe, removing trade barriers for European industry and consumers. Its mission is to foster the European economy in global finding, the welfare of European citizens and the environment. Through its services, it provides a platform for the development of European Standards and other technical specifications.

CEN is a Network Member of the International Organization for Standardization (ISO). These standards have a unique status, since they also are national standards in each of its 30 member countries. With one common standard in all these countries, and every conflicting national standard withdrawn, a product can reach an wider market with much lower development and testing costs. EN harmonise build a European Single Market for goods and services and to position Europe in the global economy. More than 60 000 technical experts and experts from the organizations are involved in the CEN network that reaches over 480 million people.

In Finland, a good example of balancing legislative approach and professional commitment: from EU directive to national legislation together with government and professions implementing together.

CEN 30 National Members work together to develop voluntary European Standards (EN).

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Cultural and linguistic differences
- Radiation doses resulting from procedures and results of examination and treatment
- Project Committee - Healthcare services - Quality management systems
- ISO 9000:2000 + EFQM + GOOD HEALTH CARE PRACTICE
- Manag. respons. Managing resources
- 1 authorizations and defining responsibilities
- An example: CEN/TC 362
- RADIATION SAFETY AUDITING
- Variation among auditors and quality system builders interpreting the criteria
- There has to be continuous evaluation of the variation among auditors and quality system builders interpreting the criteria

The Practical Auditing process is based on a Decree of the Ministry of Social Affairs and Health (423/2000). The auditing focuses particularly on the following aspects:

- Clinical and stakeholders expectations and requirements
- Care and service. Auditing takes place in five year intervals. In the first round of audits Qualisan audited over 350 units.
- Equipment used in examination and treatment
- Process improvement, clinical goal, care recommendation, patients instruct, work instructions, ICD-10
- Health, financial capacity, satisfaction, complications, errors, clinical audit, clinical handbooks, laws, regulations
- Care chains - clinical quickel, care recommand, patients instruct.

About the criteria/standards used for quality systems and auditing

- Explicit and understandable without variation
- It is almost impossible with humans
- There has to be continuous evaluation of the variation among auditors and quality system builders interpreting the criteria

International
- Cultural and linguistic differences
- Acknowledgement (EU, CEN)
Questions relating to quality standards and audits from the European perspective

- Is healthcare different from other enterprises from the management point of view?
  - Professional leaders - professionals as leaders
- Does healthcare need standardisation venues different from other enterprises?
  - We are accountable to patients - common people as well as persons working in the other enterprises

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Developing the QM system in Lahti 2004 - 2008

The average length of stay and the number of geriatric patients 2005 - 2007

- Elderly Hip-replacement patients
  - 150% increase in efficiency
  - Outcome: 2005 1/3 went home - 2007 2/3 go home - elderly patients are not left into the bed to wait

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Experiences of QM from Lahti 2004 - 2009

- Systematic building of ISO 9001 quality management system since 2004
- Innovation techniques to redesign the processes
- Training for the management system, leadership
- Quality manual available for whole personnel in intranet
- QM system is there to support process management
- Process management has to reach the experts - they have to feel it to be their own
- Results: better patient satisfaction, health outcomes, efficiency (the mean of the whole organisation +15%)

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HAVE WE LEARNED ANYTHING?

- In Finland
  - Half of the organisations report positive development through QM techniques
- Almost half of the organisations do not feel the need to apply QM techniques
- In Finland, there are positive functional and economical results of QM in hospitals as well as other enterprises
- If there is a potential, why have not adapted the management techniques throughout the health care enterprise?
- It seems that most of the health care organisations do not see the possibilities of the QM techniques and lack the vision of how to use them
- There is no scientific evidence that QM makes a difference in health care as an entity. There is evidence that health organisations that are using a QM scheme do better than the ones that do not. Regardless of the scheme that they used.
- Health care is still unsafe, risk of getting injured or dying
  - during the hospital / health care stay
  - due to preventable errors
  - greater than medication errors
- Focus should be on the patient processes and there is scientific evidence through QM management, and this could reduce the numbers of preventable errors etc by 50% and save up to 30% of total health care costs

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