The Scale of Quantitative Assessment Adherence to Treatment «QAA-25»: Updating of Formulations, Constructive and Factor Validity and a Measure of Consent

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Aim: To update the definitions of selected questions of the "QAA-25" (quantitative adherence assessment) scale and evaluate it according to the criteria of validity and measure of agreement.

Materials and Methods. In a descriptive cross-sectional study including 200 patients with coronary heart disease, adherence was determined using traditional and alternative versions of selected questions of the QAA-25 scale, followed by assessment of construct validity, factor validity, and measure of agreement.

Results. Alternative question versions did not significantly affect test results, with 81% of respondents in the outpatient sample and 69% in the inpatient sample rating them as "more acceptable." The QAA-25 scale has good construct and internal validity (α – 0.818, α_{st} – 0.832), with moderate agreement (κ – 0.562) and demonstrates high reliability of internal validity – when scale items are consistently excluded, α values remain in the 0.801-0.839 range.

Conclusion. The QAA-25 scale with modified question definitions should be used instead of the previous version of the scale. Good construct validity and factor validity, sufficient measure of agreement and specificity, high sensitivity and reliability of the QAA-25 scale allow to recommend it as a tool for assessing adherence to drug therapy, medical support, lifestyle modification and integral adherence to treatment in scientific and clinical practice.

Key words: questionnaire, scale, adherence to treatment, validity, measure of consent.

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Introduction

Thirteen years have passed since the first publication for the quantifying adherence to treatment questionnaire QQA-25 [1]. It was created in 2008 to quantify adherence to treatment in patients with cardiovascular pathology [1], quickly demonstrated its versatility, and in 2016 was recommended to quantify adherence to treatment in adult patients with chronic somatic diseases, as well as to assess potential adherence to treatment in healthy respondents [2-4].

In 2017, the questionnaire served as the basis for the First Russian consensus on quantifying adherence to treatment and was approved by the XII National Congress of Physicians [5, 6]. In 2020, seven professional scientific medical associations (Russian Scientific Medical Society of Therapists; Scientific Society of Gastroenterologists of Russia; National Association of Specialists in Thrombosis, Clinical Hemostasiology and Hemorheology; Gerontological Society at the Russian Academy of Sciences; Russian Society of Oncohematologists; Russian Society of Phthisiologists; Society of Evidence-Based Neurology) developed on based on the QQA-25 scale and adopted two interdisciplinary consensus documents - clinical guidelines «Treatment management based on adherence» and clinical guidelines «Treatment management based on adherence: algorithms for recommendations for patients» [7, 8].

In 2020, the National Association of Specialists in the Prevention, Diagnostics and Treatment of HIV Infection included the QQA-25 questionnaire as a tool for assessing adherence to treatment in the clinical guidelines «HIV infection in children» approved by the Russian Ministry of Health [9], and a group of researchers from the State budgetary institution of health care «Research Institute of Emergency Medicine named after N.V. Sklifosovsky in the Moscow Department of Health» studied and recommended its use outside the traditional cohort of patients with chronic somatic diseases, to monitor the adherence level of recipients before and after transplantation [10].

Also, during the use of the QQA-25 scale in scientific research and clinical practice, the authors of the questionnaire and independent experts [11-13] identified several issues that require clarification and interpretation. One of the most pressing issues is the actualization of the wording of several questions for the QQA-25 scale, the content context of which has ceased to adequately correspond to the value public perception that has changed since the questionnaire was created, or turned out to be poorly applicable in certain target groups. The significant expansion in recent years of the demand for the QQA-25 scale in scientific research has generated a request for the publication of relevant data on the main characteristics of the questionnaire as a tool for clinical research practice.

The study aim is to update the wording of selected questions of the «QAA-25» (quantitative adherence assessment) scale and assess it according to the criteria of validity and measure of agreement.

Materials and methods

A descriptive cross-sectional study, the object of which was 200 patients with stable coronary heart disease (CHD), and the study subject was the possibility of modifying the wording of several questions of the QQA-25 scale, was approved by the local ethical committee of the Federal State Budgetary Educational Institution of Higher Education Omsk State Medical University of the Ministry of Health of Russia (Protocol No. 6).

The study included respondents with an established diagnosis of coronary heart disease (n=100) who independently applied for routine outpatient care at the clinic of the Tyumen Cardiological Research Center, that is, a branch of the Federal State Budgetary Scientific Institution «Tomsk National Research Medical Center of the Russian Academy of Sciences» in the period from May 01 to May 31, 2021, who signed informed consent and are fluent in Russian, and 100 respondents with an established diagnosis of coronary heart disease, hospitalized routinely in the Budgetary Health Care Institution of the Omsk region «Clinical Cardiological Dispensary» in the period from May 01 to May 31, 2021. The sample size was calculated according to R. Lehr at a confidence level of 95% [14].

The respondents were questioned on the QQA-25 scale [4] by the method of self-filling a questionnaire, in which alternative (tested) wordings of questions were additionally included in a random order, followed by interviews. Treatment adherence was calculated using the SCOPA computer program. The following indicators were assessed: adherence to drug therapy (Cd), adherence to medical supervision (Cm), adherence to lifestyle modification (Cc), integral adherence to treatment (C) [6].

The reliability of the questionnaire (relative constancy, stability and consistency of test results during its initial and repeated application on the same subjects and independence from the action of random factors) was assessed by measuring construct validity (the validity type that reflects the representation degree of the investigated construct in the test results) and factor validity (an analysis that allows you to determine the factor composition and factor loadings of the test result), as well as measures of consent (the variability of the dependent variable explained by the regression model).

The construct and factorial validity (Cronbach's alpha) and the measure of consent (Cohen's kappa) [15] were calculated using Microsoft 2010 software, the Python programming language, and specialized data analysis libraries (Sklearn, NumPy, Pandas).

Differences between unrelated samples were assessed using descriptive statistics methods: parametric (Student's t-test) and nonparametric (Wald-Wolfowitz). In all cases, preference was given to the most sensitive criterion. The null hypothesis was rejected at p values $\leqslant 0.05$.

The values of quantitative traits are given in the text as the sample mean deviation (M) and standard deviation (σ) or as the median (Me) and interquartile range (25% - 75%). Statistical processing of the material was performed using the certified Statistica 6.13 software package (StatSoft Inc., USA).

Results

The samples are comparable in terms of the main indicators (Table 1).

A preliminary contextual analysis of the QQA-25 questionnaire scale identified three questions, the wording of which required updating in the authors' opinion. After discussion in the team of authors, the following wording of questions were additionally included in the standard test version of the QQA-25 scale in random order, taking into account the recommendations made by the involved independent experts - specialists in the field of cognitive and medical psychology:

- «How important is your sex life to you?» is an alternative to the previous wording of question 7 «If you have a sex life, how important is it for you to keep it at the usual level?»;
- «Chronic illness can lead to disability. How important is it for you to receive social assistance from the state?» is an alternative to the previous wording of question 10 «Chronic illness can lead to disability. How important is it for you to obtain or confirm a disability group?»;
- «The doctor said that the prescribed medications can impair sexual performance. Will you then take such medications?» is an alternative to the previous wording of question 21 «The doctor said that the prescribed medications can worsen sex life. Will you take such medications after that?»

The questionnaires were filled in by respondents in parallel in two independent research centers - Tyumen («outpatient sample») and Omsk («inpatient sample»). After that, the interviewers asked the respondents which of the three tested wording of questions - the alternative or the previous one - was acceptable for the respondent and why.

After statistical processing of the outpatient (Table 2) and inpatient (Table 3) samples, it turned out that the use of new wordings of questions for different testing options (assessment of the original scale version; assessment of the scale with one replaced question No. 7; assessment of the scale with one replaced question No. 10; assessment of the scale with one replaced question No. 21; assessment of the scale with all three replaced questions) didn't significantly affect test results for any of the assessed adherence characteristics, including in separately assessed sub-samples of men and women (in all cases: Wald-Wolfowitz runs test; $p > 0.05$).

Table 1. General characteristics of samples

Sample	Parameter	Me	Min	Max	25%	75%
Outpatient respondents	Age, years	63	27	91	49,5	76
	Height, cm	167	152	184	162	172
	Weight, kg	83,5	52	147	69,5	90
Inpatient respondents*	Age, years	62.5	28	82	55	69
	Height, cm	165	151	184	161.5	175
	Weight, kg	85	54	135	80	93

* – according to comparable parameters (age, height, weight), statistically significant differences between the samples «outpatient respondents» and «inpatient respondents» are absent (in all cases: Student's t-test; p>0.05)

Table 2. Results of testing "alternative" questions of the " QAA-25" scale in the sample "outpatient respondents"

QQA-25 scale tests	Subsamples	Adherence, Me (interquartile range)			
		to drug therapy (C_d)	to medical support (C_m)	to lifestyle modification (C_c)	integral (C)
Initial	All	73.7 (49.1-93.3)	57.8 (62.8-72.2)	54.9 (29.4-72.2)	63.1 (41.9-78.9)
	Men	83.8 (52.0-100)	57.8 (30.2-57.8)	54.9 (18.7-57.8)	69.8 (37.3-78.9)
	Women	63.0 (49.1-90.2)	66.7 (58.7-74.7)	58.9 (30.6-77.8)	60.8 (49.4-87.4)
Testing question 7	All	73.7 (49.1-93.3)	57.8 (52.7-72.2)	50.0 (29.6-72.2)	63.1 (42.7-78.9)
	Men	83.8 (52.0-100)	57.7 (30.2-59.8)	46.2 (18.6-57.8)	66.9 (37.3-78.9)
	Women	63.0 (49.1-90.2)	66.7 (58.6-74.6)	58.9 (31.7-77.8)	60.8 (49.4-87.4)
Testing question 10	All	75.1 (52.0-100)	63.9 (52.7-74.7)	57.8 (29.3-75.1)	67.1 (41.9-79.6)
	Men	83.8 (52.0-100)	57.8 (35.9-62.2)	54.9 (18.7-57.8)	72.2 (38.2-78.9)
	Women	63.0 (49.1-90.2)	70.8 (58.7-80.6)	58.9 (30.6-77.8)	61.6 (49.4-87.4)
Testing question 21	All	73.7 (47.2-93.3)	57.8 (52.8-72.2)	54.9 (29.4-72.2)	63,7 (40.0-78.9)
	Men	83.8 (52.0-100)	57.8 (30.2-57.8)	54.9 (18.7-57.8)	69.8 (37.3-78.9)
	Women	63.0 (45.3-90.2)	66.7 (58.7-74.7)	58.9 (30.6-77.8)	61.7 (49.4-87.4)
Final	All	75.1 (47.2-93.3)	63.9 (53.8-74.7)	50.0 (31.8-74.7)	66.8 (42.3-79.9)
	Men	83.8 (52-100)	57.8 (35.9-62.2)	46.2 (21.7-60.7)	69.3 (38.2-79.9)
	Women	63.0 (45.3-90.2)	70.8 (58.7-80.6)	61.8 (40.1-77.8)	61.6 (49.4-87.4)

There are no statistically significant differences between the test samples for all adherence scales (in all cases: Wald-Wolfowitz runs test; p>0.05)

Table 3. Testing results of "alternative" questions of the " QAA-25" scale in the sample "stationary respondents"

QQA-25 scale tests	Subsamples	Adherence			
		to drug therapy (C_d)	to medical support (C_m)	to lifestyle modification (C_c)	integral (C)
Initial	All	58.3 (40.5-75.1)	57.8 (44.4-72.2)	45.2 (30.2-57.8)	55.8 (37.3-66.5)
	Men	56.0 (33.3-83.8)	47.2 (30.2-69.3)	48.9 (25.0-56.7)	57.9 (32.6-69.8)
	Women	58.3 (48.0-75.1)	64.0 (51.3-74.7)	44.3 (31.8-57.8)	53.6 (49.0-61.9)
Testing question 7	All	58.3 (40.5-75.1)	57.8 (44.4-72.2)	43.9 (30.4-57.8)	56.2 (36.9-65.9)
	Men	56.0 (33.3-83.8)	47.2 (30.2-69.3)	43.3 (25.0-53.7)	57.1 (30.7-66.9)
	Women	58.3 (48-75.1)	64.0 (51.3-74.7)	44.3 (31.8-57.8)	53.4 (49.0-61.9)
Testing question 10	All	58.3 (40.5-75.1)	61.3 (46-75.1)	45.2 (30.2-57.8)	56.0 (37.5-67.2)
	Men	56.0 (33.3-83.8)	55.6 (35.9-72.2)	48.9 (25.0-56.7)	57.9 (32.6-72.2)
	Women	58.3 (48.0-75.1)	61.3 (53.7-80.6)	44.3 (31.8-57.8)	54.0 (49.0-61.8)
Testing question 21	All	58.5 (45.2-75.1)	57.8 (44.4-72.2)	45.2 (30.2-57.8)	54.4 (37.3-67.1)
	Men	58.7 (35.8-83.8)	47.2 (30.2-69.3)	48.9 (25-56.7)	55.3 (32.6-69.8)
	Women	58.3 (49.0-75.1)	64.0 (51.3-74.7)	44.3 (31.8-57.8)	53.6 (49.2-62.1)
Final	All	58.5 (45.2-75.1)	61.3 (46.0-75.1)	43.4 (31.7-60.7)	54.6 (38.2-68.2)
	Men	58.7 (35.8-83.8)	55.6 (35.9-72.2)	43.4 (28.3-53.7)	55.3 (32.8-69.3)
	Women	58.5 (49.0-75.1)	62.6 (53.7-80.6)	44.3 (31.8-60.7)	55.6 (49.0-61.6)

There are no statistically significant differences between the test samples for all adherence scales (in all cases: Wald-Wolfowitz runs test; p>0.05)

Data are presented as Me (25%-75%)

In the outpatient sample, respondents with all testing options demonstrated significantly greater adherence to drug therapy (Wald-Wolfowitz runs test; p=0.0017) and lifestyle modification (Wald-Wolfowitz runs test; p=0.019) than in the inpatient sample. At the same time, a unidirectional, but statistically insignificant trend towards an increase in the assessment of adherence to medical care was revealed in both samples of questions.

In interviews after filling out the questionnaires, 81% of respondents from the outpatient sample and 69% of the inpatient sample (as «they didn't

Table 4. Indicators of construct and factorial validity of the " QAA-25" questionnaire and statistics of items in relation to the total score when items are excluded

The serial number of the scale question	Scale an average when excluding point	Scale a variance when excluding point	Corrected correlation between point and total	Square of multiple correlation coefficient	Cronbach's alpha (α) when excluding point
VAR00001	103.8548	269.588	0.199	0.224	0.817
VAR00002	104.4917	255.430	0.438	0.646	0.808
VAR00003	104.8218	248.558	0.539	0.794	0.803
VAR00004	105.0462	245.024	0.564	0.747	0.802
VAR00005	105.7789	246.027	0.475	0.400	0.805
VAR00006	104.3597	268.132	0.171	0.204	0.818
VAR00007	106.2541	283.554	-0.158	0.353	0.839
VAR00008	106.1089	256.303	0.341	0.329	0.812
VAR00009	105.7228	256.062	0.335	0.418	0.812
VAR00010	105.1848	268.873	0.086	0.109	0.824
VAR00011	103.9736	266.688	0.281	0.222	0.815
VAR00012	105.0792	266.802	0.136	0.126	0.821
VAR00013	105.7063	252.678	0.376	0.271	0.811
VAR00014	105.3828	260.164	0.288	0.227	0.814
VAR00015	105.8713	257.516	0.310	0.287	0.814
VAR00016	104.2211	254.537	0.572	0.710	0.805
VAR00017	104.4587	247.984	0.635	0.826	0.801
VAR00018	104.5380	247.587	0.605	0.744	0.801
VAR00019	105.6799	245.761	0.493	0.422	0.805
VAR00020	105.5479	253.143	0.377	0.290	0.810
VAR00021	105.0891	259.750	0.249	0.424	0.817
VAR00022	104.9175	252.665	0.496	0.483	0.806
VAR00023	104.8680	254.718	0.460	0.490	0.807
VAR00024	104.5347	254.011	0.492	0.509	0.806
VAR00025	104.2508	257.063	0.469	0.489	0.808
	Cronbach's alpha, α			Cronbach's alpha based on standardized points (Cronbach's alpha, α_{st})	
	0.818			0.832	

Interpretation: α⩽0.5 insufficient validity; 0.5-0.6 bad validity; 0.6-0.7 questionable validity; 0.7-0.8 sufficient validity; 0.8-0.9 good validity; >0.9 very good validity

notice the differences» - 17% and 29%, as «they are less acceptable» - 2% and 2% of respondents, respectively) assessed the new wording as «more acceptable». Respondents most often used the definitions «more understandable», «more correct» and «more accurate» as characteristics of greater acceptability.

The database obtained during the updating of the QQA-25 scale was also used to assess construct and factor validity (Cronbach's alpha) and the measure of the questionnaire consent (Cohen's kappa). The calculation results are presented in Tables 4 and 5. It turned out that the QQA-25 scale has good construct and internal validity (α - 0.818, αst - 0.832) with moderate consent (κ - 0.562). We note that the scale demonstrates high reliability of internal validity - the α values remain in the range 0.801-0.839 when scale points are consistently excluded.

Discussion

The authors believe that the study obtained enough data to demonstrate the feasibility of modifying and

Table 5. The indicator of the agreement measure for the "QAA-25" questionnaire

Consent measure	Value	Asymptotic root mean square error	Approximate T	Approximate significance
Cohen's kappa, κ	0.562	0.039	13.989	0.000

Interpretation: κ<0 poor agreement; 0-0.20 slight agreement; 0.21-0.40 fair agreement; 0.41-0.60 moderate agreement; 0.61-0.80 substantial agreement; 0.81-1 almost perfect agreement

using all three studied questions in the tested wordings on the QQA-25 scale. This is, first of all, proven by the overwhelming share of respondents who used the questionnaire, who indicated an increased ease of perception and accuracy of the proposed wordings.

Basically, this refers to the new version of the question about the possibility of receiving social assistance from the state in the event of the development of a disability-related limitation or disability, where the difference in the assessments of younger and older respondents turned out to be very noticeable. Respondents over the age of 50, for whom the concept of "disability group" is familiar, well-established and well associated with social benefits, considered the new wording the best in 62% of cases, and 36% of them did not note significant differences. Respondents under the age of 50, focused on the modern system of concepts of social goods, indicated the advantages of the new wording in 91% of cases.

The updated scale of the QQA-25 questionnaire is as follows:

1. The doctor has diagnosed you with a chronic illness. Is it important for you to know what signs it manifests itself?
2. Your doctor has prescribed a medicine for you to take every day for many years. How difficult is it for you to follow this recommendation?
3. Your doctor has prescribed a medicine that you need to take several times a day for many years. How difficult is it for you to follow this recommendation?
4. Your doctor has prescribed several medicines for you to take every day for many years. How difficult is it for you to follow this recommendation?
5. The doctor suggested that you record the present manifestations of the disease every day for many years. How difficult is it for you to follow this recommendation?
6. Chronic illness has its own manifestations. How important is it for you not to feel these manifestations?
7. How important is your sex life to you?
8. Chronic illness forces to change the usual way of life. How difficult is this change for you?
9. Chronic illness forces you to change your diet. How difficult is this change for you?
10. Chronic illness can lead to disability. How important is it for you to receive social assistance from the state?
11. Chronic illness can change the work of internal organs along with analyzes. How important is it for you to know the results of analyzes?
12. All people believe or do not believe in God. How important is it for you to believe in God?
13. Chronic illness leads to the need to regularly visit a doctor. How difficult is it for you to be monitored by a doctor?
14. Taking medication can be unpleasant. How difficult will it be for you to bear such sensations?
15. Chronic illness can limit the usual life and outdoor activities. How difficult is it for you to go for such restrictions?
16. The doctor has prescribed a medicine to be taken every day for many years. Will you follow this recommendation exactly?
17. The doctor has prescribed a medicine that needs to be taken several times a day for many years. Will you follow this recommendation exactly?
18. The doctor has prescribed several medicines to be taken every day for many years. Will you follow this recommendation exactly?
19. The doctor suggested that every day for many years to record the existing manifestations of the disease. Will you follow this recommendation exactly?
20. The doctor has advised that the prescribed medications may cause discomfort, including those that you have now. Will you take these medications?
21. The doctor has told you that the prescribed medications can impair your sexual performance. Will you take such medications after that?

22. The doctor has told you that you need to make changes in your lifestyle due to the illness. Will you follow this recommendation exactly?
23. The doctor has told you that you need to change your diet due to illness. Will you follow this recommendation exactly?
24. The doctor has told you that you need to visit him regularly due to illness. Will you follow this recommendation exactly?
25. The doctor has told you that you need to be tested regularly for your illness. Will you follow this recommendation exactly?

The authors consider the obtained information on the QQA-25 scale validity and measure of consent to be important, which answer the fair comments of Yu.V. Lukina. et al [13] on the absence of such information in previously published materials.

Cronbach's alpha (0.818) and Cronbach's alpha based on standardized points (0.832) indicate good construct and factorial validity, and the conformity degree of the content and analysis Cohen's kappa (0.562) indicates a moderate value of the consent measure. The QQA-25 questionnaire can be assessed as one of the most mathematically verified domestic tools for assessing adherence taking into account previously published data on sensitivity (93%), specificity (78%) and reliability (94%) [4].

The authors consider that the study limitations are possible sampling bias associated with the nosology of the underlying disease; decrease in the reliability and quality of the information received due to the impossibility of obtaining systemic information about the opinions, motives and values of the respondents; the risk of a relative distortion of the information provided, associated with the inability to differentiate the aggregate of the respondents' ideas, formed under the direct influence of practical activity and personal experience, from the aggregate of his ideas, formed under the influence of external factors and contacts.

Conclusion

The QQA-25 questionnaire scale, with its modified question wording, should be used instead of the previously used version of the scale.

Good structural and factorial validity, sufficient measure of consent, high sensitivity and reliability of the QQA-25 questionnaire allow to recommend it as a tool for assessing adherence to drug therapy, medical management, lifestyle modification and integral adherence to treatment in scientific and clinical practice.

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