Ethics in Medical Research and Publication

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Date of Submission: Apr 28, 2014

Date of Acceptance: May 10, 2014

How to cite this article: Masic I, Hodzic A, Mulic S. Ethics in Medical Research and Publication. Int J Prev Med 2014;5:1073-82.

ABSTRACT

To present the basic principles and standards of Ethics in medical research and publishing, as well as the need for continuing education in the principles and ethics in science and publication in biomedicine. An analysis of relevant materials and documents, sources from the published literature. Investing in education of researches and potential researches, already in the level of medical schools. Educating them on research ethics, what constitutes research misconduct and the seriousness of it repercussion is essential for finding a solution to this problem and ensuring careers are constructed on honesty and integrity.

Keywords: Ethics, medical research, publication

Review Article

INTRODUCTION

Science is a key link in the educational system, it is part of the culture of the nation, further on it contributes to overall well-being and security in everyday life, and represents a source of real knowledge of mankind. In most cases, the scientist is a person of exceptional diligence, which is at the same time, very focused on what it does. If one deals with the scientific work, can significantly improve the human condition; thus, it will make a great effort and sacrifice many daily pleasures.[1]

PRINCIPLES OF WRITING A SCIENTIFIC PAPER

Scientific research demands precision.[2-4] Scientific writing should respect this precision in the form of clarity. Unfortunately, a glance at almost any scientific journal will reveal that the above-stated ideal is often not attained in the real world of scholarly publication.[5,6] Indeed, many of the accusations by nonscientific of "obscurity" and "elitism" within the scientific community probably originate in the sad fact that many scientists are not capable of expressing their hypotheses and conclusions clearly and simply.[7]

The scientific way of thinking and application of scientific methods require honesty, criticality, trust, creativity and openness, and acceptance of these principles as desirable prerequisites for successful engagement in science by students and young researchers, qualifying research institution that produces

competent promoters (initiators) for the future technological cultural and political development of society.[1]

Defining principles of good scientific and good laboratory practice should encourage the development of standardized principles and guidelines for accurate and quality data in scientific research.[1]

The text of observational and experimental articles is usually divided into sections in accordance with so-called "IMRAD" structure: Introduction, Methods, Results, and Discussion. Papers related to public health programs and practice might have different than IMRAD structure (drug). There is a key question for each section of the IMRAD structure of the paper, which an author needs to keep in mind, while writing the manuscript.[6]

Title of the scientific paper contains a brief description of the content. The title should accurately describe the content of the article. There are two types of titles: Indicative title talks about the work that covers and informative title-convey the message of the article and recommended for beginners. A good title should be: (a) Short, (b) correct, (c) a clear, (d) complete, (e) informing, (d) attractive. It should also include: Characteristics of the article, showing what is most important in the work. It is necessary to specify the names of the authors and their affiliations.

Abstract/summary and title can be written in two forms: Reference and Information. It can be written in author's native language and English. The structure of the summary should look like this: Introduction, goal, materials and methods, the location of the study, measuring the outcomes of the study, the results and conclusions.

Summary is the distillate of which will be presented and should show: What has been done, what are the results, what the results means. Writing an introduction has its own rules: A clear definition of a the problem, why exactly this issue was explored, there is no need to explain what can be found in the textbooks, do not need to explain the terms of the title.

Materials and Methods describe how the study was conducted and the characteristics of the sample (experimental group, controls, and their properties). It is necessary to explain what is researched, asked, tested as follows: Sampling (random, consecutive, and representative), the sample size (patient gender, age), the control group, and the criteria for exclusion from the study, the control group if any.

It should be described how the research was done: Type of study (prospective, retrospective or combined), data collection (surveys, inventory or checkup), the technique of measuring results (operative treatment, laboratory tests). It is necessary to specify where the research was conducted. Results are an important part of writing an article.

The research results are usually most carefully read and should be a detailed plan, well-documented at the optimal dose. Discussion is a critical review of the data described in the results. He results should be compared with other findings and discuss the theoretical and practical research outcome. Conclusion should be short, clear and precise. It is necessary to: Make the final statement of what logically follows from the results of the work, list only the most important and give the message. Good conclusions should not surprise attentive reader. The reader should get the impression that he himself had written it. References should be in accordance with the instructions provided by the journal, and otherwise used Vancouver or Harvard citation style.[8]

Papers related to public health programs and practice might have different than IMRAD structure. Anyhow, the paper should be written in logical order consisting informative or indicative title, an introductory section with description of the subject or public health problem and objectives, the current status or situation, recommended or realized program and activities, lessons learned, experiences, results and recommendations, and finally conclusions and a list of references. Special importance and validity have papers which describe new practice, approach and activities, have clear description, design of the practice, approach and activities, offers possibilities for implementation of the practice, approach and activities in other settings and environments, presents the experiences gained, lessons learned, and recommendations.[7]

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

The World Medical Association (WMA) has developed the Declaration of Helsinki [Figure 1] as

Figure 1: The Declaration of Helsinki. Retrieved from: New edition of Declaration of Helsinki Available: http://www.hopitalmontfort.com/en/new-edition-declaration-helsinki

a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. Consistent with the mandate of the WMA, the declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles:[9]

General principles

The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care".

It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

Medical progress is based on research that ultimately must include studies involving human subjects. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures, and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this declaration.

Medical research should be conducted in a manner that minimizes possible harm to the environment. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, burdens and benefits

In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects

may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable groups and individuals

Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.

Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a nonvulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific requirements and research protocols

Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and as appropriate, animal experimentation. The welfare of animals used for research must be respected. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain:

- A statement of the ethical considerations involved and should indicate how the principles in this declaration have been addressed
- Information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for posttrial provisions.

Research ethics committees

The research protocol must be submitted for consideration, comment, guidance and approval to the concerned Research Ethics Committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and confidentiality

Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed consent

Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the

researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, poststudy provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the nonwritten consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.

When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a Research Ethics Committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.

The physician must fully inform the patient, which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

For medical research using identifiable human material or data, such as research on material or data contained in bio banks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations, the research may be done only after consideration and approval of a Research Ethics Committee.

Use of placebo

The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option.

Posttrial provisions

In advance of a clinical trial, sponsors, researchers and host country governments

should make provisions for posttrial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research registration and publication and dissemination of results

Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this declaration should not be accepted for publication.

Unproven interventions in clinical practice

In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgment it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and where appropriate, made publicly available.[9]

PUBLICATION ETHICS

Academic publishing depends, to a great extent, on trust. Editors trust peer reviewers to provide fair assessments, authors trust editors to select appropriate peer reviewers, and readers put their trust in the peer-review process. Academic publishing also occurs in an environment of powerful intellectual, financial, and sometimes political interests that may collide or compete. Good decisions and strong editorial processes designed to manage these interests will foster a sustainable and efficient publishing system, which will benefit academic societies, journal editors, authors, research funders, readers, and publishers.

Good publication practices do not develop by chance, and will become established only if they are actively promoted.[10]

The general principles of publication ethics are:

Transparency

Sources of funding for research or publication should always be disclosed. Editors should state this directly in their editorial policy. Authors should routinely include information about research funding in all papers they prepare for publication. Where a clinical trial registration number is available, this should be included.

Authorship acknowledgment

The International Committee of Medical Journal Editors (ICMJE) provides a definition of authorship that is applicable beyond the medical sector. The ICMJE authorship criteria state 'authorship credit should be based on:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Authors of research papers should state whether they had complete access to the study data that support the publication. Contributors who do not qualify as authors should also be listed and their particular contribution described. This information should appear as an acknowledgment. Sample authorship description/acknowledgment. Collecting authorship information for research papers, authorship should be decided at the study launch. Policing authorship is beyond the responsibilities of an editor. Editors should demand transparent and complete descriptions of who has contributed to a paper.

Editors should employ appropriate systems to inform contributors about authorship criteria (if used) and/or to obtain accurate information about individuals' contributions.

Editors should ask authors to submit, as part of their initial submission package, a statement that all individuals listed as authors meet the appropriate authorship criteria, that nobody who qualifies for authorship has been omitted from the list, and that contributors and their funding sources have been properly acknowledged, and that authors and contributors have approved the acknowledgment of their contribution.

Attributing authorship to a group

The ICMJE provides guidance for instances where a number of authors report on behalf of a larger group of investigators.[1]

This guidance is applicable outside the medical sector.

International Committee of Medical Journal Editors guidance states: "When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above… When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name". The individual authors who accept direct responsibility for the manuscript should list the members of the larger authorship group in an appendix to their acknowledgment.

Protecting research subjects

Journals should ask authors to state that the study they are submitting was approved by the relevant Research Ethics Committee or Institutional Review Board. If human participants were involved, manuscripts must be accompanied by a statement that the experiments were undertaken with the understanding and appropriate informed consent of each.

Editors should reserve the right to reject papers if there is doubt whether appropriate procedures have been followed. If a paper has been submitted from a country where there is no Ethics Committee, Institutional Review Board, or similar review and approval, editors should use their own experience to judge whether the paper should be published. If the decision is made to publish a paper under these circumstances a short statement should be included to explain the situation.[10]

THE MAIN FORMS OF SCIENTIFIC AND PUBLISHING MISCONDUCT

The Oxford English Dictionary describes fraud as "wrongful or criminal deception intended to result in financial or personal gain" and deceit as "the action or practice of deceiving someone by concealing or misrepresenting the truth".[11]

Research organizations and the literature have defined these behavioral patterns within the umbrella title of "Research Misconduct".[12]

There are three major and most severe forms of scientific fraud, scientific and publishing dishonesty or misconduct, in proposing, conducting or evaluation of research and presentation of the research results:

- Inventing data and results (fabrication);
- Alteration or changing the results (falsification); and
- Plagiarism (plagiarism), including self-plagiarism (self-plagiarism), fragmented, repetitive and double publication (duplicate publication).

Besides these, there are a number of other kinds of misconduct that scientists should know how to recognize and avoid that is, "pathology" of authorship, conflict of interest, conflicts of loyalty, "pathological" science, etc.

In the process of publishing scientific papers, it is important to know how a completed research should be described in a scientific paper.[6]

Falsification/fabrication of data

The integrity of research depends on the integrity of the data and the data record. As falsification and fabrication call into question the integrity of data and the data record, they represent serious issues in scientific ethics. Falsification is the practice of omitting or altering research materials, equipment, data, or processes in such a way that the results of the research are no longer accurately reflected in the research record. Fabrication is the practice of inventing data or results and recording and/or reporting them in the research record. Both of these schemes are probably among the most serious offenses in scientific research as they challenge the credibility of everyone and everything involved in a research effort.[13]

However, it is questionable whether a clinical researcher who fabricates data to enroll a terminally ill patient into a trial that ultimately may lead to that individual receiving treatment that may prolong their life should receive the same

penalty as someone fabricating data for their own professional gain.[14]

These offenses make it very difficult for scientists to move forward as it is unclear to anyone what if anything is true and can be trusted-can lead students and colleagues to waste precious time, effort, and resources investigating dead ends.[13]

Plagiarism

The term plagiarism stems from the Latin word plagium, meaning kidnapping a man. It literary means theft, taking material authored by others and presenting as someone else' Plagiarism is basically intended to deceive the reader's. Izet Masic reminded of the comment of Samuel Johnson, dealing with a manuscript that he sent for evaluation: "Your work is both good and original. Unfortunately the parts that are good are not original, and the parts that are original are not good".[13]

Referring to the United States' Office of Research Integrity (ORI) definition of plagiarism, which is "unattributed textual copying", many have questioned its applicability in real life situations. One definition of plagiarism suggests it is the repetition of 11 words or the overlap of 30 letter strings, although this is by no means a standard definition. Furthermore, "salami-slicing"-the selective use of research-project results to maximize the number of presentations possible-has also been classed as a type of plagiarism by some, but not by others.[14]

Plagiarism can be divided into direct (plagiarism of the text); mosaic (the borrowing ideas and opinions from original source and a few verbatim words of phrases without crediting the author) and self-plagiarism (which refers to re-using one's own work without citations).[15]

Researchers rely on the published data, and have to be skilled to selectively process these data, to incorporate previous knowledge into a new paper, and to distinguish original ideas and research results from already publicized ones. Authors are obliged to follow ethical, moral, and legal regulations acceptable by the scientific community. To do so, they must properly cite relevant publications and quote borrowed published or unpublished ideas and words. Simply, when an author copies others' text word for word, the borrowed passage should be enclosed in the quotation marks (inverted commas). The reader should be clearly informed over what is original and recycled from other sources.[15]

Redundant (multiple) publication

Journal instructions should clearly explain what is, and what is not, considered to be prior publication. Journals may choose to accept (i.e. consider "not redundant") the re-publication of materials that have been accurately translated from an original publication in a different language. Journals that translate and publish material that has been published elsewhere should ensure that they have appropriate permission (s), should indicate clearly that the material has been translated and re-published, and should indicate clearly the original source of the material. Editors may request copies of related publications if they are concerned about overlap and possible redundancy. Re-publishing in the same language as primary publication with the aim of serving different audiences is more difficult to justify when primary publication is electronic and therefore easily accessible, but if editors feel that this is appropriate they should follow the same steps as for translation. Editors should ensure that sub-group analyses, meta-and secondary analyses are clearly identified as analyses of data that have already been published, that they refer directly to the primary source, and that (if available) they include the clinical trial registration number from the primary publication.[16]

NATIONAL BODIES

One of the oldest organizations dealing with research misconduct is the ORI in the United States. Set up in 1992, it oversees and directs Public Health Service research integrity activities. With a huge budget of $30 billion, it provides significant funds in the areas of health, research, and development, and oversees bodies such as The National Institute of Health and The Office of Public Health and Science.[14]

The Committee on Publication Ethics (COPE) was established in 1997 by a small group of medical journal editors in the UK, but now has over 7000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics. Several major publishers (including

Elsevier, Wiley-Blackwell, Springer, Taylor and Francis, Palgrave Macmillan and Wolters Kluwer) have signed up some, if not all, of their journals as COPE members. COPE provides advice to editors and publishers on all aspects of publication ethics and in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases. COPE does not investigate individual cases, but encourages editors to ensure that cases are investigated by the appropriate authorities (usually a research institution or employer).[17]

The UK Research Integrity Office is another body representing the interests of over 50 universities and organizations dedicated to scientific research. Set up in 2006, its aims are to:

- Promote the good governance, management, and conduct of academic, scientific, and medical research;
- Share good practice on how to address poor practice, misconduct, and unethical behavior; and
- Give confidential, independent, and expert advice and guidance about the conduct of academic, scientific, and medical research.[18]

CONCLUSIONS

If one wants to create a scientific work, must have on his mind that creating a scientific work requires creativity and openness, honesty, trust, and obeying the ethical principles for writing a scientific paper.

As well an author in medical sciences should always follow the words; "The health of my patient will be my first consideration", (Declaration of Geneva, Adopted by the 2nd General Assembly of the WMA, Geneva, Switzerland, September 1948).[19]

While working on a an biomedical research involving human subjects medical workers should have on mind that it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

The subjects should be volunteers-either healthy persons or patients for whom the experimental design is not related to the patient's illness.

The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Investing in education of researches and potential researches already in the level of medical schools, educating them on research ethics, what constitutes research misconduct and the seriousness of it repercussion is essential for finding a solution to this problem and ensuring careers are constructed on honesty and integrity.

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Source of Support: Nil, **Conflict of Interest:** None declared.