



Accomplishment Over Ethics : Human Experimentation – A Review

¹Dr. Rajiv Ranjan Das , ²Dr. U.S.P. Keshari, ³Neha Das

¹Junior Resident , ³Third Year Undergraduate ,

^{1,2}MD Pharmacology , RIMS RANCHI

³KIMS Bhubaneswar

***Corresponding Author:**

Dr. Rajiv Ranjan Das

Junior Resident, MD Pharmacology , RIMS RANCHI

Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Keywords: NIL

Introduction

“Sometimes we choose priorities over ethics, we tend to accomplish, contentment in deceit.

Becoming a great man doesn't imply one can leave basic ethics like fairness, honesty and fidelity”

Ethics can be defined as the principles that govern a person's behavior. it is a general idea to distinguish right from wrong. but is it fair to forget our moral values to reach a distinct height in scientific area? One of the most conspiratorial subject has been no other than human experiments. They are categorized as unethical because they were illegally performed on humans without their prior knowledge or consent. The experiments include radiation experiments, chemical experiments, drug trials, surgical experiments, torture experiments etc.

Most of these tests were performed on sick, mentally ill patients, pregnant women, children, criminals and poor. but there are also evidence that the tests were performed on people on the basis of religion and race. People considered “worthless” to the society were subjected to immense pain and trauma by people labelling themselves as “highly educated” ones.

As most of the experiments violated the law, some were personally sponsored by the government to

study medical science. sounds like their policy must have been – “torturing people for their own benefit”

Though it is almost impossible to analyze all the unethical experiments throughout the history, efforts has been made to include most of the significant ones

United States

Since the 19th century, several human experiments were performed that were later labelled as unethical. many of the targeted subjects were mentally ill, sick and poor who were receiving radioactive chemicals, toxins etc in the name of “medical treatment”

Fort Detrick in Maryland and US was the headquarters of US biological warfare experiments in World War 2. Other experiments conducted were Tuskegee syphilis experiment from 1932 to 1972, and project MK Ultra. But soon in 1962, the Kefauver Harris drug amendment was passed in United State Congress that lead to the development of FDA in which every food and drug was assessed before going to the market. Other such experiments are discussed later in this paper

Nazi Germany

They mainly experimented on prisoners and jews, who were considered “useless” to the society. not only them but homosexuals and even disabled Germans were subjected to unethical experiments. Experiments conducted were to cure homosexuality,

resistance to cold, adapting to high altitudes, creating conjoint twins, treating gas gangrene etc. these resulted in death, trauma, illness and even permanent disability. From 1941-1945, sterilization experiments were conducted so that fast and cheaper method could be developed for sterilizing people who were weak minded, insane, blind, deaf or physically impaired.

Australians

Due to scientific racism, aboriginal Australians were subjected to medical experiments on pain endurance. Blood and urine samples were taken forcibly without any informed consent.

Japan

During World War 2 several experiments were conducted on prisoners including women and children. Vivisection, surgery and amputation were performed on them without prior knowledge and consent.

In 1958 infants were subjected to experiments in which sugar was forcibly inserted through their nose and then a tube was inserted into their anuses to determine whether the sugar was processed by the digestive system. Many infants suffered from severe diarrhea and bleeding

North Korea

Experiment in North Korea was conducted on prisoners and on people who tried to flee the country. It was mainly done to study how body reacts to gas chambers, chemical weapons, toxic vegetables and surgery without anesthesia.

Soviet Union

The very famous laboratory 1,12 and Kamera also known as the poison laboratory of the soviet secret services was in Russia in the 19th century. The experiments were conducted on prisoners and the goal was to find a tasteless, odourless chemical that could not be detected in post mortem report. The prisoners were subjected to all kinds of poisons and their effects were recorded by the scientist in charge.

Drug trials in African nations

African nations have been a site for chemical testing since the late 20th century. Diseases such as meningitis, HIV/AIDS vaccines have been clinically

tried on the population. due to the side effect many rural communities have developed fear of doctor

Some of the unethical cases are as follows:

- 1) Psychosurgery
- 2) The Monster study
- 3) The Human Radiation experiments
- 4) Medical experimentation on Black Americans
- 5) Doctors trial for Nazi experimentation
- 6) UK mental institutions
- 7) Milgram experiment
- 8) Stanford prison experiment
- 9) Study 329

Psychosurgery

Psychosurgery also known as neurosurgery of mental disorder has a history of interest. During the 1970's , Harvard neurosurgeon , Vernon Mark and psychiatrist Frank Erwin wrote a book "Violence and the Brain" which raised many eyebrows. The national commission of biomedical and behavioral research in 1977 made sure the limited use of psychosurgery. In the US, the Member of operations has further declined for the last 40 yrs, a period during which no major advances in ablative surgery was performed. radical brain surgery and lobotomy were performed by a university of Mississippi, neurosurgeon on African American boys as young as 6yr who were aggressive and hyperactive. A procedure he recommended for rioters after Watts.

The Monster Study

The study is named after experiment performed in 1939 on orphan children by Wendell Johnson at the university of Iowa, Davenport, Iowa. The study was conducted on 22 orphanage children. none were told about the intent of the research and they believed that they were to receive speech therapy. The study was actually meant to induce stuttering in healthy children. On 17 august 2007, six of orphan children were awarded cash by the state of Iowa for such lifelong and emotional scars. although none of the children were stutters but the incident is really shameful and regrettable.

The Human Radiation experiments

Human radiation experiments were directed by USAEC and the Manhattan project during 1970's. 18 people were injected plutonium by Manhattan project doctors, especially Albert Stevens was a the most notorious doctor. In Nashville, pregnant women were given radioactive mixtures. In Cincinnati, 200 patients were irradiated over a period of 15yrs. in Chicago. Around 103 people received injections of strontium and cesium solutions. in Massachusetts 74, schoolboys were fed oatmeal that contained radioactive substances. in all of the above cases, the subjects did not know what was going on and did not give any informed consent. In 1993, then president bill Clinton ordered an investigation and change in policy nearly covering most of the mishaps done by the government agencies.

Medical experimentation black Americans

During colonial period owners would hire out or sell slaves to physician for use as guinea pigs in medical experimentation. During 19th century black cadavers were exploited for profit by whites, who shipped them to medical school for dissection purpose. during 1932 to 1972, Tuskegee syphilis study, in which 600 syphilitic black men were left untreated us US public health service and were allowed to die untreated so that their cadaver could be used for research. American medical research project conducted by the US public health service from 1932 to 1972 examined the natural course of untreated syphilis in black men.

The subjects, impoverished sharecroppers from Macon county Alabama were unknowingly participants in the study, they were not told that they had syphilis, nor were they offered effective treatment after a cure was found

Black Americans have been always unwitting subjects of human Experimentations, J. Marion Sims case was one of them. In 1960's Ionia state hospital, Michigan was among one of the most notorious experimentation site for Psychiatric patients. Doctors at this hospital diagnosed normal African Americans as schizophrenic just because of their ideas on civil rights. The unwilling participation of black in experiments of torture, abuse, and humiliation at the hands of doctors has let to Black Iatrophobia – a

Latin term coined by Washington meaning fear of medicine.

1. 1932: 300 black syphilitic males recruited
2. 1933: 300 controls added
3. 1943: penicillin for military
4. 1949: Nuremberg code
5. 1951: penicillin widely available
6. 1966: local ethics committee review
7. Study widely reported in medical journals
8. Peter Buxton and NYT publicity
9. 1972: PHS Tuskegee panel (Broadus Butler and Jay Katz had major role in calling for regulation)

Nazi doctor trial

Nazi human experiments were series iof controversial medical experiments on large number of prisoners, typically experiments resulted in death , disfigurement or permanents disability . according to the arraignment at the subsequent Nuremberg trial, these experiments included the following

1. Experiments on twin children were created to show similarities and differences in eugenics of twins
2. Freezing experiment – a cold water immersion experiment to learn how to treat hypothermia
3. Malaria experiments- these were done to investigate immunization for the treatment of malaria.
4. Mustard gas experiments – these experiments were done to investigate most effective treatment of wound caused by mustard gas.
5. Sulfonamide experiment: 1939-1945, during this period experiments were done to investigate the effectiveness of sulfonamide on the wounds infected with bacteria such as streptococcus, gas gangrene and tetanus.
6. Sea water experiments – this was done to study the methods of making sea water portable
7. Sterilization experiments- the purpose was to develop a method of sterilization in minimum time and effort.
8. Experiments with poison- this was done to survey the effect of various poisons
9. Incendiary bomb experiments- these were conducted to test the effects of pharmaceutical preparation on phosphorus burn
10. High altitude experiments

UK mental institutions 1960

During 1960's hidden abuse and inhuman treatment of psychiatric patients were done away in the institution of UK, Barbara Robb documented her personal difficult experience of being treated at ELY hospital, she wrote a book and started a campaign.

Milgram experimentation

His experiments on obedience to authority figure include a series of notable social psychological experiments conducted by YALE university. these experiments were controversial and considered by some scientist as physically and psychologically abusive. Psychologists DYNA BAUMRIND, considered the experiments harmful because it may cause permanent psychological damage and make people to be less trusting in the future

Stanford prison experiment 1971

This experiment include study of the psychological effects after becoming prisoner or prison guard. It was led by professor Phillip Zimbardo.

Study 329

Canada US 1994-2001, SmithKline Beechan conducted a clinical trial for a period from 1994 to 1997 in 12 psychiatric centers of north America to study the efficacy of Paroxetine, and antidepressant on teenagers. the data suggested that drug was not efficacious as the Paroxetine group were more likely to have suicidal thoughts.

With every action(event/experiment) comes a reaction

After Nuremberg trial 1947 comes the **Nuremberg code** which has following facts:

1. Established for the purpose of preventing the atrocities of the Nazi experiments from happening again
2. Subject participation must be voluntary
3. Experiments must be supported by strong scientific material
4. Physical or mental suffering or damage is not acceptable
5. Subject has the right to withdraw from the study at any time

Then,

Declaration of Helsinki

In 1964- Helsinki declaration was adopted by the 18th world medical assembly (latest version 2000, Edinburgh, Scotland) and stresses on:

- Justice (fair distribution of burdens and benefits)
- Beneficence (maximize benefit, minimize harm)
- Non maleficence (do no harm)
- Respect (autonomy, protect the vulnerable)

Foundation of GCP (GOOD CLINICAL PRACTICE)

The code of federal regulation of FDA (1977)

- Established regulations for the conduct of clinical research in the United States
- Introduces the concepts of GOOD CLINICAL PRACTICES and data integrity
- 1997: Presidential apology

Why GCP?

- GCP guidelines carry the authority of law
- GCP guidelines are endorsed and followed by the regulators
- Requirements as per newly amended schedule Y
- Compliance with the GCP standard, provides public assurance that rights, wellbeing and confidentiality of clinical participants are observed and consistently protected
- In summary 13 GCP principles
 1. Ethical principles
 2. Risk versus benefits
 3. Rights, safety, wellbeing of subjects
 4. Non-clinical and clinical data should support study
 5. Scientific, valid protocol
 6. IEC/IRB approval
 7. Medical care
 8. Training and experience
 9. Free informed consent
 10. Recording, handling
 11. Confidentiality
 12. GMP
 13. QA and QC

International conference of harmonization (ICH)

1. Idea of ICH established in 1989
2. First steering group meeting in July 1990
3. *Harmonization* relates to the technical requirements for registration of pharmaceuticals for human use
4. ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussion of the testing procedures which are required to ensure and assess the safety, quality and efficacy of medicines

Conclusion

Experiments on either humans or animals have always been a matter of debate in the society. one cannot imagine the amount of fear, pain, trauma and suffering the individual has to go through in a small caged size room while others are watching, recording and writing down the details. Due to faster communication, technology and media such practices have declined to a larger extent. but still there are conspired theories that govt is funding and promoting secret agencies for such unethical practices. Millions of people till now have suffered and even died on record. We cannot imagine the off-record number ever. But one has to think that “Is advancement of medical science worth the mental and physical torture of an individual” ???

Maybe some words best describe it....

“Great books has been written with the alphabets, one has learnt in the childhood itself”

References

1. Faden R, Beauchamp T. A history and theory of informed consent. Oxford University Press; 1986.
2. Nelson CA. Incidental findings in magnetic resonance imaging (MRI) brain research. The Journal of Law, Medicine & Ethics: a Journal of the American Society of Law, Medicine & Ethics 2008;36(2):315–9. <https://doi.org/10.1111/j.1748-720X.2008.00275.x> .
3. The IEEE Global Initiative for Ethical Considerations in Artificial Intelligence and Autonomous Systems. Ethically aligned design: a vision for prioritizing wellbeing with artificial intelligence and autonomous systems - V2. Tech. rep. IEEE; 2018. https://standards.ieee.org/develop/indconn/ec/autonomous_systems.html .
4. The European Parliament and the Council of the European Union, Directive 95/46/EC, Tech. rep. ORNAC Journal. 1995. p. 281.
5. Bonaci T. Brains can be hacked. Why should you care?. ENIGMA; 2017. <https://www.usenix.org/conference/enigma2017/conference-program/presentation/bonaci>.
6. Prasser F, Bild R, Eicher J, Spengler H, Kohlmayer F, Kuhn KA. Lightning: utility-driven anonymization of high-dimensional data. Transactions on Data Privacy 2016;9:161–85.
7. McPherson R, Shokri R, Shmatikov V. Defeating image obfuscation with deep learning. 2016. arXiv: 1609.00408v2.
8. Munz M, Hickman T, Goetz M. Court confirms that IP addresses are personal data in some cases. 2016. <https://www.whitecase.com/publications/alert/court-confirms-ip-addresses-are-personal-data-some-cases>.
9. Wager E, Kleinert S. Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, 2010. In: Mayer T, Steneck N, editors. Promoting research integrity in a global environment. Singapore: Imperial College Press/World Scientific Publishing; 2010. p. 309–16.
10. European Commission. Horizon H2020-how to complete your ethics self-assessment. Tech.repEurope.2018. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf .
11. International Committee of Medical Journal Editors. Conflict of interest. CMAJ: Canadian Medical Association Journal 1993;148(12):2141.
12. Guillemaud T, Lombaert E, Bourguet D. Conflicts of interest in GM bt crop efficacy and durability studies. Plos One 2016;11(12):e0167777.
13. Custers R. Research misconduct – the grey area of questionable research practices. 2013. <http://www.vib.be/en/news/Pages/Research->

- [misconduct](#) —The-grey-area-of-Questionable-Research-Practices.aspx.
14. John LK, Loewenstein G, Prelec D. Measuring the prevalence of questionable research practices with incentives for truth telling. *Psychological Science* 2012;23(5):524–32.
 15. Martinson BC, Anderson MS, de Vries R. Scientists behaving badly. *Nature* 2005;435:737–8. <https://doi.org/10.1038/435737a> .
 16. ElsevierSalamislicing.2015. https://www.publishingcampus.elsevier.com/web/sites/elsevier_publishingcampus.
 17. European Commission. Responsible Research and Innovation – Europe’s ability to respond to societal challenges. Tech. rep., Europe. 2012. <https://doi.org/10.2777/11739>.
 18. Mashour GA, Walker EE, Martuza RL. Psychosurgery: past, present, and future. *Brain Res Brain Res Rev.* 2005 Jun;48(3):409-19. doi: 10.1016/j.brainresrev.2004.09.002. PMID: 15914249.
 19. Sachdev, Perminder Sa,b; Chen, Xiaohuaa,b Neurosurgical treatment of mood disorders: traditional psychosurgery and the advent of deep brain stimulation, *Current Opinion in Psychiatry: January 2009 - Volume 22 - Issue 1 - p 25-31* doi:10.1097/YCO.0b013e32831c8475
 20. Wikipedia contributors. (2022, April 27). Monster Study. In Wikipedia, The Free Encyclopedia. Retrieved 15:07, June 27, 2022, from https://en.wikipedia.org/w/index.php?title=Monster_Study&oldid=1084862388
 21. Longworth RC. A New Kind of War. *Bulletin of the Atomic Scientists.* 1999;55(4):28-31. doi:10.2968/055004010