Bioethics

Basic Concepts of Bioethics

Definition:

- Bioethics is a sub-discipline of ethics that deals with the moral implications of biological and medical procedures, technologies, and treatments.
- In the context of pharmacy, it plays a vital role in guiding how pharmacists, researchers, and healthcare professionals conduct themselves in matters involving human life and health.

Why Bioethics Is Important in Pharmacy:

- To ensure patient safety and rights are protected.
- To guide pharmacists in making morally responsible decisions.
- To regulate clinical trials, drug dispensing, and patient counseling.
- To navigate issues like euthanasia, abortion, organ donation, or stem cell research.

Core Areas Covered Under Bioethics:

- **Informed Consent**: Ensuring patients are fully informed and agree voluntarily before undergoing treatment or participating in research.
- **Autonomy**: Respecting the individual's right to make decisions about their own body and health.
- **Beneficence and Non-Maleficence**: Doing good and avoiding harm.
- **Justice**: Fair and equal treatment in healthcare delivery.
- **Confidentiality**: Safeguarding the privacy of patient health information.
- **Accountability**: Healthcare professionals are answerable for their actions.

History of Bioethics

Pre-Modern Ethics:

- Before the 20th century, medical ethics was mostly guided by philosophical and religious principles (like the Hippocratic Oath in ancient Greece).

Key Historical Milestones

1. **Nuremberg Trials (1947)**
    - Unethical human experiments by Nazi doctors during WWII were exposed.

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- Led to the Nuremberg Code, which emphasized voluntary informed consent in medical research.

2. Declaration of Helsinki (1964)

- Issued by the World Medical Association.
- Provided ethical guidelines for research involving human subjects.
- Stressed that patient welfare must come before scientific interests.
- Updated regularly and adopted globally.

3. Belmont Report (1979 – USA)

- Created in response to unethical studies like the Tuskegee Syphilis Study.
- Outlined three fundamental ethical principles:
  - **Respect for Persons**
  - **Beneficence**
  - **Justice**
- Became a cornerstone for bioethical standards worldwide.

4. Emergence of Bioethics as a Discipline

- In the **1970s**, bioethics developed into a structured academic field.
- Key contributors:
  - Van Rensselaer Potter (coined the term "bioethics")
  - Tom Beauchamp and James Childress (developed the principlism model)

5. Development in India

- Bioethics gained importance with the growth of clinical trials.
- The **Indian Council of Medical Research (ICMR)** began issuing guidelines to ensure ethical conduct in research.

Principles of Bioethics

Often summarized as the **“Four Principles Approach”** proposed by Beauchamp and Childress:

1. Autonomy:

- **Definition:** Respecting a person’s right to make their own decisions.
- **Example in pharmacy:** A patient refusing a prescribed medication must be respected unless they pose a threat to themselves or others.

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2. Beneficence:

- **Definition:** Actively doing good for the patient.
- **In practice:** Ensuring the medication prescribed will benefit the patient (not just chosen based on profit or convenience).

3. Non-Maleficence:

- **Definition:** "Do no harm."
- **In pharmacy:** Not dispensing a drug known to have harmful interactions or side effects without full disclosure or precautions.

4. Justice:

- **Definition:** Fairness in distribution of resources and treatments.
- **In pharmacy:** Equal access to essential medicines regardless of a patient’s socioeconomic status.

Other supporting principles often considered include:

- **Veracity**: Obligation to tell the truth.
- **Fidelity**: Keeping commitments and maintaining trust.
- **Confidentiality**: Protecting patient information.

ICMR’s National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)

- The **Indian Council of Medical Research (ICMR)** is India’s top body for the formulation and coordination of biomedical research.
- The **ICMR Ethical Guidelines (2017)** aim to ensure that biomedical and health research in India is conducted ethically, especially when human participants are involved.

Structure of the Guidelines:

The guidelines are divided into 12 sections. Here are key highlights relevant to pharmacy:

A. General Principles:

- ICMR outlines **12 general ethical principles**:
  1. **Essentiality**: Research must be necessary for societal benefit.
  2. Voluntariness, Informed Consent and Community Agreement.
  3. Non-Exploitation.
  4. Privacy and Confidentiality.

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5. Risk Minimization.
6. Professional Competence.
7. Accountability and Transparency.
8. **Public Domain**: Results should eventually be published.
9. **Totality of Responsibility**: Researchers and institutions share ethical responsibilities.
10. Environmental Protection.
11. Benefit Maximization.
12. Distributive Justice.

B. Informed Consent Process:

- Must be written, verbal (if applicable), and recorded in local languages.
- Subjects should be informed about:
  - Purpose of research.
  - Risks and benefits.
  - Right to withdraw at any point without penalty.

C. Risk-Benefit Assessment:

- Every study should undergo ethical review to ensure the potential benefits outweigh the risks.
- Risk must be minimized through careful design and implementation.

D. Special Considerations:

- Guidelines cover research involving:
  - **Children**
  - **Pregnant or lactating women**
  - **Vulnerable populations** (tribal communities, economically disadvantaged, etc.)
  - **Genetic research**, **stem cell research**, and **biological samples**.

E. Ethics Committee (EC) Oversight:

- Any institution conducting biomedical research must have an **Institutional Ethics Committee (IEC)**.
- IECs review and approve protocols before research starts.
- IECs must include a diverse group of members: clinicians, pharmacists, legal experts, community representatives, etc.

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