

OP 35: Adverse Events following Live Japanese Encephalitis vaccine (SA14-14-2): Results from interim analysis of Cohort Event Monitoring in Jaffna RDHS area.

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Introduction and Objectives: In Sri Lanka, live Japanese encephalitis (JE) vaccine was introduced in 2009 and its timing was advanced from 1 year to 9 months in 2011. Evidence based vaccine safety data are crucial to ensure sustainability of immunization programmes. Aim of this study was to describe the incidence and types of adverse events (AE) following live JE vaccine given at the age of 9 months.

Methods: This is an interim analysis of ongoing cohort event monitoring (CEM) for AE following live JE vaccine in Jaffna RDHS area. Infants who received live JE vaccine at the age of 9 months were recruited into the cohort over a period of one year in 2012-2013. They were followed up for 45 days by telephone interviews with a check list on days 1, 3, 14, 30, and 45 to monitor for any AE. If deemed necessary, infants were visited at home or hospitals to extract further data. Standard vaccine pharmacovigilance definitions and terminology were used during analysis of data.

Results: Of the 1995 infants recruited, 73% were followed up for 45 days, 88% for 30 days and 95% at least for one day. There were 3835 AEs reported in 1581 infants (79%): Fever (1011), sputum (662), cold (610), cough (415), and vomiting (231) were the frequently reported AEs. 62 (3.1%) were hospitalised: 7 with febrile convulsion. There were no cases of anaphylaxis, allergic purpura or angioedema.

Conclusions: Incidence of serious AE following live JE vaccine is low in this cohort.