U.S. Public Health Service STD Experiments in Guatemala (1946-1948) and Their Aftermath

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ABSTRACT The U.S. Public Health Service's sexually transmitted disease (STD) experiments in Guatemala are an important case study not only in human subjects research transgressions but also in the response to serious lapses in research ethics. This case study describes how individuals in the STD experiments were tested, exposed to STDs, and exploited as the source of biological specimens—all without informed consent and often with active deceit. It also explores and evaluates governmental and professional responses that followed the public revelation of these experiments, including by academic institutions, professional organizations, and the U.S. federal government, pushing us to reconsider both how we prevent such lapses in the future and how we respond when they are first revealed. KEYWORDS human research ethics, Guatemala STD experiments, informed consent, biospecimen research

Spector-Bagdady, K. and Lombardo, P. A., "U.S. Public Health Service STD Experiments in Guatemala (1946-1948) and Their Aftermath," Ethics & Human Research 41, no. 2 (2019): 29-34. DOI: 10.1002/eahr.500010

ramatic historical examples of ethical lapses in human research have fundamentally changed professional bioethics discourse. The U.S. Public Health Service's (PHS's) sexually transmitted disease (STD) research in Guatemala in the 1940s, "discovered" only in 2010, is one such example. The passage of more than sixty years between this research and its public revelation not only denied study subjects a remedy for the harms they endured but also erased any opportunity to modify the research ethics regime as it formed in response to this historical failure. Here, we review what happened in the Guatemala STD experiments and describe how subjects were tested, exposed, and exploited as the source of biological specimens. We also explore and evaluate governmental and professional responses that followed the public exposure of these experiments.

THE GUATEMALA STD EXPERIMENTS

he original goal of the Guatemala STD experiments was to improve STD prophylaxis among U.S. military personnel during World War II. When the study began, the prevention of STDs was considered "one of the most pressing problems of military medicine." In 1943, researchers at the PHS discovered that penicillin could cure syphilis. But penicillin was costly, and infection and subsequent treatment removed soldiers from the battlefield. PHS researchers wanted to learn how to prevent STD transmission in the first place, to improve public health generally and ensure an available and healthy fighting force.3

PHS researchers initially explored a postexposure prophylactic wash that could be applied after sexual contact to prevent the transmission of disease. John C. Cutler, a senior surgeon at PHS who later was the lead investigator in Guatemala, believed that before the wash would be ready for widespread use in the U.S. Armed Services, it should be tested via controlled experiments on subjects at high risk for infection.⁴

Juan Funes, a physician from the Guatemalan Ministry of Public Health, was a visiting researcher at the

New York PHS Venereal Disease Laboratory, where Cutler worked in 1945. Cutler later credited Funes for suggesting that the PHS team conduct their experiments in Guatemala. Commercial sex work was legal in the prison in Guatemala City, and the research team believed that they could carry out controlled prophylactic experiments using subjects with "normal exposure" (i.e., through sexual intercourse).⁵ If researchers could control the sexual contacts prisoners had, they could assign them to an "active" arm that used the experimental wash or to a "control" arm that did not. A subsequent analysis would determine the efficacy of the experimental wash in preventing the transmission of disease. This research plan was recommended for federal funding by the Syphilis Study Section of the National Institutes of Health (NIH) and the National Advisory Health Council. It was also approved by the U.S. surgeon general, Thomas Parran.⁶

When Cutler arrived in Guatemala City in August 1946, he initiated a treatment program within the military hospital to "build goodwill" among Guatemalan public health leaders in order to gain their trust before starting the experiments. He had serology testing supplies (for diagnosing syphilis) sent to the Ministry of Public Health so that public health officials could test Guatemalan citizens for syphilis more effectively. PHS researchers also trained Guatemalan laboratory personnel to use the new tests accurately and built a laboratory with U.S. funding. Cooperation from Guatemalan health leaders was critical for the first two types of research PHS investigators were about to begin.⁷

Serology experiments: 1946-53. Cutler's team began serology experiments in November 1946. Their initial goal was to determine the most accurate and reliable way to diagnose syphilis. If the researchers could not diagnose syphilis, they would not be able to tell whether their new intervention was effective. The researchers conducted these serology experiments on Guatemalan prisoners, children, psychiatric patients, and leprosy patients. They also included U.S. Air Force servicemen based in Guatemala as a control group. None of the records indicate that the researchers requested consent from the adult subjects or assent from the children to participate in these experiments; the directors and leaders of the Guatemalan institutions granted access to these vulnerable populations. Addi-

tionally, there was no scientific or epidemiologic basis for focusing on these specific groups.⁸

The researchers began by testing over 800 prisoners in the Guatemala City Penitentiary, where they had documented a high prevalence of syphilis. However, instead of asking whether the extremely high rates might indicate that their diagnostic tests were, in fact, unreliable, Cutler attributed the high rates to "factors . . . operative in the population different from those experienced in the United States or in Northern Europe."9 This conjecture reflected a common belief among U.S. researchers that syphilis affected different races differently. In the United States, virulent racism was often directed at African Americans, viewed by some as "a notoriously syphilis-soaked race," who were assumed to be immoral and thus more vulnerable to STDs.¹⁰ The Guatemalan prisoners also did not want to cooperate with the repeated blood draws, a position that Cutler attributed to their lack of education and to superstition—as opposed to reasonable suspicion or a rational aversion to invasive testing.11

PHS researchers also conducted serology studies with over 1,000 Guatemalan children from the National Orphanage, schoolchildren in the Port of San José, and children from indigenous communities in the highlands. The serology experiments with children were ostensibly to distinguish congenital syphilis from syphilis that had been acquired sexually. The children were subjected to physical examinations, venipuncture, and even lower back punctures. However, there is no record indicating that the children were involved in the later experiments that intentionally exposed subjects to STDs. ¹²

Researchers also conducted serological experiments with Guatemalan leprosy patients¹³ and were then invited by Dr. Carlos Salvado, the director of the Asilo de Alienados (Psychiatric Hospital) of Guatemala City, to begin a serological screening program there. Over 500 psychiatric patients endured blood draws, lumbar punctures, and cerebrospinal fluid sampling from the neck as part of these experiments.¹⁴

Intentional exposure experiments: 1947-48. Six months after arrival, the PHS researchers began their principal research on the prevention of STDs. Instead of conducting a long-term randomized clinical trial—which would have required more participants, time, and funding—the researchers intentionally exposed

over 1,300 sex workers, soldiers, prisoners, and psychiatric patients to STDs to test the effectiveness of their prophylactic intervention. After exposure to STDs, only about half of the subjects received any form of treatment for infection. There are no records indicating that consent was obtained from the participants, and there is evidence that some were, in fact, deceived. 15 In addition, 83 subjects died during the experiments, although the connection between the deaths and involvement in the experiments is unclear. 16

Cutler also began gonorrhea experiments in the Guatemalan military in February 1947 and, over a year and a half, exposed almost 600 soldiers to disease. Methods of deliberate exposure included having the soldiers have intercourse with infected sex workers and using a needle to insert gonorrheal pus taken from one man into the penis of another.¹⁷ Cutler also conducted spontaneous, unplanned chancroid experiments on 80 soldiers. Guatemalan physicians actively assisted with chancroid transmission, scratching soldiers' arms and rubbing infection into their wounds.¹⁸

Sex workers in Guatemala were required by law to report twice a week to a governmental venereal disease control clinic for STD testing. But-for purposes of the PHS experiments—if a sex worker tested positive, the head of the Guatemalan Ministry of Public Health would send her to Cutler. Cutler also directly infected the women by swabbing their cervixes with gonorrheal pus taken from infected men or injecting bacteria from laboratory rabbits into their cervixes, to be certain they would transmit STDs. 19

Prisoners in the Guatemala City penitentiary were also involved in the syphilis experiments. For over a year and a half, over 200 prisoners had intercourse with infected sex workers or were infected via "artificial exposure," which involved scraping the genitals of prisoners and rubbing infectious fluid into their wounds or injecting it directly into their forearms.²⁰ The PHS researchers also conducted gonorrhea, syphilis, and/ or chancroid experiments with almost 500 psychiatric patients. Dr. Carlos Salvado, the director of the Asilo de Alienados, and his staff collaborated with the PHS researchers. Cutler exposed 50 psychiatric patients to gonorrhea via pus applied to their genitals, rectum, urethra, and/or eyes.²¹ Almost 500 patients were also exposed to syphilis via placement of cotton dipped in syphilitic emulsion on the penis, by abrading their skin and having infected fluid rubbed into the wound, or via oral ingestion. Cutler also injected syphilitic emulsion hundreds of times into patients at the base of their neck in an attempt to cause neurosyphilis—a form of tertiary syphilis that takes years to progress naturally.²² Almost 50 psychiatric patients were also exposed to chancroid via abrasion of their skin.²³

Biospecimen experiments. After completing the intentional exposure experiments, Cutler and his team also conducted secondary research using biospecimens-blood, spinal fluid, and tissue-that were collected from Guatemalan participants. PHS serologist Genevieve Stout and several Guatemalan researchers continued collection from psychiatric patients via the

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Guatemala City laboratory after Cutler left in 1948. The biospecimens enabled ongoing research into effective diagnostic tests for the U.S. market, and researchers worked with these biospecimens well into the 1950s.²⁴

HISTORICAL CONTEXT: INFORMED CONSENT IN THE 1940s

While it is clear that the Guatemala STD studies would be prohibited by current regulatory and ethical schemes, there are justifiable criticisms of judging actions in the past by current standards, something called "retrospective moral judgement." 25 However, many of the contemporaneous letters between the researchers indicate that they were well aware that the experiments were below standards of ethics at the

time. For example, one PHS colleague wrote to Cutler in 1947 to tell him,

I saw [surgeon general] Doctor Parran . . . and he wanted to know if I had had a chance to visit your project. Since the answer was yes, he asked me to tell him about it and I did so to the best of my ability. He was familiar with all the arrangements and wanted to be brought up to date on what progress had been made. As you well know, he is very much interested in the project and a merry twinkle came into his eye when he said, "You know, we couldn't do such an experiment in this country." ²⁶

Additionally, many of the same PHS researchers in Guatemala had been involved in a previous related experiment in the federal prison system in Terre Haute, Indiana, where they intentionally exposed prisoners to STDs. But in Terre Haute, the informed consent process was debated extensively, and the research risks were clearly presented to participants.²⁷ Despite this experience, researchers justified the lack of consent in the Guatemala experiments by arguing that the subjects would only be "confused by explanations and knowing what is happening."²⁸

Dr. John Mahoney, Cutler's supervisor at the PHS, cautioned Cutler to use "volunteer groups" instead of the vulnerable populations he was targeting.²⁹ But Cutler ignored this advice. Dr. R. C. Arnold, who also supervised Cutler, warned that he was "a bit, in fact more than a bit, leary of the experiment with the insane people" as they "cannot give consent" and "do not know what is going on." But Cutler was allowed to continue, with the recommendation that he carefully cover up the nature of his work. ³¹

RESPONSE TO THE REVELATION OF THE GUATEMALA STD EXPERIMENTS

Because researchers knew that many in the United States would consider the intentional exposure experiments in Guatemala to be unethical, they were purposefully hidden from all but Cutler's public health colleagues and never published. Decades later, after a second career as a faculty member at the University of Pittsburgh School of Public Health, Cutler donated the records of the Guatemala studies to the school. The papers included research notes, laboratory and medical records of the Guatemalan subjects, photographs, and correspondence between the investigators.³²

In 2003, Wellesley College historian Susan Reverby discovered the Cutler documents. She presented her findings about the Guatemala experiments at an academic conference in 2010³³ and subsequently alerted the Centers for Disease Control and Prevention (CDC).³⁴ President Barack Obama apologized to President Álvaro Colom and to the people of Guatemala within several months of the U.S. government's being alerted to the experiments.³⁵ He also directed the U.S. Presidential Commission for the Study of Bioethical Issues (PCSBI) to conduct a "thorough fact-finding investigation" into what happened to the subjects of the Guatemala experiments.³⁶ The PCSBI published its report, "Ethically Impossible": STD Research in Guatemala from 1946 to 1948, in 2011.³⁷

Several professional organizations and institutions responded directly to the PCSBI's findings. The University of Pittsburgh had already canceled the "John C. Cutler Memorial Lecture in Global Health" in 2008 in response to his role in another unethical PHS study, the Tuskegee Syphilis Experiments.³⁸ In 2013, the American Sexually Transmitted Disease Association renamed their annual lifetime achievement, which had been called the "Thomas Parran Award," after the surgeon general who authorized the Guatemala STD experiments.³⁹ After the PCSBI report and sustained public controversy, the University of Pittsburgh also stripped Parran's name from the School of Public Health building.⁴⁰

In the first Guatemala-related lawsuit against the U.S. government, *Garcia vs. Sebelius*, a U.S. District Court acknowledged that the Guatemala STD experiments were a "deeply troubling chapter in our Nation's history" but ultimately concluded that the court was "powerless to provide any redress . . ." It left the responsibility for a response to the political branches, and the Department of Justice assured the Court that the United States was "committed to taking appropriate steps to address" the "terrible wrong[s]" that had occurred. ⁴¹

The day after the Department of Justice moved for the suit's dismissal, the U.S. Department of Health and Human Services (HSS) pledged to invest \$1.8 million to "improve the treatment and prevention of HIV and other sexually transmitted diseases . . . in Guatemala and to further strengthen ethical training on human research protections." About \$800,000 of that funding

was committed to the CDC to support the Guatemalan Ministry of Health and Social Assistance's surveillance and control of STDs in Guatemala, and the other \$1 million to the NIH to support research "to evaluate the impact" of the revised human subjects research regulations (the Common Rule) when they became effective. 43 These regulations just became effective in January 2019.

A second lawsuit was filed against several entities, including Johns Hopkins University (where several members of the NIH study section that reviewed and recommended the Guatemala grant for funding were faculty members), the Rockefeller Foundation (which employed several of the researchers associated with the experiments), and Bristol-Myers Squibb (which manufactured the penicillin that was used in the experiments).44 This lawsuit is ongoing.

As of February 2019—despite repeated calls for compensation—no governmental, organizational, or institutional responses have focused on identifying or making reparations to still-living subjects of the Guatemala experiments or their relatives. 45 The only direct advocacy on behalf of the subjects came from the private lawsuits that, nine years after public revelation and sixty years after the studies occurred, have yet to provide a remedy to the subjects or their families.

The PHS's STD experiments in Guatemala are an important case study in historical transgressions against research subjects and provide an opportunity to critically appraise government and professional responses when serious lapses in research ethics are revealed. While major regulatory systems were already in place by the time the experiments became publicly known, this case study demonstrates how far we still have to go to ensure that research subjects are protected throughout the lifecycle of research and in its aftermath.

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