Secure System for Remote Telemonitoring of Patients with Chronic Forms of Heart Disease

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Abstract. This paper considers modern technologies of home telemonitoring related to CPC patients. It presents a new secure intellectual telemedicine service based on remote monitoring of patients' health status, which can be used for CPS patients for their health screenings in remote and hard-to-reach locations, as well as in-house hospitals. It also discusses technologies, problems and prospects of remote telemonitoring systems' development and implementation.

1. Introduction
In the period of 1993-2006, the population of Russia has decreased by 4% (5.8 million inhabitants) [1]. About half of this number are people of working age. In terms of male and female life expectancy, Russia ranks 91st and 136th in the world respectively. At the same time, in developed countries, the population decline is associated with falling fertility rates, whereas in Russia both high mortality and low fertility rates prevail. In 2018-2019, high mortality rates of the working-age population also remained. Men of working age constitute almost one third of all deaths. Cardiovascular diseases (CVD) (55%) remain a major cause of it [2]. Thus, the CVD accounts for 38% of deaths for the most productive age group (25-64 year olds) in terms of their contribution to gross national product. The authors of studies [3,4] note that the mortality rate of the working-age population from cardiovascular diseases in Russia is 4-5 times higher compared to the European Union.
To improve the demographic situation in the Russian Federation, regulatory and legal documents allowing the use of telemedicine have been adopted. These documents have provided legitimacy for the use of telemedicine technologies for assessing individual health status. At present, with the help of telemedicine services, traditional doctor-patient communication can be supplemented with telemedicine consultations. Telemedicine technologies for early diagnosis, risk assessment, clarification of the need for additional screening and preventive counselling are being implemented into the practice of Russian health care. Telemedicine complements dispensary observation of patients with identified diseases and high cardiovascular risk. It is fundamentally important to note that telemedicine services help doctors not only assess the state of health, but also monitor the results of preventive corrective measures [5,6,7]. The article by Annenkov [6] presents a structural-functional model and a generalized algorithm for the operation of a device to monitor the patient's health.
The obligation to ensure security of data transmission lies specifically with a telemedicine service provider. This imposes a number of additional financial and organizational costs. It must be noted that information systems and telemedicine facilities directly affect the life and health of citizens. Therefore, being at a high level of attendance, they fall under a high criterion of importance. In this case, additional compliance with Federal Law No. 187-FZ "On the Security of the Critical Information Infrastructure of the Russian Federation" may be required. The rules for the use of telemedicine technologies in the Russian Federation were adopted on January 1, 2018. At the same time, amendments had been made to the Clause 2 of Article 26 "Features of the Provision of Medical Care Using Telemedicine Technologies" introduced by the Federal Law No. 323-FZ "On Basics of Health Protection of the Citizens in the Russian Federation". The new edition of the law obliges to take into account the legal requirements for processing personal data of patients. According to Clause 6 of Article 36.2, identification of the patient is carried out through the unified identification and authentication system "Public Services" [8]. This means that any citizen requesting assistance is already identified and by signing an offer agrees to medical intervention and processing of their personal data. A medical organization providing telemedicine services should have a set of documents for the protection of personal data, which contains the following information:

– the list of health professionals having access to telemedicine;
– the list of protection technologies being used and technologies used for secure data transmission over the Internet; and
– the list of technologies being used to protect authorized access to data in the patient's personal account.

According to the order of the Ministry of Health of Russia No. 965n [9], a medical organization should provide the patient with the following data about the healthcare professionals: the doctor's full name, their position, work experience, education, qualification category, previous jobs and admission schedule. Doctors should consent to the processing of their personal data being used to provide telemedicine services. The medical organization should:

– ensure the security of data transmission and protection of the patient's personal account;
– provide control of vulnerabilities on the site that receives information from users;
– Provide telemedicine services only in licensed premises.

Heads of the medical organization should understand the main tasks that need to be performed to ensure an acceptable level of telemedicine cybersecurity. First, it is necessary to constantly monitor the network perimeter protection, information system and resources. It must be noted that the creation of the telemedicine service is a common infrastructure project [10-15]. To successfully implement it, competent specialists and/or consultants in the field of information security are required. With the right approach, the provision of safe telemedicine services becomes one of many other problems, a solution of which leads to the successful work of a medical organization.

2. Problem definition
The high mortality rate from cardiovascular diseases (CVDs) in the Russian Federation is accompanied by significant losses for society. Specific aspects of preventive treatments are a priority for primary health care. At the same time, modern methods of data collection and data mining taken together can ensure the timely assessment of cardiovascular risk and the adoption of adequate measures. The presence of this contradiction determined the problem of the study. The purpose of the study is to develop methods and technologies for collecting, storing, safe transmission and analysis of the patients' data for their prompt interpretation, diagnosis of borderline conditions, formation of personalized recommendations and treatment measures aimed at reducing cardiovascular disease. Practical results will help:

– Organize a high-quality and relatively inexpensive CVD survey in remote and hard-to-reach settlements.
– Set up admission avoidance in-house hospitals for post-rehabilitation patients.

3. State of the art
To improve medical care in rural settlements in the south of the Tyumen region, a preventive screening of the adult population was organized. The survey was carried out according to a single protocol for CVD risk assessment. It was proposed to estimate the feasibility of screening procedures unification to further form preventive programs.

To solve the set objectives, the remote ECG monitoring system (REMS) has been developed [16-21]. REMS is a special case of Holter ECG monitoring. Under the National Russian Recommendations for the
Use of Holter Monitoring in Clinical Practice, the term "Holter (24-hour continuous) ECG monitoring" also includes transtelephonic ECG monitoring and self-monitoring with the use of prompt ECG recording activation at the time of symptom onset (the so-called "event recorders").

The main areas of REMS application are:

– Detection of asymptomatic arrhythmias (up to 56% in the adult population).
– Monitoring patients after surgical treatment of heart and great vessels (the leading cause of death are "late" unrecognized spontaneous arrhythmias).
– Control over the terms of pacemakers/cardioverter-defibrillators implantation (development of life-threatening Brady-arrhythmias).
– Monitoring the health status of in-house patients unable to attend the clinic.
– Control of the physically active working-age population with risk factors of sudden death, myocardial infarction and cerebral stroke (medical screenings).

There are two scenarios for the use of REMS:

1) Usage scenario No.1. Setting up of in-house hospitals. REMS provides an ability to remotely transmit the ECG monitoring results performed by in-house patients to the processing center.

2) Usage scenario No. 2. Carrying out professional screenings in remote settlements, e.g. at the premises of feldsher-midwife centers (FMCs). REMS provides an ability to remotely transmit the ECG monitoring results performed at the premises of FAP by a paramedic or nurse to the processing center.

The main participants of the System are paramedics, nurses, diagnosticians and patients. For each member of the System the corresponding software with the following major features is implemented:

– For patients - ECG data reading from the cardio recorder, ECG data visualization and ECG data transmission to the processing center;
– For diagnosticians - unprocessed ECG data upload, ECG visualization, automated ECG interpretation, preparation of medical reports and transmission of ready-made reports to the server;
– For paramedics/nurses - patient registration (if necessary), device registration and its issue to the patient, ready-made reports observation and monitoring of the ECG processing status.

The System also includes server software enabling secure data collection, storage and processing; interaction between the System participants; and ECG processing automation.

The System either can function independently or be integrated into the existing HISs.

![Figure 1. Interaction Mode: patient – nurse – diagnostican](image)

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Uploaded ECGs become available to diagnosticians. At the level of primary data processing, diagnosticians receive incoming data about patients, study them and submit their reports. The ready-made reports become available to the patient and the paramedic/nurse of that medical unit to which the patient is assigned. At the level of reports generation and analytics, specialists from MCIA, Health Department and other organizations are engaged in the collection and preparation of materials for management decision-making, as well as a compilation of statistical and analytical reports.

There is an opportunity for REMS to be connected to cost-effective event recorders, e.g. to the home ECG machine «CaRe 1.0». Information security of the System meets the following requirements:

- A set of soft-and-hardware facilities and supporting organizational measures protect the System.
- Protection is granted at all technological stages of information processing and in all operation modes. Access to the System is provided only to those users who have a registered account. Users of the System have different powers and rights of access to the resources and services of the System. The differentiation of access rights follows the principle “everything that is not prohibited is allowed”. Both the discretionary access control model and the role model are used to restrict access to System resources and services. The
discretionary model is used to determine the type of access to protected resources. The role model is used to define the authority of employees and include the following roles:

| Role          | Authority                                                                 |
|---------------|---------------------------------------------------------------------------|
| Paramedic, Nurse | Registration of patients assigned to the medical unit. Creation and observation of medical cases for patients assigned to the medical unit. Data upload of patients assigned to the medical unit into the ECG System. Monitoring of the status of request processing on the patient ECG interpretation assigned to the medical unit. Observation of ECG interpretation results of patients assigned to the medical unit. |
| Expert doctor | Observation of uninterpreted ECGs. Securing for themselves the task on ECGs interpretation. ECG interpretation and preparation of the medical report. |
| Analyst       | Obtaining regulated data samples.                                          |
| Operator      | Monitoring of the status of request processing on ECG interpretation. Distribution of requests on ECG interpretation among experts. |
| Administrator | The System's user account management. The System configuration.             |

**Figure 4. ECG analysis Role and rights**

4. Proposed methodology
To reduce the cost of personal data protection when transmitting it over open networks, the System applies depersonalization of medical information. The server performing data processing generates within the information system a set consisted of 3 GUID identifiers. Along with portable ECG machines, each FMS receives a protected USB flash drive holding a sufficient number of identifiers. When recording the screening data in FMS, two sets of information arrays are created. The first set contains publicly available information about each patient and the first identifier. The second set contains a second unique identifier and screening results. A block of public data with the first unique identifier for each examined person is separately transmitted to the server via an unprotected channel. Each block element is archived using the password-protected ARJ software. The third GUID serves as the password for each entry. In the second block, information from the portable ECG machine and data from a risk map get transmitted in the same way. This information is also transmitted as a block of password-protected archives. Sequential numbers of records in each block are generated randomly. Depersonalization and personalization take place in special programs of the client and server, respectively. Such an approach with the use of secure data transmission channels helps save more than 80% of the funds on data protection.

5. Materials and methods
ECG machine CaRe 1.0 performs 3-lead monitoring. This makes it possible to record pathological focal changes in the posterior wall of the left ventricle, changes in the anterolateral wall, as well as ischemic foci in the lower parts of the anterolateral wall of the left ventricle [22, 23]. ECG data is stored in a binary form. The sampling rate is 125 Hz or 8 ms. The data of the patient and their attending doctor is available in the first 252 bytes of the .dat file, whereas the next 12 bytes are allocated for the date and time of the screening; next, the ECG data is indicated. An outcome of the processing .dat file is an array of integer values. Well-known algorithms for analyzing digital signals can be applied to it [24] using: neural network modeling, wave transformation or time-frequency algorithms. Performance results of the algorithms of each of the classes have a selectivity of more than 95%, but since the construction of a neural network model and implementation of wave transformations requires large computing power, a decision was taken to use time-frequency algorithms QRS complex recognition. The most famous and effective algorithms for ECG analysis are smoothed three-point first derivative of the ECG signal; Murphy and Rangaraz's algorithm; applying a moving average filter, Pan-Tompkins algorithm - slope, amplitude and width of the QRS complex. The Pan-Tompkins algorithm involves the implementation of a high and low pass filter, ECG signal differentiation, as well as output signal smoothing with the use of an integrating filter. In this study, the Pan-Tompkins algorithm will be used [25, 26]. An application for interpretation of ECG obtained by ECG machine CaRe 1.0 was written in
PyCharm Community Edition 2019 using the Python 3.7 programming language, as well as NumPy, Matplotlib, math, SciPy and pandas libraries. In particular, the application allows detecting QRS complex and R-R intervals. The QRS complex displays the work of ventricles and is the largest complex on the electrocardiogram. Deviance of the QRS complex's shape and width from the norm may indicate conduction disturbances, block and ventricular tachycardia. The values of R-R intervals reflect the heart rate and rhythm regularity. Determination of R-R intervals allows establishing arrhythmia, bradycardia, tachycardia and pre-infarction state [27, 28].

Figure 5. ECG waves and intervals

The heart rate is calculated according to the following algorithm: successive R-R intervals are measured; the average R-R length in mm is calculated, heart rate is calculated using the formula:

\[
25 / \text{R-R} \times 60
\]  

6. Results
The trial operation of the ECG monitoring system involved 7 city clinics of Tyumen (70 event recorders used) and 9 regional hospitals in the south of the Tyumen region (117 event recorders used). 197 patients had been screened, and 337 records with ECG reports (5,055 fragments) had been made. The following deviations were identified:

| Deviations                                                                 | Precision |
|---------------------------------------------------------------------------|-----------|
| minor violations of intraventricular conduction and repolarization        | 61        |
| severe sinus tachycardias                                                 | 20        |
| severe sinus bradycardias                                                 | 2         |
| sinus arrhythmias                                                         | 1         |
| ventricular overexcitation syndromes, incl. WPW                           | 3         |
| single ventricular extrasystoles                                          | 7         |
| CLC syndrome                                                              | 3         |

Figure 6. Identified deviations

7. Conclusion
The REMS operating experience leads to the following conclusions:
Based on the obtained results of Home ECG monitoring, it is possible to monitor adverse events related to the patient's health, promptly respond to changes in the patient's health, remotely adjust the performance of medical prescriptions, adjust selection of individual therapy, as well as to conduct preventive screenings without the need for highly qualified specialists to visit.

There is no motivation for employees of medical organizations to perform Home ECG monitoring. The involvement of healthcare professionals needs to be addressed.

The use of such systems appears to be promising and contributes to the formation of a new level of medical decision-making, medical incidents management and the set-up of advisory support to the population.

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