

INTEGRATED MANAGEMENT SYSTEM AND ITS RELATIONSHIP WITH THE IMPLEMENTATION OF THE HOSPITAL STRATEGY – INTRODUCTION TO RESEARCH

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Purpose: The main purpose of this article is to introduce the issues related to the use of integrated management systems in healthcare facilities and their linkage to strategy. Due to the breadth of the topic, this article serves only as a theoretical introduction to a further, more detailed series of publications encompassing research assumptions.

Design/methodology/approach: The article is based on theoretical analysis and literature review.

Findings: The article describes the theoretical assumptions regarding integrated management systems, their premises and possibilities of application in medical facilities, defining the directions of further research.

Research limitations/implications: The presented content constitutes an outline of further research area.

Practical implications: The presented considerations and references to theories constitute the basis for further research, which will enable the identification of a possible impact on improving the management and quality of health services provided in medical facilities.

Social implications: Undertaking research based on the theoretical assumptions described should improve the management of medical facilities and more rational use of resources in order to improve the access to services and their quality and safety.

Originality/value: The article is addressed primarily to health care managers, as well as economists and public administration employees dealing with the issues of management in health care and public health.

Keywords: Healthcare system, management control, Integrated Management Systems, quality, accreditation, ISO.

Category of the paper: General review.

1. Introduction

The development of healthcare systems in Poland and worldwide is occurring in two fundamental directions. The dynamic growth of medical knowledge and technological advancements are resulting in growing specialization within both medical professions and the organization of healthcare services. This allows for the provision of medical services based on the latest available diagnostic and therapeutic technologies, but also requires the costly maintenance of complex organizational structures and multidisciplinary human resources. The emphasis on digitization and the integration of management systems for these healthcare entities is playing an increasingly important role in this process. Integrated management systems, which have been in use in other industries for years, play a significant and supportive role in this process.

The concept of continuous improvement, developed primarily by E. Deming, has found widespread practical application. Most contemporary enterprises see no prospects for continued market operation without the need to continually adapt to changing environmental conditions and sustainably improve the quality of their products and services. Product quality and quality management are becoming increasingly important, as the results of activities undertaken in this area directly or indirectly impact the implementation of healthcare facilities' strategies and goals (Ejdys, Kobylńska Lulewicz-Sas, 2012). Currently, the primary goal of most healthcare facilities – especially those governed by local governments – is survival in a turbulent environment and chronic underfunding. This goal is typically achieved by improving organizational efficiency. One way to improve organizational efficiency is to implement an integrated management system, which may include quality, environmental, occupational health and safety, and other management systems. It should be emphasized that a crucial factor that enterprises should consider when deciding on system integration is the identification of common elements across all these systems. What is important here is the fact that the structure of the existing standards is very similar, which allows organizations to implement these systems simultaneously or to adapt the newly implemented ones to the existing ones, while taking into account the key principles applicable to all management systems, such as (Wysokińska-Senkus, Wyrębek, 2011):

- policy and planning process,
- implementation and operation, defining the responsibilities, duties and powers of individual employees within the planned and implemented elements, as well as methods of communication between individual organizational units,
- evaluation of results in terms of comparing intentions with implemented activities,
- review of the system in terms of policy implementation and its effectiveness.

Currently, there are many documents regarding various aspects of management (in terms of quality, environment, occupational health and safety, information). They are commonly referred to as standardized or formalized management systems (Borys, Rogala, 2007), although the literature also identifies other types of management systems, such as "integrated" or "specialized" (Ejdys, Kobylińska Lulewicz-Sas, 2012).

Standardization is an increasingly frequently used tool for implementing integrated management systems, widely applicable in all areas of socio-economic life. The European standard PN-EN 45020: 2009 defines standardization as an activity aimed at achieving the optimal level of order within a given scope, under given circumstances, by establishing provisions intended for common and repeated use, addressing existing or potential problems (PN-EN 45020: 2009). The subject of standardization in a broad sense can be a product, process, or service, including any material, component, equipment, procedure, method, management system, or area of activity (Łańcucki, 2010). The skillful and widespread use of standardization achievements contributes to civilizational progress by promoting best solutions and fostering their dissemination and application. Standardized management systems are one of the tools that can be used in the process of managing an organization. These systems facilitate the establishment of a necessary, minimum set of requirements, the fulfillment of which should enable the achievement of planned, consistent goals.

The primary goal of management system integration is to streamline and optimize processes within an organization and ensure interoperability between individual management systems, including external processes implemented by suppliers and subcontractors (Matuszak-Flejszman, 2010). The decision to integrate management systems should be a strategic decision of management. The goals, expectations, results, and planned costs of the project should be determined before the decision to implement the system is made. It is worth emphasizing that the literature emphasizes two types of integration (Węgrzyn, 2007):

- unification, adaptation of analogous systems, taking advantage of the similarity of standards (norms) in relation to the structure of the system: the purpose of such unification is primarily to reduce administrative costs and audit costs,
- full integration of all procedures and instructions, based on the application of the total quality management (TQM) approach, focused on employees and customers and continuous improvement.

In turn, the implementation of management systems for various areas can be carried out according to one of the following schemes (Matuszak-Flejszman, 2007):

- building an integrated management system from scratch,
- building a single management system and gradual integration,
- expansion of the system with new elements,
- construction of autonomous management systems.

Among the key factors contributing to the integration of management systems are the similar philosophy and requirements of the individual systems' standards. Also important are the ability to simplify documentation by combining similar procedures, the use of experience and applied good management practices by those coordinating management systems, and the intertwining of environmental and quality issues in the management of individual processes within the enterprise.

The chosen topic is becoming extremely important. Topics such as "Integrated Management Systems", "Quality", "TQM", "ISO", and "Strategy" are very well described and defined in the literature. There are numerous publications and studies on the impact of these systems on quality improvement and economic aspects. However, there is a research gap regarding healthcare facilities, resulting from new legal regulations that impose specific requirements that these entities must meet.

The article is divided into the following sections: introduction, literature review, methods, accreditation as an element of an integrated management system in a healthcare facility, computerization of healthcare facilities, and summary.

2. Review of literature

The operation of medical facilities in Poland is regulated by a number of legal acts that address both organizational issues and the principles of medical examinations. Regulations regarding organizational standards, personnel qualifications, diagnostic equipment, and personal data protection are of key importance. Key regulations and guidelines include, in particular:

- Act of 15 April 2011 on medical activity, specifying the principles of conducting medical activity, including the functioning of laboratories as medical entities or their organizational units.
- Act of 5 December 1996 on the professions of physician and dentist, specifying the rules and conditions for practicing the professions of physician and dentist in Poland.
- Act of 6 November 2008 on patients' rights and the Patient Rights Ombudsman, which in turn regulates, among other things, the principles of providing access to medical records and the obligations of entities providing health services related to patients' rights.
- Act of 27 August 2004 on health care services financed from public funds, specifying – among other things – the conditions for providing and the scope of health care services.

While the issues of quality and standardization are very well known and developed, there is a significant gap in healthcare entities regarding quality, standards, and management system integration. A significant area of research in this area could be an adaptive approach to

developing a standardized systems integration template, which could serve as a guide for management staff and owners of these entities.

In Polish literature, the topic of "quality management" is well known and well-developed. Many authors have been dealing with this issue for years, resulting in numerous works. For a general overview of the topic, examples include:

- Blikle, A. *Doktryna jakości. Rzecz o skutecznym zarządzaniu.*
- Iwasiewicz, A. *Zarządzanie jakością.*
- Jazdon, A. *Doskonalenie zarządzania jakością.*
- Krzakiewicz, K., Cyfert, Sz. (eds.). *Metodologiczne aspekty nauk o zarządzaniu.*
- Kalinowski, T. *Innowacyjność przedsiębiorstw a systemy zarządzania jakością.*
- Łunarski, J. *Zarządzanie jakością: standardy i zasady.*
- Łunarski, J. *Normalizacja i standaryzacja.*
- Skrzypek, E., Skrzypek, A. *Jakość 4.0 w warunkach czwartej rewolucji przemysłowej.*
- Nowicki, P., Kafel, P. *Wybrane zagadnienia zarządzania jakością: dokumentacja i audyt systemów zarządzania jakością.*
- Skrzypek, E. *Zarządzanie jakością.*

However, strictly in the field of quality management in healthcare, the following examples can be mentioned:

- Celej, P. (ed.). *Zarządzanie jakością w podmiotach ochrony zdrowia.*
- Dobska, M., Dobski, P. *Zarządzanie jakością w podmiotach leczniczych.*
- Lisiecka, K. (ed.). *Zarządzanie jakością usług zdrowotnych.*

When considering an adaptive approach to systems integration, it is important to recognize the inextricable link between broadly understood quality issues and quality standards – particularly ISO (International Organization for Standardization) standards. From a theoretical perspective, this topic is also widely discussed. Examples include authors such as:

- Bugdol, M. *System zarządzania jakością według normy ISO 9001:2015,*
- Lewandowski, M. (ed.), *System Zarządzania Jakością według ISO 9001:2008: wdrażanie i organizacja.*
- Lewandowski, M., Ochyra, I., Konkolewska, D. *Audit wewnętrzny według norm ISO – planowanie, realizacja, dokumentowanie i ocena.*
- Michalski, R., Mytych, J. *Przewodnik po akredytacji laboratoriów badawczych według normy PN-EN ISO/IEC 17025.*
- Pacana, A., Stadnicka, D. *Nowoczesne systemy zarządzania jakością zgodne z ISO 9001:2015.*
- Sokołowicz, W., Srzednicki, A. *ISO – system zarządzania jakością oraz inne systemy oparte na normach.*
- Trela, A. *Zarządzanie jakością w działalności leczniczej: nowe wymagania systemów zarządzania – norma ISO i standardy akredytacyjne.*

From the point of view of digitalization, it is also worth mentioning the following publications:

- Bartkiewicz, W., Czerwonka, P., Pamuła, A. *Współczesne narzędzia cyfryzacji organizacji.*
- Gałaj-Emiliańczyk, K. *Wdrożenie systemu zarządzania bezpieczeństwem informacji zgodnie z normą ISO/IEC 27001:2019.*
- Glen, P., Koralewski, M., Lipka, M., Nosowski, M., Sarna, M., Lewańska, E., Brzozowska-Pasieka, M., Mizur, A. *RODO w sieci: 20 pytań i odpowiedzi dotyczących ochrony danych przetwarzanych cyfrowo.*

ISO standards, as we know, are international technical standards developed to harmonize requirements for products, services, and management systems. ISO standards are classified based on various criteria, such as their application, topic, sector, or function. For the proper management of a pathology laboratory, the following categories should be identified:

- ISO 9001 – classifying requirements for quality management systems, including: introducing supervision over documentation and records, involving management in building a quality management system, systematizing resource management, establishing product implementation processes, and making systematic measurements (of customer satisfaction, products, processes).
- ISO 14001 – describes environmental management systems and confirms the consistent implementation of all elements aimed at minimizing the negative impact of the organization on the environment.
- ISO 27001 – regulates broadly understood information security management: it helps organisations manage and protect information assets so that they remain secure, and it also helps to continuously review and improve their methods of operation, not only for today but also for the future.
- ISO 15189 – concerns requirements for medical laboratories and aims to ensure high quality and competence of medical laboratories that provide diagnostic services and conduct research on human material in order to provide information for diagnostics in medical processes or for preventive purposes in the assessment of the patient's health, and the results of a laboratory accredited for compliance with ISO 15189 are indisputable, while a laboratory with an accreditation certificate is perceived as a facility with the highest quality of research services provided.

It's important to emphasize that ISO standards – specifically those related to healthcare – are designed to enhance patient safety, streamline supply chains, and support innovation in digital health and sustainable healthcare. Given the multitude of standards mentioned above, additional, selected scopes can be identified for adaptation to the needs of healthcare facilities. These include, in particular, ISO 13402, 13485, 15223-1, and 14971.

3. Methods

The mandatory application of management control standards on the one hand, and the desire and obligation to improve the quality of services provided on the other, often mean that healthcare entities are faced with a multitude of solutions. Without integration, these solutions often duplicate requirements for management and employees and lead to an accumulation of administrative and bureaucratic responsibilities. Integration therefore seems necessary to improve the effectiveness of quality and risk management systems, and identifying the areas subject to this process is a proper introduction to action in this area.

Due to its specific nature, the provision of medical services should be covered by appropriate tools that support quality and mitigate risk. In addition to legal regulations that must be met by entities providing such services, systemic solutions are emerging and being implemented by a growing number of healthcare providers. In terms of quality management, it is worth mentioning the possibility of implementing quality management systems according to the ISO standard and accreditation standards, the correct application of which is verified by the Quality Monitoring Center (CMJ). In the context of management system integration, it is worth conducting an analysis to answer the question of whether CMJ accreditation and the quality management system according to the ISO 9001 standard are two different systems that determine the level of quality in a healthcare facility. It is increasingly common for a healthcare facility with accredited hospital status to decide to implement the ISO 9001 standard, and vice versa. A certain degree of competition then begins to emerge between the ISO standard and CMJ accreditation, and in principle, these systems should work together in the same direction, as implementing both should lead to greater benefits than using only one selected system (Głód, Głód, 2017).

The quality and safety of medical services play an extremely important role in modern medicine. Management systems are increasingly becoming a strategic goal for every entity, as they improve the quality and safety of medical services, as well as ensure greater predictability and stability of implemented processes, standardize operations, and eliminate the causes of errors. They are increasingly moving towards proactive measures aimed at counteracting the risk of threats. Technological advancements in recent years, the development of medical knowledge, and new types of medications allow medical facilities to increasingly meet patient expectations. The level of quality offered by medical facilities results from (Białas, Krakowiak, Włodarczyk, Rzeźnicki, Stelmach, 2016):

- expectations that the environment formulates towards them (individual approach, standardization of work, predictability, stability, safety of care and faster access to health services),

- shaping a strategy by healthcare managers focused on quality as one of the advantages of medical facilities, allowing them to retain and acquire new patients and ensure an appropriate standard of medical services.

In healthcare facilities where integrated management systems are implemented and operational, processes are identified and their course and sequencing are defined based on the scope of their operations. To ensure the effective and efficient operation of these systems, tools and indicators are established to monitor the progress of ongoing processes, ensuring the necessary resources for their implementation are directly supervised by those managing them. Ensuring compliance with the requirements of existing management systems compliant with ISO and/or CMJ accreditation standards can be used as effective tools in defining programs, goals, and tasks, ensuring compliance with adopted procedures, schemes, and standards of conduct, which form the basis of the facility's management process and thus improve its performance. Functioning quality management systems, often combined with risk management, are a very effective tool for minimizing threats affecting patient safety. Additionally, they translate into reduced costs for error correction and reduced compensation claims from patients (Czerw, 2012).

Considering the above management trends and the ever-increasing number of tasks aimed at continuous improvement in healthcare quality, there is a noticeable lack of uniform procedures that would enable and, above all, facilitate healthcare providers' compliance with a range of legal requirements and imposed norms and standards. Furthermore, with the current healthcare system in Poland generating requirements from multiple sources, often ambiguously formulated, inconsistent, and requiring the implementation of the same or similar actions multiple times, as well as frequent modifications and corrections, establishing a stable quality management policy in healthcare facilities becomes virtually impossible, and even requires the deployment of additional resources, which does not always translate into improved quality or increased patient safety (Kaniecka, Białas, Szrajber, Timler, Sobczak, 2018).

This article provides an introduction to theoretical issues related to the potential for integrating management systems, with particular emphasis on quality management, risk management, and management control, for use in medical facilities and other healthcare entities. At this stage, it is proposed that further research be undertaken to determine the degree of integration of management systems used in medical facilities, taking into account the following areas:

- Electronic Medical Records,
- cybersecurity,
- management control,
- certification,
- accreditation,
- ISO.

In each area, groups of factors to be assessed should be identified, including in particular:

- professional competences,
- organizational structure,
- monitoring and evaluation of the implementation of strategies, goals and tasks,
- resource security,
- risk identification, analysis and response,
- current information, internal and external communication,
- system monitoring.

This matrix will serve as the basis for conducting survey research, primarily aimed at assessing the level of preparation and advancement of the implementation process for specific legal requirements, accreditation, and other quality standards in subordinate healthcare units, as well as proposing a universal approach to implementing and integrating individual systems. The research should also consider the impact of external stakeholders (cultural, social, political, legal, regulatory, financial, technological, economic, natural, and competitive environments, key factors and trends influencing the organization's goals, and relationships with external stakeholders) and internal stakeholders (organizational governance, organizational structure, roles, policies, goals, and strategies for achieving them, resources and knowledge, information systems and decision-making processes, relationships with internal stakeholders).

4. Accreditation as an element of an integrated management system in a healthcare facility

Accreditation, as an external quality assessment method, is used for entities providing healthcare services under the Act of November 6, 2008, on Accreditation in Healthcare. Given that accreditation is intended to distinguish healthcare providers in the healthcare services market, each provider may apply for an accreditation certificate to confirm compliance with specific quality standards. This can have a positive impact on their financial situation. Possession of a certificate is one of the criteria assessed in the process of concluding contracts for healthcare services by the National Health Fund (NFZ), which may consequently translate into the inclusion of the services offered in the contract (by awarding additional points to assess their quality). It should be emphasized that the accreditation procedure described in the Accreditation Act assumes voluntary submission to a review conducted by inspectors from the accreditation center. The assessment procedure is based on a review of the healthcare provider's compliance with accreditation standards. The Accreditation Act provides a basis for assuming that accreditation in the healthcare system constitutes a significant element of statutory oversight of such an entity's activities, which include the provision of healthcare services. It is worth noting, however, that the Supreme Audit Office (NIK) pointed out significant

shortcomings of the healthcare entity accreditation system in terms of improving the quality of healthcare services and patient safety in its 2019 Audit Report (187/2019/P/19/095/LPO). The NIK noted, among other things, that the current accreditation system does not ensure the sustainability of pro-quality solutions, reports do not reflect the way healthcare entities operate, standards require significant changes, etc. It should be added, however, that having an accreditation certificate, which can be treated as a quality management system document, impacts a healthcare entity's operations in the competitive healthcare services market (Lipowski, 2022).

5. Computerization of medical facilities

Access to information is essential for effective decision-making within an organization. Information management is a strategic, multi-faceted process essential to enterprise planning and development. Today's market needs and ubiquitous competitiveness make information systems essential for a properly functioning organization, not only to meet these demands but also, often, as a condition for the company's very existence.

The basic legal act regulating the computerization of medical facilities is the Regulation of the Minister of Health of September 19, 2007, on the types and scope of medical documentation in health care facilities and the method of its processing. Based on Article 18, Section 9 of the Act of August 30, 1991, on health care facilities, a definition of the term "medical documentation" was introduced. The Regulation divides documentation into (Sawicki, 2014):

- individual documentation relating to individual patients using health care services at a health care facility, both internal and external; individual documentation is kept for individual patients using health care services, in the form of forms or printed forms, and in particularly justified cases in another form,
- collective documentation relating to all patients using the facility's health services or specific groups of these patients", collective documentation is kept in the form of books, registers, forms or files.

Documentation must be maintained in electronic form, unless other circumstances prevent this. This raises the question of how to reconcile printed and electronic formats. According to the regulation, sets of information covered by documentation may be prepared and recorded on electronic media, provided:

- maintaining selectivity of access to the information set,
- securing the information collection against access by unauthorized persons,
- securing the information collection against destruction,
- preparing a set of information to the extent allowing for the maintenance of individual documentation in the manner specified in §2, section 2 of the Act.

Today, advanced IT systems allow for the collection, integration, and interconnection of virtually any type of information. It's important to note that the systems required for a medical facility are fundamental, essential for its ongoing operation, such as the operating system (patient care, reports), accounting, and financial systems. Additional systems include, for example, a sales system (reporting to the National Health Fund), a complaints and notification system, a call center system, an external communication system (website, portal), and an HR system.

It's also worth considering the characteristics of a good IT system. These include functionality, dynamism, simplicity, reliability, and price, as well as modular design – in which case its individual modules are linked to separate operational processes. Advantages of a modular design include: the ability to better tailor the IT solution to the needs of a given entity, spreading the computerization process over time, improved project management efficiency thanks to the ability to divide it into stages, reduced project launch costs – planning for future budgets, implementing a new module without migrating previously collected data or losing it, and the ability to interrupt the implementation process without losing existing benefits. Basic medical system modules: registration, cash module, online registration, occupational medicine, doctor's office, treatment and vaccination room, dental office, diagnostics room, integration with diagnostic imaging, PACS – image archiving and transmission system, RIS – Radiology Image Processing System. Additional medical system modules: prescription, settlements with the National Health Fund, integration with the laboratory, HL7 (Health Level Seven) protocol – a standard for electronic information exchange in medical environments (includes messages regarding: data access, data download, data transfer, control, results download and clinical observations), integration with the financial and accounting system, sales, remuneration and human resources management module, IT system users, etc.

6. Summary

Integrating management systems can address the current challenges facing the Polish healthcare system. It will not only improve the quality of patient care but also increase its efficiency. Currently, there is no single, unified system, and the multitude of systems available on the market, combined with centrally imposed obligations regarding quality, cybersecurity, management control, accreditation, and ISO standards, often leads to duplication of various activities and expenditures on similar functionalities. Of course, implementing a unified model for an integrated management system faces numerous challenges that may hinder its implementation or discourage further integration. By definition, an integrated management system is a coherent system for the simultaneous management of multiple aspects by establishing and implementing policies and the resulting goals for specific aspects of an entity's

operations. However, when describing the rationale for implementing an integrated management system, it is important to mention the measurable effects of integration. The most significant factor is that the integrated management system guarantees the fulfillment of all the requirements of the individual systems. A unified system guarantees stable and repeatable processes. In turn, only repeatable and stable processes can ensure the safety and quality of healthcare services in their broadest sense. Moreover, a unified management system can contribute to a greater focus on organizational goals, reduce business risk, clearly define roles and responsibilities to maintain an integrated management system, and ultimately reduce documentation. Furthermore, a unified, integrated management system can contribute to a reduction in resources devoted to system management, a simpler reporting structure, and encourage employee skill development.

The issues described above constitute an introduction to the problem and further research into the implementation of solutions aimed at identifying the possibilities and benefits of implementing an integrated management system in medical facilities and their connection with the implementation of the strategy.

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