

Intended for healthcare professionals

🗨️Rapid response to:

Analysis

Modernising vaccine surveillance systems to improve detection of rare or poorly defined adverse events

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Rapid Response:

Can the Uppsala Monitoring Centre Evaluate India-Government Data on Deaths with Pentavalent Vaccine to Restore Public Trust

I thank Dr Rebecca Chandler for her response (1) which is alarming as it is illuminating. From her posting, it is clear that deaths and other serious adverse events following immunisation in third world countries using the WHO-AEFI classification (2) are not recorded in any database for pharmacovigilance. It is as if the deaths of children in low (and middle) income countries are of no consequence.

The WHO-AEFI classification is not used by First World countries. In these countries, adverse-event-reports for drugs and vaccines are maintained within a single database and causality assessment is approached in a similar way for all products using systems like the WHO-UMC causality criteria and the Naranjo algorithm.

Chandler's response explains why the numerous deaths after the administration of the Pentavalent vaccine (combined diphtheria, pertussis, tetanus, H influenza b and Hepatitis B vaccine) in India and Asia have not been acknowledged as a possible signal for investigation.

In contrast, narcolepsy caused by the N1H1 vaccine - Pandemrix, was noticed and reported by physicians in Sweden and Finland and the regulators confirmed it, based on reports within their national databases of suspected adverse drug reactions.

Utilising data from the Government of India, we have reported that there are 4.7 additional deaths (95% CI: 3.5-5.9) within 72 hour of immunization, per million vaccinated with Pentavalent vaccine compared to children receiving DPT instead ($P < 0.0001$) (3). Using data from states with good reporting of adverse events, we estimate that there are likely to be 7020-8190 additional deaths each year in the country, because of the

shift from DPT to Pentavalent vaccine. This is a huge mortality burden.

Is there any way in which the Uppsala Monitoring Centre can call up the data from the Government of India (and other Asian countries where the vaccine is used) and confirm or deny a possible causative association? Only such a transparent appraisal can reassure the public and build trust, and only this will reduce vaccine hesitancy.

If not the Uppsala Monitoring Centre, then who? If not now, then when?

References

1. Chandler RE. Re: Modernising vaccine surveillance system to improve detection of rare or poorly defined adverse events. BMJ 2019;365:l2268 <https://www.bmj.com/content/365/bmj.l2268/rr-8>
2. WHO. The Causality assessment of an adverse event following immunization (AEFI): User manual for the revised WHO classification. WHO/HIS/EMP/QSS. March 2013. Available at https://www.who.int/vaccine_safety/publications/aevi_manual.pdf?ua51. Accessed on 1/6/19
3. Puliye J, Kaur J, Puliye A, Sreenivas V. Deaths reported after Pentavalent vaccine compared with death reported after diphtheria-tetanus-pertussis vaccine: An exploratory analysis. Med J DY Patil Vidyapeeth 2018;11:99-105. Available at <http://www.mjdrdypv.org/downloadpdf.asp?issn=2589-8302;year=2018;volume=...> Accessed on 6 July, 2019

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