

Guatemala study researchers tried to keep information secret, new report shows

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The US Presidential Commission for the Study of Bioethical Issues has released its report on the study of the effectiveness of antibiotics in Guatemala in the 1940s and 1950s in which about 1300 people were deliberately infected with sexually transmitted diseases.

President Barack Obama, the secretary of health and human services, Kathleen Sebelius, and the secretary of state, Hillary Clinton, apologised to the president of Guatemala after the experiments were discovered last year by Susan Reverby, an historian at Wellesley College, Massachusetts (*BMJ* 2010;341:c5494, doi:10.1136/bmj.c5494).

The Guatemala study's protocol was approved by the US attorney general, the US surgeon general, military medical officials, and an array of high ranking doctors and medical school experts. However, the investigators marked many of their reports "confidential" or "keep confidential."

The commission's report, released on 13 September, suggests that the study was conducted in Guatemala so that people in the United States would not be aware of it.

Amy Gutmann, president of the University of Pennsylvania and head of the commission, said that it was important to shine light on "this dark chapter" and to honour the victims and also to "learn essential practical as well as ethical lessons . . . so that nothing like this happens again." Previous commission meetings heard recommendations for better ethical standards and procedures for obtaining consent (*BMJ* 2011;342:d3232, doi:10.1136/bmj.d3232; 2011;343:d5577, doi:10.1136/bmj.d5577).

The commission's report describes experiments conducted by the US Public Health Service and Guatemalan health authorities to investigate the effectiveness of the new drug penicillin in protecting against gonorrhoea, syphilis, and chancroid. Sexually transmitted diseases were a major problem for the US military during the second world war, making many military personnel unavailable for duty.

As many as 5500 Guatemalan prison inmates, psychiatric patients, soldiers, commercial sex workers, orphans, schoolchildren, and leprosy patients were included in the study. Many people underwent invasive procedures such as phlebotomy, lumbar puncture, cisternal puncture to inject syphilis organisms, and inoculation of gonorrhoeal pus into the

male urethra in which it was "carefully rubbed over the mucous membrane, so much so as to cause pain."

About 1300 people adults were deliberately infected with sexually transmitted organisms.

The commission's report says that:

- No people involved in the study gave informed consent
- Invasive procedures were performed on adults and children
- Not all patients were treated
- 83 patients died, although it is unclear whether deaths were a result of the study
- Record keeping was abysmal, and
- The results were kept confidential and never published.

The title of the commission's report, *Ethically Impossible*, comes from a brief item in the *New York Times* in 1947 that described exposing rabbits to syphilis and then injecting them with penicillin, a procedure that was "ethically impossible" in humans.

The report describes ethical and racial bias in the Guatemala study. A similar study had been conducted among US prisoners in Terre Haute, Indiana, but the US prisoners were fully informed about the study and gave written informed consent. However, this study was unsuccessful, and researchers turned to Guatemala, where they had links to public health and military health officials.

When the Guatemala study ended, its principal investigator, John Cutler, became a lead researcher in the Tuskegee study in Alabama in which poor black men with syphilis went untreated even when penicillin became available. Dr Cutler retired from the Public Health Service and ended his career as acting dean of the Graduate School of Public Health at the University of Pittsburgh. He died in 2003.

Ethically Impossible: STD Research in Guatemala from 1946-1953 is available at www.bioethics.gov.

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