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Digital Medicine: Bioethical Assessment of Challenges and Opportunities

SUMMARY

The digital health industry is developing rapidly: many new subjects are involved in the field of medicine; new opportunities for distant medical services, diagnostics, monitoring of patients' health, and conducting medical research are emerging; electronic medical documentation is being developed, global medical information databases are being formed, etc. At the same time, the format of doctor-patient relationships is being transformed and new issues and challenges arise that require ethical evaluation. I identified three areas of digital medicine and analyzed issues of confidentiality, informed consent, autonomy and equity in each case. The impact of digital health technologies on the ethical contexts of medicine is uneven: telemedicine possesses the smallest revolutionary potential, which changes the mechanisms of doctor-patient interaction and actualizes issues of cultural differences. mHealth technologies significantly affect patient autonomy and change ways of sharing medical information. Artificial Intelligence (AI) is diverse in medicine, it can depersonalize relationships in medicine, radically change ideas about the role of the doctor and patient, lead to a radical restructuring of the medical care system in the center of which will be the new model of patient interaction with automated medical agents and systems.

Keywords: bioethics, digital health, telemedicine, mHealth, artificial intelligence (AI).

1. INTRODUCTION

Health digitalization is a reflection of the widespread trend of information and communication technologies spreading to all areas of life. The market of medical applications, devices, and services is growing very rapidly, and with it the digital health industry is developing quickly. In addition to traditional subjects – doctors,

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patients, medical organizations, and insurance companies – more and more new ones are involved in the provision of actors: software developers, producers of information technologies, site administrators, cloud services operators, Internet access providers, and others.

ICTs create unprecedented opportunities for distance medical services, diagnostics, health monitoring, organizing distance panel of doctors, electronic medical records, medical research, and so forth. Currently, the positive potential of medical innovations is obvious – easy access to medical services, receiving recommendations and prescriptions without waiting lines, prompt support of medical care solutions, monitoring many health parameters, and so on. In addition, digital health technologies are influencing the formation of new lifestyles that extend the individual's responsibility for health.

However, new opportunities, like new actors of medical care, are causing new issues and challenges that require ethical evaluation. To understand the specifics of ethical issues, I identified three areas of digital medicine and explicated issues of confidentiality, informed consent, autonomy, and justice in each case.

2. TELEMEDICINE

According to WHO statement made in Geneva in December 1997: “Telemedicine is the delivery of health-care services, where distance is a critical factor, by health-care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, and for the continuing education of health-care providers as well as research and evaluation, all in the interests of advancing the health of individuals and their communities”.¹ Four elements are pertinent to telemedicine: 1. Its purpose is to provide clinical support. 2. It is intended to overcome geographical barriers, connecting users who are not in the same physical location. 3. It involves the use of various types of ICT. 4. Its goal is to improve health outcomes.² The opportunity of telemedicine can be classified according to the participants of interaction: health-care

1 World Health Organization (1998). *A health telematics policy in support of WHO's Health-For-All strategy for global health development: report of the WHO group consultation on health telematics, 11–16 December, Geneva, 1997*. World Health Organization: Geneva 1998.

2 World Health Organization (2010). *Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth*, 9, https://www.who.int/goe/publications/goe_telemedicine_2010.pdf (accessed: 15 December 2018).

provider – health-care provider or health-care provider – patient. Telemedicine can also be used to provide ethical counseling services.³

The advantage of telemedicine is to reduce the cost of health care, the provision of services that may be even better than those that will be available personally. In addition, telemedicine corresponds to the speed of modernity, as it frees the patient from a personal visit. However, the development of telemedicine has some barriers, primarily legal implications of: licensing; accreditation and registration of providers; reimbursement of the costs of telemedicine services; data protection; jurisdiction, and the potential conflict among differing laws.⁴ Legal issues of telemedicine have ethical aspects, since ethical and legal norms are closely related, and they have certain specificity in different countries.⁵

The relationship between a doctor and a patient was the focus of ethical reflection throughout the history of medicine: from the tradition of ancient healing and Hippocrates to the present. The introduction of ICT in medical care is one of the powerful challenges to the established tradition, which is still far from final understanding. ICT simultaneously reduces and enhances the distance in the doctor-patient interaction. In telemedicine, the first trend is more pronounced. However, in some sense, it is possible to talk about the distance between a doctor and a patient, since personal contact can be replaced by the exchange of video messages. Telemedicine influences the doctor-patient interaction and thus calls into question the traditional values that have supported these relations historically.

The issue of *confidentiality* is related to the protection of communication channels and the need to expand the concept of confidential information, which should include the patient's email address, his login in the communication program, and other identifiers that he transmitted when seeking medical help. Telemedicine erasing geographical boundaries, however, cannot overcome cultural and religious barriers. Cultural differences cause many problems in telemedicine that are common to other areas of medicine. For example, in western countries "the assessment of patients, care plans, and rules governing patient confidentiality are based on the concept of individual rights. In contrast, Arab and Muslim patients are likely to define themselves and their individual worth as relative to, rather than independent of, the rest of their family. Major decisions usually involve all members of the extended

3 Bramstedt, Katrina. A. (2016), International access to clinical ethics consultation via telemedicine, *AMA Journal of Ethics*, 18(5), 521-27.

4 Ionescu-Dima, Catalina. (2013). Legal challenges regarding telemedicine services in the European Union. In: *eHealth: Legal, Ethical and Governance Challenges* (pp. 107-133). Springer, Berlin: Heidelberg.

5 Bates, David W., Wright, Adam (2009). Evaluating eHealth: undertaking robust international cross-cultural eHealth research. *PLoS medicine*, 6(9), e1000105.

family, especially the men”.⁶ Since there is a distance between a doctor and a patient not all cultural differences are evident in telemedicine. Nevertheless, the doctor must understand that religious values and cultural practices may be the basis for cultural conflict, and try to prevent it.

Moreover, the doctor has an obligation to violate confidentiality and inform epidemiological service or the police in some cases. However, confidentiality rules vary in different countries and the doctor does not always have information on how these restrictions should be implemented. For example, according to the medical legislation of Russia, when there are threats of the spread of infectious diseases, mass poisoning and injuries, a violation of medical secrecy is allowed without the consent of a citizen or his legal representative. The list of diseases is well known to doctors and is available on the Russian-language Internet. Physician’s actions, in the case of suspected diseases such as plague, cholera, smallpox, and so on, cause ethical and legal issues in the distant format of patient interaction.

Respect for patient *autonomy* is one of the most important requirements of medical ethics, which is also reflected in eHealth Codes. B. Kaplan⁷ (2016) in the “Telemedicine Needs Ethical Guidelines” states that patients should be involved in the development of telemedicine services in order to provide access for all who need it and policies should ensure the realization of all interests – patients, clinicians, or caregivers. Distant relations in telemedicine do not affect the patients’ autonomy, and therefore there are no new specific issues.

Considering what has been said about cultural differences, the procedure and the form of *informed consent* may be one of the telemedicine issues, which requires more study. The following important aspects can be singled out: firstly, the specifics of informing (the amount of information: linguistic, religious, economic...), secondly, the specificity of the consent expression (for example, oral or written form), thirdly, checking how the patient understood the information that is necessary for consent. Patient’s digital literacy is a separate issue in the field of medicine, in this context it is only necessary to mention that P. Duquenoy et al. showed by the example of British health care, the complication of information transfer and storage methods require the patient to understand how information transfer in the British health care system works to maintain confidence in the system. The change of information transfer and

6 Hammoud, Maya M., White, Casey B., & Fetters, Michael D. (2005). Opening cultural doors: Providing culturally sensitive healthcare to Arab American and American Muslim patients. *American journal of obstetrics and gynecology*, 193(4), P. 1309.

7 Kaplan B. (2016), *Telemedicine Needs Ethical Guidelines*, <https://www.thehastingscenter.org/telemedicine-needs-ethical-guidelines>, (accessed: 05 April 2019).

storage methods cannot consider only organizational perspectives without taking into account patients who need to understand their benefits.⁸

Telemedicine is usually considered as a way to reduce the cost of health care and to democratize medical services. From this perspective, it is certainly an important contribution to solving the problem of *justice*. The most significant issue is the digital divide which is relevant for many types of eHealth. It can be understood both at the state policy and at the patient level. In the first case, the issue is connected with different possibilities of technological support of medicine, and in the second, with the difference in the competences between generations. Older people and people with disabilities cannot fully enjoy all the benefits that telemedicine provides without the support of competent people.⁹ This problem requires deep awareness and understanding, as well as consideration in all situations.

3. mHEALTH

mHealth is a new trend of using mobile communications devices for health services and information. mHealth systems include: mobile phones, tablets, patient monitoring devices, personal digital assistants, and other wireless devices. The market for medical and health applications is growing continuously, which confirms the huge number of downloads on the Apple App Store and Google Play. These technologies allow users to monitor, record and evaluate various parameters, such as menstrual cycles and ovulation patterns. They allow patients to track many body parameters independently and at the same time many devices provide data to the doctor. According to P&S Market Research Global mHealth market is projected to attain a size of \$132.2 billion by 2023.¹⁰ It is important to note that interest in mHealth is not limited to consumers and producers, state health care institutes also support the possibilities of new health care products.

The active mHealth development can be considered in a broad theoretical perspective of faith in medical technology and technological progress in general. B. Hofmann defined it as general belief in technology. As he claims “we tend to believe that the quality of healthcare services is improved by the application of new technology. Patients are satisfied if they are sent to have an MRI, CT, or PET scan or if they

8 Duquenoey, Penny, Mekawie, Nermeen. M., and Springett, Mark (2013). Patients, trust and ethics in information privacy in eHealth. In: *eHealth: Legal, Ethical and Governance Challenges* (pp. 275-295). Berlin; Springer.

9 Wu, Ya-Huei H. et al. (2015). Bridging the digital divide in older adults: a study from an initiative to inform older adults about new technologies. *Clinical interventions in aging*, 10, 193.

10 P&S Market Research (2018). *Global mHealth Market*, <https://www.psmarketresearch.com/press-release/global-mhealth-market> (accessed: 15 December 2018).

are subjected to advanced surgery. On the other hand they are discontented if the physician refuses to take laboratory tests or tells to change their diet or to exercise”.¹¹

mHealth is closely related to self-tracking and “quantified self” cultures, which refer to the different practices of gathering, analyzing, and visualizing personal data related to well-being. It is a new culture of personal data, new understanding of own bodies and new potential for political and cultural impact well beyond that of the weight scale.¹² It is formed in the context of the current cultural moment of the belief that data are superior forms of knowledge, combined with the affordances of modern digital technologies that allow individuals to produce huge masses of data about themselves. These discourses and practices cross with others concerning individualization, reinvention, the neoliberalist privileging of self-responsibility and the importance of attaining knowledge about the self as part of working upon and improving the self. Self-tracking correlates with discourses and practices of other forms of self-optimization, self-improvement, and the increasing responsibility for one’s health.¹³ Some devices collect data automatically, others assume the participation of the patient. At the same time, the user can share his personal data with other people on social networks and related websites where it can be compared with other self-trackers and can be motivation for further use. User behavior is heterogeneous and it is possible to distinguish at least five modes of self-tracking: private (for one’s own purposes only); communal (sharing data with others); pushed (supported by others); imposed (foisted upon people); and exploited (where people’s personal data are repurposed for the use of others).¹⁴

mHealth represents a major feature of prosumption (neologism combining ‘consumption’ and ‘production’) activities creating or sharing health-related content.¹⁵ As D. Lupton pointed out, “where once people were incited to confess their sexual activities to another individual as part of research or a therapeutic encounter, the

11 Hofmann, Bjørn (2002), Is there a technological imperative in health care?, *International Journal of Technology Assessment in Health Care*, 18(3), 681. <https://pdfs.semanticscholar.org/5080/b610ff4bcbd5f5f718fa7e318767ededf0e7.pdf> (accessed: 15 December 2018).

12 Crawford, Kate, Lingel, Jessa & Karppi, Tero (2015), Our metrics, ourselves: A hundred years of self-tracking from the weight scale to the wrist wearable device, *European Journal of Cultural Studies*, 18(4-5), 479-96.

13 Lupton, Deborah (2014a), Self-tracking cultures: towards a sociology of personal informatics. In: *Proceedings of the 26th Australian Computer-Human Interaction Conference on Designing Futures: the Future of Design*, 77-86.

14 Lupton, Deborah (2014b). *Self-tracking modes: Reflexive self-monitoring and data practices*. Available at SSRN 2483549.

15 Beer, David and Burrows, Roger (2010), Consumption, prosumption and participatory web cultures: An introduction. *Journal of Consumer Culture*, 10 (1), 3-12.

existence of apps that are able to record, document and communicate sexual and reproductive data brings intimate revelations to a potentially far greater audience”.¹⁶

Public posting of medical information can change the conception of confidentiality progressively. People do not keep health information in secret, but instead share it on different sites and show others the benefits of such an exchange.

Undoubtedly, mHealth devices expand *autonomy* and free choice space, allow patients to be “more effective managers of their health and healthcare”.¹⁷ Independent health monitoring, a lot of information on the Internet, and self-diagnosis show the specifics of the transition from ‘mechanical’ medicine to ‘informational’ medicine.¹⁸ The expansion of autonomy is important for the transfer of responsibility from health institutions and medical partners to an individual. But this process has a different side, which is connected with the understanding of the doctor’s attitudes towards the expansion of patient’s autonomy.

A significant part of mHealth apps is a collection of various medical information or mHealth apps contain a link to sources with *information*, so “today a patient, with the help of technology, might seek out the doctor not for the purposes of deciding the diagnosis, but rather for endorsing a diagnosis she or he brings to the consultation”.¹⁹ However, a lot of information will not automatically lead to the ability to diagnose accurately and choose the right actions. Overvaluation the patient’s own knowledge may have different consequences. For example, it can also become the basis for suspicious behavior, lead to excessive attention to oneself, the constant monitoring of some parameters. Therefore, health care professionals should take into account the patient’s readiness to use the medical devices to good advantage. In addition, they must inform about diagnostic limitations of smartphones programs, especially if they have the potential to delay the diagnosis and to harm users.²⁰

The first mobile phones were exclusive and emphasized the economic opportunities of the owners. The gradual decline in prices for telephones and other electronic devices has led to a universal access. The ICT revolution has affected the field of medicine, providing unhindered access to new medical device capabilities. In terms

16 Lupton, Deborah (2015), Quantified sex: a critical analysis of sexual and reproductive self-tracking using apps, *Culture, health & sexuality*, 17(4), 440-53.

17 Greene, Jessica, and Hibbard, Judith H. (2012), Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes, *Journal of General Internal Medicine*, 27(5), 520.

18 Nettleton, Sarah (2004), The emergence of e-escaped medicine?, *Sociology* 38(4), 661–79.

19 Lupton, Deborah, and Jutel, Annemarie (2015), ‘It’s like having a physician in your pocket!’ A critical analysis of self-diagnosis smartphone apps, *Social Science & Medicine*, 133, 129.

20 Wolf, Joel A. et al. (2013). Diagnostic inaccuracy of smartphone applications for melanoma detection. *JAMA dermatology*, 149(4), 422-426.

of *justice*, mHealth progress is a social good. Bridging the digital divide between generations and between regions will maximize the benefit of mHealth.

4. ARTIFICIAL INTELLIGENCE

Artificial Intelligence (AI) technologies are actively spreading in all spheres of our lives, therefore their appearance in medicine is expected and understandable. Big companies, like Google, Microsoft, and IBM are investing in the development of AI for healthcare and research. The number of AI start-up companies has also been steadily increasing.²¹ A think tank “Future Advocacy” conducted a detailed review of the existing literature, interviewed more than 70 experts all round the world and identified five types of use-cases for artificial intelligence technologies in health and medical research: process optimization; preclinical research; clinical pathways; patient-facing applications; population-level applications. Interestingly, the interview participants and the patient roundtable described AI as a “third participant” in the previously binary patient-HCP dynamic.²² Ethical challenges of AI in medicine are gradually entering the field of theoretical analysis of bioethics. Mark McQuain drew attention to this and posted on the blog “bioethics.net” that AI is not ethically neutral and requires the attention of bioethicists.²³

Nuffield Council on Bioethics identified the following ethical issues: the potential for AI to make erroneous decisions; the question of who is responsible when AI is used to support decision-making; difficulties in validating the outputs of AI systems; inherent biases in the data used to train AI systems; ensuring the protection of potentially sensitive data; securing public trust in the development and use of AI technologies; effects on people’s sense of dignity and social isolation in care situations; effects on the roles and skill-requirements of healthcare professionals; and the potential for AI to be used for malicious purposes. According to Nuffield Council on Bioethics a key challenge will be ensuring that AI is developed and used in a way that is transparent and compatible with the public interest, whilst stimulating and driving innovation in the sector.²⁴

21 From Virtual Nurses To Drug Discovery: 106 Artificial Intelligence Startups In Healthcare (February 3, 2017), <https://www.cbinsights.com/research/artificial-intelligence-startups-healthcare>, (accessed: 15 December 2018).

22 Future Advocacy. Ethical, Social, and Political Challenges of Artificial Intelligence in Health, <https://wellcome.ac.uk/funding/ethical-social-and-political-challenges-using-artificial-intelligence-healthcare>, (accessed: 15 December 2018).

23 McQuain M. (2017), *Is medical artificial intelligence ethically neutral?*, <http://www.bioethics.net/2017/11/is-medical-artificial-intelligence-ethically-neutral/> (accessed: 15 December 2018).

24 Nuffield Council on Bioethics (2018). Nuffield Council on Bioethics. Artificial intelligence (AI) in healthcare and research. <http://nuffieldbioethics.org/wp-content/uploads/Artificial-Intelligence-AI-in-healthcare-and-research>.

The *confidentiality* concerns of medical applications of AI are similar to those in other types of eHealth. They focus on the protection of personal information and medical data, the need to revise the concept of confidentiality, taking into account the emerging patient information exchange practices and new actors of medical care (for example, system administrators).

Automated decision-making systems will enhance patient *autonomy*, and one can even say, will strengthen the patient's independence from the doctor. They can enhance the ability to make independent decisions for people with chronic diseases, as well as for healthy people to choose further actions.

The prognostic potential of AI technology in medicine will be of great importance for enhancing preventive strategies, since it is obvious that it is easier to prevent than to cure. AI medical applications at the same time increase freedom, and may have a negative impact on autonomy, limiting the choice of options and not taking into account the interests of users.

If the AI systems are used to make a diagnosis or develop a treatment plan, but the medical professional cannot explain how they were obtained, this can be considered as restricting the patient's right to make free, informed decisions about health.²⁵ One of the key issues of using AI is the errors that may occur. Excessive trust in automated systems can lead to doctors losing their vigilance and missing system errors.

The active use of electronic devices in various spheres of society has already created some prerequisites for the use of automated systems in medicine, building patient confidence in non-human agents. However, further study is required to inform patients about the possibilities and limitations of AI medical systems. Some authors believe that certain applications that mimic a person may mislead the patient about who he communicates with. Accordingly, it can be perceived as a form of deception.²⁶

It is known that the doctor-patient interaction is based on trust, emotional contact, and confidence in the doctor's sincere desire to help. AI has the potential to gradually transform and depersonalize relationships in medicine, to increase the social isolation of patients. In traditional medicine, the quintessence of the solution is in the space of personal communication, the patient can clarify everything in the process of interaction with the doctor. In high-tech medicine, *informed consent* can become interactive.

research.pdf, (accessed: 15 December 2018).

25 Mittelstadt B (2017), The doctor will not see you now. In: Otto, P., and Gräf E., eds, *3THICS: A reinvention of ethics in the digital age?*, iRights Media.

26 Wallach, Wendell, and Allen, Colin (2008). *Moral machines: Teaching robots right from wrong*. Oxford University Press.

AI medical systems can lead to more rapid creation of new drugs and methods of treatment, reduction of waiting lists for help, which is a public good, and contributes to social *justice*. At the same time, however, further research and national and global programmes are needed to ensure that the potential of new technologies does not become the basis for increasing health inequalities.²⁷

6. CONCLUSION

'Digital health', 'eHealth', 'Medicine 2.0' or 'Health 2.0' all of these terms reflect the new reality of medicine, which can be explicated in the bioethical coordinates of confidentiality, information, autonomy and justice, covering the doctor-patient relationship. The problem of confidentiality in digital medicine is primarily concerned with the protection of communication channels and ensuring the secrecy of information. The concept of confidentiality is expanding as it includes such electronic identifiers of a person as a username, or/and e-mail. However, it can gradually change its meaning for those patients who actively share information about their health on different platforms.

All areas of digital health have an impact on patient autonomy, but the range of empowerment varies. At present, an individual can use a variety of applications to control his body, and he can also get relevant medical information from various sources in order to make independent decisions about his health, to be a more effective manager of his health. However, active involvement in "taking care of oneself" means expanding responsibility for one's health, which in the future may mean a radical redistribution of responsibility between health institutions and patients.

ICT not only expands the channels of communication, but also the flow of information, the sources of information, which are important for more effective communication in health care. However, informing is not a one-way translation of knowledge, it implies an understanding, namely verification of the patient's understanding, his awareness of various aspects of information and understanding of the results of decisions and choices. Automated systems of medical care can update the reformatting of information procedures or lead to an interactive electronic decision-making process to ensure complete and adequate information.

Medicine 2.0 is considered by the majority of authors as a social good that allows solving economic, geographic and other obstacles to free and universal access for all, and enables more equitable and efficient use of medical resources. At the same time,

27 Barreto, Mauricio L. (2017). Health inequalities: a global perspective. *Ciência & Saúde Coletiva*, 22(7), 2097-2108.

there is the digital divide issue, which can be explicated both at the state level and at the patient level. In the first case, the problem lies in the inequitable resources that countries can invest in high-tech systems for diagnosing, analyzing and processing information. In the second case, the inequality of competences between generations is important. Thus, medical and social authorities are faced with the task of eliminating or reducing this gap.

In the optics of the four bioethical principles, it becomes obvious that telemedicine possesses the smallest revolutionary potential that changes the mechanisms of doctor-patient interaction and actualizes the issues of cultural differences. mHealth technologies significantly affect patient autonomy and change ways of sharing medical information. AI is diverse in medicine, it can depersonalize relationships in medicine, radically change ideas about the role of a doctor and a patient, lead to a radical restructuring of the medical care system in the center of which will be the new model of patient interaction with automated medical agents and systems.

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Digitalna medicina: bioetička procjena izazova i mogućnosti

SAŽETAK

Digitalna zdravstvena industrija ubrzano se razvija: mnogi novi subjekti uključeni su u područje medicine; pojavljuju se nove mogućnosti medicinske usluge na daljinu, dijagnostiku, praćenje zdravlja pacijenata i provođenje medicinskih istraživanja; razvija se elektronička medicinska dokumentacija, formiraju se globalne baze podataka o medicinskim informacijama itd. Istodobno se mijenja format odnosa liječnik - pacijent i pojavljuju se novi problemi i izazovi koji zahtijevaju etičku procjenu. Identificirala sam tri područja digitalne medicine i analizirala pitanja povjerljivosti, informiranog pristanka, autonomije i pravednosti za svaki slučaj. Utjecaj digitalnih zdravstvenih tehnologija na etičke kontekste medicine neujednačen je: telemedicina ima najmanji revolucionarni potencijal koji mijenja mehanizme interakcije liječnik - pacijent i aktualizira pitanja kulturnih razlika. Tehnologije mZdravlja značajno utječu na autonomiju pacijenta i mijenjaju načine dijeljenja medicinskih informacija. Umjetna inteligencija (UI) je različita u medicini, može depersonalizirati odnose u medicini, radikalno promijeniti ideje o ulozi liječnika i pacijenta, dovesti do radikalnog restrukturiranja sustava medicinske skrbi u čijem će središtu biti nov model interakcije pacijenta s automatiziranim medicinskim sredstvima i sustavima.

Ključne riječi: bioetika, digitalno zdravlje, telemedicina, mZdravlje, umjetna inteligencija (UI).