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ЭТИЧЕСКАЯ ЭКСПЕРТИЗА НАУЧНЫХ ПУБЛИКАЦИЙ В МЕДИЦИНЕ: ЗАРУБЕЖНЫЙ ОПЫТ И РОССИЙСКАЯ ПРАКТИКА

Наталья Александровна Альшук[1], Светлана Александровна Костенко[2], Ольга Юрьевна Голицына[3]

[1, 2, 3] Волгоградский государственный медицинский университет, Волгоград, Россия

[1]nalshuk@mail.ru, http://orcid.org/0000--0001-5657-575X
[2]kostenko.ti@mail.ru, http://orcid.org/0000-0001-7851-3082
[3]aspirantura.volggmu@bk.ru, http://orcid.org/0000-0002-5722-5345

Аннотация. В настоящее время большое внимание уделяется корректному представлению результатов клинических и доклинических исследований в научных публикациях. Это не удивительно, поскольку международные стандарты оценки эффективности научной деятельности базируются на показателях цитируемости и количестве публикаций в рецензируемых изданиях. Данная традиция зародилась в Великобритании и явилась результатом борьбы за гранты в научном сообществе. Вариант оценки по индексу Хирша (индивидуальные авторы) и импакт-фактору (журналы) давал возможность количественного сравнения работ без обращения к их содержанию. Оценка последнего оставалась за редакциями журналов, и предполагалось, что она объективна. Данный метод соответствовал процессу цифровизации, но он до сих пор не получил этической оценки. Не только потому, что в научном сообществе существует достаточно большой разброс мнений по данному вопросу [1], но и потому, что моральные сюжеты вообще не комплементарны цифровым процессам.

Ключевые слова: наукометрия, медицинская наука, рецензируемый журнал, этическая экспертиза, статья, монография

Original article

ETHICAL EXAMINATION OF SCIENTIFIC PUBLICATIONS IN MEDICINE: FOREIGN EXPERIENCE AND RUSSIAN PRACTICE

Natalia A. Alshuk[1], Svetlana A. Kostenko[2], Olga Yu. Golitsyna[3]

[1, 2, 3] Volgograd State Medical University, Volgograd, Russia

[1]nalshuk@mail.ru, http://orcid.org/0000--0001-5657-575X
[2]kostenko.ti@mail.ru, http://orcid.org/0000-0001-7851-3082
[3]aspirantura.volggmu@bk.ru, http://orcid.org/0000-0002-5722-5345

Abstract. Currently, much attention is paid to the correct presentation of the results of. This is not surprising, since international standards used for assessing the effectiveness of scientific clinical and pre-clinical studies in scientific publications activities are based on citation rates and the number of publications in peer-reviewed journals. This tradition originated in the UK and is the result of a struggle for grants in the scientific community. The Hirsch index (individual authors) type of assessment and the impact factor (journals) made it possible to quantitatively compare papers without referring to their content. The assessment of the latter was accomplished by editors of the journals, and it was assumed that it was objective. This method was consistent with the digitalization process, but it has not yet received an ethical assessment. This is happening not only because there is a fairly wide range of opinions on this issue in the scientific community [1], but also because moral plots are generally not referred to digital processes.

Keywords: science metrics, medical science, peer-reviewed journal, ethical expertise, article, study

Introduction. Publication activity is very high in the field of medical sciences. At the same time, there are several features associated not so much with the subject of research (the living organism of a Human!), but with the nature of research activities. As a rule, in the modern world, lone scientists are not found in medicine research,

but rather research teams, therefore, the publications are authored by the teams.

Example. For example, the article "The prevalence of wide qrs complex (≥110 ms) among the population, depending on sex, age and place of residence" in the Russian Journal of Cardiology (2020. V. 25. No. 6. P. 15-23) has 22 authors. (*Muromtseva G.A., Vilkov V.G., Shalnova S.A., Konstantinov V.V., Deev A.D., Evstifeeva S.E., Balanova Yu.A., Imaeva A.E., Kapustina A.V., Karamnova N.S., Shlyakhto E.V., Boytsov S.A., Nedogoda S.V., Shabunova A.A., Chernykh T.M., Belova O.A., Indukaeva E.V., Grinshtein Yu.I., Trubacheva I.A., Efanov A.Yu., Astakhova Z.T., Kulakova N.V.)* There are 0.3 pages per author.

This immediately raises a purely ethical question about the personal contribution of each author. In some journals, as we *results. Either patients develop resistance to a certain group of drugs, or there appear new microorganisms not targeted by the usual drugs. The (most famous) chronology of the emergence of new antibiotics can be cited: 1942 – penicillin G, 1950 – oxytetracycline, 1956 – penicillin, 1961 – ampicillin, 1988 – azithromycin, 2015 – teixobactin. Scientific research in this area is carried out simply: there is no response to therapy with a certain antibiotic, a new one is being developed. There are already six generations of advanced antimicrobial drugs. For example, penicillin was the first natural remedy, while the third or sixth generation is already an improved version, which includes the strongest inhibitors. The dependence is direct: the more recent generations of drugs are more effective on the pathogenic microflora. But this effect, as it turned out, is temporary.*

Recently, scientists started to talk of the end of the era of antibiotics – COVID19 has made significant changes in our understanding of what is active and what is not. For example, initially, a large role was given to azithromycin. Then, the Recommendations of the Ministry of Health of Russia (No. 10) adviced on limiting its use, and the latest Recommendations generally state its ineffectiveness in the treatment of COVID19. The question arises: perhaps it is not necessary to change individual drugs, but the concept? But this requires fundamental, not applied, research.

Usually, the results of fundamental research is presented in the study report form. But only articles in peer-reviewed journals are taken into account while assessing the effectiveness in modern science metrics. And in order to fulfill the "Hirsch plan" a scientist is forced not to develop a new concept, but to feverishly publish insignificant articles. If in other sciences this simply slows down new fundamental developments, in medicine it hinders a successful treatment of patients. This effect can be regarded as a violation of professional ethics, because a doctor does not use any new concept of therapy, but is constrained by the Standards and Procedures of medical care provision, which are very far from fundamental science.

It is not ethically justified that the science metric indicators are taken only from journals. Now it is mainly a database of publications in English. There are two key words – "journals" and "English". A database, which would include all publications, books and other publications for the scientific citations references, does not exist and, most likely, no one will create it in a foreseeable future. The books are published on GoogleScholar, the Web of Science, the main citation index, has also announced that it is going to integrate publications, but these are only early attempts. As a result, the subjects in which communications mainly takes place through research reports, have, so far, been excluded from the calculations (for example, medical humanities).

Many specialists, in particular in the studies of science, which is being displaced from the expert field by science metrics, believe that the journal system is outdated, since communication through social networks is faster and more efficient. That is, a situation may arise when scientists will exchange information through social networks, but publish reports in journals only in order to quote someone. Then Facebook will become the main means of communication, and journals – an attachment to it, where you can place "likes" (see about scientific journals at https://postnauka.ru/faq/12936). There are already studies showing that "likes" on social networks in natural sciences can predict subsequent citations in scientific journals with high accuracy, so that the information status of the Web of Science database can seriously deteriorate. Or it won't be needed at all.

And, finally, the third distinction of publication policy in medicine is the need for ethical examination of a scientific research before it is published. Here it is necessary to single out two areas of such expertise:

1. Ethical content of the publication itself (conflict of interest, compliance with the rules for the authors of this journal, the presence of borrowings)

2. Compliance with ethical standards in the study.

We will not dwell on the first item, as the methodology for analyzing published materials has been established and is approximately similar in all publications. As for the second item, there are a number of differences in different editions. Let's look at it closer.

First, we can refer to the specialized bioethics journal "The American Journal of Bioethics" [2], which rules can be considered as a model of ethical requirements in the area discussed. The journal differs from others as it does not send an author to the ethics committee for the compliance confirmation, but conducts an examination (in a reduced form) in the process of submitting the material and reviewing:

*"**Complying With Ethics of Experimentation***

Please ensure that all research reported in submitted papers has been conducted in an ethical and responsible manner, and is in full compliance with all relevant codes of experimentation and legislation. All papers which report in vivo experiments or clinical trials on humans or animals must include a written statement in the Methods section. This should explain that all work was conducted

with the formal approval of the local human subject or animal care committees (institutional and national), and that clinical trials have been registered as legislation requires. Authors who do not have formal ethics review committees should include a statement that their study follows the principles of the Declaration of Helsinki".

The reference to the Helsinki Declaration is typical here. The reference to the Convention on Human Rights and Biomedicine (Oviedo) might be more convincing, but the journal is American and the Convention is European. In addition, an extremely general requirement to refer to the Declaration is alarming. It is obvious that in each specific study it is necessary to provide a justification for the use of specific provisions of the Declaration. Experience reveals that young researchers, when submitting documents to the ethics committee, simply copy the list of documents necessary to ensure the ethical correctness of the research. In any case, the experience of LECs (local ethics committees) shows an amazing uniformity in this part of the documents presented.

A distinctive feature of this journal is a separate provision on ethical guarantees for subjects:

*"**Consent***

All authors are required to follow the ICMJE requirements on privacy and informed consent from patients and study participants. Please confirm that any patient, service user, or participant (or that person's parent or legal guardian) in any research, experiment, or clinical trial described in your paper has given written consent to the inclusion of material pertaining to themselves, that they acknowledge that they cannot be identified via the paper; and that you have fully anonymized them. Where someone is deceased, please ensure you have written consent from the family or estate. Authors may use this Patient Consent Form, which should be completed, saved, and sent to the journal if requested".

It is important here that the journal emphasizes adherence to the principle of patient autonomy as the basis for the publication of the relevant research. Moreover, an IC (informed consent) form considered appropriate by the editorial board is attached. It should be noted that in Russia, for example, there is no universal accepted form of IC. The order of the Ministry of Health of the Russian Federation approved such forms a) for IVF and b) for the provision of primary health care.

Example. *When asked where the form of IP used in research came from, graduate students usually answer: "It was given by a scientific advisor (or a colleague)". Doctors often answer to the same question as: "I have downloaded it from the Internet".*

In clinical trials, IP is approximately the same, but there are fundamental differences depending on the purpose of the study and the methods used.

Example. *CR (clinical research) involves invasive intervention with the removal of biological material or the removal of biological material in the process of routine medical care and the generation of organic waste (abortive material). The patient signs a consent for the intervention, but it does not contain information about whether the patient's biomaterial will be kept by the researchers or it can be transferred to other researchers or a bio-data bank. Ethics committees, as a rule, do not pay attention to such an addition, and the editors may require a special form from authors for such consent.*

Now let's look at how ethical requirements are presented in a specialized journal **"Pharmaceuticals"** [3]

*"**Institutional Review Board Statement***

In this section, please add the Institutional Review Board Statement and approval number for studies involving humans or animals. Please note that the Editorial Office might ask you for further information. Please add "The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of NAME OF INSTITUTE (protocol code XXX and date of approval)". OR "Ethical review and approval were waived for this study, due to REASON (please provide a detailed justification)". OR "Not applicable" for studies not involving humans or animals. You might also choose to exclude this statement if the study did not involve humans or animals".

Here, in essence, the requirements are the same, but they are addressed not so much to the authors as to the ethics committee, where the certificate of the examination must be submitted by the authors. The advantage of the paragraph provided is that the types of research are clearly identified and differences in the content of the expert opinion are noted in accordance with them. At the same time, the editorial office requires detailed justification for compliance with ethical requirements! But – again, a reference to the Helsinki Declaration is very general. The profile of the journal suggests referring to other documents such as the ICH GCP (Guideline for Good Clinical Practice), Doc. E6 (R1) v. 4 (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use; ICH) etc. A stereotyped reference to the Declaration of Helsinki indirectly shows the journal's indifference to the issues of pharmacological ethics. And there are a lot of questions.

Example. *Russian researchers often cannot answer the question of where the animals for the experiments were taken from, that have not heard about the Five*

Rules of the Thumb, find it difficult to name the methods of euthanasia used in the study and are poorly informed that the reuse of animals in the experiment is strictly prohibited. This data contains in the analytical report of the chairman of LEK VolgGMU (Archive LEC VolgGMU, Analytics-3. 24.12.2020).

There is one more fact that editors of peer-reviewed medical journals might draw attention to. In medical loci, where CTs are rarely carried out, there is a practice of "pocket" ethics committees, which are created "for the research", and then "self-dismantles" [4]. In Russia, this is due to the lack of formalization of the documentation in education and LEC activities. In other countries, this is a consequence of simple pragmatism – why be distracted by working in an ethics committee, if it is not in high demand. But in fact, LEC is a permanently operating structure with a complete rotation of members every 3 years.

LEC always has an area to work on, not only for the examination of clinical and preclinical studies. Patients can apply to the committee with a complaint about the ethical attitude of the staff, medical staff can claim violation of professional ethics, obstacles or difficulties in organizing scientific work, etc. Only the continuity in the committee work can ensure the adequacy of the ethical review in accordance of the requirements of health care. Of course, it is not the task of the editorial office to check the work of the ethics committee, where the author's article was examined. But it has become a common practice in foreign peer-reviewed journals to request additional information about the expertise completed. These requests are random but it helps to improve the quality of published studies.

The situation with ethical review of publications varies in Russian medical journals. We have identified three groups in the reviewed journals. The first group has detailed ethical requirements for articles. They are not original; they are exact copies of the similar requirements in those foreign journals where the requirements are formulated. Still, in the Russian-language version, a correction is necessary, as there is a discrepancy in the interpretation of terms and stylistic errors as a result of direct translation. But this is not a drawback, a consensus in determining the ethical standards of medical publications is necessary, and this borrowing just contributes to the creation of a consensus in the scientific medical community on a wide range of issues. Let's give an example of requirements provided in the journal **"Pharmacy & Pharmacology"** [5]:

*"**Editorial Policies***

... 4.7.2. If the work involves the use of animal or human subjects, the author should ensure that the manuscript contains a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and that the appropriate institutional committee(s) have approved them. When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

4.7.3. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects, and it should be indicated in the published article. The privacy rights of human subjects must always e observed. Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Authors should identify Individuals who provide writing assistance and disclose the funding source for this assistance. Identifying details should be omitted if they are not essential. Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note".

Practically all aspects of ethical examination are taken into account here, and the requirements of the journal are confirmed by clear explanations. Special attention is paid to various aspects of the implementation of the principle of respect for patient autonomy, especially – the formulation of IP. It would be interesting to see how these requirements are implemented, since many researchers, lacking appropriate bioethical training, may regard them as excessive. In general, if there is a large number of editorial requirements, it is advisable to check their feasibility. So, in the given example, it is not obvious whether the expert of the ethics committee will check the work in such detail or will limit themselves to signing a positive conclusion. This remark is not a rebuke. Just that the training of ethics committees' members has not been established in Russia, so they act, at times, lacking necessary qualification.

The second variant of ethical requirements comes down to the obligatory mentioning and even listing them, but no specification as such. There is an informational minimalism. Here is an example from the journal ***"Experimental and Clinical Pharmacology"*** [6].

It is the main pharmacological journal of Russian Academy of Medical Sciences and Russian National Formulary society.

*"**Author responsibilities***

Credibility and study standards

If the manuscript is based on an original study, the authors must submit the reliable results of their work and an objective discussion of significance of the study. The manuscript should contain all the key data, accurate description of the study details and references in order to ensure reproducibility of the results. Data falsification or the intentionally invalid statements in the manuscript are regarded as unethical and are inappropriate.

Data availability

The Editorial Board can request the authors to submit raw data in addition to the manuscript. The author must be ready to provide public access to these data, provided that public access to the data violates neither confidentiality of the research participants nor rights of an individual or a company owning these data.

Originality, plagiarism, and citing the sources

Authors must submit only original studies. Authors must properly and accurately acknowledge the work of others. Publications that had significantly contributed

to preparing the study or underlied its design should also be acknowledged".

These are not re is no medicine here. These are requirements that apply to any specialized journal – technical, historical, chemical, etc. There are rules set for how an author should behave in relation to the journal, but no rules on the behavior with the subjects of a research. The requirements strictly correspond to the headings of the sections, only the coverage a medical article specifics as a separate section is not provided.

And, finally, the third group. These are journals where ethics, medical ethics, bioethics were not mentioned at all. So, for example, there is no corresponding section in the Rules for authors in the journal "Bulletin of the Volgograd State Medical University" [7], but it is included in the List of VAK journals, where articles of academic degrees applicants are published. Moreover, over the past 5 years (earlier issues have not been analyzed), not a single article in this journal has passed the examination of the LEK, while articles submitted to foreign journals undergo such an examination. The situation is similar with many local journals. But even in prestigious federal publications, the ethical examination of the submitted materials is either not mentioned, or, if mentioned, is not singled out as a separate block of requirements. For example, in the journal "Sechenovsky Bulletin" [8].

"... I confirm that I have received a written consent for using any personal data (of patients, other persons) in the study and I am ready to provide it at the request of the editors (only for describing clinical cases).

I confirm that the approval of the local ethics committee for the research development has been obtained...".

Everything seems to be correct. The editorial board fully trusts the ethics committee, as it has been working at Sechenov University for a long time and very successfully. But the journal also receives articles from other organizations, where the situation with ethical review may not be so professional. In addition, there are organizations where LEC does not exist or has a "pocket" nature, mentioned above. All this suggests the need for a unified approach to the ethical examination of scientific publications in medicine.

Conclusions:

1. Modern science metric criteria for the scientific and pedagogical staff member publication activity have its cons and prons. The positive sides include common grounds for quantitative analysis and the methods of such analysis implementation. To the negative – the probability of applying the same criteria in different fields of study (for example, in medicine and political science) and the lack of methods of qualitative analysis. A high citation index does not correlate with a high quality of what is cited. On the contrary, the scientific community can actively criticize the author for unreliability, lack of novelty and scientific approach, etc., thus increasing the Hirsch index of the criticised scientist. *This seems like a clear violation of scientific ethics.*

2. It is assumed that journals should be accountable for the quality of publications, since articles are peer-reviewed and, if published, the editorial board considers its quality to be high. But the science metric indicators of the journal, having nothing to do with the quality of the published materials, can be so high that a few frankly weak articles will not harm the prestige of the publication. *But what about the moral assessment of such a situation?*

3. The peculiarities of medical journal publications are their applied nature, team authorship and the availability of information that the research described in the article was not harmful for the subjects, whether animals or humans. Why is the share of basic research in medicine declining? Partly because they require a study publication form, and science metric indicators of current platforms such as Scopus, WoS, PubMed do not take this option into account. *The platforms do not display ethical attitude towards the authors.*

4. As for the ethical examination of the publication material, the editorial colleagues are content with information about its paragraph in the LEK. This information may be inaccurate, therefore medical journal editors should periodically check this information. *A block of information on ethical review should be required for the "Rules for Authors" section of any journal.*

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Information about authors

Natalia A. Alshuk – Lecturer of Department for Philosophy, Bioethics and Law with a Course in Sociology of Medicine, Volgograd State Medical University, Volgograd, Russia

Svetlana A. Kostenko – postgraduate student of the Department of Philosophy, Bioethics and Law with a course in the sociology of medicine, Volgograd State Medical University, Volgograd, Russia

Olga Yu. Golitsyna – PhD(Historical Sciences), Head of the Department of Postgraduate and Doctoral Studies, Volgograd State Medical University, Volgograd, Russia

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Информация об авторах

Н.А. Альшук – преподаватель кафедры философии, биоэтики и права с курсом социологии медицины, Волгоградский государственный медицинский университет, Волгоград, Россия

С.А. Костенко – аспирант кафедры философии, биоэтики и права с курсом социологии медицины, Волгоградский государственный медицинский университет, Волгоград, Россия

О.Ю. Голицына – кандидат исторических наук, заведующий отделом аспирантуры и докторантуры, Волгоградский государственный медицинский университет, Волгоград, Россия

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