Medical Ethics

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Hippocratic Oath

12th-century Byzantine manuscript of the Oath

Late 5th Century B.C.
Basic Principles of Medical Ethics

1. Non-maleficence
2. Beneficence
3. Autonomy
4. Justice
Primum non nocere

1.) Non-Maleficence

• NON-MALEFICENCE (not harming) is the main basis for medical decisions.
  – It’s basically based on the notion that it is more important not to harm than to do good.
  • Now, this may seem odd at first because you think it would be better to do good than no harm. Well, yes, ideally, but in the real world this doesn’t happen so the principle is applied to limit the chances of a doctor using their enthusiasm and/or opinion of treatments without adequate research, possibly harming the patient.

Bloodletting
High Oxygen for respiratory distress in premature infants
2.) Beneficence

• BENEFICENCE (benefiting or doing good) is where a doctor should act in the best interests of the patient.
  – It involves balancing the benefits of treatment against the risks and costs of the treatment.
• How?
  – In short, both BENEFICENCE (doing good) and NON-MALEFICENCE (not harming) work together to achieve this balance.

Healing should be the sole purpose of medicine, and that endeavors like cosmetic surgery, contraception & euthanasia fall beyond its purview.
3.) Autonomy

- AUTONOMY is where the patient has the right to refuse medical treatment or choose a medical treatment.
  - The choice can be based on one’s own personal interests, which may not be based on the benefits of the medical treatment itself.
- Autonomy perfectly complements Non-Maleficence and Beneficence.
  - How - & - Why
    - Prior to the ethical principle of AUTONOMY, Non-Maleficence and Beneficence allowed only a paternalistic approach.
      - In other words, these two principles (Non-Maleficence and Beneficence) alone are physician-based.
        » Physician-based is where the doctor alone makes the decisions of what are in the best interests of their patients, and, basically, the patients do not have a say.

Jehovah’s Witnesses
Primary Elective Cesareans
Cosmetic Gynecology
Counseling parents of 24 week fetus
4.) Justice

• JUSTICE is where patients are treated impartially, without bias on account of gender, race, sexuality, wealth and etc.
  – In the medical field, it usually refers to distributive justice.
  • In other words, JUSTICE usually focuses on who gets medical treatment with specific scarce medical resources.
  – For example, one of the first instances to allocate a scarce medical resource was in the 1960s with the availability of dialysis for people in chronic kidney failure. Since the demand exceeded the supply because dialysis was expensive and not accessible on a large scale, it meant not all people who needed it could receive it. So the principle of JUSTICE was applied. AND who gets the treatment or not is the ethical question at hand.

Neonatal Intensive Care Units
Transplants
Forced sterilization of mentally retarded in Virginia
A sentence of death by hanging is pronounced by a US War Crimes Tribunal upon Adolf Hitler's personal physician, 43-year old Karl Brandt. Brandt was also Reich Commissar for Health and Sanitation.

Of the 23 defendants, 7 were acquitted and 7 received death sentences; 9 received prison sentences ranging from 10 years to life imprisonment.
Tuskegee Syphilis Experiment

- Conducted by the U.S. Public Health Service from 1932-1972
- 600 Rural African-American men thought they were receiving free health care from the government.
- By the end of the study in 1972, only 74 of the test subjects were alive. Of the original 399 men with syphilis, 28 had died of syphilis, 100 were dead of related complications, 40 of their wives had been infected and 19 of their children were born with congenital syphilis.
- 1972 Whistleblower
  - PHS physician: "The men's status did not warrant ethical debate. They were subjects, not patients; clinical material, not sick people."
- Led to the creation of the Office of Human Research Protection

Peter Buxtun, PHS veneral disease investigator, the “whistleblower”.
HENRIETTA LACKS
HELA Cells

• 1951: Cervical cancer cells taken without her consent, Cells immortalized by George Gey
• Cells used to create polio vaccine and became ubiquitous in medical research
• Today ~11,000 patents involving Hela cells
John Moore was treated for hairy cell leukemia at UCLA & his cancer was developed into a cell line that was commercialized.

Moore signed a written consent form authorizing the splenectomy, which said the hospital could "dispose of any severed tissue or member by cremation". Surgeons at UCLA Medical Center removed Moore's spleen in 1976. A material fact in the case was that his doctor had been aware of the potential for financial benefit deriving from Moore's bodily tissues and fluids at the time of obtaining medical consent and had not disclosed this to Moore.

1990 California Supreme Court ruled that Moore had no right to any share of the profits realized from the commercialization of anything developed from his discarded body parts.
Greenberg v. Miami Children's Hospital Research Institute

The plaintiffs in this case were a group of parents of children who had Canavan Disease and 3 non-profit organizations who developed a confidential Canavan disease registry and database. The parents provided their children's tissue for research on the disease and the non-profit groups aided in the identification of other affected families.

The defendant was the investigator, who received these tissue samples and used them to isolate and patent the Canavan gene sequence. He subsequently developed a genetic screening test for it in 1993 & began claiming royalties whenever the test was used. The Miami facilities where he did his research, including Miami Children’s Hospital, were also defendants.

2003 decision by the U.S. District Court for the Southern District of Florida which ruled that individuals do not own their tissue samples when researchers take them for testing.
GFAP as a Marker for Periventricular White Matter Injury in Preterm Neonates

- Birth: Normal (N = 42), PWMI (N = 21)
- Admission: Normal, PWMI
- Day 1: Normal, PWMI
- Day 2: Normal, PWMI
- Day 3: Normal, PWMI
- Day 4: Normal, PWMI

Significance levels:
- p=0.02 *
- p=0.03 *
- p=0.004 *
- p<0.001 *
Jesse Gilsinger

Ornithine transcarbamylase deficiency, x-linked, liver, inability to metabolize ammonia

1999 - died from massive immune response to adenovirus vectors used to transport gene into liver

18 years old

1st person publicly identified as having died in a trial for gene therapy
FDA concluded investigators broke several rules of conduct:

1. Inclusion of Gelsinger as a substitute for another volunteer who dropped out, despite Gelsinger's having high ammonia levels that should have led to his exclusion from the trial.

2. Failure by the university to report that 2 patients had experienced serious side effects from the gene therapy.

3. Failure to disclose, in the informed-consent documentation, the deaths of monkeys given a similar treatment.

The Univ of Penn paid the parents an undisclosed amount in settlement.

Both PI and the University are reported to have had financial stakes in the research.
2001: Could librarians have prevented a death?

Healthy 24 year old lab technician at the Johns Hopkins Asthma Center that volunteered to take part in an experiment to understand the natural defenses of healthy people against asthma. Roche was part of a group that inhaled hexamethonium, a drug which induced a mild asthma attack. Physicians stood by in case of complications and to measure how the subjects responded to the asthma attack. Within 24 hours of inhaling the drug, Roche had lost one-third of her lung capacity. Within a month she was dead.

The consent form she signed warned of coughing, dizziness, and tightness in the chest, but not death. It called hexamethonium a "medication" although its approval by the FDA (as a treatment for high blood pressure) had been withdrawn in 1972.

The director of the experiment, apparently limited his hexamethonium research to one contemporary textbook and PubMed.

The use of hexamethonium in the 1950's to treat high blood pressure created an evidentiary trail revealing some disturbing risks. Several articles published in print journals during the 1950's showed that hexamethonium could cause fatal lung inflammation. Unfortunately, PubMed's coverage starts in 1966. When the FDA withdrew its approval of hexamethonium in 1972, it cited the drug's "substantial potential toxicity".

The JH internal investigation found literature on the dangers of hexamethonium in Google and Yahoo. Medical librarians who subscribe to the MedLib listserv found relevant information in online sources other than PubMed.

The federal Office for Human Research Protection (OHRP) suspended all JH research on human subjects. This halted 2,400+ ongoing experiments with 15,000+ human subjects.
1999: Kevorkian was arrested and tried for his direct role in a case of voluntary euthanasia. Convicted of 2\textsuperscript{nd} degree murder and served eight years of a 10-to-25-year prison sentence. 

6-1-2007: Released on parole on condition he would not offer suicide advice to any other person. 

Died in 2011
May 2013: Kermit Gosnell convicted on three counts of murder. He waived his right of appeal in exchange for an agreement not to seek the death penalty. He was sentenced to life in prison without the possibility of parole.
American Association of Clinical Endocrinologists recommendations on caring for patients with diabetes:

1. elevate many expensive 2nd or 3rd line drugs to more prominent positions in the prescribing hierarchy, rivaling once uncontested go-to medications like metformin, an inexpensive generic.

2. also emphasize the riskiness of established treatments like insulin and glipizide, which now carry yellow warning labels in the A.A.C.E. summary.

Practice guidelines recommended the aggressive treatment of anemia in kidney-disease patients with the drug erythropoietin, though the higher doses substantially increased the risk of heart attack, stroke and death, with little countervailing benefit. Here, too, the professional society that issued the guidelines, as well as many of the doctors who formulated them, received funding from companies marketing the drug.
Declaration of Helsinki

A set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association.

Originally adopted in 1964 in Helsenki, Finland and updated 6x the most recent in 2008.

Has increased from 11 to 35 paragraphs.

Prior to the 1947 Nuremberg Code there was no generally accepted code of conduct governing the ethical aspects of human research.
Hospital Ethics Committees

Often, simple communication is not enough to resolve a conflict, and a hospital ethics committee must convene to decide a complex matter.

These bodies are composed primarily of health care professionals, but may also include philosophers, lay people, and clergy - indeed, in many parts of the world their presence is considered mandatory in order to provide balance.
Johns Hopkins Hospital IRB

- IRB = Institutional Review Board
- The IRB reviews all research proposals and approves/declines
- NO research may be performed without IRB approval
- The IRB is an additional, neutral party safeguard to prevent inadvertent harm
Conclusions

• Ethical consideration must be a fundamental and necessary component of every research project
• Non-maleficence, beneficence, autonomy and justice must be considered
• Advances in the name of science and medicine should not be at the expense of others
• Learn your institution’s specific guidelines for ensuring ethical research