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E-HEALTH: MEDICAL DATA PROTECTION AND PATIENT RIGHTS

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CONTENT

List of abbreviations

AI – Artificial Intelligence

ICTs – Information and Communication Technologies

EH, E-Health – Electronic Healthcare

EHR – Electronic Health Record

EMR - Electronic Medical Record

EU – European Union

HIMSS – Healthcare Information and Management Systems Society

HIS – Hospital Information System

HRA – Human Reliability Analysis

IEHR - Integrated Electronic Health Record

ICESCR - International Covenant on Economic, Social and Cultural Rights

IoT – Internet of Things

MDL – Medical Diagnostic Laboratory

LIS – Laboratory Information System

PIS – Pharmacy Information System

PACS - Picture archiving and communication systems

RIS – Radiology Information System

TMC – Telemedicine consultation

WHO – World Health Organization

UN – United Nations Organization

Foreword

Informatization has rightfully become a symbol of the XXI century. The progress in the development of information and communication technologies (ICTs) in recent decades has led to qualitative changes in the healthcare sector, creating new opportunities in the field of medicine. The possibilities of ICTs in healthcare at various historical stages were determined and are determined by the state of three components: information, telecommunications and medical technologies.

One of the most significant documents for the intensive use of ICTs in the field of health was the Resolution WHA58.28 on E-Health, that was adopted in May 2005 at the 58th session of the World Health Assembly. The concept of E-Health used in the document implied "the use of information and communication technologies both in a given place and at a distance", combining everything related to the use of ICT in medicine.

The concept of *E-Health or Electronic Healthcare* (EH) includes a complex of diverse information, communication and medical services provided at a distance. The most famous are services such as telemedicine (teleeducation, telemonitoring, teleconsultations), electronic medical records, exchange of medical and managerial data, analysis of laboratory research results and image transmission, information support for scientific research, etc. EH is one of intensively developed areas [90]: the total funding made by investors in the E-Health industry from 2010 to 2020 increased from 1,1 billion U.S. dollars to 21.6 billion U.S. dollars. These systems have become even more important in the face of the pandemic COVID-19 [20]. Researchers have published numerous articles on the role of eHealth, telehealth, and/or telemedicine in delivering healthcare services to patients with chronic diseases/conditions during the COVID-19 pandemic.

According to Healthcare Information and Management Systems Society (HIMSS) today, a significant number of countries in the world have EH systems, with the United States, Canada and Australia being the leaders in this field. As the HIMSS Annual European Digital Health Survey [56] shows European Union (EU) countries have also established EH systems that are advanced and noteworthy (Sweden, Estonia, Denmark). The research in [56] analysed the biggest priorities in EH domain (Fig. 0.1). The dominant e-health priorities are related to security and data privacy issues, the development of which is not only a technical problem [90]. In this regard, in the relevant aspects of this study, we pay attention to the disclosure of certain areas of development of EH systems in jurisdictions [15]. To develop a reliable security model, privacy rights and security for eHealth must be integrated into a comprehensive legal and security framework that addresses the rights and obligations of the healthcare provider, including physicians, hospitals and healthcare enterprises, the patient, medical and cybersecurity researchers, and Internet service providers. The collaboration of government, industry and academia is crucial to the development of security models that will not only protect individual rights, but will meet the future challenges essential to the delivery of healthcare treatment [22].

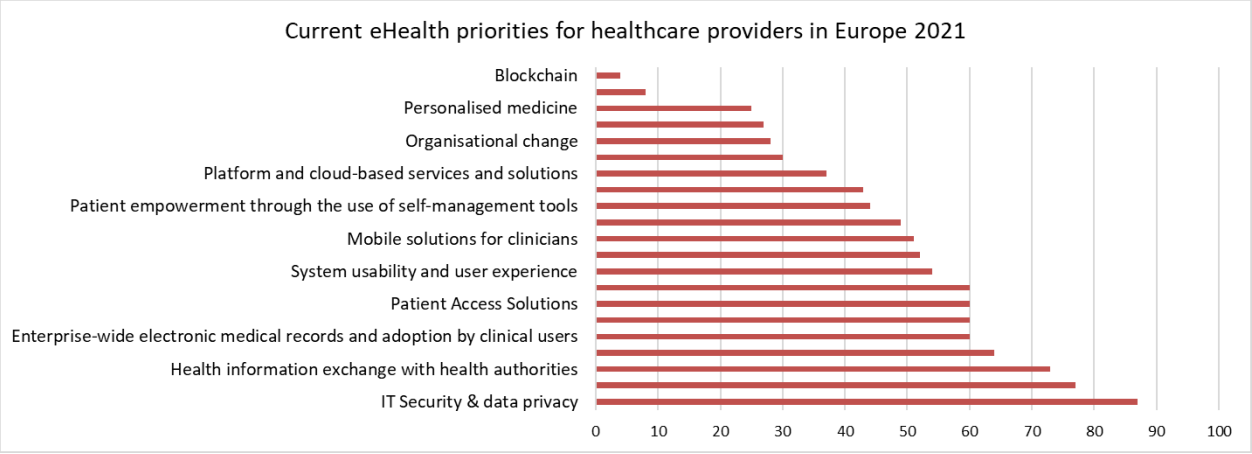

Fig.0.1. E-Health priorities

The EH is an interdisciplinary domain. In this monograph, we have considered some of the main aspects influencing the development of this area, corresponding to the priorities indicated in [56]. In particular, this monograph presents:

- the structure of the system as a socio-technical system, including a relationship from the point of view of human rights, especially in such an aspect of this topic as the relationship between the medical worker and the patient (Chapter 1);
- main E-Health components such as Hospital information systems, Electronic health records, Laboratory information systems and Electronic prescription (Chapter 2);
- systems used for medical diagnostics, such as telemedicine, platform based on GRID layers, communication systems and decision support systems (Chapter 3);
- the main mechanisms used to protect data, their advantages and limitations for implementation in E-Health systems (Chapter 4);
- an overview of the E-Health legal environment (Chapter 5);
- the possibility of using artificial intelligence methods in medicine, taking into account the patient safety and data protection (Chapter 6).

In general, the interdisciplinary nature and complexity of the study allows us to see the main trends, prospects and challenges facing states in the formation of EH systems in modern conditions.

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Chapter 1. ELECTRONIC HEALTHCARE: SYSTEMS AND PEOPLE

1.1. Electronic Healthcare: main notions

Digital processing of data and information play key role in increasing the effectiveness of the healthcare system. Automation of internal business processes in healthcare institutions, centralization of medical information related to patients and provision of due access to it, remote consulting and automatic processing of experimental research data results, on-line system of advanced training of medical professionals, supporting decision making on various branches provide essential cost reduction and improvement of medical care quality.

During last 25-30 years, Electronic Healthcare (E-Health) started to develop rapidly. Broadly speaking, E-Health is the use of information and communication technologies for health needs: treating patients, training health workers, identifying diseases, and monitoring public health trends. The conception of E-Health was formed approximately in 1999 [42]. According to [42] this conception was introduced as a marketing trend, nevertheless, the author defines E-Health in the following way: "*E-Health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.*" According to this definition the "E" in E-Health can be interpreted as the "electronic" only. But Gunther Eysenbach in [42] defined other "10 E's" which should be took into account for the conception of E-Health:

1. "**Efficiency** - one of the promises of e-health is to increase efficiency in health care, thereby decreasing costs. One possible way of decreasing costs would be by avoiding duplicative or unnecessary diagnostic or therapeutic interventions, through enhanced communication possibilities between health care establishments, and through patient involvement.
2. **Enhancing quality** of care - increasing efficiency involves not only reducing costs, but at the same time improving quality. E-health may enhance the quality of health care for example by allowing comparisons between different providers, involving consumers as additional power for quality assurance, and directing patient streams to the best quality providers.
3. **Evidence based** - e-health interventions should be evidence-based in a sense that their effectiveness and efficiency should not be assumed but proven by rigorous scientific evaluation. Much work still has to be done in this area.
4. **Empowerment** of consumers and patients - by making the knowledge bases of medicine and personal electronic records accessible to consumers over the Internet, e-health opens new avenues for patient-centered medicine, and enables evidence-based patient choice.
5. **Encouragement** of a new relationship between the patient and health professional, towards a true partnership, where decisions are made in a shared manner.
6. **Education** of physicians through online sources (continuing medical education) and consumers (health education, tailored preventive information for consumers)
7. **Enabling** information exchange and communication in a standardized way between health care establishments.
8. **Extending** the scope of health care beyond its conventional boundaries. This is meant in both a geographical sense as well as in a conceptual sense. e-health enables consumers to easily obtain health services online from global providers. These services can range from simple advice to more complex interventions or products such as pharmaceuticals.

9. **Ethics** - E-Health involves new forms of patient-physician interaction and poses new challenges and threats to ethical issues such as online professional practice, informed consent, privacy and equity issues.

10. **Equity** - to make health care more equitable is one of the promises of E-Health, but at the same time there is a considerable threat that E-Health may deepen the gap between the "haves" and "have-nots". People, who do not have the money, skills, and access to computers and networks, cannot use computers effectively. As a result, these patient populations (which would actually benefit the most from health information) are those who are the least likely to benefit from advances in information technology, unless political measures ensure equitable access for all. The digital divide currently runs between rural vs. urban populations, rich vs. poor, young vs. old, male vs. female people, and between neglected/rare vs. common diseases"

The analysis in [17] shows the correlation of the two conception "telemedicine" and "E-Health". Author in [17] supposes that the conception of "E-Health" is the extending of the conception "Telemedicine", which is the provision of health care services, clinical information, and education over a distance using telecommunication technology. The use of Internet changes some aspects of the telemedicine in point of view of developers who propose term "E-Health" [17].

There are some other definitions of E-Health. E-Health is considered as a medicine management system based on information technologies and a regulatory and methodological framework. E-Health is also defined as an info-communication system that provides quick access to all information about the patient, as well as giving the opportunity to consult the patient at a distance [44; 78; 112]. It allows you to perform clinical work remotely, process remote diagnostic data, electronically monitor the patient, use aggregated data in the field of healthcare, i.e. data obtained by combining standardized digital medical records without the ability to identify the patient, maintain standardized electronic medical records, perform remote health care and diagnostics.

We can summarize that E-Health is based on using technologies to improve the quality of healthcare, and the advances in this domain have allowed both patients and medical professionals to gain access to a variety of resources make healthcare more efficient and cost effective.

All countries try to build National E-Health infrastructure. Issues related to national E-Health programs are prioritized by international organizations (World Health Organization, Organization for Economic Cooperation and Development, European Commission, etc.). Every country takes numerous significant steps to enable quick and efficient transition to E-Health, namely, many states have already introduced local information systems in medical institutions, created a number of specialized medical registers and databases, and continue implementation of the electronic prescription service.

The main advantages of the EH include [77]:

- efficiency and quality (increasing the efficiency of medical care, reducing time and money costs due to improving the quality of medical care);
- transparency (creating a single information and communication space allows one to make the work of health organizations more consistent and transparent for external and internal control);
- accessibility (the development of ICT expands the possibilities of providing and receiving medical care regardless of the patient's location, based on the principle of social equality and justice);
- patient-centricity (the EH system gives the patient greater freedom of choice, which contributes to making an independent decision based on the information received, which in turn forms a new model of the relationship between the doctor and the patient).

The main impact of the introduction of EH is seen in the qualitative change in the system of relations between the medical worker and the patient, which determines the focus of this work, that is predominantly aimed at assessing the prospects for the development of the EH system from the point of view of human rights. As a result, based on the analysis and taking into account the human rights-based approach, we have developed a conceptual framework for the relationship between a medical professional and a patient in the context of the introduction of an E-Health system.

Current task for every country is to assemble the existing fragments of E-Health structure into a unified national system based on international standards, and to create appropriate conditions to improve international cooperation.

Main components of E-Health are the following [4]:

- Hospital information systems that are based on full informatization of a hospital activity and include all main system components such as Picture archiving and communication systems (PACS), Radiology Information Systems (RIS) and other systems.

- Telemedicine that allows a patient to receive on-line consultations with specialists who are not only outside the locality of residence, but also outside the state.
- Electronic health record (EHR) that is an automated information system of electronic healthcare documents that keep medical records in digital form, so that any patient can have remote access to his medical history, including using mobile apps (special emphasis it to be put on meeting the requirements on preservation of medical confidentiality).
- Electronic prescription that allow to obtain the necessary medicines by the patient with the use of electronic connection between the pharmacy and the appropriate database (where data are inserted by medical professionals). For example, in Belarus you do not need to carry a paper-based prescription with you (which can be easily lost or damaged); it is enough to show a special plastic card at the pharmacy, and the pharmacist will be able to see which medicines are necessary (this is especially important if the patient has chronic diseases, as well as for persons using medical benefits).

All these components are considered in Chapter 2 in details.

In should be noted that the E-Health domain is an intensively and rapidly developing one, which leads the modification of the E-health conception. In paper [27], such conceptions as Connected Health, Remote Health Care, Smart Health Care and Precise Health Care were considered. All these conceptions are developed in framework of E-Health, but with indicated specifics.

The Connected Health development is caused by the population of the world is ageing. As a result, the incidence of chronic disease is projected to increase, there are predicted shortages in health care workforce. Connected health care, via the use of health informatics, disease management and home telehealth technologies, has been suggested as an approach to ease the projected strain on future health care.

The Remote Health Care includes a telecare medicine information system, a personally controlled health records system, and patient monitoring.

The Smart Health Care is a combination of people, processes, and technology, where devices, services or interventions are designed around the patient's needs.

We can see that all these conceptions are modifications of E-Health and all of them has the interaction of patient and medical professional.

1.2. Medical professional and patient

In Healthcare, there are two main actors: medical professional and patient. Medical professionals (Healthcare Professional, Doctor, Medical worker) are individuals who have a professional medical education and carry out medical activities. Patient can be defined as an individual who is (was) a consumer of medical services [93].

In this book, the terms "doctor" and "medical worker" were used as a broader category, which includes all persons who, in accordance with the established procedure, are engaged in activities related to the organization and provision of medical care, ensuring the sanitary and epidemiological well-being of the population, conducting medical examinations (doctors, nurses, etc.). The patient is viewed as an person who has applied for medical care, is under medical supervision or receives medical care. It should be noted that the range of patients is not limited to citizens of the country – both foreign citizens and stateless persons have the appropriate set of rights, and therefore the introduction of EH should take into account their specific needs.

The new E-Health system gives fundamentally new opportunities in the development of the industry, qualitatively changes the approaches to the model of mutual support for all participants in the provision of medical care.

Medical professionals receive the necessary information at the time of providing medical care to the patient about critical inconsistencies or deviations from the current standards, or about changes in the patient's vital signs.

For technologies to be useful and transformative, they must be adopted and used by health professionals and end-users. If the tool is designed for patients, but they do not feel its value, or if they do not have enough skills to use this technology, then the digital tool does not benefit. There must also be compatibility between people, so that people's skills and way of thinking about digital health technologies coincide and that they can work with a variety of tools in different circumstances. This means that it is necessary to ensure that both patients and medical professionals have access to training in E-Health skills related to available technologies.

The ultimate goal of the development of E-Health technologies is to shift the focus in the provision of medical services from the doctor and the hospital to the patient and their well-being through the use of digital technologies. This involves using digital systems to transfer patient data into a single Electronic Health Record that can be accessed by different health professionals, or using electronic medical prescriptions to make it easier for patients to get prescribed medications.

1.3. Evaluation of human factor in healthcare

The interaction of the patient and the healthcare professional is very important for any form of healthcare and should exclude the possibility of medical error as much as possible. A medical error is a preventable adverse effect of medical care, whether or not it is evident or harmful to the patient [57]. Medical errors can result from new procedures, age extremes, complex or urgent care, improper documentation, illegible handwriting or patient actions. But human factor have dominant influence for the medical error [57]. Investigations for minimizing and preventing medical errors should be developed to provide "(healthcare)/patient safety". E-Health can significantly reduce the level of medical errors, but unfortunately they cannot be completely neutralized [66, 71]. Therefore, the analysis and evaluation of medical error is important part of E-Health. It is logical to assume that analysis and evaluation of medical error can be based on methods of *Human Reliability Analysis* (HRA).

According to the literature review the conception of healthcare safety (patient safety) is discussed in point of view of two domains, therefore two directions of study of this problem can be considered [100; 120]. The first of them is named as "cognitive" and considered in healthcare and medicine and focused on organizational, managerial, ergonomic, physiological factors and their influence on medical errors. Many investigations of this type are presented in journal BMJ Quality & Safety (https://qualitysafety.bmj.com). Other direction is named "technical" and presents the investigations on patient safety and medical error based on the use of HRA. Reviews of HRA methods in healthcare [67; 89] show that typical HRA methods have restrictions because this area have many specifics and such methods should be adopted for new area of application. There are differences in organizational and institutional contexts, and the values and needs of stakeholders in healthcare (such as clinical and professional autonomy), as well as methods from other industries, have to be adapted appropriately. Most often, according to considered reviews, in healthcare used such methods of HRA as FMEA (*Failure Mode and Effects Analysis*), SHERPA (*Systematic Human Error Reduction and Predication Approach*), SPAR-H (*Standardized Plant Analysis Risk – Human Reliability Analysis*), HEART (*Human Error Assessment and Reduction Technique*) and CREAM (*Cognitive Reliability and Error Analysis Method*). There are adaptations and developments of these methods for the analysis of specific problems in the healthcare domain. For example, FMEA has been used in cancer diagnosis and treatment [63] and SHERPA in radiation medicine [43]. The healthcare's SHERPA-based method is OCHRA (Observational Clinical Human Reliability Analysis technique) that allows evaluating of technical error in surgery [47]. One more special methods of HRA in healthcare is HFMEA (Healthcare Failure Mode Effect Analysis) [43]. It is FMEA-based method which allows providing the qualitative analysis of healthcare system and for the probabilistic evaluation of medical error.

The process of the medical error estimation starts from the data collection [34]. Techniques of data collection include ethnographic observation, questionnaires, and structured interviews, examination of time spent on specified activities, verbal protocol analysis while carrying out a complex task. This data is ambiguity, vagueness and incompleteness. Task description techniques allow the data collected to be presented in a form that is useful for error analysis and quantification. A combination of observation, structured interviews, and review of available technical manuals is used to form a structured account of the exact sequence of actions needed to complete a task. The most common approaches are hierarchical task analysis and cognitive task analysis [34]. Task simulation methods build on task description and analysis aspects in different contexts (for instance under stress or time pressure) or in combination with other tasks. This step can be interpreted as qualitative step of the error estimation. The qualitative analysis is continued in the next step on human error identification. Most of these techniques are based on initial task analysis and perhaps also a task simulation to identify a list of the potential errors that could occur associated with this task. For example, such techniques as FMEA or SHERPA can be used in this step. It should be noted that some of techniques (for example SHERPA) incorporate a phase to quantify the human error probabilities. However, mostly the quantitative analysis is provided based on other techniques [67].

There are some studies of special methods of medical error [88; 120]. The Data Mining based method for the medical error evaluation for incompletely specified and uncertain data is presented in [120]. The essential goal of this method is construction of the typical mathematical model for the reliability analysis. The well-known methods of the reliability evaluation can be used if the mathematical model is constructed. In paper [88] authors represented the Safer Clinical System program which aim is to adopt and trial in healthcare proactive safety management techniques from safety-critical industries. Authors of studies in [34; 89; 100] have shown that in medical error evaluation the failure of devises and software should be took into account too. This conception and specific of data collected for medical error evaluation cause the development or adaptation of new methods that allow processing of uncertain and incompletely specified data and quantifying medical error. In particular, the Data Mining based method in [120] allows the evaluating of the complex socio-technical system and can be recommended for analysis and evaluation of E-Health system and/or its components considered in [4].

1.4. E-Health in COVID-19 pandemic

E-Health is new technology that combines the exchange of knowledge between health professionals and gives patients access to quality services. Using E-Health apps helps to mitigate the propagation of COVID-19 and preserve the lives of medical personnel [69; 72]. The use of virtual platforms for medical care reduces the saturation of emergency patients during the pandemic. These virtual platforms allow clinicians to effectively detect patients with early signs of COVID-19 before they arrive at the hospital. Also E-Health applications improve the availability of various medical services and health care in pandemic situation such as home health control for elderly patients and helps patients with minor diseases to get the supportive care they need while minimizing their exposure to other patients.

Authors in [69] propose analysis of E-Health transformation under the pandemic of COVID-19 in a large academic healthcare system in New York City - NYU Langone Health (NYULH). A mass migration to telemedicine has been taking place during March and April 2020, co-occurring with a decline of over 80% in in-person visits. Telemedicine urgent care volume grew from 82 visits on March 4 to 1336 after 15 days. Of these visits, 55.3% were COVID-19–related, outpacing the 381 COVID-19 visits in all the NYULH emergency rooms that day. Telemedicine visits for urgent care were spread across age strata with the largest use in the group 20 to 44 years of age (Fig.1.1). According to the research in [69] the E-Health system in urgent medicine was more effective in COVID-19 pandemic. The intensive application of E-Health in pandemic of COVID-19 has already proved to be an invaluable tool to not only divert an overwhelming volume of patients from the emergency rooms, but also transform the work medical practices, across multiple specialties. E-health system and tools can reliably manage thousands of patients over a short period of time, and provide care at times of acute shortage in healthcare. The impact of COVID-19 pandemic to E-Health and telemedicine in last year leads the extension of their widespread availability.

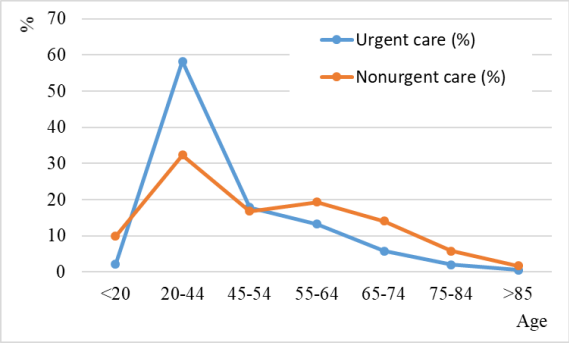


Fig. 1.1. Distribution of telemedicine visits by age

Respectively, according to [21; 69] adoption of E-Health system and virtual software platforms aids in the following:

- Decreases the time required to get a diagnosis and initiate treatment, stabilize, or quarantine a patient
- Facilitates close follow-up with patients who can be monitored from their home to avoid oversaturation of health facilities

- Reduces movement of people, minimizing the risk of intra-hospital infection
- Supports co-ordination of medical resources utilized in distant locations
- Prevents the risk of contagion, particularly for medical practitioners, who are key assets
- Aids in informing the general public
- Saves costs on disposable robes, antiseptic material, gloves, disinfecting of hospital spaces, etc.
- Trains medical practitioners who are new to the treatment of pandemic
- Monitors real-world data.

The efficiency of the E-Health systems in the pandemic is clear, but their wide application depends on some factors. Author of [21] considers three groups of factors that have great influence on the E-Health system use: organizational, technological, social. Organizational factors include:

- availability of funding (The deployment of E-Health system requires time and purchase resources and the lack of funding is a barrier for adoption of telemedicine)
- inadequate training (Medical practitioners who interact with patients through E-Health system should be trained and patients need training in adopting digital technologies.)
- workflow integration (Workflows for adoption of virtual software platforms should be drafted to minimize burden for medical practitioners and should them flexibility in providing medical care).

Technological factors are formed by:

- data privacy and access (The protection and privacy of patient's data must be important, but E-Health should guarantee data privacy and access protection, even if in urgent cases (like COVID-19) personal medical data of patients could be accessed without the need to obtain their consent)
- data security and risk (E-Health involves the digital collection and use of sensitive medical information among patients and medical practitioners, which could lead to a security risk, for the collection, use, and disclosure of sensitive personal data).
- broadband access and Wi-Fi quality (The quality of network communication is a key factor that influences adoption of telemedicine)
- availability of IT infrastructure (Uncoordinated and poor technology adoption mostly in developing countries is a major barrier to adopting E-Health)

The most important social factors are:

- licensure requirements (The licensing policy changes should be established during and after the pandemic without geographical borders).
- health insurance and reimbursement policies (Currently, most medical insurances do not cover telemedicine treatment and as such do not provide reimbursement for patients).
- lack of regulation and advocacy (E-Health system can be adopted as an effective tool in helping to manage the current pandemic. However, existing policies are also a barrier that limits how, where, and when they can be used).
- patients' and medical practitioners' willingness (The limited adoption of E-Health systems is mostly attributable to physicians' unwillingness to adopt telemedicine and many hospitals are not adopting telemedicine because many patients are not well-versed in virtual software platforms).

This experience of E-Health system application in the COVID-19 pandemic will likely create future expectations of care convenience and accessibility that will be hard to reverse once the COVID crisis abates. Similarly, the regulatory changes invoked to support easily accessible widespread telemedicine may be equally difficult to reverse.

Chapter 2. E-HEALTH COMPONENTS

2.1. Hospital Information Systems

Hospital Information System (HIS) provides full informatization of hospital activity. HISs being introduced today are moving away from the monolithic centralized systems of earlier days and now accumulate medical information in electronic health records, support networked interaction among heterogeneous components, with broad conventions and policies governing communication and interactions with other hospital responsibilities.

Hospital information system is formed by information, organizational, software, and hardware tools designed for comprehensive information support of the processes of the health organization. HIS is essentially a computer system that can manage all the information to allow health care providers to do their jobs effectively [95].

The main purpose of HIS is to automate and facilitate the decision-making process of medical and managerial personnel. The system as a whole is complex, i.e. it completely covers the activities of the medical institution. The structure of the HIS can be represented as a set of specialized workplaces of medical personnel that exchange data with each other. The workplace of each employee is formed in accordance with their direct professional and job responsibilities and provides all the necessary tools for automation, collection, transmission and processing of information, enabling the medical staff to organize the processes of diagnosis and treatment at a more professional level. The implementation of HIS in a medical institution provides reliable storage and prompt access to the data of patients of a medical institution.

The intended use and functional options of HIS depend on the territorial level of health care, as well as the special features of a particular health care organization. The main objectives of HIS usage are enhancement of efficiency of treatment (reducing of medical errors), and optimization of diagnosis and treatment expenses including health and clinical management and patient records. The most urgent and challenging task is considered to develop computer-based medical decision-support [102].

The main application fields and functions of HIS consist of the following [52]:

Patient management: patient registry, scheduling of appointments, admittance and bed control; emergency care; in-patient/out-patient system;

Clinical management: hospital releases; medical reports, electronic prescriptions; surgery appointments;

Diagnostics and treatment: laboratory examinations; medical image analysis, computer-aided diagnosis.

Supplies management: stockroom; ordering of supplies; pharmacy; current assets;

Financial management: accounts payable and receivable; banking control;

Support services: hospital infection controls; assets maintenance; vaccine control'

Research and education: library; convention center scheduling, recruiting and personnel.

The architecture of HIS corresponds to a hospital structure. The central component of HIS is Electronic Health Record (EHR) that is usually created when a patient visits the Admission department for the first time. The structure of HIS is shown in Fig.2.1.

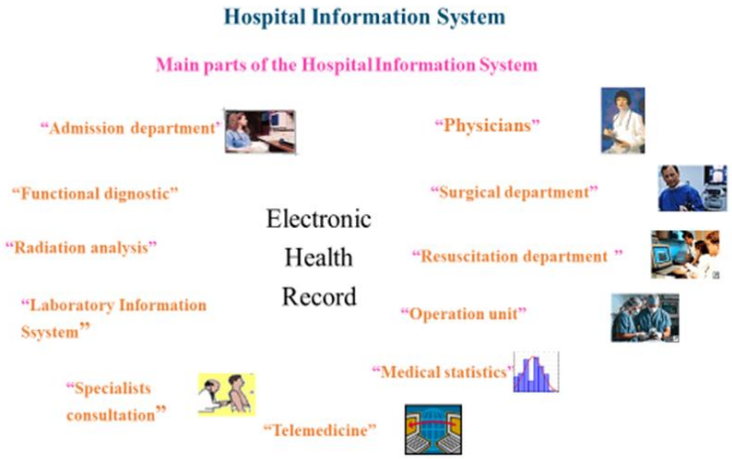


Fig. 2.1. Structure of Hospital Information System

Hospital information systems are deployed in smart hospitals jointly with medical devices and identification components to enable smart end-to-end patient care processes. Hospital information systems usually include:

- Laboratory information systems (LIS);
- Radiology information systems (RIS);
- Pharmacy information system (PIS);
- Pathology information system;
- Blood bank system;
- Picture archiving and communication systems (PACS);
- Research information system and others.

Connections between HIS and some of its components are given in Fig. 2.2.

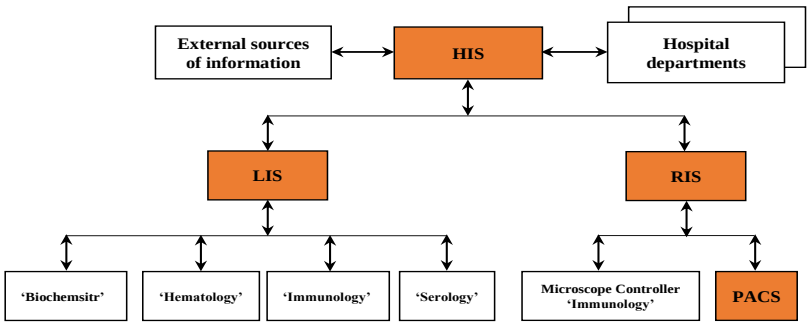


Fig. 2.2. General scheme of HIS and its subsystems

There are the following types of data in HIS:

- Patient data (e.g. electronic health records, including tests results, contact details, etc.);
- Financial, organisational and other hospital data;
- Research data (e.g. clinical trial reports) and data intended for secondary use;
- Staff data;
- Tracking logs;
- Vendor details (e.g. contact details, products used).

HIS allow for rapid access and exchange of medical information at different levels (from local, i.e. one medical institution, to regional and national), access to laboratory and other studies in real time, maintaining electronic databases of patients (with certain diseases), calculating financial costs, both for the organization and for one patient, etc. An important factor is the ability to perform a certain analysis by the system itself.

Over time, the development of artificial intelligence (AI) and the improvement of HIS will make it more likely to make diagnoses based on analytical data about the patient, i.e. the system will analyze all the data about the patient contained in the unified information space of healthcare and make a decision about the diagnosis. Of course, you can not exclude the doctor himself, but having a complete "picture" that the system will provide, the probability of a more accurate diagnosis of many diseases at an early stage will increase.

Also, an important area of EH, in general, is the creation and operation of information systems at national level, which allow monitoring the health status of various population groups in different regions and making operational decisions on health management.

In the process of health informatization, various systems have been created, providing different opportunities in medicine. Let's look at some systems created in the Republic of Belarus that involve the rights of the patient in terms of data collection and processing [93]:

1) Automated information systems (AIS):

- The main and main purpose of AIS "Clinic" is information support for the effective implementation of the functions of a hospital-type medical institution by managing information flows, collecting, analyzing and processing data obtained as a result of examinations and treatment of inpatient and outpatient patients and related documents. AIS "Clinic" is implemented and operated in many health care institutions;
- The purpose of the AIS "Polyclinic" system is to automate the processes of polyclinic-type institutions: organizing, maintaining and maintaining an information database of polyclinic patients, making an appointment with a specialist via the Internet, accumulating information about operations with patients (tests, vaccinations, etc.) and other tasks;
- AIS "Electronic Recipe" provides the implementation of the technology of circulation of electronic recipes in the Republic of Belarus using an electronic digital signature.

2) Distributed telemedicine systems (TMS):

- TMS CF - a distributed telemedicine system for remote consultations on digital fluorographic studies is designed to provide remote services for tele-interpretation and tele-consultation of radiation diagnostic images;
- TMS CM - a distributed telemedicine system for remote consultations on digital mammography studies. The main task of the system is to ensure the availability and uniform high standard of quality of medical care in any medical institution, regardless of its territorial or hierarchical position.

3) Automated information processing systems:

- The Belarusian Cancer Register (BCR) is an information and analytical complex consisting of an automated system for collecting personal information and databases on citizens of the Republic of Belarus, persons with a residence permit who have been diagnosed with a malignant neoplasm. The BCR is the most comprehensive information resource on new and previously registered cases of malignant neoplasms in the country;
- The Republican Register "Diabetes Mellitus" is a database of patients who have been diagnosed with diabetes mellitus. The main objectives of the register are personalized accounting and dynamic multi-year replenishment of patient data;
- The State Register of Persons exposed to radiation as a result of the Chernobyl disaster is a database of citizens (participants in the elimination of the consequences of the Chernobyl disaster, other radiation accidents, etc.). It was created in order to monitor the state of their health, as well as to obtain reliable data on the medical and biological consequences of the Chernobyl disaster and other radiation accidents. The register provides personalized accounting and dynamic replenishment of the necessary information about these citizens.
- The Republican register of patients with HIV infection determines the structural composition of information about patients with an established diagnosis of HIV infection. It is formed in specialized departments at the facilities of health care institutions for centralized monitoring of HIV-infected patients, automated registration of cases of the disease, centralized processing of information about patients, their clinical support, and conducted antiretroviral therapy.
- The Register of Persons Who Consume Narcotic Drugs provides for the collection, accumulation and provision of information on persons who consume narcotic drugs, psychotropic substances and their analogues.

All of the above information systems are specialized in the collection, processing, accumulation and provision of information in certain areas. From the list below, it can be seen that they have been created for certain purposes:

- automation of the processes of medical institutions ' activities;
- conducting analytical research;

- conducting remote consultations.

Also, in some cases, the creation of a particular system was preceded by certain factors (the Chernobyl disaster, the spread of narcotic drugs, etc.), which justified the need to systematize information about patients.

The primary issue is to maintain the balance of "person" and "system". Information systems are designed to automate many processes within the entire healthcare industry: systematize the accumulated information, analyze the information received, facilitate decision-making, etc., but it is necessary to take into account human rights in the functioning of this system.

In connection with the transition to registration at the place of residence, the mobility of the country's population has increased, at present, young people often change their place of residence and at the same time change the medical institution in which the service is provided. In this case, the system should provide an opportunity to receive information regardless of the location of the person (within the framework of the EHR, receiving telemedicine services, etc.), i.e. There should be full integration of the system into the unified information space of healthcare, so that a person applying to any medical institution can receive highly qualified assistance based on their previous appeals and medical history.

A separate area of EH is the creation and application of electronic services for the population: Internet-appointment to a doctor, appointment to a doctor through an so-called “infokiosk” (self-recording terminal), Internet-call of a doctor at home, patient service at the registry of a polyclinic and dispensary using a plastic patient card (PCP), patient service in the hospital's emergency department using a PCP, serving patients of a privileged category using an electronic queue system using a PCP, discharge and procurement of an electronic prescription.

Need to mention recent trends and achievements in the field of HIS development as artificial intelligence [25], big data [92], and block-chain technologies [54], as well as smart devices [30] (“Internet of Things”) for solving the real problems in healthcare and medical education. The opportunities and main challenges in these areas are examined and intensively discussed. These trends became highly sought due to recent pandemics, including COVID-19. In addition, need to say about the recent progress on 3D printing [10]. It encompasses the discussion about the application of 3D printing technology for manufacturing models of organs, permanent implants, testing medical devices, personalized 3D drug printing, and medical education.

Digitalization has been affecting and reshaping health care systems worldwide and caused medical service and education. Innovations can improve the accessibility, quality, and flexibility of healthcare for the public.

However, the clinical effectiveness of the proposed technologies and their validation must be an important step in HIS application. The second issue is the reliability and safety of such digital health innovations. It implies meticulous testing and set-up clinical studies according to ethical principles [74].

2.2. Electronic Health Records

One of the main aims of the EH system is the transition to the maintenance of patient health records from paper-based records to electronic form (Electronic Health Record, or EHR).

As we know, even up to now, hospitals in many countries use the paper-based medical record of a patient. In last 10-15 years it started to move in electronic version and it appeared such terms as Electronic Medical Record and Electronic Health Record. Electronic Medical Record (EMR) is a term often used interchangeably with EHR but there exist certain differences between them. EMR specifically refers to the digitized version of the paper chart in clinician offices, clinics, and hospitals [70]. The EMR contains notes and information collected by and for the clinicians in that specific office, clinic, or hospital setting and is mostly used by providers for diagnosis and treatment.

The Electronic Health Record (EHR) is a longitudinal systematic collection of electronic health information for a patient that is generated by one or more interactions in any health care setting. It allows the formation, collection, storage, transfer (exchange) of the patient's medical records in electronic format. This digitally-stored information should be shareable across different healthcare settings in order to follow patients wherever they go – to the specialist, the hospital, the nursing home, or even across the country [86].

Data in EHR can be divided into three kinds, namely, structured data, semi-structured data and unstructured data. Structured data which is generally stored in a fixed-mode database, contains basic information (such as birth data, nationality, etc.), drugs taken, allergies, vital signs (such as height, weight, blood pressure, blood type, etc.) and so on.

Semi-structured data usually has the flow chart including name, value and a time-stamp. Unstructured data is one kind of narrative data, including clinical notes, surgical records, discharge records, radiology reports, pathology reports. The unstructured text stores a lot of valuable medical information, but lacks a common structure. EHR typically includes such data as [108]:

- Patient personal data including demographical data, age and weight, billing information
- Medical history including former diagnosis and treatment details
- Medications and allergies
- Immunisation status
- Laboratory test results
- Radiology images
- Vital signs
- Progress notes and problem details.

Electronic Health Record is a central component of HIS in particular concerning the integration of patient information. The purpose of EHR is to store the patient information that is generated by physicians, nurses, hospital administrators, etc. The goals of digitizing medical records are, for instance, improving the medical treatment of patients and the computerized evaluation of patient data to support research in medicine. EHRs are not merely automated forms of today's paper-based medical records, but encompass the entire scope of health information in all media forms. Thus EHRs may include medical history, current medications, laboratory test results, etc. A HIS can positively impact patient care in several ways. Some advantages involve increased efficiency and higher quality documentation while others involve automated checks and reminders to assist a physician in providing optimum care.

The EHR has several advantages over the conventional paper-based medical record, including:

- Patient information is available at several working places at the same time.
- The information is available within a short time. This is important in case of emergency.
- Acquisition of data may be improved by the use of advanced user interfaces.
- Reuse of results of medical operations is supported, even over the lifetime of a patient. This may relieve patients from being checked with the same medical operations several times.
- Medical research is supported. An application area is the control of the results of specific therapies.

However, the EHR also has its disadvantages:

- It requires a larger initial investment than its paper counterpart because of hardware, software and training costs for the personnel.
- Capturing the physician-collected data for an EHR can require a lot of time and effort: physicians often use a great deal of information to make one decision.
- Data security.

Together with EHR, an integrated electronic health record (hereinafter – IEHR) can be introduced, which in essence is a collection of data related to a single person collected from electronic health records (EHRs) generated and used by various health organizations. Within the framework of this concept, EHR can be considered as an integral part of the IEHR [29].

The IEHR is patient-oriented and should contain information about the patient's personal data necessary for their unambiguous identification, about all the patient's requests for medical care, the results of observations (what happened), opinions (decisions about what should happen) and treatment plans (plans for what should happen). We can say that the IEHR is a repository of diagnostic and other test data, a long-term storage of information about the patient and about what happened to the patient or was done for him.

The IEHR data allows you to monitor the correctness of the organization of the medical and diagnostic process, make recommendations for further examination and treatment of the patient and dispensary monitoring of him, get the information necessary to establish a disability, as well as issue reference material at the request of departmental organizations.

A mandatory requirement for the functioning of the IEHR is a multi-user mode of access to viewing and editing the data of a single patient in real time. It is possible to edit the data in case of changes in the information, while outdated (no longer relevant) data must be stored in the archive. When making a medical record in the IEHR, the date and time of making the record, as well as the author of the medical record (the ID of the medical record, the full name of the medical

employee who made the record) are automatically saved. Upon request, the user is provided with the data of medical examinations for the case of the disease (updated diagnosis), which are stored in IEHR.

Thus, IEHR is a multifunctional database of clinical data necessary for treatment, support for clinical decision-making by a medical professional, research goals, the work of organizational and methodological departments, statistics departments, and other consumers.

There are many technical implementations for the EHR been used in hospitals and clinics. Methods for EHRs safety have been developed as a principal condition of their use [97]. In January 2014 the first version of the Safety Assurance Factors for EHR Resilience (SAFER) Guides was proposed. The nine SAFER Guides were designed to help health care organizations conduct self-assessments to optimize the safety and safe use of electronic health records (EHRs) in these areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry with Decision Support, Test Results Reporting and Follow-Up, and Clinician Communication. The guides are used for proactive EHR risk assessment and suggest many practices, which we, along with another author, developed to improve the safety and safe use of EHRs. One of trends in the EHRs safety is use of methods of knowledge discovery, data mining and deep leaning [96]. In addition, deep leaning based methods are useful in EHRs for [96]:

- Mortality Prediction
- Length-of-stay Prediction
- Admission Prediction
- Patient Subtyping
- Intervention Prediction
- Medical Cost.

It should be noted that a centralized and decentralized approach is distinguished in the construction of EH systems. To a large extent, this depends on whether the state is ready to take on the dominant function, i.e., on whether the state is ready to take on the dominant function. creating a single information space with integrated HIS and a single patient database (IEHR) and ensuring control over their functioning, or remaining a regulator, allowing not only private but also public health institutions the right to choose a service provider for the development of software and technical solutions and its further support, as well as the possibility of creating information systems with their further integration into a single E-Health system. In the world in general, and in the European region in particular, there are examples of both approaches.

Many countries provide a centralized approach to the construction of the EH system, which belongs to the state. At the same time, the mechanism of interaction in the EH system between public and private medical institutions in terms of providing access to medical information systems, in particular to EHR and various databases, has not yet been developed.

We consider it expedient to preserve the state's dominant function in terms of creating EH system, as well as defining rules and standards in the legal field for other participants, i.e. providing access to the EH system to private medical institutions for the full existence of single information space in the field of healthcare throughout the country.

The implementation of this approach is possible within the framework of a contract concluded between a private medical institution and the state (the holder of the EH system). It is also technically possible to provide restrictions, i.e. access only to those sections of the system that are necessary for reviewing or entering data without the possibility of deleting or modifying existing information.

This issue is very relevant, since recently private medical centers that provide a wide range of services (from laboratory and diagnostic studies to long-term "management" of the patient) have become increasingly widespread. This is primarily due to the fact that these institutions provide an opportunity to receive medical services in a more operational mode, and also a person has the opportunity to receive an alternative opinion. There are also a large number of medical personnel working in the private sector, including doctors who work in the public sector.

Thus, the placement of information obtained during a visit to a private medical institution into a single EH system is very important for the formation of a single information space for both the patient to receive qualified care and for the doctor. In this regard, it is possible to provide other options for entering information in the EHR.

If a person receives any data in a private medical institution, it is possible to enter it as additional information in the EHR by the patient himself. From a technical point of view, it is possible to provide a separate part of the EHR, in which the patient will add information about their own health (PDF files with the name of the medical institution that

issued the document and seals), to ensure the accuracy of the information. However, this option is aimed at a younger generation.

The second option may be to provide the patient with previously received information (in a private medical institution) to their attending physician, and the latter will already enter this information in the EHR.

At the same time, the disadvantages of these options should be taken into account: from the point of view of the patient – this is a time cost, i.e. a person will have to visit both medical institutions (both private and public), while planning an appointment in advance, or, when entering data independently, will have to have appropriate knowledge of using a computer and have an Internet connection; from the point of view of the doctor: also time costs when entering data into the system.

It should be remembered that first of all, E-Health should serve for the benefit of the individual, and not only for the automation of processes. Thus, in order to achieve the full realization of human rights when choosing a medical institution, without fear that the data obtained in a private medical institution will not be included in the unified EH system, it is necessary to provide for the possibility of interaction between public and private medical institutions.

The transition to electronic document management, in general, is a rather lengthy process. This is due to a number of reasons: first of all, it is a change in people's consciousness (increasing digital literacy of the population, trust), second-providing access, and finally, ensuring the protection of information.

Currently, the system of duplication of documentation in health care institutions continues to operate, i.e. information about the patient's health is entered both in electronic form in the EHR and in paper form (printed out and pasted into the patient's medical record).

Of course, in order to obtain economic benefits, it is necessary to completely switch to maintaining documentation only in electronic form. If there are two options, the advantages of electronic document management are significantly reduced, become more expensive and take much more time from the employee.

There are many technical implementations for the EHR been used in hospitals and clinics.

2.3. Laboratory information systems

One of important departments of every hospital is Medical Diagnostic Laboratory (MDL) that performs tests by laboratory personnel or directly from laboratory instruments. Workflow of MDL activity is shown in Fig.2.3.

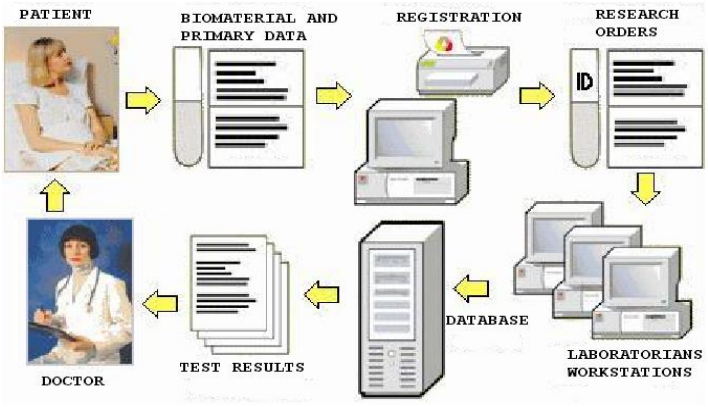


Fig. 2.3. Workflow of MDL activity

A laboratory information system (LIS) is computer software that processes, stores and manages data from MDL. LIS deals with the requirements of laboratory and pathology departments, providing interfaces to the various instruments used to assess chemistry, hematology, immunology, microbiology, genetic, and other histopathologic markers.

There are two main directions of laboratory activity automation [101]. The first direction provides the use of computers for automating information and technical processes inside laboratories. The purpose of this direction is to increase laboratory productivity and research quality, to take into account the use of reagents and materials, and to reduce the number of routine tasks performed by laboratory personnel. The second direction of laboratory activity automation deals with solving the problems of the interaction of laboratories with clinical departments. Included amongst these

problems are the automation of processes of laboratory research orders registration and the transferring of results to clinical departments, and the implementation of expert systems for attending physicians based on laboratory diagnostics. The main purposes of this direction aim to support attending physicians, reduce the delivery time of research orders to the laboratory, reduce the number of unreasonable analyses, and represent test results in a full and correct form. Advanced LIS should support the functions of both of these directions.

Fundamental to any LIS is specimen tracking result validation, and the incorporation of assay results into electronic reports that are communicated to requesting clinicians. Simple automated alert mechanisms are often implemented as part of LIS applications to warm of unexpected or critical test values outside of reference ranges.

Because MDL is the department that carries out many of the examinations performed at hospitals and produces a great deal of medical information, a LIS should be integrated into HIS (Fig.2.4).

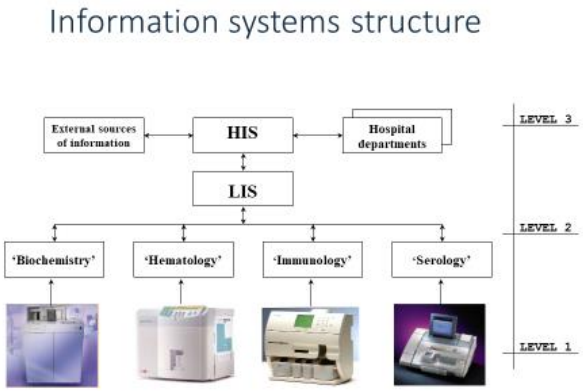


Fig. 2.4. Integration between HIS and LIS.

The general requirements of Laboratory Information System (LIS) as a subsystem of a HIS include [101]:

- Conformity to domestic and international standards.
- Binding of EHR primary data and laboratory data.
- Support attending physicians with test results and their dynamics, and managers with statistic reports.
- Access restriction control to laboratory data on ethics and functional rules.

LIS must have the following features:

- Integration into higher systems (interface with and Public Health Information Network (PHIN) networks, as well as other local and state organizations).
- High level of security (LIS must be configured to address the extremely confidential nature of the database).
- Easy-of-use for medical personnel.
- The input of data manually and from various devices and analyzers.
- A unified, scalable and customisable platform for any specialization (biological, clinical, bacteriological, cytological, etc.).
- Research order creation from outside (physicians) as well as from inside (laboratory personal).
- Data export in various data formats.
- The ability to manage input data flows of research orders.
- The ability to control the traffic of samples and the status of analyses.
- Registering checkpoint analysis times.
- Data visualisation.
- The generation of laboratory workbooks and operation plans on the basis of analysis data (order, results, laboratorians).
- To provide an accounting of time expenses of test performing.
- Preparation of operational and statistical reports in different slices.

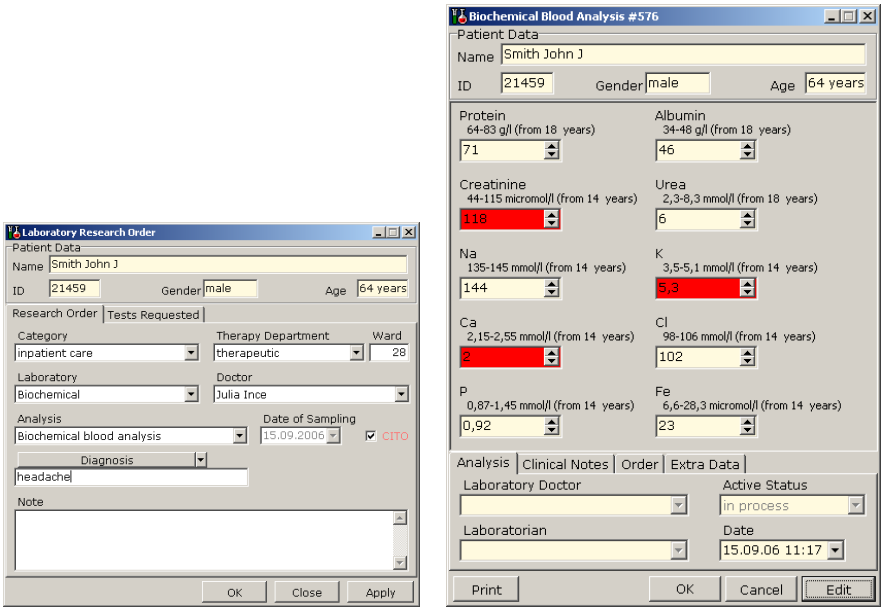
A macro model of LIS functioning follows a certain sequence of events. First, during input, research orders and biomaterial samples are registered and brought into correspondence with each other. Next, analyses (a set of laboratory

tests) are carried out automatically or manually. Then, the obtained results of these tests are passed to a requester. The following peculiarities can be outlined at this stage [101]:

- Test results (and their dynamics) are of great diagnostic importance.
- There is significant document circulation between clinical departments and
- laboratories.
- There are a great number of tests to perform.
- There is an availability of efficient automatic analyzers, information from which can be transferred.
- There is a necessity to improve the reliability and quality of laboratory research.
- There is a great deal of routine work completed by laboratory employees.
- The necessity of laboratory operational statistics preparation and availability of scientific statistics.

All of these factors work together to propel the necessity to solve the problems of transferring and storing data, as well as the need to act responsibly to ensure the reliability and quality of publicly available laboratory research results. Therefore, the best solution to these problems is the use of modern IT technologies and facilities in laboratory activities.

Laboratory information system has been also developed by Belarusian scientists [5]. LIS was integrated into the hospital informational analytical system on the basis of EHR. Common information space gives an optimal way to solve the task of construction of intellectual analytical systems on the basis of the information from a database. The LIS multilevel modular principle construction provides an opportunity for the gradual growth of a number of workstations and workgroups. The developed algorithms were directed on simplification of procedures of search, input of results, laboratory information visual perception. Fig.2.5 shows an example of a screen for developed LIS. In a research order, the following data are taken into account: biographical particulars of patient, number of a patient card, patient status (inpatient care, outpatient care, advisory commission, paid medical service, etc.), department and also laboratory, type of research, lists of tests, attending physician and notes.



A) B)

Fig. 2.5. Research order form (a) and test results form (b)

The form of test results includes biographical particulars of patient, test name, test results, units of measure, normal values, date of carrying out, state (research order, in process, completed, printed, etc.), notes and the executors. For the organization of safety and security of the information in a database, the dynamic configuration of workstations is used.

2.4. Electronic prescription

Electronic prescription started to be used in many countries in the last decade and it is based on an automated information system "Electronic prescription" (AIS "Electronic Prescription"). It is used to form a single database of electronic prescriptions and provide access to information on prescribed and dispensed medicines online.

The following main functions are implemented in the AIS "Electronic Prescription" system [93]:

- creation and maintenance of register of electronic recipes;
- automation of the process of prescribing in electronic format by doctors of health care organizations with the subsequent transfer of information to a centralized repository of electronic prescriptions;
- automation of the process of dispensing medicines by electronic prescriptions in the pharmacy organization, followed by the introduction of information about the release in a centralized repository of electronic prescriptions;
- ensuring that doctors have access to information about all medicines prescribed to the patient, including by other doctors and/or other organizations;
- providing access to information on prescribed and dispensed medicines in the operational mode for the formation of the necessary analytical materials.

AIS "Electronic Prescription" is designed to form a single database of electronic prescriptions and provide access to information about prescribed and dispensed medicines online.

The introduction of such a system has the following undeniable advantages in comparison with the issuance of a paper prescription:

- creates the preconditions for more effective and safe medical treatment – eliminates unreadable or incorrect interpretation of recipes, allowing you to see all medicines, assigned to the patient, therefore, it is possible to avoid these mistakenly dangerous dosages, undesirable interactions between drugs, etc.;
- reduces the cost of treatment due to the reduction of complications of medical treatment (wrong choice of drugs, complications of sharing, side effects)
- eliminates duplication of drug dispensation for a single patient;
- eliminates the forgery of preferential prescriptions, as well as prescriptions for the release of medicines that are subject to quantitative accounting;
- saves the doctor's time for prescribing prescriptions, especially given the possibility of extending the validity of an electronic prescription;
- allows you to avoid unnecessary visits to the clinic only to extend the validity of the prescription;
- it is the basis for the introduction of automation of reimbursement calculations for preferential medicines;
- provides various types of analysis (comprehensive accounting of prescribing preferential medicines in the context of healthcare organizations, doctors, patients, analysis of the cost of drug treatment, etc.).

An electronic doctor's prescription is created with the written consent of the patient to the processing of personal data and information constituting a medical secret in information systems, information resources, databases (banks) of data in healthcare

In a medical institution, the patient is issued a plastic card for medical care and the passport data is checked against the information in the electronic database. The barcode of the card is automatically entered into the electronic medical record of the patient by scanning. When issuing a prescription, the doctor enters the data in the medical information system "Electronic prescription". It should be noted that at present, after entering the data in the AIS, the recipe is still printed on paper. Over time, the paper version will be completely replaced by the electronic version. Subsequently, the pharmacist of the pharmacy, when scanning the card, sees information about the prescribed drug, the amount and dosage on the computer screen. It should be noted that the fact of purchase is automatically recorded in the AIS.

From the point of view of the patient-oriented approach, the introduction of an electronic prescription will allow the patient to purchase medicines both by the international name and by the name of the manufacturer, i.e. the drug that is available in the pharmacy. More than others, this innovation will be appreciated by patients with chronic diseases, since the doctor will be able to duplicate the previously prescribed drugs "at the touch of a button", and the patient, in turn, will purchase the drug in a pharmacy organization without visiting the doctor's office after presenting an electronic card.

Chapter 3. E-HEALTH SUPPORTED SYSTEMS

3.1. Telemedicine

Telemedicine, a term coined in the 1970s, which literally means “healing at a distance”, signifies the use of ICT to improve patient outcomes by increasing access to care and medical information [103]. Telemedicine is used to describe healthcare for patients remotely through the use of telecommunication services and information technologies [33].

Healthcare services, in this case may include diagnosis and treatment, providing medication, counseling, prevention and rehabilitation, health insurance, teaching, research. With telemedicine, the diagnosis and treatment with the opinion of the top experts in the middle of the central hospitals and provincial hospitals will save time for emergency patients. It also allows sharing and dissemination of knowledge in the health sector between regions, between countries, continents a simple, fast and economical, creating opportunities for local medical staff capacity building specialize. At the same time, this is an effective solution to reduce the load for the larger hospital (Fig.3.1).

Fig.3.1. Example of telemedicine consultation

There are many definitions of telemedicine. We can choose the following:

Telemedicine is the remote provision of medical services (for example, patient monitoring and consultation) and the interaction of medical professionals with each other using telecommunications technologies. The standard telemedicine network of a hospital is shown in Fig. 3.2.

Telemedicine can be classified into three main categories: store-and-forward, remote monitoring and interactive service, the most serious challenge lie in the interactive telemedicine services which provide real-time interactions between patients and the care provider [107].

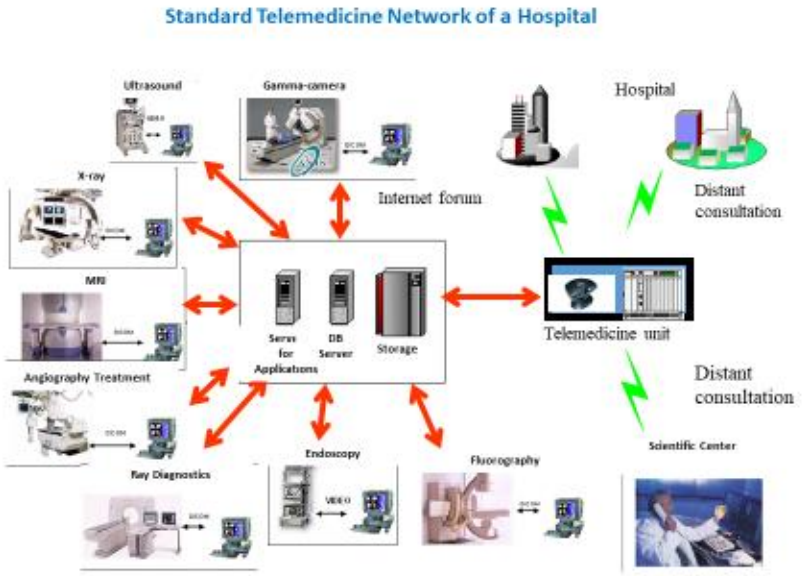


Fig.3.2. Standard telemedicine network of a hospital.

Telemedicine essentially includes five processes: tele-consultation, tele-monitoring, tele-training, tele-staff and tele-radiology [107]. Tele-radiology process is a medical procedure that covers two types of situations:

- Tele-diagnosis that allows a non-radiologist physician to obtain the interpretation of an imaging examination.
- Tele-expertise that enables the exchange of opinions between two radiologists.

Teleradiology is one of the numerous applications of E-Health. For the past 100 years, X-ray film has been almost the exclusive medium for capturing, storing and displaying radiographic images. With the latest digital imaging and compression techniques, partnered with secure communications and information technology, a Picture Archiving and Communication System (PACS) enables X-rays and other digital imaging modalities to be stored electronically and reviewed on screens. Coupling a PACS system with the capability of transmitting images allows remote viewing, diagnostics and consultations and provides a proven method for increasing the standard of delivery of health care.

As part of the provision of telemedicine consultation, the following rights of patients are legally enshrined [93]:

- the right to complete and reliable information about available telemedicine consultations and about the results of the telemedicine consultation (TMC) provided and the decisions taken as a result of its implementation;
- the right to choose where to seek telemedicine advice;
- the right to refuse a telemedicine consultation at any stage of its organization and conduct. The medical professional is obliged to inform the patient of the right to refuse to conduct a telemedicine consultation;
- the patient's right to informational self-determination. The storage, processing and transmission of information relating to the identity of the patient is prohibited until it is permitted by legal regulation or until the patient himself gives consent to it.

When providing TMC, the patient must give informed consent to the telemedicine consultation, which means fully informing the patient of the telemedicine consultation or his legal representative about the purpose, nature and scope of the transfer of medical data, possible risks arising from the transfer, and expected results. The informed consent of the patient to perform TMC is valid only if the patient or his legal representatives have received all the necessary legal information and explanations in a preliminary conversation with the attending physician and signing the consent form.

An important aspect of TMC is confidentiality. This is primarily due to the fact that information about the patient is transmitted over long distances and, as a rule, over public communication networks, since it is quite problematic to provide secure communication channels. It is becoming common to use an electronic digital signature to verify the integrity and authenticity of an electronic document, the secrecy of information, as well as "non-refusal" to fulfill a contract.

It should be noted that within the framework of the provision of telemedicine services, the rights of the patient are implemented quite widely. The legal acts reflect the right to participate in making decisions about their health, the right

to participate in making decisions about the health of other persons, the right to control access to information about their health, but there is no right to "forget".

In connection with the development of ICTs, it is necessary to provide for the possibility of a patient seeking advice without the recommendation of the attending physician, i.e., if desired, a person should be able to contact any medical institution, any doctor (by prior online appointment).

If such an opportunity is provided, doctors should provide time for conducting a teleconsultation in the reception schedule. This is due to the fact that it takes a long time to get acquainted with the patient's medical documents. Also, if a person voluntarily applies for a teleconsultation, then this service should be provided on a paid basis (this measure will allow the patient to think about whether he needs this consultation, and not to apply "for no reason").

In this way, a balance will be found between the rights of the person and the doctor. On the one hand, a person, regardless of the place of residence (currently medical care is provided at the place of residence), will be able, if necessary, to apply to any medical institution, to any doctor. On the other hand, the doctor will be able to devote enough time to consider the issue that the person addressed.

This approach will not affect the socially-oriented approach of the state. In recent years, more and more people prefer to go to private medical institutions on a paid basis, as this saves time and provides an opportunity to quickly get medical care, especially for narrow specialists. It should be noted that the provision of telemedicine consultations, including on a paid basis, is used in many countries.

3.2. Platform for E-Health based on GRID layers

The “Internet of things” is another revolution for the world given by ICTs. Devices, system components and networks are becoming autonomous, ubiquitous and interconnected. When this technological advancement applies to the healthcare sector, one of the most traditional critical sectors, the results are remarkable. Connected medical devices transform the way the healthcare industry works, both within hospitals and between different actors of the healthcare industry. All these devices should be connected by GRID-platform.

The term “GRID computing” was adopted in the 1990’s to describe an architecture and set of communication and policy standards to allow large groups of “personal” computers to work together to provide at low cost the computational power of a supercomputer by exploiting parallelism [102].

GRID can be defined as a consistent, open, and standardized environment that provides a flexible, secure, coordinated separation of computing resources and information storage resources that are part of this environment. GRID can facilitate the coupling of geographically distributed resources and offer consistent and secure access irrespective of users' physical location or access point. GRID is proven to share, select, and aggregate a wide variety of distributed resources, such as storage systems, data sources, instruments and software systems to be used as a single and unified resource.

GRID is a networked hardware and software system that enables to share computing resources of the computers in network, increasing the efficiency and speed of processing information. GRID Computing is the base technology for establishing GRID that is software base running on the traditional networked hardware devices.

A promising approach is the implementation of service-oriented architectures for an invisible GRID, hiding complexity for both application developers and end-users. While giving access to distributed services in a wide-area network of connected institutions a GRID-based system can integrate domain knowledge, powerful computing resources for analytical tasks and means of communication with partners and consultants in a trusted and secure system, tailored according to the users’ requirements in clinical applications. The main challenge in the domain of GRID-based tools and applications is given by hiding the complexity of the underlying GRID infrastructure from the application developer by integrating higher level tools and services for GRID application development [95].

The main reason for the lack of GRID-aware applications appears to be a gap between the GRID infrastructures and their developers / operators on the one side and the developers and end-users of GRID-based applications on the other side. To bridge this gap, a user-driven approach needs to be implemented, which includes all stakeholders.

E-Health GRID gives an easy integration of distributed medical datasets. E-Health GRID can align a large number of distributed data, a large-scale statistics capacity, and vast epidemiology.

It supports to develop the GRID applications to acquire high computing capacity and can transfer the very enormous of data. GRID was implemented on the base of open architecture and consists of the following layers (Fig.3.3) [109]:

• **Fabric layer**: locates the GRID resources. It consists of the hardware: computer (parallel, cluster), the servers to store data.

• **Connectivity layer**: connects all the resources on the GRID network: manages the security of GRID; sends and receives protocols on the high level.

• **Resource layer**: shares the GRID resources with some main functions: manages the system resources; supports the information services and supports to access data.

• **Collective layer**: collects and locates many kinds of resources. It allocates and revokes resources and manages data replication.

• **Application layer**: combines the user-oriented applications to access and uses the GRID resources; it consists of the computing applications on GRID.

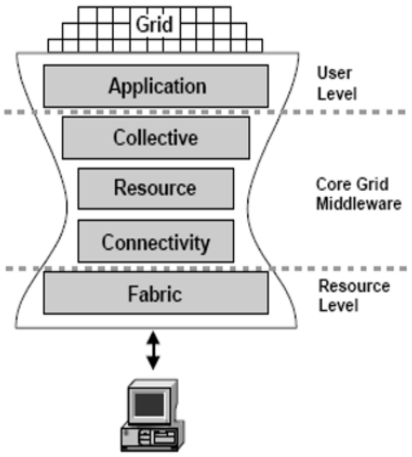


Fig. 3.3. E-Health GRID Layers

At each layer, the components are shared the common attributes and added the new features that not impact on the other:

Most modern city hospitals currently support Internet access to internal organizations, services and personal records. GRID will provide advantages and additional services to a typical patient. E-Health GRID gives an easy integration of distributed medical datasets [52].

3.3. Picture archiving and communication systems

Picture archiving and communication system (PACS) is a medical imaging technology that provides economical storage, retrieval, processing, management, distribution and presentation of medical images. Electronic images and reports are transmitted digitally via PACS systems. This eliminates the need to manually file, retrieve, or transport film jackets. It allows a healthcare organization (such as a hospital) to capture, store, view and share all types of images both internally and externally.

First Picture Archiving and Communication system project titled "Installation Site for Digital Imaging Network and Picture Archiving and Communication System" was implemented in the U.S. in 1983 with the investment of U.S. Army and managed by The MITRE Corporation in 1986. In Asia, the First International Symposium on PACS and PHD (Personal Health Data), was held in Japan (7/1982) by the Japan Association of Medical Imaging Technology. Japan leading research and early development of PACS and considers this as a national project [29]. The national resources are distributed to many manufacturers and hospitals, universities. In Europe, EuroPACS (Picture Archiving and

Communication Systems in Europe) is held every year since 1983. National Health Service (NHS) in the UK is one of the leading organizations in the research and development of PACS in Europe and also had a lot of success.

Due to the differences in operating conditions and environment, PACS are different in North America, Europe, and Asia. At first, the research and development of PACS in the U.S. set huge support from the government agencies and manufacturers. In European countries, the PACS developed through the support of local organizations and multinationals. The European research team aims to partner with a major manufacturer, because most of the components of the PACS were developed in the U.S. and Japan, not in Europe. These groups insist on modeling and simulation as well as PACS systems, survey components of PACS image processing [70].

Radiology Information Systems (RIS) are very popular in European countries and America. RIS are widely deployed in most hospitals, and also there are many components of RIS which have been developed as an open source and are available for users to learn and use.

The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine). DICOM permits PACSs, Radiology Information Systems (RIS) and more medical imaging systems to connect with and pass data to systems at other healthcare facilities [86].

There are many types of medical images: ultrasound (US), magnetic resonance (MR), nuclear medicine imaging, positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammograms (MG), digital radiography (DR), computed radiography (CR), histopathology, ophthalmology, etc. All of them are processed through PACS.

PACS systems work with digital images. Image is a digital matrix. When implemented on a computer, the matrix element is a pixel. Thus, the image can be considered as a set A={aij}, where the value of aij is equal to the value of the pixel brightness.

There are three main types of images:

- binary image has two levels of brightness, where one corresponds to the background, the other to the object in the image;
- gray-scale image consists of several levels of a halftone value and is most often a black-and-white image of photographic quality, c
- color image has three characteristics: chroma, saturation, brightness, in practice determined by three halftone pseudo-images that characterize these values or their mathematical transformations.

PACS system is divided into three main classes [107]: Class Image Devices (modalities), Class PACS server systems and Class Workstation Applications (Fig.3.4). The conventional imaging devices are digital X-ray (CR) cameras, Computed Tomography (CT), UltraSound (US) and Magnetic Resonance (MR) scanners. These devices are designed to provide medical images or video sequences.

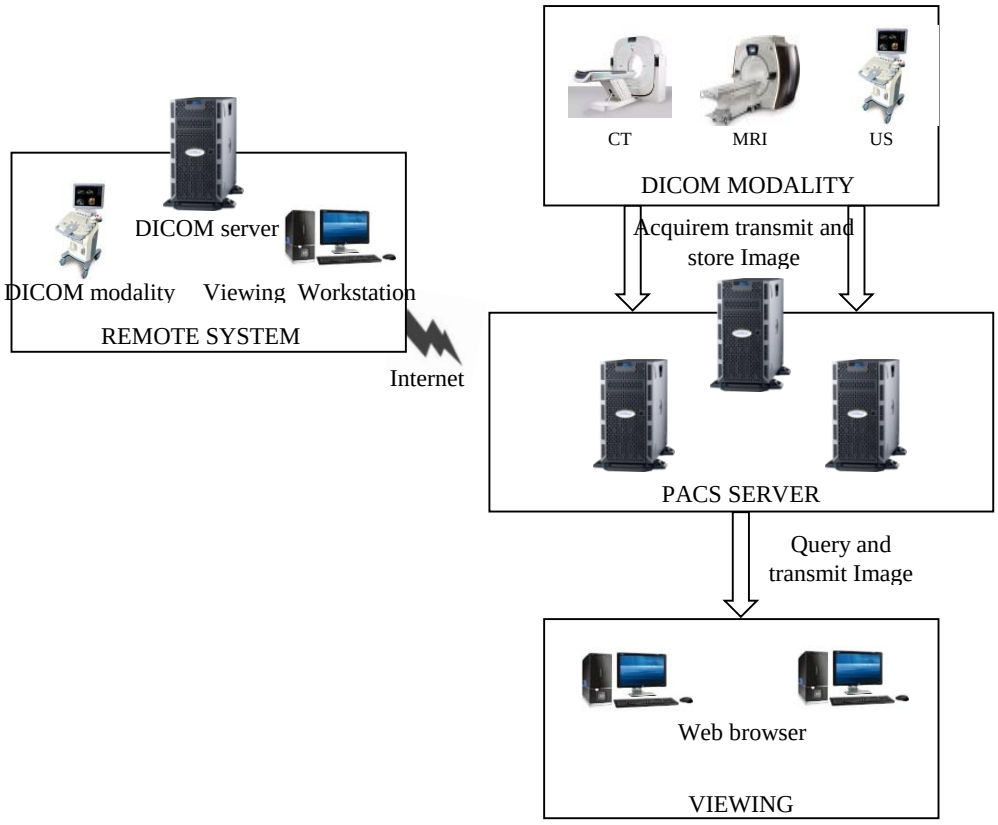


Fig. 3.4. General architecture of PACS

PACS Server is a core component of the system, responsible for three main functions:

- Collecting data from medical imaging devices immediately after patient admission photography pictures port (PACS GATEWAY).
- Organizing storage and management of medical data and other relevant information of the patient.
- Providing, coordinating the application support the examination and treatment: information function to filter, display support functions, image processing and analysis, functional diagnosis support, functional support consultation.

PACS has demonstrated an increase in department and hospital productivity by electronically managing digital image data. The system provides an efficient means for archiving, retrieving, and displaying digital data, and has three major advantages over traditional hardcopy/film-based reading and storage (Fig. 3.5) [108]:

- Enable medical image and data distribution throughout computer networks.
- Enable electronic archiving and retrieval of image data.
- Enable interactive consultations between radiologists and other physicians on the network.

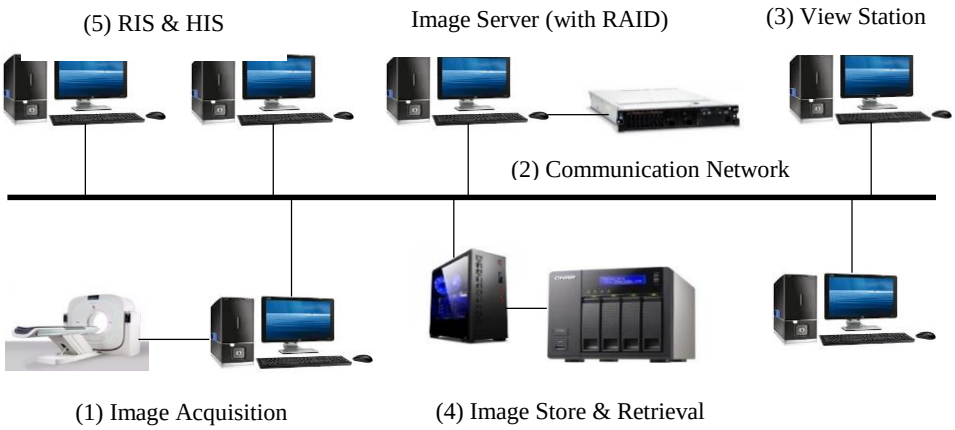


Fig. 3.5. Typical PACS Configuration

PACS should be built as open system interfaces connected on the development of data standards in the field of medical standards like DICOM and HL7.

Another system that works with images is the Radiology information system (RIS). RIS is a type of radiology software for storing and managing medical imaging data. Just like a Hospital Information System, it automates data management, but is adapted specifically for radiology departments [108].

RIS works in the same field as PACS and is often used in conjunction with it. The question can thus arise: what is the difference between RIS and PACS?

While RIS improves workflow and streamlines processes, systems such as PACS provide storage and a long-term option for the management of patient information. PACS also provides features and tools for advanced image manipulation. RIS and PACS, therefore, act as two complementary systems and are integrated in most radiology clinics.

All three systems (HIS, RIS and PACS) need to be closely connected with each other, truly meet the requirements of the hospital and fully exploit the power that the number of medical devices can bring. Links between HIS, RIS and PACS are shown in Fig.3.6 [108]. This requires that all three systems must be able to communicate with each other easily, flexibly through common data standards [58].

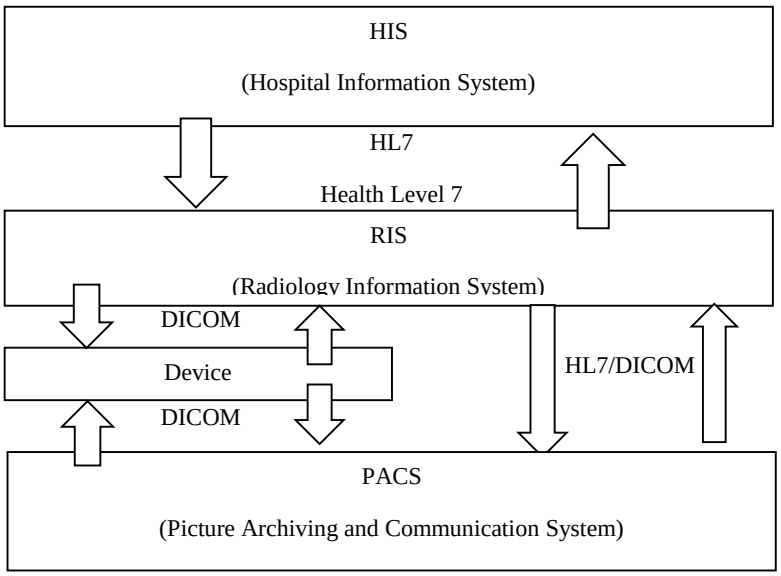


Fig. 3.6. The links between HIS, RIS and PACS

3.4. Decision support systems for medical diagnosis

Clinical decision support systems (CDSS) became very popular and useful today. Since their first use in the 1980s, CDSS have seen a rapid evolution. They are now commonly administered through electronic medical records and other computerized clinical workflows, which has been facilitated by increasing global adoption of electronic medical records with advanced capabilities.

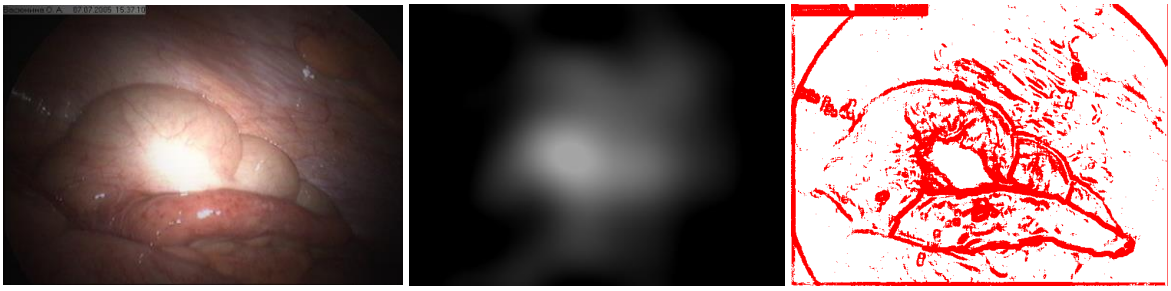
A traditional CDSS is comprised of software designed to be a direct aid to clinical-decision making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base and patient-specific assessments or recommendations are then presented to the clinician for a decision [101].

CDSS for clinical diagnosis are known as diagnostic decision support systems (DDSS). These systems have traditionally provided a computerized 'consultation' or filtering step, whereby they might be provided data/user selections, and then output a list of possible or probable diagnoses.

Diagnostic decision support systems have been developed by our colleagues. Let us mention some of them.

System for diagnosis of acute appendicitis.

The system described in paper [117] has been developed to process endoscopic image processing method to detect acute appendicitis. For this purpose, we first introduce image enhancement techniques, so that we can improve the quality of endoscopic images for further processing. Simple and effective image segmentation techniques have been developed to detect vessels and vermiform appendix (Fig. 3.7). The hierarchical set of features have been extracted and proposed for the diagnosis of acute appendicitis. It includes geometric, colorimetric, densitometric, and topological features. For each appendicitis feature, discriminant indexes have been introduced for diagnosis. This method has achieved good results in clinical application.



(a) (b) (c)

Fig. 3.7. Edge detection in the image of vermiform appendix: (a) the original image; (b) enhanced quality image; (c) image after edge detection.

After the segmentation, features for image objects are usually extracted and calculated. The following types of features are considered: geometrical, topological, densitometric, colorimetric, textural and others. On their basis, conclusions are made about the object type or quality of the image content.

All image features are separated into three groups:

- The first-level are the features calculated for any image type. They are standard geometrical (area, perimeter, etc.), topological (elongation, circularity, etc.), colorimetric (color), densitometric, basic textural, etc.
- The second-level are the features that specific for endoscopic images (17 features).
- The third-level are the features that specific for diagnosing acute appendicitis (5 features).

Features of concrete level are usually computed according to the characteristic of the previous level.

To summare, the following 5 main features are used for the diagnosis of appendicitis.

- elasticity of vermiform appendix;
- color ratio of vermiform appendix;
- color ratio of surroundings of vermiform appendix;
- maximum dispersion of color components;
- relative area of vessels.

The proposed discriminant indexes for appendicitis features are shown in Tab.3.1 [117].

Tab. 3.1. Discriminate indexes for diagnosis of acute appendicitis

Features	Acute appendicitis	Absence of inflammation
Elasticity of vermiform appendix	>74 %	≤74%
Color ratio of vermiform appendix	<0,76 or 0,98–1,1	0,76–0,97
Color ratio of surroundings of vermiform appendix	0,4 – 0,75	0,6 – 0,92
Maximum dispersion of color components	≥18	<18
Relative area of vessels	>0,167	0–0,167

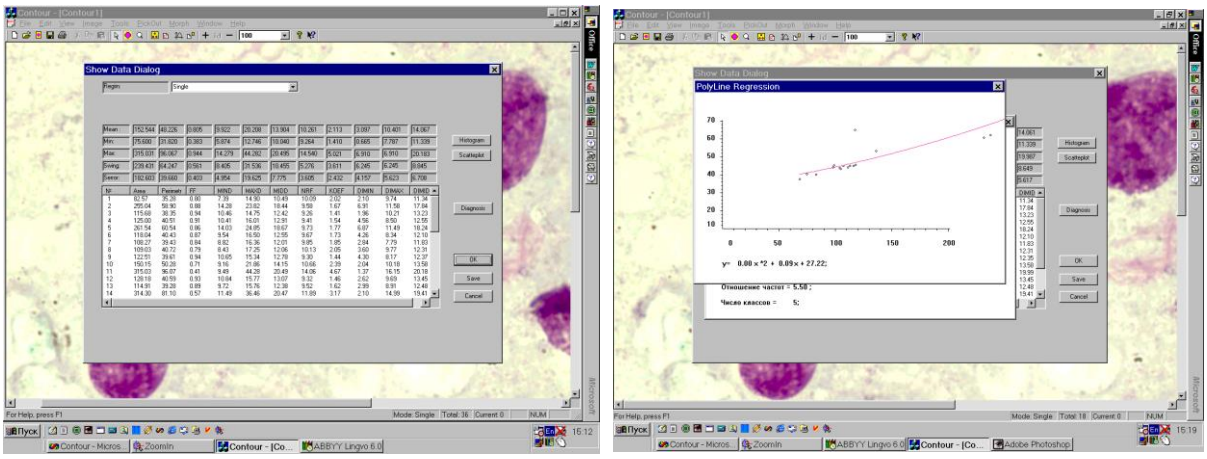
The use of computer technology allows to automatically determine image features that are useful for endoscopic diagnosis of acute appendicitis. However, dramatic changes in physical characteristics do not guarantee 100% diagnostic accuracy. The diagnostic automation system based on endoscopic image features is designed to facilitate the work of a doctor, not to replace him.

The use of this system in medical practice considerably improves the accuracy and efficiency of verification of preoperative diagnosis which is very important in the selection of surgical treatment.

System for diagnosis of thyroid cancer

An approach for cytologic diagnosis of thyroid cancer with the help of automatic morphometry was proposed in paper [76]. This approach is based on a developed computer analyser of images that aimed at: automated processing and binarization of colour images; automatic raster-to-vector transformation and formation of biological objects; morphometric assessment of biological objects by quantitative parameters characterizing the changes of cell nuclei; building of expert system with the further diagnosis of thyroid cancer.

After cytological image segmentation, various parameters for every cell and for all cells are calculated. The parameters are the following: cell area, perimeter, shape factor, diameter, (mean and max), elongation coefficient, circularity factor, etc. Obtained vector object data with their semantic information are further used to build a morphometric database (Fig. 3.8).



a) b)

Fig.3.8. Morphometric database (a) and Scattered diagrams of dependence of thyrocyte nuclear perimeter on the area (b).

The morphometrically revealed regularities of pathological changes in follicular cell nuclei of the operative material can be united into the system of quantitative parameters characterizing malignant and benign thyroid diseases. Tab.3.2 gives the system of parameters including mean thyrocyte nuclear area, numerical characteristics of scattered histograms of their area, regression equation coefficient and the discriminant index [76]. A set of boundary values of karyometric parameters between the malignant and benign pathology given in this Table is, actually, an expert system for thyroid carcinoma diagnosis.

Tab.3.2. Expert System on the Base of a Set of Karyometric Parameters of Thyrocytes of Operative Material for Thyroid Cancer Diagnosis

Thyroid pathology group	Karyometric parameters					
	Mean area, μm²	Histograms of area distribution		Regression equation coefficients		Discriminant index, %
		Ratio of frequencies	Number of classes	b	c	
Control	<54,6	0	1	>0,354	<11,36	0
Malignant	>100,1	>1	5	<0,263	>15,12	>65,3
Benign	<91,1	<1	2	>0,325	<12,06	<62,3

As the result, an expert system is created, which is based on a set of karyometric parameters reflecting the regularities of pathological changes in thyrocyte nuclei with malignant and benign thyroid pathology.

The use of this system allows raising considerably the accuracy and efficiency of verification of diagnosis at preoperative stages which is most important when the mode of operative treatment is being chosen.

System for diagnosis of breast cancer

The system for diagnosis of breast cancer based on analysis of histopatological images is described in paper [16]. The approach is based on using the U-NET neural network to isolate and classify malignant tumors in histopathological images. The test set consists of the following types of tumors are present in the training set used, benign: adenosis (A), fidroadenoma (F), phyloda (PT) and tubular adenoma (TA); malignant: ductal carcinoma (DC), lobular carcinoma (LC), mucoid carcinoma (MC), papillary carcinoma (PC) (Fig.3.10).

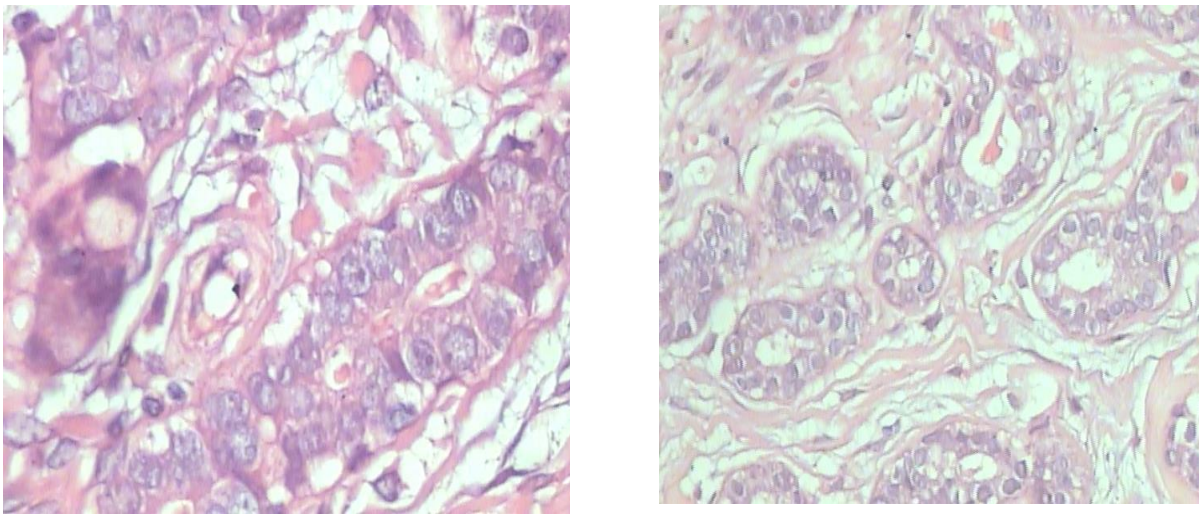


Fig. 3.10. Fibroadenoma (magnification 400x, benign tumor) on the left and carcinoma (magnification 200x, malignant tumor) on the right

The approach is to use the modified U-Net network and use the properties of some image channels. Experimentally, the best features were selected to classify images, as shown below. The main idea is to build a balanced training set and predict the result using several outputs of the neural network for the same image. The goal is the classification of 8 types of tumors (both malignant and benign) in the images [16].

The distribution of percent errors by varying degrees of increase and different classes of benign and malignant pathologies can be traced in Tab.3.3. The accuracy of the prediction of the trained model by different degrees of distribution can be traced in Tab.3.4.

Tab.3.3. The distribution of errors (%) during training

Class	Sub-class	40x	100x	200x	400x
Benign	Adenous	15.7	21.7	9.7	10.3
	Fibroadenoma	28.5	31.8	29.5	30.2

	Cystic epitaleoma	13.6	18.6	10.1	14.4
	Tubilar adenoma	23.1	19.5	15.6	16.5
Malignant	Dual	11.6	2.8	13.9	8.7
	Lobular	0.0	0.0	0.2	3.2
	Mucous	2.8	2.8	13.9	10.1
	Papillary	4.7	5.1	7.1	6.6

Tab.3.4. Prediction accuracy by varying degrees of distribution

Degree of increase	Fold1	Fold2	Fold3	Fold4	Fold5	Fold6
40x	84.37	85.91	84.86	88.08	89.20	86.48
100x	84.32	91.70	82.43	86.47	87.84	86.57
200x	86.82	92.59	85.43	87.24	88.06	88.03
400x	86.42	92.40	80.63	83.12	84.92	85.5

Corporation decision support system for diagnosis

Big Data processing has achieved a noticeable expansion recently, particularly in consumer's behaviour analysis. Therefore, many platforms for integrating, processing and applying machine learning techniques over large datasets have been developed. Many are user-friendly platforms with graphic interfaces, such as Handoop, IBM Watson, Microsoft Azure, RESTful. These are areas where mastering and understanding of a large amount of information about new developments is required, taking into account the accumulated experience and high risks when making decisions. This belongs to the field of medicine.

This is where cognitive technology is especially valuable. They provide specialists with abstract information on new advances in a specific medical field, help to choose the best treatment option for each patient, taking into account the history and specifics of his illness. The effective use of IBM Watson for the treatment of oncological diseases is known [46].

In the future, according to the estimates of the developers, this system will be adapted to other areas of medicine.

Chapter 4. DATA PROTECTION IN E-HEALTH

4.1. Medical data: standards

Usually, there are the following types of data in HIS:

- Clinical and administrative patient data (e.g. electronic health records, including tests results, contact details, etc.);
- Financial, organisational and other hospital data;
- Research data (e.g. clinical trial reports) and data intended for secondary use;
- Staff data;
- Tracking logs;
- Vendor details (e.g. contact details, products used).

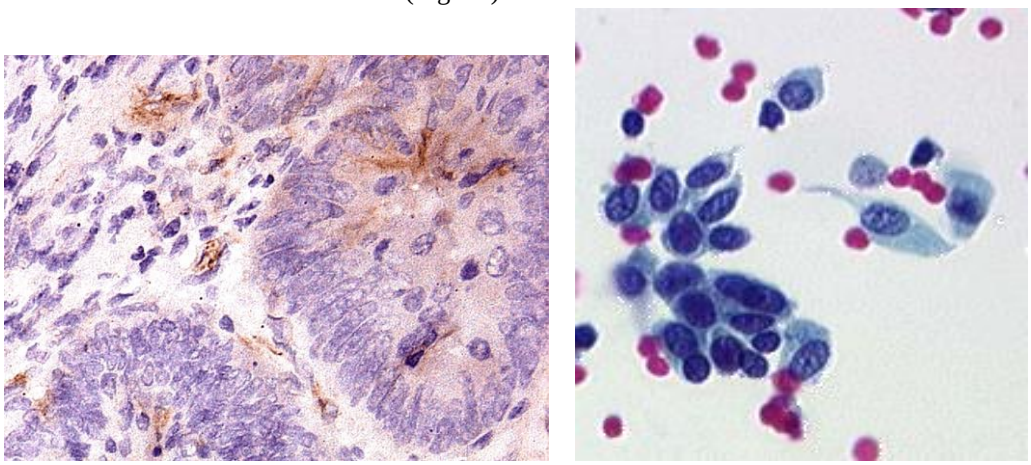
Most of these data are commonly used in various organizations. We can select medical data that are connected to the treatment process. Data that are stored in EHR are connected to the patient.

Patient's data can be stored in digits, images or various descriptions. During the last 20-25 years all medical images are transformed into digital form.

Medical images are usually classified according to the method of obtaining them and the area of use. Currently, there are quite a few ways to obtain medical images. According to the method of obtaining images, they are divided into types:

- histological images;
- images of radiation techniques;
- endoscopic images;
- thermal images.

The methods of optical and electron microscopy are the basis for obtaining histological images. Histological images reflect tissues and cellular structures (Fig.4.1).



a) b)

Fig. 4.1. Example of histological (a) and cytological (b) images.

Radiation imaging techniques are based on the analysis of specific radiation Traditionally, such images include X-ray, magnetic resonance, and ultrasound images.

Endoscopic images are obtained by optical methods, but the technique of obtaining them has a specific shade, so they are defined by a separate class.

Thermal images are obtained by registering thermal radiation and the distribution of body surface temperature is determined from them.

In medical practice, three types of images are distinguished by the field of use:

- anatomical features;
- histological (including cytological);
- physiological.

The three most common-used data standards applied to store medical images are DICOM, HL7 and LOINC. Let us briefly describe them.

DICOM (The Digital Image and Communication in Medicine) is a standard that defines the format and rules of exchange of medical images and related information. The DICOM 3.0 standard was established in 1993, grew out of earlier ACR-NEMA (American College of Radiology; National Electrical Manufacturers Association). The standard facilitates interoperability of medical imaging equipment by specifying: 1) a set of protocols for network communication followed by devices conformant to the DICOM standard; 2) a syntax and semantics for commands and associated information that can be exchanged using these protocols; and 3) a set of media storage services to be followed by standard compliant devices, as well as a file format and a directory structure to facilitate access to images, waveform data, and related information. DICOM has continually updated and adapted itself to keep pace with the changes in the imaging environment and the needs of users [35].

Health Level 7 (HL7): The computer can only the exchange data with each patient when they have a common communication protocol (communication environment and common language). Started in 1987, Health Level Seven is a standard for exchange of data between information systems. The standard's somewhat enigmatic name is a reference to the top layer of the Open Systems Interconnection (OSI) Reference Model, a tiered abstract description for communications and computer network protocol design; the seventh level of the OSI Model is the application layer, in which HL7 exist. Like DICOM, the primary purpose of the HL7 standard is to specify the formatting and structure of information exchange; it does not describe the actual technical details on how the information is to be passed from one system to another [55].

LOINC (Logical Observation Identifiers Name and Codes), a codification for clinical laboratory values and common observation. In 1994, researchers at the Regenstrief Institute developed a universal, pre-coordinated coding system for laboratory tests. Today, LOINC database contains in excess of 50,000 codes for laboratory results, clinical measurements, and findings from other diagnostic tests. LOINC has become the standard coding system for LIS [99].

4.2. Medical personal data protection

When it comes to a data-driven system, it is extremely important to ensure its protection and security. Medical data is confidential and personal, making its protection a key pillar of digital healthcare. Systems and protocols, based on the legislation on the protection of personal data, should guarantee the confidentiality of the patient's medical data in such a way that the citizen can control access to them. It is also necessary to implement security and trust systems to protect against unauthorized access.

Medical data should be stored in cyber-threat-resistant and reliable systems that guarantee their security. Trust-building systems are an important part of ensuring security, an element of which is the use of electronic identification of patients and medical professionals to gain access to data.

What does personal data mean? There is an opinion that personal data include any information about an individual that allows you to directly or indirectly identify him. This approach is enshrined in the legislation of most countries. Thus, personal data can include such information as [1]:

- last name, first name, patronymic, year, month, date and place of birth, address, marital, social, property status, education, profession, income of an individual;
- information related to admission to work (service), its passage and dismissal;
- information about the spouse, children and other family members of an individual;

- information that allows to determine the place of residence, postal address, telephone number and other individual means of communication of an individual, as well as his / her spouse, children and other members of his / her family;
- information that allows to determine the location of real estate objects owned by an individual on the right of ownership or in his use, information about income, property and property obligations;
- information about the facts, events and circumstances of a citizen's private life that allows identifying his identity, information that became known to an employee of the civil registration authority in connection with the state registration of a civil status act, language skills, education, housing conditions, sources of livelihood (income from work or other occupation, pension, including disability pension, scholarship, allowance, another source of livelihood);
- other information that directly or indirectly identifies an individual.

Objectively, any state needs to collect and process personal data. Without personal information, the state cannot perform most administrative tasks: ensuring national security, protecting public order, collecting taxes, implementing social programs and social assistance. At the same time, there should be no contradiction between the interests of the State in the collection and processing of personal data and the constitutional right of the individual to be protected from unlawful interference in his or her personal life.

In every country, the collection and processing of personal data is carried out by a large number of different entities, including state bodies and organizations, local self-government bodies, and non-governmental organizations. At the same time, the current legislation does not establish uniform approaches to the activities of the subjects under consideration for the collection and processing of personal data. There is also no single legal mechanism for protecting the rights of citizens in the processing of personal data.

The protection of personal data of the individual must be carried out not only at the national level, but also the adoption of international instruments to ensure respect for human rights and fundamental freedoms in all countries, regardless of nationality or place of residence, and especially the right to privacy in connection with the processing of personal data. This is primarily due to the fact that today personal data is present on the Internet, most of which is distributed and used in social networks. Since the Internet has a cross-border nature, the protection of personal data is possible when international agreements are adopted [87].

Medical personal data is a very important and specific type of data. Protection of medical data is a vital task for every country.

When a patient is identified for receiving medical care, he (she) must provide personal data in many cases: when registering with a medical institution, when receiving treatment, when conducting telemedicine consultations, and when issuing an electronic prescription. The personal data of the patient must be protected when entering information about the patient in the HIS.

The main mechanism for implementing the principle of confidentiality of information was the responsibility provided for by law for the dissemination of information subject to protection. I.e., it was assumed that the information contained in the information space of the country is protected. Technical progress has overtaken the development of legislation, and it should be noted that insufficient attention has been paid to the legal regulation of personal data protection.

4.3. Data protection in HIS and EHR

One of the main purposes of the HIS is to automate and facilitate the decision-making process of medical and managerial personnel. The system as a whole is complex, i.e. in case it is structures properly it should cover all the activities of the medical institution.

The structure of the HIS can be represented as a set of specialized workplaces of medical personnel that exchange data with each other. Ideally, the workplace of each employee is formed in accordance with their direct professional and job responsibilities and provides all the necessary tools for automation, collection, transmission and processing of information, enabling the medical staff to organize the processes of diagnosis and treatment in an efficient way. The implementation of HIS in a medical institution should provide reliable storage and prompt access to the data of patients of a medical institution.

One of the necessary conditions for the reliable functioning of any HIS is the regulation of access to its resources, i.e. the creation and subsequent maintenance of confidentiality, integrity and availability of information.

Information about private life and personal data refers to information, the distribution and provision of which is restricted, as well as to a legally protected secret – medical secrecy. The information contained in the HIS may also refer to "sensitive information", the disclosure of which may cause moral suffering to a person.

All information collected during the patient's lifetime is shared in terms of access to it by the medical staff. HIS are distinguished primarily by the fact that they store and process information that comprehensively determines a person's social status, and this determines a special form of relations between those who form it and those who use it. This means that, along with increased requirements for the reliability of information, moral restrictions must be imposed on access to it, as well as the legal responsibility of the persons providing it. Any medical professional is fully responsible (morally, administratively, and criminally) for the confidentiality of the information that he or she has access to in the course of his or her professional activities.

Availability, completeness and quality of the records and data in HIS are also important as they can form a basis for a subsequent analysis of the healthcare provision, especially in a conflict situation. Paper documents can be easily modified or forged. In cases when any assessment of the quality of medical care takes place, the quality of medical records is of paramount importance. The completeness of the data in HIS, the ability to track all changes in it allows one to analyze the activities of medical professionals, including in the event of conflict or dispute situations. However, the system has to be designed in a way that will not discourage medical workers from inserting all the information they consider as necessary. The problem which is seen today is that doctors, especially on the early stages of their career, are reluctant to include specific and / details information into the EHR, as they do not want to be seen as making mistakes. A paper-based format allows more flexibility, and thus doctors feel that they are less at risk.

Another important issue with regard to the protection of privacy and personal data in HIS is the delineation on access to its resources (databases), in order to ensure the required level of confidentiality, integrity and availability of information. The decision on how and to what extent to have this delineation depends on the function on the appropriate medical unit. For example, emergency care unit are usually interested in immediate and quick access to patient's data, as emergency situation can be caused or can influence any part of the body. Whether such access should be granted to the professionals in the less urgent cases – is less clear. In many cases countries decide that it is a patient who is to grant a specific medical practitioner a permission to access his data, for example, by using a one-time access code [53].

One of the main conditions for the successful functioning of the EH is the training of medical personnel to work in the system, as well as retraining and continuous professional development (conducting courses and trainings at different levels and for different medical professionals). So the training or retraining of a doctor will be different from the training of a laboratory worker, a paramedic, etc. This is primarily due to the reduction in the time spent on entering data into the system, i.e., entering information should not reduce the time that is given to the patient.

There is no doubt that all medical professionals must constantly improve their skills in accordance with the changes made to the EH system.

Also, an important aspect of the successful functioning of the EH system is the constant monitoring of the information entered into the system, control over its execution (in terms of the appointment of tests, prescriptions, etc.). Analysis of the experience of foreign countries shows that the so-called "human factor" errors should be excluded as much as possible. In this regard, we consider it necessary to provide for the possibility of automatic control of the system, i.e. if there are recommendations in the destination list, then the system itself should signal and "do not skip" further if the information is not sent in a certain direction (pharmacies, laboratories, etc.).

It is also necessary to provide a list of data that a medical professional needs to enter into the system for certain purposes (either an epicrisis, if this information is provided for other medical professionals, or a full description of the symptoms of the disease, prescriptions, development dynamics, etc.). In this regard, it is important to differentiate access to the EHR itself at different levels of medical personnel. Strict regulation of access will allow maximum consideration of the human rights to the safety of information about their health, as well as to a certain extent reduce the possibility of information leakage and disclosure of medical secrets.

Thus, data protection in HIS should be given great attention, and approaches should be constantly improved in connection with the emergence of new challenges and threats. The main actions to protect information and regulate the access of medical professionals to information should be the following:

1. User authentication-assigning a username and password when logging in. When entering ID cards, it is possible

to use identification.

2. Recording actions in the system (audit) — logging in and out of the system, viewing data (EHR), making changes (using an electronic digital signature), assigning directions (laboratory and other), issuing an electronic prescription.

3. Access regulation – the user must have access only to the information that is necessary for the performance of his official duties. Access can be carried out at different levels: within the framework of viewing, editing information (adding), deleting information from the system. When making changes, an electronic digital signature must be used.

The core of any HIS is the Database management system (DBMS). The choice of a DBMS is of key importance, since most of the specified IT security functions are implemented by standard DBMS tools.

The most serious threats to security system are [13; 14; 45]:

1. Accidental or intentional actions of registered users. As many IT professionals say, the major threat to any IT system is its user, who does not generally know modern threats and / or thinks that his actions do not pose threat to the security. Thus, for example, medical documents can be opened by the doctor and left on screen for an infinite period of time, where anyone can get access to them. Sometimes information about the dismissal of a doctor, nurse or any other worker of a medical institution that has access to HIS is not given to the IT department, and they can enter the system and see the information for a long time after they seize working. Various means are used in order to mitigate this risks, for example, electronic cards, automatic blocking of workstations, a limit on the working time during which the user can gain access to the system, regular password changes.

2. Computer viruses. Viruses can cause serious harm, as they can destroy information, block access to it, or transfer personal medical data to unauthorized people. Thus, an elaborate system must be set in order to combat this problem, which can possibly include: a complete ban on the use of unverified CDs or other media, a ban on the use of the Internet or unverified e-mail on the workstations of the system, the use of modern antivirus programs and their constant updating.

3. Third-party actions. This can include interception and modification of data, filling the network with false information packets, and other actions aimed at disabling network equipment or servers.

Thus, to sum up, the creation of HIS infrastructure call for specific attention to ensure that all territories where IT infrastructure is located have appropriate security measures, and that only authorized personnel can enter such premises. Timely update of anti-virus software can also eliminate some of the issues.

Most of the information that circulates within the information space of a medical institution falls under the definition of medical secrecy. The content of medical secrecy includes data on the fact of seeking medical help, on diagnosis and treatment, on treatment methods, on the state of health of the person who sought help (his physical and mental disabilities, intimate relationships, etc.). The protection of this data is attained by provision of specific rules and sanctions, in order to ensure that only authorized parties can have access to this information. For example, in Belarus unlawful dissemination of the medical data described immediately above can cause criminal liability.

Taking into consideration all of the above, we think that is important to turn attention to the certain principles of security system’s operation [11; 119]:

1. The system must implement a procedure for establishing the identity of users (identification, authentication, etc.). The DBMS administrator assigns each employee of the medical institution a unique login/password pair, which is used to uniquely identify the user of the system.

2. The system must be audited. To this end, the following key events must be strictly recorded: the user's entry into the system, changes in the data on the medical institution's contingent, the completion of appointments and referrals, working with the patient's outpatient card, and the end of the user's work with the HIS.

3. The HIS administrator must be able to assign and restrict access rights to users of the system. The workplace of an employee of a medical institution consists of a set of functional software modules, the composition of which is determined in accordance with the official duties of the user. Each user of the system should only have access to their workstations in the HIS.

4. For patients of a medical institution, it should be possible to allocate a group of privileged (VIP) patients and close general access to their medical and personal data.

5. The possibility of verifying the authenticity of electronic documents should be implemented. When the user approves medical documents, the electronic digital signature technology must be used with additional authentication at the time of signing the document.

4.4. Medical data protection: international legal aspects

In a modern democratic society, human rights, and in particular the right to privacy, are of paramount importance. The protection of personal data of the individual must be carried out not only at the national level, but also the adoption of international instruments to ensure respect for human rights and fundamental freedoms in all countries, regardless of nationality or place of residence, and especially the right to privacy in connection with the processing of personal data. This is primarily due to the fact that today personal data is present on the Internet, most of which is distributed and used in social networks.

It should be noted that the creation of electronic medical records is essentially an action that initiates the beginning of the processing of a person's personal data. According to the studies conducted in the EU, EU countries are divided into three groups with regard to obtaining patient consent to create an EHR

1) explicit patient consent is required both for the creation of his EHR and for the inclusion of data from the EHR in the centralized health information system (Germany, Norway, France);

2) no explicit consent is required for the creation of an EHR, but it is necessary for the inclusion of its data in the centralized health information system (Belgium, Denmark, Sweden, Estonia);

3) no explicit consent is required for the creation of the EHR and for the inclusion of data from the EHR in the centralized health information system (Finland). [79].

Thus, the overall situation with personal medical data protection is quite diverse. Moreover, changes related to the regulation of personal data (information about a person's personal life) are now taking place in many states. Special laws regulating the protection of personal data have already been adopted in more than 100 countries.

In the EU, the main approaches to data processing were laid back in 1995, when Directive 95/46 was adopted. Inter alia it laid down the duties of the so-called "data controllers" to protect the interests of those persons whose data is collected and processed. It was recognized that the participating States, in the interests of the data subject or to protect the rights and freedoms of others, have the right to restrict the right of access to information; they may, for example, establish that access to medical data can only be granted to medical professionals.

Under Article 8 of Directive 95/46, the processing of personal data, data concerning health or intimate life is prohibited, unless it is necessary for the purposes of preventive medicine, medical diagnosis, provision of medical care, treatment or management of health services, as well as if such data are in the possession of a medical professional in accordance with national legislation or regulations established by the competent national authority establishing the obligation to maintain professional secrecy, or another person also having an equivalent obligation to maintain secrecy.

It was Directive 95/46 that was considered in the landmark case considered by the EU Court of Justice in 2014 - the case "Google Spain v. Gonzales" [50]. According to the fact, during the digitization of the newspaper's archive, materials were posted on the network, including those related to certain circumstances of the plaintiff's life, which he would like to forget about. At the same time, a search for information about him in the Google service gave such information as relevant. The appeal to the newspaper for the removal of the material was not satisfied, as it was posted legally. As a result, the case was sent to the EU Court of Justice, which reviewed Google's activities in terms of Directive 95/46 (Article 2b) in order to determine whether the company carried out personal data processing and other activities under the Directive.

The court found that a person has a “fundamental right” to privacy, which extends to the deletion of information about an individual [80]. The court also recognized the obligation of Google to exclude this material from search results, even if it should not have been removed by the owner of the site that originally hosted it. Thus, the Court recognized as valid in the digital environment the “right to be forgotten” which is a component of the right to privacy.

As a result, Google has created a special mechanism within which users have the right to exercise their right: a form is currently posted on the Google website, with the help of which users have the opportunity to promptly send a request to block, delete or restrict access to "content" of Google sites [83].

These approaches to the protection of personal data, including health, were further developed in the EU regulation, which was associated, among other things, with the increasingly active development of information technologies.

On 27 April 2016, Regulation (EU) 2016/679 of the European Parliament and of the Council was adopted on the protection of natural persons with regard to the processing of their personal data and on the free movement of such data, as well as repealing Directive 95/46/EC, also called the Regulation on personal data protection, or GDPR. Two years

were given to states to take the necessary measures to implement it. On 25.05.2018, the General Data Protection Regulation (GDPR) came into force in the European Union.

The GDPR provides more rights to citizens to be better informed about the use made of their personal data, and gives clearer responsibilities to people and entities using personal data. The definition of personal data processing provided by Article 4(2) of the GDPR is extremely broad, as it includes any operation or set of operations carried out on personal data, with or without automated means, which encompasses all processes from the collection to the destruction of the personal data. Furthermore, personal data processing is only allowed if at least one of the hypotheses as provided in Articles 6(1) or 9(2) of the GDPR is present. These include (1) when the data subject has given consent to the processing of his or her personal data for one or more specific purposes, (2) for compliance with a legal obligation to which the controller is subject, (3) to protect the vital interests of the data subject or of another natural person and (4) for the purposes of legitimate interest.

The GDPR contains a broad definition of personal data: the list of protected information includes almost all data about a person, including genetic, biometric, health, sexual life and orientation. It has been established that the processing of data is lawful not only upon obtaining the direct consent of the data subject, but also in a number of other cases.

The GDPR contains a broad definition of personal data: the list of protected information includes almost all data about a person, including genetic, biometric, health, sexual life and orientation. It has been established that the processing of data is lawful not only upon obtaining the direct consent of the data subject, but also in some other cases.

At the same time, Article 9 of the GDPR classifies genetic data, biometric data for the unambiguous identification of an individual, data relating to the health, sex life or sexual orientation of an individual to a special category of personal data. The processing of such data is prohibited, except for exemptions expressly specified in the Regulations under consideration, in particular:

- processing is necessary for preventive or professional medicine, to assess the work ability of an employee, to diagnose a medical condition, to provide medical or social assistance or treatment, or to manage health and social security systems and services based on EU law or the law of a Member State,
- processing arises from a contract with a healthcare professional (subject to the established conditions and guarantees)
- processing is necessary for reasons of public interest in the field of public health, for example, to protect against serious cross-border threats to health or to ensure high standards of quality and reliability of medical care and medicines or medical equipment, based on EU law or the law of a Member State providing for acceptable and specific measures to protect the rights and freedoms of the data subject, in particular, professional secrets.

An important guarantee of the rights of citizens in this regard is the ability to demand the complete deletion of their personal data (Article 17). The GDPR explicitly recognizes the “right to erasure”, which is an extended version of the “right to be forgotten”.

The differences between the right to be forgotten and the right to erasure are as follows. The right to be forgotten, confirmed in the case of Google v. Gonzales, in its original version concerned only the so-called de-indexing of documents from the results of the search engine results. When exercising the right to be forgotten, the original text of the document is retained by the person who legally created it (for example, on the website of a medical organization; in an archive copy of a healthcare institution), but users of the system cannot access it. This caused certain problems. For example, the decision to exercise the right to be forgotten made against Google will not mean that any other search engine (e.g. Yandex) should also delete the material, whereas the number of search services today is numerous.

The right to erasure means that the relevant information must be destroyed without the possibility of its subsequent recovery (erased from the database, physical destruction of storage media, etc.). The right to erasure provides a greater guarantee of the irreversibility of actions to ensure the inaccessibility of certain information. Indeed, if you leave certain information on the server or the site, it may become available again (as a result of hacker attacks; erroneous actions of the employee; or, as in the above example, when the search service changes).

The GDPR in this regard focuses specifically on the deletion of data. The grounds for the deletion of personal data were determined (no need for data, revocation of consent to processing, illegality of processing, etc.). In addition, the person has the right to refuse to process the data, which should not affect the provision of the necessary services. If necessary, the right to data portability must be granted. All operations that are carried out with the personal data of citizens of the European Union, regardless of who and where (in the EU or not) processes the data, are subject to the GDPR.

At the same time, in particular, the presence of a website in the language of one of the EU member states is taken into account, as well as the orientation of the organization's activities in any form on subjects of personal data in the EU [51]. As a result, it has an extraterritorial nature, that is, it applies not only to EU residents, but also to companies from non-EU countries.

The GDPR states that in cases where the processing is ongoing; special categories of personal data are processed on a large scale; personal data related to convictions or crimes are processed; there is a high risk of violation of human rights and freedoms, the relevant organization is obliged to appoint a representative in the EU. The representative must be located in the EU country in which the data subjects are located. His task is to interact on behalf of the company with the EU authorities and citizens, to follow the instructions of the company. [59].

The European Union is a space in which four fundamental freedoms are realized - freedom of movement of goods, services, persons and capital. This allows citizens to freely choose their place of residence. However, when exercising this freedom, the patient's EHR may not be available abroad due to the fact that the exchange of electronic cards between states is problematic, since there are no uniform mechanisms for transferring information from them, moreover, recently, the issues of personal data protection during their cross-border transfer have become especially acute.

In this regard, the EU has begun to pay particular attention to the issues of compatibility and data transfer. The situation becomes even more difficult when moving to other states that are not part of the EU.

The enlargement of the European Union has demonstrated that the models and standards of health care in the member states differ significantly, as a result of which medical tourism has become widespread (the choice for receiving medical care is either countries with lower payments for medical services or with higher technologies). [91]. In this regard, the EU has begun to pay particular attention to the issues of compatibility and data transfer.

The epSOS project (2008-2014), which developed cross-border E-Health services, became important for the development of E-Health in the EU. Within the framework of this project, the cross-border transfer of basic information about the patient's health (in the event of an unplanned request for medical care abroad) and electronic prescriptions was tested [31].

These issues received significant development with the adoption of Directive 2011/24 / EC of March 09, 2011 on the rights of patients to cross-border medical care. In addition, in 2014, Regulation 282/2014 was adopted, which established the third multi-year EU Health Action Program for the period from 1 January 2014 to 31 December 2020.

As a consequence, since 2014, the epSOS project has been continued by the eHealth Network (eHN), a voluntary association of national eHealth authorities. The network solves the issues of interoperability of E-Health systems, standardization, knowledge exchange, monitoring and evaluation of implementation. The Network's EHG Governance Initiative (eHGI) aims to develop policy recommendations, reports, and others to better integrate EH into national health strategies [48].

In addition, it is possible to note the Trillium Bridge project developing the issues of cross-border data transfer. At the first stage (2013-2015), the project showed the possibility from a technical point of view of transatlantic data transmission between the EU and the USA, as well as in a global format. Currently, work is underway to create a universally acceptable EHR (as part of the development of an international standard for the presentation of patient data - International patient summary standard) [9].

Nevertheless, when deciding on the inclusion of a country in the candidates for membership in the Union, there are no strict requirements for the organization of the health care system. The main requirement, in accordance with the Charter of Fundamental Rights of the European Union, is the right and opportunity for all segments of the population, regardless of their place of residence and ability to pay, to receive quality medical care. Citizens should be guaranteed the right to receive quality medical care in other member countries. Patients should be guaranteed the right to a free choice of both a medical and preventive institution and an attending physician. The mutual recognition of doctors' degrees has provided them with opportunities for real mobility [91].

Thus, cross-border data transfer has two components: the issue of the security of personal health data and the issue of interoperability, that is, the possibility of accepting and working with data received from outside. [1]

In conclusion, we note that a review of the activities of the WHO Regional Office for Europe, the Council of Europe and the European Union allows us to see that a number of important initiatives are currently being implemented in the European Region aimed at the development of E-Health systems. At the same time, the implementation of specific

[1] Interoperability of products or systems is their ability to interact and function with other products or systems.

steps for their implementation into a practical plane (obtaining health data from the EHR, changing and deleting them, cross-border data exchange, other issues) from is carried out taking into account international human rights standards, which are being developed in adopted at the regional level of acts.

Chapter 5. PATIENT RIGHTS IN E-HEALTH

5.1. E-Health and human rights

If we talk about the conceptual framework of the relationship between a medical professional and a patient in the context of the introduction of the EH system, we cannot ignore the trend that is now beginning to play an increasingly important role in healthcare in general. It consists in the increasing role of the patient, the changing attitude towards him, which entails giving them a greater role in making decisions about their health, requiring, as a result, to provide them with more complete and understandable information. The information systems implemented in healthcare allow to carry out these actions quickly and in a way that is convenient and accessible to the patient.

One of the priority areas in Electronic Healthcare is the electronic storage of patient data, as well as remote access to them, which are important for several reasons at once:

- often, the patient needs the help of specialists of different profiles, and convenient data transfer between them will improve the quality of service;
- in some cases, remote consultation with a specialized specialist may be required, and then it is necessary to transfer the patient's data as quickly as possible;
- electronic data is much better protected from loss and damage. Sometimes it is happened that a patient’s card was lost in the registry;
- search for electronic data is much faster and more convenient;
- the patient can easily access their own medical data online if it is stored electronically. This will potentially encourage the development of private medical clinics.

The implementation of EH systems can contribute to the fuller realization of human rights. However, the experience available in various jurisdictions in the implementation of specific areas in the course of practical activities demonstrates certain tasks that are primarily faced by the state. Among the main such tasks is the implementation of the right to access health information, including for vulnerable groups of the population; the issue of the quality of medical care when providing the patient with the opportunity to delete data from the EHR, the limits of the right to participate in making decisions about their health, and others.

As part of the development of E-Health, ICTs are expanding the boundaries of the traditional approach to human rights in obtaining medical care. In the digital age, human rights must be transformed, providing more and more opportunities, including in the field of health.

In accordance with the Constitution of any country – everyone has the right to life. In the course of any person's life, there is a need to apply to medical institutions for qualified assistance. The Basic Law guarantees the right to health protection for citizens of the country, including free treatment in public health institutions, the development of physical culture and sports, measures to improve the environment, the possibility of using health facilities, and improving labour protection. The state creates conditions for affordable medical care for all citizens.

Understanding health as a human right imposes a legal obligation on States to ensure access to timely, acceptable and affordable health care of appropriate quality.

The rights of the patient are reflected in Article 41 of the Law "On Health Care" of the Republic of Belarus in terms of: receiving medical care; choosing the attending physician and the organization of health care; participation in the choice of methods of providing medical care; obtaining (in an accessible form) information about the state of their own health, the methods used to provide medical care, as well as the qualifications of the attending physician, other medical professionals directly involved in providing him with medical care; choosing persons who can be informed about

the state of his health; refusal to provide medical care, including medical intervention, except in cases provided for by law.

From the analysis of international human rights standards, it follows that in the implementation of the State's obligations in the EH, such obligations as to respect and protect the relevant rights are highlighted, which is fully applicable in the framework of the creation of EH systems. Within the framework of respect for human rights, the state provides for the provision of complete information about the state of the epidemiological and other situation in the country that can affect the state of human health, the confidentiality of information related to health (the rights of people with HIV, etc.). The obligation to protect includes the adoption of technical, legislative and other standards for the safety of information provided by a person in the field of health care. This issue is particularly relevant in the era of digitalization, due to the fact that the collection, processing and accumulation of information about the state of health of a particular person, as well as his personal data, occurs at different levels (regional, national, etc.), various IP systems are created (for example, registers) and are used by medical personnel.

The regulation of medical secrecy is contained in the Law "On Health Care" of the Republic of Belarus, which establishes that medical secrecy consists of information about the fact of the patient's request for medical care and the state of his health, information about the presence of the disease, diagnosis, possible methods of providing medical care, risks associated with medical intervention, as well as possible alternatives to the proposed medical intervention, other information, including personal information, obtained during the provision of medical care to the patient, and in the event of death – and information about the results of the pathoanatomical examination.

The informatization of healthcare implies a change in approaches to the traditional understanding of medical secrecy. In connection with the transition to an electronic format of all medical records, including the patient's medical record, the creation of various IP systems that store patient data, the development of telemedicine services (information exchange both inside and outside the country), it is necessary to develop a new electronic model of medical secrecy that regulates issues of confidentiality, privacy, access and responsibility.

It should be noted that for the disclosure of medical secrets – the deliberate disclosure by a medical, pharmaceutical or other employee without professional or official necessity of information about the disease or the results of a medical examination of the patient, criminal liability is provided, which once again emphasizes the importance of this topic.

5.2. The right to health in E-Health: international legal aspects

Establishing the United Nations Organization (UN) in 1945, the countries agreed that the new organization would, among other things, contribute to the solution of international health problems (Article 55 of the UN Charter).

The UN plays this significant role today. In 2015, the 2030 Agenda for Sustainable Development was adopted by UN member states in 2015. It should be noted that there are seventeen Sustainable Development Goals (SDGs) in total. Each of them is represented by specific tasks (total number - 169), which must be solved in the period up to 2030.

Goal 3 in the said Agenda is defined as follows: “Ensure healthy lives and promote well-being for all at all ages." [106].

For Goal 3, there are 13 tasks, which include:

- by 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes;
- by 2030, reduce by one-third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being;
- achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all;
- strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.

It should be noted that as a response to these initiatives, many states are actively working on the implementation of sustainable development goals at the national level. For example, in the Republic of Belarus, the post of the National Coordinator has been established, in order to carry out the overall coordination of the activities of state bodies and other organizations on the achievement of SDG by the Republic of Belarus [7]. In addition, turning to the health sector, the

Ministry of Health has created a Methodological Council for monitoring and assessing the sustainability of development. The progress in the achievement of the SDGs, including the implementation of Goal 3, is monitored by a set of national indicators [94].

The introduction of E-Health systems can contribute to the achievement of the discussed Sustainable Development Goal 3. In particular, the application of new technologies in health care expands the availability of relevant services to a wider range of people, for example, when they are provided remotely. With the help of electronic services, it is possible to more easily access information about medicines (including, possibly, about their availability in the pharmacy network, cost, etc.). The information accumulated in the E-Health systems will make it possible to more accurately and systematically assess the existing risks and take adequate and timely measures.

A significant role in global health promotion, which also include the creation of the healthcare systems, is played by the World Health Organization (WHO), a specialized UN agency that aims at the attainment by all peoples of the highest possible level of health. Since its inception in 1945, WHO has based its activities on the principle that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

It can be said that the “official recognition” of E-Health by WHO took place in 2005 [12]. It was then that Resolution WHA58.28 was adopted, which called on all countries to establish eHealth systems, covering such areas of f information and communication technologies (ICTs) use as public health, improving health services, health education, citizen information, etc.

In order to assist states in the development of eHealth in 2012, WHO and the International Telecommunication Union developed a National eHealth Strategy Toolkit. This toolkit is both a framework and method for the development of a national eHealth vision, action plan and monitoring framework. This resource be applied by all governments that are developing or revitalizing a national eHealth strategy, whatever their current level of eHealth advancement [73].

World Health Assembly Resolution WHA66.24, adopted in 2013, addresses E-Health standardization and interoperability issues. Inter alia, it recognized the importance of proper governance and operation of health-related global top-level Internet domain names, including “.health” [39].

In 2015, there were more than 7 billion mobile telephone subscriptions across the world, over 70% of which are in low- or middle- income countries. The development of mHealth was the reason for the adoption of the Report by the Executive Board in 2016 (updated in 2018 under the title “Use of appropriate digital technologies for public health”).[37; 38]

In 2018, the World Health Assembly acknowledged the potential of digital technologies to play a major role in improving public health. The Resolution WHA71.7 on Digital health urges Member States to prioritize the development and greater use of digital technologies in health as a means of promoting Universal Health Coverage and advancing the Sustainable Development Goals [115]. Inter alia, this resolution calls to consider, as appropriate, how digital technologies could be integrated into existing health systems infrastructures and regulation, to reinforce national and global health priorities by optimizing existing platforms and services, for the promotion of people-centered health and disease prevention and in order to reduce the burden on health systems.

It should be noted that the development of E-Health is directly related to the realization of the right to health, which is widely enshrined and generally recognized at the international level, as well as some other human rights. In this regard, the new mechanisms and framework for the functioning of the E-Health systems created by various states should fully ensure the preservation and observance of the relevant human rights.

Human rights instruments, continuing the approach proclaimed in the UN Charter, inextricably link the development of health care to the provision of fundamental rights and freedoms.

The basic document in this area is the Universal Declaration of Human Rights (UDHR), adopted at the third session of the UN General Assembly on December 10, 1948. This instrument formed the basis for the universalization of human rights, for the first time securing international human rights standards. Despite the fact that the provisions of this Declaration are not formally binding, their observance is ensured by its high authority.

It should be noted here that international standard is a broad category. It should be borne in mind that the human rights standard is not limited to the concept of "legal obligation" that enshrines a particular right or freedom. In this regard, in this book, international human rights standards are understood as a set of rules, models, and behavior patterns recognized by states at the international level. Sources of standards can be not only norms of international law, but also

judicial practice, interpretative documents of international bodies (for example, General Comments of the UN Committee on Economic, Social and Cultural Rights) [32; 121].

Under article 25 of the 1948 Universal Declaration of Human Rights, "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services".

In addition to this "basic" provision, Article 12 of the 1948 Universal Declaration of Human Rights is especially essential for determining the patient's rights. In accordance with this article, “No one shall be subjected to arbitrary interference with his privacy […]. Everyone has the right to the protection of the law against such interference or attacks."

Despite the fact that the provisions under consideration received their normative consolidation back in the middle of the last century, they are fully relevant and applicable in modern conditions. So, for example, it is on the basis of the provision of the Universal Declaration of Human Rights of 1948, aimed at protecting personal life (Article 12), that the boundaries of the right to control access to information about one's health are being determined today.

It is also important to note the adoption in 1966 of two major international treaties - the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).

With regard to issues related to the development of E-Health, let us pay attention to Article 17 of the ICCPR, which enshrines the right to privacy (which was previously declared in Article 12 of the UDHR). According to General Comment No. 16, “The obligations imposed by this article require the State to adopt legislative and other measures to give effect to the prohibition against such interferences and attacks as well as to the protection of this right.” [49]. It has been established that the collection and storage of personal information by any subject in computers should be regulated by law.

Every individual, in order to protect his privacy, should have the right:

- to ascertain in an intelligible form, whether, and if so, what personal data is stored in automatic data files, and for what purposes.
- to ascertain which public authorities or private individuals or bodies control or may control their files. If such files contain incorrect personal data or have been collected or processed contrary to the provisions of the law, every individual should have the right to request rectification or elimination (p. 10, General Comment No 16).

As part of the development of E-Health systems, these provisions are of particular importance, ensuring the confidentiality of the patient's medical data. In addition, in the course of improving the legal regulation of legislation on the protection of personal data, due, inter alia, to the development of new information and communication technologies, these provisions became the basis for providing citizens with real opportunities and mechanisms for correcting and deleting their data.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) also contains a number of important principles and norms, among which, in relation to the issues under consideration, article 12 deserves the greatest attention. It explicitly proclaims the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The interpretation of this article is contained in a document drafted in 2000 by the Committee on Economic, Social and Cultural Rights as the monitoring body of the Covenant to assist States parties to the Covenant in its implementation and compliance with their reporting obligations, called "General comment No. 14 - The right to the highest attainable standard of health" [23].

In accordance with paragraph 9 of the General Comment No. 14, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.

Paragraph 12 of the General Comments No. 14 further stipulates that such facilities, goods, services have to meet the following conditions:

- availability: states are to ensure the sufficient number of the facilities, goods and services , which includes the main determinants of health, such as such as adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel, etc.;
- accessibility: inter alia, physical and economic accessibility. This also means that all components enumerated above are to within reach, including in rural area, and to be accessible for all sections of population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS;

- acceptability: compliance with the rules of medical ethics and confidentiality, focus on improving the health of stakeholders;
- quality: acceptability from a scientific and medical point of view, the requirement of high quality.

The obligations of states related to the realization of the right to health are of particular importance for ensuring the proper functioning of all components of the E-Health system.

General comment No. 14 identifies three levels of obligation for countries in realizing the right under consideration: to respect, protect and fulfil the right to health. The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 of the ICESCR guarantees. The obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health (para. 33 of General Comment No. 14).

In this regard, we note that from the point of view of human rights, the state has obligations both "to act" (i.e. positive obligations) and "not to act" (i.e. negative obligations). With regard to E-Health, positive obligations include the adoption of measures that lead to the fact that E-Health provides real assistance to the enjoyment of the right to health, and negative - the obligation of the state to ensure that the new mechanism does not limit the rights or opportunities of access to health services for certain categories of people. , including vulnerable, did not create other obstacles to the realization of their rights, including making the interaction between a medical worker and a patient more burdensome and difficult from the point of view of human rights violations.

In particular, according to para. 50 of the General Comment No. 14, "the deliberate withholding or misrepresentation of information vital to health protection or treatment" constitutes a violation of the State's duty to respect the right to health. Thus, at the international level, such an important component of the right to health as the right to receive information about one's health is recognized and promoted.

One cannot but take into account the fact that there is a direct link between patient confidence and the effectiveness of medical care. An important part of this is the provision of complete and reliable information about health to the patient, which bring special attention to the issue of informed consent. Informed consent is not mere acceptance of a medical intervention, but a voluntary and sufficiently informed decision, protecting the right of the patient to be involved in medical decision-making, and assigning associated duties and obligations to health-care providers. At the moment, effective communication in doctor-patient relations in challenged in many way, especially due to the digital divide, complex structure of modern medicine, inability of medical staff to communicate clearly and to convey full information via electronic systems (as this way of explanation of health conditions, for example, differs greatly if compared to eye-to-eye contact).

Considering the right to access health information, the UN Secretary-General noted that communication should be cognizant of varying levels of comprehension and not be too technical, complex, hasty, or in a language, manner or context that the patient does not understand (para 23, [110]).

When designing E-Health systems, taking into account the outlined approaches, special attention should be paid to vulnerable categories of the population, so that the introduction of E-Health does not entail their stigmatization and discrimination.

Both of the Covenants we have considered (ICCPR, ICESCR) are binding. They are among the nine core international human rights treaties. When analyzing the provisions of these instruments, it should be borne in mind that their implementation is based on the principle of "progressive implementation", which means that States parties have a specific and continuing obligation to move as quickly and efficiently as possible towards achieving the full realization of the right to health. At the same time, retrogressive measures are not permissible (otherwise, a State must show that it has made every possible effort to use all available resources to meet its obligations) [111]. It appears that the introduction of EH systems can be an important part of moving towards the fullest possible realization of the right to health.

The right to health is closely related to other human rights enshrined in various UN instruments, in particular, in: International Convention on the Elimination of All Forms of Racial Discrimination, 1965 (paragraph e) (iv) Art. five); 1979 Convention on the Elimination of All Forms of Discrimination against Women (Articles 11.1 f), 12 and 14.2 b); 1989 Convention on the Rights of the Child (art. 24); 2006 Convention on the Rights of Persons with Disabilities (art. 25).

Continuing the consideration of the UN's activities in the aspect of realizing the right to health, including in terms of introducing digital technologies in health care, we note that, since 1979, the UN began to use special mechanisms to

study situations in specific countries or thematic issues in the field of human rights. including through the appointment of special rapporteurs.

The mandate of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (also called the Special Rapporteur on the right to health) was established by the Commission on Human Rights in April 2002 by resolution 2002/31. The mandate was endorsed and extended by the Human Rights Council with resolutions 6/29 of 14 December 2007, and was most recently renewed by resolution 42/16 of 7 October 2019 [98].

The UN Special Rapporteur on to health is an independent expert appointed by the UN Human Rights Council to help states and other actors promote and protect the right to the highest attainable standard of health.

Within the framework of his mandate, she, inter alia: monitors the situation in the field of the right to health around the world (including through country visits); examines individual complaints (from individuals or groups of individuals) on violations of the right to health; promotes the full realization of the right to health, submits annual reports to the Human Rights Council and the General Assembly.

In addition, the right to health is part of a several other mandates, such as special rapporteurs on the right to education, food, adequate housing on violence against women [111].

Considering the international aspects of the legal regulation of E-Health through the prism of human rights, one should especially dwell on the problem of international migration.

Today, according to some estimates, there are almost 200 million international migrants in the world, of which almost 90 million are migrant workers. [111].

To protect them, the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families was adopted in 1990. It contains a number of important provisions:

- migrant workers and members of their families have the right to receive any medical care that is urgently required for the preservation of their life or the avoidance of irreparable harm to their health on the basis of equality of treatment with nationals of the State concerned (art. 28);
- urgent (emergency) medical care should be provided to migrant workers and members of their families, regardless of any irregularity with regard to stay or employment (employment) (Art. 28);
- each child of a migrant worker has the right to a name, to registration of birth and nationality (art. 29) [60].
- General comment No. 14, as an integral part of the state's obligation to respect the right to health, considers the state's obligation to refrain from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum-seekers and illegal immigrants, to preventive, curative and palliative health service (para 34) [24].

This raises the question of how the rights of migrant workers can be ensured during the transition of countries to the E-Health system. In particular, it will be necessary to answer questions about whether EHRs will be created for them, the ability to access them through accounts (personal accounts), and other rights related to the right to health will be given. These aspects are already taken into account by many states when introducing E-Health systems.

All of the above allows us to unequivocally state that measures are currently being taken at the international level to improve and develop health care, taking into account human rights. A special role in this is played by the United Nations, which has a number of important instruments for carrying out this activity. At the same time, it is obvious that due to the objectively complex procedure for reaching consensus at the international level, the approaches adopted at a high interstate level are of a rather general, conceptual-orienting nature. In fact, no attention is paid to specific manifestations of the introduction of E-Health systems, such as an electronic medical record, an electronic prescription, and telemedicine services.

The foregoing allows us to say that today the creation of E-Health systems is carried out in the absence of special international legal acts dedicated to this issue. In this regard, the E-Health initiatives that are currently implemented in various regions of the world demonstrate the scope for wide discretion. At the same time, it should be borne in mind that E-Health systems in any territory are to be implemented taking into account international standards in the field of human rights, so that this process would ensure more effective cooperation and better interaction between medical workers and patients.

5.3. E-Health in the European region through the lens of human rights

In each country, E-Health systems have their own specifics, due to a complex of historical, economic, political, cultural and other reasons, which leaves an imprint on the way in which the interaction of a medical worker and a patient is carried out.

The European Union (EU) is an integration entity of a special kind, not directly attributable to either international organizations or federal states. Its participants in a number of areas have transferred exclusive competence to this supranational institution, a number of areas relate to the area of joint jurisdiction, and some are carried out by states independently. It should be borne in mind that the EU's spheres of competence have been consistently expanding throughout the entire period of its existence. Initially being an education based on common economic interests, over time, he significantly expanded his powers.

Health issues are dealt with at the highest regulatory level - the relevant standards are included in the Treaty on the Functioning of the EU (abbreviated as TFEU; adopted in Rome, 1957, as amended by the 2007 Lisbon Treaty), which is today one of the major EU treaties (anther founding treaty of the EU is the Treaty on the European Union (Maastricht, 1992, as amended by the Lisbon Treaty, 2007). According to Art. 4 TFEU, common health security issues fall under the joint competence of the EU and the Member States. Article 6 TFEU classifies the area of "protecting and improving human health" as a subsidiary competence of the EU, which means that in this area the EU is only entitled to support, coordinate or complement the actions of the Member States.

An important principle is established in Art. 168 TFEU: a high level of protection of human health must be ensured in the definition and application of all policies and actions in the EU.

As a result, today the EU member states retain ample opportunities for the formation and development of their health systems, taking into account national characteristics. This is reflected in the wide variety of E-Health systems functioning in the EU today.

It should be noted that during the first four decades of the existence of the European Communities and the European Union, neither the EU Council, nor the EU Commission, nor the European Parliament had little interest in healthcare [18]. Only after the conclusion of the Maastricht Treaty (1992) attention began to be paid to this issue. This was due, among other things, to the commercialization of the healthcare sector, the ever-increasing competition in this area within the single market. As a result, paragraph "P" was introduced into the text of the Maastricht Treaty, providing that the European Union will contribute to the achievement of a high level of protection of the health of its citizens. [91].

However, for quite a long time the regulation of social protection systems and medical services was almost entirely within the competence of the EU member states [18]. It was only in 2002 that E-Health became an important component of the e-Europe plan, which was developed by the European Commission. In the same 2002, a working group of representatives of the EU member states developed the European Charter of Patients' Rights, which did not become a legally binding act, but as a soft law act contains a number of principles that are important in the implementation of E-Health systems, in particular, the right to accessibility. medical services, obtaining information about health, giving informed consent, confidentiality, security [40].

In 2004, the European Commission published the EU Action Plan for the Establishment of a European eHealth Area.

In 2006, the Council of the EU formulated the main challenge facing the EU member states: the need to ensure the financial sustainability of health care systems without jeopardizing the shared values of the EU countries: full coverage of the population with health care, solidarity in financing, equality of access to health care and high quality health care service [105].

Already by 2007, in most of the countries that were part of the EU at that time, they began to create national E-Health systems.

Today, specific activities of the European Union for the development of EH are carried out within the framework of the EU Health Action Programs. Three programs have already been accomplished (the latest – in 2020).

A great number of activities in the area of E-Health in the European region are performed under the auspices of the UN, including within the framework of WHO. In this regard, we consider it necessary to clarify that WHO's activities in different parts of the world are carried out through six regional offices covering the whole world.

The WHO Regional Office for Europe includes 53 countries (including, among others, countries that are not usually categorized as “European” in the strict sense of the word) [113]. The actions of the Bureau are aimed at the development of E-Health in the region. A separate section of the organization's website is dedicated to a comprehensive presentation of the relevant issues [114].

It should be noted that in September 2012, the new European health policy framework – Health 2020 – was adopted. It aims to support action across government and society in order to “significantly improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred health systems that are universal, equitable, sustainable and of high quality” [8].

In order to develop E-Health, the Bureau established the European Health Information Initiative (EHII), an intercountry association in which a significant number of countries in the European region participate. In addition to government representatives, the EHIH includes various partners such as the European Commission, the Organization for Economic Cooperation and Development (OECD) and other stakeholders.

EHII carries out coordination activities in the region (in particular, collection of information on health policy, provision of analytical materials, support to countries in the implementation of new and breakthrough digital solutions in the field of health informatization, and others).

The EHII’s areas of work are diverse: it includes, inter alia, the creation of the European Health Information Portal and the annual Autumn School on Health Informatization and Evidence for Policy Development (since 2013); and the development of a toolkit to support the assessment of information systems for the development and strengthening of health strategies.

In order to summarize data on the development of E-Health in the European Region, a global eHealth survey was conducted in 2015, as a result of which the Bureau carried out significant analytical work and published the material "From innovation to implementation: E-Health in the WHO European Region" (2016) [48] ... It contains both statistical and analytical data that show the spectre of E-Health developments in the European region as a whole (47 out of 53 states in the region answered the questions). In particular, as the study showed, 28 states (74%) have national health programs that provide for the use of information and communication technologies (ICT) in E-Health. Specific areas of implementation of health information systems are also diverse: 27 countries (59%) reported the availability of electronic medical (health) records (EHR), telehealth programs (38 countries - 83%). Moreover, of the 27 countries with EHRs, 70% (19 countries) had EHRs connected to a pharmacy information system, such as electronic prescriptions. Thus, already in 2015, the introduction of ICT in the healthcare sector in the European region was at a sufficiently high levels. At the same time, the main directions in which the development of the E-Health system is carried out relate to the most important aspects of the interaction of a medical worker and a patient in new conditions.

Currently, the Regional Office for Europe is guiding countries to ensure that national health strategies include strengthening national health information systems, including E-Health and digital health [61].

Health information systems and EH are the foundation of policy-making in this area, the widespread implementation of which can reduce inequalities in access to health services and ensure patient participation and response, which must be taken into account by medical workers.

The Council of Europe (CoE) is a European intergovernmental organization established in 1949. As noted by the researchers, to date, at the level of the Council of Europe, the issue of the impact of new technologies on human rights has been considered by all key bodies (the Committee of Ministers, the Parliamentary Assembly, the European Court of Human Rights), conferences and research are being held on the development of this area in various states [64].

Among the main tasks of the Council of Europe today is the promotion of human rights and fundamental freedoms, democracy and the rule of law. A significant area of his activity is the development of international agreements on various issues within his sphere of competence. At the same time, countries that are not members of the Council of Europe may also be parties to such agreements.

One of the most important achievements of the Council of Europe in the field of legal regulation is the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms (in particular, its Article 8, which establishes the rights to the protection of privacy, today acquires a new meaning in connection with the collection and storage of personal data of citizens). However, this convention mainly enshrined civil and political rights. If we talk about social rights, which include the right to health, one cannot fail to note the European Social Charter of 1961, as well as its revision in 1996. In particular, the Charter enshrines the right to health protection (Art. 11), medical assistance (Article 13), etc.

Special mention should be made of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention, April 4, 1997), to which additional protocols have been adopted (including on biomedical research in 2005). It is believed that it was in this convention that a new right in the human rights system was first enshrined, guaranteeing that everyone has the right to see any information collected about their health (par. 2, article 10). At the same time, the need to respect the desire of a person not to be informed about this was established. The limitation of these rights can be carried out in exceptional cases - only by law and only in the interests of the patient.

The Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 1981 (Treaty No. 108) is the first international treaty that protects individuals from abuse in the collection and processing of personal data and their cross-border transfer. The disclosure and interpretation of its individual provisions was carried out in the Protocol amending the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data No.223 dated 10.10.2018.

Among the most significant acts in the field of E-Health is also the Recommendation CM/Rec(2019)2 of the Committee of Ministers to Member States on the protection of health-related data, adopted in March 2019 (Recommendation Rec (2019) 2) [84].

As the title of this document suggests, it is advisory in nature, which gives states discretion in adopting implementing legislation; however, it should be borne in mind that all resolutions, recommendations of the CE bodies (this is especially characteristic of the documents of the Committee of Ministers), including the one we are considering, contain implementation procedures, orienting states to ensure that, taking into account their own legal systems, to ensure the application of the proposed acts of principles [81].

The main purpose of this Recommendation is to ensure human rights and fundamental freedoms, namely, the right to privacy and protection of personal data, which are established by Article 8 of the ECHR.

Health-related data in Recommendation Rec (2019) 2 means all personal data concerning the physical or mental health of an individual, including the provision of health-care services, which reveals information about this individual's past, current and future health (paragraph 3). The processing of such data can only be carried out if the data subject has given their consent, except in cases where law provides that a ban on health-related data processing cannot be lifted solely by the data subject's consent. Where consent of the data subject to the processing of health-related data is required, it should be free, specific, informed and explicit. (clause 5b).

At the same time, it is very important to state that consent to the implementation of certain medical procedures (i.e. consent to treatment) does not in itself constitute consent to data processing (paragraph 63 of the Explanatory Note to Recommendation Rec (2019) 2) [41].

The data subject is granted the right to rectify the data concerning him (Clause 12.1 of Recommendation Rec (2019) 2). In addition, the act in question confirms the right of an individual to delete data, the processing of which is carried out in violation of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 1981 (Convention No. 108). In particular, it is stipulated that the data subject shall be informed of their right to withdraw consent at any time and be notified that such withdrawal shall not affect the lawfulness of the processing carried out on the basis of their consent before withdrawal. It shall be as easy to withdraw consent as it is to give it (paragraph 5b).

Recommendation Rec (2019) 2 pays attention to the rights to receive information about one's health, as well as the specifics of waiver of this right.

It has been established that one should strive to ensure that the data subject understands as much as possible the health-related information to which he has access. However, this does not mean that all health information should be stored (recorded) in an intelligible form: information is often encoded, such as diagnoses. The main thing is that access to information is provided for the data subject (or his authorized person), and the information must be in such a form that it can be understood (paragraph 108 of the Explanatory Note to Recommendation Rec (2019) 2).

Already at the moment of the adoption of the Oviedo Convention in 1997, the patient's right to realize his unwillingness to know certain information about his health was recognized. As a follow-up to this approach, Recommendation Rec (2019) 2 emphasizes that the data subject has the right to be aware of the possibility of not being informed about the results, including unexpected results, before the analysis (in the case of genetic research). Such a desire "not to know" may in exceptional cases be limited by law (in the interests of the subject, in the light of the duty of doctors to provide medical care, etc.). In addition, clause 11.7 of Recommendation Rec (2019) 2 states that the desire of

the individual not to be informed of a diagnosis or prognosis should be complied with, except where this constitutes a serious risk for the health of others.

Considerable importance is given in Recommendation Rec (2019) 2 to the right to determine the boundaries of access to information about one's health within the framework of EHR. It has been established that the exchange and provision of data between health workers should be limited to information strictly necessary for the coordination or continuity of care, prevention, or medico-social and social monitoring of the individual. Medical workers can only in this case exchange or receive data within the framework of their tasks and depending on their authority. Appropriate measures should be taken to ensure the security of the data.

Thus, the Recommendation Rec (2019) 2 provides citizens with significant rights in terms of determining the boundaries of access to their data, including in the framework of the processing of such data in E-Health systems. In general, it can be concluded that the Council of Europe currently does not orient states towards the adoption of any unified E-Health system. However, its documents identify separate "key points" that are common to all systems, the implementation of which must be carried out in such a way as to ensure the enjoyment of human rights.

5.4. Patient rights in E-Health

The importance of health data for any patient determines the fact that the information should appear in the EHR promptly and in a sufficient volume (in particular, this applies to the results of tests, data on past appointments, records of information provided to the patient during a personal visit to the doctor, data on manipulations, procedures, medical measures taken in relation to the patient).

The patient's right to access and control his health information (by using EHR functionality) can be attained exercising a number of rights, which include, inter alia:

- right to read all material in EHR;
- right to refuse to process his data in EHR,
- right to make decisions about his health (including within the framework of digital technologies such as electronic prescriptions),
- the right to remove information about himself and his health from EH systems.

Obtaining health information is an important part of realizing the right to health. Today, the availability of complete, reliable and understandable information is the basis for making further decisions about how and to what extent to receive treatment, how to plan your life taking into account the state of health, etc.

In this regard, the right to health information is an important part of States' efforts to improve public health literacy, as it enhances overall effectiveness of healthcare efforts (this can be this can be explained, among other things, by the fact that when people understand the essence of the proposed treatment, they are more likely to follow the doctor's prescriptions). The problem is that, though the advent of EHR gives the patient additional opportunities to access medical information, the question rises as to whether patients can understand the medical terms, slang and abbreviations, and come to the right conclusions about their diagnosis and conditions. The important of this issue rises, as patients tend to take a more and more active role in determining what and how should be treated. Sometimes, "pure" medical information, which is not accompanied by any comments and explanations, can be wrongly perceived by the patient. There are instances of people who thought of committing suicide after seeing in their EHR diagnose or test result that they consider as fatal to them. Thus, in some specific cases as we've just described, patient's right to information can be ensured by providing him of the said data, but only with necessary explanation, and with personal contact with a medical professional (it is obvious that in today's COVID situations, when certain restrictions on movement are in place, face-to-face contact might not always be appropriate; however there are now many technical ways that allow doctor to contact his patient and remotely discuss the details of his condition).

Let us now turn to the aspect of patient's control of access to his personal data. When EHR system is implemented, such access becomes widely possible for a virtually unlimited number of medical professionals. In this regard, the rights of the patient to determine the boundaries of access to information about their health deserve special attention.

This issue can be considered from two aspects: access to relevant information by the attending physician (or other medical professional who directly interacts with the patient) or by any third party.

The right of the patient to determine the limits of access to information about his health gives him the opportunity to independently decide whether he wants a particular medical professional to be able to see certain information about him. As we've discussed above, this can be achieved by using one-time access codes, generated by the patient who is willing to show his medical details to a specific person.

The right to control access to information about one's health may be restricted, in particular to ensure the vital interests of the person, if their consent cannot be obtained. In Finland, the law provides that consent is not required if the patient is unconscious. In France, if a person is unable to express their will and if circumstances require it, the emergency doctor may, in the best interests of the patient, decide to access the EHR without obtaining prior consent.

The issue of providing access to the EHR by the patient is controversial. In this approach, it is necessary to take into account both positive and negative aspects. The positive thing is that the person himself has the ability to control access to his EHR, i.e. independently decides whether to allow him to get acquainted with his medical history or not. On the negative side, it should be noted that the patient is not always able to understand what information the doctor needs to access to provide qualified care and make the correct diagnosis, because the human body can be considered as a well-coordinated mechanism, and the more information the doctor has, the higher the chances of choosing an effective treatment.

In recent years, the prevailing position is that it gives the patient even broader rights, namely, the right to remove information about themselves and their health from electronic health systems (or not to create an EHR in the digital environment at all). In order to answer this need, many states today have implemented the provision of citizens with the opportunity to quickly and easily "exit" from the EH system.

Part of the patient's right to participate in making decisions about their health is the ability to independently enter additional information about their health into the EHR (assessment of the dynamics (improvement or deterioration) of their condition, assessment of the impact of medicines, data on pressure, the amount of exercise performed, certain pain sensations, etc.).

Thus, EHR system shall be construed in a way that ensures patient's right to control her information. This can be achieved by implementing all or any of the options described below:

1. Currently, the creation of E-Health system envisages the of a personal account of the patient, through which it will be possible to make an appointment, call a doctor at home, get an extract from medical documents, a reminder of vaccinations and an electronic prescription, view the results of tests, etc. Implementation of many HIS is accompanied by creation or linking to it a call service or support services, where all medical information and details, i.e. on the work of medical institutions, cost of their services and other relevant data, can be accessed in one call. In order to expand the possibility to control medical information, the capabilities of such services can be extended. For example, they can operate for to ensure the need of blind people to access information about their health.

2. In order to exercise the right to choose the attending physician and the health care organization on the part of the state, a single information space can be created, with integrated IP and EHRs, both public and private medical institutions.

3. Step are to be taken to ensure fixation of the information in the EHR in an accessible and understandable form to human perception (i.e. decoding of diagnosis). It is important in order to ensure clarity of information about one's health and methods of medical care. Further steps can include the creation of information support services (patient support services): descriptions of diseases, basic treatment methods, descriptions of medicines, etc.

4. Due to various circumstances in life, patients sometimes have special interest in selecting persons that can be informed about their health status. Thus, the EHR should individually reflect the information about who the person is ready to inform about their health, as well as make decisions about patient's health if her health condition makes it impossible for the person to decide herself. It should be noted that sometime the legislation defines people that can make decision related to person's health, however this approach is not always perfect. It is obvious that one can have quite tense relations with her relatives, and thus their decisions might not be relevant. Thus, a patient might consider that other people are his "close" one, and should be able to define them, and specify this information in EHR so that medical professional are aware of this information.

5. EHR should also include and maybe even specifically mark some of the patient's decision, especially those connected with his desire not have certain medical care, including medical interventions (namely, consent to donation, blood transfusion, etc.).

Thus, the analysis of the above and the "doctor-patient" interaction in general allows to conclude that the purpose

of E-Health development is primarily the availability of services and quality of care provided by health care institutions through the use of ICT, as well as the awareness of the population about their health, the timely application of ICT in the diagnosis and treatment of diseases.

To further improve the legal framework of E-Health, further research is necessary, which should focus on the following aspects of the legislation:

- the right to information about their health and free access to information that affects the freedoms, rights, duties, interests of the patient, including the use of mobile applications;
- use of web services, remote interaction between the doctor and the patient through a variety of means: social networks, smartphone, tablet, etc. (mHealth);
- increasing the role of the patient in HIS, as a condition for the development of personalized medicine, with the right to "oblivion", etc.
- protection of personal data and legislation of certain secrets.

5.5. Rights to access medical information: technical aspects

EHR provides important opportunities for patients, compared to the “regular” way of accessing information about one’s health, which could include making appointment with a medical official, visiting a medical facility, requesting your medical card and trying to remember or obtain the copy of the information.

Introduction of a remote access to EHR provides quicker and easier option, which requires only present of a computer (or any other device that can be connected to the Internet, including regular mobile phone), logging and choosing the information that is of interest. As a whole, it seems to be an important way of the realization of the right to access health information, which is an important component of the right to health.

Let's take a closer look at the technical process of realization of these rights and describe the basic steps that a user needs to take in order to access her information [4].

The first step is authentication. In this case, the user account is used, which is defined by an open user name and an encrypted password. Each user's account is stored in a specific form in HIS. When performing the identification procedure, the user enters her name and password, which are then checked by the system for correctness.

If the first step is completed, the user opens a session with the server. All subsequent actions are performed on behalf of the account for which she successfully entered the password.

When accessing the database, the server checks whether the current user has the rights to the information that it requests. In case of a positive decision, the information is provided to the user. In case of a negative decision, the user is denied access.

So, for each HIS object a list must be set, according to which the HIS itself will check whether this user has the right to access this object or not. Such list is usually called Access Control List (ACL). The main objects of the HIS, for which an ACL must be set, are:

- information stored in the database;
- applications included in the system software package;
- commands and functions in applications that can be used with different access levels.

In this case, the order of verification should be carried out from large to small, i.e. first it is needed to pass a check for permission to access the patient card, then to its documents, etc.

5.6. Patient access to EHR: legal aspects

Every person must have right to access his (her) health information. This right takes on a new meaning within the framework of the introduction of E-Health systems, since new systems must be designed in such a way as to allow the exercise of this right at the highest possible and acceptable level for the patient. Access to health information with the help of EHRs is in many aspects faster and more convenient than obtaining such information by visiting a medical

institution, which often leads to problems such as the need to wait in line for a medical worker, limited time to receive information from him, the possibility of illness due to contact with persons who may be infected, etc.

A patient gets access to EHR only by fully identifying themselves on the network, obtaining a username and password to access the system through their personal account.

The question of obtaining the consent of the person to maintain medical records in electronic form, including personal data, remains open. Due to the fact that at present the assignment of Electronic Digital Signature (EDS) to individuals is not mandatory, the alternative may be to sign a paper version of the consent, scan this document and attach it to the EDS in a format that does not allow for changes (for example, PDF). The second option may be a centralized transition to the electronic version without obtaining consent, i.e. "default" consent. An example is the maintenance of a Population Register in a country, i.e. at birth, information about a person (personal data) begins to accumulate in electronic format, while the consent of the person in any form is not provided. When creating the register, the goal was also to create a single information space in the Republic of Belarus. At the same time, the protection of the rights and freedoms of individuals is entrusted to the State.

In connection with the creation of a centralized state E-Health system, we consider it possible to use a similar approach. The EHR will be started at birth, and subsequently new information will be entered into it. This approach is of particular importance for children with limited legal capacity and incapacitated persons, i.e. persons who do not have the ability to make decisions independently. The refusal of parents, guardians, caregivers, etc. from conducting the EHR may have consequences in the future for the person himself.

As part of the patient-centered approach, it is advisable to consider the possibilities of EHR for the patient himself. As part of the access to your EHR, it is possible to provide the following: familiarization with your medical history, the possibility of making changes, including additions and deletion of information [3].

Within the framework of the traditional approach, when there is a paper version of the medical record, the opportunity to get acquainted with information about your own health is very conditional. This is primarily due to the fact that the medical card is stored in a medical institution and its transfer to the patient "in the hands" is not provided. The second aspect is the often illegible handwriting of the doctor and the use of special medical terms, without deciphering. These factors limit the rights of a person when choosing a medical institution, since a person needs to familiarize a specialist with the entire medical history in order to receive qualified assistance, and also generates their own "ignorance" about their health. Of course, the doctor introduces the patient to the state of his health directly at the reception, however, often a large amount of information received at a time is poorly absorbed and forgotten over time.

The EHR will allow the patient to get acquainted with information about their health at any time. Access to the EHR can be carried out through the personal account, with full identification of the user, in order to exclude the possibility of familiarization of third parties.

The main component for the patient will be the "Personal Account of the patient", which will provide him with access to basic services, including EHR.

When encoding diagnoses, a reference field should be provided for obtaining general information about a particular disease. This aspect is extremely important, since it is increasingly common for people to receive information from the Internet, which is often of poor quality. In this regard, the provision of general reference information for decoding the diagnosis recorded in the EHR is desirable for the patient himself, in order to avoid misunderstandings, incorrect interpretation and subsequently self-medication, which can lead to serious consequences. There is an opinion that a person does not need to know what he is not an expert in, but this approach is not applicable at present. The more a person has the ability to obtain information, the more actively he uses all means to obtain it.

Special attention should be paid to the so-called "sensitive information", i.e. information that can affect the mental state of a person (a message about cancer, HIV, etc.). In this case, before providing access to this information in the EHR, the doctor must personally familiarize the patient, prepare him morally and give explanations, i.e. the information is entered in the EHR immediately, and access to the patient is provided after a conversation with the doctor.

The issue of providing access to the EHR by the patient is controversial. In this approach, it is necessary to take into account both positive and negative aspects. The positive thing is that the person himself has the ability to control access to his EHR, i.e. independently decides whether to allow him to get acquainted with his medical history or not. On the negative side, it should be noted that the patient is not always able to understand what information the doctor needs to access to provide qualified care and make the correct diagnosis, because the human body can be considered as a well-

coordinated mechanism, and the more information the doctor has, the higher the chances of choosing an effective treatment.

The ability to enter additional information is important. Within the framework of the EHR, it is advisable to provide a section that the patient can manage independently. Supplement the EHR with information obtained in private medical institutions (if the latter do not have access), consultations received abroad, as well as other data (pressure, temperature, etc.).

Due to the large spread of various kinds of autonomous devices that allow you to measure the pulse, pressure and other parameters of the human body and the rapid development of the industry in this area, the issue of using this information not only by the person himself, but also by the medical professional becomes relevant. Many representatives of medicine are of the opinion that it is possible to use information only with means certified by the Ministry of Health, which is logical from the point of view of the reliability of the information. However, the pace of ICT development is too fast and the response from health authorities should be immediate. In order for technologies to be useful, it is necessary to provide a person with the opportunity to use and enter information in their "own" section under their own responsibility. The use of this information should remain at the discretion of the medical professional.

As a result, within the framework of the current legislation, a centralized approach is meant, focused on the creation of a single database of IEHR owned by the state and intended for the circulation of information within the health authorities with the right to make changes only by a medical professional. From the point of view of the patient, the IEHR provides for the creation of a personal patient account, where you can: make an appointment with a doctor, call a doctor at home, get an extract from medical documents, get a reminder of vaccinations, get an electronic prescription without visiting a polyclinic, see the results of tests passed.

It should be noted that in many countries, IEHR provides only familiarizing a patient with his (her) medical data, but does not imply making any changes to their own medical record. At the same time, the technical capabilities of the systems allow to provide a person with more rights and opportunities in IEHR and EH in general.

Chapter 6. ARTIFICIAL INTELLIGENCE IN MEDICINE

6.1. Artificial intelligence: what it has achieved

There are quite a large number of definitions that treat the concept of artificial intelligence. In a broad sense, it is the science and technology of creating intelligent machines and systems that can perform creative functions that are traditionally considered the prerogative of man. Artificial intelligence includes technologies such as machine learning, natural language processing, computer vision, machine reasoning, and more, which are increasingly being introduced into our daily lives. So, according to the company Grand View Research, the volume of AI on the world market in 2017 was about $ 20 billion and will reach 35.9 billion by 2025. It is predicted that the market of robots in the service sector will approach $ 27.5 billion by 2023, in production – to $ 71.72 billion [83]. Moreover, according to statistics [28], the artificial intelligence is often used in medicine. For example, market size of AI for medical imaging industry in China is growing more than twice as much as in the previous each year.

The use of artificial intelligence in general has a positive impact on many areas of activity, since it is designed to simplify production processes, make life easier for both an individual citizen and society as a whole, but along with this, new challenges and problems arise. Automation of various sectors of the economy through the introduction of robots creates a threat of failures, unauthorized access with the possibility of modifying embedded programs and actions, the consequences of which are extremely difficult to calculate. At the same time, the regulatory support in this area lags behind the needs of today. On the one hand, this is explained by the fact that it is possible after the introduction of certain technologies – the product of legal regulation, and only then an act regulating its functioning is adopted. On the other hand, technology is developing so rapidly that it is almost impossible to do it in time, given the length of the procedure for adopting legislation, so in most countries it is not available.

The use of artificial intelligence also faces some ethical challenges. The usage of AI is more problematic in the last decades. It is caused by several reasons: 1) Huge increase in data sets sizes; 2) Huge increase in performance of computing; 3) Huge improvement in AI algorithms [36]. These ethical challenges raised due to three main factors:

- decisions of AI are not transparent: in most cases, the decision taken by AI are not understandable and intelligible to humans;
- AI is biased: the decision taken by AI is not neutral because AI algorithms are learned on training data which affects the decision process;
- privacy and surveillance: there can be concerns about using and collecting some type of data

Despite these ethical challenges, AI is considered strong and helpful in many areas of nowadays industry. It is obvious that the introduction of artificial intelligence affects the labour market, makes adjustments to the optimization of jobs, changes many professions and specialties, which requires an assessment of risks in the field of employment, the re-profiling of universities and schools, and the revision of social protection issues.

Artificial intelligence will have a great impact on the regulation of human rights in the workplace (robots, manipulators), in medicine (the use of robot surgeons, organ transplants, etc.), to some extent increasingly infringing on these rights. The widespread use of robots and AI systems poses challenges to the legislative system, the solution of which seems impossible without taking into account many technical, legal and human aspects.

The advantages of AI are undeniable; with its help you can perform those actions that a person can not or does not want to do. One example is a robot operating in a forest fire. AI can also reduce logistics costs, thanks to autonomous truck management that provides intelligent delivery routing, help in predicting and solving crimes by collecting personal data of potential suspects, viewing video surveillance, and conducting "crowd analysis" to identify suspicious behaviour.

The fields of robotics and artificial intelligence are closely related to each other. The integration of these two sciences allows the creation of intelligent robots – another direction of AI. The intelligence is the reason why these robots are much smarter and more adaptable than their predecessors without AI. Intelligence is required for robots to manipulate objects, perform navigation with localization problems (determine location, study nearby areas), plan movement (how to get to the goal), etc. Therefore, robots are machines that perceive, think, act, and communicate [2].

Their development and implementation should follow two main directions: technical and legal. From the first point of view, a robot is a hardware and software complex, in which the software that is the "brain" of the robot is "sewn". It is created by scientists and engineers. But then robots begin to work in production, in medicine, that is, to live among people. And for such joint activities, it is necessary to have a well-developed legal framework that accurately defines the norms of behavior of both in different situations.

Today, artificial intelligence is widely used in medicine. AI can accelerate the diagnosis process and medical research. The usage of AI in medicine has potential benefits to both doctors and patients. For example, patients can have benefits from AI during patient's care. On the other hand, it helps doctors solve a variety of problems:

- Assessing the likelihood of complications of diseases;
- Remote first aid and patient data collection;
- Assistance in making diagnoses and prescribing treatment;
- Real-time data analysis of critically ill patients

However, using AI in medicine have some disadvantages:

- Violation of the right of patients to privacy and confidentiality of personal data, disclosure of medical secrets.
- The data from the electronic card is available to the insurance company, which will increase the price of the medical policy and life insurance if the patient does not lead a "healthy" lifestyle and does not follow all the doctor's recommendations for treatment.
- Overdiagnosis.
- Access to the applicant's medical data. Refusal of employment due to the presence of chronic diseases and / or genetic predispositions to certain types of diseases. The threat of discrimination against people based on physical and genetic characteristics.
- Many algorithms rely on very complex mathematics, sometimes called the "black box". In some situations, we should know the reasons for decisions because in the medical area these decisions can affect a patient's health.

6.2. Smart healthcare: what is it

Smart Healthcare leverages the latest mobile and digital advances in E-Health and mHealth, driving the development of smart and connected medical devices. The approach to medicine is also changing: with smart trackers, doctors have much more opportunities to constantly monitor patient indicators outside of medical institutions and, accordingly, prevent diseases.

In past years, there appeared term "Smart medicine". By "Smart medicine" we mean intelligent healthcare, which uses the latest mobile and digital achievements in the field of E-Health and mHealth, which encourages the development of smart and connected medical devices that ensure constant monitoring of patient indicators outside of medical institutions and, accordingly, the prevention of diseases. In some cases, this type of monitoring can recognize or predict critical health conditions of patients and it can warn health institutions if immediate first aid is needed.

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

With the help of AI and machine learning technologies, medical researchers identify the relationship between the patient's diseases, the conditions in which he lives, and his habits. Even the state of the environment can tell you which patients in a given region are at the highest risk. You can also find the most vulnerable regions or segments of the population to give them recommendations in advance, before you need serious medical care [65].

IoT solutions will play a major role in Smart medicine. IoT interconnects all computational, mechanical, and digital technologies for data transmission over the Internet without the necessity of human interaction. Such interconnected

technologies can be considered as remote monitoring systems. Remote monitoring systems based on a sensor system will show, for example, the level of glucose in the patient's blood, and immediately send this data to doctors for analysis and prognosis. Based on the data, specialists will prescribe treatment and prescribe personal medications. And the patient will print the pills at home on a 3D printer. All this without being distracted by visiting a doctor and searching for a pharmacy.

The device-to-device connectivity that underpins smart city services is also opening up a new approach to healthcare. In the concept of a smart city a huge amount of data is accumulated, including on the state of health and well-being of citizens. This data can be used for planning urban space and new services. These data can also invoke some actions focused on improving public urban health - a range of issues that affect urban populations.

Together with Smart medicine, there is a notion of a Smart hospital. It can be defined as an interactive intelligent digital environment that represents the meta-system to manage clinical pathways based on on-line monitoring of vital functions in combination with the operational personnel access and patient information (including virtual councils) with the wide use of mobile applications and robotics.

Medical information is a private area, even intimate, so patient confidentiality is the most important issue. But the data can be depersonalized. This way we will get both confidentiality and data integrity. This data will be useful for introducing innovations and strengthening cooperation between suppliers and partners, which will also benefit smart city medicine, including through the exchange of knowledge between doctors from around the world.

The question arises in Smart medicine: who is the true owner of medical data? Who can dispose of them to what extent? Patient, doctor, clinic, insurance company, employer, or computing service?

Another question: can a doctor rely entirely on AI? Because cognitive systems have problems with the quality and volume of medical information. The data accumulated in patients ' medical records may be incomplete, contain errors, inaccuracies, and non-standard terms. There are not enough records of the patient's life, habits, and behavior. Effective mechanisms for collecting this information do not yet exist. In addition, many of the AI algorithms are considered as black box in which the decision-making process is hidden in network layers. This can be problematic especially in situations that are not present in data set used to train AI algorithms, which will likely result in inaccurate AI decisions.

Another topical issue that needs to be faced are the legal implications of AI systems in healthcare. As soon as AI systems start making autonomous decisions about diagnoses and prognosis, and stop being only a support tool, a problem arises as to whether, when something ‘goes wrong’ following a clinical decision made by an AI application, the reader (namely, the radiologist) or the device itself or its designer/builder is to be considered at fault [82]. Legal responsibility for decision making in healthcare will remain a matter of the natural intelligence of physicians. From this viewpoint, it is probable that the multidisciplinary AI team will take responsibility in difficult cases, considering relevant, but not always conclusive, what AI provided.

In the future, the development of intelligent health technologies can also be aimed at simplifying the patient's access to medical services. Today, in the emergency medical centers of hospitals, the order of admission of patients depends on how urgently the patient needs help. Thanks to the use of new technologies, this process can be simplified. Using the digital interface of a dedicated app, patients will be able to report their symptoms, which will be analyzed digitally using standardized symptom tracking protocols to determine the degree of urgency. Some medical services can be provided to the patient at home using digital tools and modern telemedicine. For example, trips to the doctor to ask a few questions and get a prescription for medicines can be replaced by medical kiosks, where patients can communicate with the doctor remotely and get the same answers and prescriptions. These decentralized offices will continue to rely on a reliable central health facility, which will act as the main center for building trust in digital technologies, as well as a digital service provider.

In the future, common digital formats and structures may enable the exchange of comprehensive patient information between all of that patient's healthcare providers. Multimedia and messaging standards can further improve remote treatment, remote patient monitoring, and remote diagnosis. Aggregated health data that is stored in uniform digital formats can improve medical research. Digitally stored genetic data can provide more individualized treatment for patients. Universal standardization, which can be determined by both cooperation between private enterprises and public standards policies, is a necessary prerequisite for any of these advances in E-Health.

6.3. Artificial intelligence recognizes medical images

Most diagnoses in medicine are made based on analysis of medical images. The use of AI in the analysis of medical images is under continuous evolution. A number of tools based on artificial intelligence have been developed to automate medical image analysis and improve automatic image interpretation. Diagnostic that use AI approach is usually performed quickly its accuracy is high. Diagnostic in combination with AI is becoming an important technology for future diagnostic systems. But, such diagnostic systems need to be improved in several aspects. Obtaining a reliable and accurate model using deep-learning architecture requires big data. But mostly, medical images are technical and man-made. This fact makes it difficult to build big data systems. The next problematic aspect is the creation of a database of standardized and labeled medical images can be extremely time-consuming. People usually build databases by manual pre-processing of all medical images for AI applications [118].

Medical images are usually classified according to the methods of obtaining them and the industries to which they belong. The following types of images are distinguished: anatomical (photographs, X-rays, ultrasound images, nuclear magnetic resonance (NMR) images, computer tomography models), and histological (optical and electron microscopy images).

Medical images can be divided by spatial resolution into 2D and 3D. However, traditionally images in medicine are classified according to the areas in which they are used: anatomical, histological (including cytological), physiological.

A more common classification is based on the nature of the image acquisition and on the objects present in images of this type: histological images, images of radiation methods, endoscopic images, thermal images.

Ray imaging techniques are based on the analysis of specific radiations. Traditionally, such images include X-ray, magnetic resonance, and ultrasound images.

The current level of medical science requires specialists not only to possess certain practical skills, but also to know the main general pathological processes, their nomenclature and definitions, causes, pathogenesis and outcomes, as well as their significance for the human body. General pathological processes occur at various levels: organizational, organ, tissue, cellular, ultrastructural, and molecular. The first two levels correspond to macroscopic changes visible to the naked eye, and suggest changes in the appearance of the affected organs. At the tissue and cellular levels, pathological processes are detected using a light microscope.

We can not consider all these types of medical images. Let us take only one type – histological and cytological images and their using for cancer diagnostics.

Cancer is an extremely important problem in modern society. In accordance with the conclusion of the International Agency for Cancer Research, the World Health Organization, 8.2 million deaths were caused by cancer in 2012 and according to their forecasts, another 20 million deaths are expected by 2030 [23].

Deep learning based AI shows promise and potential in histological and cytology diagnosis of different kinds of tumours. Therefore, the application of AI on this task is under strong interest of scientists. For example, the emerging role of AI is well considered in [62]. The next similar studies are [19; 82; 116]. These studies differ in used AI methods but the main idea of the conclusion is the same. The cooperation between specialists (oncologists, pathologists, radiologists, etc.) and AI will support the reliable and precise treatment of tumors.

Histopathological analysis is extremely time consuming and highly specialized procedure, the success of which depends on the experience of a specialist and is influenced by such factors as fatigue and lack of attention. Therefore, there is an urgent need to create methods for computer diagnostics, in order to reduce the load on pathologists, eliminating the most obvious benign sections of images, and thus freeing experts for much more laborious cases to diagnose.

In differential diagnosis of cancer tumors, the role of generally accepted criteria of malignancy, which are based on the whole complex of quantitative indices of cell abnormality, is limited. This leads to low frequency of cancer recognition at early stages and necessitates the development and adoption of new, more effective methods of oncological diagnosis.

Low rate of diagnosing cancer at early stages necessitates the development and introduction into practice of new and more effective modes of oncological diagnostics. One of the approaches to solving of this task is the transformation of qualitative indices of pathological changes in cells to a quantitative form with the help of the method of computer morphometry.

Similar to the traditional diagnosis based on the aggregation of qualitative signs of atypical cells, it is necessary to have a set of morphological parameters, reflecting the regularities of different sides of pathological processes occurring

in an organ both at cell and population levels. The use of aggregation of quantitative signs of atypical cells as a criterion of tumor malignancy, will allow to improve the informativity of cancer diagnosis.

Modern tools like digital microscopy and developed mathematical methods allow an automatization of cell image analysis. The analysis of cell images can be considered as image segmentation problem where cells or their kernels should be extracted Being extracted, object characteristics should be computed, analysed and used by doctors.

Recently, image processing has been actively used in many areas of human activity. Every year, more and more methods and algorithms for image processing and object selection are being developed, some of them are used to search and analyze objects by various characteristics. In addition, the characteristics are one of the most important results of the analysis. They can be either the final result – a numerical representation of the analysis, or an intermediate one-requiring additional formalization. It is on the basis of the characteristics that conclusions are drawn about the object under study and it is the characteristics that play a key role in the tasks of analysis, monitoring, and forecasting. Characteristics are used wherever the image is processed, except for direct visualization tasks.

Belarusian scientists created a number of systems for diagnosis of various illnesses. We described several systems in Section 2. We can show here examples of other systems developed by Belarusian scientists [6; 75]. Fig.6.1 shows systems for cell image analysis and calculating their characteristics.

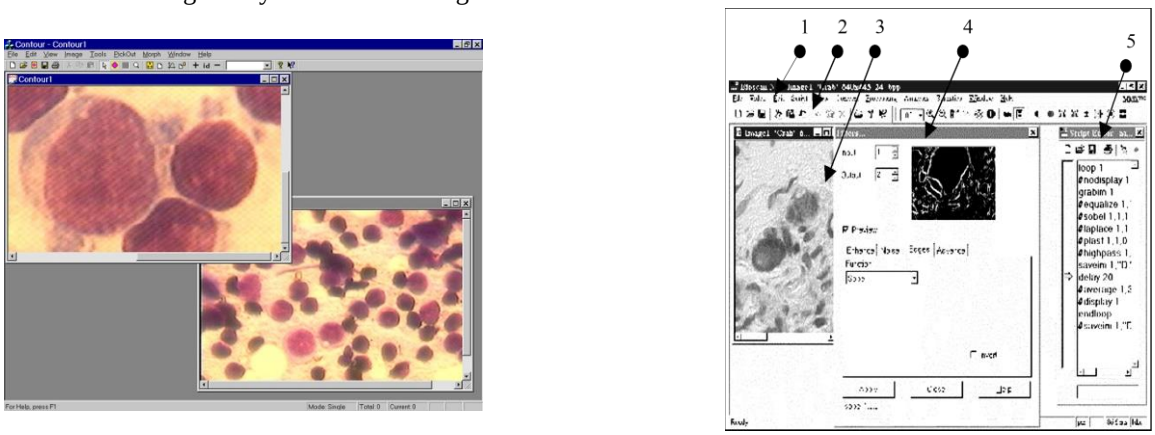
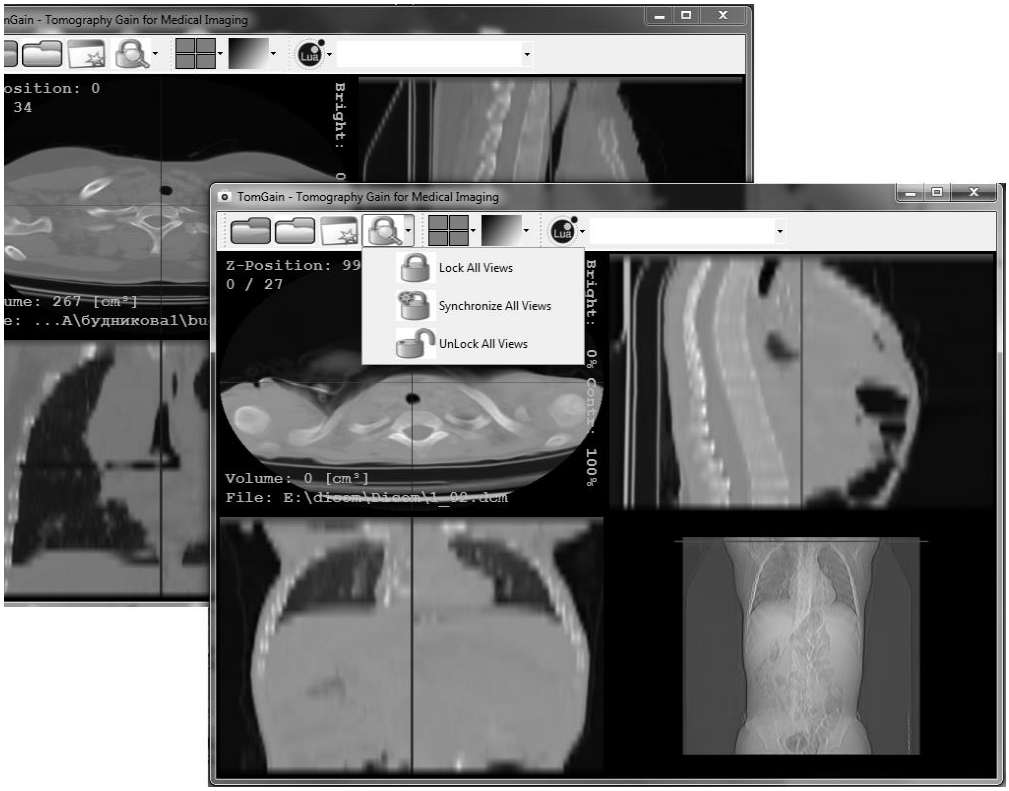
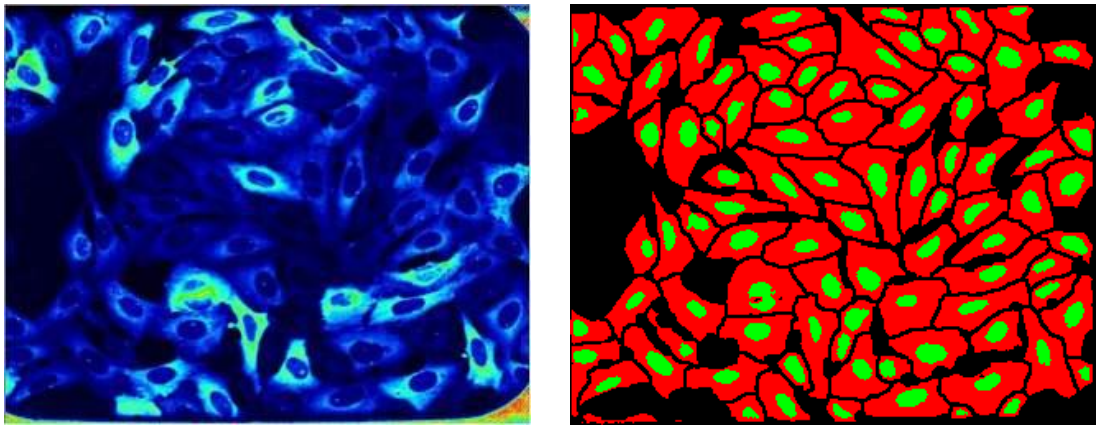


Fig.6.1. Systems for cell image analysis and calculating their characteristics.

Fig.6.2 shows computer tomography images, cell images and results of processing.



a) Computer tomography images and results of processing.



b) Cell image segmentation.

Fig.6.2. Results of image analysis: a) computer tomography images, b) cell images.

Concluding, we can say, that in the era of personalised and precision medicine, there is a growing interest in transforming medical images into mineable high-dimensional data or radiomic features which can be used to improve clinical decision-making. However, we are sure artificial intelligence can only be used as a means of help to doctors. It is important to state that medical professional intelligence, not artificial intelligence, must always be at the heart of patient care and be central to strategies that move medicine forward. At least at the moment, no one wants their radiograph data to be taken and diagnosed by Artificial intelligence without any further control and analysis by medical professional.

6.4. Data protection and patient rights in Smart healthcare

For smart medicine together with standard problems, there are new high-risk ethical issues, mainly caused using remote medical equipment, social networks and unclear laws. We can detect the following risks:

- Risk from device information leakage
- Risk from social network
- Ambiguities in the laws.

Although there are already some laws to protect information security, many laws and regulations on ethical issues are ambiguous. There is no clear indication on the subject of responsibility and the boundaries of information. For example, wrong treatment and diagnosis can cause additional pain and burden to the patient. Therefore, once information leakage occurs, it is still difficult for patients to defend their rights through legal channels. For example, when a device analyzes the users' data and draws a conclusion "do exercise", but the user's physical condition is not good, then how to define responsibility if an accident occurs? [26]

What can be done to protect personal data in Smart medicine? From technical point of view, related devices causing information leakage should be identified and protected. These include unauthorized connection to sensors, medical devices, gateways, fog nodes, and mobile devices that capture, aggregate, process, and transmit medical data to the cloud [104].

To respond to threats, IoT devices must always check and censor that the authentication is truly part of the Smart Healthcare cloud, and that strong authentication algorithms and key management systems are used to ignore and block unauthenticated requests.

Then network security is very important issue. IoT technologies such as RFID and wireless sensor networks can provide identity verification and tracking capabilities. It should be able to repel cyber-attacks.

Training for patients is also very important, for example, end users should learn how to avoid network's attacks, choose strong passwords, and not buy used equipment or equipment of unknown source.

The most important thing is that all service providers should strictly abide by the principle of autonomy priority and provide multiple choices to users. Users have the right not to use these functions or freeze sensor usage and database at any time.

Traditional medical services cannot be eliminated, people should have the right to choose between smart medical services and traditional medical services.

However, artificial intelligence brings together with benefits also various problems. We can extract the following ethical problems:

- Dominance of the technical type model
- Replacing the doctor with robotic systems
- No contact between doctor and patient
- Reducing the responsibility of the doctor
- Loss of specialized skills by doctors.

Ethical principles include trust, privacy and related data protection, property rights, dignity, fairness and proportionality. Trust must be present in E-Health in such a way that citizens need to be reassured that data are being processed properly, that they are up-to-date and of quality, and that security risks are being taken into account. People will face these problems in new future.

CONCLUSION

The introduction of Information and Communication Technologies has a significant impact on any field of activity, providing new opportunities. At the same time, there are new challenges and threats that require a response from both the state and society. In the context of digital transformation, changes often affect the realization of fundamental human rights and freedoms. New technologies should not have a negative impact, but rather promote empowerment. This requires taking into account a set of different issues that should be taken into account both when designing the process of introducing new technologies in a particular area, and when implementing the legal regulation of relevant issues, and especially when taking practical measures for their implementation.

This can be fully attributed to the process of informatization of healthcare. Every country pays considerable attention to issues related to the development of E-Health. Many E-Health systems such as Hospital Information Systems, Electronic Health Records and others have been created and work now in hospitals. Using these systems contribute greatly to improve quality of healthcare in a community.

Hospital Information Systems are started to be widely used, allowing for the collection, analysis and systematization of information in various areas, depending on the goals and objectives set. The introduction of electronic health records and the development of telemedicine services allow improving the healthcare of the population, which causes positive ratings from both doctors and patients. In general, we can say that the level of health care informatization is quite high in many countries. The next very important step is to create a single information space in healthcare throughout the country. In this regard, the issue of ensuring and expanding human rights in this area is very timely.

Evaluating this process, attention should be paid to ensuring that it is carried out in compliance with, and even can be said to be in order to realize human rights. As the analysis has shown, these issues are given a lot of attention at a high international level. There is a wide range of international standards covering the various obligations of States in the realization of the right to health, which should be fully taken into account in the context of health informatization. Significant attention is also paid to the implementation of human rights in the context of E-Health in the European region. Many of the approaches that have been developed at this level are further becoming a reference point around the world (in particular, issues of personal data protection, including the right to be forgotten and the right to delete information). If we talk about the direct formation and development of EH systems, the relevant projects have been implemented in many states today, which allows us to speak about the presence of important experiences, both regulatory and practical. In general, it can be confidently argued that the development of health care within the framework of the development of ICT is inextricably linked with the provision of fundamental human rights and freedoms in particular and society as a whole.

Introduction of ICTs in healthcare requires the development of solutions that must take into account the specifics of the digital environment. As the analysis of the experience of foreign countries has shown, the advantage of the digital environment is that it does not require the transfer of the solution that existed before its implementation, but allows you to search for a more effective mechanism. There should also be measures that will minimize the number of errors caused by the information environment itself (failures in operation, errors in the formation of electronic records, etc.).

In this regard, the proposals made in the book are aimed at creating and maintaining a certain balance of "person" and "system" in the new conditions. These suggestions were deliberately not made in the conclusion of this book, since they are directly related to the logic of the presentation. At the same time, it should be taken into account that the diversity of EH systems existing in the world also leads to differences in the approach taken to solving a particular issue, which is due to a significant number of factors specific to each state (the size of the territory, the number of people, the structure of health authorities, sources of their funding, etc.). In this regard, every country is guided by its own priorities, taking into account the experience of other countries. However, it is fundamentally important that when creating such a system, first of all, the person, his rights, as well as the need to ensure them as fully as possible in the new conditions, are taken into account.

As the analysis has shown, the practical implementation of the measures planned for further implementation, taking into account international obligations, foreign experience and national characteristics, should take into account the need to ensure human rights at the same time. It seems that only in this case, the interaction of medical worker and patient in a new electronic environment will be carried out as effectively as possible, which in general will become an important aspect of the realization of the right to health and other human rights.

We hope that this book will make its contribution to such an important area as people healthcare and will make it more effective.

Bibliography

[1] ABLAMEYKO, M. S.: [Legal regulation of personal data taking into account the input of ID-cards and biometric passports] *Pravovoye regulirovaniye personal'nykh dannykh s uchetom vvoda ID-kart i biometricheskikh pasportov*. Zhurnal Belorusskogo gosudarstvennogo universiteta. Pravo. — 2018. — № 1. — S. 14-20.

[2] ABLAMEYKO, M. S. – ABLAMEYKO, S. V.: *Pravovoye regulirovaniye vzaimodeystviya sistem iskusstvennogo intellekta i cheloveka* [Legal regulation of the interaction of artificial intelligence systems and humans]. Science and Innovations. 2020. № 1 (203). P. 40-44. http://innosfera.by/node/5086

[3] ABLAMEYKO, M. – SHAKEL, N. – ABLAMEYKO, S.– HUAFENG, CH.: Patient rights in electronic health record: legal aspects. Journal of Zhejiang Shuren University, China, Vol.21, No.3, May 2021, pp.27-31.

[4] ABLAMEYKO, S. V. – ANISHCHANKA, V. V. – LAPITSKY, V. A. – TUZIKOV, A. V.: *Medical information technologies and systems*, Minsk. UIIP NAS Belarus, 2007, 121p.

[5] ABLAMEYKO, S. – MOZHEYKO, D.: *Design and Development of the Public Healthcare Laboratory Information System*. 13th Intern. Convention and Fair «Informatica», 9–13 February 2009, Havana. – P. 2521-2557.

[6] ABLAMEYKO S. – NEDZVED A. – BELOTSERKOVSKY A. *Computer systems of histology image analysis in Belarus*. Annual Proceeding of Medical Science, Bialystok, Poland. – Bialystok, 2005. Vol. 50, № 2. – P. 23–26.

[7] About the National Coordinator for Achieving the Sustainable Development Goals: Decree of the President of the Republic of Belarus from May 25, 2017 No. 181 [O Natsional'nom koordinatore po dostizheniyu Tseley ustoychivogo razvitiya: Ukaz Prezidenta Resp. Belarus' ot 25 maya 2017 g. № 181] (in Rus.)

[8] About Health 2020. URL: https://www.euro.who.int/en/about-us/regional-director/regional-directors-emeritus/dr-zsuzsanna-jakab,-2010-2019/health-2020-the-european-policy-for-health-and-well-being/about-health-2020.

[9] About Trillium II / Trillium Project. (https://trillium2.eu/about/.) accessed: 18.10.2019.

[10] AIMAR, A. – PALERMO, A. – INNOCENTI, B.: *The role of 3D printing in medical applications: a state of the art*, Journal of Healthcare Engineering, vol. 2019, 10 pages, 2019.

[11] AHMED, S.– RAJPUT, A. *Threats to Patients' Privacy in Smart Healthcare Environment*, In book: Innovation in Health Informatics. A Smart Healthcare Primer Edition: Elsevier, March 2019. DOI: 10.1016/B978-0-12-819043-2.00016-2.

[12] ANDRUSHKO, V. *How to accelerate the introduction of E-Health services* [Kak uskorit' vnedreniye uslug elektronnogo zdravookhraneniya]. Elektrosvyaz' dlya elektronnogo zdravookhraneniya. URL: https://www.itu.int/dms_pub/itu-d/opb/stg/D-STG-SG02.14.2-1-2010-PDF-R.pdf. accessed: 16.01.2020. (In Russ.).

[13] ANWAR, M. – JOSHI, J. – TAN, J. *Anytime, anywhere access to secure, privacy aware healthcare services: Issues, approaches and challenges*. Health Policy and Technology, (2015). 4(4), 299-311.

[14] ARORA, S. – YTTRI, J. – NILSEN, W.: *Privacy and Security in Mobile Health (mHealth) Research*. Alcohol Research: Current Reviews, vol. 36, no. 1, pp. 143-150, 2015.

[15] BABAD, Y., LUBITCH, A.*: Ethical and legal issues of privacy and patient rights in the application of information healthcare delivery systems*, International Journal of Healthcare Technology and Management, 2011, 12(3-4), 230-249.

[16] BABENYA, V. – ABLAMEYKO, S.: *Classification of benign and malignant tumors in histopathological images of breast cancer by using convolutional neural networks*, Proc. of 14th Intern. conf. “Pattern Recognition and Information Processing, Minsk, BSUIR, 2019, pp. 404-407.

[17] BASHSHUR, R. L.: *Telemedicine nomenclature: What does it mean?* Telemedicine Journal, 6, 1–3. (2000).

[18] BELYAKOV, A. V. [General characteristics of health systems in the countries of the European Union] *Obshchaya kharakteristika sistem zdravookhraneniya v stranakh Yevropeyskogo soyuza* . Sovremennoye pravo. 2011. № 8. P. 138–142.

[19] BEREZSKY, O. – MELNYK, G. – DATSKO, T. – VERBOVY, S.: *An intelligent system for cytological and histological image analysis.* In Proceedings of the Proceedings of 13th International Conference: The Experience of Designing and Application of CAD Systems in Microelectronics, CADSM 2015; Institute of Electrical and Electronics Engineers Inc., 2015; pp. 28–31.

[20] BITAR, H. – ALISMAIL S.: *The role of eHealth, telehealth, and telemedicine for chronic disease patients during COVID-19 pandemic: A rapid systematic review*. Digital Health, 2021, 7(8), 1-19.

[21] BOKOLO, A.: *Exploring the adoption of telemedicine and virtual software for care of outpatients during and after COVID-19 pandemic*, Irish Journal of Medical Science, 190(1), 2021, pp. 1–10.

[22] BONIFAZI, F. – VOLPE, E. – DIGREGORIO, G. – GIANNUZZI, V. – CECI, A.: *Machine Learning Systems Applied to Health Data and System*, European Journal of Health Law, 2020, 27(3), 242-258

[23] BOYLE, P. – LEVIN, B.: *World Cancer Report 2008*, International Agency for Research on Cancer (IARC). 2008. №7. pp. 27–33.

[24] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4), URL: https://www.refworld.org/pdfid/4538838d0.pdf

[25] CHAN, K. S. – ZARY, N.: *Applications and challenges of implementing artificial intelligence in medical education: integrative review*, JMIR medical education, vol. 5, no. 1, article e13930, 2019.

[26] CHANG, V. – CAO, Y. – LI, T. – SHI, Y. – BAUDIER, P. *Smart Healthcare and Ethical Issues*. In International Conference on Finance, Economics, Management and IT Business (FEMIB 2019), pages 53-59. DOI: 10.5220/0007737200530059

[27] CHEN, S. C. – HU, R. – MCADAM, R.: *Smart, Remote, and Targeted Health Care Facilitation Through Connected Health: Qualitative Study*. Journal of medical Internet research, 22(4), e14201. (2020).

[28] China: AI medical imaging industry market size 2018-2022. Statista. URL: https://www.statista.com/statistics/1024843/china-ai-medical-imaging-industry-market-size/ (accessed on Jun 15, 2021).

[29] CHOPLIN, R. H. – BOEHME, J.M. 2nd. – MAYNARD, C.D. *Picture archiving and communication systems: an overview*. Radiographics. 1992 Jan;12(1):127-9. doi: 10.1148/radiographics.12.1.1734458. PMID: 1734458.

[30] CHUNG, K. J. – KIM, J. –WHANGBO, T. K. –KIM, K. H. : *The prospect of a new smart healthcare system: a wearable device-based complex structure of position detecting and location recognition system*, International Neurourology Journal, vol. 23, no. 3, pp. 180–184, 2019.

[31] Cross-border health project epSOS: What has it achieved? / European Commission, 2014. URL: https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved. access: 30.04.2019.

[32] DEIKALO, E. A. – VOROBYOVA, E. M. – TOMASHEVSKY, K. L.: *Business and Human Rights: Statement of the Problem* [Biznes i prava cheloveka: postanovka problemy] . in: Interdisciplinary research in the field of human rights / T.P. Afonchenko [et al]. Minsk: Ecoperspectiva, 2019 .- p. 160.

[33] DEMARTINES, N. et al.: *Telemedicine: outlook and multidisciplinary approach*// Schweizerische Medizinische Wochenschrift, 2000. Vol. 130, № 3. 314-322.

[34] DHILLON, B.S.: *Human Reliability and Error in Medicine*, World Scientific, 2003.

[35] Digital Imaging and Communications in Medicine. URL: https://www.dicomstandard.org/

[36] DISTANTE, A. – DISTANTE, C. H*andbook of image processing and computer vision:* Volume 1: From energy to image; 2020.

[37] EB139/8, URL: https://apps.who.int/gb/ebwha/pdf_files/EB139/B139_8-en.pdf?ua=1.

[38] EB142/20; URL: https://apps.who.int/gb/ebwha/pdf_files/EB142/B142_20-en.pdf?ua=1

[39] eHealth standardization and interoperability WHA66.24. URL: https://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R24-en.pdf?ua=1

[40] European Charter of Patients' Rights [Yevropeyskaya khartiya prav patsiyentov]. URL: http://www.e-stomatology.ru/detstom/zakons/prilozenie_28.pdf. 15.08.2019.

[41] Explanatory memorandum to Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data. Council of Europe. URL: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016809339f8 access: 30.03.2019.

[42] EYSENBACH, G.: *What is e-health?*. Journal of medical Internet research, 3(2), E20. 2001

[43] FAIELLA, G. – PARAND, A. – FRANKLIN, B. D. – CHANA, P. – CESARELLI, M. – STANTON, N. A. – SEVDALIS, N.: *Expanding healthcare failure mode and effect analysis: A composite proactive risk analysis approach*, Reliability Engineering & System Safety, 2018, 169, 117–126.

[44] FATEHI, F. – WOOTTON, R.: T*elemedicine, telehealth or e-health? A bibliometric analysis of the trends in the use of these terms.* J Telemed Telecare 2012; 18: 460–464.

[45] FERNÁNDEZ-ALEMÁN, J. L. – SEÑOR, I. C. – LOZOYA, P. Á. O. – TOVAL, A.: *Security and privacy in electronic health records: A systematic literature review*. Journal of biomedical informatics, 46(3), 541-562. (2013).

[46] FERRUCCI, D. A.: *Introduction to "This is Watson"*, IBM Journal of Research and Development, 56(3-4), 2012, 6177724 .

[47] FOSTER, J. D. – MISKOVIC, D. – ALLISON, A. S. – CONTI, J. A. – OCKRIM, J. – COOPER, E. J. – HANNA, G. B. – FRANCIS, N. K.: *Application of objective clinical human reliability analysis (OCHRA) in assessment of technical performance in laparoscopic rectal cancer surgery*. Tech. Coloproctol. 20(6), 2016, 361-367.

[48] From innovation to implementation: E-Health in the WHO European Region . URL: https://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf

[49] General Comment No 16 (CCPR General Comment No. 16: Article 17 (Right to Privacy) The Right to Respect of Privacy, Family, Home and Correspondence, and Protection of Honour and Reputation Adopted at the Thirty-second Session of the Human Rights Committee, on 8 April 1988), URL: https://www.refworld.org/docid/453883f922.html

[50] Google Spain SL and Google Inc. v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González. Case C-131/12. (ECLI identifier: ECLI:EU:C:2014:317). Access to European Union Law. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62012CJ0131. accessed: 20.01.2020.

[51] Grata International. Gratanet. URL: http://www.gratanet.com/up_files/General_regulations_of_data_protection_in_EU4.pdf. accessed: 26.04.2019. – p. 3.

[52] Grid Technologies for E-Health: Applications for Telemedicine Services and Delivery, 30 November 2010 by E. Kldiashvili (Editor)

[53] HAAS, S. – WOHLGEMUTH, S. – ECHIZEN, I. – SONEHARA, N. – MÜLLER, G.: *Aspects of privacy for electronic health records*. International journal of medical informatics, vol. 80, no. 2, pp. e26-e31, 2011.

[54] HASSELGREN, A. – KRALEVSKA, K. – GLIGOROSKI, D. – PEDERSEN, S. – FAXVAAG, A.: *Blockchain in healthcare and health sciences-a scoping review*, International Journal of Medical Informatics, vol. 134, p. 104040, 2020.

[55] Health Level Seven Standard. https://www.hl7.org/

[56] HIMSS Annual European Digital Health Survey 2021. URL: https://cloud.emailhimss.org/HA-Trendbarometer-01-14

[57] HOFER, T. P. – KERR, E. A. – HAYWARD, R. A.: *What is an error?* Effective clinical practice, 3(6), 261-269. 2000.

[58] HUANG, H. K.: *Telemedicine and Teleradiology*. PACS and Imaging Informatics. – John Wiley & Sons, 2010. Chapter 15. P. 454–455.

[59] Impact of GDPR on Russian personal data operators. Habr. (https://habr.com/ru/post/423733/). accessed: 30.05.2019

[60] International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, Adopted by General Assembly resolution 45/158 of 18 Dec. 1990, available at: https://www.ohchr.org/en/professionalinterest/pages/cmw.aspx [accessed 25 March 2021]

[61] JAKAB, Z.: *Health information – backbone of public health.* Public Health Panorama. Volume 5, Issue 1, March 2019. P. 7.

[62] JIANG, Y. – YANG, M. – WANG, S. – LI, X. – SUN, Y.: E*merging role of deep learning-based artificial intelligence in tumor pathology.* Cancer Communications 2020, 40, 154–166.

[63] KAPUR, A. – POTTERS, L.: *Six Sigma tools for a patient safety-oriented, quality-checklist driven radiation medicine department.* Pract Radiat Oncol, 2, 2012, 86–96.

[64] KRAVCHUK, N.V.: *Praktika Yevropeyskogo suda po pravam cheloveka po delam, zatragivayushchim ispol'zovaniye novykh tekhnologiy (obzor)* [Practice of the European Court of Human Rights in Cases Affecting the Use of New Technologies (Review)]. Gosudarstvo i pravo v novoy informatsionnoy real'nosti- 2018. - S. 184-195

[65] LEHRACH, H. – Ionescu, A. M.: *The Future of Health Care: deep data, smart sensors, virtual patients and the Internet-of-Humans*. URL: https://ec.europa.eu/futurium/en/system/files/ged/future_health_fet_consultation.pdf

[66] LIST, R. – COMPTON, M. – SOPER, M., et al.: *Preserving Multidisciplinary Care Model and Patient Safety during Reopening of Ambulatory Cystic Fibrosis Clinic for Nonurgent Care: A Hybrid Telehealth Model*, Telemedicine and e-Health, 2021, 27(2), 193-199.

[67] LYONS, M. – ADAMS, S. – WOLOSHYNOWYCH, M. – VINCENT, C.: *Human reliability analysis in healthcare: A review of techniques*. Int. Journal of Risk & Safety in Medicine. 2004, 16 (4), 223–237.

[68] MAHMOOD, H. – SHABAN, M. – RAJPOOT, N. – KHURRAM, S.A.: *Artificial Intelligence-based methods in head and neck cancer diagnosis: an overview.* British Journal of Cancer 2021, 124, 1934–1940, doi:10.1038/s41416-021-01386-x.

[69] MANN, D. M. – CHEN, J. – CHUNARA, R. – TESTA, P. A. – NOV, O.: *COVID-19 transforms health care through telemedicine: evidence from the field*. Journal of the American Medical Informatics Association, v27(7), 2020, pp. 1132–1135.

[70] MAUREEN, N. – HOOD, H. S.: *Introduction to Picture Archive and Communication Systems*, September 2006, Journal of Radiology Nursing 25(3):69-74 DOI: 10.1016/j.jradnu.2006.06.003.

[71] MOHAPATRA, S. – PARIJA, S.: *IoT-Based Modeling of Electronic Healthcare System Through Connected Environment*, Advances in Intelligent Systems and Computing, 2021, 1199, pp. 423-431.

[72] MOLLALO, A. – RIVERA, K. M. – VAHEDI, B.: *Artificial Neural Network Modeling of Novel Coronavirus (COVID-19) Incidence Rates across the Continental United States*. Int J Environ Res Public Health. 2020,17, 4204, doi: 10.3390/ijerph17124204.

[73] National eHealth Strategy Toolkit https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf.

[74] NEBEKER, C. – TOROUS, R. J. – BARTLETT, E.: *Building the case for actionable ethics in digital health research supported by artificial intelligence*, BMC Medicine, vol. 17, no. 1, p. 137, 2019.

[75] NEDZVED, A. M., ABLAMEYKO, S.: *Intellectual software of the analysis of images adapted for problems of medical diagnostics.* BGU Bulletin, Series 1. 2013. No. 1. Page 51-55.

[76] NEDZVED, A. M., ABLAMEYKO, S. V, NALIBOTSKY, B.V., ILYICH, Yu. G.: *System of analysis of medical images of histological objects*, Pattern Recognition and Image Analysis, Vol.11, No.4, (2001) 732-742.

[77] NIEVAS SORIANO, B. J. – GARCÍA DUARTE, S. – FERNÁNDEZ ALONSO, A. M. – BONILLO PERALES, A. –PARRÓN CARREÑO, T.: *eHealth: advantages, disadvantages and guiding principles for the future. A systematic review*. JMIR Preprints. 07/07/2019:15366.

[78] OH, H. – RIZO, C. – ENKIN, M. – JADAD, A.: *What Is eHealth: A Systematic Review of Published Definitions*, J Med Internet Res. 2005;7(1). doi: 10.2196/jmir.7.1 .

[79] Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services. Final report and recommendations. EU Health Programme. URL: https://ec.europa.eu/health/sites/ health/files/ehealth/docs/laws_report_recommendations_en.pdf. accessed: 01.05.2019.

[80] OWINGS, L. *The right to be forgotten*. Akron Intellectual Property Journal. 2015. № 9. P. 45-82.

[81] PAVLOVA, L. *Forms and Methods of the Council of Europe Standards Implementation in National Legislation*. Journal of International Law and International Relations 2012 — N 3. P. 3-8.

[82] PESAPANE, F. – CODARI, M. – SARDANELLI, F.: *Artificial intelligence in medical imaging: threat or opportunity?* Radiologists again at the forefront of innovation in medicine. European Radiology Experimental (2018) 2:35. https://doi.org/10.1186/s41747-018-0061-6

[83] RBK: Posledniy zakon robototekhniki [RBC: The Last Law of Robotics] URL: http://www.ctv.by/novosti-mogileva-i-mogilevskoy-oblasti/rbk-posledniy-zakon-robototehniki.

[84] Recommendation CM/Rec(2019)2 of the Committee of Ministers to Member States on the protection of health-related data, adopted in March 2019. URL: https://search.coe.int/cm/pages/result_details.aspx?objectid=090000168093b26e

[85] Remove your personal information from Google (https://support.google.com/websearch/troubleshooter/3111061?hl=en)

[86] ROBERSON, G. H. – SHIEH, Y. Y.: *Radiology information systems, picture archiving and communication systems, teleradiology – Overview and design criteria*. J Digit Imaging 11, 2–7 (1998). https://doi.org/10.1007/BF03168169

[87] ROTHSTEIN, M. A.: *Health privacy in the electronic age*. The Journal of legal medicine, vol. 28, no. 4, pp. 487-501, 2007.

[88] SUJANA, M.A. – EMBREY, D. – HUANG, H.: *On the application of Human Reliability Analysis in healthcare: Opportunities and challenges*, Reliability Engineering & System Safety, vol.194, art. no. 1061892, 2020.

[89] SUJANA, M.A. – HABLI, I. – KELLY, T.P. – POZZIC, S. – JOHNSOND, C.W.: *Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices*, Safety Science, 84, 2016, 181-189.

[90] SAJEDI, H. – YAGHOBI, S. R.: *Information hiding methods for E-Healthcare*, Smart Health, 2020, 15(3), Art. no. 100104.

[91] SANOTSKAYA, I. V.: [Concept, history of formation and development trends of legal regulation of health care in the European Union] *Ponyatiye, istoriya stanovleniya i tendentsii razvitiya pravovogo regulirovaniya z1dravookhraneniya v Yevropeyskom soyuze*. Yuridicheskaya nauka, 2017. – № 6. – P. 180-186.

[92] SHAFQAT, S. – KISHWER, S. – RASOOL, R. U. – QADIR, J. – AMJAD, T. – AHMAD, H. F. *Big data analytics enhanced healthcare systems: a review*, The Journal of Supercomputing, vol. 76, no. 3, pp. 1754–1799, 2020.

[93] SHAKEL, N. V. – ABLAMEYKO, M. S.: *Medical worker and patient: interaction in the conditions of electronic health care*. Minsk: Ecoperspektiva, 2020. 120 p.

[94] SHCHAVELEVA. M. V. – ZHUKOVA, N. P. – GLINSKAYA, T. N.: *Sustainable Development Goals as an Indicator of Progress in Health Care* [Tseli ustoychivogo razvitiya kak indikator progressa v zdravookhranenii] .Zdravoohranenie. 2019. No. 8. P. 11-16.

[95] SHESHABALAYA, T.: *Grid Computing and E-Health, HealthManagement*, Vol. 5, Issue 1, 2010, URL: https://healthmanagement.org/c/it/issuearticle/grid-computing-and-E-Health

[96] SI, Y. – DU, J. – LI, Z., et al.: *Deep representation learning of patient data from Electronic Health Records (EHR): A systematic review*, Journal of Biomedical Informatics, vol.115, 2021, art. no. 103671

[97] SITTIG, D. F. – HARDEEP S.: *Toward More Proactive Approaches to Safety in the Electronic Health Record Era*. Joint Commission journal on quality and patient safety vol. 43 (10) (2017): 540-547. doi:10.1016/j.jcjq.2017.06.005

[98] Special Rapporteur on the right to physical and mental health. URL: https://www.ohchr.org/EN/Issues/Health/Pages/SRRightHealthIndex.aspx

[99] STRAM, M. – GIGLIOTTI, T. – HARTMAN, D. – PITKUS, A. – HUFF, Sm. – RIBEN, M. – HENRICKS, Wh. – FARAHANI, N. – PANTANOWITZ, L.: *Logical Observation Identifiers Names and Codes for Laboratorians.* Arch Pathol Lab Med. 2020 Feb;144(2):229-239. doi: 10.5858/arpa.2018-0477-RA.

[100] *Surgical Patient Care. Improving Safety, Quality and Value*; SANCHEZ, J.A.; BARACH, P.; JOHNSON, J.; JACOBS, J.P. Eds. Springer, 2017, 880 p.

[101] SUTTON, R. T. – PINCOCK, D. – BAUMGART, D. C. et al.: *An overview of clinical decision support systems: benefits, risks, and strategies for success.* Digit. Med. 3, 17 (2020). https://doi.org/10.1038/s41746-020-0221-y

[102] SZOLOVITS, P.: *What Is a Grid?* J Am Med Inform Assoc. 2007 May-Jun; 14(3): 386. doi: 10.1197/jamia.M2351

[103] Telemedicine. Opportunities and developments in Member States. Report on the second global survey on eHealth. Global Observatory for eHealth series - Volume 2. WHO Library Cataloguing-in-Publication Data. 2009. URL: https://www.who.int/goe/publications/goe_telemedicine_2010.pdf

[104] TIAN, S. – YANG, W. – LE GRANGE, J. M. – WANG P. – HUANG, W. – YE, Z.: *Smart healthcare: making medical care more intelligent*. Global Health Journal, Volume 3, Issue 3, September 2019, Pages 62-65.

[105] THOMSON, S. – FOUBISTER, Th. – MOSSIALOS, E.: *Finansirovaniye zdravookhraneniya v Yevropeyskom soyuze. Problemy i strategicheskiye resheniya* [Health financing in the European Union. Problems and strategic solutions] VOZ. Yevropeyskoye regional'noye byuro. 2010. URL: http://www.euro.who.int/__data/assets/pdf_file/0016/126025/e92469R.pdf , 20.05.2019.

[106] Transforming our world: the 2030 Agenda for sustainable development, https://sdgs.un.org/2030agenda

[107] TUYET, D. V.: *Algorithms and technology for building integrated medical information systems.* Dissertation for the scientific degree of PhD in technical sciences. Speciality 05.13.17 – "Theoretical Foundations of Computer Science". Minsk. BSU. 2020. 130 p.

[108] TUYET, D. V. – ABLAMEYKO, S.: *Radiology Information System and PACS as a main part of Image management In Electronic Hospital*, Nonlinear phenomena in complex systems. 2018. Vol.21.No 3, 253-267.

[109] TUYET D. V. – ABLAMEYKO, M. – ABLAMEYKO, S. – HOANG, H. N. – KIM, D. P. T. – VAN, Q. H. – Van, H. T.: *E-Health system based on telemedicine platform and GRID layer model*. Nonlinear Phenomena in Complex Systems, Vol.24, N. 2, 2021, pp. 124 – 138.

[110] UN General Assembly, Right of everyone to the enjoyment of the highest attainable standard of physical and mental health : note / by the Secretary-General, 10 August 2009, A/64/272, available at: https://www.refworld.org/docid/4aa762e30.html [accessed 25 March 2021]

[111] UN Office of the High Commissioner for Human Rights (OHCHR), Fact Sheet No. 31, The Right to Health, June 2008, No. 31, available at: https://www.refworld.org/docid/48625a742.html [accessed 25 March 2021]. P. 24

[112] World Health Organization. e-Health, URL: www.emro.who.int/health-topics/ehealth/ (accessed 29 March 2021).

[113] World Health Organization. Europe. Countries. URL: https://www.euro.who.int/en/countries

[114] World Health Organization. Europe. Digital Health. URL: https://www.euro.who.int/en/health-topics/Health-systems/digital-health

[115] WHA71. on Digital health. URL: https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf?ua=1

[116] WU, M. - YAN, C. – LIU, H. – LIU, Q. – YIN, Y.: *Automatic classification of cervical cancer from cytological images by using convolutional neural network.* Bioscience Reports 2018, 38, doi:10.1042/BSR20181769.

[117] YE, S. – NEDZVEDZ, A. – Ye, F. – ABLAMEYKO, S.: *Segmentation and feature extraction of endoscopic images for making diagnosis of acute appendicitis*, Pattern Recognition and Image Analysis, Vol. 29, No.4, 2019, pp. 738–749.

[118] YOON, H.J. – JEONG, Y.J. – KANG, H. – JEONG, J.E. – KANG, D.-Y.: *Medical Image Analysis Using Artificial Intelligence.* Progress in Medical Physics 2019, 30, 49, doi:10.14316/pmp.2019.30.2.49.

[119] YÜKSEL, B. – KÜPÇÜ, A. – ÖZKASAP, Ö. (2017). *Research issues for privacy and security of electronic health services.* Future Generation Computer Systems, 68, 1-13.

[120] ZAITSEVA, E. – LEVASHENKO, V. – RABCAN, J. – KRSAK, E.: *Application of the Structure Function in the Evaluation of the Human Factor in Healthcare*. Symmetry. 2020; 12(1):93. https://doi.org/10.3390/sym12010093

[121] ZYBAILO, A. I. – FEDOROVA, V. L. *On the question of the legal nature and essence of international standards of human rights and freedoms* [K voprosu o pravovoy prirode i sushchnosti mezhdunarodnykh standartov prav i svobod cheloveka]. Zhurnal mezhdunarodnogo prava i mezhdunarodnyh otnosheniy. 2018. No. 1-2 (84-85). P. 26–31.

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