Original Research

Analysis ReDS technology by use Health Technology Assessment modelling, quantity and optimization methods

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Abstract

Background: The specificity of CHF is a high rate of recurrent hospitalizations for acute decompensation of heart failure (ADHF). One of the important aspects of monitoring the patient's condition is monitoring the volemic status - identifying and determining the degree of stagnation for the timely optimization of the treatment regimen in order to prevent re-hospitalization. In this regard, of great interest is a new technology for non-invasive measurement of fluid levels in the lungs, implemented in a medical product under the ReDS brand (manufactured by Sensible Medical, Israel). ReDS™ (from remote dielectric sensing) technology is a quantitative, non-invasive method for measuring total lung fluid volume in patients with fluid drainage problems, including those with heart failure. It may be implemented at inpatient, outpatient and pharmacy levels. The results of the assessment showed that at a given level of implementation of ReDS technology, the number of readmissions at the inpatient level will decrease from 375 703 to 252 208 per year, and at the outpatient level from 375 703 to 252 208 per year. This corresponds to a decrease in the annual cost of recurrent hospitalizations from 24.93 billion rubles. respectively to 20.96 (by 15.9%) billion rubles. and 19.70 billion rubles. (21.0% reduction, including additional costs for patient visits to measure for ReDS). At the same time, one-time costs for the purchase of 1 234 units of a ReDS medical device for an outpatient level or 1 129 units of a ReDS medical device for an inpatient level amount to 12.06 billion rubles or 11.04 billion rubles, respectively. The results of the "budget impact" analysis (taking into account the discount factor of 3.5%) of the introduction of ReDS technology at the outpatient level demonstrate that over 7 years it provides cost savings in the amount of 20.33 billion rubles, up to 45.92 billion rubles, and at the stationary level – 13.61 billion rubles

Keywords: health technology assessment; optimization; heart failure; medical device; remote dielectric sensing; outpatient level; inpatient level

INTRODUCTION

Cardiovascular diseases (CVD) globally are associated with significant burden[1] and in Russia CVD remain the leading cause of premature death of the population (Figure 1).[2] and therefore are a challenge to the national healthcare system.

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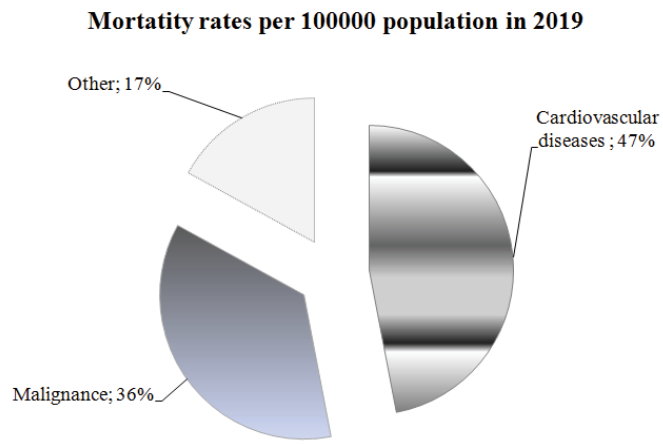

Figure 1. CVD as the leading cause of death in the Russian Federation

This is reflected in the priorities of healthcare policy: in 2019, within the framework of the national project "Healthcare", a federal project was launched to combat diseases of the heart and blood vessels , and since 2020, a program of drug provision for citizens who have suffered acute cerebrovascular accident or myocardial infarction has been launched, and also patients who underwent coronary artery bypass grafting, angioplasty of the coronary arteries with stenting and catheter ablation for heart pathology. CVD is represented by a wide range of nosological units, diseases and syndromes. One of the most common syndromes is heart failure (HF).[3,4] The latter is defined as a syndrome that "develops as a result of a violation of the ability of the heart to fill and / or empty, occurring in conditions of an imbalance of vasoconstrictor and vasodilating neurohormonal systems, accompanied by insufficient perfusion of organs and systems and manifested by complaints: shortness of breath, weakness, palpitations and increased fatigue and, with progression, fluid retention in the body (edematous syndrome)”.[5] Chronic heart failure (CHF) is represented by various forms, reflecting the etiology and pathogenesis of the syndrome. Chronic heart failure (CHF) is represented by various forms, reflecting the etiology and pathogenesis of the syndrome, and is characterized by four stages and functional classes (Table 1,2).

Table 1. Classification of CHF by stages

Stage	Description
I	The initial stage of the disease (damage) of the heart. Hemodynamics is not disturbed. Hidden CH. Asymptomatic left ventricular dysfunction
II	Clinically pronounced stage of the disease (lesion) of the heart. Violations of hemodynamics in one of the circles of blood circulation, expressed moderately. Adaptive remodeling of the heart and blood vessels
IIIa	Severe stage of the disease (damage) of the heart. Pronounced changes in hemodynamics in both circles of blood circulation. Desadaptive remodeling of the heart and blood vessels
IIIb	The final stage of heart damage. Pronounced changes in hemodynamics and severe (irreversible) structural changes in target organs (heart, lungs, blood vessels, brain, kidneys). Final stage of organ remodeling

Table 2. Classification of CHF by functional classes

Functional class	Description
I	There is no restriction of physical activity: habitual physical activity is not accompanied by rapid fatigue, the appearance of shortness of breath or palpitations. The patient tolerates the increased load, but it may be accompanied by shortness of breath and / or delayed recovery of strength
II	Slight limitation of physical activity: no symptoms at rest, habitual physical activity is accompanied by fatigue, shortness of breath and palpitations
III	Significant limitation of physical activity: no symptoms at rest, physical activity of less intensity than habitual activity is accompanied by the onset of symptoms
IV	Inability to perform any physical activity without discomfort; HF symptoms are present at rest and worsen with minimal physical activity

Based on the presented classification, the main burden of CHF for the healthcare system and society as a whole is represented by patients with advanced stages and functional classes. So, in an interview with the Chief Cardiologist of the Ministry of Health of Russia S. A. Boytsov dated July 2020, it is noted that a significant part of the costs of CHF treatment falls on hospitalizations, and the problem of a high frequency of recurrent hospitalizations in patients with CHF is also mentioned.[6]

According to Russia’s largest epidemiological study of CHF “EPOCHA”, conducted from 2002 to 2017, the prevalence of CHF increased from 6.1% in 1998 to 8.2% in 2017, while the proportion of patients with CHF III-IV functional classes increased from 1.8% in 1998 to 3.1% at the end of the follow-up in 2017.[7] The results of a study by Drapkina O. M. and co-authors, published in 2021 and devoted to assessing the socio-economic damage to CHF, showed that the financial burden of CHF in Russia is 81.86 billion rubles. per year.[8,9] These factors determine the relevance of the CHF problem in Russia.

Description of innovative technology for non-invasive fluid level measurement in the lungs

At the same time, as for any chronic disease, control of the disease becomes critical for CHF, which implies the possibility of monitoring patients with CHF in order to maintain the adequacy of the prescribed therapy and prevent recurrent hospitalizations.

The control of the volemic status occupies a key place in the management of patients with heart failure in both inpatient and outpatient settings. Non-invasive methods for evaluating fluid retention in HF include physical examination, chest x-ray, and clinical laboratory tests (measurement of brain natriuretic peptide levels). Physical examination and chest radiography are not quantitative methods, do not have a sufficient level of accuracy, and are subjective in interpretation. And measuring brain natriuretic peptide levels does not accurately assess the degree of fluid overload.

ReDS™ (from remote dielectric sensing) technology is a quantitative, non-invasive method for measuring total lung fluid volume in patients with fluid drainage problems, including those with heart failure. The technology is based on measuring the change in the parameters of radio waves when passing through tissues: low-power electromagnetic radiation passes through the tissues of the lung from the emitter to the receiver, the assessment of changes in the parameters of radio waves makes it possible to accurately measure the total volume of fluid in the tissue. The result of the examination is an absolute indicator that reflects the percentage of fluid in the total volume of the lung.[10-14]

In order to validate the ReDS technology, Offer A. et al.[15] conducted a clinical study in 2016, which involved 15 patients with acute decompensation of HF and 16 patients without it. Patients were measured using ReDS technology, and the method of computed tomography (CT) of the chest was used as a control. The measurements were carried out by independent experts who were blinded to the results obtained by an alternative method. These studies showed that the average fluid level in patients in the group with acute decompensation of heart failure, when measured by the ReDS system, was 39.8 ± 6.8% of the total lung volume, and when measured by CT, it was 40.7 ± 8.8%. In the group of patients without HF, this parameter was 28.7 ± 5.9% on CT and 27.3 ± 6.6% on ReDS. The value of the interclass correlation of the two methods in this case turned out to be 0.90 with a 95% confidence interval [0.8–0.95]. The absolute difference between the mean measurements on CT and ReDS was 3.75% with a standard deviation of 2.22%.

The ReDS technology, in comparison with traditional instrumental methods of examination, seems to be more convenient due to the fact that the duration of the measurement itself takes 45 seconds, and the duration of the entire examination procedure is about 2 minutes. In this case, the measurement by the ReDS device can be carried out on the patient both sitting and lying down, and the measuring sensors of the device themselves can be placed over clothing. The listed features of the technology predetermine its key advantages:

• the design of the device and the research technique allow for a high flow of patients in a hospital or clinic;

• the procedure can be performed by paramedical personnel, and the device does not require a special room, consumables and maintenance, which ensures a low cost of the study;

• the procedure is safe for the patient and medical staff, can be performed many times during the day, including at the patient's bedside.

The evidence base of the ReDS system is based on a number of clinical studies evaluating its efficacy and safety in patients with CHF both at the hospital level and in outpatient settings and even at home (Table 3).

The study by Offer O. et al., 2017,[16] studied the effect of using ReDS technology on the rate of rehospitalization in patients admitted to the hospital due to heart failure. The level of re-hospitalizations in patients was assessed in the previous 90 days before the use of ReDS technology and 90 days after the use of this technology. The study included 50 patients (38% women, aged 73.8 ± 10.3 years, 40% of the subjects had a left ventricular ejection fraction (LVEF) above 40%) hospitalized with acute decompensation of HF. After discharge, they were observed at home for 76.9±26.2 days. Compared with the periods before and after the use of the ReDS system, there was a decrease in the frequency of re-hospitalization for heart failure by 87% and 79%, respectively, in the treatment of heart failure under the control of ReDS technology. The risk ratio for rehospitalization during the use of the ReDS system and the period before its use was 0.07 (95% CI [0.01–0.54] p=0.01), and when comparing the time of use of ReDS technology and the period after use this was 0.11 (95% CI [0.014–0.88] p=0.037). The authors of the article concluded that the management of patients under the control of ReDS technology can reduce the readmission of patients with acute decompensation of HF after discharge from the hospital.

A study by Lala A. et al., 2020.[17] tested the hypothesis that early use of ReDS technology after the discharge of HF patients can reduce the risk of readmissions within 30 days. The work involved 220 patients hospitalized due to acute decompensation of heart failure. Control using ReDS technology was performed in 80 people (36.4%) and led to the adjustment of drug treatment in 52 subjects (65%). The use of ReDS technology was associated with a lower rate of 30-day rehospitalization for cardiovascular reasons [2.6% vs. 11.8%, risk ratio (RR): 0.21; 95% confidence interval (CI): 0.05–0.89; P=0.04] and with a trend towards lower readmissions for all causes (6.5% vs 14.1%, RR: 0.43; 95% CI: 0.16–1.15; P=0, 09) compared with patients who were not followed up with ReDS.

The ReDS technology was also evaluated in a prospective pilot study by Bensimhon D. et al., 2020.[18] to test the hypothesis about the possibility of using it to assess the readiness of a patient with heart failure to be discharged from the hospital. Of 108 patients with HF (50% men, age 73.6±12.6 years, BMI 29.3±4.3 kg/m2, LV EF 38.5±15.1%) included in the study, 32 %, residual congestion in the lungs was observed at the time of discharge, which was expected from the clinical picture. The 30-day readmission rate for heart failure was comparable in the ReDS and control groups (1.7% vs. 4.2%; p=0.44), however, patients discharged routinely without taking into account the results of ReDS technology control (with residual pulmonary congestion on ReDS≥39%) had a higher readmission rate at 30 days compared with patients who were adequately decongested (ReDS<39% at discharge) (11.8% vs 1.4 %, p=0.03).

Additionally, the authors note that when compared among patients with a ReDS score ≥39% at the time of planned discharge, no readmissions were recorded in the ReDS group within 30 days after discharge, while in the comparison group, the readmission rate was 11.8 % (p=0.13). At 90 days, readmission rates in the ReDS and control groups were 9.1% and 23.5%, respectively (p=0.33).

It should be noted that the ReDS medical product has FDA and CE certificates and is currently used in 34 countries around the world.

Thus, the ReDS technology opens up new opportunities for improving the quality of treatment for patients with CHF. At the same time, modern approaches to the organization of health care imply the need to evaluate innovative technology when it is introduced into the domestic health care system, which is primarily due to the need to justify and plan the budget of the health care system. To determine the feasibility of introducing technologies into the healthcare system, there is a special set of methods, united by the term "health technology assessment" (HTA).[19,20] It can be defined as a systematic multidisciplinary scientific analysis of the clinical and cost effectiveness, safety, ethical and social aspects of the use of new and traditional technologies, influencing the development of an effective healthcare policy.[21] In practice, the core of HTA is a clinical and economic (or pharmacoeconomic) analysis, the requirements for which for drugs have been formalized by law since 2014 . For medical devices, the HTA procedure is currently not regulated, but it is based on the same principles: the evaluation of potential technology as an investment in the health care system. In view of the above, it seemed relevant to carry out an HTA system for non-invasive measurement of fluid levels in the lungs ReDS as a tool for diagnosing and monitoring CHF in Russia at the hospital and outpatient level. This article is devoted to the presentation of the results of the HTA ReDS system performed by us.

MATERIALS AND METHODS

The described study of HTA was based on the developed model,[22-24] which, taking into account the clinical advantages of ReDS technology, made it possible to analyze the "budget impact" for it both for the whole country as a whole and at the regional level.[25,26] from the standpoint of inpatient or outpatient levels. To determine the required number of ReDS medical devices in Russia at the level of the country and individual regions, the following approach was used when developing the model. The number of required ReDS products in the model was determined by the number of medical organizations (MOs) in which it can be placed. To do this, the database of medical organizations included in the compulsory medical insurance system (CMI) as of May 2020 was loaded and adapted into the model. The base included more than 4 thousand organizations. We mention that ReDS technology may be introduced into pharmacy practice as well.

At the first stage of database adaptation, repeated entries about medical organizations, commercial medical organizations were excluded from it. The resulting list of 3 774 MOs was grouped into inpatient organizations (2961), outpatient MOs (573) and others (240). Outpatient organizations were represented by ambulances and medical / advisory clinical diagnostic centers, hospitals, in accordance with the base of the Compulsory Medical Insurance Fund (CMIF), were divided into hospitals, city hospitals, district / interdistrict hospitals, regional / republican / regional hospitals, cardiological centers for cardiovascular / micro-surgery, veterans' hospitals, district hospitals, ambulance stations, research and clinical centers. Medical units, research centers, and public health centers were classified as other MOs. In addition, the configuration of the MO base in the model contained the distribution of organizations in terms of budgets, which was represented by three groups: federal, regional and departmental. The database contained 306 MOs with departmental affiliation related to the Russian Ministry of Defense, the Federal Medical and Biological Agency, the Academy of Sciences, the Russian Ministry of Internal Affairs, the Russian Ministry of Finance, the Russian Ministry of Emergency Situations, the National Guards, the Federal Customs Service of Russia, the Federal Service for the Execution of Punishment of Russia, as well as the Presidential Administration Service. When developing the model, an abnormally low number of outpatient medical organizations in the database (523) was taken into account, which could be explained by the fact that many outpatient clinics at hospitals were not separated into separate organizations, and therefore were not reflected separately in the MHIF database. To correct this circumstance, the model used the opportunity to increase the number of outpatient medical organizations by the number of inpatient organizations (2297 medical organizations) (based on the assumption that each city, district/interdistrict, oblast/ republican/krai hospital has an ambulance). The model provided an option to set the required number of ReDS products for each of the above types of MO (Table 3).

Due to the fact that the purpose of the work being carried out was the HTA for the implementation of ReDS technology in the healthcare system of the Russian Federation, it was necessary to link the scope of supply (quantity) of products and the degree of coverage of patients. Based on the fact that the number of ReDS systems was determined by the number of MOs selected for installation, the number of population that it covers was determined for each organization. The latter was determined by the corresponding size of the settlement in which the municipality is located. If there is more than one organization of the same type (outpatient or inpatient) in a settlement, then the population was "distributed" among all medical organizations belonging to the same type. The same logic was applied to such a type of organization as a regional/republican/ territorial hospital, while the population of the corresponding subject of the Russian Federation was distributed among all medical organizations of the regional level in this subject of the Russian Federation. At the same time, the model included the ability to introduce correction factors for the number of ReDS products in a medical organization, depending on the number of people it serves (Table 4).

Table 3. The number of ReDS systems established in the model depending on the type of MO

Type of medical organization	Number of ReDS devices, pcs.
Polyclinic	1
Hospital / hospital (departmental)	1
City Hospital	2
District/interdistrict hospital	1
Regional/republican/territorial hospital	3
Medical / Consultative / Clinical Diagnostic Center	1
Cardiac Center for Cardiovascular/Microsurgery	2
Veterans Hospital	1
District hospital	1
Cardiology dispensary	3
medical unit	1
Ambulance station	1
Public Health Center	1
Science Center	1

Table 4. Correction coefficients for the number of ReDS systems in outpatient and inpatient medical organizations established in the model, depending on the number of the population served

Intervals of population per one medical organization (MO), pers.	Correction factor for the number of ReDS systems for MO at the ambulatory level	Correction factor for the number of ReDS systems for MO at the stationary level
0-10000	0.00	0.00
10001-15000	0.10	0.00
15001-25000	0.15	0.00
25001-50000	0.25	0.00
50001-100000	0.50	0.50
100001-250000	1.00	1.00
250001-500000	1.50	1.00
500001-1000000	2.00	2.00
>1000001	3.00	3.00

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The model included the parameter of covering the population of the region at the expense of regional/territorial/republican hospitals. This makes it possible to take into account in calculations that a certain part of the population from small settlements, where ReDS systems have not yet been delivered, will be able to be examined using the described technology in an organization of the regional/territorial/republican level.

The model makes it possible to assess both at the level of the entire country and at the level of individual subjects of the Federation, to form a stage of implementation of ReDS technology in the healthcare system according to the criteria of population per one municipality, population of individual settlements, level of healthcare (inpatient or outpatient) and type of organization , as well as on the basis of the sign of belonging to the federal, regional or departmental level of funding.

The model performs a "budget impact" analysis of implementing ReDS products based on an estimate of the cost of acquiring a set number of ReDS systems and budgetary savings from avoided readmissions in ReDS-covered CHF patients due to better disease control. At the same time, the assessment is carried out separately for outpatient and inpatient use of ReDS technology, due to the lack of clinical data on a comprehensive assessment of the use of technology at the hospital and polyclinic levels. The initial total number of hospitalizations of patients with CHF II-IV functional classes in Russia was taken from the publication of Drapkina O.M. and co-authors.[8] and amounted to 775 603 hospitalizations. At the same time, the proportion of recurrent hospitalizations during the year out of this number reached 60%.[27-30] After normalization, the absolute number of initial hospitalizations per year was determined to be 399 900, and recurrent – 375 703. At the final stage, the model estimated the impact of the use of ReDS technology on reducing the number of readmissions, based on the assessment at the outpatient level on the results of the work of Lala A. and co-authors, 2020.[17] and on the study by Guevarra J. et al., 2021.[31] for the use of the ReDS system in a hospital setting. The corresponding readmission rates are presented in Table 5.

Table 5. Data on the effectiveness of the ReDS technology in the model in terms of the rate of readmissions according to clinical trials

Level	Without ReDS, %	With ReDS, %
Outpatient	11.8	1.4
Inpatient	25.0	16.4

When interpreting and including in the model the values of the efficiency parameter obtained in these clinical trials, we took into account the following circumstances: firstly, the fact that these clinical trials did not have a site in Russia, and secondly, that the parameter of reccurent hospitalizations (and control CHF in general) is influenced by many factors, including factors of infrastructure and accessibility of medical care.

This predetermined the understanding that the base rate of readmissions in our country should be higher, as well as the effectiveness of the ReDS technology. For this reason, in order to avoid underestimating ReDS technology in the domestic healthcare setting, the model was allowed to determine the difference in efficiency (in terms of readmissions) between current practice and practice using ReDS technology in the form of a relative difference. Then the decrease in the number of readmissions in patients with CHF at the outpatient level using the ReDS technology can reach 88.1%, and in the hospital - 34.4%.

The cost of one averted hospitalization was determined by the respective rates of clinical statistical groups (CSG). The analysis time horizon is 7 years, which corresponds to the lifetime of the ReDS product.

RESULTS AND DISCUSSION OF REDS MEDICAL DEVICE HEALTH TECHNOLOGY ASSESSMENT

HTA modeling of the ReDS system for Russia

The results of a study of the technology of using ReDS medical equipment using HTA modeling, quantitative analysis and data optimization are presented.

This article presents the results of HTA modeling of the ReDS system for Russia as a whole at the outpatient and inpatient levels. Based on the work of Drapkina O.M. and co-authors.[8] the number of patients with CHF of functional classes II-IV was 7,096,091 people. For the assessment of ReDS at the outpatient level, 545 outpatient departments were selected and a calculation option was set up, according to which outpatient departments are taken into account at hospitals as well. This adds up to 1 234 ReDS units and provides 100% patient coverage with ReDS at the ambulatory level. In the analysis at the stationary level, the number of MOs was set at 2 721, which corresponded to 1 129 units of ReDS systems and provided access to ReDS technology to 96% of the population.

The unit cost of the ReDS product, according to the supplier, is 9 775 000 rubles. The calculation for the outpatient level contained two scenarios: an assessment without taking into account the cost of the examination service using the ReDS system and taking into account the availability of such a service. In the latter case, it was assumed that for adequate control of the condition, each patient with CHF needs to measure fluid in the lungs using ReDS at least quarterly (that is, 2 additional visits to the doctor are required in addition to the two already recommended[32] for all patients), and the cost of the measurement service was taken equal to the cost of additional visits - 295 rubles (this value was the weighted average of the tariff for a repeated / dispensary visit to a cardiologist in four constituent entities of the Russian Federation: Magadan Region, Moscow, Sevastopol and Sverdlovsk Region). The cost of one completed case of re-hospitalization due to CHF was calculated as a weighted average rate for the following DRG groups: st27.005, st27.006, st27.007, st27.008, st27.009, and amounted to 32 149 rubles. When analyzing at the hospital level, it was assumed that the cost of examining a patient using the ReDS system would be covered by the DRG tariff, and therefore this parameter was not taken into account separately in the model.

HTA results showed that at a given level of implementation of ReDS technology, the number of readmissions at the inpatient level will decrease from 375 703 to 252 208 per year, and at the outpatient level - from 375 703 to 82 782 per year. This corresponds to a decrease in the annual cost of recurrent hospitalizations from 24.93 billion rubles. respectively to 20,96 (decrease by 15,9%) billion rubles. and 19,70 billion rubles. (a decrease of 21%, when calculating at the outpatient level, the costs of additional patient visits to outpatient facilities to measure ReDS were taken into account). At the same time, one-time costs for the purchase of 1234 ReDS products for the outpatient level or 1129 systems for the inpatient level amount to 12,06 billion rubles, or 11,04 billion rubles respectively. At the final stage of the HTA, an analysis of the "budget impact" of the use of ReDS technology was carried out over a time horizon of 7 years.

The results of the analysis of the impact on the budget, both when evaluating the ReDS technology at the outpatient and inpatient levels, showed its economic advantage compared to the current standards of medical care for CHF in the medium and long term, expressed in a decrease in the total cost of managing patients with CHF by the second year of therapy and the emergence of absolute savings in the healthcare system in the third year of using the ReDS technology (Figure 2-4, the results are presented without discounting).[33]

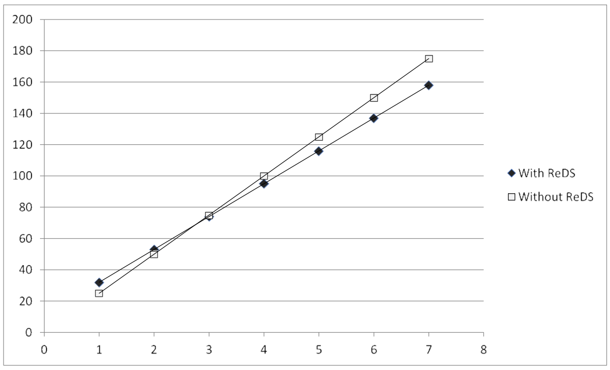

Figure 2. Results of the "budget impact" analysis (cumulative) of the use of ReDS technology at the hospital level

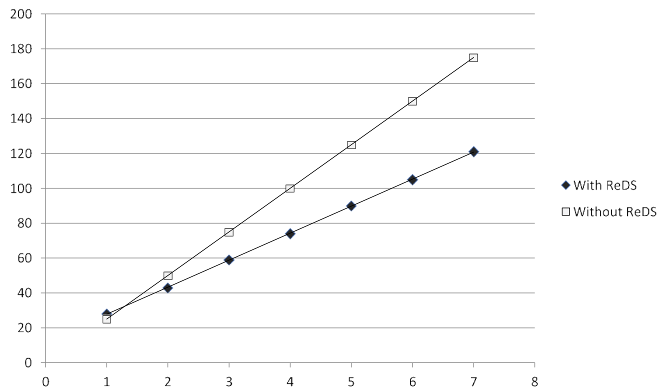

Figure 3. Budget impact analysis results (cumulative) of using ReDS technology at the outpatient level, excluding the cost of additional visits

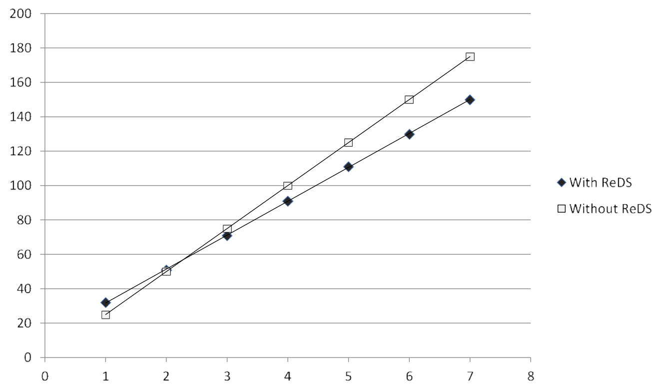

Figure 4. Budget impact analysis results (cumulative) of using ReDS technology at the outpatient level, taking into account the cost of additional visits

Taking into account the discount factor of 3.5%, the introduction of ReDS technology at the outpatient level over 7 years provides cost savings in the amount of 20 335 833 423 rubles. (including costs for additional visits) up to 45 926 532 070 rubles. (excluding costs for additional visits), and at the stationary level – 13 613 327 627 rubles.

Thus, for the first time in Russia, OTA of the ReDS technology was carried out. The developed interactive model of HTA, based on the MO MHIF, makes it possible to carry out calculations both at the level of the country as a whole and individual subjects of the Russian Federation with the determination of the completeness of coverage of the population, taking into account the actual number of medical organizations from the standpoint of the outpatient or inpatient level of medical care. The presented evaluation results for both levels of the health care system for the country as a whole demonstrate the economic feasibility of introducing ReDS technology into the practice of managing patients with CHF and reducing the clinical burden in the form of reducing the number of their readmissions, achieved through this technology.

It should be noted that the best option for HTA could be a comprehensive assessment of the ReDS technology with its simultaneous implementation both at the inpatient and outpatient levels, but, unfortunately, the available evidence.[34] base of the studied technology does not yet allow the implementation of such a HTA design. At the same time, it can be assumed that there will be a synergistic positive effect when implementing the ReDS technology immediately at the inpatient and outpatient levels due to the fact that monitoring the patient's condition at all stages of medical care is expected to give both the best clinical and administrative effect: in some medical organizations, if the ReDS system is available, for example, in a hospital, it is possible to carry out studies in an outpatient appointment, respectively, coverage of patients can be achieved with a smaller number of products. Based on the existing evidence base of ReDS technology, the HTA model took into account only the frequency of readmissions as an efficiency parameter, and the economic effect of the technology was determined by this parameter.

The absence of Russia among the countries where clinical trials of ReDS technology were conducted led to the introduction of an assumption when building the HTA model: the difference in efficiency (in terms of readmissions) between current practice and practice using ReDS technology was reflected as a relative difference.

Considering that one of the main objectives of the implemented HTA was to test the hypothesis of the economic feasibility of introducing ReDS technology into the healthcare system, the focus in terms of costs in our study was on direct medical costs. Therefore, it may be relevant to conduct further studies of the ReDS technology, taking into account both indirect costs and their possible partial prevention, due to a decrease in disability and mortality in patients with CHF (since each subsequent hospitalization and decompensation increases the risk of death and disability). The potential to reduce the burden of CHF in terms of disability and mortality follows from the study by Drapkina O.M. et al., 2021.

We would also like to note that with the complex equipping of ReDS products (especially in the outpatient department), additional positive effects can be achieved, such as a decrease in primary hospitalizations (due to the early detection of patients with progressive decompensation), but to take into account this parameter, the described practical experience of application is necessary.

In this regard, it is advisable to assess the balance of the use of ReDS medical equipment in the context of the regions of Russia and present rational proposals for optimizing the supply of the drug.

Optimization of ReDS distribution by regions of Russia

This section presents a method of rational distribution of ReDS medical equipment across the regions of Russia using quantitative data analysis and optimization tasks.

Denote the population in region P, the population by medical organizations (MO) using ReDS technology, denote M. For the region with the number i in the list, the corresponding index is entered. The proportion of the population using ReDS in region i is calculated as the M/P ratio for this region. The initial data are presented in Table 6.

Table 6. Data subject of the Russian Federation

Data subject of the Russian Federation	population	MO (medical organization)	share MO at population
Belgorod region	223921	74640,33333	33.3%
Bryansk region	16448	16448	100.0%
Moscow	12655050	253101	2.0%
Trans - Baikal Territory	350 861	87 715	25.0%
Irkutsk region	2 375 021	261 608	11.0%
Kaliningrad Region	1 018 624	131 342	12.9%
Kaliningrad Region	1 018 624	131 342	12.9%
Kaluga Region	1 000 980	223 046	22.3%
Karachay-Cherkess Republic	465 357	114 070	24.5%
Kostroma region	628 443	101 292	16.1%
Leningrad Region	1 892 711	330 239	17.4%
Lipetsk region	1 128 192	174 221	15.4%
Moscow oblast	7 708 499	1 927 125	25.0%
Murmansk region	732 864	183 216	25.0%
Novgorod region	62 502	31 251	50.0%
Penza region	1 290 898	193 612	15.0%
Primorsky Krai	1 877 844	285 477	15.2%
Republic of Altai	220 954	110 477	50.0%
Republic of Dagestan	3 133 303	116 693	3.7%
Republic of Kalmykia	269 984	67 496	25.0%
Republic of Sakha (Yakutia)	330 615	82 654	25.0%
Republic of North Ossetia-Alania	693 098	231 033	33.3%
Republic of Tatarstan	1 257 341	179 620	14.3%
Republic of Tyva	330 368	110 123	33.3%
Ryazan region	54907	54907	100.0%
Sverdlovsk region	4 290 067	541 748	12.6%

Stavropol Territory	2 792 796	277 335	9.9%
Tver region	1 245 619	273550	22.0%
Tomsk region	1 070 339	250 916	23.4%
Tyumen region	1 537 416	150 413	9.8%
Ulyanovsk region	1 218 319	148 214	12.2%
Khanty-Mansiysk JSC	30 570	30 570	100.0%
Chuvash Republic	127586	127586	100.0%
Yamalo-Nenets Autonomous District	547010	160259,5	29.3%
Summary (34 regions)	53 664 881	7 501 089	–

Table 6 shows that the share of the population using ReDS is 7,501 089/53 664 881 = 14%, this indicator is very high. To obtain a visual picture, it is advisable to transform the initial data by entering rank values (the maximum value of the indicator corresponds to rank 1). The transformed data is presented in Table 7.

The correlation coefficient of the regional share of the population and the regional share of the MO applying is 0.56. For a sample size of 35 regions, the coefficient is significant at the level of reliability of 5%. Despite this, there is a high imbalance in many regions. Visual picture of the data from the table 6 is shown in Figure 5.

Figure 5 shows that it is advisable to carry out monitoring not by volume, but in relation to the volume of involvement in ReDS technology per capita by medical organizations. At the level of absolute values, Moscow and the Moscow Region are certainly in the first place.

If we switch to relative indicators, the medical organizations of the Bryansk and Ryazan regions, the Chuvash Republic and the Khanty-Mansi Autonomous Okrug are most strongly involved in the ReDS technology. They can become experimental bases for the development of the next (Russian) generation of laser diagnostics and measurement of fluid in the lungs.

Given the significant shortage of ReDS technology in cities such as Moscow, Tyumen, Dagestan, Ulyanovsk Region, Irkutsk Region, Stavropol Territory) (where the share of involvement in ReDs is the lowest, although the population is very high), it is advisable to optimize the share of MO using ReDS.

The purpose of optimization is to show to which regions it is possible to increase the supply of medical equipment.

Notation:

Q(P) is the share of the population in this region (in formulas for region i, Q(Pi)), the sum of the shares is 1 (100%),

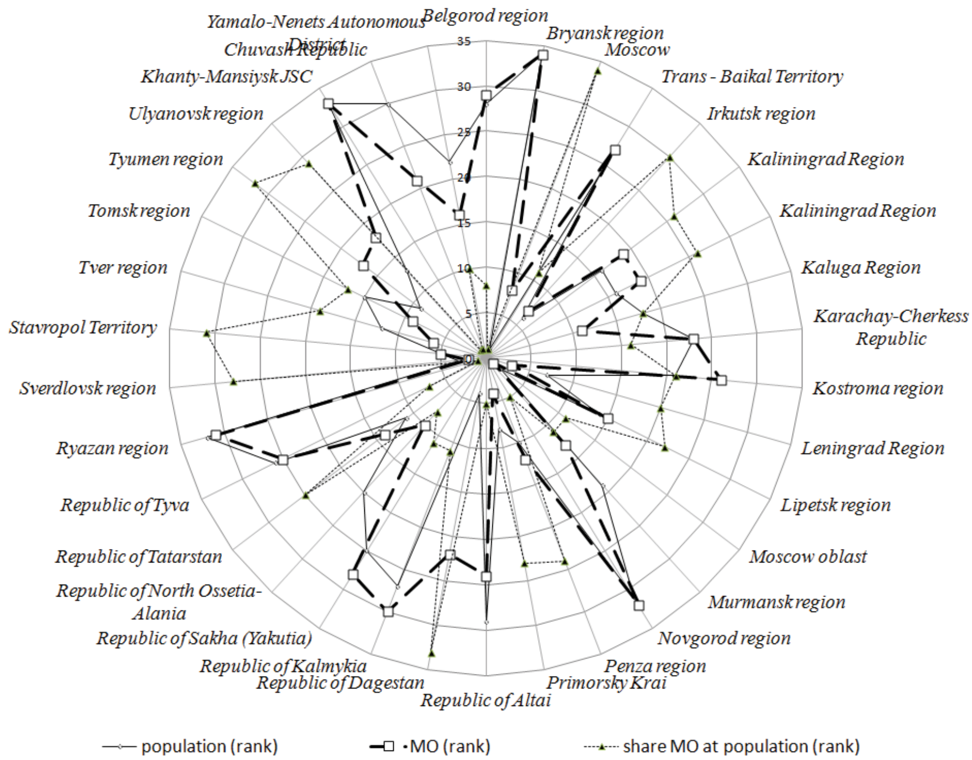

Figure 5. Comprehensive analysis of the regional implementation of ReDS technology

Table 7. Data (rank)subject of the Russian Federation

Data (rank)subject of the Russian Federation	**population (rank)**	**MO (rank)**	**share MO at population (rank)**
Belgorod region	28	29	8
Bryansk region	34	34	1
Moscow	1	8	34
Trans - Baikal Territory	24	27	11
Irkutsk region	6	7	30
Kaliningrad Region	16	19	26
Kaliningrad Region	16	19	26
Kaluga Region	18	11	18
Karachay-Cherkess Republic	23	23	16
Kostroma region	21	26	21
Leningrad Region	7	3	20
Lipetsk region	14	15	22
Moscow oblast	2	1	11
Murmansk region	19	13	11
Novgorod region	31	32	5
Penza region	10	12	24
Primorsky Krai	8	4	23
Republic of Altai	29	24	5
Republic of Dagestan	4	22	33
Republic of Kalmykia	27	30	11
Republic of Sakha (Yakutia)	25	28	11
Republic of North Ossetia-Alania	20	10	8
Republic of Tatarstan	11	14	25
Republic of Tyva	26	25	7
Ryazan region	32	31	1
Sverdlovsk region	3	2	28
Stavropol Territory	5	5	31
Tver region	12	6	19
Tomsk region	15	9	17
Tyumen region	9	17	32
Ulyanovsk region	13	18	29
Khanty-Mansiysk JSC	33	33	1
Chuvash Republic	30	21	1
Yamalo-Nenets Autonomous District	22	16	10

Q (M) is the share of the population in this region in the MO using ReDS (in formulas for region i, Q(Mi)), the sum of the shares is 1 (100%).

Optimization is carried out taking into account the number of people in the region, which will be a weighting factor. The calculation of the optimal proportions of MO using ReDS is performed.

Denote by Q*(Mi) the optimal proportion of MO using ReDS for region i, the calculation is performed by the formulas:

$Q^*(M_i) = Q(P_i) * Q(M_i)/(\Sigma\, Q(M_i))$, (1)

where Σ denotes the summation of the indicators Q(Mi) for all regions, i varies from 1 to the region with the number N, N = sample size (in our case N=34).

The results are presented in Table 8.

Table 8. Calculation of Q

subject of the Russian Federation	Q(P)	Q(M)	Q(p)*Q(M)
Belgorod region	0.42%	1.00%	0.0%
Bryansk region	0.03%	0.22%	0.0%
Moscow	23.61%	3.40%	0.8%
Trans - Baikal Territory	0.65%	1.18%	0.0%
Irkutsk region	4.43%	3.52%	0.2%
Kaliningrad Region	1.90%	1.77%	0.0%
Kaliningrad Region	1.90%	1.77%	0.0%
Kaluga Region	1.87%	3.00%	0.1%
Karachay-Cherkess Republic	0.87%	1.53%	0.0%
Kostroma region	1.17%	1.36%	0.0%
Leningrad Region	3.53%	4.44%	0.2%
Lipetsk region	2.10%	2.34%	0.0%
Moscow oblast	14.38%	25.93%	3.7%
Murmansk region	1.37%	2.46%	0.0%
Novgorod region	0.12%	0.42%	0.0%
Penza region	2.41%	2.60%	0.1%
Primorsky Krai	3.50%	3.84%	0.1%
Republic of Altai	0.41%	1.49%	0.0%
Republic of Dagestan	5.85%	1.57%	0.1%
Republic of Kalmykia	0.50%	0.91%	0.0%
Republic of Sakha (Yakutia)	0.62%	1.11%	0.0%
Republic of North Ossetia-Alania	1.29%	3.11%	0.0%
Republic of Tatarstan	2.35%	2.42%	0.1%
Republic of Tyva	0.62%	1.48%	0.0%
Ryazan region	0.10%	0.74%	0.0%
Sverdlovsk region	8.00%	7.29%	0.6%
Stavropol Territory	5.21%	3.73%	0.2%
Tver region	2.32%	3.68%	0.1%
Tomsk region	2.00%	3.38%	0.1%
Tyumen region	2.87%	2.02%	0.1%
Ulyanovsk region	2.27%	1.99%	0.0%
Khanty-Mansiysk JSC	0.06%	0.41%	0.0%
Chuvash Republic	0.24%	1.72%	0.0%
Yamalo-Nenets Autonomous District	1.02%	2.16%	0.0%
Sum	100.00%	100.00%	6.6%

The results of optimization according to formulas (1) are presented in Table 9

After optimization, the correlation coefficient of the regional share of the population and the regional share of the MO using increased to 0.64 (before optimization it was 0.56).

Table 5 shows the rank values for the indicators from Table 10.

The table of rank values (Table 5) is visually presented in Figure 6.

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Table 9. Calculation of Q*(M)		
subject of the Russian Federation	**Q(P)**	**Q*(M)**
Belgorod region	0.42%	0.06%
Bryansk region	0.03%	0.00%
Moscow	23.61%	12.24%
Trans - Baikal Territory	0.65%	0.12%
Irkutsk region	4.43%	2.37%
Kaliningrad Region	1.90%	0.51%
Kaliningrad Region	1.90%	0.51%
Kaluga Region	1.87%	0.85%
Karachay-Cherkess Republic	0.87%	0.20%
Kostroma region	1.17%	0.24%
Leningrad Region	3.53%	2.39%
Lipetsk region	2.10%	0.75%
Moscow oblast	14.38%	56.78%
Murmansk region	1.37%	0.51%
Novgorod region	0.12%	0.01%
Penza region	2.41%	0.96%
Primorsky Krai	3.50%	2.05%
Republic of Altai	0.41%	0.09%
Republic of Dagestan	5.85%	1.40%
Republic of Kalmykia	0.50%	0.07%
Republic of Sakha (Yakutia)	0.62%	0.10%
Republic of North Ossetia-Alania	1.29%	0.61%
Republic of Tatarstan	2.35%	0.86%
Republic of Tyva	0.62%	0.14%
Ryazan region	0.10%	0.01%
Sverdlovsk region	8.00%	8.88%
Stavropol Territory	5.21%	2.96%
Tver region	2.32%	1.30%
Tomsk region	2.00%	1.03%
Tyumen region	2.87%	0.88%
Ulyanovsk region	2.27%	0.69%
Khanty-Mansiysk JSC	0.06%	0.00%
Chuvash Republic	0.24%	0.06%
Yamalo-Nenets Autonomous District	1.02%	0.34%
Sum	100.00%	100.00%

Table10. Calculation of Q*(M) (rank)

subject of the Russian Federation	**Q(P)**	**Q*(M) (rank)**
Belgorod region	28	29
Bryansk region	34	34
Moscow	1	2
Trans - Baikal Territory	24	25
Irkutsk region	6	6
Kaliningrad Region	16	19
Kaliningrad Region	16	19
Kaluga Region	18	14
Karachay-Cherkess Republic	23	23
Kostroma region	21	22
Leningrad Region	7	5
Lipetsk region	14	15
Moscow oblast	2	1
Murmansk region	19	18
Novgorod region	31	32
Penza region	10	11
Primorsky Krai	8	7
Republic of Altai	29	27
Republic of Dagestan	4	8
Republic of Kalmykia	27	28
Republic of Sakha (Yakutia)	25	26
Republic of North Ossetia-Alania	20	17
Republic of Tatarstan	11	13
Republic of Tyva	26	24
Ryazan region	32	31
Sverdlovsk region	3	3
Stavropol Territory	5	4
Tver region	12	9
Tomsk region	15	10
Tyumen region	9	12
Ulyanovsk region	13	16
Khanty-Mansiysk JSC	33	33
Chuvash Republic	30	30
Yamalo-Nenets Autonomous District	22	21

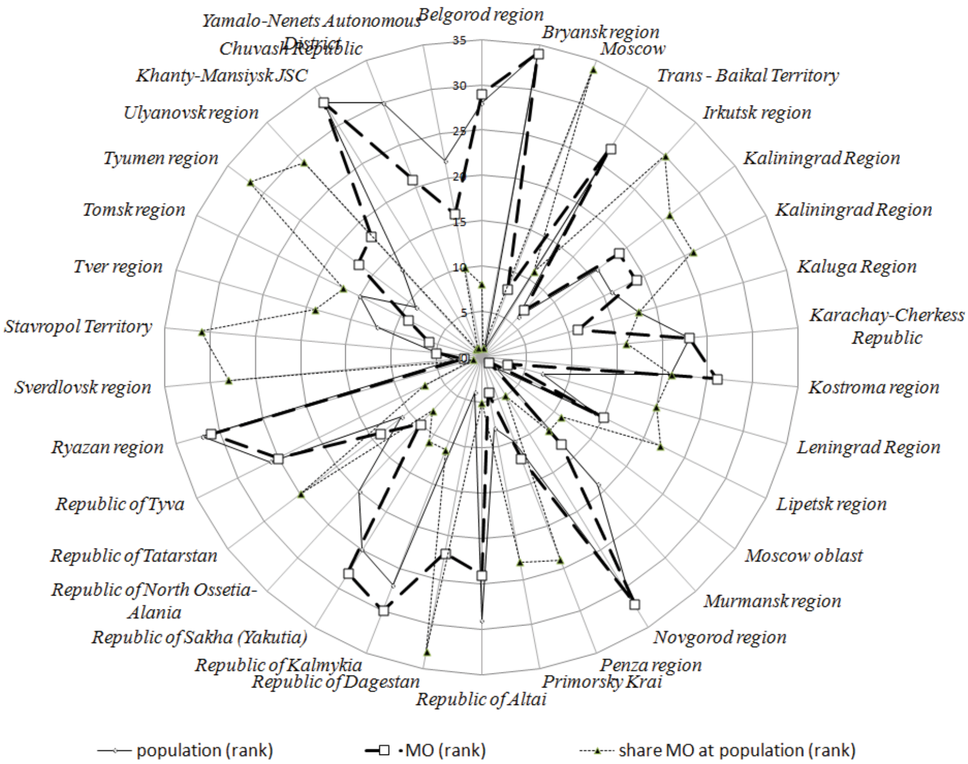

Figure 5. Comprehensive analysis of the regional implementation of ReDS technology

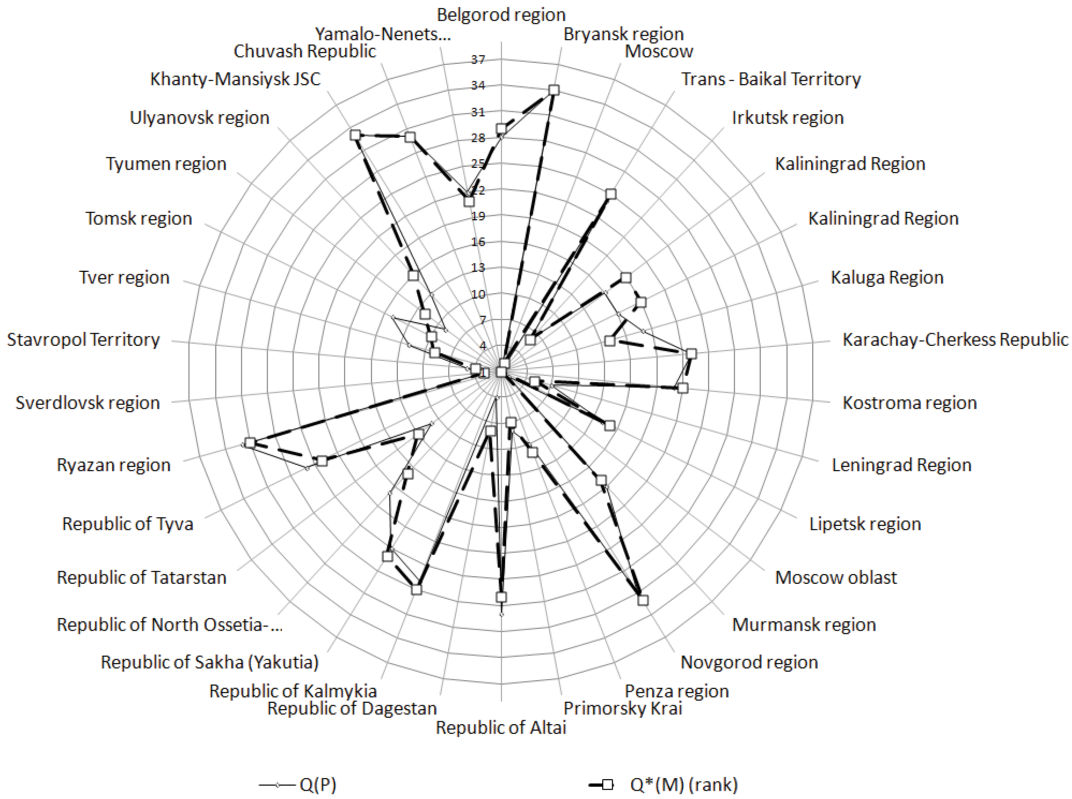

Figure 6. Optimization of regional implementation of ReDS technology

CONCLUSIONS

Conducted HTA for the implementation of ReDS technology in the Russian healthcare system from the perspective of the country as a whole, both at the outpatient and inpatient level of medical care for patients with CHF, with a total need for ReDS products in the range of 1129-1234 units, covering more than 95% of the population with this technology, showed its clinical and economic feasibility, which is expressed in a decrease in the number of readmissions and net savings in healthcare system costs already in the third year of using ReDS technology.

Use of AI tools declaration

The authors declare they have not used Artificial Intelligence (AI) tools in the creation of this article.

CONFLICTS OF INTEREST

All authors declare that there are no competing interests.

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