Ethical and Professional Issues in Epidemiology

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Outline of Presentation

• Epidemiology: research and practice
• Research ethics
• Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Epidemiological Studies (2009)
Ethics

1. moral principles that govern a person's behaviour or the conducting of an activity
2. the branch of knowledge that deals with moral principles

Professionalism

A set of values that includes:

– Altruism,
– Accountability,
– Excellence,
– Duty,
– Honor and integrity, and
– Respect for others.

*American Board of Internal Medicine (ABIM)*
Fig. 1 Attributes of professionalism (Arnold and Stern 2006)
Difference Between Professionalism and Ethics

• Generally, ethics rules tell us what we cannot do and professionalism deals with what we should do.
Epidemiology

• The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems.

Epidemiology

- "Study" includes surveillance, observation, hypothesis testing, analytic research, and experiments.
- "Distribution" refers to analysis by time, place, and classes of persons affected.
- "Determinants" are all the physical, biological, social, cultural, and behavioral factors that influence health.
- "Health-related states and events" include diseases, causes of death, behaviors such as use of tobacco, reactions to preventive regimens, and provision and use of health services.
- "Specified populations" are those with identifiable characteristics such as precisely defined numbers.
- "Application to control...“ makes explicit the aim of epidemiology—to promote, protect, and restore health.
Jurisdiction of Research in Human Subjects

• Basically, *all* research involving human subjects

  – **Research**: “a systematic investigation designed to develop or contribute to generalizeable knowledge.”

  – **Human subject**: “living individual(s) about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”
Contribution of Epidemiologic Research

• The results of epidemiologic research studies contribute to generalizable knowledge
  – by elucidating the causes of disease;
  – by combining epidemiologic data with information from other disciplines such as genetics and microbiology;
  – by evaluating the consistency of epidemiologic data with etiological hypotheses; and by providing the basis for developing and evaluating health promotion and prevention procedures.

The Professional Role of Epidemiology

• The primary professional roles of epidemiology are the design and conduct of scientific research and the public health application of scientific knowledge.

• This includes reporting research results and maintaining and promoting health in communities.

• In carrying out these professional roles, epidemiologists often encounter a number of ethical issues and concerns that require careful consideration.
Distinction between epidemiologic research and public health practice

• An expanding body of literature has considered the important ethical issues that arise in such areas of public health practice as surveillance, emergency responses, and program evaluation.

• In further specifying ethical norms in particular contexts, it is important to draw distinctions between epidemiologic research and public health practice activities.

• For example, requirements for submitting research protocols to an IRB do not necessarily apply to outbreak investigations and other emergency responses.
Difference Between Epidemiology and Clinical Medicine

1. In epidemiology the unit of study is "population" or "population at risk" while in Clinical Medicine the unit of study is a "case" or "cases".

2. In epidemiology, the epidemiologist is concerned with the disease patterns in entire population while in clinical medicine the physician is concerned with the disease pattern in individual patient.

3. Epidemiology is concerned with the both "sick" and "healthy" (case and controls respectively) while clinicians are interested in cases with diseases.
Difference Between Epidemiology and Clinical Medicine

4. Clinician is concerned with the diagnosis of disease, he derives a prognosis and prescribes specific treatment while an epidemiologist seeks to identify a particular source of infection, a mode of spread or an etiological factor in order to determine a future trend and recommend specific control measures.

5. In clinical medicine patient comes to the doctor while in epidemiological studies epidemiologist goes out into the community to find persons who have the disease or experience of the suspected causal factor in question.

6. Clinician uses laboratory reports and post mortem reports to diagnose disease while in epidemiology the subject matter is conceptual and can only be symbolized in the form of tables and graphs.
Difference Between Epidemiology and Clinical Medicine

• Clinical medicine and epidemiology are not antagonistic.

• Both are closely related, co-existent and mutually helpful.

Ethical Issues in Epidemiologic Research
When paradigms collide

Research can yield valuable information

Difficulties in implementation because of sensitive issues
Scientific design and conduct of study

• **Case:**
  – A study to examine whether and how women involved in the sex trade negotiate condom use by their male partners.

• **Ethical Question:**
  – Was the study justified in using a form of participant-observation that depended on deception?
Scientific design and conduct of study

• The research would produce reliable information on the views of these women about HIV/AIDS, their sexual practices, and their condom negotiation skills, and that this information would provide a basis for better policy-making.

• The research method breaches the ethical code – the fake customers had misled research participants.
The most infamous observational epidemiologic study ever undertaken: 1932-1972: Tuskegee Syphilis Study
The Tuskegee Syphilis Study

• US Public Health Service funded study to evaluate the natural history of untreated syphilis.

• Over 400 black men with syphilis and about 200 men without syphilis, who served as the controls, were the subjects.
The Tuskegee Syphilis Study

- The men were recruited without informed consent.
- In fact, they were misinformed and told that some of the procedures done in the interests of research (e.g., spinal taps) were actually "special free treatment."
The Tuskegee Syphilis Study

• By 1936, it was apparent that many more infected men than controls had developed complications.

• Ten years later a report of the study indicated that the death rate among those with syphilis was about twice as high as it was among the controls.
The Tuskegee Syphilis Study

- In the 1940's, when penicillin, known to be effective in the treatment of syphilis, became available, the men were neither informed of this, nor treated with the antibiotic.
- The study continued until the first accounts of it appeared in the national press in 1972, at which time an ad hoc advisory panel was formed by the government to give advice on how to assure that such experiments would never again be conducted.
The Tuskegee Syphilis Study

• The government continues to pay millions of dollars yearly to surviving subjects and the families of deceased subjects.
Important ethical issues that arise from the Tuskegee experience:

• the choice of hypothesis,
• consent and coercion,
• the absence of benefit to participants,
• frank harm,
• a miscarriage of justice, and
• the responsibilities of professional “scientific” investigators toward the study participants
African Americans Distrust of Medical Institutions

The Tuskegee Syphilis Study continues to cast its long shadow on the contemporary relationship between African Americans and the biomedical community.

Numerous reports have argued that the Tuskegee Syphilis Study is the most important reason why many African Americans distrust the institutions of medicine and public health.

However, such an interpretation neglects a critical historical point. The mistrust of African Americans predates public revelations about the Tuskegee study and has it’s origin deeply rooted in the institution of slavery as practiced here in the United States.
The 3 Basic Ethical Principles of the Belmont Report

1. Respect for persons
2. Beneficence/nonmaleficence
3. Justice

Respect for Persons

Definition:
• Individuals should be treated as autonomous agents
• Persons with diminished autonomy are entitled to protection

Application:
• Voluntary Informed Consent
**Definition:**

- Do not harm
- Maximize possible benefits
- Minimize possible harms

**Application:**

- Assessment of risks and benefits
Justice

**Definition:**

- Who ought to receive the benefits of research?
- Who ought to bear its burdens?

**Application:**

- Equitable selection of subjects
Council for International Organizations of Medical Sciences (CIOMS)

https://cioms.ch

International Ethical Guidelines for Health-related Research Involving Humans

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)

International Ethical Guidelines for Epidemiological Studies

Geneva 2016
Guideline 1
Ethical justification and scientific validity of epidemiological research involving human beings

• Scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit
Guideline 3

**Ethical review of externally sponsored research**

• An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country.
Guideline 4
Individual informed consent

• For all epidemiological research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law.
Individual versus Community Consent

• CIOMS international ethics guidelines (2002) read:
  – “In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual consent.”
Guideline 10
Research in populations and communities with limited resources

• Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:
  – the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
  – any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.
Guideline 14
Research involving children

• Before undertaking research involving children, the investigator must ensure that:
  – the research might not equally well be carried out with adults;
  – the purpose of the research is to obtain knowledge relevant to the health needs of children;
  – a parent or legal representative of each child has given permission;
  – the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and
  – a child's refusal to participate or continue in the research will be respected.
Guideline 16
Women as research participants

• Investigators, sponsors or ethical review committees should not exclude women of reproductive age from epidemiological research.

• The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation.
Guideline 18
Safeguarding confidentiality

• A healthcare provider should not submit any identifiable data about a patient to an investigator or to a database unless the patient permits such submission of data or it is authorized or mandated by law.
Guideline 20
Strengthening capacity for ethical and scientific review and epidemiological research

• In externally sponsored collaborative studies, sponsors and investigators have an ethical obligation to ensure that the research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct epidemiological research, and to provide scientific and ethical review and monitoring of such research.
Guideline 24

Use of stored biological samples and related data

• When collecting and storing human biological samples (and related data, such as health or employment records) for future epidemiological research, the investigator must obtain the voluntary informed consent of the individual donor.
Summary: Ethical Issues in Epidemiological Studies

- Consent from community & Community participation
- Inducements are not permissible
- All risks involved – explained to individual & community
- Maintaining confidentiality
- Minimize harm, maximum benefit for individuals and communities taking part in study
- Committees -- epidemiologists, clinicians, statisticians, social scientists, philosophers, legal experts and representatives from community/voluntary groups
- Should not raise false hopes.
References

