Epidemiology

Ethics in Epidemiology
Part A

History of ethics and human subjects protection in research

- Prior to 1906, there were no regulations
- 1906 Pure Food and Drug Act was passed
- 1948 Nuremberg Code was established
- 1964 Declaration of Helsinki
- 1974 National Research Act
- 1979 Belmont Report
- 1991 Common Rule

Pure Food and Drug Act

- Provided consumer protections and regulations of food and drugs
- 1950s, many pregnant women in Europe were prescribed Thalidomide as a sedative. The FDA did not approve the use of Thalidomide in the US. This drug resulted in the birth of 12,000 babies with severe deformities.
- 1962 Kefauver Amendment passed, stating that drug manufacturers needed to demonstrate the effectiveness of their products before marketing them.

Nuremberg Code

- During World War 2, there were a number of medical experiments conducted by German physicians among concentration camp prisoners.
- These individuals were tried and as a result in 1948 the Nuremberg Code was passed, stating that research participants needed to give voluntary consent to participate in any studies.

Nuremberg Trials Video Clip

1964 the World Medical Association established rules for research combined with clinical care.
- Established independent committees to review the protection of subjects in research prior to starting any study.
- Risks should not exceed benefits
- Importance of voluntary participation.

Declaration of Helsinki
National Research Act of 1974

- 1932-1972 Tuskegee Syphilis Study was conducted in the United States. 600 low income African-American males, 400 of whom were infected with syphilis, were monitored for 40 years. They were misinformed about their disease and not offered any treatment even though in the 1950s penicillin was available.
- Please watch the film “The Deadly Deception” which describes this study and complete the quiz.