Evaluation of Reporting Adverse Events Following Immunization in Selected Bangladeshi Cities

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Abstract

Background: The response of an immunization program to adverse events increases community trust. Bangladesh Expanded Program on Immunization (EPI) has been conducting surveillance to detect and manage adverse events following immunization (AEFI) from city corporations since 2003. We evaluated the simplicity, timeliness, data quality, acceptability, flexibility, stability, and usefulness of AEFI surveillance in Bangladesh.

Methods: We conducted AEFI surveillance evaluation in city corporations of Bangladesh, using mixed methods from January 1, 2014, to April 30, 2015. We used the US Centers for Disease Control and Prevention (CDC) surveillance evaluation tool developed in 2001. An adverse event was defined as a medical incident after an immunization caused concern and was thought to be caused by vaccination. According to performace of AEFI reporting in 2013, we selected Dhaka North, Chattogram, Khulna, Rajshahi and Sylhet city corporations for the in-depth interviews. We interviewed field workers, EPI supervisors, and medical officers about their reporting practices. We performed descriptive analysis of surveillance data and thematic analysis of interviews.

Results: A total of 129 AEFIs were reported by the AEFI surveillance from city corporations in 2013. Timeliness of weekly AEFI submission was 0% – to 46%. Interviews with EPI supervisors identified common factors were delay in getting reports from hospital AEFI reporting sites, shortage of manpower, excessive workloads, and paper based reporting. Common incompleteness was found in address of the child (18%) and parent information (11%). Aacceptance of AEFI surveillance was higher in nongovernmental organization (NGO) reporting sites than in hospitals and private clinics. Most field workers did not received AEFI training in previous five years.

Conclusion: Although AEFI surveillance was simple, flexible, stable, and useful, the evaluation identified gaps in timeliness, completeness and acceptability of AEFI reporting. We recommended electronic reporting (e-mail), and dedicated AEFI training for field workers upon recruitment to improve timeliness, data quality, and overall acceptability of the surveillance.

[Dinajpur Medical College Journal, 2025 Jul; 18 (2):138-145]
[Former M Abdur Rahim Medical College Journal]
DOI: https://www.doi.org/10.69861/djmcj2025v18i2s7

Keywords: Adverse Events Following Immunization (AEFI), Immunization Surveillance, Vaccine Safety, Public Health Surveillance

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Introduction

Initiated in 1979, the Expanded Program on Immunization (EPI) of Bangladesh has been maintaining nationwide coverage of >80% consistently since 2006.[1,2] In order to ensure the safety of immunization programs, EPI started a passive surveillance system of adverse events following immunization (AEFI) in 2003. Efficient AEFI surveillance is critical for the early detection and timely reporting of all suspected adverse events of vaccines, covering both severe and unusual events and enabling timely investigation and response. Globally, AEFI surveillance networks help detect and classify both programmatic errors - e.g., injection-site abscesses—and reactions associated with specific lots of vaccines.[3]

In Bangladeshi cities, when an AEFI occurs, caregivers either communicate with the field worker for advice or take the child to a healthcare facility for treatment. Both field workers and the healthcare facility designated as the AEFI reporting site then report any events to supervisors, and the supervisor compiles reports and submits hard copies to the national headquarters of the EPI every week.[4] Field workers and healthcare facilities should report a death, hospitalization, cluster, or community-concerned event immediately through the supervisors and heads of the reporting sites to headquarters. (Figure 1)

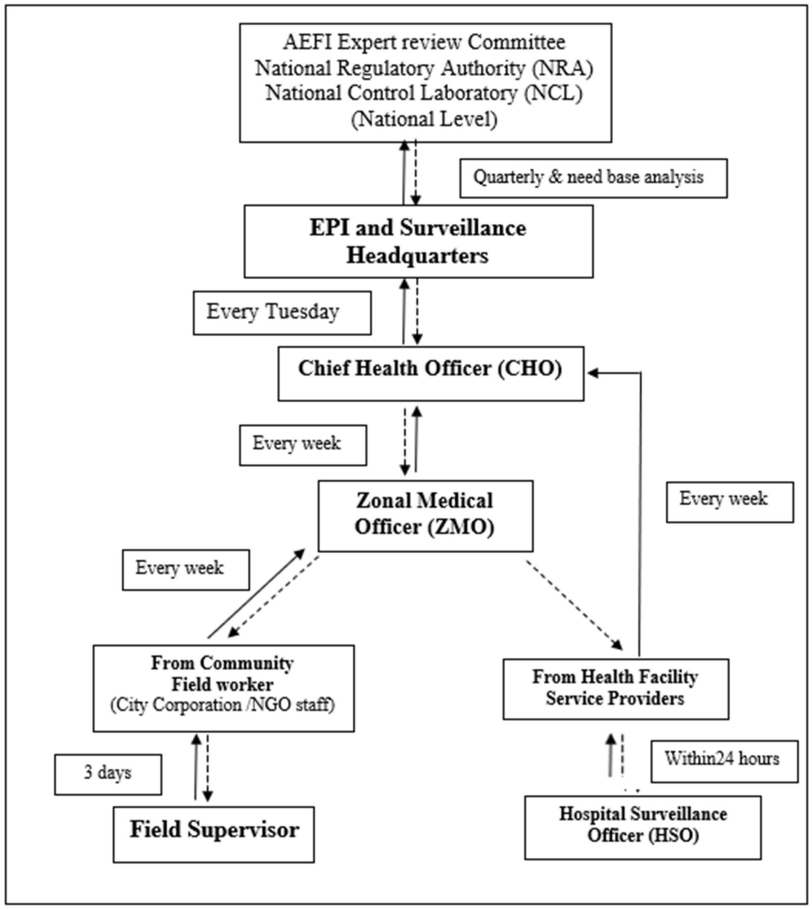

Figure 1 Weekly AEFI reporting system and time duration of reporting AEFI cases from City Corporations to EPI-HQ, 2014 (⟶:Reporting, ⟶: Feedback), NGO: Non-government organization)

EPI analyses AEFI reports and shares findings with chief health officers (CHO), national regulatory authority, national control laboratory, World Health Organization (WHO) and United Nations Children's Fund (unicef) through regular EPI bulletins, review meetings and verbal communication.[4] The 'EPI and VPD Surveillance Review and Post-Introduction Evaluation of Hib (Pentavalent) Vaccine'—have recognized gaps in reporting adverse events following immunization (AEFI), especially in urban areas. The reasons for these gaps have been high staff turnover rates and population mobility, which could potentially hamper the accurate and timely identification of AEFIs.[5]

We evaluated simplicity, timeliness, data quality, acceptability, flexibility, stability, and usefulness of the AEFI surveillance system in Bangladesh using the revised framework provided by the United States Centers for Disease Control and Prevention (CDC) to evaluate the public health surveillance system.[6,7] The study also looked for the operational gaps and areas where interventions are necessary to increase the effectiveness of the AEFI surveillance system.

Methods

Evaluation Design

We conducted a mixed methods study to evaluate the AEFI surveillance system in city corporations of Bangladesh. The evaluation was performed according to the guidelines of the CDC for evaluating the public health surveillance system.[6] We consulted key stakeholders, Directorate General of Health Services (DGHS) officials, EPI and surveillance program managers, WHO representatives, and unicef members to finalize areas of evaluation, key informants and tools for evaluation.We reviewed AEFI surveillance data in children 0–23 months from January 2013 to December 2013. We also interviewed key informants following qualitative methods. The study period was from January 1, 2014, to July 31, 2015 while we visited Dhaka North, Rajshahi, Khulna, Chattogram and Sylhet city corporations from March 23 to April 13, 2014 for key informant interviews.

Measurement surveillance attributes

- *Simplicity*: We assessed simplicity by reviewing AEFI reporting process, case definition, and data collection forms and interviewing surveillance officials.
- *Timeliness:* We measured timeliness by the proportion of weekly reports submitted on time from January 2013 to December 2013 and interviewed surveillance personnel to understand the determinants of timeliness.[6]
- *Data Quality:* We determine the percentage of complete entry of key variables on AEFI case report forms, including patient data, type of AEFI, and vaccine given in the AEFI surveillance dataset.
- *Acceptability:* We interviewed supervisors, field workers, and program managers to assess the willingness to report AEFIs.
- *Flexibility:* We interviewed the deputy program manager of training (DPM-Training) and the data manager about the challenges of introducing the Hib (pentavalent) vaccine in 2012.
- *Stability:* We interviewed the program manager and the deputy program manager about surveillance funding, any known period of system failure in the last year, and the presence of any backup data.
- *Usefulness:* We interviewed the stakeholders about their use of surveillance data in 2013 for specific AEFI monitoring and for identifying and implementing measures to control AEFI.

Selection of the city corporations and participants

We purposively selected five city corporations based on their 2013 AEFI reporting performance: Rajshahi and Khulna cities were selected for better performance and Dhaka North, Chattogram and Sylhet were selected for below-average performance. In these cities, we purposively selected the participants, including field workers, supervisors, EPI superintendents, zonal medical officers, chief health officers, and surveillance medical officers.

Data collection

We conducted in-depth interviews of the stakeholders and staff following a semi-structured questionnaire to evaluate the attributes according to their portion participation in the surveillance system. We interviewed field workers, EPI supervisors, assistant medical officers or zonal medical officers (ZMO), and chief medical officers (CHO). We also interviewed EPI and surveillance deputy program manager, program manager and directors in the headquarters. The interviews were focused on identifying attributes that need evaluation in particular. We also interviewed them about their experiences and recommendations regarding surveillance. Interviews took place in the interviewees' offices during office hours while maintaining privacy, and each interview required 30-50 minutes.

Data analysis

We calculated timeliness and completeness as proportions from the AEFI surveillance dataset. Qualitative data from the interviews were analyzed by thematic analysis. These stages involved familiarization with data, initial code generation, theme searching, theme summarization, theme defining and naming, and writing up.

Ethical Considerations

We took proper official orders from EPI and Surveillance office, Mohakhali, Dhaka and CHO of respective city corporations before the evaluation. We took informed written consent from the participants and interviewed them maintaining privacy and confidentiality.

Results

We visited five city corporations: Dhaka North, Chattogram, Khulna, Rajshahi, and Sylhet and interviewed two field workers from each city corporations, one EPI supervisor and ZMO and CHO of the city corporations regarding reporting of AEFI surveillance (Table 1).

Table I: Description of AEFI surveillance in Dhaka North, Chattogram, Khulna, Rajshahi and Sylhet City Corporations, 2015

Traits	City Corporations				
	Dhaka North	Chattogram	Khulna	Rajshahi	Sylhet
a. administrative information					
Total area (in sq. Km)	82.64	160.99	40.79	95.56	26.50
Number of wards	36	41	31	30	27
Number of zones	5	7	4	10	-
b. Components of the Surveillance system					
Population under surveillance	1,192,087	879,286	249,523	153,353	159,375
Field workers	349	385	141	175	168
Field supervisors	140	7	41	35	27
EPI Superintendent	1	1	1	1	1
Zonal medical officers (ZMO)	5	7	-	-	-
AEFI reporting sites	57	24	14	24	10

A total of 129 AEFI cases were reported from city corporations from pentavalent, BCG and Measles – Rubella vaccines in 2013. (Table II)

Table II: AEFI reporting from pentavalent, BCG and Measles – Rubella vaccines in City Corporations of Bangladesh, January – December, 2013

Vaccines and AEFIs	No. AEFI Reported	Rate of Reported AEFI (Per million doses)
Pentavalent		
High fever	58	78
Injection site abscess	39	52
Convulsion	6	8
Rash	3	4
Death	2	2.7
Persistent (>3 hours) inconsolable crying	1	1
BCG		
Abscess	3	11
Fever	4	15
Convulsion	1	3.7
Measles and Rubella		
Convulsion	4	14
High fever	4	14
Injection site abscess	3	10.6
Fainting	1	3.5

Simplicity

AEFI case definition encompasses any adverse medical event following immunization, whether causally linked or not. Reporting form, which is printed in Bengali, has demographic information, AEFI type, hospitalization, and immunization details. The field workers had no issue with the form. Data compilation at city corporation headquarter level and zonal levels facilitated local analysis and informed monthly meetings. Data processing, including entry, editing, storage, backup, and dissemination, required about an hour typically.

Timeliness

AEFI events would ideally be reported to the EPI headquarters within 6 to 14 days. In 2013, Khulna had the highest on-time submission at 46%, followed by Chattogram at 31%, Sylhet at 15%, Rajshahi at 9%, and Dhaka North at 0% (Table III). Interviews identified workforce shortages and excessive workloads, and challenges of hard copy reporting from city corporation office to EPI headquarters. Hospital reporting sites occasionally delayed the submissions of reports to city corporation office which leads to delayed compilations and reporting.

Table III: Timeliness of AEFI surveillance in Dhaka North, Chattogram, Khulna, Rajshahi and Sylhet City Corporations, January – December, 2013

City Corporations	No of weekly reports submitted on time (n=52)	Percentage of reports submitted on time
Khulna	24	46%
Chattogram	16	31%
Sylhet	8	15%
Rajshahi	5	9%
Dhaka North	0	0%

Data Quality

Data quality was assessed by verifying completeness of AEFI case report forms. Out of 129 AEFI case forms were received, out of which 82% were complete. Address of patient (18%), father/mother name (11%), and patient's name (6%) were common missing fields (Table IV). There were a high turnover of field workers working in nongovernment organization (NGO) reporting sited and most field workers had not undergone AEFI training within the past five years. Surveillance medical officers made repeated attempts to verify data to improve the completeness of AEFI data.

Table IV: Incompleteness of case forms of weekly AEFI surveillance in Dhaka North, Chattogram, Khulna, Rajshahi and Sylhet City Corporations, January – December, 2013

	Total no. of blank entries	Percentage (%) (n=129)
Address	24	18.6
Father's/ mother's name	15	11.6
Patient's name	8	6.2
Geographic location	2	1.6

* Only mentioned those variables which were not complete. All other variables had 100% completeness.

Acceptability

Reporting at NGO locations was satisfactory, while hospital locations, particularly medical colleges and private hospitals, had lower reporting rates due to excessive workloads, shortages of staff, and high rates of focal person turnover. Field workers complained about being reimbursed for travel and communication expenses related to managing AEFI cases, which were frequently not reimbursed, and therefore losing motivation for reporting. Chief health officers confirmed these issues. While interviewing the key informant of National EPI, we found that financial support for AEFI patient investigation and management was present at the beginning of the surveillance. However, most of the funds have remained unutilized. For this, it was omitted for last few years.

Flexibility

The system was shown to be flexible when the pentavalent vaccine was introduced in 2009, with it only needed to include of the vaccine's name in the reporting forms and database and the training of reporting officials. The EPI's formal 'Training of Trainers' facilitated the sharing of information on new vaccines and their respective adverse events, which allowed the system to evolve according to new needs with limited use of resources.

Stability

The stability of the AEFI surveillance system was included by government support for personnel salaries and WHO assistance for surveillance medical officers and data staff. Data entry and analysis employed Epi Info 7 and SAS software with routine backups and generator backup in case of power failure. Yet, reporting from peripheral sites was confronted with difficulties because it depended on courier and postal transport, there were inadequate special mailing staff, and the transport was interrupted by political unrest. Managers suggested starting electronic mail-based reporting to promote reliability.

Usefulness

Stakeholders reaffirmed the usefulness of weekly AEFI reporting in identifying program errors and vaccine reactions. For instance, EPI started training on vaccination as there

were increased AEFI reports from Hizla, Barishal in 2008-2009 revealed non-compliance with the open vial policy,[8] and remedial training for field workers. The strengthened surveillance system also facilitated monitoring vaccine lot-specific AEFI rates and communication with community leaders and media in abnormal situations. Field workers noted that the system helped build community trust by showing evidence of responsiveness to AEFI concerns.

Discussion

The evaluation revealed the AEFI surveillance system of Bangladeshi cities was simple, flexible, and stable. However, there are significant challenges in timeliness, and data quality, all of which are important for ensuring vaccine safety and maintaining public trust.

The evaluation identified a major challenge in submitting AEFI weekly reports on time, which was due to the submission of paper-based reports. Logistic challenges and workloads of EPI supervisors also exacerbated the challenges of paper-based submission of AEFI reports. Adoption of electronic reporting systems, i.e., internet-based or email-based submissions, had been recommended to enhance timeliness. Global experience has demonstrated that electronic reporting can significantly improve the speed and efficiency of transmission of AEFI information.[8] All the city corporations had internet network coverage and each city corporation had adequate logistics for online reporting. To improve the timeliness, AEFI weekly reports need to be submitted directly from the City Corporations to the central server through web based platform or through electronic mail (e-mail).

High turnover of NGO field workers occasionally led to untrained field workers conducting AEFI reporting.[9] Poor data entries, like missing patient data, compromised the quality of AEFI surveillance data. Regular training and capacity-building exercises were required to improve data completeness and accuracy. Focused AEFI training programs in some LMICs have increased awareness and improved reporting practices among health providers.[10]

EPI used to provide training on vaccine administration to field workers on a regular interval and introduction of new vaccines. Training on AEFI reporting was a small part of the whole vaccine administration training, and occasionally, it was not given full importance.[11] A dedicated AEFI training should be provided to all field workers during recruitment.[12]

Although AEFI surveillance was largely acceptable to health workers, challenges such as extra expenses borne by field staff and the absence of reimbursement may curtail reporting activity. Offering financial and logistic support and regular feedback could significantly enhance motivation and participation in the surveillance system. Supportive supervision and feedback mechanisms had been reported to be vital in raising AEFI reporting rates.[13]

We had limitations. During this evaluation, we found issues regarding AEFI reporting from hospital reporting sites, such as under-reporting, poor timeliness, and incomplete reporting. As the evaluation was conducted in the city corporation office, we could not visit hospital reporting sites for further evaluation. A separate, dedicated evaluation of hospital AEFI reporting sites should be performed.

Conclusion and Recommendations

The evaluation of urban EPI AEFI surveillance system of Bangladesh demonstrated underlying strengths and required strategic strengthening to counter

current challenges. The introduction of electronic reporting, dedicated AEFI training sessions, and supportive supervision were towards a stronger and broader surveillance system. These strengthening approaches were required for vaccine safety and public confidence in immunization programs.

Acknowledgments: The authors are thankful to the Field Epidemiology Training Program, Bangladesh (FETP,B) Advance and all the participants for their cooperation in the evaluation.

Competing Interests: The authors declare no conflict of interest.

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