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ORIGINAL RESEARCH

Adverse Events Following Immunization with Novel Oral Polio Vaccine Type 2, and the Experience and Challenges of Reporting in Sierra Leone

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Background: The manifestation and spread of neuroinvasive circulating vaccine-derived polioviruses (cVDPVs) across several countries, which led to the emergency use of the novel oral polio vaccine type 2 (nOPV2), raised concerns about adverse events following immunization (AEFI) surveillance. We assessed the attributes of AEFI with nOPV2 and examined stakeholder experiences and challenges in AEFI surveillance in Sierra Leone.

Methods: Using a mixed method approach, we retrospectively reviewed passive data collected during a 2021 immunization campaign, and conducted semi-structured, interviews with vaccinators, district AEFI focal persons, and key stakeholders at the national Expanded Program on Immunization and the National Medicines Regulatory Authority. AEFI were categorized using the Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) and System Organ Class (SOC). Outcomes were stratified as recovered or not, with preventability and causality assessed using the Schumock and Thornton and World Health Organization (WHO) algorithms, respectively.

Results: A total of 528 suspected AEFI were documented, predominantly affecting children aged 28 days to 23 months (63.3%). Most reported AEFI were administration site conditions and general disorders, with pyrexia being the predominant PT. Of 80 serious cases, 78 recovered, with 74 having an inconsistent causal relationship with the vaccine. Most serious cases (78) were deemed non-preventable, with only two being probably preventable. AEFI reporting was not routinely carried out across the group of people interviewed. AEFI reporting was not consistently performed, with discrepancies in defining reportable events and confusion over responsibility. Challenges with the open data kit (ODK) platform were noted, along with perceived inadequacies in training.

Conclusion: While the nOPV2 is relatively new, the majority of AEFI were not serious, and most serious cases were not causally linked to the vaccine. Participants exhibited variations in experience and awareness of AEFI reporting.

Keywords: adverse event, pharmacovigilance, vaccine, Sierra Leone, nOPV2, children

Introduction

An adverse event following immunization (AEFI) is a medical event that is untoward and which happens after vaccination. This event does not, in essence, have a causal relationship with the use of the vaccine.[1]

Vaccines are the most widely used medicines in children globally. They are typically administered to patients as well as healthy individuals, and have been shown to be safe and effective, and experience of serious adverse events is rare. Polio disease is a potentially fatal condition caused by a highly infectious virus that can affect an individual and may lead to paralysis or fatal consequences. Children are the most at risk, but when safe and effective vaccines are administered the disease is preventable.

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Polio vaccines have been in use since 1955, with inactivated polio vaccine (IPV) having been initially used, before later transitioning to a more convenient form called the oral polio vaccine (OPV), which is a live attenuated vaccine that has the potential to revert to neurovirulence, leading to circulating vaccine-derived polioviruses (cVDPVs), especially in areas of low vaccine coverage.[2]

The cVDPVs have experienced a surge across several countries, including Algeria, Burundi, Chad, Indonesia, and Ukraine, in recent years. This poses a major challenge to the goal of eradicating all of the different forms of poliovirus. Most (90%) of the cVDPV outbreaks are as a result of the type 2 variant of the Sabin vaccine, which is an oral live attenuated vaccine. These outbreaks usually occur in areas where the coverage for immunization is persistently low.[2]

During the period from December 2020 to June 2021, there was an outbreak of circulating vaccine-derived poliovirus type 2 (cVDPV2) in Sierra Leone. Initially, a total of 34 cases were confirmed in children, and this resulted in a public health emergency. Similar outbreaks were also reported in 23 other African countries. These were attributed to a reduction in routine vaccination services, mostly due to the COVID-19 pandemic, which also resulted in the decline in population immunity.[3]

A novel oral poliovirus vaccine type 2 (nOPV2), manufactured through a genetic modification of the type 2 variant of the genome of the Sabin vaccine, was evaluated in phase I and II clinical trials between 2017 and 2019.[4] This vaccine demonstrated favorable safety and tolerability results, with non-inferior immunogenicity and superior genetic stability when compared with the Sabin monovalent type 2 vaccine.[5,6]

The outbreak of cVDPV2 in Sierra Leone led to the country receiving thousands of doses of nOPV2 through the Global Polio Eradication Initiative (GPEI) to the Expanded Program on Immunization (EPI) to vaccinate children who were most at risk. This vaccine was approved for use under an emergency type approval by the Pharmacy Board of Sierra Leone (PBSL), which is the National Medicines Regulatory Agency, through a rigorous process to secure authorization for the use of the vaccine. This emergency use authorization was granted based on several conditions, including, but not limited to, the preliminary demonstration of safety and efficacy of the vaccine in preventing the disease, limited options in terms of vaccines to prevent a cVDPV2 outbreak, the positive benefit–risk ratio of the vaccine, and the impact of the disease on public health. The extent of the vaccination was agreed to be nationwide, with a target population of 1,400,000 children aged 0–59 months. The first round was conducted from 28th to 31st May 2021 and the second round was conducted from 2nd to 5th July 2021. A third subnational round was also conducted for three districts that were determined to be at higher risk (Western Area Urban, Western Area Rural, and Tonkolili District), from 27th to 30th August 2021, with a target population of 512,039 children aged 0–59 months.

With limited available data on nOPV2, in that the safety characteristics have not been extensively studied or established, coupled with the fact that the AEFI surveillance system has not previously been assessed in Sierra Leone, we examined the safety reports for vaccination exercises while exploring the experiences and challenges of the AEFI system in Sierra Leone.

Materials and Methods

Study Setting

Sierra Leone is situated on the West Coast of Africa, with a population of about 8 million. Freetown is the capital city of Sierra Leone, with at least 1 million inhabitants.[7] The country is divided into a total of five administrative regions: the northern region, north-western region, eastern region, southern region, and the western area, which has an area of 71,740 km^2. These five administrative regions are subdivided into 16 districts, with each district having district health management teams.

The specific setting for this study is the National Pharmacovigilance Centre (NPC). The NPC is situated at the PBSL, which collects AEFI individual case safety reports (ICSRs) from healthcare providers, consumers, and the EPI. The EPI uses both a paper-based reporting form and an electronic open data kit (ODK) for data collection.

The EPI submits all AEFI reports to the NPC, which holds the National Database, Vigiflow, which feeds to the global database, Vigibase. The reporting flow for AEFI in Sierra Leone starts with case detection.

In AEFI surveillance, case detection is denoted as the rate-limiting step as it is an important step in the surveillance cycle. The first person to report or detect an AEFI may be a vaccinator, clinic or hospital staff, public health worker, volunteer or caregiver (parent), or any other person. When there is suspicion of an AEFI, this is adequate for reporting.

After complaints are received from those receiving the vaccine or caregivers, an AEFI form is completed and submitted to the facility, which could be primary, secondary, or tertiary, or health management teams within the district (DHMT) or the focal persons for AEFI, depending on the case. This form is then submitted to the relevant stakeholder, depending on the type of immunization campaign.

For mass campaigns, there are usually four spheres of communication, which include the district, regional, and national levels, as well as the health worker. For routine immunization campaigns, the report goes from the health worker and EPI focal points and ends up with the PBSL.

Study Population and Period

The study was conducted from May 2023 to August 2023. This study included all ICSRs for AEFI that were collected in the pharmacovigilance database (Vigiflow) throughout the vaccination campaign.

A total of 20 vaccinators, district AEFI focal persons, and key personnel at the EPI and the NPC at the National Medicines Regulatory Authority were interviewed.

Sample Size Determination and Sampling Technique

All 528 reports received from the national Vigiflow database were included in the study. The qualitative aspect used purposive sampling to identify the 20 participants for the study.

The choice of participants interviewed represented various individuals who were in a position to detect, manage, and/or report an AEFI.

Data Collection and Validation

The STROBE guidelines for reporting observational studies in epidemiology were adhered to. All the variables for data in the quantitative segment of the study were extracted from the national database, Vigiflow. This database contains reports of all AEFI received countrywide through PBSL reporting channels, as well as those reported through the ODK used by EPI. The parameters looked at included the age, gender, vaccine type, and types of AEFI reported, the seriousness of the AEFI, and the outcome of the patient.

All AEFI ICSR data were cross-validated as part of the routine pharmacovigilance procedures prior to entry into Vigiflow.

A semi-structured and open-ended interview guide was used to guide interviews, and contained questions on knowledge, experience, and challenges with AEFI surveillance and reporting. All interviews were conducted at the participants' workplace, and lasted for no more than 60 minutes.

Data Analyses

The AEFI ICSR data were exported to Microsoft Excel and analyzed using SPSS Version 21 (SPSS Statistics Gradpack and Faculty packs, IBM Corp, Armonk, NY, USA).

The AEFI were categorized using the Medical Dictionary for Regulatory Activities (MedDRA) classification and then presented as System Organ Class (SOC) and Preferred Terms (PTs). The outcomes of the patients were stratified as either "recovered" or "not recovered".

Frequencies and proportions were also used to report the distribution of AEFI types and patient outcomes, while causality was assessed using the WHO Causality Algorithm for serious cases after eligibility checks had been conducted, and then using the checklist.

Lastly, all AEFI were categorized into "consistent causal relationship", "inconsistent causal relationship", "indeterminate", or "unclassifiable".

Preventability was assessed using the Schumock and Thornton scale, and grouped into "definitely preventable", "probably preventable", and "non-preventable".

For the qualitative study, a semi-structured open-ended guide was used to conduct each interview. Interviews were recorded via audio and the data were transcribed verbatim.

The transcripts were analyzed using themes with NVivo version 9 (QRS International, UK).

Open and initial coding of the data from the interviews was carried out; these codes were generated from the participants' narratives of their experiences in how they respond to and report an AEFI. After coding of the transcripts, the initial themes that captured relevant information with respect to the questions asked in the research were generated. This process involved identifying specific patterns in the data, including perspectives, repetitive ideas, and a description of each participant's perspectives and context.

The last aspect of the analysis in this research focused on the accounts emerging from the interview, as well as key themes or thematic areas. Quotations from participants that indicated or represented their views after analysis are presented in the Results section.

Results

Demographic Characteristics

Out of a total of 528 reports of AEFI for the nOPV2, more than half of them (63.3%) affected the age range between 28 days and 23 months. More male children (50.4%) than females experienced an AEFI (Table 1).

A total of 20 participants were interviewed on the various thematic areas on their experiences and challenges of AEFI reporting, with the majority (nine) being district AEFI focal persons. The majority (45%) of the participants had between 5 and 10 years' working experience (Table 2).

Types of Adverse Event Following Immunization Using MedDRA System Organ Class and Preferred Terms

Most (89.6%) of the AEFI reported were administration site conditions and general disorders; 54.2% were thoracic, respiratory, and mediastinal disorders; and 31.6% were gastrointestinal disorders (Figure 1). The individuals studied could have multiple AEFI and so the percentages would not add up to 100%.

Pyrexia (88.8%) was the predominant PT reported as an AEFI, with cough at 53.2% and paralysis at 2.1% (Table 3).

Seriousness, Outcome, Causality Assessment, and Preventability of Adverse Events Following Immunization

A total of 80 AEFI met the criteria for serious events, of which 78 cases recovered and two did not recover.

Table 1 Demographic Characteristics of Study Participants Who Experienced an Adverse Event Following Immunization

Characteristic	n	%
Total vaccinees	528	100
Age group		
0–27 days	9	1.7
28 days–23 months	334	63.3
2–11 years	185	35.0
Gender		
Male	266	50.4
Female	262	49.6

Table 2 Demographic Characteristics of Interviewed Participants

Interviewed Participants	n	%
Total	20	100
Gender		
Male	11	55
Female	9	45
Years of experience		
1–5	5	25
5–10	9	45
>10	6	30
Role		
Vaccinator	5	25
District AEFI focal person	9	45
EPI personnel	4	20
Medicines Regulatory personnel	2	10

These serious events included vomiting (42), anaphylactic reactions (two), paralysis (11), seizure and myalgia (12), loss of consciousness and respiratory distress (four), pneumonia and pain (two), anemia (three), facial edema (three), and jaundice (one).

Following causality assessment, 74 had an inconsistent causal relationship with the vaccine, one was determined as consistent (pyrexia) as a result of temporal association, time to onset, and biologic plausibility, while three were indeterminate owing to a lack of sufficient information and inconclusive evidence, and two were unclassifiable owing to atypical presentation of the symptoms.

Most of these serious cases (78) could not have been prevented, with only two deemed probably preventable (Table 4).

Experience of Adverse Events Following Immunization and Reporting

Eighteen participants out of 20 reported having seen an AEFI case in their current or previous places of work. Fever was a common AEFI that was reported to have been seen among respondents. Although most of them had seen at least one AEFI, they described them mostly as something that did not occur all the time.

> During my years of work, I have seen AEFI cases although most of these cases are rare. (AF5)

> We hardly see any AEFI and so they are not really a common occurrence. (V3)

Out of all participants, 10/20 (three vaccinators, five AEFI focal persons, one EPI personnel, and one regulatory personnel) indicated that they had reported an AEFI case to either PBSL or EPI.

Only four participants mentioned that they had reported an AEFI case more than once, even though they had more than 5 years' experience working within the health sector.

When asked about how recently they had sent reports, the most common answer was "a long time ago".

> I still remember a case of AEFI and some others too that I reported but it's been a while. (V2)

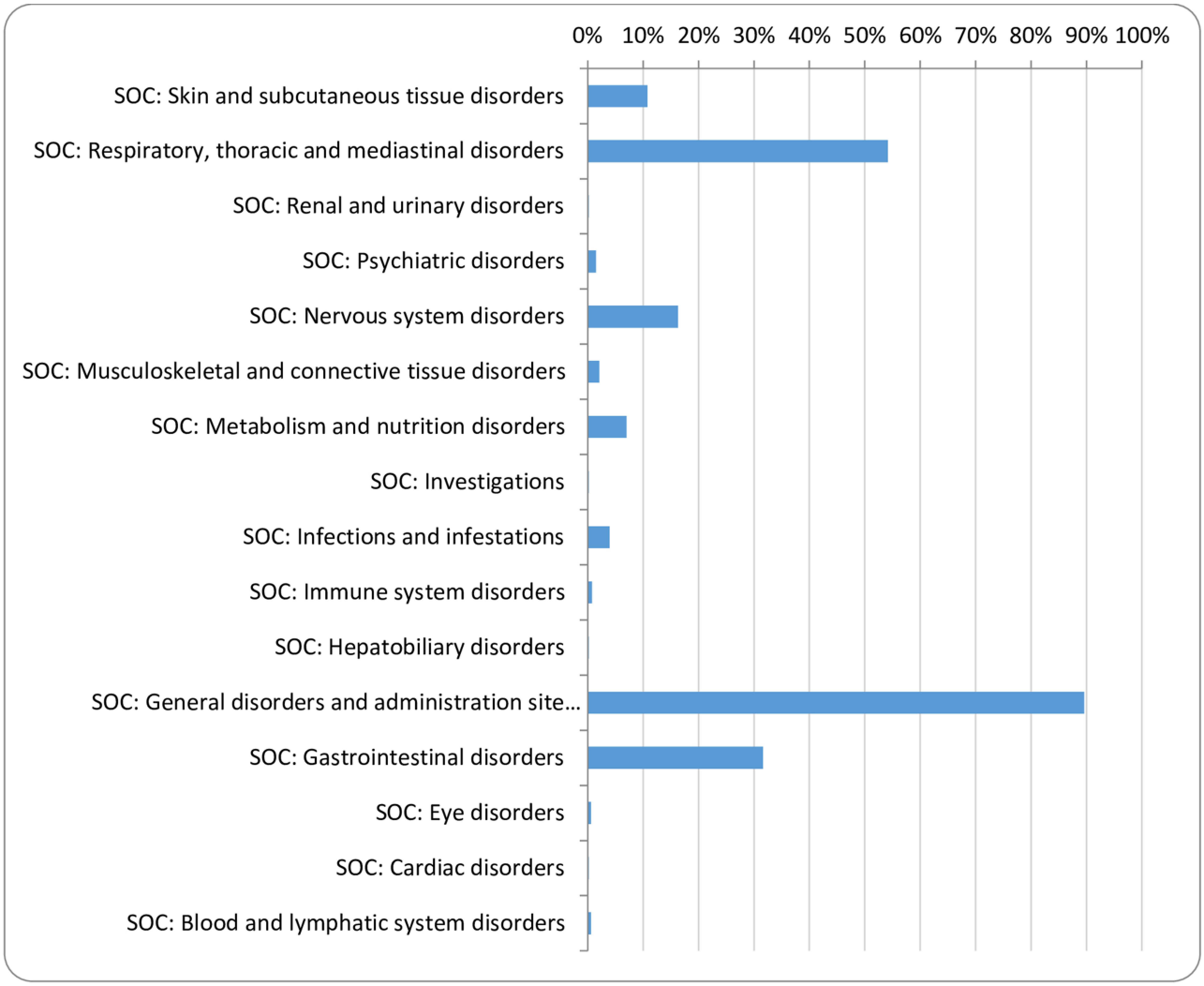

Figure 1 MedDRA System Organ Classification.
Note: Individuals can have multiple adverse events following immunization, so the percentages may be over 100%.

Awareness of Reporting an Adverse Event Following Immunization

Most participants were aware of the reporting tool and platforms, such as paper-based and electronic tools. However, three respondents were not aware that PBSL has an electronic platform for reporting AEFI.

> I know the EPI uses the ODK for reporting but I am not aware of the one used by PBSL. (V4)

> When I see an AEFI I report using the paper form but I don't know about the tool used by PBSL. (AF2)

Participants were also asked about awareness of AEFI in their workplaces, and whether AEFI had been discussed in their workstations, formally or informally.

> We discuss AEFI here as a common practice, or especially when there is an occurrence of a serious case. (AF5)

> AEFI is something we discuss on a regular basis during routine vaccination as well as during campaigns. (EP2)

Most participants were aware about policies and protocols regarding AEFI. However, two participants did not know that there was an AEFI guideline.

> I have not seen or heard about guidelines for AEFI. (V4)

> We don't have an AEFI guideline and I have not seen it before. (V1)

Table 3 Types of Adverse Event Following Immunization Using MedDRA Preferred Terms

Preferred Terms (MedDRA)	n	%
PT: Pyrexia	469	88.8
PT: Cough	281	53.2
PT: Diarrhoea	90	17.0
PT: Vomiting	85	16.1
PT: Headache	68	12.9
PT: Rash	55	10.4
PT: Decreased appetite	32	6.1
PT: Dyspnoea	25	4.7
PT: Rhinitis	13	2.5
PT: Abdominal pain	12	2.3
PT: Paralysis	11	2.1
PT: Rhinorrhoea	10	1.9
PT: Sneezing	9	1.7
PT: Chills	7	1.3
PT: Seizure and myalgia	12	2.2
PT: Arthralgia	5	0.9
PT: Crying	5	0.9
PT: Nausea	5	0.9
PT: Abdominal pain lower	4	0.8
PT: Insomnia and restlessness	8	1.6
PT: Pruritus	4	0.8
PT: Anaemia	3	0.6
PT: Face oedema	3	0.6
PT: Muscular weakness	3	0.6
PT: Nasopharyngitis	3	0.6
PT: Anaphylactic reaction	2	0.4
PT: Dehydration and erythema	4	0.8
PT: Fatigue and lethargy	4	0.6
PT: Hypersensitivity	2	0.4
PT: Loss of consciousness and respiratory distress	4	0.8
PT: Skin exfoliation and furuncle	4	0.8
PT: Lid sulcus deepened	2	0.4

(*Continued*)

Table 3 (Continued).

Preferred Terms (MedDRA)	n	%
PT: Anuria	1	0.2
PT: Conjunctivitis and eye pruritus	2	0.4
PT: Facial paralysis	1	0.2
PT: Injection site pain and abscess	2	0.4
PT: Jaundice	1	0.2
PT: Oedema	1	0.4
PT: Pneumonia and pain	2	0.4
PT: Salivary hypersecretion	1	0.2
PT: Somnolence and tachycardia	2	0.4
PT: Urticaria	1	0.2
PT: Weight increased, food refusal and feeding disorder	3	0.6
PT: Peripheral swelling and oropharyngeal pain	2	0.4

Note: People can have multiple adverse events following immunization, and, thus, the percentages do not add up to 100%.

Table 4 Seriousness, Outcome, Causality, and Preventability of Adverse Events Following Immunization

Characteristic	n	%
Serious event		
Total	80	100
Outcome		
Recovered	78	97.5
Not recovered	2	2.5
Causality		
Consistent	1	1.25
Inconsistent	74	92.5
Indeterminate	3	3.75
Unclassifiable	2	2.5
Preventability		
Probably preventable	2	2.5
Non-preventable	8	97.5

Recognition of Reportable Adverse Events Following Immunization

The participants were asked to describe or explain what AEFI they would be inclined to report. All of the participants stated that any reaction that is serious should be reported, as well as reactions that one might not expect. Reactions that are life threatening, can lead to incapacity or disability, or cause hospitalization all fall under this category.

> I have seen minor reactions before but I have never seen a serious reaction before that will require prompt response or management. (AF9)

> Most times the events that we see are fever which usually subsides but I have not experienced a serious reaction like anaphylaxis before. (V4)

Two interpretations were evident when describing a serious event:

> When an individual dies that's when it becomes a serious event. (V2)

> As long as the patient did not die then it won't be a serious AEFI. (V4)

Challenges and Barriers to Reporting

Most participants recognize the fact that PBSL, EPI, and surveillance are key stakeholders in AEFI surveillance and reporting, as well as the role played by healthcare providers.

However, there exist ownership issues with respect to AEFI reporting and surveillance:

> The pharmacists are the ones who should be responsible for AEFI activities. (AF1)

> The nurses/vaccinators who administer the vaccines should play a greater role in AEFI reporting. (V3)

> The EPI should be the one taking the lead as they are the ones who brought the vaccines into the country. (V2)

Participants were asked about what they think happens to the AEFI reports sent to either PBSL or EPI.

> The reports are assessed and then acknowledgement and feedback is sent to whoever is reporting. (PP1)

> The reports are kept and nothing is sent to those of us that are sending them in the first place. (V4)

Another important thing that came out from some participants was about the ease of using the various reporting tools:

> I find it difficult to use the ODK platform as it takes time to fill all the required variables. (AF1)

> I prefer using the paper-based form as the ODK tool takes a lot of time to fill. (V4)

Training

Most of the participants indicated that they had received some form of training on vaccine safety. EPI and PBSL personnel usually conduct training for district and hospital staff on vaccine safety issues. Some of the AEFI focal persons and vaccinators who had received some form of training on vaccine safety had some reservations about the content.

> Most times people think we have been adequately trained. The training I have received is underwhelming. (V5)

> I have had some training on immunization but not specifically on vaccine safety. (V1)

All participants recognized the fact that training can also be effective if they make use of existing continuing educational programs by their respective professional bodies.

Discussion

The findings from this study indicated that more than half of the AEFI (63.3%) affected children in the age range between 28 days and 23 months. Furthermore, 89.6% of the AEFI reported were general disorders and administration site conditions, and pyrexia was the predominant PT. Of the total 80 serious cases, 78 recovered, while 74 of these had an inconsistent causal relationship with the vaccine.

Most of the participants interviewed revealed that they have seen an AEFI in their place of work, although usually this was very rare. Participants were aware of reporting tools such as paper-based and electronic methods, although there were mixed reactions in terms of awareness of the presence of AEFI guidelines.

Most of the events seen were not serious, and there was confusion over who should take responsibility when it comes to AEFI surveillance. Challenges with using the ODK platform were highlighted by participants, and although some form of training was received, participants felt that the training was inadequate.

The implications of this study are that understanding the challenges of reporting can lead to improved strategies and ultimately improved safety monitoring. This would also enhance public trust and capacity building, as well as refining the policies governing AEFI surveillance in Sierra Leone.

More than half of the AEFI (63.3%) affected the age range between 28 days and 23 months, with more male children (50.4%) experiencing an AEFI. These findings are in line with other studies that looked at AEFI in children.[8,9] The age category can be explained by the fact that this was a vaccination campaign that targeted children. Findings from many other studies were similar, in that more males experienced an AEFI.[10–13.] Possible explanations for this could be that more male than female children were vaccinated and that male children may exhibit different immune responses compared to female children owing to biological differences, genetic factors, and immune system functions.

The targeted participants interviewed in this study were mainly key stakeholders in AEFI surveillance, with the majority (45%) of the participants having 5–10 years' working experience. Most of the pharmacists, who were AEFI focal points in the various districts, were relatively new in their positions. Healthcare workers in Sierra Leone are usually moved from one workstation to another within a short timespan as a result of need or posting obligations. Other research looking at healthcare workers with regard to AEFI surveillance showed that the majority had 0–9 years' working experience.[14] Another study of healthcare professionals dealing with AEFI looked at the mean number of years working in a professional group as 19 years.[15]

The most prevalent SOC that was affected by adverse events was "general disorders and administration site conditions" (89.6%). These events are very common and most often reported following vaccination. They are also easier for patients, caregivers, and healthcare providers to identify and report compared to more serious or rare events. This finding is consistent with several other studies on AEFI, including one study published in 2018.[10] This is also consistent with other studies looking at adverse drug reactions and AEFI, in which administration and general disorders were predominant.[11,16]

We also found that pyrexia, as a PT, was the predominant AEFI. This could be explained by the fact that vaccines work by stimulating the body's immune system, and fever is a natural immune response to a vaccine as the immune system mounts a response as a result of antigens introduced by the vaccine. This is also in line with a lot of other studies, including a study which shows fever as the predominant reaction.[10,16–18]

Eighty of the AEFI which represent a small percentage were serious events, including anaphylaxis and paralysis. One reason for this could be that since vaccines undergo rigorous testing and evaluation in clinical trials before they are approved, safety evaluation would have detected serious events or proved that the benefits outweigh the risks. Also, continuous monitoring during post-marketing surveillance is usually in place to monitor safety in real-world settings. Several studies have also found some serious AEFI, which are usually in small numbers.[19–21]

Following causality assessment, 74 cases had an inconsistent causal relationship with the vaccine, one was determined as consistent, while three were indeterminate and two unclassifiable. Studies looking at AEFI causality had similar findings in terms of having more AEFI classified as inconsistent, indeterminate, and unclassifiable.[10,17.] Since most of the AEFI had an inconsistent causal relationship with the vaccine, there are several factors that could explain this, including pre-existing health conditions in the children, and medications or other vaccines being administered around the same time as the vaccine was given. In addition, some adverse events that occur after vaccination may be coincidental and not related to the vaccine.

The serious AEFI could not have been prevented in 78 cases, as only two of the 80 serious cases were deemed probably preventable. This is consistent with results from other studies, but most importantly a study conducted in Italy[22] and another in India.[23] The fact that the majority were not preventable implies that no patient factors, vaccine factors, or practice factors were to blame. This could also be explained by the fact that there were no issues with the dose, route of administration, storage, or formulation, for practice factors; quality or issues of counterfeit product, for vaccine factors; or non-compliance or self-medication, for patient factors.

The results also showed that the outcome of these cases was that more children recovered from the AEFI than did not recover. This finding is in line with the aforementioned Italian study.[22] This implies that the AEFI did not cause permanent damage or lead to a recovery with sequelae. There may be several explanations for this, including that the

event is non-serious, individual variability in terms of response to a vaccine, proper management of the event, and having a healthy immune system.

The qualitative part of the study, which involved interviews with the four categories of participants about the experiences and challenges of AEFI reporting, was very revealing.

Reporting of AEFI was not a frequent occurrence among the groups, although knowing how to identify an AEFI was a common finding among them. There may be several reasons for this, including the rare occurrence of an AEFI and also an AEFI occurring but not being reported. This corroborates the finding that most participants take a very long time to report an AEFI more than once. Another possible reason for not reporting could be that nobody wants to take responsibility as they feel that it is a job for somebody else. These findings were also highlighted in previous research.[24]

Most participants were aware of the reporting tools and platforms, such as paper-based and electronic tools, and where to send the reports. These findings were consistent with a similar finding from a published study.[25]

However, some participants were not aware that PBSL has an electronic reporting tool for submitting reports. This could be due to the less than aggressive method used to popularize this electronic platform.

The paper-based AEFI form is found in most facilities, unlike access to the electronic reporting tool. This calls for a dissemination of the electronic link or a uniform resource locator to all health professional platforms, to make it easier for people to send reports. In addition, when training is conducted on AEFI, instruction in how to fill out and complete the electronic reporting tool should be a priority.

Participants knew about the protocols and policies regarding AEFI, but not all of the participants were aware of the national guidelines for surveillance of AEFI. The national guidelines direct stakeholders who are involved in AEFI surveillance with clear roles and responsibilities. The fact that not all participants were aware of them could be a result of their not being trained on the content of the guidelines, as well as the unavailability of these guidelines in their respective places of work. This suggests a need for stakeholders to be informed about the guidelines, to be trained on them, and to have them available at their workstations.

The participants were unanimous in saying that reactions that are serious and unexpected are the ones that they feel should be reported. Participants did not mention whether non-serious reactions should be reported. It is, however, expected that all reactions, whether serious or not, must be reported.

The lack of taking ownership of AEFI reporting was a key challenge, as participants felt that it is the responsibility of one set of individuals or organisation and not the other. The use of the ODK tool for reporting was also presented as a huge challenge. Some participants pointed to the user unfriendliness and time consumption in trying to fill out this tool. Others preferred using the paper-based form for reporting as they found it more user friendly.

It is worth pointing out that the ODK platform has many fields or variables to input, and this may deter people from filling it out. If people find the forms easier to use, then they should be readily available at all healthcare facilities in the country.

These barriers and challenges are similar to those found in previous studies conducted in different countries.[26–28]

Participants highlighted issues with the level of training on AEFI that they want to receive. Although some had received some form of training, they felt that it was inadequate for them to make a significant impact in AEFI surveillance.

This study also highlights the need to improve on professional educational programs. Adverse event surveillance should be incorporated into continuous professional development programs that are conducted for both pre-service and in-service personnel. These findings are consistent with those from other studies.[26,27]

Strengths and Limitations of the Study

The strengths of this study are that it is the first of its kind to be conducted in Sierra Leone, and its qualitative approach allows participants to detail their experiences, understanding, and challenges. In addition, data were readily available for the quantitative part of the study, and STROBE guidelines for the reporting of observational studies were adhered to.[7]

Some limitations are that not every stakeholder was interviewed, especially at the disease surveillance program, as they are not practically and regularly involved in AEFI, and that some responses may be based on the organizational context in terms of how AEFI are reported at that workstation.

Conclusion and Recommendations

The AEFI surveillance system in Sierra Leone has shown its usefulness, although it is not entirely meeting its objectives, as demonstrated by this study. While the nOPV2 is relatively new, the results showed that vast majority of AEFI were not serious, and most of those that were serious were not causally related to the vaccine.

AEFI reporting still needs improving generally, and collaboration is needed among all stakeholders, especially surveillance officers at the facility and district health management team levels.

This collaboration should include the following, in the form of recommendations: the introduction of initiatives to improve education, particularly among healthcare professionals at both undergraduate and professional levels; a review of the current AEFI guidelines and eventual dissemination at facility and district levels; and popularizing PBSL's electronic reporting tool countrywide and through the DHIS2 system, as people find it more convenient to use.

Surveillance officers at district and facility levels should take a leading role in AEFI surveillance, and periodic evaluation of the AEFI system should be conducted to ascertain whether it is performing according to set objectives.

Data Sharing Statement

The datasets analyzed are available upon request to the Principal Investigator.

Ethics Approval and Informed Consent

Approval to conduct this study was sought from the research, innovation and publication committee of the Faculty of Pharmaceutical Sciences, College of Medicine and Allied Health Sciences, University of Sierra Leone (RIPC-009-23). This study complies with the principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants after explaining the purpose and procedures of the study, including the publication of anonymized responses.

The predominant data for this study were routinely collected data from the National Pharmacovigilance database. These data are anonymized data, so they have no patient identifiers. Permission to use these data was sought and obtained from the head of the regulatory authority.

Permission was sought from the District Health Management Team to interview its personnel, as well as from the Expanded Program on Immunization and the Pharmacy Board of Sierra Leone. Data from these sources were also categorized and therefore they were anonymized as well.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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