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REVIEW OF INTERNATIONAL PRACTICE OF THE USE OF NATIONAL MEDICAL INCIDENT REPORTING SYSTEMS

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ABSTRACT. Analysis of adverse events that happen in medical organizations has proved to be a crucial instrument of improvement of quality and safety of healthcare. Foreign countries make ample use of national incident reporting systems for this aim. The work of national incident reporting systems involves not only leaders and managers of healthcare but the personnel of medical organizations as well. National systems accumulate information, analyze it and later based on this analysis the organizational decisions are being made, which are aimed at correction and prevention of future faults or associated problems in the medical organizations. Unified national system like this does not exist in the Russian Federation that is why the aim of this research was to analyze the foreign practice of using national incident reporting systems in order to form recommendations for the creation of similar system in the Russian Federation. In this study practical experience of Denmark, United Kingdom, China and Kazakhstan was described, the negative and positive aspects of the organizational decisions of these countries were highlighted, as well as the results of their performance were presented. Based on the given information the recommendations on the creation of a similar system in the Russian Federation were proposed including improvement of legislation norms, the use of digital solutions while designing and implementing the system, which will be improved regularly based on feedback and the results of performance check. It is also necessary to ensure that this system will be easy to use, transparent and fair.

KEYWORDS: incidents, quality of healthcare, adverse events, foreign practice

ОБЗОР МЕЖДУНАРОДНОГО ОПЫТА ПРИМЕНЕНИЯ НАЦИОНАЛЬНЫХ СИСТЕМ СБОРА МЕДИЦИНСКИХ ИНЦИДЕНТОВ

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РЕЗЮМЕ. Важным инструментом совершенствования качества и безопасности медицинской деятельности является анализ всех неблагоприятных ситуаций, случающихся в организации. С этой целью в зарубежных странах используются национальные системы сбора инцидентов, в функционирование которых вовлечены как руководители и организаторы здравоохранения, так и персонал всех медицинских организаций. Национальные системы аккумулируют информацию, анализируют ее, на основании чего в дальнейшем принимаются управленческие решения, направленные на коррекцию и профилактику повторения ошибок или организационных проблем, встречающихся в учреждениях здравоохранения. Подобная единая национальная система отсутствует в Российской Федерации, поэтому целью данного исследования стало изучение зарубежного опыта функционирования национальных систем сбора инцидентов, произошедших в медицинских организациях, и формирование на его основании рекомендаций по построению аналогичной системы в Российской Федерации. В ходе исследования был описан практический опыт Дании, Великобритании, Китайской Народной Республики, Республики Казахстан, и были выделены позитивные и негативные аспекты организационных решений, используемых данными странами, а также приведены результаты их деятельности. На основании изученных данных были предложены рекомендации по созданию системы сбора инцидентов в Российской Федерации, включающие в себя совершенствование законодательства, использование цифровых решений при проектировании системы, которая будет регулярно совершенствоваться на основании обратной связи и анализа результатов ее работы, а также обеспечение ее простоты, прозрачности, справедливости.

КЛЮЧЕВЫЕ СЛОВА: инциденты, качество медицинской помощи, нежелательные события, зарубежный опыт

INTRODUCTION

The activities of medical organizations are inevitably associated with risks for patients and medical personnel. The use of medications, medical equipment, invasive diagnostic and therapeutic techniques makes errors in the delivery of medical care dangerous to the health of participants in this process. This can be explained by the fact that any violation of technology and standards can lead to adverse consequences.

In this regard, it is important that information about adverse events that have occurred or may occur reaches the department heads and higher-level leaders for study and taking measures to prevent their recurrence. Accumulation of such information can be carried out through an incident collection and analysis system.

In the United Kingdom healthcare system, a "patient safety incident" is defined as "an event in the course of medical care delivery that could have resulted, or did result, in harm to a patient's health" [1]. The World Health Organization gives a similar definition of the term "incident" [2].

The collection and analysis of incidents occurring on the premises of a medical organization is a valuable instrument for its leaders. Incident reporting expands the range of information available to them, allowing them to take timely organizational measures aimed at correcting real problems.

In the Russian Federation, there is no definition of the term "incident" applicable to a medical organization at the legislative level, and there are no widespread incident repor-

ting systems. Some organizations have independently implemented this system, but on their own initiative. Its implementation was mainly associated with the preparation of medical organizations for further accreditation / certification in accordance with the standards of quality and safety of medical care (for example, international standards of Joint Commission International or national standards of Roszdravnadzor).

A different situation is observed in many foreign countries. For example, in Denmark and the United Kingdom, national incident reporting systems have existed for over 20 years. During the work of these systems, information is collected at the national level from all medical organizations to make decisions based on its analysis not only at the level of the medical organization, but also at the level of the health system as a whole.

In Sweden, incident reporting systems were implemented using the Internet in all regions of the country in the mid-2000s [3] and are still actively used in medical care today. According to a 2011 survey of healthcare leaders, incident reporting and root cause analysis have become one of the most crucial instruments for achieving high levels of patient safety [4].

Swedish law requires the leadership of each administrative region to publish annual patient safety reports. These reports have been used since 2011 to monitor trends in patient safety and correct identified gaps [5]. 19 out of 21 regions include information in the report on whether they have an electronic incident reporting system, and 18 of them also include information on the results working with incidents [6].

The experience of systematic work with medical incidents has been described not only in European countries, but also in Asian countries. The People's Republic of China has also implemented an incident reporting system, which has not yet achieved the same positive results as similar instruments in European countries.

The Republic of Kazakhstan, which is close to the Russian Federation both territorially and culturally, actively working on improving the organization of medical care that is safe for patients, including at the legislative level. This is evidenced by the development, approval and updating of regulatory documents that provide an official definition of the concept of "medical incident" and describe the procedure for working with them.

It is worth noting that work on improving the quality and safety of medical care is not limited to the creation of such a system. It also requires its constant improvement and development based on the results obtained and feedback from health workers.

Taking into account the interest of foreign healthcare leaders in using incidents as an instrument to ensure patient safety, it is advisable to consider their experience to identify the most valuable practices that can be applied in implementing such a system in the Russian Federation.

AIM

The aim of the study is to examine foreign experience in the functioning of national systems to collect incidents that occurred in medical organizations. It is also necessary to provide recommendations on the basis of this experience for creation of a similar system in the Russian Federation.

MATERIALS AND METHODS

During the research, an analysis of public data sources from the PubMed, Cyberleninka, and eLIBRARY databases was carried out to study foreign experience in the implementation of the system of incidents in national health systems.

RESULTS

A number of countries have national systems aimed at collecting information on patient safety incidents.

The first such system was the Danish Patient Safety Database (DPSD), which was created and implemented in January 2004 [7]. Initially, the system was aimed at collecting incidents that occurred in hospitals, but in 2010, it also included organizations providing primary health care [8]. As part of its expansion, the ability to collect incidents not only from medical workers, for whom participation is mandatory, but also from patients and their relatives [9], who can, if they wish, write an incident report, was implemented in 2011.

The incident report form is filled out online and includes the following information: incident

description, time and place, patient's gender, suspected causes of the incident, and proposed preventive measures. If the information is provided by medical workers, they independently indicate the type of incident and its severity. If the incident is received from a patient or a close relative, it is classified by a risk manager [10].

Incidents are considered at three levels. At the healthcare organization level, incidents are reviewed to analyze root causes and implement preventive measures. Analysis at the regional level is used to train personnel of medical organizations in the region. Incident review at the national level is conducted to monitor statistics and study the total number of incoming incidents for use as a basis for creating general recommendations.

The incident does not entail disciplinary action against the health worker who reported it, since this system is strictly separated from the systems that control or handle complaints. They exist in parallel and do not exchange information. However, if complaints or comments are received externally from supervisory authorities about this event, then the employee may still be subject to measures of influence [11].

The system has shown significant growth and increased involvement of healthcare personnel during its existence. Thus, if 12,370 incidents were recorded in 2006, then in 2012 there were already 155,791 [12]. Subsequently, the growth continued. Thus, during the 2021 study [10], incidents received from nurses, doctors, patients and their relatives for the period from 2014 to 2015 were studied. Their total number was 241,606, while the study did not include incidents received from other personnel of medical organizations (there were 131,314 of them). The statistics of the studied data showed that most often incidents were reported by nurses (81.3%) and doctors (16.1%), the share of incidents received from patients (1.2%) and their relatives (1.4%) was small. The most frequently recorded incidents were in the following categories: "medicines" (53.8%), "patient accidents" (17.2%), "treatment and care" (7.0%).

Despite the positive quantitative performance indicators of the system, its implementation and expansion has been heavily criticized by personnel. The bulk of the comments was related to the high bureaucratization of the system, which resulted in an incident recording taking 20–30 minutes and an average of 1 hour to be considered. This problem was exacerbated by the receipt of a large number of incidents describing minor situations, which could not cause significant harm to the patient. As a result, the increase in quantitative performance indicators of the system was not accompanied by qualitative results, since it proved difficult to process and identify useful patterns among hundreds of thousands of incidents [13].

In response to these comments, a working group consisting of representatives of patient organizations, trade unions, professional societies, regional and municipal leadership developed recommendations for optimizing the Danish incident reporting system. The following changes were proposed:

- limiting the range of incidents collected (collecting only those that resulted in moderate or serious harm to health, revealed new problems, were useful for training personnel or were relevant for the clinic);
- facilitating the process of their registration (simplifying the form, creating submission templates);
- priority for working with incidents at the level of a medical organization;
- organization of experience exchange between health institutions;
- inclusion of the system in quality programs of medical organizations;
- increasing the transparency of the health system (publication of information about individual incidents on the websites of medical organizations, following the example of Norway) [14].

The data published by Danish scientists indicate that the incident reporting system cannot exist statically. It needs to be constantly improved, based on feedback from the medical personnel working with it.

The United Kingdom (hereinafter referred to as the UK) is an example of active work to improve such a system. In this country, the National Reporting and Learning System (NRLS) was launched only a month later than Denmark, in February 2004 [15], and continued to function until July 2024.

The system was developed and implemented in the UK between 2001 and 2004, based on the experience of incidents in Australia and the United States of America. More than 28,000 incidents were collected during the pilot project in 2001–2002. Based on them, conclusions were

made about the project's shortcomings related to the low quality of incoming information and problems with the digitalization of the process. The work carried out following the pilot project to integrate the incident reporting process with the medical information systems of healthcare organizations made it possible to achieve significant results. Thus, in the period from November 2003 to September 2005, 303,447 incidents were received, of which 68.3% described situations that did not result in harm to the patient, and 0.7 and 0.4% reported problems that resulted in serious harm to health or death of the patient, respectively [16].

The UK National Health Service has published reports on incidents received in the database on its official website until 2023, and has also posted individual cases of using the information received to improve the provision of medical care within the national health system. Data available to the general public shows a significant increase in the use of the system by medical organizations. Thus, if about 100 thousand incidents were submitted in April–June 2005, then in the same period in 2022, more than 600 thousand were recorded [17]. The publication of reporting documentation was suspended in 2023, as part of the transition to the new system.

NRLS was discontinued on July 30, 2024, and replaced by the Learn from Patient Safety Events (LPPSE) system. Its advantage over its predecessor is the expansion of capabilities through the use of machine learning elements, as well as the optimization of its application by organizations delivering primary health care.

In the new system, when filling out a form, personnel or patients select the type of incident, what it was related to (medications, equipment, IT, blood and its components, etc.), describe the event. They also note relevant safety issues (bedsores, falls, radiation therapy issues, hospital-acquired infections, etc.), indicate the date and place of the incident, patient details if they were injured (age, severity of harm, outcome).

Incidents can be registered with a personal account or anonymously. In the second case, the initiator is asked to indicate the reason for choosing anonymity. The above points are a mandatory part of incident registration. After filling out and saving them, the initiator may, at his own discretion, complete additional sections, indicating additional details (information about the medications, equipment, etc.) [18].

Currently, in the UK, incidents resulting in serious harm or death and events that should not have happened (serious, preventable situations related to patient safety that would not have occurred if medical personnel had used preventive measures) are mandatory for registration [19]. These incidents since 2018 include, for example, performing wrong-site surgery, leaving a foreign object in the body of a patient during surgery, choosing the wrong-route drug administration, etc. [20]. The preventability of many of them is currently being questioned [21], as a result of which changes to this list are planned at the national level.

Reported incidents are subject to review, based on the results of which a decision is made on corrective measures. Unlike Denmark, the UK does not guarantee that personnel will not be punished for the event that caused the incident. However, the National Health Service encourages the development of a "fair culture", which is based on a rational approach to studying the incident and its causes [22]. Before making a decision on punishment, leadership has been asked to assess the situation on a number of points, which will help to determine the extent of the employee's personal contribution to the incident. This approach is intended, on the one hand, to protect medical staff from undeserved accusations and punishments, while reducing their fear of reporting incidents. On the other hand, it aims to leave leadership the opportunity to apply disciplinary sanctions to personnel, intentionally harmed or deviated from the algorithms and instructions [23]. The described culture has been implemented in the UK healthcare organizations, but surveys show the need for further work on this issue, including in terms of awareness of healthcare workers [24].

The People's Republic of China (hereinafter referred to as the PRC) has an even stricter position on the reporting and analysis of incidents. Thus, the PRC has the National Patient Safety Incident Reporting System (NPSIRS), launched in early 2012, which received 36,498 incidents between 2012 and 2017 [25]. Reporting incidents in the PRC is mandatory for personnel and does not provide the option to report them anonymously. Healthcare workers are required to inform the leadership of any incidents they have

participated in or witnessed through the hospital incident reporting system. The accumulated information is submitted to the national database by the manager of the healthcare organization.

Each report provided to the NPSIRS includes administrative details (time/place, participants), patient information, actions taken, harm assessment, and a field for describing the event in your own words [2].

The NPSIRS was not the first attempt to implement a medical incident information collection system at the national level. Similar initiatives were also undertaken in 2004 by the state and in 2008 by the Chinese Medical Association, but have not been widely adopted [26].

The effectiveness of the current national system for reporting patient safety incidents has also been questioned in publications by Chinese authors. The design features of the system, which involve collecting incidents in a national database for subsequent decision-making, have led to the conclusion that it is ineffective and has little impact on the care provided. This is explained by the fact that "only timely identification of errors makes it possible to take proactive actions aimed at clinical changes and improvements" [27].

The number of incidents reported to the PRC system is significantly lower than in Denmark and the UK, despite the fact that their registration is mandatory for medical personnel. Research by Chinese scientists suggests that one of the reasons is the fear of healthcare workers being blamed or punished. Articles on the study of safety culture in China highlight the fear of punishment as one of the most important obstacles to the development of this system. The survey of personnel of medical organizations in the PRC demonstrated a positive assessment of patient safety, but also indicates the prevalence of fear of blame and punishment (65%) and fear of shame (20%) among staff [28]. The survey of medical personnel in Changsha also highlighted the lack of penalties for mistakes as a safety culture parameter that needs improvement. In general, staff "worried that the errors they made would be reflected in their personal files and affect their future career opportunities" [29].

Another country that has implemented a national incident system is the Republic of Kazakhstan, where the Order No. KR DCM-147/2020, issued by the Minister of Health of the Republic of Kazakhstan on October 22, 2020 "On approval of rules for determining cases (events) of a medical incident, their recording and analysis" approved the concept of a medical incident. According to this document, this term is defined as "an event related to the provision of medical care in accordance with the standards for organizing medical care using technologies, equipment and instruments, caused by a deviation from the normal functioning of the body, which can harm the life and health of the patient, as well as lead to the death of the patient, with the exception of cases provided for by the administrative and criminal law of the Republic of Kazakhstan".

Medical incidents in the Republic of Kazakhstan include, for example, drug allergies, complications of medical interventions, as well as medical device adverse events.

According to the Order No. KR DCM-147/2020, issued by the Minister of Health of the Republic of Kazakhstan on October 22, 2020, information about the incidents is received from healthcare workers to the patient support service and internal examination of the medical organization. In this case, medical personnel get additional financial incentives for submitting information about incidents. Based on the collected information, a certificate is generated. After receiving approval from the head of the medical organization, this document is sent to an organization subordinate to the authorized body in the field of healthcare, to record cases of medical incidents. The events that occurred, their causes, and a brief description of the cases treated are indicated. The name of the medical organization is not indicated.

The authorized body shall keep records of medical incidents based on information received from medical organizations, as well as from government agencies in the areas of medical services (assistance), sanitary and epidemiological well-being of the population, circulation of medicines and medical devices or their territorial divisions.

On June 26, 2024, the Order No. 32 of the Acting Minister of Health of the Republic of Kazakhstan was approved in Kazakhstan. It came into force on October 23, 2024 and contained the Rules for the formation and maintenance of a single register of a medical incidents and insurance cases. According to the document, medical organizations must send information on the occurrence of a medical incident or insurance case

to a subordinate organization determined by the authorized body in the field of healthcare on a quarterly basis. The unified register is maintained in electronic format. It includes the following information about incidents: date, time, type, consequences, circumstances that led to it, profile, anamnesis of life / disease, patient's age / gender / diagnosis, whether assistance was provided, whether measures were taken to eliminate and prevent recurrence, whether a corrective action plan was drawn up.

Thus, the countries described have different approaches to the work and organization of the incident reporting system and subsequent work with them. The data collected during functioning of the system differ (Table 1), as well as the approach to communication with the personnel providing the information.

The reports of all the countries studied included data about the time and place of the incident, patient's gender. Three of the four also included mandatorily a description of the event, the severity of the harm caused, and the type / kind / category of the incident. The least frequently asked questions were about the participants (China) and about the safety issues associated with the incident (the UK).

DISCUSSION

International experience in the application and development of incident reporting systems demonstrates the interest of healthcare leaders in this method of improving the quality and safety of medical organizations.

However, it is impossible to talk about the existence of a global standard, since countries use different incident management programs, collect different information from each other and organize work with the received data in accordance with their own needs and projects.

Work on an incident reporting system does not end with the creation and implementation of the initial project, but often requires significant changes in its functioning, up to and including a change in the underlying architecture. This fact can be noted in the description of the experience of foreign countries: the collection and analysis of incidents in each of them underwent significant changes during its existence, up to a complete change in the instruments used. The reason for this could be widespread criticism of practical implementation (Denmark), low efficiency (the PRC), or the emergence of opportunities for its improvement through the development

Table 1

Data filled in during the creation of incident reports

Таблица 1

Данные, заполняемые в ходе формирования отчетов об инцидентах

Заполняемые сведения об инциденте / Incident details to be filled in	**Дания / Denmark**	**Великобритания / United Kingdom**	**Китай / China**	**Казахстан / Kazakhstan**
Описание / Description	Да / Yes	Да / Yes	Да / Yes	Нет / No
Время и место / Time and place	Да / Yes	Да / Yes	Да / Yes	Да / Yes
Участники / Paricipants	Нет / No	Нет / No	Да / Yes	Нет / No
Профиль / анамнез / диагноз пациента / Profile / anamnesis/ diagnosis of patient	Нет / No	Нет / No	Нет / No	Да / Yes
Пол пациента / Patient's gender	Да / Yes	Да / Yes	Да / Yes	Да / Yes
Тяжесть нанесенного вреда / Severity of harm	Да / Yes	Да / Yes	Да / Yes	Нет / No
Исход / Outcome	Нет / No	Да / Yes	Нет / No	Да / Yes
Предпринятые действия / Actions taken	Нет / No	Нет / No	Да / Yes	Да / Yes
Причины / Cause	Да / Yes	Нет / No	Нет / No	Да / Yes
Проблемы безопасности / Safety problems	Нет / No	Да / Yes	Нет / No	Нет / No
Профилактические меры / Preventive measures	Да / Yes	Нет / No	Нет / No	Да / Yes
Тип / категория / Type / category	Да / Yes	Да / Yes	Нет / No	Да / Yes

of technologies, including artificial intelligence (the UK).

Among the foreign systems described, Denmark and the UK had the best results, showing an active growth in the number of incidents entering the database. One of the reasons for this may be the specifics of the organization of their analysis, which is aimed not at punishing the guilty party, but at identifying the root causes. This approach to work helps reduce the fear of punishment experienced by personnel, thereby facilitating their involvement in the process.

Studying the experience of foreign countries, we can note the following principles that should be taken into account when creating a similar system.

1. Fixing at the legislative level the definition of the term "incident", as well as a list of incidents that must be submitted, and the procedure for collecting them. These measures are necessary to eliminate differences in the interpretation of both the essence of incidents and the need to collect them.

2. Creating a simple and convenient incident recording algorithm that does not require medical and management personnel to spend a lot of time and does not lead to excessive bureaucratization of the process.

3. Focus on the analysis and application of incidents primarily at the level of medical organizations. As the experience of Denmark and China shows, collecting incidents at the national level for further use in decision-making at the state and regional levels has been often ineffective due to the long duration of the process. Therefore, the collected incidents should be first of all analyzed at the level of medical organization for timely implementation of corrective and preventive measures.

4. Defining a clear list of incidents that should be transferred by the medical organization to higher levels (regional, state), to facilitate their processing and decision-making based on them.

5. Creating favorable conditions for the registration of incidents by employees of medical organizations. An example is the adaptation of the UK experience in building a "fair culture". This approach provides clear criteria for decision-making based on the results of a situation analysis and protects conscientious personnel from the potential consequences of recording incidents.

6. Regularly improving the system based on feedback from medical workers, as well as statistics on the information received, using digital solutions, and upgrading them as technology develops.

These recommendations are based on the experience of foreign countries that have implemented incident reporting systems at the national level with varying degrees of success. However, the article has a number of limitations: it describes the example of only five countries, while there are other countries that have similar experience, but are not considered in the study. Moreover, the features of national health legislation and model may affect the effectiveness of implementing such practices in other countries.

For example, the most important issue is the legal status of medical incidents, the possibility of using them as instruments for punishing personnel. As the studied experience shows, even the possibility of punishment within a medical organization has a sufficiently strong negative impact on motivation, that hinders the successful functioning of the system. In addition, the potential use of incidents by law enforcement agencies for the purpose of criminal or administrative prosecution of medical workers or organizations will probably completely destroy the chance to attract personnel to voluntary participation in its work.

These points should be considered in advance and taken into account when developing a project for the implementation of such a system.

CONCLUSION

The collection and analysis of incidents can be a valuable instrument for of healthcare leaders and higher authorities. However, its effective implementation requires creating a high-quality system that will ensure simple and transparent interaction with it.

Health leaders in many countries around the world are actively using this instrument to improve the quality of medical care. The success of this initiative varies depending on the approach to working with incidents and interacting with personnel. This makes these features important to study and take into account when making recommendations on the creation and implementation of a system for collecting and analyzing incidents in the Russian Federation.

Currently, in Russia, there is no legislative definition of the term "medical incident", and the collection of incidents is carried out exclusively by individual organizations as a compo-

nent of the activities of healthcare quality control services. As a result, a large share of information that could be used to improve the activities of individual medical organizations, as well as regional or interregional health management does not reach senior leaders.

For this reason, the development of a clear, legally established incident reporting system in the Russian Federation, based on the study of foreign experience, is a relevant instrument for improving the quality and safety of medical care. Creating a digital circuit that ensures the collection of this information will make its use simple, convenient and protected in terms of cybersecurity. The transition to a "fair culture" in medical organizations will increase the readiness of personnel to inform leadership about adverse events that have occurred or about potential errors and problems.

A system created on these principles will most likely be accepted by employees of medical organizations, whose voluntary and active participation in this initiative is an essential component of its success.

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ЛИТЕРАТУРА / REFERENCES

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