The Tuskegee Syphilis Study
(1932-1972)

African Americans Distrust of Medical Institutions

The Tuskegee Syphilis Study continues to cast its long shadow on the contemporary relationship between African Americans and the biomedical community. Numerous reports have argued that the Tuskegee Syphilis Study is the most important reason why many African Americans distrust the institutions of medicine and public health.
Contents

• Background information
• Chronogy of the study
• Ethical shortcomings
• John Charles Cutler
• Consequences
• Impact on daily life
Syphilis

- Treponema pallidum
- Transmission: sexual activity, congenital (pregnancy, birth)
- 4 stages of symptoms:
  1) Primary: painless, non-itchy skin ulceration
  2) Secondary: diffuse skin rash on palms of hands and soles
  3) Latent: little or no symptoms (lasts for years)
  4) Tertiary: “gummas” (granulomes), soft non-cancerous growth with neurological and heart diseases

Syphilis cerebrospinalis
Syphilis

- Diagnosis: dark field microscopy, immunofluorescence, PCR (direct)
- Screening: TPHA (4-6 weeks post infection) → FTA-Abs-Test (no false-positive results)
- Development: CMT (nonspecific)

- Prevalence (2013): 315,000 infected people worldwide (prostitutes, more men than women)
  - Hygienic measures
  - Use of latex condoms
  - decreased dramatically after availability of penicillin during 1940s
- Therapy: penicillin G (doxycycline)
Syphilis in Germany (2014)

Increase since 1990s

Incidence (2013): 5,017
Historical Context

• era of unprecedented und especially unprecedentedly lopsided prosperity
  • Extremely uneven distribution of wealth since early 1920s
  • International instability since World War I.

• → Great Depression: stock market crash on Oct 29, 1929

• “hear nothing, see nothing, do nothing policy“ under president Hoover

• 1932: Election of Franklin Roosevelt as new president (regulated state interference in the market, social insurance, wage floor)

• Start of the Tuskegee Syphilis Study
Beginning

• Usual therapy: arsephenamine, mercurial ointments and bismuth (highly toxic)
• 1931: United Public Health Service approached the Tuskegee Institute (located in Macon County) about forming a research group
• 1932: Start of the study in Tuskegee/Macon County, Alabama
• Under direction of John Charles Cutler
• Aim: “healing of syphilis disease” ↔ “study effects of untreated syphilis disease”
• Study collective: 399 infected and 201 non-infected
• Only infected participants suffering from latent form
• Only male black americans (25-60y), mostly sharecroppers
### Classification of Cases in Tuskegee Study

<table>
<thead>
<tr>
<th>Classification at initial examination</th>
<th>Controls</th>
<th>Syphilitic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases added in 1938-1939</td>
<td>0</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Total - Original classification</td>
<td>200</td>
<td>425</td>
<td>625</td>
</tr>
<tr>
<td>Controls infected during observation</td>
<td>-9</td>
<td>+9</td>
<td>-</td>
</tr>
<tr>
<td>Controls reclassified as syphilitic</td>
<td>-1</td>
<td>+1</td>
<td>-</td>
</tr>
<tr>
<td>on basis of additional history</td>
<td>-8</td>
<td>+8</td>
<td>-</td>
</tr>
<tr>
<td>on basis of treponemal tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total - Final classification</td>
<td>102</td>
<td>443</td>
<td>545</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Known dead - Number</th>
<th>97</th>
<th>276</th>
<th>373</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent</td>
<td>53.3</td>
<td>62.3</td>
<td>59.7</td>
</tr>
</tbody>
</table>

Remainder - Examined in 1968

<table>
<thead>
<tr>
<th>Number</th>
<th>36</th>
<th>53</th>
<th>89</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent</td>
<td>42.4</td>
<td>53.1</td>
<td>53.3</td>
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Benefits for participants

• Free treatment
• Free treatment of minor ailments
• Free rides to and from the clinic
• Free warm meal on examination days
• 50 $ burial insurance
Procedure

• Participants were told to be treated because they have “bad blood”

• Methods: Physical examination, blood test, x-rays, lumbar puncture (incident of neuro-syphilis), every in a 6-months rhythm (epidemiological study)

• Medical examinations only at Tuskegee University Hospital
  • Other doctors were not allowed to examine study participants (participants’ lists)

• 1936: first major report: no significant results → also examinations at special local doctors

• By 1947: penicillin became standard treatment for penicillin
  → But treatment was denied
Procedure

• Doctors who treated patients were punished (payment, revoke of medical license)

• Results: no difference in both the nature and extent of the disease among white and african americans
  → not significance or hint for difference
  → assumption regarding biological differences influenced investigators view

(between: claim that blacks suffer more frequently from cardio-vascular complications while whitse from neurological problems)
Certificate for Participants in the Syphilis Study

In 1958 this certificate was provided to participants in the Tuskegee Syphilis Study after 25 years.

The PHS leaders employed many strategies to keep the subjects happy with their involvement in the study so that as many as possible could be "brought to autopsy." This special certificate was distributed to all surviving participants in 1958, and praises them for their involvement in the "Tuskegee medical research study." Even at this late date the men did not know that the disease for which they were being observed, and not adequately treated, was syphilis.
• 1965: Irwin Schatz (young doctor from Chicago)
• Oct 1966: Peter Buxtun (Epidemiologist from PHS) found out about the study
  • not possible to stop it
  • informed Center of Disease Control in 1966
• Everybody assured him that the study had to be kept going until the death of the last patient
• 1972: shared his knowledge with journalist Jean Heller
  • article in “Washington Evening Star“ from July 25, 1972
  • 74 people of the study cohort were still alive
Ending

• Under public pressure: Conference of the PHS whether study should be stopped
  • → after 3 months: ending was confirmed

• lawyer Fred Gray sucessfully fought for the remaining participants in court → 9 million $ settlement for medical treatment
  • Wifes, widdows and offspring were added
Ethical shortcomings

• Aim of study
• Diagnosis → only „bad blood“
• No Informed consent
  • No communication possible (other subjective-symptoms?)
• Ambiguity concerning number of participants
• Racially motivated, discrimination of blacks
• No defined inclusion and exclusion criteria
• No consistent record of results (published)
• Inaccurate measures of follow-up

• Effective treatment was denied to participants (since 1947)
  → Government violated the constitutional rights of the participants
Isolated incident?

- Guatemala experiments from 1946-1948
- Initiated by PHS, direction: *John Charles Cutler*
- *Intentionally exposed* to sexually transmitted diseases (STDs) to investigate the impact of penicillin-therapy
- 1308 infected participants (prisoners, soldiers, psychiatric patients)
  - Transmission through commercial sex workers (for 25 $ payment)
  - By researchers: toothpick covered with gonorrheal pus directly in urethra
    - only about 50% were treated with penicillin
- 5128 participants (whole group) underwent diagnostic testing (blood sample, lumbar or cisternal puncture)
- 2010: first public apology by president Obama
John Charles Cutler (1915-2003)

• 1941: Medical Degree at Western Reserve University Medical School
• 1942: U.S. Public Health Venereal Disease Research
• Tuskegee Syphilis Study
• 1946-48: Guatemala Expiriments
• 1954: Experiments on Prisoners at Sing Sing (Effect of Penicillin on syphilis infection)
• 1958: Assistant Surgeon General of the United states
• 1967: Professor for “International Health“ at the University of Pittsburgh
• 1968-1969: Dean of the Graduate School of Public Health
John Charles Cutler

• “Unless the law winks occasionally, you have no progress in medicine“ - 1970

• “It was important that they were supposedly untreated, and it would be undesirable to go ahead and use large amounts of penicillin to treat the disease, because you’d interfere with the study“

  1993 in TV-documentary called “The Deadly Deception”
John Charles Cutler

- 1967: Professor for “International Health” at the University of Pittsburgh
- 1968-1969: Dean of the Graduate School of Public Health
- 2003: Death
  - not at least one of his obituaries mentioned Tuskegee or Guatemala
  - “…led the way in trying to prevent and control sexually transmitted disease throughout the world.”
  - Prof. Sharma (University of Pittsburgh): “…his appreciation of the freedom of people across the world, as well as his efforts to ensure access to reproductive healthcare services for women not only in the US, but also in the developing world.”

→ in honor: Lecture series which was called after him
John Charles Cutler

Obituary: John Charles Cutler / Pioneer in preventing sexual diseases

Wednesday, February 12, 2003

By Jan Ackerman, Post-Gazette Staff Writer

Long before AIDS became an international health problem, Dr. John Charles Cutler led the way in trying to prevent and control sexually transmitted diseases around the world.

Dr. Cutler, a former assistant surgeon general of the U.S. Public Health Service, was part of a group that in 1944 worked out the ways penicillin could be used to treat syphilis.

As one of the founders of the Family Health Council of Western Pennsylvania in 1971, he worked tirelessly to find better ways to provide affordable...
John Charles Cutler

- 2008: Lectures were stopped because his inhuman conduct in Guatemala was detected → no impact on his reputation
- Never called to account (“in his capacity as an official of the US Public Health Service“)
- Did never apologize
Consequences

• Investigators ↔ Directors (Dr. Cutler) ↔ PHS ↔ Government
• No criminal misconduct
• Cutler involvement was in his “capacity as an official of the US Public Health Service“
• Heavily involved: Johns Hopkins Institute, Rockefeller foundation
• 1974: lawyer Fred Gray sucessfully fought for the remaining participants in court → 9 million $ settlement for medical treatment
  • Wifes, widdows and offspring were added
• 2012 (Guatemala), 774 plaintiffs: „U.S. District Court of Columbia finding that the goverment has immunity from liability for harm suffered outside the U.S.”
• No cases in which anybody was called to amount or made responsible in any way

• May 16, 1997: public apology of President Bill Clinton
Consequences

• Office for Human Research Protections (OHRP)
  → C.F.R. 45: Institutional Review Board that mirrors FDA-regulations (guidance on research ethics, advises on issues of medical ethics)

• Belmond Report (1979) in Elkridge, Maryland
  → summarized ethical principles and guidelines for research involving human subjects (reference of Institutional Review Board)
    • 3 core principles: respect (protecting autonomy of all persons), beneficence (“do not harm”), justice (reasonable, well-considered procedures)
    • 3 primary areas of application: informed consent, assessment of risks and benefits, selection of subjects
  → allows for a solution to future subjects who are not capable to make independent decisions
Impact on Daily Life

• Impact on contemporary relationship between african Americans and the biomedical community

• Numerous reports and studies argued that the Tuskegee Syphilis Study is most important reason why african Americans distrust the institutions of medicine and public health

• Critics: already deep-rooted in the institution of slavery
Thank you for your attention!

Any questions?
List of References

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