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NOTE

from:	General Secretariat of the Council
to:	Working Party on Public Health at Senior Level
Subject:	Quality of Healthcare - *Presentation by the Commission*

In view of the meeting on 28 May 2010, delegations will find attached a document from the Commission on the above mentioned subject.

The section on citizen's perception of patient safety and quality has been added on page 9.

QUALITY OF HEALTHCARE: POLICY ACTIONS AT EU LEVEL

Reflection paper

Version 3

March 2010

Summary:

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 prejudge 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 a 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] At the same time, they are confronted by growing health expenditures. In this context, it is necessary to consider how to ensure the provision of high quality healthcare for all European citizens. High quality healthcare can improve an individual's health outcome on the one hand, and can contribute, in the longer term, to a cost-effective use of resources on the other hand. Therefore, it is beneficial for governments, healthcare providers and patients.

The EU is already playing a role in bringing together Member State experiences and best practice in this area. It could further develop this work so that all EU citizens can potentially benefit even more from high quality healthcare.

High quality healthcare in this paper is understood as healthcare that is effective, safe and responds to the needs and preferences of patients[2]. Other dimensions of quality of care, such as efficiency, access and equity are seen as being part of a wider debate and are being addressed in other fora.

From patient safety to healthcare quality

The European Commission acknowledges patient safety[3] as being a key dimension of healthcare quality. The Commission's initiative on patient safety (i.e. the Communication and proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections, adopted in 2008) is therefore considered as one of the first important steps towards addressing healthcare quality issues at the EU level in integrated manner. The Council Recommendation was adopted by Member States in June 2009[4] and is now in its implementation phase.

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

2 These dimensions are already reflected in the HCQI Project led by the OECD and in the Open Method of Coordination on Social Protection and Social Inclusion.

3 Patient safety means freedom, for a patient, from unnecessary harm or potential harm associated with healthcare (Council Recommendation on patient safety, including the prevention and control of healthcare associated infections)

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

The EU co-funded project EUNetPaS (European Network for Patient Safety) made the substantial contribution to raising awareness of the patient safety in Europe and to increasing willingness for co-operation between Member States in the field. A possible follow-up of the network could extend its interest from safety only to wider healthcare quality.

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 useful definitions, comprising different quality dimensions[5], as well as guidelines or recommendations about how to ensure that high quality healthcare is provided for all.[6] Quality of care is also increasingly addressed by European patients', health professionals' and health providers' organisations.

[5] 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

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

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 blood[7], tissues[8] and organs[9], quality, safety and efficacy of medicines[10], medical devices[11], guidelines for high quality cancer screening[12], quality indicators proposed by the Open Method of Coordination on Social Protection and Social Inclusion[13] or patient safety, mentioned earlier in the text). However, an overarching approach, in which various dimensions 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.[14] Council Conclusions from December 2007 on the Health Strategy[15] 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.

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7 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)

8 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)

9 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)

10 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

11 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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

13 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

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

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

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.[16]

The Regulation No 1338/2008 on Community statistics on public health and health and safety at work states that 'quality of health care shall also be considered in the data collection'[17]

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 a number of steps, including 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 have existing legislation in this area, notably the impact of statutory legal requirements on the implementation of quality improvement strategies in healthcare organisations.[18]

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 (HCQI) 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.

Another example is the VALUE+ project with the objective to raise awareness about positive impact of the meaningful involvement of patients' organisations in EU supported health projects on patient-centred, equitable healthcare throughout the EU.

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16 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)

17 REGULATION (EC) No 1338/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on Community statistics on public health and health and safety at work

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

Improving the quality of healthcare is a shared objective among EU Member States. Council Conclusions of June 2006[19] confirm that access to good quality care, together with universality, equity and solidarity constitute the overarching values on which EU health systems should be built. EU institutions have been invited to protect these 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 empowerment and patient-centred care

Patient empowerment is being seen as a core value of a modern patient-centred health system. It is also recognised as a value by the European Union, as stated in the Health Strategy that serves to guide EU health policy for the years to come. Patient empowerment is a benefit for all patients in all health systems, regardless of how these systems are organised. One of elements of patient empowerment is patient involvement in designing, measuring and evaluating policies and strategies that will have consequences for the patient community. With adequate information and resources, patients and patients' organisations can participate meaningfully in identifying gaps and needs, working with providers in order to improve quality, contributing to choosing priority for actions and providing constructive feedback about quality. Therefore, patients' involvement can be characterised as a cross-cutting theme, which has relevance to most elements of healthcare quality.

Patient-centred care is an emerging approach in health systems throughout the world and increasingly becomes a value-based decision as one of the elements in the development of democratic rights, human rights and patient rights.

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

Definitions of patient-centred approach include the one by the Picker Institute Europe, according to which patient-centred approach means:

- 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.[20]

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.[21] 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.[22] 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 at al.[23] 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.

Involvement of health professionals and other health workers in quality strategies

Good quality healthcare depends on having motivated and efficient health workforce with the right skills and of sufficient numbers[24]. In order to achieve continuous improvement of quality, health professionals need to be active part of the process, receive quality-centred training and appropriately designed continuing professional development. This equips health professionals to offer evidence-based, safe and high quality care to patients along with the opportunity to update their skills and knowledge.

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

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

22 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.

23 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

24 Green Paper on the European Workforce for Health (COM(2008) 725 final) European Commission 2008

Health professionals should ensure that quality improvement is data-driven. They should use their knowledge to assist in identifying meaningful indicators that will show gaps in quality. Doctors for example should insist on practising evidence based medicine whenever possible, using reference programs and guidelines to ensure that they follow best proven methodology.
It is further important that health professionals' expertise is appropriately sought and included in the shaping of quality strategies or policies, so that an actual impact on daily practice occurs.

Citizens' perception of patient safety and healthcare quality[25]

Half of respondents to the EU survey on patient safety and quality of healthcare felt they could be harmed by both hospital and non-hospital healthcare in their country. The majority felt that the harm could be done through hospital infections or incorrect, missed or delayed diagnoses. Over a quarter of respondents said they or a member of their family had experienced an adverse event with healthcare. However, only 28% said they had reported it.
When thinking of high quality healthcare, the most important criterion for respondents was well-trained medical staff (52%), followed by clinical effectiveness of treatment (39%). Thereafter, no waiting lists, modern medical equipment and respect of a patient's dignity received broadly equal responses (between 27 and 29%).
Although on average, most respondents rated the quality of healthcare in their country as good, significant variation (from 97% to 25%) was observed at the country level. 26% of respondents thought healthcare in their country was worse than in other EU Member States.

Problem definition

Several 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, competent, performant and engaged health workforce.

[25] Special Eurobarometer 327: Patient safety and quality of healthcare, published 16 April 2010. http://ec.europa.eu/health/patient_safety/eurobarometers/index_en.htm

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. Whilst improving outcomes, they may expose patients to previously unrecognised safety risk. However, their use can improve disease prevention and provision of treatment and help to shift some 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.

All these challenges need to be addressed in the situation of rising healthcare expenditures that result, among others, from shifting demographic profile of EU citizens and from increasing use of expensive new technologies.

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

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.[26] However, many other definitions exist and are constantly evolving[27], 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 the data comparisons are highly context dependent.

Disparities in development of quality strategies across Europe

All EU Member States agree that striving for high quality healthcare is a priority within their health systems. However, quality assurance strategies are developed, implemented and evaluated to significantly 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 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 internationally recognised organisations (e.g. the Joint Commission International or the International Accreditation Programme).[28]

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[26] 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

[27] Donabedian 1988, Maxwell 1992, Joint Commission of Accreditation of Healthcare Organisations 2006

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

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, some governments may be less willing to invest in the development of quality strategies as they may not be perceived as providing adequate financial return in the short or medium terms. However, although the literature is not always clear about correlation between increased healthcare quality and savings at system or provider level, some research shows that improving quality can save money.[29]

The core issue is the lack of evidence concerning strategies.. 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, the full costs and benefits of investing in quality strategies may not be well understood.

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 some Member States is lacking. Data related to healthcare quality (e.g. antimicrobial resistance data) exist in all Member States, they are hardly comparable.

Insufficient exchange of information and best practice among Member States

European health systems have been rather developed in isolation, with a background of a national context and the specific needs of the citizens. 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 and with the international community more generally.

Objectives

Every time quality in healthcare is measured, using outcome indicators, considerable variation is observed. The basic objective of quality improvement is to exploit this variation as a source of information that will tell where improvement is possible and sometimes even imperative.

[29] Øvretveit, J. 2009. Does improving quality save money? The Health Foundation. ISBN 978-1-906461-17-1

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 dimensions: 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 awareness and to encourage Member States to take practical steps towards quality improvement and enhanced accountability by health professionals. Those steps may include developing evidence based quality assurance systems, ensuring the appropriate assessment of health technologies, developing interactive tools enabling the capture of patient feedback, encouraging peer review tools as quality register between professionals or proposing training for health professionals in the area of quality. Actions proposed need to be evidence-based and therefore close link should be promoted between health decision-makers and researchers. 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. Active participation of health professionals and other healthcare workers as well as patients in strategies and measures designated to enhance quality should be encouraged.

3. To improve comparability of collected data

The objective is to agree to work together on the question of collecting data about quality, using WHO and OECD data work as a starting point for a discussion if one could collect and analyse such data in a comparative manner to contribute to increased transparency of quality of healthcare. Such information could 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.

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.

The role of the EU in achieving the objectives

Union action in the area of public health, according to article 168 of the Treaty on the Functioning of the European Union, 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 of healthcare 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, the Health Strategy, the Open Method of Coordination on Social Protection and Social Inclusion, the Structural Funds instruments or the Commission Patient Safety and Quality of Care Working Group) 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 a mechanism at the EU level to complement the actions taken by the individual Member States. Such a mechanism could for the first three years take the form of a joint action between the Commission and Member States, conceived as a follow-up of EUNetPaS project. A joint action could continue the work on patient safety and in addition, 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 investigate the possibility of evaluating quality assurance systems: their effectiveness, 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 reflect on principles of good quality healthcare
- to reflect on how to ensure EU collaboration on quality of healthcare, including patient safety, after the end of the joint action.

Participation in a joint action would not be obligatory.

The regular exchange of information on best practice in Member States should contribute to improving of quality assurance systems in the EU.

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 extensive 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, using existing work;
- 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, i.e. a joint action could be set up first, and the work on a recommendation could be developed at a later stage.

Option 4: Guidance on healthcare quality

This option would be to develop guidance on how to measure, assess and improve healthcare quality in the EU Member States. This would cover:

- principles of good quality of healthcare, including involving health professionals and empowering patients as key elements of quality improvement,
- indicative quality standards to be used by Member States as a reference for their own standards, such as was previously done on cancer screening,
- guidelines for evaluation of quality strategies,
- role of accreditation in quality assurance strategies,
- catalogue of best practice in healthcare quality.