

Post-Immunization Adverse Events Associated with Novel Oral Polio Vaccine Type 2 and Reporting Challenges and Experiences in Sierra Leone

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Abstract

The spread and emergence of neuroinvasive circulating vaccine-derived polioviruses (cVDPVs) across multiple countries prompted the emergency introduction of the novel oral polio vaccine type 2 (nOPV2), raising renewed concerns about how adverse events following immunization (AEFI) are monitored. This study investigated the profile of AEFI associated with nOPV2 and explored stakeholder perspectives and operational challenges related to AEFI surveillance in Sierra Leone. A mixed-methods design was employed. We retrospectively analyzed routinely collected passive surveillance data from the 2021 vaccination campaign and complemented this with semi-structured interviews involving vaccinators, district AEFI focal personnel, and key actors from the national Expanded Program on Immunization and the National Medicines Regulatory Authority. Classification of AEFI was undertaken using MedDRA Preferred Terms (PTs) and System Organ Class (SOC). Patient outcomes were grouped into recovered versus not recovered. Causality was evaluated using the WHO algorithm, while preventability was assessed through the Schumock and Thornton framework. Overall, 528 suspected AEFI cases were documented, with most occurring in infants and young children aged 28 days to 23 months (63.3%). The most frequently affected categories were general disorders and administration site reactions, and pyrexia was the most commonly reported Preferred Term. Among 80 serious cases, 78 individuals recovered, and 74 cases were classified as having an inconsistent relationship with the vaccine. Most serious events (78) were judged as not preventable, while only two were considered possibly preventable. Routine AEFI reporting was not consistently practiced among study participants. There were inconsistencies in understanding what constituted a reportable event and uncertainty regarding reporting responsibilities. Additional barriers included challenges with the Open Data Kit (ODK) system and limited training opportunities. Although nOPV2 is a relatively new vaccine, the majority of reported AEFI were non-serious, and most serious cases were not found to be causally related to vaccination. However, notable variation existed among participants in terms of knowledge, practice, and awareness of AEFI reporting procedures.

Keywords: Adverse event, Pharmacovigilance, Vaccine, Sierra Leone, NOPV2, Children

Introduction

An adverse event following immunization (AEFI) is defined as any undesirable medical occurrence that

follows vaccination, regardless of whether a causal link to the vaccine is established [1].

Vaccination is one of the most extensively used medical interventions in children worldwide. Vaccines are administered to both healthy and sick individuals and are generally considered safe and effective, with serious adverse outcomes being uncommon. Poliomyelitis is a severe infectious disease caused by a highly transmissible virus that can lead to paralysis or death. Children are particularly vulnerable, although immunization effectively prevents the disease.

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Since their introduction in 1955, polio vaccines have evolved from the inactivated polio vaccine (IPV) to the oral polio vaccine (OPV), a live attenuated formulation. Despite its advantages in ease of administration and strong intestinal immunity, OPV carries a rare risk of genetic reversion to a neurovirulent form, leading to circulating vaccine-derived polioviruses (cVDPVs), especially in populations with low immunization coverage [2].

Recent years have seen multiple cVDPV outbreaks across countries such as Algeria, Burundi, Chad, Indonesia, and Ukraine, posing a serious challenge to global eradication efforts. Around 90% of these outbreaks are linked to type 2 Sabin strains of OPV and tend to occur in areas with insufficient routine immunization coverage [2].

Between December 2020 and June 2021, Sierra Leone experienced a cVDPV type 2 outbreak involving 34 confirmed pediatric cases, prompting a public health emergency declaration. Similar outbreaks were reported in 23 African countries, largely driven by disruptions in routine immunization services during the COVID-19 pandemic and resulting declines in population immunity [3].

To respond, the novel oral poliovirus vaccine type 2 (nOPV2) was developed through genetic modification of the Sabin type 2 strain. Clinical trials conducted between 2017 and 2019 showed that nOPV2 had a favorable safety profile, good tolerability, comparable immune response, and improved genetic stability compared with the monovalent Sabin OPV2 formulation [4-6].

In response to the outbreak, Sierra Leone received nOPV2 doses through the Global Polio Eradication Initiative (GPEI) via the Expanded Program on Immunization (EPI) to immunize children at highest risk. The Pharmacy Board of Sierra Leone (PBSL), as the national regulatory authority, granted emergency use authorization following a structured review process. This decision was based on early safety and efficacy data, the urgency of controlling the outbreak, the favorable benefit-risk assessment, and the public health threat posed by cVDPV2. Vaccination campaigns targeted approximately 1,400,000 children aged 0–59 months nationwide. The first round was conducted from 28–31 May 2021, followed by a second round from 2–5 July 2021. A third subnational round took place in Western Area Urban, Western Area Rural, and Tonkolili districts from 27–30 August 2021, targeting 512,039 children aged 0–59 months.

Given the limited evidence on the safety profile of nOPV2 and the absence of prior evaluation of AEFI surveillance systems in Sierra Leone, this study assessed safety reports from vaccination campaigns. It examined stakeholder experiences and challenges in the AEFI reporting system.

Materials and Methods

Study setting

Sierra Leone lies on the west coast of Africa and has an estimated population of about eight million. Its capital, Freetown, is home to over one million residents [7]. The country is divided into five administrative regions—northern, north-western, eastern, southern, and western areas—covering approximately 71,740 km². These regions are further divided into 16 districts, each managed by district health authorities.

The study was conducted at the National Pharmacovigilance Centre (NPC), which operates under the Pharmacy Board of Sierra Leone (PBSL). The NPC is responsible for receiving AEFI individual case safety reports (ICSRs) from healthcare workers, EPI structures, and members of the public. Reporting is supported through both paper-based tools and an electronic open data kit (ODK) platform.

All AEFI reports are centralized in the national pharmacovigilance database (Vigiflow), which is linked to the global WHO database (Vigibase). The surveillance process begins with case identification, considered the most critical step in the reporting chain. AEFI can be initially detected by vaccinators, clinical staff, public health workers, volunteers, caregivers, or any other individual. Any suspicion of an AEFI is sufficient to initiate reporting.

Once identified, cases are documented using standardized reporting forms and submitted through appropriate health system levels, including health facilities and district health management teams (DHMTs), depending on the context. Reporting pathways differ between mass campaigns and routine immunization: mass campaigns involve multiple levels of communication from district to national level, while routine systems typically follow a pathway from health workers and EPI focal persons to the PBSL.

Study population and period

Data collection was conducted between May and August 2023. The study included all AEFI-related individual

case safety reports recorded in the Vigiflow database during the vaccination campaign period.

Additionally, 20 key informants—including vaccinators, district AEFI focal persons, and staff from the EPI and NPC within the national regulatory authority—were interviewed.

Sample size and sampling

All 528 recorded AEFI reports in the Vigiflow system were included in the quantitative analysis. For the qualitative component, purposive sampling was used to select 20 participants based on their roles in detecting, managing, or reporting AEFI cases.

Data collection and validation

The study followed STROBE guidelines for observational research. Quantitative data were extracted from the national Vigiflow database, which aggregates AEFI reports from across the country through PBSL and EPI reporting systems, including submissions via ODK. Extracted variables included demographic characteristics, vaccine type, type of adverse event, severity classification, and patient outcomes.

All reports were routinely verified as part of pharmacovigilance quality control before final entry into the database.

For the qualitative component, semi-structured interviews with open-ended questions were conducted to explore participants' knowledge, experiences, and challenges related to AEFI surveillance. Interviews were conducted at participants' workplaces and lasted no more than 1 hour.

Data analysis

AEFI individual case safety reports (ICSRs) were initially entered into Microsoft Excel and then processed for statistical analysis using SPSS version 21 (IBM Corp, Armonk, NY, USA).

Adverse events were coded according to the Medical Dictionary for Regulatory Activities (MedDRA) framework and summarized using System Organ Class (SOC) and Preferred Term (PT) groupings. Patient

outcomes were simplified into two categories: "recovered" and "not recovered."

Descriptive statistics, specifically counts and percentages, were applied to describe patterns of reported AEFI and clinical outcomes. For serious cases, causality evaluation was performed following eligibility screening using the World Health Organization (WHO) causality assessment tool alongside its supporting checklist. Each case was then assigned to one of four categories: "consistent causal association," "inconsistent causal association," "indeterminate," or "unclassifiable."

Assessment of preventability was conducted using the Schumock and Thornton method, with outcomes classified as "definitely preventable," "probably preventable," or "not preventable."

For the qualitative arm of the study, data were gathered through semi-structured interviews guided by open-ended questions. All discussions were audio-recorded and transcribed in full.

The transcripts were examined using NVivo version 9 (QSR International, UK) through a thematic analysis approach. Coding began with an open coding phase, where labels were generated directly from participants' descriptions of their experiences in identifying, managing, and reporting AEFI. These codes were then grouped into preliminary themes aligned with the study objectives. Analysis focused on identifying recurring patterns, shared meanings, and contextual insights across respondents' accounts.

In the final analytic stage, themes were refined and consolidated, with emphasis on dominant patterns emerging from the dataset. Selected quotations representing participants' perspectives were extracted and presented in the Results section.

Results and Discussion

Demographic characteristics

Of the 528 reported AEFI cases associated with nOPV2, over half (63.3%) occurred in children aged 28 days to 23 months. Slightly more cases were documented among males (50.4%) than females, as presented in **Table 1**.

Table 1. Sociodemographic characteristics of participants experiencing adverse events following immunization.

Variable	Category	%	N
Total vaccine recipients	—	100	528
Age group	0–27 days	1.7	9
Age group	28 days–23 months	63.3	334
Age group	2–11 years	35.0	185

Gender	Male	50.4	266
Gender	Female	49.6	262

Twenty respondents were interviewed to explore their experiences and challenges related to AEFI reporting across different thematic areas. Most of the participants

(nine) were district AEFI focal persons. Nearly half of the respondents (45%) had 5–10 years of professional experience (**Table 2**).

Table 2. Sociodemographic profile of interviewed participants.

Variable	Category	%	N
Total interviewed participants	—	100	20
Gender	Male	55	11
Gender	Female	45	9
Years of experience	1–5 years	25	5
Years of experience	5–10 years	45	9
Years of experience	> 10 years	30	6
Professional role	Vaccinator	25	5
Professional role	District AEFI focal person	45	9
Professional role	EPI personnel	20	4
Professional role	Medicines regulatory personnel	10	2

Distribution of AEFIs by MedDRA system organ class and preferred terms

According to the MedDRA classification, most reported adverse events following immunization were related to administration site conditions and general disorders

(89.6%). This was followed by thoracic, respiratory, and mediastinal disorders (54.2%), and gastrointestinal disorders (31.6%). Since some participants experienced more than one adverse event, the proportions are overlapping and therefore do not total 100% (**Figure 1**).

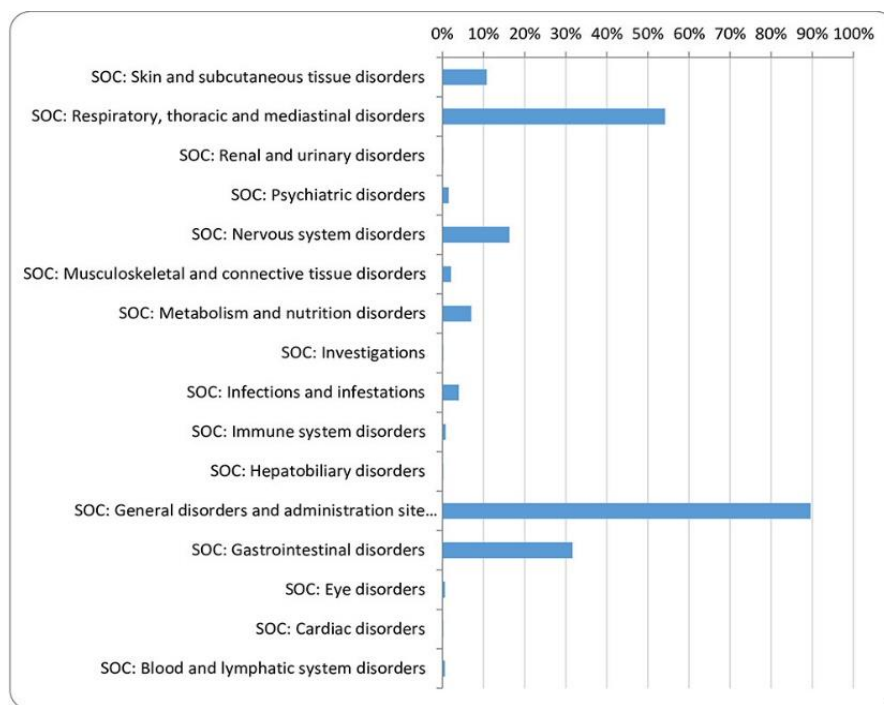


Figure 1. MedDRA system organ class distribution.

Note: A single person may experience more than one adverse event following immunization; therefore, the percentages may total more than 100%.

Pyrexia was by far the most common Preferred Term (PT) documented as an AEFI (88.8%), followed by cough (53.2%) and paralysis (2.1%) (Table 3).

Table 3. Adverse events following immunization based on MedDRA preferred terms

Preferred term (MedDRA)	%	N
Pyrexia	88.8	469
Cough	53.2	281
Diarrhoea	17.0	90
Vomiting	16.1	85
Headache	12.9	68
Rash	10.4	55
Decreased appetite	6.1	32
Dyspnoea	4.7	25
Rhinitis	2.5	13
Abdominal pain	2.3	12
Paralysis	2.1	11
Rhinorrhoea	1.9	10
Sneezing	1.7	9
Chills	1.3	7
Seizure with myalgia	2.2	12
Arthralgia	0.9	5
Crying episodes	0.9	5
Nausea	0.9	5
Lower abdominal pain	0.8	4
Insomnia with restlessness	1.6	8
Pruritus	0.8	4
Anaemia	0.6	3
Facial oedema	0.6	3
Muscular weakness	0.6	3
Nasopharyngitis	0.6	3
Anaphylactic reaction	0.4	2
Dehydration with erythema	0.8	4
Fatigue and lethargy	0.6	4
Hypersensitivity	0.4	2
Loss of consciousness with respiratory distress	0.8	4
Skin exfoliation with furuncle	0.8	4
Deepened lid sulcus	0.4	2
Anuria	0.2	1
Conjunctivitis with ocular pruritus	0.4	2
Facial paralysis	0.2	1
Injection site pain with abscess	0.4	2
Jaundice	0.2	1
Oedema	0.4	1
Pneumonia with pain	0.4	2
Salivary hypersecretion	0.2	1
Somnolence with tachycardia	0.4	2
Urticaria	0.2	1

Increased weight with feeding issues	0.6	3
Peripheral swelling with oropharyngeal pain	0.4	2

Note: Multiple adverse events may occur in the same individual; therefore, percentages are not mutually exclusive and do not sum to 100%.

Seriousness, outcomes, causality assessment, and preventability of adverse events following immunization

Eighty adverse events following immunization were classified as serious. Of these cases, 78 resulted in recovery, while 2 did not. The serious events included vomiting (42 cases), paralysis (11), seizure with myalgia (12), anaphylactic reactions (2), loss of consciousness with respiratory distress (4), pneumonia with pain (2), anemia (3), facial edema (3), and jaundice (1), among others.

In terms of causality assessment, the majority of serious cases (74) were considered to have an inconsistent

relationship with vaccine administration. One case (pyrexia) was classified as consistent, supported by temporal association, appropriate time to onset, and biological plausibility. Three cases were categorized as indeterminate due to insufficient information, while two were deemed unclassifiable because of atypical clinical presentation.

Regarding preventability, most serious cases (78) were judged not preventable, whereas only two cases were considered probably preventable (**Table 4**).

Table 4. Seriousness, outcome, causality assessment, and preventability of adverse events following immunization.

Variable	Category	%	N
Serious events	Total	100	80
Outcome	Recovered	97.5	78
Outcome	Not recovered	2.5	2
Causality assessment	Consistent	1.25	1
Causality assessment	Inconsistent	92.5	74
Causality assessment	Indeterminate	3.75	3
Causality assessment	Unclassifiable	2.5	2
Preventability	Probably preventable	2.5	2
Preventability	Non-preventable	97.5	78

Experience with adverse events following immunization and reporting practices

Eighteen of the 20 individuals interviewed reported observing at least one AEFI case during their time in their current or prior roles. Fever was the most frequently reported reaction among those surveyed. Even though many had witnessed AEFI incidents, they generally viewed them as infrequent occurrences.

“In my professional experience, I have come across some AEFI incidents, but they tend to be uncommon” (AF5).

“AEFI cases are rarely encountered in our setting, so they do not happen very often” (V3).

Out of all participants, 10 out of 20 (three vaccinators, five AEFI focal persons, one EPI staff member, and one regulatory staff member) reported that they had submitted an AEFI case to either PBSL or EPI. Only four individuals indicated they had filed more than one report, despite possessing over five years of experience in the healthcare field. When questioned about the timing of

their latest submissions, most replied that it had been quite some time since their last submission.

“I can recall reporting a few AEFI cases in the past, but it was quite a while back” (V2).

Awareness of AEFI reporting

The majority of those interviewed showed knowledge of the available reporting systems and tools, covering both paper forms and digital options. Still, three participants were unaware that PBSL maintained an electronic system for AEFI submissions.

“I am familiar with EPI’s use of ODK for reports, but I don’t know what PBSL employs” (V4).

“If I encounter an AEFI, I use the paper form to report it, but I’m not familiar with PBSL’s reporting system” (AF2).

Participants were also asked whether AEFI topics were addressed in their work environments through formal or informal discussions.

“We talk about AEFI routinely here, particularly if a severe case arises” (AF5).

“We regularly bring up AEFI matters during everyday vaccination activities and also in campaign periods” (EP2).

Most participants demonstrated awareness of the relevant policies and procedures for managing AEFI. However, two individuals were unaware of any dedicated AEFI guidelines.

“I have neither come across nor heard of any AEFI guidelines” (V4).

“There is no AEFI guideline available here, and I have never encountered one” (V1).

Recognition of reportable adverse events

The respondents were invited to describe the kinds of AEFI they believed should be reported. Every participant agreed that serious reactions, as well as any unexpected ones, needed to be documented. This included life-threatening events, caused disability or incapacity, or led to hospital admission.

“I have observed mild reactions in the past, but I have never dealt with a severe one that demanded immediate attention or treatment” (AF9).

“The reactions we typically encounter are fevers that resolve on their own, but I have not come across anything serious such as anaphylaxis” (V4).

Two different viewpoints surfaced when defining serious events:

“It only qualifies as serious if the person dies” (V2).

“If the patient survives, then it is not considered a serious AEFI” (V4).

Challenges and barriers to reporting

Participants largely recognized PBSL, EPI, and surveillance teams as the main parties involved in AEFI monitoring and reporting, while also noting the essential input of healthcare workers. Nevertheless, there were clear differences of opinion regarding who should take ownership:

“Pharmacists ought to handle AEFI-related responsibilities” (AF1).

“Nurses and vaccinators who give the vaccines should take a more active part in reporting AEFIs” (V3).

“EPI should lead these efforts since they are responsible for introducing the vaccines into the country” (V2).

When asked what becomes of the AEFI reports forwarded to PBSL or EPI, answers differed:

“The submitted reports get reviewed, and then confirmation and feedback are provided back to the reporter” (PP1).

“The reports are filed away, and we who send them usually receive no response or update” (V4).

Some participants also pointed out practical difficulties with the reporting platforms:

“Using the ODK system is challenging for me because it requires entering many details and takes considerable time” (AF1).

“I would rather stick with the paper form since filling out the ODK tool is quite time-consuming” (V4).

Training

Most participants reported receiving vaccine safety training, which EPI and PBSL commonly organized for staff at the district and hospital levels. However, several AEFI focal persons and vaccinators who had attended these sessions expressed concerns about the adequacy and depth of the material covered.

“Others often assume our training has been sufficient, but what I received felt quite limited” (V5).

“I have attended general immunization training, but nothing focused specifically on vaccine safety” (V1).

All participants agreed that integrating AEFI content into the regular professional development activities offered by their professional organizations would be beneficial.

This study’s results revealed that over half of the AEFIs (63.3%) occurred among children aged 28 days to 23 months. In addition, 89.6% of the reported cases belonged to the general disorders and administration site conditions category, with pyrexia as the most frequent Preferred Term. Of the 80 serious cases identified, 78 patients recovered, and 74 showed an inconsistent causal link to the vaccine.

The majority of those interviewed reported having encountered AEFI incidents at their workplaces, though such events were described as uncommon. Participants generally knew about both paper-based and electronic reporting options, but opinions varied regarding familiarity with official AEFI guidelines. Most observed reactions were mild, and there was uncertainty about which organization held primary responsibility for AEFI oversight. Difficulties with the ODK platform were frequently noted, and although training had been provided, many felt it was not thorough enough.

The study suggests that recognizing these reporting obstacles can help develop more effective approaches, strengthen vaccine safety monitoring, increase public

confidence, promote capacity development, and improve policies related to AEFI surveillance in Sierra Leone.

More than half of the AEFIs (63.3%) involved children aged 28 days to 23 months, with males accounting for 50.4% of cases. These patterns correspond with results from other research on AEFI among children [8, 9]. The age concentration is likely linked to the vaccination campaign's focus on this younger population. Several prior studies have similarly reported higher AEFI rates among male children [10-13], which may be due to higher vaccination rates among boys or to sex-based differences in immune responses influenced by biology and genetics.

The selected interviewees were important stakeholders in AEFI surveillance activities, and 45% had 5–10 years of work experience. A number of the pharmacists acting as district AEFI focal points were relatively new to their positions. Health workers in Sierra Leone are frequently reassigned across locations due to operational needs. Other investigations into healthcare providers involved in AEFI monitoring have found that most possessed 0–9 years of experience [14]. In contrast, one study reported an average of 19 years of professional experience among participants [15].

The most commonly affected System Organ Class was “general disorders and administration site conditions” (89.6%). These types of reactions are typical after immunization, readily noticeable by patients, families, and staff, and therefore reported more often than rarer or graver events. This aligns with various earlier AEFI studies, such as one from 2018 [10], and with broader research on adverse drug reactions [11, 16].

Pyrexia was identified as the leading Preferred Term. This is understandable because vaccines activate the immune system, and fever is a standard response to the antigens they introduce. This finding is consistent with many other investigations [10, 16-18].

Eighty cases, representing a modest share overall, were categorized as serious and included conditions such as anaphylaxis and paralysis. The low frequency may result from the stringent clinical testing and evaluation vaccines undergo before approval, along with sustained post-approval safety monitoring. Comparable research has likewise shown that serious AEFIs remain relatively rare [19-21].

Following the causality evaluation, 74 cases were classified as having an inconsistent causal association with the vaccine, one case was judged consistent, three were indeterminate, and two remained unclassifiable.

Other research examining AEFI causality has reported distributions comparable to ours, with the majority falling into inconsistent, indeterminate, or unclassifiable categories [10, 17].

The predominance of inconsistent causal relationships may be attributed to several factors, including underlying health conditions in the affected children, concurrent use of other medications, or the administration of additional vaccines at the same time. Furthermore, some events that occur shortly after vaccination may be coincidental and unrelated to the vaccine itself.

Of the 80 serious AEFI cases, 78 could not have been prevented, with only two considered probably preventable. This pattern aligns with findings from previous investigations, notably those carried out in Italy [22] and India [23]. The high proportion of non-preventable cases suggests that no contributing elements related to the patient, the vaccine, or vaccination practices were responsible. Specifically, there were no problems with dosage, administration route, storage conditions, or product formulation (practice factors); no concerns regarding vaccine quality or counterfeit products (vaccine factors); and no issues of non-adherence or self-medication (patient factors).

The study further indicated that most children recovered from the AEFI. This outcome is consistent with the Italian research mentioned earlier [22]. Such recovery implies that the events did not result in lasting harm or long-term complications. Possible explanations include the generally mild nature of many events, individual differences in immune responses to vaccination, timely and appropriate clinical management, and a robust baseline health status.

Qualitative findings on experiences and challenges

The interview component of the study, involving four distinct groups of participants, provided valuable insights into their experiences and difficulties with AEFI reporting.

Reporting AEFI cases was infrequent across the participant groups, even though most demonstrated a good ability to recognize such events. This discrepancy may stem from the overall rarity of AEFIs and from events that occurred but went unreported. This supports the observation that participants rarely submitted more than one report over extended periods. Another contributing factor appears to be a reluctance to accept responsibility, with individuals viewing it as someone

else's duty. Similar issues have been documented in earlier studies [24].

Most participants were familiar with the available reporting methods and platforms, including paper-based and electronic systems, as well as the appropriate channels for submission. These results mirror findings from other published research [25].

Nevertheless, several participants were unaware that PBSL offers an electronic reporting platform. This gap may reflect insufficient efforts to promote and raise awareness of the digital tool.

Paper-based AEFI forms were widely available in most health facilities, unlike the electronic option. This highlights the importance of widely distributing the electronic link (URL) across professional networks to facilitate easier reporting. Additionally, AEFI training sessions should place greater emphasis on practical instruction for completing the electronic reporting tool. While participants were generally knowledgeable about AEFI policies and procedures, not everyone was familiar with the national guidelines for AEFI surveillance. These guidelines provide clear direction on the roles and responsibilities of involved stakeholders. Lack of awareness likely results from insufficient training on the guidelines' content and their limited availability at workplaces. This underscores the need for better dissemination, targeted training, and ensuring physical or digital access to the guidelines at all relevant stations.

Participants consistently indicated that serious and unexpected reactions are the ones they would prioritize for reporting. They did not specifically address the reporting of non-serious events. However, standard practice requires that all AEFI cases—regardless of severity—be reported.

A major obstacle identified was the lack of clear ownership of AEFI reporting, with participants attributing responsibility to others rather than themselves. The ODK digital platform was also cited as a significant barrier due to its perceived complexity and the lengthy time required to complete all fields. Many preferred the paper-based alternative, describing it as simpler and more practical.

The ODK system's extensive list of required variables can discourage users from completing submissions. To address this, paper forms should be readily available at all healthcare facilities nationwide if they are more accessible to staff.

These identified challenges and barriers are consistent with those reported in studies from various other countries [26-28].

Participants also expressed a desire for more comprehensive training on AEFI. Although some had received training, they considered it insufficient to strengthen surveillance efforts meaningfully.

The study emphasizes the importance of enhancing professional development initiatives. Incorporating adverse event monitoring into both pre-service and in-service continuing education programs would be beneficial. These recommendations align with conclusions from prior research [26, 27].

Strengths and limitations of the study

Key strengths of this research include its status as the first study of its kind in Sierra Leone and the use of qualitative methods that enabled participants to share detailed personal experiences, knowledge, and obstacles. Additionally, quantitative data were readily accessible, and the study followed the STROBE guidelines for reporting observational research [7].

Limitations include the fact that not all relevant stakeholders were interviewed—particularly those from the disease surveillance program, who are not routinely involved in AEFI activities—and that some responses may reflect the specific operational context and reporting practices at individual workstations.

Conclusion

The AEFI surveillance system in Sierra Leone has demonstrated value, yet it falls short of fully achieving its goals, as evidenced by the current findings. Although nOPV2 is a relatively new vaccine, the results indicated that the vast majority of AEFIs were non-serious, and most serious cases lacked a causal connection to the vaccine.

Overall AEFI reporting requires further improvement, along with stronger collaboration among all involved stakeholders, particularly surveillance officers at facility and district health management team levels.

Recommended actions include: implementing enhanced educational initiatives for healthcare professionals at both undergraduate and continuing professional levels; conducting a review and subsequent distribution of the current AEFI guidelines to facilities and districts; and actively promoting PBSL's electronic reporting tool

nationwide, including integration with the DHIS2 system, given its perceived convenience.

District and facility-level surveillance officers should assume a more prominent leadership role in AEFI monitoring. Regular evaluations of the surveillance system should also be carried out to assess its performance against established objectives.

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