

2011

Historical timeline

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Historical Timeline

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Early Experimentation

- Experimentation has always taken place.
- The Hippocratic Oath originally written by Hippocrates in late 5th century first stated:
 - “I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.”
- However, in the course of experimentation people were harmed and sometimes killed.



1900 Walter Reed Yellow Fever Study

- Walter Reed, US Major in US Army appointed to study tropical disease in Cuba.
- Infected subjects with yellow fever, two died
- Subjects informed that there was a risk of possible death.
- Discovered that the mosquito is the vector for yellow fever.

1932-1972

- The Public Health Service Syphilis Study in Tuskegee, AL,
- Therapy for syphilis was as risky as the disease
- 400 recruited; 200 controls
- Free exams, medical care, “therapeutic” spinal taps, burial allowance

1939 Stuttering Study

- Dr. Wendell Johnson, a nationally renowned pioneer in field of speech pathology studied if stuttering could be induced through psychological pressure.
- Used orphans in the Iowa Soldier's Orphan's Home
- Randomized to receive abuse such as being berated, harassed, badgered and other negative therapy or were in the control group

Nazi Germany 1939-1944

- To test the effects of extremely high altitudes internees were put in vacuum chambers that duplicated low air pressure and lack of oxygen at altitudes as high as 65,000 ft.
- To test hypothermia, internees were: immersed in tubs of ice water; or fed salt water for days; or penned outside without clothing or shelter in sub-freezing temperatures for 12-14 hours and some were sprayed with cold water.
- Battlefield medicine including treatment of wounds, burns, traumatic amputations, chemical and biological agent exposure that was first inflicted on the victim.



1946 Trial at Nuremberg

- 23 Germans were tried for war crimes.
- 16 found guilty.

1947 Nuremberg Code

- Key provisions:
 - Voluntary consent
 - Research founded on animal studies
 - Avoid unnecessary physical and mental suffering



1950s Radioactive Cereal Experiments

- Fed radioactive cereal to 15 children at state run home for the retarded in Massachusetts: Fernald School to see absorption rates of nutrients as oatmeal was digested
- No consent; children told they were part of a science club
- Some exposed to more than federal limits of radiation at time
- No physical harm was suffered

Willowbrook Experiment, 1956-72

- Willowbrook State School in New York for mentally disabled children.
- Children were infected with a mild form of hepatitis. The children were going to get hepatitis anyway.
- Parents had the choice of putting their children in the cleaner ward where they would be infected with hepatitis or the regular, overcrowded ward.
- Parents were consent with a one paragraph consent form that gave permission for the children to be in the study.
- Lead to the development of a hepatitis vaccine.

Milgram Study, 1963

- Was designed to study the role of obedience to authority; why ordinary people behave in ways that seem inhumane outside a certain context.
- Stanley Milgram and an associate duped participants into thinking they were administering electrical shocks to another research participant if he answered incorrectly. The associate pretended to convulse with the shock and become unconscious. Although the associated reacted in this manner, research participants continued to increase “the voltage” at the urging of Milgram. After the experiment was over, several participants were horrified when they realized that they had delivered shocks that were enough.
- After the experiment was over, several participants were horrified when they realized that they had delivered shocks that were enough



1961 Thalidomide

- Thalidomide given to pregnant women to manage morning sickness in the first trimester.
- Children born severely deformed.

1964 Declaration of Helsinki

- Document that is updated. Latest update in 2000.
- Some Key points:
 - Death cannot be an endpoint unless the participants are the physicians themselves
 - Informed consent
 - Voluntary participation
 - Use of placebos need equipoise: meaning it is not known for use that one treatment is superior to another



1966 Beecher Article

- Appeared in New England Journal of Medicine
- Cited 22 published studies with serious ethical flaws



1971 Stanford Prison Experiment

- Philip Zimbardo used volunteer college students to play roles of prisoners and guards
- Guards abused prisoners and had to be terminated early



1974 National Research Act

- National Commission for Protection of Human Subjects of Biomedical and Behavioral Research created
- Developed the Belmont Report over a 5 year period.



1974 – 81 HHS and FDA Regulations

- Establishment of IRBs through FDA regulation 21 CFR 56 in 1974
- 1981 DHHS published 45 CFR 46 and FDA published 21 CFR 50 Protection of Human Subjects



1979 Belmont Report

- Respect for Persons
- Beneficence
- Justice

1991 Common Rule

- 16 different agencies adopted HHS 45 CFR 46 thus it's known as "The Common Rule"
 - Some agencies that did not adopt this: FDA and DOD



Studies talked about in 2010

- HeLa Cells, 1951. Henrietta Lacks was diagnosed with cervical cancer. Her physician removed some of the cancerous cells and developed the first “immortal” human cells grown in culture.

Studies talked about in 2010

- Havasupai Tribe, 1992. Blood samples were taken to study occurrence of diabetes amongst tribe members but were used for other studies as well.
- US Public Health Service in Guatemala, 1946. Male prisoners in Guatemala were infected with syphilis using infected female prostitutes.