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## **PRESENT- DAY QUALITY ASSURANCE IN HEALTH CARE SECTOR**

### **Introduction**

In order to reach a competitive advantage, organizations that are a part of the market economy must offer high quality products, function on the market and be competitive to other institutions. Service sector is particularly predestined to create competitive advantage that is based on reputation. Reputation involves reliability, and consequently, the staff that renders services, its qualifications and commitment have a direct impact on the service quality level. Health care centers are unique service providers as their products influence human health and life. The demand for medical services is not a consequence of one's expectations for the needs to be met but the result of necessity<sup>1</sup>.

The assurances of service quality in the health sector can be defined as the determination of the expectations from the staff and the supervision aiming at the most efficient way of providing the services. All organizations have four basic elements: human, material, financial and information resources. The management consists in their adequate streaming and application so that the targets of the organization are reached in the most effective way. The aim of the manager's work is to join and co-ordinate the resources by means of planning, i.e. determining the targets, to decide on the choice of the best methods of their implementation, to organize i.e. to put into order the activities and resources and to manage the work for the sake of the realization of the management process, and finally, to control, i.e. to monitor the work. The manager is responsible for the realization of the management process, which is different in small organizations and the big ones that require multilevel management<sup>2</sup>.

The introduction of methods of organization and management that are applied in the realm of economy, which aims at the increase of the effectiveness of medical care, generates a question whether it is possible to transfer mechanically the methods applied in business and public administration to such a different field as health service. In medicine, the objective is

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<sup>1</sup> A. Payne, *Marketing usług*, PWE, Warszawa 1996, pp. 21-23.

<sup>2</sup> J. Hausner, S. Mazur, *Od redakcji* (in): *Zarządzanie publiczne*, 2007, No 1.

to help the ones in need, and the scale of the help depends on the resources. The effects are immeasurable, difficult to check and depend on several factors. Managers must adapt their ways of management to the changing needs of clients / patients, which requires the creation of new adequate programs in the situation when material resources are increasingly scarce, costs and number of services are lowered and their quality is decreasing<sup>3</sup>.

The quality of service is an inseparable part of the marketing strategies of medical institutions. One could speak about quality management, which is related with the implementation of the ISO 9000 standards and the procedures of accreditation of medical units.

The article aims at the presentation of QM programs in the health sector, which result in the increase of patient satisfaction and have a positive impact on the image of a health care unit. They assist in the optimization of medical services and – generally speaking – the creation of effective management systems. Moreover, they increase the staff empathy and encourage the employees to be involved in decision-making processes.

## **1. Specific features of health care service**

According to Polish law, health service includes any activity aiming at the preservation, restoration and improvement of health, rescue operations, and other activities resulting from treatment processes or separate regulations that concern treatment principles<sup>4</sup>.

Medical services are unique in character and have several features that distinguish them from other services. They involve a high level of labor-consumption and specific requirements concerning high qualifications of the staff. They vary as regards the qualitative and quantitative aspects. Their structure, form and objectives must totally meet the demands of the patients and their families.

Moreover, the unique character of medical services consists in their elusiveness and the lack of the guarantee of effectiveness. Patients are not guaranteed that they will be cured by the treatment, and – on the other hand – they are not aware of the consequences of treatment procrastination. This is why education should also include issues that are related widely to hygiene and health prevention. Doctors should create a positive image of consulting rooms in order to encourage potential patients to use their services now and in the future. Patients are

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<sup>3</sup> K. Opolski, P. Modzelewski, *Zarządzanie jakością w usługach publicznych*, CEDEWU sp. z o.o., Warszawa 2004, pp. 39-41.

<sup>4</sup> Act on medical treatment of 15 April 2011, Dz.U. 2011 nr 112 poz. 654.(Journal of Laws, 2011, No 112 item 654)

frequently not able to assess the complexity of their health problem and, consequently, it is of great importance that the relationship between a doctor and a patient should be based on mutual trust<sup>5</sup>.

The relationship that is created when health service is provided is a significant feature and it is decisive as regards the service process; it influences its form, quality as well as patient's satisfaction. Medical services definitely belong to professional services, i.e. they involve – among other factors – specialist knowledge, high qualifications of the staff and influence on the lives of other people<sup>6</sup>.

Medical services are not just about treating patients; it involves several benefits that finally increase the value of the service provided. The awareness that the total value of the service is created by such factors as a pleasant stress-free conversation with a doctor, adequate atmosphere, efficient staff and proper facilities is of major significance<sup>7</sup>.

From the point of view of the health care that is understood as the provision of services, individual rights are of basic significance. They originate directly from human rights and freedoms which belong to every human being. They are: the right to be respected, the right of self-decision, the right to have physical and mental integrity respected, the feeling of security, and the right to have one's privacy respected. Moreover, such issues should be respected as individual's moral and cultural values, as well as religious and philosophical beliefs. It is crucial that these rights should be respected in the area of health protection due to the fact that the development of new, increasingly complicated and requiring specialist knowledge methods that need co-operation of specialist teams results in the depersonification and dehumanization of the patient.

In Polish law, regulations concerning patient's rights are included in the Constitution and several other acts. The Constitution of the Republic of Poland of 1997 defines the right to health protection in the following way : *Equal access to health care services, financed from public funds, shall be ensured by public authorities to citizens, irrespective of their material situation. The conditions for, and scope of, the provision of services shall be established by statute.*

The regulations in the Constitution emphasize the fact that the relation of patient's right to human rights is complementary in character and the regulations concerning the rights and

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<sup>5</sup> A. Bukowska-Piastryńska. Marketing usług zdrowotnych. Od budowania wizerunku placówki do zadowolenia klientów, CEDEWU sp. z o.o., Warszawa 2008, pp. 15-17.

<sup>6</sup> K.Krot, *Jakość i marketing usług medycznych*, Oficyna Wolters Kluwer Polska, Warszawa, 2008, pp. 9-11.

<sup>7</sup> H. Mruk, *Marketing gabinetów lekarskich na rynku usług zdrowotnych*, Oficyna Wolters Kluwer Polska, Warszawa, 2009, p. 76.

freedoms constitute a catalogue of patient's rights. On the 6<sup>th</sup> November 2008 the Parliament passed the Act on patient's rights and patient's rights defender, which was a part of a whole packet of health acts that reformed the health care system.

The most important acts include: medical profession act, nurses and midwives act, act on health care centers, act on mental health protection, act on transplantation of cells, tissues and organs and act on family planning, human embryo protection and conditions of permissibility of abortion. Heads of medical care centers are obliged to provide information on patient's rights. This is most frequently done by putting on information boards the Patient's Rights Charter, which is an extract of the legal acts in force.

## **2. The implementation of QM as required by the PN-EN ISO 9001:2009 standard**

When evaluating the value of the service provided, patients do not take into consideration the process itself but the final result, and their satisfaction of the service is one of the indicators of quality. QM system should consider patients as reliable informers and not just purchasers of services.

According to the requirements of the PN-EN ISO:9001:2009 standard, a health care unit should establish, document, implement and maintain a QM system, as well as work constantly on the improvement of its effectiveness. As a result, it should be able to identify and implement processes indispensable in a QM system, determine the sequences and mutual relationships of processes, define the criteria and methods necessary to ensure their effectiveness, to provide the accessibility of resources and necessary information, to monitor, measure and analyze the processes and to implement measures that are indispensable in the achievement of the targets.

When preparing a unit for the certification, the board conducts a review of the QM system to make sure whether the procedures required by the PN-EN ISO:9001:2009 standard have been implemented and function properly. After the review, a certifying unit is selected to conduct the audit and the deadline of certification is determined.

In order to check, whether all procedures function properly in a health institution, a preliminary audit is carried out, which is not an obligatory step. The real certification audit is conducted by a certifying unit that was chosen before and it lasts up to 3 days. The audit assesses to what degree the centre is prepared to operate in the QM system. Finally, a

certificate is granted or not. In the latter case, another review is indispensable after corrections to QMS that are made in accordance to the suggestions of the auditors.

The PN-EN ISO:9001:2009 standard includes the requirement of staff training, which results in personal development and the increase of knowledge among employees. Well educated workers have a higher sense of the value of their work and thanks to the knowledge gained in training courses they can be up to-date with all the novelties and current procedures. Training courses cover information on certification processes, i.e. the methods of evidence, the improvement of QM techniques, the quality policy, the role and objectives of the certificate and the scope of the PN-EN ISO:9001:2009 standard<sup>8</sup>.

The introduction of a QM system results in lowering the costs of running a health centre. Thanks to adequate procedures, hospital drug management is introduced and, as a result, waste is eliminated and every medicine goes directly to the right patient without any mistakes as the procedures define clearly how to deal with drugs. The procedures also define waste management and, consequently, after the introduction of waste segregation, the hospital may make savings by recycling the highest possible amount of waste. Sometimes, even insignificant changes may substantially reduce the costs of running a business. As a result, centers function more efficiently and the effects have their impact on staff remuneration.

The introduction of a quality management system to a hospital does not only make it more competitive but it also guarantees a high level of service, which has a positive impact on patients' trust. The certification introduces a scheme of action to the hospital, thanks to which the employees function on a higher level, their work is orderly and every individual carries out his/her duties in a responsible way. The staff, being aware that their work is regularly checked and assessed, do their best to follow the standards<sup>9</sup>.

A successful certification audit gives the opportunity to implement a complex management system – which is the assumption of the TQM idea. The implementation of the ISO 9001 quality management system is the first step to the improvement of the system. Practically, organizations that are genuinely committed to the TQM concept implement subsequent standardized management systems and integrate them into one<sup>10</sup>. As a result, service companies, hospitals included, meet quality requirements both on the domestic and

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<sup>8</sup> P. Grudowski, System zarządzania jakością wg normy ISO 9001 w małej firmie: dokumentacja, wdrażanie audit, Wyd. Ośrodek Postępu Organizacyjnego, Bydgoszcz, 2004, pp.18-39.

<sup>9</sup> M. Dobska, K.Rogoziński, *Podstawy zarządzania zakładem opieki zdrowotnej*, Polskie Wydawnictwo Naukowe, Warszawa 2008, p. 291.

<sup>10</sup> P. Kafel, T. Sikora, *Integrated Management Systems Certification – Survey Results*, Journal of Economics and Organization of Future Enterprise 2010, No. 10.

international markets. This gives the opportunity to provide services to patients from EU countries.

### **3. Accreditation of health care units. Quality Monitoring Centre (QMC)**

Among external methods of quality assurance, accreditation is the most widely tested and efficient method in the world. Its role is to find in contemporary health systems the issues that have the most significant impact on the level of services and safety of patients. Measurable criteria of health care assessment are determined for particular types of institutions – hospitals, outpatient care centers or long-term health centers – which are referred to as accreditation standards. They are dynamic in character and subject to regular modifications, depending on the pace of achieving the desired effects. Thus, the assumption of accreditation is met, which consists in a steady stimulation till the optimum level – defined by the accreditation standards – has been reached. Every time the standard requirements must be on a high, yet achievable level.

The most important element of the accreditation system is the fact that a single institution, such as a hospital, has the opportunity of self-assessment by comparing itself with the patterns of good behavior that are constituted by the accepted accreditation standards. In this way, the determination of its own weaknesses makes it possible to find ways of improving the processes that function within the institution<sup>11</sup>.

The accreditation enjoys a good reputation in Poland and institutions that apply for it eventually provide better service. This is the reason why the accreditation process is beneficial to several groups; however, the group that benefits most is the patients, who are given the opportunity to choose a better centre and obtain a high quality service.

The Act of 7 November 2008 on accreditation in health care aims at the confirmation that a health care unit meets the accreditation standards in the field of its activities<sup>12</sup>.

The accreditation program of a hospital includes 210 standards divided into 15 groups, while the accreditation program of a primary health care unit has 130 standards divided into 8 groups. The accreditation in the form of a certificate is granted by the Minister of Health on the basis of the recommendation from the QMC Accreditation Board after a successful assessment procedure. The certificate is valid for 3 years and confirms that the holder has achieved a high level of functioning and good quality of the service. At present (30<sup>th</sup> June

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<sup>11</sup> <http://www.cmj.org.pl/akredytacja/cotojest.php>

<sup>12</sup> Act of 6 November on accreditation in health care ( Journal of Laws) Dz.U.2009, No.52, item 418.

2013), in Poland there are 115 hospitals and 14 units of primary health care with accreditations.

The QMC in Health Care was established by the Minister of Health in 1994 and it is a central unit in the Ministry. The establishment of the Centre aimed at the support and promotion of actions for the sake of the improvement of the quality of medical services provided by all Polish health care institutions. Its objectives are as follows:

- to inspire and support actions that aim at the improvement of the medical service quality,
- to assess the factors that have an impact on the level of the health service,
- to assess the indicators of the results achieved by health care providers.

Independent inspectors of the QMC Accreditation Centre carry out the accreditation program of health care units along the lines of a defined set of standards. Everybody benefits from the accreditation, but patients are the main winners<sup>13</sup>.

#### 4. Comparison of the accreditation standards with the requirements of the PN-EN ISO 9001:2009 norm

The last few years have witnessed an increase of interest in the systems of management and improvement of standards in health care institutions. Hospital managers more frequently make decisions to implement a quality management system that complies with the requirements of the PN-EN ISO 9001:2009 standard than to apply for a status of an accredited unit. This is due to the fact that it is easier to obtain a QMS certificate than an accreditation certificate. . The comparison of the two systems is given in table 1.

**Table 1. Comparison of accreditation and certification systems**

| Criteria                                | Accreditation  | Certification  |
|---|--|--|
| Application range                       | Poland   | International  |
| Accreditation/Certification institution | QMC in Health Care in Krakow                                 | Over 40 institutions operating on the Polish market        |
| Certificate validity period             | 1 or 3 years   | 3 years  |
| Range of implementation                 | Whole unit   | Whole or part of the unit                                  |
| Standards                               | Management + medical standards                               | Management   |
| Monitoring team                         | Inspectors   | Auditors   |
| Monitoring                              | Optional   | Obligatory – once a year                                   |
| Field of application                    | Hospital treatment, primary medical care, outpatient clinics | Any institution, irrespective of the type and staff number |
| Person responsible for quality          | Head/Quality Manager   | Quality Officer, internal auditors                         |

Source: op.cit. M. Dobska, K. Rogoziński, Podstawy zarządzania zakładem opieki zdrowotnej, Warszawa, Wydawnictwo Naukowe PWN 2008, p.294.

<sup>13</sup> [www.cmj.org.pl/akredytacja](http://www.cmj.org.pl/akredytacja)

Due to the fact that the QM system based on the requirements of the ISO 9000 Series functions in different fields, the standards are considered universal as they can be applied both in manufacturing and service sector. Unfortunately, this feature does not make it possible to make assessments whether a particular medical process is provided on the adequate and required level. In such cases the ISO norms are supplemented by accreditation standards, which refer precisely to the values that are required in health care. This system is also more comprehensive as it covers many other elements of organization functioning whose objective is to ensure the quality. From this point of view, the lack of complexity is a weak point of accreditation since the standards do not form an integrated system, and their best supplementation is constituted by the QM system based on the norms of the ISO 9000 Series.

The relation between accreditation standards and the PN-EN ISO 9001:2009 norm works in the way that one accreditation standard most frequently corresponds to several items of the norm and vice versa, several accreditation standards correspond to one item of the norm. The advantage of the introduction of the PN-EN ISO 9001:2009 norm to a hospital is that it involves the obligation of continuous improvement, consistency of actions, a developed system of process management and a free choice of documentation on the condition of achieving the desired effectiveness. The strong points of the accreditation program are related to clearly formulated recommendations and principles that guarantee their implementation. The standards do not require additional interpretation, and the recommendations and principles are adjusted to the current organizational level of health care institutions in Poland. However, the weak point of the accreditation is that it is not consistent with the existing provisions, hospitals are not obliged to continuous improvement and the document including the accreditation program requires updating.

The implementation of a QM system in line with the requirements of the PN-EN ISO 9001-2009 norm as well as meeting the accreditation standards require commitment on the part of the whole hospital management as there are often problems with the interpretation concerning the terminology and the requirements of the norm. The two systems of quality management have the same objective to take care of the patient and to meet his/her needs and requirements during hospitalization. A detailed written plan of patient care is a key element<sup>14</sup>.

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<sup>14</sup> Materiały X. Jubileuszowej Ogólnopolskiej Konferencji Jakości w Opiece Zdrowotnej, CMJ, Kraków, 2006, Materiały XIV. Ogólnopolskiej Konferencji Jakości w Opiece Zdrowotnej, CMJ, Kraków, 2010.



## Summary

Due to the fact that global competition is increasing dramatically, the issues of quality are gaining in significance. The endeavor of companies to produce goods and offer services that meet the requirements of present-day civilization forces them to look for methods of quality improvement.

The rivalry between health care centers and changing conditions on the market result in the efforts to win the patient. Quality is becoming an increasingly significant factor in the competition among medical institutions. Patients' requirements in relation to health care and medical staff are increasing together with the rise of their awareness. They do not want to be treated instrumentally, and if they are, they lose confidence in the institutions where they are treated this way. In order to avoid such situations, many managers take measures aiming at the introduction of quality assurance and quality monitoring systems.

As a result of the implementation of a management system based on the PN-EN ISO 9001:2009 norm and the acquisition of an accreditation certificate, a health care unit may improve work organization by introducing adequate procedures, improve internal communication among employees, protect itself against claims by monitoring the equipment and reduce operational costs. Both certification and accreditation increase the quality of the service provided and, consequently, patients have bigger trust to the institution.

Accreditation and certification should be treated as complementary management systems since it frequently happens that some situations that are not accounted for by accreditation standards are taken into consideration by the ISO 9000 Series norms. The relation works both ways. Joining an accreditation system and the acquisition of a certificate of a QM system in compliance with the requirements of the PN-EN ISO 9001:2009 norm is optional. As a result, every institution has equal chances of implementing a QMS and receiving a certificate.

The increasing number of institutions with quality certificates improve the standards and, consequently, the quality of services and patient satisfaction.

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[1] [www.cmj.org.pl](http://www.cmj.org.pl)

## Abstract

The quality of medical service constitutes the main element of effective and efficient functioning of a medical institution. Under the conditions of the increasing competition, in order to ensure a high level of service, the units of health care implement quality management systems to meet the requirements of their patients / clients. Their aim is to be granted a certificate that confirms the compliancy of the systems with the requirements of the PN-EN ISO 9001:2009 norm. Obtaining the accreditation is a further natural step.

The article takes into consideration the specific features of the medical service sector and presents the concept and role of the certification and accreditation processes. It points out to the differences, similarities and benefits resulting from the implementation of the requirements of particular quality and accreditation standards.

Patients must always be in the focus of managers, irrespectively of a continuous process of reform of health service and changing standards. Patient should not only be treated as a client – recipient of medical service, but first of all as a human being who found him/herself in an unacceptable and difficult situation. The respect for patient's rights, proper relationships with medical staff and the observance of the system requirements are only some of the factors that generate patient's satisfaction and, consequently, high level of medical service.