Report of investigation into AEFI cluster of 05th March 2014 - Patiala, Punjab

Introduction

Based on the recommendation of the MOHFW and the meeting of the Punjab State AEFI Committee with the central team on 5th June 2014, a joint team consisting of the Punjab State EPI Officer-Dr. G.B. Singh and Dr. Ajit Shewale (Zonal AEFI consultant-MoHFW) visited Samana, district Patiala, Punjab for detailed investigation of cluster of 5 cases.

Case summaries

Day of Event -5/3/14

1. **A, 10 years, male**- averagely nourished child (weight approx.- 22kg-24kg) had dog bite in right gluteal region one month before the event. The bite was provoked, class III bite and dog is still healthy till date. He had received all previous four doses without any adverse event. First dose was given in private clinic while other doses were administered in SH.
   On the day of event (05/06/2014) he along with his father went to SH to receive 5th dose of ARV. At the emergency room, he had to wait for some time as the medical store in which the ARV was kept was not open. As per father's narrative the designated pharmacist was not present at the stores. After some time, the store opened and prescription copy was submitted to store department and child along with class IV worker brought the vaccines to emergency room. The class IV worker initially could not locate the ARV in the medical store and called the pharmacist who described the location of the ARV.
   Staff nurse attending the emergency room then opened vial and diluents and administered it in left deltoid region. Child along with his father went outside the hospital and after 3-4 minutes child complained of giddiness. His father tried to console him but child collapsed immediately and father rushed his child to emergency room where resuscitation was performed. According to his father child was not responding to any command and was unconscious. He was taken to RH where he was declared as brought dead.
   According to Dr. M, who attempted to resuscitate the child in SH, there was no palpable pulse and B.P. was not recordable, respiration was irregular and inefficient. CPR was given twice or thrice with oxygen, inj. Hydrocortisone, Inj. Avil and inj. Adrenaline twice. Patient pulse and B.P were recordable after CPR and patient was referred to RH approx. 25 minutes distance from SH where he was declared as brought dead.
2. **JS, 65 years, male**- A known hypertensive, he was bitten by a dog on 4th March, provoked bite on both legs approx. 13 wounds, class—III. It was his first dose of vaccine. He went to SH in afternoon. At the medicine OPD, he was advised to wash the wound. He went to emergency room for taking injection and he received injection after the child A and after 10-20 minutes he started having giddiness. He went to the OPD where he became unconscious. He regained consciousness in RH after 8-9 hours. He was fine after gaining consciousness but had general weakness. He was kept for observation for 72 hours in hospital and is healthy. He has not received remaining doses of any vaccine. He no history of previous reaction no addiction. He was unaware of reaction of antirabies vaccine to other patients until he regained consciousness in RH.
3. **RS, 26 years, male**- of average build, consumed milk of buffalo whose calf was bitten by rabid dog. Calf died after 3 days. Veterinarian advised him to take ARV. He received the first

dose on 02/02/14 and 2nd dose on 05/02/14. He went to SH on the day of event and after 2-3 minutes of injection he started having vertigo and weakness all over body and had to sit on nearby bench. He could not lift his head and was not able to convey his condition to others. He recovered from that episode after 2-3 minutes and was taken to the emergency room. He was conscious but had difficulty in speech, giddiness and stiffness in neck. He was then taken to RH. He was conscious there and was not having any symptoms in the hospital. He was kept in the hospital for 72 hours for observation. His present condition is normal. He has not received remaining doses of any vaccine. No history of previous reaction. No history of any addiction. No significant family history. He was unaware of reaction of antirabies vaccine to other patients. Patient did not take any other medication on day of event.

4. **KS,** 30 years, male- suffered a dog bite on left hand on 4th March. It was a provoked grade III bite. Patient went to SH on 5th March. Two-three minutes after getting vaccinated, he felt sudden blackening out, weakness all over body followed by frothing from mouth. He was unconscious for about 4-5 hours. He regained consciousness in RH. After recovering he was having weakness all over body and burning sensation in chest. He was kept under observation in RH for about 72 hours and was having weakness even after discharge from hospital. He was unable to join work for one month due to his weakness. His present condition is normal. He has not received remaining doses of any vaccine. There is no history of any previous reaction to any medication. He is addicted to alcohol (moderate intake). No significant family history. He was unaware of reaction of antirabies vaccine to other patients. Patient did not take any other medication on day of event.
5. **AK-** 25 year old is an averagely built female with 8 months amenorrhea in her 2nd pregnancy. A dog bit her on the left leg and forearm on 4th March. At SH on 5th March she went to emergency OPD where she was the last person to receive ARV. After 5-6 minutes, she started frothing from mouth and sudden blackening out, had weakness in all four limbs, giddiness and collapsed suddenly. She was unconscious for half an hour. She was not having any complaints in RH but was kept in the observation for 72 hours. At present her condition is normal and not experienced any other adverse symptoms since the day of event. She has not received remaining doses of any vaccine. There is no history of previous reaction. There is no history of any addiction. There is no other significant family history. She was unaware of reaction of antirabies vaccine to other patients.

- **Epidemiological investigation**- From the emergency room records, the address of a vaccine recipient of the same batch was retrieved. MK was visited. She had not experienced any side effects and was healthy.
- **Visit to SH**-
    - Team visited the emergency room, pharmacy room, Medical store room, OPD counter and speciality OPDs
    - Emergency room has been shifted to other room after the day of event. It was located just near the hospital entrance, adjacent to waiting area. ARV is administered in emergency room.
    - As per chief pharmacist, the five vials already issued to the ARV clinic was brought back in the evening for storing in the refrigerator of the medical store.
    - Cold chain maintenance was proper in the medical store. ARV was placed in middle compartment of fridge.

- Emergency room fridge which was kept in another room when examined was containing only Inj.Diltiazem, Inj.Insulin
- Resuscitation facility (Oxygen cylinder, Suction facility, Emergency tray) was available in new emergency room.

➢ **Visit to RH**

- Team visited RH where all patients were admitted after the event. Treating doctors gave the following information:
    a. Patient A, when examined in the hospital did not have any vital signs. Hence he was declared as brought dead and his body sent for postmortem.
    b. Contrary to patients' narrative, the doctor the doctors said that all patients were conscious at the time of initial examination in the hospital. Patients were having low blood pressure. They were administered antihistamines and steroids and kept under observation for 72 hours.

Conclusions- Based on all available information, documents, discussions and chronology of events the following assessment can be made:

1. Since none of the patient involved was aware of event occurring to other patient's possibility of anxiety related reaction can be ruled out.
2. Product quality related errors can be ruled out since tested product was of standard quality as revealed by lab. Report and also epidemiological investigation other patients received vaccine from same batch did not experienced any symptoms.
3. Coincidental event also can be ruled out as no other person from same locality who has received vaccine experienced similar kind of event or reported similar symptoms.
4. Event occurred immediately after the immunisation and was having clear temporal relationship with immunisation.
5. There is no other attributable factor based on the chronology of events and available information.
6. Patient who died in the event along with other patients had pattern of symptoms which does not corroborate with signs and symptoms of anaphylaxis.
7. Therefore **programme related errors** emerge out as distinct possibility which may have occurred from point of storage of vaccine in the medical store room to actual administration of vaccine. Cold chain maintenance system on day of observation did not reveal any irregularity. Though parents have alleged a person other than the designated person handed over the vial of vaccine and raised possibility of wrong product being given, it cannot be demonstrated with available information and documentary evidence. Pattern of symptoms in patients like sudden blackening out, weakness in all four limbs, vertigo low blood pressure among individual at the time of admission points towards **possibility of medication/ solution/ mixture having hypotensive properties**.