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Dear Colleagues!

This issue of the Russian Journal of Cardiology, coinciding with the Congress, includes diverse articles showing the potential and interests of cardiology as a clinical discipline. Nevertheless, the central themes of the issue are ethical, legal and psychosocial aspects of working with patients. This direction is becoming more and more relevant.

It so happens that behind the rapid developing of biomedical technologies and advances in the treatment of cardiovascular disease, communication with a patient as a part of society, as a person, an identity, is lost and lagged behind. This component is the ethical imperative of medicine. Helping a suffering person is the essence of the doctor-patient relationship. However, in the technological age, it is necessary to rethink and find new ways of interaction. This is important, firstly, in view of strengthening law role — regulation of care, informing and obtaining patient consent, medical privacy in the context of digital healthcare and during a pandemic. Secondly, in view of higher understanding of sociocultural risk factors, the role of a doctor as a communicating helping subject, a person endowed with the power of medicine, whose tasks include creating a constructive experience by a patient of his condition, increasing adherence, and establishing ways to improve the health, becomes more and more complex.

All this requires an understanding of the ethical, legal, psychological aspects of interaction between a cardiologist and a patient. A number of articles included in the issue propose this understanding from different points of view. Of course, these issues should be resolved with interdisciplinary team of clinicians, lawyers, psychologists and philosophers.

I wish you a productive Congress, new ideas and perspectives!

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EDITORIAL
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Risk communication: ethics, psychology, law

Taratukhin E. O.

When communicating with a patient, a doctor is within a certain cultural practice (science-based medicine and state health care system), falling outside the limits of which is not legal. However, a broader understanding of medicine as a cultural phenomenon with a focus on health also requires a more varied perspective on patient care. The patient's problem can be more complex than looking at it from science- and evidence-based point of view. Therefore, in risk communication as an element of work with adherence or as part of signing informed consent, different ways are needed to consider a patient's situation. An ethical and psychological perspective on clinical interactions allows for a more holistic view of the disease.

Keywords: risk factors, algorithms, clinical guidelines, medical ethics, bioethics, adherence, patient-centered care, doctor-patient relationship.

Relationships and Activities: none.

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The subject of medicine is health. And although the practice of health service provision clearly demonstrates a different perspective of the medicine subject (treatment of diseases), the health care areas related to primary prevention, habilitation, predicting and individualizing risk allow for positive health in medicine.

In the reference frame, where a person is a biosocial subject, health is defined as physical, mental and social well-being. The social one is somatized, while the somatic influences the interaction of a person with the social environment [1]. Work within the prevention is mainly aimed at the psychosocial component of a person, until functional disorders lead to pathomorphological abnormalities, fixing the impaired function in the structure.

Risk communication is about informing society and individuals about the dangers they face. In medicine, risk communication can be of a public nature (promotion of healthy diet, smoking cessation, vaccination) or individual. The risks of a particular patient are discussed, firstly, when it is necessary to inform and obtain voluntary informed consent (or refusal), and secondly, when it is necessary to form adherence to the doctor's prescriptions, and more broadly, to form a constructive attitude to the situation [2]. Medical risk communication is based on knowledge about pathogenetic mechanisms and ways to correct pathophysiological changes. This knowledge is the content of medicine.

Medicine, in turn, has existed for several millennia. Its habitual model, which forms the modern social system, scientific and evidence-based, has only tens of years of its existence. Nevertheless, thanks to science as an institution of cognition and an economic system that depends on scientific achievements, medicine is embedded in social relations in such a way as to be in the center between the four components (Figure 1): biomedical knowledge, psychology communication, legal framework, ethics (more broadly — philosophy). Legal issues should be distinguished from ethics, since law as a state institution is endowed with essential features and functions. It should also be noted that systems other than the western scientific worldview, for example, traditional Chinese medicine, would be built into the institution of society and state in a completely different way. The goals of such "other medicines" would be as different as the approaches to achieving these goals. For example, Chinese medicine, which considers external environment factors ("wind", "cold", "dampness", etc.) as a semiotic and heuristic base, influencing on human homeostasis [3], a separate medical service would mean something else. And it would not give security, since the patient himself and his psychosomatic state play a significant role in its function.

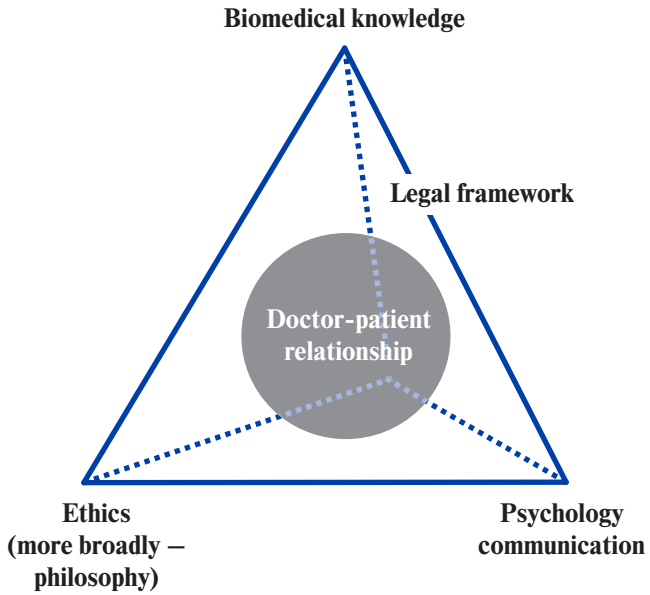

Figure 1. The four components of doctor-patient relationship.

The Western model was formed due to the rapid development of biology and chemistry in the context of commodity-money economy, as well as the creation of regulatory legal institutions. The tasks, operating techniques, and relations themselves within the Western model of medicine are outlined by this context, highlighting its certain, necessary, and appropriate aspects.

A doctor, as an actor of medical knowledge of a certain kind, is placed within the health service provision (within the broader concept of health care). This service includes 1) a biomedical basis, statistically proven by natural sciences, 2) the psychology of communication and psychological aspects of the patient's experience of the situation, 3) the interaction ethics (medical ethics), and 4) a number of legal service features and the doctor-patient relationship generally. Given the biosocial nature of human [4], ethics and psychology can influence the biomedical component, although such an influence, being a subject of humanitarian knowledge, is difficult to algorithmize.

Risk communication, i.e. informing a patient of possible negative situation scenarios, can be considered in a similar "tetrahedron":

— clinical (biomedical) side assumes *knowledge* of a doctor and institute of medicine as a whole about the typical course of a particular pathology, adjusted for the individual biomedical characteristics of the patient's body;

— psychological side includes *goals* for developing a constructive attitude (or coping) with the situation, for motivating for healthy behavior change or for following the doctor's prescriptions (adherence);

— legal side brings the situation of interaction in *accordance* with the values of a particular society and state, including, for example, requirements for voluntary informed consent;

— ethical side raises *questions* related to the very aims of interaction with a patient, ranging from the measure of truth that can (must) be reported, ending with the financial component of health service provision.

All these attributes are implicitly present in a concrete "here and now" situation of doctor-patient interaction, as a rule, not manifesting themselves until the communication stumbles upon a contradiction.

The four key concepts highlighted above outline the specifics of risk communication in a particular model of medicine. In the Western model, the knowledge of a doctor is absolute, since it is based on empirical data and large samples, allowing to achieve significance that claims to be axiomatic. The phenomenon of doctor's power lies in the fact that a doctor knows exactly about risks and possible options for event development [5]. The goal that is set in the doctor-patient communication is based on the relationship of etiology, pathogenesis, and outcomes, proven in the experience of fundamental and clinical medicine. Compliance with algorithms and other regulatory documents is required when it comes to licensed health care practices. The regulatory acts themselves represent a meta-level of the same fundamental knowledge, only even more alienated from the uniqueness of a particular patient. Here ethical questions arise.

It is most interesting to look at risk communication from the point of view of a doctor as an expert in the biological part of the issue, and a patient as an expert in himself. Considering that the biosocial nature of a person and his psychosomatic structure (as well as cultural and psychological) directly depend on the situation formed in consciousness (in the psyche, experience), the patient's knowledge about himself cannot be taken outside the interaction [1]. On the contrary, the new that a patient learns about himself as a sufferer falls on his picture of himself, transferring him to a different personal or even a different existential status. The feedback received by a doctor during communication modulates his further actions and speech, however, each action and statement also includes a doctor as a representative of medicine, health care, as a person, a helping specialist, and so on — i.e. the social role of a doctor. And there is still biomedical knowledge behind it all.

An example is the communication goal-setting about a modifiable risk factor for atherosclerosis based on cardiovascular risk stratification scales SCORE or SCORE-2. The risks in this case are ischemic events and other complications of atherosclerosis. The task of communication: to make a patient's idea of his condition adequate to the danger severity, so that he becomes motivated to modify the diet, lifestyle and can maintain this motivation, as well as to take lipid-lowering therapy. In this case, the doctor's knowledge is quite simple: there is an unconditional evidence base for the relationship between dyslipoproteinemia and coronary artery disease development. It is noteworthy that in the SCORE-2, additional stratification was made by country [6]. For example, a 72-year-old nonsmoking woman living in France with a non-high-density lipoprotein cholesterol level of 5,2 mmol/L and controlled hypertension (systolic blood pressure of 126 mm Hg) would have a ten-year risk of developing a cardiovascular event of approximately 8%, while a Russian woman with same *biological* characteristics has a risk of 31%, which is four times higher. In fact, such a serious risk increase occurs due to the introduction of additional factors that cannot be taken into account as follows: psychosocial stability, social security, economic well-being, health care system status, meal quality, cultural stereotypes of food or alcohol consumption, etc. At the same time, such a fundamental complication of the risk scale is symptomatic for the health care system to recognize the potential dead end of any stratification and the prospects of returning to work with the uniqueness of a particular patient. It is also obvious that 8% and 31% are some average values, and a resident of France with a low income and level of education, with family problems, living in a disadvantaged area may have a higher risk than a Russian woman who is a pensioner with wealthy children and grandchildren, living with them in an elite cottage village. How will risk communication between a cardiologist and these two women be arranged? Of course, there will be a turn from the epidemiological view to the individualization of specific conditions.

A significant unit in risk communication is a concept, behind which there are many attributes and prerequisites, one way or another included in it, but cannot be borne out separately due to their insufficient weight. For example, the concept of smoking may include data on current status (current/former/never-smoker) and quantity (pack per day; half pack per day, etc.), but does not include the *reasons* why the patient smokes, his psychological state during smoking or physiological changes caused by nicotine. In the example mentioned above, smoking as a component of scale in a French woman would be caused by social distress, while smoking in a Russian woman would rather due to aesthetic reasons. These and other significant units are incorporated by default into the concept of smoking due to the generalized knowledge of

smoking effect on the development of biomedical pathology in. The idea of a causal relationship between pathogenetic factors allows us not to ask the question that, perhaps, the pathological effect of a risk factor is associated not so much with itself as with its prerequisites.

Such questions can be important for risk communication, but importance can be acquired if the vector of communication. In other words, if the interaction conditions allow us to make it more individualized, patient-oriented, then the approach will become less universal. This can lead to a departure from the legal basis of such interaction, namely from the formally necessary aspects, such as guidelines and algorithms. At the population level, such a situation is difficult to imagine, if only due to the legal responsibility of decision-makers at the population level. At the level of an individual doctor's appointment, it can also be fraught with responsibility if damage is caused. On the other hand, in the case of refusal of individualization, the assessment of the resulting damage is more likely to be in favor of the doctor's innocence, since he acted in accordance with the regulatory framework.

Conclusion

The central conclusion that can be drawn from a brief consideration of the clinical situation, where the risk and prognosis options are explained, and the task is to obtain voluntary consent (refusal) or increase adherence to prescriptions, is as follows. The semantic system linking scientific biomedical knowledge with a real patient has developed in certain economic, social, and cultural conditions. Relationships within health care today are clearly defined and instrumentalized, since they occur within the state guarantee (if not for care provision, then at least for its quality control). As a result, the side of patient's condition that fits the care tools is given primary or even sole attention. Other ways of dealing with the patient's medical problem are marginalized.

Relationships and Activities: none.

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ORIGINAL ARTICLES
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Behavioral risk factors and clinical course of cardiovascular diseases and other noncommunicable diseases during quarantine in various regions of Russia

Mamedov M. N.[1], Druk I. V.[2], Turusheva E. A.[2], Eremina E. Yu.[3], Morozova T. E.[4], Iskenderov B. G.[5], Sapozhnikov A. N.[6], Drozdetsky S. I.[7], Badalov N. G.[4]

Aim. To assess the behavioral risk factors and the clinical course of cardiovascular diseases (CVDs) and other noncommunicable diseases (NCDs) during quarantine in various regions of Russia.

Material and methods. This multicenter cohort cross-sectional study included 205 men and women from 6 Russian cities. Further, 4 of them (Saransk, Nizhny Novgorod, Penza, Ulyanovsk) were combined into one group — the Volga region. The study included men and women aged 30-69 years with one or more NCDs (hypertension, coronary artery disease with or without myocardial infarction, type 2 diabetes, chronic obstructive pulmonary disease/asthma and cancer in patients receiving chemotherapy and/or radiation therapy) who were self-isolated during coronavirus disease 2019 (COVID-19) pandemic. For all patients, a questionnaire was used, which included socio-demographic parameters, behavioral risk factors, status of the underlying disease, incidence of COVID-19 and its complications. Self-assessment of the state of health was carried out using the European Quality of Life Questionnaire.

Results. In every third Muscovite, the intensity of physical activity decreased, and in the groups of patients from Omsk and the Volga region, it was 45% and 43%, respectively. An increase in meal frequency and an impairment of eating habits in Moscow and Omsk was noted in 18,2% and 18,7% of participants, while in Volga region subjects, these parameters were 2 times higher (42,4%). At the same time, no significant changes of alcohol consumption and smoking was revealed in the cohorts. Hypertensive crises during a pandemic were noted in all three subgroups, but more of them were recorded in the Volga region — in every third patient ($p<0,05$ compared to Moscow), in the Omsk group — in every fourth patient, and among Muscovites — no more than 5%. Clinical deterioration in patients with angina was noted in 15% of cases, while the smallest number was noted in Omsk subjects (5,3%), three times less than in other subgroups. Changes in intensity and regimen of hypoglycemic therapy were noted in patients from Omsk, while 30% of them ($p<0,05$ compared with the Volga region) increased the doses of medications taken. Chronic obstructive pulmonary disease was registered in the group with the largest number of Volga region patients — 14,1% ($p<0,05$ compared to Omsk), while 17% of patients in this group increased the dose of drugs. Any cancer was recorded in 13,6% of Muscovites, while in the other two groups — about 5%. The largest number of patients from the Volga region noted a health decline over the past year (30,8%), while every fifth patient from Omsk (19,6%) and 13,6% of Muscovites reported health changes.

Conclusion. During quarantine and self-isolation, changes in dietary habits and physical activity decline were noted among patients with NCDs, while alcohol consumption and smoking remained practically unchanged. The change in clinical status was characterized by an increase in hypertensive crisis incidence, an increase in doses of antihypertensive and hypoglycemic medication. Depending on the region, the health decline was noted by 13-31% of patients with NCDs.

Keywords: quarantine, self-isolation, regional characteristics, risk factors, noncommunicable diseases.

Relationships and Activities: none.

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Around the world, the coronavirus disease 2019 (COVID-19) pandemic is characterized by high morbidity and socio-economic losses, which has led to changes in health system functioning and priorities [1]. This affected the quality of care for patients with noncommunicable diseases (NCDs), which is a serious medical and social problem in general [2]. On the other hand, in the first months of COVID-19 spread, it was shown that elderly patients, smoking, obesity, hypertension, male sex, cardiovascular disease (CVD), diabetes, chronic obstructive pulmonary disease (COPD), cancer, as well as their comorbidity are predictors of complications, including death [3, 4].

The World Health Organization, as one of the main measures for COVID-19 prevention, recommended restrictions, such as quarantine and self-isolation of the population, which has led to alterations in care for NCD patients. This was due to the overload of medical institutions and limited admission of patients in primary health care institutions. All these circumstances influenced the clinical course of NCDs and behavioral habits of patients [5, 6].

In 2020, the first foreign publications on the consequences of restrictive measures on the provision of elective and emergency care for patients with NCDs appeared [7]. In Russia, this topic has been little studied. However, for the development of measures to prevent quarantine consequences, the study of risk factors (RF) and clinical status of NCD patients is relevant [8, 9].

The aim was to assess the behavioral risk factors and the clinical course of CVDs and NCDs during quarantine in various regions of Russia.

Material and methods

This multicenter cohort cross-sectional study included 205 men and women from 6 Russian cities (Moscow, Omsk, Saransk, Nizhny Novgorod, Penza, Ulyanovsk). Four cities were united into one group on a regional basis — Volga region. The study included men and women aged 30-69 years with one or more NCDs, who were self-isolated during the COVID-19 period. NCDs included hypertension, coronary artery disease with or without myocardial infarction, type 2 diabetes, COPD/asthma, and cancer in patients receiving chemotherapy and/or radiation therapy.

There were following exclusion criteria: mental disorders and severe somatic diseases, including with decompensation.

Survey. All patients were surveyed using a questionnaire prepared by the National Medical Research Center for Therapy and Preventive Medicine. It included personal data, socio-demographic characteristics, changes in behavioral RFs, including smoking, alcohol intake, diet and physical activity, clinical status of the underlying disease, received therapy, psychosomatic status (level of anxiety, depression and chronic stress) before and after the pandemic. The incidence of COVID-19 was also analyzed.

The questionnaire was the main document with material for statistical processing.

Smokers were defined as those who smoked at least one cigarette per day. There were following types of smoking status: never/former/current smoker.

Alcohol consumption was assessed according to the following criteria:

— never consumed alcohol (quit drinking);

— for men: low and moderate — <168 g ethanol per week, high — ⩾168 g ethanol per week;

Self-assessment of the health status changes over time was carried out using the European Quality of Life Questionnaire (EQ-5D).

Instrumental investigations. All patients were measured blood pressure (BP) and heart rate. BP was measured with a standard sphygmomanometer while sitting, after a 5-minute rest, on the patient's right arm. Systolic BP was recorded when Korotkov sound 1 appeared (phase I), diastolic BP — when sounds disappeared (phase V). The BP level was assessed twice with an interval of about 2-3 minutes. The average of two measurements was included in the analysis.

To assess anthropometric characteristics, height and body weight were measured, followed by body mass index (BMI) calculation. BMI (Quetelet index) was calculated as the ratio of body weight in kilograms to the square of height in meters

Table 1

Socio-demographic characteristics of the cohort patients

	Moscow, n=22 (10,7%)	Omsk, n=91 (44,4%)	Volga region, n=92 (44,9%)
Age, years	58,9±2,5	58,3±2,9	65,3±3,1
Sex (male/female)	11/11	38/57	35/56
Pre-pandemic employment status Employed	13 (59%)	56 (60,9%)	41 (45%)
Education Higher	7 (31,8%)	34 (37,4%)	40 (43,5%)
Employment status during pandemic			
Regular mode	6 (27,3%)	31 (34%)	20 (21,7%)
Remote	7 (31,8%)	1 (1%)	8 (8,7%)
Temporarily unemployed	0	9 (9,8%)	12 (13%)
Lost job	0	0	1 (1%)
Marital status			
Married	19 (86,4%)	60 (65,9%)	57 (62%)
Divorced	1 (4,5%)	8 (8,8%)	9 (9,8%)
Widower (widow)	1 (4,5%)	17 (18,7%)	25 (27,2%)
Never married	0	6 (6,6%)	1 (1%)

(BMI = m/h^2, where m — body weight (kg), h — height (m)).

Monitoring of material collection and training of researchers. Materials for publication were collected during the routine health care provision to hospitalized patients. The collection of material was carried out with the participation of primary care physicians. The study was conducted from June to October 2020. An online training was carried out on protocol and questionnaire statement. The questionnaires were randomly checked by independent experts. The results were processed at the National Medical Research Center for Therapy and Preventive Medicine.

Statistical analysis. Statistical analysis was carried out using the Scipy 1.1.0, NumPy 1.14.3 libraries for Python 3.6.5 (Python Software Foundation, USA) and the R 3.6.1 environment. The significance of differences between two independent samples was assessed using the nonparametric Mann-Whitney U-test. The chi-squared test and Fisher's exact test were used to test the relationship between categorical variables. The equality hypothesis test in more than two groups was performed using the Kruskal-Wallis test. Pairwise multiple comparisons were made with Holm correction. The differences were considered significant at $p<0,05$.

Results and discussion

The present study considered changes in behavioral RFs and clinical status of patients with NCDs in three Russian cities and regions during quarantine and self-isolation. According to the international study involving 202 doctors from 47 countries, during the pandemic, routine health care for NCD patients was moved to the virtual space [5]. In all these countries, patients with diabetes, hypertension and COPD were most affected. Moreover, 80% of doctors reported that their patients' mental health deteriorated during the pandemic and quarantine restrictions. The authors conclude that in order to avoid an increase in morbidity and mortality from diseases not related to COVID-19, it is necessary to use all resources to monitor patients with NCDs.

A number of large-scale studies have been carried out in Russia, including with creation of registers to assess the relationship between COVID-19 and some NCDs. Predictors of complications among patients after COVID-19, which indicate unfavorable outcomes among people with one or more NCDs, have been analyzed [8-12].

In the present study, 3 groups were analyzed to assess the behavioral RFs and clinical status of patients. Taking into account the small number of groups, patients from 4 cities were united into one group called the Volga region. Ultimately, the patients were divided into 3 groups: Moscow, n=22 (10,7%), Volga region (Saransk, Penza, Nizhny Novgorod, Ulyanovsk), n=92 (44,9%), and Omsk, n=91 (44,4%). The groups of patients from the Volga region and Omsk were comparable in number, while

Table 2

Changes in behavioral RFs in a cohort of NCD patients

Parameters	Moscow, n=22 (10,7%)	Omsk, n=91 (44,4%)	Volga region, n=92 (44,9%)
Smoking before the pandemic	4 (18,2%)	12 (13,2%)	6 (6,5%)
Smoking increased during the quarantine period	1 (25%)	0	4 (66,7%)
Drinking alcohol before the pandemic	11 (50%)	64 (70,3%)	30 (32,6%)
Alcohol intake increased during the quarantine period	0	0	2 (6,7%)
Physical activity decreased during quarantine	6 (18,2%)	40 (44%)	36 (39,1%)
Nutrition did not change or decreased during quarantine	18 (81,8%)	74 (81,3%)	53 (57,6%)
Nutrition increased during quarantine	4 (18,2%)	17 (18,7%)	39 (42,4%)

the group from Moscow was 4 times smaller. The groups from Moscow and Omsk were comparable in mean age, while in the Volga region group, the mean age was significantly higher ($p<0,05$). At the same time, no significant differences were found between the groups in sex composition (Table 1). The men/women ratio in Moscow was 50/50%, in Omsk — 38,5/61,5%, and in the Volga region — 41,3/58,7%. An analysis of marital status showed that the majority of Muscovites are married (90,5%), while in Omsk and the Volga region, married people accounted for 66% and 62%, respectively. In the last two groups, the number of widowers/widows was 18,7% and 27,2%, while there were 2-3 times fewer people divorced.

In the analyzed groups, the level of higher education was comparable as follows: 33,3%, 44% and 37%, respectively. Before the pandemic, every second of the cohort worked as usual. Half of Muscovites switched to a remote regimen, in the Volga region one in five was transferred to a remote working regime, while in Omsk one person ended up working remotely. The status of temporary unemployment was indicated by 21% from Omsk and 29% from the Volga region. Only one person lost his job (Volga region) during quarantine.

One of the main objectives of this study was to analyze the changes of behavioral RFs during quarantine, which included the status of smoking, alcohol intake, physical activity and malnutrition. According to the multicenter European study, the closure of fitness centers, swimming pools and other wellness centers, as well as sedentary lifestyles and dietary disorders have negatively affected the condition of patients with NCDs, especially in older people. The authors emphasize that COVID-19 restrictions influenced the concentration of vitamin D, a low level of which is associated with some NCDs [7].

According to the survey, before quarantine, 18% (n=4), 6,5% (n=6) and 13% (n=12) of patients from the Moscow, Omsk, and Volga region groups, respectively, smoked. An increase in smoking frequency was reported by 1 patient from the first group and 4 patients from the Volga region. The changes were not significant (Table 2).

Before quarantine, every second patient from the first group reported drinking alcohol, while in the Omsk and Volga region groups, this parameter was 73,6% and 33%, respectively ($p<0,0001$). During quarantine, an increase in alcohol consumption was practically not detected; in all three groups, patients reported no changes or a decrease in alcohol intake. Alcohol abuse is considered as one of the negative factors affecting the outcome of COVID-19 complications [13].

Analysis of physical activity dynamics shows that during quarantine, its intensity decreased in every third Muscovite, and in groups of patients from Omsk and the Volga region, this changes was 45% and 43%, respectively. The difference between groups was not significant.

An increase in meal frequency and malnutrition during quarantine and self-isolation was noted in the groups of patients with NCDs from Moscow and Omsk (18,2% and 18,7% of cases, respectively), while in the group from the Volga region, these changes turned out to be 2 times more common (42,4%). The difference between the last two groups was significant ($p=0,001$).

In groups of patients, changes in body weight averaged up to 1 kg (-0,76 kg in Moscow, +0,97 kg in the Volga region). Sex analysis showed that during quarantine the body weight of Moscow females decreased by an average of 2 kg, and in the Volga region, increased by 1 kg. The differences between the groups were significant ($p=0,024$). Among men, there was an increase in body weight in all groups

Table 3

Assessment of the clinical condition of patients with NCDs during quarantine

Parameters	Moscow, n=22 (10,7%)	Omsk, n=91 (44,4%)	Volga region, n=92 (44,9%)
Hypertension	19 (86,4%)	61 (67%)	78 (84,8%)
Crises during self-isolation	1 (4,5%)	21 (23,1%)	31 (33,7%)
Dosage regimen increased during self-isolation	0	1 (1,6%)	29 (37,2%)
Angina	7 (31,8%)	20 (22,2%)	41 (44,6%)
Deterioration of angina clinical course	1 (14,3%)	1 (5,3%)	4 (14,8%)
Type 2 diabetes	4 (18,2%)	22 (24,2%)	24 (26,1%)
Treatment of diabetes, dosage regimen increased during self-isolation	0	0	7 (30,4%)
COPD	0	3 (3,3%)	13 (14,1%)
Dosage regimen increased		0	2 (16,7%)
Cancer	3 (13,6%)	5 (5,5%)	3 (3,3%)

Abbreviation: COPD — chronic obstructive pulmonary disease.

on average from 0,5 to 1 kg, therefore, significant differences were not revealed.

Experts note that during the pandemic in the context of limited care for NCD patients, the incidence of crises and emergency conditions increased, which was reflected in elective treatment increase [14, 15].

According to the data in Table 3, among the included patients with NCDs, hypertension took the main place as follows: Moscow — 86,4%, Volga region — 84,8%, Omsk — 67% (p<0,02 compared to Moscow). Hypertensive crises during a pandemic were noted in all three subgroups, but their greatest number was recorded in the Volga region — in every third patient (p<0,05 compared to Moscow), the Omsk group — in every fourth patient, while among Muscovites — no more than 5%. In addition, 37,2% (p<0,001 compared with other groups) of hypertensive patients from the Volga region increased antihypertensives' doses taken. In the remaining subgroups, no significant changes were observed in therapy regimen. Exertional angina ranked second among NCDs in the examined group of patients as follows: Volga region — 45% (p<0,007 compared to Omsk), Moscow — every third (31,8%), Omsk — every fifth (22,2%). Deterioration of the clinical course of angina was noted in 15% of cases, while the smallest number was recorded in Omsk patients (5,3%) — 3 times less than in other subgroups. Type 2 diabetes was registered in every fourth patient as follows: Moscow — 18,2%, Omsk — 24,2%, Volga region — 26,1%, respectively. Omsk patients noted a change in the amount and regimen of glucose-lowering therapy — 30% increased the dose of drugs (p<0,05 compared with the Volga region). The highest incidence of COPD was recorded in the Volga region group — 14,1% (p<0,05 compared to Omsk); 17% of patients in this group noted an increase in drug doses. Cancer was reported by 13,6% of Muscovites, while in the other two groups — by ~5% of patients. Only one patient with cancer reported a deterioration in health.

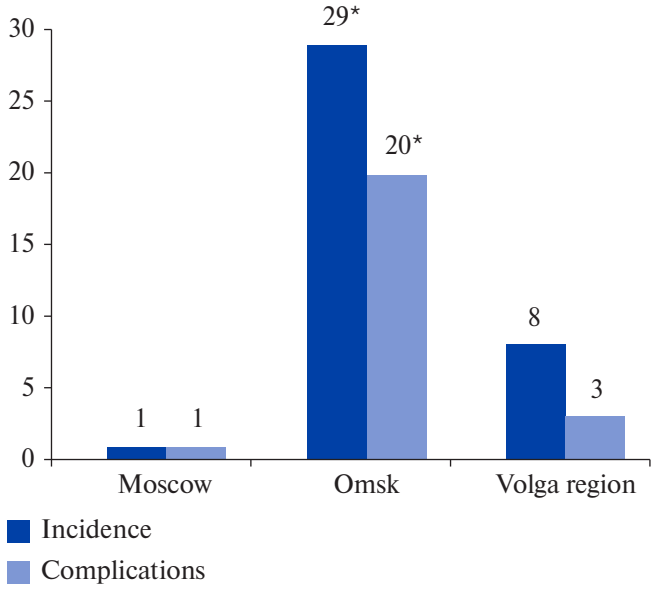

Figure 1. Incidence of COVID-19 and its complications in the Russian cohort with CVDs and other NCDs (absolute numbers).
Note: * — p<0,01 significance of differences between groups in incidence of COVID-19 and complications.

Assessment of health status dynamics in patients with CVDs and other NCDs in quarantine conditions showed that the largest number of patients from the Volga region noted condition worsening over the last year (30,8%), while a similar parameter was found

in every fifth patient from Omsk (19,6%) and 13,6% of Moscow residents.

Among patients with NCDs, 18,5% (n=38) reported COVID-19, of which 63% (n=24) had non-lethal complications (Figure 1). The largest number of patients after COVID-19 was registered in Omsk — 31,9% (p<0,01), while in the Volga region and Moscow, COVID-19 were less common — 8,7% and 4,5%, respectively. In absolute terms, the largest number of complications was noted in Omsk (n=20,69%), while in other groups, the number of complications was less than 3 cases. In this cohort, the incidence of COVID-19 was lower compared to other studies. It is obvious that quarantine measures had a positive effect on the incidence among people with NCDs. Nevertheless, according to Russian studies, the comorbidity of various CVDs and type 2 diabetes was an unfavorable RF, contributing to a lethal outcome [10, 11].

Conclusion

During quarantine and self-isolation, changes in dietary habits and physical activity decline were noted among patients with NCDs, while alcohol consumption and smoking remained practically unchanged. The clinical status of patients worsened, which required a therapy dose adjustment. Obviously, for the management of patients with NCDs, additions to the current clinical guidelines and health care provision should be developed.

Relationships and Activities: none.

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Development of personal competencies of a cardiologist

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The article considers federal educational and professional standards for doctors' training from a practical point of view. In contrast to algorithms, clinical guidelines and protocols for healthcare delivery, competence in the field of informing and communicating with a patient and legal representatives requires the humanitarian skills, that is, a fundamentally different methodological point of view. The ways to develop such skills in a general practitioner or a cardiologist during education are not clear. In many countries, research is being conducted on the need for doctors to master not just patient-centered skills, but specific communication skills for cardiology practice. Certain favorable results are evident, but such work is complicated by a completely different epistemological category of this kind of skills than the generally accepted biomedical one, which is usually called clinical.

Keywords: patient-centered care, medical education, value-based medicine, ethics, deontology, doctor-patient communication, information, adherence.

Relationships and Activities: none.

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The training of a future general practitioner, who has passed the initial accreditation, and then a cardiology resident, requires a young specialist to acquire some competencies. Federal state educational standards prescribe specific universal (UC) and general professional competencies (GPC), while professional standards provide an exhaustive list of labor functions (LF) and actions that must be implemented in educational programs of higher education. In this article, we will consider a number of special skills of a cardiologist, based on our experience in practical health care and teaching experience.

Obviously, in routine practice, a newly-minted doctor is faced not only with biomedical problems (etiology, pathogenesis, diagnosis and treatment of diseases), but also with problems of interaction with patients, their legal representatives, as well as with colleagues and institution authorities. This kind of interaction is an integral part of a doctor's work and requires psychological skills, cultural and ethical competence. These requirements are laid down in educational and professional standards.

The professional standard Cardiologist includes LFs related to informing patients, developing their healthy lifestyle skills, primary or secondary prevention, and health education [1]. These quite specific and brief requirements of the professional standard pose challenges, the implementation of which is essentially different from usual biomedical competencies, such as medical examination, interpretation of diagnostic tests, documentation, prescribing a therapy and monitoring its effectiveness and safety. The difference between these tasks is that the doctor deals with a patient's cultural and psychological features — as a person living in society, having a social circle, plans, dreams, desires, etc. The biomedical component undoubtedly dominates, first of all, due to the specifics of evidence-based healthcare model.

The federal state educational standard of a General Medicine specialist suggests the following UC and GPC [2, 3]:

— ability to analyze and take into account the *cultural* diversity in the context of intercultural interaction (UC-5);

— ability to form an *intolerant attitude* towards corruption (UC-11);

— ability to implement moral and legal standards, ethical and *deontological principles* in professional activities (GPC-1).

Professional competencies are established by an educational organization based on a professional standard. The professional standard was approved by Order of the Ministry of Labor and Social Protection of the Russian Federation of March 21, 2017 № 293n, which includes, among other things, the following labor actions and skills (A.02/7):

— *personalized* patient treatment, including pregnant women, elderly and senile patients, assessment of treatment effectiveness and safety;

— ability to collect complaints, history of a patient and *analyze* the information received;

— knowledge of the regularities of *healthy* body functioning and the mechanisms of ensuring health in the context of the theory of functional systems; features of the regulation of body functional systems in pathological processes.

The above requirements for doctor qualifications indicate the need for future specialists to develop communication skills, ethical subjectivity, ethical decision-making, the ability to analyze the patient's words, and the skills of internal psychological work. And besides, it is important to take into account the goal-setting of health care provision — preservation of health, which raises the question of health concept. Let's take a look at these categories in order.

Health. The concept of positive health goes back to the definition of the World Health Organization and is also contained in Russian legislation. Article 2 of the Federal Law On the Basics of Health Protection of Citizens in the Russian Federation dated November 21, 2011 indicates that health is a state of physical, mental and social well-being of a person, when there are no diseases, as well as organ and body system dysfunction. Obviously, health cannot be defined in terms of denial of pathology or disorders. A positive definition of health assumes full physical adaptation of the body to environment, when its widest possible changes will not significantly violate the body's function. In the same way, you can designate the psychological and social levels. And given the integrity of these levels, their interaction should also be healthy [4].

Ethical decision-making. This category is particularly difficult, since outside the bounds of legal regulation, ambiguous ethical issues require a large amount of data for an optimal solution. Risk and benefit assessment is a classic example of this decision kind, and in addition to biomedical risks, the patient's goal-setting, his attitude to the situation and the risk/benefit understanding are taken into account in the decision-making process. In this sense, for example, antithrombotic therapy is always a compromise between the prevention of thrombosis and an increase of bleeding risk [5]. Ethical burden as such (as opposed to medical risks) appears in this situation, when the result and effectiveness of therapy depends on the patient's adherence, and adherence depends on the patient's attitude to treatment and other recommendations,

on the financial component, as well as on his overall trust in doctors and health care system [6]. This raises the question of full communication.

Communication skills. Requirements for the communicative competence of a doctor are laid down in deontological imperatives, such as a doctor's oath and codes of ethics. The doctor is required to have skills for conflict resolution, motivating to follow recommendations, and increasing adherence to therapy. The doctor must inform the patient and his legal representatives (if necessary) about the legal aspects of health provision, and also answer the questions that are asked. The ability to accept the patient as he is is considered an important skill for the practitioner. And although in general such skills can be taught separately, at a more abstract level all these requirements regard a professional personality.

Internal work skills. In the psychological sense, internal work should be understood primarily as reflection, i.e. the ability to give an account of one's emotional state, its causes, external factors that have influenced and damaged one's own personality. Internal work should be a habit. However, in case of emotional burnout signs of course, a psychologist should be visited. To prevent burnout, it is important to timely reflect on the personal routine problems [7].

The listed basic cultural and psychological competences are generally included in a doctor's qualifications. In cardiology practice, this is of particular importance, since the overwhelming part of cardiovascular diseases refers to the so-called noncommunicable diseases, or rather, to pathology associated with psychosocial risk factors. It is on the outcome of a doctor's interaction with a patient that the picture of situation/disease depends, which determines the motivation of a patient. Training the healthcare professional in the right kind of communication skills is a necessary part of education.

The characteristics of cardiologist training in terms of communication are given the attention of researchers. Gigon F, et al. (2015) address the issue of so-called advance directive — a document that a person can draw up in case he loses the ability to make decisions on his own, which indicates his wishes regarding possible medical interventions. The authors note that few such documents are produced and this could be influenced by a physician working with patients. As a result of studying the questionnaire survey of doctors, the following conclusion is made. In general, doctors have a fairly high level of communication skills, but it drops sharply when it comes to death and related aspects, including the advance directive. The competence of physicians in discussing end-of-life, death, and care during these periods should be enhanced [8]. Another study of complex communication situations in cardiology practice was carried out by Berlacher K, et al. (2017). As a prerequisite, the authors note that in some cases, cardiologists need to make a choice of therapy for severe patients, and this choice should take into account the goals of treatment of the patients themselves. The interviewed doctors (89%) noted that they received training in communication skills, but it was not enough. The authors propose a learning system, called CardioTalk, that would help cardiologists improve their ability to talk to patients about difficult issues. CardioTalk is a two-day master class for physicians held at a major clinical center and includes trainings on the communication difficulties with critically ill people. It is based on the VitalTalk training designed for oncologists, nephrologists and geriatricians [9]. Another study by Cuevas AG, et al. (2019) focused on the impact of patient-centered communication on patient confidence in decision-making. Doctors were asked to watch video sketches, where a physician demonstrating a high or low level of patient centeredness informs a patient with exertional angina and three-vessel involvement about the need for coronary artery bypass grafting. Subsequent questioning of doctors (n=231) found that the distrust in the doctor and healthcare in general negatively affects the result of communication with the patient and decision-making, which subsequently affects the outcomes. The authors note that the actual training of patient-centered communication can be the ways to increase the effectiveness of interaction. Attention should be paid to what the patient is more concerned about, his priorities [10]. Psychological features of cardiology care for cancer patients is considered in study by Lestuzzi C, et al. (2020). The authors note that patients transferred from oncology departments differ from those familiar to cardiologists. Each of the situations (newly diagnosed cancer, side effects of chemotherapy or radiotherapy, etc.) is unique, including from a communicative point of view. The authors offer practical recommendations for the interaction of a cardiologist with a cancer patient [11]. Finally, the study by Svavarsdóttir MH, et al. (2016) focused on the knowledge and skills of health professionals need to educate patients with coronary artery disease. The authors assumed that additional skills beyond medical knowledge are required to effectively educate newly diagnosed patients. Interviews were conducted with cardiologists, nurses and physiotherapists, and the following presentation was obtained. An advanced theoretical and clinical knowledge is needed along with high-quality communication skills to effectively educate a patient. In particular, the clinician needs to be able to establish interpersonal relationships

with patients, to understand their need for specific knowledge, to facilitate effective dialogue and to provide personalized health education. In general, it was noted that communicative and pedagogical skills are needed, which patients do not have [12].

Conclusion

The above studies, along with the presented arguments, raise very specific questions for higher education institutions and clinical facilities involved in cardiologist training. By themselves, communication skills can be conditionally divided into two levels: more practical, instrumental, and more general, holistic. Instrumental skills training is possible in the form of trainings and master classes, which are popular today. On a more general level, training as such poses rather great difficulties, since knowledge or training is not enough to create an integral and full-fledged personality. The aforementioned ability of internal work is required, as well as the ability to draw messages from culture that will help to comprehend the difficult events. In the development of such competence, one can rely on literature, cinema and other types of art, as well as on deontological authorities, i.e. doctors who occupy an important place in medicine culture.

Relationships and Activities: none.

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Communicative competence of a cardiologist: ethical and psychological analysis

Schneider Ya. E., Pavlova E. K., Seleznev E. A., Belova M. V., Zaitsev N. V.

The article problematizes the issue behind the standard categories of psychosocial factors, informing a patient about disease, prognosis, treatment methods, etc. The issue of a doctor's role in interaction with a patient. Although psychological research methods are actively used in cardiology practice, and their results are quite transparent and demonstrate the specifics of patients experiencing the disease, affective states, soping skills, there are still questions about a physician not as a biomedical expert, but as a helping specialist. And although deontological imperatives require quite clear personal qualities from a doctor, the very realization of these qualities should be based on psychological approaches and cultural-psychological categories. As such, the way a doctor interacts with a patient can be described in terms of virtue ethics, which is an integral category that describes personal characteristics. Such characteristics, being implemented directly in clinical communication, could become a universal "recipe" for meaningful cooperation.

Keywords: risk factors, noncommunicable diseases, ethics, deontology, doctor-patient relationship, virtue ethics, person-centered approach, value-based healthcare.

Relationships and Activities: none.

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Clinical medicine involves the interaction of two individuals, one of whom is a helper, while the second — one who needs help. The intensive development of medical science has made the biological disease substrate a priority. Working with a social person, one's experience of the disease faded into the background [1]. The advantages of biomedical approach are that it is based on natural scientific methods, which means that it provides certainty, predictability, verifiability and guarantees. The disadvantages of biomedical methods are overcome by increasing the sample and achieving a sufficient number of observations. It is also convenient from the standpoint of health care systems, whose task is to implement state guarantees. To give guarantees, you need to have verified tools for their implementation [2].

But in the definition of health, which was given by the World Health Organization and included in the Russian legislation, psychological and social well-being are also indicated along with physical health. This division should be considered conditional, since the psychological level of a person's structure is the physiology of his higher nervous activity, connecting the somatic and social components [3]. Interdisciplinary studies of psychosomatics, as well as the general idea of psychosocial risk factors, demonstrate almost the higher importance of cultural components in the development of noncommunicable diseases, in particular, cardiovascular pathology. Practical medicine, therefore, cannot exclude these factors from its field of vision. The difficulty of working with them lies in the fact that, unlike natural science, cultural factors cannot be counted and recorded. They are mobile, individual, context-dependent and are studied by humanitarian sciences. They require different fundamental skills from a health professional than biomedical ones. And although from the point of view of epidemiology and medical psychology, a deep understanding of the structure of psychosocial risk factors, their interrelationships and influence on specific pathological processes has been achieved, the question remains about the direct implementation of this knowledge in work with a specific patient [3].

It is obvious that in practice, despite the presence of many auxiliary tools (scales, protocols, algorithms), the main thing is the direct communication between doctor and patient. Its tasks include not only collecting history and informing about the diagnosis, but also a wide range of other issues. So, a doctor should inform a patient *about the goals, methods of care provision, the associated risk, possible options for intervention, its consequences, as well as about the expected results of care*. Together, this is part of the disease performance, and in the time perspective, it is part of illness narrative [4]. It is quite obvious that in addition to the aspects required by law, such communication has a clear goal — to provide a coping with the disease. Taking into account the whole range of approaches to prevention, treatment and rehabilitation in atherosclerotic cardiovascular diseases, objective, transparent, meaningful knowledge of the patient about his condition is not only constitutional right, but also a psychosomatic tool. A well-formed picture of the disease will further increase adherence to the doctor's prescriptions, contribute to lifestyle modification, and, in addition, relieve frustration caused by misunderstanding. From the point of view of patient-centered medicine, the patient is an *expert* in himself, while the doctor is an expert in the biomedical part of problem [5].

All of the above poses the question of what are the requirements for a doctor personality and how clinical communication should be built in order to implement both legal and deontological imperatives. A similar *issue* was considered in a number of studies on acute coronary syndrome and myocardial infarction (Semiokhina A.S. et al. (2017), Airapetyan M.A. et al. (2017)) [6, 7]. The first study included 100 patients (mean age, 63 years) with ST segment elevation myocardial infarction and incomplete myocardial revascularization. The groups were divided depending on revascularization strategy. The analysis found that in patients with delayed intervention, compared with those not received revascularization, the quality of life was significantly higher. This study, in addition to the biomedical aspects itself, raises following questions for clinical interaction: how a doctor should discuss a strategy with a patient, how to formulate risks and expected results, what position does the doctor take. The second work regarded non-ST-segment elevation acute coronary syndrome in 51 females (mean age, 50,5 years) and 50 males (mean age, 46,7 years). The groups differed depending on following outcomes: unstable angina or myocardial infarction. It was shown that the quality-of-life features can be distinguished both by sex and by the outcome. In particular, the following components of negative coping can be noted: "loss of meaning in life" — 4% of men and 7% of women; loss of interest in hobbies or activities — 22% and 13%, respectively. Taratukhin E.O. et al. (2017) used the so-called in-depth person-centered interview, surveying young men with the first myocardial infarction during hospitalization. A number of unspoken, but as a rule, unconscious components of experiencing a disease situation were identified as follows: serious life change; anxiety and fear of sudden death and repeat

Table 1

Categories of communication of a helping specialist (adapted from K. Rogers)

Skill	Description	Application
Empathy	Epistemic empathy, i.e. the process of perceiving the patient's inner world, taking into account the subtle shades of non-verbal communication, as well as the doctor's verbalization of the perceived information about a patient (emotions, feelings, motives, meanings, needs, etc.)	The ability to inform more adequately, to reveal hidden difficulties, joint decision-making, improvement of interaction, a more complete awareness by a patient of one's role in the disease and treatment
Non-judgment	Unconditional positive regard, i.e. absence of condemnation and other negative assessment, respect for the individuality of a patient and faith in one's capabilities. The conviction that everyone has an unconditional value, regardless of their behavior, state or feelings. A specialist enables patients to be themselves, in their manifestations, since it is a patient in this case who is a sick and suffering subject	Creating a healthy, comfortable psychological environment (a prerequisite for using empathy)
Congruence	Personal psychological work of a doctor, one's ability not to be sensitive to negative statements about yourself, as well as sincerity and correspondence of the internal picture of situation to what one speaks about it	More effective interaction due to the use of the doctor's psychological resource, promotes trust
Contact	The patient's trust in a doctor, a request for help — in this case, a psychological request for help in coping with the situation	Direct action of doctor's recommendations

of the event; discourage and confusion; puzzlement; disorientation in symptoms, misunderstanding; loss of perspective for better in life; stigmatization; self-image changes; feelings of guilt and resentment [8]. These data generally coincide with international and Russian studies [9, 10].

The results of three studies, obtained at the regional vascular center in Moscow (O. M. Filatov City Clinical Hospital № 15), are representative of some psychosocial and sociocultural aspects of a doctor's work. Being devoted to the assessment of psychological factors in the context of somatic noncommunicable disease, these studies raise the question of communicative skills of a doctor.

By itself, a patient-centered care implies the patient's direct participation in all decisions concerning one's management [11]. But the notorious question of patient incompetence in biomedical matters, lack of medical experience and experience of the disease (with the exception of patients with chronic disease, for example, asthma or diabetes) casts doubt on the usefulness this approach. The solution may be the special communicative competence of a doctor who is able to regard those parties of the patient's request that really play a key role both in coping and in providing sufficient adherence, in signing informed consents for treatment in general and for specific interventions.

The concept of *virtue ethics*, which was formulated in ancient Greek philosophy, stands somewhat apart from other metaethical theories (consequentialism, deontology, emotivism), because, unlike them, it refers not to decision-making methodology, but to the qualities of a person himself, making these decisions. The idea of such a holistic, fully functioning personality passes through culture, and of course, it makes up a significant part of usual deontological imperative — "requirements" for the doctor personality. The characteristics of a helper given by the American psychotherapist K. Rogers are very close to virtue ethics [12]. The situation of help, primarily psychotherapeutic, imposes the necessary and sufficient requirements as follows: empathy, unconditional positive regard and non-judgment, congruence, as well as psychological contact as such (Table 1). It should be added that empathy itself is studied by philosophers as a virtue, i.e. a special personality trait, and not just a skill [13]. Empathy allows you to implement the communicative mechanism of empathic listening. In addition, the situation of psychological help imposes "requirements" on a patient — the ability to contact with another person and to be able to perceive positive regard and empathy addressed to him.

If we combine all the categories mentioned above, namely the biomedical problem, psychosocial factors, a patient's coping with illness, the role of a doctor as a helper, then the clinical aspects of virtue ethics and psychology become obvious. Undoubtedly, it would be rather bold and unrealistic to impose *such* requirements on a doctor personality within the state guarantees and the health care system. Nevertheless, the qualities of deontological authorities illustrate and fill the indicated communicative and personal characteristics.

There are not many attempts to study this view in cardiology practice. In general, an attempt to "ethically measure" the cardiology practice was in

1990 (Parmley WW, et al. (1990)) within a working group on the study of general principles of ethics in cardiovascular medicine [14]. Noteworthy is the publication by de Hoyos A, et al. (2013), where the authors studied ethical deliberations in cardiology. The specialty was chosen due to the severity of conditions and the difficult moral choice of doctors, which requires reassessment of value-based medicine categories. The authors conclude on a number of communicative competencies and empathy that would contribute to building a more stable doctor-patient relationship and improve prognosis, treatment efficiency, and patient adherence [15]. Cook T, et al. (2015) pointed out that respect for patient autonomy is a medical virtue. The authors noted that in clinical practice, it is necessary not only to apply the interaction principles, which makes it possible to adequately sign informed consent, to make informed decisions, but it is necessary to introduce virtue within traditional Aristotelian ethics. This is achieved by educating the individual, including directly during work in the clinic [16].

Conclusion

Modern clinical "bedside" interactions with a patient vary widely: starting with the legal component and ending with the need to take into account the existential questions of a patient. The concept of P4 medicine, i.e. predictive, preventative, personalized, participatory [17], also forces one to seek the most complete interaction within the clinical situation. The demand for a special doctor-patient communication is obviously present in society, and it is necessary to look for rational solutions how to satisfy it. The combination of philosophical anthropology doctrine of virtue with the psychological concept of the helper personality, as has already been shown in empirical research, can be the solution that is required from health care systems.

Relationships and Activities: none.

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Informed consent to medical intervention: the figure and role of a doctor

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Informed consent reflects a patient's right to decide whether to receive or refuse medical intervention. Ideally, the patient receives all the necessary information from a physician and, consciously, allows the treatment or refuses it. However, in routine practice, a doctor may influence the patient's decision: both because of professional knowledge, and because of the very fact that a patient seeks medical help. It follows from this that voluntary basis of a patient's consent can hardly be absolute, since a doctor often influences his decision to a greater or lesser degree. The article proposes criteria for assessing the admissibility of doctor's influence on a patient when deciding whether to sign informed consent to medical intervention or to refuse it, using the example of cardiac surgery.

Keywords: informed consent, bioethics, medical law, autonomy, doctor's power, discursive power, doctor-patient communication, health care delivery.

Relationships and Activities: none.

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The concept of voluntary informed consent (VIC) to health care and medical intervention is at the heart of the ethical and legal side of working with a patient. The signing of VIC, from the ethics point of view, is an affirmation of respect for the dignity of the individual, the prohibition of any inhuman treatment. From the legal point of view, VIC ensures the legal purity of health service provision, giving a patient an understanding of what he will face, and for a doctor and medical institution — verifying this understanding. Legal practice shows that correct VIC is a tool to protect the interests of the institution and medical workers. However, it is important to understand that behind the formal, legal and ethical aspects lies a psychological or communicative problem, which goes back to a more complex idea of the patient as a person. In terms of *informing*, VIC is included in the so-called narrative of the disease — the patient's idea of his condition and the fact of interaction with the health care system [1]. Clinical practice raises questions about whether a patient can fully consciously sign a consent and be *truly* informed. Thereby, paternalism in the doctor-patient relationship is abolished. Practical cardiology and, in particular, cardiac surgery have their own specifics, which means it also has features of communication with patients, their perception of those questions that require an answer from an ethical and legal point of view.

In accordance with the Constitution of the Russian Federation and universally recognized international norms, people are equal, have free will and the right to personal inviolability (Article 22). It follows from this that the doctor, despite his superior knowledge and understanding of patient conditions, has no right to dispose of his body. Even if the very fact of health service provision presupposes the doctor dominant, this does not mean objectification — transformation of a client or patient into an object. Therefore, medical intervention is possible only with the consent of a patient. This is closely related to human *dignity*, the right to protection of which is described in Article 21 of the Constitution of the Russian Federation. It is in this article that there is a direct prohibition on conducting medical experiments without VIC.

Requirements for patient consent to intervention

In order to meet the requirements from the aforementioned personal rights, consent to medical intervention must be voluntary. After all, "consent" given under pressure (for example, under pressure from a doctor authority) or under indirect coercion (for example, emotionally colored description of disease development) is not, in fact, consent. It is difficult to call the expression of will, since it reflects not will of a person, but the will of the one who exerts pressure. But in order to be able to give truly voluntary consent, a patient without medical knowledge must receive information from a doctor necessary for making a decision [2]. Therefore, medical legislation calls the patient consent necessary for the intervention informed and voluntary. Specifying the requirements for VIC, Article 20 of the Federal Law On Fundamentals of Healthcare of Citizens in the Russian Federation establishes that a consent must be received using information from health worker about the goals, methods of health provision, the associated risk, consequences and expected outcomes. Each aspect should be considered separately.

Preliminary. Preliminary of consent means that a patient must make and express decision *before* the intervention. Potentially questionable here are cases when previously unknown pathologies are detected during the intervention: it is clear that a patient could not give consent to eliminate such pathologies, because did not know about them. In elective cardiac surgery, such cases are rather an exception, because a thorough examination is carried out before such operations. However, if we talk about the surgery of defects, aneurysms and tumors, and even more so in emergency surgery, the scope of the intervention may turn out to be more extensive. In this regard, when fixing the fact of giving a patient informed voluntary consent to cardiac surgery, it is necessary to explain the procedure for doctors' actions when previously unknown pathologies are detected or, in general, the need to change the scope and tactics of intervention. At the same time, from a medical point of view, such a change can be both part of the initial treatment strategy and the result of a change in strategy due to new data.

Voluntariness. Voluntariness implies the absence of pressure on a patient when deciding whether to consent or refuse medical intervention. This aspect is described in the Oviedo Convention [3] as follows: "the person shall not be subjected to unreasonable pressure or influence. To an individual who is in a vulnerable position, even the slightest pressure can be enough to make them feel they are being forced into giving consent against their will" and "pressure involves influencing an individual to agree to something they would not agree to under normal (non-pressure) circumstances".

Of course, the above formulations are rather formal: any patient is in a vulnerable position due to his illness and lack of medical knowledge. The doctor motivates a patient, suggesting ways of treatment. In healthcare practice, this cannot be avoided. A more correct criterion for distinguishing between impermissible and permissible influences is the presence or absence of a direct connection of

a patient's illness with the doctor's motivation and arguments given in favor of the intervention. The weaker the connection between these arguments and illness, the more unfounded the pressure may be. If, for example, a doctor truthfully tells a patient that if the operation is refused, the disease will threaten life, then there is a direct connection. If a doctor is motivated not by concern for a patient's health, but, for example, by his own career, and even more so by finances, then there is clearly no direct connection. If a doctor is concerned about the health of a doubting patient and tries to convince, for example, by appealing to the patient's responsibility to his relatives (for example, "because of illness you will not be able to help your elderly parents"), then such a case could be considered as borderline and leave its qualifications to the courts. But in this case, it is noteworthy that the doctor's point of view is based on knowledge and experience but not on the patient's experience of life. Therefore, the balance between these types of pressure is not easy to maintain, and this requires a high level of communicative competence [4].

Informedness. In cardiac surgery, the aspect of consent informedness is problematic, because it is difficult for a patient without medical knowledge to have a vision of cardiovascular processes, the consequences of influencing it or refusing to intervene. A patient will not *directly* experience the beneficial result of the intervention, while, for example, the words of an otorhinolaryngologist that "the nose will be blocked" or "the ear will stop hurting" give a patient the opportunity to sensually assess the benefits of intervention and compare it with the risks. Even the anticipated result in the form of stopping angina attacks or getting rid of shortness of breath is an indirect clinical result of surgeon actions, and for which, in fact, a patient agrees. Informing in cardiac surgery occurs at the theoretical level. It is far from always that a doctor can use concepts that do not require additional clarification. And if so, then a patient is forced in many respects to take on trust and to submit to doctor's professional authority when deciding whether to agree or disagree with the intervention. As can be seen, in cardiac surgery, the concept of VIC Infor-medness is closely related to the concept of voluntariness. This imposes a duty on a doctor to pay more attention to the availability of explanations and the patient's perception of the information received.

To record the fact of giving consent, it is signed by a patient or, in certain cases, by a legal representative. Here it should be borne in mind that cardiovascular patients may have cognitive or affective disorders. In general, the somatic status creates the basis for psychosocial function [5]. Therefore, a thorough fixation of receiving VIC is especially important in view of possible legal proceedings, since can serve as evidence used in the future to resolve disputes.

Thus, based on the key regulatory legal acts, based on ethical imperatives, a number of questions arise about the concept and procedure for giving VIC. The key ones are as follows: 1) influence on the patient's decision and the communicative role of a medical worker who obtains consent; 2) amount of information and understanding by a patient of actual situation; 3) psychosomatic status of a patient related to the situation of care and information about disease [6]. Answering these questions, one should turn to the concept of *doctor's power* [7].

Doctor power as a factor in medical intervention

Clinical medicine combines biomedical practice with interaction between two following subjects: a doctor and a patient. In order to understand the logic of the legal aspects of VIC, it is worth establishing th e relationship of subjects that provoke a specific (legal) need to record the interaction between a doctor and a patient. If we present a relationship model in the form of a case with details that can be decoded, then in addition to the legal aspects of VIC, the prospect of related problems will arise.

Both a doctor and a patient are people, individuals: social, legal, ethical subjects. Doctor-patient communication is in a special context and carries the characteristics of helping professions*. Considering the figure of a doctor from the legal point of view, it is obvious that a doctor is endowed with professional duties, belongs to the medical community and is responsible for his activities according to Federal Law. There is a formal understanding *that* a doctor can do and what he should not allow in professional practice. Nevertheless, the personality of a doctor has its own philosophy and motives, an individual attitude to the profession and patients' specifics within a particular disease group. So that a doctor-personality and doctor-professional do not contradict each other in the context of medicine, there are deontological and legal standards.

Since it is impossible to program behavior in advance, the standardizing of interactions (formulation of legal rules) will be dynamic and multifactorial even if legal restrictions on actions are concretized and sanctions are articulated. The development of human sciences serves as a catalyst for experiments with various interdisciplinary concepts

* The profession of a doctor as a concept has an ethical trait of virtue, while the nature of this component can be considered separately from a psychological point of view, for example, within the framework of the phenomenon of pathological care.

of doctor-patient interaction, where the legal aspect serves as a line in the sand, and where it serves as a trigger for the bureaucratic process, compliance with which, in turn, makes it possible to distance from situations dangerous from the legal point of view and their consequences. Thus, the receipt by a doctor of medical worker status nominally neutralizes the very possibility of a criminal motive or intent, but at the same time endows a doctor with an inalienable professional privilege — discursive power [8]. The *natural* doctor-patient relationship at its core an inherent feature that distinguishes it from other types of social ties, including commercialized, which determines the rate of their interaction. This feature is *vital needs* from a patient. A patient, not having competence in cardiac surgery, deliberately delegates decision-making to a doctor, while remaining a person, an ethical and legal entity, like a doctor.

Thus, an essential problem is felt in the relationship model — *discursive power of a doctor borders on the patient's subjectivity*. In some situations, a patient loses subjectivity for physiological reasons. And this problem is solved by the concept of a legal representative and a patient centeredness, which incorporates legal and bioethical aspects, providing for situations of force majeure and the impossibility of making a decision by a patient as a person. The dignity and duty of a doctor is implied a priori in relation to the patient's care. This social-medical-legal model is the implementation of the patient's tacit need for qualified care. One way or another, a patient does not compete with a doctor, but interacts with him within a medical culture that has been forming for more than one thousand years.

VIC in the above context is a *consequence of the patient's request* (patient's right to qualified health care), the implementation of decision already made by a patient and the formal result of visiting a doctor — recording this fact. VIC also serves as a horizontal bureaucratic standard — a kind of recording a doctor-patient interaction to protect against sanctions.

Conclusion

The potentially insoluble complexity of the doctor-patient relationship, requiring in practice fairly unambiguous decisions and legal assessment, can be mitigated by a building of communication around the fact of health care. This is especially important in modern medicine, when scientific analysis of the "side" effects of non-medical actions or psychosomatic effects of communication is possible. When receiving a VIC, before an intervention, in particular, cardiac surgery, it is imperative to discuss options for action if previously unknown pathologies are detected. The motivation and arguments of a doctor should be as closely related to the disease as possible. In this case, special attention should be paid to the patient's understanding of the doctor's explanations, and the generalized task of interaction should be the formation of a constructive attitude of a patient to the disease situation. Consent or refusal must be carefully recorded.

Relationships and Activities: none.

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New opportunities for biomarkers in cardiovascular risk stratification. Resolution of Advisory board

Drapkina O. M., Kontsevaya A. V. on behalf of the working group[#]

Early detection of people with a high-risk of developing cardiovascular diseases is a key point of the prevention strategy. The existing risk scales have a number of limitations: insufficient accuracy for an individual or the appearance of a "residual risk". Existing approaches to improving the accuracy of risk prediction include the use of biomarkers. Troponin I is promising, which has proven its prognostic value in healthy and asymptomatic individuals at the population level. For example, the BiomarCARE study with the participation of 74 thousand people from 5 countries showed an association of increased troponin I concentration and the frequency of cardiovascular events and overall mortality. Similar results were obtained in other cohorts. The simulation results indicate the potential economic feasibility of using troponin I for the purpose of risk stratification. The first pilot Russian study was conducted, which made it possible to describe the population distribution of troponin levels. It confirmed the prognostic significance of the biomarker in relation to the development of cardiovascular outcomes in men in the Russian population. Further studies on large cohorts are needed to clarify the results of the pilot project.

Keywords: cardiovascular diseases, biomarkers, troponin I, cardiovascular risk, risk stratification.

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CI — confidence interval, MI — myocardial infarction, CVD — cardiovascular diseases, CVR — cardiovascular risk, RF — risk factor, ESSE-RF — Epidemiology of cardiovascular diseases and their risk factors in the regions of the Russian Federation, cTn — cardiac troponin, hs-Tn — highly sensitive troponin, Tn — troponin.

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Despite significant advances in modern medicine and increased life expectancy, cardiovascular disease (CVD) remains the leading cause of death worldwide. A large number of studies demonstrate the role of primary prevention in reducing the burden of CVDs and increasing the length of "healthy life". Primary prevention includes population-based prevention, the main task of which is to promote a healthy lifestyle at the level of the population of a country, region or municipality through a range of measures based on intersectoral interaction, and individual prevention at the health care system level. Individual prevention is based on two basic fundamental actions: accurate cardiovascular risk (CVR) stratification and optimal interventions with proven effect, which include nonmedicamental correction of risk factors (RF) and drug therapy [1, 2].

One of the main tasks of individual primary prevention is the early detection of persons with high CVR. Prediction tools are risk scales and risk stratification tables, which typically include traditional CVD RFs such as hypertension, diabetes mellitus, smoking and hypercholesterolemia, and are intended for use in conditionally healthy individuals. Examples of such scales are the Framingham Scale [3], SCORE (Systematic Coronal Risk Evaluation) [4], Q2-Risk [5], etc. In 2021, a new SCORE2 scale was published, which includes not only fatal cardiovascular events but also nonfatal complications [6]. The SCORE2 scale includes the same RFs as the basic SCORE scale, except for cholesterol: total cholesterol has been replaced by non-lipo high-density cholesterol. The SCORE2 scale is built on new data and will certainly stratify risk more accurately than the previous version, but is unlikely to solve all risk stratification problems. Risk scales predict risk for the population as a whole, but are not always accurate enough for the individual. For example, the American study showed that acute coronary syndrome developed in 74,9% of those with low CVR (<10% on the Framingham Risk Score) and in 12,7% of those with intermediate risk (10-20%) [7].

There is a concept of so-called "residual risk" due to other RFs and expressed in the development of cardiovascular events in individuals who reach the target RF parameters, such as lipids, in clinical trials [8]. The presumed mechanisms of residual risk can be inflammatory, thrombotic and metabolic [9]. For each mechanism, biomarkers such as C-reactive protein for inflammation are sought.

A number of specific cardiovascular markers, including cardiovascular troponins (Tn), are associated with the risk of cardiovascular events and may contribute to more accurate risk stratification [10, 11]. Cardiovascular Tn are structural proteins that are found mainly in myofibrils and cardiomyocytes. Three types of Tn are detected in myocardium: TnI, TnT and TnC. While the latter is also found in skeletal muscle, the first two TnI and TnT are specific for cardiomyocytes. Today, new technologies allow accurate measurement of low concentrations of circulating Tn, which can directly reflect various pathophysiological processes, including apoptosis and cardiomyocyte necrosis [12].

The use of biomarkers, such as Tn, for CVR stratification has been actively discussed recently [13]. TnI meets the basic requirements for biomarkers and is detected in the majority of asymptomatic and healthy individuals. The requirements for a biomarker applicable as a screening tool, which meets TnI, are: cardiospecificity, predictive value, change depending on CVR level, level dynamics against the background of interventions, evidence-based value, cost-effectiveness [11].

The possibility of highly sensitive methods for determining low concentrations of cardiac Tn (cTn) in the population and in asymptomatic individuals allowed to hypothesize that this biomarker can be considered as a component of CVR assessment, capable of clarifying its level and becoming an element of personalized medicine.

TnI: connection with cardiovascular outcomes

Large studies in the general population have demonstrated an association of cTnI levels with the development of adverse cardiovascular events. Thus, the largest BiomarCaRE study, which involved >74 thousand participants from 5 countries (follow-up period is 13,8 years), showed that individuals from the fifth quintile (the highest levels) of TnI compared to individuals from the first quintile, the risk of death from cardiovascular events was 160% higher, the risk of the first cardiovascular event was 92% higher, and the risk of overall mortality was 63% higher [14].

In studies (HUNT, n=9005, follow-up is 13,9 years), TnI levels were associated with the risk of fatal and nonfatal cardiovascular events [15], including cardiovascular death, myocardial infarction (MI) and hospitalization for heart failure.

The Scottish WOSCOP study with 3 thousand participants and the use of statins (pravastatin) showed that baseline Tn levels were an independent predictor of MI development or death from cardiovascular causes. Treatment of patients with elevated levels of low-density lipoproteins with pravastatin was accompanied by a 13% decrease in the level of highly sensitive TnI (hs-TnI) during the year [16].

In the PEGASUS-TIMI study, TnI levels were used to reclassify risk and determine treatment tactics in very high-risk patients [17]. Among the 8635

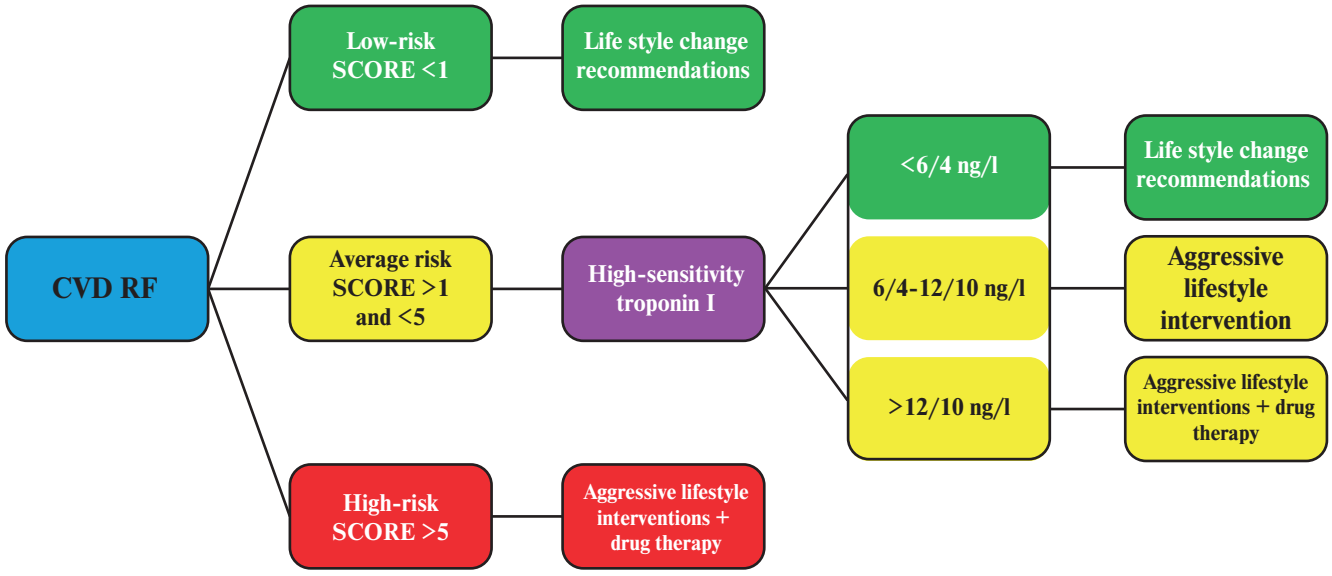

Figure 1. The proposed strategy of CVR stratification for the population as a whole, based on the established RF and tools with the addition of hs-TnI (adapted from [11]).
Abbreviations: CVD — cardiovascular diseases, RF — risk factor.

patients in this cohort study, patients with low-risk atherosclerotic coronary artery lesions and hs-TnI levels greater than 6 ng/l had the same incidence of cardiovascular events as patients classified as very high-risk patients with atherosclerotic coronary artery lesions. Similarly, in patients with very high-risk atherosclerotic lesions and undetectable hs-TnI levels, the event rate was comparable to that in patients classified as lower-risk coronary atherosclerotic patients. Tn allowed 11,9% of patients to be reclassified into a more appropriate risk group (1 of 11 patients at very high risk and 1 of 4 at low risk).

A meta-analysis of 28 cohort studies confirmed the association between hs-TnI and risk of cardiovascular complications. Those with the highest tercile of TnI levels had a risk of CVD 1,43 (95% confidence interval (CI) 1,31-1,56), CVD death 1,67 (95% CI 1,50-1,86), coronary heart disease 1,59 (95% CI 1,38-1,83), and stroke 1,35 (95% CI 1,23-1,48) compared with the lowest [18].

TnI. Economic arguments for risk stratification

In terms of health economics, a secondary analysis of BiomarCaRE [19] among 47796 people over 10 years showed that adding hs-TnI to ESC-SCORE would result in a 48 percent relative reduction in CVD, as measured by the prevention of 17 cardiovascular events (MI/stroke), 6 fatal cases and 107 saved years per 1000 people surveyed.

Cost-effectiveness modeling of TnI was performed to estimate CVR in the general population in countries with low CVR (Germany) and high CVR (Kazakhstan) [20]. Screening and effective prevention would reduce cardiovascular events by 5,1 and 5,0 per 1 thousand people over 10 years in Kazakhstan and Germany. In Kazakhstan, this strategy resulted in cost savings because the incremental cost of conducting a risk assessment using TnI was lower than the cost savings to the health care system and the economic effect through averted deaths. In Germany, this strategy turned out to be economically reasonable, as the cost per year of preserved quality of life was $6755, well below the "willingness-to-pay" threshold for that country ($27 thousand).

Pilot Russian study of the predictive role of TnI

In the Russian Federation, together with Abbott Diagnostics, a study was conducted to assess the significance of a number of biomarkers in predicting the risk of cardiovascular outcomes in men and women of productive age. The study included two stages:

— assessment of TnI level in population sample of one of the regions of the Russian Federation, formed and examined as part of the ESSE-RF study (Epidemiology of cardiovascular diseases and their risk factors in the regions of the Russian Federation), and analysis of association of Tn levels with the probability of adverse cardiovascular events during 6 years of prospective follow-up in this region;

— case-control study with cardiovascular endpoints based on data from the prospective part of the ESSE-RF study.

The first stage results of the study have been partially published [21]. The asymmetric distribution of cTnl in a sample of the Vologda region population is shown. The median cTnl level in the sample was 1,5 pg/ml (95% CI 0,80-2,50), a high Tn level was detected in men aged 45-54 years. Young men have higher Tn levels than women of the same age group. However, women's cTnl grows faster with age, at 5,9% per year, while men's cTnl grows only 2,6%. The difference in the cTnl level in men and women is leveled by the age of 72. According to the multivariate model, age, obesity, arterial hypertension, elevated levels of low-density lipoprotein cholesterol and brain natriuretic peptide were significantly associated with Tn levels. A comparison of the Tnl levels recommended for risk stratification with the SCORE risk levels revealed the following. In 25% of men and 37% of women with elevated cTnl levels, the SCORE risk was low to moderate, suggesting that the SCORE scale is not accurate enough for this population and that risk could be reclassified based on Tn levels.

Part of the results of the first stage will be published in a paper that is currently in print [22]. Men showed a tendency to reclassify intermediate risk when the number of hard cardiovascular endpoints (death from CVD and nonfatal MI) was higher in individuals with elevated Tnl levels. In assessing risk reclassification using the Cox model with $NRI_{survival}$ for survival analysis, the cTnl in the model is shown to significantly improve the risk classification of hard endpoints in men. When comparing the probability of combined endpoint (death from CVD, MI, acute cerebrovascular accident, coronary revascularization), a significant difference between three quintiles with low values and two quintiles with high levels of Tnl was obtained.

Thus, the results of the first pilot study indicate that the accuracy of SCORE risk determination in the Russian population was insufficient, and part of the sample should be reclassified. This refers to men who showed a significant increase in the likelihood of developing both severe and combined endpoints in the moderate, high, and very high-risk SCORE groups as cTnl levels increased. In addition, the probability of developing a cardiovascular event occurred at lower Tn levels compared with cutoff points of European studies. For our population, the upper quartile corresponds to the cTnl level 3,5/2,1 pg/ml, in which a connection with cardiovascular endpoints was revealed. No such association was detected in women, which may be due to the relatively short follow-up period and, consequently, the low frequency of endpoint development in women of working age. The study limitations (short follow-up period and small number of endpoints among those of working age) still allowed to obtain reliable results about the association of Tn level with the probability of cardiovascular complications, which, however, are preliminary and require refinement on a larger volume of participants in population-based studies.

The second stage of the case-control study includes an assessment of predictive significance of hs-Tnl levels in individuals with cardiovascular outcomes compared with a comparable control group, including comparison with other cardiovascular biomarkers. The resultant article has been submitted to an international journal and is in the peer-review stage. The study included 111 cases (48 cardiovascular deaths and 63 MIs, which were recorded during 6,5 years of follow-up in 8 regions of the ESSE-RF1 study) and 111 controls (individuals of comparable sex, age, region of residence, and a number of FRs who had no cardiovascular event). Tnl, cortisol, lipoprotein a, adiponectin, leptin, endo-1, interleukin-6, galectin, PCSK9, Ang ptl3 and total nitric oxide (NOx) metabolites were included in the analysis.

Elevated levels of Tnl, C-reactive protein, and nitric oxide metabolites were significantly ($P<0,001$) and independently associated with a high risk of death from cardiovascular causes.

Prospects for risk stratification

Based on the largest BiomarCaRE study, a risk stratification strategy using TnI was developed (Figure 1). TnI is important for reclassification of the average risk level according to the SCORE scale (1-4%). In determining Tn levels, there are 3 categories with gender-specific features: Tn levels <6 (in men) and 4 (in women) ng/l are reclassified as low risk and lifestyle changes are recommended for these individuals; average troponin levels of 6/4-12/10 ng/l require aggressive lifestyle changes; high levels (>12/10 ng/l) allow reclassification as high risk and are grounds for prescription of drug therapy.

The results of the first domestic TnI pilot study at the population level suggest that the risk thresholds for Tn in the Russian population may be lower than in the European population. In addition, significant associations were obtained for men, whereas no association was demonstrated for women due to the small number of cardiovascular outcomes.

The Republic of Kazakhstan plans to create a cardiovascular registry with a 10-year follow-up of middle-aged people without previously known cardiovascular disease. The main objectives of this registry are: assessment of the hs-TnI risk stratification model and implementation of hs-TnI in all health checks (screening) in the country. The register plans to use the following hs-TnI risk stratification model:

Low risk — women <4 pg/ml, men <6 pg/ml;
Average risk — women 4-10 pg/ml, men 6-12 pg/ml;
High risk — women >10 pg/ml, men >12 pg/ml.

Conclusion

One of the foundations of primary prevention of CVDs is accurate risk stratification. Risk scales are constantly being improved, but nevertheless all existing scales have limited ability to accurately stratify risk at the individual level. One way to improve the accuracy of risk stratification is to supplement the scales with biomarkers that have the ability to predict CVRs. One of these biomarkers is TnI. A significant body of data has accumulated that this biomarker is associated with the risk of cardiovascular events and meets other requirements for predictive biomarkers. The first pilot Russian study was conducted to describe the population distribution of Tn levels and to confirm the predictive significance of this biomarker with regard to the development of cardiovascular outcomes in men. Further studies on large cohorts are needed to refine the pilot project results.

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