

Report

Investigation of deaths and hospitalizations following vaccination during JE campaign during May-June 2015 from Districts Sepahijala, West Tripura and Khowai, Tripura

Introduction

A Japanese Encephalitis campaign was started in three endemic districts of Tripura (Sepahijala, West Tripura and Khowai) from 23rd May 2015. Three deaths and around 68 hospitalizations from 01st June onwards were attributed to the JE campaign. Campaign coverage was affected and on 4th June, 2015, the state requested support from the Immunization Division for investigations. A team was formed for investigation. The team comprised of the following members-

1. **Dr. Prमित Ghosh, Asst. Prof., Department of Community Medicine, Kolkata Government Medical College, Kolkata, West Bengal**
2. **Dr. Sanjib Kr Debbarma, Associate Professor, Department of Paediatrics, AGMC, Agartala, Tripura**
3. **Dr. Madhusudan Chaudhury, SEPIO, Tripura**
4. **Dr. Deepak Polpakara, Programme Manager-AEFI, Immunization Technical Support Unit, PHFI-MOHFW, New Delhi**
5. **Dr. Narender Kumar, Zonal AEFI Consultant, MOHFW, New Delhi.**

The investigations started on 08th June 2015.

Activities undertaken

The list of people met, places visited and activities conducted is given below:

Places visited	Activities
CMO Office	Briefing by CMO on the two death cases reported and status of the JE campaign.
Sub District Hospital,	Interview regarding clinical details of AH when admitted in SDH. Collected relevant clinical records. Obtained opinion of the doctors on other diseases prevalent in the area.
PHC –D	Sequence of events following vaccinations, clinical, personal, family history, health seeking behaviour, community investigation, current health status of more affected cases, etc. Status of cold chain and vaccine storage. Inspection of ILR and DFs, temperature records, vaccine and logistics and daily issue register, microplans, day wise campaign coverage reports.

Village of AH	Administered verbal autopsy form. Collected relevant health records, established sequence of events leading to hospitalisation and death. Interacted with teachers and guardians regarding arrangements for immunization and information regarding JE campaign. Examined other children who received vaccination on the same day and same class as AH. Looked for information regarding other diseases in the village, amongst school children, absenteeism, etc.
CHC- K	Inspected cold chain room for status of vaccine and logistics storage.
PHC –M	Interviewed MOIC and vaccinators for sequence of events related to KD. Cold chain room inspected. Coverage details of campaign.
Village of KD	Administered verbal autopsy form. Collected relevant health records, established sequence of events leading to hospitalisation and death. Interacted with teachers and guardians regarding arrangements for immunization and information regarding JE campaign. Examined other children who received vaccination on the same day and same class as KD. Looked for information regarding other diseases in the village, amongst school children, absenteeism, etc.
CMO office, West Tripura	Briefing regarding death of SD. Collecting relevant information pertaining to the case, campaign coverage.
PHC-M	Sequence of events following vaccinations, clinical, personal, family history, health seeking behaviour, community investigation, current health status of more affected cases, etc. Status of cold chain and vaccine storage. Inspection of ILR and DFs, temperature records, vaccine and logistics and daily issue register, checked microplan.
Village of SD	Administered verbal autopsy form. Collected relevant health records, established sequence of events leading to hospitalisation and death. Examined other children who were vaccinated the same day.
Rural Hospital	Admission records were examined from 5 th may till 10 th June 2015. Case records of all admissions in 1-15 years age group were studied for history of JE vaccination and signs and symptoms similar to Acute Encephalitic Syndrome.
CMO Office, Khowai District Hospital, Khowai	Interviewed CMO, DIO and MS regarding the JE campaign coverage, incidence of AES (JE) and other diseases. Inspected admission and case sheets in District Hospital for communicable disease trends in the district.
Tropical Diseases Hospital, Agartala	Interview to get information of clinical history and

	treatment of KD. Impression of other diseases prevalent in the area.
Department of Paediatrics, Agartala Government Medical College and G B Pant Hospital	Examined other children who had sought medical attention following JE vaccination. Also examined the hospital records of children who were admitted and recovered completely and discharged from the same hospital. Collected hospital records of all cases admitted as AEFIs following JE vaccination.
Department of Paediatrics, Tripura Medical College and Dr B. R. Ambedkar Memorial Hospital	Collected records of AH and KD, other children admitted following JE vaccination. Examined children currently admitted following vaccination during JE campaign.
Indira Gandhi Memorial Hospital	Collected hospital records of two children admitted and discharged post JE vaccination.
ILS Hospital	Examined a child admitted with symptoms of acute encephalitic syndrome and collected hospital records.
IDSP office	Collected information of AES and JE cases of 2014 and 2015 and gathered information regarding disease trends.

Findings:-

Three deaths following JE vaccination were reported in the media on 01st June 2015 from Agartala Government Medical College & G B Pant Hospital, Agartala. Two were from District Sepahijala (from different blocks) and one was from West Tripura. No death cases were reported from the third district (Khowai) which also had a JE campaign. Following these reports linking the deaths with the JE vaccination, many children who had received JE vaccine during the campaign and had fallen sick were brought to the hospitals for admission as the parents thought that the children were affected by the JE vaccination. There was an increase in patients admitted in the paediatric wards after 01st June. Of the 68 hospitalization cases reported from the three districts, 40 (59%) were from West Tripura, 23 (34%) from Sepahijala and 5 (7%) were from Khowai. The JE campaign coverage was severely affected (45-55% coverage) and subsequently it was reported by health workers that less children had come for vaccinations in the regular RI sessions.

INDIVIDUAL CASE HISTORIES

A) AH, 12 years, male, hospitalised, died.

AH was having fever and cold for 2 days prior to the day he was vaccinated with JE vaccine on 23rd May 2015 at school. After a few hours, he developed puffiness of the face and fever increased in the evening. The parents took him to a local doctor who prescribed him some medications for the fever and swelling. Despite the treatment, there was not much improvement over the next two days. He was taken to PHC D on 26th May 2015 where the doctors admitted him overnight for treatment. Next day (27th May), he was referred to Sub Divisional Hospital, where he was seen in the emergency and treated with nebulization and prednisolone tablets and again sent home in the night. Around 8:00 pm, his condition worsened and he was taken to Tripura Medical College & Dr B R Ambedkar Hospital in Agartala. He was admitted there at 10.00 pm on 29th May 2015 with complaints of breathing difficulty, cough and fever. Treatment was started at the hospital. However

the general condition of the child did not improve and gradually deteriorated and next day on 30th May 2015 at about 1.10 pm the child died in the same hospital.

As per the MPW who was vaccinating the children in the school, the child was healthy and was probably afraid of the injection. He was vaccinated around 11:30 am and observed for half an hour in the room where the vaccinations were taking place and was in the school for about two hours after the injection and he did not complain of anything.

Post mortem was not conducted according to the wishes of the parents.

Epidemiological investigation-131 children received JE vaccination in the school on the same day. The following seven children who were vaccinated on 25th May along with AH were examined in the school: Three of these children complained of sore throat and fever. One had stomatitis on examination. Two others had symptoms suggestive of gastrointestinal infection. As viral fever was prevalent during this time of the year, so most of the children complained of fever and sore throat which was not related to vaccination.

Impression: Sepsis with Multi Organ Dysfunction Syndrome

B) SD, 12 years, female, hospitalised, died

According to the father, SD was vaccinated at around 11:00 am on 27th May 2015 at the MCH clinic at PHC- M by an MPW. After vaccination, the child was kept under observation for about half an hour at the PHC after which she was allowed to go home. Her mother accompanied her on the day of vaccination. The same day she went to Agartala as she was studying in a school in Agartala. A few hours later she complained of severe headache and took paracetamol tablet for relief. However the headache persisted. She was admitted in the PHC -M the next day (29th May 2015) for about 5-6 hours and since there was no improvement in her condition, she was referred to Agartala Government Medical College (AGMC) and admitted at around 10:00 pm.

After admission to AGMC & GB Pant Hospital at 10.04 pm on 29th May, she had an episode of seizure with uprolling of eyeballs. Next day on 31st May, at 5.30 pm she had mild frothing in mouth. On examination, patient was semiconscious and drowsy. On 1st June 2015 at 7.15 am, she was discharged from AGMC hospital and air lifted to AMRI Hospital, Kolkata. She was admitted in the ICU on 1st June 2015 at 1.55 pm, where she died at 11.50 pm. The cause of death as stated in the death certificate was multi organ failure due to septic shock.

Verbal Autopsy report: Post mortem was not done. Main respondent for the verbal autopsy form were her parents. Not eating properly was the only significant information given by the respondents.

Epidemiological investigations- Other children vaccinated at the same session site as SD were examined and parents of the children were asked about any adverse events following vaccination. Except for a few cases of fever which may be related to viral etiology, other cases suggestive of acute encephalitis syndrome were not found in the community.

Impression: Viral encephalitis.

C) KD, 10 years, female, hospitalised, died

The child received the vaccination on 25th May in the school. When she came home for lunch, she complained of poor appetite. Later in the day she developed fever and was treated by a local practitioner. On Tuesday (26th May) night, she developed some kind of an allergic reaction with puffiness over the body, but mainly over the face. There was no itching. After treatment by a local practitioner it resolved. On Wednesday (27th May) afternoon, she was feeling feverish. She was treated by Dr. X at PHC- M (private consultation as it was a holiday).

On 28th May, around 06:30 in the morning, the child was admitted in Tripura Medical College. At around 2:30 pm, she was transferred and admitted in Agartala Government Medical College. However her condition did not improve and on Saturday, 1st June, at around 12:05 am, the child died in the hospital.

The child was found negative for JE serology. However, ELISA for **IgM of measles** was detected positive as mentioned in the report of serology tests.

Post mortem report: Post mortem was not done.

Epidemiological investigation – An epidemiological investigation was carried out which included interviewing the parents of other children who were vaccinated, other beneficiary children, teachers, vaccinators and other people from the community. JE vaccination given in school at around 10:00 am on 25th May 2015. Around 161 students were present that day. 84 students received vaccines on that day from the school, 42 students/guardians told that they received/would receive from other center and 35 students left or refused vaccination.

Discussion with class teacher and classmates helped in identification of 3 fellow students, who received vaccine from the same vial and were present on the day of team's visit. All these girls were healthy. Few children from other classes who received vaccination on the same day were also examined and found to be generally healthy except for some cases of fever and cold. This can be attributed to the prevalent viral infections during the months of May -June in this region due to hot and humid conditions before the onset of the monsoons.

Impression: Acute Encephalitic Syndrome

3. Observations of injection safety and cold chain management

The cold chain points at PHC D, CHC M, PHC M and CHC K were assessed and found to be generally of good quality with proper storage practises and maintenance of stock registers. Adequate syringes were present. The temperature of the ILR and Deep freezers were within normal limits. Details of day wise immunisation and information about beneficiaries was present at the cold chain sites. Maintenance of cold chain equipment was satisfactory. Vaccines were being transported to session sites using vaccine carriers. However, in CHC K, improvement is needed to improve storage practises of vaccines and documentation of stock monitoring. No frozen vaccines or vaccines with VVM in unusable stage were not found in any of the cold chain points.

In addition to the three death cases, there were 68 hospitalizations following JE vaccinations. Most of these were admitted for observation and then discharged.

1. Epidemiological investigation in district Khowai

Khowai is one of the three districts in which JE campaign was being conducted. However, it was also the district from which no deaths were reported and also the hospitalizations were very less (five out of 68). The district was visited to find out the reason why cases were not reported and to look for cases which may have been admitted and were not being reported by the district.

There are two government and no private hospitals in the district. All children and adults go to either of these two hospitals or they go to Agartala (AGMC/TMC/IGMC/ILS).

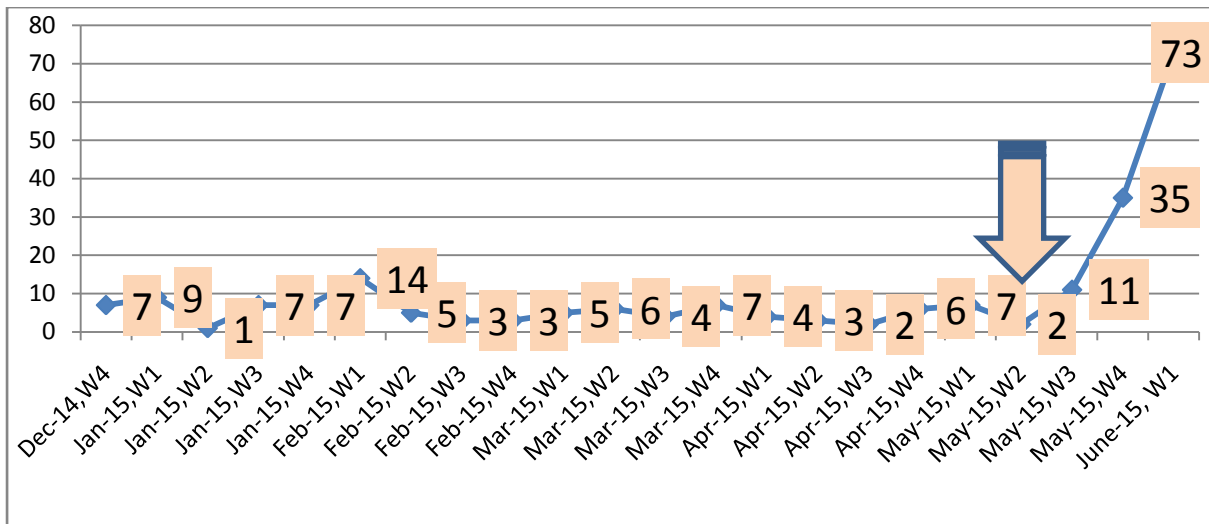
All admissions of children between 1 and 15 years age group between 05th May and 10th June in both hospitals for signs and symptoms of AES and were vaccinated were studied. No cases with convulsion or altered sensorium were found. The reason why such cases were not found as explained by the medical officers were that such cases are very less and even if they come they are immediately referred to Agartala as these cannot be managed in the hospitals in the district. Most of the cases were found to be due to malaria and acute GI upset. Very few cases of viral fevers were found in both districts. It appears Khowai district is having a better routine immunization coverage with proactive local officers and supervisors. The frontline workers are also having good liaison with local community. Better IPC and stringent screening of eligible vaccine –recipients probably resulted in lesser number of serious AEFI. The only visible banner related to JE campaign was displayed in a major crossing of the city indicating better communication plan.

6. Incidence of AES and JE in Tripura (IDSP)

On the basis of interviews with PHC and hospitals and quick assessment of causes of hospitalization in West Tripura, Sepahijala and Khowai, it emerged that there were predominantly cases of AES, viral fevers and acute gastroenteritis in West Tripura and Sepahijala. District Khowai had predominantly cases of Malaria (around 90% falciparum and rest vivax) and AGE. Viral fevers and AES were not being reported.

Information from Integrated Disease Surveillance Project office received on 10th June, reveal that a total of 221 cases of AES was reported from Tripura in 2015. Week-wise break up shows an upsurge in reporting of AES cases in Week 3 and 4 of May 2015 (11 and 35 cases respectively). In the first week of June alone 73 AES cases were reported.

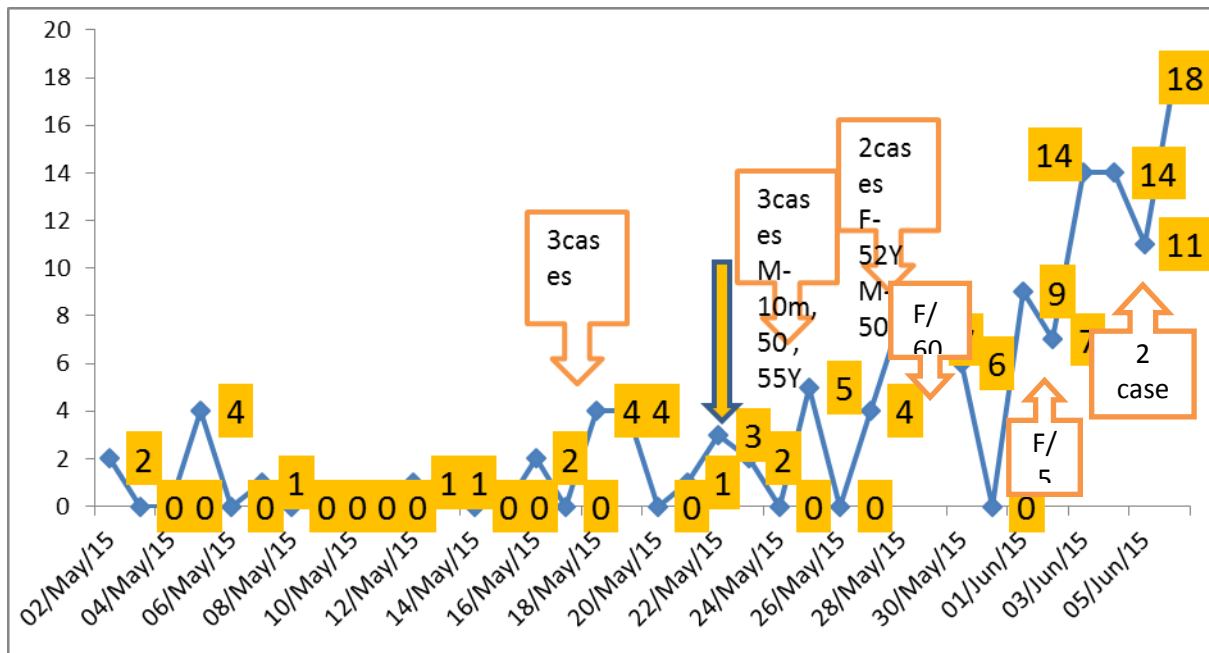
Week-wise reporting of AES cases from Tripura (2015) – IDPS, Tripura



Of these 221 AES cases, majority (102) were reported from West Tripura, followed by Sepahijala, Khowai, Gomati and South.

In 2015, 14 JE cases were also reported from these districts with most cases being reported from West Tripura (6) followed by South (3) and 2 each from Sepahijala and Gomati and one from Khowai.

As per information available with the IDSP office of the 14 JE cases, the first three were reported on 18th May 2015, three more on 24th May, two on 28th May and one on 29th May. In the first week of June, 5 cases were reported.



Majority of the reported cases were adults (71.4%).

Period: 24 Dec-14 to 6-June-2015

District	AES	No. of JE Case	Death	JE-positivity	Mortality
West	102	6	0	5.88%	0.00%
Sepahijala	34	2	1	5.88%	50.00%
Khowai	27	1	0	3.70%	0.00%
Gomati	24	2	1	8.33%	50.00%
South	19	3	1	15.79%	33.33%
Unokati	4	0	0	0.00%	
Dhalai	9	0	0	0.00%	
Others	2	0	0	0.00%	
Total	221	14	3	6.33%	21.43%

2. Discussions

1. The JE campaign started on 23rd May because the schools were closed for summer vacations till 22nd May. On 23rd May, JE vaccinations were being given only in PHCs, MCH clinics and Anganwari Centres, since schools were being informed on 23rd May regarding the campaign. Coverage was high in all three districts from 25th May to 31st May. On 1st June, it was reported in the newspapers and media that there were deaths following JE vaccination. From 02nd June onwards, coverage in the JE campaign fell drastically till end of campaign on 05th June.
2. Probable cause of death for AH was Sepsis with MODS, SD- ?Viral meningitis and KD – AES. Post mortem and CSF were not done in the three cases.
3. Five of the 68 hospitalised cases were AES. Other cases were coincidental. These were reported as the parents were worried that the children were sick due to the vaccine. Further, doctors at the Medical Colleges and State Hospital were asked to admit for observation and then discharged in healthy condition.
4. As per the IDSP data, an increase in AES cases was reported in the 3rd and 4th week of May. The first JE cases were also reported in the middle of May 2015. The JE campaign coincided with an increase in incidence of AES, JE and viral fevers.