Ethics and research involving humans

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Content

- Background to research ethics
- Who are your participants?
- Main concerns in ethics applications

Why do we worry about research ethics?

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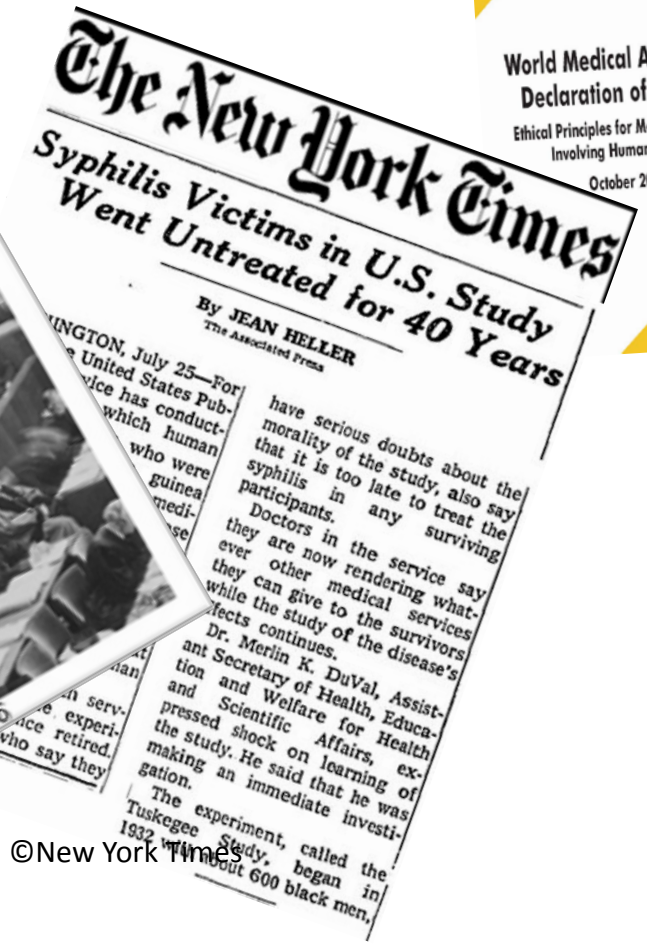
The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

©New York Times

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

October 2008

An example

- Handouts on Willowbrook experiments
- Work in pairs – one person to explore ethical concerns with the study, the other reasons to justify the study.
- List four of each

Participants vs. subjects

- Humans are participants
  - Even if single/few participants (e.g. client, colleagues)
  - Need to give consent for involvement
  - Some consider researcher a participant too?
- Formerly called subjects *(doesn't imply voluntariness)*

Considerations

- Participants – potential for harm or distress (risk assessment) – *include researcher(s)*
- Consent (incl. right to withdraw) *
- Confidentiality *
- Ownership of data *
- Design *
- Integrity *

Consent

- Voluntary informed consent considered the norm
- Dual roles e.g., clinician/lecturer and researcher *(conflict of interests?)*
- Consent for research has higher threshold of information required than consent for clinical procedures
- Opt-in vs. opt-out?
- Requirement for documented consent

Coercion

- Undue influence
- Payment?
- Extra learning opportunity?
- Deception?

Confidentiality

- Confidential and anonymised data considered the norm
- Difference between anonymity and confidentiality?
- Data Protection Acts govern storage and use of data (*storage* esp. important)
- Protocol for disclosure (e.g. illegality? welfare concerns?)
- Debriefing procedure

Right to withdraw

- At any time, for any or no reason
- Care if guaranteed anonymity
  - How can data be removed?
- (Perceived) effect on clinical service provision or progress on course?

Protection of data

- Who owns data on students?
- What are the limits of use?
- Where will data be stored?
- Who will have access?

Design

- *Unethical* to carry out poorly designed studies?
- Peer review BEFORE seeking ethics approval

Integrity

- Misconduct, e.g. falsification of data
- Authorship

Return to Willowbrook

- Any new thoughts on this research?

Study One

- A lecturer wants to see if students from “access to science” courses perform as well as students from traditional A level or Adv Higher background.
- There are 20 students from an access background and 60 from “traditional” backgrounds.
- Use of entry qualifications, performance in exams, tutorial records
- Use of comparative statistical tests

Study Two

- A tutor wants to evaluate moral distress in students
- Plans to carry out 20 face-to-face interviews about experiences when on EMS
- Thematic analysis of transcribed interviews

Study Three

- The University wants to see whether students from a particular continent do as well as those from other continents on an e-learning course (mixed methods approach)
- There are seven students on the programme from this particular continent (500 from the rest of the world)
- Use of discussion posts, test results, and final survey responses.

Study Four

- A recently completed clinical skills laboratory is not yet available to students.
- The director wants to see if students given access to the lab perform better in OSCEs than those without access.
- Half the current 4th year students will be given access (random selection) and half will not be given access.
- OSCE exam scores will be compared.

In summary

- Empathy with participants
- Consent consent consent
- Good research → good outcomes

Thank you, and happy ethical applications