

## REVIEW ARTICLES

### Quality assurance standards in healthcare

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#### Abstract

**Background:** The Association Agreement between the European Union (EU) and the Republic of Moldova (RM) creates a framework for closer cooperation in many areas, including health care. This requires adjustment of legislation and quality assurance standards in RM to the EU acts and international instruments. The article provides an overview of the concept of healthcare quality and related standardization processes for quality assurance and health care assessment. It comprises a literature review of the published work in this area with a special emphasis on the standards and normative legislature applied to healthcare as well as a brief description of the regulatory standardization structures and organizations at the local, regional and international level.

**Conclusions:** Healthcare quality does not represent an absolute standard of excellence, but rather a much wider concept comprising optimal service delivery for all involved parties and a shared commitment for continuous improvement. After proclaiming its independence, RM has adopted a series of legislations aimed at adjusting the national standards to those implemented at the EU and international level, having become an affiliated member of the European Committee for Standardization (CEN) and a correspondent member of the International Organization for Standardization (ISO). These steps are in complete agreement with the European integration course taken by the Republic of Moldova. Continuing these efforts is the key to reaping the benefits of European integration.

**Key words:** quality assurance standards; health care; ISO; CEN.

#### Introduction

Quality is a frequent concept utilized in all domains of economic and social life, representing an important aspect of performance in any organization. At the same time, the concept and vocabulary of quality are quite elusive, referring to a rather perceptual and somewhat subjective attributes or to a set of properties and characteristics that may be perceived differently by different people. The quality of medical services, for example, may equally refer to patient's satisfaction, professional audit, improved efficacy and cost reduction, being approached differently by different people involved in receiving or delivering medical care: patients, professionals or administrators of medical institutions [1].

Different definitions have been used in the literature to describe the notion of quality and its basic principles developed by the top scientists who introduced the quality concept, such as Walter A. Shewhart [2], William E. Deming [3, 4], Joseph M. Juran [5-7], Philip B. Crosby [8], Armand V. Feigenbaum [9, 10], Kaoru Ishikawa [11], etc. Among the commonly used definitions over time can be enlisted, "a predictable degree of uniformity and dependability with a standard suited to the customer" (W. E. Deming), "fitness for use" (J. M. Juran), "those features of products which meet customer needs and thereby provide customer satisfaction" (J. M. Juran), "conformance to requirements" (P. B. Crosby), "the total composite product and service characteristics of marketing, engineering, manufacturing, and maintenance through which the product and service in use will meet the expectations of the customer" (A. V. Feigenbaum). Kaoru Ishikawa,

credited with creating the Japanese quality circle movement, gives both a narrow and a broader interpretation of the quality concept, i.e., "Narrowly interpreted quality means quality of product. Broadly interpreted quality means quality of work, quality of service, quality of information, quality of process, quality of division, quality of people, including workers, engineers, managers and executives, quality of system, quality of company, quality of objectives, etc." The definition adopted by the American Society for Quality (ASQ) denotes quality as "an excellence in goods and services, especially to the degree they conform to requirements and satisfy customers". According to the International Organization for Standardization (ISO), quality represents „the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs” or „degree to which a set of inherent characteristics fulfills requirements” [12].

Achieving high quality as an ever changing or continuous process generated even the concept of „total quality”. The term is best defined as a strategy that permeates an entire organization, aiming at constant quality improvement by involving every aspect of the company: processes, environment and people, including every staff member, providers, managers and clients. All employees in organizations dedicated to the concept of total quality constantly strive for continuous quality improvement and excellence in all that they do, being involved in a shared commitment to improving quality. Thus, total quality can be also viewed as an orientation aimed at the entire organization for constant quality improvement, satisfying and exceeding client's expectations.

Nowadays, quality concept has become a vital element comprising a multitude of institutional activities related to management, evaluation, standardization, accreditation and certification, with a remarkable influence on all businesses, offices, services, education, healthcare, and other organizations.

#### The concept of quality in healthcare development

The assessment of quality in health care assessment must rest on a conceptual definition of what the quality of health care means. Dr. Avedis Donabedian, called the “Father of Outcomes Research” for his work in defining the quality of medical care and health care assessment, emphasized how difficult is to define this concept, indicating, “*The definition of quality also becomes narrower or more expansive, depending on how narrowly or broadly we define the concept of health and our responsibility for it. It makes a difference in the assessment of our performance whether we see ourselves responsible for bringing about improvements only in specific aspects of physical or physiological function or whether we include psychological and social function as well.*” Consequently, he described the quality of medical care in terms of structure, process, and outcomes. “*Structure includes the type of setting in which the care is given, such as the financial and human resources available. Process encompasses patient and provider activities to diagnose and treat an illness. Outcome refers to the patient’s health status as a result of the care provided.*” In 1980, Donabedian described the quality of care 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*” [13]. The definition adopted by the World Health Organization (WHO) in 2000 indicates “*Quality of care is the level of attainment of health systems’ intrinsic goals for health improvement and responsiveness to legitimate expectations of the population*” [14].

The concept of the quality of health care is also affected by the particularities and specifics of the provided healthcare services. *Intangibility* – refers to the inability to assess the value gained from engaging in an activity using any tangible evidence. Thus, it is often impossible to describe all involved details and consequences of provided or received medical services where there isn’t a tangible product that can be seen, tasted or touched before the patient can purchase it. In this situation, the patient may switch his/her attention to a variety of indirect, but “tangible” proofs of service quality which may include the facilities and medical personnel, the professional attitude and established communication, enlisted costs for specific services, etc. *Inseparability* – refers to impossibility to separate the supply or production of the service from its consumption. Since the production and consumption of a medical service can occur simultaneously, this makes it impossible to produce and store the service prior to consumption. The inseparability of services makes it difficult to separate a service from the service provider, rendering a medical service inseparable from the qualifications of the person providing it. Related to healthcare standards,

the concept of inseparability does not mean that the same service will be delivered to each patient; however, it should imply that the same standards of quality will be applied to each service. *Perishability* – implies that service capacity cannot be saved, stored, returned, or resold once rendered to a customer. In a healthcare system, most relevant resources, processes, and systems involved in medical care are assigned for delivery during a definite period in time and cannot be stored for sale in the future. This can significantly affect balancing supply and demand under changing circumstances or at peak times. *Heterogeneity* or *variability* – describes the uniqueness of service offerings. Health care services, regarded as heterogeneous, are typically modified for each patient or situation, since every patient requires an individual approach depending on his/her medical condition, coexisting pathology, individual response to therapy, etc. In this situation, the standardization process may become especially challenging. Nevertheless, despite the heterogeneity of service quality, it is the quality of the service that will essentially make the difference between the two health systems.

A lot of other particularities of health care services may variously affect the evaluation of their quality. For example, a patient commonly requires medical care in a period of crisis or emergency, in which situation the choice of a health care facility is usually limited by the area of residence. Even though most people acknowledge that their health is of primary importance, in a period of crisis a patient commonly becomes emotional with limited possibilities to comprehend all available medical information for right decision making and for a meaningful appreciation of service quality. In such situations, a doctor commonly decides which analyses and medical investigations are required, the type and the place of admission to a health care facility, etc. The reimbursement is then calculated according to the provided services, the resources being commonly coordinated by outside organizations (insurance companies, government resources etc). In the end, the healthcare quality and its cost-effectiveness is affected by a multitude of human, procedural and technological components such as employee’s qualifications and commitment, available equipment and facilities, existing legislature, management of the available resources, organizational strategies etc.

It should be also mentioned that the concept of quality involves two aspects – procedural and transformational. The procedural aspect is concerned with “measuring up”, having its main focus on predetermined specifications and technical standards. This concept is commonly related to “fitness for use” and is sometimes called the producer definition of quality as its main emphasis is on ensuring that products or services meet a predefined specification in a consistent fashion. The transformational concept of quality is “customer” rather than “product” focused, involving an organizational transformation with its primary goal aimed at establishing the customer’s needs, then building structures and organizational cultures which empower employees to meet them. The concept views quality as a complex process integrat-

ing “softer” and more intangible aspects of quality such as personal care, customer service, social responsibility, and customer satisfaction. The main essence of the transformational concept is continuous improvement of quality versus meeting predetermined specifications and technical standards related to the procedural aspect [15]. In this regard it is stated that while the procedural concept is about proving, the transformational approach is about improving. It is also important to mention that both concepts play a key role in achieving and improving quality. For example, in healthcare services, the procedural aspect ensures the required standard of medical care, while the transformational concept empowers the medical personnel to approach the patient's needs individually, providing them additional responsibility, flexibility, motivation and leadership in a setting that is patient centered.

### Quality standardization and organizations

Quality evaluation and comparison as well as ensuring an acceptable standard require a certain reference system. There is an old saying in management that states, “If you can't measure it, you can't manage it” and so it is with quality. Standardization is the process of developing and implementing technical standards, providing a single framework for quality as well as maximizing compatibility and interoperability of evaluated services or parameters. At the international level, as economic interdependence among nations increased, the need for an authoritative international standards organization became increasingly apparent. To address this need, the International Organization for Standardization (ISO) was founded during a meeting of national normative bodies representing 25 countries that was held in London in 1946. Formally ISO became operational the next year (1947). Currently ISO is a non-governmental organization headquartered in Geneva, Switzerland, representing normative bodies of 164 countries out of the 206 total countries in the world. The organization works to develop and promote technical standards for products and services in numerous areas except electricity, electronics, electro-techniques (managed by International Electrotechnical Commission – IEC) and telecommunications (managed by International Telecommunications Union – ITU), with a view to facilitate the international exchange of goods and services, and to develop mutual cooperation in a variety of areas such as technological, intellectual and economic activity. In 1986, Technical Committee of ISO published a set of quality terms and definitions known as *ISO 8402:1986 (Quality – Vocabulary)*. Subsequently ISO developed a new set of quality management series known as *ISO 9000 standards series*, that have been periodically updated and published as separate editions issued in 1987 (*ISO 9000:1987*), 1994 (*ISO 9000:1994*) and 2000 (*ISO 9000:2000*). The *ISO 9000:2000* quality documents have been divided into five specific areas: (1) *ISO 9000:2000* provides an overview, that includes relevant definitions of quality concepts and serves as a guide for the selection of ISO quality models applicable to specific areas, (2) *ISO 9001:2000* provides a model for quality assurance, with an emphasis on

design, development, production, installation, and services, (3) *ISO 9002:2000* provides a model for quality assurance in production and installation, (4) *ISO 9003:2000* provides a model for quality assurance in final inspection and testing of products, and (5) *ISO 9004:2000* provides guidelines for developing and implementing internal corporate quality management programs and quality systems, placing a special emphasis on stakeholder needs and taking companies beyond the requirements of the global benchmark quality management. Since stakeholders include owners, customers, internal personnel, suppliers, society and other shareholders, the *ISO 9004* audience is much broader and entails a variety of potentially different requirements. Additional quality management series include *ISO 10011 (Auditing Standards)* and *ISO 19011:2003 (Guidelines for quality and/or environmental management systems auditing)*, which provide documentation of the principles of management of audit programs as well as guidelines on planning and carrying internal or external audits. The *ISO 19011* guidelines also serve as a standard for formal certification of a quality system by a foreign agency.

A variety of ISO standards have also been developed within the field of health informatics, many of which are intended to facilitate interoperability of medical imaging equipment and information systems in different countries and health systems. One of such standards is *ISO 12052:2006 (Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management)*, which addresses the exchange of digital images and information related to the production of those images between different healthcare systems and medical imaging equipment manufactured by a variety of producers. The DICOM standard is currently used by most healthcare institutions across the globe, allowing digital images and related information to be exchanged and managed by different IT systems, vendors and healthcare facilities. Without a DICOM standard, the operation of a modern radiology department would be practically impossible. The Republic of Moldova has implemented a similar standard in this regard: *SMV EN 12052:2009 (Informatică medicală. Imagine digitală)* [16].

Of note is that a 2008 version of ISO has also been released (*ISO 2008*), introducing certain clarifications to the existing requirements of *ISO 2000* and some changes intended to improve consistency. A forthcoming version of ISO standards is expected to be published in December 2015, if the ISO members vote favorably in March 2015.

At the European level, the standardization process is coordinated by the European Committee for Standardization (*CEN; Comité Européen de Normalisation*) [17], an association that brings together the National Standardization Bodies of 33 European countries. CEN is officially recognized as a European standards body in areas other than electricity, electronics, electro-techniques (managed by the Committee for Electrotechnical Standardization – *CENELEC*) and telecommunications (managed by the European Telecommuni-

cations Standards Institute – *ETSI*). Apart from providing a platform for the development of European Standards, CEN is actively collaborating with other standardization bodies to develop mutual cooperation and conformity in relation to various kinds of products, materials, services and processes. This close cooperation has been materialized by the signature of the Vienna Agreement between International Organization for Standardization (ISO) and European Committee for Standardization (CEN). The agreement was signed in 1991, aiming to prevent duplication of efforts and reducing time when preparing standards. As a result, new standards projects are jointly planned between CEN and ISO, providing an efficient way to the benefit of international standardization [18]. CEN brings together knowledge and expertise from its members, most standards has been adopted as a response to specific needs of its member states, which are invited to actively provide their input for this purpose. Once adopted by CEN, a standard automatically becomes the national standard in 33 European countries. A legal framework in this regard has been provided for all member states under the Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 [19].

At the national level, the standardization process is commonly managed by local structures called National Standardization Bodies. In the Republic of Moldova, the coordination of standardization processes and legislature as well as the development of partnership relations with regional and international standardization bodies is managed by the Department of Standardization and Metrology (“Moldova-Standard”), as stipulated under the Legislation Nr.590-XIII of 22.09.95 related to standardization (published in the Official Monitor of R.Moldova nr.11-12 of 22.02.1996) [20]. The expertise related to standardization processes, metrology and conformity assessment is provided by the National Institute of Standardization [16]. The official publication of the National Standardization Body in Moldova is the Standardization Bulletin (*Buletinul de Standardizare*), up to present 137 editions of this bulletin have been published [16]. As a result of these efforts, the Republic of Moldova became a Correspondent Member of the International Organization for Standardization (ISO) in 1995 (Legislation nr. 596-XIII of 03.10.1995) [21], and a partner standardization body of the European Committee for Standardization (CEN) in 2007 (Legislation nr. 119-XVI of 04.05.2007) [16]. In 2009 Moldova became an affiliated member of CEN [16]. Emphasizing the importance of adjusting to European and international standards, Legislation Nr.590-XIII of 22.09.1995 referring to standardization sets one of the main objectives to adjust the national standards to those adopted at the regional and international level (chapter 5, paragraph 18/3) [20]. Furthermore, chapter 5, paragraph 19/2 stipulates that in case of conflicting standards, the legislation of regional or international standardization organizations to which Moldova has adhered takes priority over the national standards [20].

## Conclusions

1. Healthcare quality does not represent an absolute standard of excellence, but rather a much wider concept comprising optimal service delivery for all involved parties and a shared commitment for continuous improvement.

2. The quality of medical services should be viewed as a structural capacity aimed at establishing the needs of all parties involved in receiving or delivering medical care, then planning and building structures and organizational cultures which empower employees to meet those needs as well as constant monitoring of how these objectives are achieved.

3. The concepts of quality assurance standards and reference normatives elaborated at the European and international level have been developed as an innovative approach aimed not only at evaluating quality services and identifying new objectives for constant quality improvement, but also at creating a common framework for all member states, most standards have been adopted as a response to specific needs of these states.

4. After proclaiming its independence, the Republic of Moldova has adopted a series of legislations aimed at adjusting the national standards to those implemented at the European and international level, having become an affiliated member of the European Committee for Standardization (CEN) and a correspondent member of the International Organization for Standardization (ISO). These steps are in complete agreement with the European integration course taken by the Republic of Moldova. Continuing these efforts is the key to reaping the benefits of European integration.

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