

**Ministry of Health and Family Welfare  
Government of India**

**Report of the Central Team visit to the State of J&K  
after serious AEFI cases were reported from G. B Pant  
Hospital, Srinagar.**

**(12-14 October 2013)**

## EXECUTIVE SUMMARY

- On the request of Director (Family welfare) Government of J&K and Medical Superintendent, GB Pant Hospital, a Central team was deputed during 12-14 October 2013 to assist the State Government in carrying out investigation of twelve reported serious AEFI following Pentavalent vaccination in Srinagar
- The team consisted of : (1)Dr Narendra Arora, Chairman, National AEFI Committee, (2) Dr Ajay Khera, Deputy Commissioner, Ministry of Health and Family Welfare, Gol (3) Dr Satinder Aneja, HOD Paediatrics, Kalawati Saran Children Hospital, (4) Dr Jagvir Singh, NPO, National Centre for Disease Control,(5) Dr Sujeet Jain, AEFI Surveillance focal point, WHO, India.
- The activities carried out by the team included discussion with the treating physicians at the GB pant hospital, analysing medical and laboratory records of all reported cases, meeting with state, and district officials, visit to Block PHCs to interact with Medical officers, ANMs, ASHAs and other health staff on immunization including cold chain and other related areas, visit to families and community from where AEFI cases have been reported. The team visited districts of Srinagar, Badgam, Shopian and Anantnag
- As per information received up to 11 October 2013, a total of 12 serious AEFI cases have been reported from the state since the introduction of Pentavalent vaccine in Feb 2013. The detailed line-list of these cases is attached. Out of these 12 cases, there were 8 deaths and 4 hospitalizations. A total of 2.5 lakh doses of pentavalent vaccine have been administered till date in the State of J & K.
- District wise breakup of cases includes- Badgam ( 3 ) , Srinagar ( 4 ) , Shopiyan ( 2 ) , Baramulla( 2 ) , Pulwama (1)
- Out of 12 AEFI cases, 11 cases have been reported during the last one month. Of these, 10 cases have been reported by GB Pant Hospital, Srinagar and one case by Sher-e-Kashmir Institute of Medical Sciences.
- Of the 4 hospitalized AEFI cases, three have recovered and one case is still admitted in a stable condition.
- Analysis of the 8 AEFI deaths shows the age range varies from 1.5 to 4.5 months. In most of the cases, reporting to the hospital was after 24 hours of vaccine administration and death took place after a period of 2 days to 15 days. Further clinical, laboratory and verbal autopsy analysis of recent 7 AEFI deaths has revealed the probable causes as septicaemia(4), pneumonia(1), meningitis(1), liver disorder(1).
- As most of the AEFI cases have been reported from GB Pant hospital, review of hospital admissions and deaths during the year 2012 and 2013 shows no unusual change in the trend of hospital admissions and deaths. Analysis of the cause- specific infant deaths reveal that contribution of septicaemia, pneumonia, meningitis in this age group is consistent and similar in the pre- and post- pentavalent introduction period.
- Field visits by the team in the districts from where AEFI are reported did not reveal any unusual occurrence or increase of any disease in the infants during the reported period. The team found during the field visits that infants who had received the pentavalent vaccine doses from the vials that were used to vaccinate the AEFI infants

are healthy and without any illness. The assessment of cold chain system and immunization practices by health care providers was also carried out by visiting various health facilities and no program errors were observed in the field.

- In conclusion, the investigation shows that increased AEFI reporting during the last one month, specifically from one hospital, indicates enhanced AEFI surveillance activities. However, all the clinical, laboratory, verbal autopsy and epidemiological data point toward the evidence that pentavalent vaccine is not causally associated with the reported AEFI cases.
- It is recommended that the State AEFI Committee and senior faculty of tertiary care hospitals in the state such as GB Pant Hospital and SKIMS be trained in the process of causality assessment as outlined by WHO so as to be able to review the reported AEFIs from the state.

## **1. Introduction**

Government of Jammu and Kashmir introduced a liquid pentavalent vaccine (LPV- DwPT HepB Hib) into the routine immunization schedule on 27th Feb 2013 to replace the DPT and Hepatitis B vaccines and introduce Hib vaccine. Since its introduction, about 250,000 doses have been administered through the state.

As per information received up to 11 October 2013, a total of 12 serious AEFI cases have been reported from the state since the introduction of Pentavalent vaccine in Feb 2013. Out of these 12 cases, there were 8 deaths and 4 hospitalizations. 11 of the AEFI cases have been reported during the last one month and of these, 10 cases have reported by GB Pant Hospital and 1 by SKIMS (Sher-e-Kashmir Institute of Medical Sciences).

Following the request of Director (Family welfare) Government of Jammu and Kashmir and Medical Superintendent, GB Pant Hospital, a central team was deputed (Govt. Order T13020/11/2011-CC&V, dated 11th Oct 2013) to investigate the reported AEFIs. The team visited the state from 12th to 14th October 2013 to assist the State Government in carrying out investigation of these reported serious AEFI following pentavalent vaccination.

The team consisted of:

1. Dr Narendra Arora, Chairman, National AEFI Committee,
2. Dr Ajay Khera, Deputy Commissioner, Ministry of Health and Family Welfare, GoI
3. Dr Satinder Aneja, HOD Paediatrics, Kalawati Saran Children Hospital,
4. Dr Jagvir Singh, NPO, National Centre for Disease Control,
5. Dr Sujeet Jain, AEFI Surveillance focal point, WHO, India.
6. Dr Jyoti Joshi Jain, Senior Advisor AEFI, ITSU

## **2. Activities undertaken during the visit of the team from national level**

During the three day investigation the team, visited various govt. hospitals, health centres and families of children vaccinated in the districts. The activities carried out by the team included discussion with the treating physicians at the GB pant hospital, analysing medical and laboratory records of all reported cases, meeting with state and district officials, visit to Block PHCs and sub-centres to interact with Medical officers, ANMs, ASHAs and other health staff on immunization including cold chain and other related areas, review of the vaccine management and injection safety practices at cold chain points and visit to families and community from where AEFI cases have been reported. Samples of unused vials and partially used vials were also collected for laboratory analysis.

The team visited districts of Srinagar, Badgam, Shopian Anantnag, and Kulgam and this report concludes with analysis of available information and further suggestions to supplement the investigation. The field activities undertaken during the visit were as follows:

**12th Oct 2013:** The team met senior officials of the state and GB Pant Hospital including the following:

Deptt of Health and Family Welfare

- Dr Baldev Sharma, Director Family Welfare, J &K
- Dr Y C Dolma, State EPI Officer J&K
- Dr Rehana, (IDSP)
- Dr Shazia
- Ms Nighat Jabeen Assistant Drug Controlled-J and K

G B Pant Hospital

- Dr Muneer Masoodi, Medical Superintendent,
- Dr Salim, Deputy MS ,
- Dr Kaiser, HOD Paediatrics,
- Paediatricians and senior residents of the deptt.
- Dr Sartaj Bhat, Duty Medical Officer Paediatrics

The team led by Dr Arora initially met the Medical Superintendent Dr Masoodi, who urged the team to conduct a conclusive AEFI investigation and validate vaccine safety to reassure the state and the country as it would affect the confidence of the public in the immunization program.

It was shared by the Medical Superintendent that effective 1st Oct 2013, Dr Sartaj Bhat, a Senior Resident in the Department of Paediatrics, has been nominated as the AEFI focal point in the hospital and the FIRs for all the cases were being prepared by him. Dr Sartaj, along with other faculty members, then presented each reported case in detail to the team for the purpose of understanding the sequence of events leading to hospitalization and suggest the progress to the clinical diagnosis for each case.

Following review of all cases, the central team made a plan to conduct a thorough field investigation and community interviews for some of the cases. For this it was decided to split into 2 teams with representation from the Central team and State HFW officers.

**13th Oct:** 2 teams were formed and the workplan was made as follows:

- Team 1 consisting of
  - Dr Satinder Aneja,
  - Dr Ajay Khera,
  - Dr Sujeet Jain,
  - Dr Dolma
  - Dr Shazia

The team visited 4 cases ( [REDACTED], [REDACTED], [REDACTED] & [REDACTED] ), families of other children immunized and related health facilities in the districts of Srinagar and Budgam.. The sites visited include

- District Badgam, Block PHC Saibagh and Medical aid centre-Khuspura where the case [REDACTED] was immunized.
- Visit to family of [REDACTED] in village Durbal and two other families in the neighbourhood where children were immunized on the same day with same vial
- District Badgam, CHC Chattargam where the case [REDACTED] was immunized.
- Met the family of case [REDACTED] to seek details of events pre and post vaccination.
- District Srinagar, PHC Rawlpura where two cases [REDACTED] and [REDACTED] were immunized.
- Visit to family of [REDACTED] to interview his mother and other relatives on events related to [REDACTED] and his cousin [REDACTED].

The team also visited the Sher-E-Kashmir Institute of Medical Sciences (SKIMS) and met the hospital management, paediatric doctors and the pharmacovigilance centre staff of the hospital. The team met Dr Parvaiz Kaul (member NTAGI), Dr Waqar Younis(HOD Paediatircs, SKIMS) and paediatrics faculty, Prof Z A Wafii (Incharge Pharmacovigilance Centre, SKIMS), Dr Samaira, Senior Resident deptt of Pharmacology

- Team 2 consisting of
  - Dr N K Arora,,
  - Dr Jagvir Singh,
  - Dr Jyoti Joshi Jain
  - Dr Rehana

The team visited 2 cases ( [REDACTED] ) and related health facilities as well as community (including the case and healthy families) in the districts of Shopian, Anantnag and Kulgam. The sites visited include:

- PHC Zainipura and Sub centre Takiya Imam Sahab (Vaccination site for case [REDACTED])
- Family of case [REDACTED] and another healthy child vaccinated from the same vial on same day at the Sub centre
- PHC BehiBagh (Vaccination site for case [REDACTED])
- Family of case [REDACTED] and another healthy child vaccinated from the same vial on same day at the PHC.
- MCH Hospital, Anantnag and met the hospital management, paediatric doctors and the SNCU staff of the MCH hospital. This included Dr A B Majid, Med Suprintendent MCH Hospital and discussed the treatment history of the 2 cases in the hospital with the 2 treating paediatricians Dr Suhail and Dr Ejaz (Casualty medical officer-Paediatrics)

Field visits by the team in the districts from where AEFI are reported did not reveal any unusual occurrence or increase of any disease in the infants during the reported period. The team actively searched for infants who had received the pentavalent vaccine doses from the vials that were used to vaccinate the reported AEFI infants. The infants were found healthy and without any apparent illness.

The teams assembled and finalised the preliminary report and summarized the findings from the field.

**14th Oct:** The team debriefed the G B Pant Hospital and paediatricians regarding the reported cases. The enhanced reporting of AEFI cases from the hospital was noted and the specialized process of conducting an AEFI Causality Assessment was explained to the faculty and one of the reported cases was discussed in detail as an example for better understanding.

This was followed by a meeting with the State Health Minister (Shabbir Ahmad Khan), Director, Health services, Dr Yashpal Sharma, Director Family Welfare, Prof Rafiq Pampori, Principal, Srinagar Medical College and other senior state officials. The findings of the Central team was shared by Dr Arora with the leadership and it was explained that a thorough review of the cases including the reported deaths had been done and it was found that for 4 cases the history suggested the fatal outcome was due to sepsis with shock; and case history for others suggested pneumonia (1); meningitis (1) and liver disease. It was clearly evident that the pentavalent vaccine was not causally related to the reported deaths and it would be in the interest of the health of the children to continue to use the Pentavalent vaccine. The team then together with the State Health and Family Welfare officials conducted a brief media briefing to address any misconceptions regarding the safety of the vaccines. Media persons from Doordarshan, private electronic media and newspapers were present and all their queries regarding the investigation of the reported AEFI cases were answered. The media persons were also reassured of the safety of the vaccine and its benefit to the children.

## DISCUSSION

The Central team worked in coordination with the following:

- State Health and Family Welfare department,
- GB Pant Hospital
- SKIMS
- MCH Anantnag
- PHC and Subcentres of districts visited

It was heartening to meet a motivated hospital and primary health care staff, good record keeping of immunization services in the MCTS register at all health facilities and the cold chain infrastructure being maintained as per standards.

However, the controversy around the media reports regarding the pentavalent vaccine appeared to have adversely affected the uptake of immunization services and many of the ANMs reported a fall in number of target children attending the immunization clinics due to the controversy.

The team felt that conclusions should not be drawn from the preliminary reports and causality of the cases should not be attributed to the vaccine without undertaking the formal process of causality assessment. Causality assessment is a systematic process to determine if the event observed can be attributed to the vaccine. It is undertaken in a scientific manner outlined by WHO using a 4 step process after reviewing hospital records, immunization records and community assessment. Preliminary impressions based on hospital records alone may not be the final conclusions. A detailed and expert exercise of causality assessment should be done to prevent adverse impact on the brand of immunization program and hinder the reach of an essential preventive service to needy children.



## CONCLUSIONS

1. Enhanced AEFI notification has been seen from G B Pant Hospital from 1st Oct onwards due to the nomination of a nodal officer for AEFI reporting. This process of reporting AEFIs was focussed more on deaths and it would be useful to expand and include reporting of AEFIs for cases of hospitalization also.
2. Each of the admitted AEFI case had been well worked up and the clinical and lab investigations sent for each case were very useful in evaluating and preparing a plausible preliminary diagnosis for each of the cases.
3. However it was noted that additional useful information for the cases could have been provided by conducting blood cultures and lumbar puncture so as to provide evidence to validate other differential diagnosis.
4. It was seen that for the 6 cases of serious AEFIs reported from the field, other vaccinated children were found to be healthy and alive.
5. Though this type of enhanced reporting is urgently needed to strengthen AEFI surveillance in the state, it was highlighted that such reporting does not imply causality. An adverse event occurred following immunization does not imply that it happened because of immunization.
6. A need was felt to conduct a detailed AEFI reporting and causality assessment workshop for the 2 State AEFI Committees of the state (Jammu and Kashmir) so as to enable the state AEFI committees to make an informed judgement without affecting immunization coverage.
7. Review of hospital records for 2012 also showed cases of DPT induced encephalopathy although they had not been notified.
8. It was discussed that the pentavalent vaccine was already being used in the private sector in the state too in the past several years and by including it in the Universal Immunization Program, protection from Hib infections (including pneumonia and meningitis) would be available to the poorest of the poor free of cost.
9. Introduction of any new vaccine in the routine immunization program is accompanied by an increased sensitivity of AEFI surveillance and hence increased AEFI reporting. Introduction of pentavalent vaccine in the routine UIP program in Kerala too was accompanied by increased AEFI case reporting and today, Kerala continues to be the highest AEFI reporting state.
10. The Jammu and Kashmir state had conducted a very effective media engagement program during the process of introduction of Pentavalent vaccine and it already has a good immunization coverage of 85%.
11. As most of the AEFI cases have been reported from GB Pant hospital, review of hospital admissions and death records during the year 2012 and 2013 shows no unusual change in the trend of hospital admissions and deaths. Analysis of the cause-specific infant deaths reveal that contribution of septicaemia, pneumonia, meningitis

in this age group is prominent and consistent and similar in the pre- and post-pentavalent introduction period.

12. During the field visit it was seen that the cold chain infrastructure at the PHCs was being maintained as per the standard protocol. It was seen that all facilities had power backup and adequate cold chain monitoring and supervision.
13. A detailed discussion was done with the health workers in the facility including ANMs, cold chain officers, Block Medical officers (BMO) and PHC doctors in charge. The staff was found to be well trained and knowledgeable on the topic.
14. The facilities visited had a good recordkeeping on the Mother and Child Tracking (MCTS) system with all details of the cases including parents name and phone numbers which could be traced and validated. These records were very useful in tracing other healthy beneficiaries from the same vaccine (including same vial) for interview and discussion.

### **SPECIAL ISSUES FOR CONSIDERATION**

As per the National AEFI Guidelines AEFI reporting entails reporting of any serious events that occurred within 30 days following vaccination. However, it must be noted that before causality of these cases could be assessed by the state and national AEFI Committees as per the standard protocol, reports got leaked out from the hospital to the media, patients and community that the infants have expired due to vaccination with pentavalent vaccine. a

- SMSs were reportedly circulated to senior govt. officials in the central and state govt. as if to report 'breaking news' on deaths taking place due to pentavalent vaccine. Statements were issued to the media from the hospital, prior and even when the team was in Srinagar and conducting the investigation, that pentavalent vaccine was responsible for death of infants.
- During community interviews the parents of affected children informed that they have been told by the doctors in GB Pant Hospital that the death of their children was due to the pentavalent vaccine given at the health centres.
- The private sector in the state (and the govt doctors running private clinics) has been using pentavalent vaccine for quite a few years and continues to use it, without reporting any AEFI following vaccination.
- It is important to note that drawing any premature conclusions on causality and sharing with media and community can have serious implications on the National Immunization Program. Even the history and laboratory records for these cases hinted at possibility of other causes leading to such events. Therefore, whereas a strong AEFI Reporting and Surveillance is welcome, making premature conclusions without conducting any scientific causality assessment can be detrimental to National Immunization Program.

## **RECOMMENDATIONS:**

Based on the discussion with the state AEFI committee, state officials and the field visits undertaken the following recommendations are suggested specifically for these cases and in the long term for improved AEFI surveillance:

### **I. Immediate:**

1. AEFI reporting from all health facilities should be encouraged to enable a good number of AEFI reports and continuous evaluation of vaccine safety data through the state.
2. AEFI training and causality assessment workshops to be conducted immediately for the state AEFI Committees and paediatric faculty from SKIMS and G B Pant Hospital to enable the state on informed decision making on vaccine safety.
3. Causality assessment of these reported cases should be undertaken by the AEFI Secretariat with the National Collaborating centre to support the state AEFI committee and add to the national vaccine safety database.
4. Different batches of pentavalent vaccine have been used in the reported AEFI cases. Samples from the all the different lots may be sent by the state drug control department (CDSCO) for vaccine quality audit to CDL Kasauli. The reports of the laboratory audit should be shared with the State AEFI Committee and program for further review.
5. The state may ensure that media reporting about AEFIs are sensitively handled by administrators of leading medical institutions, so that essential basic services by the government like vaccination are not affected by totally avoidable rumours and misconceptions. This will ensure equity of access to life saving expensive vaccines for the poorest segment in the country through the National Immunization Program.

### **II. Long term**

- a. Regular AEFI reporting from the state including these tertiary care centres should be ensured and periodic trends should be evaluated at regular intervals.
- b. Refresher capacity building exercise of the 2 State AEFI committees should be undertaken periodically to ensure a thorough and informed causality assessment of reported cases based on the PIR and DIR, hospital records, post-mortem and other reports.



