

ethical principles of respect for the individual and justice, and also for the programme's success. The most effective incentive for a health worker to report each case of AFP is the visible result of such reporting. If each case is treated with care and competence, which health worker will not report the next case? The families of all children identified with AFP (from the time surveillance was established in 1997) must be offered domiciliary counseling about their right to rehabilitative treatment.

The interventions for eradication consist of routine immunisation for the 'herd effect' (to reduce the incidence of polio) and pulse immunisation specifically to interrupt transmission. For the former purpose, though the Indian Academy of Paediatrics' stipulation of a five-dose primary immunisation appears to be the bare minimum for reasonable personal protection in India as long as virus circulation is unabated, only three doses of OPV are given in the government's UIP schedule.

A number of children are reported to have developed polio in spite of taking three doses of OPV. Beneficence and justice demand that such children (and their families) be compensated for the 'defective service they received. From 1997, as virological data are available, every child who developed polio despite participation in the immunisation programme, no matter how many doses were taken, must be compensated. Even if the illness is not polio, treatment and rehabilitation are essential.

Finally, current virological investigations are already detecting children with polio caused by vaccine viruses. Generally speaking, a rate of one vaccine-associated case of paralytic polio is expected per 500,000 infants given the first dose of OPV. Thus, among the over 25 million first-dose recipients annually in our country, we may anticipate over 50 such cases every year. Every child who has vaccine-induced polio must be compensated with an enhanced

quantum compared to the child who develops polio due to wild virus despite immunisation as a result of the vaccine's failure. Vaccine failure is due to deficient services. Vaccine paralysis, on the other hand, is the direct consequence of participation in the programme and a more serious adverse effect deserving higher compensation. The actual expenditure for compensating victims of adverse events will be only a very small but essential fraction of the total cost of eradication.

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The ICMR's ethical guidelines: no debate?

On September 24, I attended a public debate on a draft consultative document entitled 'Ethical Guidelines on Biomedical Research Involving Human Subjects,' produced by an ICMR-sponsored committee under the chairmanship of Justice MN Venkatachalaiah of the National Human Rights Commission. The public debate was organised for the Southern region by the National Institute of Nutrition and I believe there was a similar one in Mumbai and in Calcutta for the Western and Eastern regions and a Northern regional debate is planned in the next few weeks in Delhi. All these are being minuted and sent back to the committee for finalisation by the end of the year.

There was a sincere attempt by the organisers at NIN to elicit a broader dialogue and among others, various people-oriented, gender issue related and societal related issues were raised.

However, I did feel that the debate was not based on well-informed judgement and often personal prejudices or 'status quo' urges were overshadowing a deeper 'ethical issue' exploring process.

In discussions at length with Dr V. Muthuswamy, Deputy DG and Chief,

Division of Basic Medical Sciences, ICMR, New Delhi, who is member secretary of the Committee and coordinator for the whole process, I noted:

In spite of evidently circulating over 500 copies of the draft guidelines, they (ICMR) had not received the sort of interactive response they had hoped for.

Of the 27-member committee, 19 were Delhi-based bigwigs and though they had five subcommittees (to produce ethical guidelines for Human Genetic Research, Transplantation Research, Clinical Evaluation of Drugs/Diagnostics/Vaccines/Herbals, Epidemiological Research and Assisted Reproductive Technology research) which had a slightly broader representation, the people involved were either retired people or even senior practitioners and, quite surprisingly, mostly Mumbai doctors and seven Delhi ICMR and Ministry of Health and Family Welfare representatives. Do these represent a wide cross section of opinion?

On the whole, the guidelines are comprehensive and based on ethical issues and there are serious attempts to build in controls and checks, but all of you with your extensive experience in interactive dialogue could help 'fine tune' the emerging guidelines and detect those that have slipped in advertently or consciously to justify questionable research. So do not miss the opportunity to write to Dr Vasantha.

The last guidelines of ICMR in 1980 also mentioned the need for ethical committees, informed consent, etc, but was very brief. Eighteen years later, the recent document is definitely more comprehensive and live to the new developments, but there may be a long delay before the next update. So better engage now rather than debate or critique the guidelines later.

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The proposed ICMR guidelines can be viewed at <http://www.healthlibrary.com>