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The role of standardized quality systems in the management of a healthcare provider

Abstract

Since the 1940s, the healthcare sector in Poland has been in constant evolution and requires constant improvement in the quality of services provided and customer-patient satisfaction. To facilitate quality management, systems dedicated to healthcare entities have been developed over the years, and others have been adapted to medical facilities. These methods are based on efficient, planned, repeatable, documented procedures based on current medical knowledge. The key is to choose the right system, tailored to the way the entity operates. A quality management system defines: organizational structure, available resources, procedures and processes to be implemented, the way information and documents communicate and flow, and the responsibility for quality assurance care and compliance. Creating awareness and a pro-quality attitude in the field of medical services makes it possible to learn about instruments and solutions aimed directly at healthcare provider, as well as those that can be adapted and subsequently implemented.

Keywords: ISO standards, accreditation standards, total quality management, adverse events, medical mistake, management.

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INTRODUCTION

The category of quality has been shaped since the beginning of civilisation, with documented origins dating back to 1700 BC, when the Code of Hammurabi, the oldest casuistic code in the world containing a system of penalties, was written down [1]. The first quality control systems were already established in ancient times. In Egypt, standardised measuring methods were used during the construction of the pyramids and thus verified the quality of the buildings, and during the reign of Ramses II (c. 1200 BC), lists of goods appeared, which were specifications of the requirements to be met [2]. During the reign of the Zhou Dynasty in China (11th to 18th century BC), a quality control system consisting of several departments was introduced. However, this revolutionary concept negatively affected China's economic development by preventing the implementation of new technological developments, the effects of which were felt until the 1980s [3]. In the 6th century BC Master Laozi in the Book of Tao Te Ching (translated as The Book of the Way and Virtue) defined the category of quality as a perfection that cannot be achieved but must be persistently pursued, which gave rise to the so-called Japanese school of quality [4]. However, the very concept of quality originated in Greek philosophical thought. Plato in his reflections invoked the word 'poiotes' defined as a certain degree of perfection. The Roman speaker Cicero, on the other hand, introduced the Latin word 'qualitas', which we now regard as the prototype of today's quality [5]. In modern times, A. Descartes and J. Lock explored the concept of quality, which was later challenged by I. Kant and G. Hegel, who proposed a more logical account of quality. Since the 1950s, a number of theories and concepts have been developed by W.A. Shewhart, J.M. Juran, T. Kotarbinski, W.E. Deming, A.V. Feigenbaum, J.S. Oakland, P.B. Crosby, J. Bank and S. Payson. Also in the developed ISO standards we find definitions concerning quality [6]. The currently commonly used definition, which we can find in the PWN Polish language dictionary, refers to the Aristotelian concept and means the value of something, i.e. the characteristics of an object that distinguish it from others [7].

Poland is still in the process of systemic transformation, which aims to maintain a mixed system, public-private, with a predominance of public insurance – health premiums and a widening range of medical services and private insurance. As a result of the continuous lack of radical reforms in the system, the growing competition on the Polish market of medical services is based primarily on management by quality and constant improvement of patient satisfaction. To create awareness and a pro-quality attitude in medical services, it is necessary to learn about instruments and solutions aimed directly at medical entities, as well as those that can be adapted to them, and then try to implement them [8].

There are many definitions of the term 'service', which, for the purposes of analysis, can be reduced to one broad definition, describing a service as a set of values, activities and interactions between an entity that needs them and an entity that is able to provide them and meet those needs [6]. Each service should be considered in several dimensions, as the high share of the human factor significantly hinders the standardisation

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of processes and the unification of its components. The most important of these are considered to be [7,9]:
- provider;
- recipient of the service;
- the scope of the service;
- the value of the service;
- the infrastructure required to provide the service;
- the place where the service is to be provided;
- the duration of the service;
- service methods;
- range of service provision.

Only by analysing all the factors does it become possible to determine the attractiveness and usefulness of a given service, as well as to estimate demand.

The turn of the 1970s and 1980s brought the service sphere into the field of quality research. The forerunners of these considerations were researchers from the Swedish School of Marketing and the University of Texas [2]. Of the many models developed by Ch. Grönroos, A. Parasuraman, C. King, D. A. Garvin, among others, the most important seems to be that of E. Gummesson, who distinguished several elements of perceived quality [3,7]:
1. the product;
2. manufacture;
3. delivery;
4. relationship.

Ch. Grönroos, on the other hand, already identified two dimensions of quality in 1982: technical and functional. The result of these two concepts is the combined Grönroos-Gummesson quality model, in which the quality of an offer is ultimately determined by the perception of the service purchaser [2].

By integrating empirical data from qualitative research in services and a qualitative model developed for services in a manufacturing company, a synthetic model was created showing that in a customer-directed offer, goods and services form an inseparable whole.

G.A. Cole's model of customer-perceived quality, which was developed in 1994, shows that the customer perceives quality through the prism of many factors, the elements that make up the service. It is also necessary to take into account the subjectivity of the individual customer's assessment, i.e. the perceived quality of the service, which cannot be objectified [2].

The multidimensional and ambiguous nature of service quality makes it possible to significantly improve customer satisfaction, only if the characteristics of this service are correctly defined and become a value in themselves.

The healthcare market is characterised by [6]:
- lack of stable demand;
- random distribution of demand throughout the country;
- irrational patient behaviour;
- varying levels of service provision and trained professionals between providers;
- patients suffering from different conditions, with specific needs, are considered a homogeneous group, in the face of systemic changes;
- structural decisions subordinated to regulated market mechanisms.

Medical services are characterised by the typical qualities of services: immateriality, a strong link between the provider and the recipient of the service, volatility, impermanence, inability to acquire ownership, information asymmetry, uncertainty and risk. In addition, there are characteristics specific only to medical services: highly qualified medical personnel, individually tailored delivery process, service delivery technique, limited patient decision-making, impossibility to find substitutes, complex doctor-patient relationship, influence of external factors [6].

The Harvard School of Public Health has identified three aspects that affect quality [6]:
- accessibility of the services provided, taking into account: financial, organisational, cultural, psychological factors;
- patient satisfaction with services provided;
- clinical quality: safety and reliability of services.

In the World Health Organization's 2018 revised approach, we define high quality health services as [6]:
- effective;
- safe;
- patient-centred;
- timely;
- equitable,;
- integrated.

The definition of quality in medical services has a multifaceted dimension and is highly dependent on the perspective from which it is assessed. Each medical service should be treated in a unique way, adjusted for the individual needs of the patient to whom it is offered. Patients are increasingly willing to participate in the treatment process and, as full participants in the healthcare market, are actively involved in shaping it. Managers of medical entities must consciously recognise the needs of individual groups of patients and strive to improve the level of quality of services provided, as well as take care of safety during their performance. In this process, knowledge of quality management systems, models, instruments and tools is essential.

AIM

The aim of the study is to show how complex quality management processes are implemented in every medical entity and how their full integration improves the quality of the healthcare services provided.

MATERIAL AND METHOD

A literature review from 1998-2023 was conducted. Polish legal acts, expert books, accreditation standards, articles and reports were analyzed. Websites of scientific organizations such as the WHO (World Health Organisation) and the OECD (Organisation for Economic Co-operation and Development) were also considered.

RESULTS

The healthcare sector in Poland has been in constant evolution and requires continuous improvement in the quality of services provided and customer-patient satisfaction. In order to facilitate quality management, systems dedicated to healthcare

entities have been developed over the years and others have been adapted to medical facilities. These methods are based on efficient, planned, repeatable, documented procedures based on current medical knowledge. It is crucial to choose the right system, tailored to the way the entity operates. The quality management system defines: the organisational structure, the available resources, the procedures and processes to be implemented, the way in which information and documents are communicated and circulated, and the responsibility for quality assurance and compliance [9].

Accreditation

Accreditation is an external evaluation process carried out by an impartial, independent accreditation body to which a healthcare provider voluntarily submits. The purpose of accreditation is to check the extent to which a healthcare provider meets the accreditation standards in terms of the services provided and the way it operates [10]. The system of 150 standards and 88 sub-standards proposed by the Healthcare Quality Monitoring Centre in Krakow is based on three groups: patient care, hospital management and functioning, and medical procedures carried out by the hospital, grouped into fifteen sections of the Hospital Accreditation Programme [11]. The origins of the accreditation system date back to 1991, or more precisely to 30th August, when the Act on Health Care Institutions came into force. In 1994, the Centre for Monitoring Quality in Health Care was established by an Order of the Minister of Health and Social Welfare. As a unit of the Ministry of Health, the CMJ is supposed to support hospitals in improving the quality of their services and to develop and implement the Programme for the Accreditation of Hospitals in Poland, which began in 1996 [12]. In 1998, the Hospital Accreditation Programme was finally established [13].

The Hospital Accreditation Programme is characterised by [14]:

- voluntariness;
- independence and autonomy of accreditation decisions;
- periodicity of assessment;
- self-assessment;
- compliance with a known accreditation procedure;
- openness and equality of evaluation and decision-making principles;
- educational purpose – peer review.

Work is currently underway to create new accreditation standards, as the existing ones expired on 31.12.2023. Accreditation encompasses the entire medical facility and all processes taking place within it, therefore the assessment carried out during the accreditation visit is comprehensive. A facility applying for accreditation independently submits an application and a self-assessment questionnaire to the CMJ, the full voluntariness of submitting to the assessment should be emphasised, and the readiness to join the process and meet the standards is stated by the management of the healthcare facility. The accreditation visit to verify the self-assessment of the entity always takes place on a specific date, its course and the composition of the assessment team are also public. The conduct of the assessment procedure is subject to a fee, which constitutes revenue for the state budget [10]. After the completed visit, the Accreditation Council makes an accreditation decision in the form of a resolution based on the review report, which is then forwarded to the Minister responsible for health. The Minister's decision may differ from the Council's recommendation, however this requires an additional, openly available justification.

As of 02.05.2024, 189 hospitals in Poland are accredited, including 2 highly specialised hospitals [15]. Accreditation is a clear system for supervising and supporting the development of hospitals. By putting the safety and well-being of the patient first, it ensures that hospitals are increasingly fulfilling their role in the national healthcare system and that the services they provide are of a high quality. By covering not only the medical, but also the technical and organisational aspects, accreditation motivates staff for continuous training and development and increases cost-effectiveness. By identifying areas for improvement, it provides a simple and inexpensive way to improve the quality of hospital operations. Nowadays, the key element is not to obtain the certificate itself, but to implement changes and standards for their evaluation, so that regular accreditation can influence the continuous improvement of healthcare.

ISO 9001:2015 standards

ISO 9000 standards were first developed and published in 1987 by the International Organization for Standardization (ISO) [16]. However, it is worth noting that the 'ISO' in ISO 9000 comes from the Greek word 'isos' meaning 'equal' [2]. One of the core standards is ISO 9001, the only standard with which you can be certified, and it sets out the requirements for quality management systems [12]. The current international standard PN-EN 15224:2017-02 'Quality management systems – requirements' describes requirements specific to the healthcare sector in line with PN-EN ISO 9001:2015. These are universal standards that can be applied to any organisation, regardless of its business profile. The requirements are not rigidly limited and apply to the management system itself, not to the services provided. In a nutshell, ISO standards standardise the processes currently in place in an organisation and introduce tools to monitor and improve the level of quality of services provided. By taking a process approach to an organisation's activities, the ISO 9001 standards encourage the creation, formalisation, implementation, observation and continuous improvement of a quality management system [17]. We can apply them to the entire organisation, specific areas or a selected department or function [11]. Standards also apply to healthcare entities: ISO 31000 – risk management, ISO 22000 – food safety, ISO 19011 – auditing quality and environmental management systems, ISO 9004 – systems improvement. They are only complementary to EN 15224:2017-02, and actually to EN ISO 9001:2015, which is the most common in healthcare entities [11]. Facility managers would not benefit much from the implementation of EN 15224:2017-02 if they had been improving the operations of their quality management system according to ISO 9001 for many years and taking into account the specificities of the medical sector themselves [11].

The key principles of ISO 9001:2015 are [12]:

- customer-patient orientation;
- strong and sustainable leadership;
- employee involvement;
- focus on processes;
- continuous system improvement;
- decisions based on facts and evidence;
- human resources management.

Expanded and subdivided into chapters and subsections, the standards aim to facilitate a comprehensive management approach and maximise the benefits of implementing a quality management system. Combining process management with risk management enables process improvement based on data analysis with consideration of risks and opportunities, significantly increasing the effectiveness of the system and minimising the risk of adverse events. In ISO 9001:2015, an effective quality management system is characterised by: the organisation's continued ability to deliver services, meeting regulatory requirements, and increasing patient satisfaction with healthcare services. The improvement process consists of repetitive, cyclically consecutive activities and only a continuous focus on its implementation can bring long-term results.

In summary, accreditation creates standards and procedures, while ISO creates formal procedures and instructions for staff. Increasing competition on the market for medical services, as well as the complex nature of the hospital as an organisation, forces the head of the entity to choose the most appropriate or several most appropriate quality management systems. The parallel processes of accreditation and certification can definitely have a positive impact on the long-term development of the hospital organisation and all its employees, increase patients' satisfaction with the health services provided to them, and reduce wastage of financial resources. It is also important to raise awareness of the causes and consequences of adverse events, whose risk of occurrence is significantly minimised by the standardisation of procedures.

CONCLUSIONS

Healthcare entities providing round-the-clock inpatient healthcare services mostly lacking an organizational culture, faced with a very complex and legally unstructured healthcare system carrying a high risk of adverse events, face a major challenge requiring focused attention and investment of financial resources in the implementation of effective quality management systems. Flexibility of actions taken, quick response to unpredictable situations, fair organization of work, safety of employees, reliable feedback are key principles to ensure high quality of medical services provided. It is not individual hospitals, but the entire healthcare system that should strive to improve the safety and quality of healthcare services. After minor or major emergencies, it is always worth updating plans and reassessing the opportunities and risks involved. To prevent adverse events, each problematic situation should be seen as a test of the processes that manage and minimize it, always putting patient safety first.

REFERENCES

1. Dehlgaard JJ, Kristesen K, Kishore GK. Podstawy zarządzania jakością Warszawa: PWN, 2000. p.13-4.
2. Dobska M, Dobski P. Systemy zarządzania jakością w podmiotach leczniczych. Warszawa: Wolters Kluwer Polska; 2016. p.13-107.
3. Karaszewski R. Nowoczesne koncepcje zarządzania jakością, Toruń: Towarzystwo Naukowe Organizacji i Kierownictwa. Stowarzyszenie Wyższej Użyteczności Dom Organizatora; 2006. p.86-91.
4. Dobska M, Dobski P. Zarządzanie jakością w podmiotach leczniczych. Warszawa: Wolters Kluwer Polska; 2012. p.12.
5. Karaś E. Metoda oceny jakości zarządzania przedsiębiorstwem. Rozprawa Doktorska. Wrocław: Politechnika Wrocławska; 2005. p.76-7.
6. Wiśniewska MZ. Jakość usług medycznych. Instrumenty i modele. Warszawa: CeDeWu Sp. z o.o.; 2021. p.14-20.
7. Słownik Języka Polskiego PWN. [https://sjp.pwn.pl.] (access: 08.03.2024).
8. Nojszewska E. System ochrony zdrowia w Polsce. Warszawa: Wolters Kluwer Polska; 2011. p. 175-93.
9. Hamrol A, Mantura W. Zarządzanie jakością. Teoria i praktyka. Warszawa: Wydawnictwo Naukowe PWN; 2005. p.104-5.
10. Kancelaria Sejmu RP. Ustawa z dnia 16 czerwca 2023 r. o jakości w opiece zdrowotnej i bezpieczeństwie pacjenta. Dz. U. 2023 poz. 1692. [https://isap.sejm.gov.pl/] (access: 05. 05.2024).
11. Dobska M, Dobski P. Rola znormalizowanych systemów w zarządzaniu podmiotami leczniczymi,.Warszawa: Difin; 2023. p.50-133.
12. Ćwik K. Jakość w usługach medycznych. Wpływ systemów zarządzania jakością na efektywność publicznych usług szpitalnych. Warszawa: Difin; 2023. p.73.
13. Centrum Monitorowania Jakości w Ochronie Zdrowia. Zestaw standardów. Kraków: Centrum Monitorowania Jakości; 1998.
14. Sztela A. Zewnętrzne metody oceny jakości w ochronie zdrowia – akredytacja i system zarządzania jakością według normy ISO 9001:2008. Probl Zarządz. 2021;10:213.
15. Centrum Monitorowania Jakości w Ochronie Zdrowia. Lista akredytowanych podmiotów. [www.cmj.gov.pl]. (access: 02.05.2024).
16. Opolski K, Dykowska G, Możdżonek M. Zarządzanie przez jakość w usługach zdrowotnych. Warszawa: CeDeWu Sp. z o.o.; 2023. p.32-111.
17. Kwiatkowska M. Zdarzenia niepożądane w lecznictwie szpitalnym i podstawowej opiece zdrowotnej. Warszawa: Wolters Kluwer Polska; 2020. p.92-3.
18. Bukowska-Piestrzyńska A. Marketing usług zdrowotnych. Od budowania wizerunku placówki do zadowolenia klientów Warszawa: CeDeWu Sp. z o. o.; 2023. p.17-9.

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