



**NOVEL ORAL POLIO VACCINE
TYPE 2 (nOPV2)
VACCINE RELATED EVENT (VRE)
RESPONSE PLAN**

Contents

Contents.....	1
1. ACRONYMS.....	3
2. BACKGROUND.....	3
VRE definition and types.....	3
Why does VRE preparedness matter and what is its linkage to nOPV2 roll out under EUL?.....	4
About this document.....	5
How this document should be used.....	5
3. PREPARE: Preparing for and preventing a VRE.....	5
AEFI surveillance stakeholder engagement activities.....	6
Map AEFI surveillance stakeholders.....	6
Develop an AEFI surveillance stakeholder engagement plan.....	6
Strengthen communication response to VRE.....	6
Develop a VRE communication plan.....	6
Map media outlets.....	6
Develop a media engagement plan.....	7
Develop a crisis communication plan.....	7
Community engagement.....	7
Develop a community engagement plan.....	8
Healthcare worker engagement.....	8
Develop an HCW engagement plan.....	8
4. DETECT: Detecting VRE.....	8
Strengthen AEFI and AESI surveillance.....	8
Strengthen media and social media “listening” and analysis.....	9
Assess caregiver and community perceptions regarding immunization.....	10
VRE investigation.....	10
Steps for investigating AEFI and AESI.....	10
Steps for investigating non-AEFI VRE.....	10
Assess VRE impact: low, medium, or high-impact VRE.....	11
5. RESPONDING TO A VRE.....	13
Response for AEFI or AESI VRE.....	14
Response for low-impact AEFI or AESI VRE.....	14
Response for medium-impact AEFI or AESI VRE.....	14

Response for high-impact AEFI or AESI VRE	15
Response for non-AEFI or AESI VRE	16
Response for low-impact non-AEFI or AESI VRE	16
Response for medium-impact non-AEFI or AESI VRE	16
Response for high-impact non-AEFI or AESI VRE	16
6. SUSTAIN: POST VRE	17
VRE response evaluation	17
Policy development	17
7. ANNEXES	18
Sample AEFI surveillance stakeholder engagement strategies	18
Sample media engagement strategies.....	18
Sample community engagement strategies	19
Sample HCW engagement strategies.....	19
Sample AEFI surveillance strengthening strategies	19
VRE investigation and risk communication flowchart	19
nOPV2 communications products to assist with country planning.....	20
nOPV2 Readiness Checklist Tool: Advocacy, Communication, and Social Mobilization Requirements and Considerations	20
nOPV2 Readiness Checklist Tool, Vaccine Safety Requirements and Considerations.....	24
8. References	28

1. ACRONYMS

ACSM	Advocacy, Communication, and Social Mobilization
AEFI	Adverse Event Following Immunization
AESI	Adverse Events of Special Interest
AFP	Acute Flaccid Paralysis
C4D	Communications for Development
EPI	Expanded Programme on Immunization
EUL	Emergency Use Listing
GPEI	Global Polio Eradication Initiative
HCW	Health Care Worker
MICS	Multiple-Cluster Indicator Surveys
MOH	Ministry of Health
nOPV2	Novel Oral Polio Virus Vaccine
UNICEF	United Nations Children’s Fund
VAPP	vaccine-associated paralytics polio
VRE	Vaccine Related Event
WHO	World Health Organization

2. BACKGROUND

VRE definition and types

Vaccine-related events (VRE) are “events related to vaccines that can negatively affect a vaccination program.” The six types of VRE are: an adverse event following immunization (AEFI), a new study or experimental data related to vaccines or immunization, a press report or local rumor about vaccines, a temporary suspension of a vaccine, a vaccine recall, or a replacement of a vaccine (World Health Organization Regional Office for Europe, 2013). AEFI are any untoward medical occurrence which follows immunization, and which do not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease (World Health Organization, 2018). Adverse Events of Special Interest (AESI) are a subset of AEFI that typically fall under one of the following categories: 1. proven association with immunization in general; 2. proven association with a vaccine platform and/or adjuvant; 3. theoretical concern based on immunopathogenesis; 4. theoretical concern related to viral replication during wild type disease; and 5. theoretical concern due to demonstrated event(s) in an animal model with one or more candidate vaccine platforms.

In this document, VREs are broken down into two types:

AEFI/AESI VRE: This is a vaccine-related event stemming from an AEFI or AESI that has been reported to the health system using appropriate channels (e.g. AEFI reported by caregiver/healthcare worker at a health facility, and an AEFI Reporting Form created; AESI identified through active surveillance and reported via the AESI Reporting form) where a specific affected individual or group of individuals and location is defined.

Non-AEFI/AESI VRE: These can include: a new study or experimental data related to vaccines or immunization; a press report or local rumor about vaccines; a temporary suspension of a vaccine; a

vaccine recall; replacement of a vaccine. However, the most common non-AEFI/AESI VRE will be a press report or local rumors about nOPV2. Some AEFIs/AESIs may be reported informally or brought to the attention of the routine immunization or polio program from social listening or community engagement activities, when there is a rumor or unverified report of an AEFI/AESI occurring (e.g. picture of children paralyzed by OPV circulating on WhatsApp). These types of informal AEFI/AESI reports may emerge on social media and tend to highlight more serious or severe outcomes linked to immunization (e.g. paralysis, death), where it is not often clear who was affected, or where, but wider dissemination of the informal report has potential to impact the immunization program. These AEFIs/AESIs should be confirmed if the immunization program has reason to suspect that they are authentic. If they are inauthentic and gain traction across more communities or platforms, or increase in volume, these rumored AEFIs/AESIs need to be corrected for the record to protect trust and confidence in the vaccine and the immunization program.

Why does VRE preparedness matter and what is its linkage to nOPV2 roll out under EUL?

VRE preparedness safeguards an immunization program's reputation. Preparedness can help ensure that information reaches affected people and communities quickly, and that coordinating mechanisms within government and among stakeholders work together smoothly to offer a united response, delivering on the government's promise to offer safe, effective vaccines for all those who need them. Adequate and timely response to VRE is critical for mitigating long-term impacts on confidence in the immunization system.

Although wild poliovirus is endemic in only two countries, dozens of vaccine-derived poliovirus outbreaks have occurred to date. Fears about vaccine safety and low acceptance of OPV have contributed to low immunization coverage, prolonging poliovirus circulation in country by several years and continuing to subject children to risk of vaccine-associated paralytic polio paralysis as an AEFI. Although the use of nOPV2 is designed to minimize risk of mutation that would lead to vaccine-associated paralytic polio (VAPP), some nOPV2-specific rollout concerns include: community resistance about a vaccine being introduced under Emergency Use Listing (EUL); community resistance if vaccine is temporally associated with acute flaccid paralysis (AFP) cases; a new manufacturing process which includes genetic modification and may not have obtained *halal* (*i.e.*, meat prepared as prescribed by Muslim law) certification or meet similar purity standards; potential for vaccine failure due to abbreviated efficacy and safety record compared to a vaccine that has been in use for decades. It is especially important that the nOPV2 VRE plan anticipates all these scenarios.

There have been no significant safety signals associated with nOPV2 thus far, though data is limited. Based on summary safety data from the World Health Organization a number of conditions are likely to be of interest for nOPV2 AEFI and AESI surveillance. Active AESI surveillance during the initial 2 rounds of nOPV2 use will help detect more complex adverse events that may be anticipated based on what is currently known about nOPV2, while passive AEFI surveillance, which will be ongoing before and after nOPV2 campaigns, will be particularly important in detecting unexpected events.

Although all vaccine introductions and routine use are subject to vaccine related events, nOPV2 use under EUL adds unique dimensions to the vaccine safety and AEFI surveillance work that have implications for public communication and engagement. Demand and crisis communication strategies,

developed at the country level and aligned with GPEI guidance, will consider and plan for some of these dimensions.

About this document

In this document, we synthesize global and regional guidance on AEFI surveillance, nOPV2 AESI surveillance (Centers for Disease Control and Prevention, 2020), and vaccine safety and VRE communication (Global Advisory Commission on Vaccine Safety, 2020) (World Health Organization Regional Office for Europe, 2013). This document also connects to GPEI nOPV2 Strategic Communication Guidance, communications planning tools for cVDPV outbreak response including the use of nOPV2 (Annex 7.7) and specific Readiness Checklist activities for nOPV2 use under EUL (Annexes 7.8 and 7.9) (e.g. from annex 7.9: “the nOPV2 vaccine-related event (VRE) response plan has been adapted to the country context, with stakeholder roles/responsibilities outlined” (item F4)). The Readiness Checklist outlines requirements for using nOPV2 under EUL. As AEFI are distinct from the other VRE types, we have further sub-divided actions based on whether a VRE is an AEFI VRE or a non-AEFI VRE. As AESI are a subset of AEFI, throughout the document when AEFI is mentioned, AESI are implied.

How this document should be used

This VRE Response plan is intended to be used by vaccine safety focal persons, such as the Vaccine safety coordinator, working in conjunction with communications focal persons. Some of the activities described below are best practices for a VRE response. In the context of nOPV2 use under EUL, these activities, particularly the communications-focused activities, will be folded into the communications planning tools for cVDPV outbreak response including the use of nOPV2. Because this document is primarily meant for vaccine safety focal points who may not have extensive communications exposure to aid them in all types of VRE response planning activities, explanations of suggested activities, the reasons why, and explicit linkages to related guidance documents where communications staff would take the lead in the public response are made. GPEI has developed several strategic communications guidance documents. Vaccine safety focal points should refer directly to the communications planning tools for cVDPV outbreak response including the use of nOPV2 for additional details regarding communication activities and coordinate with crisis communication focal points on issues of joint concern.

3. PREPARE: Preparing for and preventing a VRE

In this section we describe routine, ongoing activities for preparing for and preventing both AEFI/AESI and non-AEFI/AESI VRE. The activities described here tie directly to the nOPV2 country readiness requirements, specifically the Advocacy, Communication, and Social Mobilization (ACSM) activities (Annex 7.8) and the nOPV2 vaccine safety readiness activities (Annex 7.9). However, the section below provides critical guidance specific to VRE that should be implemented as part of those country readiness activities. Vaccine safety focal points should refer directly to the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use for additional details regarding communication activities.

AEFI surveillance stakeholder engagement activities

Map AEFI surveillance stakeholders

AEFI surveillance stakeholders have a leadership role or a stake in the outcome of an AEFI event, investigation or response at the central and peripheral levels. Stakeholders can include the Ministry of Health, the Expanded Program on Immunization, the National Drug Regulatory Authority, governmental structures, the pharmaceutical industry, health care worker associations (such as doctors and nurses in public and private settings), the media, the public, and the affected patient/family/community. Gather information on AEFI stakeholders and create a list of names and contact information. The list of AEFI stakeholders may have some overlap with general nOPV2 roll out under EUL stakeholders but also may include stakeholders not reflected elsewhere in general communications planning, such as national or regional regulatory authorities or technical advisory groups.

Develop an AEFI surveillance stakeholder engagement plan

In coordination with stakeholders, assign roles and responsibilities and create a regular rhythm of activities, monitoring, and feedback related to strengthening AEFI surveillance and response. Establish regular touchpoints to address AEFI-related topics, usually in the context of larger immunization-related professional consultations for the stakeholders identified through mapping activities. As part of nOPV2 readiness activities for advocacy, communications and social mobilization (ACSM)—specifically, the country-level advocacy strategy—engagement with medical practitioners, health officials and managers, pediatric societies, religious and community leaders, local governments, and other opinion makers should be conducted. Refer to Annex 7.1 for additional specific strategies for stakeholder engagement.

Strengthen communication response to VRE

A comprehensive country-level vaccine safety communication plan will include ongoing routine risk communication and crisis communication components. The activities described below should align with the nOPV2 readiness Advocacy, Communication, and Social Mobilization (ACSM) activities. Specific guidance for these activities will be provided in the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use (Annex 7.7).

Develop a VRE communication plan

A VRE communication plan should include the following components: background, goals, objectives, target audience, messages, strategy, time frame, budget, monitoring and evaluation (World Health Organization Regional Office for Europe). For nOPV2 introduction, there will not be a standalone VRE communication plan. A plan for communicating about VRE will be incorporated into the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use. It is important to ensure alignment between the different components described in this document and components in plans by Ministry of Health, the immunization program and partners playing a leading role in risk communication or demand generation (i.e. WHO, UNICEF, civil society organizations). Please refer to Annex 7.7 for a list of GPEI nOPV2 communications reference and guidance documents that have been designed to assist with this planning.

Map media outlets

Major media outlets include print (newspaper and magazines), broadcast (television and radio), and internet-based media. The process for mapping media outlets includes gathering information in order to create a simple table outlining major media outlets, their circulation, slant, key journalists and

their area of specialization that cover general interest, health, scientific and related topics nationally and sub-nationally. Regional media or media specific to a linguistic or ethnic group or at-risk population can be included to ensure coverage. There will not be a standalone activity, led by vaccine safety staff, to map media outlets. Refer to the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use for how this activity will be carried out in the context of nOPV2 roll out under EUL. Note that the overlap may be large with a general mapping of media outlets targeted for nOPV2 introduction but may also include specialty publications respected in the scientific and medical community that can be used to bolster a credible general communications response.

Develop a media engagement plan

Media engagement should be captured in the crisis communication plan that the country creates/has in place for cVDPV response including nOPV2 (please see guidance documents in Annex 7.7), and in the country's ultimate communications plan, which is a component of nOPV2 readiness ACSM activities (Annex 7.8). However, due to the non-routine nature of nOPV2 vaccine use under EUL, special care may need to be taken to sensitize journalists to the science and rationale for use of nOPV2 under EUL. Many mass media journalists may not have specific training in covering health or scientific issues and may have difficulty reporting accurately on nOPV2 use under EUL without additional engagement and training on the more technical aspects of nOPV2 roll out. From a vaccine safety perspective, consider conducting more targeted engagement of journalists and media on specialized medical or health beats that can write accurately about more technical issues.

Develop a crisis communication plan

As described in the nOPV2 Readiness checklist, "a crisis communications plan has been developed and the plan addresses the needs identified in the nOPV2 VRE response plan for AEFI and possible public controversy (including tailored content to respond to misinformation on social media)." Some of the activities involved in developing a crisis communication plan include establishing a crisis communications team, identifying internal and external partners to inform when a crisis occurs, identifying and media-training spokespersons that will communicate during the crisis (long before the crisis), informing internal and external partners about designated spokespersons, and developing a workplan and staffing for responding to the crisis (World Health Organization Regional Office for Europe, 2013). There will not be a standalone VRE crisis communication plan, but instead, a VRE plan should be developed as part of overall crisis communication planning. The Ministry of Health, partners and UNICEF have developed the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use (Annex 7.7).

Community engagement

Regular ongoing community engagement on a wide array of vaccine topics is important and should be included in any general communications or demand plan, developed in conjunction with MOH, GPEI and other routine immunization stakeholders. It is expected that these organizations have already mapped out trusted community leaders at the national, regional and local level. This should be reflected in each country's crisis communication for cVDPV response, including nOPV2.

When speaking to the community about vaccine safety, in order not to spur unwarranted concerns, staff should speak about safety in context of benefits versus risk of vaccination, and about the diseases the vaccines prevent. Vaccine safety will rarely become a solo topic in community discussions unless a major vaccine safety concern emerges and needs to be directly addressed. In the crisis communication plan

that the country creates/has in place for cVDPV response including the use of nOPV2, it may be appropriate to involve vaccine safety focal points in activities to effectively address community concerns in scenarios involving community engagement in the event of a vaccine safety issue

Develop a community engagement plan

A community engagement plan will be developed as part of the nOPV2 readiness ACSM activities, as described in the Strategic Communications Guidance for cVDPV Outbreak Response Including the Use of nOPV2 (Annex 7.8). Sample community engagement activities are also described in Annex 7.3. There will not be a standalone VRE community engagement plan, as this activity will be incorporated into the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use.

Healthcare worker engagement

Develop an HCW engagement plan

Frontline healthcare workers play a pivotal role in vaccine safety. Gaps in awareness on AEFI response and investigation principles can be identified and addressed through activities such as trainings or development of job aids. Trainings for frontline healthcare workers are part of the Strategic Communications Guidance for cVDPV Outbreak Response Including the Use of nOPV2 (Annex 7.8). The GPEI is also developing a frontline healthcare worker nOPV2 training module. Additional sample healthcare worker engagement activities are also described in Annex 7.4. There will not be a standalone VRE HCW engagement plan, as this activity will be incorporated into the country communications plan for cVDPV response including nOPV2 use.

4. DETECT: Detecting VRE

Strengthening VRE surveillance includes addressing both AEFI and non-AEFI VRE.

Strengthen AEFI and AESI surveillance

The AEFI surveillance cycle includes AEFI detection, notification, investigation, analysis, causality assessment and feedback and corrective action (World Health Organization). All AEFI detected through the health care system should be documented, notified and reported to the Expanded Program on Immunization and national drug regulatory authority using an AEFI Reporting Form.

Strengthening each component of this cycle will enhance the ability to respond to AEFI. AEFI investigation, analysis, causality assessment, and feedback and corrective action will be discussed later in this document.

As part of the “Implementation steps prior to nOPV2 use” countries should ensure national-level AEFI surveillance guidelines exist, establish an independent national advisory committee for safety/causality assessment (if not already present), provide training on nOPV2, and conduct national and subnational-level WHO training in AEFI investigation, among other activities (Annex 7.9). Additionally, training materials, guides, and reporting forms should be developed and/or updated to include aspects particular to nOPV2.(Annex 7.9).

Figure 1. AEFI Surveillance Cycle



Active nOPV2 AESI surveillance will occur for the first two rounds of nOPV2 use. As AESI are a subset of AEFI, the AESI surveillance cycle mirrors the AEFI surveillance cycle described above (Figure 1). Prior to initiation of active AESI surveillance, a number of activities will take place, including the development of AESI tools and data systems and training of surveillance and causality assessment staff. For additional information, please refer to the Guide to Surveillance for Adverse Events of Special Interest during nOPV2 use (Centers for Disease Control and Prevention, 2020).

Strengthen media and social media “listening” and analysis

Media and social media “listening” will strengthen the ability to detect VRE. This activity can serve as an early-detection mechanism to identify potential issues before they mushroom into larger societal vaccine safety concerns, especially those not rooted in an adverse event reported into the health system. Social media especially can amplify and multiply misinformation around vaccine safety events through different networks, driving traditional media coverage of vaccine safety topics. It can also point to related issues about awareness and safety of immunization among specific groups, the general population’s trust and confidence in the government, the Ministry of Health, vaccines and the vaccinators. As part of nOPV2 ACSM readiness activities, GPEI partners or government partners should monitor social media for rumors, opinions, and perceptions about immunization, vaccines and vaccine safety concerns (Annex 7.8). There will not be standalone VRE-specific listening and analysis, as this activity will be incorporated into the country communications plan for cVDPV response including nOPV2 use.

Assess caregiver and community perceptions regarding immunization

Identifying and quantifying public concerns surrounding vaccines through community engagement, cross-sectional surveys and monitoring of community opinion and preferences, as well as social media will help assess caregiver and community perceptions regarding immunization (Global Advisory Commission on Vaccine Safety, 2020). These can both be quantitative (i.e. surveys; UNICEF's Multiple-Cluster Indicator Surveys (MICS)) or qualitative (i.e. observation of immunization sessions; focus group discussions) in nature. Countries can also go back to existing EPI data, reflections from past campaigns or Coverage Evaluation Surveys.

It is important to ensure perceptions are captured from at-risk and vulnerable communities, where vaccine safety concerns may manifest with fewer linkages to information networks and the health system. If funds permit, consider regular assessments to map trends over time.

If not already complete, caregiver and community perceptions should be assessed as part of nOPV2 ACSM readiness activities (Annex 7.8).

VRE investigation

VRE investigation includes both AEFI and non-AEFI VRE.

Steps for investigating AEFI and AESI

A detailed AEFI investigation should be undertaken for AEFI that fit at least one of the following criteria: serious AEFI; part of a cluster; part of a suspected signal; suspected immunization error; is on a list of events defined for AEFI investigation; or causes significant parental or public concern (World Health Organization).

Each country should investigate AEFI according to the procedures described in their AEFI surveillance guidelines. Steps to undertake include: obtain information from the patient and/or caregiver, obtain information from the immunization service provider and medical care service providers, inquire about vaccines and drugs administered, establish a more specific case definition if needed, investigate other vaccines, investigate the AEFI in unvaccinated persons, formulate a hypothesis as to what may have caused the AEFI, and collect specimens as appropriate. For a more comprehensive list of steps involved, refer to the WHO Aide-Memoire on AEFI investigation (World Health Organization).

The investigation of AESI will take place according to methods described in the Guide to Surveillance for Adverse Events of Special Interest during nOPV2 use (Centers for Disease Control and Prevention, 2020). All AESI cases will be investigated and causality assessed, if temporally linked to vaccination. Causality assessment is a systematic evaluation to determine the likelihood that an event might have been caused by a vaccine or vaccination.

Steps for investigating non-AEFI VRE

Depending on the non-AEFI VRE type, different steps will be involved in its investigation.

For example, investigation into a new study or vaccine recall VRE will involve ensuring public health experts becoming knowledgeable on the new study or the vaccine involved in the recall. Some information to gather include indications of serious, dreaded, dramatic or memorable safety events implied by the new study or recall, the involvement of pregnant people or children, and the relevancy of the event to the public in the country (World Health Organization Regional Office for Europe, 2013).

For a rumor or media report VRE, gathering the above information will be useful, and likely should be captured in planning social listening activities under the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use. Specific additional information to gather include audience size, the credibility/believability of the rumor or media story and whether the event or information plays on emotional fears. For a rumor VRE, public health communication experts will need to investigate the source and spread of the rumor. For a media report, these experts will need to understand the spread of the report and speak to the media group that initiated the report if possible.

For a social media-amplified rumored VRE, determining the veracity, reach of audience, author, and source may be much more difficult, especially if the report emerges from closed networks such as encrypted messaging platforms (i.e. WhatsApp) or closed groups (i.e. Facebook private group). The speed of information-travel using non-traditional platforms highlights the need to act quickly, though tracing the veracity of non-AEFI VRE can be challenging. Communications focal points should be central to these investigations.

If the rumor or press report indicated that persons experienced AEFI, public health experts may undertake the steps involved in the AEFI surveillance cycle (Figure 1), such as notifying the EPI program about the AEFI, filling out an AEFI report, and investigating the AEFI if appropriate. A similar AESI-specific investigation should take place.

Assess VRE impact: low, medium, or high-impact VRE

It is important to assess the potential negative impact a VRE can have on the vaccination program as this will inform the decision to communicate or not communicate regarding the VRE. A rapid assessment of potential impact can be conducted based on monitoring, social and epidemiologic data. It is critical that this activity is conducted as a joint activity involving vaccine safety focal points and communication focal points. There are two issues to address by both vaccine safety and communication focal points: public health response and reputational risk. However, vaccine safety focal points will be primarily concerned with mounting an effective public health response (e.g. investigating events as per AEFI/AESI surveillance guidelines, adhering to nOPV2 EUL use protocols, reporting to regulatory authorities). Communications focal points will be primarily concerned with mitigating reputational damage to the routine immunization program or polio program (e.g. crisis communication, demand generation), which can harm confidence in vaccines and undermine a campaigns success and affect uptake of future vaccines.

Some factors to consider when assessing impact include: whether the event had unknown or uncertain causation, if it was a serious, dreaded, dramatic, or memorable event, whether it was part of a mass immunization campaign, if the event involved a new vaccine, whether the event was an AESI, if the event was relevant and salient to the public, could there be media attention, and whether the event or information play on emotional fears (World Health Organization Regional Office for Europe, 2013). Other factors to consider include the involvement of pregnant people or children, credibility and believability of a rumor or media story, and size of the audience (i.e., readership, viewership, Twitter following, etc.).

Table 1 below highlights the potential impact of various VRE types on the vaccination program. Please note that the table below is part of WHO Regional guidance and the severity of VRE impact will need to be modified based on country-specific considerations (World Health Organization Regional Office for

Europe, 2013). Please note that this table is a starting point for country level discussions. What constitutes a low, medium, or high impact VRE must be tailored to the country context.

Note that even if a VRE is classified as low impact, it can escalate and move from low to medium to high very quickly; rarely does a high-impact VRE downgrade to a medium or low impact event. This underscores the importance of re-evaluating the impact and level regularly as new information is received. It is also likely that a low-impact VRE will be localized and may be best addressed at the sub-national level, whereas a medium or high-impact VRE can be expected to have more widespread impact, which will likely require a national level response.

Table 1: Assessing VRE impact



Increasing public attention to event and increasing impact on public trust

Potential Negative Impact on the Vaccination Programme (and Type of Response Required)			
Type of Event	Low	Medium	High
Vaccine reaction (AEFI or AESI)	<ul style="list-style-type: none"> - Reaction is not serious or dramatic - Reaction is serious but not relevant to the public (e.g. in another country with a vaccine not used in our programme) 	<ul style="list-style-type: none"> - Serious reaction in my country - Serious reaction with some relevance to public (e.g. in another country with a vaccine used in our programme) - Anticipated media attention - Reaction among children, teenagers, pregnant people 	<ul style="list-style-type: none"> - Actual media attention - Serious reaction(s) with unknown cause - Reaction that is dreaded, memorable, or dramatic - Serious reaction during a mass campaign - Serious reactions with a new vaccine, especially unexplained death
Study or new experimental data published	<ul style="list-style-type: none"> - Research has low credibility - Research is unlikely to receive public attention 	<ul style="list-style-type: none"> - Research receives some public attention 	<ul style="list-style-type: none"> - Research receives significant public attention - Source has high credibility or influence - The research is relevant (e.g. mass immunization programme, new vaccine)
Media report or local rumor (including social media)	<ul style="list-style-type: none"> - Story receives little to no public attention - Story does not play upon emotions and/ or fears - Story is not believable 	<ul style="list-style-type: none"> - Story receives some public attention - Story triggers some emotional fears - Story is plausible 	<ul style="list-style-type: none"> - Story receives significant public attention; taps into emotional fears - Source has high readership/viewership - Source is credible and influential - Story is relevant

	-Story is limited to a small geographic area, community or platform	- Story has spread beyond initial geographic area, community or platforms	- Story is reported from multiple sources and constituencies, and may have evolved and combined with other sociopolitical concerns
Temporary suspension of a vaccine	N/A	- Any suspension that is not in my country	- Any suspension in my country
Recall of a vaccine	N/A	- Any recall of a vaccine not used in my country	- Any recall of a vaccine we use
Vaccine replacement	N/A	Always	- Replacement was the result of an adverse event following immunization

5. RESPONDING TO A VRE

The response for VRE will differ depending on the type of event, whether the VRE is an AEFI/AESI VRE or non-AEFI/AESI VRE, and whether the VRE is deemed to have a low, medium or high negative impact on the immunization program. Some activities will be undertaken for all types and impacts of VRE, and some will be specific for the VRE type and impact. The responses below are to be undertaken for AESI/AEFI that are temporally linked to vaccination.

Table 2 summarizes suggested specific actions for AEFI/AESI and non-AEFI/AESI VRE, depending on their impact. Please note that this list of actions is a starting point. The specific actions to take must be tailored to the country context. These are all in-country scenarios and are meant to align well with the crisis communication plan that the country creates/has in place for cVDPV response, including nOPV2 use. Additionally, efforts must be taken to align these responses with the response protocols present in the crisis communication plan.

Table 2: Specific actions for low, medium, and high impact VRE

ACTION	Low		Medium		High	
	AEFI or AESI	non-AEFI or AESI	AEFI or AESI	non-AEFI or AESI	AEFI or AESI	non-AEFI or AESI
Feedback, corrective action, supervision, and training for health staff if needed, and communicating findings and actions to affected vaccinees and caregivers	x	n/a	x	n/a	x	n/a
Routine ongoing communication with all vaccinees and caregivers	x	x	x	x	x	x
Monitoring in case public concerns emerge	x	x	x	x	n/a	n/a
Plans for addressing the VRE should be shared with internal and external partners	x	x	x	x	x	x

Be prepared in case the situation rapidly escalates into a high-impact VRE	x	x	x	x	n/a	n/a
Implement precautionary, passive actions	n/a	n/a	x	x	n/a	n/a
Determine if the VRE necessitates the need for communication actions	n/a	n/a	x	x	n/a	n/a
If decision is made to communicate, activate the crisis communication plan	n/a	n/a	x	x	n/a	n/a
Consider local suspension of vaccine	n/a	n/a	n/a	n/a	x	x
Causality assessment	n/a	n/a	n/a	n/a	x	n/a
Activate crisis communication plan	n/a	n/a	n/a	n/a	x	x

Response for AEFI or AESI VRE

Response for low-impact AEFI or AESI VRE

Response for low-impact AEFI or AESI can include feedback, corrective action, supervision and provision of training for health staff if needed, and communication of findings and actions to affected vaccinees and caregivers (World Health Organization).

Low impact AEFI or AESI VRE typically will not require any specific external public communication, though routine ongoing communication with vaccinees and caregivers can occur. Activities to undertake include monitoring for the emergence of public concerns. Plans for addressing the VRE should be shared with internal and external partners. Be prepared in case the situation rapidly escalates into a high-impact VRE (World Health Organization Regional Office for Europe, 2013). This activity will be led by communication focal point, as part of crisis communication, with input from vaccine safety focal points (see Annex 7.10).

Response for medium-impact AEFI or AESI VRE

Depending on the event type, precautionary and passive actions may be most appropriate for medium impact AEFI or AESI (World Health Organization Regional Office for Europe, 2013). As with low-impact AEFI or AESI feedback, corrective action, supervision and provision of training for health staff if needed, and communication of findings and actions to affected vaccinees and caregivers should be undertaken, as should routine ongoing communication with all vaccinees and caregivers (World Health Organization). The program should also monitor the public's response, if a response emerges. Examples of precautionary and passive actions include having more specific information about expected AEFI or AESI publicly available on a trusted website or outlining benefits of immunization and risks, including the risk of AEFI or AESI, appropriately contextualized, in a media statement (see Annex 7.10).

The program will need to determine if the VRE necessitates the need for public communication actions. It is critical that this decision is made jointly by vaccine safety and communication focal points. If the decision is made to communicate, the crisis communication plan should go into effect. Plans for addressing the VRE should be shared with internal and external partners. Finally, the program must be prepared that the situation can escalate rapidly, and the medium-impact VRE may evolve into a high-impact VRE (World Health Organization Regional Office for Europe, 2013). This activity will be led by communication colleagues, as part of crisis communication, with input from vaccine safety focal points.

Response for high-impact AEFI or AESI VRE

High impact AEFI or AESI VRE will require comprehensive and active action (World Health Organization Regional Office for Europe, 2013). As with low- and medium-impact AEFI or AESI, feedback, corrective action, supervision, and provision of training for health staff if needed, and communication of findings and actions to affected vaccinees and caregivers should be undertaken, as should routine ongoing communication with all vaccinees and caregivers. Plans for addressing the VRE should be shared with internal and external partners. Local suspension of the vaccine in question may be a component of the response (World Health Organization).

Causality assessment is a formal process to determine if a causal relationship exists between a vaccine (and/or vaccination) and an adverse event. These assessments typically take place by a trained causality assessment committee for serious AEFI, clusters of AEFI, occurrence of events above the expected rate or of unusual severity, signals, or other AEFI as decided by the review committee or an investigation team such as immunization errors, significant events of unexplained cause occurring within 30 days after a vaccination (not listed in the product label), or events causing significant parental or community concern (World Health Organization). For nOPV2 initial use, all AESI will undergo causality assessment if temporally linked to vaccination.

The steps for causality assessment are (1) determine the eligibility of the case; (2) review the checklist to ensure that all possible causes are considered; (3) use algorithm to determine trend of causality; and (4) classify causality.

Different actions are to be undertaken depending on the outcome of the causality assessment. Some actions include “providing feedback, training, modifying systems, refining tools, research, etc. to avoid and/or minimize recurrences (World Health Organization).”

Importantly, if the adverse event is high profile and serious, waiting for causality to be assessed before communicating to the public is insufficient, especially as time passes and outrage potentially builds, with additional related news heightening public concerns (e.g., additional AEFI reported; media coverage of AEFI). Refer to the GPEI communications planning tools for cVDPV response that includes nOPV2 use to see how to communicate regarding Causality Assessment.

Implementing the country-developed crisis communication plan will be crucial for maintaining trust in governments and other health authorities.

The public communication response for high impact AEFI or AESI should take place in a timely, transparent and credible manner. Some best practices regarding communicating during a high impact event in the first 24 hours include: implement the crisis communication plan, select a spokesperson, select the medium for communication, prepare and/or tailor communication materials. Within 72 hours, consider releasing a press release and holding a press conference (World Health Organization Regional Office for Europe, 2013).

Ongoing activities during the crisis should include advocating publicly regarding the vaccine’s safety and advocacy with opinion leaders such as politicians and traditional, religious and community leaders (World Health Organization Regional Office for Europe, 2013).

Offer an opportunity for impacted stakeholders to air their concerns and have their needs addressed. Usually, a closed-door setting is the most appropriate forum for this activity.

Media engagement should be tailored to the nature and scope of the VRE. Actions to consider include distributing fact sheets, Q&A and position statements to targeted media outlets and providing spokespersons the press can contact (World Health Organization Regional Office for Europe, 2013).

Health workers of all levels can be involved in the VRE communication response. Professional health care organizations (ex: for physicians, nurses) can be involved. Front line health care workers, including community health workers and vaccinators should also be involved (World Health Organization Regional Office for Europe, 2013).

Response for non-AEFI or AESI VRE

Response for low-impact non-AEFI or AESI VRE

Low impact non-AEFI or AESI VRE typically will not require any specific external public communication, though routine ongoing communication with all vaccinees and caregivers can occur. Plans for addressing the VRE should be shared with internal and external partners. The program should also monitor the public's response, if a response emerges. Be prepared in case the situation rapidly escalates into a medium or high-impact VRE (World Health Organization Regional Office for Europe, 2013). This activity will be led by communication colleagues, as part of crisis communication, with input from vaccine safety focal points (see Annex 7.10).

Response for medium-impact non-AEFI or AESI VRE

For medium impact non-AEFI or AESI VRE, precautionary and passive actions may be most appropriate (World Health Organization Regional Office for Europe, 2013). Examples include having more specific information about expected AEFI publicly available on a trusted website or outlining benefits of immunization and risks, including the risk of AEFI, appropriately contextualized, in a media statement.

As with low-impact VRE, the program should document and monitor the VRE and monitor the public's response, if a response emerges. The program will need to determine if the VRE necessitates the need for communication actions. Examples of when public communication would be warranted include the circulation of public rumors at the community level by word-of-mouth spread and/or through social media that affect multiple communities or are voiced by community leaders as a concern. It is critical that this decision is made jointly by vaccine safety and communication focal points. If communication action is not needed, no further action beyond documenting and monitoring will be taken.

If the decision is made to communicate publicly, the country crisis communication plan should go into effect. Plans for addressing the VRE should be shared with internal and external partners. Finally, the program must be aware that the situation can escalate rapidly, and the medium-impact VRE may evolve into a high-impact VRE. This activity will be led by the communication focal point, as part of crisis communication, with input from vaccine safety focal points.

Response for high-impact non-AEFI or AESI VRE

As with low and medium-impact VRE, the program should document and monitor the VRE and monitor the public's response. Routine ongoing communication with all vaccinees and caregivers should occur. Plans for addressing the VRE should be shared with internal and external partners.

The public communication response for high impact non-AEFI or AESI VRE should take place in a timely, transparent and credible manner. Refer to the crisis communication plan that the country creates/has in place for cVDPV response including nOPV2 use for a comprehensive list of actions to be undertaken.

Some best practices for the first 24 hours following a high-impact event include: implement the crisis communication plan, select a spokesperson, select the medium for communication, prepare and/or tailor communication materials. Within 72 hours, consider releasing a press release and holding a press conference (World Health Organization Regional Office for Europe, 2013). If social media channels are used to communicate to the public, reflect developments there in a timely manner.

Ongoing activities during the crisis should include advocating regarding the vaccine's safety with opinion leaders including politicians, traditional, religious and community leaders (unless definitively proven otherwise).

Media engagement should be tailored to the nature and scope of the VRE. Actions to consider include distributing fact sheets, Q&A and position statements to targeted media outlets and providing spokespersons the press can contact (World Health Organization Regional Office for Europe, 2013).

Health workers of all levels can be involved in the VRE response. Professional health care organizations (ex: physicians, nurses) can be involved. Front line health care workers, include vaccinators should be involved as well (World Health Organization Regional Office for Europe, 2013).

6. SUSTAIN: POST VRE

VRE response evaluation

Every crisis represents an opportunity to strengthen a program and organization. Incorporate lessons learned in a document or meeting in the aftermath of a VRE response and involve stakeholders to provide additional feedback and recommendations that may lead to policy updates to strengthen future AEFI and communications responses.

Policy development

If bottlenecks or lack of clarity in policy on what to do in a specific situation are exposed at any point during the AEFI response and communications process, consider updating policies to address gaps. For example, if the VRE plan says that a social media post should be simultaneously made with a public press conference to address the general public's questions, but policies dictate a lengthy approval process for each social media post that could delay public online communication, a policy update could include a streamlined social media approval process in the event of a VRE.

7. ANNEXES

Sample AEFI surveillance stakeholder engagement strategies

- Develop and implement mechanisms and guidance for systematic and timely exchange of vaccine safety related information between public health authorities at the central and peripheral levels.
 - Develop a team of recognized medical experts, including from the national health promotion department, to conduct stakeholder engagement meetings
 - Develop and distribute materials including presentations on Country EPI overview, cVDPV outbreak, Response strategy including the use of nOPV2 and its advantages, ACSM activities; Q&As, Guidance for healthcare workers and opinion makers
 - Develop AEFI and AESI-specific FAQs for various audiences, including leadership, HCW and nOPV2 implementation teams
 - Conduct coordination and information exchange meetings between EPI, NDA and other stakeholders
 - Set up a rapid communication channel (e.g. WhatsApp) for reporting vaccine safety issues and to push out updated guidance quickly
- Incorporate vaccine safety topics into existing engagements with stakeholders
- Conduct high level advocacy regarding nOPV2 vaccine safety topics with medical practitioners, health officials and managers, pediatric societies, religious and community leaders, local governments, and other opinion makers

Sample media engagement strategies

- Link with journalists and provide them contact information for communication spokespersons so they can reach out rapidly if needed
- Train journalists on immunization and related topics
- Conduct field visits to journalists
- Proactively disseminate information to the media
- Provide journalists with key messages, fact sheets, graphs showing reduction in VPDs, that they can have on hand, etc. on a regular basis
- Identify and media-train spokespeople
- Identify reputable third-party experts for journalists to contact
- Create a contact list to blast out important AEFI or immunization-related news and announcements
- Ensure UNICEF has stand-by partnership agreements, long-term agreements or a memorandum of understanding with TV and radio production agencies, media buying of airtime, creative design agencies and printshops, digital media engagement, telecommunication and mobile companies
- National health authorities to develop special arrangements with national and sub-national television and radio to broadcast health-specific messages or public service announcement messages for free or at discounted rates

Sample community engagement strategies

- Communicate on the risks and benefits prior to vaccination in a manner that is salient and addresses concerns of the vaccine recipient, their care givers and the public
- Develop print and social mobilization materials and social media content for the general public and caregivers.
- Conduct advocacy activities with religious and community leaders and other opinion makers.

Sample HCW engagement strategies

- Provide appropriate supervision, training and resources to health staff to ensure that vaccines are administered in a safe and conducive environment
- Promote IPC training for health care workers
- Train healthcare workers to communicate on the risks and benefits prior to vaccination in a manner that is salient and addresses concerns of the vaccine recipient, their caregivers and the public
- Develop AEFI and AESI-specific FAQs for various audiences, including leadership, HCW and nOPV2 implementation teams

Sample AEFI surveillance strengthening strategies

- Use spontaneous reporting systems as a primary pillar for AEFI signal surveillance (spontaneous reporting should be stimulated by making stakeholders aware of the system)
- Regularly review reports submitted to safety surveillance systems to identify unexpected patterns and frequencies, paying special attention to serious outcomes
- Characterize background rates of conditions that may be temporally associated with vaccination
- Develop and implement a framework and process at the country level to refine vaccine safety signals and determine which signals should be prioritized for more rigorous evaluation and assessment of risk
- Strengthen investigation of serious AEFI to provide high quality data for causality assessment
- Establish in- and inter-country processes to evaluate vaccine safety signals rapidly and rigorously for further assessment of risk
- Establish and develop expert committees with clear terms of reference for causality assessment of serious AEFIs, clusters of AEFI and other vaccine-related events that cause public concerns.

VRE investigation and risk communication flowchart

A VRE investigation and risk communication flowchart will be developed once other guidance has been finalized.

nOPV2 communications products to assist with country planning

- Strategic communications guidance for cVDPV outbreak response including the use of nOPV2
- Communications planning tools for cVDPV response including nOPV2 use (includes C4D and crisis communication planning)
- Regional Advocacy Plan
- Digital engagement strategy document
- FLW training modules for nOPV2
- Updated FAQ

nOPV2 Readiness Checklist Tool: Advocacy, Communication, and Social Mobilization Requirements and Considerations

Requirements for nOPV2 Vaccine Deployment

Category	Reference #	Requirement	Requirements for using nOPV2 under EUL – <i>All countries to complete</i>	Additional Requirements for Initial Use Period – <i>Only required during the Initial Use Period</i>	Date of Completion	Status update for incomplete items (include date of update)
Advocacy, Communications and Social Mobilization	G1	Advocacy strategy for key in-country stakeholders (e.g. medical practitioners, religious and community leaders) has been finalized	<input type="checkbox"/>			
	G2	The C4D action plan has been developed. Key components: nOPV2 communications and messaging have been adapted to the local context; key actors including front-line workers have been trained; all stakeholders have been mapped and sensitized; concrete plans for digital platforms have been	<input type="checkbox"/>			

		developed; all necessary messaging, tools and products have been developed				
	G3	A crisis communications plan has been developed and the plan addresses the needs identified in the nOPV2 VRE response plan for AEFI and possible public controversy (including tailored content to respond to misinformation on social media)	<input type="checkbox"/>			

Considerations

This section contains additional area-specific information and reference materials that may be useful during assessment and preparations. These should be reviewed and considered as you work to complete the requirements for nOPV2 use, which are noted in the "Checklist" tab.

This tab should be viewed in conjunction with other existing ACSM and Frontline Worker guidance tools and materials for polio campaign planning, which will provide more detailed guidance.

Considerations for establishing communications coordination and partnerships

1. Has the polio emergency operations centre communication (sub-)working group been activated and chaired by the relevant national or subnational health authority?
2. Are GPEI partners among the members of the polio emergency operations centre communication (sub-)working group?
3. Are international nongovernmental organizations and national nongovernmental organizations part of the communication (sub-) working group?
4. Does UNICEF have standby partnership agreements, long-term agreements or memoranda of understanding with:
 - TV and radio production agencies
 - Airtime media buyers
 - Creative design agencies and print shops
 - Digital media engagement specialists
 - National and international nongovernmental organizations for community engagement and social mobilization
 - Telecommunication/mobile companies
 - Religious groups

Research and monitoring organizations

Capacity-building training professionals.

5. Do national health authorities have special arrangements with national and subnational television and radio stations to broadcast health-specific messages/public service announcements free of charge or at discounted rates?

6. Do national health authorities have mechanisms to engage other government agencies (e.g. the ministries of education, of information and communication, etc.) in response to polio outbreaks?

7. Are health workers trusted and do they remain the main source of information about child health and well-being (including immunization)?

8. Do national health authorities have partnerships with nongovernmental and civil society organizations at the community level?

Considerations for finalizing the C4D action plan

1. Has the C4D action plan been developed? Key components: nOPV2 communications and messaging adapted to the local context; key actors, including front-line workers, have been trained; stakeholders who have all been mapped and sensitized; the development of concrete plans for digital platforms; and the development of all necessary messaging, tools and products.*

2. Is the polio C4D strategy and action plan informed by social research (case investigation, and knowledge, attitudes and practices on polio and immunization)?

3. Does the C4D strategy and action plan include special strategies for high-risk and hard-to-reach communities?

4. Does the C4D strategy and action plan include information on anti-vaccination and opposition groups and activities to guard against rumours and misinformation?

5. Does the C4D strategy and action plan include a framework with monitoring and evaluation indicators for ACSM? Examples:

Are case social investigation and refusal assessment tools available to and used by partners?

Are tools for the rapid assessment of knowledge, attitudes and practices on polio and communication aspects available?

Are any digital applications (U-Report, RapidPro, Kobo, ODK, etc.) used for collecting and analysing social mobilization activities?

Do GPEI partners or government partners monitor social media for rumours, opinions and perceptions about immunization and vaccines?

Considerations for updating, designing and producing nOPV2 communications and social mobilization materials

1. What polio print materials have been developed and made ready for production for the following key actors?

General public and caregivers (posters, banners, leaflets, fliers, etc.)?

Local governments, community and religious leaders, and journalists?

Social mobilizers and volunteers?

Health workers, including front-line health workers?

2. Has TV and radio broadcast content on polio been developed and pretested (e.g. public service announcements, radio jingles, short videos, documentaries, etc.)?

3. Has a media plan been agreed with TV and radio stations?

4. Has social media content for polio campaigns been prepared for Facebook, WhatsApp, etc.?

Considerations for the crisis communications plan and risk management plan for AEFI, the vaccine-related event response plan, and possible public controversy regarding nOPV2 use

1. Has a crisis communications plan been developed, and does the plan address the needs identified in the nOPV2 VRE response plan for AEFI and possible public controversy (including tailored content to respond to misinformation on social media)?*

2. Have key spokespersons and authorized staff been identified and trained within each GPEI partner and health ministry?

3. Have key communication products with key messages for AEFI and vaccine controversy been prepared and made available to key spokespersons?

Considerations for advocacy with medical practitioners, health officials and managers, paediatric society, religious and community leaders, local governments and other opinion-makers conducted in support of an nOPV2 outbreak response campaign

1. Has the advocacy strategy for key in-country stakeholders (e.g. medical practitioners, and religious and community leaders) been finalized?*

2. Has a team of recognized medical experts (including from the national health promotion department) been formed to conduct advocacy meetings?

3. Have meeting materials been duly produced and distributed at the meetings? Note: These include presentations on country EPI overviews, cVDPV outbreaks, a response strategy including the use of nOPV2 and its advantages, ACSM activities, Q&As, and guidance for health care workers and opinion-makers.

KEY/LEGEND

*A Requirement in the Readiness Checklist for use under EUL

nOPV2 Readiness Checklist Tool, Vaccine Safety Requirements and Considerations

Requirements for nOPV2 Vaccine Deployment

Category	Reference #	Requirement	Requirements for using nOPV2 under EUL - <i>All countries to complete</i>	Additional Requirements for Initial Use Period - <i>Only required during the Initial Use Period</i>	Date of Completion	Status update for incomplete items (include date of update)
Safety monitoring	F1	An active AESI safety monitoring protocol has been developed and all materials are available for AEFI surveillance and AESI active case search	<input type="checkbox"/>			
	F2	All disease surveillance officers have been trained on AEFI surveillance and AESI active case search	<input type="checkbox"/>			
	F3	The causality assessment committee has been trained to conduct AEFI/AESI causality assessment and has been oriented on nOPV2 AESI case definitions	<input type="checkbox"/>			
	F4	The nOPV2 vaccine-related event (VRE) response plan has been adapted to the country	<input type="checkbox"/>			

		context, with stakeholder roles/responsibilities outlined and relevant trainings conducted				
	F5	The plan for the implementation of active safety surveillance in the local context has been finalized and ethical approvals secured, if needed, in conjunction with the CDC		<input type="checkbox"/>		

Additional Considerations for Safety Surveillance

This tab contains additional area-specific information and reference materials that may be useful during assessment and preparations. These should be reviewed and considered as you work to complete the requirements for nOPV2 use, which are noted in the "Checklist" tab.

This tab should be viewed in conjunction with other existing AEFI and vaccine safety guidance tools and materials, which will provide more detailed guidance.

Initial assessment of infrastructure to detect, investigate and respond to AEFI during nOPV2 use

1. Does the country have national AEFI surveillance guidelines?
2. Has the country conducted an AEFI surveillance assessment since 1 January 2018?
3. Does the country use an AEFI case-based reporting form that includes the minimum 25 key variables, as recommended by WHO?
4. Has the country met WHO's minimum criteria for AEFI surveillance (>10 AEFI reports per 100 000 surviving infants) in 2018?
 - 4.a Proportion of reported AEFI determined to be serious AEFI in 2018?
 - 4.b Proportion of serious AEFI investigated in 2018?
 - 4.c Proportion of serious AEFI with causality assessment determination in 2018?
 - 4.d Proportion of districts with non-zero AEFI reporting in 2018?
 - 4.e Proportion of districts with silent AEFI reporting in 2018?
5. Has the country undergone WHO training in AEFI investigation since 1 January 2018?
 - 5.a At the national level
 - 5.b At the subnational level
6. How many Guillain-Barré Syndrome cases were identified among non-polio AFP cases within the last year? (>0)
7. Is there an independent national advisory committee for vaccine safety?
 - 7.a Has the national advisory body for vaccine safety undergone WHO training for causality assessment?
 - 7.b Does this group have a clear SOP?
 - 7.c How many times has the committee met within the last year?
 - 7.d How many causality assessments have been conducted in the last year?
8. If no national vaccine safety advisory committee exists, are there provisions for establishing one to review serious AEFI cases?

Implementation steps prior to nOPV2 use

1. National AEFI surveillance guidelines have been established (if not already present).
2. An independent national advisory committee for safety/causality has been established (if not already present).*
3. An active AESI safety monitoring protocol has been developed and materials are available for AEFI surveillance and AESI active case search. *

4. Trainings have been completed for passive AEFI reporting using a reporting form that includes the minimum 25 key variables.
 - 4.a At the national level
 - 4.b At the sub-national level
 - 4.c For front-line health care workers.
5. Trainings have been completed for AEFI investigation
 - 5.a At the national level
 - 5.b At the sub-national level
6. The causality assessment committee has been trained to conduct AEFI/AESI causality assessment and has been oriented on nOPV2 AESI case definitions .*
7. The nOPV2 vaccine-related event (VRE) response plan has been developed and adapted to the country context, with stakeholder roles/responsibilities outlined and relevant trainings conducted.*
8. The plan for the implementation of active safety surveillance in the local context has been finalized and ethical approvals secured, if needed, in conjunction with the CDC.**
9. All disease surveillance officers have been trained on AEFI surveillance and AESI active case search.*
10. AESI active surveillance tools have been printed and distributed.
11. AESI active surveillance data systems have been established.

Indicators to monitor during and after an nOPV2 outbreak response

1. In districts using nOPV2: Proportion with silent AEFI reporting (<10%).
2. In districts using nOPV2: Proportion with >10 AEFI reports per 100 000 surviving infants (>80%).
3. Number of AEFI reported in the last 30 days (all).
4. Number of serious AEFI reported in the last 30 days.
5. Proportion of serious AEFI investigated = 100%.
6. Time between the identification of serious AEFI, investigation, and the causality assessment (<7 days).

KEY/LEGEND

*A requirement in the Readiness Checklist for use under EUL

**Additional requirements for the initial use period, noted in the Readiness Checklist

8. References

- Centers for Disease Control and Prevention. (2020). *Guide to Surveillance for Adverse Events of Special Interest (AESI) during novel Oral Polio Vaccine type 2 (nOPV2) Use (in process document)*.
- Global Advisory Commission on Vaccine Safety. (2020). *Vaccine Safety Blueprint, version 2.0*. Retrieved from https://www.who.int/vaccine_safety/Draft_GVSB2.0_20190929.pdf?ua=1
- World Health Organization. Aide-memoire on AEFI Investigation Retrieved from https://www.who.int/vaccine_safety/initiative/investigation/New_aide-memoire_AEFI.pdf?ua=1
- World Health Organization. AIDE-MÉMOIRE ON AEFI INVESTIGATION. Retrieved from https://www.who.int/vaccine_safety/initiative/investigation/New_aide-memoire_AEFI.pdf
- World Health Organization. Aide-memoire on causality assessment. Retrieved from https://www.who.int/vaccine_safety/initiative/investigation/New_aide_mem_causal_assmt.pdf?ua=1
- World Health Organization. (2018). Vaccine Safety Basics e-Learning Manual. Retrieved from https://www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/
- World Health Organization, (2018). Communication for the Investigation of Serious AEFI. Retrieved from https://www.vsc-library.org/applications/core/interface/file/cfield.php?storage=cms_Records&path=UNICEF_WHO_AEFI-2.pdf&fileKey=SUFQdDVVb3VxVnpTaS9VRHhteVcwVmh0WlI3Q09HWFVORmJsdnFIY2Q2L0hFZ2ZnK1JENTBwZE0rS3g5bitEM2lvMzImb3E0QmYwODI4ZU9XL3FEVFExdUVWbzdZcllUSWIXRjNRV0o=
- World Health Organization Regional Office for Europe. Crisis Communication Plan Template. Retrieved from http://www.euro.who.int/_data/assets/pdf_file/0014/333140/VSS-crisis-comms-plan.pdf?ua=1
- World Health Organization Regional Office for Europe. (2013). *Vaccine Safety Events: managing the communications response*. Retrieved from http://www.euro.who.int/_data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response.pdf