Assessment of prevalence and monitoring of outcomes in patients with heart failure in Russia

Shlyakhto E. V., Zvartau N. E., Villevalde S. V., Yakovlev A. N., Solovyeva A. E., Fedorenko A. A.,
Karlina V. A., Avdonina N. G., Endubaeva G. V., Zaitsev V. V., Neplyueva G. A., Pavlyuk E. I.,
Dubinina M. V., Medvedeva E. A., Erastov A. M., Panarina S. A., Soloviev A. E.

The increasing prevalence of heart failure (HF) serves as a reverse side of the effective treatment for cardiovascular diseases (CVD) and increasing patient survival. Data on the epidemiology of HF and related mortality in Russia are limited. According to the EPOCHA trial (hospital phase), the prevalence of HF in the Russian Federation is 7%. HF can significantly contribute to cardiovascular mortality. However, its recognition is limited by the peculiarities of the mortality coding system in Russia. The article presents the authors' view on the registration of HF-related morbidity and mortality cases and perspectives of using left ventricular ejection fraction <50% for statistical reporting.

Keywords: heart failure, prevalence, morbidity, mortality, left ventricular ejection fraction.

Relationships and Activities: none.

Almazov National Medical Research Center, St. Petersburg, Russia.

Shlyakhto E. V. ORCID: 0000-0003-2929-0980, Zvartau N. E.* ORCID: 0000-0001-6533-5950, Villevalde S. V. ORCID: 0000-0001-7652-2962, Yakovlev A. N. ORCID: 0000-0001-5656-3978, Solovyeva A. E. ORCID: 0000-0002-0013-0660, Fedorenko A. A. ORCID: 0000-0002-9836-7841, Karlina V. A. ORCID: 0000-0001-9912-7789, Avdonina N. G. ORCID: 0000-0001-9871-3452, Endubaeva G. V. ORCID: 0000-0001-8514-6436, Zaitsev V. V. ORCID: 0000-0003-1905-2575, Neplyueva G. A. ORCID: 0000-0001-8811-2450, Pavlyuk E. I. ORCID: 0000-0002-0108-5996, Dubinina M. V. ORCID: 0000-0001-7980-4279, Medvedeva E. A. ORCID: 0000-0002-5130-5192, Erastov A. M. ORCID: 0000-0003-3218-3502, Panarina S. A. ORCID: 0000-0003-3450-9916, Soloviev A. E. ORCID: 0000-0003-2378-9940.

*Corresponding author: zvartau_ne@almazovcentre.ru

Heart failure is one of the key contributors to hospitalizations and mortality.

The implementation of a wide range of effective therapies for cardiovascular diseases (CVD) has improved survival and increased life expectancy in patients. The downside of the achieved success is the increased prevalence of heart failure (HF). Among patients with myocardial infarction, especially the elderly ones, there is a decrease in in-hospital mortality, accompanied by an increase in the number of cases of HF [1]. Today HF covers ~60 million people in the world [2] and its prevalence varies significantly — from 0,3% in India to 5,8% in Australia [3]. These proportions can be significantly higher taking into account undiagnosed and unreported cases.

A set of measures in modernization of the healthcare system, in particular, the successful implementation of the Vascular program on emergency care for patients with acute coronary syndrome [4] has led to reduced cardiovascular mortality rate by 36,6% in the Russian Federation (RF) between 2005-2018. Extrapolation of the data of the Russian epidemiological studies EPOCHA-CHF (1998), EPOCHA-Hospital-CHF (2005) and EPOCH-Decompensation-CHF (2015) to the entire population of the Russian Federation demonstrates that from 1998 to 2014 the number of patients with HF of any class increased from 7,19 to 14,9 million cases, and the prevalence of HF — from 4,9 to 10,2% [5]. The greatest growth (from 1,2 to 4,1%) was noted for class III-IV HF. The average prevalence of HF in the Russian Federation is 7% [6], which is significantly higher than in other countries [3]. The duration of the studies, the relatively small sample size, the criteria used to confirm the HF (6-minute walk test and at least one sign on following tests: electrocardiography, chest x-ray, echocardiography [6] emphasize that the data obtained in epidemiological studies on the prevalence of HF in the Russian Federation may not reflect the actual situation.

The presence of HF determines a high risk of adverse outcomes. Despite the treatment using modern drugs and implantable devices, heart failure in terms of progression rate and "malignancy" of the course in many aspects is comparable to the most aggressive types of cancer [7]. Foreign studies indicate a fivefold increase in the death risk in patients with HF [8]. The 1-year survival rate according to a meta-analysis, including 1,5 million patients with any class of HF, averages 87% [9]. About half of patients with heart failure are hospitalized at least once a year, which aggravates the prognosis [10]. The results of early observational studies in the Russian population indicate that the annual mortality rate for any class HF is 6%, and for severe HF — 12% [10]. Decompensated HF is the hospitalization cause for 16,8% of patients with CVD [10], representing a special vulnerable period with the highest risk of adverse events during hospitalization and the next month after discharge. In the large register ORACUL-RF (41 research centers, 20 cities of the Russian Federation), among 2498 hospitalized patients with HF, in-hospital mortality was 9%, 1-month and 1-year mortality after discharge — 13 and 43%, respectively, and rehospitalization rate — 31 and 63,4% [11].

The federal project on the prevention of cardiovascular diseases provides the achievement of the target level of cardiovascular mortality of <450 cases per 100 thousand people by 2024 [12]. This means that in relation to the current level (at the end of 2019, 573,2 cases per 100 thousand people), cardiovascular mortality must be reduced by 21,5% over the next 5 years [4]. The high contribution of HF to the mortality emphasizes the importance of a strategy for the prevention and treatment for HF, which cannot be implemented without regular monitoring of morbidity, mortality and quality control of healthcare specifically in this population.

Prerequisites for the modification of record keeping system for HF patients

Analysis of the cardiovascular mortality patterns in the Russian Federation at the end of 2019 shows that the proportion of acute types is small and amounts to 6,4% for myocardial infarction and 15% for stroke [4]. The dominant cause of death is chronic types of coronary artery disease (46,2%) [4]. It can be assumed that the main contribution to mortality in this subgroup is made by HF, however, data on morbidity and mortality from HF are not published. Some features of CVD coding limit the reporting of HF cases. Since acute and chronic heart failure are severe manifestations of a wide range of cardiovascular or non-cardiac diseases, diseases leading to the HF or associated with it (arrhythmias, sudden cardiac death, pulmonary embolism) are more often taken into account in the structure of morbidity and mortality from CVDs, but not the HF itself. Despite the presence of a I50 code in the International Classification of Diseases of the 10th revision (ICD-10), in most cases, HF is coded as a complication of the underlying disease. Thus, using HF as an indicator of CVD severity and the need for monitoring remains unrealized. The analysis of seeking medical attention in 2018, 2019 and January-November 2020 in St. Petersburg demonstrates that the number of patients with ICD codes of HF or those with its probable presence (I11.0 — hypertensive heart disease with heart failure, I25.5 — ischemic cardiomyopathy, I42.0 —
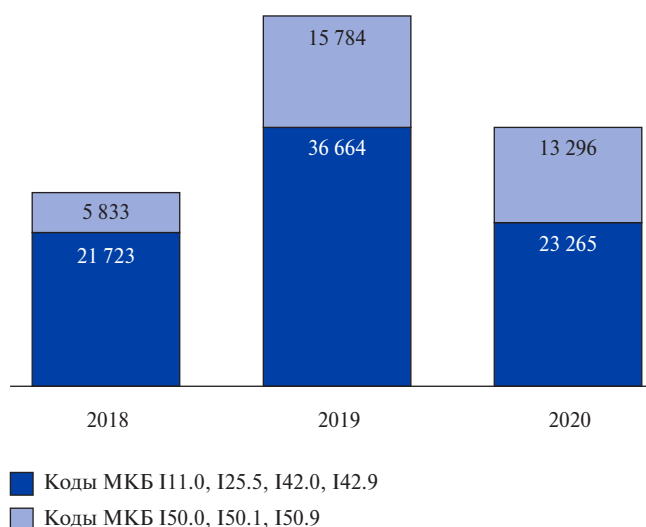
Figure 1. Cases of diseases with ICD codes, potentially including HF (based on data from Chronic Heart Failure registry, which began in 2018 and included individual medical organizations in the pilot phase).
Abbreviation: ICD — International Classification of Diseases.

dilated cardiomyopathy, I42.9 — unspecified cardiomyopathy) significantly exceeds the number of patients with ICD codes that directly encode HF — I50.0, I50.1, I50.9 (Figure 1). Along with this, the mandatory requirement to enter the HF diagnosis code (I50) for all patients with CVD may be associated with a number of organizational problems.

Another factor that complicates the assessment of the real prevalence of HF and associated outcomes is its heterogeneity. In particular, the current criteria for the diagnosis of HF have a number of limitations. The clinical symptoms of HF are nonspecific, the left ventricular ejection fraction (EF) is variable, and the level of natriuretic peptides (NPs) depends on a wide range of concomitant factors that can both underestimate and overestimate the NP values. Taken together, this determines the complexity of identifying and confirming the HF in a particular patient, and, therefore, assessing the prevalence at the population level.

Echocardiography and assessment of left ventricular ejection fraction as a tool in identifying patients with heart failure

Echocardiography is one of the necessary diagnostic methods for patients with CVDs, listed among the criteria for qualitative healthcare, according to the 2020 guidelines on chronic heart failure [9]. The classification criterion for diagnosis and prognostic factor for echocardiography in patients with HF is EF. There are 3 phenotypes of HF, depending on the value of EF — HF with reduced EF (HFrEF <40%), HF with mid-range EF (HFmrEF 40-49%), HF with preserved EF (HFpEF ⩾50%). In the case of symptoms and (or) signs of HF and EF <40%, the diagnosis of HF is beyond doubt. To confirm HFmrEF and HFpEF, additional criteria are required — structural and functional myocardial changes according to echocardiography and an increase in natriuretic peptide. It should be noted that recent studies of the features and effects of drug therapy in HFmrEF indicate the similarity of this phenotype with HFrEF, which may be reason to rename mid-range to mildly reduced EF [13-15], but most importantly, it emphasizes the expected improvement in outcomes in this group, similar to the HFrEF group.

The HFpEF phenotype remains the most controversial in relation to the diagnostic algorithm and management tactics. In patients with unclear dyspnea, the current criteria for HFpEF showed low sensitivity when compared with the gold standard for HF diagnostics — assessment of stress intracardiac hemodynamics [16], and the proposed new scores [17, 18] are not always consistent with each other [19]. Despite the expectedly smaller error in the diagnosis of acute heart failure with preserved EF, analysis of data from a Heart Failure Association EURObservational Research Program Heart Failure Long-Term Registry indicates that HFpEF is confirmed after discharge only in half of the cases [20]. Another unresolved clinical issue is the search for effective proven methods of treatment in this group of HF. To date, none of the drugs studied in numerous randomized clinical trials (RCTs) have shown a beneficial effect on the prognosis in HFpEF [18], and the management of patients with HFpEF is mainly aimed at controlling comorbidities and conditions.

Analysis of the prognostic significance of EF categories according to echocardiography in RCTs and national databases of Australia (NEDA) [21], the USA and England [22] indicates a J-shaped curve of the relationship between all-cause and cardiovascular mortality from EF. In general, outcomes in patients with an EF <50% (especially with an EF <30%) are worse compared to patients with an EF >50%. Although the normal values of EF continue to be discussed, taking into account the threshold EF levels in the current guidelines [10], the most reasonable initial strategy for recording patients with HF and assessing the effectiveness of treatment seems to be the selection and registration of a group of patients with HF with EF <50% (Figure 2). Timely identification of this subgroup and the appointment of drug therapy with proven effectiveness can significantly increase the life expectancy of patients and reduce the risk of hospitalization.
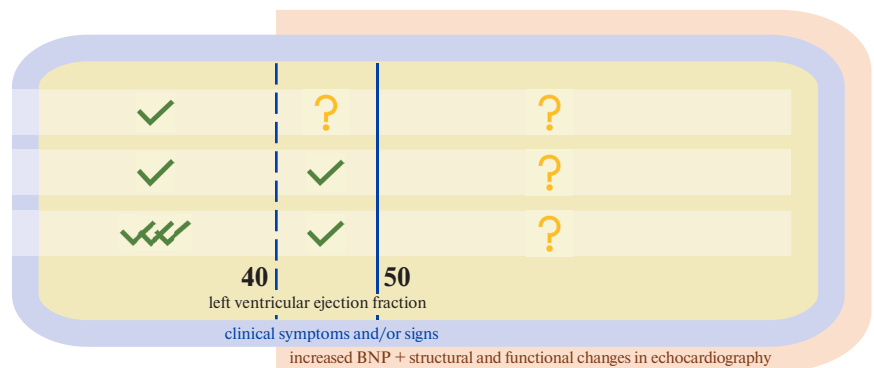
Figure 2. Advantages of the initial strategy for organizing recording system for patients with HF with ejection fraction <50%.
Abbreviation: BNP — brain natriuretic peptide.

Proposed changes in federal statistical survey as the main source of data on morbidity and mortality in the Russian Federation

To take into account the prevalence of HF as a complication of the underlying disease, changes are proposed to the following forms of federal statistical survey and forms of reporting medical documentation (Figure 3):

— Form № 12 (approved by Rosstat order dated November 22, 2019 № 679),

— Form № 14 (approved by Rosstat order dated November 19, 2018 № 679),

— Form № 30 (approved by Rosstat order dated December 30, 2019 № 830),

— Form № 066/u — statistical card of released patient (approved by order of the Ministry of Health of the Russian Federation dated December 30, 2002 № 413),

— Form № 25 — slip of an outpatient receiving medical care (approved by order of the Ministry of Health of the Russian Federation dated December 15, 2014 № 834).

Form № 12 contains information on the number of diseases registered in patients living in the service area of a medical organization, and is one of the main sources of information on the morbidity in the Russian Federation. Data on the prevalence of certain types of CVD are entered in tables (1000, 2000, 3000, 4000). Form № 14 contains information on the activities of departments of a medical organization that provide inpatient health care. Data on the prevalence of certain types of CVD requiring inpatient treatment are entered in the table (2000).

In Forms № 12 and № 14 (tables 1000, 2000, 3000, 4000) it is proposed to add additional columns containing information about EF — "less than 50%", "50% or more" or "not analyzed". These columns are filled in only in patients with the main diagnosis of CvD (ICD-10 I00-I99) and reflect information on the presence of a complication of the main diagnosis in this group of patients. The method for

measuring EF is not regulated and it is assumed that it is possible to enter the results of echocardiography or other research methods. Form № 12 contains data on the last value of EF within a year from the date of registration of the disease, while in Form № 14 — on the last value of EF within a year from the moment of discharge from the hospital.

Form № 30 contains information about the medical organization and reflects the number of ultrasound examinations performed annually, including in table 5115 — echocardiography. It is proposed to add additional lines containing information on the number of patients with detected EF <50%, which will allow to indirectly estimate the prevalence of HF in the population. However, a more detailed study is possible only if changes are made to Forms № 12 and № 14.

To implement the presented statistical changes and conduct a thorough control over the reliability of the data entered, it is proposed to amend the following forms of reporting medical documentation:

— Form № 066/u — statistical card of released patient (approved by order of the Ministry of Health of the Russian Federation dated December 30, 2002 № 413),

— Form № 25 — slip of an outpatient receiving medical care (approved by order of the Ministry of Health of the Russian Federation dated December 15, 2014 № 834).

— Form № 066/u contains information about the ICD-10 main diagnosis code for each patient who was in the hospital. Information on the presence of HF and EF can be presented as a separate item requiring completion, or as an additional column in Table 26. It is advisable to provide a choice of 4 options ("50% and more" — 1, "less than 50%" — 2, "not implemented" — 3, "not applicable" — 4). The option "not applicable" is used if the main diagnosis is not related to CVD, while in all other cases one of the first three options should be selected.

(2000)

Подготовлено с использованием системы **КонсультантПлюс**

Наименование болезни	№ строки	Код по МКБ-10 пересмотра	А. Взрослые (18 лет и более)										Фракция выброса левого желудочка при болезнях системы кровообращения I0-I99		
			Выписано пациентов			Проведено выписанными койко-дней	Умерло						Более 50%	Менее 50%	Не анализировалась
			Всего	из них: доставленных по экстренным показаниям	из них пациентов, доставленных скорой мед. помощью (из гр. 5)		Всего	из них:							
								прове-дено патолого-анатоми-ческих вскрытий	из них установ-лено расхож-дений диагнозов	прове-дено судебно-медицин-ских вскрытий	из них установ-лено расхож-дений диагнозов			
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
хронический отит	9.1.2	H65.2-4, H66.1-3										X	X	X
болезни слуховой (евстахиевой) трубы	9.1.3	H68 – H69										X	X	X
перфорация барабанной перепонки	9.1.4	H72										X	X	X
другие болезни среднего уха и сосцевидного отростка	9.1.5	H74										X	X	X
болезни внутреннего уха	9.2	H80, H81, H83										X	X	X
из них: отосклероз	9.2.1	H80	X				X			X	X	X	X	X
болезнь Меньера	9.2.2	H81.0	X				X			X	X	X	X	X
кондуктивная и нейросенсорная потеря слуха	9.3	H90	X				X	X	X	X	X	X	X	X
из них: кондуктивная потеря слуха двусторонняя	9.3.1	H90.0	X				X	X	X	X	X	X	X	X
нейросенсорная потеря слуха двусторонняя	9.3.2	H90.3	X				X	X	X	X	X	X	X	X
болезни системы кровообращения	**10.0**	**I00 – I99**												
из них: острая ревматическая лихорадка	10.1	I00 – I02												
хронические ревматические болезни сердца	10.2	I05 – I09												
из них: ревматические поражения клапанов	10.2.1	I05 – I08												
болезни, характеризующиеся повышенным кровяным давлением	10.3	I10 – I13												
из них: эссенциальная гипертензия	10.3.1	I10												
гипертензивная болезнь сердца (гипертоническая болезнь с преимущественным поражением сердца)	10.3.2	I11												
гипертензивная болезнь почек (гипертоническая болезнь с преимущественным поражением почек)	10.3.3	I12												
гипертензивная болезнь сердца и почек (гипертоническая болезнь с преимущественным поражением сердца и почек)	10.3.4	I13												
ишемические болезни сердца	10.4	I20 – I25												
из них: стенокардия	10.4.1	I20												
из нее: нестабильная стенокардия	10.4.1.1	I20.0												
острый инфаркт миокарда	10.4.2	I21												
повторный инфаркт миокарда	10.4.3	I22												
другие формы острых ишемических болезней сердца	10.4.4	I24												
хроническая ишемическая болезнь сердца	10.4.5	I25												
из нее постинфарктный кардиосклероз	10.4.5.1	I25.8												

Figure 3. An example of changes proposed to Form № 14.
Abbreviation: ICD — International Classification of Diseases.

Table 1

Signal indicators for monitoring the system of medical care for heart failure

№	Parameter	Estimation of method, unit of measure	Target value	Explanation
1	Proportion of registered CVD cases with ejection fraction <50% of all CVD cases in the subject of the Russian Federation	Number of identified patients with CVD with EF <50% among all registered patients with CVD in the current year, %	Will be figured out after receiving primary data	Reflects the contribution of the highest risk heart failure to the structure of CVD morbidity — with reduced EF (EF <50% is a predictor of unfavorable outcomes)
2	Prevalence of CVDs with EF <50%	Number of registered patients with CVD with EF <50%, per 100 thousand population at the beginning of the analyzed period	Will be figured out after receiving primary data	Reflects the primary and general incidence of CVD with EF <50%, and indirectly — the effectiveness of primary and secondary prevention in groups of high and very high cardiovascular risk
3	Proportion of patients who died from CVDs with EF <50% of all deaths from CVDs in the subject of the Russian Federation	The death rate from CVD with EF <50% in the current year, of all registered deaths from CVDs, %	Will be figured out after receiving primary data	Reflects the contribution to the structure of mortality from CVDs of the CVD cohort with EF <50% (highest risk groups)
4	Reduction of mortality from CVD with EF <50%	Change in the number of deaths from CVDs with EF <50% in the current year (compared to the previous year/same period of the last year), from all registered deaths from CVDs with EF <50%, %	Decrease no less than 1% compared to the previous year/ same period last year	Shows the effectiveness of the organization of healthcare system and dispensary monitoring of patients with CVDs with EF <50% (highest risk groups)
5	Proportion of in-hospital deaths from CVD with EF <50% of all in-hospital deaths from CVDs	Number of in-hospital deaths from CVDs with EF <50%, of all registered in-hospital deaths from CVDs, %	Will be figured out after receiving primary data	Demonstrates the contribution of mortality in a cohort of CVD patients with EF <50% (highest risk group) to in-hospital mortality from CVDs in general
6	Reduction of in-hospital mortality in patients with CVDs with EF <50%	Change in the number of patients with CVDs with EF <50% who died in the hospital in the current year, from all hospitalized patients with CVDs with EF <50% compared to the previous year/same period of the last year, %	Decrease no less than 5% compared to the previous year/same period of the last year, correction is necessary after obtaining the baseline value	A complex indicator reflecting the effectiveness of both inpatient and indirectly outpatient (late admission, late hospitalization, therapy ineffectiveness) stages of healthcare for patients with CVDs with EF <50% (highest risk groups)
7	Proportion of patients with CVDs with ejection fraction <50% under dispensary monitoring	Proportion of people with CVDs with EF <50%, who are under dispensary monitoring, who received medical services in the current year as part of dispensary monitoring, of all patients with CVDs with EF <50%, who are under dispensary monitoring, %	No less than 80%	Reflects the effectiveness of the outpatient care to patients with CVDs in terms of coverage of dispensary monitoring of patients in the CVD group with EF <50% (highest risk), as well as the continuity of inpatient and outpatient stages of treatment
8	Influenza vaccination coverage of CVD patients with ejection fraction <50%	Proportion of people with CVDs with EF <50% who received influenza vaccination in the current year, from all patients with CVDs with EF <50%, %	No less than 50%	Reflects the effectiveness of the outpatient care to patients with CVDs in terms of the implementation of preventive measures on outcomes in a cohort of CVD patients with EF <50% (highest risk)
9	Pneumococcal vaccination in patients with CVDs with ejection fraction <50%	Proportion of people with CVDs with EF <50% who received pneumococcal vaccination in the previous 5 years or in the current year, from all patients with CVDs with EF <50%, %	No less than 50%	Reflects the effectiveness of the outpatient care to patients with CVDs in terms of the implementation of preventive measures on outcomes in a cohort of patients with CVDs with EF <50% (highest risk)

Abbreviations: CVD — cardiovascular disease, RF — Russian Federation, EF — ejection fraction.

— Form № 25 contains information on the ICD-10 final diagnosis code of each outpatient. It is advisable to provide information on the presence of HF as an additional item to be filled out. For example, immediately after information about the nature of the injury, there may be information about EF in patients with CVDs (ICD-10 I00-I99). In this case, the choice from the previously described 4 coding options is also discussed.

The introduction of the presented changes (Form № 066/u and Form № 25) will allow the formation of measures for independent control over the quality of entering statistical data, and will also provide tools for the quick and correct collection of the necessary information about HF. This will allow the services of the territorial fund of compulsory medical insurance to conduct independent accounting and control of HF prevalence in the region. Isolated changes in the forms of federal statistical survey without the formation of available tools for collecting the required information can lead to the receipt of distorted data.

Monitoring the prevalence and outcomes in patients with heart failure

Isolation and registration of groups of patients with CVDs and EF <50% provides an opportunity to assess the prevalence of HF with reduced and mid-range EF (<50%) in each subject of the Russian Federation and use these data to calculate indicators characterizing the system of healthcare for this category of patients.

Despite prescribing effective drugs for the survival of high-risk patients is the main strategy for reducing cardiovascular mortality, and HF in particular, the assessment of the quality of drug therapy by the frequency of use of recommended drug classes and the percentage of achieving target doses is limited by the need registration of personal data of patients (hemodynamic status, renal function, comorbidities, contraindications), currently unavailable. Similar restrictions apply to the recording of the number of performed high-tech treatments for HF, since they are recommended for patients with a life expectancy of more than 1 year with persistence of HF symptoms while taking maximum tolerated doses of drugs for 3 months. Accounting for these parameters requires an expert assessment.

At the initial stage, monitoring of the indicators listed in Table 1 is proposed as signal indicators for assessing the system of healthcare for HF.

Assessment of the mortality rate in patients with CVDs and ejection fraction <50% in a specific medical institution and at the regional level may reflect the possibilities and effectiveness of the use of drug therapy and mechanical circulatory support, extracorporeal membrane oxygenation, renal replacement therapy,

multidisciplinary team work with the involvement of related specialists for determining tactics in non-standard and difficult cases.

An effective system for the identification and long-term follow-up of patients with HF in primary care institutions, including the implementation of seamless management with continuity of healthcare between inpatient and outpatient stages, timely identification of patients with HF and admission to dispensary observation, are of decisive importance in strategies to reduce mortality [23, 24]. The implementation of a similar model in the Russian Federation, compared with standard management, was associated with a 21,2% reduction in 2-year all-cause mortality risk [25]. Vaccination programs require active attention, including educational work with patients. The results of actual clinical practice and observational studies indicate the possibility of reducing the risk of all-cause death by 20% due to influenza and pneumococcal vaccination in patients with HF. In Denmark (n=134048), annual influenza vaccination of patients with HF was accompanied by a 19% reduction in the risk of death [26]. The results of a meta-analysis of 7 observational studies (n=163756) indicate that pneumococcal vaccines are associated with a 22% reduction in the death risk in patients with CVD, including HF, or with a very high risk of their development. Currently, RCTs are being conducted to assess the severity of the effect of influenza and pneumococcal vaccination [27]. However, the available data made it possible to include these strategies in the European and American guidelines for the diagnosis and treatment of HF. According to Russian guidelines, influenza and pneumococcal vaccination is recommended for all patients with HF (in the absence of contraindications) to reduce the risk of death [10].

Conclusion

Data on the epidemiology of HF in the Russian Federation are limited. The increase in the prevalence and potential contribution of HF to mortality pattern emphasize the social and economic significance of the problem, the monitoring of which is not possible without creating a current epidemiological picture by recording and collecting official statistical information. The cumulative assessment of HF prevalence (ICD-10 coding and EF <50%), as well as the calculation of integral indicators characterizing the healthcare system at all stages is a promising direction for implementation of the federal project on the prevention of cardiovascular diseases and control of achieved targets.

Relationships and Activities: none.

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