ORIGINAL RESEARCH

Country readiness in responding to COVID-19 Vaccine-Related Events (VREs) in Malawi

Save Kumwenda[1]*, Mphatso Nyamasauka[1], Davis Makupe[2], Sandra Machiri[3], Nenani Chisema[4], Mavuto Thomas[5], Rhoda Chado[4], Alvin Phiri[5], Atupele Kapito[6]

1. Department of Public and Environmental Health Sciences, Malawi University of Business and Applied Sciences (MUBAS),Blantyre 3, Malawi
2. Department of Mathematics and Statistics, Malawi University of Business and Applied Sciences (MUBAS)
3. African Field Epidemiology Network, Lugogo House, Lugogo By-Pass, Kampala, Uganda
4. Ministry of Health, Expanded Programme on Immunisations, Lilongwe, Malawi
5. Ministry of Health, Health Education Unit
6. Kamuzu University of Health Sciences, Chichiri, Blantyre 3, Malawi,

*** Corresponding Author: Save Kumwenda**; E-mail: skumwenda@mubas.ac.mw

Abstract

Introduction

The Malawi Ministry of Health (MMoH) and partners developed a comprehensive Coronavirus Disease 2019 (COVID-19) Vaccine Related Events (VREs) response plan in 2022. A VRE is any anticipated threat that could erode the public's trust in vaccines or vaccination delivery. We explored the MMoH's readiness to implement the plan by assessing the availability of VRE-related documents describing the overall process of identifying, reporting, investigating, and coordinating a VRE response; and by assessing the strengths and weaknesses of the current system.

Methods

We conducted a cross-sectional assessment among MMoH staff involved in VRE response at national, district, and health facility level using a survey and a semi-structured interview guide in ten districts in Malawi in 2023. Ten VRE-related documents were assessed and their availability visually confirmed. We assessed each of the survey findings by district and zone. Ten key themes pertaining to VRE identification, reporting, investigation, and response were explored in 109 Key Informant Interviews (KIIs) and six Focus Group Discussions (FGDs).

Results

More than 60% of respondents reported having access to VRE-related documentation, but less than 10% reported access to non-Adverse Events Following Immunisation (non-AEFIs)-related guidance. Participants identified existing processes for AEFIs, but noted the lack of training, coordination, and budgetary support for both AEFI and non-AEFI activities. Health facilities with VRE response teams or committees had implemented aspects of the response plan, emphasizing the need to formulate teams or committees in all health facilities.

Conclusion

Adequate implementation of Malawi's VRE response plan will require expanded training opportunities, sustained funding, and improved coordination across all levels of the health system.

Keywords: Vaccine-related events (VREs); vaccination; community engagement; feedback; training; Adverse Events Following Immunisation (AEFI); VRE response plan; vaccine safety preparedness, and Malawi

Introduction

Globally, vaccination has proved to be an effective means of preventing communicable diseases. However, inadequate identification, investigation and response to Vaccine-Related Events (VREs) can negatively affect confidence in a vaccination programme1 and later undermine efforts to achieve and sustain vaccination coverage[2–5]. A vaccine-related event is any anticipated threat "which could potentially create uncertainty and/or erode the public's trust in vaccines and/or vaccination and the authorities delivering them"[6]. VREs include Adverse Events Following Immunisation (AEFIs) or Adverse Events of Special Interest (AESIs); new scientific data on vaccines' benefits and risks; events such as a temporary suspension of a vaccine or recall or change in vaccine or introduction of a new vaccine; negative messaging, e.g. news and other media reports, misinformation, or the actions of anti-vaccine activists, including social media; community attitudes and beliefs; and low acceptance of vaccines[7]. An AEFI is any unforeseen medical condition that occurs after immunisation which may be caused or not caused by the vaccine or vaccine administration. The second broad category is the non-AEFIs, which are non-medical occurrences in people receiving vaccines. The non-AEFI VREs include "a new assessment or experimental data related to vaccines, press report or local rumour, suspension and recall or the replacement of a vaccine". While strategies to reduce non-AEFI VREs including engaging the media to disseminate correct information, calling upon researchers and academicians to give out correct information about vaccines, tracking and tackling emerging and circulating fake news have been investigated[8–12], limited information is available on the availability and use of guidelines for investigating and reporting of VREs.

AEFI surveillance systems are well known and in place worldwide[13], whereas the broader concept of VREs has been developed by WHO, with guidance published in 2013[1], antigen-specific guidance for polio vaccine in 2022[14] and for COVID-19 vaccine in 2020[7]. A VRE response system consists of a formalized process for identifying, reporting, investigating and responding to VREs in an integrated

https://dx.doi.org/10.4314/mmj.v38i2.3

manner across health system levels and between vaccine safety focal points and health promotion teams[15]. Despite the availability of guidance, gaps in training and costs have been attributed to delays in changing from AEFI surveillance into a holistic system to detect and respond to VREs[16].

Some high- and middle-income countries have established effective vaccine surveillance systems for adverse events reporting[17]. It was found that more than 9 countries have operational frameworks, though the study noted that many countries lack structured systems globally[17]. In a related study, no-fault compensation programmes for vaccine injuries which are a key component of VRE response were examined and found 25 countries had implemented such schemes by 2018 showing an improvement from 19 countries in 201018. These were mostly high-income countries, with recent expansions to low-and middle-income countries (LMICs). For specific vaccines, it was reported that 56 LMICs representing 41% of all LMICs had initiated national Human Papillomavirus vaccination programmes by 2021, including implementing VREs elements like monitoring performance and addressing rumours about the vaccine[19]. Regionally, the Pan American Health Organization adapted the WHO guidelines on Events Supposedly Attributable to Vaccine or Immunisation (ESAVI) monitoring in America, giving a framework that is adopted by multiple countries in the region[20].

Challenges in implementing VREs are mostly prevalent in countries with limited resources. One of the major challenges in such countries is the lack of effective reporting systems which leads to under-detection of rare adverse events and the shift from fearing the disease to fearing the vaccine[17]. The other challenges include operational barriers in compensation programmes such as low public awareness, long claim timelines and difficult proof requirements which usually affect the efficiency and fairness[18]. Some challenges in Human Papillomavirus vaccination programmes include the overcoming vaccine rumours, reaching out to populations in schools, estimating targets and ensuring sustainability with limited resources[19]. In terms of challenges in implementing vaccination information systems, the most frequently reported challenges were data quality, security and privacy concerns, lack of standardization, usability issues, limited internet connectivity, inadequate infrastructure, insufficient funding, low awareness among stakeholders, low computer literacy and lack of training[21]. In Malawi, there was a decline in childhood immunisation rates especially during COVID-19 vaccination coverage and this indicated a need to strengthen existing systems[22–24]. In 2022, the Malawi Ministry of Health formalized its VRE response system and published a COVID-19 VRE response plan, disseminating it to focal points in all zones and districts in the country[15]. The plan provides a framework for monitoring, investigating and communicating vaccine-related safety concerns following COVID-19 vaccination[25].

Thus far, no assessment has been conducted to evaluate Malawi's readiness to implement the COVID-19 VRE response plan that would help draw lessons for other antigens. Our objective was to assess the Ministry of Health's readiness and ability to identify, report, investigate and respond to VREs (AEFI and non-AEFI) in the initial period following the development of Malawi's national plan in 2022. We assessed Malawi's readiness to identify, report, investigate and respond to VREs and examined strengths, weaknesses and opportunities for improving the national VRE response system.

Materials and Methods

Study Design and Assessment setting

This cross-sectional exploratory study collecting both qualitative and quantitative data on readiness assessment was conducted in ten districts, drawing from each of Malawi's three Regions (North, Central and South) during April—May, 2023. We purposively selected two districts in each of the five health zones, including the district that houses the zonal headquarters. Mzuzu and Rumphi Districts comprise the Northern Zone from the Northern Region; Kasungu and Salima Districts comprise the Central Eastern Zone from Central Region; Lilongwe and Dedza comprise the Central Western Zone from Central Region; Blantyre and Nsanje comprise the South Western Zone from the Southern Region and Mangochi and Zomba comprise the South Eastern Zone from South Region were included in this assessment. The district with the zonal headquarters were purposively selected in order to target the zonal offices while the other districts were randomly selected using Excel-generated random numbers.

For the quantitative component of this assessment, we collected data from each health facility and district health office on the availability of VRE-related documents, the frequency and types of AEFIs and non-AEFI reported by district, and the frequency of investigations and causality assessment meetings. For the qualitative component, we conducted key informant interviews (KIIs) with national and zonal coordinators, Integrated Disease Surveillance and Response (IDSR) focal points, and Health Promotion coordinators and focus group discussions (FGDs) with health facility staff and Health Surveillance Assistants to understand the current process for VRE identification, reporting, investigation and response as well as perspectives on the strengths, weaknesses, and capacities of the current system.

Inclusion criteria and sampling

In each district, we purposively sampled participants from the District Health Office, the District hospital or Central hospital, and Health Facilities. Inclusion criteria for participants included a role as a health worker involved in the immunisation programme at a national, district, and health facility level, being at least 18 years of age, willingness to have the discussion recorded and providing written informed consent. KII and FGD sample sizes were set with the expectation of reaching saturation in themes, with overall estimated sample size of 176 participants. We assessed the availability of VRE-related documents by surveying the AEFI focal point or their designee at each site of qualitative data collection.

Sample size, Data collection and Management

The total number of health workers involved in COVID-19 delivery in the targeted facilities was estimated at 176, however, we targeted all those that were available from April to May 2023. For the key informant interviews (KIIs), personnel involved in managing COVID-19 vaccines and VREs were involved. These included the EPI focal person, IDSR focal person, Medical Assistant or Health Centre In-Charge at Health Centre level, EPI coordinator, Medical Doctor, Nurse and Health Promotion Officer at District

https://dx.doi.org/10.4314/mmj.v38i2.3

Hospital Level and Coordinator at zonal level. We also targeted the national level where we interviewed officers at EPI, Health Education Section, Causality Assessment Committee, Pharmacy and Medicines Regulatory Authority (PMRA) and partners (UNICEF and WHO). One Focus Group Discussions (FDGs) in each zone was done involving clinicians, medical assistants, nurses, Health Surveillance Assistants (HSAs), IDSR focal persons and Senior HSAs at the selected health centres.

Data was collected using a pre-programmed checklist on Kobo Collect (an open source android application for data collection, management, and visualization used globally for research and social good) to assess the availability of VRE-related documents, the reported use of these documents in the event of a VRE, the presence of teams to investigate VREs, and the most recent number and types of AEFIs and non-AEFIs reported at each district and health facility visited. The VRE-related documents included a list of reportable AEFIs, guidelines for AEFI reporting, guidelines for AEFI investigation, guidelines for AEFI causality assessment, agenda from the most recent AEFI investigation meeting, minutes from the most recent COVID-19 causality assessment committee meeting, a community assessment plan or protocol, report or findings of previously conducted assessment, social media monitoring Standard Operating Procedures (SOP)/guidelines, social listening reports, crisis and risk communication plan and communication materials development plan. We conducted semi-structured interviews with participants at the national level in English; district and health facility semi-structured interviews and focus groups were conducted using in English or Chichewa, depending on the preference of participants. Data collectors used a KII guide, FGD guide, and checklist to guide the discussion. We collected audio recordings of the interviews and discussions, and transcribed them, and translated the Chichewa transcriptions into English. No individually identifying information was collected.

Measures and Analysis

Responses to the quantitative elements were summed to the district level and reported by region. The quantitative analysis reported on the availability of VRE-related documents, with response options yes or no to the demonstration of document availability at the site. Document availability was visually verified. The use of VRE-related documents was self-reported as ever used or never used for each document. The availability of a team to investigate VREs was self-reported as yes or no. AEFI types, including serious local reaction, seizure, abscess, sepsis, fever, headache, and other were measured using the AEFI reporting forms in the six months preceding the assessment (November 2022—March 2023) for each health facility. WHO standard definitions were used in the classification of adverse events following immunisation[26]. Non-AEFIs reported were summed by district and reported by region, along with a qualitative description for each. When AEFI-specific elements, processes, or documents were mentioned, we describe these as AEFI. The non-AEFI VREs investigated were those applicable at community and facility level including misinformation, rumours and fake news. The readiness in terms of availability of teams and guidelines was investigated.

We calculated the count and proportion of all documents available for each VRE document type by district and region, and then compared the proportion of all documents available by region. We summed total number of AEFIs reported by type in the previous six months for each of the three Regions. All quantitative analyses were conducted using IBM SPSS Version 20. For the qualitative analysis, researchers collectively identified themes based on the interview and discussion guides and conducted an inductive thematic analysis of transcripts both manually and with NVivo 14. The main themes identified were VRE response plan; Documentation for VRE planning, identification, reporting and response; Committees for VRE response; VRE response coordination and reporting; Community listening; Media engagement; Challenges in VRE response; Community misinformation and myths; health facility training, coordination, and hesitation to report.

Data Quality Assurance

The research design was presented to research committees in the ten districts before submission to the National Health Research Ethics Committee which also reviewed it. All comments from the committees were discussed by authors and necessary revisions were made. After ethical approval, we recruited and trained data collectors. The data collectors had a minimum qualification of a university degree in Environmental Health, Medicine, Nursing and Social Sciences. They assisted in translating the tools, which were already translated to local language by authors before submission for ethical review, back to English to check if they were accurate and consistent. The tools were thereafter pre-tested in Chiradzulu in Southern Malawi. During data collection, the first author supervised the data collection process. Challenges met during each day of data collection were discussed and resolved before the next day. During data cleaning, questionnaires with more than 10% missing data were not included in the analysis.

Ethical Considerations

Permission to conduct this assessment was sought and obtained from all the ten districts. The permission letters together with the protocol were sent and approved by the National Health Research Ethics committee (Protocol #23/02/3178). The Human Subjects Office at the Global Health Center at the US Centers for Disease Control and Prevention (CDC) reviewed this protocol for a non-research determination. Written informed consent was obtained from all health workers who participated in this study.

Results

We conducted six FGDs on VRE identification, reporting, investigation, and response and 109 interviews with participants from national, zonal, district and health facility levels (Table 1).

We collected quantitative data from 109 respondents. It was observed that 35.9% of these respondents were working in the district hospitals while 62.1% were working in the health centres. The FGDs involved 33 participants as shown in the Table 2.

The cadres that participated in the discussions included the Medical Assistants, the clinicians, nurses, IDSR focal persons, SHSAs and HSAs. These varied per health centre depending on availability (Table 2).

Availability of documents, materials for VRE investigation, and capacity building to conduct VRE monitoring activities

More than half of respondents reported having prepared

https://dx.doi.org/10.4314/mmj.v38i2.3

lists of reportable VREs and VRE reporting guidelines. However, very few respondents reported the availability of the remaining required documents. The least available documents included guidelines for causality assessment (8.4%), social media monitoring standard operating procedures (6.5%), crisis and risk communication plans (9.5%), minutes of recent COVID-19 assessment meetings (5.3%), and social listening reports on non-VREs (6.5%) (Table 3).

It was shown that over 50% of the respondents said they had these materials. Capacity to conduct assessments, investigations, and respond to VREs was determined by the presence of special committee or team to look into these activities. It was observed that many health facilities had the required teams in place (Table 3).

AEFIs reported using reporting forms

Respondents from all Regions reported using the AEFI reporting form to record at least one VRE in the previous six months. Respondents from all regions identified non-AEFIs (Table 4).

Abscess, fever and other VREs were observed by more than half of the respondents (74.7%, 77.3%, and 60.0%, respectively). In a few health facilities, respondents observed seizures, sepsis, thrombocytopenia, anaphylaxis, and URTI (12.0%, 9.3%, 2.7%, 1.3%, and 4.0%, respectively). About 35% of the respondents reported COVID-19 vaccine recipients presenting with headache (Table 4).

Qualitative Findings: Process for identifying, reporting, investigating, and responding to VREs

KII participants described the overall process for identifying, reporting, and investigating VREs, as well as the coordination mechanisms for response. The VRE system starts at the community level, where community members report VREs to their respective Health Surveillance Assistants (HSAs), Village Health Committees (VHCs), volunteers, or directly to health facility staff. The first healthcare worker to receive notification of a VRE is responsible for completing a VRE reporting form and submitting it to a clinician or immediate supervisor.

"People who have been trained on how to detect a VRE case are able to link up. When a clinician has seen a case, they are able to link with an HSA and say, 'Here is a case we need to report.' We use the technical guides when training community members, religious leaders, and healthcare workers." (**Health care worker, South Region**)

If the VRE is classified as serious, the report is submitted to the district EPI coordinator and the IDSR coordinator, who may make a determination or refer the case to the zonal or national-level Expanded Programme on Immunisation (EPI) Unit. The EPI Unit may investigate the VRE and make a determination, or it may refer the VRE to the Causality Assessment Committee (CAC) (Figure 1). The CAC is a component of the Pharmacy and Medical Regulatory Authority, which is responsible for medicine safety and quality.

Following the decision of the National Causality Committee, the findings are transmitted to the national level EPI Unit, then to the zonal office and the district VRE investigation committee, and finally to the health facility staff who reported the VRE for follow-up with the case, the caregivers, and the community. When the causality assessment is made at a lower level of the health system, the findings are meant to be conveyed back to the community through a process similar to that used for national-level causality committee determinations. Most health facility staff interviewed had experience reporting AEFIs to the district EPI coordinator and the national EPI division; however, none reported that these AEFIs were escalated to the PMRA Causality Assessment Committee (CAC) for causality assessment. In contrast, the national EPI division indicated that it reported the AEFIs to the National Causality Committee and received feedback on the assessments.

VRE reporting: Identified Strengths and Weakness identified

Thematic findings on the VRE system are outlined in Table 5. All participants reported using both paper-based forms and WhatsApp to report VREs to the next level of the health system. Health facility staff noted that they completed paper forms but submitted them electronically to the district via WhatsApp. At the district level, the data are entered into the District Health Information System 2 (DHIS2) through the Health Management Information System (HMIS). However, differences in reporting processes across districts were observed, notably, district VRE investigation committees frequently bypassed the zonal office and sent investigation requests directly to the national EPI unit.

Participants noted that the VRE reporting process was challenging due to resource constraints and data management issues. Delays in transmitting reports to the district level were attributed to inadequate staff, limited transport for paper-based reports, and uneven or costly mobile network coverage for electronic reporting. Furthermore, participants highlighted that these paper reports are not always documented and stored in easily-accessible registries, leading to an increased risk of losing documentation related to VREs. Additionally, some health workers expressed fear of reprimand or blame for reporting VREs involving themselves or their colleagues, regardless of the cause.

Health facility level participants noted challenges in both the identification of VREs at the community level and the reporting of VREs at the health facility level. A health worker in the Central Region added that the challenges start from the community level and HSAs because AEFIs are considered as normal outcomes and not reported to the health workers:

"The people in the communities are not able to identify VREs especially AEFIs. I remember this other time, I went to the field, I found a mother and she told me not to vaccinate the child on the spot I wanted and she showed me the spot where she wanted her child to be vaccinated. When I asked the reason, she showed an abscess which had healed. And when I asked her how the child got that, the mother said that after the child received the vaccine, the child developed that and the mother took the child to a private clinic where they blew up the abscess. This means that the mother did not consider that a VRE, had it been the mother reported to the facility, it would have been recorded in the VRE form" (Health care worker, Central Region).

KII with a health care worker in the South Region indicated that not all the staff are familiar with the reporting system, inadequate coordination among health care workers to record VREs, and suboptimal referral practices to appropriate personnel for recording and investigation.

https://dx.doi.org/10.4314/mmj.v38i2.3

"When the challenge is on the vaccine, then reports go to the district office but when there are AEFIs caused by the vaccine administrator like abscess, they are dealt with at the facility and later we meet the concerned personnel and inform them on proper administration of vaccines" (Health worker, South Region).

Health workers from Central and South Regions reported instances in which health workers provided treatment for AEFIs without recording these AEFIs on the reporting forms. Furthermore, the participants expressed a need to train VHCs on the VREs. However, there were participants from each of the Regions who indicated that there were no challenges with VRE coordination and reporting.

"We are trying to have health talks but also Continuous Professional Development meetings where we can discuss issues on pharmacovigilance so that every clinician and nurse should know what to do where and where to report in case, they meet such a case. Especially on the issue of reporting, we don't have a clear system so sometimes you feel like for you to start the reporting system, you waste time but if it is a proper reporting system it's easier to do" (Health care worker, South Region).

Although the process for VRE reporting is meant to go from district to zone and national level, actual reporting often bypasses zonal offices and participants reported circumstances where zonal staff received notification of VREs in their zone following the receipt of a national-level investigation and response.

"Don't even bother because we don't have database so we need to ask from the national office. I can't say I will extract from DHIS 2 because it only gives numbers and not all details on type of VREs but I know there is need to have a database that one can easily access information from of course with rights," (Health care worker, North Region).

Opportunities to Strengthen VRE Investigations

Following the identification of a VRE, health workers are responsible for referring the case to the HSAs, who document the VRE on official reporting forms and either investigating the VRE or referring the case to the relevant health worker for assessment. Some health workers reported that they did not know the steps required to complete the VRE investigation process. A participant explained that although EPI coordinators participate in VRE investigation teams, the infrequency of investigations leads to a lack of experience and subsequent uncertainty on how to undertake an investigation.

"I know that the guidelines are there talk on how we should organize ourselves, prepare for the investigations, things that would need to be investigated, seek help, report to the administration, etc. These are some of the things I can remember. Maybe because we haven't had a serious VRE case requiring an investigation so I think my team members cannot know all these steps as well. It can be a very tough issue if we can have a VRE case requiring investigation today" (**Health worker, North Region**).

Participants in the North, Central and South Regions noted that the responsibility for distinguishing serious and minor VREs was not consistently assigned. One health worker in Central Region noted that HSAs were responsible for distinguishing, while another in Central Region indicated that the health worker was responsible for this determination, and a third participant could not determine the role responsible for this decision.

"We don't have that team which distinguishes the VREs because when VRE comes usually it's the clinician who is the first contact, sometimes the clinician asks the EPI focal or SHSA to discuss about the VRE and if it's serious it's referred to higher level and minor ones are observed at the health facility" (**Health care worker, South Region**).

Health workers in each Region noted that serious AEFIs had been detected in their health facility, with symptoms ranging from paralysis to seizures, abscess and convulsions. However, some participants noted that there had not been any serious AEFIs reported in the past six months, or that they had never registered any serious AEFI case. Health workers in the Central Region added that when there is a serious AEFI and the facility cannot handle it, the patients are referred to the medical short stay at the regional hospital, for advanced diagnostics. The investigations are done at district level and the findings are documented and sent to national EPI office. One Health worker described the investigation process from district level:

"When the case was reported to the [District Health Officer], we followed up that case… . We wanted to understand what happened to the child, what vaccine did the child receive, batch number of the vaccine, what time was the child vaccinated, after vaccination what happened up until the parents reported to the hospital. The investigations were conducted in 2 days, the first day they went to investigate at the health centre then the second day they went to the health center then thereafter to the village" (Health care worker, South Region).

Causality Assessment on the reported serious AEFIs

Participants from seven districts reported that their districts had not established district level causality assessment committees; thus, causality assessment could not occur at the district level. District level participants from all three Regions further explained that they are only responsible for investigations and that causality assessments are conducted at national level by the Ministry of Health, WHO, pharmacovigilance and other key stakeholders.

"Of course, I can say, at the district we don't do the causality assessment and we do not have that team, in fact ours we do just the investigations" (**Health worker, South Region**).

Responding to VREs

Participants at all levels of the health system emphasized the importance of sharing the results of an investigation and causality assessment with community members to build and sustain trust between the community and the health system. Following an investigation or upon receiving the results of a causality assessment, the DHO is responsible for calling the facility in-charge or EPI focal person, who then shares the findings with the case, the caregivers of the case, and surrounding community. While most participants

https://dx.doi.org/10.4314/mmj.v38i2.3

did not report experience with responding to non-AEFI investigations, a participant from the North Region reported that investigation findings from two non-AEFIs had been addressed by the district level Health Education team. Participants from Health Facilities noted infrequent dissemination of investigations and causality assessments from either the national level or the districts. One FGD participant in Central Region attributed these inconsistencies to the lack of formal processes for responding to VREs:

"I remember there was one woman whose child had an AEFI where the injection site got hardened and darkened, she went to the HSA in the community who referred the client to the Clinician here and after the Clinician examined the child, he said the injection site has recovered therefore no medication was required so she was sent home. The HSA later followed the client to her home and provided some health talk to those surrounding" (**Health worker in Central Region**)

For serious AEFIs, participants noted that the investigations are supposed to start within 24 hours if reported directly to the facility and 72 hours if identified in the community. However, participants in Central Region noted that investigations typically did not begin until two weeks after the identification of a serious AEFI. Investigation delays were attributed to lack of clinical staff availability, inadequate supplies of stationery and AEFI reporting forms, lack of allowances, and no dedicated fuel for transport of the AEFI reporting forms. Participants suggested that timeliness of investigations could be improved with faster identification and reporting of VREs to the district and national level.

"When a serious VRE is investigated, it goes from a facility level, to district and then national level. It is at the national level where it is delayed because the national level comes and conducts its own investigation" (**Health worker, South Region**).

Key informants noted that investigation findings were meant to be transmitted to the community, but this feedback did not often reach the community.

"*The challenge is that feedback [from the CAC] is not there in most cases unless it's a special case, for example when COVID-19 vaccine was just initiated there was feedback in most cases that were being reported and the reason could be because there were a lot of rumours (Non-AEFIs) so it was one way of clearing the rumour and also the VREs were new to health workers. For routine immunisation, feedback was not frequently done"* (**Health care worker, South Region**).

Considerations for non-AEFIs: Community and social listening

Participants in all three Regions highlighted the absence of guidance documents and assessments on community and social listening at the district and health facility level. In addition, a participant from South Region noted that HSAs also routinely receive social reports from community members and during health facility interactions.

"Each and every HSA is supposed to conduct assessment activities in their areas. We give our micro plans to the [Senior HSA] SHSA who compiles them and make a plan for the facility. On reports, every HSA writes a report when they find a VRE case and give it to the SHSA" (**Health worker, North Region**).

Community listening sessions varied by district, with some noting that these sessions are regularly conducted during bi-monthly outreach sessions or by mobile phones and others reporting no activities in the previous six months.

"These outreach clinics are done once or twice a month. As a facility, we do not have community listening tools but rather we get information through personal mobile phones as other community members have our phone numbers and they contact us anytime" (**Health worker, South Region)**

Health Facilities staff reported community listening conduits, including community meetings with local leaders, Facebook pages, Community Health Action groups (CHAG), Health Advisory Committee (HAC), Area Development Committee (ADC), Village Health Committees (VHCs), Village Development Committees (VDC), suggestion boxes, Health promoters, an ombudsman office at the facility and encouraging community to report anything to the nearest health facility or the HSAs in their catchment area. Supplemental resources during the COVID-19 pandemic supported community listening through a phone hotline, community listening sessions, or radio call-in shows.

"Sometimes we have panel discussions on community radios, we have three community radios … so sometimes we utilize these to have panel discussions where the community are given time to ask questions through phone calls and we respond to them immediately or we just give the message via the radio and I give my number so that in case someone has a question should call directly to me and be explained to individually" (Health worker, South Region).

Most participants stated that their Health Facilities do not produce social listening reports. Three participants, one from Central Region and two from South Region, noted that their district developed social listening reports. Each described a process of sharing social listening reports at district level with the HPO, DHO, and HMIS focal points, then disseminated either the social listening report or a strategy to address the VREs identified to HACs. Most participants indicated that informal social listening channels existed to address rumours through community engagement with local leaders, religious leaders and influential leaders, HAC, VDC, health education services like health talks, and community interface meetings.

"*We utilize the opportunity when there are local leader's meetings. [He] invites HSAs to his meetings and at some point… said that he wants his chiefs to be exemplary by getting vaccinated in their vaccination sites. Apart from this we established a committee known as Champions committee composed of chiefs, youths, women who got vaccinated of COVID-19 vaccine specifically all the 2 doses or booster. So, their main role is to sensitize the community on COVID-19 vaccine and dispelling all the rumours surrounding the vaccine"* (**Health worker, Central Region**).

Coordination mechanism

https://dx.doi.org/10.4314/mmj.v38i2.3

Table 1. Key Informant Interview participants by role and region.

Participant role	North	Central	South	Total
National and zonal coordinators	1	8	1	10
District level Expanded Programme on Immunisation (EPI) Coordinators	5	8	12	25
Integrated Disease Surveillance and Response (IDSR) Coordinators	4	7	10	21
Health Promotion Coordinators	1	4	2	7
Health facility staff	9	13	21	43
Health Surveillance Assistant	2	0	1	3
Total	22	40	47	109

Table 2: Focus Group Discussions Participants

District	Name of the selected Health Centre where FGD were done	Number of Participants
Blantyre	Mpemba	6
Dedza	Mua	5
Lilongwe	Nathenje	5
Mangochi	Kukalanga	5
Rumphi	Mzokoto	6
Salima	Lifuwu	6
Total		33

Table 3. VRE Documentation and Self-reported Investigation Capacity by Region.

Resource (Valid number of values)	Total n (%)	Region		
		Centre	North	South
DOCUMENTS				
List of reportable VREs (95)	74(77.9)	22(71.0)	22(95.7)	30(73.2)
Guidelines for VRE reporting (95)	58(61.1)	20(64.5)	11(47.8)	27(65.9)
Guidelines for VRE investigation (95)	31(32.6)	7(22.6)	7(30.4)	17(41.5)
Guidelines for causality assessment (95)	8(8.4)	4(12.9)	3(13.0)	1(2.4)
Community assessment plan (62)	10(16.1)	2(9.5)	3(21.4)	5(18.5)
Report of previously conducted assessment (62)	19(30.6)	4(21.1)	3(21.4)	12(44.4)
Social media monitoring SOP guidelines (62)	4(6.5)	0(0.0)	0(0.0)	4(14.8)
Social listening reports (62)	14(22.6)	2(9.5)	5(35.7)	7(25.9)
Crisis and risk communication plan (42)	4(9.5)	2(13.3)	0(0.0)	2(11.1)
Communication materials development plan (42)	6(14.3)	2(13.3)	0(0.0)	4(22.2)
Community engagement plan (103)	30(29.1)	11(31.4)	10(41.7)	9(20.5)
Agenda for the most recent meeting (95)	33(34.7)	6(19.4)	9(39.1)	18(43.9)

A well-functioning VRE response system requires strong coordination between both community members and the health system as well as within health system structures. In particular, health facility and district level coordination between surveillance and communication focal points requires strengthening for effective VRE response. The participant in the Central Region noted that training on VREs had only included HSAs and recommended expanding training offerings on VRE to the relevant communications and health promotions focal points. Some participants highlighted the availability and use of an overarching crisis and risk management plan as a crucial element of their successful coordination across stakeholders, while others cited the absence of this plan in their district as a barrier to proactive coordination. Some participants noted that their district team developed risk communication plans on an as-needed basis to tailor planning for the specific issue arising. These plans are implemented through local key stakeholders such as local leaders and can include dedicated resources for community engagement. In addition, these plans include components to equip volunteers:

"We do capacity building to either volunteers or healthcare workers such as HSAs. Sometimes we even go beyond HSAs to other cadres like clinicians and nurses depending on what issue we are handling" (**Health worker, Central Region**).

Media Engagement

VRE responses can also involve media engagement, either through the Health Education Unit at national level or the Health Education Promotion and District Information officer at district level. The Health Education Unit has a guideline that outlines what to expect and how to communicate whenever something new has happened. It also guides on the channels of communication and engagement that can be employed. All the Health Education and Health Promotion officers interviewed stated that they monitor the media and develop communications messages to rapidly respond to potential VREs. Media engagement also occurs through community radio Q&A programmes or media visits to health facilities or district offices. The Health Education Unit in the Ministry of Health conducts community mobilization, sensitization and produces promotional materials.

Participants identified funding sources to support VRE response. In South Region, a participant noted COVID-19 VRE plan implementation was supported with funding from international organizations, while another

https://dx.doi.org/10.4314/mmj.v38i2.3

Table 3 Cont

Minutes for recent covid assessment (94)	5(5.3)	1(3.2)	2(8.7)	2(5.0)
Social listening reports on non-VRE (62)	4(6.5)	1(4.8)	0(0.0)	3(11.1)
MATERIALS				
Social mobilisation materials (103)	75(72.8)	28(80.0)	16(66.7)	31(70.5)
Training materials (103)	55(53.4)	17(48.6)	12(50.0)	26(59.1)
AVAILABILITY OF TEAMS TO DO VRE ACTIVITIES				
Investigating VRE (95)	57(60.0)	19(61.3)	12(52.2)	26(63.4)
Assessing causality for VREs (95)	17(17.9)	7(22.6)	3(13.0)	7(17.1)
Responding to VREs (95)	80(84.2)	26(83.9)	18(78.8)	36(87.8)
Distinguishing between serious and non-serious VREs (95)	66(69.5)	19(61.3)	16(69.6)	31(75.6)
Responding to non-VREs (95)	61(64.2)	17(48.6)	12(50.0)	26(59.1)

AEFI: Adverse Events Following Immunisation, SOP: Standard Operating Procedure, VRE: Vaccine Related Event

Table 4. VRE reported by health facility across all antigens by type and by region from November 2022—March 2023.

		Region		
VRE (N = 75)	n(%)	Central (22) n(%)	North (22) n(%)	South (31) n(%)
Severe Local Reaction	13(17.3)	1(4.5)	7(31.8)	5(16.1)
Seizures	9(12.0)	0(0.0)	2(9.1)	7(22.6)
Abscess	56(74.7)	17(77.3)	13(59.1)	26(83.9)
Sepsis	7(9.3)	0(0.0)	2(9.1)	5(16.1)
Encephalopathy	0(0.0)	-	-	-
Toxic Shock Syndrome	0(0.0)	-	-	-
Thrombocytopenia	2(2.7)	2(9.1)	0(0.0)	0(0.0)
Anaphylaxis	1(1.3)	1(4.5)	0(0.0)	0(0.0)
Upper Respiratory Tract Infection (URTI)	3(4.0)	0(0.0)	2(9.1)	1(3.2)
Headache	26(34.7)	3(13.6)	9(40.9)	14(45.2)
Fever	58(77.3)	18(81.8)	18(81.8)	22(71.0)
Other	45(60.0)	9(40.9)	15(68.2)	21(67.7)

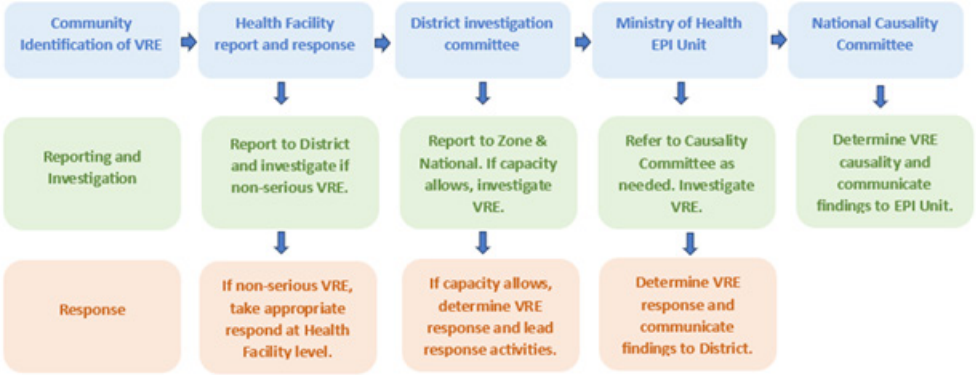

Figure 1. Vaccine Related Events (VRE) reporting, Investigation and response process, Malawi. EPI stands for Expanded Programme on Immunisation

https://dx.doi.org/10.4314/mmj.v38i2.3

Table 5. Key issues and findings identified through Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) by district, November 2022—March 2023

	Main Themes Key issue	Key findings	Verbatim examples	Districts mentioned
1.	Documentation for VRE planning, identification, reporting and response	List of reportable Adverse Events Following Immunisation (AEFIs) is available in almost all health facilities and AEFI reporting forms	*"Here, we have a list reportable AEFIs and also the AEFI reporting forms".*	Nsanje, Salima, Blantyre, Mangochi, Dedza, Mangochi, Mzuzu, Rumphi, Lilongwe, Kasungu
		Social listening is done in some districts and reports are generated	*"The social listening reports are very useful to us, and we always encourage speaking out on these issues because when going with interventions in the community, the issues that has been presented are incorporated so that the fears and challenges that may be there are cleared out."*	Rumphi, Mangochi, Kasungu
		Vaccine Related Events (VREs) plan not available	"We do not have a VRE plan"	Lilongwe, Mzuzu, Dedza, Rumphi, Salima, Zomba
		No documentation for rumours and community engagement	*"For rumours, we utilize the opportunity when there are local leader's meetings. These are informal and not documented".*	Mzuzu, Nsanje, Mangochi, Zomba, Kasungu, Dedza, Lilongwe, Rumphi
		Coronavirus Diseases 2019 (COVID-19) VRE plan available	"Yes, I have a copy of the COVID-19 VRE plan for Malawi".	Lilongwe
2.	Committees for VRE response	Causality assessment is done at national level. It is done by the Medicine Safety and Quality Monitoring Committee (MSQMC) at national level	*"Of course I can say, at the district we don't have the causality assessment team, in fact ours we do just the investigations. Causality assessment is done at national level".*	All the ten districts including Pharmacy and Medicines Regulatory Authority (PMRA)
		The health centres do not have VRE investigation committees.	*"Once the VRE has been identified as serious here at health centre, we report to the district for investigations".*	All the ten districts
		Health Centres are willing to establish VRE investigation committees	*"Despite not having an investigation committee, we are able and ready to investigate".*	Kasungu, Dedza, Rumphi
3.	VRE response Coordination and reporting	Formal structures for coordination and reporting available from health centre level	*"I know that the guidelines describe how we should organize ourselves, prepare for the investigations, things that would need to be investigated, seek help, report to the administration, etc. These are some of the things I can remember".*	All ten districts
		Coordination and reporting of VRE by-passes the zonal coordinators	*"As a zone we don't respond to AEFIs because we are not directly involved since the reports go straight to the national but the strength that we have is that we do capacity building by playing a supervisory role to see how things are going about and provide expertise".*	Mzuzu, Salima, Lilongwe
4.	Community listening	There are no formal structures for community listening; however, others use Health Advisory Committees, Community Health Action Groups and others like hotlines	*"We do not have formal written procedures for community listening and reporting…..".*	Dedza, Kasungu, Lilongwe, Mangochi, Mzuzu, Nsanje, Rumphi, Salima, Zomba
		Health Surveillance Assistants (HSAs) are supposed to do community listening	*"Each and every HSA is supposed to conduct community assessment and listening activities in their areas. We give our micro plans to the [Senior HSA] SHSA who compiles them and make a plan for the facility".*	Blantyre, Zomba, Mzuzu
5.	Media engagement	Mainly done at district level and national level by Health Promotion Officer (HPO). Health centre engagement is done after getting permission from the district	*"Media engagement is only done at national and district level by going through the health education unit which has a spokesperson who talks on behalf of the Ministry of Health".*	Mzuzu, Mangochi, Dedza, Zomba
6.	VRE response plan	All did not have the VRE plan except one officer in Lilongwe and Blantyre districts who had the COVID-19 VRE plan	*"I got the COVID-19 VRE plan during the meeting…".*	Lilongwe, Blantyre
		COVID-19 VRE plan is similar to what could be the plan for all antigens	*"VREs plan for COVID-19 vaccination needs to be inclusive of all the other vaccines……".*	Zomba, Nsanje, Salima, Mangochi, Lilongwe
7.	Challenges in VRE response	Delayed or no feedback form the district and national level on VRE investigations	*"The challenge is that feedback is not there in most cases unless if it's a special case…",*	All

participant from Central Region noted funding from Kamuzu University of Health Sciences. Others stated that their plans were either unfunded or that no funded source had been identified.

Discussion

We assessed Malawi's system readiness to implement a COVID-19 VRE response plan using a mixed methods assessment in ten districts representing all three Regions. We found that elements of the VRE response plan were being implemented, particularly pertaining to the subset of AEFIs. Over half of the visited facilities reported to have a list of reportable VREs and guidelines for reporting VREs while all the other documents were reported by less than half of the facilities. It was also found that facilities with a team to distinguish between serious and non-serious VREs and with VRE investigation guidelines had implemented more aspects of the VRE plan than facilities without these elements. There is limited literature on the implementation of the VRE response plan in the African setting, a study in Ghana documented processes to follow when developing the VRE plan[27]. It was interesting to note the differences between the nurses and clinicians in reporting the AEFIs as reported in the unpublished study done in Ghana. The study reported that community nurses and midwives reported more AEFIs than clinicians and similarly those with more experience also reported more AEFIs[28].

Participants highlighted the unmet need to implement cohesive VRE response plan framework at district and health facility level, particularly with regards to community and social listening, VRE investigation feedback to community, and communication between surveillance and communication pillars. In Malawi, the dissemination was not done widely. Participants also highlighted the need to strengthen the identification and response to non-AEFIs. Participants recommended strengthening and standardizing the safety surveillance and infoveillance systems, including the investigation flow process feedback. The recommendation concurs with the call for strengthening vaccine safety systems, research, and regional collaboration in Africa by the 8th meeting of the African Advisory Committee on Vaccine Safety held virtually in 2025[29]. To address reporting delays, there is a need to consider and use appropriate technologies for the rapid transmission for sensitive records. Other studies recommend a real time surveillance, however near real time initiatives would be ideal[30]. The real time data surveillance would be ideal but costly in terms of human and financial resources.

There is a need to invest in the sustained funding for VRE systems, particularly for community listening and community feedback mechanisms. Listening to patients in vaccination and safety is

https://dx.doi.org/10.4314/mmj.v38i2.3

Table 5 Cont...

8.	Community misinformation and myths	Community misinformation and myths	*"Some myths and misinformation affect vaccine uptake in the district".*	Lilongwe, Mangochi, Mzuzu, Dedza, Nsanje, Zomba
9.	Health facility training, coordination, and hesitation to report	Difficult for HSAs to report AEFIs from cases they themselves vaccinated	*"Some clients find it easy to report the VRE to HSAs but the HSAs sometimes do not report to use especially if they were the ones administering the vaccination".*	Lilongwe, Blantyre, Zomba
		Blame game between health worker cadres for low detection and reporting of VREs	*"…some cadres accuse others of causing VRE and also of not reporting them".*	Mzuzu, Kasungu, Mangochi and Zomba
10.	Lessons Learnt	Health Advisory Committee (HAC) helps in solving misinformation	*"During community meetings to discuss VREs, we involve HAC members because they stay in the community and are easily understood".*	Nsanje, Salima, Rumphi, Mzuzu, Blantyre, Dedza, Mangochi, Zomba
		Need to use non-technical language during media engagement, community engagement meeting and also during training of health workers	*"In addition to that, sometimes the media changes the meaning of the message that was intended for the communities because some messages are presented in technical terms…".*	Salima, Mangochi, Zomba, Mzuzu, Lilongwe, Dedza, Rumphi
		Solution to allowance culture is by holding meetings in communities	*"The community have great expectations that they will get allowances whenever they attend a community listening session outside their village".*	Dedza

important in increasing vaccine uptake[31].

These findings add to the literature by identifying system needs to implement a VRE response system in low- and middle- income countries. Similar concerns of reprisal were identified by health workers in Kenya[32] and highlight the need for both positive incentives to report VREs and regular training and mentorship to support health worker competencies in identifying VREs[33]. The challenges in terms of providing feedback and incomplete investigations were also reported in Zimbabwe, however, partnership between institutions involved in immunisations and the regulatory authority was reported to have improved the surveillance[34]. Phone applications have been successfully piloted to reduce delays in AEFI reporting and response in Germany[35]; technological solutions like this could be further explored in lower resource settings. System assessments in Nigeria and Kenya also identified budget constraints as a key barrier to successful implementation of these systems[32,33,36]. More research is needed to identify options to increase and sustain investment in VRE systems.

One key strength lies is the breadth of participants perspectives, with over 100 health workers interviewed, representing ten districts from the health facility to national level. It is the first assessment to evaluate Malawi's readiness to implement a VRE response system of which we are aware in an LMIC. However, several limitations should be considered. First, this assessment was cross-sectional and thus only represents the immediate time period following the development of Malawi's VRE response plan, when COVID-19 funding was still available in country but before widespread dissemination of the plan itself. The involvement of staff that is more engaged in vaccinations might have assisted to collect data from those directly involved in the delivery of vaccines and hence improved the data quality. In addition, the ten districts and participants were purposively selected and limits generalisability. The qualitative results provide context specific challenges in the VRE response system. However, results relating to the VRE reporting system and its challenges including delayed or lack of feedback on VRE investigation, the lack of committees and guidelines for VRE affecting services affect the whole country.

Conclusions

This system readiness assessment identified the need to strengthen processes and communication within the health system and with the community. To strengthen the AEFI-related structures, training for AEFI identification and reporting among healthcare workers at health facility level is recommended, including incentivizing AEFI reporting to overcome fear and reprimand. Having a VRE team or committee was also important in terms of the implementation of the VRE plan. Delays in reporting, investigation and feedback to the health facility and community were identified as crucial challenges in the current system. Developing an electronic reporting system would help to reduce delays. By fully implementing Malawi's VRE response plan, Malawi's health system can more readily identify, report, investigate and respond to VREs, safeguarding population health and bolstering confidence in vaccination.

Patents

Not Applicable

Supplementary Materials: Supplementary materials consist of Table on sample and Figure on study area. Transcripts and excel file are available upon request from the corresponding author.

Author Contributions: Save Kumwenda (SK) reviewed the protocol, data collection tools, collected data, conducted data analysis and produced the first draft and participated in revising the manuscript for final submission, Mphatso Nyamasauka (MN) collected data, conducted the qualitative data analysis and helped in writing draft manuscript, Davis Makupe (DM) participated in data collection, conducted qualitative data analysis and participated in draft manuscript writing, Sandra Machiri (SM) reviewed the protocol, helped in drafting the manuscript, Nenani Chisema (NC) participated in protocol development, data collection and drafting of the manuscript, Mavuto Thomas (MT) helped in community mobilization, data collection and participated in draft manuscript writing, Rhoda Chado (RC) assisted community mobilization for data collection, data analysis and participated in draft manuscript writing, Alvin Phiri (AP) helped in reviewing the protocol, data collection and participated in draft manuscript writing, and Atupele Kapito (AK) led the protocol development, data analysis, data collection and draft manuscript writing.

Funding: This assessment was funded by the Centers for Disease Control and Prevention.

Institutional Review Board Statement: Before data was collected the study was cleared by the National Health Research Ethics Committee (Protocol #23/02/3178). All subjects provided an informed written consent before participating in the study.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data in form of transcripts, recordings and excel file is available upon request to the corresponding author.

Acknowledgments

https://dx.doi.org/10.4314/mmj.v38i2.3

The authors wish to thank all participants for sharing their rich experiences with Vaccine-Related Event response in all levels of the health system. We also wish to thank the data collectors, particularly Dr. Robert Thindwa, Nyokase Phiri Msiska, Chrissy Soda, Brian Kapito, Daisy Mtonga, Mavuto Yesaya and Thoko Makuwira for their efforts to recruit and interview participants. We extend thanks to the US-CDC team for technical and financial support including Jane Gidudu, Nuadum Muriel Konne, Sandra Kiplagat, and Kimberly E. Bonner.

Conflicts of Interest

The authors declare no conflicts of interest.

References

(1)Vaccine Safety Communication: Guide for Immunization Programme Managers and National Regulatory Authorities; World health organization, Ed.; World health organization: Geneva, 2016.

(2)Nnaji, C. A.; Owoyemi, A. J.; Amaechi, U. A.; Wiyeh, A. B.; Ndwandwe, D. E.; Wiysonge, C. S. Taking Stock of Global Immunisation Coverage Progress: The Gains, the Losses and the Journey Ahead. International Health 2021, 13 (6), 653–657. https://doi.org/10.1093/inthealth/ihz120.

(3)Christou-Ergos, M.; Wiley, K. E.; Leask, J. Willingness to Receive a Vaccine Is Influenced by Adverse Events Following Immunisation Experienced by Others. Vaccine 2023, 41 (1), 246–250. https://doi.org/10.1016/j.vaccine.2022.11.034.

(4)Motta, M.; Stecula, D. The Effects of Partisan Media in the Face of Global Pandemic: How News Shaped COVID-19 Vaccine Hesitancy. Political Communication 2023, 40 (5), 505–526. https://doi.org/10.1080/10584609.2023.2187496.

(5)Ni, Y.; Xu, Z.; Wang, J. Understanding Vaccine Hesitancy with PCV13 in Children: Results of a Survey in Shanghai, China. PLOS ONE 2023, 18 (4), e0284810. https://doi.org/10.1371/journal.pone.0284810.

(6)World Health Organization. Vaccine Crisis Communication Manual: A Step-By-Step Guidance for National Immunization Programmes, 2022. https://iris.who.int/server/api/core/bitstreams/687b9eaa-e977-446b-9bf6-5bd051e3dd0e/content (accessed 2025-12-17).

(7)COVID-19 Vaccines: Safety Surveillance Manual, 1st ed.; World Health Organization: Geneva, 2020.

(8)Geoghegan, S.; O'Callaghan, K. P.; Offit, P. A. Vaccine Safety: Myths and Misinformation. Front. Microbiol. 2020, 11. https://doi.org/10.3389/fmicb.2020.00372.

(9)Islam, M. S.; Kamal, A.-H. M.; Kabir, A.; Southern, D. L.; Khan, S. H.; Hasan, S. M. M.; Sarkar, T.; Sharmin, S.; Das, S.; Roy, T.; Harun, M. G. D.; Chughtai, A. A.; Homaira, N.; Seale, H. COVID-19 Vaccine Rumors and Conspiracy Theories: The Need for Cognitive Inoculation against Misinformation to Improve Vaccine Adherence. PLoS One 2021, 16 (5), e0251605. https://doi.org/10.1371/journal.pone.0251605.

(10)Rzymski, P.; Borkowski, L.; Drąg, M.; Flisiak, R.; Jemielity, J.; Krajewski, J.; Mastalerz-Migas, A.; Matyja, A.; Pyrć, K.; Simon, K.; Sutkowski, M.; Wysocki, J.; Zajkowska, J.; Fal, A. The Strategies to Support the COVID-19 Vaccination with Evidence-Based Communication and Tackling Misinformation. Vaccines 2021, 9 (2). https://doi.org/10.3390/vaccines9020109.

(11)Whitehead, H. S.; French, C. E.; Caldwell, D. M.; Letley, L.; Mounier-Jack, S. A Systematic Review of Communication Interventions for Countering Vaccine Misinformation. Vaccine 2023, 41 (5), 1018–1034. https://doi.org/10.1016/j.vaccine.2022.12.059.

(12)Marco-Franco, J. E.; Pita-Barros, P.; Vivas-Orts, D.; González-de-Julián, S.; Vivas-Consuelo, D. COVID-19, Fake News, and Vaccines: Should Regulation Be Implemented? International Journal of Environmental Research and Public Health 2021, 18 (2). https://doi.org/10.3390/ijerph18020744.

(13)Amarasinghe, A. Global Manual on Surveillance of Adverse Events Following Immunization, Revised March 2016.; World Health Organization: Geneva, Switzerland, 2016.

(14)Asekun, A.; Nkwogu, L.; Bawa, S.; Usman, S.; Edukugho, A.; Ocheh, J.; Banda, R.; Nganda, G. wa; Nsubuga, P.; Archer, R.; Nebechukwu, T.; Mohammed, A.; Shuaib, F.; Bolu, O.; Adamu, U. Deployment of Novel Oral Polio Vaccine Type 2 under Emergency Use Listing in Nigeria: The Rollout Experience. Pan Afr Med J 2023, 45 (Suppl 2), 3. https://doi.org/10.11604/pamj.supp.2023.45.2.38033.

(15)Ministry of Health. COVID 19 Vaccine Related Events Response Plan (2022 - 2024), 2022.

(16)Ansah, N. A.; Weibel, D.; Chatio, S. T.; Oladokun, S. T.; Duah, E.; Ansah, P.; Oduro, A.; Hollestelle, M.; Sturkenboom, M. Barriers and Strategies to Improve Vaccine Adverse Events Reporting: Views from Health Workers and Managers in Northern Ghana. bmjph 2025, 3 (1). https://doi.org/10.1136/bmjph-2024-001464.

(17)Kumar, S.; Singh, S. P.; Gupta, A.; Rao, Y.; Taneja, S. Vaccine Adverse Events Reporting System Globally. Int J Biomed Res 2016, 7 (3).

(18)Mungwira, R. G.; Maure, C. G.; Zuber, P. L. F. Economic and Immunisation Safety Surveillance Characteristics of Countries Implementing No-Fault Compensation Programmes for Vaccine Injuries. Vaccine 2019, 37 (31), 4370–4375. https://doi.org/10.1016/j.vaccine.2019.06.018.

(19)Tsu, V. D.; LaMontagne, D. S.; Atuhebwe, P.; Bloem, P. N.; Ndiaye, C. National Implementation of HPV Vaccination Programs in Low-Resource Countries: Lessons, Challenges, and Future Prospects. Preventive Medicine 2021, 144, 106335. https://doi.org/10.1016/j.ypmed.2020.106335.

(20)Manual for Surveillance of Events Supposedly Attributable to Vaccination or Immunization in the Region of the Americas - PAHO/WHO | Pan American Health Organization. https://www.paho.org/en/documents/manual-surveillance-events-supposedly-attributable-vaccination-or-immunization-region (accessed 2025-12-21).

(21)Rahmadhan, M. A. W. P.; Handayani, P. W. Challenges of Vaccination Information System Implementation: A Systematic Literature Review. Human Vaccines & Immunotherapeutics 2023, 19 (2), 2257054. https://doi.org/10.1080/21645515.2023.2257054.

(22)Lubanga, A. F.; Bwanali, A. N.; Munthali, L.; Mphepo, M.; Chumbi, G. D.; Kangoma, M.; Khuluza, C. Malawi Vaccination Drive: An Integrated Immunization Campaign against Typhoid, Measles, Rubella, and Polio; Health Benefits and Potential Challenges. Human Vaccines & Immunotherapeutics 2023, 19 (2), 2233397. https://doi.org/10.1080/21645515.2023.2233397.

(23)Africa CDC. Africa CDC - COVID-19 Daily Updates. Africa CDC. https://africacdc.org/covid-19/ (accessed 2023-09-24).

(24)WHO and UNICEF. Estimates of Immunization Coverage in Malawi: 2022; 2023. www.data.unicef.org.

(25)World Health Organization. Regional Office for Europe. Vaccine Safety Events: Managing the Communications Response: A Guide for Ministry of Health EPI Managers and Health Promotion Units, 2013. https://iris.who.int/items/a0d08aa4-16bd-4140-8569-b06455457b48 (accessed 2025-12-22).

(26)Organization, W. H. Adverse Event Following Immunization, Aide-Mémoire on Causality Assessment. Geneva: WHO 2014.

(27)Darko, D. 1; Seaneke, S. 1; Nkansah, E. 1; Sabblah, G. T. 1; Appiah, R. E. 1; Ashie, A.; Amoakohene, A. A.; Ewudzie-Sampson, J.; Achiano, K. A.; Mohammed, N. T. F.; Drugs Authority, A. Development of Vaccine Related Event (VRE) Response Plan: A Case Study of Ghana. 2024, 1423–1424.

(28)Ampon-Wireko, S.; Laar, S. D.-P.; Nkrumah, J. K. Factors Affecting the Reporting of Adverse Event Following Immunization in Ahafo Region of Ghana. medRxiv December 30, 2025, p 2025.12.29.25343182.

https://doi.org/10.64898/2025.12.29.25343182.

(29)Tagbo, B. N.; Ejekam, C. S.; Oppong-Amoako, W.; Yameogo, T. M.; Mitiku, A.; Esangbedo, D. O.; Khuzwayo, N.; Mahlangu, G.; Badar, S. M.; Agbenu, E. A.; Adechina, R. M.; Nyarko, K. A.; Tagbo, B. N.; Ejekam, C. S.; Oppong-Amoako, W.; Yameogo, T. M.; Mitiku, A.; Esangbedo, D. O.; Khuzwayo, N.; Mahlangu, G.; Badar, S. M.; Agbenu, E. A.; Adechina, R. M.; Nyarko, K. A. Strengthening Vaccine Safety Systems, Research, and Regional Collaboration in Africa: A Call to Action. Vaccines 2025, 13 (6). https://doi.org/10.3390/vaccines13060661.

(30)Lieu, T. A.; Kulldorff, M.; Davis, R. L.; Lewis, E. M.; Weintraub, E.; Yih, K.; Yin, R.; Brown, J. S.; Platt, R.; Team, for the V. S. D. R. C. A. Real-Time Vaccine Safety Surveillance for the Early Detection of Adverse Events. Medical Care 2007, 45 (10), S89. https://doi.org/10.1097/MLR.0b013e3180616c0a.

(31)Holt, D.; Bouder, F.; Elemuwa, C.; Gaedicke, G.; Khamesipour, A.; Kisler, B.; Kochhar, S.; Kutalek, R.; Maurer, W.; Obermeier, P.; Seeber, L.; Trusko, B.; Gould, S.; Rath, B. The Importance of the Patient Voice in Vaccination and Vaccine Safety—Are We Listening? Clinical Microbiology and Infection 2016, 22, S146–S153. https://doi.org/10.1016/j.cmi.2016.09.027.

(32)Masika, C. W.; Atieli, H.; Were, T. Knowledge, Perceptions, and Practice of Nurses on Surveillance of Adverse Events Following Childhood Immunization in Nairobi, Kenya. BioMed Research International 2016, 2016, e3745298. https://doi.org/10.1155/2016/3745298.

(33)Omoleke, S. A.; Bamidele, M.; Kiev, L. C. de. Barriers to Optimal AEFI Surveillance and Documentation in Nigeria: Findings from a Qualitative Survey. PLOS Global Public Health 2023, 3 (9), e0001658. https://doi.org/10.1371/journal.pgph.0001658.

(34)Pm Nyambayo, P.; Manyevere, R.; Chirinda, L.; N Zifamba, E.; F Marekera, S.; Nyamandi, T.; Mehta, U.; S Gold, M. Descriptive Research Study of the Adverse Events Following Immunization (AEFIs) Surveillance System in Zimbabwe. CCRS 2023, 2 (2). https://doi.org/10.59657/2837-2565.brs.23.023.

(35)Nguyen, M. T. H.; Ott, J. J.; Caputo, M.; Keller-Stanislawski, B.; Klett-Tammen, C. J.; Linnig, S.; Mentzer, D.; Krause, G. User Preferences for a Mobile Application to Report Adverse Events Following Vaccination. Die Pharmazie - An International Journal of Pharmaceutical Sciences 2020, 75 (1), 27–31. https://doi.org/10.1691/ph.2020.9734.

(36)Omoleke, S. A.; Getachew, B.; Isyaku, A.; Aliyu, A. B.; Mustapha, A. M.; Dansanda, S. M.; Kanmodi, K. K.; Abubakar, H.; Lawal, Z. I.; Kangiwa, H. A. Understanding and Experience of Adverse Event Following Immunization (AEFI) and Its Consequences among Healthcare Providers in Kebbi State, Nigeria: A Qualitative Study. BMC Health Services Research 2022, 22 (1), 741. https://doi.org/10.1186/s12913-022-08133-9.