Novel Oral Polio Vaccine Type 2 (nOPV2)
NATIONAL Vaccine Related Event (VRE) PLAN
GUIDANCE NOTE

(Addendum to nOPV2 Vaccine Related Response Plan Guidance Document)

Context

This guidance note outlines the elements that must be included in your national Vaccine-Related Event plan to meet the related nOPV2 readiness requirement (F4). It should be used together with the nOPV2 Vaccine Related Response Plan Guidance Document, which provides more detailed guidance on developing a VRE plan.

What are VRE?

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.

The purpose of a VRE Response Plan and how it should be used

A VRE Response plan helps ensure that a coordinated national plan for responding to VREs is in place. It's intended to be used by vaccine safety focal persons, such as MOH vaccine safety focal points, working in conjunction with EPI and polio communications focal persons.

In the context of nOPV2 use under EUL, some of the elements that are described as part of overall nOPV2 communications planning (e.g., mapping media outlets, a community engagement plan to capture key stakeholders)[1] are important to apply to the national VRE response plan. In these cases, the country can simply mention those same plans in this template document**. However, it is important to note that this VRE response plan captures more than just communications information—it also captures safety information and describes how safety and communications focal points will coordinate with one another in the event of a VRE**.

There are two issues to address by both vaccine safety and communication focal points:

i. public health response and
ii. 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 campaign's success and affect uptake of future vaccines.

[1] Note: Please refer to the nOPV2 communications planning tools (the Behavioral Strategy Template, C4D Guidance Document, and Crisis Communications Planning Toolkit). For the latest documents and planning tools, please feel free to reach out to your WHO/UNICEF Regional Offices and/or to the nOPV2 Readiness Verification Team

Developing your national VRE plan

When developing your national VRE plan, please make sure all the key components detailed in the table below are addressed. The VRE Plan relies heavily on the crisis communications plan and the AESI/AEFI surveillance protocols. Please be sure to have copies of both those plans to reference as you develop this. The VRE plan should be developed jointly by the communications and safety teams; please ensure there is time set aside to work collaboratively on this.

This VRE guidance is divided into four sections:

1. **PREPARE:** activities need to prepare for and prevent a VRE
2. **DETECT:** detecting VREs
3. **RESPOND:** responding to a VRE
4. **RECOVERY + EVALUATION:** evaluating the VRE response

For additional details and guidance on each section, please refer to the full nOPV2 Vaccine Related Response Plan guidance document that is located on the nOPV2 website.

Legend

Green Boxes highlight elements that may be covered in other plans (i.e. crisis communications plan, other safety plans) and should be cross-referenced to see if there are overlaps, and to cut and paste relevant sections/link to relevant sections.

Text in *italics* features explanations and background on some of the activities. The **checkboxes** indicate the components that should be present in the plan itself.

1. PREPARE: Preparing for and preventing a VRE

	Component	Details on what needs to be done for this
☐	**1.1 AEFI surveillance stakeholder engagement activities**	**Map and describe AEFI surveillance stakeholders** Please list the key stakeholders for AEFI surveillance. If you have mapped this out elsewhere, please feel free to cut and paste it here, but this list should be included here. Describe the activities that have been undertaken to map AEFI surveillance stakeholders. If this process has already been mapped elsewhere, please list the name of the other document where they have been mapped, including page numbers for reference if possible, or cut and paste the relevant text here. **Develop an AEFI surveillance stakeholder engagement plan** Please describe the activities you have undertaken, or plan to undertake, to engage AEFI surveillance stakeholders. Examples of such activities can be found in Annex 7 in the nOPV2 Vaccine Related Response Plan guidance document that is located on the nOPV2 web page, under "Sample AEFI surveillance stakeholder engagement strategies."
☐	**1.2 Strengthen communication response to VRE**	**Develop a VRE communication plan** *The following elements may already be included in your crisis communication plan, and thus only need to be summarized here.*

		For elements that are not covered in the crisis communication plan, please provide this information in the VRE plan. You can consult and input information from the nOPV2 Crisis Communications Planning Template, as appropriate, when developing this section. **1. Develop a crisis communication plan** Please briefly describe (less than one page) the major elements of your crisis communication plan here, to give context to safety officers who may not read the full document. **2. Develop an nOPV2 Issues Map specific to the local landscape** (Note: the nOPV2 Issues map summarizes several potential issues that could arise in nOPV2 rollout; further guidance on issues mapping is provided in the nOPV2 Crisis Communications Planning template.) **3. Address VRE-related crisis scenario from the communications perspective** Note: This section may have already been completed as part of nOPV2 crisis communications planning. If so, please indicate the page number reference in the comms planning document or cut/paste the relevant text here. **4. Map media outlets** Please describe the activities you have undertaken, or plan to undertake, to map media outlets. If they have been mapped elsewhere as part of the communications planning process, please indicate the page number reference in the relevant document or cut/paste the relevant text here. **5. Develop a media engagement plan** Please describe your media engagement plan. Please indicate the page number reference in the communications plan or cut/paste relevant text here.
☐	**1.3 Community Engagement**	**Develop a community engagement plan to capture key stakeholders** Briefly describe (less than one page) the community engagement plan that has been developed as part of nOPV2 communications planning (specifically, the Behavioral Strategy to prepare and respond to CVDPV outbreaks).
☐	**1.4 Healthcare worker engagement**	**HCW engagement plan** Briefly describe (less than one page) your plan for engaging HCW. While you are encouraged to copy/paste key elements from your comms plan, please **be sure to highlight here how gaps in awareness regarding vaccine safety will be addressed.** Examples of

		such activities can be found in Annex 7 in the nOPV2 Vaccine Related Response Plan guidance document that is located on the nOPV2 web page, under "Sample HCW engagement strategies".

2. DETECT: Detecting VRE

☐	**2.1 Strengthen AEFI and AESI surveillance**	**AEFI and AESI surveillance plan** Please describe briefly (in one page) your country's AEFI activities and plans for nOPV2 AESI surveillance. You can refer to your AEFI surveillance guidelines and your nOPV2 AESI surveillance protocol. Briefly describe the activities related to detection, notification, investigation, analysis and causality assessment
☐	**2.2 Strengthen media and social media "listening" and analysis**	**Media and social media listening and analysis plan** Please describe your country's plans for media and social listening and monitoring activities and the process by which you will analyze its impact. Please describe the specific efforts that will be made to identify vaccine-related events in your listening and analysis plan.
☐	**2.3 Assess caregiver and community perceptions regarding immunization**	**Caregiver and community perception assessment plan** Please describe your country's plan to identify and quantify public concerns surrounding vaccines through community engagement, cross-sectional surveys and monitoring of community opinion and preferences. If this activity has already taken place, please describe the activity. Some examples of potential assessments are described in the nOPV2 VRE response plan guidance document on the nOPV2 web page. If this information is already included in another document, please indicate the document name and the page number reference or cut/paste the relevant text here.
☐	**2.4 VRE investigation**	*AEFI and non-AEFI VRE will be investigated in a different manner, depending on the nature of the VRE. In order to ensure key information can be found in one document, in case of a VRE, please outline the following:* **Steps for investigating AEFI and AESI** Provide a brief description of how AEFI and AESI (which follow vaccination) are investigated and/or will be investigated. General guidance on the steps are provided in the VRE Response plan guidance document. You can refer to information from your AEFI surveillance guidelines and your nOPV2 AESI surveillance protocol to complete this section.

		Steps for investigating non-AEFI VRE* Depending on the non-AEFI VRE type, different steps will be involved in its investigation. In this section please provide a description of how you plan on identifying and gathering information regarding rumors or media reports, new studies or vaccine recalls, and other types of non-AEFI VRE. You can refer to the "Steps for investigating non-AEFI VRE" in the *VRE response plan guidance document* for specific suggestions of activities.
☐	**2.5 Assess VRE impact: low, medium, or high-impact VRE**	*Develop a framework that describes the potential impact of various VRE types on the vaccination program. As a starting point, refer to Table 1, which is in the Annex and also found in the VRE response plan guidance document on the nOPV2 web page.* ***Vaccine safety and communication focal points should develop this framework together. Please note that you must adapt this table to your specific country's context.*** *Please ensure that you specifically speak to vaccine safety as you complete the table. You could integrate/harmonize the framework to be in line with your Risk Assessment framework that is part of your crisis communications planning process.* **Country specific Table 1: Assessing VRE impact** Adapt table 1 (in annex) to describe the process your country will undertake to assess impact once an event occurs. Describe your use of monitoring, social and epidemiological data and how you will involve vaccine safety and communication focal points when assessing VRE impact. NOTE: Table 1 (in annex) must be adapted to your country-specific context and done jointly by the communications and safety focal points in order for nOPV2 readiness verification to be obtained.

3. RESPOND: 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.	
	Adapt table 2: "Specific actions for low, medium, and high impact VRE" to the country context	**Specific actions for low, medium, and high impact VRE:** *This section of the VRE guidance describes suggested activities which you will need to assess for suitability to your country context.* Adapt table 2 (see annex) to your country context, including details of your country's framework for responding to low, medium, and high impact VREs, distinguishing between actions for AEFI and non-AEFI or AESI VRE.

		Describe the specific actions that will take place for each type and impact of event. You can briefly describe the activities that are undertaken as part of AEFI and AESI surveillance. Describe the roles and responsibilities of various actors, including how you will involve vaccine safety and communication focal points. *Note that you only need to describe these actions briefly.* NOTE: Table 2 (in annex) must be adapted to your country-specific context and done jointly by the communications and safety focal points in order for nOPV2 readiness verification to be obtained.

4. RECOVERY + EVALUATION

☐	**4.1 Evaluating the VRE response**	*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.* Describe your country's plans for evaluating VRE response efforts. Include information on how you would follow up with relevant stakeholders and those impacted to gather metrics and data for the evaluation.

Annexes

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)	- 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)	- 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	- 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	- Research has low credibility - Research is unlikely to receive public attention	- Research receives some public attention	- 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)	- Story receives little to no public attention - Story does not play upon emotions and/ or fears - Story is not believable -Story is limited to a small geographic area, community or platform	- Story receives some public attention - Story triggers some emotional fears - Story is plausible - Story has spread beyond initial geographic area, community or platforms	- Story receives significant public attention; taps into emotional fears - Source has high readership/viewership - Source is credible and influential - Story is relevant - 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

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

	Low		Medium		High	
ACTION	**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