Ethics in clinical research

Greetings ladies and gentlemen, welcome to another podcast by SBV

This topic is the need for the hour as bioethics has now become a part of our medical curriculum and is one of the grey areas which is usually neglected. The word ethics is derived from the Greek word ethos which means character and reflects human’s interaction with nature & his fellow beings on their freedom, responsibility, and justice. Ethics in clinical research focuses largely on identifying and implementing acceptable conditions for exposure of selected individuals to risks and burdens for the benefit of society as a whole.

Formulation of Ethical guidelines for conducting human experiments was mandated witnessing the inhuman behavior of the study subjects during the conduct of the research experiment in earlier days. Science rush during World War II wherein research experiments were conducted on soldiers and prisoners inflicting harm both physically and mentally. All the insane experiments by the Nazis in their concentration camps were considered barbaric and brutal. In some of their dreadful experiments the prisoners were kept in freezing water, compression chambers, and high altitudes, inflicting gunshot injuries, & inoculating infections to see how the body responds to such adverse conditions. Death would be the end point of all these experiments and if not, they will be subjected to antemortem dissections to study the body changes.

These inhumane practices stunned the whole world and were the cornerstone for the formulation of the Nuremberg code of 1947, which was the first international treatise on the ethics of research on humans which emphasized the necessity of obtaining voluntary consent, ability to withdraw from the study and ban such studies which can cause potential harm to the participants.

With no honor to the Nuremberg code, some researchers continued to abuse and exploit patients for their research needs e.g. The Willowbrook state study on the natural course of infective hepatitis & Jewish chronic disease hospital study on cancer patients

To put an end to these intolerable unethical practices the world medical association developed a set of guidelines and rules primarily to safeguard the rights and wellbeing of the participants. this was later known as the Declaration of Helsinki which has undergone seven revisions since its inception. Governed by 32 principles, it mainly stresses voluntary informed consent, scientific reason for a study, vulnerable population, confidentiality of data, and the need for an ethics committee for reviewing and approving the study.

The Belmont report of the US following the unethical behavior in The Tuskegee syphilis study laid the foundation of regulations on ethics and research on human subjects in the US which speaks on informed consent, assessment of risk vs benefits & unbiased selection of participants.

In order to curb the exploitation of developing and underdeveloped countries by the pharmaceutical industries to conduct research experiments, the World Health Organization (WHO) & Council for International Organizations of Medical Sciences (CIOMS) have put forth the ‘International Ethical Guidelines for Biomedical Research Involving Human Subjects’ which stresses on ethical issues like consent, vulnerable population, appropriate inducements, therapeutic misconceptions & Post trial access.

Ethical regulations in India took its shape only in the early 80’s and the ICMR with its release of Policy Statement on Ethical Considerations involved in Research on Human Subjects was the first in kind statement which mandated establishment of ethics committee in all research institutions/centers. Initially this was not taken seriously by the indian researchers who continued with their unethical experiments. This urged the regulatory body to come up with rigorous a guideline to streamline research involving humans which was called as Ethical Guidelines for Biomedical Research on Human Subjects in 2000 which was incorporated in Schedule Y of Drug and cosmetic Act of 1940. Since then, it has undergone 3 revisions and the latest being the National Ethical guidelines for Biomedical Research Involving human participants 2017.

The guideline has elaborated the four basic principles aka the pillars of ethics namely, Autonomy, beneficence, maleficence & justice by inducting 12 principles which are considered necessary for an ethically sound study. Principle of

Essentiality, voluntariness, non-exploitation, social responsibility, ensuring privacy & confidentiality, risk minimization, professional competence, maximization of benefit, transparency, totality of responsibility etc.

It’s the researcher & the stakeholder’s responsibility to protect the dignity, rights, safety and wellbeing of all the participants enrolled in the study.

Ethics committee will look into matters like informed consent process, vulnerability, adequacy of infrastructure and facilities, risk benefit ratio, plans to maintain confidentiality and plans for post-trial access and compensations.

Ethics in clinical research in India has undergone significant evolution and if there is a question “are we following them” the answer would be NO. this is because these guidelines are just recommendations and are not Law unlike countries like US and European nations. Another reason is lack of adequate training in fundamentals of bioethics. It a welcome move by the NMC to induct Bioethics in the undergraduate medical curriculum which is need of the hour when it comes to patient care & clinical research.

Finally, I conclude by saying practice leads to perfection and perfection leads to succession.

Let’s make India a competent and credible place for ethical research

Jai hind