

# Digital health in Bulgaria: Imagination or possible reality?

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## Abstract

Digital health is an emerging, strategic health priority for years. Even prior to the COVID-19 pandemic, the use of digital health technologies to make health systems and services more effective was widely recognized. Many countries around the globe have successfully digitalized their healthcare systems in some form. However, Bulgaria still falls behind in this matter and will need a rapid boost to provide a modern digital medical information system, accessible to all citizens. We did a two-step policy environmental and questionnaire-based analysis to describe the barriers, opportunities, and benefits of successful health care system digitalization in Bulgaria. digital health legislation and strategy framework are the neediest tools for the Bulgarian health systems at that point. Given the challenges and barriers to digital health transformation in Bulgaria, a well-defined regulatory and strategy framework can provide the necessary structure, guidelines, and support to drive the adoption and implementation of digital health solutions.

## Keywords

digital health, transformation, ecosystem, healthcare, challenges, solutions

## Introduction

A sustainable and effective healthcare system has always been a fundamental part of every society. However, in the recent years healthcare systems around the world have started to change due to many reasons, including the implementation of patient-centered concept and the increasing access and utilization of new health technologies (Durrani 2016). Digital health is becoming an important part and main driver of this change (Kruk et al. 2018).

Digital health has been seen as an emerging, strategic health priority for years. Even prior to the COVID-19 pandemic, the use of digital health technologies to make

health systems and services more effective was widely recognized (Fagherazzi et al. 2020). Countries have also indicated the importance of digital health. Linked to WHO's 13<sup>th</sup> General Programme of Work, the European Programme of Work commits to ensuring better access to health for people throughout the Region through universal health coverage and recognizes digital health as key to realize this vision (WHO 2020).

Many countries around the globe have successfully digitalized their healthcare systems in some form. However, Bulgaria is one that falls behind in this matter and will need a rapid boost in order to provide a modern digital medical information system, accessible to all citizens.

Bulgaria is also among of the EU countries that faces many challenges on its way to the digital transformation of the healthcare system (Tăran 2022).

In this respect there is a certain need to analyze the current situation in terms of barriers and opportunities for a more strategic approach towards a successful digital health transformation in the country as the goal of this study.

## Material and method

We did a two-step policy environmental and questionnaire-based analysis to describe the barriers, opportunities, and benefits of successful health care system digitalization in Bulgaria.

The policy analysis was based on the review of existing regulatory and policy documents in the country for the digitalization of the health care system, as well as documents and practices of non-governmental organizations engaged in the digitalization of healthcare in Bulgaria.

The questionnaire consisted of 21 questions – 16 closed and 5 opened exploring the level of knowledge about digital health and what are the expected benefits of digital transformation of the healthcare system in Bulgaria. The questionnaire was distributed online among different relevant stakeholders (healthcare professionals, regulatory institutions, pharmaceutical industry, medical and pharmacy students) and covered 6-month period (June–December 2021). The data was analyzed with descriptive statistics in Excel.

Based on the results from the policy analysis and questionnaire we created a list of the possible challenges and barriers and provided a set of recommendations for step-by-step successful digital transformation of the Bulgarian healthcare system.

## Results

### Policy analysis of digital health transformation across the EU

The Ministry of Health developed a National Health Strategy 2030 (Ministry of Health 2022) and a National Plan for Recovery and Sustainability 2021–2027 (Ministry of Council 2020), in which one of the main priorities is the digital transformation of the health sector to improve the quality of life and change radically the way of providing healthcare services. Key priority of the National Healthcare Strategy (2021–2030) is Priority 4 “Electronic Healthcare”. It should be developed as a “Sector strategy for digital transformation of healthcare”. This sector strategy includes certain elements: strategic framework; national health information system; approved nomenclatures; workforce capacity building; cyber security and data privacy; primary and secondary use of health data. Among the main goals of the digital health strategy are the establishment of unified digital platform and digital

services for improvement of diagnostics and treatment of socially important diseases. This platform is expected also to facilitate the communication between the healthcare professionals and other relevant stakeholders (Ministry of Health and National Health Information System 2023).

Currently the process of digital transformation has covered the adoption on national health information system (HIS) which provides the possibilities for the creation of electronic health record for health insured citizens and electronic prescription (e-prescription) (Ministry of Health 2022)[6]. The latter was introduced recently and currently is available only for reimbursable medicinal products (Bulgarian Drug Agency 2023).

The environmental analysis shows that Bulgaria still falls behind in digital health transformation and will need a rapid boost to provide a modern healthcare system, accessible to all citizens.

In these terms, we could summarize the main factors for slower digital health transformation in the Bulgarian health system as regulatory barriers, lack of infrastructure, funding constraints, and cultural factors. Understanding their characteristics and importance could provide approach to their solution – Table 1.

Based on the barriers that were identified from the environmental analysis we created a set of steps that could be included in one basic digital health framework:

- (1) **Standardization and interoperability among various healthcare systems, devices, and platforms** – It establishes a common language and format for sharing health information, enabling seamless communication and integration between different healthcare stakeholders to facilitate the flow of information and improving care coordination;
- (2) **Data Governance and Security** – ensures that health data is managed and protected in compliance with relevant regulations and privacy standards. By establishing clear guidelines for data access, consent, encryption, and storage, a framework promotes trust among patients, healthcare providers, and other stakeholders, encouraging the adoption and use of digital health technologies. Moreover, it allows innovators, researchers and private sector to access health data regulated and use the secondary data for testing, piloting, validating and crating innovation;
- (3) **Infrastructure and Technical Requirements** – hardware, software, connectivity, and IT infrastructure needed to support digital health initiatives. By providing guidance on technical specifications and requirements, this helps healthcare organizations make informed decisions about the technology infrastructure necessary for successful digital transformation;
- (4) **Governance and Stakeholder Engagement** – identifies key stakeholders, such as ministries, government agencies, healthcare providers, technology companies, and patient advocacy groups, and encourages their active engagement, participation and

collaboration. By engaging all stakeholders and fostering partnerships, that ensure that all relevant parties are involved in the digital transformation process, promoting a holistic and effective approach;

- (5) **Adoption and Implementation Support** – may include educational programs, guidelines, and best practices to help healthcare organizations and professionals navigate the digital health landscape. By offering assistance and promoting knowledge sharing, this framework facilitates the successful integration of digital technologies into healthcare workflows, driving widespread adoption and utilization;
- (6) **Monitoring and Evaluation** – metrics and indicators to assess the outcomes and benefits of digital transformation efforts. By regularly measuring progress and analyzing results, a well-developed framework enables healthcare organizations and

policymakers to make data-driven decisions, identify areas for improvement, and refine their digital strategies for continuous enhancement. Often, the way to do that is to develop pilot project and not disturb the current condition of the health system until you prove concrete results.

Taking the above, in November 2018 9 companies and 2 non-profit organizations founded the Digital Health and Innovation Cluster in Bulgaria (DHI Cluster) with the idea to support the digital health transformation in Bulgaria. The main idea behind DHI Cluster is to support innovative companies and organizations in the field of digital healthcare solutions to build an expert digital health community and establish a sustainable and efficient healthcare environment for patients, medical professionals, society and institutions. (DHI Cluster 2023)The DHI Cluster started a

**Table 1.** Factors influencing the delay of digital health transformation.

Factors responsible for the delay of digital health transformation in Bulgaria	Characteristics	Solution and importance
<b>Regulatory barriers</b>	The current regulatory framework does not adapt to the rapid technological progress and does not meet the needs of the society and the tech industry. There is a lack of concrete regulations, such as a telemedicine framework and data usage guidelines.	Streamlining and clarifying regulations can facilitate faster adoption and implementation of business processes, digital solutions, clinical systems, data analysis, etc., creating an effective, sustainable, and predictive environment for patients, healthcare professionals, the government, and other stakeholders.
<b>Lack of infrastructure</b>	Insufficient internet connectivity, particularly in rural areas <b>Outdated systems</b> . Bulgaria has faced challenges in terms of internet connectivity, particularly in rural areas. According to a study (DESI) by the European Commission, Bulgaria ranks lower in terms of broadband coverage compared to other European countries (DESI 2022).	Sufficient access to high-speed internet can prevent the implementation and effectiveness of digital health solutions at local level and do not permit the effective utilization of clinical information systems and digital tools. Updated systems can maintain the smooth integration and exchange of health information and expand the potential of the health data and its analysis in terms of prevention, precise diagnostic, personalized care, long term care, crating a predictable environment for effective decision-making.
<b>Funding and investment</b>	Budget constraints, which may have limited the allocation of funds for digital health initiatives.	Adequate funding is crucial for the development, implementation, and maintenance of robust digital health systems. The digital health transformation is an evolutionary process that requires initial investments to create strong fundamentals of an advanced and sustainable healthcare system which can adequately respond to the increased health needs of the society.
<b>Data privacy and security concerns</b>	Stringent data privacy and security regulations can sometimes slow down the adoption of digital health technologies.	Balancing the need for privacy with the efficient sharing and utilization of health data is crucial to foster trust and encourage the adoption of digital health solutions. Implementing a data sharing framework is essential to drive the development of digital health solutions and encourage innovation creation.
<b>Cultural and organizational factors</b>	Resistance to change is one of the biggest problems in any country which can totally prevent the digital health transformation.	Increased levels of digital skills and data literacy are crucial for the adoption of new technologies and unfortunately Bulgaria marks very low digital skills levels. This leads to the urgent need for developing new skills and competencies at university level and integrate new approaches for digital health education and data literacy among HCPs, patient and relevant stakeholders.
<b>Organizational barriers</b>	The fragmentation of healthcare delivery and the lack of standardized practices across healthcare institutions is creating challenges for the implementation of digital health. Lack of coordination and interoperability among different healthcare providers can prevent the seamless exchange of health information which is fundamental to the digitalization process.	Increased coordination and interoperability among different healthcare providers can support the seamless exchange of health information which is fundamental to the digitalization process.

specific initiative to support the digital transformation of the healthcare in the country by developing a framework of a sectoral strategy for digital health transformation of the Bulgarian health system. The document is based on a methodological and organizational foundation in the form of a National Health Architecture, which should become the basis for consensus on the direction of development of digital health topics at national level. The goal is to use transformation models successfully introduced by European partners, as well as proven methodologies and platform solutions. This is expected to lead to:

- the creation of a comprehensive strategy for the digitalization of the healthcare system and quality improvement;
- the transformation towards a Healthcare Ecosystem involving all stakeholders in the sector and closer integration with Europe and other international partners.

Important strategic objectives were developed as follows:

- to create a Healthcare Ecosystem with integration of all stakeholders in the medical sector (healthcare system, insurers, ICT ecosystem, pharma industry, education, and society);
- to establish an expert group which should manage the digitalization process on national level. This group should include leading experts in digital and future technology topics related to healthcare together with representatives of the Ministry of Health and its specialized directorates.
- to define a National Healthcare Architecture as a methodological and organizational framework which aggregates and develops all digital topics in the sector in the future;
- to implement a new generation Digital Health Platform, which will provide regulated access for primary and secondary processing of medical data to all participants in the Health Ecosystem and which will integrate and upgrade the existing national health information system (NHIS);
- to create a centralized archive for structured and unstructured imagery data as a basis for qualified medical solutions and for the future development of the medical research topic;

- to re-model the existing Electronic Health Record (EHR) into a modern one, which relies on tools for analysis, association, and correlation of medical data (Medical Insight) using technologies in the field of artificial intelligence;
- to achieve a state of “information intelligence” on national level in the focus groups “society”, “health-care professionals” and “education”.

The Digital health strategy was recognized among all the stakeholders in the healthcare system. The strategy was introduced during several events, including round tables with the State, international and national webinars, and others significant events. Due to its potential, the document was published in the Resilience and Recovery plan in Bulgaria, by the Ministry of health as a digital health reform.

## Inquire results

380 stakeholders from the health sector in Bulgaria responded to the online questionnaire, among which 280 patients, 22 representatives of the pharma industry, 12 representatives of the tech industry, 9 representatives of the regulatory authorities, 41 healthcare professionals (pharmacists and physicians) and 49 pharmacy and medical students. The results show that 43.7% of the respondents are actively interested in the process of digital transformation and 56% think that there is a need for an informational campaign prior implementation. 66% of the respondents think that digitalization of healthcare will improve the work of healthcare professionals and access to health services, reducing the burden on hospital care by targeting prevention and early diagnosis. 50% think that this would also improve transparency in decision making and financial resource allocation. 47% respondents suggest that courses on digital health must be included in the curriculums of medical universities in order to improve the digital literacy among future healthcare professionals.

Most of the respondents related the main challenges for digital transformation of the healthcare system to difficulties regarding older people's engagement with digital platforms, lack of security and lack of data. The main challenges that we identified for a successful digital transformation of healthcare in Bulgaria and the possible solutions are summarized in Table 2.

**Table 2.** Challenges and possible solutions for the digital transformation of healthcare in Bulgaria.

Challenges	Solutions
Clear vision and strategy including the digital transformation of healthcare	Sector strategy for digital transformation of healthcare as part of the National Healthcare Strategy (2021–2030): three step approach including analysis, architecture, and road map
Digital health awareness and data literacy of healthcare professionals and policy makers	Digital health and data literacy included in the curriculum of the medical universities; courses for healthcare authorities
Access to quality digital health solutions bringing certain outcomes to individual patients and public health	Legislative changes, health technology assessment, and reimbursement
Lack of digital literacy among future healthcare specialists	Creation of courses for digital health in the medical universities
Build thriving healthcare ecosystem	Healthcare ecosystem mapping and investment in the key enablers: academic culture; entrepreneurial culture and risk capital; workforce; infrastructure; ecosystem

### Possibilities for implementation of digital health and expected benefits.

Based on the priorities set in the National Health Strategy and results from the questionnaire for digital health a three-step approach could be proposed for further digital transformation of health care – Fig. 1.

The initiative is divided into three phases, which cover some sub-objectives and expected results. They are summarized in Table 3.

The realization of the described goals should be subject of a Sector strategy for digital transformation of the Bulgarian healthcare system and the collaboration between the public administration, academia, and the private



**Figure 1.** Three-step approach for digital transformation based on the priorities set at the National Health Strategy.

**Table 3.** Recommendations for the three-step digital transformation of healthcare in Bulgaria.

Phase	Sub-goals	Expected results
Phase 1	• Start of the digitalization process by defining the National Healthcare Architecture.	• The foundations of a sustainable digitalization process are created and a consensus on digital health issues is achieved.
	• Definition of the strategy regarding medical data, its architecture, and the accompanying regulatory changes.	• The definitions of the medical data in the Republic of Bulgaria are upgraded as a preparation for the regulated access by all stakeholders.
	• Laying the foundations of the Digital Health Platform (Medical Infostructure) and the integration of the NHIS.	• The processes in the healthcare system and its subcontractors is optimized, and at the same time models for monitoring the efficiency of the digitalization process and its real value for society are defined and active.
	• Transformation of the existing EHR into its future model.	• Modern infrastructure (medical infostructure) is built according to the future requirements of digital healthcare, which will allow state healthcare institutions to optimize their technological budget.
	• Integration of the healthcare system stakeholders into the Digital Health Platform. Establishment of a centralized archive of imagery medical data.	• A future oriented EHR is set up to help healthcare professionals and patients, effectively saving time and bureaucracy in favor of improving the quality of health services. • A technological inclusion of the participants in the healthcare system is possible to achieve a state of information intelligence, in which decisions are made based on centralized, comprehensive data.
Phase 2	• Establishment of a centralized archive for medical imagery data.	• A precondition for centralization of unstructured data in aid of healthcare professionals and to increase the financial efficiency of healthcare institutions is established.
	• Launch of an integration process involving stakeholders from private sectors with the accompanying regulatory changes.	• The diagnostic process is significantly improved in the presence of comprehensive medical data, regardless of which health institution requires them.
	• Creation of an open market for digital solutions as an added value for medical professionals and patients.	• A basis for establishment of national programs for prevention and protection of public health is institutionalized.
	• Collaboration with the field of education through the Digital Health Platform as a foundation for adequate training of future staff in the healthcare system.	• The open market for digital solutions is open to all stakeholders using the capabilities of the Digital Health Platform, which increases the quality of services offered to the public. Topics as telemedicine are supported by a strategy which leverages technology innovation and additional investments within the sector.
	• Encouragement of the future development of medical research.	• Technological and organizational support is provided to the field of education in order to attract new and future talents in the healthcare system. • Medical research is enhanced by centralized data and contributes directly to finding solutions to current and future systemic and personalized challenges.
Phase 3	• Society is enhanced by information intelligence regarding digital healthcare solutions.	• Through planned training of the focus groups “society”, “healthcare professionals” and “education” in digital health solutions, several positive effects are achieved as in adequately prepared current and future healthcare professionals, and a society that is confident in the service and benefits provided by digital healthcare.
	• Creation of a “medical data economy”.	• The economy of medical data leads to new models for secondary processing of information, which benefits primarily the patient, but also all those wishing to use said information as a basis for innovation within the sector.
	• Focus on medical research and development of associated digital products.	• This helps the development of medical research and development activities.
	• Alignment of the objectives for the next programming period with the requirements of the European Commission and projection of future healthcare sector needs.	• Thus, the overall foundation of the digitalization process turns Bulgaria into an equal partner at European and global level in terms of digital healthcare – always on par with current and future topics.

sector. This is the way to create adequate framework, in which all stakeholders participate and in which there is the necessary professional expertise to achieve the expected results, such as those achieved in the developed and highly digitalized healthcare systems across the world.

The successful development of these projects should be supported by investment in building and/or upgrading information systems in digital healthcare; in the cross-border exchange of EU citizens' health information; in providing a cyber-resistant environment for medical data storage; in increasing the capacity to implement digital healthcare systems (Ministry of transportation and communication 2023).

The National Health Architecture will define a framework for digital transformation of the healthcare system in Bulgaria and will begin the process of creating a Health Ecosystem with participants from all levels of public life and business. This ecosystem, with its Digital Health Platform, will put and integrate medical data in its own center, allowing regulation and secure access to health information from the perspective of patients, medical professionals, private business, education, and government institutions.

Digital transformation of healthcare system could support key public health initiatives like prevention, early diagnosis, precision treatment, and quality of life of the patients. It could also support the system thinking and strengthen the healthcare system in general. It could improve the access to quality healthcare services bringing certain outcomes to the patients and to the society. Finally, it's the basis for taking strategic and informed decisions in a very sensitive sector like healthcare.

## Discussion

The main reasons for unsuccessful digitalization are already identified by experts. They are related to failure to understand the need for cultural transformation, the humans themselves are ultimate barrier to digital transformation and lack of knowledge about digital health among policy makers (Duman 2021; Stoumpos 2023).

Digital health technologies generate information and data that are critical for the prevention, diagnosis, treatment, monitoring and management of health and lifestyle. More and more of this data is now digitized; it can be stored and accessed on electronic health records and personal devices, shared among patients and healthcare professionals (Keshta 2021). European Commission analysis on the e-health environment in the European Union based on studies of digital health utilization in hospitals and among general practitioners shows that in 2013 60% of general practitioners used e-Health tools, or 50% more than in 2007 (European Commission 2023). The analysis also shows that the most E-Health tools used among the hospitals and general practitioners include electronic health records, health information exchange, remote health services and personal health records. The report shows that the leading countries in the utilization of

e-health services in hospital settings are Denmark, Estonia, Sweden, and Finland while in terms of digitalization of patients' health records leading are the Netherlands, Denmark, and the United Kingdom. Most of the barriers in e-health utilization reported among hospital physicians and general practitioners are lack of compensation, not sufficient digital knowledge, lack of software compatibility and finally lack of regulatory framework (Savigny 2009; Senbekov 2020).

The Medical Futurist issued a free report about the best digital health practices that policymakers can adopt. This can help them take the first steps in shaping their healthcare regulations. The report highlighted how policymakers should create a regulated digital health landscape. This is achievable by heeding to patients' needs through a patient-centric approach (The Medical Futurist 2018; Mesko 2023).

To our knowledge this is the first article to analyze the regulatory and policy background or digital transformation of healthcare and to examine the attitudes and expectations of the relevant stakeholders involved in the process.

Our study shows that the digital transformation of healthcare has been initiated as process on policy level but we still need to adopt the regulation in line with the European one. However, cultural transformation is still not fully engaging all relevant stakeholders.

Universities could also play an important role in the healthcare ecosystems in terms of innovative ideas, prototyping, and further commercialization. Cluster organizations across the EU are in a favorable position to accelerate that process being ecosystem orchestrators and following the vision for sustainable and effective healthcare systems based on innovation, data and technology (Menvielle 2017; Reichert 2019). The results from our study also support this vision as almost half of the respondents stated that courses on digital health must be included in the curriculums of medical universities.

It is important to say, that digital health legislation and strategy framework are the neediest tools for the Bulgarian health systems at that point. Given the challenges and barriers to digital health transformation in Bulgaria, a well-defined regulatory and strategy framework can provide the necessary structure, guidelines, and support to drive the adoption and implementation of digital health solutions. It can help overcome regulatory barriers, address infrastructure limitations, allocate funding appropriately, ensure data privacy and security, and promote collaboration among stakeholders. By establishing a digital health framework, Bulgaria can lay the foundation for a more efficient, sustainable, and patient-centric healthcare system. A well-structured digital health framework, inc. legislation activities, could provide the necessary structure, standards, and guidance to support the digital transformation process in the healthcare system. It ensures interoperability, data governance, infrastructure requirements, stakeholder engagement, adoption support, and monitoring and evaluation, all of which are critical for successful digital health implementation.

## Conclusion

Healthcare is one of the largest and most complex socio-economic sectors in any country. COVID-19 has shown the world that there can be no successful economy without adequate healthcare. The only way to effectively combat these new challenges is by improving the long-term sustainability and efficiency of the national healthcare system by launching a digital transformation of the sector. It should be based on clear vision and strategy that

follows the ecosystem approach and systems thinking for strengthening the healthcare system.

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