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RESEARCH ARTICLE

STUDY ON AEFI (ADVERSE EVENT FOLLOWING IMMUNIZATION) IN THE DEPARTMENT OF PAEDIATRICS, GAUHATI MEDICAL COLLEGE & HOSPITAL, GUWAHATI (ASSAM)

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ABSTRACT

Background: Immunization programme is an important determinant of the health status in a region. Full awareness regarding usefulness and safety of vaccines are required. Proper evaluation of vaccine related adverse events are essential. Objective of study was to analyze pattern of Adverse Events Following Immunization (AEFI) in children below 12 years of age.

Methods: Observational prospective study was carried out in the Department of Paediatrics, Gauhati Medical College & Hospital, Guwahati, where children receiving routine immunization were analyzed & followed up through telephonic survey of parents. Vaccine Adverse Event Reporting System (VAERS) form was used to record AEFI.

Results: Total 1378 children received total of 3361 vaccine doses. 17.7% AEFI were reported. Most common AEFI per 1000 doses of all vaccinations was Fever. DPT vaccine was most common vaccine associated with AEFI.

Conclusions: Strengthening of AEFI reporting and assessment is essential for improving immunization coverage.

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INTRODUCTION

Immunization against vaccine preventable diseases is one of the safest and the most cost effective intervention to improve child survival. Routine Immunization is one of the most cost effective public health interventions and was first introduced in India in 1978 (Immunization Handbook for Medical Officers, 2008). As per the recent nation-wide survey data, of the targeted annual cohort of 26 million infants in India, only 61 per cent had received all due vaccines (United Nations International Children's Fund, 2010). An Adverse Event Following Immunization (AEFI) is defined as 'any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine' (WHO, 2013). The Vaccine Adverse Event Reporting System (VAERS) is an important tool which is designed to collect and analyze information from reports of adverse events (possible side effects) following vaccination (http://vaers.hhs.gov/about/faqs). Pharmacovigilance as such has gathered pace in India only in recent times.

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Pharmacovigilance on vaccines, although was started along with Universal Immunization Programme in 1985 (Chitkara *et al*., 2013), but yet it has not gathered full momentum. In view of recent changes in disease patterns and health hazards, there is an increasing need of Pharmacovigilance of vaccines on a large scale in India (Budhiraja, 2010 and Karande *et al*., 2003). The present study is aimed to collect data on various AEFI and to do active search of adverse events in paediatric population.

MATERIALS AND METHODS

The study was conducted in the Department of Paediatrics, Gauhati Medical College & Hospital, Guwahati after taking approval from Institutional Ethics Committee. It was an observational prospective study conducted from September 2014 to February 2015 (duration- 6 months). The children aged 0 to 12 years attending the immunization clinic in the outpatient Paediatrics department (OPD) were recruited. The parents were explained in detail about the study and were asked to fill an informed consent form if they agreed to participate in the study. Extremely sick patients and patients with other coexisting diseases were excluded from the study. Follow up of the children were done by a two phase telephonic survey, consisting of an initial call at one week and a second

call at 30 days after the vaccine administration date. The parents of children were questioned about the appearance of any type of reaction that had followed administration of the vaccine. If any of the parents complained of any adverse event, they were called up to our hospital and were examined by the visiting paediatrician for AEFI. The VAERS form was used to record the AEFI (https://vaers.hhs.gov/resources/vaers_form.pdf). The demographic data, adverse event description, nature of the reaction, vaccine suspected for AEFI were recorded. Causality assessment was done using the Naranjo Adverse Drug Reaction Probability Scale (Naranjo score) (Naranjo, 1981). The data was analyzed using Microsoft office exel 2007.

RESULTS

A total of 1378 children were included in the study over a duration of 6 months. Out of 1378, 716 (52%) were male and 662 (48%) female. Gender distribution of AEFI is shown in Figure 1.

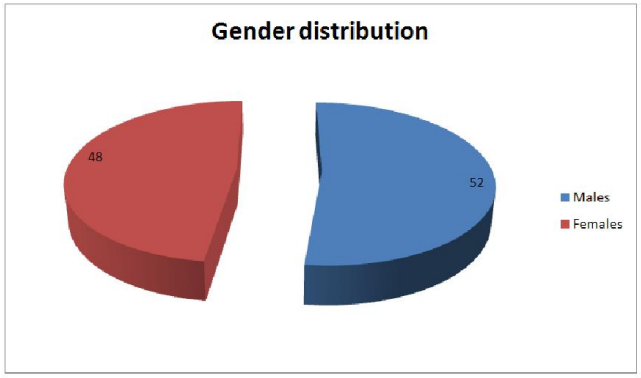

Figure 1. Sex distribution of AEFI

Out of 1378 children, 23 received 4 vaccines at a time, 779 received 3 vaccines at a time, 356 received 2 vaccines and 220 received 1 vaccine at a time. Total vaccine doses administered were 3361 (1075 were oral, 2286 were injectable vaccines). OPV doses were given to 1075 children, DPT to 990, Hepatitis B to 844, measles to 406 and BCG to 46 children. Distribution of vaccines is shown in Figure 2.

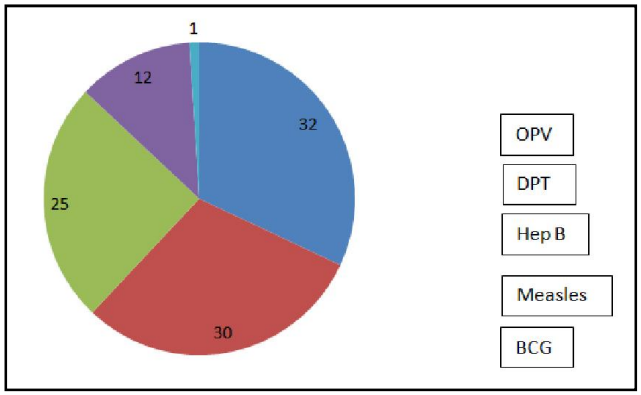

Figure 2. Distribution of vaccine doses in children

A total 244 AEFI were reported out of a total of 3361 vaccine doses given. So the rate of AEFI per thousand vaccine doses was 72.59 and the incidence of AEFI was 17.7% (244 AEFI out of 1378 children).The distribution of AEFI in various age groups was uneven as shown in figure 3. Most AEFI was seen in the 4-9 months age group followed by 2-4 months and 9-18 months. Least AEFI was seen in 3-6 years of age.

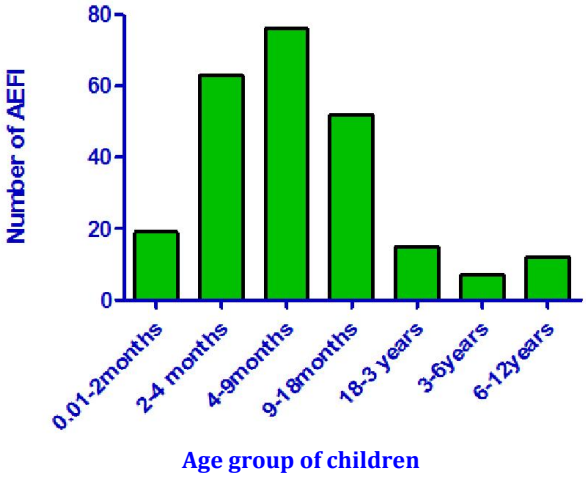

Figure 3. Age Group-wise Distribution of AEFI Registered

Most common AEFI per 1000 doses of all vaccinations was Fever (41.95) followed by swelling at injection site (24.93) as shown in Table 1. Convulsion was the least common AEFI as seen in only one child.

Table 1. Analysis of Types of AEFI Registered

Type of Adverse Event	Number of AEFI Reported (%)	Rate per 1000 Doses of All Vaccinations
Fever	141	41.95
Swelling at injection site	57	24.93
Excessive Crying	36	10.71
Diarrhoea	32	9.52
Nodule at injection site	5	2.18
Abscess at injection site	2	0.87
Rash	2	0.59
Convulsions	1	0.29

AEFI: Adverse Event Following Immunization; #Total doses of vaccine administered (n=3361) is the denominator for all except for 'swelling at injection site', 'nodule at injection site' and 'abscess at injection site' for which only the number of vaccines which were administered by injection (n=2286) is taken as denominator.

Table 2. Distribution of Types of AEFI and Vaccines Implicated for them

Type of AEFI	BCG	DPT	Hep B	OPV	Measles	TT
Fever	6+11*	24+113*	11+110*	0	12+8*	6
Swelling at injection site		48			9	
Excessive Crying	5*	31*	31*		5*	
Diarrhoea				32		
Nodule at injection site		5			0	
Abscess at injection site	2					
Rash	1	1*	1*			
Convulsions		1				

In case of generalized systemic adverse events where more than one vaccine could be responsible for the event, it was difficult to point out single vaccine. So, all vaccines were considered responsible. As mentioned in Table 2, with BCG vaccination, fever (117) and excessive crying (5) was the most common complication. For DPT, fever (137) and swelling at

the injection site (48) was a common AEFI and for Hep B, fever (121) and excessive crying (31) was a major reason for concern. Diarrhoea (32) was the commonest AEFI in children who received OPV. For measles and TT also fever was the commonest AEFI.

Table 3. Pattern of adverse events among male and female

Type of adverse event	Male	Female
Fever	69	52
Swelling at injection site	25	15
Fever and Swelling at injection site	10	7
Excessive crying	22	11
Fever with Excessive crying	3	0
Diarrhoea	23	9
Nodule of approximately 2 cm diameter at injection site of DPT	2	0
Nodule of approximately 2-3 cm diameter at injection site of DPT	0	1
Abscess at injection site	2	0
Rash	0	2
Convulsions	1	0
Nodule of approximately 2.5 cm diameter at injection site of measles	1	1

Table 3 shows the pattern of adverse events among male and female. As seen, fever was the commonest AEFI in both males and females. Some children had more than one co existing adverse event, the most frequently occurring of which was the presence of Fever and Swelling at injection site.

DISCUSSION

Immunization is an important health event in any community or country. Successful immunization coverage is essential for the development of health status in any region. Proper immunization practise will improve coverage and decrease adverse events. The present study was conducted to determine the nature, severity and rate of occurance of AEFI in children less than 12 years of age. The vaccines administered were OPV, DPT, Hepatitis-B, Measles, BCG and TT vaccine. Similar studies were done by Aherkar et L. 2016, Joshi *et al*. (2013), in India, Carrasco-Garrido *et al*. 2004 in Spain, (Carrasco-Garrido, 2004) Aagaard *et al* (2011) in Denmark, Mansoor *et al* in New Zealand (Mansoor, 1997). A total 244 AEFI were reported. 52% of the AEFI occurred in males. Most AEFI was seen in the 4-9 months age group followed by 2-4 months. This finding correlates with the findings of Aherkar et L. 2016 who found most of the AEFI occurred in age less than one year (Aherkar, 2016).

The incidence of AEFI in present study population is 17.7 %. Joshi *et al*. 2013 [11] in their study found the incidence rate to be 20.8% and Aherkar, (2016) found it to be 22.3%. The rate of AEFI per thousand vaccine doses was 72.59. Aherkar et L. 2016 found it to be 86.19 while Joshi *et al*. 2013 [11] found it to be 99.2. Fever was the most common encountered AEFI followed by swelling at injection site which correlates the findings of Aherkar et L. 2016. [10] This can be explained by the fact that fever is the most common symptom accompanying any ailments. Improper injection techniques, unsterilized techniques, post injection exposure to dirty environment are some of the causes of swelling at injection site. Joshi *et al*. (2013), also found fever to be the most common AEFI but the second common AEFI in his study was excessive crying. DPT showed the most number of AEFI in our study followed by Hepatitis B. Diarrhoea as a complication was seen only with OPV. There was a single case of convulsion after DPT administration. It might be due to other comorbid factors or a rare AEFI. Such AEFI may be life threatening and cause permanent damage to the child.

Limitations of This Study

In case of generalized systemic reactions, it was difficult to specify single vaccine responsible, so, both vaccines were considered responsible for the reaction. Certain minor ailments might not be reported. There might be seasonal variations in the AEFI which was not possible to be evaluated due to short duration of the study. Hence long duration studies encompassing larger geographical areas are needed to determine the exact scenario in AEFI incidences.

Conclusion

Consciousness regarding reporting of AEFI should be brought about in the guardians and also in the health care professionals. At present most of the AEFI goes unreported and unevaluated. Hence active surveillance is a good method for detecting and quantifying those reactions that, owing to their mild nature, tend not to be reported by passive surveillance systems. Moreover certain myths prevail in our society regarding ill effects of vaccination which hamper immunization coverage by discouraging the parents. Hence proper evaluation of the AEFI is needed to enhance our knowledge and to assure the parents regarding the safety of the vaccines. The benefits of immunisation in preventing disease continue to significantly outweigh the risks of immunisation-related adverse events. Although AEFI reporting and assessment are an integral part in immunization programs, however the fulfilment of the goal is far away. AEFI reporting and assessment will go a long way in strengthening the vaccine programs and increase coverage.

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REFERENCES

Aagaard, L., Hansen, E.W., Hansen, E.H. 2011. Adverse events following immunization in children: retrospective analysis of spontaneous reports over a decade. *Eur J Clin Pharmacol*, 67(3):283-288.

Aherkar, R.Y., Deshpande, P.K., Ghongane, B.B. 2016. Study of the pattern of adverse events following immunization of children in a tertiary care hospital. *Int J Basic Clin Pharmacol*., 5:609-15

Budhiraja, S. 2010. Pharmacovigilance in vaccine. *Indian J Pharmacol,* 42(2):116-119.

Carrasco-Garrido, P., Gallardo-Pino, C., Jiménez- García, R., Tapias, M.A., de Miguel, A.G. 2004. Incidence of adverse reactions to vaccines in a paediatric population. Clin Drug Invest., 24(8):457-63.

CDC, Food and Drug Administration. Vaccine Adverse Event Reporting System. VAERS Form. Available at https://vaers.hhs.gov/resources/vaers_form.pdf

Chitkara, A.J., Thacker, N., Vashishtha, V.M., Bansal, C.P., Gupta, S.G. 2013. Adverse Event Following Immunization (AEFI) surveillance in India: position paper of Indian Academy of Pediatrics, 2013. *Indian Pediatr*, 50:739-41.

Immunization Handbook for Medical Officers, Department of Health and Family Welfare, Government of India, 2008

Joshi, N.D., Prajapati, H.K., Solanki, K.C., Sukhlecha, A., Trivedi, H.R., Gajera, M.V. *et al*. 2013. Pattern of adverse events following immunization in an Indian teaching hospital. IJMSPH., 2(1):62-8.

Karande, S., Gogtay, N.J., Kshirsagar, N.A. 2003. Efficacy and safety of vaccines in Indian children: a review. Paediatric and Perinatal Drug Therapy, 5 (3):124-34.

Mansoor, O., Pillans, P.I. 1997. Vaccine adverse events reported in New Zealand 1990-5. *N Z Med J.,* Jul 25; 110 (1048): 270-2.

Naranjo, C.A., Busto, U., Sellars, E.M, Sandor P, Ruiz I, Roberts EA, *et al*. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30:239-45.

United Nations International Children's Fund. *Coverage evaluation survey: all India report 2009*. New Delhi: Government of India and UNICEF; 2010.

Vaccine Adverse Event Reporting System (VAERS): About VAERS program (FAQ). Available from http://vaers.hhs.gov/about/faqs

World Health Organization. Causality assessment of adverse event following immunization (AEFI): user manual for the revised WHO classification. 2013. Available at http://apps.who.int/iris/bitstream/10665/80670/1/9789241505338_eng.pdf?ua=1

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