

# The Effectiveness of QMS Implementation in Applying of Quality Health Care for Patients in Health Institutions of Kosovo

**Samir Lleshi**

PhD.cand. European University of Tirana, Albania

## Abstract

Continuous improvement of quality in health system is a challenge for many countries, particularly for those which are undergoing difficult period of transition from the system where the quality was not even known, measured or hasn't consequently been improved in a system where the health service offers are different. In its route toward the European integration in the recent years Kosovo has set up the basis in terms of quality of infrastructure. Even though compared to its neighbors it is still staying behind in terms of quality of legal infrastructure by creating a quality system according to the requirements of EN ISO 9001 standards, while making easier instalment and constant monitoring of the healthcare standards by setting the guidelines for best application practices, particularly in well-known international fields Health sector in Kosovo is one of the most important sectors and has been continually stated as a priority for development of the country, therefore, creating of conditions for a continuous quality improvement, safety of health services and evaluation of such services is a major challenge associated with a patient and citizens to offer more and higher qualitative health services.

**Keywords:** quality management system, standards, health sector, health services.

**UDC Classifications:** 005. 6

## Introduction

Quality is an integral part of international competition all around the world. In terms of economic development in the EU, the activity of standardization plays even a more important role for companies, enterprises, academic and scientific institutions, governmental and non-governmental organizations, laboratories, certification & inspection authorities by recognizing the importance of standards relying on the legislation as an effective instrument for development, manufacturing, trading and products & services offers, conformity assessment and certification activities for implementation of standards and current innovations in such a faster science and technology development.

Health system in Kosovo is mainly public. The state provides most of services that are offered to public in the field of promotion, prevention, diagnosis and treatment, whereas, the private sector is still in its early stages of development.

Providing of quality assurance (QA) is the guarantee that the service offered product meets the accepted standards of quality. Planned control procedures (CP) occur "before, during and after the product service has been offered", and the main goal is to be performed "good since in the first time and every time too". Quality assurance (QA) should bear the responsibility of everyone involved in creating the product or service. Providing of the quality assurance should be implemented in every stage of production development and production process. (Picker Institute Europe, 2002).

Standardization is a creative activity with respect to current and potential problems, provisions for common and repetitive use which aim to achieve an optimum degree of order in a given context (Cutting-Decelle,2015). The activity of standardization includes the processes of development, approval, publishing and the application of standards through the fulfilment of the principles and rules of standardization. The standards are developed and published to serve the public interest and they present strong tools for sharing of information and mutual understanding between the partners (Nwabueze, 1997).

## 1. The aim and study goals

Quality and safety of health services in the health system of Kosovo is not a new concept. It originates from the standards and regulations of a health system that have been applied since the early seventies of last century. Since then, the application of the quality and safety of health service concepts has experienced its ups and downs, reflecting the political, economic and social challenges.

Quality management consists in providing management practices for products and offered services, maintaining and improving characteristics of those products and service, making sure a minimum standard or quality has been achieved. For a long period, providing health sector and quality of it, was a common duty of public authorities, applying minimal standards required by the law.

When talking about the health system, we understand two existing complementary parts, public and private sector. In case the private sector is subject to all planned market rules by adapting the management in the function of success, the public sector stays behind in this direction. Today the main pressure of health care towards the population is carried by the public sector. Another issue to be addressed is that in Kosovo there are plenty of professionals with their professional profile in health management and in their absence in charge of health management they have assigned the staff which with a lack of prior experience in the management. Public health institutions should be led by professional managers with excellent experience in management in health institutions. Thus, the curse of such institutions led by the professionals will enable institutions to offer to the population the indispensable and high quality service.

The objective of the study deals with the effectiveness of QMS implementation in applying of quality health care for patients in Health Institutions of Kosovo. The study also aims to explain the way how the implementation of quality systems of management in health institutions of Kosovo has risen, and also aims to explain the influence of quality application of standards on quality services offered by health institutions, by treating practical samples in Kosovo, while addressing the stands upon the decision taking.

Health Policy of the Republic of Kosovo is in accordance with health policy in developed countries of the European Union, because the quality is an essential health care component in every activity performed in health and medicine sector. Relying on this fact, Kosovo government has approved the "Strategy for Quality Improvement and Health Services 2012-2016", declaring that "Government of Kosovo, respectively the Ministry of Health, is keen on implementation of ISO standards in health care with the aim of continuous improvement of health services".

Quality and safety of health services are becoming more and more important among the countries in the region and further, this because of increasing result of level of expectations for a better and good health of citizens in those countries (Grant, 1988), associated with various expectations related to health care institutions and health care personnel, paralleling with a demand for rapid development on medical technology, while medical technology offer is increasing in quantity and quality worldwide (Enriko, 2012).

Satisfaction surveys are often the structural mechanism through which patients can alert providers about their concerns, needs, and perceptions of treatment. The feedback of Patient's satisfaction is also important to the quality assessment process since it helps health care providers identify potential areas for improvement. Some of those areas are patient education and follow-up, specific quality of care issues, and hospital procedures. Satisfaction surveys are also useful for purposes of program planning and evaluation (Donabedian, 1981 - urbanaffairs.unlv.edu). Clearly patient satisfaction measurement is the application to healthcare of customer satisfaction, a concept coming both from quality management and marketing (ISQua webinar, 2014).

High-quality of medical service completely meets the needs of those who are mostly in need of health services, i.e. patients. The aim of improving the quality in health care is the best possible treatment for the patient. Quality service in medicine is reflected in the safety, effectiveness, availability, efficiency, availability, fairness and accuracy too. When it aims to improve the quality in health care it is necessary to consider the impact of quality in all involved parties. How to improve the quality in health care related to patients, how to improve quality in health care related to doctors and how to improve the quality in health care related to the management of health institutions are the main questions in front of Kosovo health care system. In order to efficiently succeed toward the improvement of the quality in health care it is necessary to unify all the involved parties, i.e. patients, doctors, public health institutions as well as private ones (ISQua, 2007). With the application and implementation of quality management system would have increased savings in all other categories of cost and improving the quality of services provided. (Lleshi, 2015).

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Standardization is a creative activity, with respect to current and potential problems, provisions for common and repetitive use, aiming to achieving an optimum degree of order in a given context of standardization. The activity of standardization includes the processes of development, approval, publishing and the application of standards through the fulfilment of the principles and rules of standardization. The standards were developed and published to serve the public interest and they present strong tools for sharing of information and mutual understanding between the partners. (Nwabueze, 1997).

Doctors still do not consider patients as their clients, but patients are considered as health care consumers, whereas, patients as clients should be treated with the same level of service in any subject which offers health care services. Thus, this issue shall start changing by starting with development of management systems for certification of Quality Systems Management (ISQua, 2007). Over half of the real costs of its failure are internal and are not easily controlled by senior management. This is because management has not applied and implemented instruments for their prevention. Taking into account also the data from the conducted research, it is necessary for laboratories that are in function within the health institutions, regardless, whether they are in primary, secondary or tertiary health system to start the requirements of Systems Quality Management to laboratories for the purpose of accreditation (EN ISO 17025; ISO 15189) .With the beginning of the application of the requirements of these standards reliability of patients will start to raise in the values of laboratory tests (ISO: IWA 1:2005; ISO 15189).

### 3. Methodology

The study surveyed 201 respondents. The sample was formed by a random selection. The questionnaire was specifically designed for this study based on previous theoretical materials, experiences and practices with the needs of patients under the consideration. In the survey, an anonymous questionnaire with 15 questions was used.

Several descriptive statistics tools were used to describe the population under the study. Except the average value (arithmetic mean) rate variability (standard deviation) and relative numbers,  $\chi^2$  test was used to determine the significance of the difference between characteristics. Satisfaction of respondents expressed an average score on a scale of 1 to 5, where 1 = very dissatisfied and 5 = very satisfied.

In the empirical analysis of the paper, the questionnaire data has been used and processed with the statistical program SPSS V.20 (Statistical Package for Social Sciences). Results of descriptive analysis, namely the cumulative data have been presented below.

The methodological framework is developed on the basis of the two dimensions: the efficiency and the effectiveness of services. These dimensions comprise the performance of a hospital for the estimation of health care subjects' management and human resources management from the viewpoint of the health care system managers as well as from the viewpoint of the patients, concerning their perception about health services quality (Gounaris, 2008).

The proposed model covers these two dimensions that are crossed towards the perspective of the efficient operation of the hospital. The centripetal processes of this perspective are Efficiency and Quality (Gounaris, 2008). The fundamental questions that are covered from the research and are attempted to be approached by the methodological framework are:

- a) the development of appropriate efficiency measurement models,
- b) the investigation in the determining factors of efficiency,
- c) the development of the appropriate structure for the estimation of service quality,
- d) the investigation of the determining factors of service quality.

### 4. Results

Research hasn't found yet a simple, direct correlation between patient satisfaction and improved outcome. Patients can play an important role in defining quality care by determining what values should be associated with different outcomes, while they may not have the necessary knowledge to accurately assess the technical quality of care they receive, patients

certainly appreciated its importance (Cleary & McNeil, 1988). Equity, effectiveness, cost containment and quality of care are primary objectives of health policy and delivery of health service (WHO, 2000). In many review of published literature of QMS in European hospitals - ISO 9001 certification is utilized in a variety of way as a vehicle for health care organizations to identify systemic breakdowns and close gaps, streamline workflow and maximize resource utilization, focus of patients and provider needs and expectations, facilitate compliance to health care accreditation standards and regulatory requirements (Stoimenova, 2014 ). Many authors, especially health staff feel that patients are not competent to assess the work of health workers, because they do not have enough professional knowledge.

However, most authors agree that patients are able to reliably estimate the human component of the physician-patient relationship, which comes with the communication skills of the doctor and ability to gain the trust of the patient. Patient-customer satisfaction is a complex relationship between the identified needs, expectations from the health service and experiences with the service they have received (Veronda, 2001).

However much healthcare organizations may resemble - at least on the surface - other large, complex organizations, thoughtful analysis reveals that healthcare organizations are considerably more than mere businesses (Golden, 2006). Peter Drucker (1993) tells us that healthcare organizations are the most complex form of human organization we have ever attempted to manage. To those of us working within these structures, this observation comes as no surprise. Multiple stakeholders, cross-functional services, cutting-edge technologies and highly skilled workers work in a coordinated fashion to add value to improve our health ( Lazarus, FACHE, & Chapman, 2013).

Satisfaction of the patient with health care is an essential component in evaluating the quality of health care. (Murray, Locker & Mock, 1997). The importance of the patient's opinion and his vision for the treatment and care in health institutions is now recognized in all developed systems of health care (Abdal Kareem, Aday & Walker, 1996). Measuring of satisfaction has an important role in identifying problems in the health industry, and finding the key points which can connect these problems. In this way, with an objective assessment of the quality, satisfaction contributes to overall assessment of the functioning of the system and the fulfillment of its role. Better information can significantly contribute to the quality and effectiveness of services and ensuring the continuity of health care, even more than advice with verbal communication (Aizpuru, 1993).

The methodological framework of this study includes the results of the controls for the study hypotheses that concern efficiency and responsiveness in health care services in examined hospitals. The present thesis presents specific methodological approach for the estimation of hospital performance. It aims the development of models for the estimation of two critical factors of evaluation that concern on the estimated or perceived efficiency and the quality of health care.

Table 1: Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
<b>Laboratory tests and other services</b>	201	4	1	5	2.14	.120	1.697	2.880
<b>Communication and access</b>	201	4	1	5	1.66	.095	1.351	1.825
<b>Sufficient information related to treatment</b>	201	4	1	5	1.49	.082	1.162	1.351
<b>Practical</b>	201	4	1	5	1.39	.073	1.039	1.080

<b>organization in health intuitions</b>									
<b>Reliability in public health institutions</b>	201	4	1	5	2.75	.132	1.876	3.518	
<b>Valid N (list wise)</b>	201								

Source: Author

Question: "Do you consider laboratory analysis and other services reliable?" in a group of 201 people, with a statistical average 2.14 and with an error and a deviation 0.120, shows that people don't consider reliable the services offered from health care institutions, as well as these institutions are not reliable too, in the eyes of general public, since standard deviation and variance are in a contrary proportion, concretely 1.697 and 2.880.

Table 2: Laboratory tests and other services

	<b>Observed N</b>	<b>Expected N</b>	<b>Residual</b>
1	130	40.2	89.8
2	12	40.2	-28.2
3	7	40.2	-33.2
4	5	40.2	-35.2
5	47	40.2	6.8
<b>Total</b>	201		

Source: Author

The question "How do you consider communication and access of administrative personnel to the patients" in a group of 201 individuals, shows that with an statistical average 1.66 and error deviation 0.95, the communication and access towards patients from administrative personnel is not adequate and is not acceptable form the patients point of view, since the standard deviation and variance are in a contrary proportion, concretely 1.351 and 1.825.

Table 3: Communication and access

	<b>Observed N</b>	<b>Expected N</b>	<b>Residual</b>
1	155	40.2	114.8
2	12	40.2	-28.2
3	1	40.2	-39.2
4	13	40.2	-27.2
5	20	40.2	-20.2
<b>Total</b>	201		

Source: Author

The answers to the question "Do you get enough information about medical treatment" in a group of 201 individuals, with a statistical average 1.49 and deviation error .82, shows that patients – clients of public health care institutions doesn't have enough information related to their health treatment during their stay at the hospital and during their visits to health care professionals. The values of standard deviation and variance are in a contrary proportion, specifically 1.162 and 1.351.

Table 4: Sufficient information related to treatment				
	Observed N	Expected N	Residual	
1	162	40.2	121.8	
2	15	40.2	-25.2	
3	5	40.2	-35.2	
4	3	40.2	-37.2	
5	16	40.2	-24.2	
Total	201			
Source: Author				

The answers to the questions “Do you consider that public health care institutions have an practical management” in a group of 201 individuals, with a statistical average 1.39 and a deviation error 0.73, shows that patients have a perception that health care institutions are not organized in a practical manner, that leads to a low level of services towards patients. The values of standard deviation and variance in a contrary proportion, specifically 1.039 and 1.080 show this.

Table 5: Practical organization in health intuitions				
	Observed N	Expected N	Residual	
1	171	40.2	130.8	
2	7	40.2	-33.2	
3	6	40.2	-34.2	
4	8	40.2	-32.2	
5	9	40.2	-31.2	
Total	201			
Source: Author				

The answers to the question “in what level is your trust to the public health care institutions” in a group of 201 individuals, with a statistical average 2.75 and deviation error 0.132, with a standard deviation and variance in a contrary proportion, specifically 1.876 and 3.518, show that patients relatively trust to the public health care institution.

Table 6: Reliability in public health institutions				
	Observed N	Expected N	Residual	
1	98	40.2	57.8	
2	13	40.2	-27.2	
3	7	40.2	-33.2	
4	7	40.2	-33.2	
5	76	40.2	35.8	
Total	201			

Source: Author

Table 7: Model Summary <sup>b</sup>									
Model	R Square	R Square	Std. Error of the Estimate	Change Statistics					
				R Square Change	F Change		df1	df2	Sig. F Change
1	.811 <sup>a</sup>	.657	.656	.17766	.657	381.927	1	199	.000
<b>a. Predictors: (Constant), Log Reliability in public</b> <b>b. Dependent Variable: Log Laboratory Test</b>									
Source: Author									

At the regression model where dependent variable is logarithm of "analysis and laboratory tests" with explained independent variables "your trust at public health care institutions" have R<sup>2</sup> (coefficient of determination) 65.7%, so, independent variable describes 65.7% of dependent variable, which means that the independent variable explain very good dependent variable.

Table 8: ANOVA <sup>a</sup>						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	12.055	1	12.055	381.927	.000 <sup>b</sup>
	Residual	6.281	199	.032		
	Total	18.336	200			
<b>b. Dependent Variable: Log Laboratory Test</b> <b>c. Predictors: (Constant), Log Reliability in public</b>						
Source: Author						

F-testy or AVONA shows that there is significance in a scale of 1%, so, there is an indication between these two variables, where there is an indication of them to each other.

Table 9: Coefficients											
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Zero-order	Partial	Part	Tolerance	VIF
		1	(Constant)	-.027			.018		-1.517	.131	
	Log Reliability in public	.746	.038	.811	19.54	.000	.811	.811	.811	1.0	1.0

					3					
<b>a. Dependent Variable: Log. Laboratory Test</b>										
Source: Author										

Simple regression shows that the scale of trusts' indication at the reliability of laboratory tests indicates positively where the constant was  $-0.027$ , while with the increase of reliability in  $0.746$ , it will be an increase of reliability to the public health care units.

The simple linear regression curve, expressed in a linear line between reliability and laboratory tests shows that there is a statistical indicative co-relation between these variables.

## 5. Conclusions

The data and information obtained from the research are not representative in order to make the implementing of the strategic macro decision, but as an information for making decisions and measures at the level of healthcare institutions.

As a priority, Kosovo must improve the system of licensing for providers and carry out the responsibility on the establishment of quality standards and accreditation of health institutions, which is foreseen according to the national strategy, irrespective of whether they are private or public. Strategic orientation in building quality systems in health care, except for orientation to the patient, patient safety should be also on focus. Therefore, establishment of an effective system of regulations and inspections of safety and quality of the health sector, to provide standards, in particular protecting patients and staff from harmful practices is needed.

Another element should be the strengthening of quality management capacity. This will be achieved through personnel training implementation in the field of quality with the implementation of quality systems, quality management and supervision of quality improvement, including all employees in the health sector.

Doctors still do not consider their patients as clients, but patients are considered as health care consumers, while patients as clients should be treated with the same level of service in any subject which offers health care services. Thus, this issue shall start to change by starting with development of management systems for Certification of Quality Management Systems.

Taking into the account also the data from the conducted research, it is necessary for laboratories that are in function within the health institutions, regardless, whether they are in primary, secondary or tertiary health system to start the requirements of Systems Quality Management to laboratories for the purpose of accreditation. With the beginning of the application of the requirements of these standards reliability of patients will start to raise in the values of laboratory tests. Other very important element is that the health care systems are complex, and have subcomponents of internal and external interconnected with each other or through clear rules or through visible understanding. Assessing the issues of human resource management is essential to understand how these systems function.

At the end the results of research partially confirmed our claim that the level of dissatisfaction is the overall results of the patient perception of quality of health services.

## 6. References

- [1] Abdal Kareem, A., Aday, L.A. & Walker, G.M. Jr. (1996) Patient satisfaction in government health facilities in the state Qatar. *J Community Health*, 21: 349-58.
- [2] Aizpuru, B. F. (1993). Barriers to verbal communication and consumer satisfaction with consultations in general medicine. *Gac Sanit*, 7(34): 27-31, [www.arbetterbeginnings.com](http://www.arbetterbeginnings.com)
- [3] Cleary, P. D. & McNeil B. J. (Spring, 1988). Patient satisfaction as an indicator of quality care: 25(1):25-36.
- [4] Donabedian, A. (April, 1981). Criteria, Norms and Standards of Quality: What Do They Mean? *American Journal of Public Health*. 409-412, [www.urbanaffairs.unlv.edu](http://www.urbanaffairs.unlv.edu).
- [5] Drucker, P.F. 1993. *The New Realities*. New York: Harper & Row.



- [6] EN ISO 17025. General requirements for the competence of testing and calibration laboratories. International Standards Office, Geneva.
- [7] Enriko, C. (2012). Problems Involved in Improving the Quality of Life in Albania in the Years 2000 – 2012, *Mediterranean Journal of Social Sciences*, [www.mcser.org](http://www.mcser.org).
- [8] Golden, B. (2006). Transforming Healthcare Organizations, *Healthcare Quarterly*, 10(Sp) November 2006: 10-19. DOI:10.12927/hcq.18490 , [www.longwoodsreview.com](http://www.longwoodsreview.com)
- [9] Gounaris, C. (2008). Health Services Quality and Management in Greece Efficiency and Effectiveness of NHS Secondary Health Care Units , pp. 6. Athens University of Economic and Business, [www.dmst.aueb.gr](http://www.dmst.aueb.gr)
- [10] Grant, E.S. (1988). Quality Medical Care. A definition. *JAMA*: 280:56-61.
- [11] ISO: IWA 1:2005. Quality Management System. Guidelines for process improvement in health service organization. International Standards Office, Geneva.
- [12] Stoimenova, Assena, Ani Stoilova, and Guenka Petrova. "ISO 9001 certification for hospitals in Bulgaria: does it help service?", *Biotechnology & Biotechnological Equipment*, 2014.
- [13] ISO 15189. Medical laboratories. Requirements for quality and competence. International Standards Office, Geneva.
- [14] ISQua (2007). International principles for healthcare standards. Dublin, A framework of requirements for standards
- [15] ISQua webinar (November, 2014). International standards for Quality in the health, Subashnie Devkaran.
- [16] Lazarus I. R., FACHE, & M. W. Chapman (2013). "ISO-Style" Healthcare: Designed to Keep Patients, Practitioners and Management Safe Principals, *Creative Healthcare*, [www.beckershospitalreview.com](http://www.beckershospitalreview.com).
- [17] Lleshi, S. (2015) The impact and effectiveness of QMS in Kosovo health, *Ditët e studimeve shqiptare*. European University of Tirana.
- [18] Murray, H., Locker, D., Mock, D. (1997). Patient satisfaction with a consultation at a craniofacial pain unit. *Community Dent Health*, 14(2): 69-73.
- [19] Nwabueze, U. (1997). Editorial: Total Quality Management in Health Care, *Total Quality Management*, Vol. 8, No. 5, pp. 203, <http://www.tandfonline.com/doi/abs/10.1080/0954412979442>
- [20] Picker Institute Europe (2002). *International Journal for Quality in Health Care*. Guidelines of quality management healthcare, Picker Institute Europe.
- [21] Shaw, C., Groene, O., Mora, N. & Sunol, R. (2010). Accreditation and ISO certification: do they explain differences in quality management in European hospital? *Int.J Qual Health Care*: 22(6); 445-451, [www.scielo.org](http://www.scielo.org).
- [22] Veronda, M. F. (2001). Patient satisfaction in managed care: Department of Public Administration, University of Nevada, Las Vegas.
- [23] Cutting-Decelle, A.-F., G.-I. Magnan, C. Mouton, and R.I.M. Young. "A Common Vocabulary to Express Standardization Features : Towards the Interoperability of Industrial Data Standards", *Enterprise Interoperability*, 2015.
- [24] WHO (2000). *Health Systems: Improving Performance*, Geneva <http://www.fmh.ch>.