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Creation and Validation of the Russian Version of the Questionnaire for the Assessment of Utility Indexes in Pediatric Practice

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The health related quality of life (HRQL) is the assessment correlating with life expectancy, changing due to violations of the current functional state, self perception and social opportunities that are affected by illnesses, traumas, treatment or personal beliefs. The article presents the results of the adaptation and validation of the questionnaire used to assess the utility HUI index of health in children older than 5 years old. The obtained data allowed to make the conclusion that the Russian version of the HUI questionnaire can be used in scientific and clinical-economic researches for assessing life quality in pediatric practice.

Keywords*: quality of life, HUI questionnaire, utilitarian health index, clinical-economic analysis, QALY.*

Experts from different countries are unanimous in the opinion that the index of quality of life (QL) can be used to evaluate the effectiveness of therapy [1-5]. It was suggested to include it in the economic calculations to measure the effectiveness of health programs and treatments, as well as to recognize this indicator as an integral part of the analysis of "cost-efficiency" back in the 70s of the twentieth century [6]. Later this approach was developed in the analysis of "cost-utility." The analysis of the "cost-usefulness (utility)" is the version of the "cost-effectiveness"

analysis in which the results of the intervention are evaluated in terms of "usefulness", such as improving the quality of life.

In health care, the concept of economic efficiency is inseparable from the concept of health care effectiveness. The effectiveness of health care is the degree of achievement of particular results, which reflect the dynamics of the patient's condition at certain level of expenditure. The effectiveness of medical care can be measured by useful indicators such as "utility", QALY, DALY. The Integrated indicator QALY (Quality-Adjusted Life Years) is most commonly used in analyzing the "cost-utility", meaning the quality of lived life a year or quality of saved years of past life. "Utility" is considered as a value of certain level of individual health or a society as a whole. The indicator "utility" is situated in order of reduction of life quality from absolute health (1, 00) to death or unconsciousness (≤0, 00). Having taken these indicators as basis, it is possible to calculate the indicator of life expectancy correlated with its quality [7].

QALY demands the consideration of the quality of life, depending on the various states of health. The number of QALY in every specific case is calculated by multiplying the additional years of won life appreciably to treatment by the factor of utility (usefulness, a utilitarian index) of the achieved health level, measured from 0 to 1 [8].

Various standardized questionnaires are used for the assessment of utilitarian index. These questionnaires are diverse in structure, differ from ordinary tools of an assessment of quality of life and are called «multi attribute measures of usefulness». There are many different questionnaires to assess the measure of usefulness, but the gold standard questionnaire does not currently exist for QALY calculation [9].

There are no translated and adapted tools to calculate the utility index in Russia. In this regard, laboratory of the problems of medical support and quality of life of the children population Scientific Center of Health Care RAMS produced a translation, adaptation and validation of Health Utilities Index questionnaire (DH Feeny, WJ Furlong, GW Torrance, ON Dundas; Canada) versions HUI23P2RU.15Q HUI23S2RU.15Q. This tool was chosen due to its widely studied (over 300 studies in more than 20 countries around the world) and proven reliability and validity. The questionnaire was originally designed for pediatric patients [10, 11], which makes it more perspective and specific.

Patients and Methods

Questionnaire version HUI 15Q was translated and linguistically validated, representing a multi attribute classification of health states on the basis of single-and multifactor classification system.

This survey consisting of 15 questions for self-completion, was modeled in such a way that it sets the minimum number of required questions to classify the respondents' health in accordance with the classification systems of both versions of the questionnaire: Health Utilities Index Mark 2 and Mark 3 (HUI 2 and HUI 3.) System 2 and HUI 3 contains two main components: a classification system of the health status and an additional system for HRQL determination. Additional questions No 16, 17 and 18 do not apply to the HUI, but were included in the questionnaire, because the information contained in them was often required in studies to assess the state of health.

There are two versions of the survey: Self-assessment and Proxy-assessment. Version of the self-assessment is formulated in such a way as to obtain information on the health status of respondents aged 12 and over from their own point of view. Version of the Proxy-assessment is designed to collect information on the health status at the age of 5 years and older by being interviewed by a wide range of experts (parents and health professionals). Both versions of the survey estimate information for the last 2 weeks.

Concept "trustee" is being used for describing the relationship between the examinees and the person completing the survey. Anyone except for the examinee can act as Trustees. They do not necessarily express the opinion of the surveyed; they can provide answers to questions based on their own observations. The survey includes a sample cover sheet for filling the data that is considered important for each survey (such as the identification number of the surveyed and date of the survey).

HUI 2 classification system consists of seven attributes: senses, mobility, emotion, cognition, self-care, pain and fertility. The complex status of health represents a seven-element vector, 1 level for each attribute. The HUI 3 system is continuation of HUI 2 and contains 8 attributes: vision, hearing, speech, ambulation, fine motor skills, emotions, cognition and pain. Each attribute of HUI 3 stands out from 5 to 6 levels, and the complex status of health is presented by an eight-level vector. The levels for each attribute may vary from 5-6 (severe malfunction) to 1 (normal operation).

Assessment of the "current" state of health is often used in clinical trials and economic analysis of health programs, which aims to monitor changes in health status with treatment. Assessment of the "normal" state of health is used in population studies, the results of which do not significantly affect short-term diseases such as ARVI.

The tool 15 Q has been developed at the University of McMaster by a special group HUI (utility health indices) and has been used in a lot of research. The level of each attribute is determined by the relevant patient's responses, which are processed by using a standard encryption algorithm. Utility scores to determine the health status of the HUI are calculated by using standardized and

published procedures provided by the author. The calculation is done by using formulas and tables [12, 13].

The purpose of linguistic ratification (validation) is to create a translated version, equivalent to the original version, which is clear and easily understood. The translated instrument needs to be understood by the most respondents, the carriers of the native language, regardless of their educational level. For cross-cultural comparisons equivalence is required between the original and the translated transfer. Equivalence should not have any differences in meaning between the source and content of language and the translated version. The last can be achieved through a process called linguistic ratification.

Linguistic ratification of the survey "Quality of life" should consist of at least three stages:

- Direct translation (including the production of "coherent" version)
- Back Translation
- Testing on patients.

Results and discussion

At the first stage the original version of the survey was translated into Russian. Translation was performed by two professional translators, native speakers, independently from each other. In translation process each translator made direct translation of an original questionnaire, the instruction and versions of answers. After comparison of both versions of translation and coordination, the incorporated verified version — Version 1 was created. At the 2nd stage the translation of verified Version 1 into English language was carried out. Interpretation was made by professional translators, native speakers. One of the conditions of back translation was an absence of the translator's access to the original version of a survey.

At the 3rd phase of the creation of Russian version, we tested 2nd version on patients. This step was necessary to determine the acceptability of interpretation (instructions, questions and types of answers). Two main aspects were tested - the equivalence of the items and answers translated from the original. The test was attended by seven respondents; three children aged 12, 14 and 16, and four parents of children aged 5 to 12 years. All surveyed were native Russian. Filling out the questionnaire was carried out by each respondent independently from each other; surveyed addressed difficulties directly to the interviewer. At the end of the interview the interviewer also clarified whether the respondent was having any problems in understanding the survey and filling it out. Correction of the formulation of questions and versions of answers on the basis of surveyed wishes was being conducted during survey.

After completing all the stages of translation and adaptation a report in English was provided to the author, indicating the total number of participants, their age, the time it took to fill out

questionnaires, difficulties in translation, interpretation and filling in the questionnaire, as well as proposed solutions. As a result the final version was created, the instruction on how to recode conversions of answers and author's permission for using this version were obtained.

The next step in order to validate the translated version of the survey was a pilot study and determination of the utility indices in children with cystic fibrosis. The study was conducted at the Department of Pulmonary and Allergy Research Children's Health Center. The study involved 17 parents and 16 children aged 5 and older. Quality's of life assessment was carried out on systems HUI 2 and 3. The single-attribute and multi attribute indexes corresponding to each system were evaluated.

These study results are presented in Table 1 and 2.

Various functional disorders (deviations) upon various parameters are evaluated by using these indices. In Tables 1 and 2 children with cystic fibrosis have violations of the parameters "Cognitive abilities" and "Pain" in the majority. At the same time the disease affects a little functional parameters such as "Vision," "Rumor," "Sensation," and «Mobility." Although given the small number of samples, we can not talk about the high reliability of the results and need further study in this cohort of patients.

Multi attribute indices of HUI 3 and 2 systems are calculated which equaled to 0.82 and 0.86, respectively. The obtained data will be used to calculate the QALY index in order to further analyze the "cost-utility", i.e., the next phase of our work.

Thus, summarizing the results of research, we can draw some conclusions:

• Russian version of the questionnaire about assessing children's utility index was created;

• The version showed its availability, ease of understanding and ease of use;

• Preliminary results were obtained in children with chronic illness;

• A single database utility indices in children with various conditions is necessary for their further use in scientific, clinical and economic studies.

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Table 1: Single-attribute indices of health (HUI 3)

Vision	Hearing	Speech	Cognitive ability	Ability to move	Small motility	Emotions	Pain
1,0	1,0	0,96	0,93	0,98	0,98	0,96	0,94

Table 2: Single-attribute indices of health (HUI 2)

Feelings	Mobility	Cognitive ability	Self service	Emotions	Pain
1,0	1,0	0,93	0,98	0,96	0,94