

## Study of Adverse Events following Pentavalent Vaccination in a Tertiary Care Hospital

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**Abstract:** Vaccines are given to the healthy individuals prophylactically, in order to prevent some serious diseases such as measles, diphtheria, polio, meningitis, etc., immunization is important for children from birth to 5 years of age. As vaccines are having some serious adverse events, there is a need of Pharmacovigilance program for immunization. To analyze all suspected adverse events in children reported for pentavalent vaccination and to detect increases in known adverse events. A 3 months prospective observational study was conducted on adverse events following pentavalent vaccine in Mahatma Gandhi Memorial Hospital, Warangal. 200 children were enrolled in our study and adverse events were reported through telephone enquiry after 48 hours of administration. Out of 200 children reported for pentavalent vaccination, 120 children are complained about adverse events following pentavalent vaccination. The most commonly observed adverse events are fever (36.8%), following swelling at site of injection (28.1%). No reactions are seen in 70 (35%) children. Total reactions observed among study population are 263. Most of the adverse events occurred were mild and non serious. The occurred adverse events may be due to pertussis component which is present in pentavalent vaccine.

**Keywords:** Immunization, Pentavalent Vaccine, Adverse events .

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### I. Introduction

Pentavalent vaccine is a combination vaccine which protects against five killer diseases those are Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B [1]. The global Alliance for Vaccines and Immunizations (GAVI) and WHO recommended the use of this pentavalent vaccine in developing countries to replace the DPT vaccine. Before being introduced in India, the pentavalent vaccine had been used in Bhutan, Sri Lanka and Pakistan [2]. Vaccination is an essential component of the public health programs. Immunization constitutes one of the most effective modern public health measures for preventing serious diseases. Vaccines are given prophylactically to healthy individuals, often young children. So, expectation to the vaccine safety is much higher than the drugs. Immunization of the paediatric population prevents and protects the population from serious diseases; however administration of vaccines to healthy children also involves risks of adverse events. More than 3 million children in developing countries die each year from vaccine preventable diseases such as measles, diphtheria and polio [4]. Advantages to combining childhood vaccines include reducing the number of visits, injections and patient discomfort, increasing compliance, and optimizing prevention. The World Health Organization recommends that routine infant immunization programs include a pentavalent vaccine [5]. The immunogenicity and safety of pentavalent vaccine was assessed in four clinical trials and a large post marketing surveillance study. Pentavalent vaccination was found to be highly immunogenic in each of the primary vaccination studies and was also shown to be suitable as a booster with the advantage that it could be given concomitantly with measles vaccine [6]. Hemophilus influenza type B (Hib) is a leading cause of bacterial meningitis among infants and young children and the second leading cause of bacterial pneumonia deaths among children under 5 years.

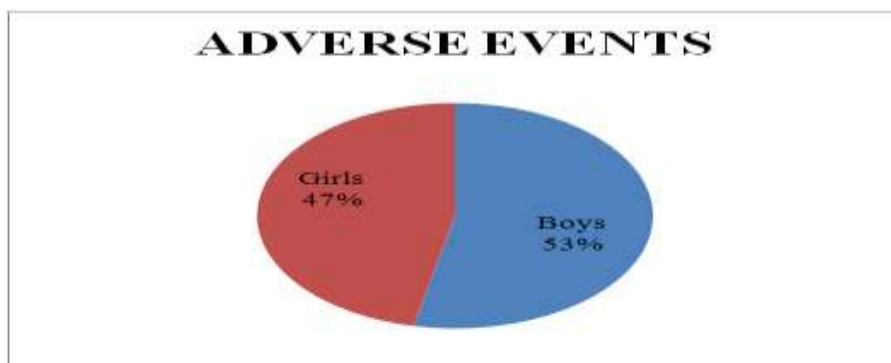
The India Ministry of Health and Family Welfare introduced pentavalent DTP vaccines in the UIP with the aim of reducing the burden of Hib-related morbidity and mortality in April 2008. Subsequently liquid pentavalent vaccine (LPV) was launched in the Kerala and Tamil Nadu on a pilot basis in December 2011 [7, 8]. Vaccines are given prophylactically to healthy individuals, often young children. Vaccines like other pharmaceutical product are not entirely risk free; while most side effects are mild and non-serious. So, the vaccine safety is much higher than the drugs [3]. As Pharmacovigilance on vaccines in India is still in cradle stage and only few Indian studies on adverse events on vaccines were done. We wished to collect data on adverse event following pentavalent in paediatric population [3]. The main aim of this study is to analyze all suspected adverse events in children reported for pentavalent vaccination and to detect increases in known adverse events.

**II. Materials And Methods**

This is a prospective observational study which was undertaken for a period of three months in 2015. This study was approved by the Ethics committee. The children who are reported for vaccination of pentavalent according to the immunization schedule were included in the study. We included children taking first dose at 45 days of age. We have included only first dose because pentavalent vaccine has been introduced in Mahathma Gandhi Memorial Hospital from July 2015, and the children are not reporting for further doses within time, as they might have taken at immunization centres nearer to their homes. This study was conducted in a tertiary care hospital (MGM, Warangal). The data was collected from the parents or guardian. The proforma contains name of child or mother name, age, sex, contact number. The occurrence of adverse events was noted through a telephone survey after 48 hours of administration of vaccine. The parents or guardians of children were questioned about the appearance of any type of reaction that had followed administration of vaccine.

**III. Results**

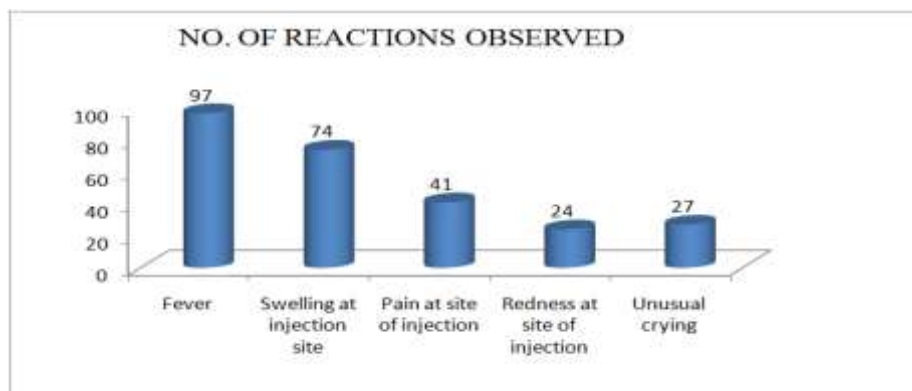
A total of 200 children involved in our study. All the children are of age 45 days and some of them are 46-60 days they have taken vaccine late due to medical or personnel problems. Out of 200 children involved in our study 110 (55%) are males and 90 (45%) are females. Among 200 children the adverse events were seen in 120 (60%) children. and in 70 children no adverse events were observed. We could not collect information among 10 children due to technical reasons. Total number of adverse events reported in our study is 263. The adverse events occurred among 120 children. The boys and girls were almost equally reported, the percentage of children affected according gender wise are shown in figure 1. Among 263 observed adverse events, the different types of adverse events occurred in our study are shown in table: 1. The most commonly observed adverse events are fever (36.8%), swelling at site of injection (28.1%). And other events occurred were pain at site of injection, redness at site injection and unusual crying these reactions were observed in few children. In our study period we do not found any deaths due to the pentavalent immunization.



**Figure1:** Graphical representation showing occurrence of adverse events among gender

**Table 1:** Number and type of adverse events

Type of reaction	No. of reactions observed (%)
Fever	97 (36.8)
Swelling at injection site	74 (28.1)
Pain at site of injection	41 (15.5)
Redness at site of injection	24 (9.1)
Unusual crying	27 (10.2)



**Figure 2:** Graphical representation showing number of reactions

#### IV. Discussion

Our study identified that the pentavalent immunization has no major harmful adverse events. According to Jacob puliey et al.,<sup>[9]</sup> his study reported that pentavalent vaccine is doing harm, he noticed 8 deaths in Bhutan, 25 serious adverse events in srilanka which included 5 deaths in India. Our study results were completely controversy to this study as we did not found any deaths or serious adverse events.

AK Dutta et al.,<sup>[10]</sup> study in 2009 and Baraff L et al.,<sup>[15]</sup> reported the prevalence of adverse events The type of events occurred were similar to our study but varies in the number of children affected with the particular adverse event. Our study has reported commonly ocured adverse event is fever and this study reported common adverse event abnormal crying. Our study has similar results with the Sreelakshmi sreedhar et al.,<sup>[11]</sup> study which was conducted in 2014. This study reported only mild adverse events such as fever, unusual crying, swelling and no serious adverse events were recorded.

In 1989 Marcel proustet al.,<sup>[16]</sup> study reported 35% of redness which was more in comparison to our study. Cody et al.,<sup>[17]</sup> study reported 37.4% of redness, swelling 40.7%, pain 50.9% and fever 31.5%, adverse events occurred were similar to our study. Common symptoms occurred with the DTP immunization were crying, feverishness are more common and also serious events are convulsions and cyanosis according to the Pollock et al.,<sup>[14]</sup> study.

Our study has not reported any serious adverse events. The result of the Blumberg et al.,<sup>[13]</sup> study is, sixty children experienced severe reactions within 48 hours of administration of DTP immunization. Of which 32 had seizures, 14 had hypotonic-hypo-responsive episodes. Children with seizures had higher rates of personnel and family histories of seizures. It was conducted in 1993. This study results were completely controversy to our study as we did not noticed any serious adverse events.

According to Feery BJ et al.,<sup>[18]</sup> study reported local reactions about 47.8% in DTP immunization and most commonly occurred reactions were irritability and fever and 2 children had convulsions. Prevalence of fever occurrence was slightly similar to our study. We did not found any deaths, convulsions and collapse (observed for half an hour and made follow up after 48 hours). All the adverse events occurred are mild.

A major limitation is that we do not know to which extent the causality of these adverse events following pentavalent immunization can be confirmed. Our study has small sample size, and information about adverse events was noted after 48 hours of administration. We did not gather the information about to which extent children suffering from adverse events following immunization later recovered from those events.

#### V. Conclusion

All the adverse events reported were mild and non-serious. As our study did not found any deaths for pentavalent vaccination, we conclude that pentavalent vaccine can be given safely. We also suspect the occurred adverse events are may be due to Pertussis component which is present in pentavalent vaccine. Health care providers should make more effort in enlightening parents about immunization.

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