

Health Equity and Social Justice in Human Subjects Research

Ochsner Health Responsible Conduct of Research Lecture Series

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Disclosure Statement

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.

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Overview

- Chronicle the history of health equity and social justice in the US from the 19th century to 2021
- Discuss how health inequity and social justice concerns have impacted the field of human research protections
- Identify mitigating strategies which can enhance human research protections moving forward

Health Equity in the United States

Racial Health Inequity

- Earliest documented health inequity dates back to slavery
- The U.S. made meaningful attempts during two periods:
 - Reconstruction following the Civil War
 - The decade of the 1960s during the Civil Rights Movement
- Health inequity continued after each instance due to other factors such as: access, education, resources, healthcare delivery system models, and healthcare workforce development

Byrd and Clayton, 2001, An American health dilemma: a history of Blacks in the health system. *JAMA*

Health Equity in the United States

Gender Health Inequity

- Health inequity based on gender is less documented
- The U.S. made meaningful efforts towards gender equality in areas other than healthcare (e.g. political participation, workforce compensation, education)
- Health inequity has been acknowledged in terms of cost of healthcare, insurance coverage, and accuracy of diagnoses

<https://www.americashealthrankings.org/learn/reports/2019-senior-report/findings-health-disparities-by-gender>

Social Justice in the United States

What is Social Justice?

- Political and philosophical theory that focuses on the concept of fairness within society and equal access
- Concept birthed during the 19th century during the Industrial Revolution relative to social class structure
- Beginning in the 1960's and continuing today, shifted to an emphasis on human rights and improving the environment for those historically disadvantaged

<https://corporatefinanceinstitute.com/resources/knowledge/other/social-justice/>

How did the Historical Health Equity and Social Justice challenges impact human subjects research?

Syphilis

“A mysterious epidemic, hitherto unknown, which struck terror into all hearts by the rapidity of its spread, the ravages it made, and the apparent helplessness of the physicians to cure it.”

<https://jmvh.org/article/syphilis-its-early-history-and-treatment-until-penicillin-and-the-debate-on-its-origins/>

Effort to Address Health Inequity: The Rosenwald Fund

- Julius Rosenwald (1862 – 1932)
 - Jewish-American businessman and philanthropist
 - Co-owned Sears, Roebuck, and Company
 - Established the Rosenwald Fund
- The Rosenwald Fund
 - Patron of Booker T. Washington and the Tuskegee Institute
 - Financed the construction of many schools for Black students
 - **Partnered with the Public Health Service to expand medical services to poor Black areas in the South**



“The Study of Untreated Syphilis in the Negro Male”: True or False?



Address the following statements:

- The human subjects in the Syphilis Study knew they were in a research study but just did not know what the study was about.
- The human subjects in the Syphilis Study were injected with the syphilis bacteria.
- The Syphilis Study is an example of inequitable subject selection.
- The researchers tricked the human subjects into participating in the Syphilis Study by calling the disease “bad blood” instead of “syphilis.”

Myth #1: The human subjects in the Syphilis Study knew they were in a research study but just did not know what the study was

“The future of the Negro lies more in the research laboratory than in the schools” – Dr. Thomas Murrell

Macon County Health Department

ALABAMA STATE BOARD OF HEALTH AND U.S. PUBLIC HEALTH
SERVICE COOPERATING WITH TUSKEGEE INSTITUTE

Dear Sir:

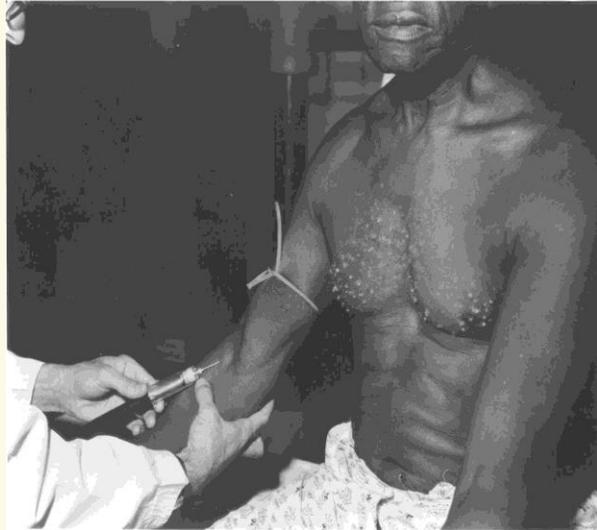
Some time ago you were given a thorough examination and since that time we hope you have gotten a great deal of treatment for bad blood. You will now be given your last chance to get a second examination. This examination is a very special one and after it is finished you will be given a special treatment if it is believed you are in a condition to stand it.

If you want this special examination and treatment you must meet the nurse at _____ on _____ at _____ M. She will bring you to the Tuskegee Institute Hospital for this free treatment. We will be very busy when these examinations and treatments are being given, and will have lots of people to wait on. You will remember that you had to wait for some time when you had your last good examination, and we wish to let you know that because we expect to be so busy it may be necessary for you to remain in the hospital over one night. If this is necessary you will be furnished your meals and a bed, as well the examination and treatment without cost.

REMEMBER THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT. BE SURE TO MEET THE NURSE.

Macon County Health Department

Myth #2: The human subjects in the Syphilis Study were injected with the syphilis bacteria.



- Between 1929 and 1931, the Public Health Services surveyed six rural areas in the South. The highest prevalence of syphilis was found in Macon County, Alabama. A more focused program in Macon County (36% of the population had syphilis) found that virtually none of the cases had been treated.
- Eligibility criteria (1932-33): black male with syphilis for at least five years*; had not received treatment
- *in 1933, a control group of non-syphilitic men were added

Myth #3: The Syphilis Study is an example of inequitable subject selection.



- According to the Belmont Report, the third ethical principle, justice, is most readily manifested by ensuring that there be equitable procedures and outcomes in the selection of research subjects. The social level of subject selection requires a distinction be drawn between those benefitting and those burdened. The individual level of subject selection requires fairness.
- In the case of the Syphilis Study, the research questions could only be answered through collecting data from Black males with syphilis. Since both this location and this population had the highest incidence, subject selection was reasonable.

Myth #4: The researchers tricked the human subjects into participating in the Syphilis Study by calling the disease “bad blood” instead of “syphilis.”



- During the era in which the Syphilis Study began, the general topic of venereal or sexually-transmitted disease (STD) was considered taboo. To discuss a sexually-transmitted disease, a discussion regarding sexual activity, sexual intercourse, and the cleanliness and function of sexual organs would also have to take place. Society was uncomfortable with these conversations and since it disproportionately affected the poor, even doctors were disinterested in acknowledging the damage it could potentially do to a population.
- Since syphilis was not openly discussed and consequently not well understood, it was also not used with the human subjects in the Syphilis Study. The terminology “bad blood” was used instead since it was a common local term used for illnesses ranging from STDs to anemia to fatigue.

Timeline of Events – Untreated syphilis in the Negro Male

Gray, F.D. 1998. *The Tuskegee Syphilis Study*



- 1930 – Spends \$50K for syphilis treatment demonstrations in six states (Alabama: Macon County)
- 1931 – Rosenwald funding is cut for treatment programs; physicians decide to follow the men diagnosed untreated
- 1932-33 – Follow up becomes a study of 399 syphilitic and 201 controls referencing a syphilis study in White males conducted in Norway.
- 1945 – Penicillin accepted as the preferred treatment for syphilis
- 1947 – PHS establishes treatment centers
- 1968 – Concerns raised about the study
- 1969 – CDC reaffirms the need for the study
- 1972 – Study condemned in major news outlets; study ends

Implications of “The Study of Untreated Syphilis in the Negro Male” for human subject research

- Funding
- Vulnerability
- Equity
- Informed Consent
- Subject Recruitment
- New Information
- Others?



“The Immortal Life of Henrietta Lacks” (2011)

- In 1951, a woman with cervical cancer at Johns Hopkins Hospital (in the “colored” ward) had cells removed during a biopsy
- Cells were cultured and showed resiliency never before seen
- Became know as “HeLa” cells, used worldwide in biomedical research and in the treatment of many diseases



Implications for human subjects research: The “Lacks Effect”

- Cultural and social considerations
- Informed consent
- Human subject definition
- Rights to profit from scientific advances
- Use of technology and genetic information for research



Lack of Health Equity during COVID-19

- Blacks
 - 1x for infection
 - 2.8x for hospitalization
 - 1.9x for death
- COVID-19 Vaccines
 - Pfizer – 9.8%
 - Moderna – 9.7%
- Hispanic
 - 2x for infection
 - 3x for hospitalization
 - 2.3x for death
- COVID-19 Vaccines
 - Pfizer – 26.2%
 - Moderna – 20.0%

Social Justice during COVID-19

- Voting rights
- Immigration
- Race relations
- Criminal Justice
- Equality
- Income
- Gun violence
- Hunger and food security
- HEALTHCARE

Where do we go from here?



The Belmont Report: Ethical Principles for Human Protections

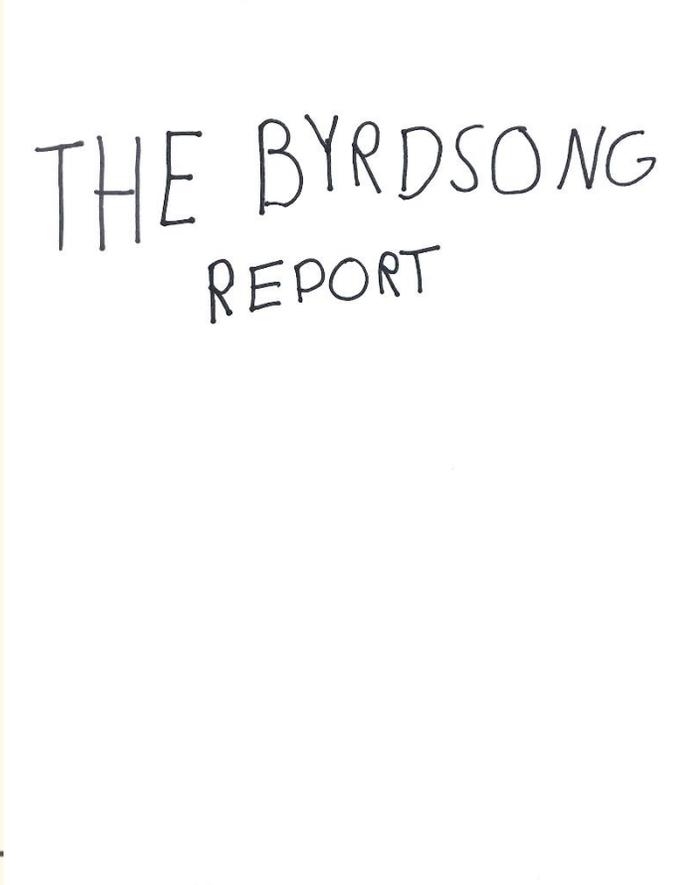
- Respect for Persons
- Beneficence
- Justice



“The Byrdsong Report”

Ethical Principles for Health Equity and Social Justice

- Information
- Independence
- Importance



THE BYRDSONG
REPORT

Ethical Principle: Information

- Enhances decision-making
- Facilitated by trust climate
- Address barriers to information exchange
- Avoid assumptions and selective sharing
- Become comfortable with lengthy discussions



Ethical Principle: Independence

- Subject decision is paramount
- Reduce appearance that others' opinion and expertise should supersede their own
- Statements of finality and desperation impact authentic autonomy
- Perceived reduced autonomy and actual reduced autonomy are the same thing
- Reiterate and encourage their autonomy at time of consent and throughout the study



Ethical Principle: Importance

- Comprehensive concern and compassion for every research subject
- Data is critical but recognize a human being is behind the data
- Empathy along with sympathy
- Circumstances and characteristics do not define individual value
- Never use participation as a means of the subjects' importance



Summary



- Anyone could potentially be vulnerable as a subject of research
 - Context over category
 - Lack of information, independence, or importance could be anyone's situation
- Ethical research is not just about how we conduct a study but, how we treat people
 - Trust
 - Compassion
- The good of science can never be considered over the importance of human life
 - Accountability
 - Responsibility

Questions?



Thank You!