

Bio Ethics

- Sudarsan Padmanabhan
- Dept of HSS. IIT Madras
- Reference
- Bonnie Steinbock, John D. Arras, Alex John London, Eds. *Ethical Issues in Modern Medicine*, New York: McGraw-Hill, 2003

Moral Reasoning in Bioethics

- Nature and Scope of Bioethics
- Euthanasia
- Is it permissible
- Under what conditions
- Patients rights

Assisted Suicide – Is it moral?

- Should a doctor assist suicide under extreme circumstances?
- If a patient is suffering unbearable pain and has no chances of being cured of a disease (for example, Lou Gehrig's disease)

What is a Lou Gehrig's disease

- Amyotrophic lateral sclerosis
- A-myo-tropic – no – muscle – nourishment
- Atropy – decay, degeneration
- Lateral – area in the spinal cord where a portion of the nerve cells that control muscle movements are located
- Sclerosis – hardening of the region in the spine that controls muscle movements

Who was Lou Gehrig

- Lou Gehrig was an American baseball legend, Hall of Famer, and a New York Yankees team captain
- Gehrig lived between 1903 and 1941
- ALS became famous because of Lou Gehrig's sudden and early demise

Symptoms of Lou Gehrig's disease

- As motor neurons degenerate, they can no longer send impulses to the muscle fibers that normally result in muscle movement. Early symptoms of ALS often include increasing muscle weakness, especially involving the arms and legs, speech, swallowing or breathing. When muscles no longer receive the messages from the motor neurons that they require to function, the muscles begin to atrophy (become smaller). Limbs begin to look "thinner" as muscle tissue atrophies.

ALS – affects voluntary muscle movement

- *The nerves that are affected when you have ALS are the motor neurons that provide **voluntary movements** and **muscle power**. Examples of voluntary movements are your making the effort to reach for the phone or step off a curb; these actions are controlled by the muscles in the arms and legs.*

ALS' effect on heart

- *Remember, though, while you cannot stop your heart, you can hold your breath - so be aware that ALS may eventually have an impact on breathing.*

Heart and digestive muscles are involuntary. So, ALS does not affect them directly. But breathing can be affected by the voluntary muscles activity.

ALS – Patient Condition

- Sphincter control, sensory function, intellectual abilities and skin integrity are preserved. Patients become completely disabled, often requiring ventilatory support and gastrostomy. Death usually occurs within five years of diagnosis and is attributed to respiratory failure or cachexia.

Sphincter control

- A lack of Sphincter control would result in incontinence of the bowel.
- The ability to hold stool and maintain continence requires normal function of the rectum, anus, and the nervous system. Additionally, the person must possess the physical and psychological ability to recognize and appropriately respond to the urge to defecate. (US National Library of Medicine and National Institute of Health)

Should people with AIs be allowed euthanization?

- Should doctors assist in suicide contravening the Hippocratic oath?
- Should there be a legal prescription?
- What are the criteria for deciding when the patient needs to be euthanized?
- Would the slippery slope argument become a reality?

The domain of Bio-ethics

- Bioethics is a study of moral conduct, of right and wrong.
- It is inescapably normative.
- Bioethics asks the question whether, for example, euthanasia is morally right or wrong.
- Could euthanasia be a good social policy?
- What are the responsibilities of a physician?

Meta-ethical implications

- Is the moral and legal justification for euthanasia logically substantiated?
- Are ethical considerations adduced to support various challenges to issues in bio-ethics such as euthanasia, abortion, and stem-cell research justifiable?

Bioethical Problems and Concerns

- Bioethics movement came into prominence in the 1970s
- Some crazy headlines everyday like 'Gene for homosexuality Discovered, 'Parents insist on Treatment for Baby Without a Brain', Patients Subjected to Radiation Experiments Without Their Consent, ' Dr. Kevorkian Strikes Again'

Tuskegee Syphilis Study

http://www.brown.edu/Courses/Bio_160/Projects2000/Ethics/HISTORICALBACKGROUND.html

- “I don’t know what they used us for. I ain’t never understood the study.” – a survivor
- Syphilis is a sexually transmitted disease.
- Tuskegee is in Alabama. The Tuskegee project was a study done on African-Americans for several decades under the name of treating them for Syphilis.
- Syphilis – euphemistically called bad blood

Aim of the Tuskegee Study

- To chart the succession of phases syphilis exhibits when left to itself, uncomplicated by other morbid processes and unmolested by active treatment
- Tuskegee in Macon County, Alabama had the highest prevalence of Syphilis in 1933
- 399 African-American men with latent syphilis and 201 men without disease were enrolled in the study based on the results of a 1930 venereal diseases control projects survey.

Why Tuskegee

- Alabama was the heart of the racist South
- Tuskegee was very backward socio-economically
- The study, which lasted for 40 years included only sporadic clinical reexaminations when a Public Health physician came to Tuskegee and denied the individuals any form of anti-syphilitic therapy.

Governmental Callousness

- in 1942 when it was brought to the attention of the then Assistant Surgeon General, Vonderlehr that some of the syphilitic subjects were being called for examination prior to induction into the Armed Forces and were being directed to undergo treatment systematic steps were taken to preserve the investigation.

Human Guinea Pigs

- To prevent the draftees from receiving anti-syphilitic treatment, the investigators provided the Macon County Selective Service Board with a list of 256 names of men under the age of 45 years who were to be excluded from the list of draftees needing treatment. The Board agreed to exclude these men.

Human Rights Trampled

- When the modern-era of anti-syphilitic therapy began in 1943 with the introduction of penicillin as an effective drug, the Public Health Service did not use the drug on the Tuskegee participants unless they asked for it. The rationale published by the investigators for their decision regarding the lack of treatment provided to the infected "Negro" population was,

Racism and Exploitation at its worst

- *"...Such individuals seemed to offer an unusual opportunity to study the untreated syphilitic patients from the beginning of the disease to the death of the infected person. An opportunity was also offered to compare the syphilitic process uninfluenced by modern treatment, with the results attained when treatment had been given." □6(*

Tuskegee

- By the time the study was exposed in 1972, and ended on November 16th of the same year, 28 men had died of syphilis, 100 others were dead due to syphilis related complications, at least 40 wives had been infected and 19 children had contracted the disease at birth.

Tuskegee

- On July 23rd, eight months after the Tuskegee syphilis study was abandoned, a \$1.8 billion class action suit was filed against the institutions and individuals involved.
- Prominent civil rights lawyer, Fred Gray, demanded \$3 million in damages for each living participant and the heirs of the deceased.

Travesty of Justice

- The case, however, never came to trial and in December 1974 an out of court settlement was made. The government agreed to the distribution of \$10 million, whereby each survivor received \$37,500 in damages and the heirs of the deceased received \$15,000.

Breach of Trust

- Tuskegee residents were promised cure for Syphilis
- They were not told of the research
- Their consent was not voluntary
- They were promised economic and social development
- They were not educated about their own rights

The lure of incentives

- *"...various methods were used to maintain and stimulate their interest. Free medicines, burial assistance or insurance, free hot meals on the days of examination, transport to and from the hospital and an opportunity to stop in town on the return trip...all helped."*

Unethical Science

- Bearing in mind the low educational status of the patients and the tendency of the average African-American man to willingly agree with a perceived authoritarian figure such as the Public Health Service physician the men from Tuskegee became the unassuming victims of an unethical scientific undertaking.

No Ethical Dilemma

- *"...The county health officer shall require persons infected with venereal disease to report for treatment to a reputable physician and continue treatment until such disease, in the judgement of the attending physician is no longer communicable..."*
- **General laws of the legislature of Alabama.** Session of 1927. Montgomery : Brown 716, 1927

Legally and Morally Wrong

- the officials of a Federal Agency, the Public Health Service, were successful in withholding therapy from the participants of the Tuskegee Study, and the physicians did not detect an ethical dilemma.

Doctors Ignored the Law

- when the Judiciary Council of the American Medical Association issued a report, on December 10th, 1946, on the ethics of experiments involving human subjects the investigators of the Tuskegee Study took no steps to revise or terminate their investigation.

- The Tuskegee Syphilis Study was in violation of all three requirements proposed by the Judiciary:
- (1) the voluntary consent of the person on whom the experiment is to be performed must be obtained,
- (2) the danger of each experiment must be previously investigated by animal experimentation,

- 3) the experiment must be performed under proper medical protection and management.
- In the aftermath of the Tuskegee Study the government reevaluated its research practices to prevent another Tuskegee. The National Research Act was signed in 1974, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.

Four Decades of Moral Indifference

- Furthermore, regulations were passed that required all studies using human subjects be reviewed by an Institutional Review Board, which read the study protocols and decided whether they met ethical standards.
- The Tuskegee experimental study on Negroes (African Americans) in a liberal democracy is comparable to the experiments on Jews conducted by the Nazi Concentration Camp physicians.

The Nuremberg Code

- The idea of, "state before individual" was typical of the Nazi era and physicians began to lose sight of their moral obligations as they were swept into the dehumanizing Nazi political culture.
- The slew of exotic diseases and afflictions, a condition of the war environment, were seen as a, "national threat," and it was to these "threats" that German doctors began to assume the responsibility of acting on behalf of the state in order to improve the health of the nation.

Nazi Doctors and Moral Code

- On the basis of national thought and utilitarianism doctors no longer acted as caretakers but as puppets of a government obsessed with racial and genetic purity.
- Medical experiments committed under the guise of scientific research fell into three basic categories: (1) Medico-Military Research; (2) Miscellaneous, Ad Hoc Experiments; and (3) Racially Motivated Experiments

Holding Scientists Accountable

- The Nuremberg trial of doctors, which began in 1946, revealed evidence of sadistic human experiments conducted at the Dachau, Auschwitz, Buchenwald and Sachsenhausen concentration camps.

Landmark Nuremberg Judgement

- The Nuremberg Code is the most important document in the history of the ethics of medical research and the first of its kind to ensure the rights of subjects.
- Formulated 50 years ago, in August 1947, by the American judges heading the trial of Nazi doctors accused of conducting macabre human experiments in the concentration camps.

- During the course of the trial the judges at Nuremberg correctly recognized that strict ethical guidelines more than the Hippocratic ethics and the maxim *primum non nocere*, were necessary to ensure and protect the rights of human research subjects.

The Nuremberg Principles

- **The Nuremberg Code**
- **From "Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10", Vol. 2, Nuremberg, October 1946 - April 1949. (Washington, DC: US Government Printing Office, 1949). pp 181-182.**
- **The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts.**

Nuremberg Principles

- **The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.**

Nuremberg Principles

- **The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.**
- **The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.**
- **The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.**
- **The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.**

Nuremberg Principles

- **No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects.**
- **The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.**
- **Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.**
- **The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.**

Nuremberg Principles

- **During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.**
- **During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.**

Examples of Violations of the Principles of Bioethics

- Uranium mining in Jadugoda in Jharkhand
- Radiation experiments on humans in the US (1944 -1974)
- Radiation accidents - “experiments of opportunity”
- We can also justifiably include Saddam Hussein's use of mustard gas on the Kurds.