

Ethics of Human Experimentation

Case Study: the Tuskegee Syphilis Study

- *Background: 1930s Depression era*
 - *Loss of funding for large controlled studies of syphilis*
 - *Macon County chosen*
- *Health Service's Taliford Clark:*
 - *“A natural laboratory”*
 - *“Rather low intelligence of the Negro population”*
 - *“Common promiscuous sex relations”*
 - *These conditions would lead to high rate of spread of syphilis*

Tuskegee Syphilis Study: Details

■ *Facilities:*

- *Tuskegee Institute*
- *founded by Booker T. Washington to educate slaves*

■ *Study Design*

- *1932: Handbills offering “free blood tests” and “free treatment” to “colored people with bad blood”*
- *Blood tests performed:*
 - *399 men with syphilis*
 - *201 men without syphilis*
- *“Treatment” Offered*
 - *The first group never told they had syphilis*
 - *Both groups given medicine for colds*
 - *World War II: men kept out of draft, so that they would not be tested and treated*
- *1947: penicillin discovered, and found effective against syphilis, but withheld from the men in study*

Results of Study

- *Lasted 40 years, led to 13 scholarly articles in medical journals*
- *End of the line*
 - *1972: former Health Service employee leaked story to the AP*
 - *AP publicity brought the case to public light*
 - *1972: legal representation*
 - *1974: \$10 million settlement*
 - *May 16, 1997: apology from President Bill Clinton*



Case Study: The Willowbrook Hepatitis Experiments

- *Background*

- *Willowbrook State School in Staten Island, New York*
- *Cares for mentally retarded children*
- *Up to 5000 children by 1960*

- *Hepatitis Study – 1956 (14 year period)*

- *Goals:*

- *Study natural history of hepatitis A*
- *Study effectiveness of gamma globulin as preventative*

Details and Justification:

- *Hepatitis endemic at Willowbrook*
- *Disease course is usually mild*
 - *Most children became infected within 6-12 months of admission anyway*
 - *So the researchers deliberately injected incoming children with the virus*
- *Subjects isolated in special unit to prevent other complicating diseases*
- *Therapeutic effect: confers lifetime immunity*

Consent

- *Parental consent obtained by a group method*
- *Study approved by various official agencies*

Ethical concerns

- *Using retarded children as experimental subjects*
- *Study not directly therapeutic in any way*
- *Parents “implicitly blackmailed” into consent by group method*
- *Value of research for understanding hepatitis tainted by ethical issues*

Case Study: Regimen 076

- *Background*

- *Vertical transmission of AIDS*
- *Reduced in HIV positive women who take ZDV (zidovudine)*
- *formerly called AZT – azothiaprine*

Efficacy

- *VT reduced by 2/3: 25% → 8%*
 - *Involves 12 weeks of oral ZDV, IV dose during delivery, then 6 months oral dose in newborns*
 - *Not possible in third-world countries*
 - *Costs \$1000.00*
 - *Facilities not sophisticated enough*
 - *Alternative?*

Study details

- *NIH and CDC*
- *Short-term regimen with oral ZDV tested*
 - *But couldn't compare with 076*
 - *Therefore, compared with “standard of care” in each country (no treatment)*
- *Placebo group used against experimental group*

Informed consent obtained

- *Mothers told they had AIDS*
- *Mothers told they might receive a placebo*
- *Study stopped when early data showed that \$80 regimen of ZDV reduced vertical transmission 50%*

Ethical Concerns:

- *Use of placebos (i.e., just accept the standard of care as is)*
- *No real grasp of details by participants (no truly informed consent)*

Informed Consent and Research Studies

- *The “Informed” Part*
 - *Autonomy is underlying principle*
 - *But this requires both information and understanding*
 - *Paternalism*
 - *Some: IC is “at worst a pointless charade, at best a polite fiction”*
 - *Therefore (on this view) paternalism should prevail*

Alternative to “Informed”

- *Give patients information in a form they can use*
- *Determining adequacy of understanding is difficult*

The “Consent” Part

- *Consent must be voluntary*
 - *But patients are a vulnerable population*
 - *Children, nursing homes, prisons, mental hospitals*
 - *True informed consent difficult*
 - *Therefore, never do research studies in these groups?*

Other Questions

- *Physician as figure of authority*
- *Desire of patients to please the doctor*
- *Problematic nature of placebos*