Ethical Issues in Public Health Research

Vicente Y. Belizario, Jr., MD, MTM&H
University of the Philippines Manila
Outline

• Public Health
• Public Health Research vs. Practice
• Six-step Ethics Framework for Public Health
• Conclusion
Public Health seeks to ensure societal conditions under which people can lead healthier lives, minimizing threats to health that can be averted or lessened only through collective actions aimed at the community.

(Institute of Medicine, 1988)
Public Health

- Began as an organized discipline more than 100 years ago
- Aim: To improve health, primarily of populations rather than of individuals
- Not too many attempts to articulate the ethics of public health
- Bioethics helps health care professionals identify and respond to moral dilemmas
- Codes of medical and research ethics generally give priority that cannot be assumed to be appropriate for public health practice (Kass, 2005)
Public Health Interventions

- Maintaining a safe water supply, WASH interventions
- Immunizing school children
- Deworming preschool and school age children, pregnant women
- Newborn screening for inborn errors of metabolism
- Engaging in epidemiologic research
  - Surveillance
  - Outbreak investigation
  - “Sensitive” public health research topics: HIV/AIDS, STD, TB, Teen age pregnancy
The challenges in the prevention and treatment of “social diseases”

- People at highest risk for HIV infection, sexually transmitted diseases, and tuberculosis (TB) are often socially or economically vulnerable.

- Stigma, poverty, and discrimination are interwoven with conditions that affect both the transmission and the outcome of these infections.
The challenges in the prevention and treatment of “social diseases”

• Vulnerabilities heighten the importance of ensuring that public health investigations and interventions are conducted ethically and that appropriate protections and oversight procedures are followed in the conduct of research, including proper IRB oversight.

• If public health investigations are deemed not to represent research, then IRB procedures for protecting research participants do not come into play, and the interests of directly affected individuals and the communities at large are protected under public health laws.
Defining the boundary between public health research and practice

• Remains a critical challenge within the evolving field of public health ethics (Burris et al., 2003)

• Public health practitioners in government agencies systematically collect data for surveillance, disease control and prevention, and program development and evaluation.

• Objectives and methods of these practice-based activities often overlap with those of researchers.

• Challenge: to determine which public health investigations constitute research, as defined and governed by federal human subjects regulations, and which represent public health practice, as authorized and governed primarily by state public health laws.
Research vs. Non-research

• Based on federal human subjects regulations that include the **intent of investigators** as an essential part of the definition of research

• If primary intent is to **contribute to “generalizable” knowledge**, then the project is deemed to represent research; **IRB oversight required**

  e.g. When investigators seek to address a public health question and conduct an investigation to generalize the findings to other settings, then the project would be considered research

(Centers for Disease Control and Prevention)
Research vs. Non-research

- If project is done in the context of a public health agency’s role in preventing or controlling disease or promoting health and is aimed at a specific public health problem, then it is deemed to represent non-research or public health practice; IRB oversight not required. (CDC)

  e.g. Outbreak investigations, public health surveillance, or program evaluations conducted by public health agencies as part of their legally authorized mandate are usually considered non-research.

  In such non-research investigations, there may be secondary benefits when investigations yield insights of generalizable value that merit dissemination.

Research versus non-research determination unchanged because it is based on the primary intent. (CDC, 1999)

Delineation between research versus practice, can be difficult. (National Bioethics Advisory Commission, 2001)
Guidelines for ethical review of epidemiologic studies

• Distinction between epidemiologic research and routine practice (e.g., outbreak investigations and public health surveillance)

• Consider some of the issues associated with obtaining informed consent in epidemiologic studies

• Specific ethical issues arising in epidemiologic research and public health practice that have been highlighted in ethics guidelines include:
  - minimizing risks and providing benefits
  - informed consent
  - avoiding and disclosing conflicts of interest
  - obligations to communities, and
  - the institutional review board system

(Council of International Organizations of Medical Sciences, 1991)
Ethical considerations for prevention trials and community interventions

- Assessment of risks and benefits
- Need for voluntary participation
- Avoidance of excessive incentives
- Justice-related issues
- Need for sensitivity to ethnic and cultural habits and norms and to avoid "top-down" planning, in which the health concerns and self-defined information needs of the target population are ignored in favor of professional preoccupations and concerns
- Ethical issues in health communication include the need to avoid conflicts of interest, to present facts about health hazards or health opportunities in a truthful, balanced, and timely fashion, and to avoid distorting the facts or concealing ambiguities in the scientific evidence (Guttman, 1997)
Let us apply these concepts to Neglected Tropical Diseases (NTDs)

• Diseases of poverty
  Causing enormous chronic disability and suffering
  Greater susceptibility to other often fatal diseases

• Over 50 million future years of disability-free life lost

• Endemic in over 100 of the poorest countries in Africa, Asia and Latin America – most often with multiple diseases affecting any given community
Research or non-research? What are the ethical considerations?

Case 1: Sentinel surveillance of soil-transmitted helminth infections (worms)

Commissioned by the DOH as part of the monitoring of the Integrated Helminth Control Program which includes mass drug administration as a major strategy

Elementary school-based parasitologic assessment using WHO guidelines

Stool examination of grade 3 pupils in sentinel schools (qualitative and quantitative)

Results provided to DOH and published in peer-reviewed journal
Research or non-research?
What are the ethical considerations?

Case 2: Outbreak investigation in Zamboanga peninsula where an unusually high number of chronic diarrhea cases with several mortalities have been reported

DOH/NEC/FETP and UPM collaboration

Review of DOH/RHU records (patients, water and sanitation data)

Active case finding (history, physical examination and stool examination) and treatment

Interview with focus on food consumption and eating behavior

Environmental survey
70 dead in parasite infection; entire Zambo village afflicted

SIAYAN, ZAMBOANGA Del Norte—An intestinal parasite infection caused by worms found in freshwater fish and shrimps is transforming the village of Moyo here into a community of emaciated men, women and children.

More than 70 deaths reported in 2007
“Suspected capillariasis”
Mayor of Siayan alarmed signing for many requests for coffins

FLUIDS are fed intravenously to 10-year-old Angelo Lantubao, whose father Filomeno, is also suffering from capillariasis.

A resident of Barangay Mayo, too weak to stand, rests in a hospital after suffering from capillariasis infection.

The others died because of chronic diarrhea,” said Leo. Leo said no tests have been made on those who died earlier so she had no basis to say if these deaths were caused by capillariasis.

“Blame it on the villagers,” she said. "They don't know what they're eating.”
Six-step Ethics Framework for Public Health

An analytic tool designed to help public health professionals consider the ethics implications of proposed programs, interventions, research initiatives, and policy proposals

1. What are the public health goals of the proposed intervention, policy or program?
2. How effective is the intervention, policy or program in achieving its stated goals?
3. What are the known or potential burdens of the program?
4. How can the burdens be minimized? Are there alternative approaches to achieve the same goals?
5. Is the program implemented fairly?
6. How can the public health benefits and the accompanying burdens be balanced? What procedures will best allow for the fair consideration of differing views?

(Gostin and Lazzarini, 1997; Kass and Gielen, 1998)
1. What are the public health goals of the proposed intervention, policy or program?

- Goals in terms of PH improvement, reduction of morbidity or mortality
  - e.g. HIV screening, decreasing incidence of HIV
    Health education program on cardiac risk reduction, individuals will have fewer heart attacks
- Social benefits can accrue from PH programs
  - e.g. employment, strengthening of communities
- PH interventions often targeted to one set of individuals in order to protect other citizens’ health
  - e.g. DOTS for TB to protect others from health threats posed by others
- PH programs to protect individuals themselves
  - e.g. Health education programs, seat belt laws, speed limits
2. How effective is the intervention, policy or program in achieving its stated goals?

• Proposed interventions or programs based on certain assumptions that programs will achieve stated goals

• Examine assumptions and what data exist to substantiate them (often neglected in PH)
  e.g. Cardiac risk-reduction education program
  
  Goal: to reduce fatal and nonfatal cardiac events
  
  Assumptions: program reaching individuals at-risk, individuals will learn messages and change behavior, changes not possible without the program, behavior change resulting in fewer cardiac events
  
  Reality: Education programs effective in transmitting information, programs generally less successful at inducing behavior change (Glanz et al., 1997; Roter et al., 1998)
3. What are the known or potential burdens of the program?

• Burdens:

  Risks to privacy and confidentiality (especially in data collection activities)
  Risks to liberty and self-determination (given power to enact any measure necessary to contain disease)
  Risks to justice (if targeting interventions only to certain groups)
Public Health Research

• WOF: Harms that could occur through research participation
  Medical risks (clinical or psychological research)
  Social risks (epidemiological or social science research)
  Personal and social burdens resulting from injustice or exploitation in research (disadvantage or privilege through research participation)
  PH research findings never being implemented into health policy or practice; no benefits from research
4. How can the burdens be minimized? Are there alternative approaches to achieve the same goals?

• Ethical requirement to determine if the program could be modified in ways that minimized the burdens, while not greatly reducing the program’s efficacy

• Choose the approach that poses fewer risks to other moral claims such as liberty, privacy, opportunity, and justice, assuming benefits are not significantly reduced

  e.g. If disease surveillance is equally effective with unique identifiers as with names, a program of unique identifiers is the morally preferable choice
5. Is the program implemented fairly?

• Corresponds to the ethics principle of distributive justice, requiring the fair distribution of benefits and burdens (Beauchamp and Childress, 1979)

  e.g. Clean water cannot be limited to one community alone

  HIV screening programs cannot be implemented only in poor or minority communities without strong justification

6. How can the public health benefits and the accompanying burdens be balanced? What procedures will best allow for the fair consideration of differing views?
Conclusion

• Public health ethics is consistent with the prevention orientation of public health.
• Attention to ethical issues can facilitate the effective planning, implementation, and growth of a variety of public health programs and research activities.
• Ethical concerns can be anticipated or identified early and effectively addressed through careful analysis and consultation.