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ORIGINAL

Strategies for Enhancing Quality and Safety in Medical Services: Development and Implementation

Estrategias para mejorar la calidad y la seguridad de los servicios médicos: Desarrollo y aplicación

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ABSTRACT

Introduction: the aim of studying the quality of healthcare services requires a high level of patient safety in hospitals; therefore, the aim is to study the specifics of creating and implementing healthcare safety standards. In this paper, you can find an analysis of modern scientific publications and regulatory acts.
Method: this study's methods are based on a scientific and theoretical approach and on the new conditions governing patient safety. The study's aim is systematic data monitoring by the requirements of ISO 9001:2015 and ISO 15189:2022.
Results: in the course of the analysis of literature sources and current regulations, a hypothesis was put forward about the possibility of implementing a monitoring system based on the use of wireless technologies. These are contact and non-contact medical sensors and contactless peripheral sensors. The formation of the monitoring system is based on the regulation of accreditation of medical laboratories and supervision over compliance with regulatory requirements.
Conclusions: the study's scientific novelty is the creation of new standards and regulatory documentation aimed at improving the quality of service. The main focus is on the use of specialised (medical) equipment and information tools for scientific and practical monitoring, data collection, and analysis regarding patient safety.

Keywords: Quality Improvement; Information Technology; ISO 15189:2022; ISO 9001:2015; Sensors; Management Requirements; Technical Requirements.

RESUMEN

Introducción: el objetivo de estudiar la calidad de los servicios sanitarios requiere un alto nivel de seguridad de los pacientes en los hospitales; por lo tanto, se trata de estudiar las particularidades de la creación y aplicación de normas de seguridad sanitaria. En este trabajo se analizan las publicaciones científicas modernas y los actos normativos.
Método: los métodos de este estudio se basan en un enfoque científico y teórico y en las nuevas condiciones que rigen la seguridad del paciente. El objetivo del estudio es el seguimiento sistemático de los datos según los requisitos de las normas ISO 9001:2015 e ISO 15189:2022.

Resultados: en el transcurso del análisis de las fuentes bibliográficas y de la normativa vigente, se planteó una hipótesis sobre la posibilidad de implantar un sistema de monitorización basado en el uso de tecnologías inalámbricas. Se trata de sensores médicos de contacto y sin contacto y sensores periféricos sin contacto. La formación del sistema de monitorización se basa en la regulación de la acreditación de laboratorios médicos y la supervisión del cumplimiento de los requisitos normativos.
Conclusiones: la novedad científica del estudio es la creación de nuevos estándares y documentación regulatoria dirigida a mejorar la calidad del servicio. La atención se centra en el uso de equipos (médicos) especializados y herramientas de información para la supervisión científica y práctica, la recopilación de datos y el análisis en relación con la seguridad de los pacientes.

Palabras clave: Mejora de la Calidad; Tecnología de la Información; ISO 15189:2022; ISO 9001:2015; Sensores; Requisitos de Gestión; Requisitos Técnicos.

INTRODUCTION

The healthcare sector is developing rapidly due to new technologies, advances in the pharmaceutical industry, and new diagnostic and treatment methods. However, new medical and technological developments, medicines and new medical services require not only control but also developed mechanisms to ensure the safety and appropriateness of their use. For this purpose, standards and regulations have been developed to define the procedures for providing and controlling medical services. This guarantees patients the right to quality care and increases the requirements for medical staff, contributing to developing trust in the healthcare system.[1]

Both patients and doctors support the standardisation of medical services. On the one hand, it helps avoid the unpleasant consequences of doctors' medical procedures. On the other hand, it simplifies the automated procedures for doctors, which means specialised care. In controversial situations, the standard becomes the key to objectivity. In addition, no one can deny that in cases of emergency, medical protocols, such as the precautionary approach protocols during the COVID-19 pandemic, have had catastrophic shortcomings. Thus, a critical discussion of healthcare standards, their quality, and, most importantly, safe medical technologies for monitoring medical procedures remains relevant.[2]

Assessment and improvement of the quality of healthcare services is currently a critical area of research at the global level, as healthcare is primarily responsible for the strength of any country's economy. Reforms in the healthcare sector have contributed to improving the quality of healthcare services and their structural support.[3] In addition, their implementation is multidisciplinary and provides affordable access to healthcare for patients (UHC), one of the goals of global sustainable development strategies. Many of these reforms focus on integrating healthcare systems, such as EN ISO 9001, which is more in line with the requirements of society.[4]

These simple actions prove that wearing a mask protects us from disease, as everyone followed these paradigms everywhere during the COVID-19 pandemic. Other approved rules only helped medical staff treat patients in unstable and overcrowded hospitals.[5] The boundaries of intellectual property are being violated because no one has denied it yet, and after these crises or pandemics, recovery periods will not be abused. Standardised control in medicine firmly adheres to the principles of immortality. It creates a significant risk of disability and mortality, reducing the likelihood of complications, especially those that accompany diagnostic treatment.[6]

It is important to adhere to standards for patient protection in healthcare innovation, as the challenges associated with new technologies can lead to significant complications. Standards need to strike a balance, taking into account their specific context. When legislation is in place that is based on officially recognised standards, the protection of individuals in the provision of healthcare is ensured without prejudice.[7] Given that important medical decisions are directly related to people's lives and health, the ethical component is essential in the process of standardisation involving different specialists. The challenge is to avoid the least favourable outcomes, and what can be changed in a lay environment is the reason for the paradoxical nature of specific institutional strategies to address new areas of healthcare.[8]

The introduction of new technologies in healthcare through telemedicine has increased significantly, making it possible to provide medical services to patients remotely, and the system as a whole has become more flexible. The Institute is already conducting comprehensive research on artificial intelligence in medicine, telemedicine, blockchain technologies, and other smart devices. However, many ethical issues related to the processing of personal data still need to be actively discussed. The advantage of being close to the patient is the ability to monitor their health remotely. On the one hand, this approach significantly reduces the likelihood of complications and injuries; on the other hand, it reduces the workload of medical staff.[9]

A medical system must meet all the needs of medical information systems by the specifics of the data being processed, and their use requires powerful software to process and store vast amounts of information. Modern

electronic achievements are integrated into modern means of implementing medical processes – specialised systems in hospital wards and networked computers in doctors' offices. These systems, which monitor the main vital parameters of patients, must be highly reliable and professional for continuous evaluation and research of large data sets. One such development is VitalPAD, a smartphone software that provides rapid service reporting on patient status for timely medical care.[10] Patient information management systems in intensive care units can automatically and in real-time accumulate up to 1000 units of positional information per hour, significantly affecting the volume and quality of patient actions. This necessitates the study of the effectiveness and relevance of such technologies in cutting-edge contexts.[11]

This explains why the entire healthcare sector was involved in developing new systems, namely reports for innovators, which allowed them to monitor themselves and thus counter the pandemic. To overcome this, standard emergency accreditation of remote testing laboratory systems and ISO 15189 systems that ensure compliance with laboratory diagnostic requirements became important.[12]

METHOD

In our study, we focused on aspects of the internal standards ISO 9001:2015 and ISO 15189:2022[13] and their role in improving the quality of healthcare services. We checked the implementation of these standards in Ukraine and their effectiveness. The ISO 9001:2015[14] standard is accepted in all disciplines as it relates to the improvement of quality management systems.

Digital modelling was used to plan the implementation of the standards and to check the quality of monitoring of patient's vital signs. 2D and 3D models of trauma wards were developed using computer-aided design software for medical facilities. During the implementation of the standards, zones for the provision of various medical services were proposed, and the feasibility of allocating separate functional zones was substantiated. The optimisation of several requirements for the location of medical buildings, diagnostic rooms, and office space for medical and scientific staff was considered. The layout of the building of the medical institution in the sections of the trauma unit of the auxiliary staff presents the work of a medical institution under various resource constraints and the functioning of the polyclinic. The parameters of all functional spaces and the layout of missing areas that were not intended for the free movement of surgical patients on stretchers and wheelchairs are considered. Monitoring systems, locations for actively engaged potential patients and doctors' offices, and paper medical wards for new referrals were created for patients in the trauma unit.

There was no real interaction with the respondents during the study. The study was based on data from available medical documents describing remote monitoring in inpatient hospitals, including intensive care units. The effectiveness of modern monitoring systems in detecting potentially dangerous conditions of patients and preventing infections as much as possible is also possible based on the modelling results. The results of such modelling are also more consistent with the demonstrated patterns achieved during the COVID-19 pandemic, with many influenza cases and an increase in seasonal diseases.

RESULTS

The study analysed the human resource management systems and requirements of ISO 15189:2022,[13] which relate to assessing the quality of laboratory work and organisational activities. The data is graphically presented in figure 1. This printed document contains the norms and regimes of enhanced maintenance and the entire set of international primary quality control standards.[13]

Technical requirements for laboratories by ISO 15189:2022[13]

1. *Personnel:* employees shall perform their duties according to their job descriptions and within the limits of their authority. The established procedure keeps records and other documents. There is also at least one technical supervision and regular occupational safety and health training.

2. *Environmental conditions:* there are requirements for laboratory workspaces, such as examination rooms, diagnostic rooms, and warehouses for materials and reagents with ventilation holes, temperature, humidity, light, and other parameters. Appropriate temperature conditions for storing materials and reagents, as well as other methods, were ensured.

3. *Equipment:* certified and licensed devices with operating and maintenance manuals are available. Records of work cycles, hygiene breaks, reagent changes and equipment calibration are documented. Routine and periodic faulty equipment inspections and repairs are carried out as required.

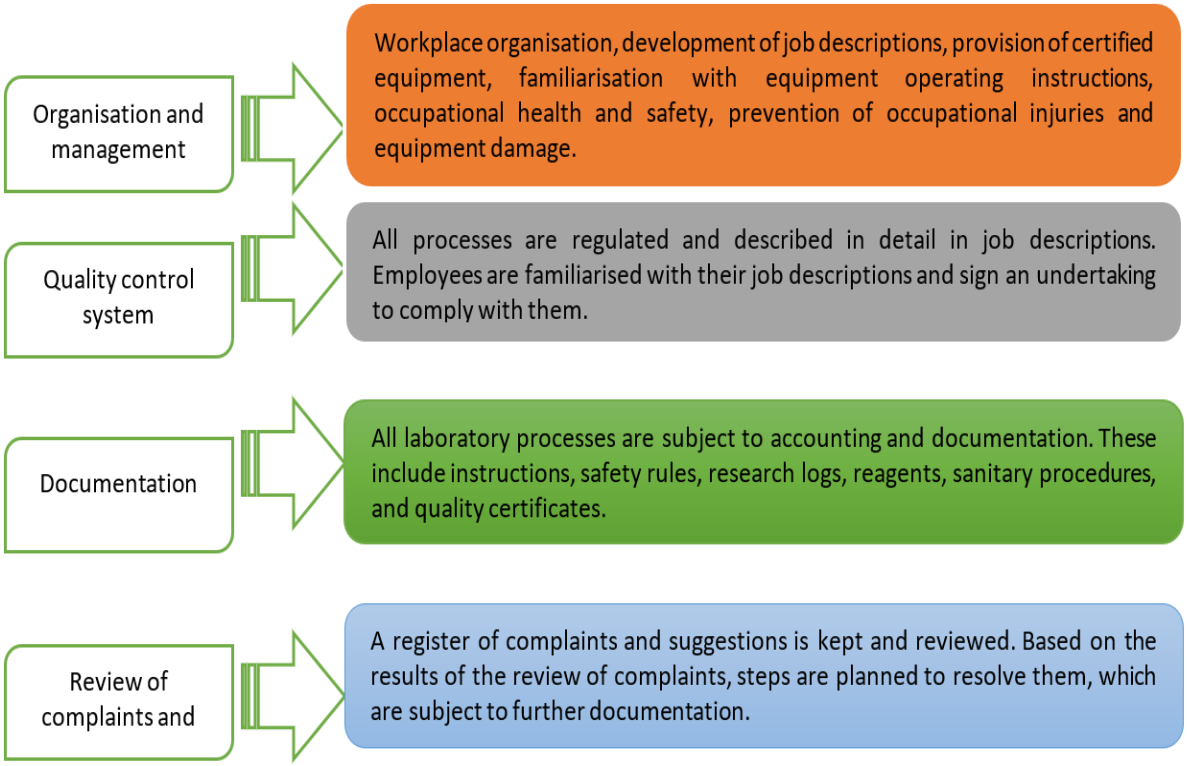
*4. Preliminary examination procedure:*it consists of a medical examination of the patient, preparation for specimen collection and access to the room for patients with disabilities, provision of test kits, and storage and transportation of specimens. All stages of laboratory diagnostics should be documented and include the patient's identity and test results. Specimens may be temporarily stored in specimen containers until test results are available for retesting due to equipment malfunctions.

5. *Research procedures:* each stage of the research is systematic and secure. Procedures are recorded at

all stages, i.e., when instructions for their implementation regarding the specifics of the material and the interpretation of the results are issued. In case of violation, all procedures must be recorded and require modification or deletion.

6. Quality assurance of procedures: the instructions for the biological material sample, reagents and all test procedures must be strictly followed. Any violation of the established norm must be appropriately documented.

7. Reporting on results: all actions are recorded based on the existing nomenclature and classification system. Reports are produced after specific prescribed periods of record keeping, nonconformity reporting, complaint reporting and problem resolution.[3]



Source: Allen[3]

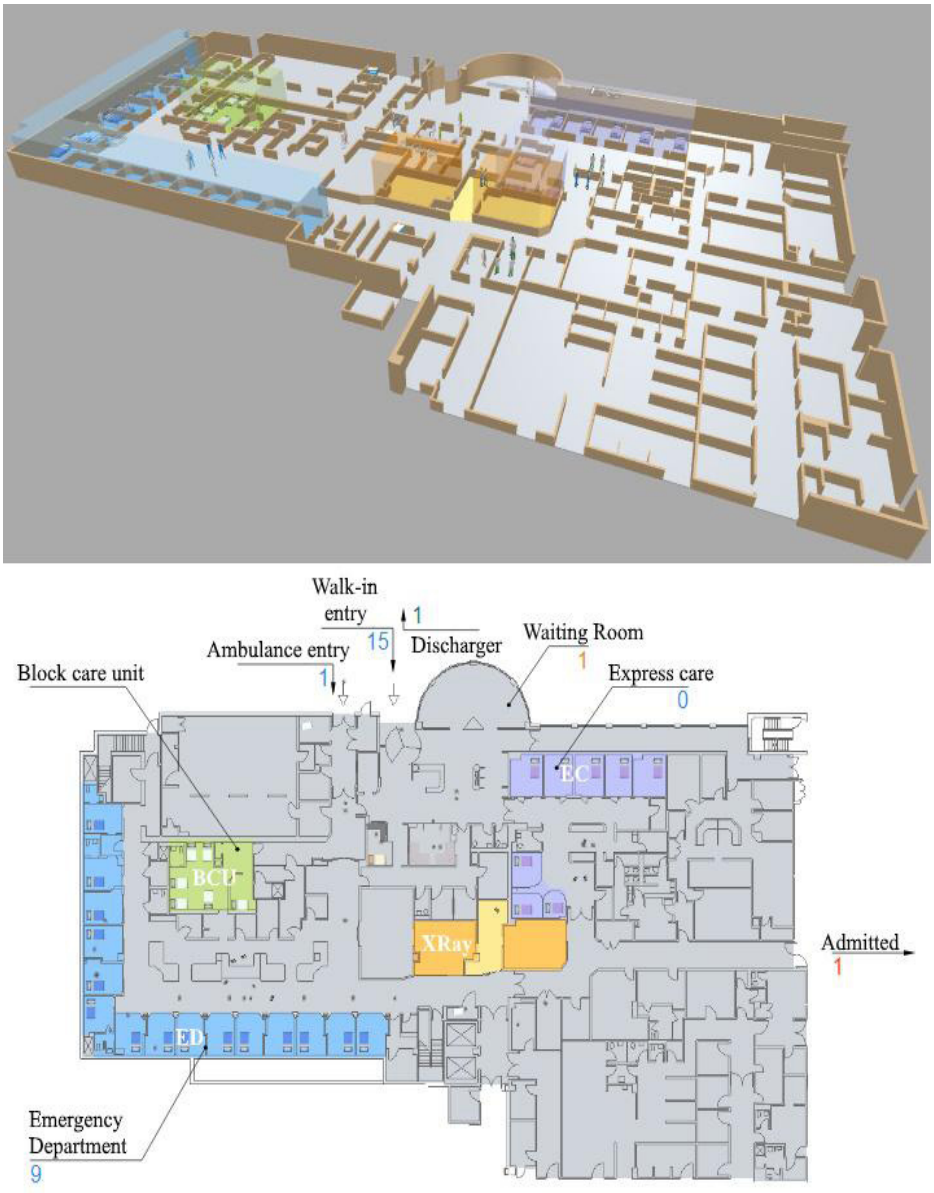
Figure 1. Requirements for compliance with the management standards of medical institutions providing laboratory diagnostics

The information in figure 2 describes the development of a digital boundary plan for emergency departments, with areas divided by type of urgency. These include the GP's office and the approaches to the invisible care office. There are also reception and diagnostic rooms, which include express laboratories, X-ray rooms, and a computed tomography room. Inpatient treatment includes treatment rooms, dressing rooms, and wards. The analysis of the educational institution is impressive because it is still a clinic where 180-220 patients are treated daily. Auxiliary X-ray diagnostics departments operate separately for patients and with the reception and outpatient departments. Medical staff offices are arranged in such a way as to ensure convenient monitoring of patient's condition. The model of the trauma unit includes the implementation of quality standards for medical services, starting with the registration of patients, as well as optimisation of staff allocation and management, equipment and workflow planning.[15]

Trauma care modelling in 2D and 3D allows you to assess the accessibility of trauma care and spatial healthcare services to the medical facility. The location of the diagnostic rooms in the central part of the building facilitates access to patient examination requirements by different departments. The use of all passageways for diagnosing patients in outpatient and emergency conditions is justified by the requirements for the permeability of the walls of these premises. However, there are no separate X-ray rooms for both infection risk groups.[17]

The selected capital of this facility provides for the daily care of 180 patients with the possibility of providing day or round-the-clock inpatient treatment. Important positive aspects include the space available for medical care; however, it is difficult to effectively monitor a large number of patients at the same time. This problem can be solved with the help of wireless monitoring systems connected to the hospital's local network for uninterrupted transmission of data on patients' vital signs. The principles of such monitoring systems are based

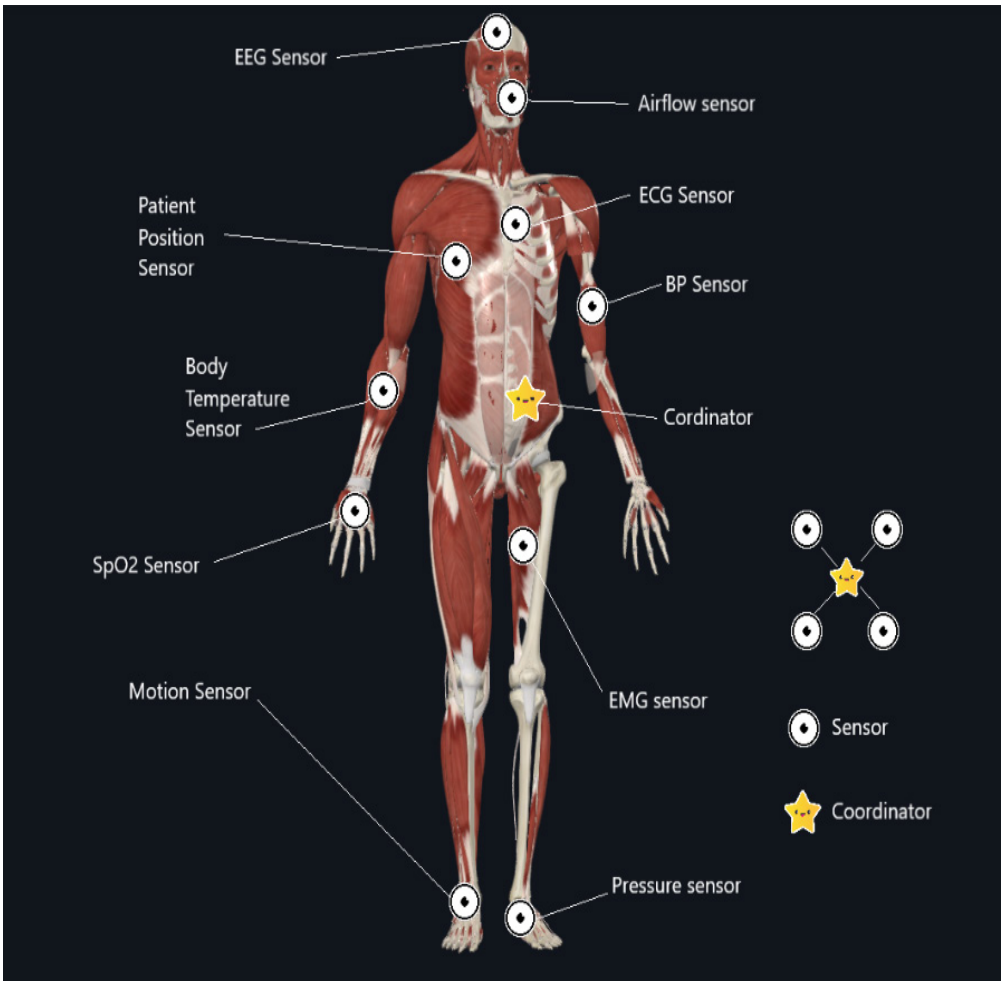
on automated data collection and continuous transmission of data from medical sensors to hospital computers or mobile devices, including smartphones and smartwatches.[18]



Source: Singh et.al.[16]
Figure 2. Digital model of a trauma centre

The analysis of the trauma centre's unit organisation shows that to comply with the basic principles of regulatory quality measures; there must be a correct division of zones. Functional zones ensure the correct division of medical staff labour and the availability of the necessary equipment. Separation of patients requiring emergency care from patients requiring outpatient care is important in preventing infectious diseases among these groups. In addition, effective zoning and adequate conditions for medical services in terms of lighting, temperature, humidity and ventilation are needed. The documents of the departments should provide for routine sanitation of premises, work surfaces, and equipment, as well as mandatory quartz disinfection of wards, treatment, and dressing rooms according to the established schedule. The terms of the standards should be posted in the wards for the medical staff to read. The development of the 2D and 3D schemes of the medical facility should be carried out at the design stage with appropriate draft documentation by the standards of ISO 9001: 2015 and ISO 15189: 2022.[13, 14]

Figure 3 shows the location of sensors and devices that capture and transmit information. Depending on the location of the patient's body, sensors are divided into electroencephalographic, which measures airflow and respiratory rate; electrocardiographic, which determines the patient's position; electromyographic, which detects motion; and electroencephalographic, which measures blood pressure and pulse oximetry.[19]



Source: Singh et.al.[16]

Figure 3. A Diagram of the location of sensors and devices for transmitting and interpreting the results of the patient monitoring system

As shown in figure 3, remote sensors have many applications in the medical field. Most of these devices are affordable and significantly reduce the workload of medical staff when measuring blood pressure, saturation, and body temperature. The monitoring system for inpatient wards usually consists of bedside monitors with connected probes.[16]

Automated measurement can also be monitored by adjusting the frequency and storing the results. For example, in intensive care units, it is important to constantly monitor vital parameters to respond to any changes in time. Instead of setting the monitor in therapeutic and surgical wards for constant measurements, they are set to take them once an hour. This limitation is important to extend the service life of the equipment, as well as to reduce the amount of unnecessary information that needs to be analysed. This also applies to monitoring data, which should be short but informative enough to save the doctor's time spent reviewing and interpreting the results. Equally important for intensive care units is the availability of a mechanism for alerting them to critical changes in physiological parameters: decreased saturation, changes in pulse or respiratory rate, and fluctuations in blood pressure. Wireless monitoring systems also significantly expand the possibilities for diagnosing patients on an outpatient basis. The combination of wireless sensor networks with a hospital system allows for the collection of information about the condition of patients in home modifiers, taking into account their usual loads and stress levels. This system is prognostically important for detecting hypertension and angina and evaluating the effectiveness of treatment for hypertension and coronary heart disease. It also speeds up diagnosis and treatment selection for routine examinations.[20]

Today, medical sensors have greatly expanded their functionality, as they can perform diagnostic and therapeutic procedures. For example, diagnostic sensors are compatible with various devices such as pulse oximeters, blood pressure cuffs, and specialised sensors for electrocardiography, electromyography, and electroencephalography. Therapeutic sensors are presented in the form of patches that release drugs in a specific concentration, ensuring controlled delivery of the drug to the target tissue. Products available can automatically switch from defibrillators to stimulants to relieve pain.[20]

The wireless sensors transmit and process physiological data through a control unit, which coordinates all the information as a dispatcher. Transferring data to a medical server via the Internet or a robust local network built into Bluetooth or Wi-Fi is possible. First, the packet arrives at the receiver and then is processed into the control unit; in the second stage, the patient's medical device, mobile phone, laptop, or computer downloads special software. The downloaded information is uploaded to the medical facility at the third stage. Similar or identical sensors can accompany other patient smart devices: phones and watches. Wireless sensors for patients can monitor physical activity, behaviour, dietary activity, calories burned, sleep and activity, and even listen in, providing surveillance to hear the conversations that lead to these outcomes. Modern digital technologies significantly impact the control of patient's physiological parameters, paradoxically increasing patient safety.[21]

DISCUSSION

International standards define the ISO 9001:2015 and ISO 15189:2022 certificates,[13,14] and they ensure that patients of medical institutions can count on quality services by reducing the negative impact of the human factor or conditions in the provision of medical services. Thus, the issuance of these certificates is advisory, and the projects of medical facilities, namely laboratories, at the stages of planning, creation, control and operation will be based on these acts. Developing such standards is an ongoing process that includes introducing the latest methods, technical equipment and improved management principles to improve the quality of medical services. Therefore, compliance with the conditions set by the standards puts medical work first in modern medical institutions. It is not a mere formality or restriction for medical practice but rather a strict recommendation to prevent adverse impacts on patients, medical staff and the environment.[6]

Along with the progress of digital health technologies, the healthcare system is also changing. Errors in the practical application of innovative healthcare technologies can jeopardise patient safety, which is why the field of innovation is up-and-coming for practical implementation. In light of the above, IT technologies that process patient data must be reliable, secure and efficient. All healthcare IT efforts should include a strict hierarchical control system for thorough checks to prevent errors that could cause patient harm.[22,23]

In terms of the scientific trajectory of the focus, Vaismoradi et al.,[24] confirmed the high probability of security breaches of new digital technologies in healthcare information systems by creating a strategy called Healthcare IT Security (HITS). Aimed at identifying new transaction risks with healthcare IT systems, this model not only tests and evaluates the ability of IT applications to perform their functions but also formulates "abuse" scenarios to identify and create new dangers in the healthcare IT system. This preventive model is not widely used due to economic considerations; however, it serves to identify gaps in post-medication care that could potentially harm patients.[24]

Despite the possible challenges associated with the use of technology in the healthcare sector, the benefits still outweigh the risks, especially in reporting, auditing and process optimisation in healthcare organisations. Digital technologies make it easier to check large amounts of statistical data to identify discrepancies and shortcomings in organisational and human resource management activities of organisations. Automated audits can identify the causes of adverse incidents with greater accuracy to improve the quality of healthcare services.[25]

Even though modern monitoring systems have not been thoroughly tested, most sensors are already certified and approved for use in medical facilities. An active search for new solutions is underway to provide convenience, cost-effectiveness, and reliability in equal measure. Allen[3] talks about the possibility of using textile-based sensors to monitor physiological parameters, which will increase comfort, as well as the accuracy and reliability of data collection. Bickell et al.,[4] explored the prospects of IoMT, which combines a network of sensors with medical devices to monitor abnormalities in human physiological parameters to assist in preventive medicine.

In any case, implementing international standards is vital to ensure the well-being of patients in healthcare facilities. These standards help reduce the risks associated with unforeseen factors such as human error. Another important issue is the procedures developed when implementing IT technologies, and one step too many is too close to a mistake, especially when it comes to confidential patient records. Risk velocity, together with improved patient safety monitoring, is a significant prospect. However, it requires more in-depth research on long-term effects that identifies possible errors and adjusts to meet international standards.[26]

CONCLUSIONS

Implementing ISO 9001:2015 and ISO 15189:2022 is a critical issue from the point of view of patient protection. These regulatory implementations relate to the quality of medical services and laboratory diagnostics. Standards of this type of support are the norms that prevent bad situations in medical care. As we know, in today's world, with the constant growth of digital technologies, the norms of the established standards need to be adapted for IT systems in medicine. Modern digital medical monitors and sensors designed to monitor patients undoubtedly improve the provision of medical services and reduce nurses' workload. In addition, they must undergo primary research before being used in healthcare facilities.

Developing a digital model of a trauma centre involves planning the creation and operation of a medical facility by the requirements of the standards, including mathematical calculations to optimise space and improve the quality of premises and zoning. Since the model is designed to serve more than 180 patients, the capabilities of modern systems for monitoring patients' physiological parameters were investigated. The simulation helps to plan and evaluate the competence of patient capture, care at multiple levels, and diagnostics involving medical staff and facility assets. The developed model illustrated the benefits of the practical, functional division of the facility structure, the use of staff and monitoring systems to control the spread of infectious and complicating conditions and critical conditions that threaten patients' lives. Such observations are critical during periods of increased flu and COVID-19 incidence.

Evaluating the performance of healthcare facilities based on the proposed digital model is a promising method that can be used at the strategic planning stage to minimise negative factors and correct shortcomings, as well as at the commissioning stage. Modelling can also be used to analyse existing facilities, for example, before upgrading patient monitoring systems or assessing the quality of medical services.

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