

## Quality Management as a Dimension of Evidence-based Medicine

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### Abstract

*Council of Europe, starting with 2000, emphasized that the improvement of the quality system is a set of integrated and planned activities and measures at various levels in the health care organization, aimed at continuously assuring and improving the quality of patient care.*

*The quality management system, irrespective of the level of approach (organizational, local, national, European), needs to be implemented, assessed and, above all, developed on the basis of standards and practice models. The purpose of this analysis is to emphasise the fact that quality improvement efforts and the support of the management/decision-makers are the key drivers of quality and patient safety improvement at any level of the health system. Based on the latest theoretical and practical considerations, we could say that is necessary to evaluate continuously not only the results obtained from the analyses of the quantitative and qualitative data, but also the tools used in the field of quality management, in order to decide based on clear evidence and real practice. In this context, as a conclusion, we could talk about a complex activity for health care organizations, in order to implement, evaluate and continuously improving a quality management system.*

**Key words:** quality, health care, management, patient safety

**J.E.L. classification:** I1, I18, M10, M16, M20

### 1. Introduction

In the last few decades the health sector has undergone changes and significant development. The circumstances of illnesses and deaths, diagnostic methods and therapeutic technologies applied in the health care sector have changed. At the same time, the structure of the health system, the organization and complexity of services are different in comparison with the 90s. The request for health care services, at different levels, did not follow either the development of medical science or the medical techniques, nor the needs or expectations of the beneficiares/patients. As a result, the discrepancy between the available financial resources and the needs of the health system (in order to satisfy the request that has increased in time, while the health of the population has not improved or, even worse, in some areas deteriorated) has escalated. Having present that the health system comprises the four groups of health determinants -environmental, biological dowry, behavior, and health care – a few questions arise. Is it sufficient to address quality in the health system from the perspective of clinical practice or from the perspective of the organizational management? Is it sufficient to implement quality management at the organizational level without an suitable approach to the strategic health policies? Is this a problem that is specific only to the health care

provider? The answer is, with no doubt, not! Therefore, in the field of quality management in healthcare, the key-word is the strategy and it is mandatory to have one established on medium – term and even on long - term. Achieving quality and financial goals is quite a challenge for any type of organization that is currently activating in healthcare, this subject being left open to further in depth assessments.

## 2. Theoretical aspects and research methodology

As World Health Organization and European Commission emphasised, in order to shift from performance measurement, to performance assessment, qualitative information and in-depth assessments of the health system are needed. This aspect is creating the premises that the policy decisions in health care are elaborated according to an evidence-based framework

The way in which a health system is organized, operated and funded and, last but not least, the way in which healthcare is provided is directly reflected in the quality of care, taking into account all its dimensions: (Maxwell,1992)

1. Efficacy - the ability to achieve the best results in improving health through the best care;
2. Efficiency - the degree to which the care received has the expected effect, with a minimum of effort and costs;
3. Optimization - the balance between the costs of health care and the effects obtained from such care;
4. Accessibility - the ease with which the patients can get the care they need, when they need it, according to their wishes, needs and expectations;
5. Legitimacy - providing health care in accordance with the social principles expressed through norms, values, laws and regulations;
6. Equity - providing health care to each member of society according to his/her needs. As we can see, patients should no longer be seen only as healthcare subjects but become participants in medical decision making.

When we discuss about the quality systems in healthcare it is necessary to understand that we cannot have expected results without the correlation between structures and processes related to the established objectives. (Donabedian,2003)

The following steps were taken into account in terms of *research methodology*: the identification / definition of the problem, assesment of the regulations in the area of health care, from the perspective of the patient quality and safety management, as well as examples of good practice at national and European level, setting the objectives by presenting the principles and concepts quality assurance, analysis of the major issues involved and conclusions. Thus, taking Romania as study base, it can be noticed that the needs to be met by the health system both at central and local level have changed as a result of the demographic and epidemiological transition in the country. As reported in the statistical data, the burden of morbidity in Romania, previously dominated by maternal and infant diseases and communicable diseases, is currently dominated by chronic and non-communicable diseases - e.g. cardiovascular diseases are the leading cause of death, causing 57% of all deaths; cancer, the second cause as frequency, causes 20% of them. Together, the two cause over three out of four deaths. External factors (accidents and intoxications) are the third cause of death, causing 5.6% of deaths, while infectious diseases account for only 1% of all deaths.

Yet, the current health system in Romania is based on an old model that focuses on hospital treatment, episodic of acute conditions, with patients considered as passive recipients of health care. Furthermore, as per reports of the National Authority of Quality Management in Health, quality assurance is not an daily basis preoccupation of the personnel of the healthcare providers, as it is shown so far by results of the hospitals evaluation in the first and second cicle of accreditation (the lenght of an accreditation cicle is five years).

### **3. Structural integration of the Quality Assurance (QA) and Quality Improvement (QI) in an under pressure health system**

In now days is a paradigm shift when we discuss about the quality of the health care services: is not about the providers is about the fundamental right of every person to receive high-quality care. Therefore, having present that the external factors that are influencing the health systems across Europe are putting a lot of pressure on the healthcare systems (as aging population, mobility of the citizens, mobility of the health professionals, demographic background, changes in disease occurrence, development of the new high technologies, economic changes, European and local regulations) is important to understand that a high level of quality of the care and patient safety must be guaranteed regardless of the country where the person is receiving the health care services.

The information explosion, the widespread use of new technologies and the need to improve clinical practice and health outcomes has led to a rapid development of a new concept of evidence-based medicine (EBM). Thus, for the optimization of health care, evidence-based medicine has become an important element in improving the care processes and an important and effective tool for sustainably delivering a patient-centric, quality-oriented, safe care. Evolution of the decision-making in health care it is obvious: from opinion-based decision (guided solely by experience on learning and experience, practitioners selects the approach to patient care) to care decisions based on sound scientific evidence -EBM- (Hoelsing,H.,2016)

Despite this, recent researches and studies has shown that many patients do not receive the care that they are entitled to, due to the various reasons, as the lack of accessibility, inefficient policies in the field of health care, unnecessary extensions of various structures or the shortage of the specialists in certain areas of activity, which led to a scarcity of the quality of care or even to harmful care.

Who is accountable for the level of the quality in a health system as well as for the patient safety? Each one of the stakeholders have different responsibilities in creating a proper quality culture in healthcare. Government and regulatory bodies have to provide the proper framework regulations and policies to encourage, monitor and control the system in terms of quality of health care. Those who are in charge with the financing of the health care services have to provide the resources in order to make quality improvement possible. Professional bodies must be a real support and driver for their members. The management of each healthcare provider need to put in practice their statement regarding quality improvement at all levels and structures. Professionals in healthcare (doctors, nurses etc) are responsible with the practice as well as with the interaction with the patient and continuity of care, with the aim of changing the quality for the better. Medical schools and universities must provide to the future professionals of the healthcare system, education focused on patient safety and quality improvement. Patients, as the consumers of the healthcare services, must be more involved in what are their rights, but also, assuming their obligations as they are the key player of the system. And last, but not least, the media that must inform properly and equitably the public about the quality of health services provided by healthcare facilities, in order to increase (when is the case) the trust of the population in the quality of health services and, very important, not to cultivate a blame culture. It is obvious that the development of quality culture is a long process that involves understanding the concept of quality with the aim of leading to a change of mentality. Regarding the upmentioned concept of quality, we have to link three perspectives as pilons of the quality management::

1. **Quality assurance (QA)** – all the processes must be done in order to have a coherent quality planning (objectives, standards, aims and indicators, thresholds and milestones in order to evaluate the compliance with the standards or deviations, and control loop); quality assurance strategies seek to prevent, detect and correct problems in the quality of services provided to individuals and populations.

2. **Quality Improvement (QI)**–Quality improvement strategies attempt to improve quality through continuous study and modification of the services being provided; even if these approaches tend to have different quantitative techniques and strategic perspectives, a lot of scholars are accepting the fact that are implementable. In other words, an effective quality assurance program is not an end in itself; rather, it is a means of maintaining and improving care.(O'Leary,1988)

3. **Quality Control (QC)**- is a proactive approach to improving processes and activities in a continuous manner. One of the tools used to develop systems to ensure that the services provided to the beneficiaries are meets or even surpassing their expectations, is "The four step cycle", known as Plan-Do-Check-Act (PDCA) Model, which focuses on the problem solving and, at the same time, emphasizes the importance of preventing the recurrence of errors by establishing appropriate standards. One of the key aspects of effectively implementing this tool is to instruct professionals to identify and act on variation issues in healthcare practice;( Shewhart 1986, Deming, 1993)

**Quality Management (QM)**-coordinates and facilitates all processes and activities within the assurance and control of the quality and the improvement of it. This applies to any organization, as well as to the entire health system. Quality management is implemented by the entire organization's staff and it must be a constant concern of all. As a result, an essential element in assuring and continuously improving quality remains the appropriate education and understanding of the principles that govern quality management in health care by all the key-players of the health system.

#### **4. Through an active and coherent involvement of all actors in the system, immediate results can be obtained**

Building a structured quality management system, accepted and implemented at all levels of a health system, represent the premises of the assuring and improving the quality of healthcare and patient safety, taking into account the ability to provide uninterrupted health care services in a coordinated manner, in a cost-efficient way, with a not disputable satisfaction of the patient and the personnel involved .

In examples of good practice in different European countries or in the programming documents of the regulatory bodies (European Commission, World Health Organization, ISQua), it could be noticed that the improvement of the quality, at any level of the health system, is based on the development of standards and the assessment of the level of achievement them. (European Commission initiative on "Health status in the EU",2014 )

Quality standards need to be disseminated among healthcare professionals, accepted and put into practice by all, in order to ensure a formally recognized level of quality as acceptable, so that, from the perspective of the participatory principle of evaluating the performance of a health care system, they can be part of a collaborative platform for data aggregation at regional / national level in terms of the out-comes of the evaluation of the health care providers, as an the assessment of high-level health objectives (national health strategies and policies.( World Health Organisation - Pathways to Health System Performance Assessment,2012)

This approach could provide the following information, sustained by an evidence based point of view:

- knowing the degree of exposure to risk factors for people in the care process and taking preventive,
- an early detection of pathological changes caused by exposure to risk factors,
- ensuring an integrated and interdisciplinary case management,
- harmonization of the collaboration between the three levels of healthcare, primary health care, specialized medical assistance in outpatient clinics and hospital care,
- increasing access to outpatient health services by: improving communication with patients, improving communication between professionals, ensure traceability of the patient at all levels of health care,
- compliance with the professional competence levels,
- identifying managerial malfunctions at the level of health care providers generated by the health system regulations, with possibility to provide recommendations for remediation,
- reducing variability in clinical practice.

#### **5. Conclusions**

In the last few decades the health sector has undergone changes and significant development. The circumstances of illnesses and deaths, diagnostic methods and therapeutic technologies applied

in the health care sector have changed. At the same time, the structure of the health system, the organization and complexity of services are different in comparison with the 90s. The request for health care services, at different levels, did not follow either the development of medical science or the medical techniques, nor the needs or expectations of the beneficiaries/patients. As a result, the discrepancy between the available financial resources and the needs of the health system (in order to satisfy the request that has increased in time, while the health of the population has not improved or, even worse, in some areas deteriorated) has escalated. This discrepancy is due to the ever-increasing needs of the population, both as a result of the elevated diagnosis and treatment possibilities, which lead to higher costs, as well as to the increase in the level of population which is having access to information - as examples: high-performance imaging investigations, treatments for previously incurable diseases (Gaucher disease, hepatitis C, stenosis and thrombolysis in the myocardial infarction, etc.) dialysis and so forth. Even if these diagnostic and therapeutic solutions have penetrated, due to the delayed detection of the cases they would benefit from, we still have a high level of avoidable mortality and avoidable hospitalizations. This reflects that resource efficiency is low. Furthermore, focus on patient should be adopted as a key aspect of measurement and performance assessment of health systems, yet this approach is not taking into account in developing health care policies in many regions. (OECD Initiative, Paris, January 2017)

In Romania, reliable information are collected and analyzed by the National Authority of Quality Management in Health. This data, collected during the assessment of hospitals, regarding the organizational culture, is reflecting a poor orientation on quality of medical services and patient safety and, moreover, patient-centered care is not understood as a key factor. (<https://anmcs.gov.ro/web/comunicat-de-presa-numai-1565-dintre-spitalele-evaluate-pe-baza-standardelor-recunoscute-international-indeplinesc-conditiile-de-acreditate/>)

Therefore, the implementation of quality management at the level of the building- blocks of the health system ( primary care, ambulatory, hospitals) is essential for the efficient functioning of the national health system as a whole and it must be based on evidence and scientific information critically assessed at the starting point of implementation, as well as during the improvement process. Managers are critical in meeting the challenges that they have to face during the assessment of the level of implementation of quality across their organization and, at the same time, in managing the change process required, in order to offer a sustainable high-quality of health care.

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