Portable telemedicine complex as the health service digital transformation technology

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Abstract. Telemedicine technology development is an important tendency of National Health Service development, as it facilitates an immediate medical support and health service management problem solution that is high on the agenda in isolated remote scarcely populated regions with health care personnel deficiency, and provides an economically efficient health care quality and access improvement. Using modern practices in the field of information and communication technologies is highly relevant for emergency medical services, because it allows significantly improve access and quality. The research has shown that in spite of the fact that telemedicine in Russia does not operate at full capacity many clinics use its components. The most common components are online medical appointment booking, access to personal account with prescription and research data and the “doctor-doctor” consultation format. Further, it is apparent from experiences worldwide that telemedicine can expand the range of service, complementing and improving health service for the population of villages, cities and even countries.

1. Introduction

Nowadays health care informatization used worldwide for improvement of medical assistance and health organization management is implemented in different ways. For example, health care informatization in Russia is implemented under the Concept of long-term economic and social development in Russian Federation for the period up to 2020 [1] and the Strategy of information society development in Russian Federation [2] and includes such activities as:

- developing information and technology infrastructure of health facilities;
- affording medical facilities access to the Internet;
- making information about medical institutions activity available on the Internet;
- implementing information management systems for medical facilities;
- implementing information support systems for medical assistance in activities of health care facilities;
- developing information and technology infrastructure of emergency medical services;
- information and communication technology education for medical personnel [1,2].

After an application of the article №36.2. Specific aspects of the health care drawn on the latest telemedicine technologies of the Federal Law “On Fundamental Healthcare Principles in the Russian Federation” [3] and the Order of the Ministry of Health of the Russian Federation “On Approval of the
Procedure for Healthcare Management and Delivery with Telemedicine Technologies” [4], it became important for health care informatization to develop telemedicine as:

- necessary information exchange method for the purposes of diagnostic, disease and injuries treatment and prevention, research and assessment, and also continuous education of medical personnel in order to improve human health and develop local communities by using information and communication technologies;
- providing health care services (when distance is a critical factor) by medicine personnel exchanging necessary information via information and communication technologies for the purposes of diagnostic, disease and injuries treatment and prevention, research and assessment, and also continuous education of medical personnel in order to improve human health and develop local communities [5].

Besides provision of health care access, the main goal of telemedicine development is an improvement of inpatient clinical and laboratory research quality and efficiency. These goals can be achieved through implementing information support systems for medical assistance in activities of health care facilities, for example remote diagnostic complexes – telemedicine systems.

Remote diagnostic complexes in turn should be regarded as medical electronic systems, capable of collecting, registering, storing and also transferring medical and biological information [6,7]. These complexes can be presented as:

- telemedicine centers “on wheels”;
- portable telemedicine laboratory and diagnostic complexes [8].

These types of telemedicine complexes are essentially different only in numbers of clinical and laboratory research. (Telemedicine centers “on wheels” can be equipped with any medical electronic kit, when in portable complexes it is acceptable to use only those that fit into a special case). In terms of the National State Standard 34243-2017 [9], these types of telemedicine complexes can be referred to as mobile. The major components of mobile telemedicine laboratory and diagnostic complexes are:

- various medical devices;
- audio- and video equipment;
- telecommunication equipment;
- other IT equipment [9].

For that reason laws and regulations in the field of medicine, telemedicine, hardware and software, and communication and information security [10] require consideration during mobile telemedicine complex development.

Apart from concept documents on health care informatization, Russian National Standard 52636-2006 [11], Russian National Standard ISO/TR 16056-12009 [12] and other Russian National Standards on health informatization directly refer to telemedicine as well.

For example, special emphasis should be given nowadays to the Russian National Standard 577572017 [13] of 2017. This regulatory document describes requirements for remote diagnostic that mobile telemedicine complexes are meant for. Moreover, remote diagnostics problems are mentioned in other standards:

1. National State Standard 25202-82 Group contact of data signal transfer devices. Basic parameters [14];
2. National State Standard 28270-89 (ISO 8211-85) Information-processing systems. Data file specification for information exchange [15];
3. National State Standard 30324.0-95 (IEC 601-1-88) / Russian National Standard 50267.0-92 (IEC 601-1-88) Medical electrical equipment. Part 1. General safety requirements [16];
4. National State Standard 30324.25-95 (IEC 601-2-25-93) / Russian National Standard 50267.25-94 (IEC 601-2-25-93) Medical electrical equipment. Part 2. Particular standards for the safety of ECG recorders [17];
5. National State Standard IEC 60065-2013 Audio-, video- and similar electronic equipment. Safety requirements [18];
6. National State Standard IEC 60950-1-2014 Information Technology Equipment. Safety requirements. Part 1. General requirements [19];
7. National State Standard IEC 62151-2013 Safety of the equipment electrically linked to telecommunication systems [20];
8. National State Standard IEC 62368-1-2014 Audio-, video equipment, IT and communication equipment. Part 1. Safety requirements [21];
9. National State Standard ISO 14971-2011 Medical devices. Application of risk management to medical devices [22].

2. Methods

2.1. Laws and regulations
Laws and regulations survey concerning telemedicine development and the use of telemedicine complexes revealed significant number of requirements. These requirements apply to portable (mobile) telemedicine complexes and the telemedicine network itself due to the need to report a certain type of information via special networks taking into account the protection standards and information storage safety.

For example, the document [37] indicates that telemedicine network must be based on a principle of functional standards of open systems as a decentralized system. Technology solutions providing telemedicine network must focus on communication protocol and message structure standards during medical data exchange alone and in heterogeneous networks. Application of different companies systems and various channels of communication is very important. It puts forward a task of telemedicine equipment compatibility analysis and different communication systems integration. Same-type solutions are essential for construction of city, territorial and regional medicine networks and their connection with interregional and federal medicine academic institutions. Telemedicine networks must comply with the recommendations of the Russian National Standard 50.1.022-2000 «Information technology. The Russian government open system interconnection profile» [38].

2.2. Telemedicine technology classification
An important aspect of fully achieving that goal is an information security in computer networks and hardware and software solutions. Compatible digitizing systems, analysis and sharing of medical images regardless of used medical equipment should also be provided. Now organizing videoconference, one must give preference to digital channels and corporate networks that guarantee bandpass [37].

It should also be taken into account that telemedicine networks are premised on telemedicine technologies, which include:
• medicine technologies;
• telemedicine technologies;
• telecommunication technologies [34].

Medical supplies include digital and other medical diagnostic equipment and diagnostic research methods in different medical cases. Telemedicine supplies include medical data collection, processing and storage systems; data processing and telemedicine consultation systems; recording and accounting methods for conducted telemedicine consultations. Telecommunication facilities include cable lines, radio landlines, fiber optic communication lines, radio satellite communication [35].

It should be noted that mobile (portable) telemedicine complexes must include all the mentioned components. However, hardware requirements are the most essential, since equipment must combine opportunities of videoconference terminal, local electronic archive of medical records and computer interface with peripheral and medical equipment. So workplaces must be equipped with real-time
high-speed high-resolution data communication system, remote control system for video cameras, computer hardware and application solutions for record and storage of information and access to it, that help to organize databases on patients and consulting results. All user activity on teleconsultation must be documented in paper and (or) electronic journal [37].

2.3. Remote technology method
A significant provision [13] specifies that remote user documentation of key vital functions parameters, body state information, particular physical characteristics and biomedical measurements, their transmission and assessment by a doctor (paramedic) must be accomplished with medical devices and mobile and software applications that are not medical devices actually.

Remote documentation includes photo- and video fixation of received images; photo and video images of radiological research method results printed on hard copies; audio recording; special questionnaires and interactive AI systems. While proceeding remote diagnostic, transfer and assessment of key vital functions for human activities by a doctor (paramedic), one must use electronic questionnaire which includes minimum essential list of questions in a form understandable for non-medical people. Close-end questions and clear-cut phrasing are recommended. Computer-based medical reports on assessment results of vital function for human activities must be created in compliance with clinical terms. Medical reports can be registered by type, syndrome, functional deficiencies, clinical situations. An authorized doctor (paramedic) must confirm all the electronic health records before documenting them [13].

3. Results and Discussion
Complementary to the mentioned normative acts, telemedicine system development and implementation are disclosed directly and indirectly in provisions of the Federal Laws [10]:

1. The Federal Law №326-FZ of 29 November 2010 “On Compulsory Medical Insurance in the Russian Federation” [23];
2. The Federal Law №126-FZ of 7 July 2003 “On Communications” [24];
3. The Federal Law № 149-FZ of 27 July 2006 “On Information, Information Technologies and the Protection of Information” [25];
4. The Federal Law №152-FZ of 27 July 2006 “On Personal Data” [26];
5. The Federal Law №261-FZ of 25 July 2011 “On the Implementation of Modifications to Federal Law “On Personal Data”” [27];
6. The Federal Law №210-FZ of 27 July 2010 “On the Organization of the Provision of State and Municipal Services” [28];
7. The Federal Law №63-FZ of 6 April 2011 “On Electronic Signatures” [29].

Telemedicine is able to proactively improve the health care quality and access, and allows long-distance patient and medical professional contact, assessment, diacrisis, care and further supervision of patients from the developing countries. It can provide effective access to specialized professionals consultations for regions with low level of health care service. By increasing access to medical services, telemedicine is able to help patients start medical treatment earlier and better follow prescribed procedures, thus improving the quality of life of chronic disease patients.

Telemedicine is very helpful when medical personnel of a primary health centre nearly has no opportunity to refer the patient to a specialist, but can offer the patient a remote expert consultation, otherwise inaccessible, and guarantee trust between doctors and patients. Telemedicine programs show that number of patients readressed to other facilities is reducing and so their transportation necessity. Remote health care and diagnostics via telemedicine are of benefit for patients from less economically developed countries and for health care systems. It eliminates the need for long distance transfer of specialists, expenses, time and effort input. Telemedicine programs can also motivate country doctors to stay, expand access to their professional support and give opportunity of continuing professional development [30].
Telemedicine networks in developing countries can give an added advantage. Telecommunication technologies used for telemedicine purposes have proven to be an effective instrument of connection with remote territories. Telemedicine open up new channels of communication and can provide communication between doctors from rural and remote regions and medical professionals around the world, overcoming geographical barriers and preventing “skill drain” and the mobility of human capital. It contributes to broadening networking amongst health facilities and promotes development of cooperation and collaboration between territories and countries. Such cooperation makes it easier to support medical staff in remote regions with distance education and personnel training. Telemedicine also offers an opportunity to development and professional training via information sharing and distance education of medical personnel.

Knowledge sharing, which results from territories cooperation, can be formal or informal. It is able to help medical personnel overcome professional isolation they often face in remote regions and to improve their skills and medical service quality [31].

Telemedicine can as well contribute to a closer communication between doctors and patients, as it gives health care professionals an opportunity to study on specific cases, which results can be implemented in future patients care. Using technologies, otherwise unavailable in developing countries, allows medical personnel to improve their technological skills, which can be later used in other contexts.

Moreover, shared network connection for remote facilities via telemedicine can appear to be cost-effective health care in these regions, compared to building new facilities and hiring doctors. Such systems also have high potential and relevance during force of nature, when telecommunication technologies can provide connection between trauma centre professionals and their local colleagues.

Another additional opportunity of telemedicine is an opportunity to organize patient data collection and can be useful for developing countries. Telemedicine instruments and technologies can help authorities in epidemiological surveillance effectively identify and control public health care problems and tendencies. Availability of information tracking helps to monitor disease distribution and provide operative communication for planning and mobilization of vaccination posts. Some systems can improve data management through the use of online databases and electronic records. It will allow more coordinated assistance and build capacity for more effective monitoring and assessment of patients [32].

Using mobile and wireless technologies to achieve goals of the mobile health care project can change the health care service principles on a global scale. This change results from significant combination of factors. These factors include rapid development in the field of mobile technologies and software applications, emergence of the new opportunities to introduce mobile technologies to the current electronic health care services (e-health services) and continuing increase in the number of mobile and cellular network coverage zones [33].

More developed medical data collection and processing systems (based on computer and mobile communication technologies) expand opportunities for monitoring and observing in real time and eliminate the need for health care report preparation.

Mobile communication technology progress provided support to data collection programs, such as research management in the field of health care or monitoring of diseases. Nowadays majority of the researches compare traditional “paper” methods of disease observation to mobile communication technology. The latter has advantage of enhanced accuracy, time and cost reduction and data quality improvement [31, 32].

Considering technical progress, telemedicine implementation in developing countries is a promising business as exemplified by ICT cost reduction. It can also include computing capacity increase, broadband links development and cost reduction of digital information storage. In the current economic climate [33] main telemedicine operations of recorded data transmission via email require minimum investment in hardware and software for places that already have network connection. Transmission of attached images via email allows detailed data exchange, what makes telemedicine an effective solution for territories with limited resources [33].
Telemedicine is treated as significant arrangement method in the National Health Care System and
can improve health care quality and access. Telemedicine is addressed to in national and international
laws and regulations. Telemedicine services implementation in Russia began in 2018 (after an
approved Order [4]) and is based on foreign experience. Telemedicine implementation requires
integration of medical, information and telecommunication technologies on an appropriate level of
development. For the realization of conceptual, strategic and tactical normative acts statements in
the field of telemedicine, legislation changes soon will be necessary in:
- elaboration of a legal framework of remote health care service that includes sharing of
  responsibilities between all participants of legal relations and specifies characteristics of participants,
  activity assessment criteria and standardized services;
- legislation improvement in the field of communication, computer networks in health care centers,
  financing and tax regulation;
- regulatory framework system development concerning matters of organization, invention,
  registration and licensing of telemedicine institutions (divisions) and matters of telemedicine
  complexes practical use in the context of application instructions, assessment of feasibility, specialists
  admission etc.

Regulatory changes and gathered foreign experience settled to date give a sense of the low level of
National Health Care. A total absence of or low health care problems review using telemedicine
complexes don’t allow proceed to the new (telemedicine) method of health care service in the short
term. Emphasis in this research project was shift from telemedicine in general to telemedicine
complex as a medicine device designed for diagnostics distant from health care centre.

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complexes revealed significant number of requirements. These requirements apply to portable
(mobile) telemedicine complexes and the telemedicine network itself due to the need to report a
certain type of information via special networks taking into account the protection standards
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medical data exchange alone and in heterogeneous networks. Application of different companies
systems and various channels of communication is very important. It puts forward a task of
telemedicine equipment compatibility analysis and different communication systems integration.
Same-type solutions are essential for construction of city, territorial and regional medicine networks
and their connection with interregional and federal medicine academic institutions. Telemedicine
networks must comply with the recommendations of the Russian National Standard 50.1.022-2000
«Information technology. The Russian government open system interconnection profile» [38].

An important aspect of fully achieving that goal is an information security in computer networks
and hardware and software solutions. Compatible digitizing systems, analysis and sharing of medical
images regardless of used medical equipment should also be provided. Now organizing
videoconference, one must give preference to digital channels and corporate networks that guarantee
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Also it should be considered that telemedicine networks are based on telemedicine technologies
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It should be noted that mobile (portable) telemedicine complexes must include all the mentioned components. However, hardware requirements are the most essential, since equipment must combine opportunities of videoconference terminal, local electronic archive of medical records and computer interface with peripheral and medical equipment. So workplaces must be equipped with real-time high-speed high-resolution data communication system, remote control system for video cameras, computer hardware and application solutions for record and storage of information and access to it, that help to organize databases on patients and consulting results. All user activity on teleconsultation must be documented in paper and (or) electronic journal [37].

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Design of a portable (mobile) telemedicine complex must be based on the analysis results of main information messages characteristics, its development source, registration methods subjected to recording form requirements and exchange methods between other participants. Main design steps of portable telemedicine complex for health care optimization are:

• development of message system requirements. It must begin with defining its subject field, borders and main tasks. Requirements are documented as a use case diagrams. The use case diagrams together establish a Use Case Model of system that must express all the current requirements for the system (terms of reference). The Use Case Model is the base for next steps of the project and its quality plays defining role for the whole project.

• structural analysis of message content. The main goal of structural analysis is to develop an information model which define messages data and analyze conditions and changes of the major messages class. The information model is documented with class and conditions diagrams. The information model main goal is to provide clear and self-consistent content definitions of different messages and group of messages. An information model development must be based on reference information model (RIM) by HL7. RIM is built upon main telemedicine concept analysis for the purpose of effectiveness improvement of developing specifications. Condition diagrams play a crucial role in the further development of dynamic messages model.

• messages dynamic analysis. Its goal is to develop an interaction model that expresses the main system requirements. Interactions define trigger events that start information exchange and necessary messages for every situation. Interaction model is based on application role classes, interaction charts and sequence diagrams. It must be coordinated with developed use cases and scripts. Interaction model is a prototype of message flows between applications compatible with HL7 and must express requirements for specification compliance.

• specification accomplishment. Specifications based on developed models accurately define the system compatible with HL7 messages. Message Information Model (MIM) must be a RIM subset and include description of the data contained in messages and groups. Hierarchical Message Description (HMD) is used for a tabular presentation of the messages information model. In this case, every message must have its attributes and components availability/absence status for every trigger
event. There is a special syntax for contracted representation of hierarchical message description called The Implementation Technology Specification (ITS). [36].

4. Conclusions
Authors made a conclusion, that the portable telemedicine complex is not just a set of technical devices designed for diagnostic researches, but a hardware system with a specialised software that allows entry of different data types, automated processing, storage and transfer of medical and biological information through wireless communication channels. While designing a telemedicine complex, it is necessary to address the following problems:
- identification of medical and biological information types entering the system;
- availability and access of input-output devices (ports) on a computer for wire (or wireless) connection of measuring devices;
- availability of software, for example medical information system unit designed for the conversion of data from a measurement devices to compatible formats;
- availability of a program unit for automated processing (analysis, storage and transfer) of data.
Therefore, while designing a telemedicine complex it is necessary to choose hardware and software of the main component – computer system.

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