

## **OP 1: A pilot study of Cohort Event Monitoring in detecting adverse events following immunisation associated with Measles-Mumps-Rubella and live attenuated Japanese Encephalitis (JE) vaccine**

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**Introduction:** Recent changes in the Expanded Programme of Immunisation such as administering Measles Mumps Rubella vaccine (MMR) at 1 year and advancing the live attenuated Japanese Encephalitis (JE) vaccine to 9 months call for suitable post marketing pharmacovigilant techniques to assess their safety as pre-marketing clinical trials are poor predictors of safety. Adverse events following immunisations (AEFI) are the key safety concerns with any vaccines, and they become more important when the vaccines are given during infancy.

**Objectives:** The Objective of this pilot study was to determine the suitability of the Cohort Event Monitoring, (CEM) an active prospective pharmacovigilant technique in detecting AEFI occurring with MMR and JE vaccine in Jaffna District.

**Methods:** Over a period of 3 months in mid 2012, participants were recruited into the cohort after obtaining informed consent at the time of MMR/ JE immunisation from Jaffna and Nallur MOH area clinics. Each participant was followed up for 45 days either by home visits or through telephone interviews on day 1,3,14 and 45. Pre-tested questionnaires were used in obtaining the required data and standard pharmacovigilant tools were used in analysis.

**Results:** Of the 55 (MMR: 19, JE; 36) participants recruited, 52 (93%) were followed up until 45 days: 26 AEFI in 15 (79%) infants and 74 AEFI in 24 (67%) infants were detected, respectively, following MMR and JE vaccines. Except 2 infants who were hospitalized for AEFI following JE vaccine, the remainder were non serious AEFI such as fever, irritability and injection site pain. Logistics and data collection instruments were appropriate for the purpose and cooperation of mothers and support of clinic staff was encouraging.

**Conclusion:** To conclude, CEM is found to be suitable to administer in Jaffna District to detect AEFI following MMR and JE vaccines. Large cohort is required to detect rare serious AEFI following these vaccines