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Adverse Events of Paediatric Immunization

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ABSTRACT

Introduction: Immunisation is a cost-effective program for vaccine preventable disease, but adverse events are unexpectedly noticeable especially when the vaccine was apparently healthy at the time of immunization, that's why a lot of efforts are taken to ensure the safety of vaccine by monitoring the Adverse Event Following Immunization (AEFI) after vaccination. **Method:** A record based descriptive study was conducted at in hospital of Uttar Pradesh university medical sciences (UPUMS), Saifai, Etawah in 2019 with a total of 1400 vaccinated enrolled children are analysed the data. **Result:** The study revealed that OPV was the most frequently administered vaccine among the study population of all vaccine doses followed by Pentavalent and BCG vaccine. Fever (85%) was the first most commonly noted incidence related to the all Adverse Event Following Immunization of the vaccine along with persistent crying (20%) is also noted with the administration of vaccine. **Conclusion:** it was concluded that immunisation program is done for boosting and developing immune system and it start from the birth and the observed AEFI was non serious.

Keywords: Immunization, Adverse event, Vaccine, Vaccine safety.

INTRODUCTION

Immunizations are among the most successful and cost-effective disease prevention interventions available. Vaccine is administered and it involve the process in which a person is immunized or resistant against an infectious disease [1-4], vaccine defend the person by rouse the person self-immune system. Vaccine provide the direct and influential protection against many diseases like diphtheria, hepatitis B, measles, pertussis, mumps, pertussis (whooping cough), pneumonia, polio, rotavirus diarrhoea, rubella and tetanus, etc. So, vaccines are considered as one of the most cost effective public health treatment.

Government of India, under the universal immunization programme (UIP), is providing vaccination free of cost against vaccine preventable diseases. Now a day several vaccines are commercially available in India which include Bacillus Calmette Guerin (BCG), Diphtheria Tetanus Pertussis (DTP), Measles Mumps Rubella (MMR), Rota vaccine, Chickenpox vaccine, Hepatitis-A vaccine, Hepatitis- B vaccine, Polio vaccine, etc. The benefits of immunization are not visible, particularly if the incidence of target disease is low [5]. As rates of vaccine-preventable infections have declined, attention has shifted to the safety of recommended vaccines because the vaccine safety is important and is rising in global concern. The exist over the period of time success of immunization programs confide on maintaining confidence in the safety of recommended vaccines through augmented surveillance and research. Although immunizations are generally safe, but like other medicinal products vaccine also contain adverse events, and in rare cases adverse event following immunisation (AEFI) may be serious [6-10]. AEFI is any inconvenient medical incidence which follow vaccination and which does not necessary have an emergent relationship with the use of vaccine [11-14], So It is pivotal to pay attention on the adverse events that follow immunization especially when the vaccine was apparently healthy at the time of immunization. AEFI may be contrary or unintended indication, an abnormal laboratory detection, a symptom or disease.it may range from severe [15].

AEFI observation in India was start in 1985 along with UPI, a lot of efforts are taken to ensure for greater safety in the manufacturer and uses of vaccine due to these such adverse events. Currently the inactivated formulation of vaccine is administered in children up to 4 months. Because the inactivated formulation contains the dead viruses and they avoid the serious adverse event observed with the attenuated virus formulation (OPV) [16-17].

At the site of injection some local reaction of vaccine like pain, swelling, and erythema and systemic reaction like fever, irritability, drowsiness, and rashes may also occur. The fourth dose of the diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine is associated with an increased incidence of fever and reaction at the site of injection compared with the first dose of this [18-20].

METHOD

The study was an active surveillance and record-based narrative study in hospital of uttar pradesh university medical sciences (UPUMS), Saifai, Etawah.

Adverse event following immunization (AEFI) is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine [20-21].

Study procedure

Firstly, identifying the primary questions and collect the data necessary for the study and questionnaire was provided as a patient individual case safety report and included necessary information for AEFI reporting in successive mass drive. Mandatory information included in the questionnaire were: patient name, age, sex, and

information about the adverse event after vaccination including patient description, onset date, end date, and history of a reaction on previous immunization. Before completing the questionnaire, vaccination benefit was explained as well as the probability of occurrence of adverse events.

Data analysis

After the collection of all necessary information manage the data and analyse it at last generate the report of survey.

RESULT AND DISCUSSION

Approximately 1400 vaccinated children were enrolled during the study from UPUMS Saifai hospital. Table 1 provide the types vaccine its frequency in male and female children and its adverse events following immunization and figure 1 provide the distribution of vaccine with their number of doses in the study population.

Table 1: Types of vaccines administered and its related adverse reaction name

Vaccines name with sex		Age group and frequency of vaccines administration						Types of reactions
		New born	Infants	Toddlers	Child	Teen	Adult	
BCG	Male	523						Fever, Headache, Hardness at the injection Site
	Female	426						
OPV	Male	719						Fever,Irritation
	Female	533						
ROTA	Male	234						Irritability and restlessness
	Female	102						
DPT	Male			20	18			Mild fever, stomach upset, pain at the injection site
	Female			13	14			
IPV	Male	136						Fever, redness, soreness at the injection site
	Female	87						
PENTA	Male	212						Fever, rashes, persistent crying, swelling at the injection site
	Female	108						
MMR	Male		21	15				pain, fever, redness
	Female		18	17				

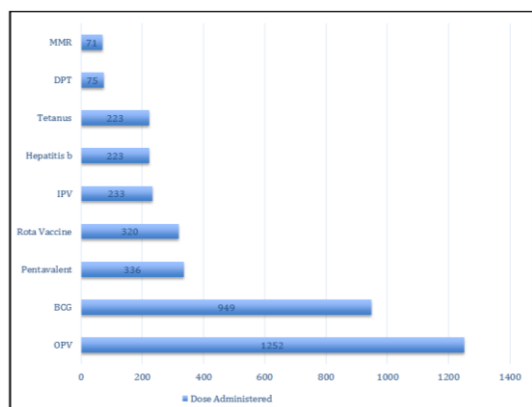


Figure 1: Doses of vaccines administered in the study population.

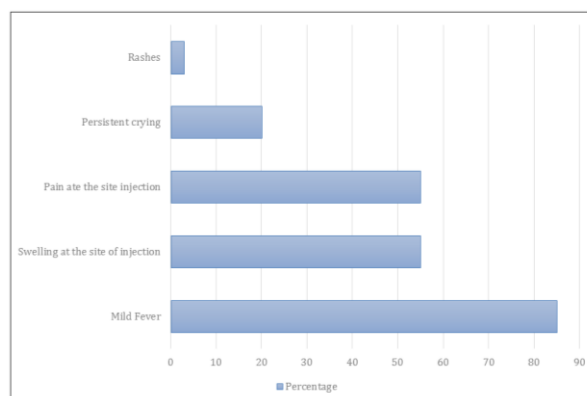


Figure 2: Adverse event following Pentavalent Vaccination

The study revealed that OPV was the most frequently administered vaccine among the study population of all vaccine doses followed by Pentavalent and BCG vaccine. The incidence of the adverse events following pentavalent vaccines administration included 85% mild fever, 55% pain at the site of injection, 55% swelling at the site of injection, 20% Persistent crying sterile abscess at site of injection, generalised rash, 3% localised rashes. Though, some studies have shown that paracetamol responses following immunization, there was no evidence for the occurrence of convulsion and encephalopathy among children who received pentavalent vaccines in our study.

Fever was the first most commonly noted incidence related to the all AEFI of the vaccine along with persistent crying is also noted with the administration of vaccine. Pain and swelling at the injection site are the injection site reaction also encountered.

During the survey it was also seen that after vaccination some adverse event are develop like fever, swelling/pain/redness at the injection site, mild diarrhoea, stomach upset etc. and for this doctor prescribe the paracetamol for fever and apply ice pack at the injection site and give advice that don't rub the injection site.

CONCLUSION

It is concluded that the Immunisation program is done for boosting and developing immune system and it start from the birth. Various program related to the immunisation are started by the government, the vaccine used in the programme are safe and effective and the observed AEFI were non-serious.

General AEFI are identified as mild fever, swelling and pain at the injection site, redness at the injection site, diarrhoea, most of the AEFI were non-serious and it just a sign that vaccine is administered accurately. The study didn't find any significant sex specific adverse events following immunization.

Conflict of Interest

Authors declare that there is no conflict of interest.

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