



UDC 352.073(477)(07)

[https://doi.org/10.32689/2617-2224-2020-4\(24\)-166-180](https://doi.org/10.32689/2617-2224-2020-4(24)-166-180)

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ELECTRONIC HEALTHCARE SYSTEM AS A MONITORING TOOL IN THE FIELD OF HEALTHCARE OF THE UNITED TERRITORIAL COMMUNITY: REGULATORY LAW

Abstract. More than 60 years have passed since the beginning of research on the use of information technology in the field of healthcare, but there is no complete clarity in determining the best strategy for informatization and the operation of the electronic healthcare system (EHS).

At present, normative-legal acts regulate informatization in the field of healthcare and the order of activity of the EHS, storage, protection of personal and medical information. However, the issues of quality assessment and monitoring mechanisms of the EHS have not been resolved. The issues of using electronic tools to assess the quality of the healthcare system, indicators of the state of health of the population, economic indicators of the healthcare system are also insufficiently studied. At this stage of development of the electronic healthcare system, the automation process has been introduced, but there is a need to develop the

mechanisms for processing and analyzing information, using the EHS as a tool for systematic and timely monitoring of healthcare performance, in particular at the level of the united territorial community in the conditions of change of the administrative-territorial system, decentralization, formation and development of the territorial communities. For the community as a whole, there is important information about the state of healthcare not so much in the administrative territory as in the community. Informatization and EHS can be an important tool for monitoring the healthcare system in the settlements that are part of a unified territorial community and serve the population of the community, rather than a single city, town, etc.

This study outlines the main purpose and activities of the EHS as a tool for monitoring the process and results of activities in the field of healthcare of the united territorial community, considered issues of legislation on informatization in the field of healthcare and activities of the EHS, liability for violations of in the field of information protection.

Keywords: informatization, healthcare sector, electronic healthcare system, territorial community, performance indicators, monitoring mechanisms, legal framework, public administration.

ЕЛЕКТРОННА СИСТЕМА ОХОРОНИ ЗДОРОВ'Я ЯК ІНСТРУМЕНТ МОНІТОРИНГУ В СФЕРІ ОХОРОНИ ЗДОРОВ'Я ОБ'ЄДНАНОЇ ТЕРИТОРІАЛЬНОЇ ГРОМАДИ: НОРМАТИВНО-ПРАВОВЕ ЗАБЕЗПЕЧЕННЯ

Анотація. Викладено, що з моменту початку досліджень у напрямі використання інформаційних технологій у сфері охорони здоров'я минуло понад 60 років, проте повної ясності у визначенні найкращої стратегії інформатизації та діяльності електронної системи охорони здоров'я (ЕСОЗ) немає.

На сьогодні нормативно-правовими актами врегульовані інформатизація в галузі охорони здоров'я та порядок діяльності ЕСОЗ, збереження, захисту персональної та медичної інформації. Проте не врегульованими залишаються питання оцінки якості та механізмів моніторингу ЕСОЗ. Недостатньо вивченими є питання використання електронних інструментів для оцінки якості роботи системи охорони здоров'я, показників стану здоров'я населення, економічних показників діяльності системи охорони здоров'я. На цьому етапі розвитку електронної системи охорони здоров'я впроваджено процес автоматизації, проте є потреба у розвитку механізмів обробки та аналізу інформації, використання ЕСОЗ як інструменту для систематичного та вчасного моніторингу ефективності діяльності галузі охорони здоров'я, зокрема на рівні об'єднаної територіальної громади в умовах зміни адміністративно-територіального устрою, децентралізації, формування та розвитку територіальних громад. Для громади загалом є суттєвою інформація щодо стану охорони здоров'я не стільки на адміністративній території, скільки на території громади. Інформатизація та ЕСОЗ може стати важливим інструментом для моніторингу системи охорони здоров'я на території населених пунктів,

які входять до складу об'єднаної територіальної громади та обслуговують населення громади, а не окремого міста, селища тощо.

Окреслено основну мету та напрями діяльності ЕСОЗ як інструменту для моніторингу процесу та результатів діяльності у сфері охорони здоров'я об'єднаної територіальної громади, розглянуто питання законодавчого регулювання щодо інформатизації у сфері охорони здоров'я та діяльності ЕСОЗ, відповідальності за порушення у сфері захисту інформації.

Ключові слова: інформатизація, галузь охорони здоров'я, електронна система охорони здоров'я, територіальна громада, показники діяльності, механізми моніторингу, нормативно-правова база, публічне управління та адміністрування.

ЭЛЕКТРОННАЯ СИСТЕМА ЗДРАВООХРАНЕНИЯ КАК ИНСТРУМЕНТ МОНИТОРИНГА В СФЕРЕ ЗДРАВООХРАНЕНИЯ ОБЪЕДИНЕННОЙ ТЕРРИТОРИАЛЬНОЙ ОБЩИНЫ: НОРМАТИВНО-ПРАВОВОЕ ОБЕСПЕЧЕНИЕ

Аннотация. Исследовано, что в направлении использования информационных технологий в сфере здравоохранения прошло более 60 лет, однако полной ясности в определении наилучшей стратегии информатизации и деятельности электронного здравоохранения (ЕСОЗ) нет.

На сегодня нормативно-правовыми актами урегулированы информатизация в области здравоохранения и порядок деятельности ЕСОЗ, хранения, защиты персональной и медицинской информации. Однако вопросы урегулирования оценки качества и механизмов мониторинга ЕСОЗ исследованы недостаточно. Недостаточно изученными являются и вопросы использования электронных инструментов для оценки качества работы системы здравоохранения, показателей состояния здоровья населения, экономических показателей деятельности системы здравоохранения. На данном этапе развития электронного здравоохранения внедрен процесс автоматизации, однако есть потребность в развитии механизмов обработки и анализа информации, использование ЕСОЗ как инструмента для систематического и своевременного мониторинга эффективности деятельности отрасли здравоохранения, в частности на уровне объединенной территориальной общины в условиях изменения административно-территориального устройства, децентрализации, формирования и развития территориальных общин. Для общества в целом является существенной информация о состоянии здравоохранения не столько на административной территории, сколько на территории общины. Информатизация и ЕСОЗ может стать важным инструментом для мониторинга системы здравоохранения на территории населенных пунктов, входящих в состав объединенной территориальной общины, которые обслуживают население общины, а не отдельного города, поселка.

Обозначены основные цели и направления деятельности ЕСОЗ как инструмента для мониторинга процесса и результатов деятельности в сфере

здравоохранения объединенной территориальной общины, рассмотрены вопросы законодательного регулирования по информатизации в сфере здравоохранения и деятельности ЕСОЗ, ответственности за нарушения в сфере защиты информации.

Ключевые слова: информатизация, здравоохранение, электронная система здравоохранения, территориальная община, показатели деятельности, механизмы мониторинга, нормативно-правовая база, публичное управление и администрирование.

Formulation of the problem. Today in Ukraine the informatization of the healthcare sector is carried out, the electronic healthcare system is introduced, its development continues, the processes and mechanisms of the activity are improved. A number of normative documents regulating the activity of the electronic healthcare system in modern conditions have been adopted.

It is established that the quality of the electronic healthcare system depends on the set processes, goals, level of funding, professional training of health workers, etc. In addition, the quality of the result is affected by the effectiveness and adequacy of the mechanisms for monitoring and controlling the quality of electronic medical data.

A well-established electronic healthcare system at the level of a united territorial community can be an effective tool for monitoring the quality of medical care to the community, forecasting the needs for certain types of medical care; promptly provide information for decision-making in healthcare management, help assess the effectiveness of the use of funds to provide medical care to the community.

With all the obvious goals and benefits of the healthcare informatization, there are still questions about choosing the optimal mechanisms for monitoring and maintaining the quality of the electronic healthcare system. There is a need to study domestic and foreign experience in this area, assessing the advantages, disadvantages and risks of informatization. The legal aspects of informatization and activity of the electronic healthcare system in Ukraine need additional study and generalization.

Analysis of recent researches and publications. Problems of medical informatization and implementation of the hospital information systems are today in the center of scientific and practical interest of doctors, organizers, lawyers and healthcare managers. O. Baeva, R. Vasylyshyn, M. Holubchikov, Ya. Huliyyev, A. Husev, S. Dyachenko, V. Kachmar, O. Mintser, V. Stepanov, N. Filippova and others made a significant contribution to the development of these issues. At the same time, the legal aspects of informatization of the domestic medicine and potential risks of introduction of the so-called E-health system are insufficiently studied today [1].

We agree with Stepanov V. Yu., who in his study notes that the comprehensive informatization of the healthcare facilities will: provide rapid access to current, most complete and reliable information (this includes all data about the patient, his outpatient card, timely receipt of results analyzes, viewing of X-rays, etc.); improve the quality and availability of services provided by the medical institutions to patients; reduce the cost of working time for patient care and management of the medical institution through full automation of routine operations for filling out paper forms; save doctors and administration from the laborious process of compiling reports; avoid information loss; minimize the “human factor” errors in the formation of the statistical reporting of the institution, etc. [2]. Therefore, the development and improvement of the quality and efficiency of the electronic healthcare system is extremely important.

The purpose of the article is to outline the legal basis for informatization in the field of healthcare and the main existing goals of the electronic healthcare system of the territorial community.

Presentation of the main material. Informatization of the branches of activity of the united territorial communities is a requirement and a need of today. The territorial community has its own healthcare system, which is provided in the context of decentralization and local self-government, depending on the needs of the community residents. The introduction of electronic tools and resources improves the accessibility and manageability of the united community, including the medical sector.

For example, the informatization of the healthcare sector of the Vinnytsia city united territorial community began in 2011. Today, the community has the ability not only to automate the process of accounting for medical data and reporting, but also to use the electronic healthcare system as a tool to monitor the industry as a whole, powerful implementation of informatization allows for systematic monitoring and evaluation of the results obtained in the field of community health. The results of the implementation of measures require a detailed study and clarification of the benefits, as well as a detailed analysis of the regulatory framework.

Ukraine has adopted a number of legal acts regulating the introduction of healthcare informatization and the activities of the EHS (the list is given in Table 1).

Studies and analysis of regulations have shown that the purpose of healthcare is to save lives and human health [6]. Therefore, the implementation and optimization of the healthcare measures that have a positive impact on the quality of medical care of the population is appropriate and extremely important.

In the perspective of this issue, the Constitution of Ukraine and the Ukrainian Strategy for Healthcare System Development, “Fundamentals of European Policy and Strategy for the 21st Century”, approved by the World Health Organization, determine the quality of healthcare and information technology.

Thus, it is undeniable that the development and improvement of the quality and efficiency of the health-

Table 1

**Normative-legal acts regulating informatization in the field of healthcare
and the activities of the EHS**

№ p/p	Name of the normative document	What regulates
1	2	3
1	Constitution of Ukraine	<p>Article 3 of the Constitution of Ukraine states that a person, his life and health, honour and dignity, inviolability and security are recognized in Ukraine as the highest social value. Human rights and freedoms and their guarantees determine the content and direction of the state. The state is accountable to man for its activities. The establishment and protection of the human rights and freedoms is the main duty of the state.</p> <p>Article 49 of the Constitution of Ukraine enshrines the right of everyone to healthcare, medical assistance and medical insurance. Healthcare is provided by the state funding of relevant socio-economic, medical and sanitary and health and preventive programs.</p> <p>The state creates conditions for effective and accessible medical care for all citizens [6].</p>
2	Ukrainian Healthcare System Development Strategy	<p>The Ukrainian Healthcare System Development Strategy is based on three fundamental principles, namely: the focus and interest of the healthcare system should be the person (patient), therefore, the measures of the system should be aimed at meeting the human needs; quality, safety, duration of services, proximity to the community and rapid response to change. The Development Strategy states that the healthcare system is a system that should govern the relationship between the various actors, including managers, service providers, service recipients and researchers, each of whom occupies a specific niche and has clearly defined responsibilities. Thus, the system should be based on trust, dialogue and mutual respect of all participants, and the effectiveness of the whole system will ultimately depend on the quality of their interaction. The Strategy states that there is a need to assess the changes made in the field of healthcare and to develop effective mechanisms for monitoring the results obtained in order to respond in a timely manner and determine directions for action.</p> <p>According to the Development Strategy, the healthcare system should be focused on the expected results (health indicators, financial security of the patients, economic efficiency and satisfaction with services), should guide the decision-making process at all levels; evaluation of the staff work should be based on the effectiveness of the services provided, carried out regularly and constantly improved. This requirement is a significant priority for the creation of a quality and working information base, according to which appropriate decisions are made. The Strategy states that currently available evidence is of poor quality and limited.</p>

1	2	3
		<p>The Development Strategy also states that focusing on the implementation of goals means that it is not enough to have good ideas, but it is important to develop, implement and monitor the implementation of detailed reform plans that clearly define responsibilities, timeframes, reporting mechanisms.</p> <p>The Development Strategy of the healthcare system includes the provision of information in the field of healthcare, transparency and accountability, supervision/emergency response. The healthcare sector must have data on comparative efficiency and effectiveness and must provide accessible, reliable, truthful, timely and transparent information on the state of health of the population and the results of healthcare activities.</p> <p>The Development Strategy states that information is an important part of improving the management. Strengthening the capacity and use of information technology improves the quality of data, exchange, use and dissemination of knowledge and information. This, in turn, enhances transparency, accountability and cost-effectiveness of the service delivery, strengthening the role of the stakeholders. New IT-services strengthen the capacity and expand the capabilities in the planning, implementation and monitoring of healthcare programs. Informatization of healthcare and the creation of an electronic healthcare system (EHS) is becoming a tool for the prompt receipt of quality, reliable, accessible medical information [7].</p>
3	<p>“Fundamentals of European Policy and Strategy for the 21st Century” of the World Health Organization</p>	<p>Identifies the need to increase the level of development of healthcare information systems and services.</p>

care system is extremely important, in today’s reality, the informatization of the healthcare system as a tool for the effective operation of the industry is a requirement and a need.

In 2017 healthcare system reform began in Ukraine. An important tool for reform is the creation of a modern electronic system that will significantly increase the efficiency and transparency of healthcare. The mechanism of introduction and development of informatization, functioning of the elec-

tronic healthcare system is provided in a number of normative-legal acts adopted in the conditions of healthcare reform (the list is given in table 2).

Thus, during 2017–2020 there were a number of systemic changes in the field of healthcare informatization, the Law of Ukraine “On state Financial Guarantees of Medical Care”, a number of bylaws, which regulated the activities of the electronic healthcare system (EHS) and institutions that should implement it - the Ministry of Healthcare

**Normative-legal acts governing informatization in the field of healthcare
and the activities of the EHS in the context of reform**

№ р/р	Name of the normative document	What regulates
1	Law of Ukraine of 19.10.2017 No. 2168-VIII "On the State Financial Guarantees of Medical Service of the Population".	Defines EHS as an information and telecommunication system that automates the accounting of medical services and management of the medical information by creating, posting, publishing and exchanging information, data and documents in electronic form, which includes a central database and electronic medical information systems, between which provide automatic exchange of information, data and documents through an open software interface [9].
2	Resolution of the Cabinet of Ministers of Ukraine "Some Issues of the Electronic Healthcare System" No. 411 of 25.04.2018	The order of functioning of the electronic healthcare system has been established [11].
3	Laws of Ukraine: - "Fundamentals of Ukrainian Legislation on Healthcare"; - "On information"; - "On Electronic Documents and Electronic Document Management"; - "On Electronic Trust Services"; - "On the Unified State Demographic Register and Documents Confirming the Citizenship of Ukraine, Identity or Special Status".	The mechanism of functioning of the electronic healthcare system is provided [12].
4	The procedure for organizing electronic information interaction of the state electronic information resources, approved by the resolution of the Cabinet of Ministers of Ukraine of May 10, 2018 No. 357.	Explains the organization of electronic information interaction [13].

(MOH), the National Health Service of Ukraine (NHSU), the State Enterprise "Electronic Health".

Data in information and telecommunication systems within the EHS should be processed in accordance with the defined, legitimate purpose and taking into account the requirements of the legislation in the field of personal

data protection and technical data protection in information and telecommunication systems.

The protection of the medical information is important. Any electronic system should include a protection mechanism to ensure the safety of documents, ensure secure access, ensure the authenticity of documents,

logging of the user actions. The data exchange system must ensure not only the transfer of information, but also its preservation from theft or modification, as well as be able to recover it quickly.

The need to ensure the protection of information, namely the creation of a comprehensive information security system (CISS) in automated systems is determined primarily by the requirements of regulatory documents (table 3).

Table 3

Normative-legal acts governing the collection and processing of personal data of the patients and the protection of information in the EHS

№ p/p	Name of the normative document	What regulates
1	2	3
1	Order of the Ministry of Healthcare of Ukraine dated February 28, 2020 No. 587.	The procedure for maintaining the Register of medical records, referral records and prescriptions in the electronic healthcare system has been approved. According to this procedure, the processing of personal data in the Register is carried out in order to ensure the implementation of the program of the state guarantees of medical care, as well as to ensure the functioning of the electronic healthcare system. The patient may independently or through his/her legal representative restrict access to the information about himself/herself contained in the Register and the consolidated medical information about the patient through his/her electronic office. The patient also has other rights to protect his/her personal data in accordance with the legislation on personal data and the electronic healthcare system.
2	<ul style="list-style-type: none"> - Law of Ukraine of 19.10.2017 No. 2168-VIII "On State Financial Guarantees of Medical Care of the Population" - Law of Ukraine "On Information Protection in Information and Telecommunication Systems"; - Law of Ukraine "On Personal Data Protection". 	<p>According to Article 11 of the Law on Financial Guarantees, access to patient data contained in the electronic healthcare system is possible only with the consent of such a patient (his legal representative) in writing or in a form that allows to conclude consent [9]. Without consent, access to patient information is possible in the following cases:</p> <ul style="list-style-type: none"> the presence of signs of direct threat to the patient's life; if it is impossible to obtain the consent of such a patient or his legal representatives (until such time as it becomes possible to obtain consent); by court decision [9]. <p>According to Article 8 of the Law of Ukraine "On Information Protection in Information and Telecommunication Systems", information owned by the state or information with limited access, the protection of which is established by law, must be processed in a system using a comprehensive information security system with confirmed compliance. Confirmation of compliance is based on the results of the state examination [14].</p>

1	2	3
3	Resolution of the Cabinet of Ministers of 25.04.2018 No. 411 "Some Issues of the Electronic Healthcare System"	The procedure for collecting and processing personal data of the patient in the EHS is regulated [11].
4	Rules for ensuring information protection in information, telecommunication and information-telecommunication systems, approved by the Resolution of the Cabinet of Ministers of Ukraine of March 29, 2006 No. 373	Paragraph 16 of the Rules states that to ensure the protection of information in the system creates a comprehensive system of information protection, which is designed to protect information from: leakage by technical channels, which include channels of spurious electromagnetic radiation and guidance, acoustic-electric and other channels formed under the influence of physical processes during the operation of information processing facilities, other technical means and communications; unauthorized actions with information, including the use of computer viruses; special influence on the means of information processing, which is carried out by the formation of physical fields and signals and can lead to a violation of its integrity and unauthorized blocking [15].

The Law of Ukraine "On State Financial Guarantees of Medical Care of the Population", the Law of Ukraine "On Information Protection in Information and Telecommunication Systems", the Law of Ukraine "On Personal Data Protection", the Resolution of the Cabinet of Ministers "Some Issues of Electronic Healthcare System" are the main normative-legal acts that regulate the procedure for collecting and processing personal data of the patient in the EHS [12, 9, 11].

Keeping medical records is a mandatory part of a doctor's work. The completeness of the information directly depends on how correctly spelled out all the relevant data is.

From March 01, 2019, the electronic healthcare system of Ukraine has the ability to keep electronic medical records. An electronic medical record is a piece of patient data that is collec-

ted in a healthcare facility and is usually stored in the medical information systems (MIS) used by that facility. The Ministry of Healthcare has introduced electronic medical records and prescriptions in the electronic healthcare system.

Healthcare facilities that collect and store electronic medical records necessary for the provision of medical services are the owners of such data with appropriate rights to process such data and are responsible for their protection and storage.

As of April 1, 2020, all healthcare providers who have signed contracts with the National Healthcare Service of Ukraine for medical care under the Medical Guarantee Program are required to keep electronic medical records.

The procedure for maintaining the Register of medical records, referral re-

cords and prescriptions in the electronic healthcare system was approved by the order of the Ministry of Healthcare of Ukraine dated February 28, 2020 No. 587.

By signing the declaration on the choice of the primary care doctor, the patient (his legal representative) agrees to access the data on him contained in the electronic healthcare system, to such a doctor, as well as other doctors in his direction within, necessary for the provision of medical services by such doctors.

All information or a set of patient information is the patient's personal data (name, date of birth, registration number of the taxpayer's account card, number and series of passport or other identity documents, address and other identifiable data of the patient). According to the wording of the Law of

Ukraine "On Personal Data Protection", personal data - information or a set of information about an individual who is identified or can be specifically identified.

The purpose of implementing a comprehensive information protection system in the EHS is to ensure the confidentiality, integrity and accessibility of information.

Patients' personal data can be entered into the electronic healthcare system by authorized persons appointed by the medical institution. They are subject to medical secrecy legislation and must ensure the protection of such personal data [12].

Responsibility for disclosure of medical data is provided (table 4).

As can be seen from the above data, the regulatory framework for the subject of the study is sufficient, there-

Table 4

Regulatory documents that provide for liability for violations in the field of information protection

№ p/p	Name of the normative document	What regulates
1	Article 145 of the Criminal Code of Ukraine	There is a liability for intentional disclosure of medical secrets to a person to whom it became known in connection with the performance of professional or official duties, if such an act caused serious consequences, so, criminal liability is established [16].
2	Article 182 of the Criminal Code of Ukraine	Criminal liability is provided for violation of privacy (illegal collection, storage, use, destruction, dissemination of confidential personal information or illegal alteration of such information) [16].
3	Code of Ukraine on Administrative Offenses	For non-compliance with the procedure established by law for the protection of personal data, which led to illegal access to them or violation of the patient's rights as a subject of personal data, administrative liability is provided (Article 188-39 "Violation of legislation in the field of personal data" and Article 188-40 "Failure to comply with the legal requirements of officials of the specially authorized central executive body for personal data protection" [17].

fore, conditioned and agreed issues of the EHS, at the same time, in our opinion, it seems necessary to further analyze and improve the mechanisms for monitoring healthcare using electronic tools and capabilities of the electronic healthcare system.

In modern conditions, it is necessary to monitor the state, changes and results of healthcare activities in a timely and high-quality manner, and healthcare reform contributes to the development of the electronic healthcare system (EHS). Obtaining reliable data, effective processing, use, evaluation of the medical data is the basis for drawing conclusions and making administration decisions in the field of healthcare, which aim to improve the quality of medical care to the population of the territorial community.

Conclusions and prospects for further research. Given the data of the literature review and the regulatory framework for the informatization of the healthcare sector, we are aware of the prospects for the rational implementation and effective operation of the electronic healthcare system at the level of the united territorial community.

We are convinced that in modern conditions the informatization of the healthcare sector and the activity of the electronic healthcare system should be considered not only as a tool for automating the process of entering and processing the medical data, but also applied and developed for effective healthcare management at the level of the united territorial community.

The normative-legal framework in this area, as shown above, is sufficient. At the same time, taking into account

the requirement of informatization, the need for high-quality and reliable statistics and widespread implementation of changes in the healthcare sector, we consider it appropriate to assess and analyze existing domestic and foreign practices, tools and mechanisms for monitoring the healthcare sector.

In addition, today there is a need for a detailed study of the results and benefits for the managers, health professionals, patients, received from the informatization of healthcare sector. It is also necessary to identify the useful and problematic aspects of existing mechanisms, upgrade effective models, tools for monitoring, administration and management of the healthcare sector and proposals for the implementation of best practices.

We also consider it necessary to expand the use of healthcare markers and strategic indicators based on the automation of the statistical data processing.

Informatization of the healthcare sector is carried out both in Ukraine and abroad, it has gone from registers to a single electronic medical card. Today we have fragmentary data on the results of the implementation of healthcare monitoring mechanisms both in Ukraine and abroad. That is why domestic and foreign experience in this field will be the subject of our further research.

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