

MINISTRY OF HEALTH AND CHILD CARE



Zimbabwe Expanded Programme on Immunization

Adverse Events Following Immunization (AEFI) Surveillance Guidelines

5th edition June 2026



Scan and report AEFI



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Foreword

The Government of Zimbabwe through the Ministry of Health and Child Care is committed to controlling, eliminating and eradicating vaccine preventable diseases among infants, children and adults. The immunization programme is a pillar for survival and improvement of health. The programme aims at reaching every child living in Zimbabwe with safe and potent vaccines. These guidelines will provide an essential platform for monitoring Adverse Events Following Immunization (AEFI) to ensure safety of these vaccines.

Safety of vaccines is an essential part of the successes of immunization programmes, this activity requires the involvement of various stakeholders whose sole mandate is to monitor safety of immunization. The National Pharmacovigilance Centre, Medicines Control Authority of Zimbabwe (MCAZ) in collaboration with the Zimbabwe Expanded Programme on Immunization (ZEPI) are the main drivers of this initiative.

These AEFI guidelines focus on improving the quality of immunization programme through activities that collect, detect, assess, monitor, prevent, and manage AEFIs. Implementation of ZEPI principles outlined in this AEFI guideline will contribute to the realization of Sustainable Development Goals (SDG) 3.3 and 3.8. The Ministry of Health and Child Care urges all healthcare workers in Zimbabwe from both the public and private sector to read and implement the guidelines that are clearly spelt in this important document.

I urge all health workers in Zimbabwe to use these AEFI surveillance guidelines to safeguard and protect the health of infants, children and adults.



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SECRETARY FOR HEALTH AND CHILD CARE

Scope

The scope of this updated Zimbabwe AEFI Surveillance 5th Edition June 2026 is in accordance with the United Nations (UN) Sustainable Development Goal (SDG) 3 of "Good Health and Well-being", Ministry of Health and Child Care policy and MCAZ policy. This guideline has been developed based on the principles described in the WHO Global vaccine safety blueprint version 2.0, the WHO's Global manual on surveillance of adverse events following immunization (AEFI) and the CIOMS guide to active vaccine safety surveillance, WHO COVID-19 Vaccine safety manuals 2020 and 2021 and WHO Global Benchmarking Tool (GBT) Maturity Level 3 (ML 3) desired standard of a stable well-functioning vaccine vigilance AEFI surveillance system(1-3).

The aim of the AEFI surveillance guide is to ensure prompt an enhanced robust effective AEFI surveillance system that results in early detection, notification, reporting of all types of AEFIs, case management, causality assessment, feedback and crisis management communication including benefit risk management and promotion of patient/vaccinees safety(4). The goal is to promote patient/vaccine safety and increase public trust in immunization/uptake and reduce vaccines preventable diseases (VPDs). The guideline aims to ensure that the benefits of vaccination programs in Zimbabwe continue to outweigh the potential risks, thorough continued strengthening of the robust post-authorization and post-licensure immunization safety monitoring systems.

AEFI detection primarily takes place through routine passive surveillance (spontaneous reporting) in many countries. This involves vaccine recipients, parents and guardians of immunized infants and children, health care workers and staff in immunization or health care facilities detecting the AEFIs and reporting them to any health care worker within the health care system. AEFIs can also be detected through active surveillance, via sentinel sites or through cohort event monitoring. Surveillance was done for safety monitoring of H1N1 vaccine and active surveillance programs that have been conducted in Zimbabwe including enhanced surveillance for AEFIs during the 2019 typhoid conjugate vaccine (TCV) campaign and the Zimbabwe stimulated telephone assisted rapid safety surveillance (Zm-STARSS) study(5, 6) . In addition, AEFIs may be detected in post authorization safety studies (PASS) where they should be independently reported, assessed and processed, in compliance with the marketing

authorization requirements and pharmacovigilance requirements(7). The importance of comprehensive surveillance of adverse events following immunization is emphasized, as it is required to detect potential serious adverse events that may not be identified in pre-licensure vaccine trials(8).

Abbreviations/Acronyms

AFP	acute flaccid paralysis
BCG	Bacillus Calmette-Guérin vaccine for tuberculosis (TB)
bOPV	bivalent oral polio vaccine
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus 2 (SARs-CoV-2) disease 2019
DHIS	district health information system
DTP-HepB-Hib	diphtheria, tetanus, pertussis, hepatitis B, Haemophilus influenzae type b vaccine
GMP	good manufacturing practices
GVP	good vigilance practice
HCP(s)	healthcare professional(s)
HPV	human papilloma virus
ICH	International Conference on Harmonisation
ICSR	individual case safety report
IPV	inactivated polio vaccine
MedDRA	medical dictionary for regulatory activities
MCAZ	Medicines Control Authority of Zimbabwe
MMR	measles, mumps, rubella vaccine
MoHCC	Ministry of Health and Child Care
MR	measles, rubella
NRA	national regulatory authority
OPV	oral polio vaccine
PCV	pneumococcal conjugate vaccine
PV	pharmacovigilance
PVCT	Pharmacovigilance and Clinical Trials
STARSS	stimulated telephone assisted rapid safety surveillance
Td	tetanus, diphtheria
tOPV	trivalent oral polio vaccine
TT	tetanus toxoid
UMC	Uppsala Monitoring Centre
UNICEF	United Nations Children's Emergency Fund
VPDs	vaccine-preventable disease(s)
WHO	World Health Organization
ZEPI	Zimbabwe Expanded Programme on Immunization

Glossary

Acute flaccid paralysis (AFP)	The WHO defined an AFP case as a child < 15 years of age presenting with sudden onset of floppy paralysis or muscle weakness due to any cause, or any person of any age with paralytic illness if poliomyelitis is suspected by a clinician.
Adverse event following immunisation (AEFI)	any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
Adverse events of special interest	is defined as a “clinically important untoward medical occurrence that is either known to occur following administration of the type of vaccine under study (for example, hypotonic-hyporesponsive episodes or febrile convulsions) or is considered to be a possible risk on the basis of knowledge of the content of the vaccine and/or its interaction with the host immune system (for example, autoimmune disease or antibody-dependent enhanced clinical disease)”
AEFI surveillance	Monitoring, detecting and responding to adverse events following immunization; implementing appropriate and immediate action to correct any unsafe practices detected through the AEFI surveillance system, in order to lessen the negative impact on health of individuals and the reputation of the immunization programme
Anaphylactic shock	A sudden, severe allergic reaction characterized by a sharp drop in blood pressure, urticaria, and breathing difficulties that is caused by exposure to a foreign substance to which a person has an extreme sensitivity, often involving respiratory difficulty and circulation failure.
Causal association	A cause-and-effect relationship between a causative (risk) factor and an outcome. Causally associated events are also temporally associated (i.e. they occur after vaccine administration), but events which are temporally associated may not necessarily be causally associated.
Causality assessment	In the context of AEFI surveillance, causality assessment is a systematic review of data about AEFI case(s) to determine the

	likelihood of a causal association between the event and the vaccine(s) received.
Cluster	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered. AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines
Coincidental events	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety
Contraindication	A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons. Contraindications can be permanent (absolute), such as known severe allergies to a vaccine component, or temporary (relative), such as an acute/severe febrile illness
Immunisation	Immunization is the process whereby a person is made immune or resistant to an infection, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection.
Immunisation anxiety related reaction	An AEFI arising from anxiety about the immunization. The term "immunization anxiety-related reaction" is used to describe a range of symptoms and signs that may arise around immunization that are related to "anxiety" and not to the vaccine product, a defect in the quality of the vaccine or an error of the immunization programme. These reactions are described as AEFI arising from anxiety about immunization and include vasovagal-mediated reactions, hyperventilation-mediated reactions and stress-related psychiatric reactions or disorders. The term "anxiety" does not, however, adequately cover the presentation of all these AEFI and anxiety may not manifest during such events. Thus, a new term is proposed that better describes this cause-specific AEFI, which is "immunization stress-related response (ISRR)"
Immunisation error related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and that thus, by its nature, is preventable.

Immunisation safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste, and surveillance of adverse events.
Immunisation safety surveillance	A system for ensuring immunization safety through early detection, reporting, investigating, and quickly responding to AEFIs.
Immunisation stress related responses (ISRR)	Stress response to immunization that may manifest just prior to, during, or after immunization.
Immunity	The ability of the human body to tolerate the presence of material ‘indigenous’ to the human ‘body’ (self) and to eliminate ‘foreign’ (non-self) material. This discriminatory ability provides protection from infectious diseases since most microbes are identified as foreign material by the immune system.
Injection safety	The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the provider and recipient are not exposed to avoidable risks of adverse events (e.g. transmission of infective pathogens) and dangerous waste is not created. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
Live viral vaccines	vaccines containing attenuated (weakened) versions of the disease-causing virus (e.g. poliomyelitis, measles). The vaccine virus causes a mild infection, usually with minimal or no symptoms, that creates immunity against that virus.
Management of Infodemics in AEFI	Infodemics refer to the rapid spread of misinformation, disinformation and conflicting information during public health emergencies. Managing infodemics is crucial to prevent harm to individuals and communities.
Mass vaccination campaign	Mass vaccination campaigns involve administration of vaccine doses to a large population over a short period of time.
Non-serious AEFI	An event that is not ‘serious’ and does not pose a potential risk to the health of the recipient. Non-serious AEFIs should be carefully monitored because they may signal a potentially

	larger problem with the vaccine or immunization or have an impact on the acceptability of immunization in general.
Safe injection practice	Practices which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.
Serious AEFI	An event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.
Severe vaccine reaction	The severity of a vaccine reaction is a measure of its intensity. A severe reaction is a reaction of high intensity, graded as mild, moderate or severe. Severe reactions may include serious and non-serious reactions.
Surveillance	The continuing, systematic collection of data that are analysed and disseminated to enable decision-making and action to protect the health of populations.
Temporal association	Two or more events that occur around the same time
Toxic shock	Toxic shock syndrome is a severe disease that involves fever, shock, and problems with the function of several body organs.
Trigger event	A medical incident following immunization that stimulates a response, usually a case investigation.
Vaccination failure	Vaccination failure may be defined based on clinical endpoints or immunological criteria where correlates or surrogate markers for disease protection exist. Primary failure (e.g. lack of sero-conversion or sero-protection) needs to be distinguished from secondary failure (waning immunity). Vaccination failure can be due to (i) failure to vaccinate, i.e. an indicated vaccine was not administered appropriately for any reason or (ii) (ii) because the vaccine did not produce its intended effect.
Vaccine	A biological preparation that improves immunity to a particular disease. In addition to the antigen, it contains

	multiple components (excipients); each component may have unique safety implications.
Vaccine associated enhanced disease (VAED)	Vaccine associated enhanced diseases are modified and severe presentations of clinical infections affecting individuals exposed to a wild-type pathogen after having received a prior vaccine against the same pathogen.
Vaccine associated paralytic poliomyelitis (VAPP)/ Vaccine derived polio virus (VDPR)	polioviruses that can cause sporadic and rare cases of paralytic polio. Inactivated Polio Virus (IPV), the only polio vaccine carries no risk of VAPP.
Vaccine pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFIs and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.
Vaccine product related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more of the inherent properties of the vaccine product, whether the active component or another component of the vaccine (e.g. adjuvant, preservative or stabilizer).
Vaccine quality defect related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects with the vaccine product, including its administration device as provided by the manufacturer.
VigiBase®	WHO global database of individual case safety reports (ICSRs) including ADRs and AEFIs, maintained by Uppsala Monitoring Centre.
VigiFlow	A web-based individual case safety report (ICSR) management system (E2B compatible) for medicines and vaccines, developed and maintained by Uppsala Monitoring Centre.
WHO Drug Dictionary	The international reference for medicinal product information and it is maintained by the Uppsala Monitoring Centre.

1. Introduction

Immunization is a successful and cost-effective public health intervention that led to global eradication of diseases like smallpox and poliomyelitis in large areas of the world(9). It is estimated that immunization averts an estimated 2 to 3 million deaths from diphtheria, tetanus, pertussis (whooping cough), cholera, COVID-19 and measles every year in all age groups(2, 10). Zimbabwe attained universal child immunization in 1990 with considerable reduction in morbidity and mortality from vaccine preventable diseases and longer inter-epidemic periods of measles to 2022 and beyond(11, 12).

As Zimbabwe continues to adopt WHO recommended vaccination strategies in its population, it is becoming imperative that surveillance of AEFI be increased(1). The vaccine products and equipment used in immunization undergo intensive World Health Organization prequalification exercises to determine quality and approve their uses in countries. These precautionary measures do not necessarily eliminate the risk of adverse events that may arise from the use of products for immunization. Previous experiences have shown that determining causality of an event to a vaccine is a challenge that requires engagement of expert opinion and thorough investigation of the event(13, 14). Zimbabwe through MCAZ was the 6th African country to successfully attain the desired WHO Global benchmarking to maturity level 3 status of a stable and well-functioning NRA including AEFI surveillance vigilance regulatory function(15).

Events that occur after vaccinations are called Adverse Events Following Immunization (AEFIs); defined as any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease(2, 6).

The safety of immunization programmes involves a wide spectrum of activities that include regulation, vaccine safety and quality, safe injections, waste disposals, and AEFI surveillance. Effective vaccines (i.e. vaccines inducing protective immunity) may produce some undesirable side effects which are mostly mild and clear up quickly. The majority of events thought to be

related to the administration of a vaccine are actually not due to the vaccine itself - many are simply coincidental events or programmatic errors(16, 17). It is not possible to predict every individual who might have a mild or serious reaction to a vaccine, although there are a few contraindications to some vaccines(18, 19). Adherence to contraindications minimizes the risk of serious adverse events. During mass immunization campaigns there usually is a general increase in adverse events following immunization. This can be attributed to two factors; the large number of vaccinations performed in a short period of time (from a few days to a few weeks) causes a temporary concentration of adverse events following immunization, and the pressure during the campaigns on vaccination teams means they may fail to observe safe injection practices(20). Public misconceptions may arise due to occurrence of AEFIs, and these may cause collective fear of vaccination(21). It is against this background that standardization and surveillance of adverse events following immunization is critical to enhance effective management of AEFIs(4, 22). This document is a guide for health workers in the management of Adverse Events Following Immunization (AEFIs), can be adapted to suit each level of health care, and is meant to cover issues of vaccine safety and quality, as well as communication of these events for management.

According to the WHO, case detection is the first important step in AEFI surveillance. The primary reporter (i.e. the one who first reports an AEFI) may be a field health worker, clinic or hospital staff, a volunteer, parent or any other person who detects the AEFI. The WHO recommends that suspicion alone is sufficient for reporting; the primary reporter is not expected to assess causality. In investigating suspected AEFIs, it is important that rapid detection and evaluation of a possible link to vaccines is carried out to ensure the continued safety of vaccines. The WHO Global Manual on Surveillance of AEFIs highlights that in the case of a suspected AEFI, it is preferable to submit a report to a suitable technical authority on time rather than waiting for all aspects of an investigation to be completed; and this is particularly true for serious reports.

To report a suspected AEFI, an AEFI VigiMobile online reporting form (**Annex 1** below) is to be completed by first scanning the code to download form online onto the mobile phone, tablet, iPad or laptop or desktop. However, if there is limited internet access a hard copy AEFI reporting form **Annex 2** is to be fully completed, dated, stamped and signed scanned copy sent to by email to DHIO/PHIO for uploading onto VigiFlow, EPI-MoHCC and MCAZ. However, for serious AEFI, an AEFI case investigation form (**Annex 3**) is required to be completed

including together with an AEFI reporting form and submitted to the ZEPI-MoHCC and the MCAZ to provide adequate information for causality assessment by the national AEFI Committee and benefit/risk minimization measures/communication. Additionally other supporting documents such as **postmortem, laboratory results** documents or information is required. For more information on AEFI reporting please also refer to the **Zimbabwe Job Aid for Adverse Event Following Immunization (AEFI) training tool for HCPs Annex 4 below.**

All events that are actively notified to the health care system by the parents/guardians or patients themselves or identified by a health care provider that are submitted to the MCAZ are assessed for causality according to the Causality Assessment of an AEFI, User Manual for the revised WHO classification, Aide-memoire and Algorithm 2019.

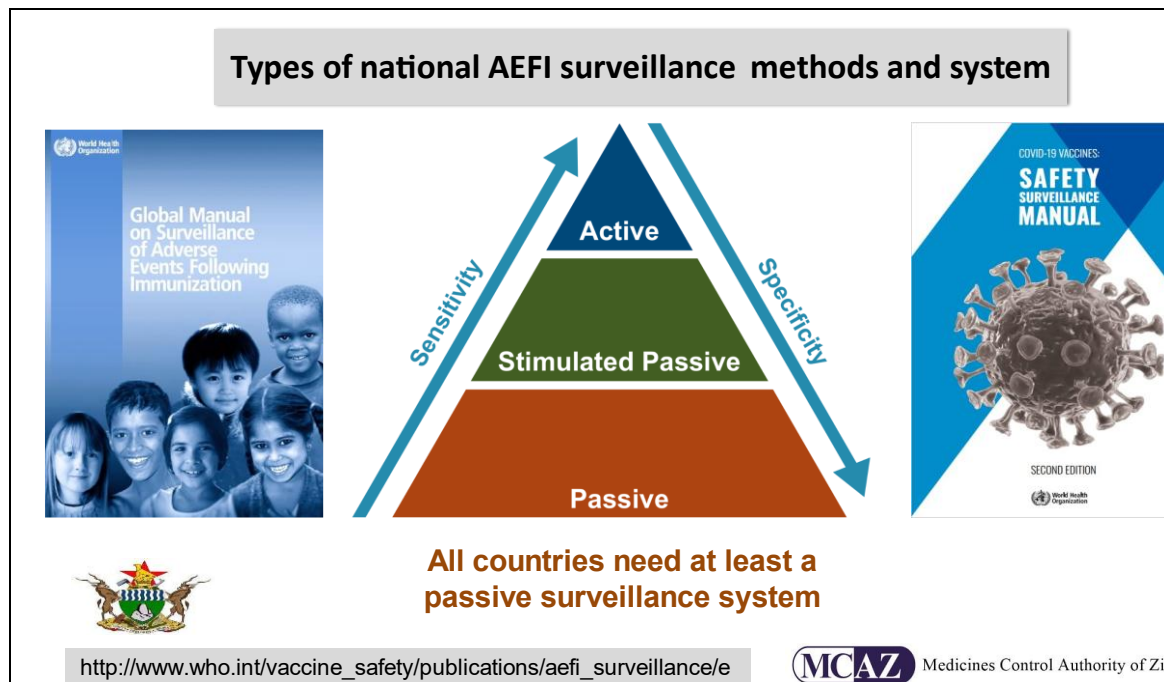
AEFI reporting ratio per 1 million COVID-19 adult vaccinees was 44 in 2021, 5 in 2022 and 29 in 2023. AEFI surveillance of AEFI cases causality assessment and feedback on the benefit/ risk assessment by the national AEFI Committee is an essential part of AEFI management when they occur to augment other safety precautions that will have been taken and do causality assessment and risk assessment. The relatively high AEFI reporting ratios of majority non-serious AEFIs and few serious AEFIs were mostly due in part to the ZEPI-MoHCC, MCAZ and partners efforts in strengthening AEFI surveillance over the years using passive (spontaneous reporting) enhanced surveillance for cholera and typhoid vaccines and active surveillance (Zm-STARSS study) for COVID-19 vaccines and routine children antigens(6).

2. Objectives of national AEFI surveillance system

- To ensure that all AEFI cases detected are investigated and reported timeously
- To analyse AEFI reports and take corrective action
- To ensure patient safety
- To minimize AEFIs in routine immunization and mass campaigns
- Promote standardized AEFI reporting tools evidence-based approaches effective vaccines safety monitoring system countrywide to identify the safety implications and risk minimization.
- Early AEFI detection, notification and case management causality assessment and feedback, risk minimisation and signal detection.
- Identify and include all stakeholders, public/vaccinees/ guardians, healthcare professionals (HCPs) of both public and private sectors including vaccine manufacturers to effectively play their roles in AEFI surveillance and vaccine safety monitoring, by collaboration and ensuring transparent collection, analyses and sharing of all types of vaccines antigens safety data;
- Provide vaccine pharmacovigilance preparedness by providing guidance for enhancing and harmonizing vaccine safety surveillance systems to guide processes for collecting, analysing and sharing safety data and information, including data management systems.
- Provide AEFI feedback information and support evidence-based programmatic decisions related to all types of vaccines; and effective benefit/risk management.
- Emergency preparedness and provide guidance to support vaccine safety communication during COVID-19 pandemic and or any other pandemic.

3. Basics of an effective national AEFI surveillance system

Figure 1 below illustrates the WHO and CIOMS recommended types of AEFI surveillance systems that includes passive (spontaneous), enhanced and active surveillance systems).



4. Zimbabwe National AEFI Process flow Figure 2

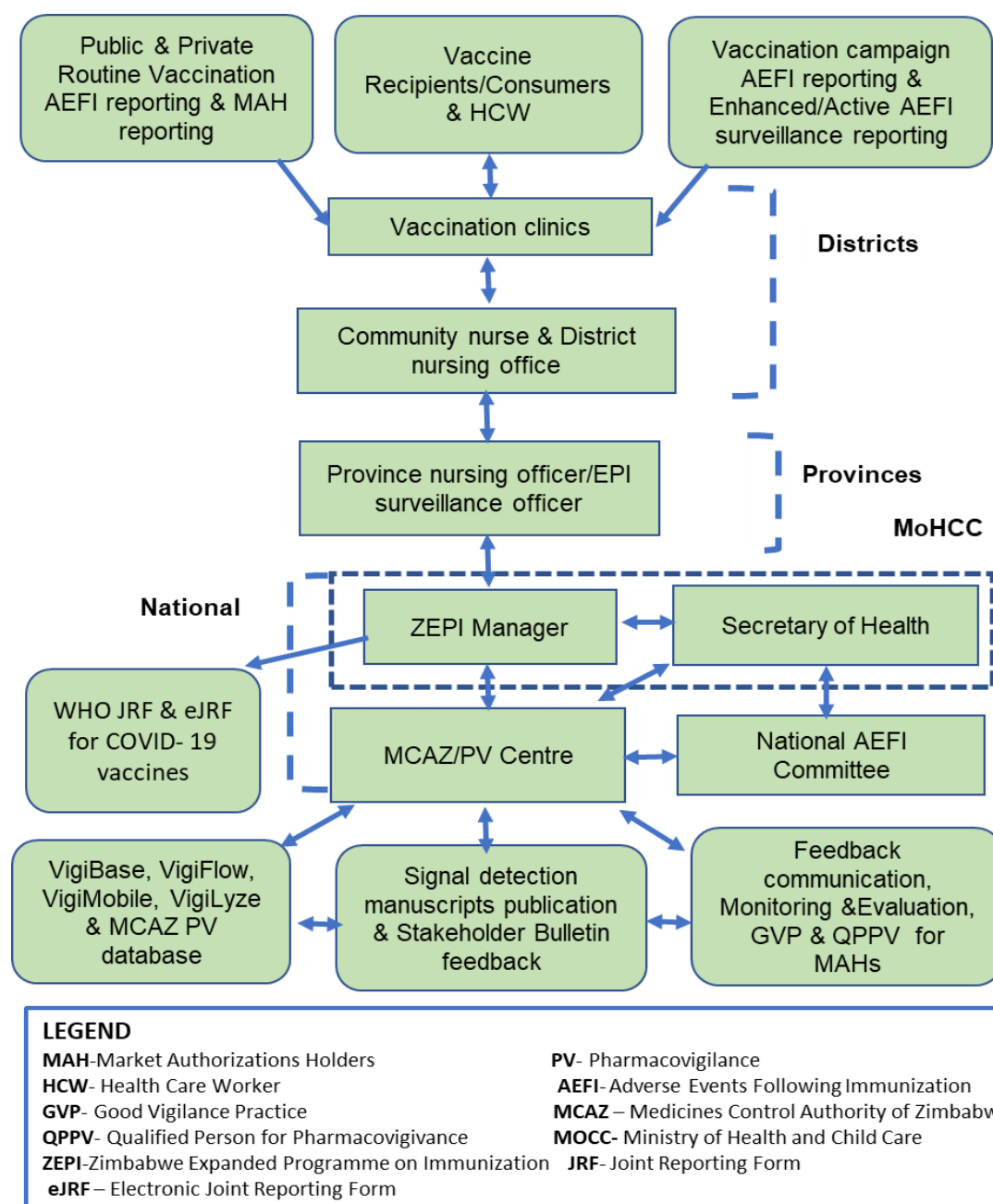


Figure 2: Zimbabwe National AEFI process flow [Adopted from the following source: Nyambayo PP, Manyevere R, Chirinda L, Marekera SF, Nyamandi T, Chaitezvi RP, Rukwata RT, Mehta U, Gold MS. Zimbabwe adverse events following immunisation surveillance system: A descriptive study with COVID-19 vaccine safety updates. Southern African Journal of Infectious Diseases. 2026 Mar 20;41(1):785.]

5. Zimbabwe Immunisation Schedule

Table 1 below shows the current approved immunisation schedule (2024) used in Zimbabwe for both private and public sectors. The vaccine administration child ages stated are the minimum age for each vaccination. Children should receive doses at these stated ages **or** at first contact after reaching that age (maximum age limits are: BCG 11 months, Rotavirus 24 weeks, and Pentavalent 23 months (these antigens **should not** be given after these age limits).

Table 1. Zimbabwe routine vaccination schedule as of August 2024 which subject to change in future in line with evidence-based practices and ZEPI-MoHCC policy.

Age Administration	Name of Vaccine	Doses	Route of administration
At birth	BCG	0.05ml	Intradermal insertion of the deltoid muscle right arm
6 weeks	bOPV 1	2-3 drops	Oral
	Pentavalent 1	0.5mls	Intramuscular antero-lateral aspect of the right mid-thigh
	PCV 1	0.5mls	Intramuscular antero-lateral aspect of the left mid-thigh
	Rotavirus 1	1.5mls	Oral
10 weeks	bOPV 2	2-3 drops	Oral
	Pentavalent 2	0.5 mls	Intramuscular antero-lateral aspect of the right mid-thigh
	PCV 2	0.5 mls	Intramuscular antero-lateral aspect of the left mid-thigh
	Rotavirus 2	1.5mls	Oral
14 weeks	Pentavalent 3	0.5 mls	Intramuscular antero-lateral aspect of the right mid-thigh
	PCV 3	0.5 mls	Intramuscular antero-lateral aspect of the left mid-thigh
	IPV 1	0.5mls	Intramuscular antero-lateral aspect of the mid left thigh
	Pentavalent 3	0.5 mls	Intramuscular antero-lateral aspect of the right mid-thigh

	Rotavirus 3	1.5mls	Oral
	bOPV 3	2-3 drops	Oral
9 months	MR 1	0.5mls	Subcutaneous on left upper arm
	IPV 2	0.5mls	Intramuscular antero-lateral aspect of the mid left thigh
	TCV	0.5mls	Intramuscular antero lateral aspect of the mid right arm
18 months	DPT Booster	0.5mls	Intramuscular antero-lateral aspect of the right mid-thigh
	bOPV 2 Booster	2-3 drops	Oral
	MR 2	0.5mls	Subcutaneous on left upper arm
5 years and 10 years	Td	0.5mls	Intramuscular antero-lateral aspect of the right mid-thigh
Grade 5 and Grade 6 10 Years and 11 years out of (Girls)	HPV	0.5mls	Right upper arm

Zimbabwe was part of the global polio endgame countries that switched from tOPV to bOPV in May 2016. IPV was introduced in Zimbabwe in 2019.

Vitamin A Supplementation

Vitamin A supplementation was integrated in the routine immunization since 2005. Any contact with a health worker is an opportunity to screen mothers and children for eligibility to receive Vitamin A supplementation. The optimal interval between doses for children is every 6 months until 59 months, in Zimbabwe as illustrated in **Table 2** below

Table 2. Vitamin A supplementation schedule

Target for Vitamin A	Immunization Contact	Route	Dose
Infants 6 – 11 months	Routine immunizations/Campaigns	Oral	100 000 IU
Children 12 – 59 months	Routine immunizations/Campaigns	Oral	2000 IU

6. Basics of Adverse Events Following Immunisation (AEFIs)

6.1 Definition of AEFI

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. WHO definition 2021.

6.2 Types of AEFIs

In 2012 and 2019, the Council for International Organizations of Medical Sciences (CIOMS) and WHO revised the classification regarding cause-specific categorization of AEFI. There are five cause-specific types AEFIs namely, vaccine product-related reaction, vaccine quality defect-related reaction, immunization error-related reaction, immunization anxiety-related reaction/ immunization stress related responses (ISRR) and coincidental event.

6.3 Vaccine product-related reaction

An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine such as the adjuvant, preservative or stabilizer(14). It is an individual's reaction to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. Most often the exact mechanism of a vaccine product-related reaction is poorly understood(4). The reaction may be due to an idiosyncratic immune mediate reaction (e.g. anaphylaxis) or to replication of the vaccine-associated microbial agent (e.g. vaccine-associated poliomyelitis following OPV which contains attenuated live virus). However, it is important to note that, among certain high-risk individuals, there is a higher probability of these rare vaccine product-related reactions which do not occur in the majority of vaccines.

6.4 Vaccine quality defect-related reaction

An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including the administration device, as provided by the manufacturer(4, 14). A vaccine quality defect-related reaction is a due to a defect in a vaccine (or its administration device) that occurred during the manufacturing process. Such a defect may have an impact on

an individual's response and thus increase the risk of adverse vaccine reactions. Insufficient inactivation of wild-type vaccine agent (e.g. wild polio virus) during the manufacturing process or contamination introduced during the manufacturing process could cause the vaccine quality defect-related reactions. In the early years of immunization programmes, some major vaccine quality defect-related reaction incidents were reported. However, since the introduction of good manufacturing practice (GMP) manufacturing defects are now very rare. Since vaccine manufacturers have started following GMP, and NRAs have been strengthened, the potential risk of such quality defects is now rare.

6.5 Immunization error-related reaction

An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and that thus, by its nature, is preventable(4, 14). When errors in vaccine handling such as exposure of the vaccines and or diluents, where applicable, to excess heat or cold; use of a vaccine post expiration date, or errors in vaccine prescribing, vaccine administration or non-adherence to recommendations for use occur, immunization error-related reactions result.

6.6 Immunization anxiety-related reaction (Immunization stress related responses – ISRR)

Stress responses to immunization can be triggered and may manifest just prior to, during, or after immunization. It is called Immunization stress related responses (ISRR) These reactions are common, resulting from fear of, or pain due to, injection rather than from the vaccine itself. In some cases, the cause of the AEFI remains unknown, however clusters of fainting after immunization are well recognized as anxiety-related reactions during immunization programmes targeting adolescent girls(4, 14).

6.7 Coincidental event

An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety, but a temporal association with immunization exists(4, 14). These require specific domain knowledge for comprehensive investigation and correct interpretation as they may be mistaken for vaccine reactions and could lead to inappropriate suspension of a vaccine programme.

7.Roles and responsibilities at various levels

The roles and responsibilities are as described below and summarized in table 1 at various levels of a national AEFI surveillance system.

Table 3 States the roles and responsibilities at various levels of a national AEFI surveillance system.

Level of reporting	Activity
Community	• Identification of AEFIs • Reporting to nearest health worker/health centre
Health Facility	• Identification and/or detection of AEFIs • Clinical management of AEFIs • Reassure the care giver • Completion of AEFI reporting forms and case investigation forms • Notify district of any cases of AEFIs (NB. Use fastest means of communication in case of serious or fatal AEFIs; notification to be done within 24 hours) • All fatal cases to be reported to the police for a postmortem • Refer serious cases to district hospital with well completed AEFI reporting and investigation forms • Keep the respective vaccine vial (clearly labelled) under cold chain in cases of severe reaction until investigations are complete • In case of clustering of AEFIs (more than one case) from one batch number of vaccines, stop using that batch and report immediately • Maintain line list of AEFIs • Refer all questions to the DMO • Write report and follow up • Ensure that all fields are completed
District	• Ensure all staff are trained on AEFI surveillance • Provide AEFI SOPs to all facilities and ensure adherence • Generate the AEFI report ID number and record it on the submitted AEFI reporting forms • Investigation of all AEFI cases that;

Level of reporting	Activity
	<i>a.)</i> are serious cases (death/ resulted in hospitalization/ disability) <i>b.)</i> belong to a cluster of AEFI <i>c.)</i> are a previously unrecognized event associated with an old or newly introduced vaccine involves an increased number or rates of known cause <i>d.)</i> are a suspected immunization error <i>e.)</i> appear on the list of events defined for AEFI surveillance <i>f.)</i> cause significant parental or public concern. • Classify all the AEFIs • Correct programme errors through on job training • Facilitate management of cases • Complete AEFI investigation report • Notify province of any cases of AEFIs (NB. Use fastest means of communication in case of serious or fatal AEFIs) • Maintain district line list • Ensure postmortems are done for deaths and reports are submitted timeously to next level, including the AEFI reporting and investigation forms • Refer all questions to the DMO
Provincial Level	• Contact National level focal person for severe and fatal AEFIs • Maintain provincial line list of AEFIs • Investigate or support investigation of serious AEFIs, and forward completed AEFI reporting and investigation forms to the national level • Conduct regular supportive visits to districts • Ensure training of staff and provide resources for system • Ensure all reports are submitted to national level in duplicate • Reconcile provincial and national surveillance databases on a quarterly basis • Refer all questions to the PMD
National Level	• Receive and review AEFI case reports from sub-national levels • Conduct investigations when necessary • Submit all AEFI reporting and investigation forms to the Medicines Control Authority of Zimbabwe (MCAZ), within 48 hours of notification • Give regular feedback to lower level and MCAZ • Ensure SOPs are always compliant to requirements • Provide training to all focal persons

Level of reporting	Activity
	• Provide national guidelines on all vaccine management and surveillance issues • Refer all questions to the Public Relations Officer
MCAZ Pharmacovigilance	• Receipt of a completed AEFI reporting and investigation form, • Check information on the report form for completeness and clarity. • Request for any additional information or clarification from the reporter where necessary • Table the AEFI reports for causality assessment by the Pharmacovigilance and Clinical Trials (PVCT) Committee using the 2019 WHO AEFI Aide-Memoire on causality assessment. The PVCT Committee is the National AEFI Committee. • After the Committee meeting, provide feedback letters to the reporters copying the relevant district and provincial health executive. Feedback is also sent to the EPI manager. • Bi-annually, a letter is sent to the Secretary for Health and Child Care providing feedback on the AEFI reports received. • AEFI MedDRA and vaccine WHODrug coding in Vigiflow, entering the causality assessment and committing reports to Vigibase. • Other benefit-risk communication measures include quarterly and annual data analysis for signal detection and feedback to all stakeholders through PV trainings, the medicines information bulletin, circulars and/or manuscripts

8. Steps for AEFI reporting

- Receive the report, conduct a quick assessment and inform the next level
- Take full socio-medical history
- Review available records which the patient might have brought and check any history of previous medication given
- Find out if the child had similar episodes prior to immunization or any history of allergies to food and/or medicines e.g. egg, red meat etc., injury or any rituals done
- In case of an abscess refer the child to the next level for probable laboratory tests, incision and drainage
- Find out from care giver if anyone in the community had the same problem after being vaccinated

- Notify the next level and refer patient to next level when necessary
- Compile an incident report of what transpired and submit to the next level with copy of the completed AEFI reporting forms, and AEFI case investigation forms for serious AEFIs.
- After results are out dispel myths and misconceptions.
- In case of a suspected AEFI death offer bereavement, counselling and inform the police
- Request for post mortem and parents to consent
- Refer all questions to the district medical officer (DMO)/ district nursing officer (DNO)/ provincial medical officer (PMD)/ provincial nursing officer (PNO).
- Have a fully equipped emergency tray
- Check the cold chain equipment and temperature records
- Keep the used vials under cold chain for investigation

8.1 Procedure for determining and reporting an AEFI

An AEFI reporting form should be completed to report an AEFI (**Annex 1**). For serious AEFIs, an AEFI reporting form and case investigation form (**Annex 2**) is required to be completed.

8.2 History taking

History taking should include the following:

- Vaccination history
- Chronic illnesses
- Acute infections
- Medications given before and after vaccination
- Allergies to food such as eggs, red meat, medicines
- Feeding practices
- Growth and development of child, including malnutrition
- Previous reactions to medicines
- Exposure to HIV

8.3 Examination and management of AEFI

- Resuscitate the child and conduct a head-to-toe examination

- Note any abnormalities
- Take and record the child's temperature
- Confirm type of AEFI e.g. abscess and document findings
- Counsel and reassure the care giver
- Explain procedure to be followed and manage child appropriately

8.4 Completion of AEFI reporting forms

Complete standard AEFI reporting form online using AEFI VigiMobile app (tools for AEFI reporting) and hard copy (annex 15.1)

- Ensure complete documentation
- Sign the forms
- Date stamp the AEFI reporting form
- A completed AEFI form and case investigation form for serious AEFI is required by ZEPI and MCAZ to enable causality assessment and risk assessment.

Table 4 of AEFI Reporting Tools recommended for AEFI reporting, investigation, and causality assessment.

Description	Purpose	Where to find it
AEFI reporting form for all types of AEFIs.	To collect basic reports of all AEFI cases that have been notified both non-serious and serious AEFIs	See Annex 1 below. <i>NB. More copies are available on request from the EPI-MoHCC and MCAZ email: mcaz@mcaz.co.zw website www.mcaz.co.zw WhatsApp +263772145191/2/3</i>
AEFI investigation form for serious AEFIs.	To collect detailed information when serious AEFI cases are investigated	See Annex 2 below <i>NB. More copies are available on request from the EPI-MoHCC and MCAZ email: mcaz@mcaz.co.zw website www.mcaz.co.zw WhatsApp +263772145191/2/3</i>
AEFI VigiMobile for AEFI reporting form for all types of AEFIs by healthcare	To collect basic reports of all AEFI cases that have been notified both non-serious and serious AEFIs	Accessed using the link below: https://vigiflow-eforms.who-umc.org/zwaefi/aeafi

professionals only.		OR, alternatively using the scan code below: 
Online AEFI VigiFlow Reporting form	To collate the details in the reporting form	Accessed using the link below: https://vigiflow.who-umc.org
AEFI causality assessment	To determine case classification of serious AEFI cases	Accessed using the link below: https://gysi-aefi-tools.org/index.html

8.5 Completeness of the AEFI Report (VigiGrade Completeness Score)

The VigiGrade completeness score is a measure of the amount of clinically relevant information in an AEFI report. It highlights the quality of the information presented in the individual AEFI report and gives a score for how complete the AEFI report is(23).

A completeness score is calculated for each AEFI report but is usually given as an average for all AEFI reports submitted from one country over time. The completeness score does not imply that the reported adverse event has been caused by the vaccine. It focuses on the presence of information that is important for causality assessment (clinically relevant).

A score is given to each field in the AEFI report, and the individual scores are weighted and combined into a score for the whole AEFI report. The maximum VigiGrade completeness score (for a complete report) is 1.0, and would contain adequate information for the following fields:

- time-to-onset,
- age,
- sex,
- indication,
- outcome,

- report type,
- dose,
- country,
- primary reporter, and
- comments.

For each missing dimension, a penalty, which varies with clinical relevance, is detracted from the score.

Table 5 Below is a summary showing the AEFI form VigiGrade completeness score penalties for each field(23).

Dimension	Description	Considerations	Penalty
Time-to-onset	Time from treatment start to the suspected ADR.	Imprecise information penalized if there is ambiguity as to whether the drug preceded the adverse event; with 30% if the uncertainty exceeds 1 month, 10% otherwise.	50% 30% 10%
Indication	Indication for treatment with the drug	Penalty imposed if information is missing or cannot be mapped to standard terminologies such as ICD or MedDRA.	30%
Outcome	Outcome of suspected ADR in the patient.	"Unknown" treated as missing.	30%
Sex	Patient sex.	"Unknown" treated as missing.	30%
Age	Patient's age at onset of the suspected ADR.	Age "unknown" treated as missing. 10% penalty imposed if only age group is specified.	30% 10%
Dose	Dose of the drug(s).	Penalty imposed if the total daily dose cannot be calculated from the included fields.	10%
Country	Country of origin.	Supportive in causality assessment since medical practice and adverse reaction reporting vary between countries.	10%
Primary reporter	Occupation of the person who reported the case (e.g. Physician, Pharmacist).	Supportive in causality assessment since the interpretation of reported information may differ depending on the reporter's qualifications "Unknown" penalized as missing information, whereas "Other" is not penalized.	10%
Report type	Type of report (e.g. spontaneous report, report from study, other).	"not available to sender (unknown)" treated as missing.	10%
Comments	Free text information.	Uninformative text snippets excluded.	10%

8.6 Timelines for AEFI reporting

- In case of fatal or severe AEFI use the fastest means of communication to inform the next level i.e. phone. Fatal cases to be relayed to next level within 24 hours.
- The communication should follow the normal channel: District, Provincial and ZEPI Head office
- Submit a comprehensive report and attach the AEFI reporting forms

9. Investigation of AEFIs and Adverse Event of Special Interests

Once an AEFI report has been received by the district level, an assessment should be made to determine whether an investigation is needed. The reported AEFI must be investigated if it:

- appears to be a serious event (as defined by WHO) of known or unknown cause
- belongs to a cluster of AEFI
- is a previously unrecognized event associated with an old or newly introduced vaccine
- involves an increased number or rates of known cause
- is a suspected immunization error
- appears on the list of events defined for AEFI surveillance
- causes significant parental or public concern.

The ultimate goal of a case investigation is to find the cause of an AEFI and to implement follow-up actions. Investigation should identify any immunization error-related or vaccine product-related reactions because these are preventable. If coincidental events are recognized, proving them will be important to maintain public confidence in the immunization programme. It is important to investigate suspected adverse events promptly and completely. The district level AEFI case investigation committee is responsible for carrying out the investigation.

The investigation can be a simple assessment or a more rigorous scientific evaluation of the reported AEFI to recognize its possible cause(s). The extent of the investigation depends on the nature of the reported AEFI. The WHO's Aide-mémoire on AEFI investigation, 2019 (**Figure 5**) should be used as resource material in the investigation of

AEFIs. The aide-mémoire proposes a systematic, standardized process to investigate reported serious AEFIs and ascertain the underlying cause.

9.1 AEFI Investigation

The investigation team should fill the AEFI case investigation form **Annex 2** below and submit the form to the next level, with the AEFI reporting form attached. The following should be checked:

- i. Cold chain maintenance
- ii. Immunization technique
- iii. Vaccine(s) given, Batch No. Expiry Date, VVM
- iv. Documentation practices
- v. Emergency tray
- vi. Sharps disposal

9.2 Composition of AEFI Investigation Committee / Team

- i. Programme Manager
- ii. Clinician (Paediatrician/Nurse/Epidemiologist/Pathologist/Physician)
- iii. Health Promotion Officer
- iv. Pharmacist
- v. Surveillance Officer
- vi. Logistician
- vii. Laboratory and forensic expert
- viii. Health Information Officer

Surveillance and investigation of AEFI is important in order to take corrective action and preserve public confidence in ZEPI.

9.3 How to investigate an AEFI

AEFI investigation follows standard principles of epidemiologic investigation, as shown in **Figure 3** below;

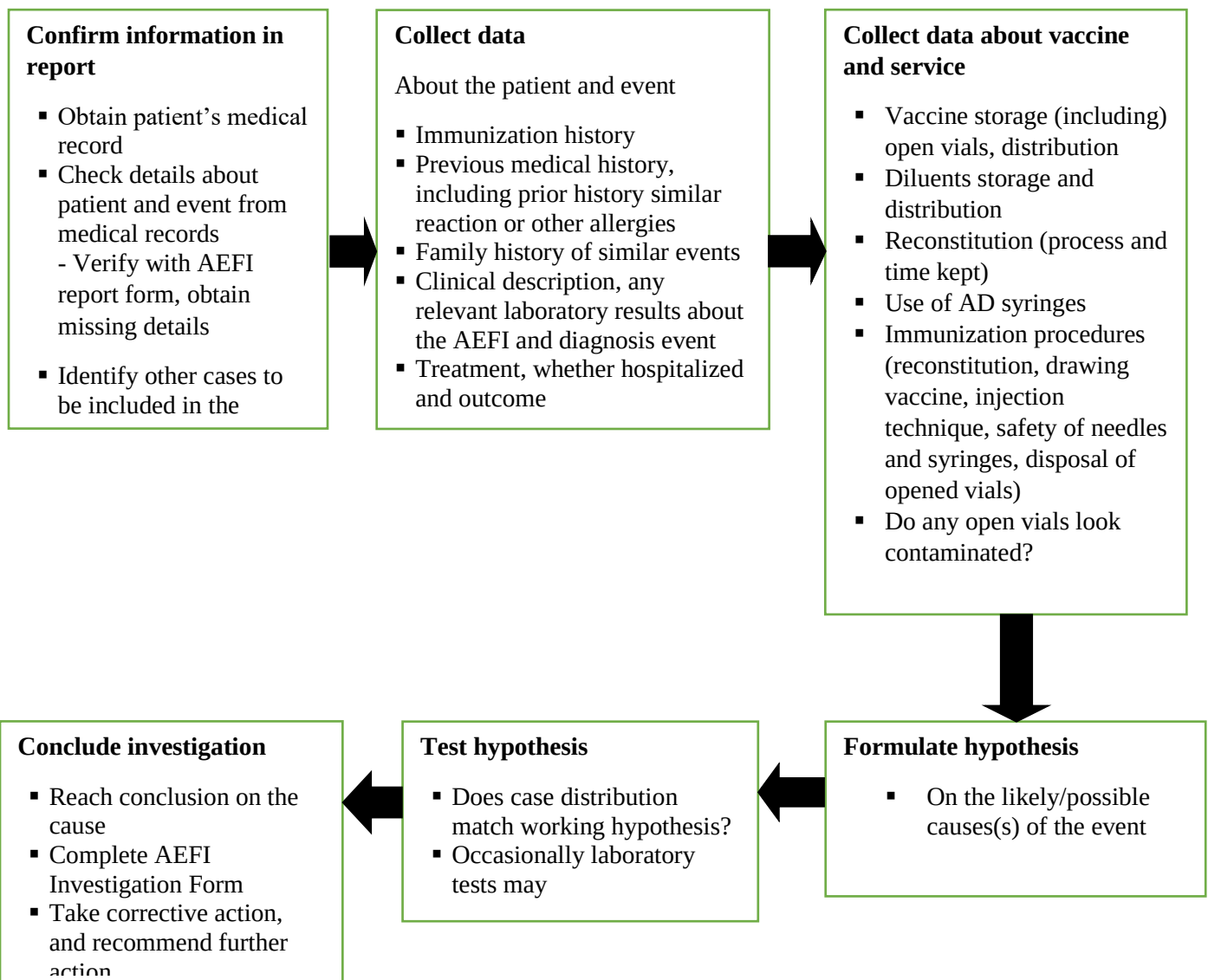


Figure 3. Adapted from the WHO Global Manual on Surveillance of AEFIs, 2020

It is important to investigate suspected adverse events promptly and completely. The investigator will primarily need to focus on the reported reaction as well as gather information from the patient/parent/ caregiver, health workers and supervisors, and community members.

9.4 Investigation of AEFI Clusters

A cluster of AEFI is defined as two or more cases of the same adverse event related in time, place or vaccine administration. According to the WHO Global Manual on Surveillance of AEFI of COVID-19 Vaccines 2020 when investigating cluster AEFIs the investigator should look for AEFIs occurring in similar age groups and populations with genetic predisposition or disease. Cluster investigation begins by establishing a case definition for the AEFI and related circumstances and by identifying all cases that meet the case definition.

Cluster identification (i.e. cases with common characteristics) is done by gathering details (who, when and where) of vaccines administered. This can be achieved by collecting and recording:

- detailed data on each patient
- programme-related data (storage and handling, etc.)
- immunization practices and the relevant health workers' practices.

Common exposures among the cases can be identified by reviewing:

- all data on vaccine(s) used (name, lot number, etc.)
- data on other people in the area (also non-exposed)
- any potentially coincident factors in the community.

When an AEFI cluster has been identified, the cause-specific definitions provide a framework for investigation and causality assessment.

The identification of the causes of an AEFI cluster may be investigated as illustrated in **Figure 4 the AEFI process flow below:**

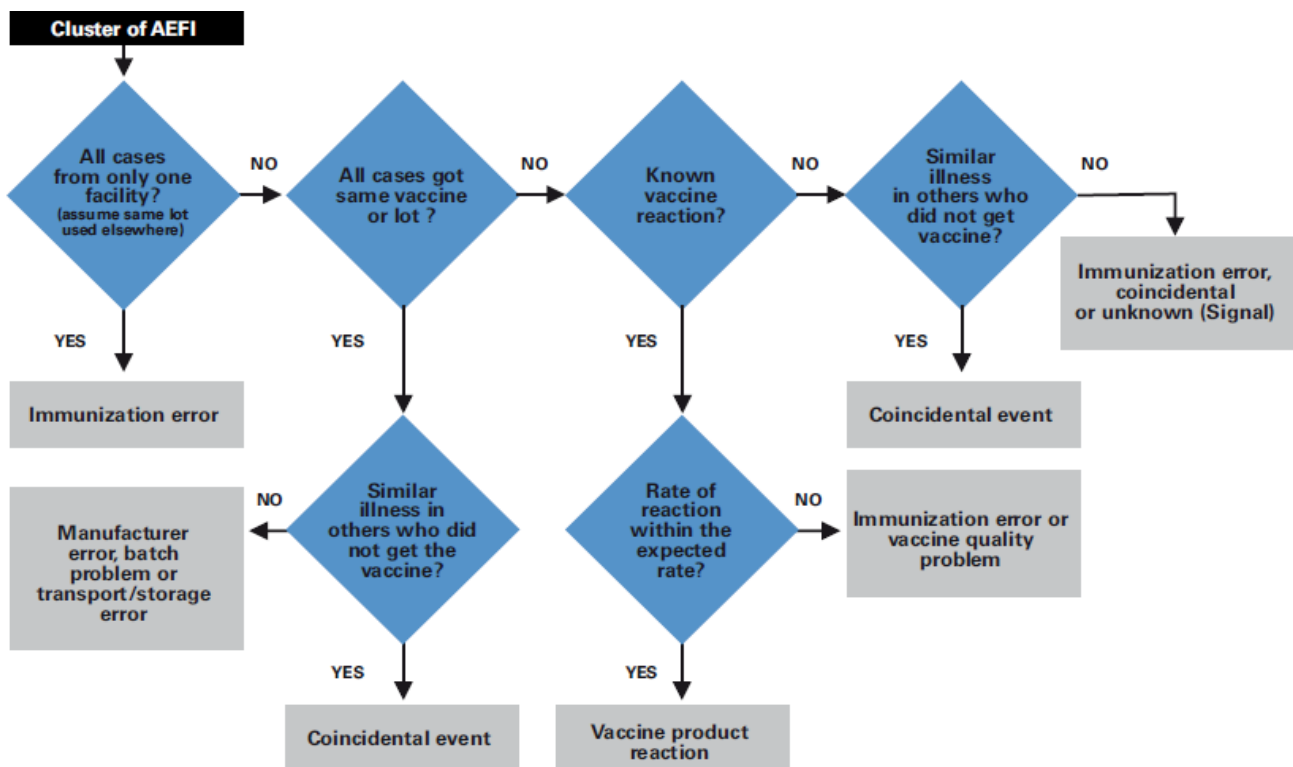


Figure 4: Adapted from the WHO Global Manual on Surveillance of AEFIs, 2020.

9.5 Investigation of serious AEFI fatal case

A field investigation of a death following immunization has to be conducted without delay as the death can cause significant community concern, and all administrative levels, including the national immunization programme, should be notified of the death.

The WHO recommends that death investigation should be carried out by a team comprising clinical, laboratory and forensic experts, and that the team should be supported by the programme managers, as listed above. All relevant information on the event should be available to the investigation team.

An autopsy is preferred and is recommended following a fatal suspected case to be associated with vaccine or immunization; however, the decision to conduct the autopsy should be taken within the context of religious, cultural and the legal framework of the country. At the time of autopsy, the pathologist should be provided with documents outlining detailed preclinical and clinical history, including laboratory and radiological findings.

10. Analysis of AEFI Data

The analysis of AEFI data is different to the analysis of adverse drug reactions and serious adverse events data. The Global Manual on surveillance of AEFI details that immunization and vaccine safety surveillance should incorporate inbuilt mechanisms for structured, systematic and continued data collection. Epidemiological analysis of data is required to measure the impact of vaccines used in the country immunization programme and to disseminate findings to advise programme managers, and other stakeholders including manufacturers.

The National AEFI Committee and MCAZ analyses AEFI data as per the WHO Global Manual on surveillance of AEFI 2019 and consider the following

- reporting source (reports of AEFI by different sources may provide a wider range of information)
- completeness of submitted AEFI forms
- verification and reassurance of data accuracy
- identifying health institutions where AEFI are not reported (determining whether this is due to failure of reporting or whether there are no AEFIs to be reported) and checking on “zero reporting” or “nil reporting”
- performance of causality assessment to classify the AEFI
- estimated AEFI reporting rates (assessing the number of reported AEFI and the rate per 1000, 10 000 or 100 000 doses of vaccine used in a specified time period)
- estimated rates by type of AEFI and by antigen (assessing the number of causes specific reported AEFI and the rate for 1000, 10 000 or 100 000 doses (review) of vaccine used in a specified time period)
- comparison of these observable rates with available or expected known events, whether vaccine reactions or background rates or historic reporting trends.

The **Table 6** below is adapted from the WHO Global Manual on Surveillance of AEFIs, 2019 and explains the purpose of AEFI data analysis at different levels of the immunization safety surveillance system, the extent and purposes of analysis at each level.

Table 6. Purpose of AEFI data analysis at different levels

Programme implementation level	What data to analyse	Purpose of data analysis at given level
Local level (immunization provision level)	Number of reports by clinics, hospitals, villages by a given time	These are programme operation/surveillance performance indicators (timeliness, completeness).
	Reported AEFI by place (clinics, hospitals), persons and time	Identification of immunization error-related events will lead to corrective action.
	Reported AEFI by antigen	Will also identify vaccine reactions and coincidence.
Subnational level (regional/ provincial/ district/ town)	Number of reports by local levels	These are programme operation/surveillance performance indicators (timeliness, completeness) at local level.
	Reported AEFI by place (clinics, hospitals), persons and time	Identification of immunization error-related events will lead to corrective action.
	Cluster analysis	Cluster analysis leads to identification of immunization error related events, coincidence and vaccine reactions.
	Reported AEFI by antigen	Will identify vaccine reactions and coincidence.
National level	Number of reports by intermediate levels	These are programme operation/surveillance performance indicators (timeliness, completeness) at intermediate level.
	Reported AEFI by place (clinics, hospitals), persons and time	Cluster analysis leads to identification of immunization error related events, coincidence and vaccine reactions.
	Cluster analysis	Will identify vaccine reactions, including detection of signals.
	Reported AEFI by antigen	Leads to operational and policy decisions being taken in the country.

Table 6 Adapted from the WHO Global Manual on Surveillance of AEFIs, 2020

The analysis of AEFI data is carried out by following four steps; as outlined in the Global Manual on surveillance of AEFI 2019;

Step 1: After verification of cases, all reported AEFI data is line-listed and entered into a data base. Line listing aides in the initial identification of clustering or any unusual or significant reporting events that need further analysis.

Step 2: AEFI data is tabulated by place, person, time, antigens and type of event. This step further filters the AEFI by different variables and furthers analysis. It is possible to identify common immunization errors at this step.

Step 3: Calculation of AEFI rates, where the number of doses administered for each antigen is the denominator for calculating reported AEFI rates for each antigen at a given time period.

Step 4: Comparison and interpretation of AEFI rates. Expected vaccine reaction rates that are available for each type of AEFI and antigen (from WHO vaccine reaction information sheets) provide a guide to decision-making on corrective action for reported AEFI.

Risk management plan, Pharmacovigilance Plan in line with International Council of Harmonization (ICH E2E), Periodic Safety Update Reports (PSURs) and Periodic Benefit Risk Evaluation Report (PBRER) is a format of safety report described by the ICH-E2C(R2) guideline which is used as a basis for the EU Periodic Safety Update Report (PSUR). The report is produced by the marketing authorisation holder (MAH) at defined time points after a chemical entity innovator medicine including vaccine has been registered in Zimbabwe in line with other regulatory international requirements. The motive of the report is to provide comprehensive and up-to-date information about the safety of a medicine. The report needs to summarize any new evidence on safety, efficacy and effectiveness that might affect the balance of risks and benefits. It provides details about the risks to Regulatory authorities and identifies where risk management initiatives may be required.

Further guidance on requirements for market authorisation holders (MAHs) and manufacturers good vigilance practice (GVP) including reporting of AEFIs may be obtained from the MCAZ, GVP current guidance document on the MCAZ website www.mcaz.co.zw

10.1 Signal Management

A signal is information that arises from one or multiple sources (including observations and experiments) which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verification. A signal is not a confirmed finding but is generally referred to as a hypothesis- generating situation that must be validated or disproved.

Signal detection, verification and response is a key activity that must be specifically addressed in the old and new vaccines context. Signals can best be identified by pooling of data from multiple sources and analyzing if the pooled data points to the occurrence of a new event that could be causally related to the vaccine. In general, spontaneous reporting using a passive surveillance approach forms the basis of signal detection worldwide. Active vaccine safety surveillance can complement passive surveillance, confirming or discarding signals detected in the passive surveillance (2).

Signal management consists of a set of activities including signal prioritization and evaluation to determine whether a signal represents a risk which may warrant further assessment, communication or other risk minimization actions in accordance with the public health importance of the issue. Following signal evaluation, a signal either becomes an identified risk, a potential risk (which implies that closer monitoring and/or further investigation is necessary), or does not constitute a risk and does not warrant further action at that time(2).

11. Management of Adverse Events Following Immunization

To ensure continuous safety monitoring and public acceptance of vaccines, it is essential to monitor the incidences of AEFI. Management of mild and moderate AEFIs will depend on the reactions. Although serious AEFI with injectable vaccines are very rare, vaccines are biologic products and such events may occur. Every vaccination centre must have an emergency kit stocked with adrenalin 1:1000, hydrocortisone, promethazine and 50% dextrose as a minimum. Anaphylaxis is a very severe reaction, which may occur rarely after any injection including a vaccination. The patient collapses with signs of shock and breathing problems hence need resuscitation.

11.1 Emergency Procedure in the Case of Anaphylaxis

Table 7 3. Management of AEFIs -Emergency procedure for anaphylaxis case

Nature of emergency	Emergency procedure
Emergency Procedure in the Case of Anaphylaxis	• Call for help and attend to patient immediately • Check breathing and heartbeat • If the patient is not breathing: ✓ Secure the airway and ventilate ✓ If there is no heartbeat ✓ Do CPR (cardio- pulmonary resuscitation) ✓ Give adrenalin 1:1000 ✓ Children under 3 years: 0.1 ml subcutaneous at once ✓ Children 3-5 years: 0.2 ml subcutaneous at once ✓ Give adrenalin as follows: 1 ampoule diluted with normal saline to 10 ml in small amounts slowly IV. The heart rate should not exceed 160/minute ✓ Give hydrocortisone sodium succinate slowly IV or IM in the following doses: Children 6 months- 5 years: 50 mg ✓ Set IV drip and run the Normal saline drip fast
	•

11.2 Key point in AEFI Management for both non-serious or serious AEFIs

The difference between a reaction related to the vaccines and an adverse event which can have other causes should be explained to patients and parents. This ensure that they have all information they need to make an informed decision about receiving an immunization for

themselves or children. Trusted and well-informed health care providers are best suited to provide such information. Information about the immunization(s) should be provided well ahead of the immunization visit. This gives parents the time to understand the information well and ask questions that will increase their trust.

12.Causality assessment of AEFIs by the National AEFI Committee

The Zimbabwe national AEFI Committee has the mandate and expertise to conduct causality assessment of AEFI reports that are received from the national immunization program EPI private and MoHCC public vaccinating sites and MCAZ. Causality assessment essentially means finding a causal association or relationship between a medicine/ vaccine and an adverse reaction/ event. It is an evaluation of the likelihood that a particular treatment is the cause of an observed adverse event (AE). Causality assessment methods are broadly classified into clinical judgment or global introspection, algorithms, and probabilistic methods. There at least 13 methods/algorithms of causality assessment e.g. **WHO AEFI causality assessment Aide-memoire 2019 illustrated under Figure 5 below,(24).**

The commonly used AEFI causality assessment method is the WHO-UMC Causality method based on Bradford Hill Criteria, otherwise known as Hill's criteria for causation, are a group of nine principles that can be useful in establishing epidemiologic evidence of a causal relationship between a presumed cause and an observed effect and have been widely used in public health research. The nine factors used to determine causality were Plausibility, Strength, Consistency, Temporality, Specificity, Biological gradient, Coherence, Experiment and Analogy and the four main factors which are used for ICSRS are Plausibility, Strength, Consistency, Temporality(24).

Important information that is required for AEFI report to be assessed for causality assessment.

- Date of onset of the reaction
- Description of the reaction
- Suspected medicine/ vaccine (including dose, batch number, expiry if available)
- Date of medicine commencement/ date of vaccination
- Date medicine was stopped (if available)
- Action taken to medicine (withdrawn, dose increased, dose reduced, dose not changed, N/A)
- Outcome of reaction (recovered, recovering, recovered with sequelae, not recovered, fatal, unknown)

- Past medical history, concomitant medication, laboratory results and post mortem.

Additional documents – serious AEFI case investigation form/ report, doctor’s notes (if available), post-mortem report (in the event of a fatal outcome), any other documents

The link for the WHO AEFI AIDE Memoire on Causality assessment[13] is <https://gvsi-aeftools.org/index.html>

12.1 The AEFI case investigation should have been completed. Premature

assessments with incomplete investigation could mislead the classification of the event. When an investigation is incomplete, follow-up efforts to obtain additional information and documents should be made.

12.2 There must be a “diagnosis” using standard or widely accepted criteria for the adverse event, clinical sign, abnormal laboratory finding, symptom and/or

disease in question. In other words, it should be clearly understood which vaccine is being associated with what specific event that was reported.

12.3 Causality Assessment Method

The WHO publication, Causality assessment of an AEFI – User manual for the revised WHO classification was developed by WHO as a method for assisting national committees for AEFI case review and causality assessment. It was patterned on an algorithm developed in the USA by the Clinical Immunization Safety Assessment network and with new AEFI definitions proposed by the Council for International Organizations of Medical Sciences (CIOMS).2019

The revised WHO causality algorithm illustrated in **Figure 5** focuses on two critical questions: “Is there evidence in literature that this vaccine(s) may cause the reported event even if administered correctly?” and “Did the event occur within an appropriate time window after vaccine administration?”, WHO 2019.

Figure 5 WHO AEFI Causality assessment Aide Memoire and algorithm illustrates that there are the following four steps in causality assessment, which are;

Step 1. Eligibility: to determine if the AEFI case satisfies the minimum criteria for causality assessment. It is to be ensured that the AEFI case investigation is completed and that all details of the case are available. One or more vaccines administered before the event are identified and a valid diagnosis selected which is thought to be casually related to the vaccination. An appropriate definition to assess diagnostic certainty is to be used (Brighton Collaboration definition, standard literature, national definition or other approved definition). If an AEFI is reported and appears to not meet the eligibility criteria because of suspected inadequate information, it is important to make attempts to collect the additional information required in order to ensure that the case can be properly assessed for eligibility, WHO 2019.

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Step 2. Checklist: to systematically review the relevant and available information to address possible causal aspects of the AEFI. The checklist is used as a guide to assemble information on patient-immunization-AEFI relationships.

Step 3. Algorithm: to obtain direction as to the causality with the information gathered in the checklist. A stepwise approach using the algorithm helps determine if the AEFI could be consistent, or inconsistent, with an association to immunization, or is indeterminate or unclassifiable.

Step 4. Classification: to categorize the AEFI's association to the vaccine/vaccination on the basis of the direction determined in the algorithm.

The final classification is based on there being available adequate information for the case and the classes are classified as;

Consistent causal association to immunization

- 4.1 – Vaccine product-related reaction
- 4.2 – Vaccine quality defect-related reaction
- 4.3 – Immunization error-related reaction
- 4.4 – Immunization anxiety-related reaction

4B: Indeterminate

B1 – Temporary relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)

B2 – Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization

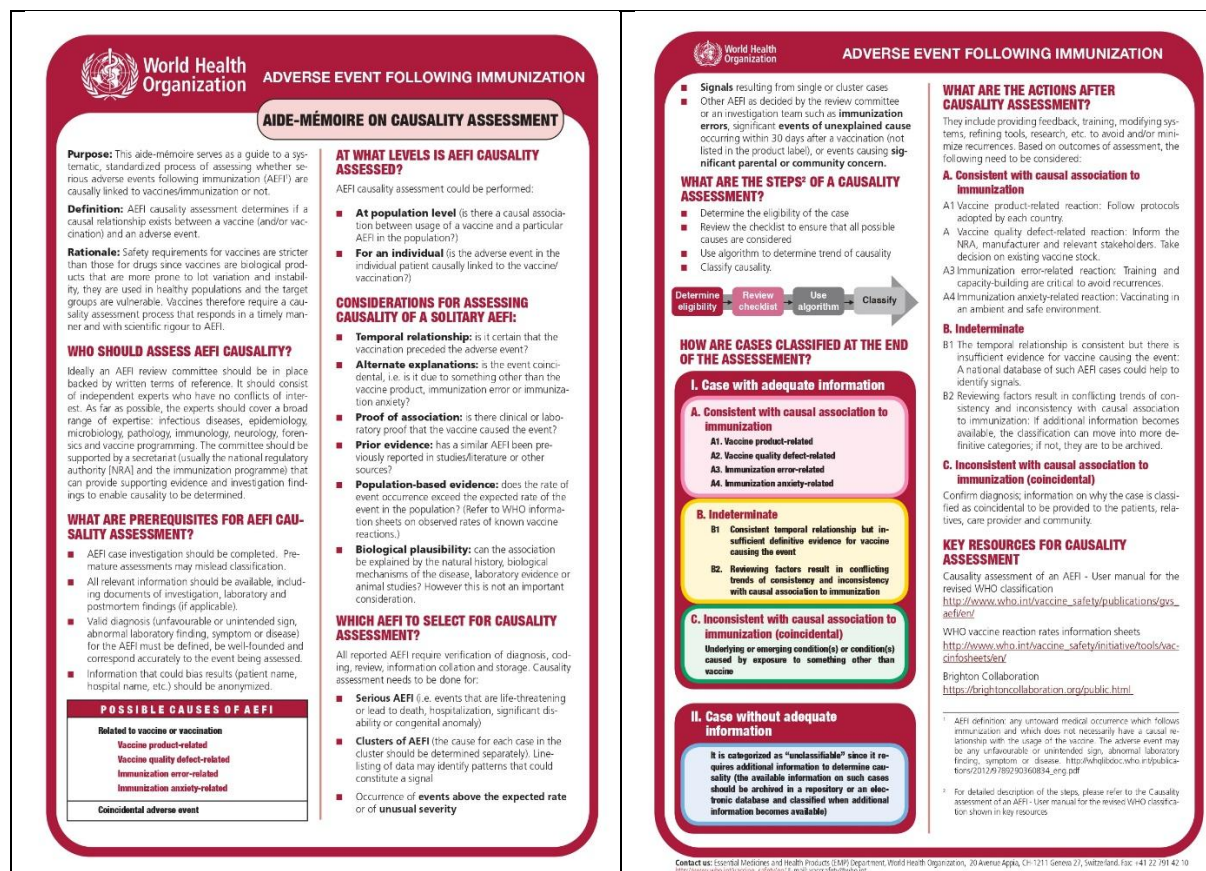
5C: Inconsistent causal association to immunization

Coincidental

5. Unclassifiable.

NB. In some cases however where an event was present before vaccination and continued after vaccination e.g. congenital disability will be classified as not an AEFI and would not meet the AEFI causality assessment eligibility criteria.

Figure 5: The WHO AEFI AIDE-MEMOIRE on causality assessment is used by the National AEFI Committee for determining causality assessment outcomes for the reported AEFIs.



ADVERSE EVENT FOLLOWING IMMUNIZATION

STEP 1 (ELIGIBILITY) Name of one or more vaccines administered before this event: _____ What is the Valid Diagnosis? (The case diagnosis of the AEFI): _____ Does the diagnosis meet a case definition? ☐

Has the _____ vaccine/vaccination caused _____? (The event for review in step 2)

STEP 2 (EVENT CHECKLIST) ☒ check all boxes that apply

I. Is there strong evidence for other causes?	Y	N	UK	NA	Remarks
Does clinical examination, or laboratory tests on the patient, confirm another cause?	☐	☐	☐	☐	
II. Is there a known causal association with the vaccine or vaccination?					
Vaccine product(s)					
Is there evidence in the literature that this vaccine(s) may cause the reported event even if administered correctly?	☐	☐	☐	☐	
Did a specific test demonstrate the causal role of the vaccine or any of the ingredients?	☐	☐	☐	☐	
Immunization error					
Was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)?	☐	☐	☐	☐	
Was the vaccine (or any of its ingredients) administered unsterile?	☐	☐	☐	☐	
Was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal at the time of administration?	☐	☐	☐	☐	
Was there an error in vaccine constitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	☐	☐	☐	☐	
Was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc.)?	☐	☐	☐	☐	
Was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?	☐	☐	☐	☐	
Immunization anxiety					
Could the event have been caused by anxiety about the immunization (e.g. vasovagal, hyperventilation or stress-related disorder)?	☐	☐	☐	☐	
III (Time). If "yes" to any question in II, was the event within the time window of increased risk?					
Did the event occur within an appropriate time window after vaccine administration?	☐	☐	☐	☐	
III. Is there strong evidence against a causal association?					
Is there strong evidence against a causal association?	☐	☐	☐	☐	
IV. Other qualifying factors for classification					
Could the event occur independently of vaccination (background rate)?	☐	☐	☐	☐	
Could the event be a manifestation of another health condition?	☐	☐	☐	☐	
Did a comparable event occur after a previous dose of a similar vaccine?	☐	☐	☐	☐	
Was there exposure to a potential risk factor or toxin prior to the event?	☐	☐	☐	☐	
Was there acute illness prior to the event?	☐	☐	☐	☐	
Did the event occur in the past independently of vaccination?	☐	☐	☐	☐	
Was the patient taking any medication prior to vaccination?	☐	☐	☐	☐	
Is there a biological plausibility that the vaccine could cause the event?	☐	☐	☐	☐	

Y: Yes, N: No, UK: Unknown, NA: Not applicable

ADVERSE EVENT FOLLOWING IMMUNIZATION

STEP 3: (ALGORITHM) REVIEW ALL STEPS AND ☒ ALL THE APPROPRIATE BOXES

Notes for Step 3:

STEP 4: (CLASSIFICATION) ☒ ALL BOXES THAT APPLY

A. Consistent causal association to immunization

☐ A1. Vaccine product-related reaction (As per published literature)

☐ A2. Vaccine quality defect-related reaction

☐ A3. Immunization error-related reaction

☐ A4. Immunization anxiety-related reaction

Unclassifiable

☐ Specify the additional information required for classification

B. Indeterminate

☐ B1. Temporary relationship is apparent but there is insufficient definitive evidence for vaccine causing event (only for new vaccine-linked event)

☐ B2. Qualifying factors result in conflicting trade-offs of consistency and inconsistency with causal association to immunization

C. Inconsistent causal association to immunization

☐ C. Coincidental

☐ Underlying or synergistic condition(s) caused by exposure to something other than vaccine

*B1: Potential signal and maybe considered for investigation

Summarize the classification logic

With available evidence, we could conclude that the classification is _____ because:

FEEDBACK AND CORRECTIVE ACTION RECOMMENDED:

13. Communication and Feedback

Communication following AEFIs is crucial to ensure public trust and confidence in immunisation programs. Serious AEFIs are usually investigated within a communication crisis, characterised by public alarm, media scrutiny and official anxiety. Stakeholders need to be engaged and informed during all stages of an investigation. AEFI are deemed newsworthy and are closely followed by the media, further fuelling public anxiety. As a result, communication must be timely.

13.1 Table 7 : Principles to be followed in effective communication for AEFI:

Principles	Action
Transparency:	Clearly explain the AEFI, its symptoms, and the investigation process.
Timeliness	Share information promptly, avoiding unnecessary delays.
Accuracy:	Provide reliable, evidence-based information, avoiding speculation or misinformation
Empathy:	Show understanding and concern for individuals affected by AEFIs

Consistency	Ensure consistent messaging across all communication channels
Risk communication	Explain the risks and benefits of vaccines, putting AEFIs into perspective.
Stakeholder engagement	Involve healthcare professionals, public health officials, and community leaders in communication efforts.
Cultural sensitivity	Tailor communication approaches to diverse audiences
Monitoring and evaluation	∴ Continuously assess the effectiveness of communication strategies

By following these principles, you can maintain public trust and confidence in immunization programs, in the face of AEFIs.

Communication with various stakeholders; parents / caregivers, the community, health staff and the media need to be carried out under many circumstances, from launching new vaccines, putting in place mass immunization campaigns, to issuing reminders to maintain vaccinations up to date. When a vaccine safety investigation is underway resulting from one of the reasons outlined in earlier chapters of this manual, communications involve keeping the public informed about the investigation, results and action already taken or going to be taken regarding the AEFI. At the same time it is crucial to highlight the benefits of immunization even while communicating about an investigation.

Trust is a key component in the exchange of information at every level. Any overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust among people involved. Admit uncertainty of AEFI, investigate fully, and keep the community informed. Avoid making a premature statement about the cause of the event before the investigation is complete. If the cause is identified as immunization related error, it is vital not to lay personal blame on anyone, but to focus on system- related problems that resulted in the immunization error(s) and steps being taken to correct the problem.

In communicating with the community, it is useful to develop links with community leaders and the peripheral health workers so that information can be rapidly disseminated. Maintaining

lines of communication with the community is important throughout the investigation. Upon completion of the investigation, the cause of the event(s) needs to be communicated to the community. This communication must include information about the steps being taken to remedy the situation and to prevent a recurrence, if such steps are needed.

13.2 Management of Infodemics in AEFI

Infodemics refer to the rapid spread of misinformation, disinformation and conflicting information during public health emergencies. Managing Infodemics is crucial to prevent harm to individuals and communities. Effective Infodemic management helps to:

- Reduce confusion and mistrust
- Prevent harm to individuals and communities
- Promote public understanding and cooperation
- Enhance the credibility of public health authorities
- Support informed decision-making

Several strategies for managing Infodemics can be used. (*See Annex: 3*)

13.3 Communication with stakeholders

There are many parties to whom communications should be tailored in order to meet their particular needs. These include:

- i. Parents and the community
- ii. Health staff
- iii. Particular stakeholders such as the ministry of health/ NRA /NCL, politicians, professionals/academia, international agencies: WHO, UNICEF, and manufacturers.
- iv. The media

In addition, there are principles of communication that apply to most if not all. These include the need to:

- i. Listen empathetically to concerns.
- ii. Reassure and support but do not make false promises.
- iii. Communicate frequently
- iv. Build up and maintain relationship among the stakeholders.
- v. Inform about possible common adverse events and how to handle them.
- vi. Prepare factsheets on adverse events and other key information for all audiences.

- vii. Continuously communicate during the investigation period to assure understanding both the situation and the risk-benefit of vaccination. Do not lay blame, especially not on the health worker(s), but focus on the correction and quality of the EPI system.

While health staff should have some training or at least experience in communication skills by the nature of their work, at the same time communication with them by public health authorities and investigators should be sensitive to their needs. Thus:

- i. Communication should be among all levels of health authorities involved.
- ii. Reassure the staff of their knowledge, ability, skills and performances.
- iii. Do not blame the health worker(s) but focus on the correction and quality of the EPI system.
- iv. Keep them updated on investigation process, progress, and findings.

Vaccine safety information needs to be shared with other stakeholders in order to ensure dissemination of correct information and, by doing so, ensure the smooth functioning of national immunization programme in the country. This may be done at two stages: sharing preliminary information at initial stage and sharing the final data/report after completion of investigation/causality Assessment. The goal is to restore public trust, minimise harm and ensure the continued success of immunisation programs.

13.4 Communicating with the media

The media (newspaper, radio, television, internet and social media) plays a significant role in public perception. Understanding what the media want from a story will assist communication with them. In certain situations, media coverage can lead to public concern about immunization. In these situations, it is important to coordinate with professional organizations, health professionals and workers before responding to or addressing the media. The coordination should include preparation on dealing with public concern on this issue, to minimize any potential harm to the immunization programme. It is also useful to have other groups and individuals that merit public respect and authority to publicly endorse and strengthen key immunization messages.

Communicating with the media requires particular skills, and these skills require training. Reporters are highly trained professionals, and their perspective must be properly understood. The media are interested in stories that will attract attention. While the success of a vaccination programme can attract attention, so can a programme that has not gone as planned. Dramatizing and personalizing events can both highlight success as well as create a sense of panic about an AEFI with a particular vaccine product – regardless of whether they are either unrelated to immunization (coincidental) or a localized immunization error. One other important fact is the media want early responses to their questions: therefore waiting for the conclusion of an investigation is rarely possible. Information may need to be disseminated early and often, and it is vital to be honest about what is known and what is not known, and to avoid being evasive and unresponsive.

At the same time, the media can be leveraged positively for the benefit of immunization. Health topics are popular among the public and, therefore, the media like to report about them. The media can be helpful allies in communicating public health messages. They can be helpful allies in reminding the public of the risk benefits of immunization. Building a personal relationship with key health reporters will help them to understand the public health perspective.

Effective communication with the media includes advance preparation. This is part of a communication plan and is particularly important before a new vaccine is introduced or before and during an immunization campaign. A communication plan can also provide ongoing communication support to routine immunization programmes. A good media plan consists of the following:

13.5. Other tips to keep in mind

Media interest is usually greatest initially when relatively little is known. In this environment, rumours can flourish and the potential for harm is huge. A media conference, convened early even if there is only very limited information to give, can provide a uniform message to all at the same time, thus avoiding any conflicting messages. This will also prevent the circulation of rumours and build a relationship with the reporters. At the end of the press conference, advise that a further conference will be held within a day or so, at which time full details of the

event and the investigation will be provided. A media or press conference requires expert planning and expert communications input to ensure that messages are clear, unambiguous and that all expert spokespersons are well prepared.

Professional organizations and other stakeholder parties may have greater credibility than the government, particularly in a crisis situation. Providing them an opportunity for their unified support for immunization and the approach being taken to handle/investigate the problem can help considerably.

13.5 Preparing key messages

Messages need to be as simple as possible. Use simple words and short sentences. It is helpful to tell a story, if possible. Create a ‘word picture’ (a graphic or vivid description) to get the message across. The key messages should be kept to a minimum and should include some of the facts. The benefit of immunization in preventing certain diseases is well proven. **Introduction of vaccines has saved millions of lives. As part of effective communication to highlight the benefit of immunization that are usually not realized when serious AEFIs occurs**

- i. It is risky not to immunize (risk of disease and complications).**
- ii. Vaccines may/do cause reactions, but these are rarely serious.**
- iii. Immunization safety is of paramount importance – maintaining confidence in immunization programs is only possible this way.**
- iv. Any suspicion of a problem is investigated (an advantage of well-established immunization safety surveillance). This investigation is an example of such action being taken.**

It is rarely necessary to suspend an immunization programme during an investigation unless it is obvious that there is a problem with the vaccine that warrants such drastic steps. The vast majority of situations prove to be coincidental or due to a very localized problem (depending on type of event), and the immunization programme must continue to keep the population safe from disease.

13.6.1. Preparing a press statement for AEFI communication

- i. All the information to be conveyed in a media conference should be prepared in advance and included in a press statement.

An effective press statement/ release must specifically answer the six questions (“W’s”) stated above and include a one-page account (400-500 words) written in short sentences outlining:

- ii. A complete account of the event, framed in its context (e.g. an isolated event or a cluster of AEFI, or a coincidental event). No technical jargon.
- iii. An outline of actions taken or planned (such as the AEFI investigation).
- iv. A description of the possible cause of the event.
- v. An assurance that corrective action will be taken, and what steps have already been taken.
- vi. Reference to any relevant publication or web site for further information.
- vii. Sender’s name and spokesperson’s details.
- viii. Quotes from key officials may be used after seeking their permission. (The quotes must be positive and carry the key messages.)
- ix. Repetition of key positive message.

13.6.2. Follow-up actions with AEFI communications

Keeping promises: If it has been promised that updates about the investigation will be disseminated, make sure that this is kept by the promised date. If the findings have been delayed, ensure the delay is communicated.

Providing answers to unanswered questions: if a question could not be answered for any reason, get back to the requestors with the answers as soon as possible.

Keeping the public informed about subsequent developments: If any decision or action is taken at the highest levels following AEFI investigations or during the investigations and the public must know about it, keep them informed through a press release to the media or other locally appropriate means.

Use of a mix of communication channels

A communication mix that takes cognizance of suitable channels that are accessible, acceptable, affordable and understandable to target communities should be adopted as stated in **Table 8** below:

Type	Example
Interpersonal communication	Face to face conversations, Community meetings, public events
Digital	WhatsApp, Facebook, X, twitter, blogs, online publications
Broadcasts	Radio, Television
Print media	newspapers, posters, billboards, magazines, flyers

These various types of communications channels have their own advantages and disadvantages.

13.7 Crisis management

A crisis is a situation in which a real or potential loss of confidence in the vaccine or in the immunization programme is triggered by information about an AEFI. Crises can often be avoided through foresight, care and training. If managed properly, the investigation and management of a vaccine safety situation will boost public confidence and acceptance and ultimately strengthen the immunization programme.

13.7.1. How to manage a crisis?

- i. Anticipate: do not wait until a crisis occurs. Prepare for the unavoidable. Develop a good relationship with the media. Good public awareness and understanding of the immunization programme is necessary.
- ii. Train staff at all levels to respond adequately: develop confidence responding to the public and the media (particularly to local media) properly and correctly.
- iii. Confirm all facts and prepare (see steps for a press conference or press release) before making any public comments.
- iv. Prepare a plan to react to a crisis when it occurs. This has to be done in advance, identifying responsible persons to handle the crisis and preparing all supporting documents and information.

Steps in Crisis Communication

It is important to put systems in place to address crises well before they arise. The following core aspects will be considered while planning and preparing our crisis response, including:

- **Crisis Anticipation:** This starts with thinking through likely crisis scenarios that may occur during nOPV2 rollout in the country. A sample crisis scenario might look like this.
- **Crisis Response Team:** The Crisis Response Team will comprise of stakeholders and individuals from authorized government institutions and partners, who will be responsible for responding to the crisis.

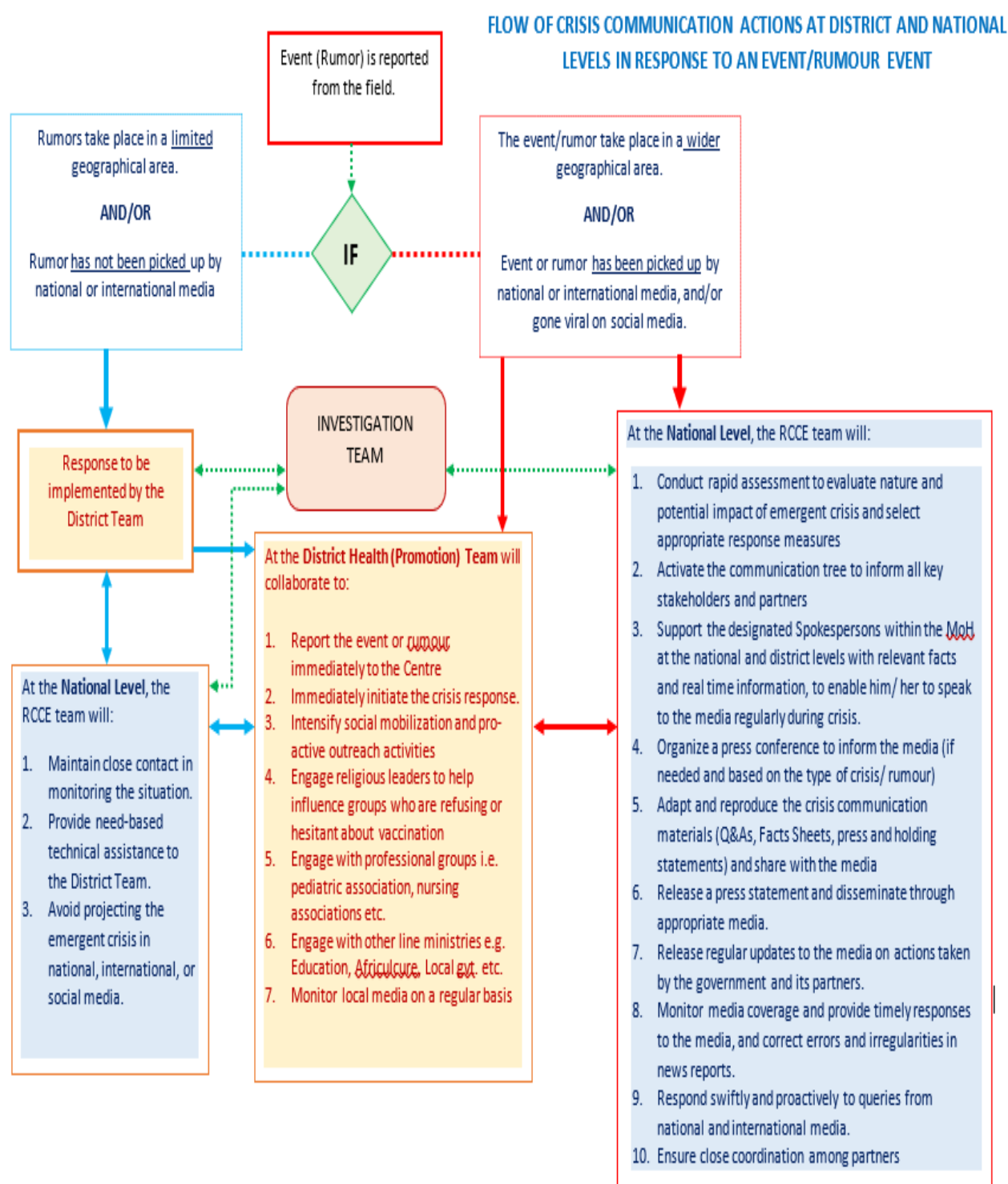
13.8 RACI (Responsible, Accountable, Consulted and Informed) Communication Matrix stated in Table 9 below.

R	Responsible	The person(s) who actually carries out and completes the task and is responsible for action/ implementation.
A	Accountable	The person who is ultimately accountable or answerable for the activity, the decision-maker. Only one accountable person can be assigned to an action.
C	Consulted	People who are not directly involved in carrying out the task but are consulted (stakeholder or subject matter expert).
I	Informed	Those who receive output from the process or task, or who need to stay informed along the way.

- In the RACI team, all stakeholders (both national and global) will be listed out who will have a role in addressing and/or reporting on the crisis. They will be recalled on a need basis.
- Teams will identify who needs to be Responsible, Accountable, Consulted, and Informed for each activity (using the guidance and definitions above).
- They will brainstorm on all the relevant activities/ tasks that are needed to respond to the crisis and by when. Any timelines and responsibilities will be reviewed and adjusted.
- An estimated budget will be prepared, and resources needed to complete the tasks.

The teams may discuss the need for separate RACIs on individual issues (for example, is there a need to add additional members if there is a negative regional media article vs. a low impact VRE).

13.9 Internal Information Rumour Management Flow illustrated in Figure 6 below;



13.10 Table 11: Media plan for communication

A database of journalists	▪ A list of print and electronic media journalists covering health (local, national, international) with contact information. ▪ Always use a database where updating can be done immediately. ▪ Update regularly any changes in the media list.
Information packages	An information package may contain the following documents both in hard copy and e-copies: ▪ Frequently Asked Questions (FAQs) on immunization in general, for specific disease, and AEFI ▪ Fact Sheet or a Technical Brief on a specific vaccine preventable disease: burden of the disease and background rates of AEFI, expected AEFI rates ▪ Recent updates – Statistics, progress made in country, WPR, globally ▪ Contact addresses of spokespersons (experts) in the Ministry. This information package needs regular updating.
The draft media release	Must specifically answer the 6 W's for journalists: ▪ Who is affected/is responsible? ▪ What has happened? What is being done? ▪ Where has it happened? ▪ When did it happen? ▪ Why did it happen? ▪ Will it happen again?
Information specific to media characteristics	▪ Local media: Read and believed by more people in the community than national media. ▪ National media: a wide reach and influences national agendas. ▪ International media: Can influence national agendas.
A spokesperson system:	▪ Identify in advance an appropriate spokesperson (or several spokespersons in the different agencies). ▪ Share contact details of spokesperson(s) with all concerned focal points at different levels of programme implementation. ▪ Ensure spokesperson(s) has experience or some training in dealing with media.

Table 13: Summary of effective communication principles: By following these principles, you can maintain public trust and confidence in immunization programs, in the face of AEFIs.

	Communication Principle	Summary of Communication Principle
1.	Transparency:	Clearly explain the AEFI, its symptoms, and the investigation process.
2.	Timeliness	Share information promptly in accordance with approved communication channel, avoiding unnecessary delays.
3.	Accuracy	Provide reliable, evidence-based information, avoiding speculation or misinformation.
4.	Empathy	Show understanding and concern for individuals affected by AEFIs.
5.	Consistency	Ensure consistent messaging across all communication channels.
6.	Risk communication	Explain the risks and benefits of vaccines, putting AEFIs into perspective.
7.	Stakeholder engagement	Involve healthcare professionals, public health officials, and community leaders in communication efforts.
8.	Cultural sensitivity	Tailor communication approaches to diverse audiences.
9.	Monitoring and evaluation	Continuously assess the effectiveness of communication strategies.

13.12 Communication and Feedback Summary

- **Communication with parents, community, staff, other stakeholders and the media is necessary and important.**
- **During communication make sure to build confidence on immunization programme. Be aware of risk-benefits of immunization and the progress and findings of the investigation.**
- **Communication needs assurance from one in authority, with knowledge and expertise in the subject.**
- **It is recommended to prepare a communication plan in advance, as this will minimize negative impact of AEFI-related matters.**

14. Conclusion

Research has shown that effective AEFI surveillance and management systems result in the minimization of AEFIs and more effective interventions where necessary. This document is expected to strengthen the AEFI surveillance and management in the country, by aligning the current guidelines to ZEPI AEFI surveillance system and the national Pharmacovigilance plan, including the support and corporation of all healthcare personnel involved in immunization activities promoting the safety of children's health.

Aligning these national vaccine safeties related policies and guidelines ensures that all stakeholders have a clear perspective on the Zimbabwean policy on AEFI surveillance and ensures that more objective decisions are made. In conclusion all healthcare professionals and vaccinees guardians are required to report all AEFIs non-serious and serious so that the safety of the vaccinees and public is promoted. Prompt AEFI case management is critical to treatment the AEFI, prevent complications and promote patient/vaccinees safety and ultimately public confidence in the national immunization program. Ultimately this will improve vaccination coverage, reduce vaccines preventable diseases and save millions of lives.

15. Annexures

15.1 Annex 1: AEFI VigiMobile online reporting forms

NB: AEFI VigiMobile online reporting forms for both non-serious and serious AEFIs. In addition to the standard AEFI form and cases investigation form, The AEFI VigiMobile form is also required to be completed for all types of AEFIs non-serious and serious using the active mobile app scan code stated above and below. Please note that the scan code open the form on all types of mobile phones, computers, laptops, tablets and iPad. The AEFI VigiMobile app form may also be accessed using the link below:

<https://vigiflow-eforms.who-umc.org/zwaefi/aeafi>

OR Alternatively, use the active scan code below for actual/ real AEFI cases non- serious or serious. Simply scan code to download the AEFI report form, complete it and send it.



15.2 Annex 2: Hardcopy standard AEFI reporting form

Dec 2020

AEFI reporting id number:

STANDARD REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

*Patient name or initials: *Patient's full Address: Telephone: Sex: ☐ M ☐ F (Pregnant ☐ Lactating <input checkbox"="" type="checkbox/>)</p> <p>*Date of birth (DD/MM/YYYY): _/ _/ _</p> <p>OR Age at onset : <input type="/> Years ☐ Months ☐ Days OR Age Group: ☐ 0 < 1 year ☐ 1- 5 years ☐ > 5 years - 18 years ☐ > 18 years – 60 years ☐ > 60 years	*Reporter's Name: Institution: Designation & Department: Address: Telephone & e-mail: Date patient notified event to health system (DD/MM/YYYY): _/ _/ _ Today's date (DD/MM/YYYY): _/ _/ _
---	---

Health facility (or vaccination centre) name:									
Vaccine							Diluent		
Name of vaccine (Generic)	*Brand Name incl. Name of Manufacturer	*Date of vaccination	*Time of vaccination	Dose (1 st , 2 nd , etc.)	*Batch/Lot number	Expiry date	*Batch/ Lot number	Expiry date	Time of reconstitution

*Adverse event (s): ☐ Severe local reaction ☐ >3 days ☐ beyond nearest joint ☐ Seizures ☐ febrile ☐ afebrile ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever ≥ 38°C ☐ Other (specify)..... Date & Time AEFI started (DD/MM/YYYY): _/ _/ _ ☐ Hr ☐ Min	Describe AEFI (Signs and symptoms):
*Serious: Yes / No ; ➔ If Yes ☐ Death ☐ Life threatening ☐ Disability ☐ Hospitalization ☐ Congenital anomaly ☐ Other important medical event (Specify _____)	
*Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died If died, date of death (DD/MM/YYYY): _/ _/ _ Autopsy done: ☐ Yes ☐ No ☐ Unknown	
Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) other relevant information (e.g. other cases). Use additional sheet if needed :	

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No	If yes, date investigation planned (DD/MM/YYYY): _/ _/ _
--	--

National level to complete:

Date report received at national level (DD/MM/YYYY): _/ _/ _	AEFI worldwide unique ID :
Comments:	

*Compulsory field

15.3 Annex 3: Hardcopy standard serious AEFI investigation form.

Oct 2020

AEFI FOLLOWING COVID 19 VACCINATION - INVESTIGATION FORM					
(Only for Serious Adverse Events Following Immunization – Death / Disability / Hospitalization / Cluster)					
Section A		Basic details			
Province/State		District		Case ID	
Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____ Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____					
Address of vaccination site:					
Name of Reporting Officer:				Date of investigation: ____ / ____ / ____	
Designation / Position:				Date of filling this form: ____ / ____ / ____	
Telephone # landline (with code):				This report is: ☐ First ☐ Interim ☐ Final	
Mobile:				e-mail:	
Patient Name (use a separate form for each case in a cluster) Date of birth (DD/MM/YYYY): ____ / ____ / ____ OR Age at onset: ____ years ____ months ____ days OR Age group: ☐ < 1 year ☐ 1–5 years ☐ > 5 years - 18 years ☐ > 18 years – 60 years ☐ > 60 years Patient's full address with landmarks (Street name, house number, locality, phone number etc.):					
Brand name of vaccines (including manufacturer) / diluent received by patient	Date of vaccination	Time of vaccination	Dose (e.g. 1 st , 2 nd , etc.)	Batch/Lot number	Expiry date
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____ Date of first/key symptom (DD/MM/YYYY): ____ / ____ / ____ Time of first symptom (hh/mm): ____ / ____ Date of hospitalization (DD/MM/YYYY): ____ / ____ / ____ Date first reported to the health authority (DD/MM/YYYY): ____ / ____ / ____ Status on the date of investigation (✓) ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Unknown If died, date and time of death (DD/MM/YYYY): ____ / ____ / ____ (hh/mm): ____ / ____ Autopsy done? (✓) ☐ Yes (date) ____ / ____ / ____ ☐ No ☐ Planned on (date) ____ / ____ / ____ Time ____ Attach report (if available)					
Section B		Relevant patient information prior to immunization			
Criteria		Finding		Remarks (If yes provide details)	
Past history of similar event?		Yes / No / Unkn			
Adverse event after any previous vaccination(s)?		Yes / No / Unkn			
History of allergy to vaccine, drug or food?		Yes / No / Unkn			
Pre-existing comorbidity/ congenital disorder?		Yes / No / Unkn			
Pre-existing acute illness (30 days) prior to vaccination?		Yes / No / Unkn			
Has the patient tested Covid19 positive prior to vaccination?		Yes / No / Unkn			
History of hospitalization in last 30 days, with cause?		Yes / No / Unkn			
Was the patient receiving any concomitant medication? (If yes, name the drug, indication, doses & treatment dates)		Yes / No / Unkn			
Family history of any disease (relevant to AEFI) or allergy?		Yes / No / Unkn			
For adult women					
• Currently pregnant? Yes (weeks) ____ / No / Unknown					
• Currently breastfeeding? Yes / No					

For infants
 The birth was ☒ full-term ☐ pre-term ☐ post-term. Birth weight: _____
 Delivery procedure was ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum etc.) ☐ with complication (specify) _____

Section C Details of first examination** of serious AEFI case

Source of information (✓ all that apply): ☒ Examination by the investigator ☐ Documents ☐ Verbal autopsy
☐ Other _____ If from verbal autopsy, please mention source _____

Name of the person who first examined/treated the patient: _____

Name of other persons treating the patient: _____

Other sources who provided information (specify): _____

Signs and symptoms in chronological order from the time of vaccination:

Name and contact information of person completing these clinical details:

Designation:

Date/time

****Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, laboratory reports and autopsy reports, **prescriptions for concomitant medication**) and then complete additional information NOT AVAILABLE in existing documents, i.e.**

- **If patient has received medical care** – attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write only the information that is not available in the attached documents below
- **If patient has not received medical care** – obtain history, examine the patient and write down your findings below (add additional sheets if necessary)

Provisional / Final diagnosis:

Section D Details of vaccines provided at the site linked to AEFI on the corresponding day

Number immunized for each antigen at session site. Attach record if available.	Vaccine name									
	Number of doses									

Name

Case ID Number

AEFI Investigation Page 3/4

a) When was the patient immunized? (☒ the ☐ below and respond to ALL questions)	
☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown	
In case of multidose vials, was the vaccine given ☐ within the first few doses of the vial administered? ☐ within the last doses of the vial administered? ☐ unknown?	
b) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes / No
c) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes / No / Unable to assess
d) Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes / No / Unable to assess
e) Based on your investigation, do you feel that there was an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	Yes / No / Unable to assess
f) Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunization session etc.)?	Yes / No / Unable to assess
g) Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes / No / Unable to assess
h) Number immunized from the concerned vaccine vial/ampoule	
i) Number immunized with the concerned vaccine in the same session	
j) Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations: _____	
k) Could the vaccine given to this patient have a quality defect or is substandard or falsified?	Yes / No / Unable to assess
l) Could this event be a stress response related to immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	Yes / No / Unable to assess
m) Is this case a part of a cluster?	Yes / No / Unkn
i. If yes, how many other cases have been detected in the cluster?	
a. Did all the cases in the cluster receive vaccine from the same vial?	Yes / No / Unkn
b. If no, number of vials used in the cluster (enter details separately)	

It is compulsory for you to provide explanations for these answers separately

Section E Immunization practices at the place(s) where concerned vaccine was used			
(Complete this section by asking and/or observing practice)			
Syringes and needles used:			
• Are AD syringes used for immunization?			Yes / No / Unkn
If no, specify the type of syringes used: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other _____			
Specific key findings/additional observations and comments:			
Reconstitution: (complete only if applicable, ☒ NA if not applicable)			
• Reconstitution procedure (☒)		Status	
Same reconstitution syringe used for multiple vials of same vaccine?		Yes	No
Same reconstitution syringe used for reconstituting different vaccines?		Yes	No
Separate reconstitution syringe for each vaccine vial?		Yes	No
Separate reconstitution syringe for each vaccination?		Yes	No
• Are the vaccines and diluents used the same as those recommended by the manufacturer?		Yes	No
Specific key findings/additional observations and comments:			
Injection technique in vaccinator(s): (Observe another session in the same locality – same or different place)			
• Correct dose and route?			Yes / No
• Time of reconstitution mentioned on the vial? (in case of freeze dried vaccines)			Yes / No
• Non-touch technique followed?			Yes / No

• Contraindications screened prior to vaccination?	Yes / No
• How many AEFI were reported from the centre that distributed the vaccine in the last 30 days?	
• Training received by the vaccinator? (If Yes, specify the date of last training _____)	Yes / No
Specific key findings/ additional observations and comments?	

Section F Cold chain and transport (Complete this section by asking and/or observing practice)	
Last vaccine storage point:	
• Is the temperature of the vaccine storage refrigerator monitored?	Yes / No
○ If "yes", was there any deviation outside of 2–8 °C after the vaccine was placed inside?	Yes / No
○ If "yes", provide details of monitoring separately.	
• Was the correct procedure for storing vaccines, diluents and syringes followed?	Yes / No / Unkn
• Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes / No / Unkn
• Were any partially used reconstituted vaccines in the refrigerator?	Yes / No / Unkn
• Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes / No / Unkn
• Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes / No / Unkn
Specific key findings/additional observations and comments:	
Vaccine transportation:	
• Type of vaccine carrier used	
• Was the vaccine carrier sent to the site on the same day as vaccination?	Yes / No / Unkn
• Was the vaccine carrier returned from the site on the same day as vaccination?	Yes / No / Unkn
• Was a conditioned ice-pack used?	Yes / No / Unkn
Specific key findings/additional observations and comments:	

Section G Community investigation (Please visit locality and interview parents/others)
Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality? Yes / No / Unknown If yes, describe:
If yes, how many events/episodes?
Of those effected, how many are • Vaccinated: _____ • Not vaccinated: _____ • Unknown: _____
Other comments:

Section H Other findings/observations/comment

15.4 Annex 4: Zimbabwe Job Aid for Adverse Events Following Immunization



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Zimbabwe Job Aid for Adverse Events Following Immunization (AEFI) Surveillance in

AEFI Surveillance Job Aid - Zimbabwe

Purpose:

To guide all stakeholders in the identification, reporting, investigation, and management of Adverse Events Following Immunization (AEFI).

Adverse event following immunization (AEFI) definition: any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine, WHO 2013 definition. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptoms or disease.

AEFI surveillance definition: Monitoring, detecting and responding to adverse events following immunization; implementing appropriate and immediate action to correct any unsafe practices detected through the AEFI surveillance system, in order to lessen the negative impact on health of individuals and the reputation of the immunization programme.

1. Stakeholder Engagement

- **Community & Caregivers**
 - Report any unusual or serious health problems post-vaccination to healthcare workers.
 - Participate in education sessions on vaccine safety.
- **Healthcare Workers (HCWs)**
 - Recognize and manage AEFIs.
 - Notify/report AEFIs using designated tools.
 - Educate caregivers and vaccine recipients.
- **Vaccinees & Guardians**



Medicines Control Authority of Zimbabwe

- Observe for any AEFI symptoms and communicate promptly to health facilities.

- **Vaccination Sites**

- Ensure proper vaccine handling and administration.
 - Immediate identification and notification of AEFIs.
-

2. AEFI Notification & Reporting Tools

- **Hard Copies of Reporting Forms**

- Available at all health facilities for initial reporting.

- **VigiMobile Application**

- For electronic reporting and data management of serious AEFIs.

- **Health Information Officers**

- Enter and maintain AEFI data in national systems (e.g., DHIS2, VigiFlow).
 - Report completeness score to enable causality assessment
-

3. Case Investigation

- **Serious AEFI Reports**

- Conduct thorough investigation using standard forms.
- Collect clinical history, vaccination details, and outcome data.

- **Post-Mortem Reports**

- Mandatory for all deaths AEFI events to immunization but not necessarily due to immunization .
 - Contribute to causality assessment.
-

4. Reporting Channels



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Figure 1 AEFI process flow : Collecting case-based data using VigiMobile, VigiFlow, VigiBase & VigiLyze in the context of AEFI surveillance





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**Figure 2 : Zimbabwe Vaccines enhanced AEFI
Mobile Deployment**



**Officially launched/deployed
by the Secretary for Health
and Child Care in April 2023**



Ministry of Health and Child Care
Harare, Zimbabwe

6 April 2023

TO: All Provincial Medical Directors: Harare, Bulawayo, Midlands, Manicaland, Masvingo, Matabeleland North, Matabeleland South, Northern, Southern, Western, Eastern, City Health Director, Harare Metropolitan, City Health Director, Harare City.

RE: DEPLOYMENT OF THE ELECTRONIC VIGILANCE AND VISUFLOW TOOLS FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION REPORTING AND DATA MANAGEMENT ON 17 APRIL 2023

Reference is made to the letter dated 26 January 2023, that invited all relevant provincial and district participants to attend the electronic vigilance and visuflow AEFI reporting training from the 28th of February to the 31st of March 2023.

Following the national and provincial training, the country intends to transition from paper-based AEFI reporting and data to the electronic vigilance and visuflow web systems to all provinces, districts and health facilities on the 17th of April 2023.

The Ministry wishes to continuously strengthen and improve the AEFI surveillance system in order to ensure vaccine safety throughout the vaccination process. The electronic vigilance and visuflow tools will assist in ensuring that the Zimbabwe vaccine safety surveillance system is national through electronic reporting which will be managed by MCAZ, Ministry of Health, and the Health Information Department as agreed during the training.

This letter serves as authorization for the deployment of the electronic vigilance and visuflow tools.

Your usual support is greatly appreciated.

Air Commodore (Dr) J. Chimpenza
SECRETARY FOR HEALTH AND CHILD CARE



Medicines Control Authority of Zimbabwe

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