against doctors? The accused doctors' statements and their image carry more weight than those of someone with no medical knowledge. So your chances of winning in a medical council are 'nil'. The (negative) opinion given by a medical council will harm' any legal case that you file, as it carries the verdict of a body of medical experts. So never go to a medical council for justice. You will only lose.

When you go to the legal system the person hearing your case has no medical knowledge. The statements of the accused doctors and the opinion of the medical council carry more weight and form the basis of the verdict.

Many doctors will sympathise with you and even give you an opinion in your favour but will not sign it. An unsigned opinion has no value in law. The doctors will say that signing will cause professional enmity. Why should they damage their reputations for a person who is not related to them?

Those judging medical negligence cases should understand the problems faced by complainants and accept unsigned medical opinions, forwarding them if necessary to a public sector hospital for comment, before deciding the case.

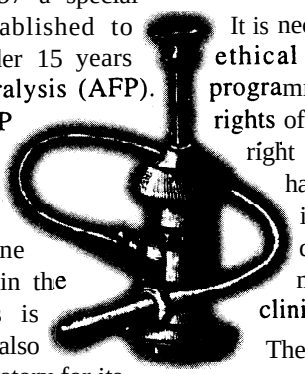
R G Raheja, *Mumbai*

Ethics, human rights and polio eradication

From the time that India became signatory to the 1988 World Health Assembly resolution to commit the World Health Organization and all member nations to eradicate poliomyelitis worldwide by the year 2000, our efforts under the Universal Immunisation Program (UIP) have improved. This is evident from the steady downward trend in the annual reported number of children with polio from 1988.

In December 1995 the Ministry of Health and Family Welfare introduced nationwide annual pulse immunisation in which all children under a specified age are offered two doses of oral polio vaccine (OPV) one month apart. Currently all children under five are encouraged to get two pulse doses each year, irrespective of the number of doses previously taken. This is the main plank of immunisation for interrupting the transmission of natural (wild) polioviruses in the country.

The Ministry has also improved upon the disease reporting system used to monitor the programme's progress and guide immunisation activities. From the last quarter of 1997 a special project has been established to detect all children under 15 years with acute flaccid paralysis (AFP). From each child with AFP two stool samples are collected on consecutive days and sent to one of the nine poliovirus laboratories in the country. If poliovirus is cultured, it is typed and also sent to a reference laboratory for its molecular characterisation: whether wild or vaccine-derived. When no more wild viruses are detected in spite of diligent search, we will know that success has been achieved. If stool specimens were not collected within two weeks of onset of paralysis, but if paralysis persists for more than 60 days, the case is clinically diagnosed as polio. In fact the 60-day follow-up is encouraged for all children with AFP to monitor the concordance between virus isolation and clinical diagnosis.



Health care workersin the public and private sectors are required to report every child with AFP. A highly paid cadre of surveillance medical officers oversees the surveillance and stool collection. Two of the polio laboratories examining stool samples also function as reference laboratories.

Routine immunisation is given free by the public-sector and for a fee by the private sector (the vaccine may be purchased). Pulse immunisation involves the public and private sector health sectors, nongovernmental organisations, local volunteers and other sectors.

The executing agency of the national polio eradication programme is the Ministry of Health and Family Welfare. The participants in this programme are all children under five who receive OPV and all children under 15 who have developed AFP. They (and their parents) participate for the benefit of the entire community, not in order to get treatment for an illness, or purely in their self interest. The time and expenses of travel, and any risk involved in participating in it, are borne by the participants themselves.

It is necessary to acknowledge the ethical obligations of the programme implementors and the rights of participants, including the right to compensation for any harm. The ethical principles involved here are no different from those for medical practice, research or clinical trials.

The basic tenets of ethics are autonomy (respect for the individual), beneficence, nonmaleficence and justice (fairness). By virtue of the fact that some children develop AFP as a consequence of their participation in the programme, it becomes ethically necessary, for the sake of justice, to offer the best possible treatment for the acute condition and rehabilitation as long as is reasonably necessary.

From 1987 to 1993, at the request of the Ministry, the Christian Medical College Hospital, Vellore, established a model project to control polio in the North Arcot District, under the guidance and support of the Indian Council of Medical Research. Every child with AFP was admitted to the hospital for a few days in the acute stage and offered rehabilitation services for two years, at no cost to the family. Transportation expenses and when necessary food expenses were reimbursed.

Under the national polio eradication programme it is imperative that every child with AFP be treated free of cost. This should be done to uphold the

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 Ch[illegible] Division of Basic Medical Sciences, ICMR, New Delhi, who is member secretary of the Commitee 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 [illegible]d at http://www/healthlibary.com