SPOTLIGHT ON CLINICAL RESEARCH

Justice & Equity in Research

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It is no secret that injustice and inequity in research have long been a part of Western medicine, with marginalized groups the victims of decades of abuse, often in the name of "research." It is crucial to acknowledge transgressions before we can have conversations with the communities that have been targets of this abuse. And it is only with sincere efforts to rebuild trust that we can hope to conduct ethical, valuable, and relevant research.

This article offers brief snippets from our nation's past that are in no way meant to be comprehensive histories. Although no journal article could account for all the atrocities that have been committed, what follows is a brief introduction to some names and topics, presented with the hope that readers will look up more information from other reputable sources and that this will simply be the start of the conversation. References and recommended reading are provided throughout and at the end of this article.

JAMES MARION SIMS

James Marion Sims is often referred to as the "Father of American Gynecology." Until 2018, he was immortalized with a statue in Central Park in New York City. A surgeon in the 19th century (1813-1883), Sims developed the first surgical treatment for a condition that impacted many Black and white women of the time: vesicovaginal fistula — an unwanted opening that forms between the bladder and the wall of the vagina, often due to difficult childbirth. This type of fistula impacted enslaved Black women at a much higher rate than it did white women, due to multiple factors including malnutrition — leading to underdeveloped bones and smaller pelvises — and age, because enslaved women gave birth on average three years earlier than white women.

Sims used enslaved Black women as test subjects. He performed surgeries without anesthesia and often invited others to view the surgeries. At that time, the only legal requirement for performing surgeries on enslaved women was the consent of their enslavers.

Historical records do not provide much information about the 12 enslaved women on whom Sims experimented. In many of his own records, he concealed their race, "portraying them as white in the illustrations that accompanied his accounts of the surgery."[1,2] We know the names of only three, all of them teenagers: Anarcha, Betsy, and Lucy. Anarcha was 17 years old when she underwent the first of her 30 surgeries.

These three young women were not only experimented on but also forced to learn how to medically care for one another. Some historians suggest that "they became skilled medical practitioners in their own right" because of this necessity, though they were never recognized for their skills.[3]

In her book chapter, "Mastering the Female Pelvis: Race and the Tools of Reproduction," author Terri Kapsalis states: "Sims' fame and wealth are as indebted to slavery and racism as they are to innovation, insight, and persistence, and he has left behind a frightening legacy of medical attitudes toward and treatments of women, particularly women of color."[4]

HEPATITIS STUDIES AT THE WILLOWBROOK SCHOOL

From 1956 through 1971, residents at the Willowbrook State School for Children with Mental Retardation were infected with live hepatitis in order to develop a vaccine. Dr. Saul Krugman, the principal investigator of the study, argued that the good that would come from development of a vaccine would outweigh the anticipated minor harms to these children. He also argued that, due to the prevalence of hepatitis at the institution, the children were bound to be exposed to the same strains even if they were not in the study.[5]

Dr. Krugman, alongside Dr. Joan Giles, oversaw more than 50 children with mental disabilities in this study. These children, between the ages of 5 and 10 years old, were either "injected with the virus itself or made to drink chocolate milk mixed with feces from other infected children in order to study their immunity."[6]

In the 1950s, testing vaccines on children did not have the stigma it rightfully carries now. However,

while parents of these children did consent for their children to participate in the study, there remain questions about whether the permission letter adequately explained the study and its risks. Additionally, Dr. Krugman would offer the opportunity for families to skip the long wait lists for admission to Willowbrook if they agreed to permit their children to participate in his trials.

Dr. Krugman certainly faced criticism for the ethics of his study. The editors of *The Lancet*, who previously published Dr. Krugman's study results, wrote that "[t]he Willowbrook experiments have always carried a hope that hepatitis might one day be prevented, but that could not justify the giving of infected material to children who would not directly benefit."[6] Many others wrote regarding their opposition to his methods and/or protested his appearances at events. Despite all of this, Dr. Krugman became president of the American Pediatric Society in 1972, was awarded the John Howland award in 1981, and received the Lasker-Bloomberg Public Service Award in 1983.

JEWISH CHRONIC DISEASE HOSPITAL STUDY[7]

Dr. Chester Southam was a "respected clinical investigator" at the Memorial Sloan Kettering Cancer Center when he had the idea to collaborate with the Jewish Chronic Disease Hospital (JCDH) in Brooklyn, New York, on a cancer trial to examine whether people with cancer lacked immunity to it. Patients at JCDH were chronically ill but, importantly, did not have cancer. To test his theory about immunity, Dr. Southam injected 22 patients at JCDH with cancer cells without their consent. He was concerned the patients would react negatively if they were told they would be receiving cancer cells, so he and his co-investigators told them they were being injected with a "cell suspension."

> **"Science without conscience is the soul's perdition."**
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> — François Rabelais

Several other physicians had declined to participate in this study citing ethical concerns. When they learned that the study had moved forward, they resigned from JCDH. In addition, a member of the board of directors filed a lawsuit, which garnered attention from the media. Comparisons to Nazi experiments were quick to follow, along with a hearing before the Board of Regents of the University of the State of New York in 1964 that pointed to the Nuremberg Code, a set of medical standards created following the trials of Nazi physicians involved in atrocities during World War II, which unequivocally states: "the voluntary consent of the human subject is absolutely essential." This hearing resulted in a one-year probation but no suspension of licenses or any formal prosecution for those involved in the study. In fact, Dr. Southam was elected president of the American Association for Cancer Research in 1968, just two years after the Board of Regents' decision. Three years later, he returned to his alma mater, Thomas Jefferson University in Philadelphia, to become the head of the Division of Medical Oncology, where he remained until 1979.[8]

TUSKEGEE STUDY

Researchers in Macon County, Alabama, began the Tuskegee Syphilis Study in 1932 to document the progression of syphilis in Black men. These researchers from the U.S. Public Health Service (PHS) and the Tuskegee Institute targeted "sick, desperately poor sharecroppers" for their study, telling the men that they would receive treatment for their "bad blood," even though no treatment yet existed for syphilis when the study began.[1] The men were also offered "free medical exams, free meals, and burial insurance."[9]

At least 600 Black men participated in the study, more than half of whom had tested positive for syphilis. Those who did not have syphilis were part of the control group. When penicillin was identified as a treatment for syphilis in 1943, treatment was still withheld from the 399 men in the study with the disease. Researchers met with local Black physicians to ask them not to treat men who were in the study, instructed military physicians not to provide treatment to the men if they were inducted into the military while in the study, and sent a list of the participants to the clinics nearby so that they would not receive treatment if they showed up there.

This study went on for four decades, only ending in November 1972 at the advisement of a Health and Scientific Affairs panel when the media became aware of the study's methods. A $1.8 billion class-action civil lawsuit was filed in 1973 to seek damages for the surviving participants and their heirs. When the lawsuit was settled, the payments amounted to "$37,500 for each living study participant, $15,000 for his heirs ... The living control-group members received even less."

A formal acknowledgement of this atrocity was not made until 1997 when then-President Bill Clinton

issued a formal apology to the eight surviving study participants. This apology was accompanied by the creation of the Tuskegee University National Center for Bioethics in Research and Health Care, which was funded in part by a grant from President Clinton and has the goal of "training and educating African Americans in bioethics."[1]

CONCLUSION

We have a long way to go to earn back the trust of marginalized communities that view health care and research as tools of abuse and surveillance. Many more instances of harm have been committed by the health care community against marginalized groups in the United States. These include:

- The forced sterilizations of Black birthing people and birthing people with disabilities, covered in *Medical Apartheid* by Harriet A. Washington and *Menace to the Future* by Jess Whatcott.
- The exclusion of voluntary female participants in clinical research until 1993, as described in the NIH Revitalization Act of 1993.
- "Research" performed on incarcerated individuals, detailed in *All in Her Head* by Elizabeth Comen, MD, and *Menace to the Future* by Jess Whatcott.

These events have contributed to a pervasive and long-lasting mistrust of and skepticism toward health care systems and practitioners.

It is a harrowing reality that many of these horrific events yielded no or minimal consequences for the perpetrators. However, there have been critical safeguards put in place in the years since these events. While these are not infallible, they are valuable and foundational to ensuring health care and research are not sources of pain but of relief. These include:

- **Nuremberg Code:** This set of 10 standards was developed in August 1947 to help us judge reported abuses of human-subjects research.
- **Institutional Review Boards:** The National Research Act of 1974 led to the development of Institutional Review Boards, or IRBs. An IRB is a committee that reviews research studies to ensure that they comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants.
- **Belmont Report:** This summary of ethical principles published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974 forms the basis of acceptable human-subjects research. The three foundational principles established in the report are respect for persons, beneficence, and justice.
- **International Council for Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use:** This statement helped established several international standards of Good Clinical Practice for the development of pharmaceutical products.
- **U.S. Food and Drug Administration (FDA):** This agency of the U.S. Department of Health and Human Services is the part of the federal government tasked with regulating research that involves food, dietary supplements, drugs, as well as medical devices and electronic products, to ensure that the data collection during these investigations is gathered in an ethical, compliant, and sound manner. Products must be considered safe before they can be marketed and made readily available for commercial use.
- **Informed Consent:** This encompasses the ongoing process of obtaining an individual's and/or their legally authorized representative's agreement to participate in research before any study activities take place. This is one of the central protections provided for under Health and Human Services regulations and falls into the Belmont principle of respect for persons.

Recommended Reading

- *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present* by Harriet A. Washington
- *American Sirens* by Kevin Hazzard
- *The Immortal Life of Henrietta Lacks* by Rebecca Skloot
- *All in Her Head* by Elizabeth Comen, MD
- *The Pain Gap* by Anushay Hossain
- *Sex Matters* by Alison J. McGregor, MD
- *Your Consent Is Not Required: The Rise in Psychiatric Detentions, Forced Treatment, and Abusive Guardianships* by Rob Wipond
- *Menace to the Future: A Disability and Queer History of Carceral Eugenics* by Jess Whatcott
- *The Viral Underclass: The Human Toll When Inequality and Disease Collide* by Steven W. Thrasher
- *Bodies and Barriers* edited by Adrian Shanker
- *The Remedy: Queer and Trans Voices on Health and Health Care* edited by Zena Sharman
- *And the Band Played On: Politics, People, and the AIDS Epidemic* by Randy Shilts
- *Sentenced to Silence: One Black Man's Story of Imprisonment in America* by Allen Hornblum

So, what does this mean for those of us in health care? What can we do to prevent occurrences like those described above from happening again? Individual actions will vary based on our roles, but at the most foundational level, the importance of education cannot be overstated. Each of us must take steps to learn about the history of health care and research in the United States if we have any hope of not repeating past transgressions.

Taking it a step further, one of the things that marginalized communities have long said is that they feel more comfortable with a clinician who looks like them. Diversity in medicine saves lives. Cherise Hamblin, MD, in a *JLGH* article[10] in 2021, provided data directly supporting this:

> A study in Oakland, Calif., showed that Black men who were seen by a Black doctor were much more likely to accept preventive and invasive services, and were more willing to talk about their health problems ... The authors estimated that "Black doctors could help reduce cardiovascular mortality by 16 deaths per 100,000 per year — leading to a 19% reduction in the Black-white male gap in cardiovascular mortality."[11]

Ciciley Littlewolf, MD, a Native American clinician in North Dakota, states: "It's so important that patients see doctors who look like them, come from the same cultural background, because it increases trust — but also that cultural awareness." According to Nicole Riddle, MD, a pathologist in Florida who uses a wheelchair: "For people with differing abilities, it's literally about trying to change the actual physical structure or architecture of a workplace — not only people's minds, opinions and actions."[12]

Staffing our health system with people who represent the communities we serve is critical.

More actions may include joining a community organization so we can be of service in situations that do not ask anything of the people seeking aid. It may look like creating a psychologically safe space within our teams to discuss events that team members have personally experienced or heard about from patients. It may be as simple as engaging with books, movies, or presentations from perspectives that differ from ours to broaden our empathy.

Recognizing what has been committed in the name of science can make people uncomfortable. Sitting with the discomfort and wrestling with our complicated thoughts and emotions that arise is important. Change is not always easy. But we owe it to one another's humanity to do the hard work, the necessary work of challenging our biases and speaking up when we see harm being done. It only takes one decision, one individual action, to spark change.

Scan to access links to the safeguards listed in bold on page 57.

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