

Russian Scientific Medical Society of Internal Medicine
Session «Adherence to Treatment»



**THE FIRST RUSSIAN CONSENSUS ON
THE QUANTITATIVE ASSESSMENT OF THE
ADHERENCE TO TREATMENT**

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THE FIRST RUSSIAN CONSENSUS ON THE QUANTITATIVE ASSESSMENT OF THE ADHERENCE TO TREATMENT

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INTRODUCTION

The Consensus on the quantitative assessment of the adherence to treatment in clinical practice and working out the most effective strategies of treatment for the patients needing a long-term or permanent treatment, has been developed for the first time. The Consensus creation has been preceded by the elaboration of the approximate practical recommendations for doctors (2016) and the Protocol of quantitative assessment of the adherence to treatment in clinical medicine (2016).

The preparation of present document and its publishing motivated by the increasing role of adherence to treatment in the therapy of patients with the chronic internal diseases and provided for the last 10 years advent of accessible and applicable in medical practice instruments which allow quantitative research of the adherence to treatment.

The essential factors shaping the demand for the quantitative assessment of the adherence to treatment are:

- stated by the Russian Ministry of Healthcare task to create a National patient-oriented system of health protection as a basis for the Strategy of healthcare development in Russia for the period up to 2025;

- implementation of the Unified state informational system in the sphere of healthcare which includes the creation of the multi-functional automated workstation for doctors, giving the opportunity to access modern highly effective systems and applications;

- formation of the cluster of the innovation-centered medical science development and healthcare for the creation and import of new medical technologies;

- steadily increasing demand of the national healthcare for automated systems supporting medical decisions in cases of a responsible choice, primarily, such necessities as the prescription of an expensive long-term treatment or medicines with a narrow therapeutic range, also, the necessity of the prescription of medicines with the high risk of dangerous interactions and medicines with the "withdrawal syndrome".

The Consensus is based on the following principles:

(I) Justification of the Consensus provision based on adequately completed researches which were detected during the comprehensive analysis of the literature;

(II) Priority of the data of the randomized controlled trials (RCT), multilevel circular trials (CT) in the medical practice and meta-analysis of similar trials taking into account the results of observational and other trials if they are of a proper scientific quality;

(III) Indication of the grades of recommendations (GD) and the levels of scientific evidence (LE) on the mainly discussed issues (*tables 1 and 2*), providing the interested reader with a standardized basis for comparing the state of scientific knowledge in different medical spheres, and drawing doctors' attention to the provisions based on data with high evidentiary, not only on the experts' opinions;

(IV) To facilitate the use of Consensus in everyday practice, the focus is mainly on the presentation of the material in the form of tables containing sets of statements and recommendations which doctors could easily and quickly refer to.

The evidence base of the Consensus is based on the publications included in the Cochrane Library, EMBASE, MEDLINE, and ELIBRARY databases. The period of researching equals to at least 25 years. Meta-analysis, systematic reviews, recommendations and consensuses of the medical societies, data of RCTs and CTs were included into the analyzed base. During the selection of publications as potential sources of evidence, the methodology used in each study was assessed, taking its validity into account.

Table 1

Classification of recommendations

CLASSES OF RECOMMENDATIONS	DEFINITION	THE PROPOSED WORDING
I class	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective	Recommended
Ila class	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure. Weight of evidence/opinion is in favour of usefulness/efficacy	Should be considered
IIb class	Conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of the given treatment or procedure. Usefulness/efficacy is less well established by evidence/opinion	May be considered
III class	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may do harmful	Not recommended

Table 2

Levels of evidence

LEVELS OF EVIDENCE	CRITERIA
Evidence Level A	Data derived from multiple randomized clinical trials
Evidence Level B	Data derived from a single randomized trial or nonrandomized studies
Evidence Level C	Consensus opinion of experts

Key definitions

Adherence to treatment is a comprehensive model of the patient's health behaviour which is implemented as the matching rates of such behaviour regarding the recommendations received from the doctor, taking medicines, following the diet and other changes of lifestyle.

Adherence to drug therapy is an ability of a patient to follow medical recommendations regarding medication for an uncertain period of time.

Adherence to medical support is an ability of a patient to follow medical recommendations regarding periodical medical supervision and health self-monitoring for an uncertain period of time.

Adherence to lifestyle modification is an ability of a patient to follow medical recommendations regarding the diet and physical activity modification and the limitation or rejection of undesirable habits for an uncertain period of time.

Integrated adherence to treatment in an average (taking into account the ratio of each controlled parameter in the calculation formula) indicator characterizing a patient's ability to follow medical recommendations regarding the drug therapy modification, medical support, and lifestyle modification.

Quantitative assessment of adherence is a way of study in which the adherence is quantified in the nominal scale and expressed as a percentage of the estimated maximum.

The level of adherence is a clustering a common feature based on given quantitative indicators of the adherence and, therefore, allows to include a patient in a group with a similar prognosis of medical interventions and to whom may be applied the treatment management model that is the same for all members of this group and which is the most effective in comparison to other groups.

Adherence sufficiency is the relevance between the identified level of adherence for a particular patient and anticipated effectiveness or safety of a particular medical intervention.

List of abbreviations and notation keys

QAA-25	– questionnaire of the quantitative assessment of the adherence, N. A. Nikolaev, YU. P. Skirdenko.
CR	– class of recommendations
RCT	– randomized controlled trial
RSMSP	– Russian scientific medical society of physicians
LE	– level of evidence
C	– adherence to treatment
C_c	– adherence to lifestyle changes
C_d	– adherence to drug therapy
C_m	– adherence to medical support
G_c	– willingness for lifestyle changes
G_d	– willingness for drug therapy
G_m	– willingness for medical support
M_c	– importance of lifestyle changes
M_d	– importance of drug therapy
M_m	– importance of medical support
WHO	– World Health Organization

TECHNOLOGICAL MODULE

Consolidated statements and toolkit

The adherence to the treatment is usually understood as a degree of the relevance between the patient's behaviour and the recommendations received from the doctor, regarding taking drugs, following the diet and other measures of lifestyle changes.

Adherence to treatment of patients suffering from chronic diseases is one of the most important factors ensuring the quality of therapy and directly influencing the prognosis. The most significant consolidated statements and agreements, which are characterized by the highest classes and evidentiary levels, are presented in *Table 3*.

Table 3

Consolidated statements regarding the adherence to treatment

CONSOLIDATED STATEMENTS (CONSENSUSES)	CR, LE
Absolute adherence to treatment which is stable during a long or an indefinite period of time, in which the patient accurately follows all medical recommendations, is registered only in specific RCTs and CTs, and is not typical for the real medical practice	I, A
Long-term adherence to any kind of treatment is low regardless of the disease, and in most cases does not exceed 50% of theoretically possible adherence	I, A
For most patients, the adherence to treatment or to the implementation of the specific medical recommendations declines over the time	I, A
Non-compliance (insufficient compliance) of medical recommendations by patients suffering from chronic diseases is a global problem	I, A
Low (insufficient) adherence to treatment has dangerous and serious consequences and is an independent factor worsening the prognosis	I, A
Special educational programmes aimed at increasing adherence to treatment have little or no effect	I, A
General adherence to treatment and its specific components can be forecasted with a sufficient degree of precision, based on an ever-expanding list of predictors and assessment tools and measurement of the adherence	I, A

One of the main methods of the assessment of the adherence (direct question; counting drugs; measurement of drug concentration or their metabolites in the human liquids; monitoring of visits and interventions, electronic monitoring; using of remote control systems, questionnaires) and the best on the ratio of labour effort to efficiency is questionnaire.

In medical practice, where questionnaires are preferable, allowing to investigate the adherence quantitatively and which are applied commonly for the patients with different diseases, have the ability of automated input and data processing. Consequently, the Russian questionnaire of the quantitative assessment of the adherence to treatment QAA-25 has been recommended by the Consensus as a tool which is implemented as a computer programme "The system of the forecasting of the adherence to permanent drug therapy" (reg. № 2015617159 RF) and its computer and network applications.

Questionnaires for the quantitative assessment of the adherence to treatment can be performed either in an automated or manual mode.

Questionnaire in manual mode

The questionnaire made on paper is filled by the respondents themselves or with the help of an interviewer. The questionnaire is a form that includes 25 questions with answer options. For each question included in the questionnaire the respondents choose the most appropriate answer in their view from a closed list of answers.

Two variants of the questionnaire are applied: to quantify the adherence to treatment of patients with chronic diseases ("Appendix 1") and to quantify the potential adherence to treatment of patients without diseases and/or those who are unaware of them, or those who are

without clinical signs and symptoms *Table 4*). The questionnaires differ in the wording of some questions with an equal number of questions and answer options.

The questionnaire form is filled in sequentially, from the 1st to 25th question.

For the questions 1, 6, 7, 10, 11, 12 there are following answer options: "absolutely unimportant", "almost unimportant", "rather unimportant than important", "rather important than unimportant", "quite important", "very important".

For the questions 2, 3, 4, 5, 8, 9, 13, 14, 15 there are following answer options: "Very difficult", "quite difficult", "rather difficult than easy", "rather easy than difficult", "almost easy", "absolutely easy".

For the questions 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 there are following answer options: "I won't do it for sure", "I'd rather do", "More likely that I won't do than I will", "More likely that I will do than I won't", "Almost certainly I will", "I will certainly do it".

There is only one possible answer for each question of the questionnaire.

After filling in the questionnaire, the result is processed with calculation formulas in a manual mode or using an automated calculator disconnected from the Internet.

Table 4

QUESTIONS		ANSWER OPTIONS
1. You have been diagnosed with a chronic disease by the doctor. Is it important for you to know what signs and symptoms it has? (If the doctor diagnoses you with a chronic disease, will it be important for you to know its signs and symptoms?)	1	Absolutely unimportant
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important
2. The doctor has prescribed you a medicine that you have to take every day for many years. How difficult is it for you to implement this recommendation? (If the doctor prescribes you a medicine that you have to take every day for many years, how difficult will it be for you to implement this recommendation?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
3. The doctor has prescribed you a medicine that you have to take several times a day for many years. How difficult is it for you to implement this recommendation? (If the doctor prescribes you a medicine which you have to take several times a day for many years, how difficult will it be for you to implement this recommendation?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
4. The doctor has prescribed you several medicines which you have to take every day for many years. How difficult is it for you to implement this recommendation? (If the doctor prescribes you several medicines which you have to take every day for many years, how difficult will it be for you to implement this recommendation?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
5. The doctor has suggested marking the signs and symptoms of the disease every day for many years. How difficult is it for you to implement this recommendation? (. If the doctor asks you to mark the signs and symptoms of the disease every day for many years, how difficult will it be for you to follow this recommendation?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
6. A chronic disease has its signs and symptoms. How important is it for you not to feel these symptoms? (A chronic disease has its signs and symptoms. How important is it for you not to feel these symptoms if you get sick?)	1	Absolutely unimportant
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important



7. If you have sex life, how important is it for you to keep it at the usual level? (If you have sex life, how important is it for you to keep it at the usual level?)	1	Absolutely unimportant/it is not present
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important
8. A chronic disease forces you to change the habitual lifestyle. How difficult is this change for you? (A chronic disease can force you to change the habitual lifestyle. How difficult will this change be for you?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
9. A chronic disease forces to change the habitual diet. How difficult is this change for you? (A chronic disease can force you to change the habitual diet. How difficult will this change be for you?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
10. A chronic disease can cause disabilities. How important is it for you to get or confirm a disability group? (A chronic disease can cause disabilities. How important will it be for you to get or confirm a disability group?)	1	Absolutely unimportant
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important
11. A chronic disease can change the work of internal organs and test results. How important is it for you to know the test results? (A chronic disease can change the work of internal organs and test results. How important will it be for you to know the test results?)	1	Absolutely unimportant
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important
12. All people believe or do not believe in God. How important is it for you to believe in God? (All people believe or do not believe in God. How important is it for you to believe in God?)	1	Absolutely unimportant
	2	Almost unimportant
	3	Rather unimportant than important
	4	Rather important than unimportant
	5	Quite important
	6	Very important
13. Results of your chronic disease make you visit the doctor regularly. How difficult is such a medical supervision for you? (A chronic disease makes you visit the doctor regularly. How difficult will such a medical supervision be for you?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
14. Taking medicines can cause discomfort. How difficult will this discomfort be for you to bear? (Taking medicines can cause discomfort. How difficult will this discomfort be for you?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
15. A chronic disease can limit your habitual life, active leisure and entertainment. How difficult is it for you to accept such limitations? (A chronic disease can limit habitual life, active leisure and entertainment. How difficult is it for you to accept such limitations?)	1	Very difficult
	2	Quite difficult
	3	Rather difficult than easy
	4	Rather easy than difficult
	5	Almost easy
	6	Absolutely easy
16. The doctor has prescribed you a medicine that you have to take every day for many years. Will you accurately implement this recommendation? (If the doctor prescribes you a medicine	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will



which you have to take every day for many years, will you always implement this recommendation accurately?)	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
17. The doctor has prescribed you a medicine that you have to take several times a day for many years. Will you accurately implement this recommendation? (If the doctor prescribes you a medicine which you have to take several times a day for many years, will you always implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
18. The doctor has prescribed you several medicines which you have to take every day for many years. Will you accurately implement this recommendation? (If the doctor prescribes you several medicines which you have to take every day for many years, will you always implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
19. The doctor has suggested marking the signs and symptoms of the disease every day for many years. Will you accurately implement this recommendation? (If the doctor asks you to mark the signs and symptoms of the disease every day for many years, will you always implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
20. The doctor has said that the prescribed medicines can cause discomfort, including that which you already have. Will you take such medicines? (If the doctor tells you that the prescribed medicines can cause discomfort, will you take these medicines?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
21. The doctor has said that the prescribed drugs can worsen your sex life. Will you take such medicines after that? (If the doctor tells you that the prescribed medicines can worsen sexual life, will you take these medicines?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
22. The doctor has said that due to the disease you have to change your habitual lifestyle. Will you accurately implement this recommendation? (If the doctor tells you that due to the disease you need to change your habitual lifestyle, will you implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
23. The doctor has said that due to the disease you have to change your habitual diet. Will you accurately implement this recommendation? (If the doctor tells you that due to the disease you need to change your habitual diet, will you implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
24. The doctor has said that due to the disease you should regularly visit the doctor. Will you accurately implement this recommendation? (If the doctor tells you that due to the disease you need to visit the doctor regularly, will you implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it
25. The doctor has said that due to the disease you should regularly have lab tests. Will you accurately implement this recommendation? (If the doctor tells you that due to the disease you need to have lab tests regularly, will you implement this recommendation accurately?)	1	I won't do it for sure
	2	I'd rather do it
	3	More likely that I won't do, than I will
	4	More likely that I will do, than I won't
	5	Almost certainly I will
	6	I will certainly do it

The questionnaire in automated mode

For automated questioning respondents (themselves or with the help of an interviewer) using a personal computer, a laptop, a smartphone, or any other electronic system providing access to the Internet, enters the site with the questionnaire (www.prognoz-med.ru) and activates the application "Adherence to treatment", where they fill in the questionnaire, sequentially entering the information into the working fields and answering the questions.

After filling in the electronic questionnaire the result is processed automatically and issued as a report with recommendations in PDF format, which can be saved by the user as an electronic document or printed out.

The questionnaire results processing

The questionnaire results can be processed either in an automated or manual mode. For each question, there are 6 options of answers which are evaluated in points. The number of points corresponding to each answer option is given in *Table 5*.

Table 5

Scoring the answers

POINTS	ANSWERS FOR THE QUESTIONS		
	1, 6, 7, 10, 11, 12	2, 3, 4, 5, 8, 9, 13, 14, 15	16, 17, 18, 19, 20, 21, 22, 23, 24, 25
1	Absolutely unimportant	Very difficult	I won't do it for sure
2	Almost unimportant	Quite difficult	I'd rather do
3	Rather unimportant than important	Rather difficult than easy	More likely that I won't do, than I will
4	Rather important than unimportant	Rather easy than difficult	More likely that I will do, than I won't
5	Quite important	Almost easy	Almost certainly I will
6	Very important	Absolutely easy	I will certainly do it

The results are processed in two stages. At the first stage, the technical indicators are calculated: "the importance of drug therapy", "the importance of medical support", "the importance of lifestyle modification" and "willingness for drug therapy", "willingness for medical support", "willingness for lifestyle modification".

Each technical indicator is a simple sum of points received after answering the corresponding questions (*Table 6*), thus the minimum possible value for each technical indicator is 5 points, and maximum possible value is 30 points.

At the second stage, the indicators of the adherence are calculated: "adherence to drug therapy", "adherence to medical support", "adherence to lifestyle modification" and their integral indicator: "adherence to treatment" (*Table 7*).

Each of mentioned above indicators is a value calculated for the particular respondent and expressed as a percentage of the theoretically possible value and regarded as 100%.

For all indicators of the adherence, a level of values in the range up to 50% is interpreted as "low", from 51% to 75% as "medium", more than 75% as "high". The interpretation of levels of adherence is presented in *Table 8*.

Table 6

Technical indicators

INDICATOR	NOTATION KEY	QUESTION NUMBERS (SCORE ON THE QUESTIONS)
Importance of drug therapy	M _d	2, 3, 4, 6, 14
Importance of medical support	M _m	1, 5, 10, 11, 13
Importance of lifestyle modification	M _c	7, 8, 9, 12, 15
Willingness for drug therapy	G _d	16, 17, 18, 20, 21
Willingness for medical support	G _m	16, 19, 20, 24, 25
Willingness for lifestyle modification	G _c	19, 22, 23, 24, 25

Table 7

Calculation of the adherence

INDICATOR	Calculation of the indicator
Adherence to drug therapy	$C_d = 1 \div \frac{(30 \div M_d) \times (60 \div G_d)}{2} \times 100$ <p>where: C_d - adherence to drug therapy, %; M_d - importance of drug therapy, points; G_d - willingness for drug therapy, points</p>
Adherence to medical support	$C_m = 1 \div \frac{(30 \div M_m) \times (60 \div G_m)}{2} \times 100$ <p>where: C_m - adherence to medical support, %; M_m - importance of medical support, points; G_m - willingness for medical support, points</p>
Adherence to lifestyle modification	$C_c = 1 \div \frac{(30 \div M_c) \times (60 \div G_c)}{2} \times 100$ <p>where: C_c - adherence to lifestyle modification, %; M_c - importance of lifestyle modification, points; G_c - willingness for lifestyle modification, points</p>
Adherence to treatment	$C = \frac{C_m + 2C_c + 3C_d}{6}$ <p>where: C - adherence to treatment, %; C_m - adherence to medical support, %; C_c - adherence to lifestyle changes, %; C_d - adherence to drug therapy, %.</p>

Table 8

Levels of adherence

LEVEL OF ADHERENCE	INDICATOR VALUE	FORECAST OF THE INTERVENTIONS EFFECTIVENESS	CR, LE
High	76% and more	Medical recommendations and based on them actions will be done or almost certainly will be done by the patients	I, B
Medium	51-75%	medical recommendations and based on them actions more likely will be done, than won't by the patients	I, B
Low	50% or less	medical recommendations and based on them actions will not be done or almost certainly won't be done by the patients	I, B

CLINICAL MODULE

Medical strategies and interventions effectiveness

Managing the treatment, regarding the identified levels of adherence for a particular patient, is aimed to achieve the maximum possible result of medical interventions for each level of adherence. The basic medical strategies elaborated in the studies which are of sufficient level of evidence on the criteria of this Consensus, and for which the full or predominant agreement of the experts have been reached, are presented in *Tables 9-11*.

Table 9

Medical strategies taking into account the level of the adherence to drug therapy

LEVEL	HEALTH STRATEGY	CR, LE
High	Medicines can be prescribed as fixed-dose or non-fixed-dose combinations, or in their combination; the quantity of drugs does not significantly affect the patient's willingness for treatment	I, B
	Taking medicines regularly up to three times a day inclusively does not significantly reduce the patient's willingness for treatment	I, B
Medium	Medicines can be prescribed as fixed-dose or non-fixed-dose combinations; prescribing three or more medicines at once significantly reduces the patient's willingness for treatment	I, B
	Taking medicines regularly more than two times a day significantly reduces the patient's willingness for taking them	I, B
Low	Medicines should be prescribed as a drug or a fixed combination of drugs; one-time prescribing of several drugs significantly reduces the patient's willingness to take them	I, B
	The ability to take medicines regularly one or more times a day is doubtful; the recommendation to take medicines regularly two or more times a day is ineffective	I, B
	There is a high risk of developing undesirable effects when taking medicines which require long-term titration of doses and (or) possessing "ricochet syndrome" ("withdrawal syndrome")	IIa, B

Table 10

Health strategies considering the level of the adherence to medical support

LEVEL	HEALTH STRATEGY	CR, LE
High	Programme of medical support should be based on the optimal frequency of planned (and also preventive) visits, including laboratory tests and instrumental examinations.	I, B
	Recommendations on the patient's self-monitoring and registration of the health condition or its certain parameters are effective	I, B
Medium	Programme of medical support should be based on the minimum possible frequency of planned office visits, limiting the number of the performed examinations	Ila, B
	Recommendations to the patient's self-monitoring of the health condition or its certain parameters are moderately effective or have little effect	Ila, B
Low	Basis of the medical support programme should be "on-demand" visits connected with changes of disease symptoms; preventive visits or scheduled examination visits are less likely to be implemented or will not be implemented at all	Ila, B
	Recommendations on the patient's self-monitoring of the health condition or its particular parameters have little effect or no effect	Ila, B

Table 11

Medical strategies considering the level of the adherence to lifestyle modification

LEVEL	HEALTH STRATEGY	CR, LE
High	Recommendations on limiting or rejecting undesirable habits (including smoking, alcohol consumption, excessive food consumption, etc.) can be wide-ranging and detailed	Ila, B
	Recommendations on correction of habitual diet (including modification of periodicity and structure of nutrition, refusal or reduction of consumption of definite products, etc.) and physical activity schedule (types, frequency, amount) can cover all aspects of the patient's health	Ila, B
Medium	Recommendations on limitation of undesirable habits should be specific and brief; recommendations on complete rejection of such habits are less likely to be implemented or will not be implemented at all	Ila, B
	Recommendations on correction of habitual diet, and also on kinds, frequency and amount of the physical activity should be presented in the form of specific brief information; these recommendations should first of all refer to the leading disease	Ila, B
Low	Recommendations on limitation of undesirable habits are reasonable to present as a limited list of solutions and actions which are the most important in reducing life-threatening risks; full or partial rejection of undesirable habits is unlikely or impossible	Ila, B
	Recommendations on diet correction and physical activity should be specific and very brief; general recommendations on correction of habitual diet and physical activity are ineffective	Ila, B

The identified adherence is used to forecast the effectiveness of specific interventions. For this purpose, the obtained data of the respondent's adherence are compared to the ranges of values corresponding to the relevant levels of adherence (high, medium, or low). If the value of the identified adherence indicator falls within the values range of the corresponding level, this indicates the forecast variant of the intervention effectiveness which is the most likely for all values within such a range. This does not exclude that in some cases the individual characteristics of a particular respondent or other unforeseen external influences may affect the actual effectiveness of interventions due to that they may be more or less effective than it is forecast.

For each level of adherence, the most probable forecast of the effectiveness of the specific intervention is presented as the following symbols:

«+» - intervention will be implemented completely or invasion is more likely to be implemented completely than implemented partially or not implemented;

«+/-» - intervention is more likely to be implemented partially than completely or invasion is more likely to be implemented partially than not implemented;

«-» - intervention is more likely not to be implemented partially or completely, or invasion will not be implemented at all.

Based on the quantitative assessment of the adherence the most likely results of interventions are described in *Tables 12-14.*, approximate recommendations are given in *Tables 15-17.*

Table 12

The expected effectiveness of specific interventions depending on the adherence level to drug therapy

INTERVENTION	LEVEL OF ADHERENCE		
	HIGH	MEDIUM	LOW
Taking one medicine once a day	+	+	+/-
Taking one medicine twice a day	+	+/-	-
Taking one medicine three times a day or more often	+	-	-
Taking two medicines separately once a day	+	+/-	-
Taking two medicines separately 2 times a day	+	+/-	-
Taking two medicines separately three times a day or more often	+	-	-
Taking three or more medicines separately once a day	+	-	-
Taking three or more medicines separately two times a day	+	-	-
Taking three or more medicines separately three times a day or more often	+/-	-	-

Table 13

The expected effectiveness of specific interventions depending on the adherence level to medical support

INTERVENTION	LEVEL OF ADHERENCE		
	HIGH	MEDIUM	LOW
Visiting the doctor "on demand" without obligatory visits; regular health self-monitoring is not required	+	+	+
Visiting the doctor "on demand" with obligatory visits more than once in 3 months; regular health self-monitoring is not required	+	+	-
Visiting the doctor "on demand", with obligatory visits more than once a month; regular health self-monitoring is not required	+	+	-
Visiting the doctor "on demand" without obligatory visits; regular health self-monitoring is recommended	+	+/-	-
Visiting the doctor "on demand" with obligatory visits more than once in 3 months; regular health self-monitoring is recommended	+	-	-
Visiting the doctor "on demand", with obligatory visits more than once a month; regular health self-monitoring is recommended	+	-	-

Table 14

The expected effectiveness of specific interventions depending on the adherence level to lifestyle modification

INTERVENTION	LEVEL OF ADHERENCE		
	HIGH	MEDIUM	LOW
Correction of habitual diet or physical activity, limitation or rejection of undesirable habits is not required	+	+	-
Correction of habitual diet and physical activity, limitation or rejection of undesirable habits is not required	+	+/-	-
Correction of habitual diet or physical activity, limitation of undesirable habits is required	+	-	-
Correction of habitual diet and physical activity, limitation of undesirable habits is required	+	-	-
Correction of habitual diet or physical activity, rejection of undesirable habits is required	+	-	-
Correction of habitual diet or physical activity, rejection of undesirable habits is required	+/-	-	-

Table 15

**Approximate recommendations for patients
 depending on the identified adherence level to drug therapy**

LEVEL	RECOMMENDATIONS FOR PATIENTS
High	<p>In most cases of chronic diseases, taking medicines permanently is required. All medicines can be divided into preventive that do not let the disease worsen or prevent its complications (for example, aspirin doesn't let blood clots form) and curative, which fight the disease (for example, insulin helps to assimilate sugar when having diabetes). For the effective treatment you need to take both kinds of medicines and you are ready for it. Following the recommendations of the doctors, you usually accurately follow their recommendations on taking medicines. If you have several diseases for which you receive treatment, inform each of the doctors whom you consult, because when having different diseases sometimes similar medicines are applied, and taking them simultaneously can worsen the state of health.</p>
Medium	<p>In most cases of chronic diseases, taking medicines permanently is required. All medicines can be divided into preventive that do not let the disease worsen or prevent its complications (for example, aspirin doesn't let blood clots form) and curative, which fight the disease (for example, insulin helps to assimilate sugar when having diabetes). For the effective treatment you need to take both kinds of medicines, however, you are not always ready for it. Having consulted the doctors, talk to them which medicines are vital for you, and taking which medicines must not ever be interrupted. If you forget to take medicines regularly or you do not always have such an opportunity, warn your doctors about it and talk to them to choose the medications which you can take only once or at least twice a day. If you have several diseases for which you receive treatment, inform each of the doctors whom you consult, because when having different diseases sometimes similar medicines are applied, and taking them simultaneously can worsen the state of health.</p>
Low	<p>In most cases of chronic diseases, taking medicines permanently is required. All medicines can be divided into preventive that do not let the disease worsen or prevent its complications (for example, aspirin doesn't let blood clots form) and curative, which fight the disease (for example, insulin helps to assimilate sugar when having diabetes). Despite the fact that you do not like to take medicines, you have to do it. Therefore, having consulted the doctors, talk to them which medicines are vital for you, and taking which medicines must not ever be interrupted. If you forget to take medicines regularly, or you do not always have such an opportunity, be sure to warn your doctors about it and ask them to choose the medications which you can take only once a day. If you have several diseases for which you receive treatment, inform each of the doctors whom you consult, because when having different diseases sometimes similar medicines are applied, and taking them simultaneously can worsen the state of health.</p>

Table 16

**Approximate recommendations for patients
 depending on the identified adherence level to medical support**

LEVEL	RECOMMENDATIONS FOR PATIENTS
High	<p>Serious chronic diseases require medical supervision and support, and you are absolutely ready for it. In most cases of such diseases you need to have regular laboratory tests, instrumental examinations and visit doctors. However, the patients can take care of their health themselves and you can do it. If necessary, you can control the level of blood sugar, cholesterol and other things yourself. Talk to your doctor what kinds of laboratory tests you need to do and how often, what indicators should be taken into account, and what changes should be a sign for you to consult the doctor. Coordinate with your doctor an approximate plan and timing of the necessary instrumental examinations. When visiting a doctor, take the results of the laboratory test and instrumental examinations, including those which are made by recommendations of other specialists.</p>
Medium	<p>Serious chronic diseases require medical supervision and support, and you are more or less ready for it. When having such diseases, it is necessary to have regular laboratory tests, instrumental examinations and visit doctors, however, if you are very busy, you can take care of your health yourself. To do this, talk to your doctor, what laboratory tests and instrumental examinations you should do and how often, and what changes should be a sign to consult the doctor immediately. Talk to the doctor which examinations (for example, blood pressure measurement, blood sugar test and others) you can do yourself - it will prevent you from additional visits to the doctor. When visiting a doctor, take the results of the laboratory tests and instrumental examinations, including those which are made by recommendations of other specialists.</p>
Low	<p>Serious chronic diseases require medical supervision and support with obligatory regular monitoring of laboratory and instrumental indicators and visits to the doctors. Despite the fact that you do not like to do it, you will have to. To simplify this, ask your doctor what laboratory tests and instrumental examinations you need and how often, how and when they should be done, and what changes should be a sign to consult the doctor immediately. Talk to your doctor which examinations (for example, blood pressure measurement, blood sugar test and others) and how often you can do yourself - it will prevent you from additional visits to the doctors. When visiting a doctor, take the results of the laboratory tests and instrumental examinations, including those which are made by recommendations of other specialists.</p>

Table 17

**Approximate recommendations for patients
 depending on the identified level of the adherence to lifestyle modification**

LEVEL	RECOMMENDATIONS FOR PATIENTS
High	<p>You realize that in case of a serious disease you will have to change your habitual lifestyle and you are ready for it. If you visit a doctor due to such a disease, ask him/her to give you detailed recommendations on how to organize the daily routine. Find out which physical activities are healthy in your condition and which are harmful. If your disease requires special exercises or other activities – ask your doctor to tell you about them, try to write them down, and do them in future. If you need to change the habitual diet, find out in details what food and beverages should prevail in the diet, and which ones are better to avoid. If you have overweight, you can normalize or reduce it significantly by following the doctor's recommendations. You are also able to significantly limit or completely reject undesirable habits – smoking or excessive consumption of alcohol (if you have them). In general, it is much easier for you than for many others to regulate your lifestyle in such a way as to live long and well.</p>
Medium	<p>You understand that in case of a serious disease, you will have to change the habitual lifestyle, and you will have to make a significant effort to do this. If you visit a doctor due to such a disease, ask him/her to give you brief and specific recommendations on how to organize the daily routine. Find out which physical activities are healthy in your condition and which are harmful. If your disease requires special exercises or other activities – choose the most important ones to concentrate on them and do them in future. If it is necessary to change your habitual diet, first of all, specify what food and beverages you have to avoid, try to remember them and if possible avoid consumption of this food and beverages. If you have overweight, ask your doctor whether you can reduce it and specify which the most effective ways in your case are. It will be difficult for you to reject undesirable habits - smoking or excessive consumption of alcohol (if you have them), but it is quite possible. If you have such habits, ask your doctor which of them are the most dangerous for you and why, highlight the most important problem and try to cope with it. Despite the fact that you do not really believe in the importance of daily routine and diet, you are able to adjust your lifestyle in such a way as to live long and well.</p>
Low	<p>You know that in case of emergence of a serious disease, you will need to change the habitual lifestyle, and even if you are not willing to do that, you will have to do it. If you visit a doctor due to such a disease, talk to him/her what is essential for you to do in order to stop your disease from progressing. Highlight the most important things in organizing your daily routine. Find out which physical activities are the most harmful and dangerous for you and try to avoid them. If it is necessary to change your habitual diet, first of all, specify what food and beverages you have to avoid, try to remember them and if possible avoid consumption of this food and beverages. If you have overweight, ask your doctor whether you can reduce it and specify what simple ways are the most effective for your disease. It is more likely to be very difficult for you to reject undesirable habits - smoking or excessive consumption of alcohol (if you have them), however, it is possible. In this case talk to your doctor which of these habits are the most dangerous for you and why, highlight the main problem and try to cope with it. Despite the fact that you do not really believe in the importance of daily routine and diet, you are able to make little but significant changes in your lifestyle in such a way as to live long and well.</p>

METHODOLOGY FOR THE CONSENSUS PREPARATION

1. The experts from all the federal districts of the Russian Federation, including President and Vice-Presidents of RSMSP, plenipotentiary representatives of RSMSP in the federal districts, the main specialists of the Ministry of Health of Russia and a number of federal districts, teaching staff and scientific employees of the institutions of the applied higher education, medical practitioners, also system analysts, specialists in programming and artificial intelligence were involved in the creation of the "first Russian consensus on the quantitative assessment of the adherence to treatment".

2. The following objective was defined: the optimization of medical interventions basing on the quantitative assessment of the adherence to treatment.

3. Working group and Committee of experts established.

4. A draft Consensus, structured on a modular basis, has been established. The modules are formed on the basis of provisions corresponding to the highest classes and evidentiary levels accepted for the present Consensus. Technological module: tools and technology for the quantitative assessment of the adherence to treatment. Clinical module: the optimization of medical interventions basing on the quantitative assessment of the adherence to treatment.

5. An Internet application "Adherence to treatment" has been created, which includes an online questionnaire for the quantitative assessment of adherence to treatment with an automated data processing and result formation.

6. The Consensus project and the Internet application are posted on the website: www.prognoz-med.ru

7. Method of Consensus validation: external expert assessment; internal expert assessment. In the preliminary versions, the Consensus was reviewed by the independent experts whose task was, first of all, to assess whether the interpretation of the evidences, underlying the document, was understandable. Also, there were given comments by medical specialists and general practitioners regarding the clarity of the Consensus recommendations and the appreciation of their importance as a working tool in daily practice. The preliminary version was also sent to reviewers who do not have medical education to receive comments regarding the prospects for understanding the Consensus recommendations by patients.

8. The questionnaires containing the basic Consensus aspects have been prepared to gather the expert opinions.

9. Distribution of the questionnaires to the members of the Consensus Committee of Experts. Good practice points (GPPs) indicators: the recommended good practice was based on the individual clinical and professional experience of the members of the Committee of experts.

10. Collecting the questionnaires, analyzing the received data and proofreading of the Consensus text. Amendments and additions which were approved by more than 90% of the experts and did not require further discussion have been made to the draft text. All of the questions which were approved by less than 90% of the experts were sent to the Committee of experts for a decision on their inclusion in the final version of the Consensus.

11. Publication of the final version of the Consensus.

12. Discussion and approval of the Consensus text at the XII National Congress of Physicians 22-24 November 2017 (Moscow).

13. Preparing for publication: full version of the Consensus, short version of the Consensus, algorithms of the Consensus, and full version of the Consensus translated into English (for the scientific translation of the Consensus text an interim working group has been formed consisting of: A.V. Nelidova, N.A. Nikolaev, YU.P. Skirdenko, E.V. Chupriyanova).

14. Publication of the Consensus versions in core journals.



15. Posting the full text of the Consensus and the Internet application "Adherence to treatment" on the RSMSP website.
16. Creation of presentations and reports including the Consensus materials.
17. Inclusion of the aforementioned reports in the programmes of scientific and educational medical activities.
18. Coordination of the Consensus with the head specialist of the Ministry of Health of the Russian Federation.
19. Submission of the Consensus to the Ministry of Health of the Russian Federation for the approval as clinical recommendations.

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