Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL 14, ISSUE 09, 2023

Adverse Events Following Immunization In Under-Five Children At The Child Health Centre Of The Department Of Community Medicine, SKIMS Soura, Srinagar

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Abstract

Background: Immunization is a global health and development success story, saving millions of lives every year. Vaccines reduce risk of getting a disease by working with body's natural defences to build protection. Immunization currently prevents 3.5-5 million deaths every year from diseases like diphtheria, tetanus, pertussis, influenza and measles. An adverse event following immunization (AEFI) is a matter of concern and its detection at right time followed by corrective measures wherever possible will further help build the faith of people in vaccination and also eliminate the preventable AEFIs.

Materials and methods: The study was conducted in the department of Community Medicine SKIMS Soura Srinagar. All the beneficiaries who received vaccines in the child health centre were eligible for the study. At day1, 8 and day 30 after vaccination, the parents/guardian were contacted and information about any AEFIs was recorded on a pre-designed questionnaire.

Results: A total of 2399 children {1210 (50.4%) males, 1189,(49.6%) females}received 19805 vaccine doses. Incidence of AEFIs was 15.1% (2998 AEFIs/19805 doses). Fever was the most common AEFI (2445 events) followed by swelling at injection site (463 events). Almost all AEFIs either resolved on their own or a very few required treatment on outpatient basis. The frequency was higher with first birth order and was higher among urban than rural children.

Conclusion: Fever was the most common AEFI followed by swelling at injection site. Most of the AEFIs were minor and resolved on their own. Thus AEFIs should not form a reason of vaccine hesitancy. More AEFIs were reported by urban people than rural. It might be because of more awareness among urban caretakers. Thus awareness generation regarding AEFIs is vital for both picking up an AEFI and reporting it and for eliminating vaccine hesitancy.

Keywords: - Vaccines, Adverse events, Hesitancy, Fever, Frequency

INTRODUCTION

Vaccination is one of the public health interventions that can really be called a success because of its role in preventing millions of deaths worldwide.(1) New vaccines are being introduced from time to time to decrease the incidence of vaccine preventable diseases. Now in today's world the vaccine preventable diseases (VPDs) have decreased to a great extent. But almost every vaccine has some intrinsic minor side effects associated with it which occur in a person after a vaccine is given. Of course the benefits of a vaccine outweigh its risks. The benefits are long term whereas the risks are temporary. However, sometimes there may be some events which are severe, sustained or life-threatening. Any untoward event that occurs after a vaccination is called an AEFI. An AEFI as defined by World Health Organization is, "Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease." (2). In today's modern world since the VPDs have decreased, more attention is drawn towards AEFIs. Besides there are always a group of people "anti-vaxxers" who oppose a vaccination drive and de motivate people for vaccination. Worldwide about 21.8 million infants still miss their basic vaccines.(3) In such a scenario, public health needs to minimize the level of AEFIs also for the successful implementation of a vaccination programme. For minimizing AEFIs, a good AEFI surveillance system needs to be in place. Detection of AEFIs followed by corrective measures wherever possible will help build the faith of people in vaccination and also eliminate the preventable AEFIs. Keeping these points in mind, the present study was conducted. The objectives were to detect the Adverse Events Following Immunization among under five children at the child health centre of the department of Community Medicine, SKIMS and to find out the factors associated with such events

METHODOLOGY

Study site: The study was conducted in the child health centre of the department of Community Medicine SKIMS Soura Srinagar.

Study size and participants: All the beneficiaries who received vaccines in the child health centre of the department of Community Medicine given under Universal Immunization Programme were eligible for the study.

Inclusion Criteria:

1. All the children under up to 5 years of age who received vaccines in the child health centre of the department of Community Medicine given under Universal Immunization Programme
2. Children whose parent/guardian provided consent for participation

Exclusion Criteria:

Vaccine recipients having diseases like cancers, immuno-compromised states and seizures. Those children whose parents did not consent to be part of the study.

Study period: The study was conducted for a period of 6 months from 1st July 2022 to 31st December 2022.

Data collection: In the immunization clinic of the department beneficiaries are routinely provided immunization card with a registration number. During the study period after vaccinating the child, the parent/guardian of the child was appraised about the objectives of the study following which

consent was obtained from them for participation in the study. The information about socio-demographic factors was obtained and noted. The phone number of the parent/guardian was obtained. The parent/guardian was informed that they will receive a call from the researchers at day1, 8 and day 30 following the vaccination for knowing any AEFIs. At day1,day 8 and day 30 after the vaccination, the parents were called and information about any AEFIs that had occurred till that time was gathered and recorded on a pre-designed questionnaire. The parent/guardian were given a phone number on which they could contact in case of any adverse event.

Outcome measures: Our outcomes of interest were any AEFIs. In addition the severity, duration, treatment required, hospitalization if required and present status of the child were noted. Any hospitalized child was followed till the outcome.

STATISTICAL ANALYSIS

The data was entered in and analyzed using IBM Spss version 23. The statistical tests were applied based on the type of variable (continuous or categorical) and the normality of the data.

RESULTS

Total number of under five children who were part of the study during the study period were 2399.

Table1: Baseline characteristics of the study participants

		Frequency(N=2399)	%
Gender	Male	1210	50.4
	Female	1189	49.6
Residence	Rural	1122	46.8
	Urban	1277	53.2
Birth Order	1	1177	49.1
	2-3	1183	49.3
	4-6	39	1.6
Birth Weight	</=2.4	218	9.1
	2.5-4	2135	89.0
	>/=4.1	46	2.0
	Total	2399	100

The distribution of males and females in this study was almost equal with 1210(50.4%) males and 1189(49.6%) females. There was slightly higher urban participation (1277, 53.2%). 49.3% children were of 2^{nd} or 3^{rd} birth order and 49.1% belonged to Ist birth order. Majority (89%)of the children were of normal birth weight.

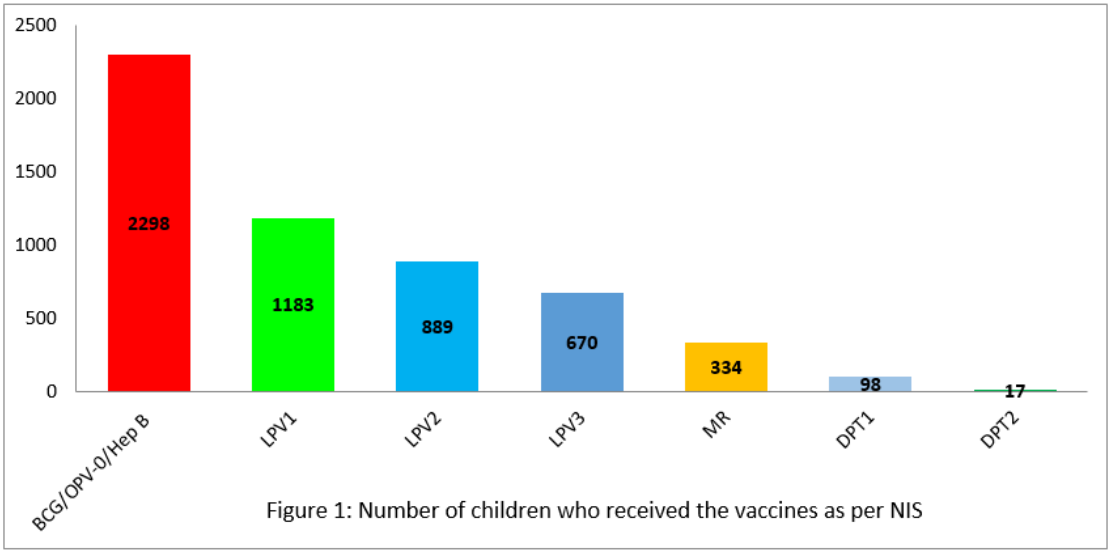


Figure 1: Number of children who received the vaccines as per NIS

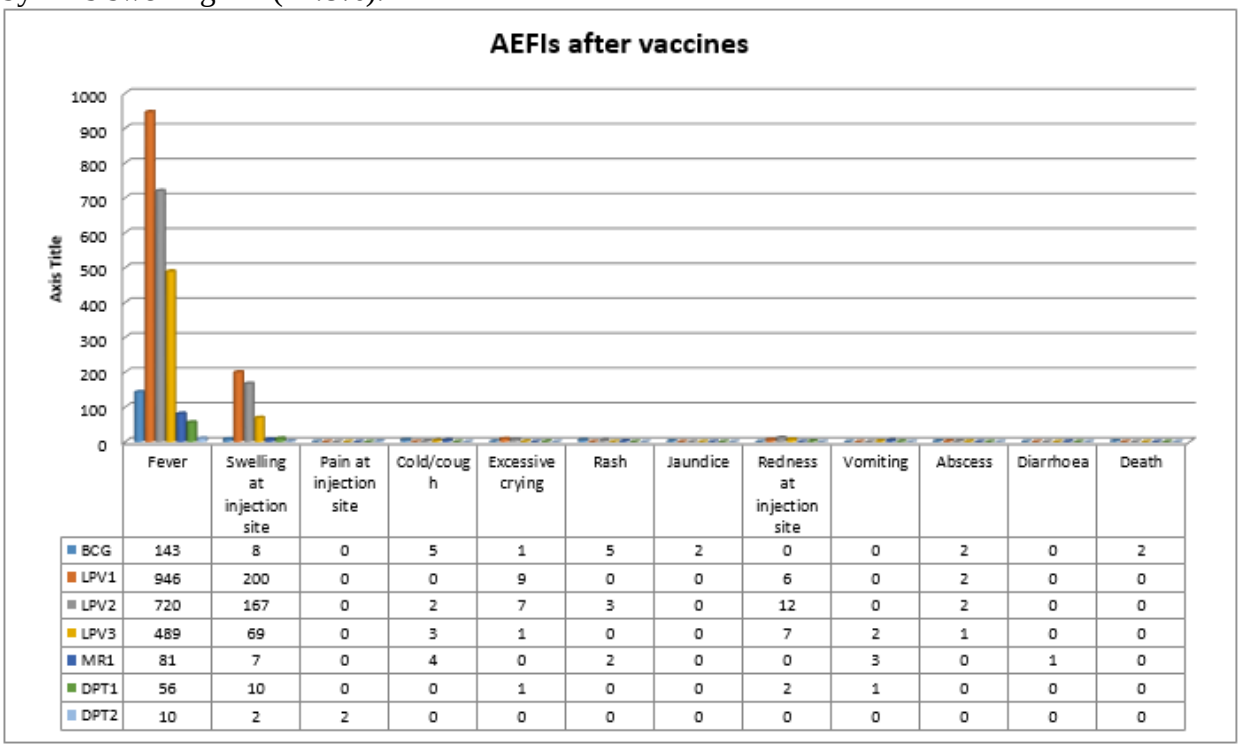
Figure 1 shows that 2298 (collectively 6894 doses) children received the routine vaccines at birth which include Inj.BCG, OPV-0 and Hepatitis B vaccine; at 6 weeks of age 1183 children(collectively 5915 doses) receivedLPV1, OPV1,PCV1, RVV, fIPV;at 10 weeks of age 889 children received (collectively 2667 doses) LPV2, OPV2, RVV;at 14 weeks 670 children received (3350 doses collectively) LPV3, OPV3, PCV2, RVV, fIPV; 334 children received (collectively 668 doses)MR1 vaccine and PCV booster at 9 months of age; 98 children (294 doses) received the vaccines given at 16-24 months of age (DPT1, OPV-booster and MR2); 17 children received DPT2 vaccine at 5 yrs of age. Thus a total of 19805 vaccine doses were given during the study period.

Out of these 19805 doses of vaccines administered, 2998 AEFIs were recorded thus showing an incidence of 15.1% (table 2). Fever was the most common AEFI (2445 events) followed by swelling at injection site (463 events). The highest incidence of fever was after the vaccines received at 10 weeks (81.0%) i.e., LPV2, OPV2 and RVV. The incidence of fever was almost same at 6 weeks i.e., 79.9%. Table 2 and figure 2 gives the break-up of AEFIs among the studied children after receiving the vaccines as per the national immunization schedule.

Table 2: AEFIs after the vaccinations

	Birth (n=2298)	6 weeks (n=1183	10 weeks (n=889)	14 weeks (n=670)	9-12 m (n=334)	16-24m (n=98)	5y (n=17)	Total
AEFI	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	
Fever	143(6.2)	946(79.9)	720(81.0)	489(73.0)	81(24.3)	56(57.1)	10(58.8)	2445
Injection site swelling	8(0.35)	200(16.9)	167(18.8)	69(10.3)	7(2.1)	10(10.2)	2(11.8)	463
Pain at site							2(11.8)	2
Cold/cough	5(0.2)		2(0.22)	3(0.4)	4(1.2)			14
Excessive crying	1(0.04)	9(0.76)	7(0.78)	1(0.1)		1(1)		19
Rash	5(0.2)		3(0.33)		2(0.6)			10
Jaundice	2(0.08)							2
Redness site		6(0.5)	12(1.3)	7(1)		2(2)		27
Vomiting				2(0.3)	3(0.9)	1(1)		6
Abscess	2(0.08)	2(0.17)	2(0.22)	1(0.1)				7
Diarrhoea					1(0.3)			1
Death	2(0.08)							2
Total AEFIs	168	1163	913	572	98	70	14	2998
No. of children having at least one AEFI	163(7.09)	960(81.14)	733(82.5)	501(74.8)	87(26%)	58(59.2)	10(58.8)	2512

After the vaccines given at birth, a total of 143 (6.2% of the children) episodes of fever were reported, swelling at injection site was reported in 8 children (0.35%), Cough or cold in 5(0.2%), Excessive crying in 1(0.04%), rash in 5(0.2%), jaundice in 2(0.08%), abscess in 2(0.08%) and death in 2(0.08%). Of the vaccines received at 6 weeks, 946(79.9%) reported fever, 200(16.9%) reported limb swelling, 9(0.76%) reported excessive crying, 6(0.5%) reported redness at injection site, and 2(0.17%) reported abscess. After the vaccines received at 10 weeks fever was again the most commonly reported AEFI in 720(81.0%) children followed by limb swelling in 167(18.8%) children, redness at injection site was reported by 12(1.3%), rash by 3(0.33%), abscess by 2(0.22%) and excessive crying by 7(0.78%). Following the vaccines at 14 weeks, 489(73%) cases of fever were reported which was the most common AEFI followed by 69(10.3%) cases of limb swelling. Other AEFIs were less commonly reported. Following the MR 1 vaccine, 81(24.3%) AEFIs of fever were reported followed by swelling at injection site in 7(2.1%) children. Of the vaccines given at 16-24 months, 56(57.1%) AEFIs of fever were reported followed by limb swelling in 10(10.2%) children. Among the children who received DPT2, 10(58.8%) cases of fever were reported followed by limb swelling in 2(11.8%).



	Fever	Swelling at injection site	Pain at injection site	Cold/cough	Excessive crying	Rash	Jaundice	Redness at injection site	Vomiting	Abscess	Diarrhoea	Death
BCG	143	8	0	5	1	5	2	0	0	2	0	2
LPV1	946	200	0	0	9	0	0	6	0	2	0	0
LPV2	720	167	0	2	7	3	0	12	0	2	0	0
LPV3	489	69	0	3	1	0	0	7	2	1	0	0
MR1	81	7	0	4	0	2	0	0	3	0	1	0
DPT1	56	10	0	0	1	0	0	2	1	0	0	0
DPT2	10	2	2	0	0	0	0	0	0	0	0	0

Figure 2: AEFIs after vaccines received as per the NIS

Regarding the treatment of these AEFIs, none of the children required hospitalization. About 62%(1524) cases of fever were treated with paracetamol drops while for the rest fever was very mild and resolved on its own. A total of 89.2% of the cases of swelling at injection site got resolved by cold fomentation while the rest resolved on their own. All other AEFIs either resolved on their own or a very few required treatment on outpatient basis. All the 7 cases of abscesses required drainage on outpatient basis.

Table 3: Association of AEFIs with some socio-demographic factors

			OR(p value)	95% C.I.for OR
Gender	Female	532(44.7%)	.914(.310)	.769 to 1.087
	Male(ref)	569(47.0%)		
Birth Order	1(ref)	583(49.5%)		
	2-3	508(42.9%)	.736(.001)	.618 to .876
	4-6	10(25.6%)	.412(.024)	.190 to .891

Residence	Rural(ref)	300(26.7%)	4.632(.000)	3.888 to 5.519
	Urban	801(62.7%)		
Birth weight	<2.5	98(45.0%)	1.025(.872)	.758 to 1.387
	>/=2.5(ref)	1003(46%)		

There was no statistically significant difference in the frequency of AEFIs with respect to gender. The frequency was higher with first birth order compared to other birth orders. The frequency was higher among the urban (62.7%) children compared to rural ((26.7%). No statistically significant difference in the frequency of AEFIs was observed with respect to the birth weight.

DISCUSSION

Monitoring of AEFIs is an important activity that should be associated with vaccination programmes. Though over 80% of children worldwide are vaccinated, vaccine hesitancy continues to be a public health issue.(4)AEFI reporting is indispensable for building the faith of the people in the vaccination programmes. It reassures people that cases are being reported and action is being taken.(5) Corrective measures can be taken if immunization error related AEFIs are reported. Unfortunately, very small number of AEFIs are reported.(6,7) Usually As per the global vaccine action plan, each country is expected to report at least 10 AEFIs for every 100,000 live births which is estimated to be 2600 for India as against the current number reported to be 1100 serious AEFIs annually.(8)Usually the reporting of AEFIs is passive. This yields a low percentage of AEFIs which come to the knowledge of the health system. (9) Low passive AEFI reporting rates are a significant barrier to detect vaccine safety signal timely (10). Therefore, this study was carried out to actively find out the AEFIs among the children receiving the vaccines at the Child Health clinic of SKIMS Soura, under the department of Community Medicine.

At the study site, the vaccines are given as per the national immunization schedule. Under the national immunization schedule a number of vaccines are given on the same day for increasing the vaccination uptake and the compliance.

In this study a total of 2399 children were followed for AEFIs. The incidence of AEFIs was found to be 15.1% (19805 doses, 2998 AEFIs). The incidence is comparable to other studies that have been conducted in India.(11-13)Fever was the most commonly reported AEFI. In most of the studies conducted across various countries, fever is reported as the most common AEFI.(3,14-16). In some of the studies swelling at the injection site was reported as the most common AEFI which is the second most common AEFI in our study.(17). The highest incidence of fever (81%) was after the vaccines received at 10 weeks (LPV2, OPV2, RVV). The incidence of fever was almost same at 6 weeks i.e., 79.96%. This might be attributed to the pertussis component of the LPV vaccine. Consequently, the frequency of fever was also high at 16-24 weeks and 5 years when DPT boosters are given.

The second most common AEFI in our study was injection site swelling. It was also common after the pertussis containing vaccines. The highest frequency of the injection site swelling was at 10 weeks (18.8%).The reason for injection site reactions may be due to the presence of aluminium salts as adjuvant in these vaccines, which are added to enhance vaccine efficacy.(18) In our study, the frequency of swelling at injection site was higher than a study conducted by Sebastian et al. In view of this, a review of the of the injection practices was done following this finding. Corrective measures wherever applicable were taken and trainings were given wherever needed.

Only 2 serious AEFIs were reported in our study and they were two deaths following the vaccines at birth. The two deaths were reported within 24 hours to the deputy CMO of district Srinagar. Causality assessment was done by the teams constituted at district level for the same for these two

cases in the shortest possible time. These two deaths were found to be coincidental by the teams. All other minor AEFIs were also reported through the monthly health information system (HMIS).

Regarding the treatment of these AEFIs, none of the children required hospitalization. About 62%(1524) cases of fever were treated with paracetamol while for the rest fever was very mild and resolved on its own. A total of 89.2% of the cases of swelling at injection site got resolved by cold fomentation while the rest resolved on their own. All other AEFIs either resolved on their own or a very few required treatment on outpatient basis. All the 7 cases of abscesses required drainage on outpatient basis. In the study conducted by Sebastian et al, most of the cases were treated symptomatically.(3)

There was no statistically significant difference in the frequency of AEFIs with respect to gender. The frequency was higher with first birth order compared to other birth orders. The frequency was higher among the urban (62.7%) children compared to rural (26.7%). This may be because of more awareness and education in urban population and therefore they might have noticed and more often reported the symptoms. It may imply more need of creating awareness about AEFIs among the rural population. No statistically significant difference in the frequency of AEFIs was observed with respect to the birth weight.

Limitations of the study: The AEFIs reported might not all be vaccine related because causality assessment was done only for serious AEFIs. Also the biochemical changes that m have occurred after some vaccines might have been missed in our study as we relied on parental reporting.

Conclusion: Fever was the most common AEFI reported after vaccines followed by swelling at injection site. Most of the AEFIs were minor and resolved on their own. Thus AEFIs should not form a reason of vaccine hesitancy among people. More AEFIs were reported by urban people than rural. It might be because of more awareness leading to more noticing of the symptoms by urban caretakers. Thus awareness generation regarding AEFIs is vital for both picking up an AEFI and reporting it and for eliminating vaccine hesitancy.

REFERENCES

1. Press WHO, Appia A, Press WHO. Global Manual on Surveillance of Adverse Events Following Immunization. 2014.

2. Manual U, The FOR, Who R, Edition S. Causality assessment of an Adverse Event Following Immunization. 2018. 48 p.

3. Sebastian J, Gurumurthy P, Ravi MD, Ramesh M. Active surveillance of adverse events following immunization (AEFI): a prospective 3-year vaccine safety study. 2019;1–9.

4. Danova J., Kocourkova A., and Celko A. M., "Active surveillance study of adverse events following immunisation of children in the Czech Republic.," *BMC Public Health*, vol. 17, no. 1, p. 167, 2017, pmid:28166783

5. Laryea EB, Frimpong JA, Noora CL, Tengey J, Bandoh D, Sabblah G, et al. (2022) Evaluation of the adverse events following immunization surveillance system, Ghana, 2019. PLoS ONE 17(3): e0264697. https://doi.org/ 10.1371/journal.pone.0264697

6. Joshi, J., Das, M.K., Polpakara, D. *et al.* Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) in India. *Indian J Pediatr* **85**, 139–148 (2018).

https://doi.org/10.1007/s12098-017-2532-9

7. Laryea EB, Frimpong JA, Noora CL, Tengey J, Bandoh D, Sabblah G, et al. (2022) Evaluation of the adverse events following immunization surveillance system, Ghana, 2019. PLoS ONE 17(3): e0264697. https://doi.org/10.1371/journal.pone.0264697

8. WHO. Global Vaccine Action Plan 2011-2020. Geneva: WHO Press; 2013. Available at: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/.

9. Griffin MR, Braun MM, Bart KJ. What should an ideal vaccine postlicensure safety syste8m be? *Am J Public Health* 2009;99Suppl 2:S345–S350. 10.2105/AJPH.2008.143081

10. O S. Achievements and challenges in global vaccine safety 25 Uppsala, 2016.

11. Joshi ND, Prajapati KH, Solanki KC, et al. Pattern of adverse events following immunization in an Indian teaching hospital. IJMSPH 2013; 2: 62–68.

12. Adherkar RY, Deshpande PK and Ghongane BB. Study of the pattern of adverse events following immunization of the children in a tertiary care hospital. IJBCP 2016; 5: 609–615.

13. Khazaei S, Rezaeian S, Razani M, et al. Adverse Events Following Immunization(AEFI) in children under 7 years of age during 2014 in Hamedan Province, Iran. Int J Pediatr 2016; 4: 1697–1703.

14. Ganaie NA, Pandit MI. Incidence of adverse events following immunization (AEFI) among infants after immunization with primary doses of scheduled vaccines in district Srinagar (J&K). Indian J Forensic Community Med 2021;8(2):91-96

15. Khazaei S, Rezaeian S, Razani M, et al. Adverse Events Following Immunization(AEFI) in children under 7 years of age during 2014 in Hamedan Province, Iran. Int J Pediatr 2016; 4: 1697–1703

16. Zhou W, Pool V, Iskander JK, et al. Surveillance of safety after immunization: Vaccine Adverse Effect Reporting System (VAERS): United States, 1991–2001. MMWR SurveillSumm 2003; 52: 1–24.

17. Adherkar RY, Deshpande PK and Ghongane BB. Study of the pattern of adverse events following immunization of the children in a tertiary care hospital. IJBCP 2016; 5: 609–615.),(Yu Hu, Qian Li, Luoya Lin, et al. Surveillance for adverse events following immunization from 2008 to 2011 in Zheiiang Province, China. ClinVaccinImmunol 2013; 20: 211–217.

18. Fiejka M, Aleksandrowicz J. Glinjakoadiuwant w szczepionkach i reakcjeposzczepienne [Aluminum as an adjuvant in vaccines and post-vaccine reactions]. RoczPanstwZaklHig. 1993;44(1):73-80. Polish. PMID: 8235346.