Ethical Principles of Public Health Research

Joint Introductory Course on Field Epidemiology and Biostatistics
Bangkok, Thailand
29 June 2015

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Outline

- Ethical principles and documents
- Principles of biomedical ethics
- Public health surveillance and research
- Ethical guidelines of public health research
- Strategies of HIV testing
- Relevant human rights documents

Why is Ethical Research Important?

- World War II Nazi Germany: unethical experiments in human beings
- Tuskegee: unconsenting (lack of informed consent) subjects in syphilis research in US 1960s and 1970s
- Industrialized countries: drug research in developing countries

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Why is Ethical Research Important?

- Protects integrity of research
- Protects and respects research subjects
- Establishes a code of conduct that justly distributes burdens and benefits of research

Essential Biomedical Ethics Documents

- Nuremberg code – 1947
  - Voluntary participation of research subjects with their informed consent
- Declaration of Helsinki – 1964
  - Fundamental document in human research ethics
  - Sets out ethical guidelines for physicians involved in biomedical research
  - Establishes ethical review mechanisms
- World Medical Association revision – 2000
  - Fully Informed consent

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International Ethical Guidelines for Biomedical Research - 2002

- Council for International Organizations of Medical Sciences (CIOMS); www.cioms.ch
- WHO collaboration
- 3rd in a series of guidelines on ethics for biomedical research [(e.g., Guidelines for Ethical Review of Epidemiologic Studies (1991)]
- Concern with the application of the Helsinki Declaration in developing countries

Universal Principles of Biomedical Ethics (1)

- **Beneficence**

  An obligation to contribute to the welfare of an individual

- **Nonmaleficence**

  An obligation not to inflict harm on others (“*primum non nocere*”)

Universal Principles of Biomedical Ethics (2)

- **Respect for persons (autonomy)**

  To acknowledge that a person has a right to hold views, make choices, and take actions based on personal values and beliefs

- **Justice**

  Treat equals equally; fair distribution of resources

Siracusa Principles (1985)

- States "may impose restrictions on some rights, in narrowly defined circumstances, if such restrictions are necessary to achieve overriding goals, such as public health or to the protect the rights of others…and the general welfare."

- Restrictions must be "proportional to the interest and constitute the least intrusive and least restrictive measure available."

UN Economic and Social Council, UN Doc E/CN.4/1984/4, 1985

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Research (1)

- A class of activity designed to develop or contribute to generalizable knowledge
- Surveillance is differentiated from pure research by intent
  - Conduct programs to prevent disease and injury and promote community health

Research (2)

- Should be conducted or strictly supervised only by suitably qualified researcher
- Should be conducted according to a protocol
- Should be conducted only after scientifically and ethically approved by an ethics body

Public Health Surveillance/Research

- Vital statistics
  - Legally established function of nation-states
- Notifiable diseases
  - TB, Sexually transmitted diseases, cancer
- Mandatory notification of some infectious diseases
- Ethics of public health surveillance largely unquestioned until HIV/AIDS
- UNHCR/UNAIDS (1984)
  - “strict rules of data protection & confidentiality”
- Use of individual names
  - Need for name must be substantiated

Gostin et al., JAMA 1996;275:1921

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Ethical Debate of Public Health Surveillance

- 1981 US Health and Human Services regulations exempted epidemiologic research using existing data from informed consent requirements
- US Health and Human Services Office for the Protection of Research Risks (1990) declared that all surveillance was epidemiologic research
- CIOMS (2002) noted that individual informed consent not always practical in epidemiological studies

Public Health Surveillance: Practice or Research?

- At the local level these are often seen as distinct
- At federal level the distinction often becomes blurry

- Surveillance is differentiated from pure research by the intent
  - Surveillance is to conduct programs to prevent disease and injury and promote community health
  - Research is to contribute to generalizable health knowledge that will benefit others

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THE GUIDELINES (21 in total)

- ***Guideline 1: Ethical justification and scientific validity of biomedical research involving human beings***
  - ***A* scientifically unsound study is an unethical study**

- ***Guideline 2: Ethical review committees***

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- ***Guideline 3: Ethical review of externally sponsored research***
  - **Guidelines applied should be no less stringent than they would be in country where research institution resides**
- ***Guideline 4: Individual informed consent***

Informed Consent

- **Voluntary**
  - **Competence** – judicially determined (usually for a category of transactions, e.g. financial)
  - **Capacity** – clinically determined (task specific & may often change, e.g. surgery)
  - **Comprehension** – risks, benefits, alternatives, e.g. isolation

Opt-In and Opt-Out HIV Testing

- Opt-In
  - Patient self-refers, VCT, Useful in non-medical sites
  - Provider initiates testing, may not be highly utilized in medical settings
- Opt-Out
  - Passive – Provider informs patient they will be tested unless they refuse
    - Possibility of coercion?
  - Active – Patient not informed, must actively tell provider they refuse test
    - Borders on mandatory?
  - Necessity in settings of generalized epidemics?
  - Breach of autonomy?

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- ***Guideline 5: Obtaining informed consent: Essential information for prospective research subjects***
  - **Includes a list of 25 separate items that should be addressed**
    - **E.g., …that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled**

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- *Guideline 6: Obtaining informed consent: Obligations of sponsors and investigators*
- *Guideline 7: Inducement to participate*
  - Acceptable and unacceptable recompense
  - Incompetent persons

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- ***Guideline 8: Benefits and risks of study participation***
- ***Guideline 9: Special limitations on risk when research involves individuals who are not capable of giving informed consent***

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- *Guideline 10: Research in populations and communities with limited resources*
  - Responsiveness to health needs and priorities of the community
  - Intervention, knowledge, or product should be made available for benefit of community

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- ***Guideline 11: Choice of control in clinical trials***
  - **As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention**

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- ***Guideline 12: Equitable distribution of burdens and benefits in the selection of groups of subjects in research***
  - **Burdens and benefits of research should by equitably distributed**

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- *Guideline 13: Research involving vulnerable persons*
  - Special justification required for use as research subject
- *Guideline 14: Research involving children*
  - Generally not used as research subjects unless knowledge needed is relevant to children
  - Child refusal should be respected

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- ***Guideline 15: Research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent***

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- *Guideline 16: Women as research subjects*
  - Should not be excluded as research subjects
  - Should be guaranteed pregnancy testing and contraception method before start of research study

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- ***Guideline 17: Pregnant women as research participants***
  - **Research should be performed only if relevant to this population**
- ***Guideline 18: Safeguarding confidentiality***

Public Health Research Definitions

- Anonymous
  - No identifiers ever collected
- Anonymized
  - Identifiers removed
- Confidential
  - Identifying information not given out to other agencies or medical professionals

Confidentiality

- Risks/benefits of participation clearly explained
- Participant gives written or verbal consent
- Voluntary
- All patient medical information confidential, more importantly for HIV than TB
- Registers and documents should be stored in secure location
- Destroy unnecessary/duplicate paperwork
- Service referrals must remain confidential
- Share on “need to know” basis
- Programs should consider written policies

MMWR 1999; 48: RR-13

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Linked Data

- Remove personal identifiers as soon as possible
  - Generally not needed for surveillance beyond facility level
- Collect and report disaggregated data where possible
- Databases with passwords/encryption

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- *Guideline 19: Right of injured subjects to treatment and compensation*
  - Research subjects must NOT be asked to waive right to compensation

International Ethical Guidelines for Biomedical Research - 2002

- ***Guideline 20: Strengthening capacity for ethical and scientific review and biomedical research***
- ***Guideline 21: Ethical obligation of external sponsors to provide health-care services***
  - **Provide health care services essential to conduct the research**
  - **Provide health care services to subjects injured as a result of research**

International Ethical Guidelines for Biomedical Research - 2002

- Protocol template – Appendix
  - 48 point checklist!

2004 UNAIDS/WHO Policy Statement on HIV Testing

Public health practice and adherence to human rights norms

Respect	Autonomy	Informed consent
Protect	Privacy	Confidentiality
Fulfill	Access to sustainable treatment	

Strategies for HIV Testing

Type	Anonymous/ Confidential	Linked	Consent
A	Anonymous	No	No
B	Anonymous	No	Yes
C	Anonymous	Yes	Yes
D	Confidential	Yes	Yes

WHO Publication: Human Rights Approach to TB

“TB is deeply rooted in populations where human rights and dignity are limited. The disease thrives on the most vulnerable – the marginalized, discriminated against populations, and people living in poverty.”

--World Health Organization, 2001

Human Rights Approach to TB (1)

- The principle of nondiscrimination is fundamental to public health and human rights practice
- Neglect of the right to information can have substantial health impacts
- Prisons are an environment that increases vulnerability to TB
- Necessity of addressing TB and HIV together in light of the human rights dimensions of both diseases

Human Rights Approach to TB (2)

- The dual epidemic of HIV and TB raises issues of individual choice and confidentiality
- Human rights can be used as a tool for data collection and analysis
- Human rights approach presented as an avenue for social mobilization to STOP TB
- Health care systems should take human rights norms and standards into account