Hindu

Opinion » Editorial

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Clinical trials in the dock

With the Supreme Court issuing notice to the Central government on the matter of illegal drug trials, the sordid state of human clinical trials is all set to be exposed. For multinational companies eager to cut corners, India offers an attractive package of weak laws, lax and almost non-existent oversight of trials, a huge illiterate, vulnerable population that can be easily exploited, very little volunteer protection and a sizeable number of unscrupulous doctors willing to compromise on ethics for gain. Recent reports of 42 mentally ill patients in Madhya Pradesh being enrolled in a trial held between 2008 and 2010 for testing the efficacy of dapoxetine in curing premature ejaculation highlights the scant regard for ethics. Mentally ill patients can be enrolled only in trials involving drugs that would directly benefit them or reduce the harm they cause to society. In fact, around 230 such patients were enrolled in several trials that do not benefit them. Cases of patients becoming a part of a study without knowing it, and of children being enrolled without obtaining informed consent from parents, have also been reported from the State. It will not be wrong to assume that in other trials the poor, unlettered parents who had signed the informed consent form — the most sacrosanct document of a trial — were ignorant or misled and misinformed of the contents. Individuals subjected to multiple trials, and principal investigators being involved in many studies have also been reported from Madhya Pradesh. The situation may be the same in other States as well. The 2010 expose of human *papilloma* virus (HPV) vaccine trials conducted without proper consent on nearly 23,500 girls in the 10-14 age group in Vadodara, Gujarat and Khammam district of Andhra Pradesh is a case in hand.

It is essential that the Central and State governments put a quick end to this sordid state of affairs. Ensuring the safety of patients is paramount as more than 1,700 persons have died in clinical trials across the country between 2007 and 2010. Doctors go scot-free despite failing to follow up serious adverse events, including deaths. Having amended the patent laws in 2005 to make India an even more attractive destination for trials, the government is duty-bound to put in place a proper regulatory and monitoring mechanism that would prevent unethical trials from being initiated and flagrant violations from taking place. Doctors and companies earning handsome profits by throwing ethics and procedures to the winds and turning vulnerable people into guinea pigs will then, hopefully, become a thing of the past.

Comments:

Fake doctors , forged medical degrees, spurious drugs, unethical drug and human clinical trials- the horrors the vulnerable section of people is sbjected to go unending. The other day, I heard a Chief Medical Superintendent shouting at the ward of an old woman to take the latter away, asking him what difference it makes if the hag succumbs or survives. This is the state of medical ethics that prevails in our country. As for your reminder to the government that it is duty-bound to keep in place a proper mechanism to prevent unethical medical practices is only a figment of imagination. For, the government itself favours and paves the way for such atrocious acts and misdemeanours. May "The Father of Medicine" forgive the violators, who take the sacred oath on him, for their venal and criminal transgression of the sanctiy of medical sciences!

from: N. Sadasivan Pillai
Posted on: Feb 10, 2012 at 09:18 IST

Clinical trials form a very important phase in the assessment of a drug before it is marketed to know the safety profile like side effects ,contra indications, drug interactions etc. These drug trials have necessarily to be conducted on human volunteers only. While agreeing with your editorial that these trials need strict supervision and control, equating these to actual treatment is erroneous. The volunteers have to be carefully selected, properly informed consent has to be taken and their health monitored and the effects of the drug including adverse reactions are to be recorded. These drug trials are multi centered including as many variants as possible to give a wider safety margin for the drug. These volunteers have to be compensated adequately and looked after well. Now a days not any hospital or doctor can get into the clinical trials programme. There are strict guidelines as to who can participate ,methodology, ethical and medico legal issues from the Medical Council of India, ICMR, Drug Enforcement authority of India. Similarly the investigator as well as the participating institute and the firm initiating the trials are lawfully bound including penal clauses. However, like all things, investigating the essential aspect of monitoring, detection of violations and enforcing the regulations have taken a back seat in the presence of a powerful Drug lobby. Till now we have been dependant on US FDA to do this dirty work and utilizing the benefits of the safe medicines. The drug trials do not end there. The drugs should be continuously monitored for any adverse drug reactions and these are recorded in a registry which is accessible to the Medical practitioners in the western and developed countries. This knowledge is essential for the safe prescription of the drugs . A number of new molecules are being introduced on the basis of US FDA approval without any way of assessing the efficacy and safety of these drugs in Indian population. Hence in the absence of such vital information your comment of" Doctors going scot free" is very uncharitable for an Indian Doctor who has to rely on literature supplied by the Medical companies very often.
Past National Vice President, Member , Pharmaco vigilance and Adverse Drug Reactions Cell, Indian Medical Association.

from: Dr.L.V.RaghavaRao
Posted on: Feb 10, 2012 at 15:43 IST

I could feel the pain while reading this article. The so called civilized people are doing these tests at the cost of poor peoples lives leaving the ethics aside. It is the prime duty of the Government to legislate an Act immediately and implement it. Poor people would not even know what these tests are though they are informed about it - what they see is immediate money. This is what the fate of our country. Unless a very stubborn rule is imposed immediately, I think we are indirectly allowing them to continue with these trials. It's so pathetic and hope that the rulers are listening.

from: Satyanarayana Maddi
Posted on: Feb 10, 2012 at 18:17 IST

Absolutely agree the way health practices are carried out in our democratic society is deteriorating day by day. It feels me sad and sorry for the state. Today i visited a well known hospital in Mumbai to my amaze i found Hospital Administration has clearly mentioned that Patients with communicable diseases and with burnt cases are not admitted . Though it is a well known Private hospital. They have every right whom to admit and whom not to admit but my question is if any vehicle caughts fire near to the hospital and if passengers get severely burnt injuries then how the hospital staff will respond in such kind of scenario. Since my childhood i have learnt after GOD it is the Doctor who saves a life of a person. Today Medical practitioners have ruined their reputation themselves. Super speicality Hospitals have become five or seven star hotels Privatisation has helped medical practices to reach in such sorry state. Rules are required so that any patient can get treatement.

from: Vikas
Posted on: Feb 10, 2012 at 18:50 IST

This is yet another marker of the rot that has set into the Indian Society in general.No field or section has been left untouched as everyone comes from the same society.Every field,every profession is corrupt as India is at this point of time,truly a corrupting society. And what is ironically hilarious is the self righteousness with which people curse those of some field whose misdeeds are brought into focus.
In the times of paid news and editorials,one should esp in the context of clinical trials should try to determine who all are responsible for such dastardly acts of commission and omission. For starters,one should try to know who all comprise a standard "Ethics Committee" for clearing medical trials in India.

from: Kunal