Formation of Interoperable Digital Medicine Information Environment: Personal Medical Data

Introduction. Modern innovation in the medical field is closely associated with digital transformations that aim at creating an interoperable digital healthcare ecosystem. All processes of digital medicine are carried out with the use of digital medical data on the human health state, i.e., personal medical data, so it is important to determine the requirements for their secure exchange and storage specifications with the ability to ensure prompt exchange without loss of information.

Problem Statement. Secure exchange of personal medical data is ensured by strict compliance with the access levels for their management to all members of the digital medicine system.

Purpose. Creating information support for the accumulation and secure exchange of personal medical data in the digital healthcare ecosystem.


Results. Based upon the analysis of medical data generation source, the two groups of personal medical data have been identified: 1) the data validated by a medical specialist according to modern standards; 2) the results of direct data collection by the patient personally, which require standardization. An algorithm for the digital medical data accumulation from the medical care system members has been developed given these data types. In accordance with the roles of the digital medicine ecosystem members, rules to provide them with access to personal medical data, which implements an algorithm for the data exchange between participants in the digital medicine ecosystem, have been developed.

Conclusions. Personal medical data that are the information basis of digital medicine are accumulated with use of the proposed algorithm, given the source and type of medical data to ensure their formalized presentation. Following the established algorithm for authorization ensures the exchange of digital medical data between patients and doctors in compliance with the requirements of interoperability and data security.

Keywords: digital medicine, personal medical data, interoperability, and right of access to medical information.
Modern innovation processes in the medical field are closely related to digital transformations. The Global Strategy on Digital Health for 2020–2025, as drafted by the WHO in July 2020, aims at creating a patient-centered, interoperable digital healthcare ecosystem with the use of information technology (IT), telemedicine, and mobile medicine [1]. At the same time, it should be noted that the peculiarities of digital transformation in medicine are caused by the specificity of digital medicine in terms of object and subject, as well as the quality of the information analyzed. These peculiarities are reflected in the main stages of its development, which cover the dynamics of the tasks from the formalized presentation of medical data and the development of registering and expert systems to the creation of modern technologies and support systems for physicians and mobile medicine [2].

Emphasizing the importance of information technology for the development of digital transformation in health care, I.C. Marques and J.J. Ferreira have identified seven areas of IT application: 1) integrated management of information technology in the field of healthcare; 2) the use of «medical images» in human health surveys; 3) electronic medical records as main carriers of medical information; 4) mobile information technologies and portable devices in the field of healthcare; 5) access to e-health systems; 6) telemedicine; and 7) confidentiality of medical data. [3].

In Ukraine, in recent decades, there have been developed and implemented many subject-oriented information technologies to support the physician activities at different stages of medical care (including researches by L.S. Fainsilberg [4, 5], M.I. Vovk [6, 7], M.L. Kochina [8, 9], O.V. Vysotska [10], and other developers [11—13]). Much attention is now being paid to expanding the scope of IT in all areas of healthcare, such as primary and secondary healthcare facilities (HCFs) and the healthcare system as a whole. The concept of e-health development in Ukraine proposed this year covers both the improvement of the existing IT and the development of support systems for clinical solutions as well as for personalized medicine and large data processing systems involving artificial intelligence methods [14].

There is one more aspect related to the study and storage of various medical data, which should be emphasized. Patient focus and personalization of medicine as the main principles of digital healthcare are expected to lead to a significant increase in medical data. It is extremely important to solve the problem of exchanging these large amounts of data, which is certainly based on the correct use of international information standards for their registration and storage [15].

The increased use of mobile devices to improve the availability and timeliness of healthcare is identified as a key feature of the medicine of the future, because of the advantages of mobile devices over other information and communication technologies, which ensure, in particular, mobility, continuity of data flow, and the ability to support sufficiently powerful computing capabilities of the intelligent information technologies implemented in software applications [16].

Today, Ukraine has launched an electronic health care system (EHS), an information and telecommunications system that aims at automating the accounting of medical services and the management of medical information in electronic form. The technical architecture of the EHS has a so-called hybrid model, a two-component system with a single central database (CDB) owned by the government and multiple electronic medical information systems (MEMIS) at healthcare facilities and service organizations. At the same time, the government sets the rules and standards of the EHS, guarantees the security of the system, while state healthcare facilities and medical business structures are responsible for providing services to users.

In Ukraine, there are many medical information systems and private Internet products for the provision of certain medical services, which support the functions of patient’s personal office that can be used to make an online appointment with a particular practitioner, to get a remote advice from a family doctor and access to a limited amount of me-
dical data from a mobile phone or personal computer. However, the main trend in the development of modern medical information services is patient-oriented, with mandatory requirements for ease of use, accessibility, and a focus on the protection of personal data. To do this, it is necessary to expand the functionality of the Personal Patient Office to the Personal Medical Storage (PMS) by adding the following features:

- aggregation of all possible medical records created by authorized medical professionals in one digital environment, since so far, the results of tests or surveys from two different laboratories exist only in paper form in the patient’s hands, so it is necessary to implement such data in digital format with a clear data structure;
- entering personal medical records of the patient, which he/she makes him/herself or automatic download of data from mobile medical devices of the patient for dynamic monitoring of his/her health;
- the patient ability to give an authorized medical professional access to his/her data.

All these changes and transformations are innovative, and their main goal is to improve the results of patients’ treatment, and the basic tasks are to streamline the work of doctors, to optimize the healthcare system, to reduce the risk of human error and costs due to increased experience with information via the Internet and mobile devices.

These digital medicine processes are implemented with the mandatory use of digital medical data on the human state — personal medical data (PMD) in the form of electronic medical records, digital medical images or signals [17]. That is why it is extremely important to determine the main characteristics of PMD, the requirements for their safe exchange and specifications for PMD storage facilities with the ability to ensure prompt exchange without loss of information.

The purpose of this development is to study and to create tools for providing information support for the accumulation and secured exchange of personal medical data between members of the digital healthcare ecosystem.

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**Information Flows of Digital Healthcare Ecosystem**

The main goal of personalized health care is to solve patient’s health problems, and achieving this goal is based on ensuring effective interaction of patients with physicians, healthcare facilities, and other members of the digital healthcare ecosystem, which promote the development of medical treatment, prevention of diseases, and healthcare support.

The WHO Global Strategy states that the digital medicine infrastructure is used by the healthcare community, including healthcare facilities and patients, as well as public health authorities, universities, and research institutions. The interoperable digital health ecosystem (IHES) should ensure the seamless and secured exchange of medical data between users whose circle has been significantly expanding to include healthcare providers at various levels, health system managers, and health data services [1].

It should be noted that the overall structure of information flows is a patient-oriented model, but depends on the aggregate characteristics of all participants in the interaction in this information environment (Fig. 1). If necessary, other categories of healthcare providers may be involved in the IHES infrastructure, in particular, managers of insurance medicine, employees of sanatoriums, etc.

Digital medicine provides patients and healthcare providers with intelligent and affordable tools to diagnose and to improve a wide range of human health conditions through high-quality, safe, and effective measurements and interventions based on the data obtained. It is very important to take into account the sources of these data.

**Sources of human health data.** The patient is the basic object in all processes of personal medical data (PMD) generation. It is important to divide the obtained medical data into two groups, depending on the methods and medical devices used to study the health of the patient and his/her individual physiological systems.
The sources of the first group of PMD generation are surveys carried out in laboratories and departments of functional diagnostics of polyclinics, diagnostic centers of different level with the use of certified devices and according to the approved methods of clinical examinations and surveys. Digital measurements are currently used in clinical trials for a wide range of patient monitoring tasks. For example, outpatient cardiac monitoring systems and portable ECG technologies (small patch-based heart monitors that may be worn outside hospital and send signals in real time) are used.

The results of such surveys are formed according to advanced recording standards and verified by medical professionals. Such PMDs are the main component of the digital image of a person, are suitable for storage in databases (DB) of different levels (from databases of individual hospitals to cloud storage) without prior formalization and for further in-depth analysis with the help of intelligent information technology.

The second group of PMD is data and measurements, the results of personal direct data collection, various medical records of the user (indicators of the patient’s health, electronic medical records, and digital images) obtained, in particular, with the use of mobile devices. Currently, there is a rapid increase in the mobility of all users and providers of medical services, which leads to increased attention of physicians and developers of mobile devices [18]. This group includes as follows:

- data from portable medical devices: ECG, pulse oximeter, daily pressure monitoring device, in particular diagnostic hardware and software with the use of Fazagraf technology [19] and applications such as a "Diabetic Patient Advisor" based on DIABETES-plus technology [20] etc.;
- the results of self-testing of the patient’s psycho-emotional and physical condition;
- records in digital diaries on the parameters of medication control and monitoring of sleep time characteristics, etc.;
- data obtained with the help of wellness-gadgets (the latest technologies and devices, whose direct purpose is to ensure the improvement of health, well-being, and emotional state).

All these data constitute a digital environment that is formed by the patient independently in the “home hospital” conditions (Fig. 2).

The variety of mobile medicine devices continues to expand. For many European countries and the United States, the problem of compatibility of such devices and the data obtained with their help has been gradually taking a back seat [16], while for Ukraine solving this problem is extremely important not only today, but also for the future developments in the field of mobile medicine.

It should be emphasized that the data of the second group are not validated by the healthcare
professionals and are created without taking into account the standard of electronic records storage. To formalize this data, templates are used with mandatory control of the content of each field, with the use of special input masks (to ensure the correct data format).

Another problem related to the medical data sources and faced by developers of medical information systems and cloud personalized storage of this data is the need to comply with many standards for obtaining and working with different types of data. The most important of them are as follows:

- DICOM (Digital Imaging and Communications in Medicine) is the medical industry standard for the creation, storage, transmission, and visualization of digital medical images and documents of surveyed patients;
- HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) is the advanced standard system that uses the latest web standards; the FHIR structures are built from a set of modular components called “Resources” and may be assembled into working systems that allow solving real clinical and administrative problems [21];
- API (Application Programming Interface) is a set of routines, interaction protocols, and tools for creating software;
- JSON (JavaScript Object Notation) is the text format for data exchange between computers;

JSON is based on text and readable; the format allows describing objects and other data structures.

The FHIR based APIs with a flexible set of parameters allow JSON to formalize exchange protocols between a personalized databank and a health-care facility (other users) [22].

Accumulation of PMD

As we have already mentioned, an important task of creating a Personal Medical Databank is the accumulation of medical data obtained from the mentioned sources.

The algorithm of digital medical data accumulation from members of providing medical care services has been developed given the two types of medical data which validated by a medical professional (results of laboratory and instrumental diagnostic surveys) and obtained by patients after testing with a mobile medical device. This algorithm is patient-oriented, in accordance with the principles declared in the Draft Strategy for the Development of Digital Medicine [1]. Let us consider in more detail the steps of the proposed algorithm (Fig. 3).

1. Authorization in the system. The user enters the login and password in the appropriate fields of the authorization form, then goes through the authorization process. If such a user is not identified, it is necessary to go through the standard
process of his/her registration. At the same time, the role of this user in the digital healthcare ecosystem is being determined.

If the authentication is successful, the user gets access to medical data; he/she may view the existing records and add new ones or other data obtained from various sources.

2. Inclusion of new data obtained in healthcare facilities. Depending on the category of data (tests, records, measurements) the following actions are performed:
- creating a medical record: in the section Medical records and recommendations; creating a new record by selecting the structural type (record or recommendation) and entering the content of the record indicating the date and time of the record, the doctor’s name, and specialization. The document is automatically saved in the data-
base with the obligatory entry of the ID of the user who makes the record;
- the testing results: in order to enter such results, it is first necessary to categorize their type: laboratory or diagnostic tests;
- the laboratory tests: to enter from a paper carrier according to a template; if not, to create a new template, to indicate the test name, a list of indicators and reference values; the electronic carrier is marked with the name, entered into the testing database in .pdf format, and automatically recorded in the appropriate section of the database;
- the diagnostic tests: if there is a paper carrier, to act similar to the creation of a medical record; in the presence case of a digital carrier, to determine the type and format of the test (digital image in .bmp, .jpeg, .png format and specialized .dcm format), to enter the data into the database, and, if necessary, to make comments.

3. Inclusion of personal medical records obtained by patient independently. Such data include the results of measurements, questionnaires, etc. Data from mobile devices may be entered automatically, semi-automatically and manually. For automatic input, it is necessary to create appropriate APIs for the exchange of correct digital information, after which the data are duplicated on the device and in personal databank. In the case of semi-automatic input, the data is duplicated on patient’s smartphone and transferred to the database at the request of the user. In the case of manual input, it is necessary to check whether there is a suitable template, because the use of templates provides structuring of information for further analysis and presentation of data in graphi-
Results of questionnaire surveys are also entered in the relevant section of the database.

Thus, the developed algorithm has a branched structure and enables accumulating data of different types obtained from different sources for the formation of Personal Medical Databank.

**Storage of personal medical data.** We consider that each member of interaction in the information environment has means for exchange and storage of the information for indirect interaction. To create and to add data to the Personal Medical Databank that stores digital medical data of a particular patient, an extended infographic model that defines and provides a description of the values of specific fields of database spreadsheets and internal format of each field has been formed (Fig. 4). Because of the heterogeneity of input data, there have been implemented several interconnected database components.

The **Demographic data** component (1.2) is designed to identify patient by his/her demographic data (name, gender, age, etc.). Each patient is assigned with a personal identifier that makes it possible to transfer data between mobile devices or to work simultaneously with these data both on a computer and on a smartphone.

The **Personal medical data** component (1.3) designed to record patient's personal medical data aggregates data from mobile diagnostic devices, smartphones, and data of medical measurements. Data can be divided into several categories: quantitative indicators (blood pressure, heart rate, body temperature), medical images (photos from a phone or diagnostic device), medical signals (from portable devices, such as smartwatch). For each type of data, a table is created. The obligatory fields of this table are patient’s id, id of the user who entered data, date of record, and date of data editing.

The **Medical records** component (1.4) and **Telemedicine consultations** (1.7) components are created for keeping medical records of family doctor and consultant doctor (respectively), recording recommen-
dations for treatment or rehabilitation; the data type is text information.

The Laboratory tests components (1.5) and Instrumental surveys (1.6) are designed to record the results of patient’s laboratory tests and the results of tests with the use of diagnostic equipment, respectively. The data may be entered manually, attached in a file (usually in .pdf and .jpeg format) or submitted as digital medical images in .dicom, .jpeg or .bmp formats.

The database infological model is built with the use of UML notation — the class flowchart that has a structural character with the display of classes as main elements of the flowchart and their relationships. The class record consists of the two parts: a header with the class name and a body with the description of its fields (the attributes, in UML terms) and methods (the operations, in UML terms). The attributes are written with accessibility, name, and type:

- the sign “−” means that the attribute is private, i.e. available only to clearly defined users;
- the sign “+” means that the attribute is public, i.e. open to all;
- the sign “#” means that the attribute is protected, i.e. this attribute shall be encrypted.

The operations, in UML terminology, mean methods, properties, indexers, and so on. The operations are also written with a list of accepted values, such as float, integer, or string.

The main table Patient (1.1) has a list of related auxiliary tables. The table Demographic data (1.2) contains a permanent list of fields, namely the public attributes: name, gender, age (date of birth), and the private attributes: _ID, data type is string. The table Personal medical data (1.3) has an arbitrary set of parameters and sub-tables for dynamic data generation; the attribute is secure access; the data type is string. The tables Medical records (1.4) and Telemedicine consultations (1.7) provide a permanent list of fields for the formalization of medical records and doctor’s recommendations; the attribute is secure access; the data type is string. The tables Laboratory tests (1.5) and Instrumental surveys (1.6) are formed by a constant list of fields with the option to create tables for dynamic data generation (for 1.6, also to save images, signals, and their descriptions); the attribute is secure access; the data type is string.

Components 1.4—1.7 are created on a block basis that ensures the storage of PMD on the relevant physiological system of the body (for specific diseases of the patient). This organization of personal medical databank (PMDB) allows the implementation of a flexible and user-friendly interface.

While designing the databank, we primarily pay attention to socially significant diseases with systemic disorders of carbohydrate metabolism and impaired motor and speech functions in patients after stroke. In these cases, the formation of PMD aims at enabling the patients:

- to determine the patient’s daily glycemic profile in the conditions of irregular measurements of blood glucose level, with the help of mobile devices [20], given the patient’s sensitivity to injections of insulin and glucose component of food;
- to get quality medical care and health services, including remote monitoring of rehabilitation of motor and speech functions, not only in clinical but also at home conditions, with the use of mobile devices [7].

**PMD Management**

The patient shall have closest connection with primary medical care professional, namely with the family doctor. These members may interact both face-to-face and remotely, for example, by means of video calls, recommendations via email or smartphone, and more.

It is known that electronic personal data may be accessed only with the permission of the holder of this data, i.e. the patient. The patient and his/her family doctor shall have full access to any medical data, while support staff shall have certain limitations in both the scope of accessible data and the ability to edit the information. As already mentioned, the main system-forming factor is the list of actors (members of the digital medicine ecosystem) and the tasks to be performed in the course of the data exchange.
Access to personal medical information may be divided into the three levels: personal level, the level of primary care professional, and the level of secondary care professionals, in accordance with the distribution of roles in the process of medical care provisions.

The personal level. The patient has full access to his/her data that may be divided into the three categories:

- the medical images: images obtained from various instrumental and diagnostic procedures throughout his/her life in different healthcare facilities;
- the medical records: doctor’s recommendations, prescribed medications, daily schedule, professional consultations, list of diagnoses, survey results, and laboratory data;
- the medical measurements: data obtained from mobile devices (automatically or manually entered), with the use of specialized medical devices as well as questionnaires of the physical and psychological condition of the patient.

The level of primary care professional. The principal member at this level is the family doctor who has access to the patient’s personal records (review function), to the results of laboratory tests and instrumental diagnostic surveys (review function), as well as to medical records and recommendations (creation, editing, and reviewing functions). If necessary, the patient may communicate with a nurse or a paramedic.

The level of secondary care professionals. This level involves a wider range of professionals. The diagnostician and laboratory physician have indirect access to the patient’s medical data (one-time, with a direct permission of the patient). The consultant doctor and the hospital doctor have access to separate blocks of personal records of the family doctor, the results of diagnostic and laboratory tests (review function).

Let us highlight the main elements of the specifications for access to PMD. The members of the digital healthcare ecosystem are P — patient, D1 — family doctor, D2 — laboratory doctor (laboratory tests department), D3 — diagnostician (instrumental surveys department), D4 — hospital doctor, D5 — consulting doctor.

Medical information by source of origin is classified as: IM1 — results of surveys and recommendations of the family doctor, IM2 — results of laboratory tests, IM3 — results of instrumental surveys; among them there are IM3ER — electronic medical records, IM3IM — digital medical images, IM4 — results of surveys and recommendations of the hospital doctor, IM5 — conclusions and recommendations of external advisor, IMP — data obtained by the patient him/herself. The origin of electronic medical record: ER1 — created by him/herself, ER2 — created by another user.

It is also important to consider the period during which the user may amend the record: \( t_1 \) is the time for editing, \( t_2 \) is time for deleting the record.

PMD management actions cover the four basic CRUD functions: Create, Read, Update, and Delete, with time limitations for amending the record, given its origin and possible operations with only the required portion of the stored PMD.

According to the level of access to personal medical data, the principal rules of access for each group of members of the digital medicine ecosystem have been elaborated:

\[
P = MP \rightarrow C + R + U_{ER1} + D_{ER1/2} \\
IM1 + IM2 + IM3 + IM4 + IM5 \rightarrow R
\]

\[
D1 = IM1 \rightarrow C + R + U_{ER1} + D_{ER12} \\
IM2 + IM3 + IM4 + IM5 + IMP \rightarrow R
\]

\[
D2 = IM2 \rightarrow C + R + U_{ER1} + D_{ER1/2} \\
IM3 \rightarrow C + R + U_{ER1} + D_{ER1/2}
\]

\[
D4 = IM4 \rightarrow C + R + U_{ER1} + D_{ER2} \\
IM1 + IM2 + IM3 + IM4 + IMP \rightarrow R
\]

\[
D5 = IM5 \rightarrow C + R + U_{ER1} + D_{ER2} \\
IM1 + IM2 + IM3 + IM4 + IMP \rightarrow R
\]

The created data exchange algorithm implements the order of access according to the developed rules and ways of digital medical data transfer between the members of digital medicine ecosystem (Fig. 5).

At the application level (service) that provides interfaces to patients and healthcare profession-
als at different levels, we have used JavaScript React technologies and ECMA 5 standard, which prevents asynchrony of interaction with authorization and document management services, laboratory services, JSON objects.

Thus, compliance with the algorithm for access ensures the exchange of digital medical data between patients and physicians with the implementation of the requirements of interoperability and data security.

Conclusions. The basic principle of the medicine of the future is the use of digital medicine based on personal medical data. The formation of medical databank at various levels, from databases of individual healthcare facilities to cloud storages, begins with the accumulation of these data. The proposed generalized database model takes into account the characteristics of different types of information sources and the relationship between the members of digital healthcare ecosystem, with the values of specific fields of database spreadsheets and their internal formats indicated.

To create the database and to add new data to it, an algorithm for accumulating digital medical data obtained from various members of the digital healthcare ecosystem has been developed. It includes support for the two types of medical data: those validated by a medical professional (including laboratory tests and instrumental diagnostic surveys) and those obtained by patients by means of mobile medicine devices. The components of the database are created on a block basis that which ensures the storage of PMD sorted by specific diseases of the patient. This organization of personal medical databank allows the implementation of a flexible and user-friendly interface.

According to the characteristics of the main members of the system for provision and obtain-
ment of medical care services, the levels of access to available information have been determined in the structure of digital medicine, and the access rules have been created, with the use of the four basic data management functions (Create, Read, Update, and Delete (CRUD)). The access rules form the basis of the developed exchange algorithm for implementing the procedure of access and ways of digital medical data transfer between the members of digital medicine ecosystem: patient, family doctor, hospital doctor, consulting doctor, clinical laboratory doctor, and diagnostician.

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