



## Original Article

## Clinical Management of Cardiovascular Care on the Basis of Big Data: Electronic Medical Records

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## ABSTRACT

Electronic medical records are a source of large amounts of information about human health. This study aimed to investigate the role of big data electronic medical records of patients with cardiovascular diseases to improve the clinical management of cardiovascular care processes. The study was carried out in 2017-2020. The subjects of the study were patients with cardiovascular diseases (n=2525) and cardiovascular surgeons of the vascular surgery department (n=6), forming big data with the help of digitalization and data analysis information system Interin ProMIS. Efficiency was assessed based on the results of analytical studies of the department's economic indicators, risks of end-cardiovascular points (myocardial infarction, stroke, death, bleeding), repeated surgeries, patients' persistence to optimal drug therapy, and implementation of doctor's recommendations. The study estimated the degree of cognitive and physical load on medical personnel in connection with the use of electronic medical turnover in terms of working hours, and economic efficiency of inpatient treatment. The observation time was 24 months. Analytical, statistical methods of research were applied. Revenues of the department increased from 64180 to 113497 thousand rubles. The incidence of endpoint cardiovascular events made 0.5% during two years of follow-up. The number of cardiovascular patients supervised by surgeons decreased to 4 patients per day against the background of electronic document management, which reduced the degree of cognitive and physical load. Big data analytics of electronic medical records contributes to the development of effective strategies for clinical management of the processes aimed at improving the health of cardiovascular patients.

## GRAPHICAL ABSTRACT



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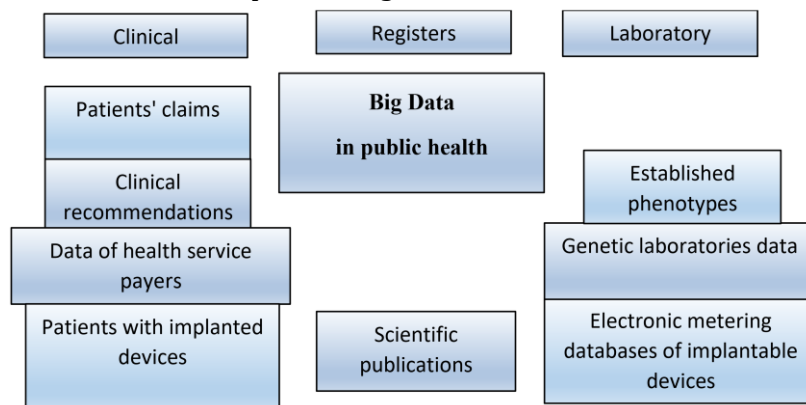
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## Introduction

Digitalization of health care, a continuously increasing amount of information in various fields of medical science against the background of improving the results of experimental and clinical studies, and increased accessibility of scientific publications contribute to improving the intellectual level of health care participants. But is the extensive information stream effectively used to improve cardiovascular care? Providers can gain unparalleled visibility into clinical and non-clinical processes by treating data as a strategic asset. They will be able to enhance decision-making by using powerful analytical methods, including artificial intelligence (AI) technologies. Patients and care teams will be brought closer together as a result of digital technology. A cultural change to a digital mindset, combined with new technologies, will allow the creation of a learning health system that is constantly improving [1–4].

For more than 50 years, cardiovascular diseases have been the leading cause of high mortality worldwide and have had a global epidemiological impact on population dynamics and the economic efficiency of managed demographic processes. Progressive population aging, urbanization, and low public commitment to implementing

recommendations for modifying cardiovascular risk factors contribute to the growth in the prevalence of circulatory diseases that surpassed infectious diseases. Despite public health achievements in improving the processes of prevention, diagnostics, and treatment, negative epidemiological trends associated with cardiovascular diseases have not significantly changed in the recent 30 years. Adverse outcomes of heart and vascular diseases remain the leading causes of disability and premature death of people all over the world [5]. About 17 million deaths a year are associated with cardiovascular causes, which is twice greater than the mortality rate from cancer. Scientists predict that by 2030 the number of deaths from heart and vascular diseases will grow to 23.3 million people [6]. Technologies based on the accumulation of significant information on human health indicators, such as big data and AI can predictably change cardiovascular negative epidemiological trends based on improving the quality of managing the processes of preserving life and health of the population. Big data in medicine represent significant amounts of experimental, clinical, economic information for analytical research in healthcare.



**Figure 1:** Sources of data in health care

Figure 1 presents the sources of big data in health care. Big data is characterized by five V's: volume, velocity, variety, veracity, and value [7]. The concept of volume of information extends the classical concept of data to a significant number of sources and types of data across all dimensions of health and life, e.g., clinical documentation,

transactions in healthcare between health care providers and counterparties.

Big data formation involves collecting disparate, unstructured information in one space with the aim of conducting analytical research to detect patterns, associations, and process trends [8–10]. Historically, most electronic medical databases were structured as tables or databases.

Structured data means highly organized information that is easy to process and analyze. Examples of structured data on cardiovascular diseases include age, drug doses, laboratory findings, electrocardiogram and echocardiography findings, and genetic data. Many unstructured data can be useful in creating a holistic view of the patient, including social and environmental factors potentially affecting health. Among them are medical instructions, reports, electronic clinical notes, reports of medical examinations, blogs, tweets, and social media posts. The technical obstacles to linking this diversity of information are a major challenge too big data analytics. The development of probabilistic algorithms on the basis of available demographic data, e.g., name, age, postcode, makes it possible to link information with an acceptable risk of error [11].

Velocity means the speed of accumulation that increases over time and the availability of information data for use. Correlated with an increased volume and speed, an increase in variety and a decrease in the overall veracity (quality) of the data develop simultaneously and consistently according to interpretability, semantic meaning, and the time of new data incorporation due to a significant diversity and variability of people, systems and processes of data acquisition. Big data should provide solutions that reduce the storage and retrieval time of data sets.

Speed requires process architecture. Operating data repositories have currently been developed that are available for retrieval and reorganization in the event of ad-hoc queries. Caches provide instant access to digital information and enable routes between applications and databases. An effective vector for increasing the speed of information in the future is using algorithms at any time based on the use of streaming data with the selection of the most valuable ones, even if their process use is stopped. The speed of information creation, storage, and analysis is an indicator of the effectiveness of big data analytic investigation and is important for its real application in research of the cardiovascular system. On the other hand, the high speed of data

generation has increased the gap between the amount of information available and the human ability to analyze and interpret it [12].

The value of the digital information space lies in the ability to conduct analytical studies of big data, the findings of which are important for assessing the processes and the quality of medical care, for improving clinical outcomes, for harmonizing the availability and accessibility of health resources with the provision of care to individuals and subpopulations, and forgetting the information on unknown clinical and economic processes in healthcare [13].

When studying cardiovascular disease developmental patterns, it is important to mention the Framingham Heart Study in the U.S.A., which began in 1948, including 5209 patients in the inception cohort and continues at present. Every year the number of people in the study increased due to additional cohorts - children, grandchildren, new spouses, and by 2014 there were more than 15 thousand subjects [14].

Since the 1980s, professional communities have been creating clinical registers that are sources of big data. The most famous ones in the U.S. are the registers of the Society of Thoracic Surgeons, the American College of Cardiology, and the American Heart Association [15-17]. The registers include structured data concerning various clinical processes, for example, percutaneous coronary interventions and coronary artery bypass surgery in patients with coronary artery disease [15].

Currently, in the U.S., there are zettabyte levels ( $10^{21}$  bytes) of big data that are used in medical analytics for forecasting risks, for example, repeated hospitalizations of patients with heart failure based on changes in the results of echocardiography [18]. The PURE study in the period from 2003 to 2018 included 140,000 people from 21 countries in five continents of the world [19]. The National Programme CALIBER (the U.K.) used electronic medical records of 1.25 million patients for studying cardiovascular diseases [20].

Modern successes of interventional radiology in improving cardiovascular care are associated

with the clinical and analytical works of pioneers of this most important field of medicine of the 20th century. The development of the system of X-ray endovascular care for cardiovascular diseases has changed the negative trends associated with circulatory system diseases [21,22]. From the very beginning of the coronary angioplasty era (1977), a German cardiologist Andreas Grüntzig, who developed a unique balloon catheter and performed the first therapeutic X-ray endovascular coronary procedure in a patient with coronary heart disease, systematically collected information from all over the world about patients who had percutaneous coronary interventions performed to better understand and improve the quality of X-ray endovascular care.

In 1994, the first version of the American College of Cardiology Catheterization and Coronary Angioplasty Register began accepting data on interventional cardiac procedures. Currently, the National Cardiovascular Disease Register (NCDR) CathPCI register remains the world's leading register, collecting data from more than 90% of percutaneous coronary procedures in the U.S. [23].

The disadvantage of the NCDR CathPCI register is that the patient data included is limited to the inpatient treatment stage and records the fact and the result of the technical stage of coronary disease treatment - performing percutaneous coronary angioplasty. Determining the long-term effectiveness of treatment is based on continuous monitoring of most patients, for which this register is not suitable. The CathPCI register is used to analyze the onset of clinical endpoints after percutaneous coronary interventions, such as death rates and myocardial infarction incidence [24].

An example of big data in cardiovascular surgery used for clinical and research purposes is electrophysiology. Remote monitoring of implantable defibrillators is currently recommended for remote determination of the reduced rate of implantable device's reaction to the development of life-threatening heart rhythm disturbance as well as fixation of episodes of asymptomatic heart rhythm disorders by the type

of atrial fibrillation. Big data on remote monitoring are collected in large-scale research registers such as ALTITUDE and MERLIN, whose analytical studies have shown significant improvement in survival in controlled patients compared with patients without remote monitoring. Similarly, data are collected on patients with heart failure undergoing remote observation after cardiac resynchronising therapy, contributing to inhibition of disease progression and improved survival rate. Remote monitoring in the coming years will be available to millions of people worldwide [25].

Analytical studies of registers' big data are used to predict the risks of end-clinical cardiovascular points development, i.e. heart attack, stroke, bleeding, death, on the basis of creating graphic models, management of routine inpatient and primary care processes, safety control of drug and medical devices turnover, support for adoption clinical decisions based on clinical recommendations and quality assessment of medical care based on approved criteria. Quality and validation of data, degree of clinical integration, and evidence of clinical usefulness are the basis for the effectiveness of using the results of analytical processes as a component of information-practical significance of the public health system [26].

In order to reduce the burden on doctors in the U.S., the HITECH provisions of the American Recovery and Reinvestment Act of 2009 were adopted based on the introduction of electronic medical records that are currently the most common source of large amounts of information about human health. Economic incentives, the need to control the expenses associated with the provision of medical services led to the introduction into the practice of electronic medical records, conversion of handwritten data into digital ones. Electronic document flow simplified interaction between medical service providers and their counterparties — pharmacies, pharmaceutical organizations, insurance companies, laboratories, suppliers of reagents, and medical consumables [27].

The disadvantage of electronic medical records is the lack of rigidity and the order of applying

approved clinical and terminological rules specific to registers and prospective studies. Analytical studies of big data contained in electronic medical records require qualified professionals to convert non-standard definitions, classifications, and terms into approved concepts. Widespread adoption of electronic health records was expected to improve patient safety and clinical outcomes while cutting down expenditures on the American healthcare system [28]. However, ten years of experience in using electronic document management in practical healthcare of the U.S. demonstrated an increase in the cognitive and physical burden on medical personnel, adding up to 2 hours of work a day. At the same time, there were no changes in the patients' hospital length of stay, rates of hospital mortality, frequency of repeated hospitalizations, and unfavorable outcomes of treatment in the improvement of average life expectancy and other health indicators of the population. The expected decline in the size and rate of economic losses related to health has not been received either [29,30].

The potential for big data analytical studies to improve the delivery of medical care for cardiovascular diseases has not been fully studied at present, neither are fully studied patterns associated with the onset and progression of heart and vascular diseases. It is a fair assumption to say that studies of the role of big data application in health care are at the stage of development, and the evidence available to date indicating that big data analytics will improve the quality of healthcare, require further scientific evidence and justification.

The purpose of the work was to investigate the role of big data contained in electronic medical records of patients with cardiovascular diseases for the effectiveness of clinical managing the processes of cardiovascular care improvement.

### **Material and methods**

The study was carried out in 2017-2020. The study bases were the department of vascular surgery (18 beds) and the clinical and diagnostic center of the Central Clinical Hospital "RZhD-Medicine," Orenburg Regional Clinical Hospital" and the Faculties of Continuing Medical

Education of the Medical Institute at the Peoples' Friendship University of Russia "Public Health, Drug, Medical Technology, and Hygiene Organization" and "Cardiology, X-ray Endovascular and Hybrid Methods of Diagnosis and Treatment." The subjects of the study were patients with cardiovascular diseases (n=2525), who were provided with inpatient and primary medico-sanitary specialized medical care. The average age of patients was 67±5,4 years. A continuous annual sample in the territorial Federal Compulsory Medical Insurance Fund was represented by 13,310 patients with angina pectoris in the town of Orenburg under the age of 70, who received inpatient medical care. Also, there were cardiovascular surgeons (n=12) and doctors of the anesthesiology and resuscitation department (n=3) who participated in this study. Electronic document management and big data formation were carried out by cardiovascular surgeons using the Internet technology and the typical information system of digitalization and data analysis Interin ProMIS (version 7), which is effectively used in medical organizations of the Russian Federation [31,32]. The medical information system Interin ProMIS 7 includes the following sections: Passport data of patients, informatization of all processes relating to the doctor and medical staff activity, cases of outpatient and inpatient care, electronic outpatient and inpatient records, the record of medical services, the record of economic indicators of medical services, the cost of consumables and medicines, record of sources of payment for medical services, record of direct and indirect costs for the treatment of the patient with detailed elaboration, accountability for consumables flows, economic indicators, i.e. costs for treatment of patients, final check, payment channels, record of medical and statistical indicators, a list of management reports of the polyclinic, hospital executives and the heads of structural units.

Efficiency of big data contained in electronic medical records for improving the processes of clinical managing the cardiovascular care was evaluated on the basis of results obtained by analytical studies which evaluated the

effectiveness of implementing preventive measures to reduce the risk of end clinical cardiovascular points, i.e. myocardial infarction, cerebral stroke, death, bleedings, repeated cardiovascular operations on the target vascular pool, the risk of repeated operations on the arterial bed due to systemic progression of atherosclerotic arterial lesions, formation of patients' adherence to optimal drug therapy and to implementation of the doctor's recommendations. The degree of cognitive and physical burden on the medical personnel was assessed as well in connection with the use of electronic medical turnover in terms of working hours, economic efficiency of inpatient treatment and optimization of the process of forming current and annual reports of the head of the structural subdivision on clinical and economic indicators of vascular surgery department functioning.

### **Result and Dissection**

The staff of doctors in the 18-bed vascular surgery department included the head of the department and 3 cardiovascular surgeons. Each specialist supervised every day from 4 to 6 patients and participated in 2-3 surgeries during the working day from 8.30 to 16.25.

Curation of 4-6 patients per day, performing or participating in 2-3 surgeries and maintaining electronic medical histories with duplication of data on paper, as well as receiving outpatients 3 times a week from 17.00 to 19.00 with data fixation in the electronic outpatient card, contributed to increased cognitive and physical burden on cardiovascular surgeons. Registration of an electronic case history when following up 6 patients contributed to the increase of working time to  $2\pm 1.84$  hours of work per day. At the same time, the burden on the middle grade medical staff did not increase, as the nurse's reporting work was arranged on a round-the-clock shift schedule and consisted mainly of electronic document management and fulfillment of doctor's administrations. The decrease in the number of patients supervised by a cardiovascular surgeon to 4 patients per day contributed to normalization of his work and rest

regime in accordance with the employment contract and the Labour Code of the Russian Federation.

The use of electronic document management, record and control of expenses related to the provision of medical care contributed to the improvement in the economic efficiency of the vascular surgery department during the period of 2018-2019 compared with 2017, which was characterized by income growth and reduction of direct expenses for the treatment of patients. Positive economic trends took place in the event if the number of annually hospitalized patients was relatively constant ( $600\pm 17.5$  patients) against the background of increased surgical activity in the treatment of patients with common arterial atherosclerosis in 2017-2019 from 54.2% to 74%, preemptive use of X-ray endovascular treatment technology (in 100% of cases), reduction in duration of patients' treatment from 14 to 7 bed days and a low frequency of repeated hospitalizations during 2 years for repeated surgeries and conservative treatment, which made 9%.

Economic indicators describing the functioning of the vascular surgery department in 2017-2019 were progressive in the ratio of income expense; growth topics were more than 2.

Continuous management of the processes aimed at improving the health of patients with cardiovascular diseases on the basis of using the big data of electronic medical records, scheduling follow-up outpatient laboratory and instrumental examinations and comparison of their results with previous indicators, personalized development and step-wise correction of therapeutic and preventive measures contributed to a high 2-year survival rate of patients, which was 100%.

Adherence to double antiaggregatory therapy after surgical revascularization was high and made 99%, that to anticoagulant therapy for atrial fibrillation made 86% and to sugar-reducing therapy in diabetes mellitus — 98%. In 24 months, the degree of adherence to optimal drug therapy did not significantly change and made 96%.

Monitoring the health of patients included in the electronic database contributed to the formation of a high commitment to preserving the health and life in most patients, which correlated with effectiveness of measures on correcting the risk factors for the progression of cardiovascular diseases and prevention of end-clinical adverse points development (stroke, heart attack, bleeding and death) during the first two years of follow-up in 0.5% of patients.

Table 1 presents the results of therapeutic and preventive measures for modifying the risk factors in the patients under study.

**Table 1:** Results of measures undertaken to modify the risk factors in the 1st and the 2nd years of follow-up and frequency of efficacy endpoints achievement.

No	Risk Factor Correction Results	1st year	2nd year
1.	Glycemia in type 2 diabetes	100%	98%
2.	Weight loss	76%	89%
3.	Stabilization of blood pressure	100%	100%
4.	Normocholesteremia	100%	100%
5.	Smoking cessation	81%	86%
6.	Hypodynamia	100%	100%
7.	Achieving efficacy endpoints (heart attack, stroke, bleeding, death)	0%	0%

In the work of the head of the vascular surgery structural subdivision, the opportunities of the Interin ProMIS 7 electronic system made it possible to prepare current and annual reports on clinical and economic performance indicators of the department and to provide senior executives with timely analytical information and proposals for improving clinical and organizational processes.

The use of electronic document management improves the clinical management on the basis of improving the quality of control processes over treatment and diagnostic processes. At the same time, the formation of big data about patients in the daily manual mode increases the burden on the medical staff and if the work is not organized in an optimal way, against the background of an increase in the clinical load on surgeons can contribute to incomplete reflection of the current state of patients when filling in digital patient-files in routine operation mode, and lead to loss of information and psychological and

professional burnout of medical personnel. A cardiovascular surgeon during the working day on a daily basis must assess the condition of the patients supervised by him, interpret and evaluate the results of the laboratory and instrumental examination methods administered and conducted the day before, develop a plan for further therapeutic and diagnostic measures, perform a surgical operation, issue current diaries with the inclusion of data on new examinations carried out and interpret the interim result of the therapeutic and diagnostic process, write interim and discharge epicrises and give recommendations to the discharged patients. We consider it optimal and safe to reduce the risk of occupational burnout of a cardiovascular surgeon and economic losses of the structural unit and the medical organization if a doctor follows up daily simultaneously not more than 4 patients with surgical diseases of the heart and blood vessels. Our findings correlate with the results of research performed by Bates (2014) [33]. Patients with cardiovascular diseases according to Bates (2014) were included in all clinical groups with high clinical and economic risk:

1. with the predicted high cost of treatment;
2. with a high probability of re-hospitalization;
3. with diseases with risks of clinical decompensation;
4. with the risks of adverse events;
5. with several concomitant diseases; and,
6. with an unspecified diagnosis and requiring further examination.

The use of big data in the cardiovascular surgery insignificantly affects the technical features of cardiac and vascular catheterization and the choice of surgical revascularization strategy. Increasing the adherence of cardiovascular surgeons to the use of X-ray endovascular technology in surgical diseases of the heart and blood vessels based on clinical recommendations is the choice of an operating surgeon on the basis of clinical recommendations and his qualification.

## Conclusion

Big data of electronic medical records help clinicians to develop programs for long-term continuous management of the processes of improving patients' follow-up and health, including after surgical care, to choose the best devices for performing intravascular procedures with the use of X-ray radiation as a result of analytical evaluations of previously performed operations and to shorten the time to prepare the reporting documentation.

Interim ProMIS electronic document management systems and electronic personified patient cards of the territorial Federal Compulsory Medical Insurance Fund based on the principles of big medical data are an effective assistant in clinical management of a medical organization in terms of operative and analytical solution of issues related to accounting the services and expenses in all categories of patients, in preparation of reports on clinical, resource and economic indicators of the structural subdivision, development of plans for the further management of clinical and preventive processes and the improvement of health care.

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## Authors' contributions

All authors contributed toward data analysis, drafting and revising the paper and agreed to be responsible for all the aspects of this work.

## Conflict of Interest

We have no conflicts of interest to disclose.

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