

QUALITY OF HEALTHCARE: POLICY ACTIONS AT EU LEVEL

Reflection paper

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This document does not represent an official position of the European Commission. It serves as a tool to explore the views of interested parties on a suggested preliminary approach. The suggestions contained in this document do not prejudice the form and content of any future proposal by the European Commission.

Introduction

Health systems strive to improve people's health status, while operating in cost-effective way. EU health systems are currently facing a number of challenges, like population ageing, citizens' rising expectations, migration, and mobility of patients and health professionals.¹ In this context, it is necessary to consider how to ensure the provision of high quality healthcare for all European citizens, i.e. healthcare that is effective, safe and responds to the needs and preferences of patients. The provision of high quality healthcare can improve an individual's health outcome on the one hand, and can contribute, in the longer term, to reduce costs on the other hand.

The EU can play a role in bringing together Member State experiences and best practice in this area so that all EU patients can potentially benefit from high quality healthcare.

State of play in the area of quality

Healthcare quality has been addressed by a number of international organisations, including the Council of Europe and WHO. They have proposed numerous definitions, comprising different quality dimensions², as well as guidelines or recommendations about how to ensure that high quality healthcare is provided for all.³

At EU level, different dimensions of healthcare quality have been addressed by the European Commission in a number of initiatives to date (e.g. quality and safety of blood⁴, tissues⁵ and organs⁶, guidelines for high quality cancer screening⁷ and quality indicators proposed by the

1 European Commission White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" COM(2007) 630 final

2 Legido-Quigley H., McKee M., Nolte E., Glinos I.A. 2008. Assuring the quality of health care in the European Union. A case for action. Observatory Studies Series No 12

3 Guidance on developing quality and safety strategies with a health system approach. WHO Regional Office for Europe 2008.

4 Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, and three implementing directives (2004/33/EC, 2005/61/EC, 2005/62/EC)

5 Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and two implementing directives (2006/17/EC and 2006/86/EC)

6 Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation 2008/0238 (COD)

7 European guidelines for quality assurance in breast cancer screening and diagnosis 2006 ISBN 92-79-01258-4

Open Method of Coordination on Social Protection and Social Inclusion⁸). However, an overarching approach, in which various aspects of healthcare quality would be addressed in a comprehensive manner, has not as yet been proposed.

The White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" foresees that the Commission provides a community framework for safe, high quality and efficient health services.⁹ Council Conclusions from December 2007 on the Health Strategy¹⁰ underlined the need for effective implementation and called upon Member States and the Commission to work together towards its implementation with a view to determining priorities and developing actions that achieve European added value.

The Commission's proposal for a directive on the application of patients' rights in cross-border healthcare currently refers, in Article 5, to Member States defining clear quality and safety standards for healthcare provided on their territory and ensuring their implementation.¹¹

In 2008, the Commission adopted a Communication and proposal for a Council recommendation on patient safety, including the prevention and control of healthcare-associated infections. The Council recommendation was adopted by Member States in June 2009.¹² This notable achievement is considered as one of the first important steps towards addressing healthcare quality issues at the EU level, patient safety being a cornerstone of healthcare quality.

Also, several research projects in the field of quality have been co-funded by the European Commission under the Framework Programmes for Research in recent years. One such project, MARQuIS (Methods for Assessing Response to Quality Improvement Strategies in Europe) put forward a number of recommendations aimed at different actors, including the European Union and EU Member States. For the EU, it recommended promoting convergence of quality improvement systems through the use of different strategies and requirements identified at national level. It also encouraged Member States which are developing their quality strategies to study the experiences of other Member States which

8 Common Indicators of the Open Method of Coordination of Social Protection and Social Inclusion
http://ec.europa.eu/employment_social/spsi/common_indicators_en.htm

9 European Commission White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" COM(2007) 630 final

10 Council Conclusions on the Commission White Paper ""Together for Health: A Strategic Approach for the EU 2008-2013" December 2007

11 Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008) 414 final)

12 Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (10120/09)

have existing legislation in this area, notably the impact of statutory legal requirements on the implementation of quality improvement strategies in healthcare organisations.¹³

In addition to projects in the research field, the EU also co-finances other healthcare quality-related projects through mechanisms such as the Commission's (formerly Public) Health Programme. For example, the Quality Health Care Indicators project, led by the OECD, has for several years worked on trying to define and agree common indicators of quality and to collect comparable data from different countries, many of which are EU Member States. Despite the many challenges, the project has managed to propose several quality indicators in a number of different areas, such as: patient safety, chronic conditions, mental disorders, cancer and communicable diseases. It has also started extensive work on patient responsiveness and patient experience.

Improving the quality of healthcare is a shared objective among EU Member States. Council Conclusions of June 2006¹⁴ confirm that access to good quality care, together with universality, equity and solidarity constitutes the overarching values on which EU health systems should be built. EU institutions have been invited to protect those values. The same Council Conclusions state that there is immense value in work at the European level on healthcare, notably to facilitate sharing experience and information about approaches and good practice between Member States.

The implementation mechanism of the Health Strategy, the Working Party on Public Health at Senior Level, agreed that the role of the EU regarding healthcare quality would be to facilitate cooperation between Member States and the exchange of information and best practices, as well as promote comparative research.

Patient-centred care and patient empowerment

Patient-centred care is an emerging approach in health systems throughout the world.

A patient-centred approach is defined by the Picker Institute Europe as:

- informing and involving patients, eliciting and respecting their preferences;
- responding quickly, effectively and safely to patients' needs and wishes;
- ensuring that patients are treated in a dignified and supportive manner;
- delivering well coordinated and integrated care.¹⁵

13 Groene O., Klazinga N., Walshe K., Cucic, C., Shaw C.D., Sunol R. 2009. Learning from MARQUS: future direction of quality and safety in hospital care in the European Union. *Qual Saf Health care* 18(Suppl I): i69-i74

14 Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01)

15 International Alliance of Patients' Organisations 2007. What is Patient-Centred Healthcare? A review of Definitions and Principles

There is some evidence that patient-centred approaches can increase patient satisfaction, reduce anxiety and improve quality of life, as well as increase doctor satisfaction.¹⁶ Some argue that patients who consider that they have experienced a patient-centred visit (i.e. when their health problem was discussed with a doctor and both the doctor and patient agreed about treatment options) may present better health outcomes than others.¹⁷ There also seems to be some evidence that patient-centred care is more efficient, even resulting in fewer diagnostic tests and unnecessary referrals. An observational study by Little et al.¹⁸ confirmed that the majority of patients in primary care want a patient-centred approach, especially a friendly, approachable doctor who communicates well and a partnership approach to both the problem and treatment.

Patient empowerment is increasingly being seen as a vital component of a modern patient-centred health system. The European Union recognises its value, underlined in the Health Strategy, with its principles and objectives that serve to guide EU health policy for the years to come. As Health Commissioner Vassiliou stated on Patients' Rights Day in April 2009, patient empowerment is seen as a benefit for all patients in all health systems, regardless of how these systems are organised.

Strengthening patient empowerment means that patients play a more active role in partnership with health professionals. This will help patients to benefit more from their healthcare and help professionals to better understand their patients.

Problem definition

Common challenges for health systems

The European *population is ageing*, with a growing proportion of people aged 65 and over, and of people over 80 years old. This has a number of consequences on health systems. Firstly, elderly people are in general more prone to illness than younger people. Therefore, they tend to use more health services. Secondly, they often suffer from multiple conditions rather than from a single illness and they need appropriate health services to manage their situation. Thirdly, the new disease pattern and increased demand for healthcare puts more pressure on services which have to be able to meet it, and that means ensuring there is a sufficient and properly trained workforce.

16 Bauman A.E., Fardy H.J., Harris P.G. 2003. Getting it right; why bother with patient-centred care? MJA 179(5): 253-256

17 Stewart M., Belle Brown J., McWhinney R., Oates J., Weston W., Jordan J. 2000. The Impact of Patient-Centred Care on Outcomes. J Fam Pract 49:796-804.

18 Little P., Everitt, H., Williamson I., Warner G., Moore M., Gould C., Ferrier K., Payne S. 2001. Preferences of patients for patient centred approach to consultation in primary care: observational study. BMJ 322:468

At the same time, *the role of the patient in health systems is changing*. Patients increasingly want to play an active role in the healthcare process. They seek more information about their conditions and expect to be involved in decisions about treatment. This concerns particularly, but not exclusively, patients with chronic conditions. Patients and their families are also increasingly likely to express their dissatisfaction if the quality of service provided does not meet their expectations or if their experience of the service is not positive.

New technologies have a considerable impact on health systems. Their use can improve disease prevention and provision of treatment and help to shift healthcare from hospitals to primary care or care at home. They can also support patient empowerment, for example through the greater use of electronic interactive tools for capturing and using patient feedback on the healthcare they have received. However, those tools need to be carefully assessed and implemented, to ensure that they are safe and effective for patients and also cost-effective.

In this context, it is crucial to consider how to ensure the provision of high quality healthcare for all European citizens, i.e. care that is effective, safe and responds to the needs and preferences of patients.

Specific issues

Multitude of definitions and differences in scope of quality action across Europe

A review of the available literature reveals a multitude of definitions of quality of care, including one from the Institute of Medicine which defines it as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Institute of Medicine 1990). This definition, which seems to be one of the most influential, covers dimensions of quality such as: safety, equity, respect, patient centeredness, continuity, effectiveness, efficiency and timeliness.¹⁹ However, many other definitions exist and are constantly evolving²⁰, some of them covering various additional dimensions including access, choice, information, satisfaction, health improvement and continuity of care.

Depending on which definition is used as the basis of elaborating a quality strategy, the tools of quality measurement differ. Consequently, the information collected is often specific to one definition and hardly comparable with other data.

19 Legido-Quigley H., McKee M., Nolte E., Glinos I.A. 2008. Assuring the quality of health care in the European Union. A case for action. Observatory Studies Series No 12

20 Donabedian 1988, Maxwell 1992, Joint Commission of Accreditation of Healthcare Organisations 2006

Disparities in development of quality strategies across Europe

Although all EU Member States agree that striving for high quality healthcare is a priority within their health systems, quality assurance strategies are developed, implemented and evaluated to different degrees across the EU. Some of strategies concentrate exclusively on patient safety and they are either focused on collecting information about adverse events through reporting systems, or on collecting and sharing examples of good practice. Others involve the production of clinical guidelines based on evidence-based medicine and/or health technology assessment. The vast majority propose accreditation or certification of hospitals and other health providers, carried out by national agencies and based on standards elaborated internally or in the collaboration with international organisations (e.g. the Joint Commission International).²¹

The variance in the degree to which quality strategies are developed may be the result of different levels of political commitment and/or the financial resources available. In the current economic crisis, governments are less willing to invest in the development of quality strategies as they will not provide adequate financial return in the short or medium terms.

Another issue concerns evaluation. To date, various strategies have been developed and implemented in EU Member States but not all of them have been evaluated yet. Therefore, very little information is available about the effects of the strategies and, as a consequence, investing in quality strategies may appear to be costly and inefficient.

Lack of clear and transparent information and comparable process and outcome data

As a consequence of the two specific issues described above, clear and transparent information about the quality of healthcare provided in Member States is lacking.

Insufficient exchange of information and best practice among Member States

Historically, European health systems have been developed in isolation. Despite the current growing tendency to work together, EU Member States still tend to look for solutions in the area of healthcare quality domestically. There is certainly room for an improved exchange of best practice and experience between the EU Member States.

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European Commission 2009. Joint Report on Social Protection and Social Inclusion. Commission staff working document. SEC(2009) 141

Objectives

The ultimate goal of possible EU action is to improve the quality of healthcare for all EU citizens. The following specific objectives could contribute to its success.

1. To achieve a common understanding of quality in EU Member States

The objective is to agree on a definition of healthcare quality and on dimensions of healthcare quality that should be addressed at MS and EU levels. The proposed common understanding of quality should take into account the following aspects: safety, clinical outcomes and patient involvement.

A common understanding of healthcare quality would facilitate the exchange of best practice among MS.

2. To promote continuous healthcare quality improvement in all MS

The objective is to increase the level of political commitment to quality improvement in healthcare and to encourage Member States to take practical steps towards quality improvement. Those steps may include developing quality assurance systems, ensuring the appropriate assessment of new health technologies, developing interactive tools enabling the capture of patient feedback or proposing training for health professionals in the area of quality. Particular attention should be paid to the effective implementation and evaluation of actions undertaken in order to ensure continuous quality improvement and the efficient allocation of resources.

3. To propose the collection of comparable data

The objective is to agree to collect and analyse data about quality in a comparative manner. Such information would help Member States to identify possible gaps in their own reflection on quality and define possible solutions. It is not the objective to produce a ranking of institutions and health authorities, but to inform the policy-making process in order to best achieve the overall quality of healthcare and to allow bench-marking.

4. To establish a culture of mutual learning among Member States

Mutual learning can be beneficial for decision-makers and, as a consequence, for patients too. However, a culture of mutual learning has to be established and maintained. This objective, if achieved, may contribute to a more coherent approach towards quality within Europe, with some Member States learning from others who are perhaps further developed in their reflection. In consequence, it would increase the chances of all EU citizens being

provided with high quality healthcare, both domestic patients and those who cross EU borders to access healthcare.

This objective can be met only if the three others are successfully achieved.

The role of the EU in achieving the objectives

Community action, according to article 152 of the Communities Treaty, shall complement national policies, encourage cooperation between Member States and lend support to their actions. In this context, the EU level seems the appropriate one to promote, in close contact with Member States, coordination of action on quality with a view to improving public health.

Several policy options, likely to help to achieve the objectives set out above, are available at EU level. They are presented below.

Policy options available

Option 1: Further work utilising existing opportunities

This option will mean continuing the current work under the existing programmes, mechanisms and structures (including the Research Framework Programme, the Health Programme, and the Health Strategy) with a view to achieving the objectives. Quality will be included in the programmes' priorities and structural and research projects will be co-financed by the Community.

Although it is desirable to continue to benefit from these programmes, mechanisms and structures, there is danger that without concerted and continued efforts by Member States to share information and experience at the EU level, the results of potentially useful projects and initiatives are not taken note of or disseminated in all Member States, depriving some EU citizens of the healthcare quality improvements which may have arisen.

Option 2: An enhanced collaboration mechanism between Member States and the EU

This option will imply setting up at the EU level a mechanism (for example a network, platform, European office or joint action) to complement the actions taken by the individual Member States. It could have the following tasks:

- to collect knowledge about quality and safety systems in place in Member States; this existing knowledge created by Member States themselves or by EU co-funded projects is often not easily accessible;

- to evaluate quality assurance systems: their effectiveness, degree of respect and the extent to which they embody a patient-centred approach, as well as analyses of factors contributing to success and/or failure of the strategy;
- to share best practices among Member States (at national, regional or local level); disseminating information about the systems that have been created, implemented and continuously evaluated and improved;
- to provide advice for those who want to create, transform, implement or evaluate a quality assurance system; to propose a methodology; this can be done through facilitating contacts with EU experts experienced in working in a similar political, economic and social context, helping to organise seminars and conferences;

This option will require the active collaboration of all Member States. Participation should not be obligatory, but if a Member State decides to join the mechanism, it would be committed to share its experiences and, if needed, to help other Member States to set up effective quality strategies.

The regular exchange of information on best practice in Member States should slowly lead to a degree of convergence of quality assurance systems in the EU. It is not excluded that, in future, the Member States will wish, within the collaboration mechanism, to agree on common objectives on healthcare quality and on a common methodology to achieve them. Therefore, the initial construction of the mechanism should allow a certain flexibility of approach.

Although it is a very desirable aim, the exchange of best practice at the technical level, without political backing from governments in Member States, may not achieve a great deal in practice. Only national governments can successfully promote and lead wholesale change in their healthcare systems, providing appropriate resources, incentives and sanctions in relation to required actions from all the stakeholders in the health system who can help to drive up the quality of healthcare delivered on their territories.

Option 3: A Recommendation on healthcare quality

This frequently used option in the area of health at the EU level would take the form of a Council Recommendation and consist of proposals to Member States and to the European Commission, aiming to put in place effective quality improvement strategies in the EU.

Among the actions for Member States, the following could be envisaged:

- to increase awareness among political bodies about the importance of quality of healthcare,
- to embed quality in the training and education of health professionals, other health workers and managers,
- to put in place or strengthen mechanisms ensuring patient empowerment and patient involvement,
- to put in place or strengthen quality assurance systems appropriate to the local context,
- to put in place or identify the monitoring authority to evaluate effectiveness of quality strategies;
- to encourage research in the field of healthcare quality;
- to report to the Commission about the effectiveness of quality strategies.

The role of the EU would be:

- to agree with Member States common indicators of quality;
- to elaborate with Member States the reporting template, including reporting period and data sharing pattern;
- to analyse reports and communicate the results in a no-blame manner;
- to help Member States improve the indicators by facilitating access to information about successful quality strategies;
- to complement efforts of Member States in the research area, mainly through financing comparative research.

Options 2 and 3 are not mutually exclusive. For example, a joint action or other cooperative mechanism could be set up first and the work on a recommendation could be developed at a later stage. Another possibility could be to start implementing the two options in parallel..

Option 4: Common quality standards for EU Member States

A more far-reaching option would be to try to establish EU standards in this area. This would cover:

- setting up common EU requirements for the quality of health services
- proposing quality standards, and
- putting in place common quality assurance systems.

Option 4 A

EU standards could be purely indicative, i.e. they could be used by Member States as a reference for their own standards.

Option 4 B

EU standards could be mandatory, in the using existing legislation, i.e. Directive 98/34/EC on the provision of information in the field of technical standards and regulations.²² Pursuant to Article 6 of this Directive, the Commission can, together with the Member States, give a formal mandate to the European Committee for Standardisation (CEN) to draw up a European standard within a given timeframe. European Standards are consensual documents established by all interested parties. Their transposition into national standards is mandatory (i.e. any conflicting national standards have to be withdrawn), but their application remains voluntary. The typical timeframe for developing a European standard is three years, followed by six months for implementation at national level.

CEN is currently working on the quality of specific social services, based on a mandate by the Community, as well as on a number of health-related services such as those provided by clinical laboratories.

²² Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204 p. 37

Questions for consultation

- 1) Are the problems related to quality of healthcare well identified and described in the document? Have you identified any other relevant issues which were not currently mentioned in the text?
- 2) The document also lists a number of possible objectives. Are these the right objectives? Are there any others you consider to be worthy of adding to the list?
- 3) Do you think that there is an added value in taking EU action on healthcare quality with regard to the four proposed objectives:
 - a. to achieve a common understanding of quality in EU Member States?
 - b. to promote the continuous healthcare quality improvement in all Member States?
 - c. to propose the collection of comparable data?
 - d. to establish a culture of mutual learning among Member States?
- 4) The document describes four possible policy options available to meet the objectives. Which of the four seems the most appropriate to you? Are there any other possible EU level initiatives you would like to propose? Why would these be better than the options set out?