

The Vaccine Adverse Event in children and Infants hospitalized to Children hospital

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Abstract: Many different types of adverse events occur after vaccination. The any reports serious adverse events involving life-threatening conditions, hospitalization, permanent disability, or death, which may or may not have been caused by a vaccine. The aim of this study was to determine the incidence of Vaccine Adverse Event of vaccination in children and infant hospitalized in Qom Children Hospital. In a retrospective study, all hospitalized children suspected to adverse vaccine effects were studied in Qom Children Hospital between October 2007 - October 2013. A specific questionnaire, including vaccine recipient profile, type of vaccine, and 18 adverse reactions were completed after hospitalization. The patients with underline disorders and coincidence of disease were excluded. This study included 145 children who were clinically suspected with Vaccine Adverse Event. The most common adverse reactions were: fever (66.9%), febrile seizures (54%), swelling at the vaccination site (3.4%), Vomiting (54.5%), cellulites & abscess at injected site (13.1%). Restlessness (7.6%), Weakness (4.1%). The most cause of hospitalization was adverse reaction of MMR vaccine. PCR of polio virus was positive in stool of patient who was presented with paralysis. Febrile seizures were most prevalent in the age of 18 months, respectively, with significant difference ($P < 0.01$) and ($P < 0.001$). In general, routine immunization program against nine common infectious Diseases have low side effects which generally are mild and transient and most disappear even without medical treatment. A careful follow-up report on the effects of the immunization program is essential. Use of acellular pertussis vaccine should be considered for decreasing the rate of post DTP side effects.

Key words: Vaccination, Vaccine Adverse Event, Children, Infant, immunization program

Introduction

Vaccination remarkable success and cost-effective in the prevention of infectious diseases has gained. WHO's immunization program resulted in a significant decrease in the prevalence of disease is. Iran and step up with the other member nations of the WHO, childhood immunization against diphtheria, the CIA cough, tetanus, polio, measles, rubella, mumps, tuberculosis and hepatitis B runs (Ng, Saw et al. 2005).

Many different types of adverse events occur after vaccination. About 85-90% of the reports describe mild adverse events such as fever, local reactions, and episodes of crying or mild irritability. Although the efficacy of vaccines used, they are very reliable and their side effects is negligible, but in general, no vaccine is not free from side effects. Those who receive the vaccine may have symptoms of mild side effects, or, in rare cases, serious and even life-threatening side effects, they are facing. These reactions may be occur by the vaccine

substances, adjuvants and in some cases due to vaccine administration errors.

Adverse effects after immunization care for the health monitoring of immunization and an immunization program helps to validate. Adverse effects after immunization are well managed and the report improper actions in society, they can prevent. The aim of this study was to determine the incidence of Vaccine Adverse Event of vaccination in children and infant hospitalized in Qom Children Hospital.

Material and Methods

In a retrospective study, 145 vaccinated children in Pediatric Medicine Research Center of MUQ were studied children between October 2007 - October 2013. A specific questionnaire, including vaccine recipient profile, type of vaccine, and 18 adverse reactions were completed. 18 adverse reactions were evaluated after 2,4,6,12,18 months as well as 4-6 year vaccination.

Through medical evaluation, it was ensured that these patients were free of Colds or other illnesses and also underline disease. The patients with underline disease and who have symptoms of other disease were excluded.

A database of this study results was set up using the Excel program, and frequency was obtained using SPSS version 16.1.

Research Ethics Committee

The study protocol was approved by the Research Ethics Committee of Qom University of medical sciences. The enrolment was performed from "October 2007 until October 2013". Subjects were invited to participate and were informed in detail about the research. Voluntary written consent was obtained from all the individuals included in the study.

Results & Discussion

This study included 145 children who were clinically suspected to Vaccine Adverse Event. The most common adverse reactions were: fever (66.9%), febrile seizures (54%), swelling at the vaccination site (3.4%), Vomiting (54.5%), cellulites & abscess at injected site (13.1%), restlessness (7.6%), weakness (4.1%), headache (3.4%), skin rash (0.7%), tremor (2.8%), paralysis (0.7%), cough (0.7%), malnutrition (0.7%), loss of consciousness (0.7%), coryza (0.7%), paleness (2.8%), and ulceration at the injected site (2.1%). Incidence of other complications were low. The most dangerous complication of the vaccine was encephalitis (one case), paralysis. The most cause of

hospitalization was adverse reaction of MMR vaccine. PCR of polio virus was positive in stool of patient who was presented with paralysis. Febrile seizures were most prevalent in the age of 18 months, respectively, with significant difference ($P < 0.01$) and ($P < 0.001$).

Previously, the case series approach has been published about incidence of febrile convulsions following DTP and MMR vaccines (Farrington, Pugh et al. 1995); the occurrence of autism following MMR vaccine (Taylor, Miller et al. 1999; Altmann 2000; DeStefano and Chen 2000; Kramarz, DeStefano et al. 2000), asthma following influenza vaccine and intussusceptions following rotavirus vaccine. (Denhehy and Bresee 2001).

In our country vaccination protocol is done against nine infectious diseases (tuberculosis, polio, hepatitis B, tetanus, diphtheria, pertussis, measles, rubella and mumps) is done. The complications should also be followed. The large difference between fever and other complications is common. According to result of this study, fever develops after DTP and OPV vaccination more than other vaccines.

Because some parents have been used anti pyrotic agents such as Acetaminophen for preventing the fever, stimulation of fever probably is made less than real rate. Therefore, the incidence of this complication due to interventions of this kind, the change is welcome. The real problem was greater than the incidence of vaccine-induced fever is gone. In this study, 37 cases were hospitalized due to fever and seizures.

Technical errors can be considered as causes of abscess formation at the site of injection. BCG Lymphadenitis is a common side effect of BCG vaccination. The incidence of this complication in the Netherlands, Poland, Sweden and the United States were reported as zero to 5%, in our study the incidence of BCG Lymphadenitis was less than 1.5%. These differences are probably due to the nature of the vaccine. The coinfection with AIDS has also been considered. Aspirin or other agents containing Aspirin should never be given to children under 16 years old because of the risk of developing Reye's syndrome. Theoretical concerns have arisen around pediatric exposure to thiomersal through vaccine administration. This concern is based mainly on data following acute toxicity of a related substance, methyl mercury, and from data on chronic exposure to mercury from the food chain. However, the low levels of thiomersal in vaccines have never been associated with these or similar conditions. In children or pregnant women. Thiomersal has been linked to a very low risk of localized hypersensitivity reactions (Leventhal et al., 2012), which can present as redness, swelling or a rash at the injection site.

Table 1. Relation between Complication and vaccination

AGE complications of vaccination	At birth CG,HB OPV	2 month DTP,HB OPV	4month OPV,DTP	6month DTP,HB OPV	12month MMR	18month OPV,DTP	72Month BCG OPV	P value
fever	1	23	12	20	4	31	6	0.01
	1	20	9	15	3	30	1	0.001>
vomiting	0	2	3	6	1	1	6	0.05<
Cellulites Abscess&	4	7	1	4	0	2	3	0.05<
agitation	0	1	4	5	0	1	0	0.05<
weakness	0	2	3	0	0	1	0	
headaches	0	0	0	0	0	0	5	
parotitis	0	0	0	0	1	0	4	
tremor	0	2	0	0	0	1	1	
diarrhea	1	1	1	1	0	0	0	
paleness	0	3	1	0	0	0	0	
BCG Abscess& Adenitis	2	0	0	0	0	0	0	
RASH	0	0	0	0	0	1	0	
Paralysis	0	0	1	0	0	0	0	
Cough	0	0	0	1	0	0	0	
loss of consciousness	0	1	0	0	0	0	0	
MalNutrition	0	1	0	0	0	0	0	
coryza	0	0	0	1	0	0	0	

Glossary

CDC: Center for Disease control and Prevention
 AEFIs: adverse events following immunization
 OPV: Oral Polio Vaccine
 DTP: Diphtheria, Tetanus, Pertussis Toxoid
 MMR: Measles, Mumps, Rubella
 HB: Hepatitis B
 BCG: Bacille Calmette & Guerin

References

Aaby, P., C. S. Benn, et al. (2007). "DTP vaccination and child survival in observational studies with incomplete vaccination data." *Trop Med Int Health* 12(1): 15-24.
 Altmann, D. (2000). "Autism and measles, mumps, and rubella vaccine." *Lancet* 355(9201): 409-410.
 Dennehy, P. H. and J. S. Bresee (2001). "Rotavirus vaccine and intussusception. Where do we go from here?" *Infect Dis Clin North Am* 15(1): 189-207, x-xi.
 DeStefano, F. and R. T. Chen (2000). "Autism and measles, mumps, and rubella vaccine: No

epidemiological evidence for a causal association." *J Pediatr* 136(1): 125-126.
 Farrington, P., S. Pugh, et al. (1995). "A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines." *Lancet* 345(8949): 567-569.
 Fisher, M. A., S. A. Eklund, et al. (2001). "Adverse events associated with hepatitis B vaccine in U.S. children less than six years of age, 1993 and 1994." *Ann Epidemiol* 11(1): 13-21.
 Heron, J. and J. Golding (2004). "Thimerosal exposure in infants and developmental disorders: a prospective cohort study in the United Kingdom does not support a causal association." *Pediatrics* 114(3): 577-583.
 Kramarz, P., F. DeStefano, et al. (2000). "Does influenza vaccination exacerbate asthma? Analysis of a large cohort of children with asthma. Vaccine Safety Datalink Team." *Arch Fam Med* 9(7): 617-623.
 Ng, K. P., T. L. Saw, et al. (2005). "Impact of the Expanded Program of Immunization against hepatitis B infection in school children in Malaysia." *Med Microbiol Immunol* 194(3): 163-168.

- Smeeth, L., L. C. Rodrigues, et al. (2002). "Evaluation of adverse effects of vaccines: the case-control approach." *Vaccine* 20(19-20): 2611-2617.
- Taylor, B., E. Miller, et al. (1999). "Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association." *Lancet* 353(9169): 2026-2029.
- Wakefield, A. J., S. H. Murch, et al. (1998). "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children." *Lancet* 351(9103): 637-641.