

President's commission considers how to protect human rights after Guatemala experiment

Janice Hopkins Tanne

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A special commission set up by President Barack Obama is considering how best to protect the human rights of people who take part in clinical trials in the wake of the discovery last year that a US agency had conducted unethical research in Guatemala in the 1940s.

The US Presidential Commission for the Study of Bioethical Issues was established in 2009. Since Susan Reverby, a historian from Wellesley College, near Boston, discovered last year that the US Public Health Service had conducted unethical research in Guatemala from 1946 to 1948, the commission has concentrated on protecting the human rights of people in such studies. The commission held its fifth public session in New York on 18 and 19 May and plans to present its report this summer.

The commission's chairwoman, Amy Gutmann, president of the University of Pennsylvania, said that the treatment of vulnerable people in Guatemala was "both stunning and sobering."

Professor Reverby said she hoped that the investigation would not make people afraid to participate in clinical trials. She told the *BMJ* that she "could not have imagined in a million years" that the scientific community would take her discovery so seriously.

In the Guatemala studies nearly 700 people were deliberately infected with syphilis and other sexually transmitted diseases in hopes of showing that the new drug penicillin could be used immediately after sex to prevent infection. Among those included in the studies were female sex workers, soldiers, prison inmates, and mental hospital patients. They were not told the study's purpose and did not give informed consent. The studies were never published. Guatemalan authorities are also conducting their own investigation into what happened.

Last year President Obama, the US secretary of state, Hillary Clinton, and the secretary of health and human services, Kathleen Sebelius, apologised to the president of Guatemala and to people involved in the study (*BMJ* 2010;341:c5494, doi:10.1136/bmj.c5494).

At the session in New York Valerie Bonham, the commission's executive director, reported that her team had visited Guatemala, met Guatemalan investigators, and visited one site still standing.

She said that they had reviewed 125 000 records and collected 14 000 records from 13 separate archives.

Christine Grady, a bioethicist at the National Institutes of Health Clinical Center, told the meeting that there was a proliferation of rules regarding protection of the rights of people in clinical trials, among them the Declaration of Helsinki and the "Common Rule" governing 17 US agencies for the protection of human subjects. She emphasised that rules alone cannot protect human trial participants.

But other speakers said that the paperwork involved in getting studies approved by institutional review boards or ethics committees could deter research. Consent forms were long and difficult to present to participants in international trials, and ever more clinical trials were taking place internationally.

Several speakers said that researchers sometimes focused on compliance with rules—"what must be done"—rather than on ethics—"what should be done."

Most speakers agreed that it was futile to try to find one perfect set of guidelines.

Professor Gutmann asked whether an experiment like that in Guatemala could happen again. It was less likely now, said Dafna Feinholz, a bioethicist at Unesco, because of better informed consent procedures and forms. And Francis Crowley, executive director of the European Good Clinical Practice Alliance, added that greater transparency also helped.

But transparency is not enough, cautioned a commission member, Anita Allen, a law professor at the University of Pennsylvania: "Both slavery and the Holocaust happened in broad daylight," she said.

James Wagner, vice chairman of the commission and president of Emory University, Atlanta, likened the situation to anaesthesia: enough was needed to protect the patient but too much would kill the patient. "It is valuable to have space to exercise judgment," he said.

The presidential commission's website is www.bioethics.gov. US government documents relating to the Guatemala study are at www.hhs.gov/1946inoculationstudy/.

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