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Epidemiology of Cardiovascular Diseases and their Risk Factors in Regions of Russian Federation (ESSE-RF) study. Ten years later

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The growing weight of noncommunicable diseases, primarily cardiovascular diseases (CVDs), is a great threat to the health of population worldwide, worsening the quality of life and reducing life expectancy. Realization of this threat led to initiation of epidemiological study by the Russian Ministry of Health to investigate the prevalence of CVDs and their risk factors, since it is CVDs that specify the high all-cause mortality in Russia. In the modern history of epidemiology of non-infectious disease, the Epidemiology of Cardiovascular Diseases and their Risk Factors in Regions of Russian Federation (ESSE-RF) study occupies a special place. This is the largest epidemiological study, which is considered as a continuation of preventive activity in order to obtain unbiased information on epidemiological characteristics of population in Russian regions. To conduct the study, the Research Organizing Committee of ESSE-RF study was created and a protocol was developed. All interested scientists and experts from following three centers took part in the work: National Medical Research Center for Therapy and Preventive Medicine, Almazov National Medical Research Center, National Medical Research Center of Cardiology. The Russian regions were justified and selected for participation. In 2012-2014 ESSE-RF study, 13 following Russian regions took part: Volgograd, Vologda, Voronezh, Ivanovo, Kemerovo, Tyumen Oblasts; Krasnoyarsk and Primorsky Krai; the Republic of North Ossetia (Alania); cities of Orenburg, Samara, St. Petersburg and Tomsk. All participated regions used a single study protocol, while biochemical parameters were determined in Federal centers using the same equipment and reagent kits. The paper presents some of the most interesting results that indicate a change in Russian epidemiological situation over the past few years. After the end of cross-sectional study, a field of priority research areas was formed in each center.

Conclusion. Epidemiological studies are the most important scientific tool for assessing the prevalence of diseases, their risk factors, as well as predicting adverse events. Based on the results obtained, healthcare system and medical community determine priorities and develop related strategies (population-based and high-risk strategies). For their implementation, a regulatory and legal framework is being created.

Keywords: risk factors, cardiovascular diseases, ESSE-RF study.

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The growing burden of noncommunicable diseases (NCDs), primarily cardiovascular disease (CVD), poses a great threat to the population health in many countries, worsening the quality of life and reducing life expectancy. Awareness of this threat prompted the World Health Organization (WHO) at the end of last century to raise the priority of programs for the prevention and control of NCD spread. This initiative has been taken up by a number of countries. Representatives of 160 Member States, including 87 Ministers of Health, took part in the First Global Ministerial Conference on Healthy Lifestyles and NCD Control in Moscow on April 28-29, 2011 [1]. At conference, Russian President Vladimir Putin noted: "*For Russia, protecting the health of people has been and remains a top priority. In matters of prevention and adherence to a healthy lifestyle, we continue to develop the traditions laid down by our outstanding compatriots, such as Botkin and others*" [2]. Based on the global strategy for prevention and control of NCDs, an appropriate action plan was developed, approved by the World Health Assembly. In September 2011, a High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases was held, which was attended by 113 Member States, including 34 heads of state and government. As a result of discussion, the Political Declaration of the United Nations General Assembly on the Prevention and Control of NCDs (New York, September 19-20, 2011) developed, which called the main goal of prevention to reduce mortality from CVDs, cancer, diabetes and chronic respiratory diseases by 25% by 2025 [3]. All this was a prerequisite for conducting an epidemiological study in Russia to study the prevalence of CVDs and their risk factors (RFs), since CVDs in mortality pattern in Russia account for almost half of all deaths.

In the modern history of NCD epidemiology, the Epidemiology of Cardiovascular Diseases and their Risk Factors in Regions of Russian Federation (ESSE-RF) occupies a special place. The study was initiated by the Ministry of Health of Russia in 2011. Thanks to qualified specialists and their experience in conducting epidemiological studies, as well as the already established interaction with the regions, it was possible to justify the need for this study and receive stable funding.

Any large multicenter study has its own background and a rather long path of protocol development, as well as a number of approval stages. Before developing a research protocol and design, as a rule, the experience of similar projects is analyzed. The ESSE-RF study was no exception. To carry out the research, the Research Engineering Committee of the ESSE-RF research was created. The following three Federal centers were the governing ones:

— National Research Center for Preventive Medicine, Director — Professor S.A. Boytsov. To date, National Medical Research Center for Therapy and Preventive Medicine, Director — Corresponding Member of Russian Academy of Sciences O.M. Drapkina

— Almazov Federal Heart, Blood and Endocrinology Center. To date, Almazov National Medical Research Center, Director — Academician of Russian Academy of Sciences E.V. Shlyakhto;

— Russian Cardiology Research and Production Complex, Director — Academician of the Russian Academy of Sciences E.I. Chazov. To date, National Medical Research Center of Cardiology, Director — Academician of the Russian Academy of Sciences S.A. Boytsov.

Each of them had experience in conducting such studies. National Medical Research Center for Therapy and Preventive Medicine had half a century of experience in conducting international epidemiological studies, including The Stress, Aging and Health Study in Russia (SAHR), grant from the US National Institute on Aging (NIA) № R01 AG026786, 2006/09/2011/08 [4]. The National Medical Research Center of Cardiology had an experience in developing the Federal Target Program on Prevention and Treatment of Hypertension in Russia [5], as well as examining the population of the Western Okrug of Moscow [6]. In addition, Almazov National Medical Research Center examined the employees of Sberbank [7] and conduct the NIKA study on the risk of cardiovascular events in metabolic syndrome [8].

In 2011, the preparation of study protocol began. All interested scientists and experts from the three centers participated in this work. The regions were substantiated and selected. In April 2012, a kick-off meeting was held, at which a study on epidemiology of CVDs and RFs in various Russian regions was announced. For the first time, the short name of the study (ESSE-RF) was announced.

The National Medical Research Center for Therapy and Preventive Medicine provided organizational and methodological support to 7 regions — Ivanovo, Volgograd, Vologda and Tyumen Oblasts; Krasnoyarsk and Primorsky Krai and the Republic of North Ossetia (Alania); Almazov National Medical Research Center supported to 3 regions — the cities of St. Petersburg, Samara and Orenburg. In addition, the National Medical Research Center of Cardiology was responsible for 2 regions (Voronezh and Tomsk Oblasts). Organizational and methodological support included the following elements: procurement of a single set of equipment and consumables, research funding; training a team of researchers from each region with subsequent monitoring visits; centralized collection of biological samples and the formation of a single database [9].

In the study ESSE-RF study in 2012-2014, 13 Russian regions (including the joined Kemerovo Oblast) took part, which used a single study protocol. Biochemical parameters were determined centrally in Federal centers

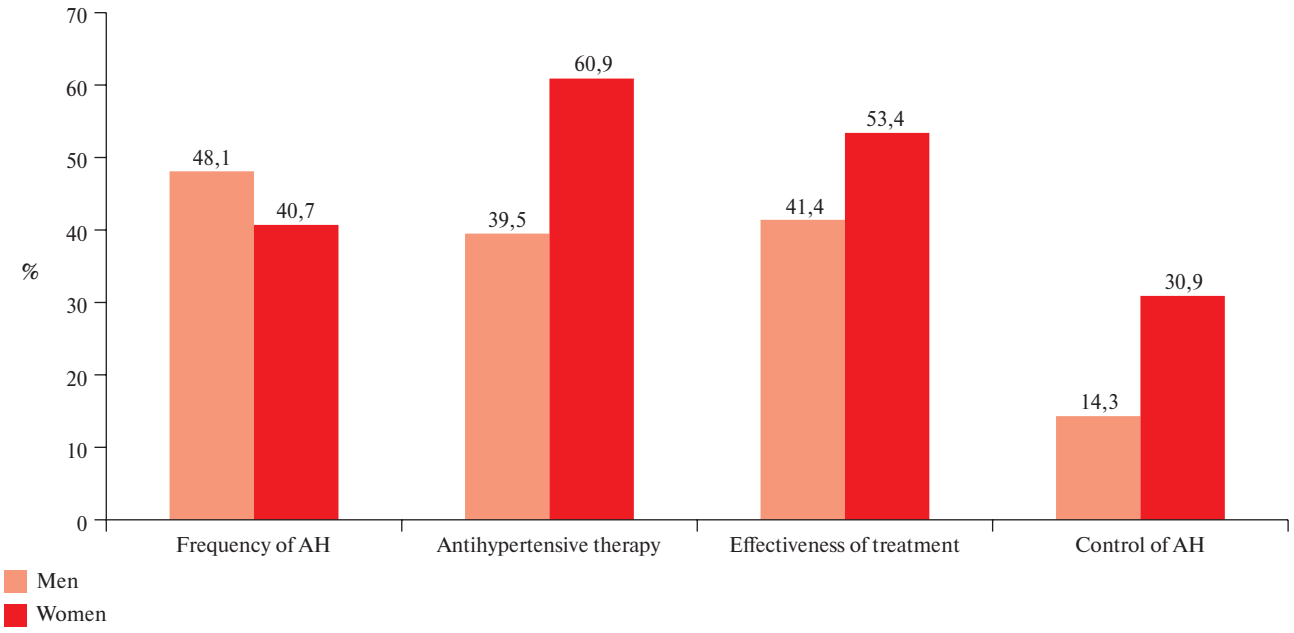

Figure 1 The prevalence of hypertension, the antihypertensive therapy, the effectiveness of treatment, and the hypertension control in men and women in ESSE-RF [10].

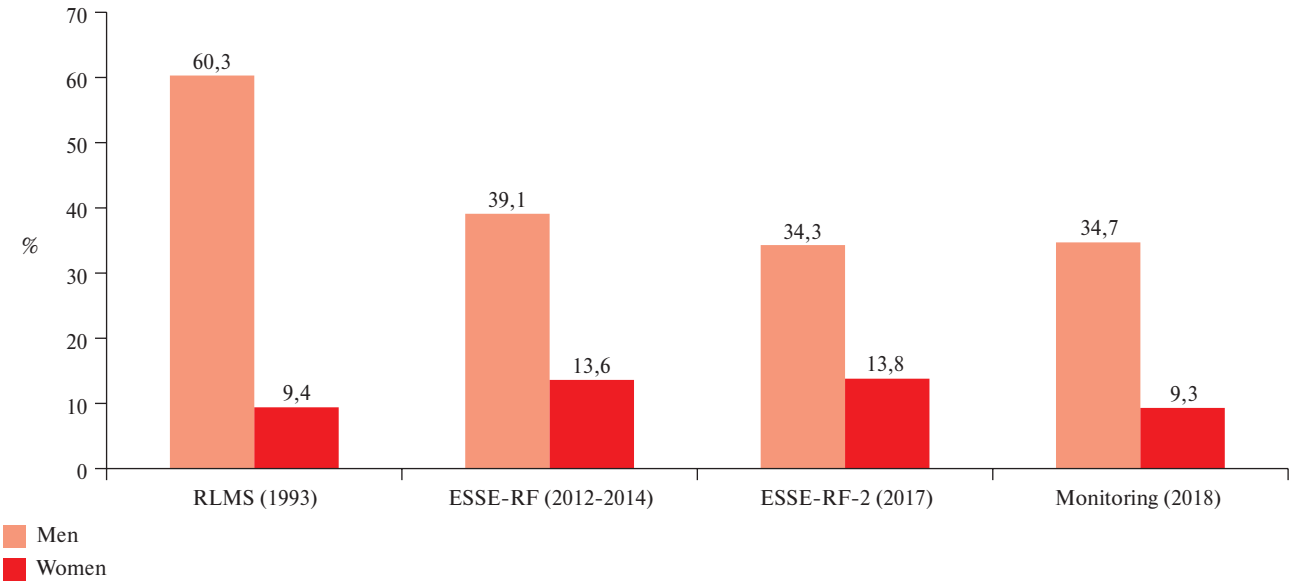

Figure 2 Smoking dynamics in Russia from 1993 to 2019.
Note: RLMS — The Russia Longitudinal Monitoring Survey.

using the same equipment and a reagent kits. The study was approved by the independent Ethics Committees of the three centers. All subjects signed informed consent.

The very first results obtained were unexpected. It turned out that the prevalence of hypertension (HTN) (blood pressure (BP) ⩾140/90 mm Hg and/or receiving antihypertensive therapy) increased to 44% compared to previous years (Figure 1) [10]. In 2017, in ESSE-RF-2, similar results were obtained — 45,2% [11]. In both studies, there was a significant increase in this indicator in men with low treatment coverage and poor BP control.

A possible reason for this BP rise can be considered an increase in the prevalence of obesity, registered in every fourth man [12].

It should be noted that there was a decrease in smoking in the male cohort, while it should be noted that not only a decrease in smoking prevalence, but also a decrease in the prevalence of smoking beginning or non-smoking was revealed (Figure 2). Young men are more likely to quit smoking, which is not the case for young women [13].

After the end of cross-sectional research, scientific directions, priority areas and analytical courses were formed in each center.

The National Medical Research Center for Therapy and Preventive Medicine have the following analytical courses:

1. The prevalence of conventional RFs and their relationship with socio-economic RFs in different Russian regions

At the same time, the characteristics of regions occupies one of the first places, since it allows one to identify specific problems with the population health and propose specific solutions.

2. Improving cardiovascular risk stratification (CVR) using the novel biomarkers

Biomarkers currently occupy an essential position in CVR reclassification at the individual and population levels. The prevalence and associations of high-sensitivity C-reactive protein and uric acid have been studied [14]. For the first time, the prevalence of elevated lipoprotein(a) levels in the working-age population and association with CVDs has been shown [15]. The role of high-sensitivity troponin I in CVR formation at the population level is considered [16]. Novel electrocardiographic markers are studied [17].

3. Behavioral RFs and adherence to healthy lifestyle

Until now, isolated studies have been conducted in Russia on behavioral habits. For the first time, an indicator "proportion of people leading a healthy lifestyle" was proposed. This index is a conditional characteristic of healthy lifestyle and includes the following components: no smoking, consumption of vegetables and fruits daily at least 400 g, adequate physical activity (a least 150 min of moderate or 75 min per week of intense physical activity), normal (no more than 5,0 g per day) salt intake, alcohol consumption no more than 168 g per week of pure ethanol for men and no more than 84 g per week for women [18]. The index has been introduced into Federal State Statistics Service (Rosstat) activities as a mandatory indicator of health in ongoing research.

4. Study of the development and progression of atherosclerosis of various localization

The ATEROGEN-Ivanovo sub-study was carried out including the Ivanovo population. As part of the sub-study, the ultrasound parameters of atherosclerosis of carotid and femoral arteries in patients with coronary artery disease were studied. The prevalence of peripheral atherosclerosis in the middle-aged population was presented for the first time [19].

5. Prevalence of familial hypercholesterolemia

The assessment of familial hypercholesterolemia prevalence in certain Russian regions was carried out [20]. On the basis of population data, the concept of prevention of autosomal recessive hereditary diseases was formed and introduced into practical health care.

6. Development of NCD risk scales (atherosclerosis, HTN, diabetes mellitus, obesity, osteoporosis, etc.) [21-23].

7. Comparative characteristics of osteoporosis and atherosclerosis RFs

Additional factors were identified that were associated with the total risk according to the Systematic Coronary Risk Evaluation (SCORE) and Fracture Risk Assessment Tool (FRAX) scales among the urban Russian population [24].

Almazov National Medical Research Center studies the following the following research directions:

1. Prevalence and association of subclinical arterial involvement with different RFs

In the St. Petersburg population, a low prevalence of subclinical arterial lesions was noted according to various diagnostics methods. Markers of subclinical arterial lesions were weakly correlated with each other, which does not allow them to be considered interchangeable diagnostic methods. The main determinants of subclinical vascular abnormalities were age and hypertension regardless of sex.

2. Prevalence of behavioral cardiovascular RFs and their relationship with socio-economic, biological RFs and psychoemotional status

In a random sample of St. Petersburg residents, a high prevalence of dyslipidemia, obesity, HTN and hyperglycemia, as well as smoking, was recorded. Male sex, young age, low income, no higher education, and anxiety-depressive disorders are the main factors determining the profile of behavioral and biological RFs.

3. Cardiometabolic and molecular genetic determinants of prehypertension in subjects in Russian population

A third of surveyed Russian residents aged 25-64 years had prehypertension with a significantly higher prevalence among men. In addition to males and older age, the risk of prehypertension is associated with obesity and metabolic disorders (dyslipidemia, hyperglycemia). The prevalence of negative behavioral RFs is higher in participants with prehypertension compared with the optimal and normal BP group. Special attention, as before, should be paid to excess salt intake.

4. Metabolic syndrome genetic markers among the Russian population

In the Russian population, an association was confirmed between the *FTO* gene rs9939609 risk allele with the development of abdominal obesity, as well as between the *TCF7L2* gene rs1225537 risk allele with hyperglycemia. A different combination of the components of metabolic syndrome was shown in the group of men and women in carriers of *FTO* gene rs9939609 and *TCF7L2* gene rs1225537 risk alleles.

5. Metabolically healthy obesity: predictors of transformation into an unhealthy phenotype

Significantly higher BP levels, insulin resistance, low density lipoproteins and uric acid at baseline, as well as an increase in glucose levels over time, were associated with the transformation of a metabolically healthy phenotype into an unhealthy phenotype in

obese individuals after 6,5-year follow-up. In all individuals with metabolically healthy obesity, there was a significant increase in waist circumference over time, accompanied by an increase in body mass index only in individuals who transformed into unhealthy phenotype.

6. Concept of early and supernormal vascular aging — prevalence and determinants at the population level

At the population level, early and supernormal vascular aging occurs in 16-19% and 10% of patients, respectively, without significant sex predominance. HTN, obesity and metabolic factors are main factors causing aging. The results of this study in the Russian population emphasize the importance of assessing the vascular wall state using various methods for assessing vascular stiffness and taking into account age, BP and metabolic profile.

7. Interrelation of sleep-related breathing disorders with CVR

The ESSE-RF study results revealed a high prevalence of complaints of snoring in the general population, with a predominance among men. With age, the prevalence of snoring and apnea increases. Common RFs for snoring and sleep apnea are male sex, body mass index, older age, and alcohol abuse. The main cardiovascular RFs and diseases are comorbid with sleep-related breathing disorders. Sleepiness was the main symptom assessed by questionnaires, the incidence of which increased with complaints of snoring and apnea. Differences in the prevalence of CVD RFs among those who complain of snoring or apnea indicate their significant subjectivity.

Specialists of the National Medical Research Center of Cardiology study the following issues:

1. Prevalence of RFs in hypertensive and prehypertensive patients, primarily metabolic, in different age groups among the Russian population. For the first time, objective data on the prevalence of main cardiovascular RFs in patients with hypertension, including obesity and metabolic disorders, which have received particular relevance in recent decades, have been obtained on a large sample [25].

2. The prevalence of obesity, metabolic syndrome, diabetes mellitus, including among people with high BP. The researchers analyzed in detail the prevalence of various types of obesity and the relationship of abdominal obesity (AO) with the socio-economic status of respondents. The prevalence of AO in Russia was 55%, while the proportion of persons with obesity, estimated by body mass index, was significantly lower (33,4%). An inverse relationship was found between AO and smoking ($p<0,0001$) [26].

The authors assessed true prevalence of diabetes in Russia, including among hypertensive patients, which showed its high levels. The prevalence of diabetes among patients with hypertension was ~14%, and newly diagnosed diabetes among people with hypertension was recorded in 5,2% of cases. Apparently, the very fact of dispensary follow-up of hypertensive patients makes it possible to assess the parameters of carbohydrate metabolism and identify diabetes mellitus [27]. The data obtained on poorly controlled HTN, high prevalence of HTN, combined with metabolic disorders, including diabetes mellitus and kidney disease, indicate insufficient outreach and awareness-raising work, both among the general population and among hypertensive patients.

3. Prevalence of prothrombotic conditions using conventional and novel markers (ThromboPas)

Specialists of the National Medical Research Center of Cardiology for the first time analyzed the coagulation system RFs of CVDs (fibrinogen, D-dimer and a global parameter characterizing the anticoagulant function of protein C — TromboPas) in the adult population of Tomsk and their relationship with the main demographic and clinical characteristics [26]. It was shown that the presence of at least one of hypercoagulation markers, which included the level of fibrinogen >3,7 g/L, D-dimer >500 ng/ml, and thrombin inhibition index in the TromboPas test (PICI%) ⩽84%, was revealed in 55,4% of subjects. The study showed a high risk of thrombotic events in the studied sample, which is the rationale for developing adequate preventive measures.

4. Study of atherosclerotic lesions and arterial stiffness by volumetric sphygmography, duplex ultrasound, etc. in various populations (in individuals with high and normal BP)

Within the ESSE-RF study, an original research of the vascular wall state by volumetric sphygmography was carried out according to in the adult population of the Russian Federation using the example of residents of the city of Tomsk. For the first time, reference values of cardio-ankle vascular index (CAVI) and aortic-ankle pulse wave velocity were obtained for Russian residents, which showed a significant dependence on age. In the surveyed sample, increased arterial stiffness estimated by aortic-ankle pulse wave velocity was detected in 37,8% of subjects, while estimated by CAVI — in 16,6%. A high prevalence of increased arterial wall stiffness among hypertensive patients was shown. The study confirmed the high potential of volumetric sphygmography for detecting asymptomatic great vessel lesions and revealed the prevalence of disorders detected by this method [28].

5. Prevalence of renal disorders in patients with HTN, obesity and diabetes

Thanks to ESSE-RF, we obtained data on the prevalence of renal dysfunction among Russian population aged 24-65 years, including those with HTN. Renal dysfunction was assessed based on the estimation of glomerular filtration rate (GFR) according to Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. In the surveyed sample, the prevalence of renal dysfunction was 26,5%. The

situation was most unfavorable in hypertensive subjects, the prevalence of a severe GFR decrease in whom was 2 times higher than in those without HTN. In addition, data were obtained on insufficient control of BP among patients with HTN and renal dysfunction. Half of people with high BP and reduced renal function did not receive antihypertensive therapy, which is an extremely unfavorable fact, and indicates insufficient coverage of this category of patients with dispensary follow-up [29].

A further expansion of ESSE-RF coverage was carried out within the ESSE-RF-2 study, which included representative samples from the population of four regions (Omsk, Ryazan Oblasts, the Republic of Karelia and Krasnodar Krai). ESSE-RF-2 protocol was changed for some modules of the questionnaire; liver biomarkers were added to the list of laboratory parameters. Thus, now the ESSE-RF includes 17 Russian centers, which include >26 thousand men and women aged 20-64 years.

The most important work carried out under the National Medical Research Center for Therapy and Preventive Medicine is prospective follow-up of cohort life status, which included persons examined within the ESSE-RF and ESSE-RF-2. Based on data on fatal and non-fatal events, RF analysis is performed in connection with general and cardiovascular mortality in Russia.

The following study is currently carried out — ESSE-RF-3. Its distinction was the unprecedented sample size (30 centers, 60 thousand people aged 35-74). Modern sampling technologies for the direct and remote determination of biomarkers and their storage in the Biobank of the National Medical Research Center of Therapy and Preventive Medicine allows for a consistent research of biomaterial role, regardless of the blood sampling time. The questionnaire has been expanded to include modules on cognitive function, coronavirus disease 2019 (COVID-19) and assessment of the area within walking distance. The list of studied biochemical parameters included lipid profile, glucose, high-sensitivity C-reactive protein, creatinine, liver function tests and fibrinogen.

The ESSE-RF epidemiological study is rich in the amount of material included. The researchers prepared dissertations, while many articles have been published in high impact Russian and foreign journals. In addition, many reports have been presented at international and Russian conferences. The study of biomarkers epidemiology becomes an obligatory part of epidemiological research as a basis for transition to personalized medicine. The study seems to be inexhaustible, but, unfortunately, it is practically the only source of information on NCD RFs in Russia.

The ESSE-RF study was carried out, as a rule, under the guidance of specialists from medical universities, research centers and regional cardiology dispensaries. In other words, the study included not only specialists in NCD epidemiology, but in most cases — clinical specialities. Participating centers were issued documents certifying their participation in the ESSE-RF multicenter study.

In conclusion, epidemiological studies are the most important scientific tool for assessing the prevalence of diseases, their RFs, as well as forecasting. Based on the data obtained, the healthcare system and medical community determine priorities, develop strategies and create a regulatory framework for their implementation.

ESSE-RF study limitations. The ESSE-RF study included data on representative samples of the population aged 25-64 years from 13 constituent entities of Russia, as well as 4 constituent entities in the ESSE-RF-2. The number of those examined did not include severe patients, because home data collection was not provided. In addition, socially troubled persons were not included.

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Relationships and Activities: none.

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