REVIEW ARTICLE

CONTENTS

Personal data protection in mHealth apps: international experience and prospects for legislative changes in Ukraine

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ABSTRACT

Aim: This study aims to analyze the legal aspects of mHealth apps in Ukraine, focusing on personal data protection and the effectiveness of the current legislation. The paper also zeroes in on examining international personal data protection standards and offers recommendations for improving the respective Ukrainian legislation.

Matherials and Methods: we employed method such as Overview to study Ukrainian and foreign legislation on personal data protection.

Conclusions: The study highlights the shortcomings in the legal regulation of mHealth apps in Ukraine, which creates risks to the privacy of users' personal data. To ensure the safe use of mHealth apps, it is necessary to implement international standards for protecting personal data, taking into account the experience of the United States, Canada, and the EU. Improving the legislation will help increase user confidence in mHealth apps and favour the interaction between patients and healthcare providers.

KEY WORDS: e-health, human rights, digital technologies, Ukraine

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INTRODUCTION

The term «mobile health» (mHealth) typically refers to the utilization of mobile telecommunication technologies essential for delivering healthcare services and promoting overall health maintenance [1].

It has to be emphasized that mHealth apps, like other digital products, should properly handle users' personal data. In this context, important are studies which estimate handling personal data of users of mHealth apps through the prism of different regulatory acts, such as General Data Protection Regulation (GDPR) [2-3] or Policy for Device Software Functions and Mobile Medical Applications [4]. There are also studies that analyze regulatory policies regarding mHealth apps in the USA, the European Union, France [5], Canada [6], Ireland [7], etc. Despite this, it is not clear whether the norms of Ukrainian law sufficiently address the use of mHealth apps. That is why we examine mHealth apps with the Ukrainian-language interface. On the other hand, we also explore the norms of Ukrainian law in the context of their possible implementation to regulate relations arising in connection with the use of mHealth apps.

AIM

This study aims to analyze the legal aspects of mHealth apps in Ukraine, focusing on personal data protection and the effectiveness of the current legislation. The paper also zeroes in on examining international personal data protection standards and offers recommendations for improving the respective Ukrainian legislation.

MATERIALS AND METHODS

In the course of our study overwiev method was employed, in order: to examine legal aspects which concern the use of mHealth apps in Ukraine.

We overviewed Ukrainian legislation in order to determine the legal norms that apply for the regulating of mHealth apps in Ukraine. To look for legislative acts, we referred to the «Legislation of Ukraine» platform on the website of the Supreme Council of Ukraine; we searched for normative-legal acts using the search engine on the website of the Cabinet of Ministers of Ukraine, as well as for orders issued by the Ministry of Health of Ukraine with the help of the search engine on the website of the Ministry of Health of Ukraine.

The main aim of our searchings was to find legal norms that regulate issues related to mHealth, electronic health care system, data privacy and personal data protection. It is due to this that we were supposed to determine the standards for the use of mHealth apps and handling confidential data of users of such apps.

REVIEW AND DISCUSSION

There has been determined the list of laws and legal acts which regulate relations arising from the use of mHealth apps in Ukraine.

THE LAW OF UKRAINE «ON PROTECTION OF PERSONAL DATA»

First of all, this law states that personal data are the object of protection. Additionally, the Law determines that personal data can be processed no longer than is necessary for legitimate purposes, and also determines the grounds for deleting personal data [8].

Article 7 of the Law states that for the purposes of healthcare, personal data are processed, in particular, in the case of:

- «establishing a medical diagnosis to ensure care or treatment or provision of medical services, monitoring of compliance with the set conditions for providing such services (including the terms of contracts on medical service to the population and contracts on reimbursement under the program of medical guarantees), the functioning of the electronic health care system, provided that such data are processed by a health practitioner, a rehabilitation expert or another person from a health care institution, a rehabilitation institution or an individual entrepreneur who received a license to carry out economic activities in medical practices, and its employees who are entrusted with the responsibility of ensuring the protection of personal data and are subject to medical privacy law, employees of the central executive body that implements state policy in the field of state financial guarantees of medical care for the population, employees of an institution that carries out state sanitary and epidemiological supervision and activities in the field of public health, which received a license to carry out economic activities in medical practices, who are entrusted with the duties of ensuring the protection of personal data» [8].

Instead, in accordance with Article 8 of the Law, to the rights of subjects of personal data belong: 1) to know about the sources of collection, the location of their personal data, the purpose of their processing, the location or place of residence (stay) of the owner or manager of personal data; 2) to receive information about the conditions for providing access to personal data, in particular information about third parties to whom their personal data are transferred; 3) to withdraw consent for personal data processing [8].

It is obvious that these provisions apply to any field of activity. Mobile apps are no exception and must meet the established requirements, in particular, we are talking about the provisions of Articles 7 and 8 of the Law mentioned above.

THE LAW OF UKRAINE «ON INFORMATION»

The law of Ukraine «On Information» equates personal data with information about an individual. This law also defines information about an individual, which means «data or an aggregate of data on an individual, who is identifiable or can be specifically identified» [9]. Additionally, the law states the need for state and public control over compliance with information legislation. The types of legal liability for violation of information legislation are defined as follws: disciplinary, civil, administrative or criminal ones.

THE LAW OF UKRAINE «ON ACCESS TO PUBLIC INFORMATION»

This law defines confidential information: «confidential information is information, access to which is limited by an individual or legal entity, except for government entities, and which can be distributed in the order determined by them at their will in accordance with the conditions stipulated thereby» [10]. This is important due to the fact that personal data actually belong to the category of confidential information.

THE LAW OF UKRAINE «ON MEDICINAL PRODUCTS»

This law, in particular, regulates issues related to distance trade of medicinal products [11]. The law obliges economic entities that have the right to carry out electronic retail trade of medicinal products to ensure the confidentiality of consumers' personal data. It is not determined though whether such electronic retail trade can be carried out using mobile apps.

ON THE FUNDAMENTAL PRINCIPLES OF THE UKRAINIAN HEALTH LEGISLATION

This law determines the possibility of the functioning of the electronic health care system in Ukraine. Article 24^2 of this

law specifies that: «Access to information about the patient located in the electronic health care system is possible only in the case of obtaining the consent of such a patient (his / her legal representative) in a written form or the form which enables drawing a conclusion that the consent has been given. Access to the patient's information is possible only:
– if there are signs of a direct threat to the patient's life;
– in case it is impossible to obtain the consent of such a patient or his / her legal representative (until the time when obtaining the consent becomes possible);
– by a court decision» [12].

Notably, there is no mentioning in the Fundamental Principles of the Ukrainian Health Legislation about the possibility to use mobile apps for ensuring the operation of the electronic health care system, as well as the standards for handling personal data when using the electronic health care system.

ON THE APPROVAL OF THE LICENSING CONDITIONS FOR CARRYING OUT BUSINESS ACTIVITIES IN MEDICAL PRACTICE

This regulation states that each health care institution is obliged in each case to process personal data in accordance with the terms of the Law of Ukraine «On Protection of Personal Data». In addition, it is stressed that such processing should also be carried out while working in the electronic health care system [13].

SOME ISSUES OF THE ELECTRONIC HEALTH CARE SYSTEM

This regulation determines the features of the functioning of the electronic health care system. In particular, it refers to the right of the subject of personal data to receive any information about himself / herself, as well as to change them based on a motivated request [14].

This regulation also enshrines the patient's right to apply for withdrawal of the application for processing personal data which is included in the central database [14].

The most significant thing is that this regulation establishes the possibility of the functioning of patients' electronic offices also through mobile apps of authorized state bodies or enterprises belonging to the sphere of their management. The consent to the processing of personal data is necessary in this case [14].

SOME ISSUES RELATED TO FORMING MEDICAL CONCLUSIONS ABOUT TEMPORARY INCAPACITY

According to this order, it is allowed to send medical documents or their copies to the doctor using «technical means of electronic communication» [15], among which are mobile apps. However, there are two nuances that should be taken into account. Firstly, the provisions of this order apply exclusively to the formation of medical conclusions about temporary incapacity. Secondly, it is possible to send medical documents or their copies to a doctor using mobile apps only during the period of martial law in Ukraine and within three months from the date of its termination or cancellation.

In the US, the use of mHealth apps is regulated by Policy for Device Software Functions and Mobile Medical Applications issued by FDA.

This act specifies that: «mobile medical app» is a mobile app that incorporates device software functionality that meets the definition of a device in section 201(h) of the FD&C Act; 19 and either is intended:
- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device» [16].

A positive aspect of this act is that it provides a detailed list of functions of software: (1) that are not Medical Devices, (2) for which FDA intends to exercise enforcement discretion, (3) that are the focus of FDA's regulatory oversight [16].

In Canada, instead, there was adopted Guidance Document: Software as a Medical Device (SaMD): Definition and Classification that determines the notion of Software as a Medical Device (SaMD) which is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device [17].

This act also states that Mobile apps that meet the following definition are considered SaMD:
- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical devices;
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms;
- «without being part of» means software not necessary for a hardware medical device to achieve its intended medical purpose,
- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device,
- SaMD may be used in combination (e.g., as a module) with other products including medical devices,
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software [17].

Exclusion criteria are also clearly outlined in this act, they include cases when the following types of software do not meet the definition of a medical device and are

therefore not subject to the Regulations:

- Software intended for administrative support of a healthcare facility;
- Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, video calling;
- Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps;
- Software intended to serve as electronic patient records or tools to allow a patient to access their personal health information [17].

In the European Union, an important document that regulates the use of mHealth apps is Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, which determines that software also belongs to «medical devices» if it is used with the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception [18].

Attention should be paid to the fact that this Directive defines four classes of devices: I, IIa, IIb,III. It must be admitted that «only manufacturers of medical devices with risk II and higher are audited by NB's» [19].

The studied norms of the Ukrainian law, as well as the above-mentioned provisions of foreign legislation regarding the regulation of mHelath apps, indicate the need to introduce changes to Ukrainian legislation in the context of the examined issue.

First of all, it is necessary to legally define what «a medical device» is and to equate software with such a device, as specified in the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. That is why we support the need to adopt the Law of Ukraine «On Medical Devices». Currently, the respective draft law has been submitted to the Supreme Council of Ukraine [20]. Notwithstanding the fact that it, to an extent, duplicates the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, there is a need for its revision.

This revision implies the need for determining criteria which allow classifying a mobile app as an mHealth app and thus carrying out an audit of such an application in accordance with the practice that has developed in the USA, Canada and the European Union. This will also enable one to figure out «…whether every mobile app needs a comprehensive approval, or as international agencies do, whether each kind of risk requires its own form of approval» [21].

Additionally, the legislation on protection of personal data needs amending, in particular in the context of handling sensitive personal data, which definitely includes information about a person's state of health. In this regard we are also taking steps towards the convergence of Ukrainian legislation and European legislation, the proof of which is the appearance of the draft law «On Protection of Personal Data» [22], which takes into account the General Data Protection Regulation.

Our opinion is that mHealth apps should necessarily contain privacy policies. The presence of privacy policy is mandatory in order to place any application on App Store platform: «All apps must include a link to their privacy policy in the App Store Connect metadata field and within the app in an easily accessible manner» [23]. The respective provisions should also be reflected in Ukrainian legislation. In particular, attention has to be paid to legal liability of the owners of personal data in case the subject of personal data has no possibility to familiarize himself / herself with privacy policy due to the fact that it is absent.

CONCLUSIONS

The development of mHealth apps leads to an increase in their popularity among users. Along with this, there are certain problems associated with ensuring the confidentiality of personal data of users of such apps. The reason for this is the imperfection of Ukrainian legislation. That is why there is a need to introduce the necessary amendments, based on the standards of handling personal data developed in the USA, Canada and the EU. The point is that the use of mHealth apps should enable such app users to more easily access medical care and these apps also have to be safe. In this case, health personnel will be certain that they can communicate with patients using an mHealth app which has the appropriate level of privacy, and that no one else will gain access to medical information. Ultimately, the development of mHealth apps enables positive changes in health care relationships, and quality legislation will allow speeding up these changes розвиток mHealth. To summarize, it can be noted that in this research attention is drawn to the imprefection of the legal regulation of mHealth apps and we express the hope that further research will help to solve the existing issues.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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