Original Research Article

Assessment of Spectrum of adverse events following immunization in under five year children in a tertiary healthcare institute in a metropolitan city- A cross sectional study

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Abstract

Background: The present study was conducted to study the time intervals associated with various AEFI and proportion of programmatic errors linked with AEFI cases and to suggest or recommend measures for strengthening AEFI management and prevention based on a study finding. **Material and methods:** The present study was a record based Cross–sectional study, conducted during period of one year [July 2012 to July 2013] among sample of 118 cases of AEFI reported. **Results:** More than half of the cases of AEFI occurred within 12 hours of immunization.(61.88%). Amongst which 37.31% of cases occurred within 6 hours after immunization. 17.79 % cases occurred after 24 hours. **Conclusion:** The concept of quality services in immunization must be promoted aggressively at all levels of healthcare through refresher training and workshops. Standard operating procedures must be designed at micro level for implementation of immunization services.

Keywords: Adverse events following immunization, Vaccine, Immunization, fever, universal immunization program

Introduction

AEFI surveillance monitors immunization safety, detects and responds to adverse events following immunization. The AEFI surveillance system in the country has become a long way since its inception in 1986. Intensive efforts are being made by the Government of India to strengthen surveillance & monitoring of AEFI in the country & facilitated in establishing state & the district level AEFI committees were established to streamline the AEFI surveillance & monitoring system .National & state level workshops were conducted by Ministry by Health & Family welfare further to intensify the system[1].AEFI surveillance program was started in India in 1988 and the AEFI Surveillance Guidelines were first published in 2005. Establishment of an AEFI secretariat with clear roles and responsibilities was proposed in 2008 to strengthen the current National AEFI Surveillance Program and support the Immunization Division, MoHFW as well as the National AEFI Committee on the various activities related to AEFI data management, monitoring, documentation of serious cases for causality assessments, operational research and trainings. Correct immunization practices reduce the negative impact of the event on health and contribute to the quality of immunization activities[1]. It is extremely important that these AEFI are reported, investigated and treated at the earliest. They will not only build public confidence but will also prevent additional clustering of cases if due to programmatic error. Quick response in case of AEFI is extremely important. Government of India has been making efforts to strengthen the AEFI surveillance system in the country through the constitution of the AEFI committee at national, state and district level[2].No vaccine is 100% safe and without any risk. It is important to know the risks and how to handle such an event when it occurs Informing people correctly on AEFI helps in maintaining public's confidence in the immunization program. Monitoring AEFI also helps improve the quality of service [3].Irrespective of the cause, when AEFI occurs, confusion is created among people to extent that they may refuse further immunizations for their children leaving them susceptible to vaccine preventable diseases which are more disabling and life threatening. Therefore, surveillance of AEFI provides information to help plan on regaining public confidence on immunization. Timely response to public concerns about safety of vaccines as well as prompt communication will protect the public and preserve the integrity of the immunization programme as well[4].Hence the present study was conducted to study the time intervals associated with various AEFI and proportion of programmatic errors linked with AEFI cases and to suggest or recommend measures for strengthening AEFI management and prevention based on a study finding.

Material and methods

"The present study was a record based Cross–sectional study, conducted during period of one year [July 2012 to July 2013] among sample of 118 cases of AEFI reported. Metropolitan city under Municipal Corporation is divided into 24 wards .F south ward office is the head office for all the 24 wards. Therefore all the AEFI cases of city were collected from F south wards. The case reports of all AEFI cases were procured and analysed to identify factors associated with reported AEFI. The questionnaires related with preliminary investigation reports (PIR) including forensic evidence of death cases were analysed. Technical discussion for further clarification was held with the concerned stakeholders and committee members of the designated AEFI committee of public health department. New AEFI cases reported during the study period were investigated using standard reporting format as per guidelines of Ministry of health and family welfare, government of India. Visits to the sites of immunization (health post/health centre) will be made to assess

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programme management recourses and for interaction with the health care providers.

Selection Criteria

Inclusion criteria

All AEFI notified to Public health department containing complete information

Exclusion criteria

All AEFI notified to Public health department containing incomplete information, Children more than 5 years, Parents not giving consent (in new cases) and adverse events caused by vaccines which were not included in universal immunization programme, were excluded from the present study.

Study procedure was divided into three phases-

Method of Data collection

1. All AEFI cases notified in Municipal corporation area are investigated by public health department using the structured surveillance form (FIR, PIR, DIR) the data regarding AEFI cases during July 2010-July 2013 were collected from PIR available in public health department
2. The data of cases occurring during the study period were collected using PIR record forms & face to face interview of parents
3. The case reports of all AEFI cases were procured and analysed to identify factors associated with reported AEFI.
4. The questionnaire related with preliminary investigation reports including forensic evidence of death cases were analysed

Statistical analysis

It was done by investigators using Microsoft excel software 2007 version. Statistical analysis was done by using SPSS version 17 software. Descriptive statistics for Socio-demographic factors were done.

All responses will be tabulated and graphically represented wherever required. Data will be analysed using Microsoft excel software. Percentage analysis will be done for socio-demographic factors. Statistical tools, like means, median, range, proportions and chi-square will be used appropriately.

Results

It is observed from table 1 that most of the cases reported were between 0-3 months of age constituting 39% (46/118) of all reported cases. This was followed by children between 12-24 months i.e. 23 %(27/118). Maximum number of cases occurred within the first year. i.e. 71 % (84/118). The mean age of all reported cases was 10.56 and standard deviation was 13.58. Most of the cases reported in both males (20.33%) and females (18.64%) were between 0-3 months of age constituting 39% (46/118) of all reported cases. Almost in all age group proportion of male more than in male than in female except in 6-12 months of age group. (Fig 1)

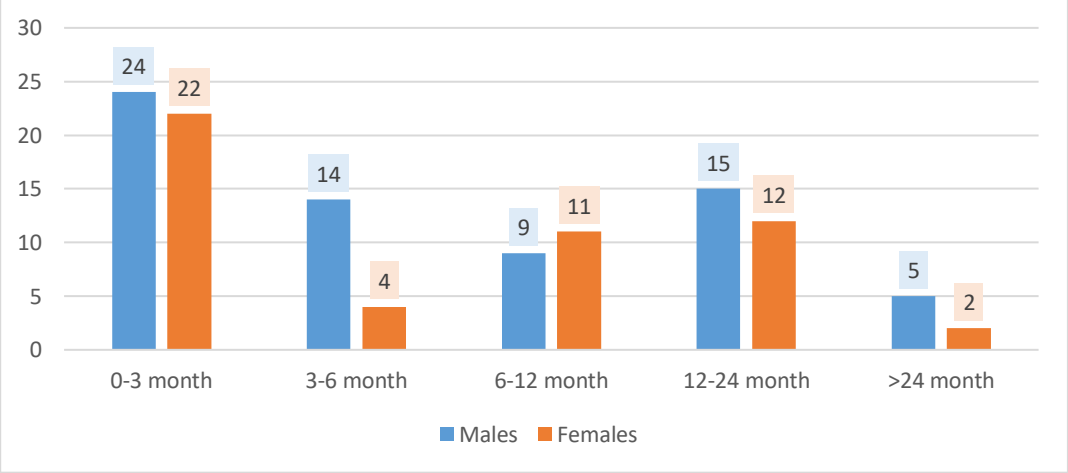

Fig 1: Age and genderwise distribution

We assessed the educational classification of the parents. We observed that parents of most children have been educated up to the middle school. Only 1.69% of mothers had graduated. (Graph 2)

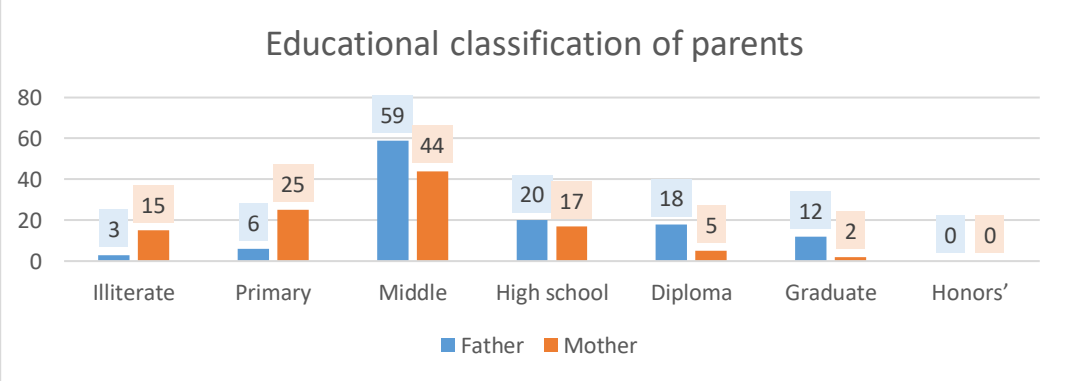

Fig 2: Educational classification

More than half of the cases of AEFI occurred within 12 hours of immunization(61.88%). Amongst which 37.31% of cases occurred within 6 hours after immunization. 17.79 % cases occurred after 24 hours. (Table 1)

Table 1: Spectrum of reported AEFI interval amongst all AEFI cases

AEFI Interval	Frequency (%)
0-6 hr	44(37.31)
6-12 hr	29(24.57)
12-24 hr	24(20.33)
>24 hr	21(17.79)
Total	118(100)

More than half cases of fever occur within 12 hours of immunization (59.41%) except for those produced by measles which commonly occur after more than 24 hours (3 out of 4 cases). Fever in case of OPV administration commonly occurs within 1 hour of vaccination. Vaccination given at the time of birth rarely causes fever. (Table 2)

Table 2: Spectrum of Reported AEFI Interval in Fever cases

Vaccine	0-6 hr	6-12hr	12-24 hr	>24 hr	Total
OPV during ORC	1	0	0	0	1
BCG/OPV/HBV given at Birth	0	0	0	0	0
OPV/DPT/HBVtogether all primary doses	15	12	12	4	43
Measles	1	0	0	3	4
Booster 1	2	8	5	3	18
Booster 2	2	0	1	0	3
Total	21	20	18	10	69
Percent	30.43%	28.98%	26.08%	14.49%	100%

More than half cases of Convulsion occur within 12 hours of immunization (65.42%) xcept those produced by measles which commonly occur after more than 24 hours (2 out of 3 cases). (Table 3).

Table 3: Spectrum of Reported AEFI Interval in Convulsion cases

Vaccine	0-6 hr	6-12 hr	12-24 hr	>24 hr	Total
OPV during ORC	2	0	0	0	2
BCG/OPV/HBVgiven at Birth	0	0	0	0	0
OPV/DPT/HBV together all primary doses	22	16	10	7	55
Measles	1	0	0	2	3
Booster 1	3	9	5	3	20
Booster 2	0	0	1	0	1
Total	28	25	16	12	81
Percent	34.56%	30.86%	19.75%	14.81%	100%

Convulsion in case of OPV administration commonly occurs within 6 hours of vaccination. Vaccination given at the time of birth rarely causes convulsion. Most cases of Local reaction occurred after more than 24 hours of immunization. (Table 4)

Table 4: Spectrum of Reported AEFI Interval in Local reaction (Swelling, Pain, Redness)

Vaccine	0-6 hr	6-12 hr	12-24 hr	>24 hr	Total
At HBV site	0	0	0	2	2
At DPT site	3	1	3	3	10
At BCG site	0	0	0	1	1
At measles site	0	0	1	0	1
Total	3	1	4	6	14
Percent	21.4%	7.14%	28.57%	42.85%	100%

Almost all cases of Local reaction at HBV site and BCG site occurred after more than 24 hours of immunization.Birth weight of most cases of AEFI in the range between 2 to 2.4 kg (44.06%) followed by range between 2.5 to 2.9(32.20%). Mean of birth weight is 2.51. (Fig 3).

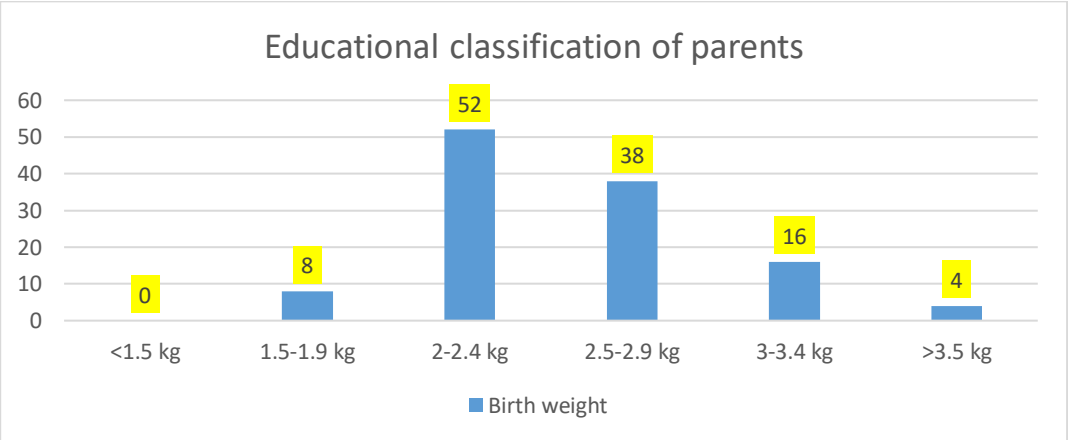

Fig 3: Birth weight of all AEFI cases

Most of the cases of adverse reaction were recovered (91%). Death occurred in 9%. No residual morbidity was seen in any of the cases reported. (Fig 4)

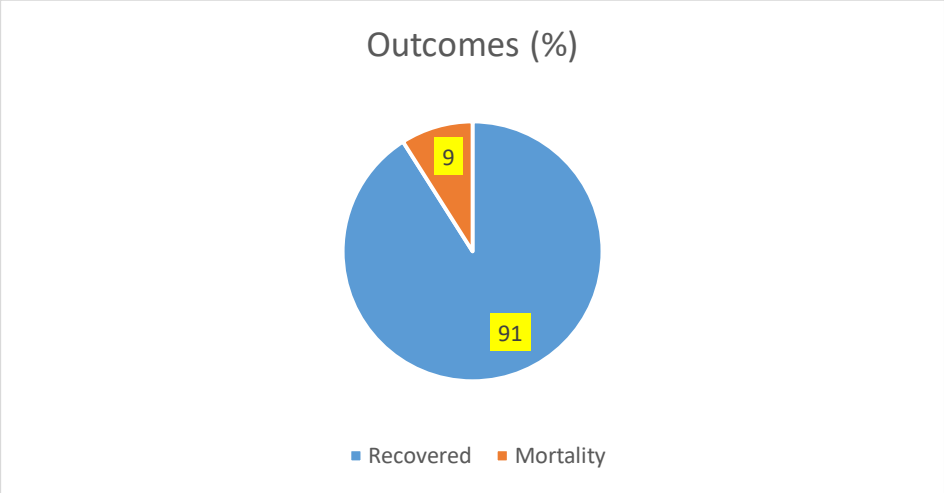

Fig 4: Outcome of AEFI Events

Discussion

It was record based cross sectional study conducted in F south ward office of Municipal Corporation which is head office for all the 24 wards to assess the sociodemographic profile, determinants of AEFI, classify AEFI according to WHO guidelines. Information was collected from Preliminary investigation report (PIR) and the information of some cases which is not available in PIR forms was collected by telephonic conversation. A total of 130 PIR forms was examined amongst them 118 was selected as per our inclusion criteria. Maximum numbers of cases reported in the study (71%) were in the first year of life, Similar findings were reported by Cunnha et al which shows children's ≤1- year old were more susceptible to AEFI.

We also observed that most commonly (39%) seen AEFI cases were in the age group of 0-3 months. Michael Gold et al[5] (Of those presenting with an AEFI, 55% were boys) in their studies. Wilson et al observed a significant relationship between socioeconomic status and vaccination at 12 month, with lower SES being associated with a higher relative incidence of events (p = 0.0075)[6]."Most reported AEFIs occur in children, not because they are necessarily at greater risk of adverse events, but because of several other factors: Children receive multiple vaccines during this period. Infants are seen frequently by healthcare professionals (HCPs) in the first year of life when they receive several immunizations, providing opportunity for reporting adverse events. Among the three doses of OPV/HBV/DPT given together more than half cases (51.90%) were reported after first dose. Over half of all documented cases of adverse reactions following vaccine administration were convulsion (68.64 %) and fever (58.47%). Both of them showed highest frequency after administration of OPV/DPT/HBV together followed by Booster 1. Fever was not reported after vaccine administered OPV/HBV/BCG given at birth.A single case of bleeding occurred after vaccine administered at birth. One case of giddiness occurred after administration of Booster 2. One case each of decreased feeding, lethargy & reduced intake occurred after OPV/DPT/HBV given together. One case of loose motion occurred after OPV vaccination. "Similar findings were reported in study done by Tamie Sugawara et al which showed Diarrhea cases in approximately 10% of patients who received OPV. For cases of diarrhea, the odds ratio of the OPV group to health check up group was 1.776. This finding strongly suggests that cases of mild diarrhea were closely related to the administration of the OPV. As many as 8000 children were monitored for 1 month after receiving the poliovirus vaccination. Among them diarrhea was reported in approximately 10% at 1-3 days post-OPV administration[7].

More than half of the cases of AEFI occurred within 12 hours of immunization (61.88%).Amongst which 37.31% of cases occurred within 6 hours after immunization. While17.79 % cases occurred after 24 hours. "Similar findings were reported by Cunha MP et al which showed that more than half (54.2%) of AEFIs occurred within 6 hours following vaccine uptake[8].More than half cases of fever occur within 12 hours of immunization (59.41%) except for those produced by measles which commonly occur after more than 24 hours (3 out of 4 cases). Fever in case of OPV administration commonly occurs within 1 hour of vaccination. Vaccination BCG/OPV/DPT given at the time of birth rarely causes fever. "Similar findings were seen in Weekly Epidemiological report Colombo Vol. 39 No. 44 which showed fever occurs within 24-48 hours of immunization except for those produced by measles vaccine which may occurs 6-12 days after immunization. However it continues only for 24-48 hours[9].More than half cases of Convulsion occur within 12 hours of immunization (65.42%) except those produced by measles which commonly occur after more than 24 hours (2 out of 3 cases). Convulsion in case of OPV administration commonly occurs within 6 hours of vaccination. Vaccination given at the time of birth rarely causes convulsion. Most cases of Local reaction occurred after more than 24 hours of immunization. Almost all cases of Local reaction at HBV site and BCG site occurred after more than 24 hours of immunization."Similar findings were seen in document AEFI: Interpretation and clinical definitions guide which showed that local reactions tend to occur within 48 hours of vaccination."Weekly Epidemiological report Colombo Vol. 39 No. 44 showed BCG causes a specific local reaction which starts as papule 2-4 weeks after immunization and may get ulcerated and healed after several months, leaving a scar[9].Birth weight of most cases of AEFI in the range between 2 to 2.4 kg 44.06) followed by range between 2.5 to 2.9(32.20) the mean of birth weight was 2.51. "The Australian immunization handbook 2013 proposed that low-birth- weight newborn infants do not respond as well to hepatitis B-containing vaccines as full-term infants. These babies may be at higher risk of some of these diseases, so vaccinating them on time is important[10]."Ministry of health Newzealand Vaccination Q & A chapter 21 proposed that low birth weight and prematurity are not contraindications to vaccination. They recommended that Schedule of immunizations should be carried out at the usual chronological age. However, if the child is still in hospital or recently discharged, the advice of the treating specialist is must[11].

Clifford V. et al showed that Lower birth weight was possible risk factors for recurrence. (p=0.04). Most of the cases of adverse reaction were recovered (91%). Death occurred in 9%. No residual morbidity was seen in any of the cases reported[12].

Conclusion

More than half of the cases of AEFI occurred within 12 hours of immunization amongst which most commonly occurred within 6

hours after immunization except for those produced by measles which commonly occur after more than 24 hours. Fever in case of OPV administration commonly occurs within 1 hour of vaccination. Vaccination given at the time of birth rarely causes fever.

More than half cases of Convulsion occur within 12 hours of immunization except those produced by measles which commonly occur after more than 24 hours. Convulsion in case of OPV administration commonly occurs within 6 hours of vaccination. Vaccination given at the time of birth rarely causes convulsion.

Most cases of Local reaction occurred after more than 24 hours of immunization. Almost all cases of Local reaction at HBV site and BCG site occurred after more than 24 hours of immunization. Most of the cases of adverse reaction were recovered. No residual morbidity was seen in any of the cases reported

Recommendations

The concept of quality services in immunization must be promoted aggressively at all levels of healthcare through refresher training and workshops. Standard operating procedures must be designed at micro level for implementation of immunization services.The medical officer in charge of immunization clinic must undergo hands on training in paediatric department to learn clinical management of children in critical illness. The presence of ready to use emergency management kit must be ensured at all times in immunization clinics. Pre immunization and post immunization counselling of parents to make them aware of possible side effects of vaccination must be viewed as indispensible component of immunization programme. The mechanism of referral of child post immunization in case of any untoward symptoms develop must be established. The contact number of health centre or doctor on call must be mentioned on immunization card. In outreach immunization programme ASHA worker may act as facilitator. The use of mobile technology for prompt management of any child developing untoward symptom post immunization may be promoted. Entire immunization record should be digitalised or computerized during immunization session A film/video on AEFI and its management explaining the role parents/doctor should be displayed at the venue of immunization training. The importance being vigilant about AEFI in the first 24 hour must be explained to parents during counselling. The cold chain maintenance, storage facility, transport of vaccines and recording of batch number should be under strict vigilance for all days through immunization nodal officer. Under national polio surveillance project (NPSP) nodal officer have been appointed in medical colleges, rural hospitals and major health centres for polio surveillance. These officers can be further involved as nodal officer for AEFI surveillance.The national guidelines advocated for conducting immunization programme must be strictly to and supervised by responsible medical officer. AEFI committee established at district and municipal city levels must be strengthened mechanism of coordination with forensic department, public health laboratory, paediatric department and microbiology department.

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