

Death of Children after Measles Vaccination

According to reports in newspapers and television media, 4 infants died on 23 April 2008 within hours of taking measles vaccination in a village outreach clinic in Tiruvallur District in Tamil Nadu(1-4). No official or authenticated information on this issue is available on the websites of the Department of Family Welfare of the Government of India (GoI)(5). No official press release was referred to in any media report(1-4). An investigating committee was appointed by the GoI including the Director General of Health Services and the Director of the National Institute of Communicable Diseases(1-4). The newspapers published statements of State and Central Health Ministers, the State Director of Public Health, a member of the investigating committee and the spokesperson of the vaccine manufacturer—a cacophony of various versions of what happened and their explanations, interpretations and responses(1-4).

The versions included the possible injection of a substance other than measles vaccine, the use of alternate vaccine diluent, ‘dirty’ syringes/needles and anaphylaxis(1-4). The particular batch of measles vaccine, from a particular manufacturer, was incriminated by the officials as responsible for the AEFI(1-3). The responses were to suspend measles vaccination in Tamil Nadu and to suspend the use of that particular batch of measles vaccine or all batches from that manufacturer in other States(1-4). Such was the panic reaction without understanding the problem or application of mind.

The manufacturer’s spokesperson clarified that the facility is pre-qualified by the WHO. Their measles vaccine had passed all quality checks including those of the national testing facility at Kasauli and several batches of vaccine had been used in several States. Even the incriminated batch had been used widely elsewhere, including in Tamil Nadu without event(1-4). This episode exposes two

problems - systemic and specific. The lack of systematic monitoring of AEFI, of its professional management and of accountability to inform the public and health professionals of facts is obvious. The training of village health workers and the supervision of outreach vaccination clinics appear to be grossly inadequate. The incident-specific problem was responded to without collecting facts and details. The devil is indeed in the detail.

According to media reports, 5 infants were ill within about half to one hour after getting measles vaccine in the morning session of an outreach clinic and 3 died(1-4). In the afternoon session two more were similarly affected and one died. The tragic AEFI were thus confined in time to one particular day, which clearly points to a local and limited problem, most probably related to one multi-dose vial of vaccine or perhaps a maximum of two. There was no need or justification to blame all measles vaccine from the manufacturer or even the one particular batch that happened to be in use.

Health workers know that multi-dose DPT vaccine vials can be used over several days within the expiry date. They might not know that DPT vials contain anti-bacterial preservative. Human tendency is similarly to save left-over measles vaccine for later use rather than wasting it. As the vaccine contains live virus it cannot have preservative. The rule for multi-dose vials is to use reconstituted measles vaccine within 4-6 hours and to discard whatever doses are left unused in the vial.

There are two potential problems if reconstituted vaccine is kept longer. The virus content may fall since temperature-stability is low in liquid state—this will affect the efficacy of vaccine. The second problem is bacterial contamination. If contaminated while puncturing the cap the liquid vaccine acts as a rich bacterial culture medium. Some contamination is virtually unavoidable but it goes unrecognized as DPT contains preservative and measles vaccine is not allowed to remain more than 4-6 hours after reconstitution.

If *Staphylococcus aureus* happens to be the contaminant in measles vaccine that was kept for long, it will multiply and secrete several exotoxins. From information available in news reports such a conclusion was the most logical one with immediate relevance as announced in a news report on 25 April(6). If preformed exotoxin is injected, the consequence is shock - as in Toxic Shock Syndrome (TSS)(6). Other contaminating bacteria are not usually life-threatening. It is quite likely that the disease in the 7 affected children was TSS and that all of them were vaccinated from one vial (or at the most 2 vials), reconstituted the previous day(6,7). Instead of examining the sequence of events and picking only the one vial (or the 2 as the case may be) several vials were collected from that batch of vaccines—thus losing the opportunity to establish evidence to pinpoint the cause. Other vials of the same batch may not have been contaminated by *S. aureus*.

Five days after the news report on TSS the investigating committee agreed with that diagnosis, putting to rest all other speculations on the manufacturer, measles vaccine in general and the particular batch used on that day(8). By then much damage had been done to measles vaccination under UIP and the vaccine had already been called “killer measles vaccine” in the media.

That the specific problem was not investigated in detail—as if reconstructing the sequence at the scene of a crime—illustrates the systemic problem of the lack of supervision of outreach immunizations and of routine monitoring and reporting of AEFI. Since just one vial (or possibly 2) was involved in a particular clinic on a particular day, jumping to the conclusion that the whole batch of vaccine was not safe shows the lack of clear thinking in the face of a crisis situation.

It is quite possible that measles vaccine vials had been habitually reconstituted by health workers the day before the vaccination clinics, but this short-cut might not have been detected due to insufficient supervision. On the fateful day the vial probably had *S. aureus*, whereas in the past other less pathogenic microbes might have been injected without serious AEFI. Such measles vaccine vials may have

contributed to increased frequency of AEFI such as pain, fever, local inflammation, abscess etc. and also to lower vaccine efficacy in inducing measles immunity. Routine monitoring of AEFI would have helped identify such practice, if it existed. Routine monitoring of measles and vaccination history of children with measles is essential to detect variations in efficacy of measles vaccines of different batches and manufacturers.

In summary, UIP in India must be strengthened by including surveillance of target-diseases and monitoring of AEFI on a routine and systematic basis. Nothing short is ethically and professionally acceptable for our children.

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