

Definition of Ethics (1)

- The discipline of dealing with what is good and bad, with moral duty and obligation
- A set of moral principles or values
- The principle of conduct governing an individual or group
 - Webster's Ninth New Collegiate Dictionary



Definition of Ethics (2)

A Dictionary of Epidemiology, 4th ed, 2001
(J.M. Last (ed))

The branch of philosophy that deals with distinctions between right and wrong – with the moral consequences of human actions



ETHICS

- Medical ethics
(patient-centered)
- Public health ethics –
(community/population-centered)
- Research ethics
(subject-centered)



PRINCIPLES OF ETHICAL PRACTICE OF PUBLIC HEALTH (1)

(adapted from PH Leadership Society, 2002)

- PH should address the causes of disease and requirements for health
- PH must respect the rights of individuals
- PH should seek input from communities
- PH should strive for health for all



PRINCIPLES OF ETHICAL PRACTICE OF PUBLIC HEALTH (2)

- PH should base policies on evidence
- PH should obtain community consent for implementation of policies/interventions
- PH should respond to health problems in a timely manner
- PH must respect diverse values, beliefs and cultures



PRINCIPLES OF ETHICAL PRACTICE OF PUBLIC HEALTH (3)

- PH programs should enhance the physical and social environment
- PH should protect the confidentiality of individuals and communities whenever possible
- PH must assure the professional competence of their employees
- PH should engage in collaborations that build public trust and their effectiveness (e.g., NGOs)



PRINCIPLES OF PUBLIC HEALTH

- Interdependence of individuals is the essence of community
- The health of the individual is tied to their community



PHILOSOPHY OF PUBLIC HEALTH (1)

- People have a right to the resources necessary for health
- PH leaders need to identify the fundamental requirements for healthy communities; e.g., safe parks/recreational areas



PHILOSOPHY OF PUBLIC HEALTH (2)

- PH action depends on public trust
- Collaboration is essential for PH action
- The individual, the community and the environment are interdependent
- Every individual has the right to contribute to the public discourse on health policy development



PHILOSOPHY OF PUBLIC HEALTH (3)

- Scientific evidence should provide the basis for policy decisions
- It is unethical to approve and support poor quality research
- In the absence of scientific evidence PH values should inform policy decisions
- Given the necessary knowledge and essential resources individuals will act responsibly



PUBLIC HEALTH AND POWER

- The need to use power to ensure health
- What should be the limits of that power?



PUBLIC HEALTH ACTION (1)

- The quandry of Human Rights!
 - ❖ Incarceration of infectious individuals; e.g., “Typhoid Mary”
 - ❖ Quarantine of contacts (China H1N1)
- Right to privacy vs. mandatory disease reporting (STDs, HIV)
- Persuasion vs. coercion vs. manipulation



PUBLIC HEALTH ACTION (2)

- Personal autonomy vs. community action e.g. fluoridation of water
- Regulation of personal behavior e.g. mandatory condom use in brothels (Thailand, Nevada)
- Proportionality – cost versus benefit (especially relevant for developing countries)



CONFLICTING PUBLIC HEALTH GOALS

- Protect the uninfected
- Protect the infected



ETHICS

The ethics of taking
action vs. the ethics of
avoiding action



ETHICAL CONDUCT OF RESEARCH



Justification of Research in Humans (1)

- Impossible to reach the important conclusions without studying humans
 - ❖ Human physiologic studies, because
 - ❖ animal responses often are not the same
 - ❖ Epidemiological studies, because they depend on human susceptibilities and human interactions
 - ❖ Agents for treating humans because animal experiments don't always predict results



JUSTIFICATION (2)

- **If you're going to treat humans, you must study humans**
- **Corollary: If you're going to treat certain kinds of humans, then you must perform studies with them; for example:**
 - ❖ **Children, mentally impaired, ethnic groups, elderly, women, and pregnant women**



History of the Ethical Research Movement



The Nuremberg Code (World War II)

- Informed consent is absolutely essential
- Qualified researchers must use appropriate research designs
- There must be a favorable risk/ benefit ratio
- Participants must be free to stop at any time



The Declaration of Helsinki World Medical Association (1964, 1975, 1983, 1989, 1996, 2002)

- “The well-being of the subject should take precedence over the interests of science and society”
- Consent should be in writing
- Use caution if participant is in dependent relationship with researcher
- Limited use of placebo, especially if treatment is available
- Greater access to benefit once research is concluded

The Belmont Report (The U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978)

Ethical Principles and Guidelines for the Protection of Human Subjects of Research:

- ❖ Respect for persons
- ❖ Beneficence
- ❖ Justice



Council for International Organizations of Medical Science (CIOMS) Guidelines 1993, 2002

Nuremberg => Helsinki => CIOMS

- Informed consent
- Research in developing countries
- Protection of vulnerable populations
- Distribution of the burdens and benefits
- Role and responsibilities of ethics committees



BASIC CONCEPTS OF ETHICAL RESEARCH



Basic Principles of Research on Human Subjects (1)

- Respect for persons
 - ❖ Choices of autonomous individuals should be respected
 - ❖ People incapable of making their own choices should be protected
 - ❖ Voluntary subjects need adequate information for informed decision-making



Basic Principles of Research on Human Subjects (2)

- Beneficence
 - ❖ Participation in research is associated with a favorable balance of potential benefits and harms
 - ❖ Maximize possible benefits, minimize potential harm



Basic Principles of Research on Human Subjects (3)

- Justice
 - ❖ Participation in research is associated with a favorable balance of potential benefits and harms
 - ❖ May not exploit or exclude vulnerable individuals who may benefit without good reason
 - ❖ Risk and benefits must be shared by all (e.g., poor and wealthy)



Summary - Principles and Foundations of Research Ethics

- All codes and regulations advocate 3 fundamental principles:
 - ❖ Respect for persons
 - ❖ Beneficence
 - ❖ Justice
- Research is a privilege, not a right
- The well-being of the participant is paramount



GENERAL PRINCIPLES

- There is absolutely no justification for inhumane treatment of participants
- Risks to participants should always be reduced to the maximum extent possible
- If a significant risk is involved, justification of the research must be examined with particular care
- Whenever vulnerable persons are participants, the need to involve them must be carefully demonstrated

TWO CASE STUDIES



CASE 1: CLINICAL TRIAL TO PREVENT MATERNAL/CHILD TRANSMISSION OF HIV

- Without treatment, 30+% of infants born to HIV-infected mothers will be infected
- Long-term treatment used in rich countries costs several thousand dollars per mother
- Poor countries cannot afford long-term treatment
- Can short-term treatment reduce transmission?

CLINICAL TRIAL TO PREVENT MATERNAL/CHILD HIV TRANSMISSION

Ethical issues

- Is a trial of short-term treatment ethical when it is known that long-term treatment is effective?
- Is it ethical to have a control group?
- What should the control group receive?
- What are the ethical responsibilities of the investigator towards participants, particularly in the control group?

CASE 2: PRE-EXPOSURE PROPHYLAXIS

- 90% of sex workers become HIV-infected within the first year of work
- Many clients reluctant to wear condoms
- No female controlled microbicide available
- Tenofovir is cheap, effective and not known to have many side effects
- Is a clinical trial of prophylactic tenofovir ethical?



A TRIAL OF PROPHYLACTIC TENOFVIR USE

- Intervention group = sex workers – daily tenofovir
- Placebo = no medication
- Counseling and condoms to avoid HIV infection provided
- Outcome variable = HIV infection rate
- Approved by IRBs in UCSF and NCHADS
- Infected sex workers receive two years of treatment with tenofovir
- Trial proceeding in other developing countries

PRE-EXPOSURE PROPHYLAXIS

Ethical concerns

- Is a clinical trial in poorly educated sex workers in a developing country *exploitation*?
- Should there be a control group?
- What should the control group receive, if anything?
- What responsibility does the investigator have for sex workers who become infected?



NEWS OF THE WEEK

AIDS RESEARCH

Cambodian Leader Throws Novel Prevention Trial Into Limbo

AIDS prevention
sex workers is
leader ordered it
the U.S. Nation-
and Infectious

Last March, the W
Unity said they would
unteers would receive
years, a period they a
them against possible



Prevention intervention. Oxfam's Rosanna Barbero led opposition to the study.

Cohen J:
Cambodian
leader throws
novel prevention
trial into limbo.
Science
305:1092, 2004.

SEX WORKER DEMANDS

- Lifetime care if she becomes HIV-infected or suffers side-effects
- Health insurance for 30 years
- More counseling
- Free female condoms



ETHICS OF TESTING



EVALUATION OF “OPT-OUT”/ROUTINE TESTING

- HIV is primarily spread by persons who do not know they are infected
- A large proportion of those infected do not know their status
- Testing is associated with stigmatization, community rejection and family discord
- Cannot access treatment if don't know HIV status



“OPT-OUT”/ROUTINE TESTING

Ethical Issues

- Does routine testing violate human rights?
- What are the obligations of the investigator toward the participants? (e.g., follow up and treatment)
- Does respecting the right to refuse testing violate the human rights of others?

