International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 6 Nov-Dec 2022, pp: 722-736 www.ijprajournal.com ISSN: 2456-4494

# A Study on Adverse Events Following Immunization (Aefi) In Paediatric Population in Tumakuru, Karnataka.

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Submitted: 15-11-2022 Accepted: 25-11-2022

**ABSTRACT**
**Background:**An Adverse Event Following Immunization can be any unfavourable or unintentional sign, odd laboratory sign, abnormal discovery symptom or sickness. Adverse events followed by immunization can be local reaction like oedema, rashes and inflammation or systemic reaction like fever, allergic reactions and this adverse reaction may be acute or delayed. AEFI is recognized either through active or passive surveillance.
**Objective:**To assess the adverse events following immunization in paediatric population in Tumakuru, Karnataka.
**Methodology:**This was a prospective and retrospective cross-sectional study conducted in randomly selected Primary Healthcare Centres, Hospitals and District Hospital Tumakuru. Predesigned materials such as Informed Assent Forms, ADR Notification Forms and ADR Reporting Forms are used to collect the data about a AEFI's from Nurses who work in healthcare centres and hospital, Parents and Documents related to immunization.
**Result:**AEFI data collected from 115 subjects. When the association of age with AEFI was studied, 24(20.9%) subjects who falls under the age group of 1-5y were followed by AEFI.AEFI percentage with each vaccine is as followsBCG-17.4%,BCG+DPT-0.9%,BCG+MR-1.7%,DPT-3.5%,DPT+Hepatitis.B-0.9%,Hepatitis.B-17.4%,MR-3.5%,MR+DPT-0.9%,OPV-9.4%,OPV+BCG-3.5%,Pentavalent-24.3%,Pentavalent+MR-1.7%,Polio+BCG-2.6%,Polio+DPT-0.9%,Rota-4.3%, Rota+BCG-0.9%.
**Conclusion:**From this study we came to know that parents are reluctant to give some of the vaccines which need to be given during particular age of their age. The reason behind the reduction in vaccination is that vaccine preventable disease continues to decline and individual in general have become increasingly concern regarding risk of vaccine.
**Key words:** Immunization, Paediatrics, Vaccination, Adverse events, Disease

## I. INTRODUCTION

Under recommended conditions, all vaccines used in national immunization programs aresafeandeffectiveifusedcorrectly. No vaccineiscompletelyrisk-free and adverse events can sometimes result after an immunization. Some people would be questioning about the importance of vaccines in the public health. Vaccine is a substance that stimulates the production of antibodies and provide immunity against several infectious disease. Vaccine not only protect humans from disease but also from dangerous infectious disease which may lead to death like measles and paralytic polio etc. An adverse event following immunizationis clinical untoward incident, which follows vaccination and doesn't actually have a casual relation to consumption of vaccine. Adverse reactions might range in severity from minimal side effects to severe reactions. They have the potential to raise public worries regarding vaccine safety. An AEFI can any unfavorable or unintentional sign, odd laboratory sign, abnormal discoverysymptomorsickness.inthe1980smanycitiz enswhoareconcernedaboutthesociety startedquestioningabouttheriskofthevaccine,untiltha ttimenomuchstudieswereconducted regarding the adverse effects ofvaccines [(1)]. Adverse events followed by immunization can be local reactionlikeedema,rashesandinflammationorsystem icreactionlikefever,allergicreactions and this adverse reaction may be acute ordelayed [(5,6,7).] DependingontheclinicalimportancetheAEFIcanbegr adedasphysiologicalandnon- physiological in intensity. Physiological adverse reaction is normal, indicating a natural reaction to the vaccineantigen

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are common, elevated body temperature, exanthema and myalgia are also included and typically have limited period. Since it is assumed that physiological reaction is common, rarely they are registered. Non physiological AEFI, often referred to as hyper reaction, are uncommon, unexpected and they are more serious than physiological AEFI, and appear to take place in patients who are patients immunocompromised, allergic to components ofvaccines [8]. AEFIisrecognizedeitherthroughactive orpassivesurveillance.Activesurveillanceoftenusesel ectronicmonitoringsystemforadverse event monitoring [11, 12,13]. More AEFI will be detected by active surveillance but majority willhavefewermoderatesymptoms.Furthermore,pop ulationbasedactivemonitoringfacilitates comparisons of AEFI concentrations by vaccination status by temporal period with passive surveillance this cannot be done. It has been used for measles, mumps, rubella (MMR), extensively in children have been shown to be safe and stable efficient for disease prevention. However,sinceitislivevaccine,theMMRvaccinehast hecapacitytocausetheadverseevents in1-2weeksafterthevaccinations.Mostrepliestothisvacci newouldbemildwith5-15percent fever and rashes 5 percent [14,15].

Classification of AEFI;

1). Vaccine product related reaction: that a vaccine triggers or precipitates because of one or more vaccine products intrinsic properties.

2) Quality defect related response: precipitated by a vaccine due to the quality of one or more defects in the substance of the vaccine, including its installation as given by themanufacturer

3)Immunization relatederrors

4)Immunization anxiety relatedreaction

5)Coincidentalevents

Serious event:If an AEFI is serious, it will be treated as suchresults indeath,islife-threatening,necessitates in-patient hospitalization or the extension of a previous hospitalization,results in persistent or significantdisability/incapacityrequires intervention to prevent permanent impairment ordamage Severeis employed to explaintheintensityofaselectedevent(asinmild,mode rateorsevere);the event itself, however, could also be of relatively minor medical significance (e.g. Fever is a common relatively minor medical event, but consistent with its severity it also be graded as mild fever or moderatefever).

## II. MATERIALS AND METHODOLOGY:

This was a prospective and retrospective cross-sectional study conducted in randomly selected Primary Healthcare Centers, Hospitals and District Hospital Tumakuru. Predesigned materials such asInformedAssentForms,ADRNotificationFormsan dADRReportingFormsareusedtocollect the data about a AEFI's from Nurses who work in healthcare centers and hospital, Parents and Documents related to immunization. The vaccination details are taken from documents and AEFI details are collected from the parents through oral questionnaires and AEFIDocuments.

STEP 1:Informed Assent Form, ADR Notification Form and ADR Reporting Form were designed.

STEP 2:The data on daily basis was collected from the Primary Health Care Centre's and Hospitals and District Hospital Tumakuru.

STEP 3:The collected data was assessed for the following;

Adverse events that are found during studyperiod

Severity of the Adverseevents

Risks of the vaccines that causes serious adverseevents

STUDY CRITERIA

INCLUSION CRITERIA:

1.All the nursingstaff are included since the study was involving pediatricpopulation

2.Immunized pediatric population who falls under the age of5years

EXCLUSION CRITERIA:

1.Geriatricpopulation

2.Pediatric population whose age is more than5years

3.Adults

4.Congenital disorder pediatricpatients

## III. RESULTS

AEFI data collected from 115 subjects.When the association of age with AEFI was studied, 24(20.9%) subjects who falls under the age group of 1-5y were followed by AEFI.

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**Table 1.1: Association of Age group with Status of AEFI, Outcome and Adverse Event**

| | | | Age group | | | $\chi^2$ Value | P Value |
|---|---|---|---|---|---|---|---|
| | | | <1y | <1Y | 1-5y | | |
| **Status of AEFI** | Mild | N | 22 | 1 | 85 | 0.321 | 0.852 |
| | | % | 20.40% | 0.90% | 78.70% | | |
| | Moderate | N | 2 | 0 | 5 | | |
| | | % | 28.60% | 0.00% | 71.40% | | |
| **Outcome** | Recovered | N | 24 | 1 | 88 | 0.565 | 0.754 |
| | | % | 21.20% | 0.90% | 77.90% | | |
| | Recovered with seqelae | N | 0 | 0 | 2 | | |
| | | % | 0.00% | 0.00% | 100.00% | | |
| **Adverse Events** | Pain | N | 18 | 0 | 54 | 10.75 | 0.824 |
| | | % | 25.00% | 0.00% | 75.00% | | |
| | Fever | N | 21 | 1 | 66 | | |
| | | % | 23.90% | 1.10% | 75.00% | | |
| | Abscess | N | 5 | 0 | 13 | | |
| | | % | 27.80% | 0.00% | 72.20% | | |
| | Diarrhea | N | 1 | 0 | 10 | | |
| | | % | 9.10% | 0.00% | 90.90% | | |
| | Rashes | N | 0 | 0 | 6 | | |
| | | % | 0.00% | 0.00% | 100.00% | | |
| | Running Nose | N | 0 | 0 | 1 | | |
| | | % | 0.00% | 0.00% | 100.00% | | |
| | Swelling | N | 0 | 0 | 2 | | |
| | | % | 0.00% | 0.00% | 100.00% | | |
| | Other | N | 0 | 0 | 1 | | |
| | | % | 0.00% | 0.00% | 100.00% | | |

*Statistical Significance set at 0.05; **N:** number of samples; **$\chi$2 Value:** Chi-Square Value

**INTERPRETATION:**
Chi Square analysis showed **NO** statistical significance association among Age group with StatusofAEFI(**$\chi$2Value=0.321;P=0.852**),Outcome(**$\chi$2Value=0.565;P=0.754**)andAdverse Event (**$\chi$2 Value =10.75;P=0.824**).

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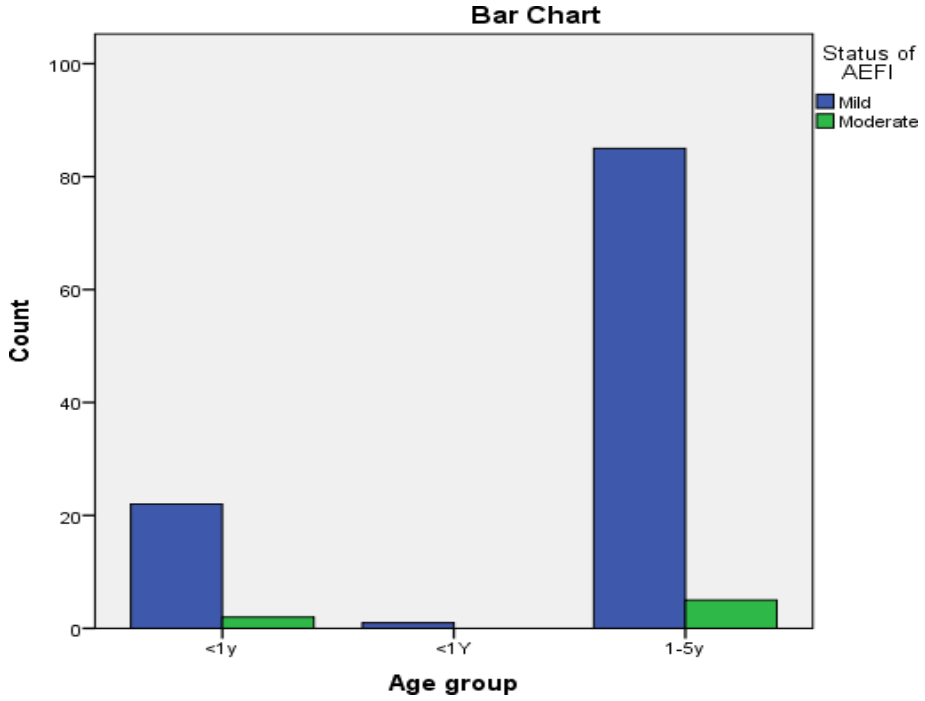


**Fig.1.1Status of AEFI in different age groups**

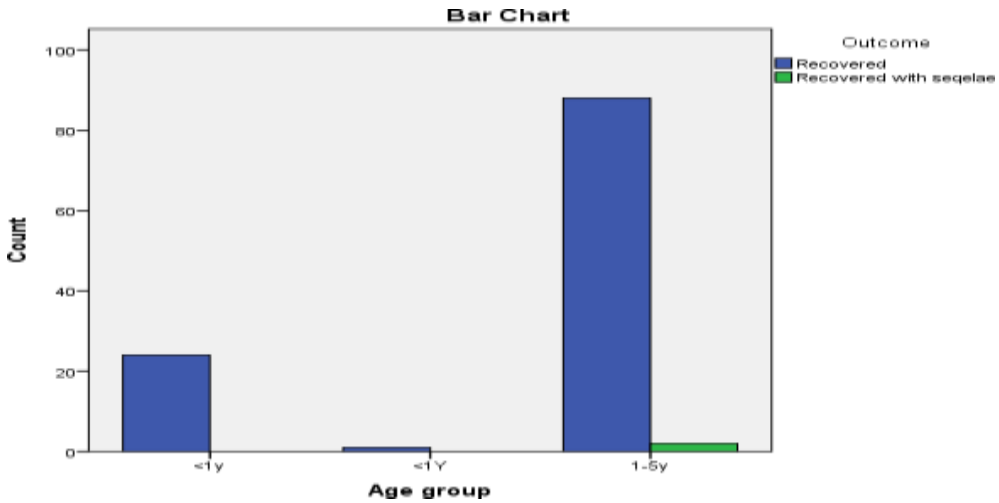


**Fig 1.2Outcome of AEFI in different age groups**

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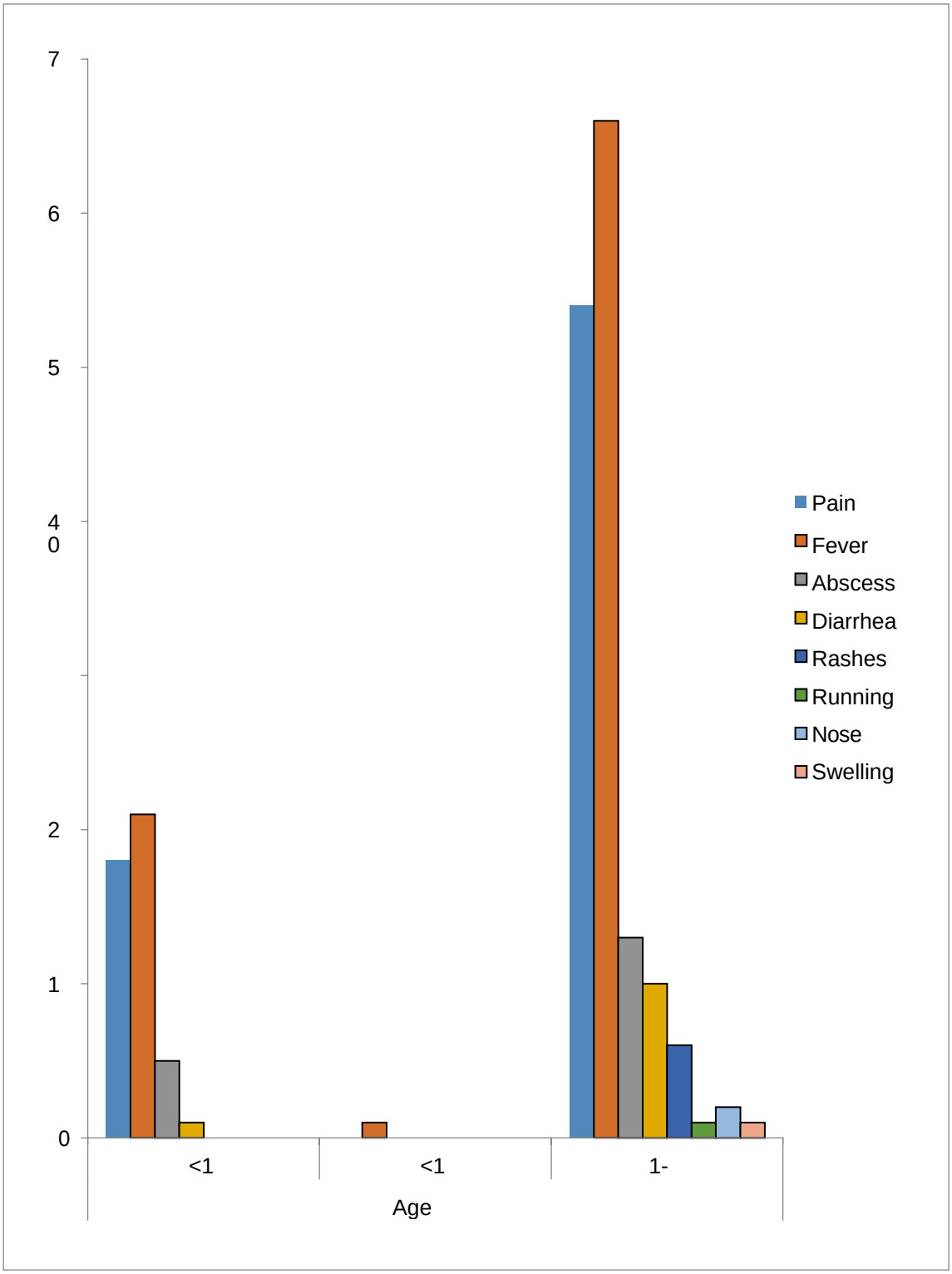


**Fig 1.3 Number of subjects encountered with different AEFI"s in different age groups**

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**Table2.1: Association of Sex withStatusof AEFI, Outcomeand Adverse Event**

| | | | Sex | | Chi Square Value | P Value |
|---|---|---|---|---|---|---|
| | | | Female | Male | | |
| **Status of AEFI** | Mild | N | 82 | 26 | 2.17 | 0.14 |
| | | % | 75.90% | 24.10% | | |
| | Moderate | N | 7 | 0 | | |
| | | % | 100.00% | 0.00% | | |
| **Outcome** | Recovered | N | 87 | 26 | 0.595 | 0.441 |
| | | % | 77.00% | 23.00% | | |
| | Recovered with seqelae | N | 2 | 0 | | |
| | | % | 100.00% | 0.00% | | |
| **Adverse_Events** | Pain | N | 55 | 17 | 2.85 | 0.943 |
| | | % | 76.40% | 23.60% | | |
| | Fever | N | 70 | 18 | | |
| | | % | 79.50% | 20.50% | | |
| | Abscess | N | 14 | 4 | | |
| | | % | 77.80% | 22.20% | | |
| | Diarrhea | N | 8 | 3 | | |
| | | % | 72.70% | 27.30% | | |
| | Rashes | N | 4 | 2 | | |
| | | % | 66.70% | 33.30% | | |
| | Running Nose | N | 1 | 0 | | |
| | | % | 100.00% | 0.00% | | |
| | Swelling | N | 2 | 0 | | |
| | | % | 100.00% | 0.00% | | |
| | Other | N | 1 | 0 | | |
| | | % | 100.00% | 0.00% | | |

*Statistical Significance set at 0.05; **N:** number of samples; **$\chi$2 Value:** Chi-Square Value

**INTERPRETATION:**
Chi Square analysis showed **NO** statistical significance association among Age group with Status of AEFI (**$\chi$2 Value =2.17; P=0.14)**, Outcome (**$\chi$2 Value =0.595; P=0.441)** and Adverse Event (**$\chi$2 Value =2.85; P=0.943)**.

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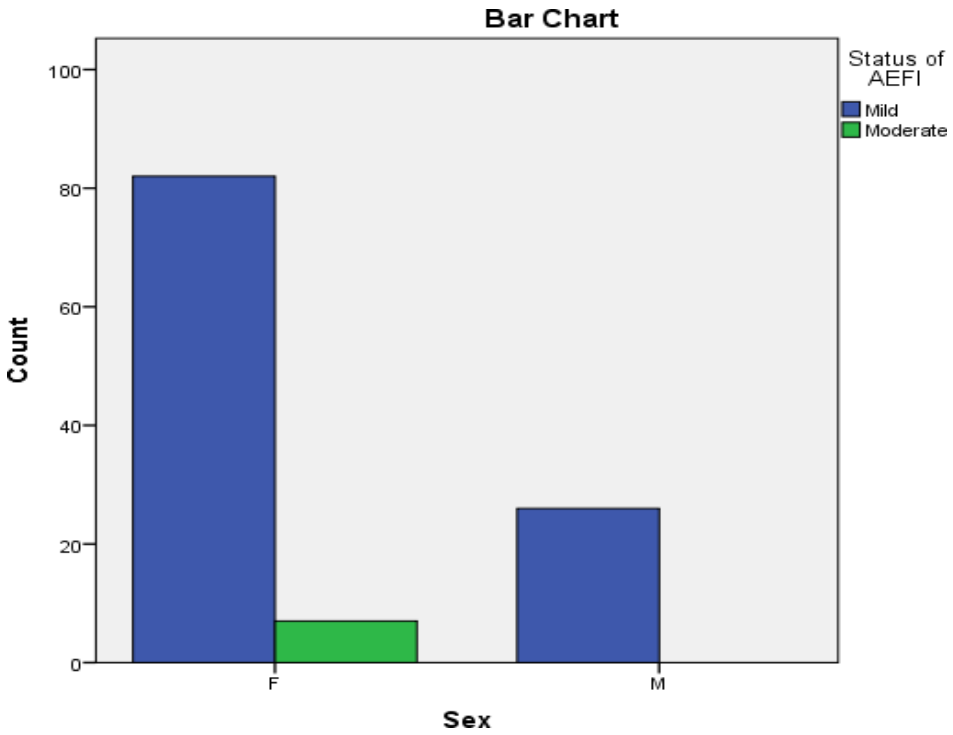


**Fig.2.1 Status of AEFI in different genders**

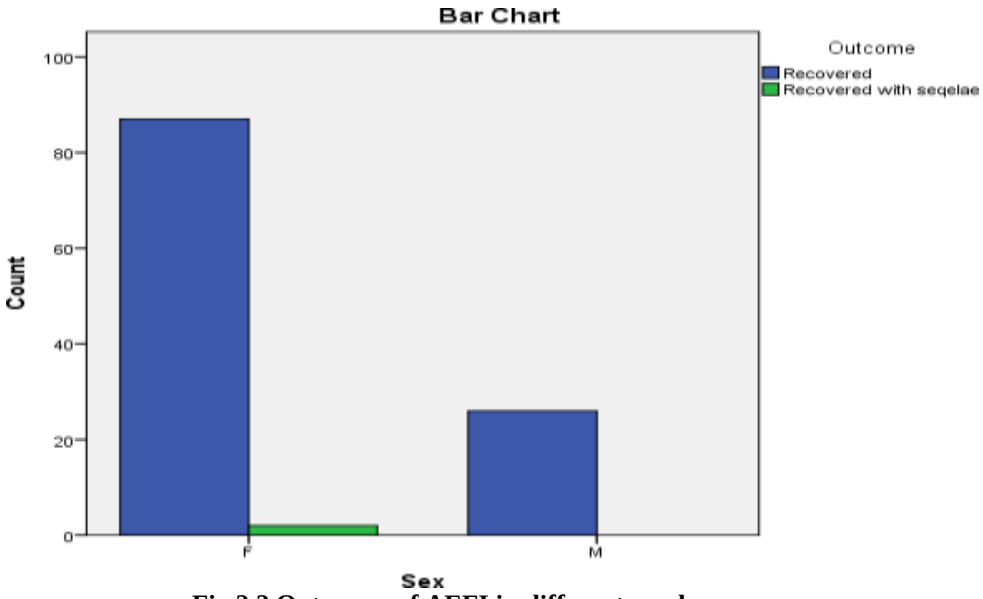


**Fig.2.2 Outcomes of AEFI in different genders**

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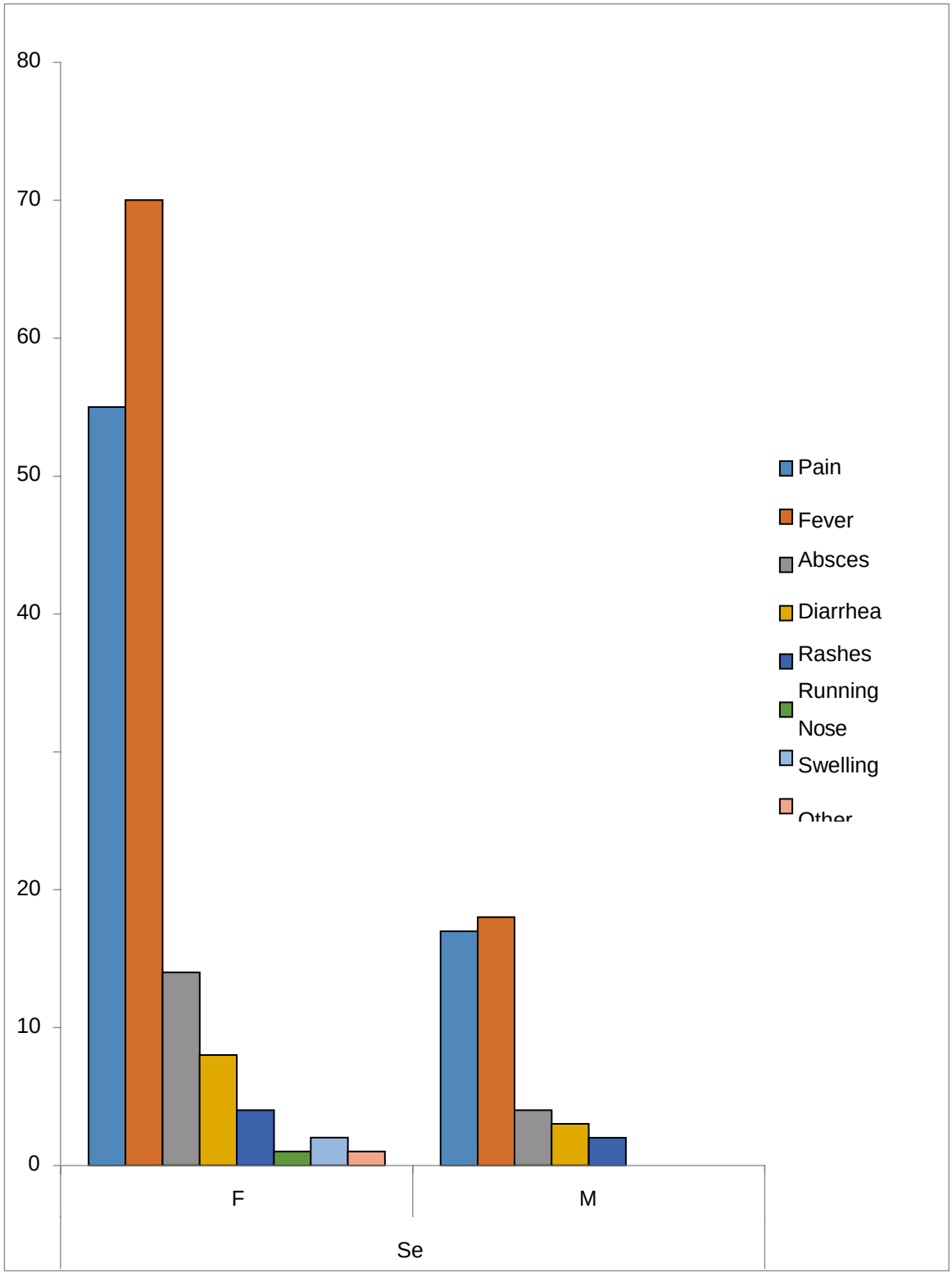


**Fig.2.3 No of subjects who encountered with different AEFI's in different genders**

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**Table 3.1:** Descriptive Statistics

| | | Frequency | Percent |
|---|---|---|---|
| **Sex** | Female | 89 | 77.4 |
| | Male | 26 | 22.6 |
| **Age group** | <1y | 24 | 20.9 |
| | <1Y | 1 | 0.9 |
| | 1-5y | 90 | 78.3 |
| **Mode of vaccination** | Missing | 1 | 0.9 |
| | Campaign | 41 | 35.7 |
| | Routine | 73 | 63.5 |
| **Name of vaccine** | BCG | 20 | 17.4 |
| | BCG,DPT | 1 | 0.9 |
| | BCG,MR | 2 | 1.7 |
| | DPT | 4 | 3.5 |
| | DPT,Hepatitis B | 1 | 0.9 |
| | Hepatitis B | 20 | 17.4 |
| | MR | 4 | 3.5 |
| | MR,DPT | 1 | 0.9 |
| | OPV | 8 | 7 |
| | OPV,BCG | 4 | 3.5 |
| | Pentavalent | 28 | 24.3 |
| | Pentavalent,MR | 2 | 1.7 |
| | Polio | 10 | 8.7 |
| | Polio, BCG | 2 | 1.7 |
| | Polio,BCG | 1 | 0.9 |
| | Polio,DPT | 1 | 0.9 |
| | Rota | 5 | 4.3 |
| | Rota,BCG | 1 | 0.9 |
| **Dose** | Missing | 19 | 16.5 |
| | 0 dose | 11 | 9.5 |
| | 1st | 84 | 73 |
| | 2ND | 1 | 0.9 |
| **No. of days adverse event lasted** | <3 days | 109 | 94.8 |
| | >3 days | 6 | 5.2 |
| **Status of AEFI** | Mild | 108 | 93.9 |
| | Moderate | 7 | 6.1 |
| **Outcome** | Recovered | 113 | 98.3 |
| | Recovered with seqelae | 2 | 1.7 |

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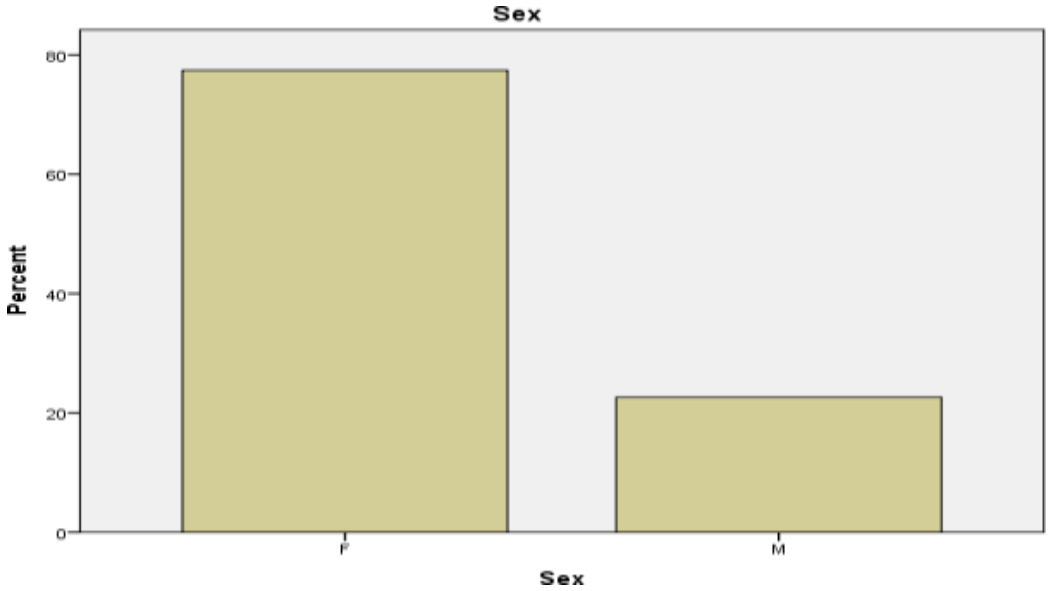


**Fig.3.1Percentage of male and female subjects who encountered with AEFI**

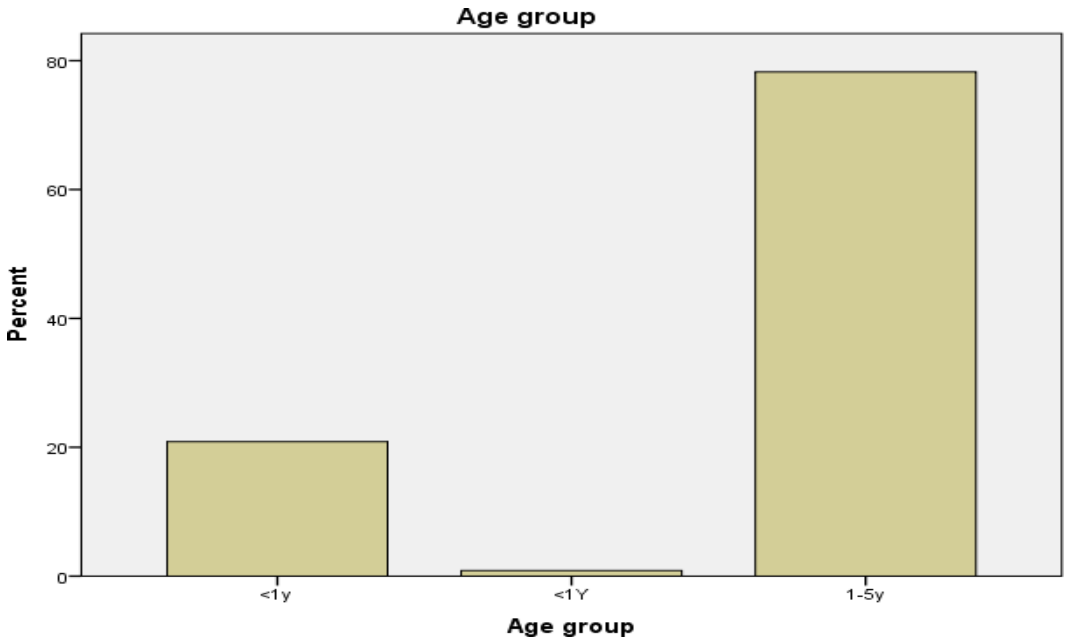


**Fig.3.2Percentage of AEFI in subjects who falls under different age groups**

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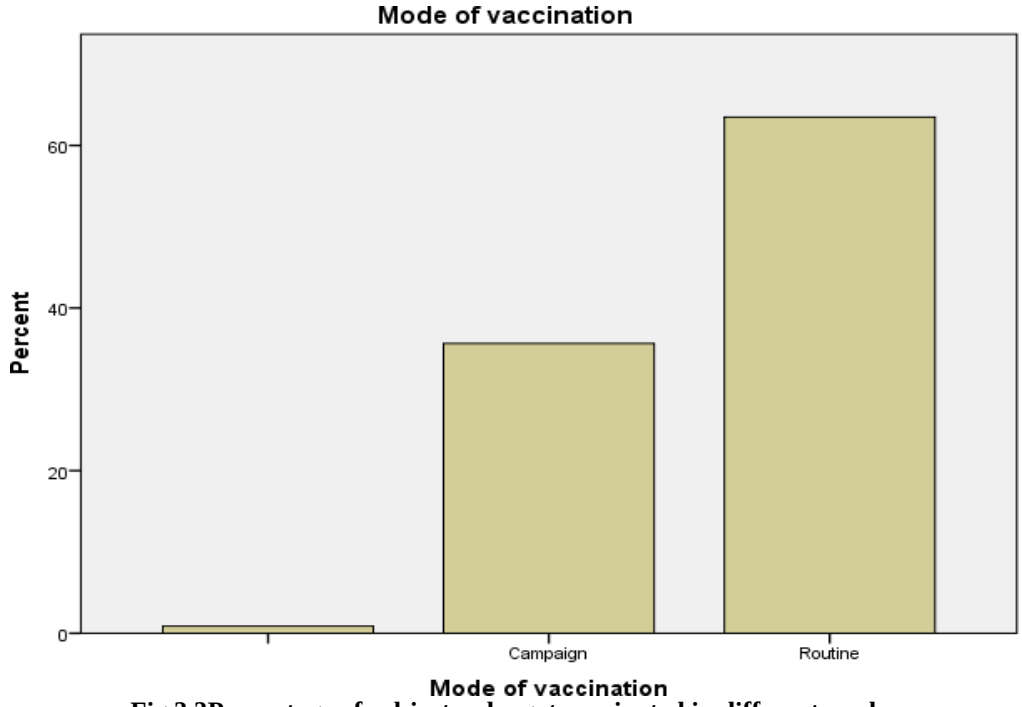


**Fig.3.3Percentage of subjects who got vaccinated in different modes**

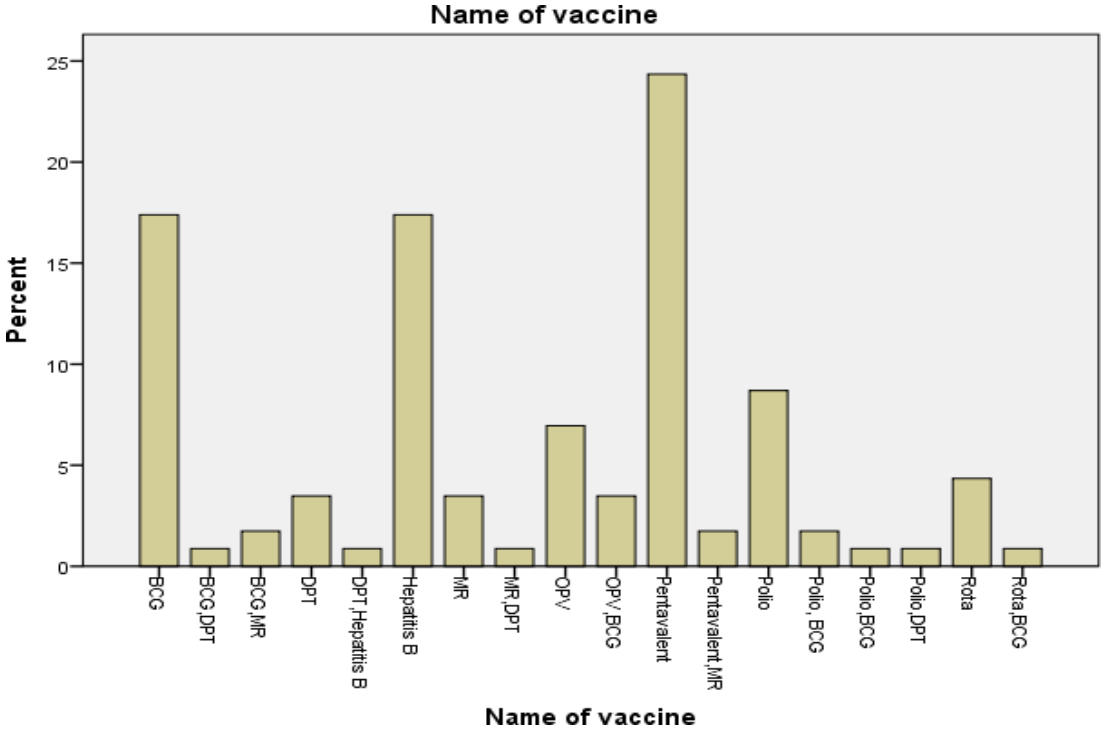


**Fig.3.4Percentage of subjects vaccinated with different vaccines**

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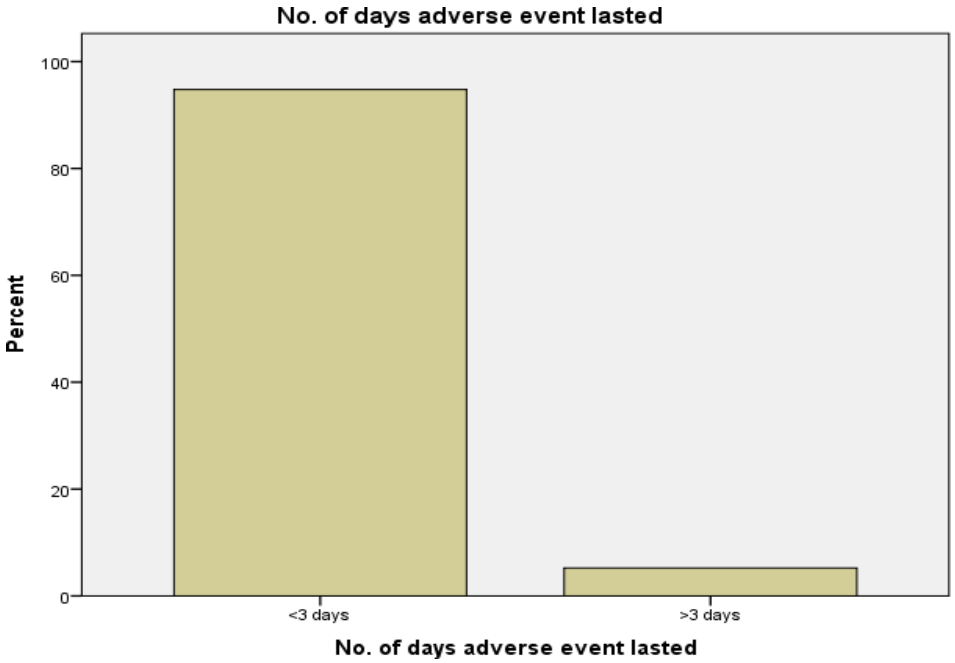


**Fig.3.5 Percentage of number of days the AEFI lasted in subjects**

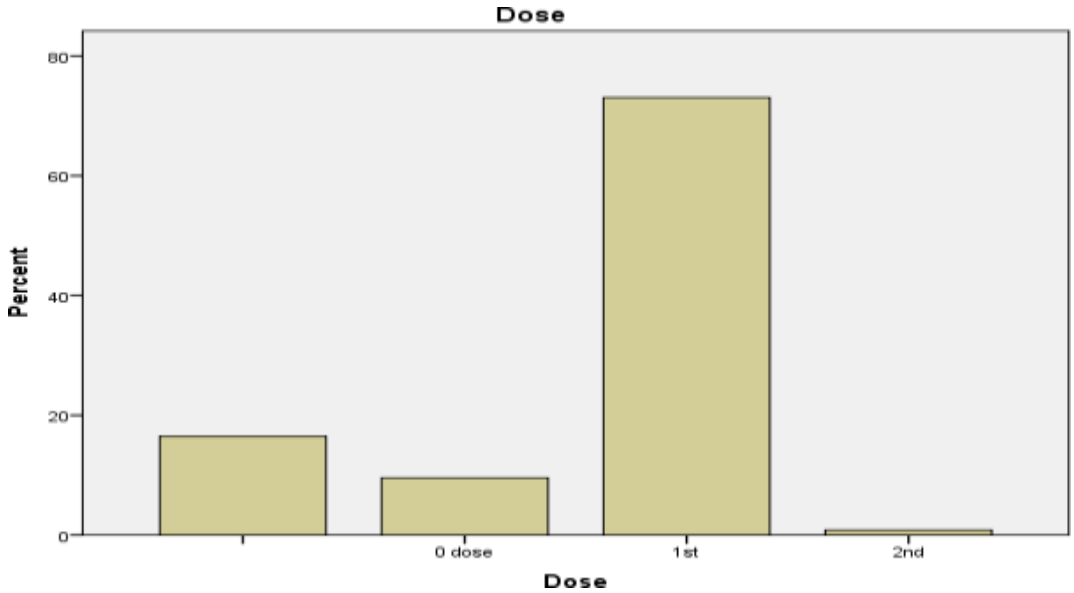


**Fig.3.6Percentage of subjects who encountered with AEFI at different doses**

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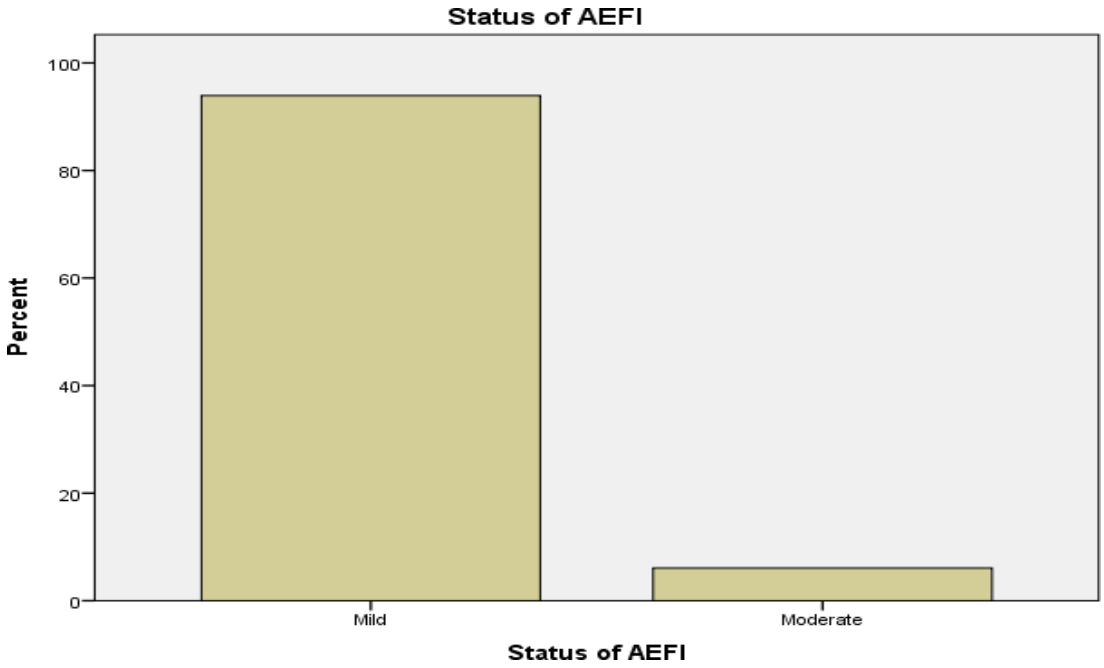


**Fig 3.7Percentage of subjects with different status of AEFI**


**Fig.3.8Percentage of subjects with different outcomes**

## IV. DISCUSSION

Vaccine is a substance given to stimulate the body's production of antibody and provide immunity againstadiseasepreparedfromtheagents that causethedisease.Mostofthevaccinesaregivenduring theearlyageofchildrensosafetyshouldnotbecompromised.Undernormalconditionsallvaccines usedaresafeandeffectiveifusedcorrectly.Inpracticeallvaccinehowever,novaccineiscompletely riskfreeandadverseeffectoccuroccasionallyresultafterimmunization.Asvaccinenotonlyprotect

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humanfromdiseasebutalsofromdangerousinfectious diseasewhichmayleadtodeathlikemeasles and paralytic polio. As vaccine preventable communicable disease still decline parents and individual in generally became increasingly concern regarding risk of vaccine. The increasing rate of parents who choose to delay or refuse recommended vaccine for their children is a growing problem resulting in resurgence of vaccine preventable disease. This study mainly focuses on adverse events followed by immunization in pediatric population below 5-year age in Tumakuru district of Karnatakastate.

As per the study we collected 115 children's vaccination details from primary Health Care Centre and Anganwadi's. Among 115 children 89 children are female which will bring a 77.4% and remaining 26 were boys 22.6%. From these 115, 90 children were aged between 1-5 that is 78% and 24 of them were age less than 1 year that is 20.9%. Majority 63.5% vaccinated as per routine vaccination and 35% vaccinated in campaign in their locality.

In this study majority of them are vaccinated with Pentavalent vaccine 28 children (24%), next commonlygivenvaccinesareHepatitisBin20children (17%),B.C.GVaccinein20children(17%), polio in 10 children (8.6%), OPV in 8 children (6.9%), Rota vaccine in 5 children (4.3%), DPT vaccine in 4 children (3.4%). Some of the children in our study they took two vaccines atonce.

All of the children who took Pentavalent vaccine in our study suffered from fever and pain and that last less than 3 days. Among them 7 of them were reported with abscess that comes around 25%. In thechildrenwhotookhepatitisBvaccine(20)allofthem sufferedwithfeverand8amongthemalso have pain after vaccination that comes around 40%. In children who took BCG the AEFI found was all of them suffered with fever and 10 of them suffered pain along with fever (50%) and 2 of the children have abscess along with fever (10%) and 1 of the children have rashes after vaccination. Two ChildrenwhotookBCGandM.Rvaccinesufferedwith painandfever.Outof8childrenwhotook OPV 4 (50%) of them faced with rashes and 3 of them suffered with fever and one among them suffer with pain along with fever. Out of 10 who took polio vaccine 6 (60%) suffered with diarrhea and 4 (40%) of them were reported with fever. Among 5 children who are given Rota vaccine 3 (60%)sufferedwithfeverand2(40%)werereportedwit hdiarrhea.Outof4childrenwhotookD.P.T vaccine all of them suffered from fever along with pain. out of 4 children who took M.R vaccine 3(75%) suffered with fever and pain and 1 (25%) suffered with pain and swelling. Two children weregivenBCGvaccinealongwithMRvaccineandbot hofthemwerereportedwithpainandfever. One child who took BCG and DPT vaccine suffered with fever and pain. One child who took DPT vaccine and Hepatitis suffered from fever along with pain. One child who took MR vaccine andDPTvaccinesufferedfromfeverandpain.Allofthe 4childrenwhotookOPVandBCGvaccine suffered with fever and pain. Two children who were given Pentavalent vaccine and MR vaccine suffered from fever, abscess and pain. 3 children vaccinated with polio along BCG all of them reportedsufferedfromfeverandpain.onechildwhohav egivenwithpoliovaccineandDPTsuffered with diarrhea. One child who had given Rota vaccine and BCG suffered with pain andfever.

From this study we came to know that most of the symptoms were mild like fever and pain and that subsides before 3 days. Among the total AEFI reported 94.8% recovered before 3 days. The rare AEFI seen in study are rashes, swelling and running nose. The adverse following immunization similar study carried out in Brazil also reported only mild symptoms like fever, rashes, pain and diarrhea. Like our study those AEFI also improved within 3 days.

## V. CONCLUSION

In this study total of 115 vaccination details of children were collected. Among these 89 children were female and 26 were male and this collected data were analyzed during the study period of 6 months. The study had a response rate of 100%.

The study results that majority of the AEFI were mild which include pain, fever, rashes, diarrhea, and also these symptoms were recovered within 3 days. 94%of the children's AEFI recovered within 3 days and 5.2% children AEFI last more than 3 days. The most common vaccine given is pentavalent vaccine, hepatitis B vaccine, BCG vaccine, polio vaccine and OPV. From our study the rarely given vaccine are DPT, MR and Rota vaccine. From this study we came to know that parents are reluctant to give some vaccine which need to be given during particular age of their age. The reasonbehindthereductioninvaccinationisthatvaccin es preventable disease continues to decline and individual in general have become increasingly concern

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regarding risk of vaccine. The increasing rate of parents who choose to delay or refuse recommended vaccine for their children is a ongoing problem resulting in resurgence of vaccine preventable disease. So, we educated parents regarding benefits of vaccination and the need of vaccine in their children. After all we make ensure that in future, they will take the all the recommended vaccine for theirchildren.

**LIMITATIONS**

1. We could not assess AEFI in the discontinuedpopulation
2. Difficulty in recalling AEFI details byparents
3. We felt difficult to collect AEFI onsettime

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