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Principles of Bioethics in India: A Review

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Review Article

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ABSTRACT

Bioethics refers to the principles and guidelines set for guiding research from its inception till the completion and scientific publication of the research results. It is an ethical theory that brings together the law, medicine, philosophy, social sciences, theology, politics and other disciplines to address questions related to clinical decision making, informed consent and medical research.

INTRODUCTION

In India, bioethics was built by both the British-India and the independent Indian state as the channel of modernity and welfare. The institutions of medical education and bioethics were developed by the province as part of the project of development [1-10].

In India, Ethical guidelines are provided by the Indian Council of Medical Research. In 1980, they formulated the first national ethical guidelines. They have designed curriculum for implementing bioethics, which would be applied uniformly in medical schools throughout the country [10-20].

After the disastrous events of trials of German doctors conducting human experiments without informed consent post World-war II subjecting them to the risk of death or permanent impairment. Therefore, the first international ethical laws were made called Nuremberg Code in 1947 followed by Universal Declaration of Human Rights was made by UNO expressing issues about rights of humans treated to involuntarily. In 1964, World Medical Association formulated general principles and specific ethical guidelines for using human participants in medical research, known as the Helsinki Declaration [20-30].

Ethical Review for conducting biomedical research in India

Principles of essentiality: It states that Research involving human subjects is considered to be essential. It is considered based on the fact that no alternative is available with existing knowledge in the related field. The decision is for proposed clinical research is taken after considering that further research is necessary for the betterment of the human health and environment [30-40].

Principles of voluntariness, informed consent and community agreement: It states that the human subject must be fully aware or informed of the research and the risk of the research on the participants. The participants have the right to withdraw from the further research participation irrespective of the legal or any other obligation, participants might have entered. If the human participant is incapable of giving consent regarding the research trials being carried out on them, still the principle of informed consent shall remain effective and the consent of the participant is obtained by someone who is empowered to take the responsibility on their behalf [40-50].

Principles of non-exploitation: It states that the research participants must be provided with the remuneration for their participation in the research activity irrespective of their social, educational and economic

status etc. The participants must be fully aware of the danger and risk arising from the research on their physical and psychological well-being. The research must be conducted without discrimination by selecting the candidates by evaluating the risk involved and the benefits. The participants must be provided compensation in the form of insurance cover or medical aftercare and rehabilitation [50-60].

Principles of privacy and confidentiality: It states that identity of the participants and the record of the research trials must be kept confidential. The details of the participants must not be disclosed without any consent or genuine legal and scientific reason which may results in social discrimination or stigmatization. The identity can be disclosed only for the essential purpose of medical or legal grounds without the consent of the participant in writing or any other authorized person [60-65].

Principles of precaution and risk minimization: It states that the effective caution and care must be taken at all stages of the research ensuring that the research participants are kept at minimum risk and from other irreversible adverse effects [65-70].

Principles of professional competence: it states that the research is carried out at all the times by qualified and competent researcher with integrity and training. They must be adhering to ethical laws without partiality in their research [75-80].

Principles of accountability and transparency: it states that the research must be conducted by the research expert in an honest, impartial, fair and clear manner with full disclosure. Conflict of interest if any must be disclosed. The records and other details of the research and participants of the research must be preserved and retained with privacy and confidentiality for the given prescribed time or for the post-research evaluation, monitoring of the research [85-88].

Principles of the maximization of the public interest and of distributive justice: it states that research experiment conducted must not only benefit socially better off but also the backward. It means, it must benefit all the human beings and the community [88-90].

Principles of institutional arrangements: It states that the research work must include all the possible institutional approvals required with respect to the research are duly made in transparent and bonafide manner [91].

Principles of public domain: it states that the research and evaluation report must be brought to the public domain through scientific publications so that the data is available for the researcher for the evaluation [92].

Principles of totality of responsibility: It states that the moral and professional responsibility, guidelines, principles, data related to funding or grants, contribution, the institution where the research is conducted must be monitored and subjected to reviewed followed by remedial action [93].

Principles of compliance: it states that the research information including human participants must be observed and compiled $^{[94]}$.

THE FUTURE IMPLEMENTATION OF BIOETHICS

The Recent advances within the sciences, the Bioethics has many roles to play among which the three important mission are: (1) to raise the questions about non-ethical practices among healthcare institutions (2) to compete with the new bioethical problems arising by implementation of new and upcoming biotechnologies (3) to challenge the public health issues and the deliverance of health care facilities among economically underdeveloped parts of the world. The attention to the moral and ethical issues related to latest technologies like nanotechnology or stem cell research requires further progress and development in the field of bioethics [95].

The basics implementation of the bioethics is: What are the ethical obligations of doctors to their patients? What are the valuable virtues of any "good doctor"? Bioethics covers critical issues in clinical and research related to scientific publications of correct data, informed consent, and confidentiality of participants, conflict of interest if any, euthanasia (assisted suicide), access to the health care and withdrawal of research on arising of ethical issues [96].

The aim of bioethics is to enable ethical issues to keep updated with the recent scientific and medical breakthroughs [97]. The scope of Bioethics has well expanded to include the moral queries raised by the Human Genome Project, artificial and in-vitro fertilization, stem cell research, the biotechnology and genetic engineering, cloning, genetic identification and diagnosis, nanotechnology and xenotransplantation etc.

Bioethics has also interacts with the new challenges exhibited by delivering health care in underdeveloped nations, where ethical standards cannot be enforced fully for the conduct of research to find treatment or vaccines against infectious diseases. HIV, or Malaria. And to what extent is manipulation or perhaps coercion can be

achieved to accomplish the goals without much effect on the risks incorporated in health care of the research participants? This population-based focus raises new questions related to ethical issues to health care provides who wants to conduct research against diseases that are epidemic in some parts of the globe [98-101].

The bioethics has expanded the scope by incorporating the field of the philosophy, religion studies, medicine, ethical law, public policy and health, nursing, and social science.

Discussion

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CONCLUSION

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