

Information ... the lower the dose, the greater the risk of side effects

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A news story in *Times of India* on 18 August 2008, '49 babies die during clinical trials at AIIMS', based on certain information disclosed under the Right to Information (RTI) Act, created a lot of furor over the propriety of the premier health care institution in India, the All India Institute of Medical Sciences (AIIMS). The health ministry ordered a high-level inquiry into the alleged death of 49 infants during clinical trials.

It seems the Public Information Officer (PIO) in AIIMS, released partial information which shows the AIIMS in poor light. This is a classic example which establishes the principle: *Before answering technical questions, PIO should be careful and disclose 'whole truth', not 'mere truth'.*

S/he should have taken some more care and supplemented her answers with adequate explanation and information; many experts have felt that the disclosure was inadequate to reach a conclusion. A public authority should present complete data instead of just filling in blanks on an application submitted by a requester. All disclosures should be uploaded on public internet site to avoid any possible misrepresentation of facts.

Transparency benefits all. RTI Act can be used to foster transparency in medical procedures. Following example shows that it is not that simple:

Irving Kirsch, from the University of Hull, under the U.S. Freedom of Information Act requested from the U.S. Food and Drug Administration (FDA) information about the clinical trials for efficacy conducted for marketing approval of most widely prescribed antidepressants approved between 1987 and 1999.

Irving used 'meta-analysis' that combines the results of several studies that address a set of related research hypotheses¹, to put together data from all the trials submitted to the FDA for four drugs: fluoxetine, venlafaxine, nefazodone, and paroxetine and found that the improvement in depression amongst patients receiving the trial drug, as compared to those receiving placebo (dummy tablets), was not clinically significant in most patients who suffer from mild or very severe depression.²

Everyone knows that clinical trial involves risk; it is very important the participant knows it. 'Informed Consent' of the participant (here, the parents) is as critical as the medicine itself. The Indian Medical Council (Professional conduct, Etiquette

and Ethics) Regulations, 2002 Regulation 7.22 requires adherence to Indian Council of Medical Research (ICMR) guidelines while conducting clinical trials.

ICMR published *Ethical Guidelines for Biomedical Research on Human Participants* in 2006, which provide guidelines on the information to be disclosed to the participants as well as media which, amongst other things, prescribe that the *investigator must provide the individual with the information in the language she or he is able to understand which should not only be scientifically accurate but should also be sensitive/ adaptive to their social and cultural context.*

Adequate information about the research is to be given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant/ Patient Information Sheet.³ Had the AIIMS followed ICMR guidelines, it would have easily avoided the controversy. The big question is: 'Had they?'



In addition, the National Institute of Medical Statistics (earlier called Institute for Research in Medical Statistics), established by the ICMR, has created the Clinical Trials Registry - India (CTRI), a free and searchable on-line register of all clinical trials being conducted in India. To register clinical trials, a 'data set' should be declared before the enrollment of the first patient in the clinical trial. Information of all clinical trials is publicly available for the first time, which ensures 'transparency, accountability and accessibility of clinical trials and their results' and 'promotes greater trust and public confidence in clinical research'.⁴

According to the Drugs and Cosmetics (Amendment) Bill, 2007, which is now under consideration of the Parliamentary standing committee, "Central Drugs Authority" will be constituted to, among other things, grant permission for conduct of clinical trials in respect of drugs and cosmetics and recommend to the Central Government measures to regulate clinical trials. The Bill prescribes stringent measures for regulating the conduct of clinical trials: Persons conducting clinical trials without such permission shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

Another important aspect is the absence of level playing field as far as the RTI Act is concerned. Medical negligence in private hospitals kills thousands of patients in India, which are not covered by the RTI Act. Records are not properly maintained and it is very difficult to access such records, if maintained; even though required by the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002. National Consumer Disputes Redressal Commission had to warn, "[w]e may also observe that in cases of non-supply of the relevant documents, adverse inference could possibly be drawn with regard to deficiency in service".⁵

Does the RTI Act put Government hospitals at disadvantage? Does it allow targeted exposure by the media to focus only on the bad things and letting people to forget millions of good things about them? For citizens worried about the well-being of the Government health care institutions, this is a great cause for concern!

Endnotes:

1. To know more about the method visit < <http://en.wikipedia.org/wiki/Meta-analysis> >
2. *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, Kirsch I, Deacon BJ, Huedo-Medina TB, Scoboria A, Moore TJ, et al. PLoS Medicine Vol. 5, No. 2, e45 doi:10.1371/journal.pmed.0050045; *Who benefits from antidepressants?*, <http://www.eurekalert.org/pub_releases/2008-02/plos-wbf022008.php>; Sarah Hiddleston, *Clinical trials and the right to information*, <<http://www.thehindu.com/2008/03/25/stories/2008032554891100.htm>>
3. Full text of the Guidelines is available at <<http://www.icmr.nic.in/guidelines.htm>>
4. < http://www.ctri.in:8080/Clinicaltrials/trials_jsp/index.jsp>
5. *S.R.Shivaprakash v M/s. Wockhardt Hospital Limited*, [NCDRC-OP No.208 of 1993,4 Oct.2005]