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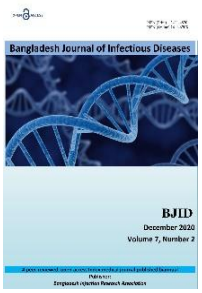

Adverse Events Following Immunization with EPI Vaccines among the Children of an Upazilla Health Complex in Bangladesh

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Abstract

Background: In Bangladesh, the Expanded Programme on Immunization (EPI) is the most successful and cost-effective public health initiative, significantly reducing morbidity and mortality in children under five, despite the inevitability of some adverse events following immunization (AEFI). **Objective:** The purpose of the present study was to evaluate the AEFI of EPI vaccines among the children of an Upazilla Health Complex. **Methodology:** This hospital-based cross-sectional study was conducted among 178 conveniently selected parents of children aged ≤18 months who received EPI vaccines within the past 3 months at the EPI corner of Nabiganj Upazila Health Complex, Habiganj, Bangladesh. From July to December 2023, a pretested face-to-face, semi-structured questionnaire was used to interview study participants at their convenience. The questionnaire was generated by the socio-demographic profile of children, the children's birth history profiles, and The AEFI status of children's EPI vaccinations during the study period. **Results:** The EPI vaccine had been given to all children, and all of them had suffered known adverse effects. After following vaccination, 61.2% of vaccine recipients experienced adverse effects from the BCG vaccine, 38.8% from Pentavalent, 20.8% from IPV, 5.6% from PCV, 2.8% from MR, 1.7 from OPV, and 0.6% from the measles vaccine. Fever (97.8%) and injection site abscess (16.9%) were the most frequent adverse effects. In 97.2% of instances, adverse effects occurred within 24 hours, and 89.3% of instances had adverse effects that persisted <7 days. Only 1.7% of the children' parents informed the EPI center about adverse effects. After getting treatment, 99.4% of them recovered, while 0.6% persisted. Among all stated AEFI cases, no one was hospitalized or died. **Conclusion:** In order to mitigate morbidities, health education and promotion initiatives should be put into place to raise parents' comprehension regarding AEFI. [*Bangladesh Journal of Infectious Diseases, June 2025;12(1):78-84*]

Keywords: AEFI; EPI vaccination; Bangladesh

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Introduction

Immunization aims to protect individuals and communities against vaccine-preventable diseases. Although vaccines used in national immunization campaigns are extremely safe and effective, there is always a risk of adverse events following immunization (AEFI). The act of immunization, not only the vaccines, can lead to adverse events[1].

The Expanded Programme on Immunization (EPI) is one of Bangladesh's most successful programmes. In Bangladesh, a fully immunized child receives 8 immunizations covering the 6 standard EPI antigens. However, completing the whole vaccine schedule remains a significant programmatic issue. Recent national studies show that 82.0 to 89.0% of children below 24 months are fully vaccinated[2,3]. Although 98.0% of children received BCG or DPT_1 vaccines, measles coverage was 89% only[3].

Another study in Dhaka district found 13% dropouts for DPT1 to measles[4]. Almost all parents bring their children for the first of three series of DPT and OPV, but many do not complete the measles vaccination, resulting in incomplete protection. Studies have shown that children who do not receive measles vaccination are more likely to be stunted, underweight, and wasted compared to fully immunized groups[5].

AEFI refers to any adverse medical event that occurs after immunization but is not directly related to vaccination use[6]. AEFIs can cause minor to life-threatening side effects in children, but they are rare. Adverse events can be induced by immunizations, administration errors, or no known cause[7]. The AEFIs can be categorized into 5 main types, vaccine product related reaction, vaccine quality defect-related reaction, immunization error-related reaction, coincidental event, and immunization anxiety-related reaction[8,9].

Improving vaccination safety is crucial as it might impact service utilization without proper monitoring and management. Vaccines have higher expectations than pharmaceuticals, and difficulties associated with them are less acceptable to the public. Effective monitoring and response to AEFIs is crucial[10]. UNICEF and WHO have improved developing nations' access to high-quality, inexpensive immunizations. UNICEF supplies EPI vaccinations from WHO-recommended suppliers. WHO pre-qualifies vaccinations and provides guidance to UN procurement agencies on their quality, efficacy, and safety. Vaccines developed and monitored according to WHO standards are generally safe, although there is always a possibility of unpleasant reactions[11,12].

Early detection and treatment of AEFI is essential. These measures will increase public trust while also preventing further clustering of cases due to software errors. Quick response to AEFI is crucial. Bangladesh's government is strengthening the AEFI surveillance system by establishing committees at the national, state, and local levels.

Methodology

Study design and settings: This cross-sectional study was carried out to evaluate the adverse events following immunization of EPI vaccines among the children of EPI corner of an Upazilla Health Complex (UHC) named Nabiganj UHC situated in the Habiganj district, Sylhet 3370, Bangladesh.

Sample selection criteria: The study included 178 parents of children aged 18 months or younger, who had received the EPI vaccine within the 3 months prior to the interview.

Data collection procedures: From July to December 2023, a pretested face-to-face, semi-structured questionnaire was used to interview study participants at their convenience. The questionnaire was generated by the socio-demographic profile of children, the children's birth history profiles, and The AEFI status of children's EPI vaccinations during the study period.

Data analysis: Data was entered, curated and analyzed using IBM SPSS Version 26 (New York, USA). Descriptive statistics were expressed as frequency (percentage) and mean (±standard deviation, or SD) for categorical and continuous data, respectively. Chi-square test and Fisher exact test were used to assess the significance of associations between two nominal variables. A p-value of <0.05 at a 95% confidence interval (CI) was considered significant for all statistical tests.

Ethical Approval: Informed consent and permission to record interviews were obtained from all participants prior to the interviews. Participation was voluntary, and participants were informed of their right to withdraw at any time without consequence. Confidentiality was maintained throughout the study. The research complied with the 2013 revised Declaration of Helsinki and its amendments, or comparable ethical standards.

Ethical approval was granted by Sylhet MAG Osmani Medical College, Sylhet 3100, Bangladesh.

Results

Socio-demographic profile of the children: Table 1 depicts the socio-demographic profile of children. The child's age was 6.2±3.8 months on a mean. The age group of ≤6 months constituted the majority of the total (61.2%), followed by 10 to 15 months (25.6%) and 7 to 9 months (12.9%). Of the children, 52.2% were female, and the remaining 47.8% were male. Of the fathers, more than one-third (37.1%) had completed secondary education, 29.2% had finished primary education, and 11.2% had graduated, whereas only 8.4% were illiterate. Approximately 48.9% of mothers had completed their primary education, 5.6% had graduated, and only 1.7% were illiterate (Figure I). Most fathers (42.7%) were businessmen, with 19.1% living overseas, and only 7.3% worked as day laborers. The majority of the mothers (96.6%) were homemakers, with the others (3.4%) working in different occupations such as students, service holders, and businesswomen. The mean family income was 18,269.7±6,518.6 taka. Approximately 72.5% of parents had a monthly family income of ≤20,000 taka.

Table 1: Socio-Demographic Profile of the Children (n=178)

Attributes	Frequency	Percent
Age Group		
≤6 months	109	61.2
7 to 9 months	23	12.9
10 to 15 months	46	25.8
Mean±SD	6.2±3.8	
Gender		
Male	85	47.8
Female	93	52.2
Father's Occupation		
Agricultural worker	30	16.9
Businessman	76	42.7
Overseas	34	19.1
Service holder	25	14.0
Day laborer	13	7.3
Mother's Occupation		
Homemaker	172	96.6
Others	6	3.4
Family Incomes		
≤20,000 taka	129	72.5
>20,000 taka	49	27.5
Mean±SD	18,269.7±6,518.6	

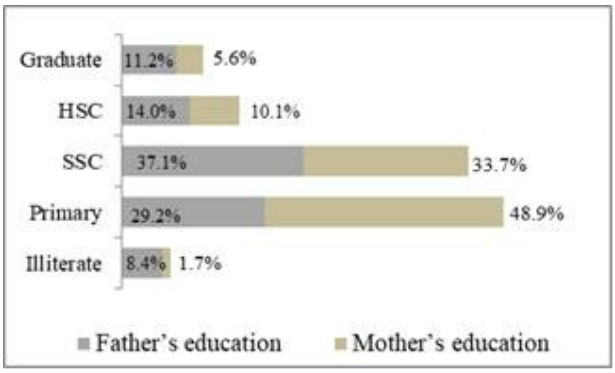

Figure I: Levels of education of the parents of children (n=180)

Birth History Profiles of the Children: Table 2 describes the children's birth history profiles. The mean current body weight was 6.1±2.2 kg. The majority of children (53.4%) weighed more than 5 kg, while the rest weighed less than 5 kg (46.6%). The mean birth weight was 2.9±0.3 kg at the 1st hour. The majority of the children's birth weight was ≥2.5 kg (97.8%), while the rest were <2.5 kg (2.2%). A full-term delivery occurred for a cent of the children. Normal vaginal deliveries accounted for 61.2% of deliveries, whereas caesarean sections accounted for 38.8%. 52.7% of the children (50.0) were born in private health settings (clinics, NGOs), 7.3% at home, and half of the children were born in government health facilities. Following birth, no complications faced by the respondent's child occurred.

Table 2: Birth History Profile of the Children (n=178)

Attributes	Frequency	Percent
Current body weight		
≤5 Kg	83	46.6
>5 Kg	95	53.4
Mean±SD	6.1±2.2	
Child birth weight		
<2.5 Kg	4	2.2
≥2.5 Kg	174	97.8
Mean±SD	2.9±0.3	
Term of birth		
Pre-term (before 37 week)	0	0.0
Full term (between 37-42 weeks)	178	100.0
Post term (after 42 weeks)	0	0.0
Mode of last delivery		
Normal vaginal delivery (NVD)	109	61.2
Caesarean section	69	38.8

Attributes	Frequency	Percent
(CS)		
Place of last delivery		
Home	13	7.3
Government health settings	89	50.0
Private health settings (NGO, Clinic etc.)	76	42.7
Complication occurred after delivery		
Yes	0	0.0
No	178	100.0

AEFI Status of EPI Vaccination of Children: The AEFI status of children's EPI vaccinations during the study period was shown in Table 3. The all respondents (100.0%) were aware of the EPI vaccine. The EPI vaccine had been given to all children, and all of them had experienced known adverse effects after receiving it. Within the last 3 months, 61.2% of the vaccine recipients suffered adverse effects from the BCG vaccine, 38.8% from Pentavalent, 20.8% from IPV, 5.6% from PCV, 2.8% from MR, 1.7 from OPV, and 0.6% from the measles vaccine (Figure II). The majority of respondents figured that fever (97.8%), injection site abscess (16.9%), and persistent inconsolable screaming (2.2%) were the most common adverse effects. Within 24 hours, adverse effects were observed in 97.2% of instances. For children, adverse effects last less than 7 days (89.3%), more than 7 days (1.7%), and till present (0.6%). Out of all the parents of the recipients, only 1.7% of them informed the EPI center about adverse effects within 3 months of receiving the vaccines, while 98.3% did not. The most cited reasons were that the child's illness was not critical (65.1%), treated at home (14.9%), and managed by a local doctor (21.1%), and the reporting procedure was imprecise (1.7%). Not a single child needed to be admitted to the hospital to manage the adverse effects. 99.4% of patients recovered after getting treatment, while 0.6% persisted. Due to a vaccine's adverse effects, nobody has died (Figure III).

Table 3: AEFI Status of EPI Vaccination of Children (n=178)

Attributes	n(%)
Parents aware about EPI vaccination	
Yes	178(100.0)
No	0(0.0)
Total	178(100.0)
History of taking EPI vaccine	
Yes	178(100.0)
No	0(0.0)
Total	178(100.0)
History of adverse effects within the last 3 months following vaccination	
Yes	178(100)
No	0(0.0)
Total	178(100.0)
Adverse effects occurred following vaccination	
Fever	174(97.8)
Local reactions (Pain, redness & swelling)	153(86.0)
Injection site abscess	30(16.9)
Persistent inconsolable screaming	4(2.2)
*Multiple responses	
Time of onset of adverse effects	
Within 24 hours	173(97.2)
Within 72 hours	5(2.8)
Duration of the adverse effects persist	
Less than 24 hours	15(8.4)
Less than 7 days	159(89.3)
Less than 1 month	3(1.7)
Till persist	1(0.6)
Reported about adverse effects to EPI center	
Yes	3(1.7)
No	175(98.3)
Reasons for not informing the EPI center about adverse effects (n=175)	
Condition was not serious	114(65.1)
Treated at home	26(14.9)
Treated by local doctor	37(21.1)
Long distance of EPI center	5(2.8)
Process of reporting is unknown	3(1.7)
*Multiple responses	
Required hospitalization for management	
Yes	0(0.0)
No	178(100.0)

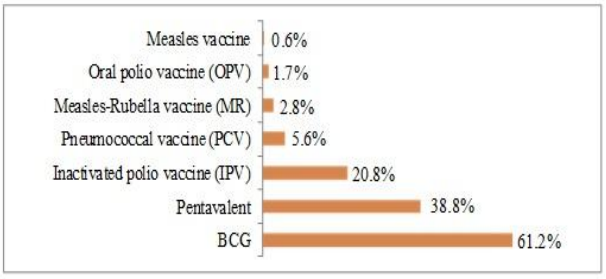

Figure II: Probable vaccine caused adverse effects

Table 4 unveils an interpretation of the association between multiple variables and the reported adverse effects to the EPI Centre. No statistically significant association was found.

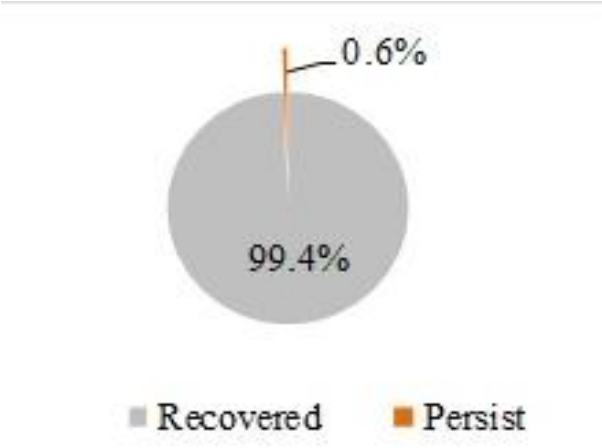

Figure III: Outcomes of AEFI (n=178)

Table 4: Association of Reported AEFI to EPI Center with Different Variables

Attributes	Reported on AEFI		P value
	Yes	No	
Father's education			
Illiterate	0(0.0%)	15(100.0%)	†0.666
Below HSC	3(2.5%)	115(97.5%)	
HSC & above	0(0.0%)	45(100.0%)	
Mother's education			
Illiterate	0(0.0%)	3(100.0%)	†0.437
Below HSC	2(1.4%)	145(98.6%)	
HSC & above	1(3.6%)	27(96.4%)	
Family incomes			
≤20,000 taka	1(0.8%)	128(99.2%)	0.184
>20,000 taka	2(4.1%)	47(95.9%)	
Adverse effects persist			
<24 hours	0(0.0%)	15(100.0%)	†1.000
<7 days	3(1.9%)	156(98.1%)	
<1 month	0(0.0%)	3(100.0%)	
Till persist	0(0.0%)	1(100.0%)	

Chi-square and †Fisher exact test done, p<0.05 considered as statistically significant value

Discussion

Since the beginning in 1974 and its introduction to Bangladesh in 1979, the WHO EPI program has been one of the most influential global health initiatives. In 1985, the WHO established a standardized vaccination schedule for the original EPI vaccines[13,14]. In this year, the Government of the People's Republic of Bangladesh committed to the Global Universal Child Immunization Initiative (UCI)[14,15], and began a phase-wise process of EPI intensification from 1985-1990.

The child's age was 6.2±3.8 months on a mean. The age group of ≤6 months constituted the majority of the total (61.2%), followed by 10-15 months (25.6%) and 7-9 months (12.9%). Of the children, 52.2% were female, and the remaining 47.8% were male. Of the fathers, more than one-third (37.1%) had completed secondary education, 29.2% had finished primary education, and 11.2% had graduated, whereas only 8.4% were illiterate. Approximately 48.9% of mothers had completed their primary education, 5.6% had graduated, and only 1.7% was illiterate. Most fathers (42.7%) were businessmen, with 19.1% living overseas, and only 7.3% worked as day laborers. The majority of the mothers (96.6%) were homemakers, with the others (3.4%) working in different occupations (such as students, service holders, and businesswomen). The mean family income was 18,269.7±6,518.6 taka. Approximately 72.5% of parents had a monthly family income of ≤20,000 taka. These finding were nearly similar to the studies[16,17].

Regarding the children's birth history profiles, the mean current body weight was 6.1±2.2 kg. The majority of children (53.4%) weighed more than 5 kg, while the rest weighed less than 5 kg (46.6%). The mean birth weight was 2.9±0.3 kg at the 1st hour. The majority of the children's birth weight was ≥2.5 kg (97.8%), while the rest were <2.5 kg (2.2%). A full-term delivery occurred for a cent of the children. Normal vaginal deliveries accounted for 61.2% of deliveries, whereas caesarean sections accounted for 38.8%. 52.7% of the children (50.0) were born in private health settings (clinics, NGOs), 7.3% at home, and half of the children were born in government health facilities. Following birth, no complications faced by the respondent's child occurred. These findings were almost similar to the studies[17,18].

The EPI vaccine had been given to all children, and all of them had experienced known adverse effects after receiving it. Within the last 3 months, 61.2% of the vaccine recipients suffered adverse effects from the BCG vaccine, 38.8% from Pentavalent, 20.8% from IPV, 5.6% from PCV, 2.8% from MR, 1.7 from OPV, and 0.6% from the measles vaccine. The majority of respondents figured that fever (97.8%), injection site abscess (16.9%), and persistent inconsolable screaming (2.2%) were the most common adverse effects. Within 24 hours, adverse effects were observed in 97.2% of instances. For children, adverse effects last less than 7 days (89.3%), more than 7 days (1.7%), and till present (0.6%). Out of all the parents of the recipients, only 1.7% of them informed the EPI center about adverse effects within 3 months of receiving the vaccines, while 98.3% did not. The most cited reasons were that the child's illness was

not critical (65.1%), treated at home (14.9%), and managed by a local doctor (21.1%), and the reporting procedure was imprecise (1.7%). Not a single child needed to be admitted to the hospital to manage the adverse effects. 99.4% of patients recovered after getting treatment, while 0.6% persisted. These findings were nearly similar to the studies in India[12,19] and in Nigeria[20,21].

The data in this study are limited to a specific region and do not represent the entire country. Due to time constraints, we were unable to assess the entire target population, resulting in a smaller sample size than initially estimated.

Conclusion

The side effects reported most frequently were local reactions (pain, redness, and swelling), fever, and injection site abscess, with the majority occurring within 24 hours following immunization. Most of the adverse effects were reported after receiving BCG, IPV, and Pentavalent vaccinations. Within 7 days, the majority of recipients recovered from the vaccine's adverse effects, and no one died as a result of events. The AEFI reporting system needs to be more user-friendly and accessible to the general public. Policymakers and stakeholders must implement more community-based strategies to enhance awareness.

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Conflict of Interest
The authors declare that they have no competing interests.

Financial Disclosure
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Authors' contributions
Conceptualization, methods and literature reviews: Nurunnabi M, and Tanu TD; Data collection: Tanu TD; Statistical analysis: Nurunnabi M, and Akter F; Draft manuscript: Nurunnabi M, Tanu TD, Akter F and Ahmed MS. All the authors work and approved the final manuscript.

Data Availability
Any questions regarding the availability of the study's supporti ng data should be addressed to the corresponding author, who can provide it upon justifiable request.

Ethics Approval and Consent to Participate
The Institutional Review Board granted the study ethical approval. Since this was a prospective study, every study participant provided formal informed consent. Each method followed the appropriate rules and regulations.

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