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**ASSESS THE IMMEDIATE ADVERSE EFFECT OF PENTAVALENT
VACCINE IN INFANTS AND ATTITUDE TOWARDS PENTAVALENT
VACCINE AMONG MOTHERS OF INFANT IN SELECTED PRIMARY
HEALTH CENTRE, VADODARA**

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ABSTRACT

Introduction: Prevention of childhood diseases of public health importance is mainly achieved by immunization. Vaccines are given to 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. Pentavalent vaccines provide immunity and protection quickly and safely. As vaccines are having some serious adverse events, this background study was planned with the following aim: **Aims:** Complete immunization coverage in India has increased from below 20% in the 1980s to nearly 61%, at present the current study was carried out to analyze all suspected adverse events in children reported for pentavalent vaccination and to detect increases in known adverse events and to find out the association

between attitude towards a pentavalent vaccine and selected socio-demographic variables. **Material and methods:** In an observational study, the descriptive research design was adapted. 152 subjects were recruited by non-probability convenient sampling technique among mothers of Infants. The data gathering was carried out with a checklist for immediate and management modalities for the adverse effects of Pentavalent Vaccine by the mothers of Infants and a Rating scale to assess the attitude of mothers. The collected data was optimized and analyzed by using descriptive statistics and inferential statistics. **Results:** With regards to the assessment and immediate modalities for the adverse effects of Pentavalent vaccine and attitude of mothers, Out of 152 subjects, the first highest immediate adverse reaction was fever 138 (90.8%), secondly swelling at the site of injection 121 (79.6%) and pain at the site of injection 98 (64.5%). Only a minimal percentage of infants who had various adverse effects reported was restlessness, anorexia, drowsiness, held the leg back due to pain and vomiting. Regarding management modalities, the majority of the infants 131 (86.2%) mothers of infants applied cold applications and none of them applied herbal products to relieve the adverse reaction. **Conclusion:** Carried out an observational study. Infants were followed up after immunization via calling their parents. The entire adverse event reported by parents had been noted. The study revealed that mothers had a good attitude towards the pentavalent vaccine. They also were willing to continue to take their children for future vaccinations, despite experiencing adverse events.

Keyword: Attitude, Mothers, Adverse effect, pentavalent vaccine, Health centre

INTRODUCTION

Despite the efforts to enhance education, personal hygiene, use of antibiotics and vaccination, infectious diseases remain the second cause of mortality and the most important reason for age-related disabilities around the world. Effects of infectious diseases may vary depending on the country or region. Vaccination is the most influential method in the prevention of disability and morbidity, as well as the reduction of treatment costs. The World

Health Organization (WHO) declared vaccination against diphtheria, tetanus, and Pertussis mandatory in 1974. This was part of the pandemic vaccine program, which significantly decreased the mortality rate caused by the aforementioned life-threatening diseases in infants and newborns¹.

Immunization is one of the most important public health interventions and a cost effective strategy to control the

infectious diseases especially in children. Complete immunization coverage in India has increased from below 20% in the 1980s to nearly 61% at present, but still more than 1/3rd children remain un-immunized².

DANISH medicine agency reported in 2011 more than 3 million children in developing countries die each year from vaccine preventable diseases such as measles, diphtheria and polio³. Pentavalent vaccine is a combination vaccine which protects against five preventable diseases those are Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B. 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^{4, 5}

Introduction of any new vaccine into the community needs lot of efforts in disseminating the knowledge to the community and getting their cooperation for appropriate compliance.. Perception of the people and their attitude play an important role in acceptance of any new strategy⁶.

Keeping the above facts in view, personal and professional experience of the investigators, Investigators felt the need to

assess immediate adverse effect of pentavalent vaccine in infants and mother's attitude towards pentavalent vaccine.

REVIEW OF LITERATURE

An analytical cross-sectional study was conducted among 353 infants on Comparison of complications of pentavalent and DTP vaccination in infants aged 2-6 months in Anzali, Iran. The result showed that 163 female (46.2%) and 190 male (53.8%), were enrolled. 229 infants (64.9%) presented with vaccination complications. Fewer side effects were noted in infants receiving pentavalent vaccination compared to those receiving DTP vaccination (P=0.38). In order of occurrence, the most common complications of DTP vaccination were fever, excessive crying, and fussiness. The study concludes that application of pentavalent vaccination not only minimizes the local reactions, but it also diminishes local discomfort through reducing the number of injections⁷.

An analytical cross-sectional study was conducted on The Comparison of the Adverse Events of Pentavalent Vaccine and DPT Vaccine in 2–6 Months Infants in Iran: A National Study. The results showed that 10,464 and 17,561 adverse events, which were associated with DPT vaccine and Pentavalent vaccine. , Pentavalent vaccine

seemed to have more recorded adverse events compared to DPT, high fever had the highest record rate for DPT vaccine (47.4%) and mild localized complications was the highest for pentavalent vaccines (31.68%). There was a significant relationship between the kind of vaccine and the type of reaction, adverse event categorization and the country that produced the vaccine ($p < 0.05$), and the study concludes that substituting Pentavalent vaccine for DPT vaccine in infants seems to reduce the adverse events among them⁸.

A mixed cohort study was conducted among 1119 children less than 1 year of age on adverse events following immunization with pentavalent vaccine: experiences of newly introduced vaccine in Iran 2015. The cumulative incidence rate of pentavalent-related adverse events during 48 hours following immunization was estimated to be 15.8% for swelling, 10.9% for redness, 44.2% for pain, 12.6% for mild fever, 0.1% for high fever, 20.0% for drowsiness, 15.0% for loss of appetite, 32.9% for irritability, 4.6% for vomiting and 5.5% for persistent crying. There is no evidence for the occurrence of convulsion and encephalopathy among children who receive pentavalent vaccines⁹.

A focused group discussion was conducted among 43 mothers on perception and attitude

of mothers regarding pentavalent vaccine in dist Bathinda, Punjab. The result revealed that a very large number of mothers (88%) had no knowledge about pentavalent vaccine while just 5 mothers i.e. 12% had just heard about the name of this vaccine. Health workers played a very poor role in imparting information regarding the vaccine to all the mothers. Only 5 % of mothers were told that their child would be administered a new vaccine, without the mothers being told about the components or the side effects of the vaccine. Only 1 mother (2%) knew that fever could be one of the side effects of pentavalent vaccine as is the case with most other vaccines. 98% of mothers had no knowledge what so ever regarding the side effects of this vaccine¹⁰.

A Study was conducted to evaluate the status of mother's knowledge, attitude and practices (KAP) and its related factors and provide evidence for further effective implementation on childhood immunization. 591 mothers who were having children under 2 years of age were taken for the study. The results indicated that mother's knowledge, attitude and practices of childhood immunization were at a low level and is influenced by educational background, country economic level, mother's age, household size and ethnic groups.¹¹.

A descriptive cross-sectional study design was conducted among 720 care-givers on Determinants of uptake of pentavalent vaccine in Benin City, Southern Nigeria. The result showed that about three-quarters 554 (76.9%) of caregivers had a good knowledge on pentavalent vaccines. Good knowledge increased with increasing level of education and being married ($p \leq 0.001$ and $p = 0.015$ respectively). Majority, 568 (78.9%), of caregivers had a positive attitude towards the pentavalent vaccination. With increasing level of education, there was an increase in the proportion of caregivers who had a positive attitude towards the vaccine ($p \leq 0.001$). The study concludes that two hundred (27.8%) caregivers had children who had experienced at least a side effect following pentavalent vaccination. Of these, 171 (85.5%) were willing to continue with the vaccine despite AEFIs experienced¹².

STATEMENT OF THE PROBLEM

“A study to assess the immediate adverse effect of pentavalent vaccine in infants and attitude towards pentavalent vaccine among mothers of infant in selected Primary Health centre, Vadodara”.

Objectives of the study:

- ✓ To determine the immediate adverse effect of pentavalent vaccine in infants.

- ✓ To assess the attitude towards pentavalent vaccine among mothers of infant.
- ✓ To find the association between attitude towards pentavalent vaccine and selected socio-demographic variables.

Assumption:

- Pentavalent vaccine is essential to prevent diseases like Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B.
- Infants receiving pentavalent vaccine encounter minimum adverse effects.

Hypothesis:

- H_1 . There is statistically significant association between attitude towards pentavalent vaccine and selected socio demographic variable

METHODOLOGY

The observational descriptive research design was adopted. The study was carried out in the health centre of urban areas of Vadodara. 152 subjects were selected by using non-probability convenient sampling technique. Infants attending Immunization OPD for first, second and third dose of pentavalent vaccination and Mothers of infant and conversant in speaking and writing Hindi or

Gujarati or English were included. Mothers of infant who are unreachable, unwilling to give consent or co-operate to participate in the study and sick during data collection period. Formal written permission was obtained from The District Medical Health Officer, Vadodara Municipal Corporation, Vadodara. The data collection was carried out in the month of January 2021- May 2021. The Investigators introduced themselves and explained the purpose of study, written consent was obtained with their anonymity and confidentiality of data. The data gathering was carried out with a check list for immediate and management modalities for the adverse effects of Pentavalent Vaccine by the mothers of Infants and Rating scale to assess the attitude of mothers. The collected data was optimized and analyzed by using descriptive statistics and inferential statistics. About 15 to 25 minutes was spent by each subject for assessment in each time. Approximately 20 to 30 subjects were assessed per week .The obtained data was analyzed using SPSS-20 software. More specifically, descriptive statistics (frequency and percentage, mean, standard deviation) were used to describe the subjects' characteristics and to know the adverse effects of pentavalent vaccine. Chi – square test used in order to find out the association

between the attitude of mother of infants towards pentavalent vaccine and selected socio-demographic variables. The level of significance was set at $p < 0.05$.

RESULTS

The data collected were analyzed according to the plan for data analysis, which includes both descriptive and inferential statistics. The findings have been organized and presented under following sections:

SECTION-A: Frequency and percentage of subjects according to selected socio-demographic variables.

SECTION -B: Frequency and percentage of subjects according to immediate adverse effects of pentavalent vaccine among infants with in 48hrs to 72hrs.

SECTION-C: Frequency and percentage of subjects according to management modalities for the adverse effect of pentavalent vaccination by the parents.

SECTION-D: Association of attitude towards pentavalent vaccine among mothers of infant with selected socio demographic variables

SECTION-A

Table 1: Shows that majority of the subjects 78 (51.3 %) belongs to the age group 20 to 25 years where as 21 (13.8%) of the subjects belongs to the age group of 31 to 35years. With respect to Gender of the child the male

were 77 (85%) whereas female subjects were 9 (15 %). In relation to the educational status of the mother, majority of the subjects 63 (41.4) were had primary education and only 01(0.7%) subject was graduated. Regarding the employment status of the mother, majority of the subjects 81(53.3%) were private employee and 12(7.9%) of the subjects were others. Regarding family income, majority of the subjects 50 (32.99%) were having 5000 Rs to 10000 and only 7 (4.6%) were having income of Rs 20001 to 25000. Majority of the subjects 148 (97.4%) were belongs to the Hindu and none of the subjects were belongs to the Christian. In relation to the types of family, 82(53.9%) of the subjects were nuclear family and 07(4.6%) of the subjects were extended family. Regarding type of diet, 96(63.2%) were vegetarian and 56 (36.8%) were having mixed diet. With respect to the birth order of the child, majority of the subjects 78 (51.3%) were in 2 and 06 (3.9%) were in 3.

Table 2, Shows that the kind of immediate adverse reaction of pentavalent vaccine that the infant experienced within 48 to 72 hours, out of 152 infants, the first highest immediate adverse reaction was fever 138 (90.8%), secondly swelling at site of injection 121 (79.6%) and pain at site of injection 98 (64.5%). And also 67 (44.1%) of infants had

Redness at site of injection, 31(20.4%)of infants were crying unusually and 26 (17.1%) of infants had nodule formation. Only minimal percentage of infants who had various adverse effects reported was restlessness, anorexia, drowsiness, held the leg back due to pain and vomiting.

Table 3 depicts that following were the management modalities for immediate adverse effects of pentavalent vaccine by the mothers of infants, in majority infants 131 (86.2%) mothers of infants applied cold application, 74 (48.7%) mothers of infants administered analgesics, 65 (42.8%) parents had consultation with a doctor, 35 (23%) mothers of infants were given antipyretic while 11(7.2%) mothers of infants not done anything, 09(5.9%) mothers of infants applied hot application, and none of them applied herbal products to relieve the adverse reaction.

Table 4, depicts that frequency and percentage distribution of mothers of infant attitude towards pentavalent vaccine, majority of the mothers 134(88.7%) had fair attitude towards pentavalent vaccine, whereas 17(11.3%) of the mothers had good attitude towards pentavalent vaccine with mean and standard deviation of 1.18 and 0.865.

Table 5, It shows that the calculated χ^2 values was less than the table value in terms

of age of mother, age of the child, gender of the child, religion, educational status of mother, employment status, family monthly income, type of family, type of diet and birth order of the child. Since no statistically significant associations was found to exist between attitude towards pentavalent

vaccines and selected socio-demographic variables. Hence the research hypothesis H₁ stated that there is a statistically significant association between the attitude towards pentavalent vaccines and selected socio-demographic variables was rejected.

Table 1: Frequency and percentage distribution of socio-demographic variables (n=152)

Sr. No.	Demographic Variables	Frequency	Percentage
1.	Age of mothers (years)		
	a. 20 to 25	78	51.3
	b. 26 to 30	53	34.9
	c. 31 to 35	21	13.8
2.	Age of child (months)		
	a. 1 ¹ / ₂	28	18.4
	b. 2 ¹ / ₂	47	30.9
	c. 3 ¹ / ₂	77	50.7
3.	Gender of the child		
	a. Male	77	50.7
	b. Female	75	49.3
4.	Education status of the mother		
	a. No formal education	2	1.3
	b. Primary education	63	41.4
	c. Secondary education	44	28.9
	d. Higher secondary education	30	19.7
	e. Graduate	1	0.7
	f. Post-graduate	12	7.9
	g. Any other	0	0
5.	Employment status of the Mother		
	a. Home maker	45	29.6
	b. Private employee	81	53.3
	c. Govt employee	14	9.2
	d. Others	12	7.9
6.	Monthly family income		
	a. 5000 to 10000	50	32.9
	b. 10001 to 15000	47	30.9
	c. 15001 to 20000	48	31.6
	d. 20001 to 25000	7	4.6
7.	Religion		
	a. Hindu	148	97.4
	b. Muslim	4	2.6
	c. Christian	0	0
8.	Type of family		
	a. Nuclear family	82	53.9
	b. Joint family	63	41.4

	c. Extended family	07	4.6
Type of diet			
9.	a. Vegetarian	96	63.2
	b. Non vegetarian	56	36.8
The birth order of the child			
10.	a. 1	68	44.7
	b. 2	78	51.3
	c. 3	06	3.9

Table 2: Mean, mean percentage and standard deviation of immediate adverse effects of pentavalent vaccine among infants with in 48hrs to 72 hrs (n=152)

S.No.	Types of adverse reaction	Frequency (f)	Percentage (%)
1.	Pain at site of injection	98	64.5
2.	Fever	138	90.8
3.	Swelling at site of injection	121	79.6
4.	Redness at site of injection	67	44.1
5.	Held the leg back due to pain	6	3.9
6.	Drowsiness	4	2.6
7.	Anorexia	0	0
8.	Restlessness	11	7.2
9.	Vomiting	8	5.3
10.	Unusual crying/long term crying	31	20.4
11.	Nodule formation	26	17.1
12.	Convulsion	1	7

Table 3: Frequency and Percentage distribution of mothers of infants is according to their management modalities for immediate adverse effects of pentavalent (n=152)

S.No.	Management modalities	Frequency (f)	Percentage (%)
1.	Cold application	131	86.2
2.	Hot application	9	5.9
3.	Administration of antipyretic	35	23.0
4.	Administration of analgesics	74	48.7
5.	Consultation with doctor	65	42.8
6.	Not done anything	11	7.2
7.	Application of herbal products	0	0

Table 4: Frequency and Percentage distribution of mothers of infant attitude towards pentavalent vaccine (n=152)

S. No.	Attitude	Frequency (f)	Percentage (%)	Mean and Standard Deviation
1.	Fair	134	88.7	1.18 & 0.865
2.	Good	17	11.3	

Table 5: Association of attitude towards pentavalent vaccine among mothers of infant (n=152)

S.No	Demographic variables	Agree	Uncertain	Disagree	Chi-square
1	Age of the mother				$\chi^2 = 8.371$ df=4 NS
	a. 20 to 25	71	7	0	
	b. 26 to 30	47	5	1	
2	Age of child in month				$\chi^2 = 4.071$ df=4 NS
	a. 1 $\frac{1}{2}$	22	6	0	
	b. 2 $\frac{1}{2}$	43	4	0	
3	Gender of child				$\chi^2 = 1.931$
	a. Male	65	11	1	

	b. Female	68	7	0	df =2, NS
	Mother education				
4	a. No formal education	1	1	0	$\chi^2 = 13.341$ df =10 NS
	b. Primary education	57	6	0	
	c. Secondary education	40	4	0	
	d. Higher secondary education	22	7	1	
	e. Graduate	1	0	0	
	f. Post graduate	12	0	0	
	Employment status				
5	a. Home maker	37	8	0	$\chi^2 = 9.971$ df =6 NS
	b. Private employee	76	4	1	
	c. Govt employee	10	4	0	
	d. Others	10	2	0	
	Monthly income				
6	a. 5000 to 10000	44	6	0	$\chi^2 = 3.133$ df =6 NS
	b. 10001 to 15000	43	4	0	
	c. 15001 to 20000	40	7	1	
	d. 20001 to 25000	06	1	0	
	Religion				
7	a. Hindu	129	18	1	$\chi^2 = 0.587$ df =2, NS
	b. Muslim	4	0	0	
	Type of family				
8	a. Nuclear family	74	8	0	$\chi^2 = 2.222$ df =4 NS
	b. Joint family	53	9	1	
	c. Extended family	6	1	0	
	Type of diet				
9	a. Vegetarian	87	9	0	$\chi^2 = 3.344$ df =2, NS
	b. Mixed diet	46	9	1	
	The birth order of the child				
10	a. 1	63	5	0	$\chi^2 = 3.423$ df =4, NS
	b. 2	65	12	1	
	c. 3	5	1	0	

df=degree of freedom, p= 0.05 level

DISCUSSION

It is widely accepted that immunization is of great importance in the prevention of childhood diseases; hence vaccination uptake is an indirect way to assess childhealth¹. Although advances in medicine have made vaccines reliably more effective with minimal adverse events, no vaccine can be found that is free from unwanted adverse events^{13, 14, 15}. The implementation of immunization is meant to protect individuals and society as a whole against vaccine preventable diseases.

The researchers observed that majority of the subjects had secondary and tertiary levels of education. These findings were supported by Ogboghodo EO *et al*¹³ study findings.

In the present study, the pentavalent immunization has no major harmful adverse events. Dr. Vasudev Kompally *et al*¹⁶ study results were similar to present study.

AK Dutta *et al.*,¹⁷ and Baraff L *et al*¹⁸ studies reported that the prevalence of adverse events and the type of events occurred were similar to current study but

varies in the number of children affected with the particular adverse events.

The present study reported that commonly occurred adverse events were fever, pain at site of injection, redness at site of injection and swelling at site of injection and Dr. Vasudev Kompally *et al*¹⁶ study reported that common adverse event was abnormal crying. And also similar results with the Sreelakshmi Sreedhar *et al.*,¹⁹ study reported that only mild adverse events such as fever, unusual crying, swelling and no serious adverse events were recorded.

The study conducted by Marcel proust *et al.*²⁰, reported that 35% of redness which was less in comparison to present study (57%). In the present study researchers observed that swelling at site of injection (48%), fever (85%), redness at site of injection (57%) and pain at site of injection (92%) . The above results were supported by Cody *et al.*^{21,22} study reported 37.4% of redness, swelling 40.7%, pain 50.9% and fever 31.5%, adverse events occurred were similar to our study.

In the present study, researchers did not notice any serious adverse events. The result of the Blumberg *et al.*²³, study results was contraindicatory to the present study results.

Researchers observed that there was a good attitude towards pentavalent vaccine in present study. The study findings were supported by Ogboghodo EO *et al*¹³.

In the present study, there is no significant association between attitude of mother and selected demographic variables.

CONCLUSION

The vaccines like DTP, Hep-B and Hib vaccine antigens were given in combination as pentavalent vaccine. Its reactogenicity to infant need to be explore. We carried an observational study. Infants were followed up after immunization via calling to their parents. The entire adverse event reported by parents had been noted. A total of 152 infants participated during study period. The adverse events reported were mild and non-serious. The study revealed that mothers had positive attitude towards the pentavalent vaccine. They also were willing to continue to take their children for future vaccinations, despite experiencing adverse events. This is good and encouraging and health care providers should take advantage of this by using these mothers as peer educators to improve on immunization coverage.

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AUTHOR'S CONTRIBUTION

Conceptualization & Supervision: Mr. Adithya.S. Methodology, Formal analysis and investigation: Mr. Adithya.S, Ms. Sayma Shaikh , Ms. Shobhana Vasava, Ms. Neha Tadvi & Mr. Dhruv Solanki. Writing - original draft preparation: Mr. Adithya.S.; Writing - review and editing: Mr. Adithya.S, Ms. Sayma Shaikh , Ms. Shobhana Vasava, Ms. Neha Tadvi & Mr. Dhruv Solanki.

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