

Brief Communication**Nuremberg Code: A landmark document on medical research ethics****Mustafa Khidir Mustafa Elnimeiri MD**

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Background

Ethics and ethical principles extend to all aspects of human activities. Ethics has been an integral part of medicine at least since the time of Hippocrates, the 5th century BC Greek physician who is regarded as a founder of medical ethics.

The basic principles of research ethics are well established. It was not always so, however. Many prominent medical researchers in the 19th and 20th centuries conducted experiments on patients without their consent and with little if any concern for the patients' well-being. Although there were some statements of research ethics dating from the early 20th century, they did not prevent physicians in Nazi Germany and elsewhere from performing research on subjects that clearly violated fundamental human rights. Following World War Two, some of these physicians were tried and convicted by a special tribunal at Nuremberg, Germany. The basis of the judgment is known as the Nuremberg Code, which has served as one of the foundational documents of modern research ethics. Among the ten principles of this Code is the requirement of voluntary consent if a patient is to serve as a research subject ⁽¹⁾.

The World Medical Association (WMA) was established in 1947, the same year that the Nuremberg Code was set forth. Conscious of the violations of medical ethics before and during World War Two, the founders of the WMA immediately took steps to ensure that physicians would at least be aware of their ethical obligations. Dr. Joseph Mengele, more familiarly known as the "Angel of death", is probably the most famous of

the Nazi doctor who used the prisoners in Nazi concentration camps for medical experimentation. Mengele sought to unlock the genetic basis for a superior race and conducted ghoulish experiments with precision going even beyond the limits of scientific inquiry. He was fanatical about twin studies, obsessing over the differences between twins, and would make them sit together in the nude for hours while he personally examined them leaving no body part untouched. Furthermore, drawing blood from identical twins was routine, which often left them, bleeding to death. Mengele was also involved in other studies that sought to design better equipment for the Nazi soldiers, and for this purpose naked prisoners were placed in ice cold vats to determine the lowest possible temperature in which a human could survive. However, Mengele wasn't alone in his medical exploits, many German doctors made trips to Nazi concentration camps where they could use the large potential subject pool without concern for the harm of the subjects ⁽²⁾.

The idea of, "state before individual" was typical of the Nazi era and physicians began to lose sight of their moral obligations as they were swept into the dehumanizing Nazi political culture. The slew of exotic diseases and afflictions, a condition of the war environment, were seen as a, "national threat," and it was to these "threats" that German doctors began to assume the responsibility of acting on behalf of the state in order to improve the health of the nation. On the basis of national thought and utilitarianism, doctors no longer acted as caretakers but as puppets of a government obsessed with racial

and genetic purity. Medical experiments committed under the disguise of scientific research fell into three basic categories: (1) Medico-Military Research; (2) Miscellaneous, Ad Hoc Experiments; and (3) Racially Motivated Experiments⁽²⁾.

The Nuremberg Code (1947)

Permissible Medical Experiments: The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

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, overreaching, 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 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 a prior 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 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⁽³⁾.

Discussion

The Code contained 10 ethical standards to which doctors should confine when conducting research involving human subjects. These standards founded the way forward for further development of the other ethical codes in the future. The main ethical standard clearly addressed in the Code was the voluntary consent of the involved human subject in the research which was described by the Code as being absolute. The ethical standards 2, 3 and 4 as shown above were focused on the experiment design and the expected outcomes and the avoidance of risks and harms on the research subjects. The ethical standard 5, prohibited the conduct of research on human subjects wherever there is a strong belief that disability or death is likely to occur. Exception was added to this ethical standard provided that the physicians were themselves were the study subjects. Such addition can be accepted only if the justification is to maximize the importance of ensuring the safety of the experiments before recruiting the human subjects. Then the argument here is that physicians themselves when became research subjects; were they allowed to expose themselves to death and disability?

Further protection of the human subjects involved in research were clearly addressed in the ethical

standards 6, 7 and 8 and these included the control of the degree of risk, the preparations and adequacy of the facilities and the qualification of the researcher in charge. The ethical standard 9 emphasized the right of the research subject to withdraw from the experiment upon his judgment of occurrence of the physical and mental risks in case he continued in the experiment. The ethical standard 10 was focused on the full responsibility of the researcher in charge and the readiness to terminate the experiment so long the risks to the human subjects are more likely to occur.

Conclusion

In conclusion the Nuremberg Code was an important landmark in the history of ethics and the 10 ethical standards stated in it laid strong foundation for the research ethics practice in the future.

References

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