Artificial Intelligence in Healthcare Services – Regulation, Implementation and Future Challenges

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***Abstract* - Digitalization of healthcare services in European Union with implementation of artificial intelligence represents one of the modern forms of healthcare delivery defined in the European digital agenda in order to assure better quality in healthcare services delivery and improve quality of healthcare systems. Authors of the paper analyse the process of digitalization and implementation of artificial intelligence in healthcare service while opening some technical, ethical and legal questions, which need to be better defined. European union is still in process of developing the regulatory framework for implementation and harmonization of digital solutions in healthcare system and the authors give an overview of actual situation and give recommendations concerning the privacy and data protection, data quality and data management as well as harmonized rules on artificial intelligence which should stand as the pillars of the regulatory framework and be the main focus of the future regulation in order to protect the patients data and patients privacy in healthcare services.**

Key words: artificial intelligence, data privacy, data protection, digitalization, European union, healthcare services, personal data protection, regulation

I. INTRODUCTION

Healthcare services are usually part of public services, organized to maintain and manage important social activities in field of public health by public institutions and government bodies in many contemporary states. This approach in providing of healthcare services are usually characteristic for European states, where provision and delivery of healthcare services represents one of the basic human rights, which is usually described as third generation of human rights, which are focused on important social services such as social housing, different types of social insurance and other types of social policy. [1] Organization and functioning of public services is specific, because of significance and importance of those services for daily life of the citizens. [2] Approach to the public services mostly depends on attitude which prevails in social life of community. In some countries can be find opinion that public services are increasingly important for public community, and states create regulatory framework for their provision. In other countries public services have relatively reduced influence on daily activity in society, and their regulation depends on delivery and provision regulated by common framework for performance of all other services in society.

Public services are important part of public administration in contemporary society. They provide many important and additional services, which are important for daily life of citizens in community. They are usually divided to different division: on central (national) and local public services, where central public services deliver type of services important for the state and its activity in society, and local public services, where local government institutions participate in organization and maintaining of this type of services. [3] Public services which are regulated and organized from central government administration and institutions operate for entire state, and their impact is global for national community. Local government services which are regulated and organized from local government institutions and bodies and operate on local level, with limited local influence to fulfil local public needs in community. [4]

Second division is services of general economic and non-economic interests, where services of general economic interests represent important public services with economic or commercial elements, and services of non-economic interests which are also important for community, but without economic character. [5] Division of public services on services of economic and non-economic interests are relatively new and define services which are based on commercial and economic interest, and other which are organized on non-profit principles, with purpose to fulfill some public needs defined as important for community, independently of their costs and organizational complexity. [6] They are usually organized and managed as non-profit institutions financed from the budget, but their activity is important for normal functioning of community. [7]

Criteria for division of public services on commercial or non-commercial services depend on approach to principles of delivery and provisions to the citizens in society. If prevail commercial interest of providers, public services are defined as economic or commercial. [8] If public interest of community is important for availability of some public service, or fulfilling of some public need in society and if those interest or need prevail instead on commercial interest

of possible provider, public services are usually defined as non-commercial. [9]

Healthcare services usually represent important part of public services, with regulatory framework which is similar to the other types of public administration. They can be defining as commercial or non-commercial services, which depends on two different types of interest, commercial or non-commercial, according to the incomes which they realize on the market. [10] If healthcare service is predominantly market oriented, then represents services of general economic interest. If it is non-profit oriented, and main principle of organization and functioning is the principle of intergenerational solidarity, then falls into the category of non-commercial services. Accordingly, health services can be defined as services of general economic interest, when they have organization and delivery based on commercial elements, or services of general interests, when their organization and delivery are primary motivated with fulfilling public needs in public community.

According to the commercial or non-commercial status of operating in community, health services are defined with specific regulatory framework, which includes two main elements: technical aspect of healthcare service providing and social aspect of healthcare service providing. *Technical aspect* defines technical conditions and minimal standards for provision and delivery of healthcare services. Minimal standards and technical conditions for maintaining of healthcare services are usually defined from central government authorities and or professional institutions with public authorities which regulates professional standards for healthcare providing. Government authorities usually prescribe propositions for healthcare services delivery, with minimal technical standards of quality. Additional standards of healthcare services provision quality establish and prescribes professional institutions such as medical chambers or professional medical associations. Those institutions usually have public authorities shared from the central government institutions, to additional regulate delivery of healthcare services.

Social aspect of healthcare service providing has accent on availability of healthcare service. If provision of healthcare services represents social category in society for fulfilling of public needs, then provision of healthcare services is widely accessible. If commercial element prevails in healthcare service organization, then accessibility of healthcare services depends on asset census. Complexity of healthcare services can be described by three different level of public healthcare: primary, secondary, and tertiary. [11] Primary level includes general medical practices, secondary special medical practices with clinical specialists and tertiary hospital healthcare services. General medical practices which operate on the primary level are simplest part of healthcare services, but actually most important because of direct communication with the patients, universal healthcare protection and availability.

In most countries, general medical practice represents main pillar of efficient and affordable healthcare services. [12] Second level of medical practice, with clinical specialists, represents upgrade to general medical practice, and assure efficient and affordable healthcare protection and available healthcare services. Hospital healthcare services are most complex form of healthcare service. This type of protection incorporates various forms of healthcare services with combination of clinical specialists and sub-specialists, which include combination of specialized care and long-term care. Because of complexity, hospital healthcare services are most expensive part of healthcare system in every country and need some type of selection to approach on its services. [13]

II. DIGITAL TRANSFORMATION OF HEALTHCARE SERVICES

Expenses of the health care system are increasing with development of medical technology and population aging. Development of technological solutions, with new diagnostic methods and more complex and comprehensive therapies lead to rising costs of healthcare services. Because of that, contemporary health systems need to use new solutions to reduce costs of the healthcare services and harmonize future development. Digitalization represents one of useful solutions to cut healthcare expenses. European countries are developing healthcare systems with characteristic such as efficiency, high quality, equity, affordability and accessibility. They are trying to balance between those values and their potential conflicts in values and goals. [14]

According to the above written, digitalization represents technological process which facilitates that healthcare services be organized, produced and delivered in new ways. In context of technological changes, digitalization also represents organizational and cultural change. [15] Digitalization of healthcare services includes technical and social component. Technological component describes new technological aspects of digitalization, which effect on various elements of healthcare services, such as structure of healthcare organizations, healthcare culture and functioning of healthcare services, functioning of medical professions, treatments and other effects of healthcare system. [16] Social aspect of digitalization includes social, political and economic impacts of digital transformation, which represents innovation in health technologies and healthcare delivery process. [17] Digital transformation can be describing as a process which introduce to significant changes in in healthcare delivery [18] One of the most important part of digitalization of health services is mobile health service, usually known as mHealth, which includes implementation of digital technologies to maintain health process and conditions in movement. This can be important

in following health conditions of patients such as asthma, heart rate, breading, but also in managing of various healthcare services important for daily life of individuals in community. [19]

Main goals of digitalization health services are effective outcomes, which can be improve, safe harm with adequate healthcare, patient-centered care with involving of patients in process of care, efficient health services with the best value for the money and with equal and available care quality for all users of services in healthcare system [20] Impacts of digital transformation in healthcare are usually visible on operating with medical records and prescriptions which are dematerialized, true therapy which can be adopted by using virtual channels via smartphones and tablets, by using voice interface, which can separate less urgent and complicate request for medical care in real time, digital connection with communication system which reduce communication distance between patients, medical staff and operators. There are several applications that can be develop for the purposes of healthcare system: extension of medical devices, which helps in maintain, diagnostic and therapy; application for health support of patient in prevention or therapy, application which measures health indicators and support healthy behavior of patients; application which gives patients useful specific disease information; application which helps in communication with their physicians and application that provides access to clinical medical information which are stored in digital system. [21]

III. HEALTHCARE SERVICES AND ARTIFICIAL INTELLIGENCE (AI)

Special part of digital transformation in healthcare services can be dedicated to artificial intelligence (AI), which represents next step in development of digital health. [22] AI is expected to radically change workplace and professions. [23] AI is considered as a tool for productivity and progress, and effects the social relations and organizational structure of healthcare system. [24]

A. Development of the ethical and legal framework of artificial intelligence at the level of the European Union

The key foundation for European initiatives to develop artificial intelligence is to create an atmosphere of trust and responsibility around the development and use of artificial intelligence. The EU has a solid and balanced regulatory framework that can serve as a foundation and world standard for sustainable access to this technology. The Union has high standards in terms of product safety and responsibility. The first rules at the EU level on the security of network and information systems and stricter rules on the protection of personal data adopted by Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of individuals in connection with the processing of personal data and on free movement of such data and on the repeal of Directive 95/46/EC (General Data Protection Regulation - hereinafter GDPR), which applies from May 25, 2018. [25] The General Data Protection Regulation ensures a high standard of personal data protection, including technical principles and integrated data protection. It guarantees the free flow of personal data in the Union. It contains provisions on decision-making solely on the basis of automated processing, including profiling. In such cases, respondents have the right to receive meaningful information about the logic of decision-making. [26] The general regulation on data protection provides the individual with the right not to be subject exclusively to automated decision-making, except in certain situations. The Commission closely monitors the application of the Regulation in the context of artificial intelligence, as well as national data protection authorities and the European Data Protection Board, which is the competent authority at the European level.

B. Ethical guidelines for the development of artificial intelligence

The first step in solving ethical issues was the drafting of ethical guidelines for artificial intelligence based on the Charter of Fundamental Rights of the European Union entitled "Ethics Guidelines for Trustworthy Artificial Intelligence by the High-Level Expert Group on Artificial Intelligence (AI HLEG) published on April 8, 2019. [26] The Commission gathered all relevant stakeholders in the European Commission's High Level Independent Expert Group on Artificial Intelligence, which participated in the development of ethical guidelines. The ethical guidelines took into account issues such as the future of work, fairness, protection, security, social inclusion and algorithmic transparency. More broadly, the impact of fundamental rights will be considered, including the principles of privacy, dignity, consumer protection and non-discrimination. [27] In the guidelines, in terms of achieving reliable AI, not only compliance with the law is required, but also one of its three components presented through the three chapters of the guidelines. It is emphasized that laws are not always in step with technological development, sometimes they cannot keep up with ethical norms or they are simply not adequate enough to solve certain problems. For AI to be reliable, they should also be ethical, ensuring compliance with ethical norms.

Based on fundamental rights and ethical principles, the Guidelines list seven key requirements that AI systems should meet in order to be trustworthy:

- Human agency and oversight
- Technical robustness and safety
- Privacy and Data governance
- Transparency
- Diversity, non-discrimination and fairness
- Societal and environmental well-being
- Accountability

Aiming to operationalize these requirements, the Guidelines present an assessment list that offers guidance on each requirement's practical implementation. [27] This assessment list will undergo a piloting process to which all interested stakeholders can participate, in order to gather feedback for its improvement. In addition, a forum to exchange best practices for the implementation of Trustworthy AI was created.

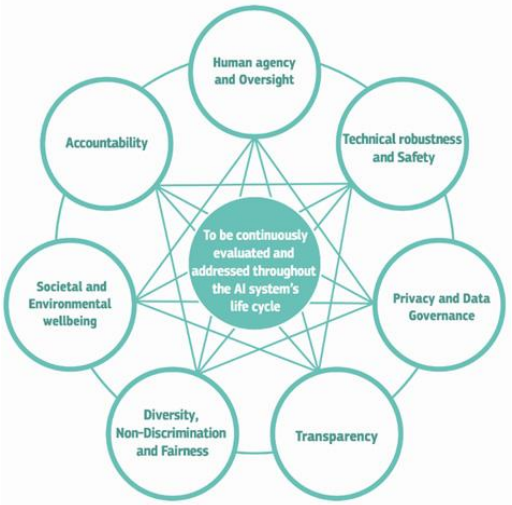

Figure 1. Seven key requirements that AI systems should meet in order to be trustworthy Ethics Guidelines for Trustworthy AI [28]

C. *Privacy protection and data management*

Closely related to the principle of harm prevention, in accordance with ethical guidelines, is privacy, a fundamental right that is particularly affected by the development of AI systems. Preventing privacy harm also requires appropriate data management that covers the quality and integrity of the data used, its relevance to the domain in which the AI systems will be deployed, its access protocols and the ability to process the data in a way that protects privacy.

AI systems must guarantee privacy and data protection throughout the entire life cycle of the system. This includes information initially provided by the user, as well as data generated about the user during their interaction with the AI system AI generated for certain users or how users responded to certain recommendations. Digital records of human behavior can enable AI systems to infer not only individuals' preferences, but also their sexual orientation, age, gender, religious or political views. In order to enable individuals to have confidence in the data collection process, it must be ensured that data collected about them will not be used to unlawfully or unfairly discriminate against them.

The quality of the data sets used is the most important for the performance of the AI system. When data is collected, it may contain socially constructed biases, inaccuracies, errors, and mistakes. This must be resolved before training with any given data set. [29] In addition, data integrity must be ensured. Feeding malicious data into an AI system can change its behavior, especially with self-learning systems. The processes and datasets used must be tested and documented at every step, such as planning, training, testing and use. This should also apply to AI systems that were not developed internally, but were acquired elsewhere.

In any organization that processes the data of individuals (whether someone is a user of the system or not), it is necessary to establish data protocols that govern access to the data. These protocols should define who can access data and under what circumstances. Only appropriately qualified personnel who are competent and need access to certain data should be allowed to do so. [30]

D. *Harmonised rules on artificial intelligence (Artificial intelligence act)*

The emergence of artificial intelligence, especially the complex system that enables it and the features of autonomous decision-making, requires reflection on the appropriateness of some established rules on security and civil liability. Given the breadth of application of artificial intelligence, it may be necessary to review both horizontal and sectoral rules.

The EU safety framework already covers the intended purpose and (mis)use of products when they are placed on the market. This has led to the development of a robust body of standards in the field of AI-enabled devices that is constantly adapting to technological advances. The further development and promotion of such safety standards and the support of standardization organizations at EU and international level will enable European companies to achieve a competitive advantage and increase consumer confidence. [31]

The Commission is now assessing whether the EU and Member States' security and liability frameworks are appropriate in the context of these new challenges and whether certain shortcomings need to be corrected. A high level of security and an effective mechanism for the legal protection of injured persons in case of compensation helps in building user trust and social acceptance of these technologies. Evaluations of the Product Liability Directive and the Machinery Directive have already been carried out. An initial assessment of existing liability frameworks in the context of artificial intelligence technologies and new technologies was also carried out. In the further analysis of these challenges, the Commission is assisted by an expert group.

Regulation of artificial intelligence in EU countries is next step in process of digital transformation of healthcare services. Main aspect of this regulation are ethical questions

which lead promising technological solutions. Ethical issue is usually related with enactment of healthcare decisions which involve strong and complex judgement and fitting into the social context, which determine decision making process. Those decisions, which are product of human reflection, become part of AI operating, with potentially far-reaching consequences. [32] Accordingly, European Parliament started the discussion regarding the influence and consequences of AI on healthcare services and European Commission proposed to European Parliament and European Council enactment of Artificial Intelligence Act, as a general legal framework for regulation of artificial intelligence in Europa. [33] This act is in legal procedure from 2021., and temporarily is in ordinary procedure in Council of European Union.

According to the proposition, Artificial Intelligence Act needs to regulate different fields of risk, which can be generally divided on unacceptable risk applications, high-risk applications, and low-risk applications. [34] The EU Artificial Intelligence Act could become global standard in Europe (and abroad), which would determine on what implementation and extent of artificial intelligence is more or less accepted or non-accepted in daily life and which application can have more positive than negative effect to the users. Second aspect, which is important in context of this proposal, is question of personal and societal harm, which will arise true implementation of this Act. [35] To reduce potentially harm (individual as societal) proposal of Artificial Intelligence Act prohibited AI practices to the group of individuals who are vulnerable according to their social or economic situation. Second important thing is classification of AI risks with clear definition that divided high risk situations in AI implementation from low-risk situation. Additional question is general purpose of AI system, where Act proposal specifies certain situation where the principles of high-risk AI system are implemented on design of AI system which can be used for many different purposes (general purpose AI). [36] Important part of AI Act proposal is implementation transparency principle according to implementation, development and use of high-risk AI. [37] New added provisions predicted obligation for users of AI emotion recognition system to inform people when they exposed to the influence of the system.

The extensive use of AI-enabled tools healthcare services as in other business-to-consumer transaction should be fair, transparent and compliant with consumer protection legislation. Citizens as users of healthcare services should receive transparent information about the use, features and properties of AI-enabled products. They should be able to control the data generated by using these tools, completly compliant to GDPR regulation, and know whether they are communicating with a machine or another human. When interacting with an automated system, special consideration should be given when users need to be informed about how to get in touch with a human and how to ensure that the system's decisions can be checked and corrected.

IV. CONCLUSION

According to the conclusion of the report on the State of Health in the European Union, only a substantial reflection on health systems can ensure that they are fit for purpose. This means that they must be systems that continue to promote health, prevent disease, and provide patient-centered care that meets the needs of citizens. Data is the key enabler of digital transformation. Health data may be available in various forms; they are not managed in the same way in all member states of the European Union or within the borders of national health systems. They are often not even available to patients themselves or to public authorities, healthcare professionals or researchers to help them develop and deliver better diagnosis, treatment or personalized care. And where they exist, health data often depend on technologies that are not interoperable, preventing their wider use. The basis of this reflection is the conclusion that health and care systems need reforms and innovative solutions in order to become more resilient, accessible and efficient in providing quality care to European citizens.

The paper gives an insight to the potential of applying artificial intelligence in healthcare, but also points out the key risks that must be managed, especially with regard to the protection and security of data in healthcare and protection of privacy of users, as well as the need for a detailed elaboration of the regulatory framework: the security, ethical and legal framework of application and use of artificial intelligence. In this regard, the application of artificial intelligence in healthcare, but also digital solutions in general, if they are purpose-built and implemented in a cost-effective way, can improve the well-being of millions of citizens and radically change the way health and care services are provided. patients.

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