EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Future EU Agenda on quality of health care with a special emphasis on patient safety

The EXPH approved this opinion for public consultation
at the 6th plenary meeting of 10 July 2014

About the Expert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent Expert Panel which provides advice on effective ways of investing in health (Commission Decision 2012/C 198/06).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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ABSTRACT

The Expert Panel on Effective ways of Investing in Health (EXPH) was asked to provide an opinion on a possible future EU agenda on quality of health care with a special emphasis on patient safety. Specifically, the EXPH was asked:

- to consider the core dimensions of quality of health care, including patient safety in the EU;
- to define the dimensions that should be given priority at EU level in order to improve quality of health care as well as the actions that could be taken at EU level to address the selected dimensions;
- to demonstrate what would be the added value of proposed EU actions;
- to specify what information is needed to assess quality and safety of health care in the EU.

The EXPH opinion emerges from and relies on the main findings from a literature review, jointly carried out with the European Commission, as well as from the evaluation of the former EU projects on quality/safety within the Framework Programs 5, 6, and 7.

The EXPH identified a subset of commonly accepted dimensions of quality/safety applicable to all health services, which should be prioritized at EU level. Indeed, regardless of the level of health care provided, all services have to be effective, safe, appropriate, patient-centred, efficient and equitable. With regard to the information needed to assess quality and safety of health care in the EU, the EXPH highlight a subset of indicators potentially suitable to quantify these quality/safety core dimensions.

In addition, the EXPH acknowledges that the EU Commission could play a crucial role in boosting actions to be taken at EU level aimed at improving the quality of health care and the safety of patients. The actions proposed cover:

- the utilisation of a comprehensive conceptual framework in relation to quality and safety;
- guideline development and the interprofessional sharing of good practices;
- funding research related to quality and safety;
- economic issues related to the defined quality dimensions;
- education and training in relation to the new roles of both patients and health professionals;
- information technology and information systems significant for health quality and safety;
- quality and safety aspects of the burden of chronic diseases and inequalities in health;
- the HTA network, and increasing attention on Health System Impact Assessment;
- miscellaneous recommendations.

The EXPH considers that undertaking such actions Europe-wide would yield financial and social benefits and would fit with the context of the recent EU actions against health inequalities, both in between and within countries.

Keywords: EXPH, Expert Panel on effective ways of investing in Health, scientific opinion, patient safety, quality of care, EU agenda

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EXECUTIVE SUMMARY

The Expert Panel on Effective ways of Investing in Health (EXPH) was asked to provide an opinion on a possible future EU agenda on quality of health care with a special emphasis on patient safety. Recently, the issue of health care quality and patient safety has become a key priority at EU level, particularly in the light of the Directive of the European Parliament and the Council of the European Union on the application of patients' rights in cross-border health care (Directive 2011/24/EU), entitling patients to seek treatment abroad and, in turn, raising concerns about their safety and on the quality of care.

The EXPH opinion relies on scientific evidence (a literature review was carried out jointly with the European Commission) and on the former EU projects on quality/safety (an evaluation of the projects of the FP 5, 6, and 7 was conducted).

The EXPH opinion emerges from both Donabedian's and the "Institute of Medicine"'s (IOM) definitions of quality of care, respectively defined as the "kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" and 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". In order to provide its opinion, the EXPH considered health care quality and patients' safety in the light of the so-called "Donabedian's triangle", consisting of a framework for measuring quality by assessing elements of structure or process with proven connections to key outcomes of interest. The resulting complex framework of health care quality and patients' safety reflects, in turn, the extreme variability of their core dimensions at the nano-, micro-, meso- and macro-level. It was challenging for the EXPH to identify commonly accepted dimensions of quality of services applicable to the broad set of services, ranging from promotion/prevention services to palliative services as well as primary care services, hospital services, emergency services, and long-term care; eventually, five core dimensions were identified. Indeed, regardless from the level of health care provided, all services have to be:

1. Effective, and improve health outcomes;
2. Safe, and prevent avoidable harm related with care;
3. Appropriate, and comply with current medical knowledge as well as meeting agreed standards;
4. Patient-centred, and involve patients/people as key partners in the process of care;

5. Efficient and equitable, and lead to the best value for the money spent and to equal access to available care for equal need, utilization and equal quality of care for all.

An additional key step of the mandate of the EXPH was to identify a subset of indicators which could measure and quantify the "amount" of health care quality and patients' safety in the light of the fore-mentioned framework. The relative importance of each indicator is a political issue for each Member State, but they could help both decision makers and patients to compare various systems. Furthermore, the importance of a single indicator may change over time as the health system develops. It should be highlighted that the quality/safety indicators have been identified according to the criteria for good indicators suggested by Mainz. A good indicator should be based on agreed definitions, and it should also be described exclusively and exhaustively; it should be highly specific and sensitive, valid and reliable; it should discriminate well and be related to clearly identifiable events for the user; it also should permit useful comparisons and be evidence-based. The selection of such indicators is crucial to measure, evaluate and compare EU health care systems from a quality/safety perspective. This will be reflected, in turn, in promoting the accountability, informing effective policy development, and fostering cross-learning at EU level.

The EXPH acknowledged that the EU Commission could play a crucial role in boosting the improvement of the quality of health care and the safety of patients. A list of actions to be taken at EU level is proposed with the aim of improving the delivery of safe and high-quality services. The EXPH proposes the establishment of a "EU Health Care Quality Board" for the coordination of all EU initiatives in health care quality as well as the establishment of a "Health System Performance Analysis Framework" at EU level to facilitate comparison across health policies and their impact; additionally, it suggests that the EU initiates a process leading to the drafting of recommendation on health care quality. The EXPH recognises the importance of allocating more funds to research activities aimed at investigating the possible strategies to scale up the resilience of health systems to promptly respond to upcoming challenges. Moreover, it is suggested that EU countries share knowledge through the implementation of an HTA network, looking at technologies, health care processes and health system impact assessment, in order to avoid the duplication of efforts. Further, the EXPH acknowledges the importance of information technology/systems encouraging blame-free reporting-related activities; within this framework, the development of EU surveillance systems should be fostered. Eventually, EU should promote/work towards a Europe-wide health education program encompassing health literacy, patient safety and health care and addressed towards a patient-centred approach.

285 The EXPH considers that these actions could lead to the delivery of high quality and safe
286 health care services as well as being beneficial to cost containment across Member
287 States.
288

1. TERMS OF REFERENCE

The Expert Panel on Effective ways of Investing in Health is requested to give its views on a possible future EU agenda on quality of health care with a special emphasis on patient safety. The opinion of the Expert Panel should take into account previous and ongoing EU activities on patient safety and quality of care. In particular, the Expert Panel is requested:

1. To consider the core dimensions of quality of health care, including patient safety in the European Union.
2. To define within this:
   - dimensions that should be given priority at EU level in order to improve quality of health care;
   - actions that could be taken at EU level to address the selected dimensions.
3. To demonstrate what would be the added value of proposed EU actions.
4. To specify what information is needed to assess quality and safety of health care in the EU.

Additionally, the Expert Panel is requested to reflect on how the effectiveness of EU policy in the area of quality and safety of health care could be evaluated.

2. BACKGROUND

Quality of health care, and in particular a key dimension – patient safety – has been addressed at EU level by various initiatives, including quality and safety of blood, tissues and organs, quality, safety and efficacy of medicines, medical devices, cancer screening, health professionals and patients' rights in cross-border health care.

In 2009 patient safety was addressed at EU level in an explicit manner, through the adoption of an overarching strategy on patient safety in the form of a Council Recommendation. Two years later the Cross-Border Health Care Directive included a series of provisions on quality and safety agenda.

The Commission Patient Safety and Quality of Care Working Group (PSQCWG), brings together representatives from all EU countries, EFTA countries, international organisations and EU bodies. The Group assists in developing the EU patient and quality agenda.

The Commission has been supporting the implementation of these provisions through funding research projects, supporting data collection and coordinating exchanges of best practice. However, most of these activities are time-limited and will end within a year or two. Thus, there is a major question about the continuity of patient safety and quality activities at EU level.

Regulation (EU) nº 1025/2012 of the European Parliament and the Council of 25 October 2012 on European standardization could give support to the process of definition of standards in the field of health care.

A number of documents on patient safety and quality in the EU have just been published:

- Special Eurobarometer 411 on patient safety and quality of care (June 2014): a survey of nearly 28,000 residents in the 28 MS to determine: perceptions of and information about the quality of health care; perceived likelihood of being harmed by health care services; experience of adverse events; information on patient safety and awareness regarding redress in their own country or another MS.
- Report on public consultation on EU action on quality of care and patient safety (July 2014): an on-line survey of stakeholder groups examining barriers to implementation of the Council recommendation, support for areas of action to improve PS identified by the EC and raising different issues not or not sufficiently covered by the Recommendation, including health workforce issues.

The second report from the Commission to Council (June 2014) (on implementation of the Recommendation) Com(2014)371 final: this updates and reviews progress since the first implementation report, Com(2012)658.

The EXPH opinion relies on the scientific evidence on quality of health care and patient safety retrieved, through a rigorous but practical approach, from both a literature review, carried out with the support of the European Commission, and the EU/MSs projects conducted within the Framework Programs 5, 6, 7 which focused on quality/safety. This approach has been followed in order to pursue the task of defining the priority dimensions and addressing the EU actions to boost health care quality. Following the so-called Donabedian triangle, the opinion has been drafted focusing on the structure, process and outcome framework of health care quality, classified across the four different levels of health care systems (macro, meso, micro and nano), and extensively enriched by a substantial orientation towards the patient perspective. In addition, five quality dimensions have been taken into account and proposed (effectiveness, safety, appropriateness, person/patient-centredness, and efficiency/equity) together with a subset of indicators necessary to measure them. In providing its point of view on the possible future EU agenda, the EXPH aims at bridging the gaps between the scientific approach, the actual situation in EU MSs, and the political decision-making processes, through a comprehensive, up-to-date and accessible document.

3. OPINION

3.1 FRAMEWORK AND DEFINITION

The Expert Panel understands high quality health care as health care that uses the available and appropriate resources in an efficient way to equitably contribute to the improvement of the health of the populations and patients. This implies that provision of care is consistent with current professional knowledge, focuses on the needs and goals of individuals, their families and communities, prevents and avoid harm related to care, and involves persons/patients as key partners in the process of care.

3.1.1 Quality of Care and Patient Safety: Conceptual Framework

Figure 1 shows the complex picture of determinants of quality, starting from the Donabedian-triangle of structure, process and outcome (Donabedian, 1988), specified in Table 1 using four operational levels: macro, meso, micro and nano, to classify the indicators of quality of care. The nano-level is seen as the single patient-provider-interaction level, whereas the micro-level contains indicators of quality that occur in the (interdisciplinary) collaboration between health care providers. The meso-level is the place where policies and organisations operate that support these collaborations. Health care system characteristics as indicators for quality are observed at the macro-level.

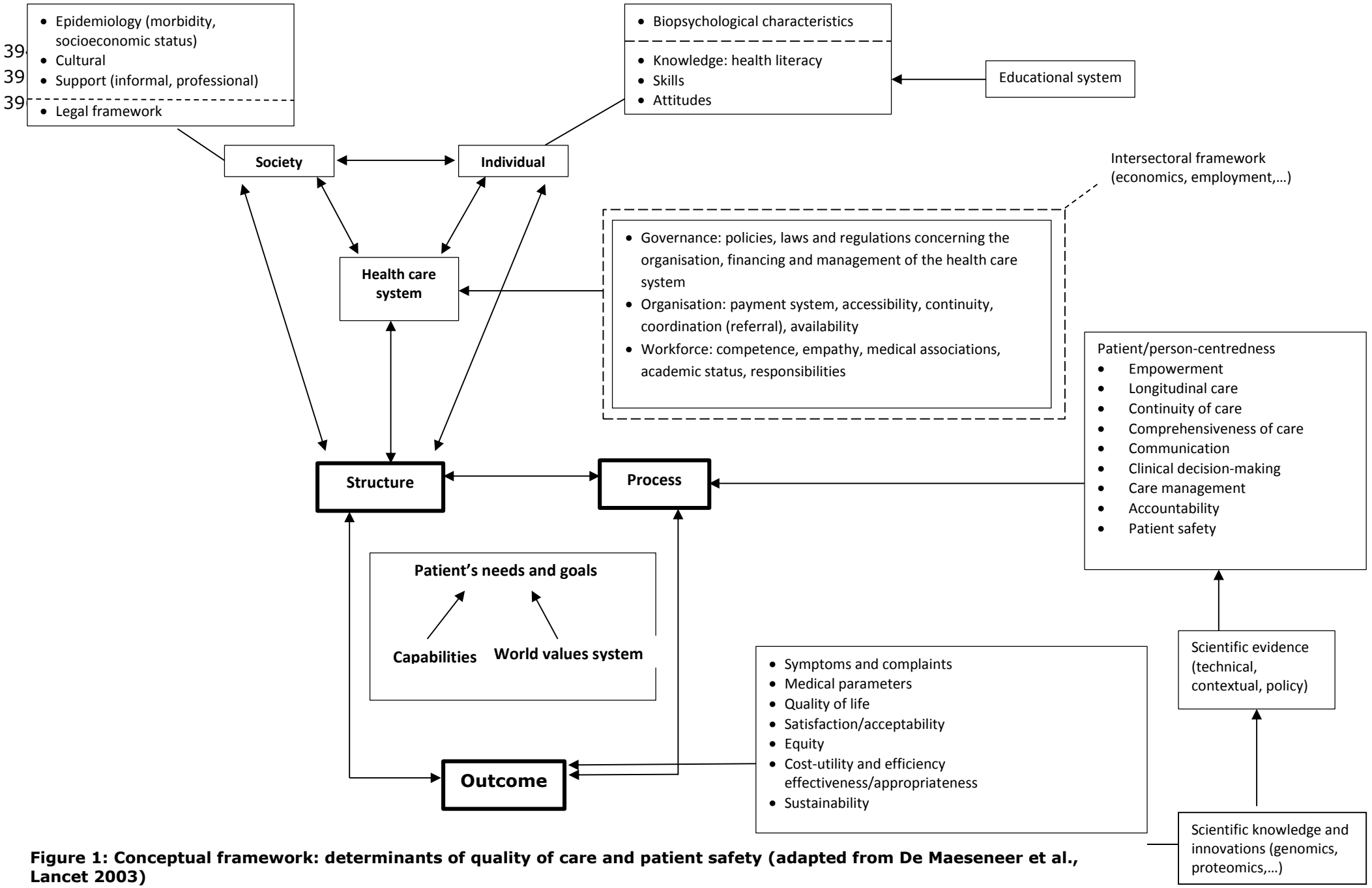


Figure 1: Conceptual framework: determinants of quality of care and patient safety (adapted from De Maeseneer et al., Lancet 2003)

	STRUCTURE	PROCESS	OUTCOME
MACRO	- Policies and regulations concerning organisation of health care system -Policies and regulations concerning financing of the health care system (solidarity) -Payment system -Economic situation (income per capita, Gini-coefficient) -Public revenue (solidarity) - Other non-medical determinants (history, demography, housing,…) -Availability (geographical, national,…) -Coordination (gate-keeping) -Universality, population covered: universal health coverage -Affordability -Organisational accessibility -Geographical accessibility and distribution -Equity in financing (PC, SC, TC) -Research on health systems -Appropriate institutions for health professional education	-Availability of norms and standards -Availability of and access to health related information -availability of guidelines and implementation-strategies -research on health services delivery, HTA,…	-Health equity -Effectiveness: avoiding premature mortality, enhancing quality of life, recovering from ill health -Efficiency -Sustainability -Patient satisfaction with health system -Health indicators -Patient safety indicators
MESO	-Coordination (integration of PC and SC) -Availability of well-equipped services	-Continuity (informational and organisational continuity of care with secondary care)	-Quality of referral and discharge
MICRO	-Coordination (collaboration with other providers) -Equity in accessibility (no risk selection)	-Continuity (informational continuity of care within PC,..) -Accountability/ responsiveness -Coordination (referral PC to SC)	-Quality and integration of care: symptoms, satisfaction, medical parameters
NANO	-Competence and empathy of HP -Health Literacy of the patient -Education of HP -Organisational accessibility -Cultural accessibility and sensitivity -Comprehensiveness (availability of equipment,..)	-Communication -Clinical decision-making -Patient empowerment -Patient safety -Continuity (availability of medical information, medical record keeping,..) -Longitudinally	-Satisfaction and Acceptability -Symptoms and complaints -Medical parameters -Quality of life -Responsiveness -Effectiveness and appropriateness -Patient safety indicators

Notes: This grid illustrates that different indicators in relation to structure, process and outcome may be situated at different levels

Table 1: Aspects of quality of care and patient safety

- **Structure** consists of three interrelated components: society, the health care system and the individual (De Maeseneer et al., 2003). Society, at the macro-level, presents a so-called epidemiological community, characterized in terms of morbidity, socio-economic status, employment, housing and other variables; a cultural community (an anthropological frame of reference); a support community with formal, informal and professional networks; and a legal framework. For the health care system, policies and regulations concerning the organisation and financing of the system (accessibility, availability, referral, universality, affordability, financing system, payment system,…) are considered on the macro-level (Van Weel, 2001; Starfield et al., 2005; Bhat, 2005; Gross et al., 2000; Verhaak et al., 2004). Coordination characteristics such as integration of primary and secondary care are considered at the meso-level (Gruen et al., 2003; Stille et al., 2005); patient- and people centred collaboration between health care providers at the micro-level (Ashworth & Armstrong, 2006; Xyrichis & Lowton, 2008). At last, the nano-level contains characteristics of health care providers such as education (CEC, 2008), clinical, technical and communicative competence and empathy. At the level of the individual, knowledge (about the functioning of the body), skills (coping, self-care) and attitudes (health perceptions and health beliefs), all influenced by the educational system, affect clinical care. Additionally, bio-psychological characteristics of the patient (e.g., genome,…) will determine the final outcome. The complex determinants identified above illustrate that for the citizen, quality is as much dependent on the socio-cultural context and subjective phenomena as it is on the criteria defined by the medical sciences or from cost effectiveness calculations.

- **Process** refers to all interventions and interaction between patients and providers. Process quality largely depends on adequate communication, medical decision-making, patient safety, care management and patient empowerment at the nano-level. Referral from primary to secondary care and informational continuity of care within the same level of care – for example within primary care – are relevant at the micro-level (Starfield et al., 2001, 2005). Informational and organisational continuity between different levels of care, is considered at the meso-level. Availability of norms and standards, health related information, guidelines and implementation-strategies are found at the macro-level, in addition to research on health services design and delivery, HTA,… Structure and process are inextricably linked in continuous interaction. Quality of communication between patients and doctors, for instance, will be determined not only by the skills of the doctor but also by patients' characteristics (eg, health beliefs) and by community characteristics (e.g., importance of integration of cultural-anthropological factors in communication with migrant populations). Medical decision-making will interact with the patient's expectations and beliefs (e.g.,

it is difficult to make clear to a patient who has unrealistic faith in medical technology that a CT scan is not needed for the diagnosis of acute sinusitis). Both structure and process will contribute to the final outcome. Conversely, quality of communication may be adversely affected if the clinician focuses solely on the symptomatic treatment of the patient (particularly in those with chronic conditions), as their condition often affects them in many spheres of their lives and interaction with a clinician who shows that they have failed to recognise this, is bound therefore to be less effective.

- **Outcome** will be assessed in the framework of the paradigm in use. In recent years, as a consequence of the demographic and epidemiological transitions towards chronic care and multi-morbidity, a paradigm shift has taken place from disease-orientation to goal-orientation (Mold et al., 1991). This consideration results in a range of relevant outcome indicators that can be measured (at the nano- and micro-level), from signs and symptoms, physical parameters (e.g., blood pressure, blood glucose, peak-flow), quality of life (functional status) (Scholten et al., 1992), patient's satisfaction, (Wensing & Grol, 2000), responsiveness, appropriateness and effectiveness. Quality of referral and discharge is observed at the meso-level.

- At the macro-level, we consider some more indicators, such as efficiency, equity, effectiveness (e.g., avoiding premature mortality, enhancing quality of life, recovering from ill health). In figure 1 and table 1, we emphasize the complexity of the different components of quality and the picture is certainly incomplete. The underlying concept is that linear mechanistic approaches are not able to guide quality improvement and that the complexity requires a circular approach.

Clinical decisions to improve quality of patients' care must be made with a good knowledge of the biomedical approach to the disease (*medical evidence*), but at the same time they must take into account patient-specific aspects of medical care (*contextual evidence)* and efficiency, equity, and rationing *(policy evidence*) (De Maeseneer et al., 2003).

Contextual evidence (van Weel, 2001) is necessary to assist doctors to address the challenge of how to treat a particular patient in a specific situation (van Driel et al., 2001). This need refers back to the principles of good doctor-patient communication to create trusting interpersonal relationships, exchange of pertinent information and negotiation of treatment-related decisions (Ong et al., 1995).

The health-policy environment determines every meeting of doctors and their patients and therefore there is a need to enrich practice with more *policy evidence*, which entails efficiency, equity and rationing. Achievement of individual evidence-based treatment benefits in itself not the final word for promotion of that treatment for all patients. Integration of equity and solidarity into decisions enhances understanding of how choices stimulate or impede best practice for all patients. This act enhances transparency of clinical performance. Regulations such as the presence or absence of gatekeeping, reimbursement and payment, regulations for advertising of medicines and continuing medical education have an effect on doctors' and patients' behavior, which goes beyond the limits of the health care system. Figure 2 shows how improving quality of practice needs integration of conclusions from the three types of evidence.

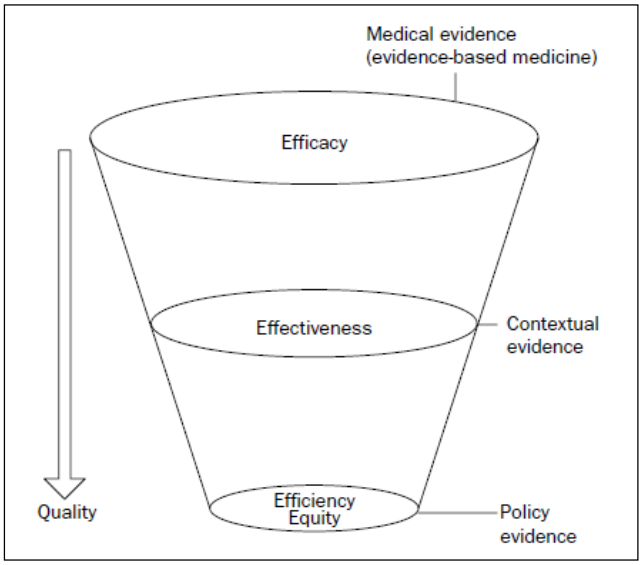


Figure 2: Three types of evidence to improve quality (adapted from De Maeseneer et al., Lancet 2003)

3.1.2 A proposal to define the quality of health services

In the public consultation carried out by the Commission one of the proposed actions at EU level was "developing a common definition of quality of care" (BEREC, 2014).

In the 2010 Reflection Paper "Quality of Health care: policy actions at EU level", addressed to the Council Working Party on Public Health at Senior Level, one of the objectives was: "to agree on a definition of health care quality and on dimensions of health care 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" (European Commission, 2010)[1].

Accordingly, the Expert Panel has been requested to consider the core dimensions of quality of health care, including patient safety, in the European Union.

Several definitions of quality of care have been developed over the years:
The Reflection Paper of 2010 uses the following definition: "health care that is effective, safe and responds to the needs and preference of patients. 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".

The European Observatory on Health Systems and Policies reviewed the most frequently used definitions on quality of care in their paper "Assuring the Quality of Health Care in the European Union" (2008). One definition commonly used was proposed by IOM (1990): "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes (effectiveness) and are consistent with current professional knowledge (appropriateness)".

Other authors or institutions included more/different dimensions:
Donabedian (1980) timeliness; Council of Europe (1998) safety; WHO (2000) responsiveness to legitimate non-health expectations of the population, etc.

There are different valid definitions depending on the purpose and the organisation responsible to choose the dimensions to be included and/or highlighted. At the same time the Expert Panel is aware that, as societies and health systems change, the definition of high quality health care will change.

[1] The commission reflection paper is included in the Council document no. 9366/1/10 of 21 March 2010: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%209366%202010%20REV%201

Table 2 provides an overview of the most frequently applied definitions of quality of care, as identified in the literature. These definitions demarcate the boundaries of quality, while a second set of definitions, presented below, more clearly distinguishes the various dimensions of the concept.

Table 2: Definitions of quality of care

Author/Organisation	*Definition*
Donabedian (1980)	Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.
IOM (1990)	Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
Department of Health (UK) (1997)	Quality of care is: • doing the right things (what) • to the right people (to whom) • at the right time (when) • and doing things right first time.
Council of Europe (1998)	Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.
WHO (2000)	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.
EC (2010)	Health care that is effective, safe and responds to the needs and preference of patients. 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".

Notes: IOM: Institute of Medicine; WHO: World Health Organisation; EC: European Commission

The definitions put forward by Donabedian and by the Institute of Medicine (IOM) have been particularly influential. Thus, Donabedian defined quality as "the ability to achieve desirable objectives using legitimate means", while quality of care was defined as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" (Donabedian, 1980). He argued that before assessing quality of care it is necessary to define whether monetary cost should enter the definition of quality. He thus distinguished a "maximalist" specification from an "optimalist" specification of quality. The maximalist specification ignores monetary costs and defines the highest quality as the level that can be expected to achieve the greatest improvement in health. In contrast, in the optimalist specification of quality, very expensive interventions that do not achieve a great improvement in health would be avoided (Evans et al., 2001). Initially, Donabedian defined quality of care from a maximalist perspective, while later he opted for the concept of value, with quality defined as the maximum that is possible given the inputs that are available.

One other very influential definition of quality of care is that proposed by the IOM in the United States and which has been adopted by a range of (mostly American) organisations including the United States Department of Health and Human Services, the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance, as well as regulatory bodies such as the Health Care Financing Administration (now Centers for Medicare & Medicaid Services) (Edinger, 2000).

Already in 1974 the IOM had commented on quality assurance, stating that its "primary goal … should be to make health care more effective in bettering the health status and satisfaction of a population, within the resources which society and individuals have chosen to spend for that care". When reviewing this early work later, the IOM realized that "quality of care" had not been defined. It also acknowledged that the method of reviewing and assuring quality depended on how quality of care was defined (IOM, 1990). Therefore, in a 1990 report, the IOM authors reviewed over 100 definitions and parameters of quality of care according to the presence or absence of 18 dimensions (IOM, 1990). Based on this review, the authors arrived at a definition of quality of care that considers 8 of the 18 dimensions identified. Consequently, quality of care was defined 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" (IOM, 1990).

The definition:

- includes a measure of scale;
- encompasses a wide range of elements of care with reference to health services;
- identifies both individuals and populations as targets for quality assurance efforts;
- is goal oriented (Mold et al., 1991), making a distinction within the health care goals depending on whether they emanate from government, patients, administrators, health care practitioners or other participants in the health care system;
- recognizes the importance of outcomes without specifying for whom, thus allowing the possibility of differing perspectives on which values of quality are most important;
- highlights the importance of individual patients' and society's preferences and values and implies that the patients have been taken into account in health care decision- and policy-making;
- underlines the constraints placed on professional performance by the state of technical, medical and scientific knowledge, implying that the State is dynamic and that the health care provider is responsible for using the best knowledge base available.

It is important to note that compared to the definition developed by Donabedian, the IOM definition narrows the goal from improving total patient welfare to improving health outcomes (Evans et al., 2001). At the same time, it shifts the focus from patients to individuals and populations, hence allowing quality of care also to incorporate health promotion and disease prevention and not just cure and rehabilitation. It also adds "desired outcomes" to the definition so as to emphasize the need to consider the perspective of the recipients of services, and by highlighting that care should be "consistent with current professional knowledge" it implies that the standards of the service also need to be defined.

Considering the definitions and arguments discussed above the EXPH understands **High Quality Health Care** as health care that uses the available and appropriate resources in an efficient way to equitably contribute to the improvement of the health of the population and patients. This implies that provision of care is consistent with current professional knowledge, focuses on the needs and goals of individuals, their families and communities, prevents and avoids harm related to care, and involves persons/patients as key partners in the process of care.

606 ## 3.2 CORE DIMENSIONS FOR QUALITY SERVICES IN HEALTH CARE
607
608 As noted above, several authors and/or organisations have defined quality of care by
609 describing the concept according to a set of dimensions (Table 3). The most frequently
610 used dimensions include (in descending order of frequency): effectiveness, efficiency,
611 access, safety, equity, appropriateness including timeliness, acceptability, patient
612 responsiveness or patient-centredness, satisfaction, health improvement and continuity
613 of care. These dimensions are, however, neither comprehensive nor mutually exclusive.
614
615 **Table 3 Dimensions of quality of care**

	Donabedian (1988)	*Maxwell (1992)*	*Department of Health (UK) (1997)*	*Council of Europe (1988)*	*IoM (2001)*	*JCAHO (2006)*
Effectiveness	X	X	X	X	X	X
Efficiency	X	X	X	X	X	X
Access	X	X	X	X		X
Safety	X			X	X	X
Equity	X	X	(X)		X	
Appropriateness	X	X		X		X
Timeliness			X		X	X
Acceptability		X		X		
Responsiveness		Respect Choice Information			Respect Patient centred-ness	
Satisfaction			(X)	X		
Health improvement	X		X			
Continuity					X	
Other		Technical competence Relevance		Efficacy		Availability Prevention/ early detection

616 Sources: Donabedian 1988; Maxwell 1992; Department of Health 1997; Council of Europe 1998;
617 IOM 2001; JCAHO 2006.
618 Notes: IOM: Institute of Medicine: JCAHO: Joint Commission on Accreditation of Healthcare
619 Organizations.
620
621 The dimensions of effectiveness and efficiency are included in all definitions of quality of
622 care analysed here. Effectiveness refers to the extent to which the intervention in
623 question produces the intended effects (Maxwell, 1992; Witter and Ensor, 1997).
624 Efficiency, in contrast, refers to the extent to which objectives are achieved by
625 minimizing the use of resources (WHO, 2000). The goal is to maximize the output for a
626 given input, or conversely to minimize the input for a given level of output, for example

by comparing the unit cost associated with the intervention with the unit cost elsewhere for the same intervention or service (Maxwell, 1992).

Access (to care) is also an important dimension in all definitions of quality of care considered in the literature, except for the one put forward by the IOM (IOM, 2001). Access can, in very simple terms, be operationalized as the proportion of a given population in need of health services that can obtain them (WHO Regional Office for Europe, 1998). It is important to note that access has been attributed different meanings by different authors (Saturno, Gascon and Parra, 1997). However, the common concern is to quantify whether a health service or treatment is available to the person needing it, at the time it is needed.

Safety refers to the reduction of risk and forms an important component of several definitions. According to the IOM, patient safety is "freedom from accidental injury due to medical care, or medical errors", with medical error being defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim…[including] problems in practice, products, procedures, and systems" (Kohn, Corrigan and Donaldson, 2000). Patient safety has traditionally been considered as one among many dimensions of quality of care, but it is increasingly being seen as absolutely key to quality overall. As a consequence, the policy debate concerning patient safety has developed in parallel to mainstream quality of health care initiatives. It is therefore important, in our opinion, to reiterate that patient safety forms but one dimension of quality in health care. However, a current serious discussion about patient safety being something different from health quality is ongoing, and needs to be heeded.

Equity, as a separate, if related, dimension is also included in some classifications. This is different from, but often confused with, equality. Equity implies considerations of fairness so that, in some circumstances, individuals will receive more care than others to reflect differences in their ability to benefit or in their particular needs. Equity can be seen as one of the corner-stones of European health care, in contrast to some other developed health care systems. As a principle it is recognised in the Treaty, and therefore, rather than being acknowledged in the dimensions referred to next, it would be implicitly assumed as a cross-cutting issue affecting all of them.

The next sets of dimensions most frequently mentioned refer to the extent to which care meets the medical, social and aspirational needs of patients. These dimensions are: appropriateness (how the treatment corresponds to the needs of the patient) including timeliness (receiving treatment within a reasonable time frame); acceptability (how

humanely and considerately the treatment is delivered); responsiveness to patients or patient-centredness (consideration of individual patients' and society's preferences and values); satisfaction (how the treatment and the improvement in the patient's health meets her/his expectations); and continuity of care (the connectedness between stages along the patient pathway). As will be seen later, continuity of care is regarded as the most important concern by those patients who are receiving care abroad. Generally, fragmentation and lack of coordination is identified by patients with chronic diseases as a major obstacle in the way of good quality care. (EPF, 2011)[2]

An overriding dimension mentioned specifically by Maxwell, that could also be included in the appropriateness dimension, is that of relevance (Maxwell, 1992). It refers to the optimal overall pattern and balance of services that could be achieved, taking into account the needs and wants of the population as a whole. The Council of Europe also includes two notions that are not included by the other definitions considered here, namely those of efficacy and assessment. Efficacy constitutes for the individuals in a defined population the probable benefit of a given medical technique for a specific medical problem, in ideal circumstances, and as such is a rather more limited element of effectiveness. Assessment refers to the degree to which effective health care has been implemented and achieved and results have been attained (Council of Europe, 1998).

The choice of dimensions to measure quality of care is critical as it will influence the health care policies adopted. Thus, Shaw and Kalo (2002) underline the key challenge for every country to recognize these diverse but legitimate expectations and to reconcile them in a responsive and balanced health system.

There are five dimensions that are commonly accepted as dimensions of quality of services (sometimes the term used is not the same). These dimensions can be applied to promotion and prevention services, primary care services, hospital services, emergency services, long-term care, palliative care, etc.

Having analysed the different dimensions, the EXPH considered the following as the core dimensions for which goals, standards and indicators should be developed in order to guarantee high quality health care services in the MS and at EU level.

1. Effectiveness (improve health outcomes)

[2] European Patients' Forum response to the European Commissions' stakeholder consultation on the reflection process on chronic diseases (2011), p.6. Available at http://www.eu-patient.eu/Documents/Who%20we%20are/News/EPF%20chronic%20diseases%20consultation%20response-Final.pdf

2. Safety (prevent avoid harm related with care)
3. Appropriateness (comply with current medical knowledge, meet standards)
4. Person/patient-centredness (consider patients/people as key partner in the process of care)
5. Efficiency and Equity (optimal use of available resources without differences, variations and disparities in the health achievements of individuals and groups)

The Expert Panel consider that until now health care systems have paid attention primarily to the first three dimensions: effectiveness, patient safety and appropriateness, and perhaps the aspect of patient-centred health care has not been sufficiently highlighted. It is not only a question of patients "desires" been taken into account. Nor only a question to "responding" to the needs and preferences of patients. These are necessary but not enough. Patients, families and people, should have the possibility to actively participate in the process of care and self-care, mainly for chronic conditions, health promotion and disease prevention activities. The patients (the persons, if we consider that a person can have health conditions that can be improved through their life) are, in this respect, active participants in the process. So, the services have not only to be developed "for" individuals and populations, but also "with" and "through" individuals and populations. It is not only a question of "expectations", but of empowering and increasing the capacity of the persons/patients to be able to care for themselves in partnership with professionals (e.g. in relation to diabetes, mental disorders, ageing with autonomy, etc.) and to achieve the "goals" in their lives that are relevant to them. This new paradigm, derived from the best education of the people, and the demographic and epidemiological transitions, must not be confounded with the inappropriate shifting of responsibility to patients, or with the reduction of public health resources in times of crisis. Nor is it that the patient has to assume the role of health professionals, or that computer programs (apps) might replace medical services of high quality. Better informed and empowered patients (user, person) will be able to maintain optimal well-being and will manage their health condition more effectively in the context of everyday life, with appropriate support of health professionals working in a well-funded and structured health care system. This could also imply the option to choose not to receive the treatment proposed. The empowered patient may choose not to participate (be involved) leaving decisions to the health professionals or, in other circumstances, the empowered patient may choose the 'no treatment' option.

Currently, there is no globally agreed definition of patient-centred health care. Several definitions have been put forward, with varying terminology – e.g., some refer to person-centred rather than patient-centred care while the basic concept is similar. Similarities

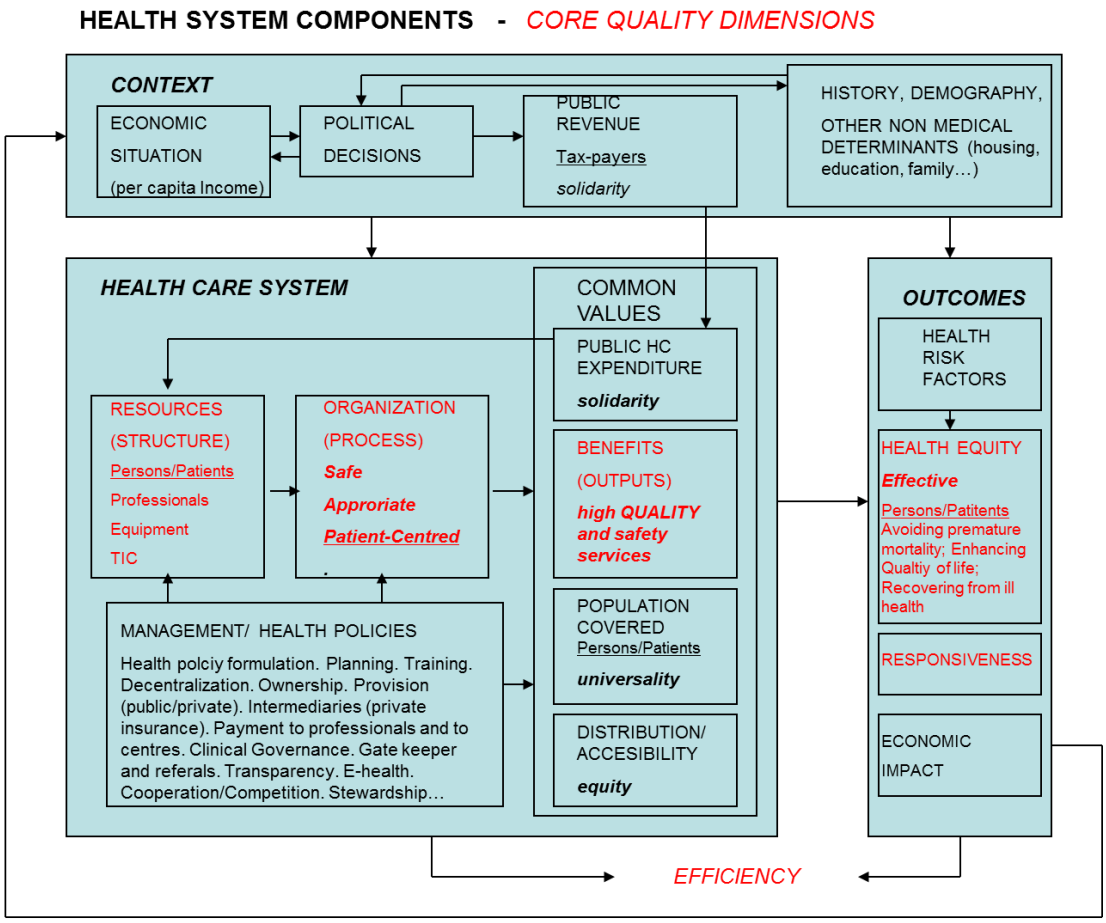
738 can also be found with definitions of integrated or "joint-up" care (e.g., National Voices
739 [UK] 2011).[3] Despite the problem of definitions, literature is accumulating on this topic,
740 including guidelines for implementing and measuring patient-centred care approaches.[4]
741
742 The Institute of Medicine (2001) defined patient-centred health care as care that is
743 "respectful of and responsive to individual patient preferences, need, and values, and
744 ensuring that patient values guide all clinical decisions."
745
746 The Health Foundation defines a person-centred health care system as follows: "one that
747 supports people to make informed decisions about, and to successfully manage, their
748 own health and care, able to make informed decisions and choose when to invite others
749 to act on their behalf. This requires health care services to work in partnership to deliver
750 care responsive to people's individual abilities, preferences, lifestyles and goals."[5]
751
752 The International Alliance of Patients' Organizations (2005) has developed 6 principles of
753 patient-centred health care – *respect* for patients' unique needs, preferences and
754 autonomy; *choice* of an appropriate treatment option that best fits the patient's needs;
755 *patient empowerment and involvement* in decisions that concern their health; *access* to
756 safe, high-quality, appropriate services and support; *information* that is reliable, relevant
757 and understandable; and *patient involvement in health policy* to ensure services are
758 designed with the patient at the centre.[6] A recent UK "thought paper" identified four
759 principles of person-centred care: affording people *dignity, respect and compassion*;
760 offering *coordinated* care; offering *personalised* care; and being *enabling*.[7]
761
762 The Patient-Centred Healthcare Improvement Guide (2008) identifies the following
763 elements in patient-centred care: providers working partnership with patients and their
764 families; identifying and satisfying the full range of patient needs and preferences;
765 ensuring health care professionals have both the ability and motivation to provide
766 effective care. It also stresses that safety and high clinical quality are fundamental to
767 patient-centred approach. [8]
768

[3] www.nationalvoices.org.uk/principles-integrated-care
[4] http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/Richmond-group-from-vision-to-action-april-2012-1.pdf
[5] *Helping measure person-centred care. A review of evidence about commonly used approaches and tools used to help measure person-centred care*. The health Foundation (2014)
[6] Declaration on patient centred health care: www.patientsorganizations.org/showarticle.pl?id=712;n=312
[7] Alf Collins; "Measuring what really matters. Towards a coherent measurement system to support person-centred care". The Health Foundation, April 2014.
[8] Frampton S. et al., *Patient-Centered Care Improvement Guide*. Derby, Connecticut: Planetree; October 2008

From these definitions, albeit diverse, some common elements can be distinguished. These include empathy/compassion (dignity); patient engagement/participation; and the patient experience of care. Shared decision-making, self-management, and information/health literacy are also commonly mentioned. Overall, patient-centred care is seen as an *approach* to health care that affects "the entire health care sector and … requires the involvement of all health care stakeholders."[9]

An accurate elicitation/assessment of the patients' needs and preferences is a fundamental starting point for a re-design of care in order to become more patient-centred.

Figure 3: Health system components: core quality dimensions



Modified from EXPH, 2014

Figure 3 illustrates how the conceptual framework may be translated in an operational interaction between the different health systems components. EU Member States defined

[9] *Person-centred care. Co-creating a health care sector for the future*. DNV GL and Monday Morning / Sustainia (2014)

the following "Common Values" of health systems: universality, equity, solidarity and access to *high quality and care* (Council Conclusions, 2006). Over the years, EU Member States have implemented different strategies to improve the quality and safety of health care services. Table 4 presents the most relevant EU projects referring to quality and safety within the Framework Programs 5, 6, and 7.

Table 4: Relevant Framework Programs' EU Projects on quality/safety

Most relevant EU quality/safety related projects	**FP**
Exchange of knowledge on Quality Management in health care	5
The future for Patients in Europe	6
Methods of Assessing Response to Quality Improvement Strategies (MArquiS)	6
International scientific conference on research on patient safety	6
European Cross Border Care Collaborations (Cross Europe)	7
Quality and costs of primary care in Europe (QUALICOPC)	7
WeCare: Towards a Sustainable and Affordable Health care	7
Operations management and demand-based approaches to health care outcomes and cost-benefits research	7
European Consortium in Health care Outcomes and cost-benefit research (ECHOUTCOME)	7
International Research Project on Financing Quality in Health Care (InterQuality)	7
Learning from International Networks about Errors and Understanding Safety in Primary Care (LINNEAUS Euro-PC)	7
Quality and safety in European Union hospitals: A research-based guide for implementing best practice and a framework for assessing performance (QUASAR)	7
Deepening our understanding of quality improvement in Europe (DUQuE)	7
Improving quality and safety in the hospital: The link between organisational culture, burnout, and quality of care	7

Additionally, important work in the field of patient safety, patient involvement/empowerment, quality indicators/guidelines has been developed (Table 5).

Table 5: Additional EU work on quality/safety

European Union Network for Patient Safety and Quality of care (Joint Action PaSQ, 2012-2015)
European Commission's Patient Safety & Quality of Care Working Group (PSQCWG)
OECD Health Care Quality Indicators Project (HCQI Project)
Work Package 4 - Safety Improvement for Patients in Europe (SImPatIE)
Guidelines International Network (G-I-N)
DECIDE collaboration
The Grading of Recommendations Assessment, Development and Evaluation WG (GRADE)
Empowering patients with chronic diseases (EMPATHIE) (tender EAHC 2013/health04)

As mentioned above, the EXPH considers five dimensions of health care quality

1.Effectiveness
2.Safety
3.Appropriateness
4.Person/patient-centredness
5.Efficiency and Equity

The dimensions and a selection of possible related goals are presented in the tables hereafter (tables 6-10)

EFFECTIVENESS	Tackling new challenges in health
Concept	Related Goals
Effectiveness refers to the extent to which the intervention in question produces the intended effects (Maxwell 1992; Witter and Ensor, 1997). In other terms, changes in health status brought about by health care –or health system- activities (Hurst J, Jee-Hughes M, OECD, 2001).	*Improving Prevention of Diseases and Health Promotion* • Prevent risk factors, and improve life styles o Develop initiatives at EU level to support MS in the development and strengthening of national programs and strategies in health promotion and disease prevention as the most cost-effective interventions. o Promote mental health and well-being in workplaces (EC 2011, EASHW 2011) *Improving Equity in Health* • Prevent and correct inequities in health. o Disparities in health (between regions, income groups, gender, ethnic groups, etc.) are a major issue in EU and in each MS. A first step has to be to establish systematic measure of these disparities, and analyse the causes that can be modified through cost-effective interventions. o Inequities in health affecting mental health problems should have specific consideration in EU programs. *Identifying the main health problems and define health strategies* • Reinforce information systems and the capacities for burden of diseases analysis at EU level. o Develop tools and offer support to MS for the use of burden of diseases analysis in the formulation of health strategies. • Reinforce EU capacities to monitoring, early warning of and combating serious cross-border threats to health (Decision 1082/2013 on serious cross-border threats to health) o Support MS to develop, strengthen and maintain the capacity to detect, assess, notify and respond to public health emergency of international concern. o Introduce a common procedure for the joint procurement of medical countermeasures, and in

	particular of pandemic vaccines (on a voluntary basis) in order to facilitate more equitable and efficient access to vaccines for the MS involved. ○ Ensure the development of the Health Security Committee capacities to be able to cope with their mandates (information system, analytical capacity, decision making process, etc.). *Improving Health through All Policies approach* • Ensure EU capacities to guarantee application of the article 168 of the Treaty on the Functioning of the European Union (TFEU): a high level of human protection should be ensured in the definition and implementation of all Union policies and activities. ○ Establish mechanisms to systematically introduce health impact assessment at EU level. ○ Elaborate proposals to improve impact on health of different policies (labour, education, housing, energy and environment, migration, fiscal systems, etc.)".

820 **Table 6: Core dimensions: Effectiveness**
821

822

SAFETY	Creating a culture of patient safety in the Health System
Concept	Related goals
The degree to which health care processes avoid, prevent, and ameliorate adverse outcomes or injuries that stem from the processes of health care itself (Cooper JB-National Patient Safety Foundation, 2000, OECD, 2006). Freedom from accidental injury due to medical care, or medical errors (Kohn, Corrigan and Donaldson, 2000).	*Development of safety systems (including authorities, bodies, culture of patient safety, standards/guidelines) and strategies (policies, programs).* • Establishment and development of national/ regional/ local policies and programs on patient safety aimed to avoid or reduce unjustified health care related harm with special emphasis in Mental Health interventions. (Abbayati MA, 2011) *Development of patient safety information and learning systems* • Establishment of Information Systems on the extent, types and causes of errors, adverse event and misses. (Hoffman, 2008; Williams SK, 2006; Etchegaray JM, 2014) *Education and training of health care workers, management and administrative staff in health care setting (formally required, included undergraduate, postgraduate training).* • Embedding patient safety in undergraduate and postgraduate education. *Encouragement of multidisciplinary patient safety on-the-job education and training of all health professionals, other health care workers and relevant management and administrative staff in health care settings. (Jansson M, 2013; Metsala E, 2014)* • Empowering and informing citizens and patients, including patient involvement in safety policies and activities (Council recommendation, 2009); Involving patients in health professionals' education; patient and family reporting of patient safety incidents (reports of the relevant sub-groups of the EC PSQC WG, 2014)

823 **Table 7: Core dimension: Safety**

824

825

APPROPRIATENESS. EVIDENCE-BASED PRACTICE	Stimulating involvement of health professionals in redesigning the Health Care System
Concept	Related goals
The degree to which provided health care is relevant to the clinical needs and the goals of the patient, given the current best evidence (Kelley E, Hurst J, OECD, 2006), and is applied in a timely manner. How the treatment corresponds to the needs of the patient (The European Observatory of Health Systems and Policies, 2008).	*Health Professionals and health care infrastructure development* • An adequate number of well trained and motivated health professionals (physicians, nurses, etc). • Specific programs/strategies aimed to motivate health professionals in health system performance improvement (training, incentives and payment systems, clinical governance and participation, etc.) • Appropriate infrastructure and equipment, properly maintained (authorisation and periodic control of health care infrastructure and equipment) *Ensuring continuous education, access and use of evidence based information: clinical excellence* • Developing, maintaining, disseminating and stimulating adherence to adequate Guidelines and evidence based medicine tools (Boström AM, 2013; Connellan C, 2013; De Belvis AG, 2009; Lugtenberg M, 2009; Schnoor M, 2010) • Improving continuing training programmes for health professionals in order to guarantee that they can apply current professional knowledge (understanding and applying evidence) (Chapman L, 2006; Damiani G, 2010) *Ensuring and monitoring of health care quality* • Existence of a comprehensive, accredited Inspection System and support for Peer review systems (Veerbeek L, 2011) • Waiting time for care has to be adequate and should not be a cause for unnecessary pain, deterioration of health conditions or complications. • Management of waiting lists according with the needs of the patients should be evaluated and improved (De Belvis AG, 2013)

	Redesigning the system • Health systems and health services organisations should be able to cope with the challenges of the present and future times. Epidemiological, demographic, economic and cultural changes require new ways of thinking and permanent redesign of services. (Prades J, 2011) • Integrated/coordinated approach (primary care, social care, specialised care, long term care, etc). developing adequate care pathways, guaranteeing appropriate care along the processes (multi-morbidity) and through different circumstances of life, ensuring accessibility, flexibility, safety, etc (Barbieri A, 2009; De Allegri M, 2011; Dean JE, 2007; Dick, 2006; Henderson CR, 2008; Killaspy H, 2013; Stuit ,2011; Uña E, 2010; van Dam PA, 2013; Van Houdt, 2013). • With citizen health literacy increasing and a greater acceptance of an active role for citizens in the management of their own health and illnesses, the role and training of professionals will need to change accordingly. For greater efficiency the relative roles of professionals will also need to be closely scrutinised (e.g. impact of nurse specialists on traditional medical responsibilities and how much this principle could be extended). *Improving quality through the use of information technology, Big Data, telehealth and telecare, …* • Transform Data into information and better (informed) decisions. Improving quality and utilization of information technology systems (Van der Mussele H, 2006; Verhoeven F, 2007; Zegers M, 2011) o Health Card o Medical record o Receipt dispensation o Telemedicine o On-line administrative procedures and health system information o Creating and managing Information from Health Data-Bases for: planners, clinicians, patients, researcher.

Table 8: Core dimension: Appropriateness. Evidence-Based Practice

828

PATIENT-CENTREDNESS	Recognising and making operative a new role for patients and people in the Health System
Concept	Related goals
The degree to which a system actually functions by placing the patient/user/person at the centre of its functioning and delivery. This means that the health care system is respectful of and responsive to individual patient goals, preferences, needs and values and ensures that patient values guide all clinical decisions (Institute of Medicine, 2001). In this paradigm the patient is a key partner of the health care system. We include here the	*Access to care and responsiveness to needs* • The health care system aims at ensuring that patients have access to services according to their health condition based on their needs and on a non-discriminatory basis, at the same time considering the non-health factors that impact on their approach to health care choices and management. *Respect* • The health care system aims at ensuring that the needs, preferences, values and goals of patients, as well as their autonomy and independence (International Alliance of Patients' Organisations, 2012) are considered when delivering services. (IAPO, 2012) *Information and communication* • The health systems aims at ensuring that understandable information is available to patients according to health literacy principles, enabling them to take informed decisions about their health care path and living with their condition. Communication is seen as a key empowerment factor and a means to strengthen the partnership between patient and caregiver. • Information from patient-reported experience is utilized as a key learning resource for continuous improvement of quality and safety (Boyce MB, 2014; Howell E, 2007; Marshall S, 2006). *Continuity and integration of care: care pathways* • Services aim to implement fully integrated care which demands communication and cooperation between professionals at different levels, centres, programmes or services. Ensuring connectedness and smooth transition (both at the nano and micro-level) is a feature of the care process. Care trajectories can either be "linear" (e.g. traditional referral from primary to secondary care for new health care problems), or "spiral" (e.g. in multi-morbidity, with both horizontal and vertical integration). (Quansching K, 2013;

following aspects (sub-dimensions): access to care and responsiveness, respect, information and communication (which includes the transferability of knowledge), continuity and transition of care, patient choice and empowerment (including self-care), patient involvement in health policy at all levels and relevance.	Redfern E, 2009; Tholin H, 2014). • Integration of services also between health care and social care/support (EPF, 2011) *Patient choice and empowerment* • The health care system ensures patients the right to participate as partner in making health care decisions that affect their lives, according to their capacity and wishes. Shared decision-making; Health literacy. • Patient self-management of health conditions: self-care. (Siebes, 2007). Engaging people in their own care (APPG, 2014). *Patient involvement in health policy at all levels* • The health care system aims at having patient actively involved in sharing the responsibility at all levels of policy-making and decision-making in health and related policies, to ensure they are focus on the needs and role of patients. • Framework for "meaningful patient involvement" for (collective) patient involvement in projects and policy is provided by the Value+ project (EU health programme, 2009) *Relevance* the optimal overall pattern and balance of services could be achieved, taking into account the needs and wants of the population as a whole (care that really matter, both for the individual and for society)

Table 9: Core dimension: Patient-Centredness

EFFICIENCY AND EQUITY	Ensuring value for money in the health care system and a fair distribution of health care and financial contributions
Concept	Related goals
The degree to which health systems create desirable outcomes in relation to the scarce resources available. "Efficiency is the system's optimal use of available resources to yield maximum benefits or results (JCAHO, 1997)." Equity refers to the fairness of financing, process and delivery of health care.	*Attaining highest possible health outcomes given the available resources* • The health system aims at and is designed to attaining best outcomes for patients with available resources. This requires a good structure of the health care system, including the financing and delivery side and measurement of outcomes. Assessing efficiency requires clarity about health care goals. *Meso level efficiency* • Health care providers should be stimulated to increase efficiency, i.e. to maximally contribute to desired outcomes given available resources and context (e.g. case mix). Mechanisms like outcome based financing may contribute, but require adequate outcome measurement. *Micro level* • Health Technology Assessment can be used in order to ensure that there is good information available regarding the value for money technologies present, to inform decision making about their use. *Equity in health and health care* • Health care systems should contribute to an equitable distribution of health and health care. Health care is to be distributed on the basis of need. Reducing inequities in health and health care consumption can be an explicit policy goal. *Equity in financing* • Equity in financing of health care can be viewed as contributing on the basis of ability to pay. Proportionality of contributions to the health care in relation to income can be measured. Degree of insurance coverage is also important, as well as for instance level of out of pocket payments. *Avoiding "inequity by disease"* • Specific access to services is increasingly conditioned by the diagnosis of the patient. Inequity by

	disease refers to the phenomenon whereby patients get access to care, which is less or not accessible to patients with the same functional status (equal need for health care) based on their diagnostic label (diagnosis) but with a different diagnosis. In short, who does not have the 'right' disease or condition, has no or less access to care (De Maeseneer J et al., May 2012).

Table 10: Core dimension: Efficiency and Equity

3.3 EFFICIENCY AND EQUITY

In this section some health economic aspects of quality and safety are considered. We focus on efficiency and equity. Note that efficiency can be investigated and addressed at different levels within a health care system: the system level (macro), the organisational level (meso) and the intervention level (micro and nano).[10] Efficiency relates resource use (costs) to outcomes (benefits).

Efficiency

Although this is not uncontroversial, the IOM definition of quality of care includes efficiency as a core dimension. The IOM notes that in an efficient health care system "*resources are used to get the best value for the money spent*". Or as Kelly and Hurst (OECD, 2006) write: "*Efficiency* is the system's optimal use of available resources to yield maximum benefits or results (JCAHO, 1997)". Using this definition, efficiency is therefore not *extrinsic* to quality of care, yet an integral part of the quest for quality.

Given that efficiency in itself already refers to the relation between costs and benefits (or input and outputs), as explained below, some of the other elements (e.g. effectiveness) of quality are also part of efficiency. It needs noting that the different dimensions of quality may sometimes compete (e.g. effectiveness and patient centredness; effectiveness and equitability), which clearly also is the case for efficiency (e.g. versus pure effectiveness, safety or equitability).

Efficiency can mean different things. Technical efficiency refers to a situation in which there is no waste and given goods are produced with the minimal amount of resources. Cost-efficiency broadly refers to producing given goods at lowest costs. Allocative efficiency includes the former two types of efficiency, but also refers to a situation in which those goods are produced, that are valued most by society. In any case, efficiency relates means and ends, resources and outcomes, costs and benefits. This makes it, by definition, a multidimensional concept, hampering its direct measurement. Still, measuring and improving efficiency remains important, since as long as systems, providers or interventions are not fully efficient, increasing efficiency implies that

[10] Note that the OECD uses the terms "macro-economic" and "micro-economic" efficiency." Kelly and Hurst (2006) write: "Macro-efficiency refers to the overall allocation of public and private expenditures in the health system, i.e. is overall health spending at the "right" level? In some of the country frameworks, macro-efficiency is alternatively termed "*sustainability*" or "affordability". Micro-efficiency refers to the value for money realized with available resources, i.e. is the health system as productive as possible in light of the system inputs and desired outputs?" In order to avoid confusion, this terminology will not be followed here since the latter term still refers to the system level.

resources are freed which can be used to achieve better outcomes in terms of health, wellbeing and equity.

In order to make meaningful statements about efficiency of a health care system or a health care intervention, one needs to study both the resources required for that system or intervention as well as the benefits (e.g. health gains, welfare gains) that the system or intervention brings. This is an important but not an easy task, especially not at a system level, where it involves multiple resources as well as multiple outcomes, which need to be traded-off and weighted.

Macro level efficiency

Quality of care can be seen as the outcome of decisions (at different levels) in health care, which are bounded by several constraints, including resource constraints. At the macro-level, the resources consumed by the health care sector can be approximated by health care expenditures. Aggregate health care expenditures are commonly measured (e.g. OECD, 2013), although definitions of health care systems and provisions within systems may differ (although extensive efforts are undertaken to standardise through National Health Accounts). The OECD also provides insight into health insurance coverage for a core set of services (OECD, 2013).

Expenditures can be presented in different ways, for instance as a percentage of GDP or as absolute expenditures per capita[11] (preferably adjusted using appropriate[12] purchasing power parities). In both cases, large differences in spending are observed throughout Europe. Such differences do not indicate differences in efficiency. They merely indicate differences in (financial) opportunities for achieving desired outcomes.

In order to measure efficiency on a system level, health care expenditures (costs) need to be related to health care outcomes. This poses numerous difficulties for several reasons, including the following. First, most of the routinely measured 'outcomes' relate either to treatment results or availability of health care (e.g. number of physicians per 1,000 inhabitants, number of hospital beds per 1,000 inhabitants) or represent intermediate outcomes (e.g. percentage vaccinated children against specific diseases, percentage of women above a certain age screened for breast cancer). While these variables may be informative and signal the need for improvement and policy action,

[11] General expenditures can be broken down in expenditures per sector or disease (e.g. Meerding et al., 1998; Frank and Glied, 2006; Heijink et al., 2008). This can highlight relative spending on diseases, shifts in spending over time, facilitate more detailed system comparisons and analyses of efficiency of different parts of the health care sector (provided adequate outcome measures are available). Such information is now not routinely produced in Europe.

[12] Choice of appropriate PPPs requires attention

ultimate outcomes relate to gains in health (longevity and quality of life) and well-being. Second, if two countries have equal health care expenditures yet different outcomes (e.g. health levels), this does not necessary imply differences in efficiency of the system. Health care is one of the determinants of population health, but clearly not the only one. Differences between countries in terms of, for instance, dietary habits, childhood poverty, smoking habits or environmental factors may result in different health outcomes that are difficult to relate to the functioning of health care systems. Third, in order to make statements about the efficiency of a health care system at the macro-level, the goals of the system need to be clear. For instance, the WHO (WHO, 2000) defined three broad goals: fair financial contributions, responsiveness and health, but it is unclear whether this list is exhaustive and how these goals should be weighted (EXPH, 2014).

At present, systematic attention to macro-efficiency is lacking, as is the required underlying information on (weighted) goals, costs, outcomes and processes. In our view that priority should be given to enriching the informational base throughout Europe, by systematically and uniformly gathering more data on key parameters, which could ultimately feed into an efficiency framework. Moreover, further development of a framework facilitating comparisons of European health care systems remains important, including discussions on health policy goals. Such a framework could be adapted and expanded, allowing more detailed comparisons (e.g. for antenatal care or mental health care). It could also improve our understanding of how system performance relates to aspects like organisation of health care system, incentives, remuneration, etc., facilitating countries learning from each other's experiences and choices.

Moreover, when addressing the issue of macro-efficiency, it should be emphasised that health and health care contribute to wealth. The health care system, through contributing to better health, has an impact on the wider economy (e.g. through increased productivity or reducing the need for informal care), which should ideally be included in assessments of efficiency (EC, 2013a; Usher, 1973; McKee et al., 2009; Figueras et al., 2009; Figueras and McKee, 2012; Suhrcke et al., 2012; Jamison et al., 2013). This remains an underexplored area.

The economic impact of health expenditures and the financial protection of individuals is also important. Financial protection ensures everyone who needs health services can get them without undue financial hardship (WHO 2010). It makes a significant contribution to two key policy goals—efficiency and equity—with welfare gains accruing to individuals, the health system and the wider economy (Moreno-Serra et al 2013). Out-of-pocket payments can cause financial hardship and reduce the use of health services, potentially

contributing to socio-economic differences in health and poverty traps. Financial protection can be measured by estimating the extent to which out-of-pocket spending on health services prevents people from spending on other essential goods ('catastrophic' out-of-pocket spending on health) or pushes them (further) into poverty ('impoverishing' out-of-pocket spending on health) (see below).

Macro level equity

The distributions of financial contributions to the health care sector, health care itself and health play are important to monitor, since equity of health, health care distribution and health care financing are highly important policy goals.

In terms of health equity, this refers to the distribution of health itself in the population. It is well-known that large differences exist between for instance socio-economic groups in terms of (healthy) life expectancy. Measurement techniques for inequities in health (and health care) are available (Van Doorslaer and van Ourti, 2011).

In terms of an equitable distribution of health care, it is often argued whether health care is distributed (consumed) according to need. Inequalities in health care consumption may be entirely appropriate when the need for health care differs between groups, but otherwise it may signal inequities. This can and should be monitored, which is now not routinely and comparably done. (Van Doorslaer and van Ourti, 2011)

It is also important to monitor equity in financial protection. This can be assessed by estimating the incidence and distribution of catastrophic and impoverishing out-of-pocket spending on health care using household budget survey data (Wagstaff and van Doorslaer 2003, Xu et al 2003, Moreno-Serra et al 2013). There are good examples of financial protection analysis in individual EU member states (Võrk et al 2009, Kronenberg and Barros 2014).

Moreover, equitable financing of health care (solidarity) remains important. Different financing mechanisms exist throughout Europe. In many countries, financial contributions towards the health care system aim to ensure solidarity between the rich and the poor as well as between healthy and sick people, but the degree to which differs. Fleurbaey and Schokkaert (2013) write: "*In most societies there is a widespread conviction that health care is not a commodity like other commodities, because health care expenditures are largely imposed on individuals, rather than freely chosen. It follows that the financial burden should not disproportionately rest on those who suffer from illness, i.e. that it should be largely independent of the health risks.*" Fairness in financing the health care

system can be assessed by estimating the proportionality of contributions in relation to income. Methods for doing so have been developed (e.g. Kakwani et al., 1997; O'Donnell et al., 2007), but they are not systematically used in Europe.

Fairness of health care financing, delivery of health care, financial protection and health outcomes remains important to measure and monitor. (EXPH, 2014)

Meso level efficiency

Evidence on efficiency at the meso level within health care systems is scarce as well. Two topics can be distinguished: (i) measuring the efficiency of health care providers and (ii) improving this efficiency using economic incentives.

Regarding the first, it is important to again emphasize that appropriate and available measures of outcome (corrected for contextual factors such as case mix, when appropriate) are required in order to assess efficiency (e.g. Gyrd-Hansen et al., 2012). A large body of literature exists on provider (especially hospital) efficiency (see e.g. Jacobs et al., 2006 and Hussey et al., 2009 for good overviews). While results from several studies suggest marked differences in provider efficiency (and hence room for improvement of quality), Hussey et al. (2009) provide an important cautionary conclusion: "*Efficiency measures have been subjected to few rigorous evaluations of reliability and validity, and methods of accounting for quality of care in efficiency measurement are not well developed at this time*." Good evidence on and systematic use of these tools is lacking.

Regarding the second point, improvement of quality and safety can importantly be influenced at the meso level. One way of doing so, is through improved (financial and other) incentives to and within organisations (e.g. pay for performance measures). Meacock et al (2014) report evidence that pay for performance schemes in the Advancing Quality initiative in the UK were a cost-effective way of improving quality. Other studies have also reported positive effects of financial incentives on quality in specific disease areas (e.g. Karunaratne et al., 2013; Peabody et al., 2013), but others find no evidence (e.g. Shih et al., 2014). More evidence on the impact of pay for performance incentives on quality at the meso level is required, again requiring sound measurement of appropriate outcomes.

Micro level efficiency

Quality, expenditures and efficiency are highly influenced by the interventions (technologies) provided in and organisational features of a health care system (e.g.

Cutler, 1995; Cutler and McClellan, 2001; Smith et al., 2009). In essence, health technology assessment tools were designed to inform health care decision makers about the costs of interventions and their contribution to health care goals. Economic evaluations, often taking the form of cost-effectiveness or cost-utility studies, form an important component of health technology assessment (e.g. Drummond et al., 2005). The evidence on and use of cost-effectiveness of health care interventions is growing (Allen et al, 2013). However, much emphasis has been put on assessing the cost-effectiveness of pharmaceuticals, while other interventions (e.g. public health, medical devices, mental health programs, long term care) have been evaluated less systematically and the methods for doing so, for instance in the long term care sector, are not always available (e.g. Makai et al., 2013). Moreover, there are clear differences between countries in selecting interventions for funding / inclusion in basic benefits packages (Allen et al., 2013).

EUnetHTA (www.EUnetHTA.eu) attempts to bring different HTA agencies together and learn from each other, but large differences exist in (i) which criteria are considered important and (ii) how these criteria are operationalised and (iii) how assessments are used in policy making. The Health Basket project indicated important differences between in this respect (Schreyögg et al., 2005) and these still persist. These differences relate to the criteria used for selecting technologies for funding (some do not consider efficiency), the methodology used in measurement, the transparency of the decision making framework and process, as well as the policy tools (practice guidelines, price negotiations, etc.) for using HTA results (e.g. Claxton et al., 2002; Rutten et al., 2005; Franken et al., 2013). Further harmonization is useful in light of current differences in policy context and methodology. The Expert Panel considers systematic and institutionalised use of economic evaluations in health care decision making (e.g. funding decisions or medical guidelines) as a quality indicator of health care systems/organisations (which may be seen as a process quality indicator).

Improving quality

The value added of improving health care quality is almost self-evident, given the broad definition used here. On a macro-level, by improving quality, higher outcomes (in terms of health, wellbeing, and/or equity) may be attained at similar levels of costs or similar achievements would be possible at lower costs. On a meso- and micro-level, the position is analogous.

Note that in general, higher outcomes are attained through higher spending. This can still be efficient (and involve a potential increase in quality), as long as the benefits attained

exceed the additional costs. Such evidence is easier to obtain on a micro level, in controlled settings, but also on the macro level evidence suggests that, in general, increased health care spending in the last decades has contributed to health increases in a cost-effective way (e.g. Cutler et al., 2006; Cutler and McClellan, 2001; Moreno-Serra and Smith, 2012). However, this evidence is limited and requires (strong) assumptions on the contribution of health care to increases in health. Newer developments, such as the use of registries to measure and monitor the efficiency and quality of care (in daily practice), can help to build the evidence base for quality improvement.

Quality can also be improved in combination with lower costs of care, for instance through avoidance of unnecessary and inappropriate care use, which does not result in health gains yet increases costs. An example is the avoidance of re-hospitalisations because of wound infections. There are many examples of waste/inappropriate use of medical resources (e.g. Fasola et al., 2014; Shipman and Sinsky, 2013). However, while reducing waste is a clear goal, it is often unclear how exactly to cut out (only) the waste (and how cost-effective measures to reduce waste are). In a broad sense, evidence is lacking on cost-effectiveness of quality controls and inspections. Moreover, other ways of improving outcomes (e.g. investing in professionalization) may be more efficient.

The fact that the use of efficiency indicators at the micro level is not common practice in different European countries and that its use is not systematic across health care interventions, is an important call for policy action. Not only to steer optimal investments in health, but also, if required, to select areas for disinvestment (for instance due to budget cuts) that save money at minimal health costs.

It is crucial to define appropriate outcome measures in order to be able to judge efficiency and quality. At present, a common set of relevant outcome indicators is lacking, which hampers measurement of efficiency and quality. These may include health measures like (avoidable) mortality and quality of life, but also aspects of equity, patient satisfaction and process indicators like timeliness. Moreover, elements like the validity of measurement, timing of measurements, comparability across settings, etc are important to consider.

Safety

Safety (e.g. avoiding accidents in hospitals, wrong prescriptions, infections, contamination through unsafe blood products, health damaging implants) is an important goal and much effort is focused on increasing safety. (Effective) safety measures contribute to health and may also be considered to be a valued element of a responsive

health care system (i.e. a process indicator). While important, safety measures should be evidence based – i.e. having been shown to be effective and cost-effective, this is not always the case.

Moreover, some safety measures may be considered very expensive in relation to the health they preserve (i.e. not cost-effective by common standards – e.g. Custer and Hoch, 2009). Where such high costs are accepted, this may partly be explained by loss aversion (the fact that harm caused by the health care sector receives more weight in health care decisions than similarly important benefit) and the fact that all patients may benefit from the 'feeling of safety'.. This deserves more attention in research. Other safety measures (e.g. those avoiding hospital acquired infections) may have the potential of producing (health) benefits while lowering costs at the same time – for instance through reducing length of stay. This also indicates that safety measures do not necessarily improve quality.

3.4 QUALITY OF CARE IN THE CONTEXT OF CROSS-BORDER CARE IN EUROPE

The quality agenda as it relates to cross-border care in Europe has two aspects. The first is the extent to which a patient can be assured of high quality care if they are receiving that care within a different Member State. This raises questions about the use of terminology (for example, what do terms such as licensing and registration of physicians mean in different Member States), standards, and regulatory systems. The second is whether the quality of care can be ensured for patients whose care involves elements that take place in two or more member States. This raises questions about communication and co-ordination of processes in each Member State. Each of these issues can be considered in terms of the various elements that are required to deliver care. These are human resources, such as health workers, physical resources, such as pharmaceuticals, technology, and facilities, and knowledge resources, such as guidelines. An overarching element is the availability of information for patients who may be receiving care in another Member State, including the use of European Reference Networks.

3.4.1 Legal framework

In 2011, the European Parliament and the Council of the European Union (EU) adopted the Directive 2011/24/EU on the application of patients' rights in cross-border health care (European Union, 2011). The aim of the Directive is to lay down rules to facilitate access to safe and high-quality cross-border health care within the EU, as a means of enabling patient mobility in accordance with the principles of the existing case law, and to encourage cooperation between Member States in the field of health care, while fully respecting Member States' competence in the organisation and delivery of services. The process of agreeing the Directive was long and complex, reflecting the different situations to which it would apply and the challenges involved in balancing harmonization of processes while respecting the rights of Member States to manage their systems (Legido-Quigley, Glinos et al., 2012).

The Directive applies to individual patients who seek health care in another Member State than the Member State of affiliation. However, the Member State of affiliation can restrict reimbursement of cross-border health care reasons related to the quality and safety of health care.

In practice, the vast majority of health care is obtained in the patient's own Member State, close to their place of residence. Indeed, it has been suggested that the Directive is, to some extent, a solution in search of a problem and there are concerns that vested

interests, who would benefit from the opening of markets in health care, are exploiting concerns about patients' rights to travel abroad, thereby introducing competition for domestic health care providers, are exaggerating the scale of actual or potential flows. Indeed, in some short-lived examples, such as arrangements for patients from the English NHS to obtain care in France, Belgium or Germany, the purpose was explicitly to inject competition into the domestic system and, once this competition was created by measures to encourage domestic private providers to enter the market, the initiative ceased.(Rosenmöller, McKee et al., 2006) Yet, while it is essential that the response to cross-border care is kept in proportion, there are issues that need to be addressed.

The most important issues arise from a fundamental tension in the legislation. The Directive, like European case law, is based on the principle of mutual recognition, whereby services provided in one Member State are deemed equivalent to those provided in another, subject to meeting certain criteria (Legido-Quigley and McKee, 2010). In many areas of cross-border activity, such as trade in agricultural products, the criteria are extremely tightly specified, encompassing size, colour, means of processing and much else. In health care in contrast, the criteria are minimal, with medical education specified simply as hours of study completed rather than the possession of particular competences. This minimalist approach reflects the political imperative to respect the right of the member States to organise their health systems in ways that they see fit, but it does create considerable challenges when seeking to ensure that patients crossing borders can be sure of obtaining high quality care.

The next sections examine quality in relation to the main elements of care.

3.4.2 Elements of health care

Health professionals

Can a patient obtaining health care in another Member State be assured that the health professional treating them has the appropriate skills and expertise to deliver high quality care? This question is concerned with the processes by which the professions are regulated in each Member State. This issue has been examined in most detail in relation to doctors.

The qualifications necessary to be considered as a health professional, and thereby to obtain the right to practice in another Member State, were first set out in a Directive of 1975, with subsequent revisions. This simply specified the number of hours of training to be completed. A series of high profile cases, where doctors who have moved from one Member State to another and have been involved in serious incidents causing harm to patients stimulated a revision to the legislation, agreed by the Council and Parliament in 2013. This will establish a European Professional card, containing details of the doctor's qualifications, an alert mechanism to ensure that regulatory authorities are aware of cases of malpractice and disciplinary proceedings, and the ability for the Member State receiving the doctor to establish their language competence.

One immediate problem relates to the terminology that is used. *Licensing* has been defined as "the process of authorization or authenticating the right of a physician to engage in medical practice, its monitoring (regulation) and renewal or extension" (Rowe and García-Barbero, 2005). The same source defines *registration* "as all the processes associated with the issuing of licenses/authorizations to practice medicine and ensuring that the professional activities carried out under this authority maintain the professional standards on which it is based". These definitions display considerable overlap and, as a recent study showed, in practice, the two are used in different ways in different Member States (Kovacs, Schmidt et al., 2014). There is also considerable variation in the duration of registration and/or licensing, the procedures required to complete these processes, the eligibility of those applying (with some countries having bi- or multi-lateral arrangements that reflect historical ties with other countries), and even the availability of registers for public scrutiny.

A second issue relates to the establishment of whether a doctor remains fit to practice. In some Member states, some or all doctors must undergo regular assessments of their competence. By far the most extensive, in terms of its depth of assessment and its breadth, covering all licensed medical practitioners, regardless of whether they have any patient contact, is in the UK. However, many other countries have no system in place, assuming that once a doctor is registered they will ensure that they remain fit to

practice, while others have systems in place for specific groups, such as general practitioners in The Netherlands.

A third issue relates to the response to doctors whose behaviour calls into question their ability to practice. Again, the arrangements in place vary enormously. A recent study in which regulatory authorities were asked how they would respond to vignettes describing actions by doctors, including those that related to patient safety, clinical competence, probity, and other behaviour that while not related to their clinical practice might cast doubt on their judgement or integrity demonstrated a very wide range of responses, including whether the action would be considered at all by anyone, whether the professional regulator, employer, or professional association, and what sanctions would be imposed.(Risso-Gill, Legido-Quigley et al., 2014)

Although most of the research so far has been undertaken about doctors, it is highly likely that the same issues apply to nurses and other professional groups.

Given the very different views of professionalism in different Member States, which have been characterised as lying on a spectrum from state medicine, where the doctor's behaviour is regulated by the statutory authorities, to the idea of the liberal professions, whereby it is the sole responsibility of the professions to regulate themselves, it is not realistic to think that it will be possible to harmonise procedures within the EU. However, there is clearly a need for much greater clarity on the processes that are in place and the implications for quality of care.

The foregoing discussion assumes that there are health professionals available to provide care. However, worldwide, there is a severe shortage, especially of doctors and nurses. EU Member States are failing to train enough health professionals and, in many of them, previous assumptions about the numbers needed to sustain the workforce have been found wanting as unexpectedly high numbers take early retirement. The situation is especially problematic in many of the new Member States, many of whose health professionals have taken advantage of free movement to relocate to Western Europe. However, these highly skilled workers face few barriers to mobility globally, such is the demand for their skills. It has been estimated that the USA alone will need to recruit 130,600 overseas trained doctors by 2025 and 808,000 nurses by 2030[13]. An effective response is complicated by the limited amount of work that has been undertaken to estimate future health workforce needs and to plan accordingly. However, there are now a few efforts to address this gap, such as the EU Joint Action on Health Workforce

[13] http://www.kingsfund.org.uk/time-to-think-differently/trends/professional-attitudes-and-workforce/international-flows

Planning & Forecasting[14] while a number of civil society organisations have come together to create Healthworkers 4All[15] to promote a sustainable global health workforce.

Pharmaceuticals and medical technology : ensuring quality in each Member State

Can patients crossing borders within Europe be assured that the medicines they are prescribed are of adequate quality?

Medicines regulation

Unlike the situation with many of the other inputs to health care, the regulation of medicines within the EU is clearly specified. The European Medicines Agency (EMA) was established in 1995 and there are now two mechanisms by which a medicine can be authorized for use within the EU. The first is the centralised scheme, whereby the application is submitted to the EMA. The second is a decentralised process whereby the application is made to a national regulatory body, enabling regulatory bodies in other Member States to accept this authorization under the principle of Mutual Recognition.

The main issue in relation to quality relates to the transparency of the process. The group alltrials.net has raised serious concerns about the refusal of the EMA to make available the data on which it bases its decisions, a refusal that the EMA has sought to justify on grounds of commercial confidentiality, an approach that it has persisted with even though the EU's Ombudsman has called for the release of data on adverse reactions to certain medicines. In response to widespread criticism, the EMA is progressively implementing a new, more transparent approach to data sharing but concerns about the extent and pace of openness remain.

Medicines reimbursement

Efficiency is one dimension of quality. Allocative efficiency exists where the best possible use is made of existing resources. The increasing cost of certain pharmaceuticals, some of which offer limited health gain, has led some Member States to put in place systems to assess the cost utility of new medicines. Public authorities can then compare new products on the basis of, for example, cost per quality adjusted life year (QALY). One of the best known examples is NICE in England. However, its decisions are sensitive to both the immediate costs of new products and the indirect costs involved in developing models of care to deliver them. There is considerable scope for extending this approach into other Member States and, especially in the case of the smaller Member States that

[14] http://euhwforce.weebly.com/
[15] http://www.healthworkers4all.eu/gb/home/

cannot hope to replicate the infrastructure required, to examine the scope for possible European collaborative models.

Safety of medicinal products

In many parts of the world it cannot be assumed that a pharmaceutical product obtained from a pharmacy is safe or effective, even though it may be packaged and presented as an authorised medicine. There are two reasons why this may be so (Attaran, Barry et al., 2012). The first is that it may have been manufactured or stored in conditions that led to it containing inadequate active ingredient or becoming contaminated. The second is that it may have been deliberately falsified, in other words that it is counterfeit. Both have important consequences for quality of care, posing a risk of poisoning or inadequate treatment. Where the product is an antibiotic, a further problem arises as there is a risk of accelerating the development of resistant micro-organisms. Both cases are covered by consumer safety legislation, although there is as yet no co-ordinated international action against the criminal trade in deliberately falsified drugs, analogous to that covering illegally produced banknotes. These issues should not be confused with a third category, medicines that are manufactured and packaged in ways that imitate products lawfully on the market, both branded and generic, but which are manufactured so as to replicate the composition and formulation of the original product. This category raises issues of intellectual property but not quality and safety.

Medical technology

The quality of medical technology within Europe is governed by general product safety legislation. However, as innovative technology has an opportunity cost, as is the case with medicines, it is important to ensure quality that what is procured is cost-effective. In 2004 the Commission and Council identified the importance of European collaboration on health technology assessment (HTA). As a result, EUnetHTA was established, seeking to create a sustainable network for collaboration on HTA across Europe. EUnetHTA is a voluntary collaboration of European HTA organisations that shares knowledge on HTA and promotes good practice in the conduct of HTA.

Pharmaceuticals and medical technology: continuity of care across borders

According to the Directive on the application of patients' rights in cross-border health care, a patient who has legally been prescribed a medicine in one Member State should be able to have that prescription dispensed by a pharmacist in another Member States, as long as it is authorised there (Art 11). Restrictions on the recognition of individual prescriptions are prohibited unless limited to what is necessary to safeguard human

health or based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription. Medicinal products subject to special medical prescription are not regulated by the Directive.

Even though a "long-list" of possible cross-border prescription elements was proposed in 2011, it was only in 2012 that the Commission used an implementing act to require prescriptions that are issued upon the request of a patient who intends to have the medicines dispensed in another Member State should contain a minimum non-exhaustive set of elements - including professional qualifications and contact details of the prescriber - to recognized abroad (the so-called "cross-border prescriptions"). Additionally, with some exceptions, these types of prescriptions should be written using international non-proprietary names (INN)[3].

A recent survey completed by nearly 1000 pharmacists in seven Member States dealing with foreign prescriptions for eight pathologies found that 55% of patients would have faced difficulties in getting prescribed products dispensed in another country. The key challenges that emerged from the study were the verification of the prescriber, exacerbated in handwritten prescriptions, language barriers, and missing information. These concerns were also identified in a "shopping experiment" carried out in 2011 and 2012. Belgian and Finnish prescriptions were presented in pharmacies in different Member States in order to assess whether pharmacists would dispense the prescribed product. Products were dispensed in fewer than half of cases.(San Miguel, Baeten et al., 2013)

Telehealth and telecare

Advances in electronic communications have enabled patients in one Member State to be diagnosed and treated by health professionals in another Member State by means of telehealth and telecare. A systematic review was conducted of studies that described the use of telehealth and telecare to deliver cross-border health care and identify the factors that hinder or support its implementation.(Saliba, Legido-Quigley et al., 2012) Ninety four papers were included in the final analysis. They involved 76 countries worldwide, most involving collaborations between high and low or middle income countries. Most described services delivering a combination of types of telehealth and telecare but specialties most represented were telepathology, telesurgery, Emergency and trauma telehealth and telecare and teleradiology. Most link health professionals, with only a few linking professionals directly to patients. A main driver for the development of cross-border telehealth and telecare is the need to improve access to specialist services in low and middle income countries and in underserved rural areas in high income countries.

Factors that hinder or support implementation clustered into four main themes: (1) legal factors; (2) sustainability factors; (3) cultural factors; and (4) contextual factors.

A qualitative study of a teleradiology clinic in Barcelona, offering services to hospitals in a range of European countries, was undertaken to identify the challenges faced in providing such a service.(Legido-Quigley, Doering et al., 2014) It identified the need for a clear legal framework to govern such services, especially in relation to areas such as redress and liability and comparability of clinical governance arrangements. For example, patients in Sweden benefit from a no-fault compensation scheme when treated by domestic providers but this does not extend to providers established abroad. In other areas there is a European legal framework, such as data transfer, but one Member State, the UK, insisted on additional, highly complex provisions.

These studies provide a basis for further legal clarification to ensure quality and safety.

Ensuring overall quality of care in another Member State

Quality assurance activities

Can a patient obtaining treatment in another Member State be assured that there are systems in place to ensure overall quality? The Directive directly refers to quality and safety in several Articles. Article 4 states that cross-border health care is provided in accordance with the legislation of the Member State of treatment, the European Union legislation on safety standards, and the standards and guidelines on quality and safety laid down by the Member State of treatment. However, a comprehensive review of systems to ensure quality in Member States, undertaken within the EU-funded Europe for Patients project, found that there was little information on systems in place in many member States and those that were often had been implemented on a small scale and had rarely been subject to evaluation.(Legido-Quigley, McKee et al., 2008; Legido-Quigley, McKee et al., 2008)

Member States of treatment should ensure that health care providers provide quality and safety information. The Member State of affiliation may refuse to grant prior authorisation where it has grounds to believe that the patient would be exposed to safety risks or where the cross-border health care would be provided by a health care provider about which there are concerns in terms standards and guidelines on quality of care and patient safety (Art 8). A cross-sectional survey of cardiology departments in 315 hospitals in the Czech Republic, France, Poland and Spain showed that although certain quality and safety requirements are frequently met (administrative support or informed consent using forms in various EU languages) others are largely absent (existence of case-managers, communication with patients' general practitioners). (Groene and Sunol,

2010) Additionally, communication problems meant that patients were poorly informed about their condition and treatment. The EU funded study "Methods of Assessing Response to Quality Improvement Strategies" (MARQuIS) on cross-border care explored the quality improvement strategies in health care systems across the European Union (EU). Data from 389 acute hospitals in eight Member States found that structures and processes to ensure safety were generally well developed but there was considerable variation in the implementation of mechanisms to promote patient safety such as electronic prescribing systems.

Guideline development

One means of improving quality of care involves the development and implementation of evidence-based guidelines. A recent survey found that most Member States have some system in place to develop clinical guidelines, with processes taking place at national, regional and local levels.(Legido-Quigley, Panteli et al., 2012) However the processes used vary greatly, especially in respect to the explicit use of evidence and the transparency of the process. Only a very few Member States, such as Latvia, place guideline development on a statutory basis. However, some have national, or in the case of NICE, which covers only England within the UK, sub-national bodies responsible for guideline development while in others, such as France, national bodies provide overall guidance on guideline development. Although there is widespread acceptance of the value of the AGREE instrument, which set out criteria for assessing guideline quality, it is only used to a limited extent while a few Member States have adopted similar instruments. Several member States do not have any mechanisms for assessing guideline quality.

A related study undertook a systematic review of studies of implementation of guidelines in member States.(Brusamento, Legido-Quigley et al., 2012) It identified only 21 studies. Few examined the cost of implementation or outcomes of care. It was concluded that there was a need for a substantial expansion of research on strategies to implement clinical guidelines in Europe.

A further systematic review examined those studies that have used the AGREE instrument to assess the quality of clinical guidelines in Europe, identifying nine studies that had assessed 28 guidelines.(Knai, Brusamento et al., 2012) The main weaknesses identified were in areas of editorial independence, stakeholder involvement, and rigour of development. The authors concluded that there was considerable scope for improvement.

A reflection should be added about the relationship between "guidelines" and "multi-morbidity". Nowadays, as multi-morbidity becomes the rule rather than the exception, we are confronted with the need for a paradigm shift in patients with multi-morbidity.

Yearly, implementing the disease specific guidelines, will lead to contradictions in patients with multi-morbidity (e.g. a patient with COPD and diabetes: when using corticosteroids for COPD, this will worsen the diabetes). Moreover, there is a fundamental "intellectual" problem when applying these specific guidelines to patients with multi-morbidity as the evidence that underpins the guideline, comes from RCTs where "patient with co-morbidity were excluded". These fundamentally questions the use of those guidelines in patients with multi-morbidity. Therefore, a paradigm-shift from "disease-oriented" towards "goal-oriented care" is needed (De Maeseneer J et al., Jul 2012).

Ensuring overall quality of care in when crossing borders

Continuity of care

Several articles in the Directive relate to continuity of care for patients crossing borders. Thus, the Member State of treatment should ensure continuity of care by providing patients the access to a written/electronic medical record of such treatment (Art 4); the Member State of affiliation, where a patient has received cross-border health care and where medical follow-up is necessary, should provide the same medical follow-up as it would have been if that health care had been provided on its territory (Art 5); prescriptions issued in another MS should be recognised, under certain conditions, "in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment" (discussed above).

Discharge from hospital can be a challenging time for patients, particularly for patients who have received care abroad[1]. The EU funded "MARQUIS" project called for a standardised European discharge summary and the EU funded project "HANDOVER" found many problems in the discharge process within countries, attributed to a deep focus of hospital providers and a low priority attributed to the provision of comprehensive discharge summaries. HANDOVER depicted that the amount and quality of information provided to patients, families, and primary care providers was often insufficient.(Hesselink, Flink et al., 2012; Hesselink, Vernooij-Dassen et al., 2013) Additionally, discharge summaries within EU countries vary greatly. Indeed, while some countries propose national standards or suggest minimum data requirements, others propose a standard form for all electronic discharge summaries or a set of national standard headings for the structure and content of clinical records including discharge summaries. As presented in the conclusions of the opinion, a European harmonised discharge summary has been recently suggested.

Health professionals report limited knowledge of processes that might support continuity of care across borders. (Glonti, Hawkesworth et al. (in press)) There are, however, examples of good practice that can be learned from, such as the provision of dialysis

services to tourists visiting the Veneto Region of Italy, the subject of a recent case study.(Footman, Mitrio et al. (in press))

Obtaining information

One of the crucial elements of the cross-border Directive is the empowerment of patients to make informed choices when seeking health care abroad. Consequently, it makes provision for the establishment of national contact points (NCPs) that will provide potential patients with clear information on their rights to seek treatment across Member States, as well as the information they need on quality and safety standards enforced in the country of interest and any specific medical, organisational and financial aspects of the health care services and the treatment options on offer. Two recent studies are relevant to NCPs. A study of the experiences of German patients choosing hospital care abroad found that most (49%) obtained information from health care professionals on health-related (hospital performance and professional qualifications), and financial issues (coverage of costs by insurers and reimbursement mechanisms). The second study evaluated the quality of information on NCP websites (Santoro et al, in press). It found that the websites that do exist provide much of the information required, including quality and safety standards as well as information on patients' rights and entitlements, complaints procedures, and mechanisms to seek remedies and to settle disputes. However, not all Member States have created websites and some of those that do exist lack key information.

European Reference Networks

The Commission supports Member States in the development of European reference networks that can provide highly specialist care for patients with rare diseases. A prerequisite is the compilation of the criteria and conditions for the establishment and evaluation of reference networks and health care providers in it.

It is possible to learn from experiences of existing bilateral collaborations. One such example is the longstanding Malta-UK collaboration that enables Maltese patients access to highly specialized care that is not available locally. A study using interviews with policy makers, clinicians, and parents of children obtaining treatment identified four factors that facilitated implementation of what was considered a successful programme: long established personal relationships; communication and data sharing; shared care approach; and well established support systems. The key challenges are logistical, financial, communication and cultural and psychological (Saliba, Muscat et al., 2014).

Health services in border regions

The Directive encourages Member States to conclude agreements among themselves that enable co-operation in health care provision in border regions. Information and communication technology (ICT) is identified as a key pillar to strengthen such cooperation across countries. Member States are also requested to ensure that information on the right to practise of health professionals listed national registries is made available to other Member States. Mutual assistance should be boosted also in relation to the exchange on information referred to standards and guidelines on quality and safety.

Given that patient mobility in border regions concerns mostly secondary care the Directive focuses on hospitals. A recent publication investigating strengths and weaknesses of hospital collaborations across borders identified several concerns.(Glinos and Wismar, 2013) The solutions adopted were often extremely complex as the facilities in each member State remain are anchored in their domestic health systems and authorities tend to prioritise domestic solutions to service provision. Moreover, benefits are often stakeholders-oriented rather than patients-oriented and, in some cases, the role of the EU was perceived to be marginal.

3.5 INFORMATION NEEDED. ASSESSING QUALITY INDICATORS

Member States and European Union have developed information systems capable to offer ample information for institutions, professionals and patients, to monitor health care quality.

Some initiatives have been performed till now: OECD-Health Care Quality Indicators Project (HCQI), European Community Health Indicators (ECHI), WHO-European Health-For-All Database (HFA-DB), Social Protection Committee Indicators, Eurostat indicators, etc. Health Care Quality Indicators Project is an integral part of the activities of the EU in the areas of health indicators and health systems. The objective of HCQIP is to establish international definitions on a limited number of recognized quality indicators and to identify additional evidence-based quality indicators. The EU Commission provides financial support for HCQIP.

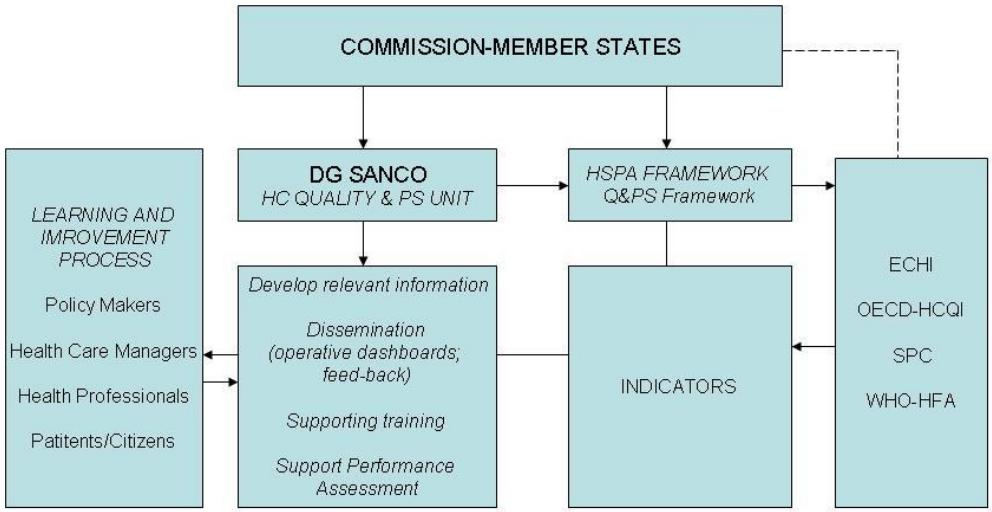
The selection criteria for good indicators have been suggested by several authors. The Expert Panel adopted the definition by Mainz (Mainz J, 2003). The key characteristics are stated as follows: first of all an indicator should be based on agreed definitions, and it should also be described exclusively and exhaustively; it should be highly specific and sensitive, valid and reliable; it should discriminates well and be related to clearly identifiable events for the user; it also should permit useful comparisons and be evidence-based.

DG SANCO promoted a study on "Evaluation of the use and impact of the European Community Health Indicators by Member States" (August 2013). Among its conclusions the report stated that there is a general consensus on having a system of European Indicators like ECHI in place (page 10). The report also stated that it is necessary to review the management (from "project-based" to "institutional-based") and to reinforce its financial stability.

In another context, a report by the Committee on Quality Measures in the US (IOM 2013) recommended the adoption of a logic model or conceptual framework to help identify loci for measures; the adoption of a set of recommended criteria to select measures of quality; a system to manage measures and an entity to endorse measures of quality for the multisectoral health system.

On the other hand, if the development of indicators is important, it is also important to develop the capacity to create information and operative tools useful for different stakeholders (policy makers, managers, health professionals, patients and citizens). Building information systems, such as patient's registries, post-market efficacy studies for assessment of risk benefit, or comparative (relative) effectiveness research, are needed for assessing quality.

DEFINITION AND DEVELOPMENT OF INDICATORS



EXPH, 2014

The EXPH considers that

a) It would be useful to develop a Health System Performance Assessment Framework at EU level, in order to better identify the dimensions and quality measures required.

b) At the same time it seems convenient to define the institutional structure responsible for the management of the Information of Health Systems at EU level.

The EXPH believe that the Commission should lead an initiative to define with MS a Framework for HSPA, including quality of care and patient safety, and a common and comprehensive set of indicators, based in ECHI, SPC-Health indicators or OECD-HCQI.

The Commission should also define through which structure the information system should be managed (elaboration of information, dissemination, support training and motivation of health professionals and decision makers to benefit from the use of the Framework and the information system, support performance assessment, etc).

Proposal for additional indicators.

In the process of elaborating this Opinion we have identified certain aspects that, being important for Health Quality measurement, seemed not sufficiently covered by the forementioned set of indicators.

The EXPH suggests that, after the EU decides the managerial structure for the health information system, indicators to measure these further aspects should be defined and developed.

For those indicators listed below and followed by an asterisk, an international benchmark could be identified. Indicators without an international benchmark have also been considered because of their relevance to the mandate.

1. Process indicators

PATIENT SAFETY

- Are patient safety strategies or programs in place?* (SANCO reports to Council 2012/2014)
- Is there established and functioning an adverse events information system?* (see: PSQCWG subgroup report (1) 2014)

APPROPRIATENESS

- Proportion of professionals that attend continuing education programmes on a regular basis, including patient safety*
- Proportion of centres/professionals that adhere to appropriate (up-to-date evidence based) clinical guidelines
- Proportion of Health Care centres/professional assessed through systematic processes

PATIENT-CENTREDNESS

Respect

- Percentage of patients who feel they were treated with respect in their interaction with the health care system/ organisation

Information and communication

- Proportion of patients who declared they were given the right amount of easily understandable information to enable them to participate actively in medical decisions.
- Proportion of patients and families who are able to comprehend the information and instructions given to them in relation to discharge or transfer to other care institutions

Access to care and responsiveness

- Evidence that a mechanism to capture patients' and families/ carers' feedback is in place and is used as learning and improvement resource.

Continuity and transition of care

- Proportion of patients/families who experience the care process as being "joined up" according to their needs

Patient choice and empowerment

- Proportion of patients with chronic conditions who actively participate in the development of a treatment plan focusing on their goals (in terms of quantity and quality of life) with their health care provider
- Assessment of availability of professional-led, or peer-led, education/training programmes for patients to enable them participate in decisions relating to their

health and care, and to support self-management of chronic conditions.

Patient/Citizen involvement in health policy at all levels

- Patient and Patient Organisations meaningful participation in planning, management and regulation of health services

2. Outcome indicators

PREVENTING PEOPLE FROM DYING PREMATURELY

Babies and young children

- **Neonatal mortality** rate is the number of neonates dying before reaching 28 days of age, per 1,000 live births in a given year*
- **Infant mortality** is the death of a child less than one year of age*

Cardiovascular disease

- **Mortality rate from cardiovascular disease** in people under 70 years of age*

Respiratory disease

- **Mortality rate from respiratory disease** in people under 70 years of age*

Liver disease

- **Mortality rate from liver disease** in people under 70 years of age*

Cancer patients

- **Five years survival from all cancers**. In additions specific data on cancer survival in children (under 15 years of age), in breast cancer, in prostate cancer, in lung cancer and in colorectal cancer should be collected*

Psychiatric disease

- **Mortality rate in people under 70 years of age, who have a diagnosis of a serious mental illness***

Elderly people

- **Life expectancy at 75 years of age** (the life expectancy of both males and females should be monitored)*

ENHANCING QUALITY OF LIFE FOR PEOPLE WITH LONG-TERM CONDITIONS

- **Proportion of patients that feel supported in managing their chronic condition** in a national/European patient survey
- **Employment of people with long-term conditions** (separate analysis on the employment of people with mental illness should be included)*
- **Emergency-based hospitalisation for chronic ambulatory care sensitive conditions** (both in adults and in children with chronic conditions)*

HELPING PEOPLE TO RECOVER FROM EPISODES OF ILL HEALTH OR FOLLOWING INJURY

- **Emergency admissions within 30 days of discharge** from hospital*
- **Total health gain as assessed by patients for elective procedures** (hip replacement, knee replacement, cholecystectomy, cataract surgery)
- **Functionality independence measure at discharge and 6 months after severe trauma***
- **Functionality independence measure at discharge and 6 months after stroke***
- **Functionality independence measure at discharge and 6 months after fragility fracture***
- **The proportion of elderly patients (over 75 years) who are offered rehabilitation** following discharge from acute or community hospital

ENSURING THAT PEOPLE HAVE A POSITIVE EXPERIENCE OF CARE

- **Patients experience of service/care with FFT*** (indicator on positive experience of care is also included under "patient-centredness" section)

TREATING AND CARING FOR PEOPLE IN A SAFE ENVIRONMENT AND PROTECTING THEM FROM AVOIDABLE HARM

- Patient safety **incidents reported***
- Safety **incidents involving severe harm or death***
- **Hospital deaths** and the hospital deaths attributable to problems in care*
- **Deaths from venous thromboembolism** (VTE) related events*
- Incidence of **health care associated infection** (HCAI) (MRSA, C. difficile)*

EFFICIENCY AND EQUITY INDICATORS are listed in section 3.

1582 **3. Economic indicators**

EFFICIENCY

Outcomes (see WG outcomes)

Responsiveness (see WHO)

- Timeliness of treatment (waiting lists and waiting times)
- Patient satisfaction

Expenditures

Health care expenditures

- %GDP, per capita spending (€PPP)*
- Public spending on health as % GDP
- Public spending on health as a share of public spending
- Public as % total spending on health
- OOP as % total spending on health
- Break down per sector/disease
- Process: good accounting practice – NHA

Financial protection

- The incidence of catastrophic and impoverishing out-of-pocket payments

Equity

- Distribution of (healthy) life expectancy (according to socio-economic characteristics)
- Distribution of health care utilization across relevant (socio-economic) groups (in relation to need)
- Distribution of catastrophic and impoverishing out-of-pocket payments across socio-economic groups
- Distribution of health care financing mechanisms (Kakwani index)

MESO LEVEL
• Link between payment and outcome at meso level • Process: quality measurement and audits
MICRO LEVEL
• Systematic use of cost-effectiveness analysis in funding and guidelines

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3.6. PROPOSED ACTIONS AT EU LEVEL

The 21st Century is confronting health systems with new (and not so new) challenges, and with new opportunities. Economic crises, epidemiological trends, cultural changes, technological revolutions, etc., are posing risks and creating possibilities to maintain and improve European Health Systems. One of the four common values of our Health Systems is access to high quality and safety services.

Since health-care costs, quality, and outcomes vary widely, there is enormous potential for European research into health systems to enable countries to make their systems more efficient and to improve outcomes. Research into these issues can make important contributions to national policy development and bring improvements even in highly cost-constrained health systems. Research priorities for Horizon 2020 seem to neglect research questions considered very important by health policymakers and leaders at a national and European level, such as the quality and safety of health care, the financial sustainability and productivity of health systems, innovations in health-care organisation and delivery, the effectiveness and efficiency with which health-care interventions are used, and the health-care workforce.

The EU Commission could play a crucial role in boosting the improvement of the quality of health care and the safety of patients. Specifically, the EXPH identified a list of actions to be taken at EU level leading to an improvement of the core dimensions of the quality of health care which, in turn, reflect into benefits of the overall framework. The EU could support these initiatives, giving "high-priority" to the key interventions (listed as "HP"). Broadly, EU proposed actions could be focused on:

0. The utilization of a comprehensive conceptual framework in relation to quality and safety
1. Guideline development and the sharing of good practices
2. Funding research related to quality and safety
3. Economic issues related to the defined quality dimensions
4. Education and training in their new roles for both patients and health professionals
5. Information technology and information systems significant for health quality and safety
6. Quality and safety aspects of the burden of chronic diseases and inequalities in health
7. The HTA network; increasing attention for Health System Impact Assessment
8. Miscellaneous recommendations

Guideline development and the sharing of good practices

- HP: To establish an EU Health Care Quality Board (Management/Team) for the coordination of all EU initiatives in HCQ.
- HP: to establish a Health System Performance Analysis Framework at EU level to facilitate comparison of health policies and their impact on different dimensions of health systems.
- HP: to initiate a process at EU level (perhaps via the PSQCWG) aimed at persuading Council to make a Recommendation on health care quality similar to the one that it made on patient safety in 2009.
- HP: to develop and promote European guidelines and checklists for similar conditions across EU MS and regions to ensure common approaches and procedures (for example as in the GRADE project.).
- To promote the inclusion of economic evidence into medical guidelines.
- To promote further research on the interprofessional transferability of good practices (for example as in WP3 of the EMPATHIE project).
- To support research into the impact of good practice repositories (as for example is being developed within the EIP on AHA).

Funding research related to quality and safety

- HP: to promote further research on the potential economic benefits of a patient centred approach.
- HP: to support further research on the redesigning of health systems aimed at responding to current challenges within and outside of health systems (in line with current themes within the Horizon 2020 programme).
- To support research on the expectations of patients and their fulfilment, evaluating the patient experience in the context of the "patient journey".
- To support research into defining patient centred health care including the development of indicators for use by MS to assess the level of patient centredness in their health care systems and organisations.

Economic issues related to the defined quality dimensions

- HP: Promote the further development and systematic use of economic evaluations in health care, with an emphasis on enabling its use in all relevant sectors and strengthening the link between HTA and health care decision making at different levels.
- HP: Promote research aimed at development of efficiency measures, especially at the macro- and meso-level. This includes development of methods, but also routine collection of data.

- HP: Promote the use of registries to collect data on health care quality and efficiency of different treatment options
- HP: Promote the further systematic use of advanced measures of equity in health (health, health care and health care financing), through collection of required data in a uniform manner within Europe.

Education and training in their new roles for both patients and health professionals

- HP: to continue supporting MS in promoting continuing education and training programmes to improve the quality of health care services and to promote revalidation of Doctors with an appraisal every 5 years, including patient safety education and training.
- HP: to support MS in promoting education and training on patient safety for patient's families and informal carers, setting benchmarks and identifying best practices.
- HP: to promote the training of health professionals in their new role of "trainers" for patients with chronic conditions and in addition develop ways, means time and motivation for professionals to learn better communication skills to engage and involve patients in their care.
- To recognise and support the new role for the involvement of patients, carers and patient associations as key partners in health services and in the health system, particularly in planning health services, assessment of patient needs and preferences, assessing quality of care by developing patient feedback as a learning and quality improvement resource and involvement of the above in policy at all levels.
- To share methodologies and approaches to optimise the involvement of health professionals in health system performance (clinical governance) and in the coordination/integration and continuity of care.

Information technology and information systems significant for health quality and safety

- HP: to further promote the development of blame free reporting and learning systems, encouraging reporting by health professionals and valuing the input from patients on patient safety incidents.
- HP: to promote the implementation, evaluation and access to systems in MS to ensure that health care providers make available quality and safety information about their activities.
- HP: to continue to support the development of harmonised EU wide surveillance of health care associated infections.
- To promote a more transparent approach to data sharing in the field of medicines regulation (e.g. the release of data on adverse reactions)

- To coordinate the use of big-data and case-registries to improve knowledge and support health care quality strategies.
- To support through evidence based knowledge, legal clarification on the use and implementation of telehealth and telecare to deliver cross-border health care.

Quality and safety aspects of the burden of chronic diseases and inequalities in health

- HP: To support the implementation of quality and safety aspects including patient empowerment in the context of ongoing policy work in this area (for example the Joint Action on Chronic Diseases).
- HP: To promote definition of priorities for health care effectiveness in the context of chronic disease and also tackling health inequalities.
- To support MS in the further development of European Reference Networks that can provide highly specialised care for patients with rare diseases.
- To Encourage MS to implement National Contact Points` websites to provide clear information on patients` rights to seek treatment across other MS particularly providing information on the quality and safety standards available in that MS and any specific medical, organisational or financial aspects of their health care services.

The HTA network

- HP: to promote and support the further balanced development of HTA practices in all EU countries within EUnetHTA through exchange of research outcomes and knowledge among the relevant institutes and organisations including voluntary networks.
- To promote further cooperation on HTA studies at an international level and above all, support their transferability and adaptation in national environments.
- To promote original HTA research based on clinical data as well as systematic reviews within EUnetHTA.

Miscellaneous recommendations (further to the categories listed above)

- HP: to research into the impact on quality of care of workforce shortages, burnout and poor working conditions (for example the ORCAB project).
- HP: to support MS in defining and developing clear processes to regulate health professionals across the EU in order to ensure that national and foreign health professionals are qualified and fit to practice.
- To support strategies to ensure continuity of care for patients crossing borders (for example appropriate sharing of written or electronic records).
- To implement a new, more transparent approach to data sharing (EMA)
- To set up a website for the collection of the MS data.

- To standardize in health care services: it is a long-term objective that has to be built over previous work (see "Proposed Actions") and should be leaded by health authorities.

3.7. ADDED VALUE OF PROPOSED ACTIONS AT EU LEVEL

The aforementioned actions could lead to an added value for the quality of care and patient safety at EU level.

Value of quality in health care: per se

Dealing with the issue of quality in health care at European level means facing an extremely heterogeneous background in search of a common denominator that should really represent a guarantee of efficacy and safety of treatments for European citizens and a vector of continuous improvement for health care systems in EU MSs.

Measuring, evaluating and comparing the quality of health care systems at EU level is important for three main reasons: to promote accountability, to inform effective policy development, and to help health care providers learning from each another.

There are now few health care policy initiatives that do not seek to improve the quality of care in Europe, or that do not depend on being able to measure the quality of care.

However, to achieve 'quality-led governance', it is necessary to measure whether or not the system is delivering effective, safe and patient-centred care and to promote the creation of European common quality standards in health care.

A number of factors are making health policies and health systems across the European Union increasingly interconnected and the Cross Border Healthcare Directive (2011/24/EU) represent one of most important example of this and a great opportunity to be seized in order to shape effectively European quality standards capable to influence each MSs in providing health care to every person.

Financial value of quality in health care

The European welfare and health care systems are the most comprehensive and secure because they are based on a social guarantees framework.

However, an increasing number of signs indicate that, at their current rate of growth and under the pressure of the spending reviews imposed by the financial crisis, European society's ability to invest in health care, research, education and additional aspects of the economy becomes ever more limited.

In fact, while health care discussions focus predominantly on controlling costs, it is the concept of health that should be uppermost, valorising the socio-economic impact of investments on social guarantees.

Commonly, we have two streams of concern—quality improvement and cost containment—that create conflicting incentives for both, citizens and health care professionals. Some quality improvement initiatives are designed to improve patient self-management by increasing participation in specific high-value interventions that are becoming costlier to patients. Others to shape facilitated path for specific diseases through the value framework in health care, e.g. the systems, networks and pathways approach.

Measurable clinical efficiency can then be defined by combining composites of quality with resource use-cost measures in the same population of patients. The choice of what level (individual clinicians, sites, groups, integrated delivery systems, health plans) of the health care system to attribute measures of quality and resource use is also a major challenge with important trade off.

Measuring, reporting, and comparing outcomes at EU level are perhaps the most important steps toward rapidly improving outcomes and making good choices about reducing costs in each MSs. Systematic, rigorous outcome measurement remains rare, but a growing number of examples of comprehensive outcome measurement provide evidence of its feasibility and impact.

Value of quality in health care and his role in addressing inequalities in EU MSs

Inequalities in health have been an important part of the work of the European Union (EU) since 1992 when specific competencies for public health were included in the Maastricht treaty. However, large differences in health still exist between and within all countries in the EU, and some of these inequalities are widening.

These inequalities have significant economic implications for the EU and for member states. When health is valued as a capital good, inequalities related losses have been estimated to cost around €141 billion in 2004 or 1.4% of GDP. This rises sharply to €1,000 billion or 9.5% of GDP when health is valued as a consumption good (Mackenbach, 2007).

The European Portal for Actions on Health Inequalities (http://www.health-inequalities.eu), part of Equity Action (the Joint Action on Health Inequalities) funding by

European Union in the framework of the Health Programme, presents data and some examples about the current state of heath inequalities between MSs:

- More than five times as many babies die before the age of one in some countries than in others;
- In 2007, between Member States, there was an 8-year difference in life expectancy at birth for women and a 14-year gap for men;
- Large differences of up to 20 years exist in the number of years lived in good health (Healthy Life Years);
- Roma populations can expect to live 10 years less than the majority population in some countries.
- Differences in life expectancy at birth between lowest and highest socio-economic groups reach 10 years for men and 6 years for women.

Although there are few and recent policy initiatives that seek to directly address health inequalities in Europe, different programmes and projects clearly acknowledge the need to fight inequalities as a prerequisite for growth and competitiveness.

In June 2010 the EU adopted its new strategy "Europe 2020: A strategy for smart, sustainable and inclusive growth". This process will undoubtedly impact health inequalities between and within EU countries, above all with the European platform against poverty and social exclusion, one of the Commission's seven 'flagship initiatives'.

Similarly, working on the creation of European common quality standards in health care through clear directives, e.g. the 2011/24/EU, undoubtedly EU will address inequalities effectively, helping local governments in take the right decisions and implementing the correct policies and avoiding the increase of "push"- and "pull"-factors caused by health inequalities.

4. LIST OF ABBREVIATIONS

AGREE	Appraisal of Guidelines for Research and Evaluation
COPD	Chronic Obstructive Pulmonary Disease
Cross Europe proj.	European Cross Border Care Collaborations
CT scan	Computerised Tomography scan
DECIDE project	Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence
DG SANCO	Directorate-General for Health and Consumers, European Commission
DTP	Diphtheria, Tetanus and Pertussis
DUQuE project	Deepening our Understanding of Quality improvement in Europe
EAHC	Executive Agency for Health and Consumers
EASHW	European Agency for Safety and Health at Work
EC	European Commission
ECHI	European Community Health Indicators
ECHOUTCOME proj.	European Consortium in Healthcare Outcomes and Cost-Benefit research
EFTA	European Free Trade Association
EIP-AHA	European Innovation Partnership on Active and Healthy Ageing
EMA	European Medicines Agency
EMPATHIE project	Empowering patients with chronic diseases
ENOPE	European Network on Patient Empowerment
EPF	European Patients' Forum
EU	European Union
EUnetHTA	European network for Health Technology Assessment
EXPH	Expert Panel on effective ways of investing in Health
FFT	Friends and Family Test
GDP	Gross Domestic Product
G-I-N	Guidelines International Network
GP	General Practicioner
GRADE project	Grading of Recommendations Assessment, Development and Evaluation
HANDOVER project	Improving the Continuity of Patient Care Through Identification and Implementation of Novel Patient Handover Processes in Europe
HCAI	Health Care Associated Infection
HCQI(P)	Health Care Quality Indicators (Project)
HFA-DB	European Health for All Database

HP	Health Professionals / High Priority
HSPA	Health Systems Performance Assessment
HTA	Health Technology Assessment
IAPO	International Alliance of Patients' Organisations
ICT	Information and Communication Technology
INAHTA	International Network of Agencies for Health Technology Assessment
InterQuality proj.	International Research Project on Financing Quality in Health Care
INN	International Non-proprietary Names
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LINNEAUS project	Learning from International Networks about Errors and Understanding Safety in Primary Care
LRTI	Lower Respiratory Tract Infection
MArquiS project	Methods of Assessing Response to Quality Improvement Strategies
MRSA	Methicillin-Resistant Staphylococcus Aureus
MS	Member States
NCP	National Contact Points
NHS	National Health Service (United Kingdom)
NICE	National Institute for Health and Care Excellence (United Kingdom)
OECD	Organisation for Economic Co-operation and Development
OOP	Out-Of-Pocket payment
ORCAB project	Improving quality and safety in the hospital: The link between organisational culture, burnout, and quality of care
PaSQ	European Union Network for Patient Safety and Quality of Care
PC	Primary Care
PPP	Purchasing Power Parity
PS	Patient Safety
PSQCWG	Patient Safety & Quality of Care Working Group
QALY	Quality Adjusted Life Years
QIS	Quality Improvement Systems
QUALICOPC project	Quality and costs of primary care in Europe
QUASAR project	Quality and safety in European Union hospitals
RCT	Randomised Controlled Trial
SC	Secondary Care
SImPatIE project	Safety Improvement for Patients in Europe
SPC	Social Protection Committee

1921	**TC**	Tertiary Care
1922	**TFEU**	Treaty on the Functioning of the European Union
1923	**VTE**	Venous ThromboEmbolism
1924	**WeCare** project	Towards a Sustainable and Affordable Health care
1925	**WG**	Working Group
1926	**WHO**	World Health Organisation
1927	**WP**	Work Package

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6. GLOSSARY

ACCEPTABILITY: how humanely and considerately the treatment is delivered (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

ACCESS (TO CARE): the proportion of a given population in need of health services that can obtain them (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

ACCOUNTABILITY: the core concept of accountability is answerability: that is, being obligated to answer questions about decisions and/or actions (Ref. Brinkerhoff DW, 2004. Accountability and health systems: towards conceptual clarity and policy relevance. Health Policy and Planning, 19(6):371–379.).

APPROPRIATENESS: how the treatment corresponds to the needs of the patient (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

ASSESSMENT: refers to the degree to which effective health care has been implemented and achieved and results have been attained (Ref. Council of Europe (1998). The development and implementation of quality improvement systems (QIS) in health care - Recommendation No. R (97) 17 and explanatory memorandum (1998)

CENTREDNESS (patient-centredness or patient responsiveness)[16]: consideration of individual patients' and society's preferences and values (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies).

CONTINUITY OF CARE: the connectedness between stages along the patient pathway (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

COST-BENEFIT ANALYSIS: is one form of economic evaluation that takes into account the major economic costs and benefits expressed in monetary units, and assessed from a

[16] A more comprehensive definition needs to be designed, considering the multi-faceted approach of patients' needs and preferences, which would include the partnership with patients and carers, consideration of patients' experience of care and their empowerment, delivery of effective care by professionals, and would place the empathy/compassion (dignity) as a core element.

societal perspective (Ref Drummond, M.F., O'Brien, B., Stoddart, G.L., and Torrance, G.W., 1997. Methods for the Economic Evaluation of Health Care Programmes (2nd ed.), Oxford University Press, Oxford; Mishan, E., 1975. Cost Benefit Analysis (2nd ed.), Allen and Unwin, London).

COST-EFFECTIVENESS ANALYSIS: is one form of economic evaluation that compares the economic costs with the benefits expressed in "natural" units. The units expressed are particular to a specific sector; for the case of health interventions, health benefits are expressed in units such as health episodes, deaths, or disability-adjusted life-years averted [Drummond, M.F., O'Brien, B., Stoddart, G.L., and Torrance, G.W., 1997. Methods for the Economic Evaluation of Health Care Programmes (2nd ed.), Oxford University Press, Oxford; Gold, M.R., Siegel, J.E., Russell, L.B., and Weinstein, M.C., 1996. Cost-effectiveness in Health and Medicine, Oxford University Press, Oxford.; Tan-Torres Edejer, T., Baltussen, R., Adam, T., Hutubessy, R., Acharya, A., Evans, D.B., Murray, C.J.L., 2003. Making Choices in Health: WHO Guide to Cost-effectiveness Analysis, World Health Organisation, Geneva].

COST-UTILITY ANALYSIS: when alternative interventions produce different levels of effect in terms of both quantity and quality of life (or different effects), the effects may be expressed in utilities. Utilities are measures which comprise both length of life and subjective levels of well-being. The best known utility measure is the quality-adjusted life year, or QALY. Alternative interventions are compared in terms of cost per unit of utility gained (e.g. cost per QALY) [Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.]

EFFECTIVENESS: effectiveness refers to the extent to which the intervention in question produces the intended effects (Maxwell 1992; Witter and Ensor 1997)

EFFICACY: efficacy constitutes for the individuals in a defined population the probable benefit of a given medical technique for a specific medical problem, in ideal circumstances, and as such is a rather more limited element of effectiveness (Ref. Council of Europe (1997). The development and implementation of quality improvement systems (QIS) in health care - Recommendation No. R (97) 17 and explanatory memorandum (1998).

EFFICIENCY: efficiency refers to the extent to which objectives are achieved by minimizing the use of resources (WHO 2000)

EMPOWERMENT (for health): In health promotion, empowerment is a process through which people gain greater control over decisions and actions affecting their health (The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/)

ENOPE: European Network on Patient Empowerment (www.enope.eu)

EQUITY: the extent to which individuals receive more care than others, reflecting differences in their ability to benefit or in their particular needs (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

EVIDENCE-BASED: Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values (Ref. Sackett D et al. Evidence-Based Medicine: How to Practice and Teach EBM, 2nd edition. Churchill Livingstone, Edinburgh, 2000, p.1)

FINANCIAL PROTECTION: The extent to which people who need health services are able to get them without undue financial hardship (WHO World Health Report 2010)

GUIDELINE (clinical practice): Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (Ref. Institute of Medicine. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, editor(s). Clinical practice guidelines we can trust. Washington (DC): National Academies Press; 2011. 2p)

HEALTH TECHNOLOGY ASSESSMENT (HTA): a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology (Ref. INAHTA -International Network of Agencies for Health Technology Assessment, HTA Resources. 2009).

INDICATOR (health): a health indicator is a characteristic of an individual, population, or environment which is subject to measurement (directly or indirectly) and can be used to describe one or more aspects of the health of an individual or population (quality, quantity and time). (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/)

OUTCOME (health): A change in the health status of an individual, group or population which is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/)

PASQ: European Union Network for Patient Safety and Quality of Care (www.pasq.eu)

PATIENT SAFETY: patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events (Ref. AHRQ PSNet Patient Safety Network. Patient safety http://psnet.ahrq.gov/glossary.aspx#P)

POLICY (health): A formal statement or procedure within institutions (notably government) which defines priorities and the parameters for action in response to health needs, available resources and other political pressures (Ref. The WHO Health Promotion Glossary at www.who.int/healthpromotion/about/HPG/en/)

PROCESS (of care): it refers to a "set of activities that go on within and between practitioner and patient" (Ref. Mark, B.A., Salyer, J. & Geddes, N. (1997). Outcomes research: Clues to quality and organisational effectiveness? Outcomes Measurement and Management, 32(3), 589- 601).

QUALITY (of care): Health care that uses the available and appropriate resources in an efficient way to equitably contribute to the improvement of the health of the populations and patients. This implies that provision of care is consistent with current professional

knowledge, focuses on the needs and goals of individuals, their families and communities, prevents and avoid harm related to care, and involves persons/patients as key partners in the process of care (EXPH, 2014).

RELEVANCE: it refers to the optimal overall pattern and balance of services that could be achieved, taking into account the needs and wants of the population as a whole (Ref. Maxwell, R (1992). Dimensions of quality revisited: from thought to action. Quality in Health Care, (1):171–177)

SAFETY: "freedom from accidental injury due to medical care, or medical errors (Kohn, Corrigan and Donaldson 2000)

SATISFACTION: how the treatment and the improvement in the patient's health meets her/his expectations (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

STEWARDSHIP: sometimes more narrowly defined as governance. It refers to the wide range of functions carried out by governments as they seek to achieve national health policy objectives. In addition to improving overall levels of population health, objectives are likely to be framed in terms of equity, coverage, access, quality, and patients' rights. National policy may also define the relative roles and responsibilities of the public, private and voluntary sectors - as well as civil society - in the provision and financing of health care (Ref. http://www.who.int/healthsystems/stewardship/en/)

STRUCTURE (of care): it involves the "relatively stable characteristics of the providers of care, of the tools and resources they have at their disposal, and of the physical and organisational settings in which they work" (Ref. Mark, B.A., Salyer, J. & Geddes, N. (1997). Outcomes research: Clues to quality and organizational effectiveness? Outcomes Measurement and Management, 32(3), 589- 601)

TIMELINESS: receiving treatment within a reasonable time frame (Ref. The European Observatory on Health Systems and Policies. Assuring the Quality of Health Care in the European Union. A case for action. Observatory Studies Series No 12. World Health Organisation 2008, on behalf of the European Observatory on Health Systems and Policies)

TRANSPARENCY (health care): The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction (Ref. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the Twenty-First Century. National Academies Press. 2001)

ANNEXES

FULL LIST OF INDICATORS

Underlined indicators are those chosen by the Panel Experts.

Process	Appropriateness	Presence of programs guaranteeing the quality of infrastructure and equipment
Process	Appropriateness	Organisation of services guarantees enough time to offer a high quality service
Process	Appropriateness	Proportion of professionals that attend continuing education programmes in a regular base: including patient safety
Process	Appropriateness	Proportion of professional with access to medical Evidence-Based information, and training to benefit from their use
Process	Appropriateness	Proportion of professionals that use appropriate clinical guidelines
Process	Appropriateness	Proportion of professionals that participate in the development of clinical pathways
Process	Appropriateness	Inequalities in doctor consultations
Process	Appropriateness	Screening for cancer (cervical, breast, colorectal)
Process	Appropriateness	Unmet care needs by income level
Process	Appropriateness	Consultation skipped due to costs
Process	Appropriateness	Medical tests, treatment of follow up skipped due to costs
Process	Appropriateness	Prescribed medicines skipped due to costs
Process	Appropriateness	Inequalities in dentist consultations
Process	Appropriateness	Inequalities in cancer screening
Process	Appropriateness	In-hospital mortality following acute myocardial infarction
Process	Appropriateness	In-hospital mortality following stroke
Process	Appropriateness	Adequate control and treatment of pain
Process	Appropriateness	Average time dedicated per specialist consultation
Process	Appropriateness	Average length of stay
Process	Appropriateness	Caesarean sections rate
Process	Appropriateness	Electronic medical records adequately performed
Process	Appropriateness	Systematic discussion of clinical cases by responsible team
Process	Appropriateness	Proportion of Health Care centres / professionals activities assessed through systematic processes
Process	Appropriateness	Proportion of centres/professionals that adhere to appropriate clinical guidelines (up-to-date evidence based)

Process	Appropriateness	Presence of enough well trained and motivated professionals
Process	Appropriateness	Vaccination against DTP, measles, hepatitis B, children aged 1
Process	Appropriateness	Influenza vaccination for older people, 65 and over
Process	Appropriateness	Health promotion habits in childhood, coverage of programs (primary care)
Process	Appropriateness	Health problems detection in adults, coverage of programs (primary care)
Process	Appropriateness	Total volume of antibiotics
Process	Appropriateness	Volume of quinolones and cephalosporines as proportion of all antibiotics
Process	Appropriateness	Nursing care plans in the assigned population
Process	Appropriateness	Diabetic patients with good control
Process	Appropriateness	Hypertensive patients with good control
Process	Appropriateness	(Regular) doctor spending enough time with patients during the consultation
Process	Appropriateness	Electronic medical records adequately performed
Process	Appropriateness	Waiting time for planned PC
Process	Appropriateness	% of patients who are able to get appointment with GP within 2 days.
Process	Appropriateness	Waiting time for Tests/complementary diagnostic procedures
Process	Appropriateness	Percentage of patients seen within 4 weeks from GP referral
Process	Appropriateness	Percentage of patients waiting 3 months or more for planned surgery
Process	Appropriateness	Waiting time for cataract surgery
Process	Appropriateness	Waiting time for hip replacement
Process	Appropriateness	Waiting time for knee replacement
Process	Patient safety	Exchange of knowledge, experience and good practice in patient safety
Process	Patient safety	Guides on education and training of health professionals in patient safety, and on effective setting up and functioning of reporting and learning systems
Process	Patient safety	Countries that have developed research programmes on patient safety
Process	Patient safety	Projects funded by EU
Process	Patient safety	Compatibility and comparability of information between EU MS
Process	Patient safety	Presence of patient safety education and training programs in health care settings
Process	Patient safety	Presence of patient safety education and training programs in health care settings for all personnel involved
Process	Patient safety	Proportion of institutions with training programs
Process	Patient safety	Proportion of personnel trained

Process	Patient safety	Proportion of undergraduate programs (for doctors and nurses) that include patient safety
Process	Patient safety	Proportion of postgraduate programs that include patient safety
Process	Patient safety	Education and training on patient safety formally required in health care institutions
Process	Patient safety	Hand washing
Process	Patient safety	Decubitus ulcer
Process	Patient safety	Establishment and functioning of an adverse events information system
Process	Patient safety	Compatibility and comparability of information within the country
Process	Patient safety	Establishment and functioning of blame-free reporting systems
Process	Patient safety	Opportunities for patients and other caregivers to report their experiences identifying threats to safety
Process	Patient safety	Complain and redress procedures clearly established
Process	Patient safety	Systematic use of the information to prevent/ameliorate safety risks and unjustified events
Process	Patient safety	Assessment of suicidal risks in patient with mental disorders
Process	Patient safety	Obstetric trauma
Process	Patient safety	Birth trauma
Process	Patient safety	Admission of full-term babies to neonatal care
Process	Patient safety	Incidence of harm to children due to failure to monitor
Process	Patient safety	Misidentification of patients
Process	Patient safety	Intravenous administration of epidural medication
Process	Patient safety	Complications of anesthesia
Process	Patient safety	Doctors dealing with missing clinical information (proportion per patients seen)
Process	Patient safety	Missing of faulty equipment (proportion per operations performed)
Process	Patient safety	Percentage of impatient risk assessment completed and linked to care plan
Process	Patient safety	Falls for unrestricted windows
Process	Patient safety	Postoperative pulmonary embolism or deep vein thrombosis in adults
Process	Patient safety	Postoperative hip fracture
Process	Patient safety	Foreign body left in during procedure
Process	Patient safety	Patient strategies or programs in place
Process	Patient safety	Presence of competent authorities and bodies designed
Process	Patient safety	Presence of health quality improvement organisations, with appropriate means and methodologies
Process	Patient safety	Organisation regularly assessed on the issue of developing safety culture

Process	Patient safety	Establisment of safety standards on the territory
Process	Patient safety	Application of safety guidelines
Process	Patient safety	Development of specific programs to assess and reduce unjustified variation
Process	Patient safety	Medication error
Process	Patient safety	Intravenous drug administration errors
Process	Patient safety	Non-intravenous drug administration error
Process	Patient safety	Infections due to medical care
Process	Patient safety	Postoperative sepsis in adults
Process	Patient-Centredness	Patient experiences take into account (captured through feedback system and used as learning and improvement resource)
Process	Patient-Centredness	Presence of effective communications between providers and patients
Process	Patient-Centredness	Proportion of (users/persons…) satisfied with the received information
Process	Patient-Centredness	Access of patients to medical records authorised and free of charge
Process	Patient-Centredness	Evidence that a mechanism to capture patients' and families/ carers' feedback is in place and is used as learning and improvement resource
Process	Patient-Centredness	Proportion of Patients´ (persons) with acceptable knowledge about quality (including patient safety) standards and guidelines in country of residence and other EU countries
Process	Patient-Centredness	Percentage of patients who feel they were treated with respect in their health care system/ organisation interaction
Process	Patient-Centredness	Information available for every interested person
Process	Patient-Centredness	Care providers guarantee the optimal care when different providers are needed
Process	Patient-Centredness	Presence of means of communication between levels (e-mail, phone, meetings)
Process	Patient-Centredness	Regular use of means of communication between levels
Process	Patient-Centredness	Proportion of patients who declared they were given the right amount of easily understandable information to enable them to participate actively in medical decisions
Process	Patient-Centredness	Proportion of patients and families who are able to comprehend the information and instructions given to them in relation to discharge of transfer to other care institutions
Process	Patient-Centredness	Presence of available ways of communication with the patient (e-mail, phone, video)
Process	Patient-Centredness	Regular use of ways of communication with the patient
Process	Patient-Centredness	Presence of protocols for coordination between levels/centres/professionals, and adequate means to do that (including time)

Process	Patient-Centredness	Presence of effective reference systems in place
Process	Patient-Centredness	Electronic medical records compatible between centres/institutions/countries
Process	Patient-Centredness	Presence of experiences of integrated care (primary care, hospital care, social care)
Process	Patient-Centredness	Patients/citizens actively participate in their care
Process	Patient-Centredness	Proportion of patients/families who experience the care process as being "joined up" according to their needs
Process	Patient-Centredness	Meaningful informed consent properly regulated
Process	Patient-Centredness	Presence of education and training programs for patients to help them participate in decisions related to their health/care, and for training patients in self-management of chronic conditions
Process	Patient-Centredness	Proportion of patients/clients with chronic conditions who actively participate in the development of a treatment plan with their health care provider
Process	Patient-Centredness	Presence of training programs for health professionals aimed to involve patients in all decisions about care and treatment
Process	Patient-Centredness	People/patient rational use of service
Process	Patient-Centredness	Possibility of choice between practitioners, centres, etc.
Process	Patient-Centredness	Assessment of availability of professional-led, or peer-led, education/training programmes for patients to enable them participate in decisions relating to their health and care, and to support self-management of chronic conditions
Process	Patient-Centredness	Proportion of children whose parents routinely received all aspects of family centred care
Process	Patient-Centredness	Patient and Patient Organisations meaningful participation in planning, management and regulation of health services
Process	Patient-Centredness	Patients´ organisations actively participating in health related policy-making at all levels
Process	Patient-Centredness	Proportion of population considering health services (health system) function well or very well
Process	Patient-Centredness	Proportion of patients considering their care (primary care, hospital, etc.) has been good of very good
Process	Patient-Centredness	Proportion of patients satisfied with each aspect of the services provided
Outcome	Enhancing quality of life for people with long-term conditions	Proportion of patients that feel supported to manage their chronic condition in a national/European patient survey
Outcome	Enhancing quality of life for people with long-term conditions	Employment of people with long-term conditions
Outcome	Enhancing quality of life for people with long-term conditions	Emergency-based hospitalisation for chronic ambulatory care sensitive conditions

Outcome	Enhancing quality of life for people with long-term conditions	Emergency-based hospitalisation for asthma, diabetes and epilepsy in under 19s
Outcome	Enhancing quality of life for people with long-term conditions	Health-related quality of life of carers
Outcome	Enhancing quality of life for people with long-term conditions	Employment of people with mental illness
Outcome	Enhancing quality of life for people with long-term conditions	Estimated diagnosis rate for people with dementia
Outcome	Enhancing quality of life for people with long-term conditions	A measure of effectiveness of post-diagnosis care in sustaining independence and improving quality of life
Outcome	Ensuring that people have a positive experience of care	Friends and family test (Would you recommend this service to friends and family?
Outcome	Ensuring that people have a positive experience of care	Patients experience of service/care with FFT
Outcome	Ensuring that people have a positive experience of care	Patient experience of hospital care
Outcome	Ensuring that people have a positive experience of care	Patient experience of outpatient services
Outcome	Ensuring that people have a positive experience of care	Patient experience of accident and emergency services
Outcome	Ensuring that people have a positive experience of care	Patient experience of primary care services
Outcome	Ensuring that people have a positive experience of care	Women’s experience of maternity services
Outcome	Ensuring that people have a positive experience of care	Bereaved carers’ views on the quality of care in the last 3 months of life

Outcome	Ensuring that people have a positive experience of care	Patient experience of community mental health services
Outcome	Ensuring that people have a positive experience of care	Children and young people's experience of outpatient services
Outcome	Ensuring that people have a positive experience of care	Responsiveness to in-patients' personal needs
Outcome	Helping people to recover from episodes of ill health or following injury	Emergency admissions within 30 days of discharge from hospital
Outcome	Helping people to recover from episodes of ill health or following injury	Total health gain as assessed by patients for elective procedures (hip replacement, knee replacement, cholecystectomy, cataract surgery)
Outcome	Helping people to recover from episodes of ill health or following injury	Emergency admissions for children with LRTI
Outcome	Helping people to recover from episodes of ill health or following injury	Functionality independence measure at discharge and 6 months after severe trauma
Outcome	Helping people to recover from episodes of ill health or following injury	Functionality independence measure at discharge and 6 months after stroke
Outcome	Helping people to recover from episodes of ill health or following injury	Functionality independence measure at discharge and 6 months after fragility fracture
Outcome	Helping people to recover from episodes of ill health or following injury	Proportion of stroke patients reporting improvement in activity/lifestyle on the Modified Rankin Scale at 6 months

Outcome	Helping people to recover from episodes of ill health or following injury	Proportion of patients recovering to their previous level of mobility/walking ability at 30 and 120 days
Outcome	Helping people to recover from episodes of ill health or following injury	Proportion of older people (65 and over) who were at home at 91 days after discharge from hospital into reablement/rehabilitation service
Outcome	Helping people to recover from episodes of ill health or following injury	Proportion of elderly patients (over 75 years) who are offered rehabilitation following discharge from acute or community hospital
Outcome	Preventing people from dying prematurely	Potential years of life lost from causes considered amenable to health care
Outcome	Preventing people from dying prematurely	Life expectancy at 75 years of age
Outcome	Preventing people from dying prematurely	Mortality rate from cardiovascular disease in people under 70 years of age
Outcome	Preventing people from dying prematurely	Mortality rate from respiratory disease in people under 70 years of age
Outcome	Preventing people from dying prematurely	Mortality rate from liver disease in people under 70 years of age
Outcome	Preventing people from dying prematurely	Mortality rate from cancer in people under 70 years of age
Outcome	Preventing people from dying prematurely	Five year survival from all cancers
Outcome	Preventing people from dying prematurely	Five year survival from breast, lung and colorectal cancer
Outcome	Preventing people from dying prematurely	Infant mortality
Outcome	Preventing people from dying prematurely	Neonatal mortality

Outcome	Preventing people from dying prematurely	Five year survival from all cancers in children (under 15 years of age)
Outcome	Preventing people from dying prematurely	Mortality rate in people under 60 years of age with a learning disability
Outcome	Preventing people from dying prematurely	Mortality rate in people under 70 years of age, who have a diagnosis of a serious mental illness
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Patient safety incidents reported
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Safety incidents involving severe harm or death
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Hospital deaths and the hospital deaths attributable to problems in care
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Deaths from venous thromboembolism (VTE) related events
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Proportion of patients with category 2, 3 and 4 pressure ulcers
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Admission of full-term babies to neonatal care
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Incidence of harm to children due to 'failure to monitor'
Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Incidence of health care associated infection (HCAI) (MRSA, C. difficile)

Outcome	Treating and caring for people in a safe environment and protecting them from avoidable harm	Incidence of medication errors causing serious harm
Economics	Macro level	Health care expenditure; per capita; percentage of GDP (€PPP)
Economics	Macro level	Public health care expenditure: per capita, as a percentage of total health spending, as a percentage of public spending, as a percentage of GDP
Economics	Macro level	Private health care expenditure: OOPs as a percentage of total health spending
Economics	Macro level	Private health care expenditure; per capita; percentage of GDP
Economics	Macro level	Pharmaceutical expenditure; per capita; percentage of GDP
Economics	Macro level	Break down per sector/disease
Economics	Macro level	Finance mix
Economics	Macro level	Process: good accounting practice - NHA
Economics	Macro level	Gini-coefficient
Economics	Macro level	Distribution of health financing mechanisms (Kakwani index)
Economics	Macro level	Incidence and distribution of catastrophic and impoverishing OOP payments
Economics	Macro level	Benefit incidence analysis
Economics	Meso level	Degree of integration health, welfare, housing, employment
Economics	Meso level	Performance to link patient-related information across the different levels, sectors, organisations and providers

Methodology for process indicator: a widely accepted methodology is not available for any of the indicators selected, therefore further work needs to be undertaken, in terms of agreeing a set of indicators and developing the methodology to collect and analyse them. However, the starting point can be the work of the Picker Institute for NHS and the Quality for patient experience in adult NHS services, as well as other possible resources, some mentioned in the list of references. It is essential that patients through their representative organisations are involved in developing the indicators and methodology.

Methodology for outcome indicators: the outcome indicators are based on the indicators used by the English NHS that were compared to list of indicators collected as the background material. The indicators, their availability and modifications were then discussed in the Working Group meetings.

Methodology for economic indicators