

American Medical and Research Ethics through World War II

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Revolt Against the AMA Code

- As we discussed last week, the first generation of laboratory-science educated doctors rebelled against the AMA's 1847 Code of Ethics. The reasons for this were three-fold:
 - 1) "Sanitarianism" and confidentiality;
 - 2) The "consultation clause"; and
 - 3) Unwillingness to submit to the constraints of the organization.
- In light of the background provided by Warner in his article, do you support the position of the "Old Coders" or the "New/No Coders"?

Revolt Against the AMA Code (2)

- “New/No Code” organizations like the Association of American Physicians (AAP) seized control of the AMA in 1903, replacing its mandatory Code of ethics with a purely advisory statement.
- As a result:
 - 1) The Principles of Medical Ethics, as they became to be called, became unenforceable; and
 - 2) The social contract conception of medical ethics inherited from Percival was thus replaced with ideals practitioners chose impose upon themselves.

The Nazi Doctors Trial

- The 1946-1947 Nuremberg War Crime Trial was actually the second tribunal. The first trials were originally designed to indict leading Nazis like Hermann Göring.
- 23 defendants were tried, including eminent professors of medicine and high ranking public servants.
- 1,750 victims were identified in the indictment, although this only represented a small proportion those who were killed or injured as a result of medical experimentation in the concentration camps.



1931 German Research Regulations

Medical science, if it is not to come to a standstill, cannot refrain from introducing in suitable cases New Therapy using as yet insufficiently tested agents and methods. Also, medical science cannot dispense completely with Human Experimentation.

Medical ethics rejects any exploitation of social or economic need in conducting New Therapy.

- (a) **Without consent, non-therapeutic research is under no circumstances permissible.**
- (b) Any human experimentation which could as well -be carried out in animal experimentation is not permissible. Only after all basic information has been obtained should Human Experimentation begin. This information should first be obtained by means of scientific biological or laboratory research and animal experimentation for reasons of clarification and safety. Given these presuppositions, unfounded or random Human Experimentation is impermissible.

Translation: Hans Martin Sass

1933 Animal Research Regulations

National Socialist German Workers' Party [NSDAP/Nazi Party] press release:

The Prussian minister-president Goering has... stated that starting 16 August 1933 vivisection of animals... is forbidden ...**persons who... participate or perform vivisections on animals...will be deported to concentration camps.**

Among all civilized nations, Germany is thus the first to put an end to the cultural shame of vivisection! The New Germany not only frees man from the curse of materialism, sadism, and cultural Bolshevism, but gives the cruelly persecuted, tortured, and until now, wholly defenseless animals their rights [Recht].

What Reichschancellor Adolph Hitler and Minister-president Goering have done and will do for the protection of animals should set the course for the leaders of all civilized nations!

Translation: Hans Martin Sass

World War II-era Experiments



World War II-era Experiments (2)

- How did Nazi physicians and other collaborators justify these experiments?
 - 1) To support the war effort -- everybody, even the worst criminals, were expected to contribute to victory.
 - 2) Utilitarianism -- sacrifice a few to save many, as in the case of the typhus experiments.
 - 3) Racial hygiene -- to quote one Nazi doctor:
“Experiments will be conducted not on prisoners but only on Poles ... strictly speaking, Poles are not humans.”

Research Ethics and the AMA

- In 1946, the AMA's House of Delegates adopted a set of research ethics principles developed by Andrew Ivy.
- These were the first research ethics principles promulgated by any professional group, and include such notions as:
 - I. Voluntary [**but not informed**] consent;
 - II. Prior animal experimentation; and
 - III. Proper medical supervision.
- Ivy feared that the Nuremberg trials could turn into a trial of American medicine unless a more sophisticated strategy was pursued.

Myths Perpetuated by Ivy

- Researchers Routinely Obtain Informed Consent:

Experiments performed on human subjects without their consent, or by coercion, is contrary to the laws of humanity and the ethical practices of the medical profession which have been in practice for 22 centuries.

- Ivy A. (1946). Report on War Crimes.

Myths Perpetuated by Ivy (2)

- **Nazi Experiments Were Bad Science:**

The climax of this tragedy, which surpasses all of the inhumanities of man to man recorded in human history, is the fact that ... no new discoveries were made.

- Ivy A. (1946). Report on War Crimes.

Research Ethics Prior to 1946

- Prior to 1946, only two types of facilities followed the universal rules of research conduct that Ivy described:
 - US military facilities.
 - German facilities abiding by the 1931 research regulations.
- No professional society or non-military research institution anywhere—including in the US—required the informed consent of research subjects or Ivy's other universally-accepted rules.

In-Class Assignment 1

- Ivy created the myth that the Nazi experiments were bad science, a myth that persists to this day.
- In fact, researchers still debate the utility and usability of much of this data, particularly the freezing experiments.
- Consider the following question: Is it ever acceptable to use data collected unethically, particularly if those data could save a large number of lives? Why or why not?

The Nuremberg Code: Preamble

The great weight of the evidence [is that] **medical experiments on human beings [...]** conform to the ethics of the medical profession.

The proponents of the practice ... justify [it] on the basis that ... results for the good of society that are unprocurable by other methods or means of study. **All agree [on] certain basic principles** must be observed in order to satisfy moral, ethical and legal concepts.

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion ...
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

The Nuremberg Code (2)

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; *except, perhaps, in those experiments where the experimental physicians also serve as subjects.*
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

The Nuremberg Code (3)

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

The WMA and Nuremberg

- WMA report on German physician complicity in the Holocaust:

In the course of the experiments [German researchers] misused their medical knowledge and prostituted scientific research. They ignored the sanctity and importance of human life, exploiting human beings both as individuals and in mass. They betrayed the trust society had placed in them as a profession? The care of the individual patient ceased to be the doctor's primary aim and the humanitarian purpose of medical science was subordinated to the needs of war.

- World Medical Association. (1949).

American Researcher Attitudes

- Prior to 1972, the events in Nazi Germany and the resulting Nuremberg Code and Declaration of Helsinki were not considered to be directly relevant by American researchers.
- As historian David Rothman writes:

The violations had been the work of Nazis, not doctors ... not scientists. **Madness not medicine was implicated at Nuremberg.** The prevailing view was that [the defendants] were Nazis first and last; by definition. No code drawn up in response to them was relevant to the United States.

What Happened in 1972?



Tuskegee Syphilis Experiment (1932-1972)

For next week ...

- Your written assignment asks you to consider some of the challenges posed by the Nuremberg Code, as written, for the biomedical research endeavor.
- At the start of class next week, be prepared to discuss these issues.
- Pay special attention not only to the Nuremberg Code but also the WMA's Declaration of Helsinki (1964), which was drafted in part to address these problems.