Editorial

Ethics in clinical research

Volume 2 Issue 1 - 2015

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Received: February 09, 2015 | **Published:** February 23, 2015

Abbreviations: RCTs, randomized controlled trials; ICMR, indian council of medical research; REC, research ethics committee; HIPPA, health insurance portability and accountability act

Editorial

Ethics is derived from the Greek word 'ethos', which means the common moral spirit of the community. Historically, the root of biomedical ethics has been documented as duty of physicians and Hippocratic Oath is one such document.[1] With the advancements in medicine, it becomes prudent for the physicians to have both scientific-technical proficiency and knowledge of clinical ethics. However in the recent times, there has been a report of scientific misconduct and issues related to scientific ethics. This has led to withdrawal of publications. This has an direct impact not only on the credibility on medical professionals performing such work but also raises suspicion and loss of confidence among the patients in general. The basic principle of ethics in research has been well documented. The four cardinal principles of ethics include autonomy, beneficence (do good), non maleficence (do not harm), and justice. However, we can describe medical research ethics as work that contribute to the well being of society in general. So, social value of a research has been upcoming an important criteria for a worthy research.

Randomized controlled trials (RCTs) are considered gold standard evidence in medical practice. They have been instrumental in the progress of medicine. However, various horrifying incidents of trials conducted on human subjects in the past such as the trials by the Nazi doctors on world war prisoners, the Tuskegee Syphilis study have been keystone in the development of National level guidelines concerning the protection of rights of the human subjects involved as participants in various trials. Nuremberg code,[2] declaration of Helsinki[3] and Belmont reports[4] are the three important documents which were developed consequent to the reports of atrocities and coercion by the researchers on human subjects. Essentially, all of them emphasize on preserving the autonomy, integrity, health and interests of the participants. They have attempted to balance the necessity of generating sound medical evidence with the interests of the research participants. Declaration of Helsinki,[3] is the official statement by the World Medical Association which has been most influential on researchers across the world. It centered on the principle that the interests of individual subject always take precedence over the interests of science and society. It is society and the investigator that benefit from research. Accordingly, society and the investigator have a moral obligation to ensure the well being of human research subjects. Belmont report[4] released by National commission for protection of Human Subjects of Biomedical and Behavioral Research in 1978 had focused on providing a framework of cardinal principles of respect for persons, beneficence, and justice which should underpin any research activity. Subjects undergoing research under the influence of anesthesia are even more vulnerable to be exploited for research against their wish. This increases the responsibility of researchers in the field of anesthesia.

In the Indian context, Indian Council of Medical Research (ICMR) has put forward 'Ethical Guidelines for Biomedical research on human subjects'[5] in the year 2000, last revised in the year 2006. These are a set of twelve guidelines to be adhered to by every researcher in the country doing trials on human subjects. These guidelines emphasize basic principles of ethics and having an social value. These also emphasize safety of the subjects in all aspects.

The researchers are aided by a group of people to help/guide on these ethics for the research. These come under the designation of Ethics/research committees. Research Ethics Committee (REC) should approve any research before its perusal. REC should have a minimum of five members, with atleast one scientist, one non-scientist and one person from outside the institute.[6] These people should be knowledgeable in law and standards of professional conduct. Since it is the researcher and the society who are to benefit from the study and not the patient in most instances, we have the moral duty of ensuring the well being of the research subjects. Accordingly, the REC takes into account the scientific relevance of the study in question as well as the welfare and dignity of the research subject before giving a nod to it.

Informed consent is the cornerstone of any ethically conducted research.[5,7] There has been a paradigm shift in the doctor patient relationship from the initially paternalistic approach to that of a shared decision making in the present era. A fully informed consent is paramount to respect the principle of autonomy. Information regarding the nature of the study, its purpose, risks and any perceived benefits should be sufficiently disclosed in an easily understood language to the patient or their legal representative. 'Therapeutic misconception'[1,8] and 'situational coercion'[9] should be avoided at all costs. Patient should be given due time for giving his consent to participate or refuse. It should be clearly informed to them that they are not obliged to participate and they can withdraw from the study at any time without the compromise of the standard of care provided.[7]

In case of a clinical trial on a new unlicensed drug, it is mandatory to obtain indemnity from the manufacturer on its side effects. All drug trials which involve drug outside the product license require permission from medicine control agency.[10] Another issue with drug trials is active controlled trial versus a placebo controlled trial. There has been a concern of deception and possibility of harm to participants receiving placebo instead of active drug in the control group.[11,12] The last revised formulation of the Declaration of Helsinki has provision for this issue. It mentions that "use of placebo is acceptable under condition that no proven treatment exists or it is necessary to determine the efficacy or safety of the intervention provided that the group receiving placebo will not be subjected to any risk of serious or irreversible harm".[3] However, 'escape' analgesics and antiemetic should always be provided on request.

Confidentiality is mandated by various state laws like Health Insurance Portability and Accountability Act (HIPPA).[13] Disclosure of identity of research subjects has been prohibited unless any compelling legal or other reason exists. Data acquired during the study should also be kept confidential. A sensitive issue in relation to research is experiments involving vulnerable population like children, elderly, poor, illiterate patients, prisoners and mentally challenged persons, terminally ill and comatose patients since they can easily be coerced into participation. REC should ensure the inclusion of this population for research is justified and there is no scope of exploitation.[5,7] For incapable adults, REC approval must be sought, intervention must relate to the primary condition with which the said patient is suffering from, and research should not be against the best interest of the patients. Never conduct a study on vulnerable population if it can possibly be conducted on competent patients. Assent from the relatives should always be obtained for this category of patients to minimize legal discourse.[10] Children are particularly vulnerable to exploitation for research purposes. Their dissent is often not regarded as important even if they have the required decision making capacity. Federal law of United States requires accent from any minor 7years and older to be recruited for research purposes.[9]

There remains some issues pertaining to research with regards to topic of research. It has been seen that major funding in research is spent on less common health related problems. There is no document made for the funding agencies regarding funding on more common public health issues which remains a social value for any research. Also, we need to have curriculum and its appropriate dissemination for Research ethics education.[14]

Clinical research has undoubtedly contributed to advancement of medical science. The practice of medicine and research without Ethical principles can turn into worst form of crime. If the basic moral principles are kept in mind for the conduct of research, ethical dilemmas are unlikely to arise. Just as what was engraved in the theory of 'primum non nocere' ages back, intentional harm should never be inflicted. Ethical misconduct is not pardonable in research ethics as much as it is in routine clinical practice. We as physicians should strive for protection of research subjects from any involved risk while maximizing the benefits. Knowledge of the ethical principles and adherence to the high standards of professional conduct will go a long way in promoting quality medical research.

Acknowledgments

None.

Funding details

None.

Conflicts of interest

Authors declare that there is no conflict of interest.

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