ECONOMICS AND MANAGEMENT IN PUBLIC HEALTH SERVICE

ORGANIZATION OF WORK WITH UNDESIRED EVENTS WITHIN THE SYSTEM OF MEDICAL ACTIVITIES QUALITY AND SAFETY INTERNAL CONTROL WITH THE USE OF DIGITAL TECHNOLOGY

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ABSTRACT

In accordance with the current legislation a healthcare organization shall be obliged to provide conditions for safe delivery of healthcare to patients and medical personnel performance.
Implementation of effective model of medical activities quality and safety internal control producing meaningful result is a current license requirement to a healthcare organization.
Implementation of risk-oriented approach to medical activities quality and safety management is an important constituent of modern stage of the Russian Federation healthcare functioning.
It is necessary to understand sources of potential hazard within an organization, consider and analyze all undesired events and incidents arising in the process of a healthcare organization functioning and their reasons, take preventive actions to avoid them.
The tasks of digital transformation in the Russian Federation healthcare are development of integrated digital contour, transition to electronic document flow, reduction of medical personnel's time expenditure not involving delivery of healthcare.
Implementation of customer centricity and digitalization principles is an absolute trend of modern stage of development of the Russian Federation healthcare. It determines necessity of development of present-day accounting and analyzing data system on undesired events in a healthcare organization.
The article presents the experiment of Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul, Russian Federation) in establishing system of work with undesired events and managerial decision-making on their avoidance and prevention with the use of present-day digital technology resulting in credible frequency reduction of undesired events in the space of 2.5 years.

Key words: *undesired events in medical activities, medical activities quality and safety internal control, digital technology in healthcare*

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ОРГАНИЗАЦИЯ РАБОТЫ С НЕЖЕЛАТЕЛЬНЫМИ СОБЫТИЯМИ В СИСТЕМЕ ВНУТРЕННЕГО КОНТРОЛЯ КАЧЕСТВА И БЕЗОПАСНОСТИ МЕДИЦИНСКОЙ ДЕЯТЕЛЬНОСТИ С ПРИМЕНЕНИЕМ ЦИФРОВЫХ ТЕХНОЛОГИЙ

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РЕЗЮМЕ

Медицинские организации обязаны соблюдать условия для безопасного оказания медицинской помощи пациентам и работы сотрудников.
Применение эффективной модели внутреннего контроля качества и безопасности медицинской деятельности, дающей реальный результат, – это действующее лицензионное требование ко всем медицинским организациям.
Внедрение риск-ориентированного подхода к управлению качеством и безопасностью медицинской деятельности – важная составляющая современного этапа функционирования здравоохранения РФ.
Необходимо точно знать и идентифицировать источники потенциальной опасности внутри учреждения, учитывать и анализировать все нежелательные события и инциденты, которые возникают в процессе деятельности медицинской организации, причины и следствия, прогнозировать возможное наступление и своевременно принимать профилактические управленческие меры для их предотвращения.
Задачами цифровой трансформации в здравоохранении РФ являются создание единого цифрового контура, переход к электронному документообороту, сокращение временных затрат медицинских работников, не связанных непосредственно с оказанием медицинской помощи.
Внедрение принципов пациенто-центричности и цифровизации – абсолютный тренд современного этапа развития здравоохранения в РФ. Необходимость создания в медицинской организации современной системы учёта и анализа данных по нежелательным событиям направлена на реализацию трендов развития современной клиники и обеспечения безопасности пациентов и сотрудников.
В статье представлен опыт ФГБУ «Федеральный центр травматологии, ортопедии и эндопротезирования» Минздрава России (г. Барнаул) по созданию системы работы с нежелательными событиями и принятия управленческих решений по их устранению и предупреждению с применением современных цифровых технологий, что позволило получить достоверное снижение частоты нежелательных событий за 2,5 года.

Ключевые слова: *нежелательные события в медицинской деятельности, внутренний контроль качества и безопасности медицинской деятельности, цифровые технологии в здравоохранении*

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INTRODUCTION

Ensuring the quality and safety of medical activity remains one of the topical issues of domestic healthcare in current conditions, despite the research conducted in this area and the numerous approaches proposed to solve this problem [1].

At the modern stage of the development of healthcare in the Russian Federation, the requirements for the quality of medical care and the safety of medical activities have been strengthened, the requirements for the internal control system have been formed, which is implemented in the latest changes in legal regulation [2]. Implementation of effective model of medical activities quality and safety internal control producing meaningful result is a current license requirement to a healthcare organization [3].

Medical activities quality and safety internal control is carried out in order to ensure the rights of citizens to receive medical care of the necessary volume and proper quality in accordance with current legislation and compliance with mandatory requirements for ensuring the quality and safety of medical activities [1].

To achieve this goal, a healthcare organization needs to create an effective system of medical activities quality and safety internal control based on current regulatory requirements and modern technology, including digital technology.

The results of primary audits of the quality and safety of medical activities of 30 healthcare organizations in 11 regions of the Russian Federation by multidisciplinary working groups of experts revealed the existing systemic problems in the organization of work and the lack of unified approaches in almost all sections of this area in general and in the organization of recording and analysis of adverse events in particular [4].

Medical activity belongs to the category of very high-risk industries. Risk management helps to prevent, minimize or eliminate possible harm to the life and health of patients and personnel. The introduction of a risk-based approach to managing the quality and safety of medical activities is an important component of the current stage of the functioning of healthcare in Russia. Risk management is an integral part of the organization's management and is of fundamental importance [1, 5, 6].

Review data from different authors recorded the proportion of identified adverse events in the implementation of medical activities from 2.9 to 16.6 % of all hospital admissions in an analysis of up to 30,000 in-patient medical records [7].

The systems of organization of reporting on adverse events and errors in the field of healthcare, functioning in many foreign countries, differ in their organizational structure (public, private, public – agencies, foundations, relevant ministries and committees to which all healthcare organizations of the country are required to send their information), but almost everywhere they have a national or governmental status. Most countries have legislation providing for the confidentiality of information contained in reports. However, sociological surveys have shown that about 70 % of the population would like to have free access to information about adverse events in the healthcare area and healthcare organizations [8].

In the Russian Federation Presidential Decree No. 474 dated July 21, 2020 "On the national development goals of the Russian Federation for the period up to 2030", two of the five national development goals of the Russian Federation are devoted to the preservation of public health and digital transformation. The basic principle of management in all sectors of the state is the orientation towards social results for people, the achievement of indicators of national development goals. Result-oriented performance also implies the creation of risk management system – identifying risks in a timely manner and establishing actions to prevent and mitigate them.

Implementation of customer centricity and digitalization principles – improving the quality of life and the level of public confidence, changing approaches to working with people to solve their life situations, proactive informing about new opportunities, including through the introduction of new digital solutions – is an absolute trend of the modern stage of development of various industries in the Russian Federation [9, 10, 11].

Citizens' demands for the high quality of public services, in general, for the quality of life – housing, medicine, education – are constantly increasing, and the growth of the population's requests is outpacing the rate of the changes [9]. The protection of patients' rights, the activities of human rights organizations have acquired a separate focus and degree of tension. Digital technologies create new opportunities. In addition, digitalization increases the availability of services [9].

The strategic goal in the development of modern medicine is to create an integrated digital contour based on Uniform State Health Information System (USHIS) and to manage the indicators of achievement in an incident-management mode [12, 13].

The main tasks of digital transformation are the transition to electronic document flow in the Russian Federation healthcare; reduction of medical personnel's time expenditure not involving delivery of healthcare. At the same time, the problems of the current state of healthcare that can be solved with digitalization are the following: weak data management due to the lack of integrated applications, unified reference and regulatory information management environment; increased workload on healthcare workers as a result of working with multiple systems and a large amount of manual data input, the need to maintain documentation, including medical, in paper form; long terms, difficulties in the development and implementation of "end-to-end" services and business processes due to the need to integrate several information systems, registries and registers; fragmentation of healthcare information systems, lack of uniform standards of information interaction; limited interdepartmental electronic interaction [12].

In 2022, the Accounts Chamber of the Russian Federation analyzed the current state of healthcare informational support and identified a number of problems that hin-

der the digital transformation of this sphere [14]. The quality of data is negatively affected by the need to multiple information input. According to the inspection, medical workers have to input patient data into several unrelated information systems at the same time. Insufficient formalization of the processes carried out in healthcare organizations significantly hinders their automation and digital transformation, and also leads to different approaches of regions and healthcare organizations to the implementation of the functionality of health information systems. Information technologies as a tool, in addition to solving control and recording tasks, must ensure a reduction in the labor costs of healthcare workers. The introduction of information systems without rejection of hard-copy document flow significantly reduces the productivity of medical personnel and creates an additional workload for doctors. Almost 90 % of doctors interviewed for the inspection believe that digitalization is necessary. However, only 30 % of healthcare workers noted the effect of informational support, since it has become easier to process patient documentation. 27 % noted a reduction in time spent on work [14].

Digital system architecture of the Ministry of Health of Russia, The Federal Fund for Mandatory Medical Insurance and other authorities, as well as the requirements for regional systems must ensure seamless integration and the creation of a single information space in healthcare. The key issue of unification of business processes on the basis of unified directories, data models and registers must be addressed as quickly as possible.

THE PROCEDURE FOR RECORDING AND ANALYSIS OF ADVERSE EVENTS AS A PART OF INTERNAL QUALITY CONTROL AND SAFETY OF MEDICAL ACTIVITIES

The main objectives of Internal Quality Control and Safety of Medical Activities are to improve approaches to the implementation of medical activities to prevent, identify and prevent risks to the life and health of citizens and minimize the consequences of their occurrence, prevent violations in the provision of medical care and make management decisions to improve approaches to the implementation of medical activities [2].

One of the actions carried out as a part of Internal Quality Control and Safety of Medical Activities is the recording of adverse events during the implementation of medical activities (facts and circumstances that pose a threat of causing or entailing harm to the life and health of citizens and/or healthcare workers, as well as leading to an extension of the terms of medical care) [2, 15].

Many processes in the field of healthcare do not have legal regulation, and their implementation differs between healthcare organizations and regions, which complicates their further automation through information systems. This leads to a different approach in the implementation of the functional modules of state and health information systems in the subjects of the Russian Federation, in healthcare organizations and complicates the "end-to-end" exchange of information.

The procedure for recording and analysis of adverse events in the implementation of medical activities is not regulated by federal legislation as a whole (the procedure for reporting, the procedure for recording and analysis, consideration, etc.). The regulation of this issue is in international standards, which causes certain difficulties, different approaches are used in organizations when implementing these actions [16].

There is no exhaustive universal classifier of adverse events in the implementation of medical activities, which healthcare organizations could use as a basis for the organization of internal recording and analysis of indicators, the formation of unified reporting, adapting it to the specifics of their organization.

There is a regulation on certain thematic areas, which is not sufficiently harmonized between them for the purposes of the process approach: Order of Roszdravnadzor (Federal Service for Supervision in Healthcare) No. 4513 dated May 20, 2021 approved the classification of adverse events connected with medical devices circulation; Order of the Ministry of Health of the Russian Federation No. 1108n dated November 29, 2021 approved the procedure for revealing and recording at a healthcare organization of cases of infectious diseases connected with delivery of healthcare, nomenclature of infectious diseases connected with delivery of healthcare subject to revealing and recording at a healthcare organization; Order of Roszdravnadzor (Federal Service for Supervision in Healthcare) No. 1071 dated February 15, 2017 approved the procedure for pharmacovigilance; Order of the Ministry of Health of the Russian Federation No. 1113n dated October 19, 2020 approved the procedure for reporting by subjects of medical devices circulation of facts and circumstances creating danger to life and health of general public and medical personnel during use and operation of medical devices. However, the spectrum and list of undesired events are much broader, which requires systematization at the federal level [17–20].

Global trends in the digital transformation of the healthcare industry and priority areas for the development of this type of technology allow electronic recording and analysis systems to be classified as Predictive Analytics – the intelligent use of data, predictive modeling of future events, support and justification of managerial decision-making [21].

According to experts, Health Information Technology (HIT) is the most effective tool for improving the quality, efficiency, safety of medical care, but it is also the most expensive. Studies show that in institutions that have switched to an electronic incident reporting system (web systems), the frequency and timeliness of reporting, the accuracy of key indicators and the systematic organization of work in this area have increased [22].

An important issue, which also represents a traditional problem, is the system of electronic intradepartmental and interdepartmental document flow for the operational formation and provision of various forms of reporting to dif-

ferent departments and divisions, which, according to current legislation, is to be put into operation in the Russian Federation on December 31, 2024 [23].

The above arguments became the basis for setting the goal of creating a system of recording and analysis of adverse events (AEs) in our healthcare organization for managerial decision-making on avoidance and prevention of risks with the use of digital technology, reducing of adverse events. Creation of a unified digital system in the Russian Federation seems to be the optimal solution to this issue.

To achieve this goal, the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul) has developed a "Procedure for recording adverse events in the implementation of medical activities and other incidents", containing the following sections:

- goals, objectives, principles of operation, classification and basic definitions, an approximate list of AEs in the implementation of medical activities and other incidents (including markers (signs) of adverse events);
- the procedure for reporting (registration) by the employees of the institution, patients and visitors about an adverse event;
- unified form of AE recording;
- the procedure of AE investigating, identifying the type of AE by consequences;
- the procedure for calculating and analyzing parameters, monitoring the dynamics and trends of AE for established periods;
- the form of the corrective action plan, the procedure for monitoring the effectiveness of the actions taken;
- informing employees, the procedure for internal personnel training, the procedure for feedback.

Electronic Adverse Event Recording System (Incident notifications) is a web-based system that allows employees of a healthcare organization and patients to voluntarily report problems that have occurred.

The system is integrated with the internal Medical Information System (MIS) and the Electronic Health Record (EHR) of a patient for automatic (without personnel involvement) detection, reporting and recording of information about an adverse event with the help of key trigger indicators (critical values of laboratory and other instrumental indicators, the volume of blood loss, labeled medical formulations recorded in the medical documentation, other).

The developed electronic adverse event recording system has a number of advantages:

- immediately, in real time, automatically detects, independently detects and reports serious incidents to the medical chat of the institution (excludes the presence of "unrecorded" incidents);
- automates and simplifies data input and analysis, reduces the work time with this incident on its processing (ready-made templates have been created) and informing all officials (operational information about the adverse event is immediately reported to the hospital chat);
- minimizes the involvement of personnel in detection and recording of the adverse event;
- standardizes the procedure and structure of reporting, the process of analyzing the causes of the adverse event and the development of corrective actions;
- helps to improve clinical processes (based on the developed SOP and algorithms);
- helps to predict and identify potential risks.

THE SYSTEM OF DEALING WITH ADVERSE EVENTS

The Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul) has a system for dealing with adverse events, structured by stages (Fig. 1).

A computer program for recording adverse events has been created on the Bitrix platform (contains 66 accounting parameters), which is implemented on the website of the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul).

The first stage is the establishment of the fact of an adverse event, notification (registration) of the AE in the electronic recording system (computer program): employees (medical and non-medical personnel, patients and visitors), MIS (according to established triggers: words and critical levels of monitoring indicators), the initial processing of the notification by the Department of Internal Quality Control and Safety of Medical Activities.

The second stage is the analysis of the AE by consequences (errors with little or no harm, errors with significant harm and extreme events that are considered based on significance within 48 hours (urgent) or monthly).

The third stage is an internal inspection of the AE by a task force using the RCA (root cause analysis) method, preparation of a plan and implementation of corrective actions, consideration by a medical commission (efficiency control), changes in internal algorithms (orders).

The fourth stage is the analysis of monitoring indicators for the established periods, identification of dynamics, informing employees, additional internal personnel training, feedback from patients and visitors (if necessary).

RESULTS OF FUNCTIONING OF THE SYSTEM OF HANDLING WITH ADVERSE EVENTS AS A PART OF INTERNAL QUALITY CONTROL AND SAFETY OF MEDICAL ACTIVITIES

The system organizational actions carried out as a part of Internal Quality Control and Safety of Medical Activities, based on strict recording of AE with the use of digital technologies, root cause analysis of occurrence and development of a set of preventive actions, allowed to reduce the values of the main control monitoring parameters of AE at the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul) for 2.5 years (2020–2022); thus, we have implemented actions to improve the level of safety for patients and employees.

Over 2.5 years (2020–2022) the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Bar-

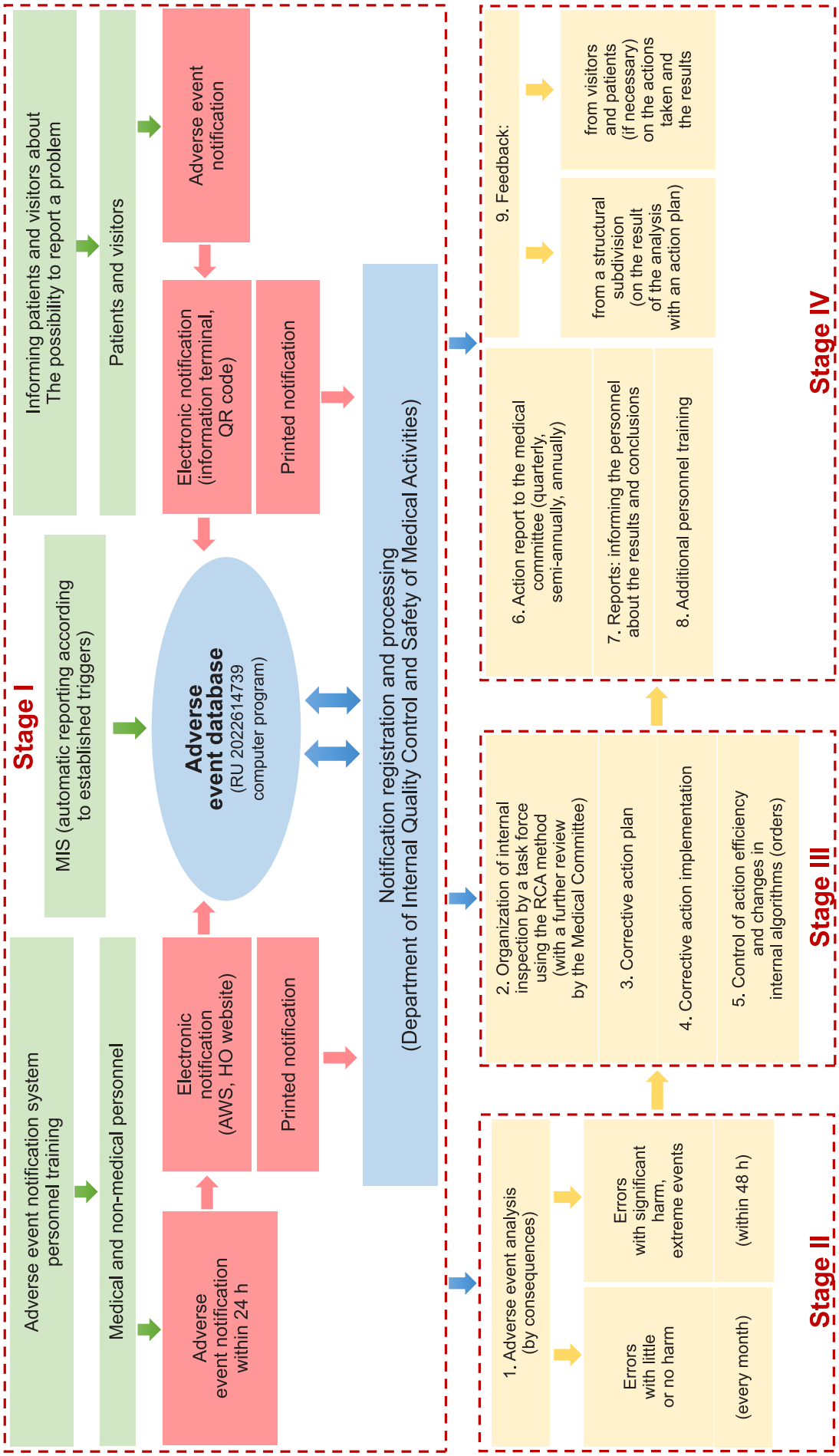

FIG. 1.
Stages of work with undesired events at the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul)

naul) has analyzed 19,639 cases of hospital admission to the "Traumatology and Orthopaedics" and "Neurosurgery" departments and registered 269 adverse events.

On March 24, 2022, we successfully completed the procedure of state registration of the computer program "Recording of adverse events during implementation of medical activities" in the Federal Service for Intellectual Property (Rospatent), which complies with the requirements of legislation on information security and personal data protection. The Certificate of State Registration (No. 2022614739) was received [24].

The indicators of the AE rate (per 1000 treated patients) were established in the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul) according to our approved internal order rubrics from the highest to the lowest: 1st – the AE rate parameter, events during the treatment of the patient – 2.85, 2nd – other incidents (non-medical) – 2.24, 3rd place – events related to surgical interventions or other procedures – 1.22, 4th – markers (signs) of adverse events during the implementation of medical activities – 1.02, 5th – events related to the use of medical devices – 0.61, 6th – events related to the use of medicines – 0.41, 7th – events related to infection and events related to the implementation of anesthesia, – 0.2 for each category.

We rank all structural divisions of the Federal Center for Traumatology, Orthopedics and Endoprosthetics (Barnaul) according to the final indicators of the rate of adverse events from the highest parameter to the lowest. A rating of departments is formed according to the AE indicators, which is used in the system of remuneration and bonuses of employees as one of the supporting stimulating indicators established by a local legal act.

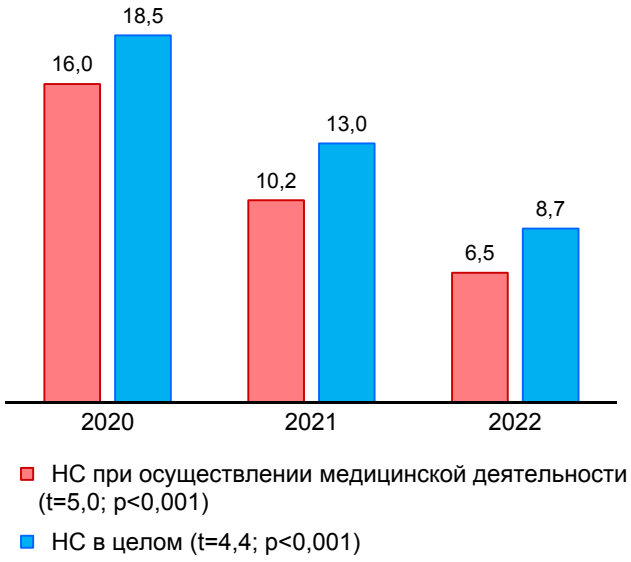

FIG. 2.
Trend data of undesired events frequency in the course of medical activities and other incidents in the years 2020–2022 (for 1000 treated patients)

The introduction of the system for managing adverse events as a part of Internal Quality Control and Safety of Medical Activities, including streamlined procedures for registration, analysis, control and managerial decision-making aimed at prevention and improvement, allowed us to obtain a significant reduction in the rate of adverse events in a healthcare organization for 2.5 years (Fig. 2).

We have registered a decrease in the AE rate in the implementation of medical activities (per 1000 treated patients) from 16.0 in 2020 to 10.2 in 2021 and 6.6 in the first half of 2022 ($p = 0.0001$; $p < 0.001$); decrease in the AE rate (in general, including non-medical, other) – from 18.5 in 2020 to 13.0 in 2021 and 8.7 in the first half of 2022. ($p = 0.0003$; $p < 0.001$).

Thus, a systematic approach to the identification, recording, analysis of adverse events using digital technologies, operational management actions as a part of Internal Quality Control and Safety of Medical Activities allowed to successfully achieve reducing the rate of adverse events in the implementation of medical activities for 2.5 years (2020–2022).

Conflict of interest

There are no obvious and potential conflicts of interest related to the publication of this article.

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