Sarancha V, Sulyma V, Pros N, Vitale K. Approaches to the international standards application in healthcare and public health in different countries (Review article). SEEJPH 2017, posted: 07 June 2017. DOI: 10.4119/UNIBI/SEEJPH 2017-145

REVIEW ARTICLE

Approaches to the international standards application in healthcare and public health in different countries

Vitaliy Sarancha[1], Vadym Sulyma[2], Nenad Pros[3], Ksenija Vitale[1]

[1] School of Public Health "A. Stampar", Medical School, University of Zagreb, Zagreb, Croatia;

[2] Department of Traumatology, Ivano - Frankivsk National Medical University, Ivano – Frankivsk, Ukraine;

[3] Quality Management Department, Pastor TVA JSC, Croatia.

Corresponding author: Vitaliy Sarancha, MD;
Address: 4 Rockefeller St., Zagreb 10000, Croatia;
Email: saranchavi@gmail.com

Abstract

As a result of consequent development, and guided by an increasing demand of different types of the organizations regarding structured management, the system of standardization has been established. The idea behind standardization is adjusting the characteristics of a product, process or a production cycle to make them consistent and in line with the rules regarding what is proper and acceptable.

The “standard” is a document that specifies such established set of criteria covering a broad range of topics and applicable to commissioners of health, specialists in primary care, public health staff, and social care providers, as well as the local authorities and service users. Health products, ranging from medical devices and health informatics to traditional medicines and unconventional healing tools are all in the focus of standards’ application.

Different countries have their own quality management traditions based on their history, mentality, socio-economic environment and the local regulations. Taking into consideration that community social system organization and the quality of social infrastructure are the main foundations of social relations and future prosperity, here we review the existing standardization environment in the health sector in different countries, both developed and those on a convergence path. We focused on standardization environment in the United States of America, Great Britain, Germany, Ukraine, Russian Federation, Croatia and Albania. In order to simplify comprehension, we also demonstrate the algorithm of standardization, as well as the opportunities for application of the international standards in healthcare and public health.

Keywords: healthcare, international standards, public health.

Conflicts of interest: none.

Introduction

First traces of quality development appeared more than four thousand years BC, at the time when commodity barter had been replaced by the development of trade among Greek, Roman, Egyptian, Arab and Phoenician traders (1). Artisans described to their suppliers, by experience, using simple words, what kinds of materials they preferred. This was common practice, since the craftsmen had no tools to measure the composition, strength, chemical or physical characteristics of a given material. Industrial revolution contributed to the development of product specification (2). Manufacturers began issuing precise descriptions of materials and processing methods in order to ensure that supplies met certain quality criteria (3). Thus, producers were obliged to take samples from each batch, which was then subjected to tests determining its elasticity, tensile strength, etc. When the first factories were established, requirements for a higher degree of order, greater focus on precision and monitoring quality control of a product were introduced. Evolving through different stages, beginning with the 'division of labour' in the late 1700s until the beginning of the 20th century, the scope of activities from the beginning of a production cycle to the final phase led to the occurrence of the first model-based managerial approach (4). When the demands of tasks became too complex basic managerial principles, such as planning, execution, monitoring, controlling, completion and improvement were implemented (5). Therefore, to form a structurally oriented organization, systematic quality control became a necessity. Later on, such quality patterns and models became generally accepted and are today known as the Standards. In the modern society, social infrastructure quality is the main foundation of social relations and future prosperity, thus the purpose of this article is to review the existing standardization environment in the health sector in different countries, both developed and those on a convergence path; as well as to demonstrate a common algorithm for standardization and the opportunities for the application of international standards in healthcare and public health.

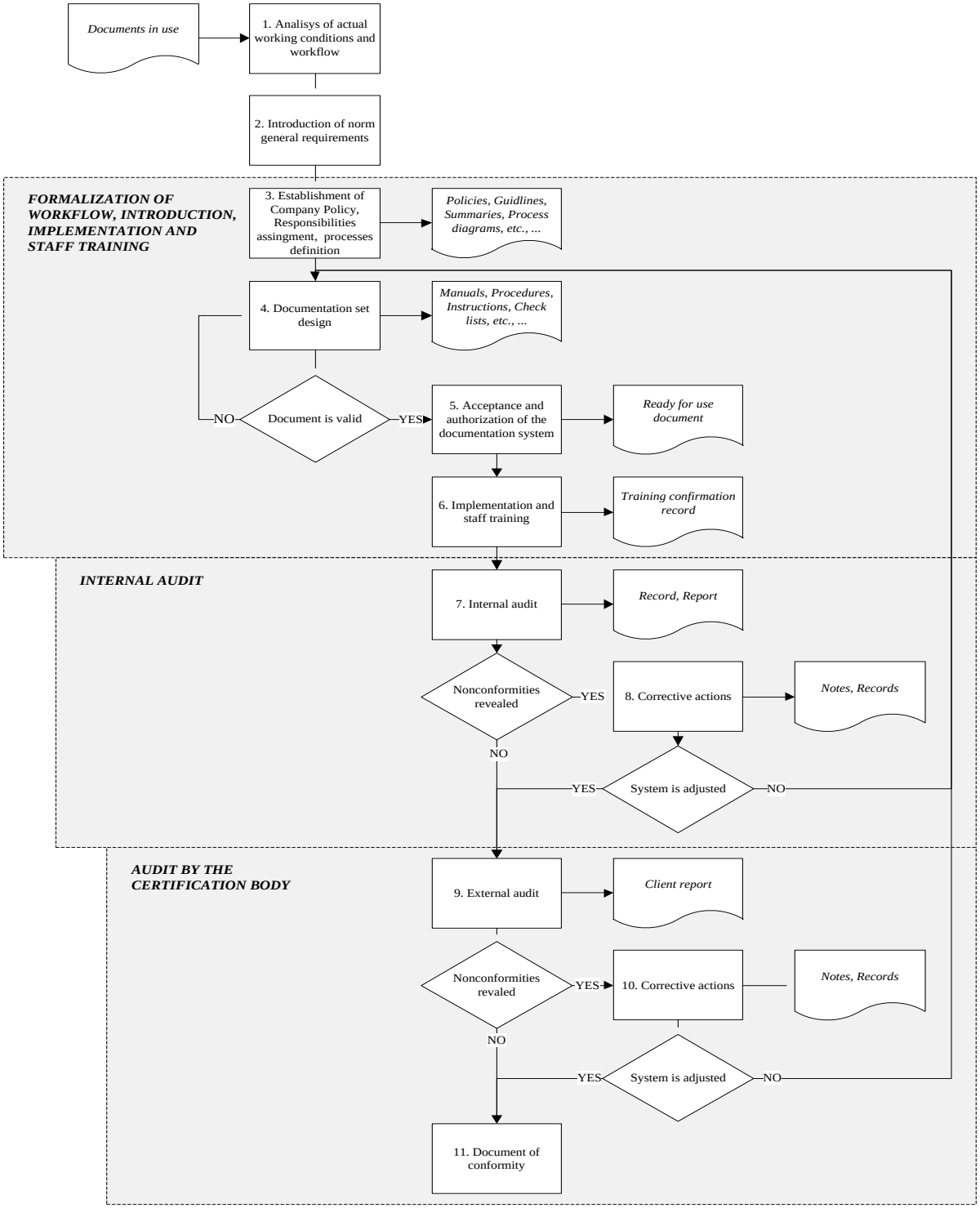
Definition and different types of standards

The idea behind standardization is adjusting the characteristics of a product, process or a production cycle as to make them consistent and in line with the rules regarding what is proper and acceptable. Standard is a document that specifies such established set of criteria. More than 21000 International Standards covering almost all aspects of human activity, including healthcare, have been published since February 1947, when the delegates from 25 countries met at the Institution of Civil Engineers in London and founded the International Organization for Standardization (ISO). Today, it encompasses 162 member countries and more than 238 technical committees taking care of the development of standards (6). After the foundation of the European Union a network of new institutions, such as the European Standardization Organizations (ESOs) consisting of 33 European countries, and CEN - the European Committee for Standardization, has been established. CEN together with the European Committee for Electro-technical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI) are officially recognized by the European Union and by the European Free Trade Association to be responsible for developing voluntary standards on the European level (7). Regarding various products, materials, services and processes, CEN provides a platform for the European Norms (ENs) development (8). EN is to be implemented on a national level by being given the status of a national standard, and by withdrawing any conflicting national standards used previously. Therefore, the European Standard becomes a national standard in each of the 33 CEN-CENELEC member countries once adopted by the national body (9). For example, Croatia after entering EU had to harmonize the local HRNs (Croatian Norms) to conform to the ENs.

Standardization process

The functional diagram (Figure 1) introduces an 11-step assessment construct having been passed by any organization in attempt to obtain a particular certificate.

Figure 1. The 11-step assessment construct that an organization needs to go through in order to obtain a certificate *(source: Sarancha V, Nenad Pros 2016)*



Certification Body is a third party auditing firm that assesses organization against a specific international standard. Taking into account a huge amount of relevant documents and the complexity of the procedures, it is important to correctly identify the procedure required for the certification process at the beginning.

Approaches in different countries

Different countries have their own quality management traditions based on their history, mentality, socio-economic environment and the local regulations (10,11). This otherness is fundamental when considering well-developed countries such as the USA, Germany and Great Britain in comparison with the converging countries of Eastern and South-East Europe (12,13). Thereby, the USA has developed a quality infrastructure and there are many organizations that provide accreditation services covering various aspects of healthcare and public health. Some of them include the Accreditation Association for Ambulatory Health Care (14), the Community Health Accreditation Partner, the Joint Commission and the Accreditation Commission for Health Care, the American Accreditation Council, and the Healthcare Quality Association on Accreditation (15). One of the main acknowledged bodies in healthcare is the National Association for Healthcare Quality (NAHQ). It certifies professionals in healthcare awarding the Certified Professional in Healthcare Quality (CPHQ). CPHQ plays an important role in clinical outcomes, reliability and financial stability of the healthcare organizations. The key elements of their knowledge refer to information management, measurement and analytics, quality measurement and improvements as well as planning, implementation, evaluation, training, strategic and operational tasks concerning patient safety. In Great Britain, the national standards body is BSI Group (16). One of the outstanding resulting documents created by a group of representatives from BSI to help organizations put in place occupational health and safety performance is the Occupational Health and Safety Assessment Series 18000 (OHSAS) with its next revision OHSAS 18002 which was accepted as a standard. In the updated edition “health” component was given greater emphasis and current version became more closely aligned with the structures of ISO 9000 and ISO 14000. Thereby organizations could more easily adopt OHSAS alongside the existing management systems (17). Another institution is the United Kingdom Accreditation Forum or UKAF. Founded in 1998 by a group of leading healthcare accreditation organizations, nowadays UKAF is an umbrella structure for organizations providing healthcare accreditation. It operates with an interest in developing assessment and accreditation programmes in healthcare and public health (18). The National Institute for Health and Care Excellence (NICE) provides guidance and contains governance information, publications, and policies concerning healthcare. It collaborates with the public health institutions, social care professionals and service users, and it also designs concise sets of statements and guidelines to drive measurable quality improvements within a particular area of healthcare (19). Furthermore, there is a supervisory structure in the UK called the Professional Standards Authority. This body is responsible for overseeing the UK’s nine health and care professional regulatory bodies (20). Referring to the topics that focus on the subject it is important to mention the United Kingdom Accreditation Service (UKAS), the National Health Service (NHS), the Department of Health, etc. In Germany, as a result of agreement with the German Federal Government, the national standards body is the German Institute for Standardization (DIN). Its experts administer about 29,500 standards and it was one of the first well-structured certification institutions in Europe. DIN remains the competent authority in respect to the technical issues and widely known specifications for products and materials. The accreditation body for the Federal Republic of Germany is DakkS. It has a special Health/Forensics division, which among other tasks attests third-party certification bodies taking care of Healthcare, Forensic Medicine, Medical Laboratory

Diagnostics and Medical Devices. The German Worker's Welfare Association (AWO) also plays an important role. Together with ISO they have formed an effective tandem that ensures quality in AWO rehabilitation facilities and health organizations. The model combines requirements of ISO 9001 with those of AWO quality and risk assessment guidelines. Consequently, quality of a particular facility is measured by the care provided, the organization structure and the satisfaction of patients and residents. In addition, important requirements for patient safety are formulated by a German initiative called the German Coalition for Patient Safety. It provides a basis in processing the audits that are conducted in the client's premises, with the aim of providing the client with a feedback regarding the degree of implementation of the quality dimension of "patient safety", e.g. regarding a particular healthcare system unit. Speaking of developed economies, it can be concluded that as of today standardization has taken a strong position. In our opinion this is due to understanding by the managers of its effectiveness, as well as the level of comfort regarding integration of standards, clear description of the processes and therefore adherence to the relevant rules and procedures. In spite of positive sides of standardization, we have to understand that human factor in healthcare should also be taken into account, which means inapplicability of one approach only, the engineering approach to the human being as a mechanism. In comparison with the quality management systems present in the developed countries, Ukraine has relatively unbalanced quality infrastructure. It bears elements of the former USSR standardizing paradigm that has to be re-evaluated, updated and adapted to suit the existing economic and social environment. There are state and industry branch systems of standardization in Ukraine (21). The State branch includes the Ukrainian Scientific Research Institute of Standardization Certification and Informatics, and the Ukrainian State Research and Production Centre of Standardization, Metrology and Certification (22,23). The most flexible are the Service standards departments and the Industrial Standards Departments. State social standards in the health sector are regulated by the Ukrainian Law "Fundamentals of Ukraine on Healthcare" (24). Since Ukraine has become a participant of the Euro-integration process, the reform on the adaptation of local standards to the European and international norms has been significantly accelerated (25). The main principles are shown in the "National Strategy on Reforming the Healthcare System in Ukraine" which has been accepted for implementation in the period from 2015 – 2020 (26). More often, private clinics and research centres all over the country engage certification bodies to perform an external audit with the aim of meeting international quality requirements. Standardization in Russian Federation is based on GOSTs. The word GOST (Russian: ГОСТ) is an acronym for "государственный стандарт" which means the National Standard. There is a set of technical norms maintained by the Euro-Asian Council for Standardization, Metrology and Certification (EASC) (27). One of the steps towards the standardization is by issuing the Ordinance of the Ministry of Health "On the introduction of standardization into healthcare" (28). There are also many national programmes and ordinances in Russia dealing with the implementation of particular standards in public health (29). The problem in Russia is actually in hyper-regulation as regards the standardization. Numerous ordinances, guidelines and procedures on one hand, and a lack of specific implementation mechanisms on the other hand causes confusion and regress with regard to the harmonization of national standards with their international counterparts. Thus, the Organization for Economic Co-operation and Development (OECD) Series on Principles of Good Laboratory Practice (GLP) currently operates with GOST R53434-2009 "Principles of Good Laboratory Practice" together with the support of other 14 interstate standards which have already been successfully implemented. In Croatia, accreditation is provided only by the Croatian Accreditation Agency (HAA) which is a national accreditation body that complies with the requirements of the international and European standard for accreditation bodies adopted in the Republic of

Croatia as the Croatian Standard HRN EN ISO/IEC 17011: 2005. The HAA is a member of the International Laboratory Accreditation Cooperation (ILAC) and the European co-operation for Accreditation (EA). The ILAC is an international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020). The EA is an association of national accreditation bodies in Europe which are officially recognised by their national governments to assess and verify (in line with the international standards) the organizations that carry out evaluation services such as certification, verification, inspection, testing and calibration (also known as conformity assessment services). On the other hand there are agencies in Croatia dealing with quality control issues on the national level. Thus, the Agency for Quality and Accreditation in Health Care is an authority whose competence refers to quality improvement in healthcare services and social care, as well as medical technology assessment according to the corresponding law (Official Gazette of the Republic of Croatia 124/11) (30). Targeted assistance in further development of Quality Infrastructure in Croatia has been successfully implemented by the Joint Research Centre of the European Commission with amended action programmes such as CARDS - Croatia project on the “Development of National Metrology, Standardization, Conformity Assessment and Accreditation System” (31). Other institutions that cope with quality paradigm introduction into the Croatian healthcare and public health system are Andrija Stampar School of Public Health and the European Society of Quality in Healthcare (32). According to the 2009 Ministry of Health National Background Report “Health in Albania”, the country has performed very well in sustaining high rates of economic recovery after the financial collapse of 1997 (33). Quality assurance of health systems has been outlined as a priority in Primary Healthcare Reform: A Pilot Project to Provide Evidence for Health Policy (34). The national agencies are empowered by the government to be responsible for accreditation of hospitals and licensing medical personnel. Albania maintains the initiatives and continuous a dialog with the public institutions such as the Institute of Public Health, private laboratories and clinics as well as with the international NGOs, WHO, UNICEF, WB and USAID regarding a more active participation of the country in the international activities of the quality system implementation (35). International quality bodies are successfully co-operating with the aim to internationalize standardizing efforts in healthcare. One of such example is the International Society for Quality in Health Care (ISQua). It is a parent institution for bodies providing international healthcare accreditation. ISQua provides services in guidance to health professionals, providers, researchers, agencies, policy makers and consumers as to achieve excellence in healthcare delivery to the public and to continuously improve the quality of care (36). Among others, quality bodies working on the international level are ASTM International (37), the International Accreditation Forum (IAF) (38), and the Council for Health Service Accreditation of Southern Africa (39), the Quality Management Institute, etc.

Quality paradigm implementation in healthcare and public health

Standards cover a broad range of topics and are applicable to commissioners of health, specialists in primary care, public health staff, and social care providers as well as the local authorities and service users. Health products, ranging from medical devices and health informatics to traditional medicines and unconventional healing tools are all in the focus of standards application (40). Standards are designed to establish patterns of quality and performance including the measures to protect and improve the safety of patients, to promote a culture of continual improvement, support efficient exchange of information and data protection while benefiting the environment. Depending on the scope of responsibilities and

areas of activity every organization is able to voluntarily choose among the standards it wishes to implement. ISO has created about 1200 health standards that are grouped in families. Some of them, such as Environmental Management ISO 14000, Occupational Health and Safety OHSAS 18000, Guidance on social responsibility ISO 26000, Environmental management 14000 are featured as widely applicable to public health and healthcare. A family contains a number of standards, each focusing on different aspects of a corresponding topic. According to 2012 ISO Press release the most commonly used standard is Quality Management Standard ISO 9001 (belongs to ISO 9000 - Quality management systems). Due to its generic basis, it is applicable to all types of organizations. It enables a company to develop a Quality Management System (QMS) which implies the introduction of quality planning, quality assurance, quality control and quality improvement, and it is a perfect tool to measure the fundamental way of developing health services. ISO 9001 has been updated and together with the Cooperation for Transparency and Quality (KTQ) for Hospitals became the most acknowledged "brand" for quality recognition in healthcare. KTQ certification is aimed at hospitals, medical practitioners and institutions, rehabilitation centres, nursing homes, hospices, and emergency medical services. It shows that the focus is primarily on patient satisfaction, from the preparation of the patient's stay until his discharge. A good example of such practical application of quality management in a combined clinic is perfectly demonstrated in the article by Eckert H. and Schulze U., (2004) (41). ISO 13485:2016 – Medical devices, is also a useful standard. It is designed to define the requirements of Quality Management System with the aim of demonstrating a company's ability to provide medical devices and related services that meet the clients' and regulatory requirements. Together with EN 15224:2012 - Certification of quality management systems in healthcare, with its emphasis on the hospital process and risk management, both standards become strong indicators of quality level of care provided at an institution. The best way to find a relative ISO standard is to search through the work of a particular ISO technical committee (TC) on the ISO web page, as follows: TC 76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use; TC 84, Devices for administration of medicinal products and intravascular catheters; TC 94, Personal safety - Protective clothing and equipment; TC 106, Dentistry; TC 121, Anaesthetic and respiratory equipment; TC 150, Implants for surgery; TC 157, Contraceptives/STI; TC 168, Prosthetics and orthotics; TC 170, Surgical instruments; TC 172, Optics and photonics; TC 173, Assistive products for persons with disability; TC 181, Safety of toys; TC 194, Biological evaluation of medical devices; TC 198, Sterilization of healthcare products; TC 210, Quality management and corresponding general aspects for medical devices; TC 212, Clinical laboratory testing and in vitro diagnostic test systems; TC 215, Health informatics; TC 249, Traditional Chinese medicine; ISO/PC 283, Occupational health and safety management systems.

Challenges, opportunities and benefits

Twenty-first century and the globalization bring new challenges to the organizations exposed to the global market. With a drastic number of competitors, growing demands of consumers and legislators, quality requirements of goods and services together with a lack of resources are constantly increasing (42). Be it in environmental protection, in the food industry or public health objective testing and calibration play a notable role. Assessments ensure that tested products, methods, services or systems are reliable with regard to their quality and safety, that they correspond to the technical criteria and conform with the characteristics, guidelines, and laws. Observational findings indicate that nowadays OECD countries have a relatively developed infrastructure of standards implementation in almost all segments of human activity, including social care and public health. According to ISO Health report,

healthcare is one of the world's largest and fastest-growing sectors of the society. In 2009 about 12.4% of gross domestic product of OECD was spent on healthcare. These countries are the basis for research and development, as well as the improvement of international standardization environment. On the other hand, studies have shown that South European countries together with Ukraine and Russia are, in the long run, heading towards the social paradigm shift and understanding of standardization principles. Most frequently cited problems refer to failure of recognizing positive effects of a systematic approach, financial means, long waiting lists, systematic delays in first aid providers, lack of competent staff due to "brain-drain" and insufficient organizations' preparedness for the implementation of structural changes at all levels. Some health centres, clinics and hospitals are funded by the state or county budget revenues (Beveridge's model) or partly from social insurance contributions deducted from the citizens' wages (Bismarck model), and consequently do not recognize the need to increase the level of quality, responsibility and international standards compliance (43). In addition, high payroll taxes in Eastern and South European countries are discouraging formal employment, dampening labour demand and increasing employment in the informal sector (44). A study published in British Medical Journal estimates that medical errors are the third leading cause of death in the United States, that caused a quarter-million fatalities in 2013 alone (45). It obviously means that the reduction of risks of all kinds is also an important problem that needs to be resolved (46). Despite relatively well-structured *lex artis* in standardizing processes, its efficiency in many cases remains controversial. Sometimes, due to enormous amount of paperwork and bureaucracy, standardization can become a nuisance causing waste of time and human resources. Combination of all these factors, together with the unfair competition, weak governance and corruption may cause unwillingness towards continuous improvement which is the ultimate precondition for an efficient functioning of standardization in healthcare and public health (47). Public health and healthcare are vital and sensitive issues, and their importance pervades all aspects of social life due to their medical, social, political, ethical, business, and financial ramifications. Looking into the future, it is impossible to predict exactly how our world is going evolve, but current trends suggest that together with climate change, migration, urbanization, a growing and ageing population, poverty, emerging diseases, food and water shortages and a lack of access to health services, the future of health sector appears to be complicated. New fields of expertise such as medical tourism are on the rise (48). They create a pool of migrating specialists whose services and reliability need to be properly examined and permanently reviewed. In our opinion standardization is a step-by-step process that requires commitment and cooperation of all parties. It may flow both in the bottom-up and in the top-down directions. The key element of this evolutionary process is the end-user of services - the patient, in whose best interest the described changes should be made. The patient, service provider, health insurance officer, public health institution, legislative body - all of them form an integral network of relationships and responsibility. Therefore, awareness regarding the benefits of the standardization process and full understanding of its stages, by those included, are key factors in the overall success of its implementation. Quality management systems based on the international standards should be a strategic decision of the national public health institutions in an attempt to meet long-term strategic goals. If an organization wishes to use one of the worldwide-recognized norms it has to ensure its adherence to best practices in everything it is involved in (49). It also includes the mapping processes, setting performance targets and making sure that it continually improves and meets the goals of shareholders, clients, and patients. Regular audit processes and subsequent annual assessments meet the needs of health service providers, patients, in this way guaranteeing the quality of services and achieving maximum results. In this way, the standardization creates powerful tools in order to fine-tune the performance and manage the risks while operating in

more efficient ways that allow time and capacity for innovation and creativity, finally leading to an overall success. As a result, public health and healthcare sectors may become sustainable and reliable social partners with a high level of responsibility, encouraging committed and motivated employees and satisfied patients.

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