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Assessment of causality of individual adverse events following immunization (AEFI): a WHO tool for global use.

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Dr Malik, as part of the India Government Ministry of Health, has information on the AEFIs with Pentavalent vaccine and their investigation. I mention individual instances because Dr Malik is familiar with them and it best illustrates the harm done by the new system of AEFI classification.

Of the 54 deaths reported to the Government of India some have been investigated and the AEFI reports are available here

The deaths as described below could well have been caused by 'multisystem generalized reaction to one or more vaccine components' (page 50 of the CIOMS/WHO report). But a case definition for this entity has not been developed as yet by the Brighton group. When such multisystem reactions occur they appear like the multiple organ dysfunction syndrome (MODS) that follow sepsis but it must not be confused with it. The AEFI committee assumes that all MODS are due to due to sepsis or, if it is associated with unconsciousness, it must be meningitis/encephalitis. The new AEFI algorithm seems to promote and propagate this confusion.

1) The manner in which the deaths are declared as unrelated to the vaccine is instructive. The first of these deaths was in a child who was vaccinated at 11 AM. That evening at 5 PM the child had fever for which she was given paracetamol. The baby woke up several times that night crying. She was found dead in her bed next morning. There was blood around the nostrils.

On postmortem examination a large swelling around the injection site 9.8 x 7.9 x 4.7 cm with edema and infiltration involving muscle and subcutaneous tissue was noted. The internal organs including brain, kidneys and lungs were congested. There were petechiae on the surface of the lungs and bilateral adrenal bleeds. The report said the autopsy findings were consistent with death due to hypersensitivity reaction.

The AEFI report however says the death is unlikely to be a programme error or 'due to vaccine associated to the vaccination' (sic)

2) The central team looked at the 15 deaths in Kerala . One death in Pathanamthitta is reported in detail. The healthy 6 week baby was vaccinated on 26 December 2012 at 12 noon. The mother noted swelling of legs and the baby was 'grunting' and reluctant to feed. She was given 4 drops of paracetamol syrup for 'fever and crying' at 5 PM and 2 times on the next day. The

baby was found dead with blood stained discharge from the nose at 4-30 AM on the morning of the 28th. No postmortem examination was performed.

The AEFI report classified this death as "Unknown unclassifiable category" in spite of the fact that the parents are available and gave a detailed history as part of the verbal autopsy.

3) The AEFI report has more interesting details that I quote verbatim: "Temporality of vaccination with death cannot be established as a causal relationship since it may also be possible that in the child had a subclinical infection (therefore no obvious signs and symptoms) and it aggravated in cold conditions, led to Bronchiolitis and death. This may be the reason for death due to pulmonary edema (manifesting as blood from the nose and in some postmortem findings of blood in respiratory tract)."

The cold conditions reported as leading to pulmonary edema and death is intriguing. Kerala has a climate that borders between a tropical savanna climate and a tropical monsoon climate. As a result it does not experience distinct seasons. The mean maximum temperature is 34 °C mean minimum temperature is 21 °C and the lowest temp recorded in December in Thiruvanthapuram was 20 °C..

The death in babies in Kerala who were apparently completely well in the morning when they went for immunization but who became unwell soon after vaccination and deteriorated rapidly to death cannot rationally be attributed to 'subclinical bronchiolitis infection aggravated by cold conditions' leading rapidly to pulmonary edema and death.

Any explanation no matter how outlandish seems adequate but the likelihood of there being a causative association with the vaccination, which is obvious, is not considered.

This is akin to a person found dead under the rubble after a house collapse. The house-insurance-company may refuse to pay the next of kin, saying the house collapse could have been coincidental and cannot be blamed for the death till it is proved that the deceased had not suffered a heart attack just before the house collapsed.

4) 8 deaths in Kashmir were investigated by the AEFI team.

There had been 1 death each in June September and December 2013, but in October there were 11 deaths according to a RTI response (AD/FW/K/RTI/822-24).

Many local newspapers reported the deaths in October were associated with use of a brand of Pentavalent vaccine called Easyfive which vaccine had previously been disqualified because of quality concerns but had just been reintroduced. Easyfive is not being used in the Kashmir Government immunization programme currently.

Like in Kerala, the deaths in Kashmir were attributed blithely to sepsis with metabolic disorder (in Aisha who had convulsions and normal CSF and no blood culture evidence of sepsis),

meningitis (in Mozim based on persistent vomiting, metabolic acidosis, convulsions and crying excessively), pneumonia with aspiration (in Nida with fast breathing and gasping respiration with a family history of sibling death following pneumonia), liver disorder with metabolic acidosis (in Karneez with fever followed by repeated seizures but no CSF examination), sepsis with metabolic acidosis (in Shaistha crying excessively and irritable for 3 days after vaccination, convulsions on the third day, put on ventilator till death on 9th day). It is paradoxical, these diagnoses were reached on the clinical symptoms and laboratory findings of MODS without specific blood culture evidence of sepsis or CSF evidence of meningitis, suggesting the criteria for making these diagnoses are not strict like the algorithm needed to arrive at a diagnosis of death caused by vaccine. No death was attributed to MODS due to 'multisystem generalized reaction to one or more vaccine components'. The most obvious possibility is not even mentioned in the differential diagnosis.

5) The doctors in the Kashmir hospital who noted the sudden increase in cases of deaths in October (11 cases in one month against the previous rate of 1 case in 2 months) sent telephonic text messages to senior government officials in the central government and state government to appraise them of these events but the AEFI team comes down heavily on them for sending these messages "as if to report 'breaking news'". Apparently they were expected not to take notice of these deaths and continue with business as usual and perhaps not to alert anyone.

It seems that after the October spike in incidence of AEFI deaths, the brand of vaccine was changed and the numbers of death have come down but the Government AEFI report does not mention it. It appears that although all brands of the vaccine have been associated with AEFI deaths in different countries, some brands may be particularly lethal.

A good AEFI reporting system must have picked up all these linkages which the new algorithm makes studious efforts to avoid.

Permalink http://www.ncbi.nlm.nih.gov/pubmed/24021304#cm24021304_3490