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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 18 : Bioethics

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Chapter 18

Bioethics

Basic Concepts of Bioethics

- Bioethics is the study of ethical issues that arise in the fields of healthcare, medicine, and biotechnology. It is concerned with the biological research and application about what is right or wrong, good or bad, just or unjust, in relation to human life and health.
- Bioethics seeks to provide a framework for addressing ethical issues that arise in the fields of healthcare, medicine, and biotechnology, and to ensure that these issues are addressed in a way that is respectful of human dignity, promotes justice and equity.

History of bioethics

- The history of bioethics dates back to ancient times, where moral and ethical considerations were given to medical practices. However, modern bioethics began to emerge in the midtwentieth century, as the result of advances in medical technology and research that raised ethical issues.
- One of the most significant events in the development of bioethics was the Nuremberg Trials, which took place after World War II. The trials exposed the horrific medical experiments conducted by the Nazi regime, which highlighted the need for ethical guidelines in medical research.
- In the late 1960s, the concept of brain death was introduced, which raised questions about the definition of death and the ethics of organ donation. This led to the development of the first bioethics committees, which were established in hospitals to address ethical issues in patient care.
- In the 1970s, the field of bioethics expanded to include issues such as reproductive rights, genetic testing, and end-of-life care. The famous case of Karen Ann Quinlan, a woman in a persistent vegetative state, sparked (started) national debate about the right to die and the ethics of life-sustaining treatment.
- In the 1980s and 1990s, advances in biotechnology raised new ethical issues, such as cloning and genetic engineering. The Human Genome Project, which mapped the entire human genome, led to discussions about the ethics of genetic testing , based on genetic information
- Today, bioethics remains a rapidly evolving field, as advances in medical technology continue to raise ethical questions. The field now encompasses a wide range of issues, including stem cell research, assisted reproductive technologies, and the use of artificial intelligence in healthcare.
- Bioethicists continue to grapple (engage) with complex ethical questions and work to develop guidelines to ensure that medical practices are conducted in a way that respects human dignity and autonomy.

Principals of bioethics

The four main principles of bioethics are:

- 1) **Respect for autonomy** : This principle emphasizes the importance of respecting the decisions and choices of individuals. It involves providing patients with information to make informed decisions about their medical care, and respecting their right to make decisions about their own lives.
- 2) **Beneficence** : This principle requires that healthcare providers and researchers act in the best interests of their patients or research subjects, and seek to promote their well-being.
- 3) **Non-maleficence** : This principle requires that healthcare providers and researchers avoid causing harm to patients . It involves minimizing the risks associated with medical treatments or research, and ensuring that the benefits outweigh the potential harms.
- 4) **Justice** : This principle emphasizes the need to treat individuals fairly and equitably, and to distribute benefits and burdens of healthcare and research in a just manner. It involves ensuring that resources are allocated (distribute) fairly, and that vulnerable populations (minorities) are not exploited.

These four principles are often referred to as the "principles of biomedical ethics" and provide a framework for analyzing and resolving ethical issues in healthcare, medical research, and biotechnology.

Brief overview of ICMRs

- The Indian Council of Medical Research (ICMR) is the apex (highest) body in India for the formulation, coordination, and promotion of biomedical research. It was established in 1911 and operates under the Department of Health Research, Ministry of Health and Family Welfare, Government of India
- ICMR's National Ethical guidelines for biomedical and health research involving human participants The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants is a document developed by the Indian Council of Medical Research (ICMR) that sets the ethical principles and procedures that must be followed in conducting medical research in India involving human participants.

Some of the key principles and procedures the guidelines include

- **Informed consent** : The guidelines emphasize the importance of obtaining informed consent from participants before they are enrolled in a research study. The consent process must be voluntary, based on adequate information provided to the participants.
- **Risk-benefit assessment** : Before conducting any research involving human participants, the potential risks and benefits must be assessed. The benefits must outweigh the potential harms, and steps must be taken to minimize any risks to participants.
- **Privacy and confidentiality** : The guidelines emphasize the importance of protecting the privacy and confidentiality of participants in research studies. Researchers must take steps to ensure that participant data is secure and protected from unauthorized access.
- **Ethical review** : All research studies involving human participants must undergo ethical review by an independent ethics committee, which will assess the scientific validity and ethical implications of the study.
- **Vulnerable populations** : Special consideration (care or reward) must be given to vulnerable populations, such as children, pregnant women, and persons with disabilities, who may be at greater risk of harm in research studies.
- **Data sharing** : Researchers are encouraged to share data generated in research studies in a responsible manner, taking into account issues such as confidentiality, privacy, and intellectual property rights.

These guidelines provide a framework for ensuring that ethical standards are maintained in medical research involving human participants in India

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