

Chapter-19

Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants

Introduction

Bioethics is an interdisciplinary field of study that examines the ethical, social, and legal implications of biomedical research, healthcare delivery, and healthcare policy.

Bioethics is concerned with questions of right and wrong in healthcare, and it seeks to provide ethical guidance to healthcare professionals, researchers, and policymakers.

Basic Concepts of Bioethics

- Bioethics is concerned with the ethical dilemmas that arise in the practice of medicine and biomedical research.
- These dilemmas may involve questions of patient autonomy, beneficence, non-maleficence, justice, and the sanctity of life. Patient autonomy refers to the right of patients to make decisions about their own healthcare, based on their own values and preferences.
- Beneficence refers to the duty of healthcare professionals to promote the well-being of their patients. Non-maleficence refers to the duty of healthcare professionals to avoid harming their patients. Justice refers to the fair distribution of healthcare resources, while the sanctity of life refers to the value that is placed on human life.

History of Bioethics

- Bioethics emerged as a distinct field of study in the late 1960s and early 1970s, as a response to a series of high-profile ethical controversies in the fields of medicine and biomedical research.
- One of the most well-known of these controversies was the Tuskegee syphilis study, in which African American men with syphilis were left untreated so that researchers could study the natural progression of the disease.
- This study was widely criticized for its unethical treatment of vulnerable populations and led to the development of the Belmont Report, which established the ethical principles of respect for persons, beneficence, and justice.

Principles of Bioethics

The principles of bioethics are based on the ethical considerations that arise in the practice of medicine and biomedical research. These principles include:



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1. **Respect for Persons:** This principle requires that individuals be treated with dignity and respect, and that their autonomy and freedom of choice be respected.
2. **Beneficence:** This principle requires that healthcare professionals act in the best interests of their patients and that they seek to promote the well-being of their patients.
3. **Non-Maleficence:** This principle requires that healthcare professionals avoid causing harm to their patients and that they take steps to prevent harm.
4. **Justice:** This principle requires that healthcare resources be distributed fairly and that all individuals have access to the healthcare they need.

Indian Council of Medical Research (ICMR):

- The Indian Council of Medical Research (ICMR) is the premier medical research organization in India, and it has developed the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
- These guidelines provide guidance to researchers, ethics committees, and other stakeholders on the ethical conduct of biomedical and health research involving human participants.
- The guidelines are based on the principles of respect for persons, beneficence, non-maleficence, and justice, and they provide guidance on a wide range of issues, including informed consent, confidentiality, risk assessment, and the use of vulnerable populations in research.

Informed Consent

- One of the most important principles in biomedical and health research involving human participants is informed consent.
- Informed consent is a process by which participants are provided with information about the research, including its purpose, methods, risks, and benefits, and are given the opportunity to ask questions and make an informed decision about whether or not to participate.
- The ICMR guidelines emphasize the importance of obtaining informed consent from participants in biomedical and health research.
- They require that the consent process be conducted in a language that the participant understands, and that the information be provided in a way that is easy to understand.

Confidentiality and Privacy

- Another important principle in biomedical and health research involving human participants is confidentiality and privacy.
- The ICMR guidelines require that participants' confidentiality and privacy be protected throughout the research process.
- Researchers must take steps to ensure that participants' personal information is kept confidential and that their privacy is respected.



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- They must also obtain participants' permission before using their personal information for any other purpose.

Risk Assessment

- Risk assessment is an important component of biomedical and health research involving human participants.
- The ICMR guidelines require that researchers conduct a risk assessment before initiating any research involving human participants.
- The risk assessment should consider the potential risks and benefits of the research, as well as the vulnerability of the participants.
- Researchers must take steps to minimize the risks to participants and ensure that the potential benefits of the research outweigh the potential risks.

Use of Vulnerable Populations

- The ICMR guidelines recognize that certain populations are vulnerable and may require special protections in biomedical and health research.
- These vulnerable populations include children, pregnant women, mentally ill individuals, and individuals with disabilities.
- The guidelines require that researchers take extra care when conducting research with these populations and that they obtain informed consent from the participants and their guardians, if applicable.

Ethics Committee Review

- The ICMR guidelines require that all research involving human participants be reviewed and approved by an ethics committee.
- The ethics committee is responsible for ensuring that the research is conducted in an ethical and responsible manner and that the rights and welfare of the participants are protected.
- The committee must include members from diverse backgrounds, including medical professionals, social scientists, legal experts, and community representatives.

