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AEFI (ADVERSE EVENTS FOLLOWING IMMUNIZATION) AMONG CHILDREN LESS THAN 2 YEARS FOLLOWING PENTAVALENT VACCINE– A CROSS-SECTIONAL STUDY IN INDIA

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Abstract:
Introduction: Despite significant progress in vaccine-preventable disease control, Immunization is not free of controversies. Vaccine safety is increasingly becoming important because of alleged safety issues that can derail vaccine programs worldwide.

Aims: To study AEFI (Adverse Events Following Immunization**)** following the Pentavalent vaccine among children under two years old getting immunized at the session site.

Methods and Material: The study was a population-based cross-sectional study. A total of 209 children got vaccinated at the selected sub-centers for one year. The investigator contacted the mothers of the vaccinated children through two home visits. A pre-designed, pre-tested, semi-structured schedule was used to gather data. Categorical data was presented as a percentage (%). The descriptive analysis of data was depicted in graphs and percentages after statistical analysis.

Results: It was observed that AEFI incidence rate per 1000 doses was higher following the first dose of pentavalent vaccine (312.05), followed by the second dose (290.78) and third dose (271.42), fever [31.3% (1st dose), 29.1% (2nd dose), 27.1% (3rd dose)] was the most common AEFI observed. All the mothers (100%) were told that the vaccine was responsible for the occurrence of AEFI in their children and wished to continue vaccinating their children for further doses.

Conclusion: All the AEFI observed were minor. The benefits of vaccines outweighed the AEFI observed, as the mothers were willing to continue vaccinating their children even after the occurrence of AEFI.

Key-words: Vaccination; Immunization; Adverse Events Following Immunization; pentavalent vaccine; AEFI

Introduction:

Vaccination is a proven and one of the most efficient and effective child survival interventions. All countries worldwide have an immunization program to deliver selected vaccines to the targeted beneficiaries, primarily focusing on pregnant women, infants, and children at a higher risk of diseases preventable by vaccines. There are at least 27 causative agents against which vaccines are available, and many more agents are targeted for the development of vaccines [1].

More people than ever before are being reached with Immunization. India's Expanded Program for Immunization (EPI) was launched in 1978. In 1985, it was renamed the Universal Immunization Program (UIP). Since 2006, Hepatitis B, Haemophilus Influenza B, second dose of measles, and Japanese Encephalitis (J.E.) vaccine have been introduced in UIP. During the same period, several other vaccines have become available for significant killers like pneumonia and diarrhea, which are being used in the immunization programs of many developing and developed countries. The pentavalent vaccine is a combination vaccine that protects against five diseases: diphtheria, pertussis, tetanus, hepatitis, and Haemophilus influenza type B. It was introduced in India in a phased manner in 2011 [2].

Adverse events following Immunization (AEFI):

Any untoward medical condition that follows Immunization and does not necessarily have a causal relationship with the vaccine administration. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease. AEFIs are divided into five categories.

1. Vaccine product-related reaction
2. Vaccine quality defect-related reaction
3. Immunization error-related reaction
4. Immunization anxiety-related reaction
5. Coincidental event

In India, the following reporting reports guide AEFI investigation and causality assessment.

1. Case reporting form (CRF):- to be filled within 24 hours.
2. Preliminary Case Investigation Form (PCIF):- to be filled within ten days.
3. Final Case Investigation Form (FIF):- to be filled within 70 days.

AEFI Committees

AEFI committees are established at the District, State, and National levels. AEFI committees' objective is to strengthen AEFI reporting at all levels, ensure National Policy and standards maintenance, and ensure a prompt and thorough investigation of severe AEFI [3].

Despite significant progress in vaccine-preventable disease control, Immunization is not free of controversies. Vaccine safety is increasingly becoming important because of alleged safety issues that can derail vaccine programs worldwide. Different AEFI reporting systems exist in countries such as VARES in the USA and PSAEFI in Brazil [4].

There are several well-described limitations of such reporting systems. These include variability in report quality, biased reporting, under-reporting, and the inability to determine whether a vaccine caused the adverse event in any individual report. Pharmacovigilance on vaccines in India is still in the cradle stage. There is a need for pharmacovigilance of vaccines on a large scale in India [5].

After reviewing various pieces of literature and assessing the lack of data and extended research, this study was planned to evaluate AEFI in children (less than two years) vaccinated with the Pentavalent vaccine.

Aims and objectives

To study AEFI (Adverse Events Following Immunization**)** following the Pentavalent vaccine among children under two years old getting immunized at the session site.

Materials and Methods

The study was a population-based cross-sectional study carried out over one year, and all the children under two years who got immunized with the pentavalent vaccine were included. The study was conducted in block Lakhan Majra of District Rohtak, Haryana, INDIA, catering to a population of approximately 1.1 Lacs within a Community Health Centre, Chiri jurisdiction. CHC Chiri is the rural field practice area of the Department of Community Medicine, Pt. B.D. Sharma PGIMS, Rohtak (H.R.) is used for teaching, training, and research activities. The necessary Ethical approval was obtained from the Institutional Ethical Committee following the principles outlined in the Helsinki Declaration. The participants in this study were treated with utmost respect for their autonomy, privacy, and well-being and written informed consent was obtained for enrollment in the study. Subjects unwilling to participate in the study and those who could not be contacted after two visits were excluded.

Sampling technique

A simple random sampling technique was employed for the study area, i.e., the area under CHC Chiri. There were 3 PHCs and 20 sub-centers. Amongst these 3 PHCs, one PHC (CHIRI) was selected randomly by lottery. From the selected PHC, two sub-centers were selected randomly where the study was conducted. Thus, two sub-centers out of 20 were selected to gather the information. As most of the studies related to AEFI were either record-based or hospital-based and community-based studies covering a specific area could not be retrieved, all the children less than two years of age getting vaccinated with the Pentavalent vaccine at the session sites (over one year) under the selected 2 Sub-centres were included in the study. In our study, 209 children were vaccinated at the selected sub-centers over one year. Six children could not be contacted after two follow-up visits and were excluded from the study. The confidentiality of the data about study subjects was ensured by allotting subject numbers. A few days before the first visit to each sub-center, the community health worker was contacted along with the help of the concerned Accredited Social Health Activist (ASHA); mothers of the vaccinated children were contacted by home visit on the 8^{th} and 30^{th} day following vaccination in the first sub-center and the 9^{th} and 31^{st} day following vaccination in the second sub-center by the investigator himself.

Informed and written consent was obtained from either of the parents. The interview started with a general discussion to build rapport with the study subjects and gain their confidence. The interview schedule included information like the mother's name, age, education status, and occupation. The socioeconomic status of the study population was measured using the Udai Pareek scale for rural areas [6]. Pareek's criteria comprise nine variables: caste, education, occupation, land, social participation, no. of family members, house, farm power, and material possession. Differential weights are assigned to the various items on each variable. In these criteria, social classes are grouped under five categories: upper, upper middle, middle, lower middle, and lower. After collecting the above information, the mothers were asked whether any AEFI had occurred in their children following the last vaccination. If they had encountered any AEFI, then the details about AEFI were asked from the mothers by the investigator using a pre-designed, pre-tested, semi-structured schedule, and the second visit was done after 22 days of the first visit to detect if any more AEFI had appeared following the first visit.

Collected data were coded appropriately, entered in a Microsoft Excel (M.S. Excel) spreadsheet, and later cleaned for any possible errors in SPSS (Statistical Package for Social Studies) for Windows ver. 20.0. the statistical data analysis was done using SPSS (Statistical Package for Social Studies) for Windows ver. 20.0. Categorical data was presented as percentage (%). The descriptive analysis of data was depicted in graphs and percentages.

Results: During the study period, 209 children got vaccinated with the pentavalent vaccine at the selected sub-centers, out of which only 203 children could be included in the study 6 children could not be contacted after two follow-up visits and were excluded from the study. The socioeconomic diversity and type of family were also recorded. (Table 1) These 203 children received a total of 422 doses of pentavalent vaccine. Following 422 doses, 123 AEFIs were reported over one year.(Table 2)
It was also observed that the AEFI incidence rate per 1000 doses was higher following the first dose of the pentavalent vaccine (312.05), followed by the second dose (290.78) and third dose (271.42) (Figure-1). Overall, the AEFI incidence rate per 1000 doses of pentavalent vaccine was higher in the case of males (330.35) than in the case of females (247.47). (Table 2)

In our study, it was also observed that following the pentavalent vaccine administration (1^{st}, 2^{nd}, third doses), fever [31.3% (1^{st} dose), 29.1% (2^{nd} dose), 27.1% (3^{rd} dose)] was the most common AEFI observed followed by irritability in child [23.5% (1^{st} dose), 17.7% (2^{nd} dose), 17.7% (3^{rd} dose)] respectively. (Table 3) It was also observed that AEFI following the pentavalent vaccine interfered with the children's daily activities in 75% of the cases following the first dose, 65.9% following the second dose, and 65.8% following the third dose but did not prevent daily activities. (Table 4) Most mothers (80.5%) did not consult any health facility following an AEFI in their children; nearly one-tenth (9.8%) consulted a government health facility, and only 2.4% consulted a private hospital. All the mothers (100%) said that the vaccine was responsible for the occurrence of AEFI in their children and wished to continue vaccinating their children for further doses.

Discussion:
Our population-based prospective study was carried out over one year on 203 children. In our study, an active search of cases was done through home visits. We could not find any study in the literature with the same methodology. Our methodology was slightly similar to a study by Joshi et al. [7] in 2011, in which an active search was done using a telephone survey over one year on 4320 cases. Bg R et al. also actively searched cases following the J.E. vaccine in Kolar, Karnataka, in 2007 [8]. Carrasco-Garrido et al. conducted an active search using a telephone survey over six months on 946 cases [9].

Our study revealed that most cases where AEFI was observed were males (60.2%). Maximum AEFI rate per 1000 doses was observed following the first dose of pentavalent vaccine (312.05) (Figure-1). The overall AEFI incidence rate per 1000 doses was higher in males (330.35) than in females (247.47). (Table-2) The findings in our study were similar to a record-based study conducted by Pagar et al., which revealed that 66.94% of AEFI cases were males [10]. In their record-based study, Laryea et al. observed that a higher proportion of AEFI reports were among males than females [11].

In contrast to the findings in our study, a retrospective record-based study conducted by Mittal et al. revealed an incidence of 33.0 AEFIs per 100 doses of vaccines administered [12]. The majority of AEFIs were reported in the age group of 0-1 years. Understanding the age-related distribution is crucial for tailoring vaccination strategies and addressing potential vulnerabilities in different age groups. Fever was reported as the most common AEFI (47.6%), followed by swelling (25.0%). Identifying the predominant adverse events helps in prioritizing interventions and management strategies. The study highlighted that the Pentavalent + oral polio vaccine (OPV) had the highest incidence of AEFIs (48.8 per 100 doses). This highlights the need to evaluate individual vaccines and their safety profiles. Studies conducted by Dey et al., Stratton et al. and Shimabukuro et al. also revealed that females had more adverse events or minimal differences between genders [13-15].

A higher AEFI incidence rate is observed in our study compared to other studies; the reason might be the difference in the study design between our study and the studies discussed. Most of the studies discussed were either record- or hospital-based, but an active search of cases for any AEFI was done in our study. The other reasons for the differences might be the difference in the manufacturers of vaccines included in our study, and the studies discussed, the difference in the products used for manufacturing the vaccines (e.g., the strain of the antigen, adjuvants, preservatives) included in our study and the studies discussed.

Types of AEFI observed concerning vaccine-implicated

In our study, it was observed that the AEFI incidence rate per 1000 doses was maximum following the first dose of pentavalent vaccine (312.05), which decreased with further doses, (290.78) second dose, and (271.42) third dose. Fever was the most common AEFI reported after receiving pentavalent vaccine [(31.3%) first dose, (29.1%) second dose and (27.1%) third dose followed by irritability in child [23.5% (1^{st} dose), 17.7% (2^{nd} dose), 17.7% (3^{rd} dose)], pain/tenderness [13.2% (1^{st} dose), 11.4% (2^{nd} dose), 13.5% (3^{rd} dose)], redness [11.4% (1^{st} dose), 11.4% (2^{nd} dose), 7% (3^{rd} dose)] and nodule [7.1% (1^{st} dose), 8.5% (2^{nd} dose), 7% (3^{rd} dose)].

The findings in our study are in coherence with the study carried out by Hansen et al., who observed that after receiving Hib/T.T./DTwP vaccine, fever was the most common AEFI reported followed by child feeding less than usual, swelling, excessive crying, and erythema [16].

Similarly, in a descriptive record-based study conducted by Monterio et al., it was observed that the highest proportion of AEFI occurred after the first dose of the DTwP/Hib vaccine (48.8%), dropping to 35.1% following the second dose and 16.1% following third dose [17]. Fever was observed in 29% (1^{st} dose), 31.6% (2^{nd} dose), and 29.8% (3^{rd} dose) of children, and local pain/redness/overheating in 6.1% (1^{st} dose), 5.2% (2^{nd} dose) and 5.7% (3^{rd} dose).

Similarly, in their record-based study, Izadi et al. observed that AEFI reported following the DTwP/Hib vaccine were fever, pain/redness/heat, headache and vomiting, and local hot abscess. Similarly, Khatereh et al. [19], in their study, revealed that after receiving DTwP/Hib, fever was the most common AEFI observed, followed by local pain, redness, irritability, swelling, and loss of appetite [18].

The findings in our study were in contrast to the study conducted by Karami et al. [20], which revealed that after receiving the DTP/Hib vaccine, the most frequent adverse events reported were local pain, followed by irritability, fever, and erythema.

In their record-based study, Danova et al. observed that AEFI observed after receiving DTwP/Hib vaccine was fever followed by pain/redness/heat, headache and vomiting, and local hot abscess [21]. Dhingra et al. in their study revealed that after receiving the DTwP-Hib vaccine, the most common AEFI observed was pain (32.84%), followed by irritability (29.74%), crying (22.89%), local swelling (19.74%) and local redness (12.11%) [22].

Most of the adverse events following the pentavalent vaccine are caused by the pertussis component of the vaccine. Immunization with wP (whole cell Pertussis) vaccines is frequently associated with minor adverse events, such as local redness and swelling, induration, fever, and agitation. Prolonged crying and febrile convulsions are less common and hypotonic–hyporesponsive episodes are rare [23]. High fever was the most commonly recorded adverse event for the DPT vaccine (47.4%), while mild localized complications were highest for the Pentavalent vaccine (31.68%) [24].

The difference in the incidence rate of AEFI observed in our study and other studies discussed might be due to the difference in the study design. In most of the studies discussed, AEFI was reported passively. The other reasons might be the difference in the age group of the study subjects included in the study and the difference in the number of vaccines used to calculate the overall AEFI incidence rate per 1000 doses of all vaccines.

Impact outcome and highest level of care obtained following AEFI

Regarding the impact of an AEFI, our study revealed that there was interference in the daily activities in three-fourths of the children (75%) following the pentavalent first dose, dropping to 65.9% (2^{nd} dose) and 65.8% (3^{rd} dose).

All the children (100%) in whom AEFI was observed fully recovered with medication. Most mothers (80.5%) did not consult any health facility following an AEFI in their children, 9.8% consulted a government health facility, 7.3% took health advice from a health professional telephonically, and only 2.4% consulted a private hospital.

Similar findings were observed in a study conducted by Ogundele et al., which revealed that Approximately 38% of the youngsters have encountered an AEFI. Most moms (67.5%) attributed AEFIs to the pentavalent vaccination. The most prevalent AEFI were fever, reported in 88.0% of cases, and pain and swelling, reported in 76.0%. Over half of the mothers (53.7%) provided home therapy in response to an AEFI. Younger mothers who gave birth at a healthcare facility and had knowledge about reporting AEFI were more inclined to respond correctly to AEFIs [25].

In contrast to the findings in our study, Mahalingam et al., in their cross-sectional descriptive study, revealed that 90.5% of the mothers in urban areas and 71.5% of mothers in rural areas had informed the healthcare workers about the side effects [26].

It is evident from the study that the mothers were already informed by the health care functionaries regarding possible adverse events following vaccination; they did not consult any health facility and were aware that the adverse events observed were minor and would suffice on their own. More mothers consulted government health facilities than private institutions; this shows their faith in government institutions compared to private ones.

Conclusion:

Our study findings highlight the significance of vaccination as a crucial tool in protecting against vaccine-preventable diseases. Interestingly, all the mothers involved in the study believed that adverse events following Immunization (AEFI) in their children were linked to the vaccines. Despite this, it is noteworthy that all of them (100%) expressed their willingness to continue immunizing their children with further vaccine doses. These observations indicate that the mothers in our study had a strong faith in both the vaccinator and the vaccination program implemented by the government of India. They weighed the potential benefits of vaccination against the observed AEFI and concluded that the advantages of Immunization outweighed any associated risks. This finding underscores the importance of effective communication and education about vaccines and their potential side effects.

Overall, our study reinforces the critical role of vaccination in preventing vaccine-preventable diseases and emphasizes the need for continued efforts to ensure public trust and confidence in immunization programs.

Conflict of Interest: "The authors have no conflicts of interest associated with the material presented in the paper."

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Author Contribution:

Conceptualization: P.D., V.G., and P.P. Data Cuartion: P.D. and V.G. Formal analysis: P.D., P.P., V.G., and A.B. Methodology: P.D., P.P. and V.G. Project administration: P.D., P.P. and V.G. Data analysis: P.D., P.P. and A.B. Manuscript creation and Writing: P.D., P.P., and A.B. Review and editing: P.P., V.G. and A.B.

References:

1. Rodrigues CM, Plotkin SA. Impact of vaccines; health, economic and social perspectives. Frontiers in microbiology. 2020 Jul 14;11:1526.
2. Nandi A, Kumar S, Shet A, Bloom DE, Laxminarayan R. Childhood vaccinations and adult schooling attainment: Long-term evidence from India's Universal Immunization Programme. Social Science & Medicine. 2020 Apr 1;250:112885.
3. Joshi J, Das MK, Polpakara D, Aneja S, Agarwal M, Arora NK. Vaccine safety and surveillance for adverse events following immunization (AEFI) in India. The Indian Journal of Pediatrics. 2018 Feb;85:139-48..
4. Hviid A, Hansen JV, Frisch M, Melbye M. Measles, mumps, rubella vaccination and autism: a nationwide cohort study. Annals of internal medicine. 2019 Apr 16;170(8):513-20.
5. Bellavite P. Causality assessment of adverse events following immunization: the problem of multifactorial pathology. F1000Research. 2020;9.
6. Majumder S. Socioeconomic status scales: Revised Kuppuswamy, BG Prasad, and Udai Pareekh's scale updated for 2021. Journal of Family Medicine and Primary Care. 2021 Nov;10(11):3964.
7. Joshi ND, Prajapati HK, Solanki KC, Sukhlecha A, Trivedi HR, Gajera MV, Vyas BR. Pattern of adverse events following immunization in an Indian teaching hospital. Int J Med Sci Public Health. 2013 Jan 1;2(1):62-8.
8. Ranganath BG, Hiremath SG. Adverse events following immunisation with SA 14-14-2 Japanese encephalitis vaccine in children of Kolar in Karnataka. Journal of the Indian Medical Association. 2012 Jan 1;110(1):10-2.
9. Galindo BM, Concepción D, Galindo MA, Pérez A, Saiz J. Vaccine-related adverse events in Cuban children, 1999-2008. MEDICC review. 2012 Jan;14(1):38-43.
10. Pagar VS, Chavan SS, Patil SP, Borde A, Kinge AD, Khargekar N. Epidemiological study of adverse events following immunization in under 5 year children. Journal of Family Medicine and Primary Care. 2021 Jul;10(7):2482.
11. Yamoah P, Mensah KB, Padayachee N, Bangalee V, Oosthuizen F. Assessment of adherence to pre-vaccination precautions and AEFI reporting practices during BCG vaccination in 4 hospitals in Ghana. Human Vaccines & Immunotherapeutics. 2023 Dec 31;19(1):2199654..
12. Mittal S, Rawat CM, Gupta A, Solanki HK, Singh RK. Adverse Events Following Immunization Among Children Under Two Years of Age: A Prospective Observational Study From North India. Cureus. 2023 Apr 30;15(4).
13. Dey A, Wang H, Quinn H, Hiam R, Wood N, Beard F, Macartney K. Surveillance of adverse events following immunisation in Australia annual report, 2017. Commun Dis Intell. 2019 Jul 16;43:1-28.
14. Institute of Medicine (US). Committee to Review Adverse Effects of Vaccines, Stratton KR, Clayton EW. Adverse effects of vaccines: evidence and causality.
15. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the vaccine adverse event reporting system (VAERS). Vaccine. 2015 Aug 26;33(36):4398-405.
16. Hansen J, Decker MD, Lewis E, Fireman B, Pool V, Greenberg DP, Johnson DR, Black S, Klein NP. Hypotonic-hyporesponsive Episodes After Diphtheria, Tetanus and Acellular Pertussis Vaccination. The Pediatric Infectious Disease Journal. 2021 Dec;40(12):1122.

17. Monteiro SA, Takano OA, Waldman EA. Surveillance for adverse events after DTwP/Hib vaccination in Brazil: sensitivity and factors associated with reporting. Vaccine. 2010 Apr 19;28(18):3127-33.
18. Izadi S, Mohammadi M, Sartipi M, Karami M, Karimi H. Acute adverse events following immunization with DTP-HB-Hib pentavalent vaccine in the first year of life. Eastern Mediterranean Health Journal. 2023;29(1):6-14.
19. Khatereh A, Koruosh G, Alireza T, Daryuosh J, Parastoo B. Adverse Events Following Immunizations in Infants Under 1 Year of Age in Lorestan Province, Western Iran. Journal of Preventive Medicine and Public Health. 2023 Mar;56(2):172.
20. Karami M, Ameri P, Bathaei J, Berangi Z, Pashaei T, Zahiri A, Zahraei SM, Erfani H, Ponnet K. Adverse events following immunization with pentavalent vaccine: experiences of newly introduced vaccine in Iran. BMC immunology. 2017 Dec;18(1):1-7.
21. Danova J, Kocourkova A, Celko AM. Active surveillance study of adverse events following immunisation of children in the Czech Republic. BMC Public Health. 2017 Dec;17:1-5.
22. Dhingra MS, Rao R, Bhat S, Joshi R, Kalra V, Parikh HR, Rao SN, Sethi GR, Shah N, Muzaffaruddin M. Evaluation of the immunogenicity and safety of an indigenously developed DTwP-Hib tetravalent combination vaccine (Shan 4) with EasyFourTM in Indian infants administered per EPI schedule: A phase III trial. Human vaccines. 2010 Jul 1;6(7):572-7.
23. Tandy CB. An Epidemiologic Study of Vaccination Exemptions and Pertussis Risk.
24. Khazaei Z, Moradi G, Zahraei SM, Gouya MM, Goodarzi E, Yaghini F, Roshani D. The comparison of the adverse events of pentavalent vaccine and DPT vaccine in 2–6 months infants in Iran: a national study. Annals of Global Health. 2020;86(1).
25. Ogundele OA, Fehintola FO, Salami M, Usidebhofoh R, Abaekere MA. Prevalence and patterns of adverse events following childhood immunization and the responses of mothers in Ile-Ife, South West Nigeria: a facility-based cross-sectional survey. Osong Public Health and Research Perspectives. 2023 Aug;14(4):291.
26. Mahalingam S, Soori A, Ram P, Achappa B, Chowta M, Madi D. Knowledge, attitude and perceptions of mothers with children under five years of age about vaccination in Mangalore, India. Asian Journal of Medical Sciences. 2014 May 16;5(4):52-7.

Table 1: Socio-demographic profile of participants (n = 203)

Socio-demographic profile	**Frequency**	**Percent**
Gender		
Male	87	42.8
Female	116	57.2
Caste		
Schedule caste	49	24.1
Lower caste	25	12.3
Prestige caste	16	7.9
Dominant caste	113	55.7
Socioeconomic status		
Upper middle class	17	8.4
Middle class	64	31.5
Lower middle class	93	45.8
Lower class	29	14.3
Family Type		
Nuclear	44	21.6
Joint	153	75.4
Three Generation	6	3
Total	**203**	**100**

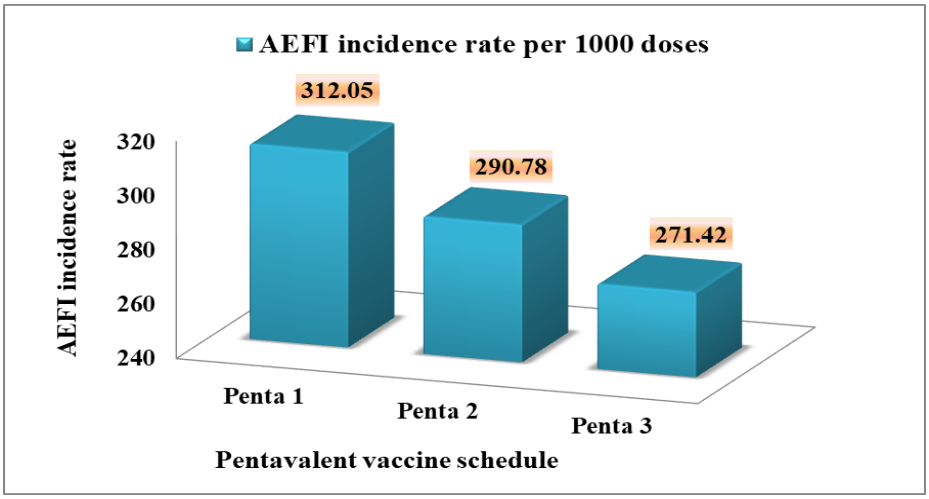

Figure 1: Pentavalent vaccine schedule and AEFI incidence rate

Table 2: Distribution of AEFI cases according to gender, vaccine dose implicated and doses administered

Vaccine dose	Males			Females		
	Doses administered (a)	AEFI observed (b)	AEFI Incidence rate per 1000 doses (b/a x 1000)	Doses administered (c)	AEFI observed (d)	AEFI Incidence rate per 1000 doses (d/c x 1000)
Penta 1	75	25	333.3	66	19	287.8
Penta 2	75	23	306.6	66	18	272.7
Penta 3	74	26	351.3	66	12	181.8
Total	**224**	**74**	**330.35**	**198**	**49**	**247.47**

Table 3: Distribution of type of AEFI according to Pentavalent vaccine dose implicated.

Types of adverse events	Pentavalent Vaccine dose implicated		
	Penta 1st dose (n=141)	Penta 2nd dose (n=141)	Penta 3rd dose (n=140)
Fever	44 (31.3)	41 (29.1)	38 (27.1)
Irritable	33 (23.5)	25 (17.7)	25 (17.7)
Feeding less than normal	33 (23.5)	25 (17.7)	25 (17.7)
Swelling at injection site	25 (17.7)	18 (12.8)	17 (12.1)
Pain/Tenderness	19 (13.2)	16 (11.4)	19 (13.5)
Redness	16 (11.4)	16 (11.4)	10 (7)
Nodule	10 (7.1)	12 (8.5)	10 (7)
Total	**180 (127.7)***	**153 (108.6)***	**144 (102.1)***

(Figures in parenthesis indicate percentage) (*= multiple responses)

Table 4: Distribution of vaccinated children reporting AEFI according to impact of AEFI (n = 123)

Impact	Penta 1	Penta 2	Penta 3
No interference with daily activities	11 (25)	14 (34.1)	13 (34.2)
Interfered but did not prevent daily activities	33 (75)	27 (65.9)	25 (65.8)
Prevented daily activities	0 (0)	0 (0)	0 (0)
Total	**44 (100)**	**4 (100)**	**38 (100)**

(Figures in parenthesis indicate percentage)