HUMAN RIGHTS EXPLOITATION IN HUMAN CLINICAL TRIALS – STUDY ON NON-COMPLIANT CLINICAL TRIALS

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The following short comments article focuses on the existing system of human clinical trials in India, the current regulatory framework and the practices involved in the selection of trial subjects adjudged according to its impact on human rights.

INTRODUCTION

India for a long period has been the testing ground for multinational drug companies of highly developed countries and its many factors have proved to be an advantage for them and a curse to the citizens of our country. Large population, lack of regulating factors, low cost are few of the many factors that has turned this country to the "most desirable testing hub''. Human clinical trials has been defined by WHO "Any research project that prospectively assigns human participants or groups to one or more health related interventions to evaluate the effects on health outcomes.'' Human clinical trials are not be completely dreaded in fact proper regulation of such trials is encouraged to develop the health industry and to generate significant revenue from multinationals but harmful usage/misuse of such drugs due to improper regulation is what has become the rising concern of the day.

Shocking Revelation: In the recent years over 2,500 Indians have died during the course of human clinical trials, government figures reveal. The health ministry admitted that 2,644 people died during the clinical trials of 475 drugs from 2005 to 2012. Apart from the figures being daunting enough, the unbelievable aspect of all this brutality is the way the "consent" is obtained from the participants of such trials, human clinical trials are usually done amongst poor people who obtain medical services either freely or in the form of support in the form of special government funds, thereby making them vulnerable to exploitation. They are dismayed by doctors who give them expensive foreign drugs and make them feel as though they are blessed to receive such drugs which under normal circumstances they will not be able to afford but in the midst of this act little is known to the consumers of the drug that they are in fact being tested and these drugs have little or no effect to the disease for which they originally approached the doctor. The consent forms are either in English or improperly translated in the local language thereby making it impossible for the locals to fully understand the content and thereby giving a consent which is not valid on any grounds. One of the clear indications that the drug is a clinical drug is that in most cases the particular drug in question will not be available in the ,local easily accessible pharmaceutical stores and most only with the doctors. [1]

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[1] Sue Lloyd-Roberts , "Have India's poor become human guinea pigs'' BBC Newsnight [1 November 2012]

Bhopal- the place where the most horrific industrial tragedies in the history of mankind has taken place is also one of the blooming places for human clinical trials. After the horrific incident took place,

The Bhopal Memorial Hospital was set up as per the directive by the Supreme court of India to provide advanced treatment to the victims of the gas leak tragedy and the public at large, but in reality the patients visiting the hospital most of which are the gas leak victims have to been exposed to harmful human clinical trials worsening their conditions. All these incidents have alarmed and given rise to many petitions and awareness by Ngo's and other social activists bring these atrocities to the limelight.

Human Rights v. Blooming Economy: All these issues and concerns have resulted in a mixed response, many doctors are against the allegations and stand firm to their belief that human clinical trials are not being tried out to harm the poor people. But why are poor people the participants of such trials?, the responses have not been satisfactory. Some argue that no standard protocol had been followed and to say that all deaths are due to human clinical trials is exaggeration of facts. The revenue that is being generated due to human clinical trials should be of significant importance for it is said that this industry is likely to generate $1billion by 2016 , where it had generated about $485 million. The question of regulating the human clinical trials has raised concerns about the impact of such regulation on the development of this promising industry, development of the quality of health care. In the battle between human rights and increasing money, human rights should never be compromised.

CURRENT REGULATORY MEASURES

THE DRUGS AND COSMETICS ACT 1940

Schedule Y of the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics act 1940 is of fundamental importance. It lays down the requirements and guidelines for the conduct of such clinical trials in India. Rule 122 DA (Permission to conduct trials), Rule 122 DAA (Definition of Clinical Trials), R122DAB (Compensation in case of trial related injury or death), Rule 122DAC (Conditions of Clinical trial permission and inspection), Rule 122DD (Regulation of Ethics Committee), Rule 122E (Definition of New Drugs). Though the act is comprehensive in its nature as it includes the responsibilities of the sponsor of the trial who includes an individual or institution who undertakes to manage, initiate or finance the trial without engaging into the actual conduct of the trial and the act also lays down the responsibilities of the investigator who oversees the conduct of the entire trial, definition of informed consent and also the nature of drugs to be tested in forms of phases of trials. The act also has a special provision with regard to clinical trial participant who is a pregnant woman and lays down special safeguards in that regard. These guidelines and requirements though seem holistic in its approach are not free from criticisms.

Role of Ethics Committees

In understanding the present regulatory framework to comprehend the effect of clinical trials regulation in India the role of ethics committee is of fundamental importance. The Ethics Committee which was set up as per the regulations issued by the Indian council of Medical Research in 1980. The prime responsibility of these ethics committees is the general regulation of the clinical trials along with the government's regulatory authority- The Drug Controller General Of India (DCGI)[2] Though the objective and the laid down functions of these clinical trials has the potentiality of ensuring integrity and protection of human rights in theses clinical trials, however the reality is far from the desired outcome. It has been nearly 30 years since the establishment of these ethics committees but even today they are suffering from basic issues like inadequate or no standard operating procedures (SOPs) and noncompliance with the Schedule Y recommendations. The EC has the prime responsibility of regulating clinical research and safeguarding the rights and safety of research participants, however, the institutions and hospitals that focus on enhancing their research facilities tend to ignore the EC, which approves their research. ECs have to deal with basic issues such as lack of trained manpower, heavy workload, inadequate space allocated for EC operations, lack of administrative support, and inadequate remuneration offered to members serving on EC boards. These issues culminate into reluctance of trained individuals to serve as members of the EC[3].

Informed Consent

Schedule Y of the drugs and Cosmetics rules, 1945 defines informed consent as that in all trials a **freely given, informed written consent** is required from the trial subject. The Investigator must provide information about the study verbally as well as supplying patient information sheet in a language that is non-technical and easily understandable by the trial subject. The Subject's consent must be in writing using an "informed consent form". In case the subject is unable to give informed consent, such should be provided by a legal representative on behalf of the trial subject. In practice however this process of obtaining informed consent has been vitiated by fraud and manipulation of trial subjects and the victims of this exploitation are vulnerable groups.

A resolute stand was taken by the apex court in 2013 in questioning the approval of 162 global clinical trials by the health ministry[4]. The Drugs and Cosmetic Rules,1945 was amended in 2013. According to the amended act, it imposes complete and ultimate liability on the sponsor of the clinical trials to reimburse any cost incurred by the trial subjects for the medical treatment of 'any injury' suffered by trial subject and financial compensation for injury or death [previously prior to the amendment compensation had to be provided only in the case of death], failure to do so would lead to cancellation of license of the sponsor by the licensing authorities and can even enable them to be debarred from conducting future clinical trials in India and in the case of serious adverse event (an untoward medical occurrence

[2] Rashmi Kadam, Shashikant Karandikar "Ethics Committee Facing Challenges", Indian Society of Clinical Research

[3] Thatte U, Bavedkar S. "Clinical Research In India- Great Expectations?", J Postgrad Med

[4] The Supreme Court's direction came following a PIL filed by an NGO Swasthya Adhikar Manch

during a clinical trial which is associated with death) reporting of such event should be made within 24 hours to the licensing authority, sponsor and ethics committee.[5]

The constant amendments to regulate the evolving evil practices provides hope and confidence that the brutality in human clinical trials will be reduced in the near future and safety and protection of human rights will triumph over exploitation and inhumane acts.

[5] Karwa M, Arora S, Agrawal SG (2013) Recent Regulatory Amendment in Schedule Y: Impact on Bioequivalence Studies Conducted In India. J Bioequiv Availab 5: 174-176