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Стаття надійшла до редакції 18.12.2023;
затверджена до публікації 14.04.2024



UDC 614.8:004.942(497.2)

<https://doi.org/10.26641/2307-0404.2024.2.307703>

R. Vazov¹, 
R. Kanazireva¹, 
T.V. Grynko², 
O.P. Krupskiy^{2*}, 

STRATEGIES FOR HEALTHCARE DISASTER MANAGEMENT IN THE CONTEXT OF TECHNOLOGY INNOVATION: THE CASE OF BULGARIA

Faculty of Economics and Business Administration, Sofia University "St. Kliment Ohridski"¹
Tsarigradsko shose blvd., 125, Block 3, Sofia, 1113, Bulgaria
e-mail: vazov.rado@gmail.com

Oles Honchar Dnipro National University²
Gagarin av., 72, Dnipro, 49000, Ukraine
*e-mail: krupskyy71@gmail.com

Факультет економіки та ділового адміністрування Софійського університету Св. Климент Охридський¹
бульв. Цариградське шосе, 125, Блок 3, Софія, 1113, Болгарія
Дніпровський національний університет ім. Олеса Гончара²
пр. Гагаріна, 72, Дніпро, 49000, Україна

Цитування: Медичні перспективи. 2024. Т. 29, № 2. С. 215-228

Cited: Medicni perspektivi. 2024;29(2):215-228

Key words: healthcare disaster management, e-health, telemedicine, strategies for healthcare

Ключові слова: управління надзвичайними ситуаціями у сфері охорони здоров'я, e-Health, телемедицина, стратегії охорони здоров'я

Abstract. Strategies for Healthcare Disaster Management in the Context of Technology Innovation: the Case of Bulgaria. Vazov R., Kanazireva R., Grynko T.V., Krupskiy O.P. In Bulgaria, integrating technology and innovation is crucial for advancing sustainable healthcare disaster management, enhancing disaster response and recovery, and minimizing long-term environmental and social impacts. The purpose of the study is to assess the impact of modern technological innovations on the effectiveness of disaster management in health care in Bulgaria with a focus on Health Information Systems (HIS), Telemedicine, Telehealth, e-Health, Electronic Health Records, Artificial Intelligence (AI), Public Communication Platforms, and Data Security and Privacy. These innovations, when integrated effectively, can significantly strengthen Bulgaria's preparedness and response capabilities, improving efficiency and reducing the environmental footprint of disaster interventions. Collaboration with technology experts, research institutions, and international organizations is essential for successful implementation. The research aims to assess how these technologies can enhance disaster management efficacy, adopting a methodical approach using Systematic Literature Reviews (SLRs). Systematic Literature Reviews (SLRs) utilize precise criteria for research selection and evaluation to reduce bias, systematically compiling and analyzing data from various studies to offer evidence-based insights. They are crucial for uncovering research gaps, indicating areas needing further exploration. Findings highlight the transformative potential

of technology integration in streamlining communication, data management, and operational efficiency. The study underscores the urgent need for an integrated approach and a culture of innovation within the healthcare sector, emphasizing ongoing assessment and adaptation of technology-based strategies. While acknowledging limitations and calling for further research, the study provides valuable insights into Bulgaria's healthcare disaster management strategies and sets the stage for future investigations to refine and expand upon these strategies. It advocates for a strategic framework guiding the efficient integration of technology into disaster management, aiming for resilient and patient-centric healthcare systems.

Реферат. Стратегії управління надзвичайними ситуаціями у сфері охорони здоров'я в контексті технологічних інновацій: приклад Болгарії. Вазов Р.Г., Каназірєва Р., Гринько Т.В., Крупський О.П. У Болгарії інтеграція технологій та інновацій має вирішальне значення для розвитку сталого управління надзвичайними ситуаціями у сфері охорони здоров'я, покращення реагування на надзвичайні ситуації та відновлення, а також мінімізації довгострокових екологічних і соціальних наслідків. Мета дослідження – оцінити вплив сучасних технологічних інновацій на ефективність управління надзвичайними ситуаціями в охороні здоров'я Болгарії з акцентом на медичні інформаційні системи (МІС), телемедицину, телеохорону здоров'я, електронну охорону здоров'я, електронні медичні картки, штучний інтелект, платформи громадського зв'язку, а також безпеку і конфіденційність даних. Ці інновації, за умови їх ефективної інтеграції, можуть значно посилити готовність і спроможність Болгарії до реагування, підвищити ефективність і зменшити вплив на навколишнє середовище в разі надзвичайних ситуацій. Співпраця з технологічними експертами, науково-дослідними установами та міжнародними організаціями має важливе значення для успішної імплементації. Дослідження має на меті оцінити, як ці технології можуть підвищити ефективність управління надзвичайними ситуаціями, застосовуючи методичний підхід з використанням систематичних оглядів літератури. Систематичні огляди літератури використовують точні критерії відбору та оцінки досліджень для зменшення упередженості, систематично збираючи та аналізуючи дані різних досліджень, щоб запропонувати науково обґрунтовані висновки. Вони мають вирішальне значення для виявлення прогалів у дослідженнях, вказуючи на сфери, які потребують подальшого вивчення. Результати дослідження демонструють трансформаційний потенціал інтеграції технологій для оптимізації комунікації, управління даними та операційної ефективності. У дослідженні підкреслено нагальну потребу в комплексному підході та культурі інновацій у секторі охорони здоров'я, наголошуючи на постійній оцінці та адаптації стратегій, заснованих на технологіях. Визнаючи обмеження і закликаючи до подальших досліджень, у роботі надано цінну інформацію про болгарські стратегії управління надзвичайними ситуаціями у сфері охорони здоров'я і створено основу для майбутніх досліджень, спрямованих на уточнення і розширення цих стратегій. Також наголошено на необхідності створення стратегічних рамок для ефективної інтеграції технологій в управління катастрофами, спрямованих на створення стійких і орієнтованих на пацієнта систем охорони здоров'я.

In an era where technological innovation plays a pivotal role in shaping healthcare outcomes [5, 23], the importance of integrating advanced technologies into healthcare disaster management cannot be overstated [1, 29]. The use of digital health technologies in disaster management is a promising area, but more research is needed to understand their resilience and effectiveness [26]. The impact of digital transformation on national disaster management systems is profound and requires a new set of disaster-context determinants [2]. Interdisciplinary education and training, such as the EmTASK Course, are crucial for disaster risk reduction [33]. Hospital disaster risk management can be improved through a range of strategies, including organizational-managerial, preventive, preparedness, response, and recovery strategies [4]. Researchers have proposed a number of strategies for healthcare disaster management in the context of technological innovation. Hillol Bala with colleagues proposes to develop an integrated IT architecture, universal data warehouse, web-based disaster communication and coordination, an IT-enabled disaster support system, and standardized IT-

enabled disaster response processes [6]. Madanian and Parry presents a framework that integrates the Internet of Things, cloud computing, and big data to provide accurate and efficient medical care during disaster phases [28]. Lokmic-Tomkins with colleagues emphasizes the need for climate-resilient digital health technologies [26], and Quiram with colleagues addresses the use of information technology and data systems in disaster preparedness for health care and the general public [32]. Together, these strategies emphasize the potential of technology to improve disaster response and health care delivery.

This article attempts to *answer the question*: How technology innovations, such as e-Health, Telemedicine, Artificial Intelligence, and data security measures, be effectively integrated into healthcare disaster management strategies to enhance the resilience and efficiency of the healthcare system in Bulgaria, while ensuring equitable access, ethical considerations, and environmental sustainability? Thus, the *purpose of this study* is to evaluate the impact of current technology innovation strategies on improving emergency management effectiveness to

optimize communication, data management and operational efficiency through an integrated approach to evaluate and adapt strategies based on innovative technologies in the health sector.

MATERIALS AND METHODS OF RESEARCH

Systematic Literature Reviews (SLRs) were chosen in this academic research for several key reasons. SLRs provide a thorough and comprehensive overview of existing research on a particular topic. This is essential for understanding the full scope of what has been studied, the findings of different researchers, and the gaps in knowledge that still exist. Unlike traditional literature reviews, SLRs follow a rigorous and predefined methodology. This includes clearly defined criteria for selecting and evaluating research, which helps minimize bias in the review process. By systematically gathering and analyzing data from a range of studies, SLRs provide evidence-based insights. SLRs are instrumental in identifying gaps in existing research. By synthesizing what is already known, they highlight areas where further investigation is needed. In many fields, SLRs are used to help policymakers and practitioners make well-informed decisions. The structured approach of SLRs enhances the reproducibility and transparency of the research process. By documenting the search strategy, inclusion and exclusion criteria, and methods of analysis, SLRs allow other researchers to understand and replicate the review process. For researchers and students, conducting an SLR is a valuable exercise in critical thinking, research synthesis, and academic writing. It helps in developing skills that are essential for academic and professional growth. In summary, the use of Systematic Literature Reviews is crucial for providing a clear, unbiased, and comprehensive understanding of existing research, which is essential for advancing knowledge, informing policy, and guiding future research directions.

This methodology is widely used across various academic disciplines, especially in the fields of health sciences, social sciences, and education. Here is a detailed description of the SLR process that we used in this article. The first step involves clearly defining the research questions the SLR aims to address. These questions are specific, measurable, attainable, relevant, and time-bound (SMART). A protocol is established which outlines the methods that will be used throughout the review. This includes inclusion and exclusion criteria for studies, databases, and other sources searched keywords for the search, and methods for data extraction and analysis. Searching for Literature involves a comprehensive and systematic search of relevant databases and sources to gather as much pertinent literature as possible (The depth of literary search in our study was 30 years).

Common databases include PubMed, Scopus, Web of Science, and others, depending on the field of study. The following terms were used in databases searches: "health system", "health disaster management", "e-health", "telemedicine", and "strategies for health". For example, in the Scopus database for the period 1993-2023, records of 118,840 documents were found. Moreover, if in 1993 there were only 400 publications that dealt with this topic, in 2023 there are 12037 such publications indexed. Further we excluded from the search publications that were not open access, published in books, book series or conferences – the number of indexed documents amounted to 59625 articles. In the next step, we excluded publications that were not published in Europe. We considered this important because the frequency and characteristics of health emergencies differ qualitatively between continents [13]. Over a period of 0 years, 10560 papers were published in Europe that met these restrictions, with 87 articles published in Bulgaria. After we excluded the articles that were clearly technical in nature and this allowed us to limit the sample to 8002 documents, with only 507 articles dealing with decision making and emergency management in public health. Next, we analyzed titles, abstracts, and full texts to determine relevance to our research task. A total of 703 studies (8.79%) were selected to analyze the major themes, patterns, and finding that were relevant to our research question. At the final stage, we compiled the SLR, followed by a discussion of the findings and their placement in the context of the existing literature and research questions. This procedure was also performed for articles indexed in PubMed and Web of Science databases, but we found significant overlap between the findings. Therefore, we do not present the results of literature selection for analysis from PubMed and Web of Science databases in this article. The algorithm is repeated in full, and the results obtained were similar.

RESULTS AND DISCUSSION

1. The role of technological innovations in Healthcare Disaster Management Strategies

Strategies for healthcare disaster management are pivotal in ensuring the resilience and adaptability of health systems during unexpected events [7, 20]. When it comes that technology innovation, these strategies can be particularly impactful, offering solutions that can rapidly adapt that changing circumstances and demands [8]. When tailoring healthcare disaster management strategies with technological innovations specifically for Bulgaria, it is crucial that consider the nation's specific challenges, resources, infrastructure, cultural nuances, and regional threats.

A key element of these strategies is eHealth, based on which processes can be managed more adequately based on real data, quantitative and qualitative indicators. Electronic data is a reliable means of performing objective analyses, and this, in turn, will allow proper upgrading, planning and refinement of the system in a way that satisfies patients, professionals and society in general [41].

The term "electronic health care" came into use at the end of the 90s of the 20th century. The development of information technologies allows them to enter the field of health care.

Gunther Eysenbach [18] defines e-Health as "a field at the intersection of medical informatics, public health, and business, concerned with health care and information provided or distributed via the Internet and related network technologies. By this term, the author understands not only technical development, but also a state of mind, a way of thinking, an attitude, and a solution for networked, global thinking to improve health care at the local, regional, and global level through the use of information and communication technologies.

World Health Assembly adopted resolution WHA58.28 [40] defines eHealth as "the cost-effective and secure use of information and communication technologies in support of health and health-related fields". The resolution calls to "mobilize" multisectoral collaboration for determining evidence-based e-health standards and norms, that evaluate e-health activities, and that share the knowledge of cost-effective models, thus ensuring quality, safety and ethical standards and respect for the principles of confidentiality of information, privacy, equity and equality".

Eysenbach [18] emphasized the integration of medicine, informatics, and business, whereas the World Health Assembly [40] places a strong emphasis on economic efficiency and safety. The 5-year gap between these definitions suggests a transition from purely technical challenges to the realms of safety and economic viability in implementing this idea. This temporal evolution indicates the dynamic nature of issues arising from the convergence of healthcare, informatics, and business. Additionally, it underscores the importance of adopting a holistic approach that addresses both technical and socio-economic aspects for successful integration.

World experience [3, 19] confirms that through high-tech information solutions applied in healthcare, optimal use of resources – financial, material and human – can be achieved in the healthcare system and reduction of inefficient costs. Van Gemert-Pijnen [36] claims that: "e-health development must be holistic, evidence-based, and people-centered; it must take into account how people live within their own

environments and respond that stakeholders' needs. With such solutions, greater transparency is created - it is possible to follow the activity as much as possible and to limit redundant procedures". Along with this, the efficiency and quality of the provided health services increases, the patients' awareness of their treatment activities increases [10, 27]. It is also of particular importance to improve the relations of those employed in the health sector, their mutual awareness when conducting the treatment and its results [9].

For these reasons, it is considered that electronic health care is an essential tool for ensuring the effective functioning of the health system [31]. A key measure is integration and connectivity in the field of health care, through the construction of a national health information system and ensuring citizens' access to the system through an electronic identifier. Ongoing adjustments in service management are required to enhance its effectiveness and alignment [11]. The unified healthcare information system is the basis on which the development of healthcare crisis management will stand. E-health with its main components – for example, e-health record, e-prescription, e-referral, telemedicine, etc. are key to the implementation of a sustainable AI-based health crisis management system. Wootton et al. examine that "improved collaboration between networks could help attenuate the lack of resources and improve sustainability" in a study of the health-related uses of information and communication technologies (ICT) in low - and middle-income countries [39].

According to Vinarova & Mihova, electronic health care is an intensively developing field in which medical informatics, public health care, the provision of health services and information through the use of modern information and communication technologies interact [37]. According to the modern understanding, electronic health care is a complex of measures based on an organizational, technological, and legal framework and covering the whole aspect of functioning of the health system [15]. In this sense, eHealth encompasses not only technological development but also a global thinking approach to improve health services at local, regional, and global levels.

The basic principles on which Strategies are based for Healthcare Disaster Management in the context of Technology Innovation:

- Efficiency – one of the main goals is to increase the quality and volume of the services offered in healthcare;
- Equal access – enabling all citizens to access medical information via the Internet. Promoting a new type of relationship between citizens and health institutions, where decisions are made with the participation of both parties;

- Adequate training of health personnel [35] who use the information from the information system;
- Interoperability of information systems in the various spheres and activities in health care [42];
- Equal quality of health services, regardless of the territorial location of the medical facility and social status of the patient [22];
- Inspires, motivates, provides emotional comfort and a sense of security and, as a result, employee commitment; creates and implements a model of behaviour adopted in organizations [24];
- Ethics – new forms of relationship between patient and doctor are created, poses new challenges and ethical problems in relation to online practices, informed consent, confidentiality, etc.

Electronic healthcare has been identified as one of the main priorities in European development plans [17]. Initiated by the European Commission, a European Health Data Space is being established in 2022 to promote access to health data for research and innovation on new preventive strategies, as well as on disease diagnosis and treatment to improve health outcomes, while ensuring that citizens have control over their own personal data. The European Health Data Space (EHDS) aims to make the most of the potential of digital health to deliver high-quality healthcare and reduce inequalities [27]. The improved collection and use of safe health data with security could improve monitoring and prevention systems, as well as improve people's ability to better understand and engage with their own well-being through a range of applications and tools.

2. Assessment of Current Technological Infrastructure in Bulgaria

2.1. National Health Information System in Bulgaria

The National Health Information System (NHIS) is an integrated information system that collects, processes and stores information on the health of the population in Bulgaria. It was established by the Health Act and is maintained by the Ministry of Health (MoH). NHIS includes data on electronic health records of all citizens, as well as information obtained from registers, databases and systems maintained by the Ministry of Health, its subordinate budget managers, medical facilities, the National Health Insurance Fund (NHIF), insurance companies, etc.

From 2020 until now, a number of modules and functionalities of NHIS have been developed and implemented, including:

- Health Information Portal (HIP) – provides a single-entry point for accessing NHIS. Access to electronic health records, applicable standards and specifications for data exchange and ensuring interoperability, and up-to-date information on the

development of the system's technical capabilities and functionalities are provided through the HIP.

- A unified environment for the exchange of medical data, health information standards and nomenclature – is the core of the NHIS and through it the integration of the system with multiple software, such as medical software, NHIF, National Council on prices and reimbursement of medicinal products and other key institutions in the healthcare environment, is carried out. To achieve interoperability of information systems in health care, national nomenclatures have been developed and introduced, which are mandatory for use in the health care sector in relation to medical information and its exchange in real time. In addition to nomenclatures, health information standards have also been introduced, through which the exchange of medical information is carried out.

- Electronic medical file (EMF)/Electronic health record (EHR) – a key module of the NHIS, which ensures the maintenance of all records relevant to the health of citizens, by collecting and processing all essential information related to the health of citizens, regardless of the type of medical facility and the source of funding. The purpose of the EMF/EHR is to provide citizens and medical professionals with health information that is relevant in the process of diagnosis, determining a therapeutic plan, as well as providing rehabilitation. The module stores information about the origin of the data, at the record level, as well as a complete history of actions.

- Electronic prescription and electronic referral modules – provide standardized services for prescribing and dispensing medicinal products, medical devices and dietary foods for special medical purposes and issuing and fulfilling medical referrals. Information from prescribed and issued electronic prescriptions and issued and completed electronic referrals is stored in the citizens' health records.

- Subsystem for the collection of information from hospitals (SCIH) – collects data from medical facilities for inpatient and out-of-hospital care regarding hospitalization/ dishospitalization events of patients. The purpose of SCIH is to cover the entire activity of medical facilities for hospital care, including the creation of a database containing medical-statistical and financial data for hospitalized patients and for hospital outpatients.

- System for monitoring and control in health care (DWH – Data warehouse) – provides an opportunity for analysis and inquiries based on the available modules and data in the NHIS, with which the process of making management decisions can be supported. Based on the data obtained from the performed medical activities, the system allows a set of dynamic and static inquiries.

The purpose of the NHIS is to provide citizens and medical professionals with access to up-to-date and reliable health information, which will contribute to the improvement of health care in Bulgaria.

2.2. Integrated information system of the NHIF

The integrated information system (IIS) of the National Health Insurance Fund (NHIF) is designed to support the implementation of its functions and work processes. It contains information on all participants in the health insurance system in Bulgaria, including medical facilities, pharmaceutical companies and control bodies.

IIS consists of the following systems:

- The integrated informative system (IIS) of the national health insurance fund (NHIF) stores all the information about the health insurance system and is intended for automation on working one's processes related to receipt and payment on medical services on health insurance persons in Bulgaria. With stems from the following basic modules: Electronic reports – module for collection, processing and storage on the electronic ones reports on the contractual partners of the NHIF. Preliminary and subsequent control – module for doing preliminary and subsequent checks on performed medical services. The electronic ones reports everything submitted from the contractual partners of the NHIF, including performers on medical assistance, laboratories, pharmacies, etc. The reports everything sign with qualified electronic signature (QES) and send in xml format remote in the custom informative system (CIS) of the NHIF. The reports everything download in the corresponding regional health insurance cash register (RHICR) and se import into IIS. After the closing of the reporting period, the information everything transfers automatically in the PIS.

- The personalized information system (PIS) of the National Health Insurance Fund (NHIF) is designed to provide access to health information to health insured persons in Bulgaria. PIS is accessible through digital certificates or unique access code (UAC). The PIS contains information from the Integrated Information System (IIS) of the NHIF, the HOSP_CPW system, which is used to manage contracts with medical facilities, the online reported activities of GPs, health facilities, laboratories, and pharmacies. The information in the PIS is stored centrally in the NHIF and is used to create a patient file. The patient file includes personal information about the patient, including name, address, telephone number and health fund number, information about the patient's previous registrations with a general practitioner, information about the activities performed and reported by the general practitioner, specialist doctors, hospitals, laboratories, pharmacies,

and doctors of dentistry. PIS has implemented web services for data transmission and communication between the information system of the NHIF and the information systems of the various medical care contractors. This allows the PIS to receive information about the activities performed by the medical care providers in real time and is of key importance for the development of healthcare disaster management systems. New features are planned to be added, such as the ability to share information between different medical professionals caring for the same patient.

- HOSP_CPW – system for managing contracts with medical institutions. It is intended for collecting and processing information about hospitalizations and discharges in medical facilities in Bulgaria. The system is centralized and works in two modes. Data transmission mode - in this mode, medical facilities daily submit data about hospitalized patients in XML format. The data is submitted through the PIS system of the National Health Insurance Fund (NHIF). Data processing mode - in this mode, the NHIF processes data from medical institutions and checks their validity. The information collected by HOSP_CPW includes the following, patient details including name, address, telephone number and health fund number, details of the medical facility where the patient is hospitalized, details of the patient's illness or injury, details of the medical procedures performed. HOSP_CPW is an important part of the health insurance system in Bulgaria. It provides the NHIF with information necessary for payment of the medical services provided in the medical facilities. HOSP_CPW is connected to other information systems of the NHIF, including IIS, PIS and civil registration and administrative services. This allows the HOSP_CPW to obtain information about the health status of patients and the medical procedures performed from other sources. HOSP_CPW is under development. New features are planned to be added in the future, such as the ability to track patients' treatment progress.

- Health portal of the NHIF – a portal that provides information about the health insurance system to citizens and medical professionals [30].

- Registration system of hospitalization and dehospitalization events – a system for collecting data on hospitalizations and dehospitalizations in medical facilities.

- Specialized information system for business analysis (SISBA) – a system for analyzing data from IIS.

- IIS is an important part of the health insurance system in Bulgaria. It provides the NHIF with the necessary data and tools for effective work and control.

IIS is an integrated system, which means that its various modules work in sync and exchange data with each other. This allows the NHIF to obtain a comprehensive picture of the health insurance system. The IIS has been developed in accordance with national framework agreements, the Health Insurance Act, and other regulatory frameworks.

The other systems included in the national health information system are:

- Information System for Registration and Tracking of Received Calls (ISRTRC)
- The National Registry of Invasive Cardiology (NRIC)
- National Information System to Combat COVID-19
- The electronic system for the purchase of medicinal products for the needs of medical institutions in the Republic of Bulgaria;
- The Specialized Electronic System for the Tracking and Analysis of Medicinal Products;
- Information systems for follow-up and treatment of patients with tuberculosis, patients with HIV and patients with viral hepatitis;
- Information system for collecting and analyzing data on the incidence of influenza and acute respiratory infections in Bulgaria;
- Information system for collecting and analyzing data on the incidence of measles, mumps and rubella in Bulgaria;
- Information system for surveillance of acute flaccid paralysis in Bulgaria;
- Electronic system Medical Expertise;
- National information desk (HELPDESK) for biocides, on the basis of Art. 16 of the Law on Protection from the Harmful Effects of Chemical Substances and Mixtures, resp. Art. 81, par. 2 of Regulation (EU) No. 528/2012;
- The system for control activity and inspection of objects and products;
- Electronic platform for maintaining the National Pharmacy Card;
- Unified information system for monitoring personnel in health care.

2.3. Basic problems

In Bulgaria, there are a number of registries and databases in the field of healthcare, which are managed by public and private entities. The regulation of these registers and databases is scattered in various legal acts, which leads to legal uncertainty, restrictions on access to and exchange of information and a lack of sufficient guarantees for citizens' data.

The main public administrators of registers and databases in the health sector are the Ministry of Health (MoH), the National Health Insurance Fund

(NHIF), the National Center for Public Health and Analyzes, the Regional Health Inspections, the Medicines Executive Agency, and Executive Agency "Medical Supervision". Some registries and databases are managed by medical facilities and other private entities.

In relation to some of the registers and databases, a requirement has been introduced to maintain interoperability and an automated interface providing the information in a machine-readable format through which it can be used by other information systems. For other registers and databases, there are no legally established requirements regarding the form, content, and security of the information.

In some cases, the exchange of information between medical care providers and public authorities is regulated, but in other cases there is a lack of legally defined channels, standards, and technical requirements.

The Health Insurance Act [25] stipulates that the NHIF store data on the insured persons for a period of 5 years after the end of their health insurance and data on the contractors – for a period of 5 years after the expiration of the relevant agreement with the NHIF. The Health Insurance Act lists six specific purposes for which data related to the health-insured person may be used.

In addition to the above, administrative bodies, medical facilities and other organizations with public functions are covered by the Cyber Security Act (CSA) and should comply with its requirements. Scattered and unsystematized regulation that leads to legal uncertainty, restrictions on access to and exchange of information and lack of sufficient guarantees for citizens' data. Absence of legally established requirements regarding the form, content, security of information for some registers and databases. Lack of legally defined channels, standards, and technical requirements for information exchange between medical care providers and public authorities. Limited scope of permissible purposes for data processing for health insured persons.

Citizens' control over their own data is a fundamental element of the eHealth system. In Bulgaria, there are a number of regulations that guarantee this right, but they are scattered in various legal acts and are not fully aligned with the General Regulation for the Protection of Personal Data (GDPR).

According to the HL [21], citizens have the right to access their health information, which is stored by medical institutions. In addition, the citizen has the right to receive a copy of the health information, which may be in electronic form [12]. However, the Law on Health Insurance does not specify the conditions under which access, and provision of

copies may be carried out. The possibility for patients to manage their own data is also not regulated.

According to the Law on Health Insurance, insured persons can receive information about medical and dental services used by the NHIF in the last five years. This happens according to the Internal Rules for issuing a unique access code to the personalized information system of the NHIF, adopted by the NHIF. In practice, electronic access to this information can be done with the help of a digital certificate (qualified electronic signature), a unique access code issued by the NHIF, or an individual identification code issued by the National Revenue Agency.

It is necessary to envisage mechanisms to ensure real and effective control of citizens over their own personal data by creating prerequisites for the exercise of their rights, including the use of such data for research and statistical purposes. In addition, the security of citizens' personal data should be guaranteed during the exchange of information between participants in the electronic health care system.

The multi-layered structure and lack of a systematic approach when creating the legal framework leads to gaps and contradictory interpretations when applying the existing rules. Lack of a comprehensive and well-structured legislative approach to the creation of an appropriate and effective legislative environment in the field of e-health leads to insufficient definition and regulation of e-health as a priority area.

There are a number of problems that hinder the development of e-health care (Telemedicine, Electronic prescription, Electronic health record, Electronic health card) in the country. The general regulation of e-governance does not guarantee the right of access to health care in an electronic environment, especially for cross-border health care. For example, according to the Law on Electronic Identification, only Bulgarian citizens and foreigners who have a single civil number, respectively the personal number of a foreigner, have the right to an electronic identifier. Pursuant to the Electronic Government Act, citizens of an EU member state are identified by their national electronic identifier in accordance with the act under Art. 12, paragraph 8 of Regulation (EU) No. 910/2014 [16].

Another important problem is that no appropriate regulatory framework has been created for telemedicine. Telemedicine has the potential to improve the quality of medical care, provide adequate follow-up of patients outside hospital and outpatient settings, reduce hospital stays and treatment costs. But at the moment, the scope of medical assistance under the mandatory health insurance does not explicitly include the various services that could fall within the scope of telemedicine. In addition, there are no

established rules, order, and standards for the provision of health care at a distance to ensure access to and quality of services. Accordingly, there is a lack of adequate regulations for the implementation of state control over medical services provided at a distance, and for the professional responsibility of the persons engaged in the provision of such services.

The third problem is that there are shortcomings in the regulatory framework for the protection of health information. The Health Act contains special provisions in relation to the protection of health information, including explicit grounds on which its disclosure is possible. However, some of these grounds (e.g., for the needs of the Ministry of Health, NHIF, NSI) are formulated in general terms and, depending on the specific situation, may lead to problems.

It is necessary to take measures to improve the regulatory framework in the field of electronic health care in Bulgaria. For example, expanding the scope of the right to an electronic identifier to include all citizens of Bulgaria, regardless of their nationality. Creation of appropriate regulatory framework for telemedicine to guarantee access to and quality of services, as well as to ensure adequate protection of patients. Clarifying the grounds for disclosure of health information in the Health Act, ensuring that these grounds are in line with the requirements of Regulation (EU) 2016/679 (GDPR). There is a need to create a national health data registry to ensure more efficient management and access to health information. Regulations to address issues related to the use of artificial intelligence in healthcare.

The e-prescription is a set of services allowing the prescription and dispensing of medicinal products, medical devices, and dietetic foods for special medical purposes electronically by a medical professional and collecting data for subsequent processing. It covers medicines paid in full or in part by the NHIF. An electronic prescription is a digital version of the standard paper prescription. Electronic prescriptions are sent over the Internet at the moment they are written, and in this way the entire process of purchasing the drug is facilitated, and the possibility of making mistakes and deformations in this activity is significantly reduced.

Electronic Prescription aims to build a centralized online system that covers the activities of prescribing and dispensing medicinal products, medical devices, and foods for special medical purposes. This includes the registration, execution, and management of e-prescriptions.

An electronic prescription creates conditions: to improve the control over prescribing and dispensing medicinal products, medical devices and foods for special medical purposes; make it easier for patients

and doctors – if a mistake is made when prescribing the drugs, it can be corrected immediately without having to visit the doctor again; receiving drugs takes place in real time; allows to analyze the needs, problems and benefits of its introduction into the NHIF system, to exercise effective control over incoming information, the behavior of doctors and patients, the expediency of prescribing drugs.

The electronic health record is part of the NHIF's information system. It aims to make it easier for patients to access their health records and offers new electronic services – notification of health services and due examinations via text and email, online switching of GPs and more. The goal is to provide citizens and medical professionals with summarized medical information that is relevant in the process of diagnosis, determination of a therapeutic plan, as well as in the conduct of treatment and rehabilitation.

In the electronic medical file, medical data for each patient is recorded and stored – general health information, data from examinations, treatments carried out, medical interventions, outpatient sheets, laboratory tests, directions and prescriptions issued, territorial expert medical commission decisions, data on blood donations, including and of blood plasma, and now also a certificate of vaccination against Covid-19, etc. Each patient has access to his file through the health information portal of the NHIS – through a qualified electronic signature. Typically, data from patients' electronic health records are automatically transferred to specialized medical registries based on certain criteria.

The medical file includes all medical events for a person, regardless of whether they are initiated by a health fund, national programs, or private health insurance. Simultaneously with the creation of an electronic health file, the system also generates a unique personal identification code (PIC) of the person in a format that prevents the extraction of personal data from it. The personal identification code is immediately communicated to the person by electronic message in the manner specified by him.

The benefits of implementing the electronic file are:

- for the patient – facilitating access to medical information for contractual partners and access to the patient's health information in real time;
- for NHIF – control of spent public funds, real assessment of the value of medical services, effective expenditure of funds and timely planning and forecasting of the budget;
- for doctors – accurate, rich, and timely information for making an informed decision. For the file to start working in full volume and collecting electronic information, the other modules of the health

information system, such as referrals and prescriptions, must also work in full.

It is of particular importance to anticipate what access to the health record will be. Since the electronic health record contains sensitive information, there is a need to use different storage systems to prevent unregulated access and abuse. In addition, it is regulated under what conditions and who will have access to it in order to protect the patient's information, its storage, transmission to different medical professionals when necessary and to have visible benefits for the patient from its electronic storage. In all cases, however, access must be secure and there must be a very clear possibility of absolutely establishing that the one currently accessing the system is the person who is authorized to do so: an authorized physician or the patient himself.

As part of the general information system, the presence of the patient file allows to raise the level of service to a qualitatively new level, ensuring the exchange and availability of data for the patient regardless of where he is located. Through it, in addition to convenience and cost savings, the various medical service providers achieve continuity in the follow-up of the patient.

The electronic health card is an element of the complex information and telematics infrastructure in the health system. The degree of its use can be an indicator of the level of e-healthcare in the country. The presence of an e-card for the management of the health system means a very well-synchronized mechanism of interaction in technical and organizational terms between hospitals, general practitioners, health funds, pharmacies. The introduction of such activities presupposes the presence and maintenance of a serious telecommunications infrastructure – reliable applications for communications in networks and distributed systems, working specialized health and pharmacy systems at all levels, established standards and registers, a legal framework, and transparent financial calculations for the various activities.

Usually, the electronic health card is a plastic card with a microprocessor (chip) on which the patient's health data is recorded. Any health insured person can use this card to be served by the personal doctor, enter a hospital for treatment, go to the dentist and buy medicines at the pharmacy without carrying any other documents with them, such as referrals, prescriptions, research results and the like. In practice, the electronic health card is the "health passport" of the insured person, which contains complete information about the medical condition of the insured person, past illnesses, presence of allergies, blood type, contacts of relatives, etc.

The electronic health record serves for real-time control over the consumption of a given type of

medical service, which can limit potential abuses to a certain extent. In addition, the electronic health record guarantees access to the patient's own medical record at any time, thereby improving the control over the providers of medical care.

In 2021, a system for electronic prescriptions was introduced in Bulgaria as a means of reducing unnecessary personal contact with medical facilities, after which a system for electronic referrals and electronic health records was introduced later in the year. Electronic health records and medical data for each patient are recorded and stored in the system, incl. about examinations, treatment, prescription forms, laboratory tests, referrals.

The implementation of electronic health care creates an opportunity to carry out online more administrative and health services in the sector, provides real and fast access to the patient to information about his own health, improves the interconnections between the individual levels of the system and along the chain of the various providers of medical services. As a final result, the implementation of the e-health project allows to improve the quality of medical services and increase the efficiency and control over the spending of public funds for health care.

The unification and systematization of the regulation of registers and databases in a single normative act will lead to greater clarity and efficiency in the application of legislation in this area. Setting specific requirements regarding the form, content, security of information for all registers and databases will ensure that the information is reliable and secure. Regulating the exchange of information between healthcare providers and public authorities will facilitate the provision of quality healthcare and public health monitoring. Expanding the permissible purposes of data processing for health insured persons will allow the data to be used for better medical decisions. Setting specific conditions for access and providing copies of health information to citizens will ensure that citizens have access to their health information and can use it to make informed decisions about their health. Regulating the ability of patients to self-manage their own data, including by allowing them to choose which third parties have access to their information, will give patients more control over their personal information. The implementation of security measures to protect citizens' personal data in the exchange of information between participants in the electronic health care system will ensure that citizens' personal data are protected from unauthorized access and use. The implementation of these recommendations will contribute to the creation of a more effective and modern national legal framework in the field of health care.

One solution is to create a special law or ordinance to govern this area. This law or regulation could define the basic concepts and principles related to Healthcare Disaster Management, as well as to establish rules for the provision of health and administrative services through electronic means. In order to further develop the regulatory framework of the NIS, a new regulation can be adopted that will regulate in more detail the structure, functions and rules for the functioning of the system. This regulation could introduce new requirements for security and data protection, as well as expand access to information from the NHIS for citizens and other interested parties.

In order to protect citizens' rights to their own data, a new regulation could be adopted to regulate the rules for citizens' access to and control over their own health data. This regulation could require entities that collect and process health data to provide citizens with access to their information and give them the ability to control how that information is used.

In order to regulate the secondary use of information and data for research, statistical and other purposes, a new regulation can be adopted to regulate this area. This regulation could determine which entities are competent to authorize the secondary use of health data and establish rules for such use.

2.4. What is expected from e-Health?

The introduction of electronic health care allows more complete medical information to be provided to health professionals. This will lead to full treatment and, accordingly, to a shorter period of treatment, as well as to a higher working capacity of people of active working age.

An opportunity is created for effective communication between health professionals – increasing their qualifications and more effective preventive and curative activity. The population's access to health information and transaction transparency [38] improves, which leads to an increase in its medical culture, contributes to the achievement of the effect of preventive medicine, and hence – a reduction in the risk of morbidity.

In the era of digitization, patients have become active participants in the healthcare process, serving as controllers of transparency within the health system. As individuals seeking medical care, we now have the ability to observe and track various aspects of our healthcare journey. This includes monitoring prescribed medications, assigned examinations, and conducted tests. Additionally, the digitalization of health records eliminates the need to navigate from one specialist to another, as our comprehensive medical history is easily accessible. All this allows forming a scientific and methodological basis for effective

design, creation, management and development of multi-level systems with human participation [34].

In this environment, the attention of the participants in the healthcare system – medical staff and patients – is focused on the quality of performance of the main activities related to medical care, and the performance of the activities related to the provision of information activity is provided to the relevant specialists and IT the companies.

In addition, the construction of an integrated information environment ensures and guarantees an interoperable automated exchange of medical and other information and data between the participants at all levels of the system – personal physicians, specialized medical care, and hospital care.

According to the Strategy, the full introduction of ICT in all types of health services will make it possible to build a National Health Information System (NHIS) [14]. The following will have the right to use the services of the NHIS free of charge: citizens (in an established manner), medical and health facilities, NHIF, insurers and insurers, and others for which it is provided for in a normative act.

The construction of the NHIS covers:

- Development and implementation of a legal framework regulating electronic health care;
- Introduction of national nomenclatures and health information standards;
- Centralized storage, management, and exchange of medical information in real time between all participants in the healthcare sector:
 - Electronic medical file/Electronic health record;
 - Electronic prescription and Electronic referral;
 - Integrated public and official registers;
 - Construction of a monitoring and control system in healthcare;
 - Building a subsystem for collecting information from hospitals;
 - Single sign-on for citizens is authentication.
 - Construction of a health information portal for citizens' access to medical information;
 - Provision of electronic administrative services in the sector.

The goal is to create a unified information platform in the healthcare sector, guided by the following principles. Every participant in the sector contributes information about activities regulated by the applicable regulatory framework. Each participant receives the necessary information, and every event is recorded. Health information is transmitted in real-time, ensuring semantic, syntactic, and technical interoperability.

NHIS covers all participants and main information flows in the "Healthcare" sector: electronic health record (patient file); Electronic prescriptions (e-pres-

criptions); Electronic directions (e-directions); Unified health information portal providing public information.

The unified health information portal provides citizens and users of medical services with controlled access to their personal electronic health records (patient files), including the history of issued e-Prescriptions and e-Directions.

In Bulgaria's healthcare landscape, multiple registries and databases managed by both public and private entities exist, but their regulation is fragmented across various legal acts. This fragmentation results in legal uncertainties, limited access to information, and insufficient data security measures. While some databases adhere to interoperability standards and automated interfaces for data exchange, others lack clear requirements, leading to disparities in information handling. Moreover, the absence of standardized channels and technical guidelines for data exchange between healthcare providers and public authorities exacerbates these challenges.

Citizens' rights to control their health data are enshrined in scattered regulations, yet alignment with GDPR standards remains incomplete. Although legislation guarantees access to health information stored by medical institutions, specific conditions for access and data management by patients are lacking. Furthermore, the absence of a comprehensive legislative approach hampers the development of e-health initiatives such as telemedicine, electronic prescriptions, and health records. These gaps in regulation hinder the integration of electronic healthcare services and the establishment of robust data protection measures.

To address these issues, a unified regulatory framework is imperative. Consolidating regulations into a single normative act would enhance clarity and effectiveness in implementation. Standardizing requirements for all databases, ensuring secure data exchange, and expanding permissible data processing purposes would bolster information reliability and citizens' rights. Additionally, clear provisions for patient data access and control, alongside robust security measures for data exchange, are crucial for fostering trust in the electronic healthcare system. Implementing these recommendations would establish a modern and efficient legal framework conducive to advancing e-healthcare in Bulgaria.

CONCLUSION

1. In the rapidly evolving field of healthcare, technological innovation stands out as a beacon of potential and promise. Digital health records, telemedicine, data analytics, infrastructure resilience, and communications platforms – each of these components not only offers specific benefits, but also

collectively mark a paradigm shift in how health care is delivered, accessed, and experienced.

2. The integration of these strategies underscores the democratization of access to health care, ensuring that regardless of geographic, economic, or social barriers, quality care remains within reach. For example, the digital transformation of health records ensures that patient records are not tied to physical files or specific locations, but can move seamlessly across systems and borders. Telemedicine, on the other hand, eliminates the physical gap, ensuring that expert consultations are a click away, even in the most remote corners.

3. Data analytics and predictive modeling are shifting the healthcare narrative from a reactive to a proactive stance. Rather than simply reacting to healthcare crises, the focus is shifting to predicting and preventing them. The ability to anticipate disease outbreaks or patient trajectories based on historical and real-time data can revolutionize preventive healthcare, reducing the burden on healthcare systems and improving population health.

4. Infrastructure resilience ensures that these innovations are housed in a robust environment that can withstand challenges, whether natural disasters or cyber threats. In an era where data breaches can have consequences as severe as traditional disasters, the importance of resilience cannot be overemphasized.

5. Communication platforms act as threads that tie these components together, ensuring that the exchange of information between doctor and patient or between different healthcare systems remains seamless, secure and efficient.

6. While the benefits of this integration are varied, it is important to recognize the challenges and proactively address them. Challenges such as data privacy, technology adaptation, regulatory frameworks, and the digital divide cannot be ignored. However, through the collaborative efforts of policy makers, healthcare professionals, technologists, and the public, these challenges can be addressed.

7. Looking to the future, the convergence of emerging technologies such as artificial intelligence, augmented reality and the Internet of Things (IoT) with healthcare promises even more transformative change. The future of healthcare is not just about treating disease, but holistic wellness that is data-driven, technology-driven, and centered on the patient.

8. In conclusion, as we stand on the cusp of a revolution in healthcare, it is critical to embrace these innovations, invest in their potential, and collectively work toward a future in which quality healthcare becomes a universal truth, not a privilege.

Contributors:

Vazov R. – conceptualization, methodology, formal analysis, writing – original draft;

Kanazireva R. – data curation, writing – review & editing;

Grynko T.V. – writing – review & editing, supervision;

Krupskyi O.P. – investigation, writing – review & editing, project administration.

Funding. This research received no external funding.

Conflict of interests. The authors declare no conflict of interest.

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Стаття надійшла до редакції 19.01.2024;
затверджена до публікації 26.03.2024

