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PMO plea ignored: Rotavirus vaccine trial results must be made public immediately

By OUR CORRESPONDENT

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The trial of the Rotavirus vaccine (called the 116E vaccine) in Vellore, Tamil Nadu, by the Christian Medical College, Vellore, and the Department of Biotechnology of the Government of India, has raised doubts about "ethical standards" in clinical trials. One is reminded of the Tuskegee experiment 40 years ago when black Americans were studied for progression of syphilis, without treatment and without their knowledge.

Imagine a trial involving six-week-old infants. Their parents trustingly allow their babies to be experimented on. The trial shows serious, statistically significant increase in risk of a potentially fatal complication. The sponsors of the study refuse to disclose the study results and want to continue to use the drug without informing other volunteering parents of the risks that the trial has already shown.

Clinical trials are done on human volunteers who participate from altruistic motivations in what could be a dangerous enterprise. Prior informed consent must be obtained after full disclosure of the risks involved. If during the trial, it shows up unacceptable risks, the trial must be stopped.

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The 116E Rotavirus vaccine was tested in three centers -- Delhi, Pune and Vellore. A dreaded complication of this vaccine is intussusception, where the intestine telescopes into itself and there is a risk of gangrene and death. However, the trial doctors have so far refused to disclose the figures from Vellore, of how many babies developed clinical evidence of intussusceptions among the vaccinated and how many did so among the patients who received the placebo – a dummy drug given for comparison. A call for disclosure of this data was published in the peer reviewed medical journal *Vaccine*, but the researchers are playing deaf.

Another Rota-vaccine called Rotasheild used to be marketed in the USA, but had to be withdrawn because of intussusceptions. According to data published, the number of intussusceptions with the new 116E vaccine is 5-10 times higher than the vaccine that is banned. The number of intussusceptions in Vellore was particularly high, 20 times higher in Vellore than in Delhi. This suggests there is perhaps regional susceptibility to this complication.

The vaccine was given to 1,000 infants in Vellore and another 500 served as “controls”. The authors claim that the sample size in Vellore was not adequate to look for rare adverse events. Experts in medical statistics, however, point out that this is disingenuous. If adverse events are 10 times more frequent with the new 116 E vaccine, it is inevitable that statistical significance will be demonstrated in a smaller sample.

The World Health Organization (WHO) has strongly advocated for public disclosure of all clinical trial results. According to the “WHO statement on Public Disclosure of Clinical Trial Results” released on 14 April 2015, when data is not released, it means that the doctors, patients and medical regulators cannot make informed decisions about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed.

Without disclosing this data, there is a plan to do a study of the same vaccine on 100,000 more children exposing them to this risk without their knowledge. This violates the basic rules of ethical clinical research. The data on adverse events in Vellore has not even been shared with the Government’s advisory body -- the National Technical Advisory Group on Immunization (NTAGI) -- despite repeated requests.

More tellingly, the Prime Minister’s Office (PMO) has requested analysis of the segregated Vellore data, twice, but it has been denied. In response to the reference (PMO No. 4219998/2015, dated 22.06.15) made to the “Subjects Experts Committee (SEC)” asking it to examine the Vellore data, the minutes of the SEC meeting of 30 June 2015 merely state that they did not find the concerns of non-disclosure of safety data from Vellore well authenticated. On being asked a second time to look at the segregated Vellore data, the minutes of the SEC meeting of 29 July 2015 states: “Further review of data with respect to the site at Vellore with regard to intussusceptions may (be) under-taken, if required, based on observations of the Hon’ble High Court of Delhi”. Thus, it appears that the SEC will take instructions only from the High Court and not the PMO in this matter. Under the Right to Information Act 2005, this data, acquired with Gol funding, must be supplied on request to any citizen of the country. It is this information that has been denied to the PMO.

According to an article published in newspaper *DNA* by Supreme Court lawyer Neha Rathi, the Ministry of Health and Family Welfare has told the Delhi High Court that “site specific data on safety is inappropriate for release as per protocol and its inappropriate interpretation or publication would lead to disinformation about the product (that has been) developed by government with great effort and expense, and will give unfair advantage to multinational products which were never tested in India, (and) yet (were) licenced.” In other words, the safety data is not being disclosed to enable the vaccine to be sold and the costs incurred in the trial to be recovered.

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It may be noted that the patent of this so called “Indian vaccine” (Patent: (G9P11) US 5773009 A) is held by the US Department of Health and Human Services and so they are to profit from its sales.

One wonders if this explains the impunity with which the PMO and the interests of the country’s children are being disregarded.

(The author is a member of the National Technical Advisory Group on Immunization. The views are his own.)