

Research Article

Adverse Events Following Immunization (AEFI) Reporting in Urban and Rural Bangladesh

Mallick Masum Billah^{1,*} , Alden Keith Henderson² ,
Syed Muhammad Baqui Billah³ , Tajul Islam Abdul Bari⁴ ,
Emily Suzanne Gurley⁵ 

¹Department of Epidemiology, Institute of Epidemiology, Disease Control and Research (IEDCR), Dhaka, Bangladesh

²Department of Public Health, University of Hawaii, Honolulu, U.S

³Department of Medical Education, Directorate General of Medical Education, Dhaka, Bangladesh

⁴Infectious Disease Division, International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh

⁵Department of Epidemiology, Johns Hopkins University, Baltimore, U.S

Abstract

Complete reporting and management of adverse events following immunization (AEFIs) helps maintain the quality of vaccine delivery and monitor vaccine safety. We assessed AEFI reporting of Bangladesh with neighboring and high resource countries and also between rural and urban providers in Bangladesh. We calculated AEFI rates per 100,000 injectable vaccine doses from national vaccination program (2010-2014) between urban and rural providers using a z-test for two proportions. Non-abscess AEFI rates were used to assess reporting differences, while abscess rates indicated vaccine delivery quality. We compared Bangladesh's AEFI data with reports from neighboring and high-resource countries. Of 97,620,629 reported vaccine doses, 8,003 AEFIs were recorded; 4,763 (60%) were non-abscess AEFIs, and 3,240 (40%) were abscesses. AEFIs were most frequently reported for pentavalent (12/100,000 doses), followed by BCG (6/100,000), and measles-rubella (3/100,000) vaccines. Non-abscess AEFI rates were higher in rural (5.3/100,000 doses) than urban areas (2.3/100,000 doses, $p < 0.001$), while abscess AEFI rates were higher across all vaccines in rural areas (3.5/100,000 doses vs 2.3/100,000 doses, $p < 0.001$). Overall reported AEFI rates (pentavalent: 7.6/100,000, BCG: 1.7/100,000, MR: 2.6/100,000) were lower than in other countries. Low rates in both urban and rural area of nonabscess AEFI compared with expected rates inherent for each vaccine suggested underreporting of AEFIs in Bangladesh. Despite likely underreporting of AEFIs, abscess AEFI rates were higher than several other countries, suggesting attention should be focused not only on the reporting of AEFIs, but also on the quality of vaccine delivery in Bangladesh, particularly in urban areas.

Keywords

Immunization, Adverse Event Following Immunization (AEFI), Vaccines/Adverse Effects, Adverse Drug Reaction Reporting Systems, Bangladesh

*Corresponding author: drmasumbillah@yahoo.com (Mallick Masum Billah)

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1. Introduction

Adverse events can occur after administering immunobiological agents, including vaccines. [1, 2] Addressing these adverse events following immunization (AEFIs) is critical to ensure the continued success of vaccination programs. [3] Vaccination remains one of the most effective public health tools to reduce infant and under-five mortality. [1, 4] When AEFIs occur in healthy individuals, they can undermine people's confidence in vaccines subsequently decreasing parents' willingness to get their children fully vaccinated. [4] Reporting of AEFIs helps vaccination programs manage the quality of service delivery and monitor for vaccine-related safety issues. [5]

In 2014, the World Health Organization (WHO) classified AEFIs into five categories: vaccine product-related, quality defect-related, immunization error-related, immunization anxiety-related, and coincidental events. [1] Among these, immunization error-related events—especially abscesses at injection sites—are largely preventable when vaccine delivery guidelines are followed. [2] Abscess AEFIs are commonly related to lapses in quality of vaccine service delivery, including non-sterile injection techniques, reconstitution with incorrect diluents, injection at incorrect sites, and administration of vaccines exposed to excessive heat and cold. [2, 6] The reported rate of abscess AEFI, therefore, is related to the quality of vaccine service delivery and quality of reporting. The remainder of AEFIs are local and systemic reactions, which are inflammatory reactions of the body to foreign antigens (e.g., high fever, allergic reactions, convulsion), and can be grouped together as non-abscess AEFIs. The World Health Organization (WHO) published the observed rate of non-abscess AEFIs, also known as vaccine reactions for several vaccines. [1, 5] Consequently, when the AEFI rate is above the observed rate, we need to consider the quality of vaccines, community sensitization and rule out whether the event is coincidental. [7, 8]

In Bangladesh, the Expanded Programme on Immunization (EPI), under the Ministry of Health and Family Welfare (MOHFW), oversees vaccine delivery and AEFI surveillance. [9] Since 2009 the childhood EPI schedule included *Bacillus Calmette-Guérin* (BCG) at birth, oral polio vaccine (OPV) at birth and 6, 10, and 14 weeks, the measles vaccine at 9 months, and a pentavalent vaccine (diphtheria, pertussis, tetanus, *Haemophilus influenzae* type B, and hepatitis B) at 6, 10, and 14 weeks. [10] In 2012, the measles-rubella (MR) vaccine and a second dose of a measles-containing vaccine (MCV-2) were added at 15 months. [11] By 2011, over 80% of children aged 0-24 months received vaccines on time, although coverage levels varied by location. [12-15] A 2015 survey showed higher rural coverage than urban coverage (87.1% vs 83.9%). [15]

Vaccination services follow Bangladesh's administrative divisions—rural areas include districts and subdistricts, while cities and municipalities are considered urban. [9] Though the

same vaccines, delivery guidelines, and AEFI reporting systems apply nationwide, delivery differs: MOHFW vaccinators serve rural areas, while urban vaccination is carried out by non-governmental organizations (NGOs) and private hospitals under the Ministry of Local Government and Rural Development (MOLGRD). [6, 9]

EPI received anecdotal reports from the urban and rural service providers on the overall quality of vaccine service delivery. We used a novel way to analyze the AEFI data to assess quality of vaccination service delivery through AEFI reporting. We analyzed EPI surveillance data on AEFI to compare rates of AEFIs in rural and urban areas of Bangladesh and to assess quality of vaccine delivery in terms of the occurrence of abscess AEFI and completeness of AEFI reporting.

2. Methods

2.1. AEFI Surveillance in Bangladesh

The Expanded Programme on Immunization (EPI) launched nationwide AEFI surveillance in 2003 to ensure vaccine safety by detecting, reporting, and investigating adverse events for timely corrective actions (11). AEFIs are typically reported by caregivers to vaccinators or identified by healthcare workers during clinical visits. Vaccinators report AEFIs from the community to healthcare facilities. Doctors or nurses also identify AEFIs from patients seeking care in healthcare facilities. AEFIs identified in the community and healthcare facilities were required to be reported weekly to the national EPI headquarters. [5] Deaths, hospitalizations, incidents of community concern, or clusters of cases (i.e., more than one AEFI case in an administrative area) associated with AEFIs are required to be reported immediately, in addition to weekly reporting. AEFI reporting is completed in urban areas by the government and in rural areas by nongovernment organizations. Completeness and validity of the reported data are checked by local surveillance medical officers employed by WHO.

2.2. Study Population and Data Sources

We analyzed AEFI surveillance data collected from January 2010 to December 2014 for children aged 0-24 months. Reports included the child's age, sex, hospitalization status, caregiver's address, reporting source, type of AEFI, and suspected vaccine.

2.3. AEFI Classification

From 2010 to 2013, surveillance followed the earlier WHO definition of AEFI as any medical incident believed to be vaccine-related. In 2014, Bangladesh adopted the updated

WHO definition, which defines AEFI as any medical event occurring after immunization, not necessarily causally linked. [1] We categorized injection site abscesses as abscess AEFIs and all other local and systemic reactions—such as fever, convulsions, rash, and encephalopathy—as non-abscess AEFIs.

2.4. Vaccination Coverage Data

To estimate AEFI rates, we used monthly administrative data on vaccine doses delivered by EPI vaccinators. These data were not disaggregated by age or sex, limiting stratified analysis. We classified vaccine doses by delivery site: cities and municipalities were defined as urban, while districts and subdistricts were considered rural.

2.5. Data Management

We excluded incomplete records missing critical information (child's name, age, sex, AEFI type, or suspected vaccine). Reports for children older than 24 months were excluded per EPI guidelines. When multiple vaccines were implicated in a single AEFI, we selected the vaccine most commonly associated with the reported reaction type and location. [16-19]

2.6. Statistical Analysis

We calculated AEFI rates as the number of events per 100,000 injectable doses administered. Differences in abscess and non-abscess AEFI rates between urban and rural areas

were assessed using a z-test for two proportions, with $p < 0.05$ considered statistically significant. We also analyzed AEFI rates by age, sex, vaccine type, and administrative division. Non-abscess AEFI rates were compared with WHO-reported vaccine reaction rates from high-income and regional countries. [16-19] Total AEFI rates were compared to published estimates from countries in the WHO Southeast Asia Region (SEARO) and high-resource countries (2006-2015). For vaccine-specific comparisons, we evaluated Bangladesh's rates for pentavalent vaccine against other DTP-containing vaccines, and MR vaccine rates against those from countries using measles combination vaccines (e.g., MMR, MMRV), adjusting expectations based on the number of antigens in the vaccine. [19]

2.7. Ethical Considerations

We obtained permission from the Bangladesh EPI under the Ministry of Health and Family Welfare to analyze de-identified data.

3. Results

A total of 97,620,703 injectable vaccine doses were administered in Bangladesh from 2010 to 2014. Of these, 32% were given in Dhaka, 24% in Chittagong, 14% in Rajshahi, 9% in Khulna, 8% in Sylhet, 7% in Barishal, and 6% in Rangpur division. By vaccine, 56% of doses were pentavalent, 19% BCG, and 25% measles or MR. (Table 1)

Table 1. Distribution of adverse events following immunizations (AEFI) by age, sex, division, years and vaccines, Reported in Bangladesh from 2010-2014.

Variables	AEFI	Percentage
Age (years)		
< 28 days	214	2.7
28 days - 6 months	6,670	83.3
6- 12 months	858	10.7
> 12 months	122	1.5
Sex		
Male	4,243	53.0
Female	3,760	47.0
Reported adverse events*		
High fever	3,872	48.4
Injection site abscess	3,240	40.5
Severe local reaction	202	2.5

Variables	AEFI	Percentage
Convulsion	199	2.5
BCG-lymphadenitis	135	1.7
Rash	132	1.7
Loss of consciousness	64	0.8
Death	11	0.1
Others	148	1.8
AEFI reported from		
AEFI by vaccines		
Pentavalent	6,164	77.0
BCG	1,153	14.4
Measles	379	4.8
Combined measles and rubella	307	3.8
AEFI by divisions		
Chittagong	2,100	25.8
Dhaka	2,061	25.2
Khulna	1,404	17.5
Rajshahi	1,262	15.8
Sylhet	448	5.6
Rangpur	424	5.3
Barishal	304	3.8
Total	8,003	100.0

There were 8,303 reported AEFIs, of which 300 (3%) were excluded for being outside the recommended vaccination age. Another 135 AEFIs (2%) had multiple suspected vaccines; we retained a single most likely vaccine based on the type and location of the AEFI. Among the 8,003 AEFIs included, most were reported from Chittagong (2,100, 26%) and Dhaka (1,061, 13%) divisions. The majority occurred in children

aged 28 days to 6 months (6,670, 83%) and in males (4,243, 53%).

Of all AEFIs, 4,763 (60%) were non-abscess AEFIs and 3,240 (40%) were abscess AEFIs. (Table 1) Pentavalent vaccine was linked to 6,164 AEFIs (77%), followed by BCG and measles/MR vaccines. Only 121 AEFI reports (1.5%) listed more than one suspected vaccine. Of all vaccine doses given.

Table 2. Comparison of rate of total, preventable and inherent AEFI (Per 100,000 injectable vaccine doses) between urban and rural areas by vaccine and geographical division of Bangladesh, 2010-2014.

A. By vaccines

Vaccines		Doses	Total AEFI		Non-abscess AEFI		Abscess AEFI	
			Rate	p	Rate	p	Rate	p
Pentavalent vaccine	Urban	7,962,247	6.2	<0.001	3.2	<0.001	3.1	<0.001
	Rural	46,414,560	12.4		8.3		4.1	
BCG	Urban	2,562,812	2.4	<0.001	0.3	<0.001	2.1	<0.001

Vaccines		Doses	Total AEFI		Non-abscess AEFI		Abscess AEFI	
			Rate	p	Rate	p	Rate	p
Measles and Rubella (MR)	Rural	15,921,325	6.2	0.002	1.9	0.2	4.3	0.003
	Urban	3,144,941	2.3		1.7		0.7	
	Rural	21,614,818	2.8		1.4		1.5	
Total	Urban	13,670,000	4.6	<0.001	2.3	<0.001	2.3	<0.001
	Rural	83,950,703	8.8		5.3		3.5	

B. By Geographic Locations

Division		Doses	Total AEFI		Non-abscess AEFI		Abscess AEFI	
			Rate	p	Rate	p	Rate	p
Dhaka	Urban	6,081,614	5.9	<0.001	1.5	<0.001	2.4	<0.001
	Rural	25,519,861	7.1		3.2		4.0	
Chittagong	Urban	3,702,294	3.8	<0.001	3.2	<0.001	0.5	<0.001
	Rural	18,789,734	10.4		8.3		2.1	
Khulna	Urban	1,196,126	7.6	<0.001	2.1	<0.001	5.5	<0.001
	Rural	7,547,538	17.4		12.4		5.0	
Rajshahi	Urban	1,169,947	9.9	0.7	3.2	0.9	6.7	0.2
	Rural	11,990,706	9.6		3.8		5.8	
Sylhet	Urban	465,298	2.2	0.0004	1.5	0.0006	0.6	0.3
	Rural	6,917,004	6.3		5.1		1.2	
Rangpur	Urban	572,572	2.4	0.003	1.6	0.1	0.9	0.006
	Rural	7,584,891	5.4		2.6		2.6	
Barishal	Urban	482,149	3.9	0.2	2.1	0.9	1.9	0.2
	Rural	5,600,96	5.1		2.1		3.0	

86% were administered in rural areas and 14% were administered in urban areas.

The overall AEFI rate was 8.2 per 100,000 doses—4.9 for non-abscess and 3.3 for abscess AEFIs. By vaccine type, non-abscess AEFI rates for pentavalent and BCG were significantly higher in rural areas (8.3 vs 3.2 and 4.3 vs 2.1 per 100,000 doses, respectively), while measles/MR vaccine showed no significant urban-rural difference. Abscess AEFI rates for all three vaccines were higher in rural areas. (Table 2a).

Non-abscess AEFI rates were generally higher in rural areas across most divisions, except Rajshahi, Barishal, and Rangpur, where urban-rural differences were not significant.

Abscess AEFI rates were also higher in rural areas, with the exception of Rajshahi, Barishal, and Sylhet, where differences were minimal. (Table 2b) Notably, rural abscess AEFI rates in Sylhet were twice as high as urban rates, though not statistically significant.

Over time, non-abscess AEFI rates from pentavalent vaccine increased from 2011 to 2014, while abscess rates peaked in 2011 and declined thereafter. BCG-related abscess AEFI rates declined steadily; non-abscess rates remained stable. For measles/MR vaccines, non-abscess AEFI rates initially declined, then rose from 2011 to 2014, while abscess rates decreased overall. (Figure 1)

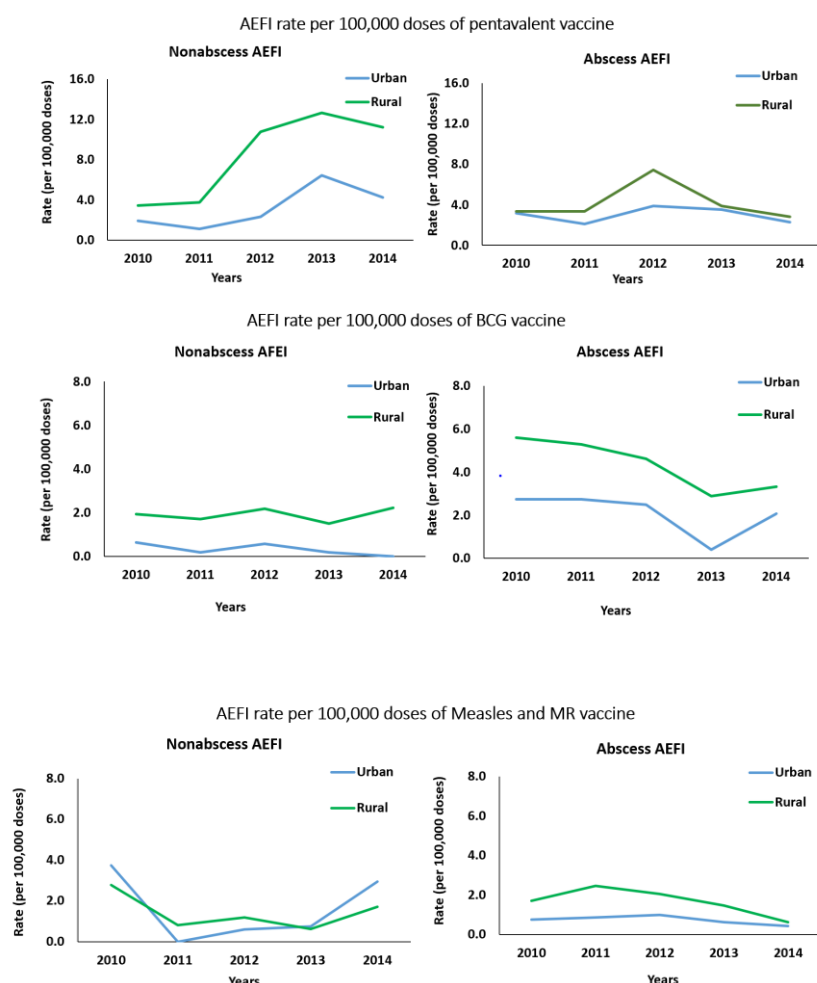


Figure 1. AEFI reporting rate per 100,000 vaccine doses of pentavalent, BCG, Measles and MR vaccine in urban and rural areas in Bangladesh, 2010-2014.

Compared to WHO-reported AEFI rates for pentavalent, BCG, and MR vaccines, Bangladesh's non-abscess AEFI rates were 20-30 times lower. (Table 3)

However, abscess AEFI rates were higher in Bangladesh than in Oman, a high-resource setting. Total AEFI rates in Bangladesh were lower than in Australia (13.9/100,000),

Canada (14.8/100,000), and Oman (8.3/100,000). [20-22] Vaccine-specific AEFI rates in Bangladesh were also substantially lower than those reported in Sri Lanka—410 (pentavalent), 100 (BCG), and 170 (MMR) per 100,000 doses. [23] (Table 3)

Table 3. Comparison of rate of total, preventable and inherent AEFI (Per 100,000 injectable vaccine doses) between urban and rural areas by vaccine and geographical division of Bangladesh, 2010-2014.

Vaccines	AEFI rate (per 100,000 vaccine doses)								
	Non-abscess AEFI		Abscess AEFI		Total AEFI				
	Bangladesh Non-abscess 2010-2014	WHO observed	Bangladesh abscess 2010-2014	Oman 2006-2015	Bangladesh 2010-2014	Sri Lanka 2012	Australia 2013	Oman 2006-2015	Canada 2011-2012
Pentavalent (DTP-HepB-Hib) vaccine	7.6	250	4.0	1.3	11.5	410	53.2 (DTP-IPV-HepB-	15.1	148.2 (DTP-IPV-HepB-Hi

Vaccines	AEFI rate (per 100,000 vaccine doses)								
	Non-abscess AEFI		Abscess AEFI		Total AEFI				
	Bangladesh Non-abscess 2010-2014	WHO ob- served	Bangladesh abscess 2010-2014	Oman 2006-20 15	Bangladesh 2010-2014	Sri Lanka 2012	Australia 2013	Oman 2006-20 15	Canada 2011-201 2
BCG	1.7	30	4.0	2.8	5.7	100	Hib)	37.9	b)
Measles	4.5	34	6.4		2.4				
Combined Measles and Rubella (MR)	2.5	>34	1.6	0.3 (MMR)	6.4	170 (MMR)	83.6 (MMR)	3.6 (MMR)	68.2 (MMR)

(DTP- Diphtheria, tetanus and pertussis vaccine, MMR- measles, mumps and rubella vaccine, DTP-IPV-HepB-Hib: hexavalent combination of diphtheria, tetanus and pertussis, inactivated polio, hepatitis B and *Hemophylus influenza* vaccine)

4. Discussions

Our study provides a comprehensive analysis of AEFI rates and vaccine service quality in Bangladesh from 2010 to 2014. We observed a gradual increase in reported non-abscess AEFIs, likely reflecting improved completeness of reporting, alongside a decline in abscess AEFIs, indicating improved vaccine service delivery. However, both trends suggest that AEFIs are still underreported—especially non-abscess types, which remain lower than expected compared to global data.

AEFI reporting improved for measles and MR vaccines during 2012-2014, aligned with two national training programs for vaccinators—during the introduction of MR vaccine in 2012 and a mass MR campaign in 2014. [24, 25] These trainings likely improved sterile technique, cold chain maintenance, and record-keeping. The simultaneous rise in non-abscess AEFI reporting and decline in abscess AEFIs suggest that these trainings improve reporting and service delivery. This evidence supports the need for similar training before introducing new vaccines.

While non-abscess AEFI reporting increased for the pentavalent vaccine, BCG-related AEFIs remained stable, likely because their major adverse events (e.g., lymphadenitis, osteitis) develop over months and are more often reported by doctors. [17] As vaccinators reported most AEFIs in the surveillance, training had a limited impact on the delayed onset AEFIs of BCG vaccination. Nonetheless, the declining trend in abscess AEFIs for both BCG and pentavalent vaccines suggests improved injection practices. This highlights the value of refresher training that includes recognition of delayed AEFIs like those related to BCG.

Urban-rural discrepancies in AEFI reporting were also evident. Despite better health indicators in urban areas, vaccine

coverage and AEFI reporting were lower, especially in slums. In 2014, rural immunization coverage (85.3%) slightly exceeded urban coverage (82.7%). [15]. These gaps reflect structural differences: rural services are managed by the Ministry of Health and Family Welfare, while urban services are the Ministry of Local Government and Rural Development and NGOs. Furthermore, many urban families seek care at private clinics that are not integrated into the national AEFI reporting system. Including private providers in AEFI surveillance would increase completeness and representativeness. [26]

High vaccinator turnover in cities like Dhaka and Chittagong—where NGOs manage service delivery—may also hinder reporting. In contrast, Rajshahi and Barishal cities, which employ permanent vaccinators, showed no statistically significant urban-rural differences in non-abscess AEFIs. This suggests stable staffing enhances reporting quality. [11] EPI could address this by deploying government vaccinators in cities or strengthening supervision of NGO vaccinators. The assessment of Post-Introduction Evaluation of PCV/IPV introduction highlighted one of the critical problems in terms of AEFI reporting related to the inability of NGO staff providing immunization services in the urban areas to perform basic activities related to the AEFI, absence of supportive supervision and etc. This indicated an essential need for enhancing the capacity of NGO managers of middle-level managerial skills (management, coordination and supervision), as well as a critical need for training of vaccinators employed by NGOs in immunization practices and reporting. [27]

Despite underreporting, Bangladesh's abscess AEFI rates are higher than in many countries. Passive surveillance data from Oman and China reported similar or lower AEFI rates. [28, 29] Differences in vaccine schedules and use of online reporting systems may influence these results. In contrast, Sri Lanka's national record review revealed higher AEFI rates

than ours, suggesting passive systems may underestimate the true burden. [23] The Bangladesh vaccine coverage survey, 2014 estimated abscess AEFI rates at 1,300 per 100,000 reports. [15], likely inflated due to recall bias and reporting across multiple vaccine doses. Our dose-specific calculations were lower, but the true rate likely lies between these estimates. We recommend Bangladesh EPI to conduct an evaluation of vaccine delivery, focusing on the quality of vaccination practices to identify the reasons for higher abscess AEFI reporting rates and urban-rural differences.

Cold chain management remains a key factor for maintaining vaccine effectiveness. A prior evaluation found that 8-13% of vaccine storage refrigerators and 5-37% of transport boxes exposed vaccines to harmful temperatures. [9] This compromises vaccine potency and increases AEFI risk. [6] MR vaccine introduction and campaigns improved storage systems. [25], which may explain the post-2012 decline in abscess AEFIs. Sustaining improvements requires regular monitoring to prevent both non-abscess and abscess AEFIs.

Our study had several limitations. No “gold standard” exists for AEFI underreporting. However, we used the full set of nationwide reported data (unlike the BD survey, which used a sampling method). We also used a surrogate marker for expected rates of reporting (nonabscess AEFI) that provides further insight. We also compared this against other reports in other countries, both high and low-income. The data quality metric relies on reporting completeness, so independent assessment of delivery quality isn’t directly possible with these surveillance data. While we used nationwide vaccine coverage data, it lacked age and sex breakdowns, limiting subgroup analysis. Vaccine formulations and AEFI reporting systems vary between countries, limiting cross-country comparisons. Nonetheless, the findings establish a baseline for improving AEFI surveillance in Bangladesh.

5. Conclusion

This study identified important areas of improvement in AEFI reporting and vaccine delivery quality before introducing vaccines like SARS-CoV-2. Nationwide periodic refresher trainings on AEFI reporting for urban rural vaccinators are needed to improve service quality and AEFI detection, especially for delayed events. Urban reporting gaps can be addressed by involving private clinics and stabilizing vaccinators. Sustained cold chain monitoring can further reduce abscess AEFIs. Bangladesh EPI should conduct a national AEFI record review to validate passive surveillance data and consider piloting online AEFI reporting systems to enhance timeliness and completeness.

Abbreviations

AEFI	Adverse Event Following Immunization
BCG	Bacillus Calmette-Guérin
CDC	Centers for Disease Control and Prevention

DPT	Diphtheria, Pertussis, Tetanus
EPI	Expanded Program on Immunization
HepB	Hepatitis B vaccine
Hib	<i>Haemophilus influenzae</i> type B
MCV-2	Measles-containing Vaccine, Second Dose
MMR	Measles, Mumps, and Rubella
MMRV	Measles, Mumps, Rubella, and Varicella
MOHFW	Ministry of Health and Family Welfare
MOLGRD	Ministry of Local Government and Rural Development
MR	Measles and Rubella
MSD	Measles Second Dose
NGO	Non-Governmental Organization
OPV	Oral Polio Vaccine
SEARO	Southeast Asia Regional Office (WHO)
WHO	World Health Organization

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Author Contributions

Mallick Masum Billah: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Resources, Software, Validation, Visualization, Writing - original draft, Writing - review & editing

Alden Keith Henderson: Conceptualization, Resources, Supervision, Validation, Writing - review & editing

Syed Muhammad Baqui Billah: Formal Analysis, Methodology, Supervision, Visualization, Writing - review & editing

Tajul Islam Abdul Bari: Formal Analysis, Project administration, Supervision, Visualization, Writing - review & editing

Emily Suzanne Gurley: Conceptualization, Formal Analysis, Supervision, Validation, Writing - review & editing

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Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

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