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Medical Ethics
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RESEARCH ETHICS

- Research conducted for the purpose of contributing towards science by the systematic collection, interpretation and evaluation of data and that, too, in a planned manner is called scientific research: a researcher is the one who conducts this research.

The results obtained from a small group through scientific studies are socialized, and new information is revealed with respect to diagnosis, treatment and reliability of applications.

- Before beginning the scientific research, the researcher should determine the subject, do planning and specify the methodology. In the Declaration of Helsinki, it is stated that 'the primary purpose of medical researches on volunteers is to understand the reasons, development and effects of diseases and develop protective, diagnostic and therapeutic interventions (method, operation and therapies).

  Even the best proven interventions should be evaluated continuously by investigations with regard to reliability, effectiveness, efficiency, accessibility and quality.

- Scientific research can be classified in several ways. Classification can be made according to the data collection techniques based on causality, relationship with time and the medium through which they are applied.

1. According to data collection techniques:

- Observational
- Experimental

2. According to causality relationships:
    - Descriptive
    - Analytical
3. According to relationships with time:
    - Retrospective
    - Prospective
    - Cross-sectional
4. According to the medium through which they are applied:
    - Clinical
    - Laboratory
    - Social descriptive research

Or it can be classified into descriptive and Analytic.

- A brief history of research ethics

Ethics in medical research received world attention after significant events in the first half of the twentieth century, including the shocking human experiments by Nazi doctors on victims of World War II. Also Japan conducted human biological experiments between 1833 and 1945. Under Stalin rule, poisons was introduced to prisoners. Also U.S doctors carried

out research studies in Tuskegee and Guatemala in vulnerable social groups.

- Codes of Ethics in Research
  - The Nuremberg trials of 1944, the human experiments carried out by Nazi doctors on prisoners during World War II. One of the first documents on modern research ethics, Nuremberg Code of 1947, emerged from these trials are part of judgment documents. It emphasized the need for voluntary consent in medical research.
  - The World Medical Association was established in 1947 and adopted the Declaration of Helsinki 1964as document on research ethics.
  - The National commission for the protection of human subjects formed in 1974 to investigate reports of unethical medical research in the USA, released the Belmont Report in 1979. It was the first national guidelines for medical research.
  - The Counsel for international organization of medical sciences (CIOMS) in collaboration with the WHO drew up the ' International Ethical guidelines for biomedical research involving human subjects'1993'.

- In 2002, the Nuffield Council on Bioethics in UK published report on 'The Ethics of Research Related to Health care in Developing Countries' Every country was encouraged to develop its own ethical guidelines for medical research.
- Good Research Practice (GRP): term used to describe ethical standards in procedure, review and conduct for doctors involved in research.

- Principles of Research Ethics

The principle of research ethics are derived from principles of medical ethics. In research it applies to the conduct of the doctor as researcher and his interaction with the patient participants. The goal is the 'promotion of good quality medical research, ensuring the protection and respect of human participants'. Principles of research ethics include the following:

-Beneficence

-Nonmaleficence

-Respect

-Justice

-Integrity

- Beneficence and Nonmaleficence

Beneficence is the principle at the heart of clinical ethics and include the professional duty to do what is best for the patient. In research too, this principle ensures that the outcome of the study is beneficial and the participants is protected from harm. The participant may or may not drive any direct benefit, but the study must not be undertaken unless the outcome can benefit science, medicine, or wider human community. So the essentialness of research is critical in human studies.

The principle of nonmaleficence advice the researcher to do no harm. Since the very nature of research is exploratory, it may not be possible to entirely prevent harm to the participants, but the principle is upheld by ensuring minimum risk or harm to human participants in research.

There must be assessment of the possible benefit and risk of every study by the researcher and the ethics committee. This would include a review of scientific feature, social feature and risk analysis of the proposed research.

Even in phase-1 trial using healthy voluntaries, there is need for protection of participants. The death of a healthy volunteer in an asthma study at

John Hopkins University in 2002 drew world attention to the importance of oversight in medical research.

- Scientific merit of research (feature or characteristic);

(Drug or device tested, is its feature in study design or methodology? or outcome of the study? Will it add to the body of knowledge in science or medicine?

- Social feature of research (it's more difficult to assess than scientific feature, does the research address a health priority or need? Will this study improve medical care or reduce suffering in some way? Can the results of this study inform health policy?

- Role of the ethics committee

  Every research proposal involving human participants, human tissue samples or human data has to be reviewed by a registered ethics committee. This committee is constituted by the hospital or institution where research is carried out and is ideally composed of

persons from diverse backgrounds, including medical, nonmedical, philosophy, law, sociology, religion and laypersons.

The committee is expected to independently review the risks and benefits of the study, methodology, relevance (relation), and, most of all, the protection of participants. The consent process, confidentiality, funding, and conflict of interest are carefully examined. The committee examines the credentials and experience of researcher to ensure that the study will be carried out in a professional manner.

This process ensures unbiased, objective review of the study, not always possible by the researcher or participants.

The ethics committee also evaluate the compensation protocol for participants who may suffer from adverse effects or harm during research. After approval, the committee is expected to follow up with reviewers to ensure the protocol faithfully implemented.

- Respect

  It's an essential component of research. The word 'subject' used in earlier documents on research ethics has been changed to participants in acknowledgment for the contribution of patients to

research. Participants are respected to possess human value, autonomy, and human rights.

Human value is intrinsic and not linked to race, productivity, inheritance, wealth or talent. Even disabled, comatose, impoverished patients participating in a study must be protected and treated with respect.

Individual autonomy allows the freedom to decide on matters concerning the body and health. Information about the risks and benefits of the study enables the participants to arrive at a decision regarding consent. A patient should be able to refuse to participants or even remove himself from the study at any time.

- Justice

  To ensure justice in research, there should be no discrimination among participants based on race, gender or status. Selection of participants must be fair.

  In recent years research studies designed in developed countries are conducted in less developed countries including India. Cost of clinical trials is lower and shorter timeframe.

Medical research should be shared, if drug is tested and found to be effective, it should be affordable and available to all groups.

Research funding: there is another kind of injustice when only 10% of the research funding worldwide is used for studies on diseases that affect 90% of the world population. This is called 10/90 gap in research. The quantity and quality of research linked to available funds. Countries that provide funding will be in position to decide research priorities.

- Integrity

  Good quality research depends greatly on the integrity of the researcher and the unique pressure in research could test personal integrity and lead to unethical practices.

  The pressure to publish (or perish!) is the motivation of many doctors and researchers because promotions and incentives are linked to research and publications.

Pharmaceutical companies may pressure investigators to conduct drug trials as quickly as possible, at lower costs, so that they can bring the drug to market earliest.

These pressures could lead to shortcut and lower standards in research misconduct like data tampering, fabrication of data, manipulation in data, plagiarism, duplication in publication.

Bad research is damaging to the professional community and can be dangerous to patients.