PROFESSIONAL ETHICS

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Informed Consent

- Viewing engineering as social experimentation, human beings are affected by technology as the experiments are performed on persons, not on inanimate objects.
- In this respect, on a much larger scale, engineering closely parallels medical testing of new drugs or procedures on human subjects.
- It is morally and legally required to ensure that subjects in experiments participate on the basis of informed consent.

Informed Consent

- Informed consent is understood as including two main elements:
- Knowledge: The subjects should be given not only the information they request, but all the information needed to make a reasonable decision.
- Voluntariness: The subjects must enter into the experiment without being subjected to force, fraud, or deception.

Informed Consent

- Valid consent is defined by the following conditions:
  - The consent was given voluntarily.
  - The consent was based on the information that a rational person would want, together with any other information requested, presented to them in understandable form.
  - The consenter was competent (not too young or mentally ill, for instance) to process the information and make rational decisions.

Informed Consent

- To keep up with an ever growing market, pharmaceutical companies in the US are outsourcing a large number of their clinical trials to clinical research organizations or CROs.
- Clinical trials are research studies performed on human subjects, and CROs are big business.
- CROs now test drugs and vaccines in more than 115 countries.
- The outsourcing has really escalated in the last 20 years.
- There are now 20 times more foreign clinical trials than there were back in 1990.

Case Indian Trials

- With more than a billion people, India has no shortage of potential test subjects.
- International pharmaceutical companies and CROs say, India has a huge population and that is why it is attractive for clinical trials.
- But what they don't tell is that India also has huge poverty and a growing gap between rich and poor.
- And conducting clinical trials within such a context will raise serious ethical issues.

Case Indian Trials

- Bhopal is known for the most catastrophic industrial disaster in history.
- Poisonous gas leaked at a pesticide factory belonging to Union Carbide, an American company now owned by Dow Chemical.
- This is the site where the Union Carbide gas disaster happened in 1984.
- Now the US corporation has built a hospital to treat those who have survived the gas leak.
- But it's now becoming clear that hospital has also become a site for clinical trials.

Case Indian Trials

- Lakshmi and her late husband, ShanKar lal lived within a few blocks of the factory when the leak happened.
- Shankar's health never improved.
- The last time he got sick before passing away in 2008, he went to Bhopal Memorial Hospital and Research Center, the hospital built for the survivors.
- The pills were ticagrelor, a medicine for heart attacks and strokes that was being tested for approval in a number of markets, including the US.
- Study group. AstraZeneca, the pharmaceutical company that makes the medicine ran the trial in 43 countries.
- While there's no evidence linking Shankar's death to the pills, Lakshmi says her family had no idea Shankar was participating in a clinical trial.

Case Indian Trials

- Many other illiterate people also participated in the trials.
- Ramadhar is 56 years old, he also says that he had no idea he was on that clinical trial at Bhopal Memorial.
- He said, they made me sign a paper, it was written in English and I couldn’t understand it.
- AstraZeneca told Thought Lines there were cases where consent forms were not properly filled out.
- It says, it doesn't know how many, and it could not confirm whether any follow up care or compensation was provided to the patients in question.

Case Indian Trials

- Another story is based in Mumbai, the CROs says for this trial, it pays people per milliliter of blood that they lose.
- They receive more money when the drugs have serious side effects.
- Off record, staff told us that 95% of the participants are poor.
- The other 5% are university students.
- One of the reasons that companies go to these other countries is they know that the patients are desperate. They have no medical care.
- This is not the kind of circumstance that could be described even remotely as informed consent.

Conclusion

- Same standard should be used for trials whether in US or outside US.
- The ethical oversight of clinical trials in the third world countries is less than it is in the United States.
- The idea of there being inspected by United States government is much less than it would be here.
- So it's ideal, and it looks like they are exploiting the third world enormously.

References

- Mike Martin and Ronald Schinzinger, “Introduction To Engineering Ethics”, McGraw Hill, New York, 2010
- Miscellaneous Journals and Internet Resources.