DEPÓSITO LEGAL ZU2020000153
ISSN 0041-8811
E-ISSN 2665-0428

Revista de la Universidad del Zulia

Fundada en 1947
por el Dr. Jesús Enrique Lossada

Ciencias Exactas, Naturales y de la Salud

77
ANIVERSARIO

Año 15 N° 43
Mayo - Agosto 2024
Tercera Época
Maracaibo-Venezuela

REVISTA DE LA UNIVERSIDAD DEL ZULIA. 3ª época. Año 15, N° 43, 2024
Serhii Petryk et al //Quality and Safety Standards in Health Services… 238-258
DOI: https://doi.org/10.46925//rdluz.43.15

Quality and Safety Standards in Health Services: Development and Implementation

Serhii Petryk*
Valentyna Zenkina **
Viacheslav Stepanenko ***
Anatolii Shevchuk ****
Kostiantyn Yurchenko *****

ABSTRACT

Aim. This research work aims to identify the characteristic features of the development and implementation of quality standards for patient monitoring and safety services in medical institutions, in order to improve quality based on the developed digital model, and describe the requirements for the implementation of quality control according to ISO 9001:2015 and ISO 15189:2022 Standards. Methods. The work uses a digital model of the Traumatology Center, built using the AnyLogic programming environment. This model is designed to identify and analyze effective solutions for implementation, such as patient registration processes, staffing, scheduling of specialized departments, identification of clinical characteristics and early symptoms of diseases to prevent complications during the incubation period. Results. It was discovered that modern wireless technologies and data analytics can be used to develop a remote health monitoring system, enabling early detection of chronic diseases to prevent complications. The scientific novelty of the study consists in the development of a sequence for the implementation of documentation on standardization and quality of service in medical institutions to prevent harm to patients, and improve their safety with the help of a complex of measuring devices and technologies. of the information.

KEYWORDS: Quality improvement, Information technologies, ISO 15189:2022, ISO 9001:2015, Sensors, Administration requirements, Technical requirements.

* Doctoral Student, Department of National Security, Public Administration and Management, Faculty of Public Administration, Law and International Relations, Zhytomyr Polytechnic State University, Zhytomyr, Ukraine. ORCID: https://orcid.org/0009-0002-5766-5313. E-mail: kebpua_dom@ztu.edu.ua

**Associate Professor, Department of Hygiene, Occupational Safety and Health, Bogomolets National Medical University, Kyiv, Ukraine. ORCID: https://orcid.org/0000-0001-5125-6557. E-mail: v_zenkina@ukr.net

***Associate Professor, Department of Physical Therapy and Occupational Therapy, Lesya Ukrainka Volyn National University, Lutsk, Ukraine. ORCID: https://orcid.org/0000-0002-8361-5507. E-mail: stlsmu@gmail.com

**** Associate Professor, Department of Emergency and Military Medicine, Vinnytsya National Pirogov Memorial Medical University, Vinnytsya, Ukraine. ORCID: https://orcid.org/0000-0001-9646-6312. E-mail: anatoliishevchuk2020@gmail.com

*****Candidate of Technical Sciences, Associate Professor, Deputy Head of the Department of National Security, Security Institute, Interregional Academy of Personnel Management, Kyiv, Ukraine. ORCID: https://orcid.org/0000-0003-2054-4307. E-mail: adunkt@gmail.com

Recibido: 24/01/2024 Aceptado: 21/03/2024

Estándares de calidad y seguridad en servicios de salud: Desarrollo e implementación

RESUMEN

Objetivo. Este trabajo de investigación tiene como objetivo identificar los rasgos característicos del desarrollo e implementación de estándares de calidad del servicio de monitoreo y seguridad del paciente en instituciones médicas, con el fin de mejorar la calidad con base en el modelo digital desarrollado, y describir los requisitos para la implementación del control de calidad según Normas ISO 9001:2015 e ISO 15189:2022. Métodos. El trabajo utiliza un modelo digital del Centro de Traumatología, construido utilizando el entorno de programación AnyLogic. Este modelo está diseñado para identificar y analizar soluciones efectivas para su implementación, como procesos de registro de pacientes, dotación de personal, programación de departamentos especializados, identificación de características clínicas y síntomas tempranos de enfermedades para prevenir complicaciones durante el período de incubación. Resultados. Se descubrió que se pueden utilizar tecnologías inalámbricas modernas y análisis de datos para desarrollar un sistema de monitoreo remoto de la salud, que permita la detección temprana de enfermedades crónicas para prevenir complicaciones. La novedad científica del estudio consiste en el desarrollo de una secuencia para la implementación de documentación sobre estandarización y calidad del servicio en las instituciones médicas para prevenir daños a los pacientes, y mejorar su seguridad con la ayuda de un complejo de dispositivos de medición y tecnologías de la información.

PALABRAS CLAVE: Mejora de la calidad, Tecnologías de la información, ISO 15189:2022, ISO 9001:2015, Sensores, Requisitos de la administración, Requisitos técnicos.

Introduction

Health services are an integral part of everyday life for people, as the human body tends to lose some functional properties of organs, and prevention and rehabilitation play a vital role in treatment and recovery. However, in providing medical services, it is essential to consider the trends and changes that involve improving the quality of service in the provision of medical care and free medication for the preservation of patients' lives, referred to as medical reform (Pelzang et al., 2019). Medical reforms aimed at improving the quality of continuous assessment and improvement of medical care for patients are being carried out in every country worldwide (Berman et al., 2018).

Continuous improvement in the health care system is a challenge for many countries, especially those undergoing a complex transition from a system where quality was not considered at an adequate level and outdated service quality standards were not taken into

account for new developments and implementation to improve quality according to EN ISO 9001 standards. Quality is an integral part of international competition worldwide. From an economic development perspective in the EU, standardization plays a more significant role for companies, enterprises, academic and research institutions, laboratories, as well as certification and inspection bodies, recognizing the importance of standards based on legislation (McGrath et al., 2021).

Legislation is an effective tool for developing and implementing standards and potential innovations in the context of rapid scientific and technological development (Lleshi, 2020). Therefore, ensuring quality requires involving everyone responsible for product and service development and implementation at each stage of the realization and production process (Nadziakiewicz et al., 2019).

Standardization activities aim at developing, approving, publishing, and applying standards per the methodology, principles, and standardization rules. The standards are developed and published to serve public interests, acting as powerful tools for information exchange (Halamoda-Kenzaoui et al., 2019).

Thus, for establishing, implementing, and controlling medical service standards, the management of any healthcare institution should continually reassess the processes for providing medical services to offer high-quality care to more diverse patient groups. Modern technologies allow the development and improvement of medical service quality to prevent and reduce unforeseen events, using computer technologies and systems to enhance measurements and provide continuous monitoring for patient observation (Giuliano, 2017).

Healthcare institutions are complex structures with a high risk of incidents while providing medical services. In these institutions, people may become victims of preventable harm during medical care, raising concerns about global patient safety in such establishments. Patient safety entails reducing the risk of unnecessary injury during medical treatment. Some events and circumstances leading to avoidable patient harm are safety incidents. Also, in some cases, incidents resulting in harm are adverse events. Modern technologies, along with medical reforms, enable the identification and prevention of incident occurrences and adverse events aimed at reducing patient harm. Among these contemporary technologies is a strategy to enhance patient safety, characterized by information systems and monitoring incidents in the healthcare sector (Silva et al., 2021).

Patient involvement plays a crucial role in improving service quality to regulate and prevent harm cases, as it facilitates the identification of existing or potential medical issues, providing valuable insights for developing medical services. This concept allows for anticipating qualitative outcomes and service effectiveness while efficiently reducing patient injuries and associated medical expenses, significantly improving health status (Han et al., 2023).

Supervision and monitoring represent separate processes in patient care. Monitoring involves the observation, measurement, and recording of physiological parameters. Meanwhile, supervision is a systematic, purposeful process based on early detection of signs of change, interpretation of the clinical consequences of such changes, and initiation of prompt appropriate intervention. Monitoring relies on observation and evaluation, while nursing supervision involves monitoring with the recognition and interpretation of the clinical implications of changes to make decisions about further actions (Giuliano, 2017).

The development and implementation of medical information technologies (IT) within a complex adaptive healthcare system (integrated with all aspects of medical service delivery) possess significant potential for improving medical care. However, it may also be accompanied by unforeseen consequences and new safety problems, necessitating a more detailed study (Sittig et al., 2020). Therefore, a significant challenge for enhancing patient safety in healthcare systems using IT lies in developing and implementing evidence-based strategies for investigating safety issues in healthcare and patient safety (Singh et al., 2016).

As noted by the Institute of Medicine, "Medical information technologies, if properly developed, implemented, and used, can be a positive factor in transforming the way healthcare is delivered." Hence, medical IT holds significant potential for increasing service efficiency, enhancing healthcare quality, cost-saving, and patient engagement during medical service provision (Wienert et al., 2019).

The development and implementation of service quality, monitoring, and patient safety standards have significantly impacted the COVID-19 pandemic. They led to increased demands on the work of doctors and medical personnel concerning patients care. The pandemic presented an unexpected opportunity to elevate patient safety, involving patient monitoring for harm and various approaches to prevent injury related to the specific location of patient treatment in the hospital (Pronovost, 2022).

The purpose of this study is to identify and develop standards for the quality of medical care, monitoring, and patient safety in order to improve the effectiveness of medical care and ensure patient safety. At the same time, the main attention is paid to the improvement of medical care processes, as well as the development and implementation of new methods and technologies to ensure the quality of medical care. Also, the research involves the analysis and improvement of the management processes of medical institutions, taking into account modern digital technologies and monitoring systems.

1. Problem statement

Monitoring and patient safety during the provision of medical services demand increasing scientific research utilizing modern technologies to develop and implement new quality control standards aimed at delivering effective healthcare services by medical institutions. However, it is essential to analyze the interrelation of applying international standards to develop an efficient strategy for planning and utilizing an appropriate methodology concerning standardization. For instance, to implement new quality systems, it is necessary to identify critical factors and requirements through which medical staff could enhance service quality while providing medical assistance.

It is necessary to pay attention to the current (existing) quality control standards to study the implementation issues and realization of guidelines, instructions, and standards. As known, the development of contemporary documentation covering all necessary implementation conditions is outlined in the quality service standard ISO 9001:2015 - Quality Management Systems – Requirements. This standard applies to all existing activity domains, including enterprises, companies, and private structures on a national level. Based on this standard, ISO 15189:2022 - Medical laboratories - Particular requirements for quality and competence have been developed. They reflect adherence and fulfillment of requirements by medical personnel.

Therefore, it is vital to scrutinize available sources and standards describing the methodology of conducting various procedures and operations to analyze potential challenges in implementing monitoring and patient safety standards.

2. Literature review

The World Health Organization defines patient safety as the absence of harm to patients that can be prevented and aims to prevent unnecessary harm from medical practitioners. It is reported that unsafe medical care results in the loss of 64 million years of life with a disability annually worldwide. Patient harm during medical care is recognized as one of the top 10 leading causes of disability and mortality globally (Vaismoradi et al., 2020).

The dynamic development of digital technologies provides opportunities for improving the healthcare system, particularly in ensuring patient safety. According to the World Health Organization, electronic tools will play a crucial role in enhancing safety, especially in areas such as:

- using electronic health records for more accurate and comprehensive patient tracking;
- timely and reliable exchange of medical data;
- supporting diagnosis, monitoring, and treatment of illnesses and conditions;
- behavior modification and reducing health risks;
- expanding patient and family involvement in self-care;
- facilitating communication between healthcare professionals to reduce errors and improve coordination;
- reducing unnecessary consultations and hospitalizations;
- improving access to health knowledge and management for both specialists and patients (Dymyt, 2020).

Modern information technologies allow data collection from various sources and locations, such as monitors and bedside devices, as well as through physically separated computers. The volume of such data can be vast and complex to process. Accessing and integrating the data required for decision-making can be time-consuming and complicated due to multiple system inputs, the need to use different computers for specific tasks, and sources being occupied or unavailable for other reasons, leading to information flow delays (Flohr et al., 2018).

The emergence and implementation of wireless networks using body sensors enable continuous patient health monitoring without disrupting their daily activities while transmitting real-time health information through wireless networks (Classen et al., 2021).

DOI: https://doi.org/10.46925//rdluz.43.15

Implementing such technology can develop a framework for remote health monitoring, intelligent accident detection, real-time notifications, rapid response alerts, and optimizing traffic for emergency assistance.

A pre-pandemic report hypothesized that routine monitoring of hospitalized patients using continuous pulse oximetry and heart rate measurement devices was associated with reduced mortality (Sullivan et al., 2022). Although there is limited evidence that patient monitoring with COVID-19 in hospital wards improves treatment outcomes, it is likely that enhanced patient monitoring outside intensive care units may have benefits (Pronovost et al., 2022).

Continuous remote monitoring of hospitalized patients in general medical facilities improves treatment outcomes. Also, when integrated into electronic medical records, it enhances accuracy and reduces the burden on overworked and resource-constrained personnel by automating tasks that must be performed several times a day for each patient (Burgers et al., 2020). The patient safety monitoring system has achieved a stability level, making it useful for consistently measuring inpatient safety.

3. Aims

The study aims to identify the features of developing and implementing service quality standards for patient monitoring and safety in medical institutions. That will help to improve the quality based on the developed digital model and description of requirements for quality control implementation using ISO 9001:2015 and ISO 15189:2022 standards.

The following tasks need to be addressed to achieve the set goals:

- to conduct a literature review on patient monitoring and safety in healthcare institutions.
- to analyze the use of international standards for developing and implementing safety enhancement and quality control guidelines.
- to identify characteristic management and technical requirements according to existing standards.
- to analyze the use of modern information technologies with monitoring devices and instruments for patient safety.

The scientific novelty of this research lies in developing a sequence for implementing documentation related to standardization and service quality in healthcare institutions to

avoid harm to patients and enhance patient safety by utilizing a complex of measuring devices and information technologies.

4. Methods and materials

4.1. The use of monitoring and security software

The research model considers a digital model of a traumatology center, which was constructed using the AnyLogic software environment. The built digital model reflects the features of monitoring medical staff and patients. For instance, these include their movements, service delivery, and procedures performed by the specialists. Theoretical and practical materials enable the combination of production processes with the provision of medical services in the digital model for their reproduction in the software environment using information technologies. Sensors (e.g., pulse, temperature, etc.) and monitors with cameras can be utilized for transformation. They allow easy tracking of patients and medical personnel's movements within the premises.

4.2. The main standards of quality control for health services

The main standards used in the design and implementation of service quality improvement are ISO 9001:2015 Quality management systems - Requirements (Source: ISO 9001:2015) and ISO 15189:2022 Medical laboratories - Specific requirements for quality and competence, which is based on ISO-9001 (Source: ISO 15189:2022). The implementation of the international standard ISO 15189:2022 (the outdated previous version of ISO 15189:2012) is the basis for quality assurance for healthcare facilities with laboratory environments.

ISO-9001:2015 is an international standard that describes the requirements for managing a quality control system and contains a list of recommendations for process approaches to developing, implementing, and improving the performance of a quality management system (QMS). The process approach is based on the "Plan - Do - Check - Act" methodology used to improve the QMS continuously. Therefore, in designing and implementing healthcare services, this standard plays a vital role in healthcare reforms and quality improvement in healthcare facilities.

ISO 15189 is an international standard defining specific medical laboratory and facility requirements. A particular difference from ISO 9001 is that, in addition to management requirements, it also contains technical requirements. It includes requirements for

personnel, environmental conditions, equipment and supplies, analytical and procedural requirements, and addresses all quality aspects. The management requirements and technical requirements are summarized in Table 1. They reflect the main characteristics to improve the quality system of a healthcare facility.

Table 1. Requirements for administration and technical standards according to ISO 15189:2022

A complex of general requirements according to ISO 15189:2022	
1. Administration requirements	**2. Technical standards**
Organization and administration	Living and environmental conditions
Quality control system	Laboratory equipment
Document control	Preliminary examination procedures
Verification of contracts	Expert proceedings
Verification by reference laboratories	Ensuring the quality of expert procedures
External services and supplies	Follow-up procedures
Advisory services	Reporting on the results
Complaint handling	
Identification and control of non-conformities	
Corrective actions	
Preventive actions	
Constant improvement	
Quality improvement	
Quality and technical documentation	
Internal audit	
Analysis by the management team	

Source: (Allen, 2013, p. 1188).

The Institute for Quality Management in Healthcare (IQMH, formerly QMP-LS - the Quality Management Program - Laboratory Services) is engaged in the accreditation and testing of laboratories. This is a mandatory prerequisite for licensing and providing medical laboratories with training and resource materials, as well as for developing an accreditation program and external evaluation.

APLAC is a regional body of the International Laboratory Accreditation Cooperation (ILAC), which promotes the harmonization of accreditation practices with ISO standards. The accreditations granted by respective bodies that have signed the MRA are recognized worldwide.

Therefore, based on the developed digital monitoring model and the use of existing standards, it is necessary to analyze the administrative and technical requirements of medical staff more closely. It is crucial to determine the feasibility of implementing a quality control system with patient tracking that can effectively serve to avoid unwanted harm to both patients and medical staff. For this reason, the latest technologies and innovations in healthcare provision include management tools, products, and processes aimed at improving the quality and efficiency of services provided in these patient care settings (Silva et al., 2021).

5. Results

Let us take a closer look at the requirements for medical personnel management (Table 1) and compliance with technical standards (Table 2) based on ISO 15189:2022. These requirements contain a list of items to be fulfilled as per the standard to ensure quality control of a medical laboratory to provide medical services to patients. Standardization, in this case, is aimed at the elaboration and implementation of guidelines, instructions, and improvement of existing standards for compliance with the requirements of high-quality service by medical personnel.

Table 2. Requirements for medical institution administration

Organization and administration	The facility's laboratory has an organizational chart, and responsibilities are assigned to medical staff. The laboratory has effective communication processes.
Quality control system	Processes and procedures are documented, implemented, and shared with staff, including a program for calibration and maintenance of existing equipment, reagents, and systems.
Document control	The laboratory has an effective document control system, including a document-control log that lists the current versions in effect and their distribution. All documents are uniquely identified and authorized for their release. Employees are not allowed to use outdated documents. The staff has up-to-date, approved records available for use.

Verification of contracts	The requirements are set out following the contracts of the laboratories that provide referrals.
Verification by reference laboratories	A register of all specimens sent by the sending laboratory allows for tracking of returned results and helps in the event of sample loss. The sending laboratory is responsible for ensuring that the results are communicated to the person who made the request.
External services and supplies	Procurement and inventory procedures ensure that staff handles and stores consumables consistently. Inspection of all consumables (calibration devices, reagents, and control devices) prior to their use minimizes the potential for errors during usage.
Advisory services	Medical staff have mechanisms for making personal contributions to the services provided by the laboratory.
Complaint handling	The process of recording, investigating, and addressing complaints, which are documented and analyzed for corrective action.
Identification and control of non-conformities	The process of investigating, handling, and correcting any non-compliance with the implemented requirements. The procedures for disclosing the results in case of non-compliance are involved.
Corrective actions	Processes for conducting corrective investigation actions, including action plans and root cause analysis that have been implemented.
Preventive actions	Potential sources of non-compliance and how they can be improved through documented research and analysis to produce a preventive action report.
Constant improvement	Laboratory procedures are systematically reviewed at regular intervals to identify potential sources of non-conformance. If non-conformities are identified, laboratory management develops, documents, implements, and reviews improvement action plans. The quality indicators are established and monitored, and opportunities for improvement are considered.
Technical quality records	Under this requirement, all records are arranged and stored securely as per the respective conditions.
Internal audit	Verification of all operations (transactions and services) for compliance with QMS requirements. The internal audits of the QMS and technical procedures are conducted regularly to verify their compliance with the QMS requirements.
Analysis by the management team	The management assessment process ensures the ongoing suitability and effectiveness of the QMS. The management assessment includes evaluating the status of all the above steps.

Source: (Allen, 2013, pp. 1190-1191).

The digital model of the traumatology center consists of several sections, namely:

- the visitors' entrance block;
- the ambulance entrance block;
- the patient care block;
- the discharge block;
- the waiting hall block,
- the express aid block;
- the emergency aid block;
- the admission block.

Such a center can serve more than 200 patients daily and approximately 40-50 thousand patients annually. The model is designed to include a regular emergency care department and a special emergency care department operating only during increased workload periods. The model is developed to analyze the effectiveness of various improvements, such as patient registration processes, staff scheduling, and special department scheduling, as well as to identify clinical characteristics and early symptoms of illnesses to avoid complications during the disease incubation period.

Figure 1 illustrates the functioning of the traumatology center in 3D and 2D, displaying all the aforementioned blocks. However, it is worth noting that the radiology scanning block serves to detect joint fracture pathologies in patients. Typically, such blocks do not have information and measuring equipment that uses information technologies.

As a result of technological advancements, modern wireless technologies, and data analysis, information collection sensors can be used as a system that can serve for remote health monitoring. The wireless sensor network consists of sensor nodes that collect data on the patient's physical health, process it, and transmit it using wireless technology. It enables early detection of chronic illnesses to prevent complications, such as asthma, heart attacks, diabetes, gastrointestinal infections, viral diseases during the incubation period, and more.

Figure 1. A digital model of a traumatology center.

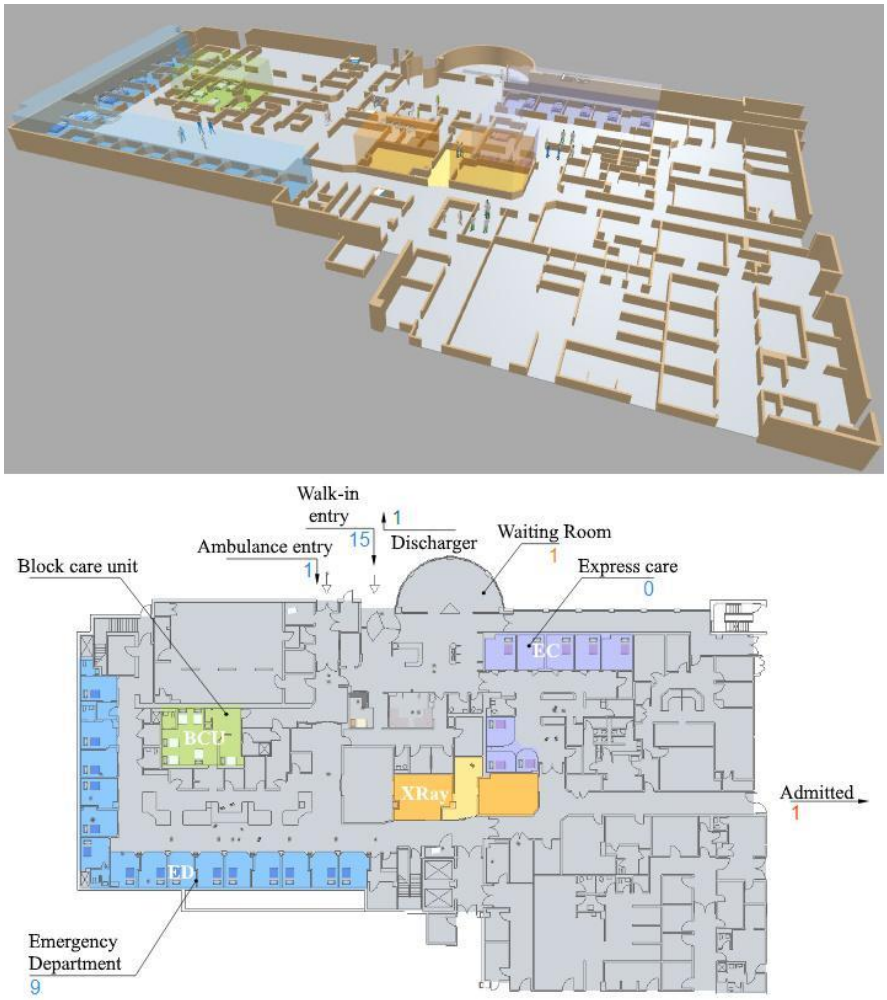
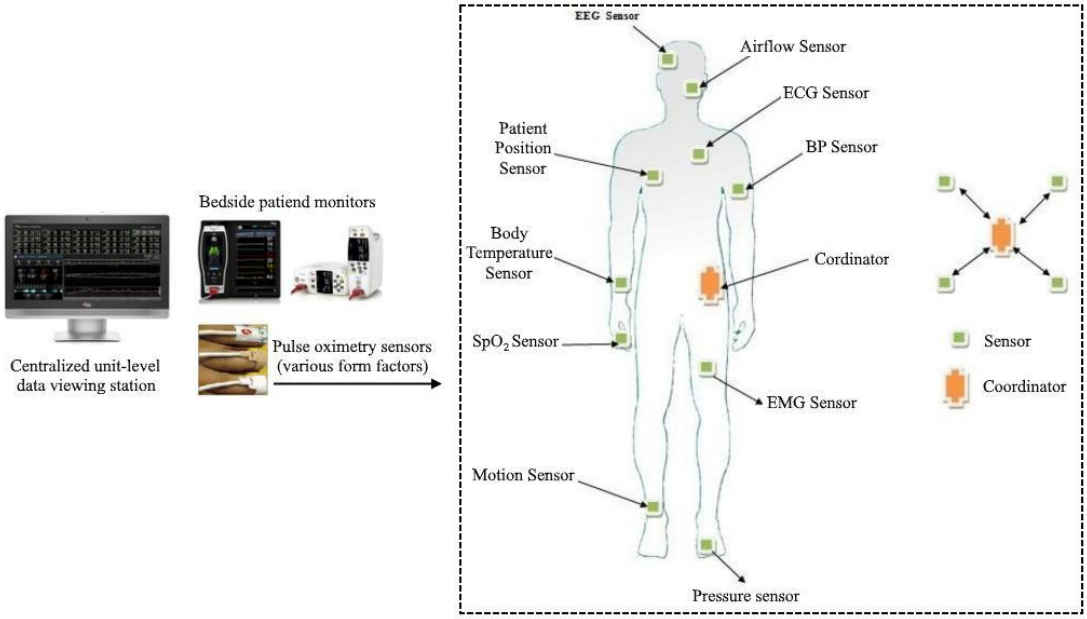


Figure 2 shows the application of electronic devices with the following sensors:

- the electrocardiogram (ECG) sensor;
- carbon dioxide (CO2) sensor;
- humidity sensor;
- temperature sensor;
- blood glucose sensor;
- pulse sensor;
- arterial pressure sensor;
- motion sensor, etc.

Figure 2. Application of information technology-based electronic devices and sensors for monitoring and security



Source: (Singh et al., 2021).

These sensors can be implemented for everyday use and are also integrated with other electronic devices such as smartphones, fitness bracelets, and so on.

Suppose such concepts can be visualized in 3D. In that case, it is possible to see how the use of sensors and electronic devices can avoid undesirable consequences of harm and illness to patients with respiratory diseases, for example, in the case of the COVID-19 pandemic. Figure 3 shows how a potential patient with respiratory disease can be tracked remotely by using information technologies.

The analysis of the digital model of the traumatology center and its management requirements with the technical specifications suggests that each section in Figure 1 should be implemented based on a Quality of Care Standard. For example, it should consider the requirements for implementation with appropriate equipment, devices, and facilities for the provision of medical care (item 3 in Table 3), with a preliminary examination procedure for collecting laboratory samples of the patient (item 4 in Table 3). This should ensure that the procedure is complete and performed in a standardized manner (item 5 in Table 3).

Figure 3. An example of using motion, pressure, and temperature sensors.

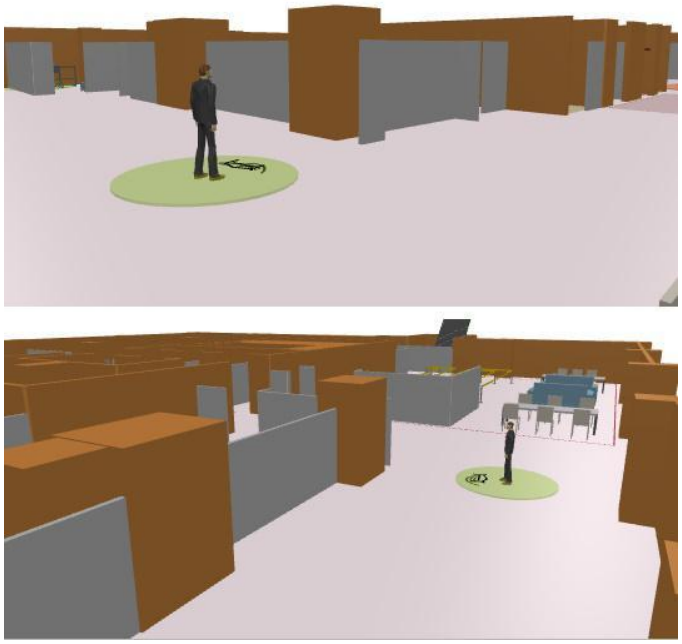


Table 3. Technical requirements for medical personnel

Personnel	Implementation of recruitment, training, skills assessment, performance evaluation, and continuous learning procedures. Job descriptions are available for all staff jobs. Training records are maintained to ensure that staff have received the appropriate training. Staff competency assessments and appraisals are conducted regularly. The management assessment process provides the ongoing suitability and effectiveness of the QMS. The management assessment includes evaluating the status of all the above steps.
Living conditions and environment	The environmental conditions are the temperature and humidity in the laboratory, assessed as suitable for the optimum functioning of the equipment. The laboratory has sufficient space, lighting and is free of hazards. The sample collection area meets the requirements of confidentiality and accessibility for patients with disabilities.
Laboratory equipment	The laboratory has sufficient equipment to meet service requirements. There are procedures for the selection, installation, calibration, operation, maintenance, service and preventive maintenance, and taking equipment out of service. The records that include maintenance and service, preventative maintenance, equipment and safety checks, and calibration checks for equipment (including small laboratory equipment such as pipettes, thermometers, timers, and clocks) are filled out. An equipment logbook is a useful way to document equipment requirements.

Preliminary examination procedures	The Laboratory Sample Collection Manual contains procedures for all aspects of the preliminary examination process, including ordering tests, identifying patients, collecting, transporting, accessing, and storing the samples. The logging of all samples received in the laboratory ensures that results are reported for all items and helps to locate lost or misplaced samples.
Research procedures	The lab procedures for the tests are complete, standardized, accessible to staff, and based on the manufacturer's guidelines. All procedures have been validated prior to use, and shortened procedures are subject to a document control. The procedures for all aspects of laboratory work help with training, troubleshooting, and process updates.
Ensuring the quality of expertise procedures	Quality control and external quality assessment programs are in place for all testing procedures. All issues and non-conformities are documented, analyzed, and responded to with a corrective action. Cross-instrument comparisons are performed across all platforms.
Follow-up procedures	There are appropriate processes to verify and report laboratory results. The samples are stored appropriately for retesting if necessary. All samples are disposed of safely.
Reporting on the results	Patient records contain all the necessary information. The reports use standardized vocabulary and nomenclature. The results are legible, with no transcription errors, and there is a process for reviewing transcribed results. The deadlines for results submission are set. The critical values are established, and there is a procedure for reporting on essential values. Report changes are clearly defined.

Source: (Allen, 2013, pp. 1191-1192).

Following the research procedure, verifying and publishing the laboratory research results (item 6) and ultimately providing a report to the patient (item 7) is necessary.

Monitoring plays a significant role in this model to prevent infections, as some patients may be infected without realizing it during the incubation period. In the case of a COVID-19 pandemic, this would help avoid mass gatherings among infected patients seeking medical assistance, thus protecting other patients and medical staff from exposure. Utilizing information technology with sensors through monitoring and notification systems can prevent undesirable health consequences for people.

6. Discussion

After analyzing ISO 15189 standards, it becomes evident that various requirements demand precise details. For this purpose, multiple standards support a medical laboratory while implementing a management system that complies with ISO 15189. These standards typically provide more detailed information to demonstrate compliance of critical processes with the standard's requirements and guide the laboratory in planning and implementing measures to manage risks and opportunities associated with various processes. They form the basis for enhancing the management system's effectiveness, achieving better outcomes, and preventing adverse consequences that could harm patients, laboratory staff, and the surrounding environment (Fedele et al., 2022).

In the research by Sittig D. F. & Singh H. (2020), the authors argue that the safety of medical information technologies requires more significant improvement. Even though scientific knowledge may improve over the time, much remains to be learned and researched. This challenges the key tasks that need to be accomplished before it is possible to count on the safe, reliable, and efficient IT-based systems that are required to deliver patient care.

A key challenge to improving security in healthcare systems that use medical information technologies is to develop reasonable and feasible strategies to measure security issues at the intersection of medical IT and patient safety (Wienert, 2019).

In response to the fundamental conceptual and methodological gaps related to the definition and measurement of patient safety connected to health IT, Singh H. & Sittig D. F. (2016) developed the Healthcare IT Security measurement framework (HITS) to provide a conceptual framework for measuring, monitoring, and improving patient safety related to healthcare IT. The HITS framework is consistent with both continuous quality improvement (CQI) and socio-technical approaches. It calls for new actions and measurement activities to address safety concerns within three related areas:

- the issues that are unique and technology-specific (to address challenges related to insecure health IT that arise from unavailability or defective hardware or software);
- the problems arising from improper use or misuse of a healthcare IT (reducing the number of unpleasant notifications in the electronic medical record (EMR));
- the use of health IT to monitor risks, processes, and outcomes of healthcare delivery and identify potential security issues before they can harm patients (the use of

algorithms based on electronic health record data to identify patients at risk of medication errors or delays in medical aid).

The joint development of forms for reporting, investigating, and monitoring healthcare incidents, as well as the development of a prototype as a tool, are contributing to the creation of an information system. It will facilitate data collection on incident reporting and investigation and will also be able to monitor indicators through the reporting process. The development of the information system is ongoing, and the validation process will be carried out at each screen and stage of development, namely: user registration, notification screens, research screens, dashboard, as well as data export and reporting functions (Silva et al., 2021).

In the study by Nadziakiewicz M. & Mikolajczyk A. (2019), the authors present the quality, safety, and quality assessment system as essential tools for supervising a healthcare organization. Quality comprises a set of properties and characteristics of a product, process, or service that meet the specified requirements. However, in the case of healthcare, it is difficult to assess the level of quality. Therefore, common indicators become a useful tool, and the development of such quality indicators requires both data collection and its proper processing. The high quality of medical services requires constant improvement and adaptation to the patient's needs.

Therefore, after analyzing this paper, it is possible to conclude that the developed digital model and the requirements for quality control are the same set of properties and features of services during the treatment that meet the specified requirements according to the international standard ISO 15189 (Source: ISO 15189:2022).

Conclusion

Healthcare and rehabilitation services are undergoing significant changes due to the improvement of the existing methods, as well as the elaboration and implementation of new quality assessment systems, which affect the improvement of the efficiency of medical assistance. Even though the modern world has undergone transformational changes from the computer to information technologies, some research methods also allow combining information technologies with modern capabilities. For example, it becomes possible by linking electronic devices and equipment with the human body via digital technologies, such as sensors, electronic bracelets, etc.

This article describes the possibility of using digital technologies to ensure monitoring and safety during medical treatment. This involves the application of international standards ISO 9001 and ISO 15189, which are the main standards for implementing a quality system in healthcare facilities. ISO-9001:2015 is an international standard that describes the requirements for managing a quality management system and contains a list of recommendations for process approaches to developing, implementing, and improving the performance of a Quality Management System. The international standard ISO 15189 defines specific requirements for medical laboratories and facilities. The standard contains management and technical requirements, including requirements for facility personnel, environmental conditions, equipment and supplies, and analytical and procedural requirements. It also considers compliance with all quality aspects.

The digital model of the traumatology center was developed to identify and analyze effective solutions for its implementation. For example, this model includes the process of patients' registration, staff scheduling, and special department scheduling, as well as identifying clinical indicators and early symptoms of the disease to avoid any complications during the incubation stage of the disease.

Due to modern wireless technologies and data analysis, the sensors can be used as a system that can serve for remote health monitoring. A wireless sensor network contains sensor nodes that collect data about a patient's physical health, process it, and then send it via wireless technology. This, in turn, allows for early detection of chronic diseases to prevent their complications.

Monitoring plays a significant role in this model for avoiding infection, as some patients may be infected without realizing it during the incubation period. In the case of the COVID-19 pandemic, this would help to avoid massive crowds of infected patients seeking medical assistance, which could endanger other people around them and the medical staff. With the help of information technology involving sensors, monitoring, and information systems can help to avoid undesirable consequences that are harmful to human health. Thus, the development of a digital model with the considered requirements for its implementation can serve as a basis for future research on safety and health issues during the provision of medical services in the case of a pandemic.

References

Allen, L. C. (2013). Role of a quality management system in improving patient safety – laboratory aspects. *Clinical Biochemistry*, *46*(13-14), 1187-1193; DOI: 10.1016/j.clinbiochem.2013.04.028

Berman, L., Raval, M. V., & Goldin, A. (2018). Process improvement strategies: Designing and implementing quality improvement research. In Seminars in pediatric surgery. *WB Saunders*, *27*(6), 379-385; DOI: 10.1053/j.sempedsurg.2018.10.006

Burgers, J., van der Weijden, T., & Grol, R. (2020). Clinical practice guidelines as a tool for improving patient care. *Improving patient care: the implementation of change in health care*, 103-129; DOI: 10.1002/9781119488620.ch6

Classen, D. C., Munier, W., Verzier, N., Eldridge, N., Hunt, D., Metersky, M., … & Battles, J. (2021). Measuring patient safety: the Medicare patient safety monitoring system (past, present, and future). *Journal of patient safety*, *17*(3), 234-240; DOI: 10.1097/PTS.0000000000000322

Dymyt, M. (2020). The Role of eHealth in the Management of Patient Safety. *Journal of e-health Management*, *2020*, 1-13; DOI: 10.5171/2020.341252

Fedele, A., Avruscio, G., Barison, L., & Scipioni, A. Standards to Support ISO 15189 Implementation for Medical Laboratories Accreditation. *Clin Case Rep Int. 2022*, *6*, 1310.

Flohr, L., Beaudry, S., Johnson, K. T., West, N., Burns, C. M., Ansermino, J. M., … & Görges, M. (2018). Clinician-driven design of vital pad–an intelligent monitoring and communication device to improve patient safety in the intensive care unit. *IEEE journal of translational engineering in health and medicine*, *6*, 1-14. DOI: 10.1109/JTEHM.2018.2812162

Giuliano, K. K. (2017). Improving patient safety through the use of nursing surveillance. *Biomedical instrumentation & technology*, *51*(s2), 34-43. DOI: 10.2345/0899-8205-51.s2.34

Halamoda-Kenzaoui, B., Holzwarth, U., Roebben, G., Bogni, A., & Bremer-Hoffmann, S. (2019). Mapping of the available standards against the regulatory needs for nanomedicines. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology*, *11*(1), e1531. DOI: 10.1002/wnan.1531

Han, S., Xu, M., Lao, J., & Liang, Z. (2023). Collecting Patient Feedback as a Means of Monitoring Patient Experience and Hospital Service Quality–Learning from a Government-led Initiative. *Patient preference and adherence*, 385-400. DOI: 10.2147/PPA.S397444

ISO 15189:2022 Medical laboratories — Requirements for quality and competence Available at https://www.iso.org/standard/76677.html [Accessed on 24 July 2023]

ISO 9001:2015 Quality Management Systems — Requirements. Available at https://www.iso.org/standard/62085.html [Accessed on 24 July 2023].

Lleshi, S. (2020). The Effectiveness of QMS Implementation in Applying of Quality Health Care for Patients in Health Institutions of Kosovo. *European Journal of Medicine and Natural Sciences*, *3*(1), 26-34; DOI:10.26417/ejis.v5i1.p95-103

McGrath, S. P., McGovern, K. M., Perreard, I. M., Huang, V., Moss, L. B., & Blike, G. T. (2021). Inpatient respiratory arrest associated with sedative and analgesic medications: impact of continuous monitoring on patient mortality and severe morbidity. *Journal of Patient Safety*, *17*(8), 557; DOI: 10.1097/PTS.0000000000000696

Nadziakiewicz, M., & Mikolajczyk, A. (2019). The quality and safety of health care services. *Management Systems in Production Engineering*, *27*(2), 100-104; DOI:10.1515/mspe-2019-0017

Pelzang, R., & Hutchinson, A. M. (2019). Patient safety policies, guidelines, and protocols in Bhutan. *The International Journal of Health Planning and Management*, *34*(2), 491-500. DOI: 10.1002/hpm.2729

Pronovost, P. J., Cole, M. D., & Hughes, R. M. (2022). Remote patient monitoring during COVID-19: an unexpected patient safety benefit. *Jama*, *327*(12), 1125-1126; DOI: 10.1001/jama.2022.2040

Silva, K. T. D., Filgueiras, R. C., Gamaski, R., & Göttems, L. B. D. (2021). Prototype for monitoring incidents in the health services: innovation for patient safety. *Texto & Contexto-Enfermagem*, *29*; DOI: 10.1590/1980-265X-TCE-2019-0185

Singh, H., & Sittig, D. F. (2016). Measuring and improving patient safety through health information technology: The Health IT Safety Framework. *BMJ Quality & Safety*, *25*(4), 226-232; DOI: 10.1136/bmjqs-2015-004486

Singh, P., Raw, R. S., & Khan, S. A. (2021). Development of novel framework for patient health monitoring system using VANET: an Indian perspective. *International Journal of Information Technology*, *13*, 383-390; DOI: 10.1007/s41870-020-00551-4

Sittig, D. F., Wright, A., Coiera, E., Magrabi, F., Ratwani, R., Bates, D. W., & Singh, H. (2020). Current challenges in health information technology–related patient safety. *Health informatics journal*, *26*(1), 181-189; DOI: 10.1177/1460458218814893

Sullivan, Z. P., Zazzeron, L., Berra, L., Hess, D. R., Bittner, E. A., & Chang, M. G. (2022). Noninvasive respiratory support for COVID-19 patients: when, for whom, and how?. *Journal of intensive care*, *10*(3), 10; DOI: 10.1186/s40560-021-00593-1

Vaismoradi, M., Tella, S., A. Logan, P., Khakurel, J., & Vizcaya-Moreno, F. (2020). Nurses' adherence to patient safety principles: A systematic review. *International journal of environmental research and public health*, *17*(6), 2028; DOI: 10.3390/ijerph17062028

Wienert, J. (2019). Understanding health information technologies as complex interventions with the need for thorough implementation and monitoring to sustain patient safety. *Frontiers in ICT*, *6*, 9; DOI: 10.3389/fict.2019.00009