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ACTIVE SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI): A PROSPECTIVE OBSERVATIONAL STUDY

Community Medicine

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ABSTRACT

Background: Vaccines used in national immunization programs are regarded as safe and effective, although immunization safety has surpassed vaccination program efficacy in importance. A single serious adverse event followed by immunization (AEFI) or a series of incidents may cause the public to lose faith in the program, which might have a serious negative impact on immunization coverage. This study was conducted to assess the incidence of AEFIs in children up to 5 years of age.**Material and Methods:** A prospective observational study was conducted among 518 eligible children in the age group 0–5years receiving vaccination from the immunization center at a tertiary health centre of south Rajasthan in the month of March 2023. Study participants were monitored on day 0, 3 and 7 to identify all AEFIs. **Results:** 157 cases of AEFIs from 518 vaccinated subjects were reported. The majority of the AEFIs were reported in the age group 0-1 year. The incidence of AEFIs was 8.65 per 100 doses of vaccines administered. The most common AEFI reported was fever (67, 42.7%), followed by swelling (47, 29.3%). Among the vaccines, Pentavalent + oral polio vaccine (OPV) + Rota virus vaccine (24.8 per 100 doses) was majorly responsible for AEFIs, followed by Diphtheria Pertussis Tetanus (DPT) + Measles and Rubella (MR) + OPV (15.3 per 100 doses). Strikingly none of these 157 cases of AEFI were reported at the centre.**Conclusion:** A Low incidence rate of AEFI was observed in our study population when compared with previous published studies, all of them were minor and no serious AEFIs were identified. The awareness among health professionals and the public regarding the reporting of AEFIs should be continued to increase the safety profile of vaccines. There is major lapse at reporting of AEFI at immunization centre.

KEYWORDS

INTRODUCTION

Vaccination is one of the most cost-effective child survival health interventions.[1] It is considered to be one of the best health interventions money can buy and prevents between 3.5 and 5 million deaths worldwide each year from illnesses like diphtheria, tetanus, pertussis, influenza, and measles.[2] Vaccine-preventable illnesses in India are thought to be the cause of 0.5 million child deaths, and 8.9 million additional children are at risk of contracting them because they are either unimmunized or just partially immunized.[3] Vaccination coverage has stagnated over the past ten years, despite the fact that it is one of the most effective public health treatments. Global coverage decreased from 86% in 2019 to 81% in 2021.

India's full immunization coverage has increased to 75.5% in 2020-2021 (NFHS-5) from 62.0% (NFHS-4).[4] The situation in Rajasthan has also improved from 54.8% in 2015-16 to 80.4% in 2020-2021.[5] Vaccines used in national immunization programs are considered safe and effective when used correctly. Vaccines are; however, not risk-free and adverse events will occasionally occur following vaccination.[6] Adverse events following immunization (AEFI) are defined as 'any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of the vaccine.' The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding, a symptom, or a disease.[7] The aim of AEFI surveillance is to monitor vaccine and immunization program safety and to detect population-specific, rare, late-onset or unexpected adverse events that may not be detected in prelicensure vaccine trials. However, in the majority of cases, AEFI shows a temporal association between vaccination and adverse events and not a causal relationship between the two. Although most adverse events are minor (e.g., pain, swelling, redness at the injection site, fever), more serious reactions (e.g., seizures, anaphylaxis) can occur, though at a very low frequency.[6]

To maintain public trust in the immunization program, AEFI occurrence needs to be minimized. Multiple studies in different parts of India have reported misconceptions about AEFI as a major barrier identified for low immunization coverage.

This study aimed to detect AEFI for all vaccines under NIS administered to the 0 to 5 years of pediatric population at the immunization center of a tertiary care hospital of south Rajasthan.

MATERIALS AND METHODS

Study Design: A prospective Hospital based observational study

Study Period: Approximately One month

Study Population: All children aged 0-5 years receiving vaccination from the immunization center

Sample Size: Considering rate of AEFI reported by a prospective study from North India for the calculation of sample size[8].Assuming an average rate of occurrence of AEFIs of any nature to be 33% with 5% of margin of error, the expected sample size for this study was 340. Considering the dropout rate of 20%, sample size came out to be 408. We screened 572 children for AEFI which is more than the expected sample size for this study.

Inclusion Criteria:

The children aged 0 to 5 years who were accompanied by their mothers or family members; those who gave written informed consent on behalf of their offspring were included in the study.

Study Tools And Materials-

Predesigned and Pre-tested Proforma. Face-to-face interview while collecting proforma.

Study Analysis-

Microsoft Excel software and analysis by IBM SPSS software (Trial version 26.0)

Ethical clearance was obtained from the Institutional Ethics Committee of Jhalawar medical college before starting the study.

Study Procedure:

Data was collected using a pretested, semi-structured questionnaire that contained 18 questions regarding the socio-demographic characteristics of the participants, vaccination details, and the AEFI history of the child. The interview of the eligible participants was done by a postgraduate resident of the Community Medicine department which was of around 15-20 minutes duration. All the mothers who

came for the vaccination of their child were explained about the study and written informed consent was taken from them. A follow-up telephonic call on the third and seventh day of vaccination of the enrolled study subjects was done to identify if any AEFI occurred. If yes, details about AEFI were recorded further using the same questionnaire which was filled out at the session site.

Collected data were coded appropriately, entered in a Microsoft Excel spreadsheet, and later cleaned for any possible errors in SPSS Statistics for Windows v.26.0 (IBM Corp., Armonk, NY). Analysis was also carried out using SPSS. Categorical data are presented as a percentage. The descriptive analysis of categorical data is presented as frequencies and percentages. The chi-square test was used to assess the association between two categorical variables and $p < 0.05$ was considered statistically significant.

RESULTS:

A total of 572 children who received vaccination were screened; from these, the mothers of 9 children refused to participate in the study. Of the enrolled 563 children, 518 of them completed the two telephonic follow-up assessments following vaccination with a response rate of 92%. Hence final study sample comprised of these 518 children.

Table 1 Sociodemographic Profile Of Study Participants

Variable	Categories	Total (N=518)	%
AGE	0 to 28 days	245	47.3
	28 days to 1 year	219	42.3
	1 to 2 years	34	6.6
	2 to 5 years	20	3.9
GENDER	Female	243	46.9
	Male	275	53.1
RELIGION	Hindu	393	75.9
	Muslim	122	23.6
	Jain	2	0.4
	Buddhist	1	0.2
TYPE OF FAMILY	Nuclear	101	19.5
	Joint	116	22.4
	Three Generation	301	58.1
EDUCATION OF MOTHER	Illiterate	41	7.9
	Primary	81	15.6
	Secondary	209	40.3
	Graduation and above	187	36.1
BIRTH WEIGHT	Normal	384	74.1
	Low Birth Weight	126	24.3
	Very Low Birth Weight	8	1.5

In Table 1, we observed that out of 518 children included in the study, the majority were in the age group of 0 to 28 days (47.3%), males (53.1%), Hindu by religion (75.9%), residing in a Three Generation family (58.1%) and had birth weight >2500 grams (74.1%). Mothers of 92.1% of children were literate. In total 1814 vaccine doses administered to the study population, 157 AEFI were reported from 518 vaccinated subjects.

Table 2 Association Of AEFI In Children With Age Group And Gender

Variable	Categories	Children with AEFI n (%)	Children without AEFI n (%)	Total (N=518)	P Value
Age group	0 – 28 days	15 (6.1)	230 (93.9)	245	P < 0.0001
	28 days – 1 year	119 (54.3)	100 (45.7)	219	
	1 – 2 years	22 (64.7)	12 (35.3)	34	
	2 – 5 years	1 (5.0)	19 (95)	20	
Gender	Male	73 (26.5)	202 (73.5)	275	p=0.047
	Female	84 (34.6)	159 (65.4)	243	

Out of 518 children with AEFI, the majority (89.6%) were aged less than one year. There was significant association of AEFI with Age group and Gender as shown in Table 2.

Table 3: Distribution Of AEFI Rate Per 100 Doses According To Vaccines Administered

Age	Vaccine administered	Doses of vaccine (b)	No. of AEFIs (a)	AEFI incidence per 100 doses [a/b*100]
< 1 Week	BCG, HEP B, OPV 0	744	16	2.1
6 Weeks	OPV 1, PENTA 1, ROTA 1, PCV 1, f-IPV 1	285	35	12.3
10 Weeks	OPV 2, PENTA 2, ROTA 2	177	44	24.85
14 Weeks	OPV 3, PENTA 3, ROTA 3, PCV 2, f-IPV 2	260	31	11.92
9 Months	f-IPV 3, MR 1, VIT A	184	8	4.3
16-24 Months	DPT BOOSTER 1, MR 2, OPV BOOSTER, VIT A	144	22	15.27
5 Years	DPT BOOSTER 2	20	1	5.0

BCG: Bacillus Calmette-Guerin vaccine; hepatitis B: hepatitis B vaccine; OPV: oral polio vaccine; IPV: inactivated polio vaccine; Pentavalent: pentavalent vaccine; measles: measles vaccine; MR: measles and rubella vaccine; DPT: diphtheria pertussis tetanus vaccine

Table 3 shows that AEFI incidence following administration of Pentavalent + oral poliovirus vaccines (OPV) + Rota at the age of 10 weeks was highest (24.8 per 100 doses) followed by the vaccines for diphtheria pertussis tetanus (DPT) + measles and rubella (MR) + OPV (15.27 per 100 doses) at 16 to 24 months of age. Following Pentavalent + inactivated polio vaccine (IPV) + OPV administration + PCV + Rota virus vaccine, the incidence was 12.8 per 100 doses when administered at the age of six weeks whereas it was 11.9 per 100 doses at the age of 14 weeks. 16 AEFI's were reported after bacillus Calmette-Guerin vaccine (BCG) + Hepatitis B + OPV administration at less than one week of age with the least incidence (2.1 per 100 doses) followed by measles/MR at nine months to one year of age with incidence (4.3 per 100 doses). Overall AEFI incidence reported was 8.65 per 100 doses.

Table 4: Frequency Distribution Of Various AEFI According To Administered Vaccines

Vaccines	Fever	Persistent crying	Swelling	Abscess formation	Vomiting	Diarrhea	Pain	Total
At Birth (BCG, HEP B, OPV 0)	8 (11.94)	3 (25)	0 (0.0)	0 (0.0)	0 (0.0)	4 (57.14)	1 (7.14)	16 (10.19)
6 Weeks (OPV 1, PENTA 1, ROTA 1, PCV 1, f-IPV)	13 (19.40)	5 (41.6)	13 (28.2)	1 (14.28)	0 (0.0)	0 (0.0)	3 (21.4)	35 (20.95)
10 Weeks (PENTA 2, OPV 2, ROTA 2)	19 (28.35)	3 (25)	13 (28.2)	4 (57.14)	1 (33.33)	0 (0.0)	4 (28.57)	44 (28.02)
14 Weeks (OPV 3, PENTA 3, ROTA 3, f-IPV 2, PCV 2)	12 (17.91)	1 (8.3)	12 (26.1)	2 (28.57)	0 (0.0)	1 (14.28)	3 (21.42)	31 (19.74)
9 Months (MR 1, f-IPV 3, PCV BOOSTER, VIT A)	5 (7.46)	0 (0.0)	1 (2.2)	0 (0.0)	1 (33.33)	0 (0.0)	1 (7.14)	8 (5.09)
16-24 Months (DPT BOOSTER 1, MR 2, OPV BOOSTER)	10 (14.92)	0 (0.0)	7 (15.2)	0 (0.0)	1 (33.33)	2 (28.57)	2 (14.28)	22 (14.01)
5 Years (DPT BOOSTER 2)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.63)
Total	67 (42.67)	12 (7.6)	47 (29.3)	7 (4.45)	3 (1.9)	7 (4.45)	14 (8.91)	157 (100)

Note: Numbers in parenthesis represent percentages.

Table 4 shows that out of a total of 157 cases of AEFIs, fever was the most common AEFI (67; 42.67%) with most of the cases of it after administration of Pentavalent + OPV + Rota vaccines (19; 28.35%) at 10 weeks , followed by swelling at the injection site (47; 29.3%) with most cases of it after administration of Pentavalent + OPV + Rota vaccine (13; 28.2%) at 6 and 10 weeks, and the least common was

vomiting (1.9%).

It was observed that all the AEFI were reported in the interval between the day of vaccine administration and the first telephonic follow-up (Third day), and none was reported between the first and second telephonic follow-up (Seventh day). The study found that 95% of children recovered at the time of the first telephonic follow-up and all of them recovered at the second follow-up.

DISCUSSION

The present work was done to study the adverse events following immunization among children less than five years of age. In current study, the majority of AEFI were among children in the age group of less than 1 year (85.3% AEFI). These results were expected, as maximum doses of vaccines according to National Immunization Schedule are given in this age group.

The results are comparable to a study by Aherkar et al. and Badur et al., in which the most common age group was less than nine months and one year respectively [9,11].

In present study, of the total AEFI, the most common was fever (42.7%), followed by swelling at the injection site (29.3 %) as in previously published studies [9,10,11]. Overall Pentavalent + OPV (24.8 per 100 doses) was majorly responsible for AEFI followed by DPT + MR + OPV (15.3 per 100 doses) which is consistent with the findings of other studies [10,11]. In the present study, 10.2% AEFI were reported after BCG + hepatitis B + OPV while in a study by Badur et al., 35.5% AEFI were reported [10]. The incidence of AEFI in the study was 8.65 per 100 doses of all vaccines which was almost similar when compared to that reported by Aherkar et al. (8.61 per 100 doses) and Sebastian et al. (13.7%) [9,10]. In a study by Patel et al., the AEFI rate was 8.3 per 100,000 doses [12].This variation in rates of reported AEFI in different studies could be explained by the type of surveillance, variable case definitions, reporting criteria, variable compliance with reporting, and sample size of the study population. No serious AEFI was identified in present study. Any child weighing <1500g is not vaccinated, this Guideline issued at our health centre is strictly followed. This practice might have helped in preventing serious complications following immunization. It was also observed that all universal safety precautions are meticulously followed at study area. For causality only temporal association was relied upon.

Limitations

There was the possibility of recall bias as the identification of AEFI was based on history taken from mothers which could lead to under or over-reporting of AEFI. It was not possible to identify which vaccine was responsible for many of the AEFIs since multiple vaccines were administered to the children at each of the immunization visit.

CONCLUSION:

The incidence of AEFI was 8.65 per 100 doses in the present study but no serious adverse events attributable to vaccines were reported. The study revealed that the vaccines were safe and well-tolerated as the majority of the children recovered spontaneously without any formal consultation. There is major lapse at reporting of AEFI at immunization centre. The awareness among health professionals and the public regarding reporting of AEFI should be continued to increase the safety profile of vaccines, and to increase public trust in immunization programs.

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