Minutes of Meeting

Date: 22.04.2013

Venue: Office of Prof S K Panda, Head of Department Pathology (AIIMS)

Participants:

1. Dr N K Arora, Chairman, National AEFI Committee, (INCLEN)
2. Professor S K Panda Head of Deptt, Pathology AIIMS
3. Professor A P Dubey, Head of Deptt, Pediatrics, MAMC
4. Dr. Jyoti Joshi Sr Advisor AEFI, PHFI-ITSU
5. Dr Sujeet Jain , AEFI Focal point WHO Country office
6. Dr Jacob Puliyel, Head of Deptt, Pediatrics St Stephens Hospital

Apologized

1. Dr S. Aneja , Head of Deptt, Pediatrics, LHMC
2. Dr M K Agarwal (DC _immunizaton)
3. Dr Ajay Khera, DC(Ch &I) MoHFW

Dr. N K Arora welcomed all to the meeting for the purpose of sharing & discussing the AEFI deaths reported from Tamil Nadu & Kerala and the cumulative experience in AEFI program since Dec 2011.
To provide the context he informed that 2 causality assessment workshops have been conducted since 2011- one in November 2012 and another in February 2013 at Pediatrics Department, Lady Harding Medical College. In addition, MoHFW has established an Immunization Technical Support Unit (ITSU) with Public Health Foundation of India (PHFI) to augment immunization services in the country. He mentioned that as requested by the National AEFI committee, AEFI surveillance program has been strengthened with the establishment of AEFI Secretariat at AEFI unit of ITSU and clinical support to AEFI program will be provided by the Paediatric department, LHMC.

CIRCULATION OF BACKGROUND PAPERS

Background papers were circulated to the group which included, Minutes of the AEFI causality assessment committee held in Feb 2013 and a technical update on the experience post introduction of Pentavalent vaccine in the country.

KEY POINTS OF DISCUSSION

Only reported AEFI deaths were discussed in this meeting and a total of 14 deaths had been reported from Kerala in the period from Dec 2011 to March 2013.

1. The deaths were sporadic from different parts of the state, there was no clustering and adverse events have not been reported from other children who have received the vaccine from the same vials.
2. Co-morbidities were present in 6 deaths that could have contributed to mortality.
3. The clinical manifestations, age group, season, and time of the death in 8 infants were consistent with presumptive diagnosis of SIDS (Sudden Infant death Syndrome).
4. There was seasonality in death cases with 5 cases in April – October while 9 cases during December – February (cooler months).
5. Since post mortem tissue was available for 3 of the 4 cases, the committee had requested Dr Panda to review the available specimens. The Post Mortem review had suggested that death was probably

due to vasogenic shock the cause of which cannot be determined with the currently available evidence.

6. In view of the uncertainties surrounding the deaths reported from the field, MoHFW is planning to commission special studies such as self- controlled case series study to review infant deaths to assess the possible unmasking of infant deaths due to Sudden Infant Death Syndrome (SIDS) and other coincidental causes of death in state like Kerala and Tamil Nadu with low Infant Mortality Rate (IMR), where trainings for AEFI surveillance may have resulted in higher reporting rates too.
7. During the meeting, AEFI secretariat presented data regarding vaccine doses given till date in Kerala and Tamil Nadu. However, the no of doses mentioned in the document were 400,000 which all members felt that needed to be cross checked from official records. [On review from the records, it was found that 27.72 lakh doses of pentavalent vaccine have been distributed in the Kerala from Dec 2011 to March 2013 and 14 Deaths have been reported during this period].
8. It was also suggested that the since the manufacturing process of a combined vaccine like Pentavalent is an extremely sensitive process, it is important to know the exact content and process followed in its current manufacturing sites.

RECOMMENDATIONS

The group deliberated over the findings of the causality assessment committee and reviewed summary of causality assessment report of the AEFI deaths reported with pentavalent vaccine in Kerala. Based on the discussion points above, the chair requested that the following required information be collected at the earliest so that the research study may be expedited.

1. The chronology of events with time series of each case from the time of administering the vaccine to onset of first symptoms and the final event (death) to be explicitly presented along with the causality assignment review by the causality committee of the National AEFI Committee may be discussed further including the comorbidities reported.

(Action: MoHFW-AEFI Secretariat)

2. Information regarding the total no. of Pentavalent doses distributed during the specified time period in Kerala state i.e. Dec 2011-March 2013.

(Action: MoHFW)

3. Information on no. of children vaccinated in Kerala during the reported time period of Dec 2011-Mar 2013) and the infant cohort for the same duration so as to make an assessment of the Infant Mortality Rate (IMR) and Post Neonatal Mortality Rate(PNMR) of Kerala..

(Action: Kerala State)

4. The details of the pentavalent vaccine content, manufacturing process (product dossier) may also be requested from the manufacturer through the CDSCO) to determine the exact nature of components and the chemical interactions that may occur in the process of vaccine preparation.

(Action : CDSCO-MoHFW)

It was decided that the required information shall be collected for further discussion.