

Doctor-Patient-Artificial Intelligence Relations in Smart Healthcare

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ABSTRACT

Artificial intelligence (AI) has become widely used in the medical field, as it has numerous actual and potential for doctors and patients. However, this process inevitably creates new challenges and problems. This study analyzes the moral challenges and human rights issues brought by the application of AI in intelligent medicine and expounds the application of AI in intelligent medicine from the perspectives of information technology and legislation. The article points to the over-diagnosis of AI on patients, the violation of privacy and confidentiality, and emphasizes the importance of the patients' rights protection. Specific focus is placed on artificial intelligence technology and doctor-patient relationship in smart treatment; some legal issues are highlighted in this respect. The relationship between AI and doctor, and doctor and patient is described in detail, and the right to know about the use of AI diagnosis by patients and the confirmation of data security by developers are emphasized. Finally, the paper puts forward some suggestions on how to improve the legal framework of intelligent medical treatment.

Introduction

Smart Healthcare leverages the latest mobile and digital advances in E-Health and mHealth, driving the development of smart and connected medical devices. The approach to medicine is also changing with smart trackers and other similar devices, doctors have much more opportunities to constantly monitor patient indicators outside of medical institutions and, accordingly, prevent diseases. In recent years, the term "Smart Medicine" has emerged and is becoming more widely used. By "Smart medicine" we mean intelligent healthcare, which uses the latest mobile and digital achievements in the field of eHealth and mHealth, which encourages the development of smart and connected medical devices that ensure constant monitoring of patient indicators outside of medical institutions and, accordingly, the prevention of diseases. In some cases, this type of monitoring can recognize or predict critical health condition of patients and it can warn health institutions if immediate first aid is needed. The Smart medicine

will allow the doctor to quickly communicate with the patient, conduct a remote course of treatment. Through special sensors and chips installed on the human body, the doctor, regardless of the location, will be able to get acquainted with important information about the patient's health status. For example, the doctor will be able to track body temperature, pulse, respiration rate, blood sugar, and blood pressure.

Together with the concept of "Smart Medicine", the concept of "Smart Hospital" began to be actively applied. Smart Hospital can be defined as interactive intelligent digital environment that represents the meta-system to manage clinical pathways based on on-line monitoring of vital functions in combination with the operational personnel access and patient's information (including virtual councils) with the wide use of mobile applications and robotics. Current development of technologies paves a way to the situations when most medical institutions will implement

computer science and other contemporary ways of provision of medical support in their activities. This is not only a way to provide better healthcare, but also to minimize costs to uniform digital solutions. Doctor-Patient relations have already changed due the developments brought by Smart medicine. Further developments come to place with the active processes that bring Artificial Intelligence (AI) technologies into the medical field. It should be noted here that AI is not one technology, but rather a collection of them; and thus, specific processes and tasks that they support can vary widely [1]. The numerous uses of AI are already changing and will change even more the relationship between the patient and the doctor. AI systems can be beneficial for doctors and patients, as they can provide them with new tools and opportunities. However, many ethical and legal challenges need to be resolved, such as obtaining informed consent to the use of AI, security, reliability and reliability of data sets, transparency of algorithms, algorithmic fairness and impartiality, data ownership, data confidentiality. We will look at these issues in our paper.

Artificial Intelligence and how it Can Be Useful for Doctors and Patients

Today, artificial intelligence is widely used in various fields of medicine, appropriate systems are developed by many scientists and companies. The usage of AI in medicine has a number of potential benefits to both doctors and patients. Patients can benefit from the application of AI systems from the point they get access to medical services. Today, in the emergency medical centers of hospitals, the order of admission of patients depends on how urgently the patient needs help. New technologies, e.g., special apps with AI system in it, can analyse patient's symptoms in order to determine the degree of urgency. AI can accelerate the diagnosis process and medical research; thus, patients can have benefits from AI during patient's care. And even the patients are not in the medical institutions, they can anyway get personalized information and advice, for example, in case AI systems are used in chat-bots and provide answers to patient's request. Thus, even when the patients are at home, they can use digital tools and modern telemedicine to get necessary advice, answers and prescriptions.

On the other hand, it helps doctors enhance their abilities in provision of healthcare services and solve a variety of problems:

- Assistance in making personalised diagnoses and prescribing treatment. For example, AI systems can analyse data from Electronic Health Record (EHR) systems, biosensors, watches, smartphones, conversational interfaces and other instrumentation, software can tailor recommendations by comparing patient data to other effective treatment pathways for similar cohorts [2].
- Real-time data analysis of critically ill patients. This analysis may predict the risks of developing medical complications or conditions such as sepsis and ARDS, or use of clinical and physiological data to aid in the monitoring of patients undergoing ventilatory support [3].
- Assessing the likelihood of complications of diseases. Using AI and machine learning technologies, medical researchers can identify the relationship between the patient's diseases, the conditions in which he lives, and his habits. Even the state of the environment can help to establish which patients in a given region are at the highest risk. It is also possible to find the most vulnerable regions or segments of the population, which can help to give them recommendations in advance, before serious medical care is required [4].
- Remote first aid. It may include real-time analysis, so as to prevention or notification of possible negative tendencies in their health conditions.

Application of AI can be valuable also in the process of overcoming patient's non-compliance and absent of proper involvement into the process. As some studies show, less than 25 % of the patient are highly engaged in the healthcare process [5]. This means that patients do not take prescriptions, do not follow instructions from doctors and do not comply with the requirements of doctors. This can significantly influence the quality of the medical service. AI systems are viewed as a way to change patient's behaviour, as they can analyse and address patient's needs, by alerting patients at proper times, by providing them with targeted information and content to provoke actions and compliance with recommendations [6].

The application of AI system is Smart medicine is a reality which needs to be assessed from various points of view. However, there's a very important question which arises when we discuss the creation of any E-health system in the context of Smart medicine: who is the true owner of medical data of a concrete patient? Who is owner of Electronic Health Record of a patient? Who can dispose of them (patient, doctor, clinic, insurance company, employer, or computing service) and to what extent? These are the questions that are important not only from theoretical point of view; they need to be addressed and solved in practice, and necessary legislative amendment might be necessary to regulate in detail all the relations of the parties concerned so as to ensure security and personal health data protection. There are two main types of formation and storage of data about patient health in Electronic Health Record:

- Hospital-oriented system when EHR is owned by a hospital (polyclinic).

- Patient-oriented system when a patient is the owner of his EHR. It is he who decides what to store, where to store and to whom to give access to his EHR.

We considered the first case in our work [7]. In this paper, we pay more attention to the patient-oriented system. Thus, we will discuss the issues that are connected with the said approach, e.g., right of patient to obtain information about his health, to give informed consent to the application of AI, diagnosis and liability.

Patient and his Communication with AI and Doctor in Smart Healthcare

The patient oriented EHR system allows a patient to generate, administer and manage medical data from one central location using online technologies, which makes resource storage, retrieval and sharing extremely efficient. Each patient has absolute control over their medical records and can share medical data with a set of consumers, such as medical report providers, family members and friends. Although it is simple to provide access to EHR to anyone and everyone, there seems to be a number of security and privacy issues. The main cause of concern is whether patients have absolute control over their EHRs [8]. The ideal EHR includes personal medical information from various sources and provides complete and accurate personal medical information via the Internet or portable media, while maintaining security and confidentiality [9]. Cloud servers' merit specific attention. Many EHR system are transferred to data storage on cloud servers as a result of the advent of cloud computing, which allows for more flexible use of resources and lower operating costs. However, when placing EHR data in the cloud, patients will face privacy issues. External cloud storage systems are often vulnerable to various attacks. It is extremely important to have precise "data access control" that works with untrusted servers to ensure that users (patients) manage their own EHRs. Thus, before storing data in cloud, it is advisable to encrypt it [10]. The EHR owner must choose how to encrypt the data and who has access to it. Only users who have been provided with the decryption key can access the EHR, while the rest of the clients must remain confidential. In addition, the patient should always be able not only to log in, but also to get authorization permission when he believes that it is really required. However, with such extensibility of the EHR system, patient-centered privacy is often at risk. Thus, it may be difficult to ensure proper access to medical information while maintaining flexibility and responsiveness in the encryption process [11].

Secure sharing of personal health records in the cloud is an area of specific concern, as patients are sometimes allowed to upload encrypted EHRs to the cloud, giving users access to certain parts of the EHR [12]. The owners grant each user in a group of users of a later type of access to the EHR to a certain extent, depending

on the role of the user. Another important requirement of "patient-oriented" EHR is that each patient has a specification about who has access to their personal EHR information. The EHR may be banned for some users [13].

Privacy and Security Concerns in Smart Healthcare

Medical information is a private area, which is even considered intimate by many people, so patient confidentiality is the most important issue. Thus, it is not only highly desirable, but strictly important to ensure that there are appropriate security measures in place, as digital data can be easily transferred anywhere in the world, as this is the mechanism of functioning of global networks. Storage and transmission of medical results, medical analysis and tests requires specific attention. Doctors need to ensure that they will not disclose private and sensitive information about the patient to any third party, as it is very simple when new devices are used, and there are many perpetrators that try to obtain this information [14]. Security is one of the most serious problems for artificial intelligence in healthcare. To realize the potential of AI, developers need to make sure of several key things [15,16]:

- a) Reliability and reliability of data sets: the data sets used must be reliable and valid, because the better the training labeled data, the better the AI will work.
- b) Data sharing: the need for huge amounts of data for analysis requires extensive data sharing.
- c) Ensuring the transparency of algorithms: in the interests of the safety and trust of clinicians and patients, it is necessary to ensure some degree of transparency of algorithms, although in the real world there are problems related to the protection of investments and intellectual property, as well as cybersecurity.

Many AI systems that operate in healthcare rely on the existence of the big amounts of sensitive data, which sometimes conflicts with the data protection legislation. Of course, the data can be depersonalized, especially for the reasons of scientific research and big data analysis, which is often performed by AI. By performing depersonalization of data (anonymization), we will get both confidentiality and data integrity. This data will be useful for introducing innovations and strengthening cooperation between suppliers and partners, which will also benefit smart city medicine, including through the exchange of knowledge between doctors from around the world.

Informed Consent for AI Application in Smart Healthcare

A right to seek, receive and impart information and ideas through any media and regardless of frontiers is one the major human rights enshrined in Article 19 of the Universal Declaration of Human Rights. The right to access one's personal information is not

only part of respect for basic human dignity, but it is also central to effective personal decision-making; for example, access to medical records, for example, can help individuals make decisions about treatment, financial planning and so on [17]. Does the patient need or has the rights to give access to the information about the application of AI in diagnosing his or her condition? This is a question to be answered.

Issues related to obtaining informed consent for the use of AI:

- Under what circumstances should the doctor notify the patient that AI is generally used for diagnosis, diagnosis and choice of treatment method?
- Under what circumstances should the principles of informed consent be applied in the field of AI?

It is also needed to consider the limits of the provision of information on AI to public. AI might take important decisions as to one's health. Many algorithms rely on very complex and difficult to deconvolute mathematics, sometimes called the "black box". In the medical area there are situation where it can be extremely important to know the reasons for decisions because they can affect not only patient's health, but his life in general. But can a patient ask to have the algorithm disclosed? On one hand, a patient who is diagnosed with a severe condition using AI system, or received a specific prescription (presumable, on the basis on big data analysis by AI) might be interested in knowing the reasons and algorithm that formed the basis for the decision.

On the other hand, the developer of the appropriate AI system might also have ground to object to such disclosure, so as to protect his investments and effort, as he might be afraid that in such a way his competitors will discover his know-how and violate other IP rights, including reverse engineering of the software. Let us look at one example from another sphere. In a *Wisconsin v. Loomis* case (USA), a criminal defendant challenged a state trial court's use of a (non-machine learning) risk assessment algorithm (developed by a private company) to determine his sentence. He argued that his due process rights were violated, as the company refused to disclose how the risk score there determined, claiming that information was a "trade secret", and due to the "proprietary nature" of the algorithm he could not assess the information that was used for sentencing. The Wisconsin Supreme Court rejected the defendant's arguments, stating that the company had the right to protect its proprietary information; and it release sufficient information that satisfied due process requirements [18].

However, sometimes knowing of the algorithm is important, as it can be a way to overcome a so called "algorithmic bias", which is cases by the decisions of AI which are based on factors that should not be in fact relevant to the case. For example, training data can be

biased because they are based on discriminatory human decisions. Such situation occurred at a medical school in the UK in the 1980s, where a computer program was introduced to sort the applications. The training data were the admission files from earlier years, when selection of the applications was done by persons. And it turned out that computer program discriminated against women and against people with immigrant background [19]. Another possible algorithmic bias can be caused by the under-representation of poor people in a data set; poor people are less likely to have smartphones and other smart devices, and lower possibilities of access to paid medicine services in general, thus they might not be fully taken into account in the medical studies. Attentions should also be given to the ways of overcoming the so-called "automation bias". Automation bias is a tendency to believe computers without additional consideration of the results; as human decision-makers tend to follow computer advice, either because they try to minimize their responsibility, or because they do not have enough time, context or skills to make an adequate decision in the individual case [20]. Thus, it is important to properly train doctors and other medical workers so as to ensure that they do not trust the AI algorithms blindly and take due care so as to ensure the accuracy of the results, taking into consideration other possible options.

Diagnosis-Making Using AI Systems and Liability

The most AI systems are used to help doctor to make a diagnosis. Most of diagnosis in medicine are made based on analysis of medical images. The use of AI in the analysis of medical images is under continuous evolution. There are already very good results that are shown by AI systems in detection of skin cancer: in 2017, the case was reported were researchers have trained a neural network (a dataset of 129450 clinical images consisting of 2032 different diseases was used); and the neural network achieved performance on par with all tested experts, demonstrating that AI was capable of classifying skin cancer at a level of accuracy comparable to that of dermatologists [21]. As some reports show, the impact of AI is especially relevant in neuroscience (neurosurgery, neurology). This area is based on the combination of AI-mediated technologies with advances in photonics (merging of applied optics and electronics) and engineering, together with other clinical disciplines (pharmacology, psychology) and related sciences (biology and genetics, biochemistry) [22]. AI systems are able to analyse complex data, moreover, they need data to learn and to operate properly. The quality of data affects the quality of the outcome. One part of the problem is the time and expenses that are needed to collect and insert this data into appropriate AI system in healthcare [23]. It is especially problematic in situations when patient's data are stored in different institutions in a random way and incompatible formats, thus requiring additional resources for their collection and standardization.

As we discuss diagnosis, we can briefly note one more issue. AI systems can also create a new method of remuneration of medical workers. At the moment, doctors are encouraged to have many visits from patients, and take multiple tests (which are often viewed as unnecessary and burdensome), and thus basically their work is assessed on the volume of treatment, which is then reflected in the remuneration. AI systems might be able to assess the value of the treatment for the patient, that is, whether the treatment was successful or not, and how the strategy which was proposed by the doctor influenced patient's condition in general. It is expected that a value-based remuneration will provide additional incentive for doctors to improve their skills and knowledge [24]. Another question: can a doctor rely entirely on AI? One of the common mechanisms of application of machine learning (which is a form of AI) in healthcare is precision medicine, that is, predicting what treatment protocols are likely to succeed on a patient based on various patient attributes and the treatment context; this requires a training dataset for which the outcome variable (e.g. onset of disease) is known (so called "supervised learning" [25]). However, the cognitive systems have problems with the quality and volume of medical information. The data accumulated in patients' medical records may be incomplete, contain errors, inaccuracies, and non-standard terms. There are not enough records of the patient's life, habits, and behaviour. Effective mechanisms for collecting this information do not yet exist. In addition, many of the AI algorithms are considered as black box in which the decision-making process is hidden in network layers. This can be problematic especially in situations that are not present in data set used to train AI algorithms, which will likely result in inaccurate AI decisions.

Application of AI in healthcare thus causes concerns when we think about possible liability issues. We agree with the research that say that while it may be fairly easy to identify a wrongful act or effect resulting from the use of an AI system, it will often be less straightforward to identify the blameworthy actors [26]. Specifically, criminal liability generally requires showing knowledge or intention of the relevant actors, and it is clear that AI systems have no such mental state [27]. In case AI itself bears no legal liability, who is going to be liable? Which criteria do we need to use to choose the guilty one? Can be a doctor that relied on AI assistance? Or a technical worker that inserted, maybe unintentionally, wrong data, which lead to the wrong results? Or shall we put blame on the software developer, who did not think about possible options and did not teach AI system properly? This all-causes concerns and leads to the certain degree of unpredictability. However, it clear that legal solutions to these issues need to be further discussed. One the possible ways which is proposed by some scholars it to rethink the liability principles, so as maybe to split liability between

manufacturers of AI systems (they can be held liable for their product causing harm under the general product liability regime), physicians and patients [28]. There are already some developments in the legal sphere in considering liability for the actions of robots; e.g. under German tort law the following principles apply:

- There can be no fault-based liability if the malfunction of the robots is not foreseeable to the person using it;
- Liability is excluded if the patient has consented to the use of the medical robot; however, the patient is to be informed beforehand about all the circumstances and risks of the medical intervention, and also about all the alternative treatment measures which are equal at the achieving of the same treatment goal [29].

Of course, as robots "do not make independent movements and do not make their own decisions, but are completely controlled by the operator", current law does not have any gaps in liability in this respect [30]. AI systems are of course different due to their nature. However, the approaches described above might be taken into consideration in developing legal rules on liability for the decisions and actions of AI systems. One of the main questions is: "What data processing can be considered an interpretation that has a real risk of harm to the patient's health?" It is proposed to consider the processing of clinical data about a patient as such an interpretation, as a result of which new, clinically significant information missing from the initial data is produced (formed), which is necessary and used when making a clinical decision and/or performing a medical intervention [31]. It should be noted here that there's no doubt that mistakes are inevitable. As some studies show, even not, according to data collected from several EU nations, medical errors and healthcare related adverse events occur in eight to twelve percent of hospitalizations; preventing such mistakes could help to prevent more than 3.2 million days of hospitalization each year within the EU [32,33]. Thus, application of AI by doctors needs to be done in such a way that minimizes the possibilities of mistake.

Having said that, it is important to note that legal regulations should also aim at taking due account of situations when AI technologies are used for evil purposes. For example, there's a risk that medical worker would like to introduce changes into human genome or make other illegal activities. Thus, it is necessary to introduce appropriate safeguards, so as to ensure that patients are not at risk when there's application of AI technologies by doctors. This may be achieved by introduction of specific forms of notification of authorities and control mechanism. And of course, it is necessary to raise patient's awareness so that they know the signs that can show that there can be danger in dealing with the specific medical institution.

Conclusion

In this article, our intention was to consider AI use in Smart Healthcare from two different aspects: information technologies and legislation. There's no doubt that information technologies are actively developing and will make medicine much more effective and will help people to have healthier life. However, at the moment legislative framework has not yet been fully adapted to the new reality where medical professionals increasingly rely on AI systems. In our mind, any further improvements to the legal framework of Smart Healthcare, need to be based on the study and development of the following aspects of the legislation:

- Defining responsibility rules for medical doctor, AI and patient in making diagnosis and choosing the treatment.
- Increasing the role of the patients in Hospital Information Systems, as a condition for the development of personalized medicine, with the possibility of limiting access to their Electronic Health Records.
- The right to information about their health and free access to information affecting the freedoms, rights, duties, interests of the patient, including the use of mobile applications.
- The use of web-services, remote interaction between the doctor and the patient through a variety of means: social networks, smartphone, tablet, etc.
- The protection of personal data and legally defined secrets.
- So, the triad: medical achievements, information technology and advanced legislation will change the medicine of the future.

Conflict of Interest

The authors declare no conflict of interests.

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