

REPORT OF AEFI INVESTIGATION in Palla PHC and at BK Hospital, Faridabad (Haryana State, India) following Pentavalent vaccination (25.04.2013)

Introduction

Background:

An AEFI death following Pentavalent vaccine was reported on 11/4/2013 from Faridabad district of Haryana. A team from the National level was assigned to support the state team in the field investigation. The team comprised of the following:

1. Prof (Dr) Harish Pemde : Faculty Pediatrics, Lady Hardinge Medical College, New Delhi
2. Dr Jyoti Jain: Sr Advisor ITSU-AEFI unit
3. Mr Somnath Basu : Assistant Drug Controller (India), CDSCO, DGHS (GoI)
4. Dr Sujeet Jain : WHO AEFI focal point
5. Dr Amrita Sekhar : RA, ITSU-AEFI unit
6. Dr Suresh Dalpath, SEPIO Haryana

The team conducted a field visit to the District, went to the health facilities and met various officials in context of the AEFI death. The officials met included:

1. CMO Faridabad District
2. Dr Rajesh Chopra, Immunization Officer, Faridabad District
3. Dr Kalpana, Consultant Immunization Haryana state
4. Dr Anurag, Pediatrician FRU
5. Dr Sandhya, Paediatrician, BK Hospital

This report presents activities undertaken by the investigation team, discussions with members of the District AEFI committee other health officials and community investigation. The report concludes with analysis of available information and further suggestions to complete the investigation.

Case Details

Case History (by interview of parent and Bua (sister of the father of Child) using verbal autopsy technique): A male child [REDACTED] (DOB: 23 February, 2013) was vaccinated with the first dose of the recently introduced pentavalent vaccine at outreach session of Palla PHC in Faridabad at 11:30 am on 10 April 2013. The child received the 4th dose from a 10 dose vial and 8 children were vaccinated with the same vial in that session.

Following vaccination the child returned home. He had little oozing of blood from the injection site which was red but otherwise fine. Ice cubes were put on the site and the baby also took feed 3-4 times and slept intermittently though he cried following vaccination. However, at around 5: 00 pm the child started crying persistently and loudly and also developed fever. By 8.00 pm. Crying reached peak and the parents consulted a nearby chemist (?RMP who also advised PCM syrup due to fever post vaccination. The parents note that the injection site had developed a bluish discoloration. However, the fever and crying persisted throughout the night (even till 12.00-1.00 am) and no feed was taken during the night.

By 5.00am the child was grunting (not crying) and parents give history of intermittent tonic seizures with neck tilted to one side (side of injection) and back arched up. Parents note that one eye closed completely and was difficult to open even manually. The movements of one side limbs (same side on which the eye opening was difficult) were less in comparison to the other side limbs. In the morning on 11th April(8.30-9.00am) the child was taken to the First referral unit (FRU) and examined by the

paediatrician there who states that the child had altered sensorium and suffering from seizures (arched back). According to parents the tongue was rolled up as the attempt to administer PCM failed and child was referred to BK Hospital.

History of vaccination was established from the PHC (one relative was asked to verify it from the PHC) and since ambulance was not available the parents brought the baby to BK Hospital themselves. The Bua noted an episode of black coloured vomitus (staining her clothes) in the morning while going to the FRU

At B K Hospital child was examined by 11.30 am by the Paediatrician (Dr. Sandhya) who noted seizures. The parents state that at BK Hospital both the eyes of the child closed and were difficult to open. +. The attending Paediatrician made working diagnosis of ?IC Bleed (intracranial bleed), ?Meningitis, or ?Encephalitis. Child was admitted and treatment started with I/V Glucose, antibiotics, and Phenytoin drip. Investigations by bedside were prescribed but the patient was sent for x-Ray and blood investigations (Bua and parents took the child at 3.00pm but were sent back to come at 3.30 pm, then sent back again to eventually be told to come the next day). The child died at 4:00 pm at BK hospital in spite of all efforts of resuscitation.

SEPIO of Harayana (Dr. Dalpath) requested a team from the centre to assist in the investigation of the case to determine whether the death was linked to the vaccine.

Antenatal history: Uneventful. G2P1 mother with previous 2 and half year daughter, Forthipregnancy ANC care+, Inj TT taken

Birth history :FTNVD at FRU on 23rd Feb 2013, Birth wt is 3.9 kg

Previous history (Prevaccination): No report of any fever/ear discharge/ diarrhoea/ cold/cough

Family History: No H/o TB/HT/DM/Bleeding diathesis

Treatment History: IV fluids, IV ceftriaxone, IV Amikacin, IV phenytoin, IV hydrocortisone and supportive oxygen.

Investigations conducted:

No samples were collected for blood, chest X-ray was done which was normal.

No CSF tests are conducted at the hospital as the post of Pathologist is vacant and family has to agree to take the sample for test outside the hospital

No other samples were collected/conducted.

Post mortem was not done as the body was handed over to the parent who buried the same as per religious rituals

Vaccines used for immunization: LPV and OPV. Batch no.s

Liquid Pentavalent vaccine, 10-doses in 5 ml clear glass vial with grey BB rubber stopper and Aluminium Capping;

Each dose of 0.5 ml vaccine suspension for Intramuscular Injection contains:

- I. Diphtheria Toxoid í í í ..NMT 25 Lf
- II. Tetanus Toxoid í í í NLT 2.5 Lf
- III. B. pertussis (Whole cell) í í í ..NMT 16 OU
- IV. HBsAg (r DNA) í í í í í í ..NLT 10 mcg
- V. Purified Capsular Hib polysaccharide (PRP) conjugated to Tet Toxoid í í í .10 mcg
- VI. Adsorbed on Aluminium Phosphate í í í í í NMT 1.25 mg
- VII. Preservative í í í í í í í í .Thiomersal í í í í í ..0.005 %

This vaccine is licenced to M/s Serum Instt. Of India, Hadapsar, Pune under the Drug Mfg. Licence No. 10 (In Form-28D) of drugs and Cosmetics Act 1940 which was renewed for the period 01/01/2012 to 31/12/2016. The Vaccine is licenced for export / UNICEF/PAHO/WHO etc. (meeting WHO requirements). During investigation it was found that the innermost label of penta-valent vaccine vials has no mention of the Date of manufacture which is mandatory under Rule -96 of Drugs and Cosmetics Rule 1945. The reason for this rule violation is due to the fact that way back on 30/07/1998 this manufacturer obtained one No Objection Certificate from the Drugs Controller (India) that the labelling of Export Consignment may be done without mentioning of manufacturing Date

Other medications given: PCM had been administered at home 2 times

Interview of medical staff:

According to the Paediatrician at the FRU (Dr.Anurag)

She suspected an AEFI and sent the patient to B.K. hospital. Did not perform any first aid. She did not think it was meningitis. Suspected vaccine- induced encephalopathy.

According to her she examined the child at ~ 10:00 am. At this point the child was semi-conscious, vital signs normal, fever present, was not taking feed but there were no visible seizures and the child was crying. According to Dr.Anurag she was not aware of any previous episode of seizures after vaccination. The child was in altered sensorium. Child was not given any treatment at the FRU. Parents took the child to BK hospital. FRU did not send the child in an ambulance

According to the paediatrician at B.K. hospital (Dr.Sandhya)

Child came to B.K. at 11:45 am and was seen in OPD. Child was diagnosed as being very sick and the paediatrician reported the child suffering from seizures. The anterior fontanelle were found to be raised and the tone increased. The baby had not taken any feed for 12 hours prior to hospitalization. A swelling was also observed at the injection site The child transferred to casualty. All prescribed injections were given (amikasin, phenytoin) Then chest X-ray was done. Child declared dead at 4:00 pm. Child buried by 6:00 pm. No post-mortem.

The preliminary diagnosis was suspected meningitis

Note: As per DR Sandhya , BK hospital is short staffed on nurses so it is not possible to gather information on the general condition of the child between the time of hospitalization and death.

According to information in the PIR

Child very sick with high grade fever, anterior fontanelle full, increased tone and induration at the injection site. Child had a staring look with impaired vision with a stiffness of the neck. The abdomen was observed to be normal and the child was not accepting any oral feed. The tone of the limbs was found to be increased.

Epidemiological review of cases in area: No perceptible increase of meningitis/encephalitis reported from the area. All other children vaccinated from the same vaccine vial were normal

Field activities undertaken during the visit

Cold chain records of Palla PHC was reviewed and found to be adequate. However, April records showed temperature between 5-8 celsius and touching 8 celsius on many days. These are manually maintained in printed booklet format.

Immunization session was not observed as team reached PHC at 2.00pm.

Preliminary findings of the team Absence of any investigation like CSF /blood collection and no autopsy hamper in confirming the cause behind death. However, based on history of child by verbal autopsy technique and clinical observations as per records the possible differential diagnoses based on the evidence include:

- meningitis or
- encephalitis
- Inadequately treated seizures
- Possibility of Intracranial bleed cannot be ruled out.

Conclusion and Recommendations;

Based on above observation the team recommends that the event may be classified into ‘co-incident’ category.

The team gave the following recommendations specifically for these cases and in the long term for improved AEFI surveillance:

- 1. Immediate: Quality of care at FRU and Hospital needs to be examined**
- 2. Long term: Conduct AEFI training to prevent fear of AEFI in clinical staff**