

# Principles of Bioethics

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# Defining Bioethics

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- ❑ Bioethics is an interdisciplinary enterprise crossing the boundaries not only of moral philosophy and religion, medicine, nursing and the biomedical sciences but also of law, the social sciences including economics and public policy.
- ❑ Bioethics will definitely enrich rational and enlightened decision-making as well as be enriched by the reflective and deliberative practice of health professionals.

# Defining Bioethics

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- Its goal is not only the development of, or adherence to a code of set of precepts but a better understanding of the issues.
- It is prepared to ask deep philosophical questions about the nature of ethics, the value of life, what it is to be a person, the significance of being human.
- Embraces issues of public policy as well as the direction and control of science.



# Interest in Bioethics

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- ❑ New technology (organ transplant) and developments (stem cell research) in health care and biomedical sciences
- ❑ Increasing power of scientists and doctors over patients and communities
- ❑ The value-laden nature of medical decision-making and a critical questioning of the bases of decisions
- ❑ New social perspectives – abortion, right to die, etc.



# Basic Principles of Ethics

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- ❑ Autonomy / Respect for Persons
- ❑ Beneficence
- ❑ Non Maleficence
- ❑ Justice

The Belmont Report, 1979

US National Commission for the Protection of Human  
Subjects of Biomedical and Behavioral Research



# Medical Ethics

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- Patient-Doctor relationship
  - Veracity
  - Disclosure
  - Confidentiality
  - Trust
- Doctor-Doctor relationship
- Doctor-Pharmaceutical relationship

# Distinction between Medical Practice and Research

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- Practice – interventions designed solely to enhance the well being of an individual patient or client. Purpose – provide diagnosis, preventive treatment or therapy
- Research – intended to test a hypothesis, permit conclusions to be drawn, develop or contribute to generalizable knowledge; described in a research protocol



# 1. Respect for persons

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- Autonomy – capacity to deliberate about personal goals and action
  - Requires giving weight to a person's opinions and choices and refraining from obstructing their action unless they are detrimental to others
  - Respect for freedom of action
  - Respect for different cultural values
  - Requires giving protection to those with diminished autonomy





# Autonomy in Research

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- ❑ Voluntary participation
- ❑ Adequate information to make informed consent
- ❑ Comprehension
- ❑ Full disclosure of risks and benefits
- ❑ No undue inducement
- ❑ Voluntary termination
- ❑ Continuing disclosure
- ❑ Legally authorized representative
- ❑ Culturally appropriate consent

## 2. Beneficence

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- ❑ Common definition – acts of kindness or charity that go beyond strict obligation
- ❑ Making efforts to secure well being
- ❑ Doctor's duty – an obligation
- ❑ Do no harm and maximize benefit and minimize harm
- ❑ In research – not to injure one person despite benefits that may accrue to others
- ❑ Risk/ benefit assessment
  - When is it justifiable to seek certain benefits despite the risks involved?
  - When should benefits be foregone because of the risks?



# Beneficence

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- ❑ Macro orientation in scientific research – Society recognizes longer term benefits and risks that result from improvement of knowledge and development of new procedures.
- ❑ Micro orientation – Individual investigators and sponsors should plan how risks may be minimized and benefits maximized.



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“I will follow that system of regimen which according to my ability and judgment , I consider for the benefit of my patients and abstain from whatever is deleterious and mischievous.”

Hippocratic Oath, 400 BC

# Assessment of risk in research

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- Risk – possibility that harm may occur
- Benefit – something of positive value
- Probabilities and magnitude of possible harm and anticipated benefits should have a favorable ratio
- Types of risks in research
  - Minimum risk – risk encountered in everyday life
  - More than minimum risk but with direct benefit to the subject
  - More than minimum risk without direct benefits to the subject but benefits society
  - More than minimum risk but no perceived benefits



# Types of Benefits

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- ❑ Individual benefit
- ❑ Community benefits
- ❑ Social benefits

# Types of Community Benefits in Health Research

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- ❑ Provision of health care in resource poor communities
- ❑ Salaries, infrastructure, incentives to research participants, etc.
- ❑ Sustaining health care improvements by planning for gradual phase-out with the community and local authorities
- ❑ Appropriate training and technology transfer.
- ❑ Access to trial products, infrastructure and knowledge by the research participants, the community and the host country.



# Community Benefits

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- Post study benefits may also include:
  - a) disseminating the study results with the study participants, the community and health authorities;
  - b) presenting results in simple, understandable language;
  - c) establishing personal contacts and attendance of community meetings.





# Considerations to justify research

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- ❑ Brutal or inhuman treatment of human subjects is never morally justified.
- ❑ Risks should be reduced to levels necessary to achieve research objectives and alternative procedures should be considered.
- ❑ Significant risk should be justified.
- ❑ Use of vulnerable subjects should be justified.
- ❑ Risks and benefits should be explained in the consent form.

### 3. Justice

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- ❑ Equal treatment – Different treatment requires justification (experience, age, deprivation, competence, merit, position, etc.)
- ❑ What is deserved – giving a person the benefit one is entitled to
- ❑ Fair distribution
- ❑ Associated with political representation, taxation, punishment, etc.

# Principles of distribution of burden and benefits

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- ❑ To each person an equal share
- ❑ To each person according to individual need
- ❑ To each person according to individual effort
- ❑ To each person according to societal contribution
- ❑ To each person according to merit



# Justice questions in health research

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- ❑ Recruitment of charity ward patients while benefits of health care enjoyed by private patients
- ❑ Nazi use of war prisoners perceived as grave injustice
- ❑ Tuskegee patients deprived of treatment when it was already available
- ❑ Recruitment of vulnerable population because they are available, easier to manipulate and not because they manifest any condition related to the study



# Justice questions in health

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- Use of public funds require priority setting to address top mortalities and morbidities
- Access to treatment and drugs by people involved in research
  - Not available – lack of drugs in primary care facility
  - Not accessible physically – distribution channels
  - Not affordable – patent and profit with high price
  - Not acceptable – adverse reactions, cultural...
  - Not good quality – substandard, hidden adverse reactions.

# Principles to Guide Access to Medicine

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- ❑ Justice - what the participant deserves in return for their contribution (acceptance of risk and inconvenience, contribution to knowledge generation and the development of a new health intervention)
- ❑ Equity through provision of access to drugs or affordability to the community where the study was conducted or to the poor in general
- ❑ Involves balancing availability with profitability and marketability.

# Individual and Social Justice

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## □ Social justice

- Identifying a participation criteria based on ability of a class to bear burdens and appropriateness of further burdens on a group
- Order of preference in subject selection (adults before children, etc.)

## □ Individual justice

- Not to offer beneficial research only to some patients researchers favor
- Select only ‘undesirable persons’ for risky research



# Injustice

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- Unjust social patterns
  - Social class
  - Racial, ethnic bias
  - Gender and sexual bias
  - Cultural bias
  - Developed vs. developing countries
  - Consider social justice in subject selection and distribution of risks and benefits



# Global Injustice in Research

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- Global Forum for Health Research Findings
  - **10/90 disequilibrium or research gap**
  - **Need to focus research efforts on the health problems of the majority of the world's population, especially the poor**
  - **Need to improve the allocation of research funds**
  - **Need for priority setting based on the burden of diseases and their causes**
  - **Priority setting at the local, national and global levels**



# Global Recommendations

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- ❑ Earmark 2% of national health budget to research
- ❑ National, regional and global programs to strengthen research capacity
- ❑ Bilateral aid programs to assign 5% of budget to research capacity building (Com on Health research for Development, 1991)
- ❑ National mechanism for priority setting (ENHR)