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237 deaths by Pentavalent vaccine and still counting

By JACOB PULIYEL (/author/jacob-puliyel) | NEW DELHI | 13 November, 2016

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Representational photograph

Under Right to Information we know that up to August 2016 there have been 237 deaths reported to the government here within 72 hours of vaccination with Pentavalent. We examined deaths in states which were giving DPT and Pentavalent vaccine concurrently.

There were three deaths following the use of Pentavalent vaccine in Sri Lanka. The Government of Sri Lanka suspended the use of the vaccine. WHO experts investigated the deaths. They found there was a clear temporal association of the deaths to the vaccine (WHO terminology, meaning the deaths followed soon after vaccination) and there was no alternate explanation for the deaths. According to the standard protocol in investigation of vaccine deaths these deaths would have to be declared as “probably” caused by Pentavalent vaccine. The experts balked at the

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prospect of giving such a report. No country would use this vaccine after that. Instead they wrote in their report that they were deleting “probable” and “possible” from the standard classification. The report maintained that although it was probably related to vaccine, they were reporting it as “unlikely” to be related to vaccination.

The full report was not published online, only the conclusion was made public.

The full report was presented to the Delhi High Court in a vaccine case. Once this devious methodology employed by the WHO experts was known, it was exposed by the British Medical Journal.

Following the exposé, the WHO set up a 40-member committee called the CIOMS/WHO committee. 19 of the 40 were representatives of vaccine manufacturers with conflicts of interest. They developed a new algorithm for investigating adverse events after immunization, which decreed that any reaction seen first in Phase 4 trial must be ignored.

When a drug is developed it is tested in a randomised controlled trial called the Phase 3 trial. The numbers tested are limited to a few thousand. If there is no adverse reaction the drug is licensed for Phase 4 trials with it given to a larger number. Reactions that happen less than 1 in 10,000 are noticed for the first time in Phase 4 trials. If the same reaction happens repeatedly it is considered as a “signal” that the reaction is caused by the drug and studies in the community in the form of case-control investigations are done to establish if the reactions happen in the community setting.

According to the CIOMS/WHO classification, if a reaction was not seen in Phase 3 trials and noticed for the first time at the Phase 4 stage, they are simply deleted as “Not a case of [AEFI]”. No cognizance of them is taken. These changes were prompted by repeated deaths with Pentavalent vaccine in Sri Lanka, Bhutan, Pakistan, Vietnam and India

Three deaths in Sri Lanka prompted the government to suspend the use of the vaccine. Under Right to Information we know that up to August 2016 there have been 237 deaths reported to the government here within 72 hours of vaccination with Pentavalent. We examined deaths in states which were giving DPT and Pentavalent vaccine concurrently. We were careful to do this so that comparisons are done in the state only after AEFI surveillance was improved in the state with introduction of Pentavalent vaccine. Deaths with Pentavalent were double that with DPT. It is often said deaths following vaccination are coincidental natural deaths and it is the normal rate of sudden unexplained deaths (SIDS). If all deaths with DPT are natural deaths and that is the standard SIDS rate, then the excess deaths with Pentavalent vaccine must be caused by this vaccine.

The data is available with the government but they have turned a blind eye and continue to roll out the vaccine. The author is a member of the committee set up by the National Technical Advisory Group on Immunization (NTAGI) to examine these deaths more than two years ago. In spite of repeated reminders the committee has not met after the first meeting.

Recently a National Seminar on New Vaccines was held by a number of organizations at NIHF New Delhi. The presentation on how adverse events are misclassified is available on YouTube <https://youtu.be/4aVNKN-dDal> (<https://youtu.be/4aVNKN-dDal>) for those interested in learning more.

So who is to blame for the deaths of these infants of poor illiterate parents who form the majority of our population?

The WHO that altered how adverse reactions are investigated making it more permissive of these deaths, is complicit. As a member of the NTAGI committee who could not get it investigated, I am to blame. The literate readership of this article must also assume responsibility for the deaths of the innocent children.

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