Report

Two deaths reported following vaccination with BCG, OPV and Pentavalent in January-February, 2016 from District Nalanda, Bihar

1. Introduction:

A request was received on 26 February 2016 from the State EPI Officer, Bihar to investigate AEFI cases reported following pentavalent vaccine in the last two months. A team was constituted by MOHFW on 01st March 2016 and the team investigated the cases on 4th March 2016.The team comprised of

1. ***Professor A P Dubey, Department of Paediatrics, Maulana Azad Medical College, New Delhi.***
2. ***Mr Raj Shekhar, Drug Inspector, CDSCO, East Zone, Kolkata;***
3. ***Dr Narender Kumar, Zonal AEFI Consultant-East, MOHFW***
4. ***Dr Deepak Polpakara, Associate Advisor-AEFI, AEFI Secretariat, ITSU***.

Only one serious AEFI case was received by the MOHFW in January - February 2016 from Nalanda. The CRF and other details of the second case was received at the time of the visit.

2. Activities undertaken

The following activities were conducted on 04th March 2016 during the investigations:

Places visited	**Activities**
State Health Society Office, Patna	Introduction of team, plan of activities, collection of AEFI surveillance information
Civil Surgeon Office, Nalanda	Briefing on two reported AEFI death cases – one in last week of January and other on 12th February 2016.
PHC S	Assessing status of cold chain and vaccine storage- inspection of ILRs and DFs, temperature records, vaccine and logistics and daily issue register and interview of cold chain handler. Interview with ANM and MO to ascertain sequence of events, etc.
Village BS(Child M)	Interviewed parents of child M and administered verbal autopsy form. Interviewed AW worker and ASHA. Examined other children who received vaccination on the same day. Visit to local village and spoke to various people, including parents of other children vaccinated in the second AW Centre.
Village D(Child B)	Administered verbal autopsy form. Collected relevant health records, established sequence of events leading to death. Examined other children who received vaccination on the same day and same site. Looked for information regarding other diseases in the village.
PHC R	Inspected cold chain room for status of vaccine and logistics storage. Interviewed ANM about the vaccination and sequence of events related to child B.

Case Summary-Child M

2 months old child was administered BCG, Pentavalent-1 and OPV-1 on 27th January 2016 at 10.00 am at the Anganwadi Centre X, village BS. The child was observed for 20 minutes after vaccination and then taken home. He was alright and was breastfed multiple times during the day. He slept at around 4.30 pm and woke up at 8 pm

The child's birth weight is unknown, but according to the mother he was average in weight, delivered normally, full term at home with no complications during pregnancy or child birth. He was exclusively breast fed since birth. The child did not have any fever, diarrhoea, excessive sweating, stool changes, lethargy, difficulty in breathing, fussiness or excessive crying, poor feeding, vomiting or seizures as per the mother.

In the night before the child was found dead, he was wearing a shirt, sweater and pyjamas and slept with his mother in the cot. He was positioned on his left side touching the surface of the cot, facing the mother who was sleeping with the right side of her body on the surface of the cot. In the morning when the mother woke up at about 5.00 am to breastfeed the child, she found him dead with bleeding from nose and mouth and bluish/blackish discolouration of the left side of the body, soft and spongy to touch. Also as stated by the mother the family used angeethi to warm the room but at 10 pm they removed the angeethi from the room.

The family belongs to the lower socio economic class and lives in a joint family. Both husband and wife are daily wage labourers. They have a 5 year old male child. The family slept in a 10x10 sq. feet room, which is poorly ventilated, cramped with household objects with a charpai. A rajai was being used to protect from the cold.

Post Mortem was done on 28th January 2016 at 12.15 pm at the district hospital.
Cause of death as per post mortem report is – Death caused due to exposure to cold.

Field investigation:

Two vaccination sessions were held in Village BS on 27th January 2016. One was in Anganwadi Centre number X and the other in Anganwadi Centre number Y. The same ANM vaccinated at both sessions – first at AWC X in the morning and then at AWC Y in the afternoon. Separate vaccine carriers were used at both session sites.

Session at AWC X –As per the tally sheet and the ASHA, 5 children were due for vaccinations that day, but only 4 turned up for vaccinations. One of the vaccinated child was examined and was found to be underweight but otherwise healthy. The other two children were examined and found to be healthy.

When the news of the death of the child spread in the village, it was reported that 3-4 children vaccinated at the other AWC No Y had minor AEFIs which were treated by the local village doctor and are now alright. Only one child could be tracked to have complained of a minor AEFI. The AWC worker, ASHA and all people interviewed and spoken to said that the

ANM was a good worker and had no complaints against her regarding immunization activities in the village. In interactions with locals, it was found that there were no outbreaks of any kind in the village in the past three months and almost all children were healthy.

The cold chain equipment were assessed at PHC S. The same cold chain room was shared by PHC and the urban Bihar Sharif but the equipment and vaccine stock was separately maintained. PHC S had a small DF and a large ILR. The vaccines were properly stored and no vaccines in unusable stage were found. The log books had been checked by the MO every 10-15 days. Overall, the cold chain was quite well maintained.

Impression: Cause of death could be 1. SIDS or 2. Accidental asphyxia

Summary-Child B

1.5 months old Child B was vaccinated at 11.00 am on 12/02/2016 at Anganwadi Centre Z under PHC R with OPV -1st dose and Pentavalent-1st dose. As per the parents, the child was taken for vaccination by the mother and the grand-mother, was observed at the session site for 20 minutes after vaccination and then brought home. The child was last breastfed at 3.30 pm and after 10 minutes the child died with bleeding from mouth and nose. As per the mother, the child was apparently healthy before vaccination and did not had any fever, diarrhoea, excessive sweating, stool changes, lethargy, difficulty in breathing, fussiness or excessive crying, poor feeding, vomiting or seizures before or after the vaccination. Post mortem was not done according to the wishes of the parents. Weight of the child was 3.5 kgs on the day of vaccination. The child was the first born child in the family. The family belongs to lower socioeconomic status. The house is semi-pucca type and surroundings were unclean.

Field Investigation-Six other children received vaccination from the same pentavalent vial. Some of these were examined and they were found to be healthy. Interaction with locals did not reveal any outbreak of diseases in the past two months.

The ANM who had vaccinated the children on 12th February was interviewed. She said that she was informed by the ASHA at 4.00pm in the evening about the death of the child. She said that she was being harassed by the family of the deceased. She was accused of ill-behaviour by the family members. The Medical officer said that the family was very agitated about the death.

The cold chain at PHC R was assessed. There were two small ILRs and a large DF. Here also the thermometers were found with loose alcohol column probably causing the temperatures to be recorded above +9 degrees on some days. The large DF seemed to be an ILR converted into a DF. The temperature was -5 at the time of inspection. Stock registers and daily issue registers were properly maintained. Overall, the cold chain and vaccine logistics were adequately maintained.

Impression: Cause of death –1. Inconclusive or 2. SIDS

Conclusions

1. The cause of death in case of Child M seems to be Sudden Infant Death Syndrome (SIDS) or accidental asphyxia.
2. In case of child B, since post mortem was not conducted, cause of death is inconclusive. Post mortem should be encouraged in all death cases.
3. No programmatic error in vaccine storage and administration is evident.
4. Support should be provided to ANMs to restart immunization sessions in both villages through confidence building measures.