IJMDRR
E- ISSN –2395-1885
ISSN -2395-1877

Research Paper

SWASTHYA ADHIKAR MANCH, INDORE & ANR. VS. MIN. OF HEALTH & FAMILY WELF. & ORS - MEDICAL RESEARCH INVOLVING HUMAN BEINGS – AN ANALYSIS

Adv. Asha Sundaram

Abstract

Medical research is the foundation on which modern medical science is built. The apex court of India made all state governments and union territories parties to public interest litigation, directing to submit information on medical research in their jurisdictions. From time immemorial it is a common practice that to entrust the duty of decision making relating to the patients to the doctors. This paternalistic approach has gradually been changed by promoting patient individuality and autonomy, whereby patients and doctors share the decision-making responsibility. Conflicts exist in medical community to correctly demark the duties, rights and responsibilities of both the patients and the doctors. It becomes more complex when the doctor takes the role of a researcher. This paper discusses various issues revolving medical research involving human beings and highlights several instances of human rights violation in the name of medical research.

INTRODUCTION

Health care sector is one of the ever growing sectors of Indian economy because of growing population, diseases and increased awareness level. Medical research as non-therapeutic in nature demands greater responsibilities from the health professionals even when motivated with advancement of science or with the intention to identify the efficiency of a newly introduced drug.

The Supreme Court of India while hearing a suit which alleges wide abuse of people, who participated in medical research in Madhya Pradesh by an international drug company, opined that a one-line direction may be issued that all these clinical trials which affect many people must stop forthwith. The court asked, "Why the laxity and lethargy in such a matter when every human life is precious."

The Judges R.M.Lodha and A.R.Dave also opined that the entire medical research may be stopped in the country unless the health ministry provides it the information within a month on deaths, compensation and general practices when medical research is conducted. "Every day, one death is allegedly taking place. If it is true, it is most unfortunate. People are dying and the state government is saying it is taking action when mere penalties are being imposed on erring researchers. There cannot be laxity in this issue. Though we have issued notice (on the PIL) in February, the Centre has not responded. We do not know what information it is gathering. But the matter appears serious," The bench said while asking the Centre and the state governments to respond within six weeks.

The Apex Court of India on Jan 14 2015 ordered the union government to answer to the question as to what initiation it took on the report given by the standing committee of the parliament regarding various malpractices on medical research of cervical cancer vaccine involving human beings. The apex court questioned the government to submit an affidavit explaining who shall be held liable for any adverse effects and death of human beings who are subjected to medical research. The court directed to file affidavit mentioning the procedure of getting informed consent from those who are subjected to medical research. The court directed to ascertain the aftermath and the consequence of vaccination. The court also asked to probe into whose responsibility is to pay compensation. The bench questioned the reason of conducting or selecting that particular state and district for the conduct of cervical cancer vaccine. The apex court also directed the concerned state which sanctioned the research to give information about how many research participants died or injured.

Common Perception of Victimization during Medical Research

Only if the questions of how victimization occurs in the name of medical research, how commonly it happens etc are answered the issues may be understood better. Even though considerable advancement has been made in the humanitarian and human rights fields, none of these questions are answered. There are many instances of victimization of research participants of which most of them are vulnerable. History reveals that prisoners, children, elderly, racial minorities and women are victimized in the name of medical research and advancement of medical science for the benefit of the humanity at large. Utilizing a research subject who does not have the

medical condition which the researcher is addressing is a clear cut violation of right to his life and personal liberty even if it brings beneficial results for the public.

The doctrine of informed consent is considered as the cornerstone of patient's rights. Advancement of medical science and medical research has always gone hand in hand. The dignity and privacy, the basic rights of the patients need to be protected and promoted along with the advancement of medical science. Before going into the definition of the term medical research, it is essential to understand the meaning of the term research subject.

Specific Understanding of Medical Research and Research Subject

The role of a doctor is different when he is acting as a physician and a researcher even if the physician and the researcher are the same person. The duties entrusted on a physician are different from the duties of a researcher. The physician's primary responsibility is to provide therapeutic benefits to the particular patient and also to take care of the health and well-being of the patient.

In the United States Federal Guidelines a human research subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or with identifiable private information. The term medical research covers "any investigation in human subjects intended to discover or verify the clinical, pharmacological, and or other pharmacodynamic effects of one or more investigational medicinal product(s), and or to identify any adverse reactions to one or more investigational medicinal product(s) and or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their)safety and/or efficacy."

Medical research is defined in Indian Good Clinical Practices formulated by Central Drugs Standard Control Organization as, a systematic study of pharmaceutical products on human subjects – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics), and / or adverse effects, with the object of determining their safety and / or efficacy.

Medical Research v. Medical Practice.

The border line between the medical research and the medical treatment may be clearly and accurately demarcated. Medical practice is always therapeutic and geared toward the welfare and benefit of the patient. On the other hand, medical research is non therapeutic and does not presume to benefit or help in curing the ailment of the patient participant. Research is carried out in the presumption of anticipated benefits that its findings will benefit other patients in the future. In most cases the medical research is non therapeutic, only in few cases it helps in treating the research participant.

Therapeutic Research and Non-Therapeutic Research

Therapeutic Research offers participants an opportunity to receive an experimental treatment that may have beneficial effects (e.g. treatment with an experimental drug).Non-therapeutic research allows accumulation of information that may be for the welfare of the society and coming generation but may not benefit those involved in the research.

The distinction drawn previously between therapeutic and non-therapeutic research is now regarded by many as unhelpful and potentially misleading. The use of a medicine is therapeutic if, a doctor may use an untested drug on a patient who is suffering from a particular disease, believing the drug to be the best. Sometimes there may be only a hope of curing the disease. The medicine is given for the benefit of that patient. On the contrary, If a doctor seeks healthy volunteers to test a drug's possible side effects – the use is non- therapeutic. The medicine is not given to improve the volunteers health, but rather to test the medicine to see, whether it can be used on other people. For example, clinical trials that involve medicines include both therapeutic elements – the medicine being given – and non therapeutic element – the taking of a blood sample. Moreover the term therapeutic may cause confusion because the outcome of the research may not provide a treatment that benefits the individual participant alone.

The European Convention on Human Rights and Biomedicine categorizes the research on the basis of the benefit which the research subject attains. ECHRB specifies that the results of the research may have the potential to produce real and direct benefit to the health of the research subject. Research may also aim at improving the scientific understanding of the individual's condition, disease or disorder. The ultimate attainment of results may be capable of conferring benefit to the persons concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition. Thus in essence ECHRB recognizes therapeutic and non- therapeutic research.

The preamble to the Convention on Human Rights and Biomedicine 1996, convinces the need to respect the human being both as an individual and as a member of the human species and recognizes the importance of ensuring the dignity of human being. Hans Jonas opines that progress is an optional goal, not an uncompromising commitment. More importance may be given to the protection and freedom of the individual research subject than interest of the society.

Types and Phases of Medical Research

There are different types of medical research like, treatment research, prevention research, diagnostic research and quality life research .Treatment research involves experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. Prevention research looks for better ways to prevent disease in people who never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes. Diagnostic research are conducted to find better tests or procedures for diagnosing a particular disease or condition, screening research test the best way to detect certain diseases or health conditions. Quality of life research (or Supportive Care trials) explores ways to improve comfort and the quality of the life for individuals with a chronic illness.

The research involving human subjects include: studies of a physiological, biochemical or pathological process or of the response to a specific intervention- whether physical, chemical or psychological in healthy subjects or patients. It also includes controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons designed to demonstrate a specific generalizable response to these measures against a background of individual biological variations. The research on human beings also aim at conducting studies designed to determine the consequences for individuals and communities of specific preventive and therapeutic measures and studies concerning human health related behavior in a variety of circumstances and enviournment. Medical Research is conducted in four phases, as defined by the National Institutes of Health [NIH]. The medical research at each phases have a different purpose and help scientists answer different questions.

Phase I trial

To evaluate the safety of the experimental drug, the researcher applies it on a small group of people. The issues which need to be identified are safety, appropriate dosage range, and also to establish the side effects if any. What shall be the dosage of the drug in the subsequent stages is also tested in phase I. In phase I how a drug is transformed and broken down inside the human body and how it effects in the process of excretion is also studied. Generally those who are fit and healthy are enrolled for the phase I trial. But for testing the drug for diseases like cancer, phase I research subjects may be patients who have already undergone treatments and there is no hope with existing and approved therapies.

Phase II trial

After the successful completion of the phase I trial, the researcher advances to a phase II trial normally consisting of around 200 research participants. The main study done in the phase II is to identify the safety and side effects, clear cut description of appropriate doses, and get an early appraisal of whether the drug has some therapeutic value or not. It is in this second phase the drug is normally tested in the actual patients. Compared to phase one trial the number of research subjects on whom the study is done is usually less. The therapeutic use effective range of the dosage and safety of the drug is also affirmed.

Phase III trial

In phase 3 trials, the study drug which needs to be experimented is given a large population. The effectiveness of the drug is confirmed, the side effects are closely monitored. In this stage the new drug is compared to the accepted and recognized medicines available. Another task is to accumulate information through which the experimental drug is used safely.

People from different localities and background will be enrolled in a phase III trial to test whether their experiences differ. If the medicine is already tested and accepted in other countries, trial is primarily done to confirm its safe application on Indian patients when it is recommended in the product monograph for the claims made.

Phase IV

Phase 4 Studies are conducted after marketing of the drug. Pharmaceutical products are categorized and trials are carried out on which authorization for marketing will be granted usually in the form of post-marketing surveillance, therapeutic value assessment, treatment strategies, safety profile etc. Phase IV studies may use the same scientific and ethical standards as applied in pre-marketing studies.

These phases are divisions of convenience for a continuous expanding process beginning with a single subject closely observed in the laboratory and proceeding in tens of subjects through hundreds of patients to thousands before the drug is agreed to a medicine by a national and international regulatory authority and is licensed for general prescribing.

Understanding of the Roots of Human Rights Violations and Some Illustrative Models

Taking into account all the different phases and stages of medical research it is evident that it is natural and unpredictable that a best intentioned researcher may go wrong about the efficiency and safety of the procedures involved. Even though all research has a design to guide how to go forward, the failure to achieve expressed value formulations leads directly to moral turpitude and pragmatic failure. The risk and the consequent harm involved in these stages may be remedied to a great extent by practising and employing ethical and moral guidelines and principles during the stages of medical research. It is essential that all medical research may be conducted according to the strict ethical principles or standards to infuse trust in the public and to the participants.

The death of 254 Indian women from modest backgrounds in the course of a 15-year US-funded medical research which was conducted without giving adequate information to give informed consent has triggered a raging debate about its ethicality as it is evident that many are pitilessly performing crude and cruel experiments and killing lacks of human beings every year in the name of medical research. There were many reports of instances of illegal medical research involving human beings in India. During 1976-88, 1158 women with different degrees of cervical dysplasia were included in a medical research for a long term basis as an attempt to study rates of progression to malignancy. By the end of the study, 71 women had developed malignancies. The researchers failed to follow the informed consent principle and other ethical requirements as majority of research participants were uneducated and from lower strata of the society. In India illegal and barbaric type of medical research have been carried out in New Delhi, West Bengal and Karnataka in 1998 .There was no licence obtained for the use of quinacrine under the Drugs & Cosmetics Act, 1945.

A writ petition was filed against the distribution and use of Quinacrine as a means of non-surgical sterilization on women. Provisions of sections 10-A and 26-A of the Drugs and Cosmetic Act, 1940 through which the import, manufacture, sale and distribution of quinacrine was prohibited. In this mode of sterilization, pellets of quinacrine are inserted into the fundus of the uterus which results in inflammation of the uterus which is followed by the formation of scar tissue which is expected to close the Fallopian tubes and hence result in sterilization. The effect of this type of sterilization is high pain, body ache, dizziness, painful menstruation, irregular bleedings etc. The chances of failure were also very high. There were reports that this method has caused ectopic pregnancy in the fallopian tube with fatal side effects to both child as well as the mother.

In regional cancer centre, Thiruvananthapuram, kerala, from November 1999 to April 2000 medical research was done on 26 patients having cancer without even conducting any study in animals. Because of hue and cry from the public, media and from the part of the NGOs the government was compelled to take appropriate steps and action on the incident .The physicians who conducted the research study were accused of having breached ethics in medical research, opined that the research was conducted with the informed consent of research subjects, hospital ethics panel, and also have informed the government officials about the said research. The government's intervention resulted in withholding the research for six months. ICMR also initiated an enquiry into said allegations involved in the medical research. The health ministry in India and the University which sponsored the research Johns Hopkins University in Baltimore, Maryland, also started investigating the allegations s that levelled against the doctors that they breached ethics when they conducted the drug testing on Indian patients with oral cancer .The drug was developed at Johns Hopkins. When all these incidents were happening Johns Hopkins University was already at under black mark because of its over use of inhaled hexamethonium in medical research involving human beings for asthma.

In 2003 the Monthly Index of Medical Specialities in India report that, more than 400 women who had been trying in vain to conceive. This was done without their knowledge or consent to take part in medical research conducted in many places in India to test whether a drug called Letrozole induced ovulation. Letrozole used in India was copied (with permission) by Sun Pharmaceuticals, an India based generic drug company, from a patented product of the same name of Novartis, which the multinational drug maker introduced globally for solely treating breast cancer and not for any other use in any country, including India. A complaint on the Letrozole case, too, was filed in the Supreme Court by yet another Delhi-based NGO.

The judiciary has in several cases discussed the ethics and morals which a doctor needs to be maintained in his profession. The court expressed no hesitation in saying that it is expected of the members of the legal profession which is the other honourable profession to honour the persons in the medical profession and see that they are not called to give evidence so long as it is not necessary. It is also expected that where the facts are so clear it is expected that necessary harassment of the members of the medical profession either by way of requests for adjournments or by cross examination should be avoided so that the apprehension that the men in the medical profession have which prevents them from discharging their duty to a suffering person who needs their assistance utmost, is removed and a citizen needing the assistance of a man in the medical profession receives it.

During the resumed hearing of a PIL filed by an NGO Swasthya Adhikar Manch, the court sought an end to illegal medical experimentations of untested drugs by multinational companies. The NGO has alleged that massive medical research involving human beings which is estimated at Rs8,000 crore is conducted annually by various pharmaceutical firms, using Indian citizens as guinea pigs. The petitioners Swasthya Adhikar Manch (SAM) had also urged the court to order the formation of a committee of experts, consisting members of civil society especially, All India Drug Action Network, to examine the present legal provisions concerning clinical trials both in India and abroad and to make recommendations for framing guidelines on the issue. Lots of matters regarding medical research and involving human beings are raised in Parliament. The main concern being the situation of using human beings as guinea pigs, involving human beings without following the procedures of the doctrine of informed consent, deaths of research subjects during the course of medical research etc

An application lodged by two Bhopal-based NGOs in the pending petition by " Swasthya Adikhar Manch" revealed human rights violations against the sufferers of the poisonous gas leak from Union Carbide factory while undergoing treatment at Bhopal Memorial Hospital . Recently it is revealed that such people were being used as research subjects without their informed consent. During hearings on purported disregard of laws by pharmaceutical companies in organizing medical research on humans, the court had directed the health ministry not to continue with the medical research of 157 new drugs/formulations till a stricter laws for regulating these research was put in place. Records kept at the Bhopal Memorial Hospital and Research Centre (BMHRC) indicates that medical research was conducted on 279 patients of which 215 were gas victims. At least 12 of them died from medication given and many were poor patients who depended on the hospital for free of cost treatment. "

After the direction given by the Supreme Court, the government and drug controller general of India (DCGI), supervise the quality of drugs as well as different stages of research, currently formulated and announced specific guidelines for conducting medical research and recording and lodging of information pertinent to deaths. The authority has also formulated a scheme determining monetary damages to those who die during medical research. As per the new rule put in place in January 2013, an independent expert committee monitors the reported adverse events and makes recommendations to the licensing authority or DCGI, which will finally take a call on the amount of damages.

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2013

The Bill has separate chapters on medical research. It put forwards certain changes in the legal framework of the, manufacture of medicines to ensure safety, efficacy, quality and conduct of medical research. Medical research is defined in relation to drugs, cosmetics, medical, and involves their systematic study with the objective of determining their safety, efficacy, performance or tolerance. Anyone initiating a medical research has to register with the Central Drug Authority (CDA) an over reaching body and get approval from an Ethics Committee registered with it.

The Bill seeks to establish a 19-member overarching body to regulate the drugs and cosmetics sector that will be headed by the Secretary, Health and Family Welfare. The Bill creates provisions for the medical treatment and compensation in case of injury or death of a person during participation in a medical research or due to it. The Central Government shall establish a CDA to subsume the existing Central Drugs Standards Control Organisation. The CDA will be composed of representatives from the Ministries of Health and Family Welfare, Law, Commerce and Industry, Science and Technology, Chemicals and Fertilisers, DCGI, Indian Council of Medical Research, Directorate General of Health Services, and other experts nominated by the central government, including those from state licensing authorities. The CDA shall among others, specify guidelines, structures and requirements for the effective functioning of the central and state licensing authorities. It has the power to review, suspend or cancel any licence or permission issued by them. It also has the power to decide on disputes between two or more state licensing authorities relating to the provisions of the Act and rules and regulations made under it. In medical research increased funding rate as compared to earlier time, use of technologies, introduction of improved clinical tools etc are creating greater demand for human subjects. Access to patient records and human biological materials are also increased. Overall there are new pressures nationally and internationally to subordinate the interests of the subject to those of science and society.

Now, law relating to this issue in other jurisdictions may also be noted. In USA the legal framework for a medical research involving human being emerges from the principles of, the Nuremberg Code and the Declaration of Helsinki. The Declaration of Helsinki stipulates that the protection and interest of the basic rights of the research subject need to have predominance over the interest of the medical science and humanity. The principle of reduced risk and the doctrine of informed consent are the corner stone of the regulations by which US government seeks to ensure the rights and wellbeing of the research participants.

CONCLUSION

When human beings are the research participants there are certain necessary conditions to be taken care of. The aim and objective of such research is to generate knowledge and for the betterment of all the species in the universe. Medical research may be organized under specific policy that no one becomes simply a method for welfare of others and that research participant's dignity, privacy and wellbeing are protected. The research need to be done under a proper transparent professional standard. Special care need to be taken to ensure that the research participants are not put at any level of risk than what is permitted taking into account the welfare of the research participant.

Undoubtedly medical research is an uncertain activity, in which there is no substitute for learning and training on sick patients. Sometimes mistake may happen, results in injury or even death may occur. Deciding whether to participate in a medical research is not easy, no matter where the study takes place. Patients are faced with a mountain of information about the potential risks and uncertain benefits of becoming research subjects.

Common man approaching for treatment may not understand what is being explained about the risk or the benefit. He looks for the cure of his disease with less expenditure. Add to that heady brew the stark disparity among patients in rich countries and those in developing nations, and concerns pertinent to quick growth of medical research taps the poor and vulnerable section of the society as research subjects.

In this case even though the court's intervention is an appreciable one in furtherance of the spirit of justice. The measures taken thereafter to protect the rights of the research participants may also be brought to the lime light making the general public aware about the actions taken by the government for protecting the basic human rights of vulnerable and marginalized section of the society . Swift actions need to be taken to indemnifying the rights of the victims. Justice delayed is always justice denied. A scheme of compensation which is based on ethical ground and victim friendly need to be formulated as we find in other Jurisdictions.

REFERENCE

1. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. Democratic Women Association vs. Union of India, (1998)5 SCC 214.
3. Ganapati Mudur, "Indian doctors defend "unethical" anticancer drug trial"323 BMJ 299(2001).
4. Ganapati Mudur, "Indian study of women with cervical lesions called unethical" 314 BMJ 1065(1997).
5. Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects",98 Daedalus, 219 (1969).
6. Hebert. P.C, Doing Right: A Practical Guide to Ethics for Medical Trainees and Physicians. (New York: Oxford University Press, 1996).
7. Indian GCP guidelines. http://cdsco.nic.in/html/gcp.htm ,Viewed on 22/2/2014.
8. Indrajit Basu, India's clinical trials and tribulations , http://www.ahrp.org/infomail/04/07/27.php viewed on 23/12/2014.
9. International Ethical Guidelines for Biomedical Research Involving Human Subjects (NGO),1993.
10. Parmanand Katara vs Union Of India & Ors, 1989 SCR (3) 997.
11. Rakesh Bhatnagar, "End illegal drug trials: Supreme court" DNA, Friday, Jan 4, 2013.
12. Rema Nagarajan, "Row over clinical trials as 254 Indian women die" TNN,April.21,2014.
13. Woodward. B, "Challenges to Human Subject Protections in US Medical Research."20 JAMA 282(1999).
14. WP (C) 33 of 2012, Order dated: 3rd January 2013, with W.P(C)No.79 of 2012, http://courtnic.nic.in /supremecourt /temp/wc%203312p.txt 8.10.2012, 26.7.13