Effects of the nuremberg trials on experiments and ethics

Laws of clinical trials-the Nuremberg phenomenon

Human research and war- German and the allied

German:

The Second World War (1939-45) is considered as the time when human research got a great attention along with all its flaws. The experiments conducted by the German government got all the attention, though the allied were also involved in such experiments.

The experiments that were done can be divided into three categories

1. Experiments aimed at facilitating the survival of Axis military personnel.- In Dachau, physicians from the German air force and from the German Experimental Institution for Aviation conducted high-altitude experiments, using a low-pressure chamber, to determine the maximum altitude from which crews of damaged aircraft could parachute to safety. Scientists there carried out so-called freezing experiments using prisoners to find an effective treatment for hypothermia. They also used prisoners to test various methods of making seawater potable.
2. Experimentation aimed at developing and testing pharmaceuticals and treatment methods for injuries and illnesses which German military and occupation personnel encountered in the field- At the German concentration camps of Sachsenhausen, Dachau, Natzweiler, Buchenwald, and Neuengamme, scientists tested immunization compounds and sera for the prevention and treatment of contagious diseases, including malaria, typhus, tuberculosis, typhoid fever, yellow

fever, and infectious hepatitis. The Ravensbrueck camp was the site of bone-grafting experiments and experiments to test the efficacy of newly developed sulfa (sulfanilamide) drugs. At Natzweiler and Sachsenhausen, prisoners were subjected to phosgene and mustard gas in order to test possible antidotes.

3. Experimentation sought to advance the racial and ideological tenets of the Nazi worldview- The most infamous were the experiments of Josef Mengele at Auschwitz. Mengele conducted medical experiments on twins. He also directed serological experiments on Roma (Gypsies), as did Werner Fischer at Sachsenhausen, in order to determine how different “ races” withstood various contagious diseases. The research of August Hirt at Strasbourg University also intended to establish “ Jewish racial inferiority.”
4. Others- Other gruesome experiments meant to further Nazi racial goals were a series of sterilization experiments, undertaken primarily at Auschwitz and Ravensbrueck. There, scientists tested a number of methods in their effort to develop an efficient and inexpensive procedure for the mass sterilization of Jews, Roma, and other groups Nazi leaders considered to be racially or genetically undesirable.

Apart from the German experiments the other axis nation Japan had formed the unit 731, which had supposedly carried out human experimentations including germ warfare, weapon testing and vivisection. However the Japanese work was never tested on an accredited legal trial. Hal Gold, Unit 731 Testimony, 2003, p. 109 claims that this was mainly because MacArthur secretly granted immunity to the physicians of Unit 731, including their

leader, in exchange for providing America, but not the other wartime allies, with their research on biological warfare.[1]Under leadership of Lev Smirnov, one of the top Soviet prosecutors at the Nuremberg Trials, The Japanese doctors and army commanders who had perpetrated the Unit 731 experiments received sentences from the Khabarovsk court ranging from two to 25 years in a Siberian labour camp. The Americans refused to acknowledge the trials, branding them communist propaganda.

The allied experiments[2]–

The office of scientific research and Development (OSRD) was formed in the summer of 1941, by the executive order of the president of USA, to look over two committees –one related to weapons research and other the Committee on Medical Research (CMR)—to combat the health problems that threatened the combat efficiency of American soldiers. During the years the OSRD funded 600 research proposals valued at $25 million with 135 institutes. [3]The CMR not only provided the organisational basis but also the intellectual justification of post-world war NIH (national Institute of Health, USA). The CMR's major concerns were dysentery, influenza, malaria, wounds, venereal diseases, and physical hardships (including sleep deprivation and exposure to frigid temperatures).

The dysentery trials of CMR residents of the Ohio Soldiers and Sailors Orphanage in Xenia, Ohio; the Dixon, Illinois, institution for the retarded; and the New Jersey State Colony for the Feeble- Minded. The residents were injected with experimental vaccines or potentially therapeutic agents, some of which produced a degree of protection against the bacteria but, as evidenced by fever and soreness, were too toxic for common use. In the

malaria trial researchers chose to infect residents of state mental hospitals and prisons. A sixty bed clinical unit was established at the Manteno, Illinois, State Hospital; the subjects were psychotic, backward patients who were purposefully infected with malaria through blood transfusions and then given antimalarial therapies. Similarly, residents of state facilities for the retarded (Pennhurst, Pennsylvania) and the mentally ill (Michigan's Ypsilanti State Hospital) were used for the anti- influenza trials.

Thus the wartime experiments both in the Nazi Germany and the Allied countries were promoting teleological as opposed to deontological ethics; " the greatest good for the greatest number" was the most compelling precept to justify sending some men to be killed so that others might live.

Post war changes – the Nuremberg Trial-

The epic shift in universal regulations of human experimentations as it is hailed by some came after the Second World War. The basis was the German Exploitation of the Jews in various camps and the subsequent war crimes trial that are combined to be known as Nuremberg trial. The trial comprised of one International Military Tribunal (IMT) and twelve trials of other accused war criminals before the United States Nuremberg Military Tribunals (NMT) [4].

The NMT case 1- U. S. A. vs. Karl Brandt, et al, or the doctors' trial as it is popularly known in public domain formed the basis of this regulation. Four counts of charges were brought against 23 doctors and researchers.[5]The counts included

1. common design or conspiracy

2. war crimes
3. crimes against humanity
4. Membership in a criminal organisation.

The specific crimes charged included more than twelve series of medical experiments concerning the effects of and treatments for high altitude conditions, freezing, malaria, poison gas, sulfanilamide, bone, muscle, and nerve regeneration, bone transplantation, saltwater consumption, epidemic jaundice, sterilization, typhus, poisons, and incendiary bombs. These experiments were conducted on concentration camp inmates. Other crimes involved the killing of Jews for anatomical research, the killing of tubercular Poles, and the euthanasia of sick and disabled civilians in Germany and occupied territories. The defendants were charged with ordering, supervising, or coordinating criminal activities, as well as participating in them directly.

The trial began on Dec 9, 1946 and ended on Aug 20, 1947. The trial saw 85 witnesses and 1500 documents. Out of 23 defendants, 7 were acquitted of all charges, 16 were found to be guilty and 7 of them were executed. The argument for the defendants that were placed before the tribunal were-

1. The defendants had obeyed the laws of the Nazi regime. In fact, their experiments were the result of legally valid orders given by government authorities
2. They were not guilty of any crime, and certainly not of a crime against humanity, because they were licensed physicians, engaged in

research. And the research pattrn was not different from that in other places of the world.

3. They had not violated any law or stature by which they were governed in place during the time of the crime.

The NMT was not keen on trying the 1931 German guidelines, which was actually in force at the times of committing the crime, even after representation by defendants.[6]A document was hastily put in place on the advice of medical experts Harold Sebring, Leo Alexander, and Andrew Ivy, which later became famous as Nuremberg Code. It comprised of ten sets of guidelines as follows[7]–

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; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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 knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

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.

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 probably 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 subjects.

However the Nuremberg Code was not a law into itself. It was merely a loose collection of ideas drafted hastily to provide a trial. Apart from article 4, 5, 9 & 10, the Nuremberg code literally draws from the 1931 German Directive, though there are no acknowledgements of such and thus makes itself guilty of Plagiarism.[8]While article 4 & 9 are non-controversial, the article 5 & 10 are poorly worded and actually provided loopholes by virtue of being poorly structured. Article 5 seems to suggest that studies that are endangering the life of subjects are permissible, if the investigator also is a subject. This runs against natural justice, just because the investigator is ready to risk his own life, he has no right to endanger another person’s life. By this token, a drunken pilot should be allowed to fly, since his own life is at jeopardy along with that of his passengers. Similarly in article 10, investigator is not

required to terminate the trial, but should be merely prepared to do so, if he/she thinks there is risk of death or serious injury to the subject. The difference between being required to stop and ready to stop has been lost on the authors of the document.[9]

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[1]Takashi Tsuchiya, “ The Imperial Japanese Experiments in China,” in *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2008), 35–42.

[2] *Enclyclopedia of Bioethics* .

[3]Ibid.

[4]“ Nuremberg Trials Project — Introduction,” accessed April 12, 2014, http://nuremberg. law. harvard. edu/php/docs_swi. php? DI= 1&text= overview.

[5]“ Nuremberg Trials Project — Medical Case Overview,” accessed April 12, 2014, http://nuremberg. law. harvard. edu/php/docs_swi. php? DI= 1&text= medical.

[6]Sass HM, “ Ambiguities In Judging Cruel Human Experimentation: Arbitrary American Responses to German and Japanese Experiments” 13, no. 3 (May 2003): 102–4.

[7]“ The Nuremberg Code (1947).”

[8]RavindraB Ghooi, “ The Nuremberg Code-A Critique,” *Perspectives in Clinical Research* 2, no. 2 (2011): 72, doi: 10. 4103/2229-3485. 80371.

[9]Ibid.