Applications

DOI https://doi.org/10.15407/csc.2020.05.070
UDC 004.75+004.932.2:616

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FORMALIZED REPRESENTATION OF INFORMATION AND TECHNOLOGICAL PROCESSES OF DIGITAL MEDICAL DATA EXCHANGE IN THE DIGITAL MEDICINE INTEGRATING ENVIRONMENT

The general structure of information flows of the digital medicine integrative environment is described and the formalized representation of health care business processes are developed. An analysis of the characteristics of the main actors actively involved in medical care was done. As an obligatory condition of personal medical data secure exchange, the access level to medical information of each participant, which is in particular in the case of mobile medicine, was determined. A model of business processes for medical care has been developed using descriptive logics.

***Keywords**: digital medicine, information flows, business processes of medical care, level of access to digital medical data, eHealth.*

Introduction

The digital transformation of society has led to the emergence of digital medicine, which effectively affects the quality of health care and communication methods for participants in this process. Telemedicine, artificial intelligence-enabled medical devices, and electronic medical records are just a few specific examples of the digital transformation in healthcare that are completely change the way health professionals interact, the way data exchange between providers, and the decision-making mechanisms for diagnosis, treatment, rehabilitation, and health outcomes.

There is no doubt that the secure health information exchange will enable citizens to more actively manage of personal health data, to improve their health. The ability to accumulate large amounts of health data and its changes due to internal and external factors also provides for large-scale and in-

depth clinical studies, so interoperability is defined as one of the leading principles of digital medicine [1, 2]. The demand for electronic medical record systems (EHR), which collect and manage personal health data, and the need for free access to them increases with the development of health care management system [3, 4].

To ensure the effectiveness of health services, it is important to involve available mechanisms for interaction between patients and health care facilities (HCF) at different levels. The balance between the medical care availability and its quality is quite shaky, so it is necessary to identify the most important barriers to patients' rapid access to information, as well as ways to overcome them [5]. To do this, it is necessary to analyze the technological process of information exchange in the medical care process and identify the main participants in this process and their characteristics. This analysis makes it possible to take into account the tasks for all participants, the requirements for access to the necessary information for the medical data rapid exchange to make adequate decisions on diagnosis and treatment, as well as to form mechanisms to increase access to health care.

Problem Statement

All the shifts in the digital transformation in the medical field are innovative, the main goal of which is to streamline the work of doctors, optimize the health care system, improve patient outcomes, reduce human error and reduce costs, primarily through experience on the Internet and mobile devices.

Unfortunately, the healthcare industry is lagging behind in implementing digital strategies. Studies of the pace of digital medicine implementation have found that by 2014, only seven percent of health care facilities in different countries have switched to digital technology, compared with 15 percent of companies in other industries [6]. In most European countries and the United States, where the electronic medical records implementation in health care is expanding, electronic systems for monitoring patient-physician interactions are still slowly being introduced [7]. And Ukraine needs to make much greater efforts to turn its standard practice into advanced digital technology.

Advances in health information technology have contributed to the eHealth paradigm development, which aims to improve the means of obtaining, storing and analyzing health data. The term eHealth was introduced in the field of health information technology to define the scientific and practical field, which combines the development of medical informatics, health care and business and is the basis for improving health services and expanding the data exchange provided by the Internet and information technologies [8, 9].

Recently, the vast majority of patients visited their doctors only when they felt a sharp health deterioration and underwent the necessary examinations on average once a year. At present, with the development and implementation of digital technologies, prevention and maintenance of one's own health are among the top priorities, so it becomes important to provide patients with the necessary prompt and more complete information about their health. Many devices are designed to provide mobile monitoring of patients` state, especially for those who are at high risk of sudden deterioration. As noted in [10], by 2023 the volume of the market for mobile medical devices will reach more than $ 27 million, while in 2017 this volume did not exceed $ 8 million.

The use of eHealth technologies will facilitate the exchange of clinical, administrative and other health data. We provide the basic definitions of the components of the eHealth system information model.

Participants in the health care system are actors in digital medicine systems. In a broad sense, the term "health system participants" is defined as a "person" or "group" that has a relationship with the health care system, including patients and their families, physicians, nurses, laboratory technicians, and employees of other external management organizations, insurance companies, etc.

Patients are end users of services. A large group of providers include clinicians, consultants, nurses, nutritionists, health managers, social workers and hospital administrators, who offer and provide medical services to solve the specific health problems faced by these consumers.

Patients and healthcare providers are connected by communication flows, and their interaction can be facilitated through common eHealth programs and basic infrastructures, which are usually created and maintained by network operators, database managers, system administrators and include objects such as specialized software applications, information processing algorithms and data storage systems.

For such diversity of participants in the medical services process, it is necessary to define their specific features and clearly set restrictions on access to personal medical information.

Electronic medical records. The most well-known form of clinical data is the electronic medical record, which contains a lot of important information. An electronic medical record is a digital version of medical information and medical history maintained by a healthcare professional. Specific blocks of the electronic medical record must be clearly and in detail prescribed taking into account the technological features of obtaining and analyzing medical information.

Sources of health data. Interaction of patients with healthcare professionals serves as a health information source at the main points of contact between the healthcare professional and the patient. This information, once recorded, becomes health information. These data usually include metadata (record of services received, time and conditions of these services, etc.) and clinical outcomes resulting from these services [11]. Information that is often collected and contained in medical records also includes administrative data, patient demographics, progress information, vital signs, previous diagnoses, doctor's appointments, immunization dates, allergy information, and laboratory test results [12].

Undoubtedly, a person is the source of all data about the state of his health. There are many cases where the easiest way is often informal personal data collection, in particular through mobile devices. Also examples of direct collection of information about patients' compliance with medical instructions are entries in the personal calendar of medical procedures, ie individual verification of how they took their medication or counting the amount of sleep indicating the period of observation. Such data require formalization to allow for further storage and analysis.

With the fusion of eHealth and mobile technology, the concept of mHealth has emerged, which is generally defined as a medical practice supported by mobile devices. The development of mHealth has provided new opportunities for generating patient health data, including biometrics, treatment history, lifestyle choices, and other information created, recorded, collected, or transmitted by patients to healthcare facilities to track, analyze, and store personal medical information. mHealth allows patients to monitor and report their condition outside the clinical setting [13].

Considerable attention is now being paid to strengthening patients 'responsibility for their own health and ensuring patients' self-control over changes in their health through mobile applications. For this purpose, it is extremely important to carry out operational monitoring of these changes and to establish constant communication with their doctor in real time, supported by a smartphone, especially in the case of chronic diseases [14]. At the same time, it should be emphasized that the data of self-monitoring by means of a mobile application should be transferred to the system of electronic medical records of the hospital for further infection and analysis.

Thus, eHealth and mHealth are organizing a patient-centered healthcare system in which patients may manage their own health through new mobile technologies that enable the collection and evaluation of online digital information [15].

The purpose of the paper is to analyze and formalize the components of the integrative environment of digital medicine to ensure effective interaction between patients, family physicians and health care workers at different levels.

General Structure of Information Flows in the Integrating Environment for Digital Medicine

The integration environment for the digital medical data exchange between different participants in the medical care process combines several main func-

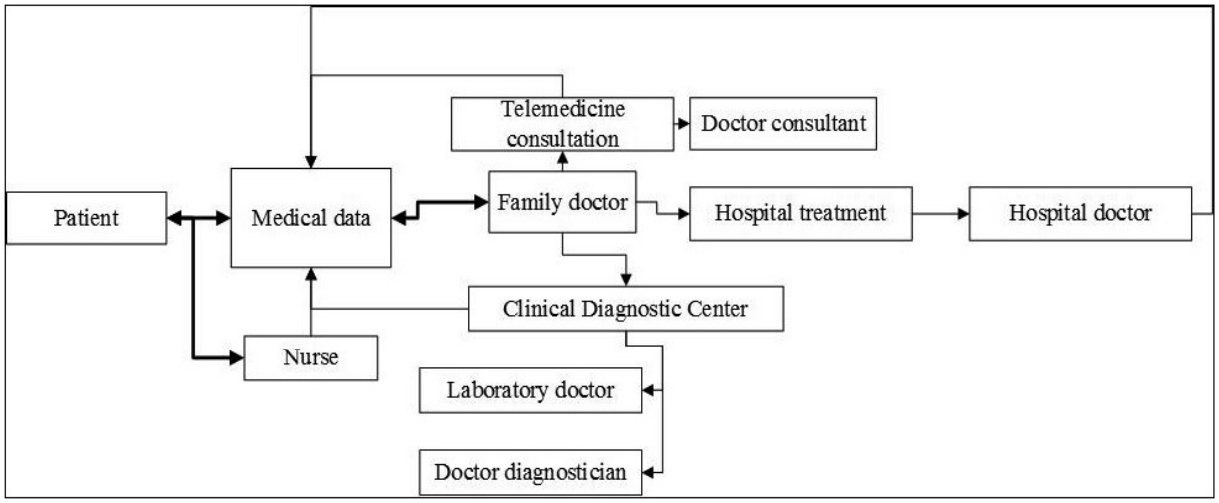

Fig.1. Scheme of interaction between the participants of the digital medicine infrastructure

tional components: formalized business processes with definition of information flows and characteristics of participants (actors), digital medical data storage subsystem (CMD), and functionalities (algorithms) of accumulation and further exchange of digital medical data.

The Draft Global Strategy on Digital Health 2020–2025, published by the WHO in July 2020 [16], noted a change in the health actors definition. The implementation of information technologies and mobile medicine has necessitated the consideration of a wide range of participants in medical care or medical services: public or private hospitals, various laboratories or clinical diagnostic centers, family physicians, paramedics, pharmacists, and other related service providers.

To ensure the safe interaction of such a wide range of participants in the digital medicine integrative environment, the requirements for determining the levels of their access to medical information and the ability to change this information have been increased.

Users can be divided into two generalized categories: healthcare professional and patient, each of which may have a set of subcategories. Depending on the model of interaction of health care entities, the number of subcategories may vary. Suppose we are considering a "home hospital" or palliative care system, and in this case the medical staff will include a doctor (therapist), a paramedic or a nurse. The patient can follow the doctor's recommendations himself or relatives are responsible for him. If we take the scale of the secondary level of medical care, it is necessary to add doctors-diagnosticians, doctors-consultants, and in case of hospitalization – hospital doctors.

The generalized structure of interaction between mentioned participants can be given by such model (Fig. 1).

Consider the characteristics of the main components of medical care in the structure of digital medicine [17].

1. *Patient* is a person, who can control access to personal medical data and their content, has the opportunity to change them within its authority.

2. *Means* for measuring or diagnosing medical, psycho-emotional and statistical data of the patient: devices or software products that in automatic or manual mode, through its own interface or with the help of third-party software, can record personal medical data and enter database tables.

3. *The family doctor* is a person authorized by the patient, so he has access to the patient's medical data and can provide advice and make recommendations for further treatment or rehabilitation.

4. *Laboratory doctor* is an unauthenticated person who provides the results of laboratory tests.

5. *Physician-diagnostician* is an unauthenticated person who provides the results of research of instrumental functional diagnostics.

6. *Hospital doctor* is an authorized by the patient person who has access to the patient's medical data, medical records and recommendations of the family doctor, and can provide recommendations for further treatment or rehabilitation.

Note 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. 2).

Model of Information Interaction Between Participants in Digital Medicine Infrastructure

The realization of the principle of interoperability in digital medicine infrastructure is based on the formalization of the main business processes of information exchange during the medical care processes as a first step. To accomplish this task, a model of information interaction between the participants of these processes has been developed with the help of descriptive logic, which makes it possible to describe the procedures for generating, accumulating and storing personal data about the patients` health.

Let's define in detail some steps of digital medicine subjects interaction according to the developed model.

The interaction of each subject (primarily the patient) with another subject (family doctor, doctor-consultant, etc.) is the leading line of the model.

Taking into account the mobile medicine needs, we will consider such an interaction with the patient's use of a mobile device to determine and record their physiological indicators for further communication with the family doctor with the possibility of transmission to either a doctor or a consultant:

$$\forall\_(p \in P) \subseteq \exists \text{ has.(smartfone} \cap \text{indicators.}T) \rightarrow \forall\_(p \in P).\text{set treatment(internist} \cap \text{indicators)},$$

where: $p \in P$ is patient p from a set of P patients.

In the next step, the family doctor caring for the patient (internist) sends his or her recommendations for treatment or rehabilitation to the patient.

If the family doctor deems it necessary, he gives the patient an electronic referral for examination to a clinical laboratory or functional diagnostics department, then we have:

$$\rightarrow \forall\_(p \in P).\text{research} \subseteq \exists \text{ has.(internist} \cup \text{indicators} \cup \text{electronic referral.}T).$$

In the absence of the need for such examinations and their recording in the patient's electronic card, the following objections are used:

$$\text{set treatment} \equiv \neg\text{EHR or } \forall\_(p \in P) \subseteq \text{set treatment.} \perp,$$

where EHR is thepatient's electronic card.

In the absence of information about the medical examinations results, carrying out medical services to the patient will be detained:

$$\text{internist.set treatment} \subseteq \exists \text{ has.(indicators} \cap p.T) \rightarrow \text{internist.set treatment} \subseteq \forall \text{ to appear. recommendation} \rightarrow .$$

The Functional Diagnostics Department, having an electronic referral from the family doctor, carry out the laboratory tests and then sends the results of the study to the doctor as an record in an electronic medical document:

$$\text{functional diagnostics.set research} \subseteq \forall \text{research result.internist} \cap \text{EHR}$$
$$\text{laboratory} \subseteq \exists \text{ has.(electronic referral} \cap \text{internist.} T) \rightarrow$$

Similarly, the clinical laboratory, having an electronic referral from the family doctor, carry out a study of the patient and sends his results to the doctor as a record in an electronic medical document.:

$$\text{laboratory.p\_research} \subseteq \exists \text{ realize.(electronic referral} \cup \text{patient})$$
$$\text{laboratory.set research} \subseteq \forall \text{ research result. internist} \cap \text{EHR}$$

In turn, the family doctor, having the results of clinical examinations received from the patient or recorded in EHR, if necessary, recommend them the consulting physician, using mobile means:

$$\text{internist.p\_data} \subseteq \exists p \text{ \_data.EHR}$$
$$\text{internist.diagnosis} \subseteq \exists \text{ realize.(laboratory} \cap \text{functional diagnostics} \cap \text{telemedicine} \cap \text{Doctor Consultant}) \rightarrow$$

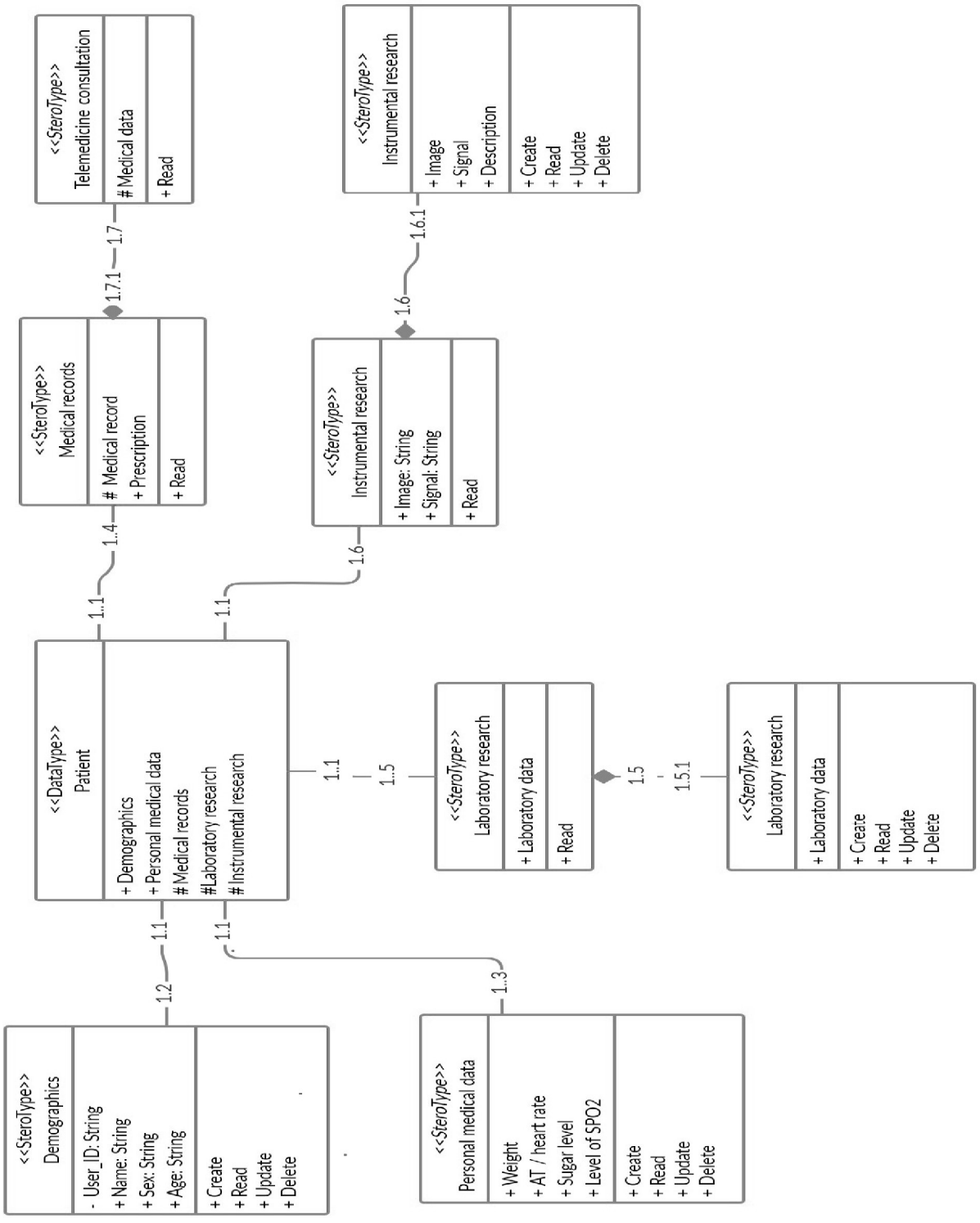

Fig. 2. The general structure of information flows in the participants interaction in the integrative environment of digital medicine

The DoctorConsultant analyzes the received medical data (extract from the electronic medical document, digital images, etc.) and sends the results of the consultation to the doctor who sent this data with a request for a consultation.

After receiving an advisory opinion, the family doctor enters it in an electronic medical document (EHR) and makes recommendations to the patient for correcting his health:

$$\text{individual treatment period} \subseteq \exists \text{ determined.}(\text{patient} \cap \text{diagnosis})$$

$$\text{DoctorConsultant} \subseteq \exists \text{consultation.}(\text{indicators} \cap \text{internist.}\, T) \rightarrow \text{Doctor Consultant.set consultation} \subseteq \forall \text{consultation result.set}$$

$$\text{functional diagnostics} \subseteq \exists \text{ has.}(\text{electronic referral} \cap \text{internist.}\, T) \rightarrow \text{functional diagnostics.}p\text{\_research} \subseteq \exists \text{ realize.}(\text{electronic referral} \cup \text{patient}).$$

It is mandatory to define restrictions on the specified roles of participants in providing medical services.

Thus, the formed model formalizes the main business processes of information exchange during the medical care, taking into account the peculiarities of the objects' interaction, generation and exchange of medical data, as well as the necessary supporting documents.

Conclusions

One of the factors to increase the efficiency of the health care system is to ensure the compatibility of information systems, devices and means of mobile technology, which determines the promptness and reliability of interaction for all participants in medical care.

The proposed formalized representation of medical care business processes of mHealth and eHealth reflects the interaction of participants in these processes (patient and different groups of health professionals) and information flows that arise in this interaction.

The implementation of IT and mobile medicine has necessitated the consideration of a wide range of participant in the medical service in addition to the patient and the doctor, and an increase in the requirements for determining their levels of access to medical information for secure exchange.

The developed models of information interaction during the medical care in the digital medicine infrastructure and the identified characteristics of the main participants in these processes are the basis for developing algorithms for safe and efficient exchange of digital medical data in diagnosis, correction and rehabilitation.

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Received 03.10.2020

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ФОРМАЛІЗОВАНЕ ПОДАННЯ ІНФОРМАЦІЙНО-ТЕХНОЛОГІЧНИХ ПРОЦЕСІВ ОБМІНУ ЦИФРОВИМИ МЕДИЧНИМИ ДАНИМИ В ІНТЕГРУВАЛЬНОМУ СЕРЕДОВИЩІ ЦИФРОВОЇ МЕДИЦИНИ

Вступ. Для забезпечення ефективного надання медичних послуг важливо забезпечувати доступні механізми для взаємодії між закладами охорони здоров'я різного рівня та пацієнтами. *mHealth*, *eHealth* та інші технологічні розробки, такі як телемедицина, становлять нову цифрову парадигму здоров'я.

Метою роботи є розроблення формалізованих складників інтегрувального середовища цифрової медицини для забезпечення ефективної взаємодії між пацієнтами, сімейними лікарями та працівниками закладів охорони здоров'я різного рівня.

Результати. Описано загальну структуру інформаційних потоків інтегрувального середовища цифрової медицини та розроблено формалізоване подання бізнес-процесів закладу охорони здоров'я. Надано аналіз характеристик основних учасників (акторів) процесу надання медичної допомоги та визначено рівень доступу до медичної інформації кожного учасника, що є невід'ємною умовою, зокрема у разі застосування мобільної медицини. З використанням засобів дескриптивних логік розроблено модель бізнес-процесів надання медичної допомоги.

Висновки. Формалізоване подання бізнес-процесів надання медичної допомоги із застосуванням засобів *mHealth* та *eHealth* відображає взаємодію учасників цих процесів (пацієнта та різних груп медичних працівників) та інформаційні потоки, які виникають за цієї взаємодії. Для забезпечення надійних механізмів обміну цифровими медичними даними прописано рівні доступу під час підключення кожного учасника до системи *eHealth*.

Ключові слова: *цифрова медицина, інформаційні потоки, бізнес-процеси надання медичної допомоги, рівень доступу до цифрових медичних даних, eHealth.*