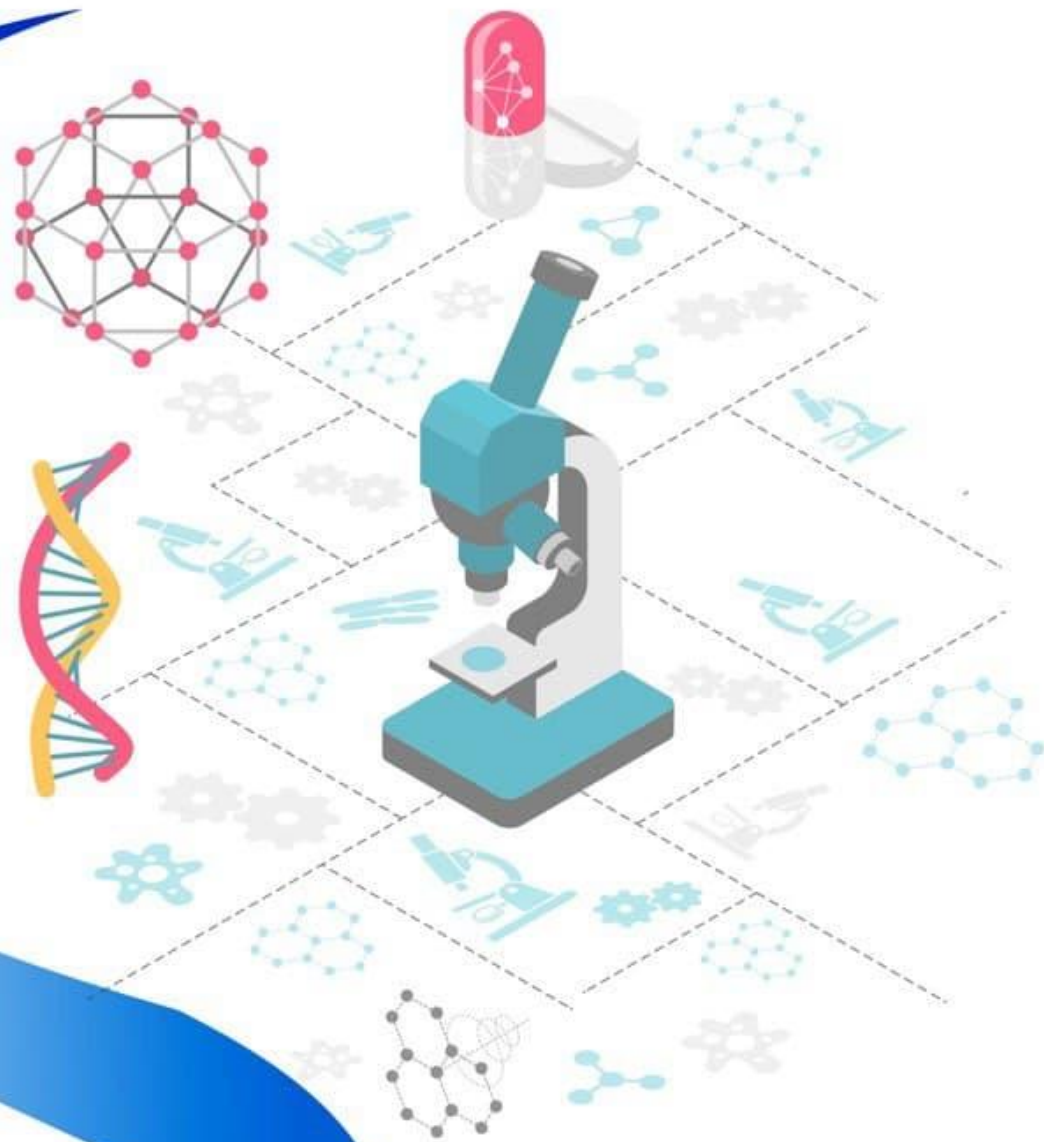


ASIAN JOURNAL OF PHARMACEUTICAL  
AND BIOLOGICAL RESEARCH

# AJPBR



Indexed by:



Universal  
Impact Factor



IMPACT FACTOR  
SEARCH

## Editorial board

**Dr. Madhu Bala** Scientist 'F' and Joint Director, Institute of Nuclear Medicine and Allied Sciences (INMAS), India

**Dr. Sandip Narayan Chakraborty**

Research Asst, Translational Molecular Pathology, Ut Md Anderson Cancer Center, Life Sciences Plaza, Houston, TX 77030

**Dr. Tushar Treembak Shelke**

Head of Department of Pharmacology and Research Scholar, In Jspms Charak College of Pharmacy & Research, Pune, India

**Dr. Subas Chandra Dinda**

Professor-cum-Director: School of Pharmaceutical Education & Research (SPER), Berhampur University, Berhampur, Orissa, India.

**Dr. Jagdale Swati Changdeo**

Professor and Head, Department of Pharmaceutics, MAEER's Maharashtra Institute of Pharmacy, S.No.124, MIT Campus, Kothrud, Pune-411038

**Dr. Biplab Kumar Dey**

Principal, Department of Pharmacy, Assam downtown University, Sankar Madhab Path, Panikhaiti 781026, Guwahati, Assam, India

**Dr. Yogesh Pandurang Talekar**

Research Associate, National Toxicology Centre

**Dr. Indranil Chanda**

Assistant Professor, Girijananda Chowdhury Institute of Pharmaceutical Science, Hathkhowapara, Azara Guwahati-17, Assam, India.

**Dr. Sudip Kumar Mandal** Department of Pharmaceutical Chemistry, Dr. B. C. Roy College of Pharmacy & AHS, Bidhannagar, Durgapur-713206, India.

**Sodikova Dilrabokhon** Andijan state medical institute

**Dr.**, associate professor **Kuryazova Sharofat** Tashkent Pediatric medical institute

**Dr.**, Abdurakhmanova Nigora Nazimovna Tashkent Pediatric Medical Institute

**Abdullaeva Umida** Bukhara state medical institute

**Dr. Neeraj Upmanyu**

Prof., Peoples Institute of Pharmacy & Research Center, Bhopal, MP, India.

**Dr. Mirrakhimova Maktuba Khabibullaevna** Tashkent medical academy Uzbekistan

**Dr. Nishanova Aziza Abdurashidovna**, Tashkent State Dental Institute

**Dr. Sadikova Minurakhon Adkhamovna** Andijan State Medical Institute

**Kurbanova Sanobar Yuldashevna** Tashkent State Dental Institute

**Zokirova Nargiza Bahodirovna** Tashkent Pediatric medical institute

**Khabilov Behzod Nigmon ugli** Tashkent State Dental Institute

**Dr. Domenico De Berardis** Department of Mental Health, Azienda Sanitaria Locale Teramo, 64100 Teramo, Italy

**Dr. Azizova Rano Baxodirovna** associate professor of the Department of neurology of the Tashkent Medical Academy

**Dr. Ishankhodjaeva Gulchekhra** Tashkent Medical Academy

Institute of Nuclear Medicine and Allied Sciences (INMAS), India

Brig SK Mazumdar Marg, Timarpur, New Delhi, Delhi 110054 India

## **THE IMPORTANCE OF QUESTIONNAIRES FOR ASSESSING THE QUALITY OF LIFE OF PATIENTS WITH CHRONIC OTITIS MEDIA**

(Literature review)

**Nurov Ubaydulla Ibodullayevich<sup>1</sup> Uktamov Ibrat Gayratovich<sup>2</sup>**

Head of the Department of Otorhinolaryngology and Ophthalmology of Bukhara State Medical Institute Ph.D., associate professor; Bukhara, Uzbekistan<sup>1</sup>

Basic doctoral student of the Bukhara State Medical Institute in the specialty of otorhinolaryngology; Bukhara, Uzbekistan<sup>2</sup>

**Summary:** In the article, 20 scientific works were analyzed as sources, of which 6(30%) authors belong to the CIS countries, while the remaining 14(70%) belong to authors from abroad. The results of the analysis showed that the use of questionnaires that assess the quality of life (QOL) in the diagnosis of ENT diseases, including patients with chronic middle otitis, is of great help in improving the effectiveness of diagnosis and treatment. With COMQ-12 and COM-5 in different languages, it is possible to assess the course of the disease and its outcomes in different social and cultural settings around the world. This makes it possible to obtain a more complete and objective picture of the disease under investigation, and a tool for its evaluation. The high prevalence of COM, the serious complications of this pathology and the ambiguity of the surgical treatment approaches make it necessary to study this medical problem and find possible ways of optimizing the care of patients. The contradictions described by different authors in the evaluation of the results of the intervention are the consequence of the lack of a single tool for interpreting the obtained data and do not allow for a unified treatment approach.

**Keywords:** questionnaire, CES, COMOT-15, OM-6, COMQ-12, COM-5

**Introduction.** The wide prevalence of COM, serious complications of this pathology and the ambiguity of approaches to surgical treatment determine the relevance of the study of this medical problem and the search for possible ways to optimize patient management [3; 4; 19]. The contradictions described by different authors when evaluating the results of surgical intervention are the result of the lack of a single tool for interpreting the data obtained and do not allow to unify the approach to treatment [5].

It also becomes obvious that the lack of a single and understandable tool for standardizing the results does not allow us to get a complete picture and evaluate the advantages of different surgical techniques, and also raises the question of more careful selection of patients for a specific type of treatment, since often, flawlessly performed surgery does not provide a corresponding improvement in the patient's quality of life. Questionnaires on health-related quality of life have recently become a connecting element between the patient's hopes and the surgeon's capabilities [13].

**The purpose of the study:** Assess the significance of questionnaire on quality of life evaluation in Otorhinolaryngology, particularly in the diagnosis of chronic otitis media

**Object and methods of research:** scientific articles, abstracts, dissertation works on the topic of questionnaires assessing the quality of life in Otorhinolaryngology, in particular in the diagnosis of COM, being acquainted with methodological puddles and monographs of famous otorhinolaryngology doctors

### **Assessment of the quality of life in otorhinolaryngology**

In the last 40 years, the world scientific community has been paying more and more attention to the quality of life of patients [6; 11]. In 1999, The World Health Organization has proposed to consider the concept of "quality of life" as the optimal state and degree of perception by individuals and the general population of how their needs (physical, emotional, social, etc.) are met in achieving welfare and self-realization. Interviewing patients by getting answers to standard questions and assessing the degree of agreement with the statement is currently the most effective method of assessing QOL [20]. To date, there are numerous reports on the use of various questionnaires; methodological recommendations have been created on the choice of a specific methodology and interpretation of the results [6].

Only in the review by T. M. Gill, A. R. Feinstein analyzed 104 literary sources describing about 150 devices for measuring QOL, and according to the Russian Interethnic Center for QOL Research in 2005, more than 400 different questionnaires were used [13].

Depending on the tasks, there are two main types of questionnaires: general and disease-specific. General questionnaires are designed to assess the quality of life regardless of the nosology, severity of the disease and type of treatment. The following items should be included in the universal questionnaires:

- pain (assessment of the amount of subjective pain in the respondent for the last 1, maximum 4 weeks);
- General state of health (assessment of the general state of health at the time of examination);
- Physical activity (the amount of daily physical activity not limited by the state of health) -
- Role-based emotional functioning (the degree of limitation of daily activities by emotional problems);
- Mental health;
- Social activity;
- Vitality (assessment of the state of vitality for the last 1, maximum 4 weeks)
- Role-based physical functioning (the degree of restriction of daily activity for health reasons) [1; 6; 13].

At the same time, general questionnaires do not take into account the special features of the course of a particular disease and do not allow them to be fully used to

assess the patient's condition and optimize the quality of medical care for a specific pathology [6].

Special questionnaires are used for a specific nosology and are more sensitive when assessing changes in the patient's condition and the severity of the disease during treatment, and allow you to assess the dynamics of the condition in a short period of treatment and observation. According to A.E. Uskov et al. [6], these questionnaires must meet the following requirements:

- to assess physical and emotional health;
- to reveal the essence of the disease and its clinical manifestations
- to assess the patient's condition for the last 2 weeks, a maximum of a month;
- be brief and clear;
- The patient should be able to fill it out on their own;
- The answers to the questions should be converted into a digital expression for subsequent statistical processing

The advantage of special QOL questionnaires is that the respondent directly determines the severity of complaints, taking into account the greatest contribution to the reduction of QOL, which helps the doctor to navigate and build therapeutic tactics taking into account the individual expectations of the patient. From a research point of view, QOL evaluated directly by the interviewee, makes it possible to compare various surgical and non-surgical methods of treatment in terms of effectiveness, as well as compare them with objective clinical data that can serve as a basis for adjusting management standards. [15;16].

An example would be the patient's fear and often long-term rejection of ear surgery with the behind-the-ear approach for this reason, while at the same time a calmer perception of the endaural approach. Questionnaires used in international practice should be tested not only in clinical trials, but also in clinical practice, and be multidimensional, simple and concise, acceptable and applicable in various linguistic and social cultures [13].

In otorhinolaryngology, numerous studies have been conducted to assess QOL in patients with chronic rhinosinusitis, otosclerosis, exudative otitis media, benign laryngeal formations, vestibular dysfunction, etc. [2; 3; 6]. In a review by S.P.C. Koenraads et al.[12], devoted to QOL questionnaires in otorhinolaryngology (ORL), it is proposed to divide them into those used in pediatric practice, otology, rhinology, laryngology, for oncological diseases of the ENT organs, sleep disorders and after head surgery and the neck. The authors note a significant increase in the use of questionnaires.

The Cummings Otolaryngology: Head and Neck Surgery manual [7] describes the following questionnaires recognized as relevant for assessing outcomes in ORL: 1) general questionnaires and scales determining the state of health – SF-36, WHO-QOL, QWB; 2) special for malignant tumors of the head and neck, taking into account both the local influence of the oncological process in the form of functional disorders, and the patient's condition when using radiation therapy – UWQOL,

FACT, EORTC, HNQOL, QOL-RTL/H&N, PSS; 3) for otology – HHIE, HSS, APHAB, EAR, DHI, THI, Nijmegen, CAMP, designed to assess QOL associated with hearing impairment, dizziness and tinnitus, as well as with the results of treatment of conductive hearing loss, the effect of cochlear implantation and, in general, the results of rehabilitation for ear diseases; 4) for rhinology – NOSE, SNOT-20, CSS, RhinoQOL, mRQLQ, ROQ, based on the assessment of nasal symptoms obstruction, duration and severity of clinical manifestations in sinusitis and rhinitis; 5) in pediatric practice - TAGSI, OM-6, OSD-6, OSD-18, used in the study of QOL of patients after tonsillectomy, as well as those suffering from otitis media and nocturnal apnea; 6) others used in the assessment of QOL in adult patients with sleep apnea, difficulty swallowing, voice disorders and appearance defects - FOSQ, SAQI, MDADI, SWAI, QOL, VHI, VOS, V-RQOL, ROE, BOE.

Thus, despite the availability of a wide range of tools for assessing QOL in ENT, an important task is to continue research in this direction for the development and validation of questionnaires specific to each nosology and widely used in domestic otorhinolaryngology.

#### **Methods of assessing the quality of life of patients with chronic otitis media**

The complications of COM described above determine the high social significance of this disease. Objective indicators of treatment results, such as audiogram and computed tomography data, the frequency of exacerbations of the disease and complications, are certainly important in assessing outcomes, but do not always reflect the degree of COM influence on the patient's quality of life. Currently, both general and special questionnaires are used to assess QOL after surgical treatment of patients with COM.

For a long time, the attention of scientists has been focused on the study of QOL in children with COM, and the first questionnaire with reliability confirmed in the study by R.M. Rosenfeld et al. [16] was OM-6, containing an assessment of the degree of physical discomfort, hearing loss, speech disorders, emotional distress and parents' concern about the health of children with COM. The OMO-22 questionnaire for evaluating the results of surgical treatment of chronic otitis in children was an expanded version of OM-6, supplemented by the introduction of individual parameters of specific variables. The COM-5 questionnaire [18] was also one of the modifications of the OM-6 questionnaire.

Assessing the quality of life of adult patients, of course, requires a different approach and the development of tools other than those used in childhood. The study by PC Wang et al. [19] is devoted to the approbation of the CES (Chronic Ear Survey) questionnaire developed in 1997 and the assessment of its reliability, sensitivity and validity in adults. CES was used in 91 patients with COM together with a special questionnaire HHIA (questionnaire of hearing disorders for adults) and a general questionnaire SF-36. The HHIA scale takes into account the severity of social and emotional discomfort associated with hearing disorders, the SF-36 questionnaire is devoted to the general state of health and is divided into subscales

assessing the restriction of physical activity, difficulties with self-care and routine activities, the presence of the severity of pain syndrome, general well-being, energy, restriction of social activity, emotional problems and mental health. The proposed CES questionnaire included three subscales: 1-"Activity Restriction Subscale", 2-"Symptoms" (Symptom Subscale), 3-"Medical Benefits" (Medical Resource Subscale). Because of the study, the high reliability, validity and sensitivity of the CES questionnaire for assessing QOL in patients with COM was demonstrated. With the revealed close correlation between the results of this questionnaire and HHIA ( $r = 0.54$ ;  $p = 0.0005$ ) the advantage of the CES was not only the assessment of hearing disorders, but also the consideration of symptoms subjectively assessed by the patient, as well as seeking medical help with fewer questions.

The results of audiometry do not always adequately reflect the nuances that are important for the patient related to the outcome of treatment, therefore, the CES questionnaire was recognized as a valuable addition and allowed to take into account complaints related to hearing disorders that cannot be fixed with the help of an objective study and methods. It is also assumed that these quality of life assessments can both contribute to the selection of patients for surgical intervention and serve as a criterion for the effectiveness of surgical treatment in terms of hearing improvement). When comparing CES with SF-36 in a study by P. C. Wang et al. [19] also revealed a correlation of these questionnaires in relation to the assessment of pain syndrome, general well-being, restrictions on social activity and mental health. On the other hand, the absence of statistical differences when comparing the results of QL in patients with COM according to the SF-36 questionnaire with normal values in the general population indicates that SF-36 is not a sufficiently accurate tool for assessing treatment outcomes associated with COM as a specific nosology.

As a result of the study by P.C.Wang et al. [19], the CES was recognized as a reliable and adequate tool for assessing the quality of life of patients with COM and was used by a group of scientists J. B. Jr. Nadol et al. in a prospective longitudinal non-randomized study to study the results of surgical treatment of adult patients with chronic otitis media in parallel with the use of SF-36. The study included 147 patients, the examination was carried out before the operation, as well as 6 and 12 months after the intervention. The authors note that although the assessment of QOL according to the SF-36 questionnaire in patients before surgical treatment was reduced, it did not significantly differ from normal indicators for the general population, and the improvement of QOL after surgery was not statistically significant. The CES questionnaire data showed a significant improvement in QOL after surgery in the same group of patients, and also revealed factors that were associated with the greatest progress in terms of quality of life. It should be emphasized that the improvement in QOL after 12 months was significantly more significant than after 6 months, which is important to take into account when assessing long-term results.

In the dissertation work of V. E. Kuzovkov [8], when comparing the SF-36 and CES questionnaires, the high efficiency of the latter for assessing QOL in dynamics in patients with COM before and after surgical treatment was also noted.

In 2011, a group of scientists J.Y. Byun et al. The CES questionnaire was adapted for Korean patients and was named K-CES. With the help of this questionnaire, S.Y. Choi et al. investigated not only the results of surgical treatment (tympanoplasty with or without mastoidectomy) in adult patients (21-67 years old), but also factors affecting its effectiveness. There was a significant improvement in both the results of audiometry and quality of life assessment 12 months after surgery.

With all its advantages, the CES questionnaire contained questions and gave information about the degree of their severity for the patient. In this regard, a group of researchers I. Baumann et al. [6] set out to develop and validate (validate) a questionnaire specific to COM, taking into account, among other things, the subjective assessment of QOL by the patient. The first stage of the study included 50 respondents, with the help of statistical data analysis, a questionnaire was formed from 15 points of KOMOT-15, including three subscales, according to which the patient could assess ear symptoms, hearing and mental well-being, as well as two additional questions concerning the impact of COM on the quality of life and the frequency of visits to the doctor in connection with COM. At the second stage, 121 patients were prospectively examined, the high validity and reliability of the questionnaire was shown.

In 2014, a group of authors J. S. Phillips et al. A new COMQ-12 questionnaire was proposed, which represented the result of the synthesis of the CES, COMOT-15 and COM-5 questionnaires, and patients initially participated in the selection of questions, assessing the relevance and accessibility of formulations for understanding, as a result of which 14 out of 33 questions were identified [9]. The experts excluded two more, the result was COMQ-12, which included questions about hearing disorders, tinnitus, the need for restrictions on contact with water, pain and discomfort in the ear, the need to take medications, restrictions arising in everyday life due to the disease, the presence of discharge from the ear, dizziness, frequency of seeking medical help and a decrease in quality of life due to COM. As a result of studying the experience of using COMQ-12 in 50 respondents, it was recognized as valid for assessing the quality of life in patients with exacerbation of CSR (Cronbach's  $\alpha$  was 0.889, which indicates good statistics on the reliability of internal consistency). The COMQ-12 questionnaire has been translated into Dutch, its high sensitivity, diagnostic accuracy and stability of results have been confirmed. The limited number of publications on the use of COMQ-12 indicates the need to continue research on its applicability in various conditions and socio-cultural communities, however, in general, the prospects for using this questionnaire as a specific tool for assessing the decline in the quality of life of patients with CSD are very optimistic.



## Conclusion

The development of questionnaire is not implemented for a single population. It is very important to establish centers in different countries and to study the problems while covering different cultures, an important feature of a quality of life assessment tool is its reliability, justification and ability to work in different populations. This process requires the translation of the original questionnaire into the native language of each country, taking into account the linguistic and cultural characteristics of speech, in order to correctly understand the essence of the questions. The presence of COMQ-12 in adults and COM-5 in children in different languages makes it possible to assess the course of the disease and its consequences in different social and cultural conditions around the world. This allows us to get a complete reference and evaluate the exact and objective nature of the disease under study.

## REFERENCES:

1. Agafonova, T. D. Quality of life of patients with functional voice disorders / T. D. Agafonova, N. V. Puzankova // Russian otorhinolaryngology - 2002. - N 4. - P. 20–22
2. Kozina, I. G. Vestibular dysfunction and its role in the deterioration of the quality of life of patients: author. dis... cand. honey. Sciences 14.00.04 / Kozina Irina Genadievna. - St. Petersburg, 2005. - 27 p.
3. Kotyanina, O. V. Comprehensive rehabilitation and quality of life of patients with benign laryngeal formations: author. dis... cand. honey. Sciences: 14.00.04 / Kotyanina Olga Vladimirovna. - Novosibirsk, 2009. - 25 p.
4. Novyachkin, VN Quality of life of patients in the surgical treatment of chronic rhinosinusitis: author. dis... cand. honey. Sciences: 14.00.04 / Novyachkin Vladimir Nikolaevich. - M., 2007. - 26 p.
5. Uskov, A. E. Quality of life in patients with chronic stenosis of the larynx and trachea: the current state of the issue and preliminary results of testing the questionnaire / A. E. Uskov [et al.] // Russian otorhinolaryngology. - 2005. - No. 4. - P. 115–124.
6. Baumann I, Kurpiers B, Plinkert PK, Praetorius M. [Development and validation of the Chronic Otitis Media Outcome Test 15 (COMOT-15). Measurement of health-related quality of life in patients with chronic otitis media]. *HNO*. 2009;57:889–95. doi: 10.1007/s00106-008-1870-3
7. Cummings Otolaryngology: Head and Neck Surgery / ed. by Paul W. Flint et al. – 6th Edition. – Elsevier, 2015.– P.280.
8. De Greve G, van Dinther J, Maryn Y, Vanspauwen R, Zarowski A, Offeciers E. Validity and test-retest reliability of the Dutch version of the Chronic Otitis Media Benefit Inventory. *J Int Adv Otol*. 2019;15:34–7. doi: 10.5152/iao.2019.6339.
9. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): Development and initial validation. *Otol Neurotol*. 2014;35:454–8. doi: 10.1097/MAO.0000000000000205.

10. McSweeney, A. J. Health-related quality-of-life assessment in medical care / A. J. McSweeney, T. L. Creer // *Dis. Mon.* – 1995. Jan. – N 41 (1). – P. 1–71.
11. Maile, E. J. Quality of life measures in otitis media / E. J. Maile, R. Youngs. // *The Journal of Laryngology & Otology.* – 2013. – T. 127. – № 05. – P. 442–447.
12. Koenraads, S. P. Quality of life questionnaires in otorhinolaryngology; a systematic overview / S. P. Koenraads, M. C. Aarts, E. L. van der Veen, et al. // *Clin. Otolaryngol.* – 2015. Nov 17.– P. 1–8.
13. Relic, A. Investigating quality of life and coping resources after laryngectomy / A. Relic, P. Mazemda, C. Arens, et al. // *Eur. Arch. Otorhinolaryngol.* – 2001. Dec. – N 258 (10). – P. 514–517.
14. Richards, M. Quality-of-life outcomes after surgical intervention for otitis media / M. Richards, C. Giannoni // *Archives of Otolaryngology – Head & Neck Surgery.* – 2002. – T. 128. – № 7. – P. 776–782.
15. Robinson K, Gatehouse S, Browning GG. Measuring patient benefit from otorhinolaryngological surgery and therapy. *Ann Otol Rhinol Laryngol.* 1996; 105:415–22. doi: 10.1177/000348949610500601.
16. Rosenfeld, R. M. Quality of life for children with otitis media / R. M. Rosenfeld, A. J. Goldsmith, L. Tetlus // *Archives of Otolaryngology – Head & Neck Surgery.* – 1997. – T. 123. – № 10. – P. 1049–1054.
17. van Dinther, J. Validity and Test-Retest Reliability of the Dutch Version of the Chronic Otitis Media Questionnaire 12 (COMQ-12) / J. van Dinther, V. Droessaert, S. Camp, et al.// *J. Int. Adv. Otol.* – 2015. Dec. – N. 11 (3). – P. 248–252.
18. Vlastos IM, Kandiloros D, Manolopoulos L, Ferekidis E, Yiotakis I. Quality of life in children with chronic suppurative otitis media with or without cholesteatoma. *Int J Pediatr Otorhinolaryngol.* 2009;73:363–9. doi: 10.1016/j.ijporl.2008.10.030.
19. Wang, P. C. Validation of outcomes survey for adults with chronic suppurative otitis media / P. C. Wang, J. B. Nadol Jr, S. Merchant, et al. // *Ann. Otol. Rhinol. Laryngol.* – 2000. Mar. – N 109 (3). – P. 249–254.
20. Wood-Dauphinee, S. Assessing quality of life in clinical research: from where have we come and where are we going? / S. Wood-Dauphinee // *J. Clin. Epidemiol.* – 1999. Apr. – N 52 (4). – P. 355–363.