Public Health Ethics Part 1

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Why a lecture on ethics?

- Increased interest in ethics
- Infectious disease outbreaks
- Human rights, social justice, and access to care
- Anticipated future certification of public health professionals

The Principles of Medical Ethics

Four philosophical principles dominated the field of medical ethics over the last three decades:

1. Autonomy -the right to self-determination
2. Beneficence -doing good
3. Nonmaleficence -avoidance of doing harm
4. Justice – fairness
5. Veracity – truth telling underlies all ethical principles

Philosophical Basis

- Informed consent is rooted in the ethical principle of autonomy
- The obligation to respect the competent adult's right to self-determination

Autonomy

- Originated from the ancient Greeks, and related to the rights of municipalities to self rule and to self govern
- The concept as later extended to include:
  - Liberty rights
  - Rights of privacy
  - Individual choice, and
  - Being one's own person

Beneficence

- Physicians were motivated by the ethical principle of beneficence
- Acts of mercy
- Kindness and charity
- Benefit another
- Obligation to help others
- Protection from harm

Obligations:

1. One ought to prevent evil or harm
2. One ought to remove evil or harm
3. One ought to do or promote good (action driven)

Nonmaleficence

- Hippocratic tradition:

Primum non nocere, "Above all (or first) do no harm"

One ought not to inflict evil or harm (passive)

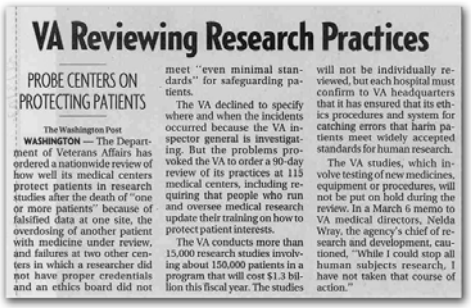
Justice

- *Medical care:*
  - Scarce resources are distributed fairly
- *Research:*
  - All subjects are treated fairly
  - Research should not involve those who could not benefit (studies conducted in 3rd. World countries where the people have no monetary means to benefit from the research- AIDS)
  - This is the balance between risk and benefit

Justice (*Cont.)*

- Research Ethics
- Ethics of Health Promotion & Disease Prevention

Tampa Tribune- March 13, 2003



VA Reviewing Research Practices

PROBE CENTERS ON PROTECTING PATIENTS

The Washington Post

WASHINGTON — The Department of Veterans Affairs has ordered a nationwide review of how well its medical centers protect patients in research studies after the death of "one or more patients" because of falsified data at one site, the overdosing of another patient with medicine under review, and failures at two other centers in which a researcher did not have proper credentials and an ethics board did not meet "even minimal standards" for safeguarding patients.

The VA declined to specify where and when the incidents occurred because the VA inspector general is investigating. But the problems provoked the VA to order a 90-day review of its practices at 115 medical centers, including requiring that people who run and oversee medical research update their training on how to protect patient interests.

The VA conducts more than 15,000 research studies involving about 150,000 patients in a program that will cost $1.3 billion this fiscal year. The studies will not be individually reviewed, but each hospital must confirm to VA headquarters that it has ensured that its ethics procedures and system for catching errors that harm patients meet widely accepted standards for human research.

The VA studies, which involve testing of new medicines, equipment or procedures, will not be put on hold during the review. In a March 6 memo to VA medical directors, Nelda Wray, the agency's chief of research and development, cautioned, "While I could stop all human subjects research, I have not taken that course of action."

History of Research Ethics

- 1890s: Public scandal in Prussia because of experimenting on unsuspecting patients who were inoculated with the spirochete that causes syphilis resulting in the government requiring consent for any further experimentation
- Walter Reed developed a contract, including discussion of the risks, that participants in the Cuba yellow fever experiments had to sign

History of Research Ethics (*Cont.)*

- 1931: Germany developed guidelines for human experimentation- more rigorous than the Nuremberg Code or the Helsinki Declaration
- Guidelines were not routinely followed

Nuremberg Code

Post the WW II War Crimes Trials, the Nuremberg Code was developed:

"all contemporary debate on human experimentation is grounded in Nuremberg"
(Annas & Grodin, 1992)

Doctors Trial

- Nazi physicians who took an active role in the Nazi racial extermination programs were charged with "murder, tortures and other atrocities committed in the name of medical science" (Annas & Grodin, 1992)
- Atrocities that bordered on torture were particularly egregious because of the involvement of doctors- supposedly a source of comfort

Nazi Experiments

- Exposure of inmates to cold water or low air pressure to observe the events that would lead to their deaths
- Mass sterilization of inmates by irradiating their gonads
- Injection of typhus and other pathogens in order to study the disease
- Others were exposed to epidemics such as malaria, and jaundice
- Subjects were forced to drink seawater or breathe mustard gas
- Others were placed in ice water until they froze

Many of these subjects were killed when they were no longer useful to the experiments in which they participated

The Nuremberg Code (1947)

http://ohrp.osophs.dhhs.gov/references/nurcode.htm

- Voluntary consent absolutely essential
- Fruitful results have to be shown for the experiment to continue
- Human research must be based on animal experimentation
- Researchers must avoid inflicting suffering on their subjects
- There should be no *a priori* reason that death or disability would result
- Only reasonable risk should be taken by the researcher
- There need to be adequate facilities to conduct the research
- Researchers need to be qualified in the area in which they are conducting the research
- Subjects should be informed that they can end the experiment at any time
- Researchers are obligated to terminate the experiment if injury results

2 Problems with the Nuremberg Code

1. Did not address those who lacked capacity (children and the cognitively impaired)- appeared that experimentation involving these groups was not permissible
2. The code lacked enforceability

The Declaration of Helsinki (1964)

http://www.wma.net/e/policy/17-c_e.html

- In response to the deficiencies of the Nuremberg Code, the World Medical Association developed the Declaration of Helsinki
- Designed to regulate international medical research regardless of the location in which the research occurs
- It incorporates all the points addressed in the Nuremberg Code
- The aim of this declaration is to protect subjects' health and rights

Uniqueness of the Declaration of Helsinki

- The declaration addresses the rights of minors to assent to participation in the research
- Allows for proxy consent when in the subject's best interest- for incompetent individuals
- It outlines the need for an independent ethical review committee to oversee the conduct of the research

Uniqueness of the Declaration of Helsinki *(Cont.)*

Publication of Research Results

- Addresses researchers' and publishers' responsibility to accurately report positive and negative results of the research, and to clearly identify sources of funding, institutional affiliations, and other conflicts of interest
- Special provisions for obtaining consent from subjects who are in a dependent relationship with the researcher, such as those in a patient/physician relationship, are made

Publicized Cases in the US Upon Human Subjects

- Experimentation on the institutionalized mentally ill, on prisoners, and on "political" prisoners
- Subjects were never informed of the nature of the experimentation
- Exploitation was inconsistent with the Nuremberg Code

Publicized Cases in the US *(Cont.)*

1956-1970 Willowbrook State Hospital

- Deliberate injection of viral hepatitis into developmentally disabled children
- Promised parents admission in exchange for their consent to participate in the experiment (coercion)
- Parents were not given full disclosure of the risks
- Parents were often misled as to the nature of the experiment

Publicized Cases in the US *(Cont.)*

1963 Jewish Chronic Disease Hospital

- Live cancer cells were injected into elderly patients without their knowledge or consent
- Claimed little or no risk
- Claimed that knowledge would likely frighten the patients

Publicized Cases in the US *(Cont.)*

1932-1972 The Tuskegee Syphilis Study

- Study was conducted in Macon County, Alabama by the US Public Health Service- the parent organization of the NIH, and the predecessor of the CDC
- Aim of the study was to determine how lethal syphilis was, when untreated
- 400 African-American men infected with syphilis
- 200 who were not infected served as a control group

The Tuskegee Syphilis Study *(Cont.)*

- The infected men did not receive any treatment for their syphilis, but were told that the periodic diagnostic spinal taps were a treatment
- Members of the control group who became infected were transferred to the experimental group(!)

The Tuskegee Syphilis Study *(Cont.)*

- They were not told of their infection, and they also did not receive any treatment, which exposed their families and sexual partners to the infection
- Although penicillin was discovered in the 1940s to be effective in the treatment of syphilis, and there was no reason to continue the study, the study was not halted

The Tuskegee Syphilis Study *(Cont.)*

After the study was finally stopped in 1972, in response to the *New York Times/Washington Star* exposé, the scientific community concluded that:

1. The Tuskegee syphilis study was racially motivated
2. The men were not informed that they were participating in a study
3. The men were deceived by being told that the diagnostic tests were a treatment
4. The study had no scientific merit

END OF Part 1 of 2

Watch the documentary:
The Deadly Deception

Public Health Ethics Part 2

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The role of public health

- The "right" to smoke
- The "right" to drink
- The "right" to be obese
- The "right" to engage in legal behavior
- The "right" not to wear a seatbelt
- The right to be "foolish"
- Do public health professionals have the right to use derogatory terms (e.g. foolish) to describe people's risky behavior?

A Definition of Public Health

- *"Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy."*

(http://www.cdc.gov/cvh/Action_Plan/full_sec2_core_functions.htm)

A Public Health Challenge

- Victim blaming
- "You the individual can do more for your own health and well-being than any doctor or hospital or exotic medical device." (Secretary Joseph Califano)
- Califano also stated: "... what role government should play, if any, in urging citizens to give up their pleasurable but damaging habits. But there can be no denying the public consequences of those private habits."

Is it our "duty" to be healthy?

- Where does our duty end and government's duty begin?
- Does the government have a duty to rescue us when we precipitate our own problems?
- Do we have a duty to stay healthy to save public resources?

When is paternalism justified?

Definition: "paternalism is the attempt to impose limitations upon someone or to require actions by someone for his or her own good" (Bayer, p. 149)

- With children
- With cognitively impaired adults

Paternalism & Public Health

- Should the discipline of Public Health embrace paternalism?
- Is imposing clean water and uncontaminated food paternalistic? Is this justified in the name of protecting the public's health?

Ethics of Social Marketing

- Is it justifiable to have public health campaigns to counteract commercial campaigns that advocate cigarette smoking and alcohol consumption?
- "Advertisements should be to promote good health products and not products that kill" (APHA)

Sin Taxes

- For an interesting review of the origin of sin taxes, access: http://www.bos.frb.org/economic/nerr/rr2003/q1/taxhabits.htm
- Critiques:
  - Overburdens the poor
  - Overburdens all users rather than abusers
- Advantages:
  - Helps to fund services
  - Discourages minors from starting certain behaviors (e.g. smoking)

Sin Taxes on Tobacco Products

- Early death results in limiting social security payments
- Early death limits long-term care expenses

Competing Values

- What are your personal values?
- Can you reconcile your personal values with stated Public Health values?