International Research Journal of Advanced Engineering and Science
ISSN (Online): 2455-9024

Fundamental Principles of Ethics and the Implementation of Those Principles in Biomedical Research in Vietnam Today

Nguyen Thanh Tinh
Colonel, Ph.D., Dean of Marxist-Leninist Ideology Faculty, Vietnam Military Medical University

Abstract**—** *During the construction and development of the Vietnamese healthcare industry, promoting biomedical research is essential to improve the quality of healthcare for people. In fact, there have been many research projects that bring practical effects in treatment, but some scientific projects in the implementation process violated the fundamental principles of ethics in research. Therefore, firmly understanding the fundamental principles of ethics and implementing those principles in biomedical research in our country today has not only theoretical but also profound practical significance.*

Keywords**—** *Medical ethics and medical ethics education.*

I. Introduction

Hypocrate, who is considered as the ancestor of the medical profession in Greece ancient medicine, more than 2,500 years ago, brought up the ethical basis that physicians must follow and swear before starting their medical practice. In his vows, he said: The physicians, at any time practicing to care and treat the patients, must only do good things, not anything harmful to the life of the patients [8]. Hai Thuong Lan Ong, a Vietnamese great physician in the eighteenth century, gave 9 medical-training aphorisms to teach his students to seriously follow in their professional practice. Although ethical issues in medical practice were mentioned very early, there have been a number of human trials regarding the causes of pathogenesis, new treatments or diagnosis that have violated the human life, dignity, ethicality. Therefore, the medical ethics in biomedical research in general, especially thorough understanding of fundamental principles of ethics in biomedical research in our country today needs to be deeply understood and properly applied.

II. Three Fundamental Principles of Ethics, the Current Situation and Some Solutions to Effectively Implement Those Principles in Biomedical Research in Our Country Today

1. Three fundamental principles of ethics in current biomedical research

The ethical principles in biomedical research were mentioned very early, especially tests of new remedies or diagnosis. The first international document on ethics in research is Nuremberg charter. After that, The United Nations Council adopted a global statement on human rights in 1948 and the International Convention on Civil and Political Rights in 1966. In 1964, the World Medical Association (WMA) issued the Helsinki Declaration, an important document pointing out the fundamental ethical issues in biomedical research. This Declaration was revised many times, the last time was in 2000. Derived from the above documents, nowadays, scientists around the world have agreed to come up with three fundamental principles of ethics in biomedical research: Respect for rights; Beneficence and Justice [9], [10], [11], [12].

1.1. Respect for rights

Respect for rights is the fundamental principle of ethics and is also the fundamental principle of ethics in biomedical research. Respect for rights expressed in ethics in research includes:

Respect for self-determination: All biomedical studies must respect the choice of voluntary participation in research, or decision on withdrawal from research at any time of the research subjects. Research subjects have the right to know all the information related to the research which they participate in, including the benefits and risks for them to consider and decide. They have the right to have their personal information kept confidential.

Protection of people whose self-determination is limited: Respect for rights in research, especially in biomedical research, is a fundamental principle of ethics, in addition to respect for self-determination, respect for rights also includes providing guidelines to protect those whose self-determination is limited. This group of people in researches is classified as vulnerable group including children, ill people who are unable to make their own decisions, those with special circumstances, who do not dare to make decisions such as poor, dependent people, those who are imprisoned or suffer from certain penalties. Ethical guidelines in research require regulations for each type of subject in the vulnerable group to protect them against the damages caused by the research and to prevent them from being abused in researches.

Self-determination of the research participants is reflected in the informed consent forms. The informed consent is the agreement of individuals who agree to participate in a certain biomedical research study after having been provided with sufficient information related to research and careful consideration, then they voluntarily decide to participate in the research.

The informed consent form is a mandatory requirement for biomedical research studies when research study designs are reviewed, related to the ethical principle of "respect for rights", the principle of self-determination regarding whether they want to participate in a research study or not. The

Nguyen Thanh Tinh, "Fundamental Principles of Ethics and the Implementation of Those Principles in Biomedical Research in Vietnam Today," *International Research Journal of Advanced Engineering and Science*, Volume 4, Issue 2, pp. 375-377, 2019.

informed consent is an agreement of individuals who are competent to make decisions without being subject to any coercion, domination, inducement or threat.

For the vulnerable research group including children, ill people or those who are incapable of making decisions on whether or not to participate in a research study, the informed consent will be assigned to a responsible representative who have a legal basis to represent, he or she will make a decision on informed consent.

The informed consent is a two-way information process between researchers and research subjects, before and during the research. Research subjects have the right to withdraw from the research at any time without loss of their benefits.

1.2. Beneficence

This is a fundamental principle of ethics in biomedical research, which aims to set standards to ensure that the hazards (risks) in the research have been carefully considered and minimized, the benefits of research are fundamental. To achieve these standards, the research design must be scientific, effective and feasible, the researchers must master the research-related issues. Researchers not only must be capable of conducting research but also have to ensure the benefits of research subjects. Beneficence also implies not deliberately harming people (no malice). This aspect of Beneficence is sometimes expressed as a separate principle of ethics that is no malice (not causing harms). Therefore, before conducting any research, researchers must always consider the risks and benefits of such research.

Every human-related biomedical research study always has two issues: the benefits and the risks (risks or damages) of the research study. These two issues contradict each other and if the risks are greater than the benefits, the level of harm to the research subjects will be higher. Principles of ethics in research require researchers to maximize benefits and minimize the harmful effects of the research. The Research Ethics Committee will review and evaluate this issue. A research study can only be approved for implementation upon careful consideration of benefits and risks, ensuring that the level of damages to the subjects is minimal or zero while ensuring that the research study gives maximum benefits for research subjects.

Assessment of benefits and risks is a very fundamental principle of ethics, which governs other principles of ethics. When it comes to the assessment of benefits and risks, we have mentioned three fundamental principles of ethics: Respect for Rights, Beneficence and Justice. Assessment of benefits and risks in research ethics is understood as consideration, review, comparison of benefits and risks of a certain biomedical research to consider whether it is possible to conduct a particular research or not.

1.3. Justice

Along with the principles: Respect for rights and Beneficence, Justice is also one of the fundamental principles of ethics in biomedical research. The essence of this principle is the equality of interests and responsibilities for each person in the process of research. Justice in biomedical research firstly refers to fairness in the distribution of benefits and risks to research participants, including the vulnerable group. Justice requires researchers to protect the rights and interests of vulnerable people, should not be concerned about its benefits and take advantage of the inability of under-resourced countries or vulnerable communities to conduct low-cost studies to avoid the complex regulatory system of industrialized countries in order to create markets in favor of these countries.

2. Current situation and some solutions to effectively implement the fundamental principles of ethics in biomedical research in Vietnam today

From the fundamental principles of ethics in biomedical research, each country provides legal guidance on ethical standards in research in accordance with common standards and international ethical guidelines in research, the specific characteristics of each nation, customs, social and economic circumstances, etc. In Vietnam, the ethical consideration and evaluation of biomedical research studies have gained attention very early. In 1975, the Minister of Health signed off the Regulation on clinical trial treatment. In 1996, the Minister of Health issued the Regulation on assessment of the safety and effectiveness of traditional medicine. In 2002, the Minister of Health signed the Decision No. 5129/2002/QD-BYT dated December 19, 2002, promulgated the "Regulation on organization and operation of the Ethics Committee in Biomedical Research". On January 11, 2007, the Minister of Health signed the Decision No. 01/2007/QD-BYT promulgated the "Regulation on clinical trials" [2], [3], [4], [5]. In addition to legal documents, the Ministry of Health published documents related to good practice of clinical trials and ethics in biomedical research, conducted pilot training courses based on the above content. Nowadays, in the trend of international integration and strong development of science and technology in general and the medical and pharmaceutical industry in particular, there have been more and more new pharmaceutical products in Vietnam (including new medicines, vaccines, traditional medicine, probiotics used for treatment) in clinical trial studies (human trials) recommended by foreign and domestic manufacturers. However, under the strict guidance of the Ministry of Health, with high sense of responsibility of the scientists, in recent years, research, development and application of new biomedical products ensure safety and efficiency, protect rights and health of research participants. Many research studies, upon successful clinical trials, were quickly deployed into the treatment process, which brought practical results for improving the quality of healthcare for people. However, the survey results of a recent research study with 481 scientific staff of 6 central hospitals showed that: the percentage of scientific staff who are interested in knowledge, ethics and practice of biomedical research in hospitals is very high (nearly 90%). However, the percentage of scientific staff with knowledge about these issues is still very low (<4%), the highest percentage of those who participated in biomedical research studies and have correct knowledge of this issue in the group is only 10.8%, the percentage of staff who made research records as required is also very low (21.6%) [6]. Due to the limited knowledge, ethics and practice of biomedical research of researchers, the violation of ethical principles in the research process in different levels is inevitable.

From the above situation, to ensure proper implementation of fundamental principles of ethics in

research, development and application of biomedical products, the functional agencies and researchers are required to implement some basic solutions as below:

Firstly, being well-done in education, training and self-education to improve the qualifications and ethical qualities of researchers.

In fact, doctors working in hospitals often only try to cultivate knowledge of clinical expertise, the participation in scientific research is usually only done with the research knowledge, and the requirements of ethics in the research process are very limited. So when they begin to study, they are not aware of mistakes in scientific research, leading to loss of the State budget and violation of the ethical principles in the research process. Therefore, for medical staff, before getting into their research career, they need to undergo a training course to master the principles of ethics, theory, philosophy and methods of biomedical science research. In addition, it is necessary to organize continuing education courses on scientific research methods and principles of ethics in scientific research for clinical experts involved in research projects. In addition, during the process of professional activities, researchers need to actively take the initiative in learning and training to improve their qualifications and skills to study and cultivate the necessary ethical qualities to help the research process reach higher efficiency.

Secondly, creating a legal corridor and specific ethical requirements to help researchers effectively perform research studies.

Research ethics of researchers are expressed through their research projects. These activities affect patients, the development of the health sector and broadly the whole society. Therefore, in order to help researchers effectively implement their projects, the Ministry of Health authorities are required to create a legal corridor and specific standards to help researchers effectively implement the principles of ethics in research. In addition to the legal documents issued by the Ministry of Health, it is necessary to develop specific ethical requirements in research such as: standards for researchers or institutions; things to do with the research subjects (normal people or voluntary patients); research method standards (medicines, tests, treatments, etc.); organization and how it works to monitor and supervise the implementation of regulations, etc. Legal documents and ethical standards will be the basis for a transparent behavioral orientation for researchers during the research process.

Thirdly, improving the performance quality of the Ethics Committee in biomedical research.

The Ethics Committee in biomedical research (also known as Independent Ethics Committee-IEC) is a committee at the local level (institutional level), national or inter-national level consisting of members who are scientists, health professionals and members who may not work in the medical industry. The Committee is responsible for reviewing clinical trials (CTs), giving approvals or disapproval for CTs to ensure the safety, benefits and health of research participants, ensuring publicity, science and transparency in the review. The main task of the Ethics Committee in biomedical research is to ensure the rights, safety and voluntary participation of research participants, ensuring fairness for all parties involved, ensuring the scientific, feasibility of research, safety for researchers and the community; evaluating and approving biomedical research records (research protocols, relevant reports and documents), ensuring the legality, objectivity and honesty; monitoring, inspecting and supervising the compliance with research standards of good clinical practice; evaluating and appraising research results according to approved research protocols based on current guidelines and regulations; training, guiding and developing researchers for the health sector according to the criteria of good clinical practice (GCP) and ethics in research.

III. CONCLUSION

Ethics is a system of standard rules of virtue to regulate human behaviors and prevent the possibility to cause harms to others, the society and selves. Human harms are not only physical harms but also harms to other aspects such as honor, position or prestige, etc. Accordingly, the researchers' behaviors which accidentally or intentionally cause harms to others, the society and even themselves are unethical. Therefore, studying the fundamental principles of ethics and thoroughly grasping these principles in biomedical research must always be established and have an important position for the researchers.

REFERENCES

[1] Secretariat Committee, *Resolution No. 46-NQ/TW on the protection, care and improvement of people's health in the new situation*, Hanoi, 2005

[2] Ministry of Health, *Decision No. 186/BYT-QD dated May 6, 1975 of the Minister of Health promulgating regulations on clinical trial treatment.*

[3] Ministry of Health, *Decision No. 371/BYT-QD dated March 12, 1996 of the Minister of Health promulgating regulations on assessing the safety and effectiveness of traditional medicine*.

[4] Ministry of Health, *Official Letter No. 505/BYT-KHDT dated January 24, 2006 of the Department of Science and Training under the Ministry of Health guiding the technical process of drug testing in clinical practice*.

[5] Ministry of Health, *Decision No. 01/2007/QD-BYT dated January 11, 2007 of the Minister of Health promulgating "Regulations on clinical trial"*.

[6] Nguyen Ngo Quang, Do Duc Van, Ngo Quy Chau, Pham Quoc Bao, Hoang Hoa Son, Knowledge, attitudes and practices on good clinical trial practice of scientific staff in some central hospitals, *Tạp chí Y học thực hành (763)*, Vol. 5/2011, pp. 70-73, 2011.

[7] Nguyen Van Tuong, Nguyen Tran Hien and collaborators, *Đạo đức trong nghiên cứu y sinh học,* Medical Publishing House, 2006.

[8] Rees J.P., Wiliams G.D., Ethics, *Principles of clinical medicine*, pp. 7-8, 1995.

[9] Regniew B., Good clinical practice, *Eur J Clin Microbiol Infect Dis*, 9 (7), pp. 519-522, 1990.

[10] Switula D., Principles of good clinical practices (GCP) in clinical research, *Scien Eng Ethics*, 6(1), pp. 71-77, 2000.

[11] http://www.fda.gov/oc/gcp/, *Good Clinical Practice in FDA-Regulated Clinical Trials.*

[12] http://www.mhra.gov.uk/home, *Good Clinical Practice.*