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EN ISO 9001:2015 Quality Management System for Health Care Sector in Accordance with PN-EN 15224:2017-02 Standard and Accreditation Standards of the Minister of Health – Comparative Analysis

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Abstract

The aim: *The aim of this article is to indicate similarities and differences between EN ISO 9001:2015 quality management system in accordance with PN-EN 15224:2017-02 standard and the accreditation standards of the Minister of Health.*

Material and methods: *A comparative analysis of two documents describing requirements of the quality management system EN ISO 9001:2015 in accordance with PN-EN 15224:2017-02 and accreditation standards of the Minister of Health issued by the Quality Monitoring Centre was performed.*

Results: This comparative analysis concerns individual aspects/quality requirements of the PN-EN 15224-02 standard with reference to thematically analogous accreditation standards. According to the following analysis designation of both the PN-EN 15224:2017-02 standard and accreditation for health care sector causes natural, very high convergence and similarity between both systems. For specialist and expert on discussed subject, there is no bigger problem with connecting mutual reference of requirements of individual quality aspects described in the standard and accreditation standards. The PN-EN 15224:2017-02 standard, similarly to accreditation standards, pays particular attention to obligation to manage clinical risk during planning, implementation and control of individual process which becomes the key element of quality management system for clinical activities. In both cases, data related to significant events connected with hospitalization should be analyzed and assessed, and conclusions and observations should be used to conduct improvement projects in important health care areas in accordance with the E. Deming quality improvement methodology (PDCA cycle). However, they can`t be said to be identical. Differences result from the very structure of the documents. Accreditation standards are divided into 15 subject areas, gathering a total of 221 standards. The PN-EN 15224:2017-02 standard, in accordance with the ISO/ IEC Directives, Part 1, Consolidated ISO Supplement, Annex SL, contains common, consistent structure of new revised management system standards. Another difference between discussed systems concerns scope of both documents, the standard has international dimension and the set of standards is definitely national.

There are, of course, many more similarities as well as differences, which this article deals with in full.

Conclusions: *Carried out analysis shows clearly that, despite formal differences, there are numerous connections and analogies between requirements of individual quality aspects of the PN-EN 15224:2017-02 standard and requirements of the accreditation standards. Effective implementation of both requirements of the ISO standard in question and accreditation standards can constitute the basis for creating a single, consistent and effective management system for treatment entity as a whole.*

Key words: *ISO, accreditation, certification, quality, safety.*

Introduction

The quality providing process in treatment entities requires a holistic and interdisciplinary approach. Health services provided in health care units should be realized not only in accordance with specific standards but also based on current medical knowledge and values that are important from patient`s perspective [1]. Quality management systems based on international ISO standard and accreditation granted by the Minister of Health are the basic instruments which guarantee the highest quality of health services. Both systems impose on the treatment entity number of actions which, by reducing risk associated with provision of health services and standardizing of medical and organizational procedures, in significant way impact on increase of the knowledge about the entity and possible irregularities, enabling initiation of appropriate improvement actions led directly to improve safety of provided health care.

One of the most popular management systems implemented and maintained in medical entities, which constitutes basis to build integrated management systems, is the quality management system according to ISO 9001. However, if we think of system influencing the process of improving quality and safety of patients, there is the accreditation of the Minister of Health, whose holistic nature and explicit purpose for assessment of health care allows collecting information about global health system and its real problems [2].

In the environment dealing with implementation of quality guarantee systems (including representatives of the Center of Quality Monitoring in Health Care (CMJ), employees of individual certification bodies in accordance with ISO standard, management of medical entities) there is a clear lack of compliance: if the accreditation granted by the Minister of Health and certification according to ISO standards are competing or rather complementary systems for assessing functioning of medical facilities [3]. Supporters of ISO management systems emphasize that current standards regulate the requirements in such way that all organizations can use them to measure effectiveness of their activities and are definitely more likely

to indicate compatibility of the requirements of accreditation standards and only implementation of accreditation is insufficient mechanism to achieve a significant improvement in the quality of services [4]. However, supporters of accreditation indicate its orientation in key areas related to improvement of quality and safety of care, without finding too many connections with the requirements of ISO standards where, in their opinion, scope of the assessment is too general and arbitrary, often fragmentary, or even agreed with the interested party. However, there is no doubt that the accreditation of the Minister of Health and certification for compliance with ISO standard are methods of review and evaluation of medical entities. However, the approach to ISO has been changing, especially since management standard in medical entities in accordance with PN-EN 15224:2017-02 was adopted and implemented. "EN ISO 9001:2015 quality management system for health care sector" (first edition of the standard in Poland, 2013 – PN-EN 15224:2013-04) [5].

The aim of this article is to indicate similarities and differences between EN ISO 9001:2015 quality management system in accordance with PN-EN 15224:2017-02 standard and the accreditation standards of the Minister of Health.

Material and methods

A comparative analysis of two documents describing requirements of the quality management system EN ISO 9001:2015 in accordance with PN-EN 15224:2017-02 and accreditation standards of the Minister of Health issued by the Quality Monitoring Centre was performed [6]. Due to the length of both documents, only some part of assumptions and requirements which were considered the most important in the quality improvement process in medical entity were analyzed in detail. The element enriching the analysis and conclusions presented in the article are observations and thoughts of two of co-authors of the article who have many years of experience in implementing and maintaining these systems in medical entities.

Results

This comparative analysis concerns individual aspects/quality requirements of the PN-EN 15224-02 standard with reference to thematically analogous accreditation standards. The first quality aspect of the PN-EN 15224:2017-02 standard is proper/adequate care. As it is indicated in Table 1, related elements can be found among accreditation standards of at least four areas: Patient Rights (PP), Patient Condition Assessment (OS), Care of Patient (OP) and Improvement of Patient Quality and Safety (PJ).

Firstly, according to the PP 1 standard, each patient is informed about their rights and obligations, these rights should be written down, legible and made available in the places where patients stay. In Poland the patient rights are defined in the Act of November 6, 2008 on patient rights and the Patient Rights Ombudsman (Journal of Laws 2009, No 52, item 417), where at the very beginning in Chapter 2 we read about the right to health services provided with proper diligence, in conditions which correspond to professional and sanitary requirements [7]. With regard to accreditation standards in the area of OS, it fully refers to comprehensive and team assessment of condition of the patient as the basis for establishing a care plan including diagnostic and therapeutic activities.

There is definitely an analogy to this qualitative aspect in the form of the rank and importance of the interview and physical examination, nursing assessment and daily medical assessment, as well as in accordance with the requirements of accreditation standards in the area of PJ, the need to identify and assess the risk of adverse events. Undoubtedly, we can also find a connection among the accreditation standards in the area of Care of Patient, such as OP 1 and OP 1.1, regarding the development of a care plan and its modification depending on needs.

The subject of *availability of services*, *equal treatment* or *timeliness*, referred to in the following quality requirements of the PN-EN 15224:2017-02 standard, was included by the authors of the accreditation standards both in the area of Patient Rights (PP) and in the area of Improvement

of Patient Quality and Safety (PJ). As before, compliance with rights and obligations of patient obliges medical entities to provide patients, when possibilities to provide appropriate health services are limited, right to transparent, objective, based on medical criteria procedures which determine order of access to these services. Moreover, according to Art. 7 sec. 1 of the Act, patient has right to immediate medical services due to threat to their health or life [7]. The part of Improvement of Patient Quality and Safety in PJ 1 accreditation standard indicates obligation to develop program of activities for quality improvement and, in accordance with the indicated explanation, a written program can also include improvement of service availability, while in PJ 5 *Patient Safety* standard, among adverse events requiring monitoring and analysis untimely provided care was included.

Continuity of care is another qualitative aspect and similarly named CO accreditation standards department, definitely in both cases emphasizing need to perceive individual services provided to patient during hospitalization as elements of comprehensive medical care, where successive phases of medical care require continuity and guarantee of continuation of treatment [6].

The greatest number of connections between quality aspects indicated in quality standards for health care sectors and individual areas of requirements of accreditation standards can be found with regard to effectiveness and efficiency of undertaken activities and patient safety. In fact, true will be statement that they are the most important areas to the provision of health services. Therefore it is not difficult to find existing analogies. The connection of quality aspects of the PN-EN 15224:2017-02 standard – effectiveness and efficiency with individual areas of accreditation standards can be successfully found in following parts: (1) Care of Patient (OP); (2) Infection Control (KZ), (3) Treatments and anesthesia (ZA), (4) Pharmacotherapy (FA), (5) Laboratory (LA), (6) Improvement of Patient Quality and Safety (PJ), (7) General Management (ZO), (8) Human Resource Management (ZZ), (9) Information Management (ZI), (10) Management of Care Environment (ŚO).

References to aspects of patient safety, which in both systems have been called very similarly and both refer to the concept of quality improvement of E. Deming (PDCA cycle: plan/ do/check/ act) [8] as an effective tool to improve quality of clinical processes and management processes, we can find among the following accreditation areas: (1) Care Continuity (CO), (2) Improvement of Patient Quality and Safety (PJ), (3) Human Resource Management (ZZ), (4) Information Management (ZI), (5) Management of Care Environment (ŚO). In fact, practically each of 11 quality aspects or 221 accreditation standards has an element aimed at directly or indirectly ensuring safety of patients, their families and health care staff.

Considering another quality aspect of the PN-EN 15224:2017-02 standard – care based on evidence/ knowledge, you can again find similarities to accreditation standards in such areas as: Patient Rights (PP), Care of Patient (OP), Improvement of Patient Quality and Safety (PJ) and Human Resource Management (ZZ). Similarly to the aspect of adequate/ proper care, obligatory observance of patient`s rights obliges medical entities, in accordance with the Act on Patient Rights and Patient`s Rights Ombudsman of November 6, 2008, to provide health services in accordance with current medical knowledge, provided with due care and in conditions which meet professional and sanitary requirements [6]. Among OP standards, care based on evidence and knowledge is indicated by, for example, OP 2 standard. In the hospital, Standard Operating Procedures (SOP) work, including in emergency life-threatening situations. SOP should be developed in each ward and based on clinical practice guidelines. Undoubtedly, provision of health services based on evidence and knowledge will also be influenced by actions taken and implemented as part of meeting the requirements of accreditation standards in area of PJ, such as PJ 2. Regular analyses of important events related to hospitalization (extended stays/ deaths/ readmissions/ reoperations) or PJ 5 are performed in the hospital. Patient safety (identification, collection and analysis of data on adverse events, use of conclusions from conducted analyzes), which properly reported and, above all, thoroughly analy-

zed, provide the most valuable knowledge about the organization and its processes, capture areas for improvement, provide opportunity to learn from possible mistakes. Also very important for care based on evidence and knowledge is taking up policy of continuous improvement of staff qualifications, i.e. the accreditation standard ZZ 5, along with defining educational needs of individual professional groups ZZ 5.1, planning and implementation of training ZZ 5.2 – ZZ 5.5

Patient-centered care is another one of qualitative aspects of the PN--EN 15224:2017-02 standard, focusing on personal preferences and needs as well as on physical, mental and social integrity of the patient. Such an approach can be found in at least several areas of accreditation standards, with particular emphasis on Care Continuity (CO), Patient Rights (PP), Patient Assessment (OS), Care of Patient (OP), Improvement of Patient Quality and Safety (PJ). Exactly as indicated in the discussed qualitative aspect, the PP 6 accreditation standard concerns he patient`s conscious agreement for performed procedures, preceded by gaining understandable information on proposed treatment method, expected benefits, risk, long-term effects and other possible ways of acting [7]. In the case of accreditation standards, approvals are also connected with following requirements:

- CO 1 Patient admission procedures (including method of obtaining patient`s consent for hospitalization) has been developed and implemented in the hospital,
- PP 5 List of procedures requiring additional patient consent has been defined,
- PP 7 Patients give their conscious consent to anesthesia,
- PP 8 Patients give their conscious consent to participate in medical experiment.

Comprehensive approach to the patient, focusing on his physical, mental and social integrity we can also find among accreditation standards in area of Patient Condition Assessment, such as OS 1. Scope of medical interview and physical examination OS 2 has been defined in the hospital. The hospital defined scope of nursing assessment, OS 5.3 results of

physical examination, OS 5.4 assessment of patient mental state and OS 5.5 assessment of patient social status, in which family and environmental interview is integral part of holistic assessment of the patient health. Based on interview, physical examination and preliminary test results, a care plan is developed, which was also referred to earlier, it concerns OP 1 accreditation standard in the area of Care of Patient (OP).

The last analyzed quality requirement of the PN-EN 15224:2017-02 standard is patient involvement. Mentioned above accreditation standards related to patient consent to either hospitalization or individual medical procedures are consistent with subject of the matter because the patient involvement, referred to discussed norm, is primarily his active participation, first in making decisions and then in implementation of individual medical procedures related to treatment process. Analyzing on, elements which engage the patient, and even more, his family, can be found in accreditation area of Care Continuity (CO), Patients Rights (PP) and Nutrition (OD).

Table 1 shows quality aspects/ requirements of the PN-EN 15224:2017-02 standard with thematically relevant areas of accreditation standards which have been discussed in detail in this part of the article.

Table 1. Connection of quality aspects/ requirements of the PN-EN 15224:2017-02 standard with thematically relevant areas of accreditation standards

	Quality aspect/ requirement in the standard PN-EN 15224:2017-02							
Accreditation standards (areas)	Proper, adequate care	Availability; Own Capital/ equal treatment; Timeliness (punctuality)/ availability	Care continuity	Effectiveness, Efficiency	Care based on knowledge evidence	Patient--centered care, including physical, mental and social integrity	Patient involvement	Patient safety
Care Continuity (CO)			+			+	+	+
Patient Rights (PP)	+	+			+	+	+	
Patient Condition Assessment (OS)	+					+		
Care of Patient (OP)	+			+	+	+		
Infection Control (KZ)				+				
Treatments and anesthesia (ZA)				+				
Pharmacotherapy (FA)				+				
Laboratory (LA)				+				

Image Diagnostics (DO)								
Nutrition (OD)			+				+	
Improvement of Patient Quality and Safety (PJ)	+	+		+	+			+
General Management (ZO)				+				
Human Resource Management (ZZ)				+	+			+
Information Management (ZI)				+				+
Management of Care Environment (ŚO)				+				+

According to the above analysis designation of both the PN-EN 15224:2017-02 standard and accreditation for health care sector causes natural, very high convergence and similarity between both systems. For specialist and expert on discussed subject, there is no bigger problem with connecting mutual reference of requirements of individual quality aspects described in the standard and accreditation standards. However, they can`t be said to be identical. Differences result from the very structure of the documents. The PN-EN 15224:2017-02 standard, in accordance with the ISO/ IEC Directives, Part 1, Consolidated ISO Supplement, Annex SL, contains common, consistent structure of new revised management system standards in form of following points (universal structure):

1. Scope of the standard
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operational activities
9. Assessment of effects of the activities
10. Improvement

Reaching specific qualitative, discussed above, aspects requires thorough understanding and exploring entire content because information about them is included both in the introduction and in operational activities, and descriptions and explanations of requirements from other sections of the standard in question constitute a complement of holistic approach to quality management in health care.

Accreditation standards are divided into 15 subject areas, gathering a total of 221 standards. Subject accreditation areas (strictly defined structure):

1. Continuity of Care (CO).
2. Patient Rights (PP).

3. Assessment of Patient Condition (OS).
4. Patient Care (OP).
5. Infection Control (KZ).
6. Treatment and Anesthesia (ZA).
7. Pharmacotherapy (FA).
8. Laboratory (LA).
9. Medical imaging (DO).
10. Nutrition (OD).
11. Quality Improving and Safety of the Patient (PJ).
12. General Management (ZO).
13. Human Resource Management (ZZ).
14. Information Management (ZI).
15. Care Environment Management (ŚO).

Another difference between discussed systems concerns scope of both documents, the standard has international dimension and the set of standards is definitely national. In the case of the PN-EN 15224:2017-02 standard, obtaining the certificate takes place if all requirements of the standard are met (it is acceptable to exclude requirements which don`t apply, from scope of the system, such exclusion should be justified and proved that it doesn`t affect the medical entity`s ability to ensure compliance of provided services). Accreditation system assumes granting of certificate after meeting at least 75% of the standards.

Moreover, the PN-EN 15224:2017-02 standard establish periodic audits of system compliance in 3-year certification cycle – usually in form of 2 surveillance audits, accreditation in present form doesn`t provide for such solutions.

Method of compliance assessment is also different. In the case of the standard, assessment is the most often performed by a certification body chosen by a given medical entity, in accreditation system only CMJ. In the standard compliance with given requirement is assessed, accreditation standards differ in importance assigned to them (4-point scale: 1.0, 0.75, 0.5, 0.25), and the final result is component of importance and assessments of standards for which a three-point scale was adopted, points

1, 3 or 5, where 1 means non-compliance with the standard, 3 is a partial compliance and 5 confirms full compliance with a given requirement, or two-degree scale, points 1 or 5, in the case of even partial non-compliance the standard is rated 1.

Discussion

Providing high quality services should be priority value for each medical entity, because quality translates to health, trust, safety and also patient life [9]. Along with progress of science and technology, nowadays certification becomes one of the most important tools supporting further development of both production companies and service sector [10]. Obtaining accreditation is a proof of implementation of adopted standards of conduct by a given entity, including medical entity, element increasing prestige and confirmation of readiness for further development and continuous improvement of implemented processes [11]. The system compliant with ISO standards is system of general requirements which relate to establishment, documentation, implementation and maintenance of quality management system and continuous improvement of its effectiveness [1]. Accreditation, unlike ISO 9001 certification, which has industrial origin, has been dedicated since the very beginning to health care system – initially it was developed on basis of experience of hospitals, and then it was used in all medical entities [12].

According to the subject literature review, opinion on reasonability and effectiveness of implementation of management systems in medical entities in accordance with ISO reference standards and accreditation of the Minister of Health is clearly divided. As Budgol [13] notes, there are no ideal systems, pointing out that in typically medical areas the ISO quality management system allows to order patient service processes, strengthen documents supervision, raises quality awareness and contributes to its further improvement, improving organizational culture. According to Golinowska, accreditation is a mechanism insufficient for achieving a significant improvement in quality of services but it is a good

"tool" for assessing quality of provided services [4]. However, Niżankowski emphasizes that characteristic feature of accreditation is that assessment is made by specialists in a given field. Inspection I carried out by accreditation commission which focuses on a comprehensive and reliable assessment of activity of the entity. Essence of assessment is level of compliance of actual state with standards which the medical entity should meet [2]. The expert also points out that management systems compliant with ISO are "industrial systems" which are more effective in typical production activities than in health care entities [13]. However, it should be emphasized that in the analyzed quality management system EN ISO 9001:2015 according to the PN-EN 15224:2017-02 standard, basis and background for the concept of "health" were based on five health components of the International Classification of Functioning, Disability and Health (ICF) prepared by WHO [14, 15].

Interest of medical entities in implementation of individual ISO management systems or accreditation of the Minister of Health has shown a clear upward trend for many years [16] and may result from: (1) awarding additional points by the National Health Fund (NFZ) as part of offering and contracting process [17]; (2) possibility of obtaining additional funds [18], (3) willingness to direct treatment activities to needs and expectations of the patient.

Most of accreditation standards focus on areas related to patient safety and those elements of care which have high risk of error and adverse events. For this reason, accreditation visit means not only meeting with top level management or documentation review, but also direct visiting over 50% of area of care provision (e.g. wards, operating theatres, laboratories and diagnostic facilities) as well as care environments (e.g. sterilization point, pharmacy, archives, staff, economic department, technical department or medical equipment department). Standards which are dynamic and subject to periodic modification, are of fundamental importance for accreditation process. Thanks to that, the assumption that accreditation will constantly stimulate to achieve optimum level which is determined by accreditation standard, is met. Each time requirements of

standards must be on as high level as possible but realistically achievable [16]. Undoubtedly, it is noteworthy that accreditation is granted by only one center in Poland – CMJ, and this certainly allows to include entity with accreditation certificate among medical entities in which health care safety is manifested in practically every aspect of its activities. All medical entities with accreditation are closely monitored, and information about them is available on the CMJ website. Moreover, accreditation doesn`t give possibility to exclude any of 221 accreditation standards grouped into 15 subject areas. In the case of ISO management systems, things are a little different. First of all, there are many accredited certification bodies which grant ISO certificates. Additionally, justified exclusions of individual requirements of standards are allowed if they aren`t referenced in the scope of the entity activity. There is also possibility to certify only selected locations or a narrow scope of activities without need for holistic management of all implemented processes.

On one hand we have accreditation, proven and recognized in the world health care assessment system, created from the beginning on basis of experience of hospitals [13], and on the other hand universal guidelines of international ISO standards which originally were not created for the purposes of health care. Nevertheless, due to the PN-EN 15224:2017-02 standard as dedicated to health care sector, they should become a part of process of difficult but effective management of medical entities.

The performed analysis clearly shows that, despite formal differences, there are numerous connections and analogies between requirements of individual quality aspects of the PN-EN 15224:2017-02 standard and requirements of accreditation standards, yet, neither one nor the other approach should be discredited, because in both cases, reliable preparing the entity for very complex system implementation process is a guarantee of success. It is very important to be aware that rank and value of accreditation or selected and implemented management system for a given medical entity largely depends on approach, knowledge, skills and commitment of the board and top management. The PN-EN 15224:2017-02 standard, similarly to accreditation standards, pays particular attention

to obligation to manage clinical risk during planning, implementation and control of individual process which becomes the key element of quality management system for clinical activities. In both cases, data related to significant events connected with hospitalization should be analyzed and assessed, and conclusions and observations should be used to conduct improvement projects in important health care areas in accordance with the E. Deming quality improvement methodology (PDCA cycle) [8]. Only continuous improvement and systematic monitoring of level of fulfillment of individual requirements in both systems guarantee implementation of process in friendly and safe environment for patients, their families and health care staff.

Conclusions

According to the above discussion the most important conclusions from the conducted comparative analysis are as follows:

1. Despite formal differences, there are numerous connections and analogies between requirements of individual quality aspects of the PN-EN 15224:2017-02 standard and requirements of accreditation standards.
2. Implementation and maintenance of one system should not exclude the other one, on the contrary, it can constitute basis for creating single, coherent system for managing the medical entity as a whole.
3. Due to costs, implementation and maintenance of the system compliant with requirements of the ISO standard as the first one can be more advantageous for the medical entity, and at the same time providing basis for effective implementation of further accreditation standards.
4. If only purpose of implementation process is to gain certificate for benefits connected with contracting or obtaining additional funds, both accreditation and individual management systems (including these compatible with the standard in question) become only a labor consuming and bureaucratic obligation.

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