Indians sitting ducks as drug trials turn fatal

In last 4 yrs, 1,725 persons have died in clinical trials; weak law compounds risks

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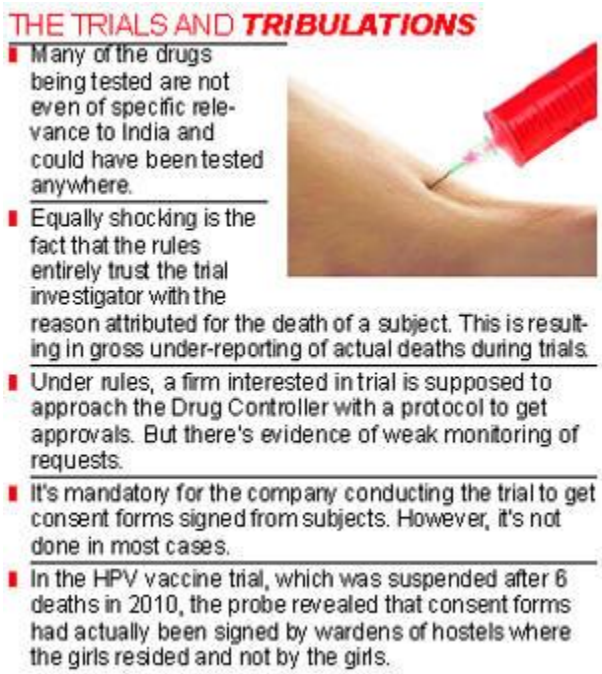
For the first time since 2010 when six tribal girls from Gujarat and Andhra Pradesh involved in the clinical trials of anti-cervical cancer HPV vaccine died, the government has admitted that 1,725 persons have lost their lives to drug trials in the last four years.

The number of deaths has risen from 132 in 2007 and 288 in 2008 to 637 in 2009 and 668 last year, indicating the complete ineffectiveness of regulatory controls over the $400 million sector. Last year, the government gave compensation in just 22 cases out of the 668 that resulted in deaths due to "serious adverse events" during drug trials, Health Minister Ghulam Nabi Azad told Parliament this week.

Currently, 1,868 clinical trials are going on as per the Clinical Trial Registry of India maintained by the office of the Drug Controller General of India (DCGI). Many of the drugs being tested are not even of specific relevance to the country and could have been tested anywhere. Equally shocking is the fact that the rules, under the Drugs and Cosmetics Act, entirely trust the trial investigator with the reason attributed for the death of a subject. This is resulting in gross under-reporting of actual deaths during clinical trials.



Dr Chandra Gulhati, a leading medical practitioner, who led several clinical trials in the UK, says the number of deaths would be much more than we will ever know. "We have no system of independent auditors to investigate the cause of death of subjects involved in clinical trials. Whatever the investigator says is believed even if he attributes the death to a prior disease. Such investigators are always hired by the firm conducting the trial. How can we expect them to be objective all the time?", he asks.

Under the rules, a company interested in trial is supposed to approach the Drug Controller with a protocol to get approvals. But there has been evidence of weak monitoring of requests. “I just investigated a case where 800 pages of protocol were submitted to the DCGI for approval. The permission was granted in four days whereas even a clinician like me would require at least a month to understand the whole project. Clearly, people in the DCGI office are not vetting the requests properly,” said Gulhati, who is now investigating the cause of 81 deaths due to recent clinical trials in Indore.

The rules further mandate the company conducting the trial to get consent forms signed from subjects. The idea is to have safeguards but it’s not working. In the HPV vaccine trial which was suspended after 6 deaths last year, the government inquiry concluded that consent forms had actually been signed by wardens of hostels where the girls resided and not by the girls themselves. In both Gujarat and Andhra, over 22 pc of the vaccinated girls were tribals even though our law bar trials on tribals unless the drug being tested is of specific benefit to them.

Dr Amit Sengupta, who helped expose loopholes in the HPV trial conducted by the US NGO PATH, says India must drastically reduce the number of trials happening here. “Why should we allow trials of drugs for medical conditions that prevail elsewhere in the world? Trials for diarrhoea, malaria etc are understandable, but why should foreign firms come to us to test anti-cancer drugs? Cancer is prevalent in their countries also. Let them test there,” he says. The reason is: since the cost of testing in India is 80 per cent less than in the developed world, firms come here. Experts, meanwhile, also want the DCGI to frame rules to specify that trials will be allowed only in cases where the firm in question undertakes to make the drug available to Indians at affordable prices.

Promoters of the HPV vaccine trial for instance wanted the vaccine included under India’s Universal Immunisation Programme even though it costs Rs 9000 per eligible girl (age 9 to 15 years). Vaccines for trial came free of cost from pharma giants GSK and MSD. Considering 1.25 crore girls enter the age group 9 to 15 years annually, the promoters could have made Rs 11, 250 crore per year had the government accepted public distribution of the HPV vaccine.