Medicines Control Authority of Zimbabwe

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GUIDELINE FOR PHARMACOVIGILANCE OF COVID-19 VACCINES-AEFI SAFETY SURVEILLANCE

EFFECTIVE DATE:

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1.0 APPLICATION

The guideline was developed by the Medicines Control Authority of Zimbabwe for COVID-19 Vaccines Adverse Event Following Immunization (AEFI) surveillance. The Zimbabwe Expanded Program on Immunization (ZEPI)-Ministry of Health and Child Care (MoHCC) and the Medicines Control Authority of Zimbabwe (MCAZ) are the main drivers in vaccine safety surveillance. This was conducted in line with the Ministry of Health and Child Care COVID -19 Vaccines Deployment and Rollout Plan. COVID-19 vaccine safety surveillance will be guided by already existing Zimbabwe Adverse Events Following Immunization (AEFI) surveillance guidelines 3rd Edition 2017 https://www.mcaz.co.zw/index.php/downloads/category/15guidelines?download=163:adverse-events-following-immunization-surveillance-guidelines-3rd-edition-jan-2017 , the Zimbabwe National Pharmacovigilance Policy Handbook 2nd Edition 2016 https://www.mcaz.co.zw/index.php/downloads/category/15guidelines?download=157:zimbabwe-national-pharmacovigilance-policy-handbook both authorized by the Secretary for Health and Child Care and the WHO COVID-19 vaccines safety surveillance manual.

2.0 PURPOSE

This guideline is in line with the Authority's mandate to ensure accessible medicines are safe and of good quality.

3.0 INTRODUCTION

3.1 The COVID-19 pandemic affected Zimbabwe resulting in 34 949 positive cases and 1382 deaths as of 11 February 2021.The high numbers of both positive cases and deaths has prompted the country to plan for the introduction of a vaccine. The country has secured over a million doses and vaccinations in priority groups have commenced in February 2021. In addition, an operational budget to fund the implementation of planned activities is in place and has been shared with Treasury. The country COVID-19 vaccination and deployment plan identifies key areas for the successful rollout of the vaccines. This guide should also be used in line with the MoHCC COVID -19 Vaccine Deployment and plan in which the broad aim is to enable high-quality vaccination services, reduce morbidity and mortality due to COVID 19 disease. The specific objectives are to:

3.1.1 To vaccinate eligible population on a voluntary basis for free
3.1.2 Vaccinate a minimum of 60% of the total population to achieve herd immunity.
3.1.3 To initiate vaccination through eligible high-risk target populations.
3.1.4 To provide adequate vaccines and supplies for the activity.
3.1.5 To ensure the availability of functional cold chain equipment at all levels.
3.1.6 To monitor progress, AEFIs, and provide corrective action.
3.1.7 Create demand for immunization.

3.2 In partnership with MoHCC- ZEPI, the National Pharmacovigilance and Clinical Trials Committee also the national AEFI Committee and MCAZ National Pharmacovigilance Centre are the main drivers of vaccine safety surveillance.

3.3 COVID-19 vaccine safety monitoring, effective reporting of adverse events following immunization (AEFIs), investigation and assessment of reported cases and; taking

necessary actions requires broad and timely collaboration between national, regional, and global stakeholders. These stakeholders include:

3.3.1 Policymakers such as MoHCC who recommend the use of vaccines, and specify the relevant vaccine target groups;

3.3.2 National regulatory authorities such as MCAZ who initially approve vaccine clinical trial protocols, assess their results and, if shown to be safe and efficacious, grant marketing authorizations, and withdraw marketing authorization if the vaccine is found to be unsafe;

3.3.3 The vaccine developers, and manufacturers who are responsible for the vaccine(s) quality, safety, effectiveness and benefit-risk management plan;

3.3.4 The public and private health institutions that administer vaccines, investigate, assess, monitor and report adverse events;

3.3.5 Beneficiaries, healthcare providers, high-risk groups and public.

3.3.6 International collaboration is essential to verify the safety and effectiveness of the many

3.4 COVID-19 vaccines that will be produced and used in many different countries and administered to large numbers of people in a short period of time. Therefore, mapping national, regional and global stakeholders and their responsibilities is key for ensuring appropriate vaccine safety monitoring of these newly developed vaccines.

4.0 DEFINITIONS

4.1 **Active safety surveillance Active (or proactive) safety surveillance** is an active system for the detection of adverse events. This is achieved by active follow-up after vaccination. Events can be detected by asking patients directly or by screening patient records. It is best done prospectively.

4.2 **Adverse event following immunization (AEFI):** Any untoward medical event that follows immunization and that 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.

4.3 **Adverse event of special interest (AESI).** A pre-identified and predefined medically significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies.

4.4 **Causality assessment:** In the context of vaccine AEFI surveillance, a systematic review of data about the AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received.

4.5 **Risk management plan (RMP)** The risk management plan is a document established by the vaccine manufacturer that contains the following elements: (a) identification or characterization of the safety profile of the medicinal product(s) concerned; (b) indication of how to characterize the safety profile of the medicinal product(s) concerned further; (c) documentation of measures to prevent or minimize the risks associated with the medicinal product, including an assessment of the effectiveness of those interventions; (d) documentation of post-authorization obligations that have been imposed as a condition of the marketing authorization.

4.6 **Signal (safety signal):** 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 action.

4.7 **SAGE Values Framework:** Values Framework, developed by WHO's SAGE, offers guidance globally on the allocation of COVID-19 vaccines between countries, and

guidance nationally on the prioritization of groups for vaccination within countries while COVID-19 vaccine supply is limited.

4.8 **Vaccine:** A biological preparation that elicits immunity to a particular disease. In addition to the antigen, it can contain multiple components, such as adjuvants, preservatives, stabilizers, each of which may have specific safety implications.

4.9 **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.

4.10 **Vaccine Pharmacovigilance:** The science and activities relating to the detection, assessment, understanding and communication of AEFI and other vaccines- or immunization-related issues, and to the prevention of untoward effects of the vaccine or vaccination.

4.11 **VigiBase WHO global database:** are individual case safety reports (ICSRs) including ADRs and AEFIs, maintained by Uppsala Monitoring Centre.

4.12 **VigiFlow:** A web-based on individual case safety report (ICSR) management system (E2B compatible) for medicines and vaccines, developed and maintained by Uppsala Monitoring Centre.

4.13 **Zimbabwe MCAZ Electronic e-PV System of individual case safety reports (ICSRs) including ADRs, SAEs and AEFIs** has E2B and XML compatible formats that are compatible with the WHO VigiBase database maintained by MCAZ and has several reporting tools via mobile phone android iOS, tablets iPad, laptops, computer and Desktop offline application. The e-PV system hyperlink is accessible on https://e-pv.mcaz.co.zw/

5.0 GUIDELINES

5.1 Framework for COVID-19 Vaccines use in Zimbabwe

5.1.1 The COVID-19 vaccine(s) are emergency vaccines authorized by MCAZ under Emergency Use Authorisation (EUA) procedures, in terms of section 75 of the Medicines and Allied Substances Control Act Chapter 15:03.

5.1.2 The MCAZ National Pharmacovigilance Centre, and Pharmacovigilance and Clinical Trials Committee which is also the national AEFI will implement vaccine vigilance plans to monitor the safety and effectiveness of the COVID-19 vaccine in use.

5.1.3 The vaccine consignment(s) shall be physically verified and cleared by MCAZ upon arrival.

5.1.4 The consignment(s) shall be cleared based on the standard vaccine lot release documentation.

5.1.5 The MoHCC and ZEPI-MoHCC will set up and implement the safety monitoring plan to enable swift detection of any Adverse Events Following Immunization (AEFI).

5.1.6 The MoHCC will consider a study/studies to confirm the immunogenicity of the product in the local population.

5.1.7 Instituting active surveillance of Adverse Events of Special Interest following COVID-19 vaccination.

5.1.8 Reporting of all AEFIs into the MCAZ e-PV system and then uploading them on the WHO VigiBase database for further signal detection

5.1.9 Benefit-Risk Communication and advocacy and feedback to reporters and stakeholders, and WHO AEFI Joint Reporting Form (JRF).

5.2 Roles of key players in COVID-19 safety surveillance

5.2.1 The role of the Medicines Control Authority of Zimbabwe

The MCAZ is responsible for ensuring that any pharmaceutical product including vaccines used within the country is of good quality, effective and safe for the purpose or purposes for which it is proposed. The core functions of the MCAZ are:

i. marketing authorization activities(registration);
ii. pharmacovigilance, including surveillance of AEFIs;
iii. NRA batch release, with a system for batch release of vaccines;
iv. laboratory access, with use of laboratories when needed;
v. market surveillance and control;
vi. regulatory inspection, with regular inspection of vaccine manufacturers for good manufacturing practices (GMP) compliance; and
vii. regulatory oversight of clinical trials, with the evaluation of clinical performance through authorized clinical trials

In the context of COVID-19 vaccine safety monitoring, MCAZ is also expected to:

i. oversee preparations for Emergency Use Listing (EUL);
ii. verify submission and review of risk management plans prior to marketing authorization and making risk-based recommendations for post- authorization safety surveillance;
iii. oversee communication and information sharing with immunization programmes, Pharmacovigilance Centre and other key institutions on COVID-19 vaccines

safety updates to enhance the MCAZ's ability to make evidence-based decisions to protect public health;

iv. have authority to mandate COVID-19 vaccine safety studies by the vaccine manufacturers and importers of vaccines, as required;

v. have the independent authority to investigate potential safety signals and assure the continued post-authorization safety of COVID-19 vaccines;

vi. oversee the monitoring of COVID-19 vaccine safety by reviewing the periodic safety update reports (PSURs) / periodic benefit-risk evaluation reports (PBRERs);

vii. ensuring timely submission of COVID-19 AEFIs and adverse events of special interest (AESIs) data from ZEPI-MoHCC and all vaccination sites across the country for data compilation, analysis, and signal detection

viii. share safety information generated with national, regional, international decision-makers, vaccine manufacturers WHO global pharmacovigilance database, VigiBase.

5.2.2 Role of ZEPI-MoHCC for COVID-19 Vaccination and Surveillance

i. Collaboration with all COVID-19 Vaccine safety key stakeholders MoHCC, ICC, partners, public and community advocacy for vaccine acceptance and uptake.

ii. Non-serious and Serious AEFI reporting and AEFI case investigation and district AEFI case investigation committees.

iii. Development and adaption of training materials for all activities.

iv. Trainings of trainers (TOTs) for provincial and district trainers.

v. Provincial and district trainers will in turn train health workers at service delivery centers.

vi. EPI will support the planning and conduct of the TOTs.

vii. Online, in-person and blended learning (combination of online and in-person) are the most common methods which will be used to train staff.

viii. Areas of training to include; vaccine storage, communication, surveillance, vaccination and M and E, management of AEFI and waste management

ix. Vaccination (Service Delivery)

x. Supply Chain Management

xi. The immunization supply chain of Zimbabwe consists of four levels which are Central, Provincial, District and service delivery.

xii. Vaccine distribution follows this channel from the Central Vaccine to 1O Provincial and 63 district vaccine stores; and then to more than 1,800 service delivery facilities.

xiii. The Central Vaccine Stores distributes vaccines to Provincial Vaccine Stores

xiv. Provinces distribute vaccines to district vaccine stores and districts to service delivery as well.

xv. Distribution of the COVID-19 vaccine will follow the existing distribution structure of routine vaccines and supplies.

xvi. Biohazard and immunization waste management

xvii. Monitoring and evaluation

xviii. Development of an M and E Framework to guide planning and implementation

xix. There will be pre-vaccination demographic data collection

xx. Conduct preparedness assessment to assess readiness at all levels

xxi. Development of data collection tools; i.e. tally sheets, summary sheets, vaccination cards

xxii. Consolidation and reporting of the number reached will be done on a daily basis using existing platforms and structures

xxiii. Disease surveillance will include AEFI monitoring

xxiv. There will be blood collection to determine antibodies before and after vaccination.

xxv. Conduct a Post Campaign Coverage Survey to validate administrative data
xxvi. Conduct a Post Introduction Evaluation to assess the quality of the introduction of the COVID-19 vaccine and help inform future introductions.

5.2.3 The Role of the National AEFI Committee

The main routine responsibilities of AEFI review committees are to,

i. provide guidance for AEFI investigations so that the cause can be determined correctly;
ii. assess potential causal links between AEFIs and vaccines, using standard procedures;
iii. monitor reported AEFI data for potential signals of previously unrecognized vaccine-related adverse events and support further investigations to establish if causality exists;
iv. make the necessary recommendations to rectify problems, communicate with national stakeholders and other national and international experts, when required.

The terms of reference for the AEFI review committees for COVID-19 vaccine safety monitoring also include:

i. assessing potential causal links between AEFIs and AESIs and COVID-19 vaccines;
ii. monitoring AEFI data for identification of potential signals of previously unidentified COVID-19 vaccine-related adverse events;
iii. reviewing all serious AEFIs presented for expert opinion and arranging further investigation to establish causality, if required;
iv. communicating with other national and international experts, when required, to establish causality and resolve vaccine quality issues;
v. advising MCAZ and ZEPI-MoHCC, on COVID-19 vaccines AEFI- and AESI-related issues when requested and
vi. advising the Ministry of Health and Child Care (MoHCC) on COVID-19 vaccines and Immunization safety-related matters when requested.
vii. 5.2.3.3 The committee should be independent and the members should have no conflicts of interest.

5.2.4 The Role of the Vaccine Beneficiaries

The roles of beneficiaries are the same in the context of COVID-19 vaccine safety monitoring as for routine vaccine safety monitoring, and include to:

i. understand the risk and benefits of vaccines and immunization, viewing this as part of being a responsible citizen;
ii. play an active role in identifying what they feel is important to help define certain adverse effects, if possible;
iii. differentiate between genuine and false information and ensure that correct information is communicated, and prevent the circulation of false information;
iv. demand the right to safe and effective immunization programmes from policymakers and participate in public-health discussions;
v. be involved in key decisions about immunization processes;
vi. participate and contribute to the immunization delivery process and
vii. convey the needs and perspectives of their communities to policymakers.

5.2.5 The Role of the Media

The routine roles of the media are to:

i. understand the benefits of, and concerns about, immunization in order to accurately report on and effectively promote immunization programmes;
ii. engage the country, regional and global advocacy beyond the immunization community to ensure vaccines and immunization are understood to be a right for all; and
iii. use effective communications techniques to convey messages about vaccines and to address safety concerns

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The roles for media for COVID-19 vaccine safety monitoring are expected to also include:

i. keeping up to date with media releases, press information packages, briefing papers, web materials, talking points disseminated by MoHCC on COVID-19 vaccines and vaccination
ii. proactively identifying, filtering out and preventing the spread of misinformation
iii. participating in MoHCC media workshops and training sessions to learn about the rationale for COVID-19 vaccine introduction and understand the key messages; and
iv. ensuring the dissemination of clear, factual messages that have been confirmed by the relevant authorities to the public

5.2.6 The role of the Health care workers

The routine roles of health care workers are to:

i. provide vaccine and vaccination information and then providing high-quality immunization services;
ii. identify areas where immunization services could be improved and innovations implemented;
iii. serve as proactive, credible advocates to promote the value of vaccines and vaccination and recruit other advocates;
iv. use existing and emerging technologies to improve information delivery and capture, using beneficiaries;
v. if possible; dialogue with communities use effective communications techniques to convey messages about vaccines; and
vi. address clinical case management for adverse events.

The roles for health care workers for COVID-19 vaccine safety monitoring are expected to also include:

i. ensuring staff training on detection, management and reporting of COVID-19 vaccine AEFIs identified through active and passive surveillance;
ii. providing supervision to ensure both serious and non-serious AEFIs are captured and that serious AEFIs are adequately investigated; and
iii. developing a communication protocol, including the use of a trusted spokesperson, to promptly inform the public about any investigation or rumors.

5.2.7 Roles and responsibilities for AEFI reporting at various levels (community level, service delivery level, district level, provincial level, and national level) are as summarized in the flowchart for AEFI management (Appendix 1). The flowchart also shows the reporting timelines that should be followed. This process flow also includes the private sector vaccination clinics including COVID-19 vaccination centers are also encouraged and trained to report AEFIs.

5.3 Format and components of Risk Management Plans (RMPs) for COVID-19 vaccines

5.3.1 The vaccine manufacturer is encouraged to adopt existing formats, such as the European Medicines Agency RMP format, which contain essential elements such as a safety specification section, pharmacovigilance activities, risk minimization activities, and evaluation of the effectiveness of the risk minimization measures. RMPs in alternative formats, such as a global or core RMP, are also acceptable provided they contain the essential elements mentioned above.

5.3.2 In addition, when requested, a region-specific annex (referred to as a regional annex hereafter) to the core RMP that takes into consideration additional context-specific to the region where the vaccines are to be deployed, should be provided. In general, the regional annex for COVID-19 vaccines in the RMPs should highlight any differences in safety concerns in the regions where the COVID-19 vaccines are launched, e.g., differences in the frequency, severity or nature of safety concerns, resulting from differences in the epidemiology of COVID-19 and the target population. It should also confirm that the pharmacovigilance (PV) and risk minimization activities are compatible with the safety concerns specified. https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_pharmaceutical_industry.pdf

5.4 Routine Pharmacovigilance Plan as part of the Risk Management Plans (RMPS)

5.4.1 Both routine and additional PV activities contribute to the maintenance of a positive benefit-risk balance for a vaccine. They form part of the RMP, along with further PV measures that are appropriate for the evaluation of efficacy and safety of vaccines.

5.4.2 For COVID-19 vaccines, as part of routine PV activities, the vaccine manufacturer should describe in the RMP the:

i. specific activities for the collection, compilation, assessment, and reporting of adverse reactions to the NRA
ii. format, content and periodicity of the PSURs/PBRERs
iii. other requirements defined in the regional annex

5.4.3 Challenges related to restrictions during the pandemic (e.g. due to social distancing or limited medical resources) or to the volume of reports of adverse events following immunization (AEFIs) to be processed (e.g., associated with a mass vaccination campaign) should be considered and reflected in the planning document. The reporting patterns following mass vaccination campaigns during a pandemic are likely to differ qualitatively from routine reporting, and this needs to be taken into account when performing the analyses.

5.4.4 During the pandemic, the usual 6-month reporting cycle may be too long for the assessment of COVID-19 vaccine safety because it is expected that there will be high levels of exposure within a short period of time. Therefore, it is recommended that monthly safety summaries are provided focusing on adverse events of special interest (AESIs), at a minimum. The monthly safety summaries are intended to complement the regular 6-monthly PSURs for COVID-19 vaccines during the pandemic period and should include:

i. a summary of vaccine distribution (number of doses, locality of distribution, etc)
ii. global numbers (with country of origin) and analyses of AESIs reported in individuals following immunization, following the Brighton Collaboration recommendations for COVID-19 vaccines and
iii. numbers of deaths and relevant case histories, including observed over expected analyses

5.4.5 In addition to the monthly safety summaries, a 6-monthly cumulative PSUR/PBRER should be submitted following the PBRER ICH E2C (R2) format3. This provides a cumulative overview of all available information which provides the vaccine's overall benefit-risk profile. Following the first 6-month report, and as experience with the vaccine evolves, the periodicity of the monthly summaries and of the PSURs/PBRERs should be reviewed by the regulator. https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_pharmaceutical_industry.pdf

5.5 Recommended safety surveillance activities for all countries introducing COVID-19 vaccine(s).

Table 1 below summarizes the recommended safety surveillance activities for all countries introducing COVID-19 vaccine(s) regardless of AEFI surveillance capacity

Objective	Recommended AEFI surveillance activities
Strengthen routine passive AEFI surveillance reporting systems for the management of increased frequency or severity of AEFI reports (mild, moderate and severe)	i. Conduct training on identification and reporting of AEFI for health care workers. ii. Update, print and distribute AEFI surveillance tools. iii. Use both vaccine tracking information and passive AEFI reporting information to perform vaccine-specific safety analyses. iv. Review and adapt processes for timely reporting, reviewing and data sharing nationally, regionally and globally, e.g. uploading data to global databases such as WHO's VigiBase. v. Develop clear standard operating procedures (SOPs) for coordination between the NRA, NIP/EIP, and other institutions with responsibilities for AEFI surveillance. vi. Consider coordination of activities with Public Health Emergency Units. vii. Consider setting up AEFI committees at the subnational as well as national level, particularly in large countries.
Investigate potential AEFIs causing concern, such as clusters, serious events, programmatic errors, community concerns	i. Prepare investigation teams and train them for AEFI investigation activities that are relevant to the population being vaccinated. ii. Update, print and distribute AEFI investigation tools to obtain information on specific outcomes iii. Ensure the collection and storage of all relevant data to help make a causality assessment (AEFI reporting and investigation forms, clinical case records, laboratory reports, autopsy reports, etc.). iv. Provide feedback to reporting health care worker, including suggestions for the management of the AE at the local level.

Perform systematic causality assessment of AEFIs causing concern	i. Constitute a National AEFI committee to review and respond to AEFI safety signals and public concerns or contact the WHO Country or Regional Office or send an email to gvsi@who.int to ask for assistance. ii. Provide training on causality assessment processes using WHO causality assessment guidelines for members of the National AEFI committee. iii. Provide regular updates to the Committee members on COVID-19 vaccine development and safety data, including safety reports from ongoing phase III clinical trials or any events reported in clinical trials. iv. Foster and use the committee's expertise to identify AEFI cases in need of further investigation, such as AESIs. v. Anticipate an increased number of AEFI reports that will need to be reviewed and consider including AEFI committees at sub-national as well as national level, particularly in large countries.
Use AEFI and disease surveillance data to detect potential safety signals or clustering of events	i. Regularly review and report AEFI surveillance data, particularly those relevant to AESIs or other conditions identified during pre-licensure COVID-19 vaccine clinical trials. ii. Explore the use of disease surveillance data to complement AEFI surveillance systems for the detecting of AESIs, if indicated. iii. Consider use of early signal detection methods, especially for certain AESIs.
Prepare comprehensive plans to respond rapidly to all COVID-19 vaccine-related events	i. Outline roles and responsibilities of key stakeholders (both public and private, including vaccine manufacturers) for the implementation of safety surveillance activities and response to vaccine-related events. ii. Keep stakeholders up to date with COVID-19 vaccine safety information. iii. Communicate with WHO regions and headquarters and share data on outcomes of AEFIs and AESIs in a rapid, timely and regular manner.
Address concerns of HCW and maintain community confidence	i. Create and share a COVID-19 vaccine safety communication plan with relevant stakeholders. ii. Train and support personnel at all levels to address concerns that may arise before, during and after COVID-19 vaccine introduction. iii. Develop, print, and distribute messages concerning the safety COVID-19 vaccines

https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_surveillance_systems.pdf

5.6 Specific provisions for additional national safety monitoring activities by COVID-19 vaccine manufacturers

5.6.1 COVID-19 vaccine manufacturers are also responsible for monitoring the safety of their COVID-19 vaccines introduced and for addressing any safety issues that occur. Additional safety surveillance activities should be carried out by vaccine manufacturers to continue collecting information on safety beyond that collected during pre-licensure COVID-19 vaccine trials.

5.6.2 The processes of engaging with the pharmaceutical industry, reviewing risk management plans and outlining the legal provisions and guidelines for COVID-19 vaccine safety are described in the engaging with the pharmaceutical industry module. Additional pharmacovigilance activities such as post-authorization safety studies (PASS) that should be performed to assess any identified risks or potential risks and provide important missing information are also described.

https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_pharmaceutical_industry.pdf

5.7 Crisis communication

5.7.1 The goal of vaccine safety communication is to maintain public trust in vaccines and immunization safety toward sustaining the immunization programme with high immunization coverage's to prevent and control vaccine-preventable diseases in the country. Planning and preparing to communicate about COVID-19 vaccine safety should take place as early as possible, ideally well in advance of vaccines being deployed and should include:

i. involving the communications team in vaccine safety work
ii. establishing strategic partnerships,
iii. setting up communication pathways with the public
iv. identifying potential threats to confidence in vaccine safety

5.7.2 Communication can be done via writing manuscripts, publications and bulletins, AEFI training feedback presentations, feedback letters and vaccine fact sheets.

5.7.3 Coordination between all stakeholders handling deaths should be established for reporting deaths in persons with a history of COVID-19 vaccination and specific protocols for investigating these deaths should be defined.

5.7.4 Communication about any adverse events and response to public concerns should be rapid in order to maintain public confidence, in the setting of high media and public attention on COVID-19 vaccines

5.8 Development of a COVID-19 vaccine safety communication plan

5.8.1 A vaccine safety communication plan does not eliminate risk, but will help to prepare to communicate more effectively with the public, and collaborate with partners and the media in the face of risks. The plan may include the following activities:

i. Designate responsibilities
ii. Nominate spokespeople
iii. Develop a decision tool to help determine your communications response to a vaccine-related event
iv. Identify and secure resources required to perform the plan, define target audiences and audience segments

v. Identify key influencers and ambassadors
vi. Determine key communication channels, e.g. the lead organization and stakeholder websites, social media platforms, media releases, local/national media, brochures or hand-outs, public forums, schools and other educational institutions
vii. Seek input from key stakeholders when developing your vaccine safety communications plan, especially those representing audiences who have specific information needs or concerns, i.e. older people, health care workers
viii. Agree on procedures to coordinate information dissemination with partners, including who releases what, when, and how
ix. Create contact lists of key individuals in your organization, the media and strategic partners
x. Create key messages and communication materials to disseminate through the planned communication channels
xi. Determine training needs, such as media and de-escalation training for spokespeople, who often can become the focus of public anger and concerns and must perform well under pressure to be effective, develop strategies to monitor and evaluate communications. These may include evaluating the effectiveness of communications, documenting challenges and lessons learned, identifying gaps in skills and resources, and identifying actions to improve communications in the future.
xii. Evaluate communications using various tools, including social media listening, media monitoring and monitoring at the community level via health care workers, community-based mobilizers or social mobilizers, seeking feedback from the community and religious leaders and civil society organizations. Input from strategic partners will also be useful.
https://www.who.int/publications/m/item/covid-19-vaccines-safety-surveillance-manual---communication

5.8.2 The COVID-19 safety communication plan should not be overly long. This plan will need to be regularly revised, especially after any vaccine-related events; to incorporate lessons learned and to keep contact lists up to date.

5.9 Communicating with parents, community and health staff

5.9.1 Key point to consider when communicating with the parents/ relatives of the recipient and community;

i. Listen empathetically to parents and their concerns, reassure and support them but do not make false promises and constantly update them regarding the progress of the patient.
ii. Prepare a fact sheet on the adverse events for parents, community, health staff and media.
iii. Reassure the staff's confidence in the immunization programme, vaccine quality and partial investigation.
iv. Reassure their knowledge, ability, skills and performances.
v. Do not blame the health worker(s) instead focus on the correction and quality of the national immunization program.
vi. Keep updating them on the investigation process, progress and findings.

5.10 Crisis management

5.10.1 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. Often crises can be avoided through foresight, care and training. If managed

properly, the crisis will strengthen the immunization programme and boost public confidence and acceptance.

5.10.2 How to manage a crisis

i. anticipate, do not wait until a crisis occurs, prepare for the unavoidable
ii. develop a good relationship with the media
iii. good public awareness in necessary
iv. train staff at all levels to respond adequately and confirm all facts before making any public comments
v. 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

5.11 Death following COVID-19 Immunization

All countries should define specific protocols for investigating deaths following COVID-19 vaccination. Guidance on investigating deaths following vaccination is provided in the Global manual on surveillance of AEFI. Individuals who die following COVID-19 vaccination, including those with any related diagnosis that is an AESI, should be included in the protocol for investigating deaths following COVID-19 vaccination. Due to the high number of deaths during a pandemic, coordination with all stakeholders handling deaths should be established for reporting deaths in persons with a history of COVID-19 vaccination. Specific protocols for autopsies of people with a suspected cause of death given as COVID-19 have been developed, and these could be used for the autopsy of COVID-19 vaccinated individuals who die. If indicated, tissue samples should be collected for in-depth pathologic, virologic and genetic testing. If an autopsy is not done, a complete verbal autopsy using standard protocol should be conducted and the findings documented and sent to the national AEFI committee.

5.12 Reporting of AEFIs during COVID-19 vaccination programs

Who should report? All key players including ZEPI-MoHCC, Healthcare workers, beneficiaries and manufacturers should report all non-serious and serious AEFIs that occur in Zimbabwe to the MCAZ, National pharmacovigilance center using all available reporting tools**, MCAZ e-PV system accessible on** https://e-pv.mcaz.co.zw/**.** For detailed guidance on how to navigate the e-PV system, please refer to the Pharmacovigilance Electronic Reporting System User Manual accessible at:
https://www.mcaz.co.zw/index.php/downloads/category/15-guidelines?download=318:mcaz-electronic-reporting-system-user-manual

NB. If electronic systems are not available, hard copy AEFI reporting form appendix 1 and AEFI case investigation form Appendix II below may also be scanned and emailed to MCAZ and ZEPI-MoHCC.

5.13 Product Defects and Substandard / Spurious / Falsely Labelled / Falsified / Counterfeit Medical Products (SSFFCS)

5.13.1 Any person, health professional, an applicant who comes across a product defect or suspected counterfeit vaccine is required to complete a product defect form (Appendix III) and report to MCAZ as they pose a risk to the public.

5.13.2 When medicines, vaccines or medical device products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information must be reported to the

MCAZ. The MCAZ Guideline for the Notification of a Medicinal Product Problem/Defect and Recall Procedure are intended to ensure that in the event of a necessary recall, the recall operations are effectively and efficiently carried out by the manufacturer, importer, distributor or certificate holder of pharmaceutical product in order to safeguard public health. The guide is accessible at: https://www.mcaz.co.zw/index.php/downloads/category/15-guidelines?download=75:guidelines-for-the-notification-of-medicinal-product-problem-defect-and-recall-procedure)

5.13.3 Hard copies of the product defect forms (PVF 05) and medication incidence form (PVF 45) are available on request from MCAZ email mcaz@mcaz.co.zw or downloadable on mcaz website www.mcaz.co.zw.

5.14 Monitoring and evaluation and overcoming barriers to reporting

5.14.1 MCAZ and ZEPI-MoHCC will provide singed feedback to reporters and stakeholders including bulletins, manuscripts published in journals, virtual presentations and trainings and/or meetings.

5.14.2 The reporting of AEFIs needs continuous stimulation, confidence-building and reassurance and trust. It is important to achieve the development of a positive attitude towards pharmacovigilance among healthcare professionals so that ADRs/SAEs and or AEFIs reporting becomes an accepted culture of promoting patient safety with no fear of victimization.

6.0 KEY RELEVANT DOCUMENTS

6.1 Zimbabwe Ministry of Health and Child Care Vaccine Deployment plan

6.2 Zimbabwe National Pharmacovigilance Handbook 2nd Edition February 2017 https://www.mcaz.co.zw/index.php/downloads/category/15guidelines?download=157:zimbabwe-national-pharmacovigilance-policy-handbook

6.4 Zimbabwe Adverse Events Following Immunization 3rd Edition January 2017 https://www.mcaz.co.zw/index.php/downloads/category/15guidelines?download=163:adverse-events-following-immunization-surveillance-guidelines-3rd-edition-jan-2017

6.5 COVID-19 Vaccines Safety Surveillance WHO Manual. December 2020 https://www.who.int/publications/i/item/10665338400

6.6 Hampton LM, Aggarwal R, Evans SJ, Law B. General Determination of Causation Between Covid-19 Vaccines and Possible Adverse Events. Vaccine. 2021 Jan 29.

6.7 WHO Global Bench Marking Tool (WHOGBMT) Indicators Version VI, 2018 for a National Drug Regulatory Agency

6.8 European Medicines Agency /European Union Guide for COVID -19 vaccines Emergency Use 2020

6.9 COVID-19 Vaccines Manual Communication, https://www.who.int/publications/m/item/covid-19-vaccines-safety-surveillance-manual---communication

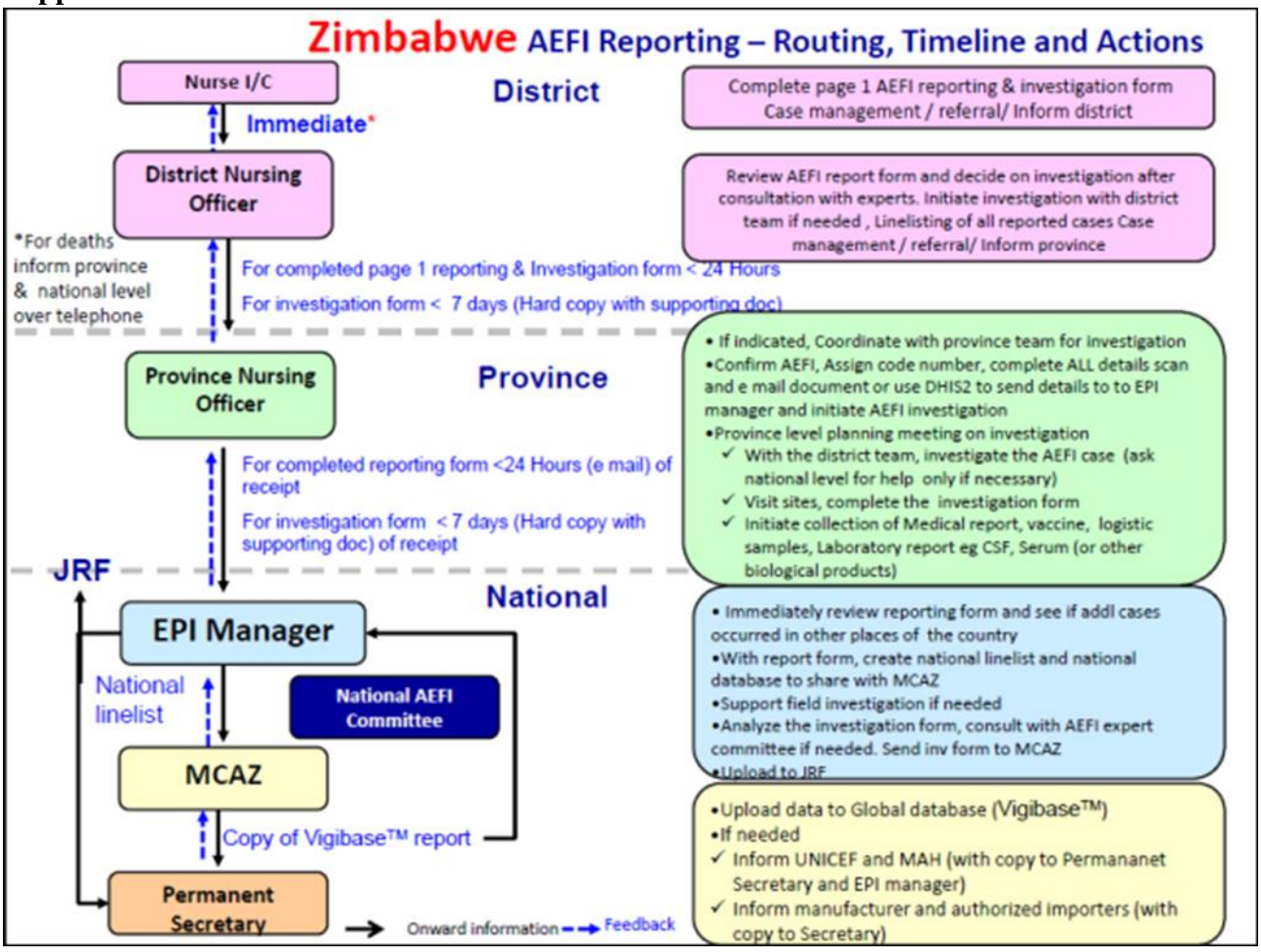
6.10 COVID-19 Vaccines Manual Pharmaceutical Industry, https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance manual/covid19vaccines_manual_pharmaceutical_industry.pdf

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	New document
N/A	N/A	

APPENDICES

Appendix I: Zimbabwe National AEFI Process Flow



(Source Zimbabwe Adverse Events Following Immunization 3rd Edition January 2017

Appendix II: AEFI Report Form

AEFI Report ID Number (ZW-PR-DS-FAC-000-YR): ZW-_ _ _-_ _ _-_ _ _-_ _ _-_ _ _-_ _ _ _

ZIMBABWE REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Patient first name:* **Surname *Next of Kin:* **Patient's physical address:* Telephone: Sex: ☐M ☐F **Date of birth (DD/MM/YYYY):* __ __ / __ __ / __ __ __ __ *OR Age at onset :* ☐☐*Years* ☐☐ *Months* ☐☐☐ *Days*	**Reporter's Name:* Designation, Department & address: District/ Province: Reporting Institution Telephone & e-mail: *Today's date (DD/MM/YYYY):* _ / __ / __ __

Health facility (or vaccination centre) name:

Vaccine						*Diluent*		
**Name*	**Date of vaccination*	**Time of vaccination*	Dose (1st, 2nd, 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 Was the patient hospitalized? ☐Yes ☐No Date patient notified event to health system (DD/MM/YYYY): __ __ / __ __ / __ __ __ __	Describe AEFI (Signs and symptoms):

Treatment provided: yes/ no

**Serious: Yes/ No;* *If yes,* ☐ *Death* ☐ *Life threatening* ☐ *Disability* ☐ *Hospitalization* ☐ *Congenital anomaly*

**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 other relevant information (e.g. other cases). *Use additional sheet if needed :*

First decision making level to complete (District level):

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*

Appendix III: AEFI Investigation Form

AEFI INVESTIGATION FORM

(Only for Serious Adverse Events Following Immunization – Death / Disability / Hospitalization / Cluster)

Section A Basic details

Place of vaccination *(✓)*: ☐ Govt. health facility ☐ Private health facility ☐Other (specify) _____
Type of site *(✓)* ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____
Vaccination in *(✓)*: ☐ Campaign ☐ Routine ☐ Other (specify) _____

Name of Investigating Health Worker:

Date AEFI reported: __ __ / __ __ / __ __ __ __
Date investigation started: __ __ / __ __ / __ __ __ __
Date investigation completed: __ __ / __ __ / __ __ __ __

Designation / Position:

Telephone # landline (with code): Mobile: e-mail:

Patient Name

(use a separate form for each case in a cluster)

Sex: ☐M ☐ F

Date of hospitalization *(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)*: __ __ / __ __ / __ __ __ __ *(hr/m)*: __ __ / __ __
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 previous vaccination(s)	Yes / No / Unkn	
History of allergy to vaccine, drug or food	Yes / No / Unkn	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unkn	
History of hospitalization in last 30 days, with cause	Yes / No / Unkn	
Was patient on medication at time of vaccination? (If yes, name the drug, indication, doses and treatment dates)	Yes / No / Unkn	
Did patient consult faith healers before/after vaccination? *specify	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:_____

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

a)	When was the patient vaccinated? (✓ 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. cold chain failure 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 vaccinated from the concerned vaccine vial/ampoule	
i)	Number vaccinated with the concerned vaccine in the same session	
j)	Number vaccinated with the concerned vaccine having the same batch number in other locations. Specify locations: _____	
k)	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 'yes' 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)

	Status		
• Reconstitution procedure (✓)			
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents used the same as those recommended by the manufacturer?	Yes	No	NA

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 from the refrigerator to the vaccination centre:	
• Was cold chain properly maintained during transportation?	Yes / No / Unkn
• Was the vaccine carrier sent to the site on the same day as vaccination?	Yes / No / Unkn
• Were conditioned coolant-packs 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 affected, how many are • Vaccinated:_____ • Not vaccinated:_____ • Unknown:_____
Other comments:

Section H Other relevant findings/observations/comments

Appendix IV: Medication Incidence Reporting Form

Medicines Control Authority of Zimbabwe

PVF 45

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

MEDICATION INCIDENCE FORM

Date of event:	**Type of Facility:** Government Private				**Location of event:**			
	Hospital	Clinic	Pharmacy	Other(specify)	Ward	Pharmacy	Clinic	Other(specify)
Time of event:								

Please describe the incidence: description/sequence of events and medical/nursing care or management done:

Immediate action or intervention done:

Corrective action taken on the incidence:

In which process did the incident occur?

Prescribing	Dispensing	Administration	Others (Specify)

Did the error reach the patient? **Yes** **No**

PLEASE TICK THE APPROPRIATE (INCIDENCE OUTCOME CATEGORY (SELECT ONE)

NO INCIDENCE
Potential error, circumstances/events have potential to cause incident

INCIDENCE, NO HARM
An incidence occurred and reached the patient, but did not cause patient harm
Additional monitoring required

INCIDENCE, HARM
An incidence occurred and reached the patient. Treatment intervention required – caused temporary harm
An incidence occurred and reached the patient. Treatment intervention required – caused permanent harm
An incidence occurred that required intervention necessary to sustain life

INCIDENCE, DEATH
Death

INDICATE THE POSSIBLE INCIDENCE CAUSES(S) AND CONTRIBUTING FACTORS eg inexperienced personnel, wrong medication given due to use of product with similar packaging , wrong dose administered

Which category was responsible for the incident?

Doctor	Nurse	Pharmacy personnel	Other (specify)

Which category detected the incident or recognized the potential incident?

Doctor	Nurse	Pharmacy personnel	Other (specify)

IF AVAILABLE, PLEASE PROVIDE PATIENT'S PARTICULARS – NO PATIENT IDENTIFIERS ARE NEEDED

Age years/months	**Gender** Male Female	**Indication for therapy:**

PRODUCT DESCRIPTION	**Intended product**	**Product Administered in error**
Medication name (generic &/or brand)		
Dose, frequency, duration, route		
Strength & Dosage form		
Manufacturer		
Type & size of container		

Reported by: *(this section is optional)*	
Name:	Address:
Designation:	Email address:
Contact number:	Signature: Date:

Please send or email completed form to the Director-General, MCAZ, Email address mcaz@mcaz.co.zw , Physical Address: 106 Baines Avenue, Harare Tel: +263772145 19/2/3

Rev 2 _Oct 2020 Page **1** of **1**

Appendix V: Product Defect Form

Medicines Control Authority of Zimbabwe

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

PVF 05

REPORT ON MEDICINAL (PHARMACEUTICAL) PRODUCT DEFECT OR PROBLEM

To be completed by Pharmacists, Pharmacy Technicians, Medical Practitioners, Nurses, Veterinary Surgeons and other Distributors of Medicines.

1. Product Name (Brand and Generic)			
2. Description of the Device/Medicine	3. Intended Use	4. Size/Type of Container	5. m Registration No.
6. 6. Batch Number		7. 7. Expiry Date	
8. Name and Address of Manufacturer			
9. Name and Title of Reporter			
10 .Your Practice Location and Address of Hospital, Clinic, Retail Surgery etc.			
11. Phone Number		12. Date Problem Occurred or Observed	
13. If requested will the actual product involved be available for examination by MCAZ. **YES** **NO**			
14. Signature of Reporter		15. Date	
16. Defects/Problem Noted or Suspected (see a-j below)			

NATURE OF DEFECT OR PROBLEM

a) Presence of foreign material
b) Unusual odour
c) Colour changes
d) Fungal growth
e) Suspected contamination
f) Parenteral solution – leaks, particulate matter, discoloration etc.
g) Wrong label, wrong packaging, wrong strength
h) Lack of therapeutic response
i) Leakages
j) Other (specify)

Return To: The Director-General
Medicines Control Authority of Zimbabwe
106 Baines Avenue
P O Box 10559
Harare
Tel: +263-4-736981/2/3/4/5, 708255 or 792165

For Office Use Only
Report Number:
Date Received:

Appendix VI: AEFI Reporting form Adapted for COVID19 revised 19 February 2021

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 ☐) ***Date of birth (DD/MM/YYYY)*: _ _/_ _/_ _ _ _** *OR Age at onset :* ☐☐ *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 (1st, 2nd, 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*

Appendix VII: AEFI Case investigation form adapted for COVID 19 Revised 19 February 2021

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:

Designation / Position:

Date of investigation: __ __ /____ /_____

Date of filling this form: __ __ / __ __ / __ __ __ __

This report is: ☐ *First* ☐ *Interim* ☐ *Final*

Telephone # landline (with code): Mobile: e-mail:

Patient Name Sex: ☐ M ☐ F

(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. 1st, 2nd, 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

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		

Name **Case ID Number** AEFI Investigation Page 2/5

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 3/5

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 <u>at the place(s) where concerned vaccine was used</u>** ***(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	NA
	Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
	Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
	Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents used the same as those recommended by the manufacturer?		Yes	No	NA
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

Name **Case ID Number** AEFI Investigation Page 4/5

• 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
o If "yes", was there any deviation outside of 2−8° C after the vaccine was placed inside?	Yes / No
o 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/comments

Appendix VIII: WHO AEFI Line list template

According to the Zimbabwe AEFI process flow, the EPI manager at MoHCC-ZEPI completes the WHO AEFI Line list (as known as the Joint Report Form) for all AEFIs received by the ministry of health. The line list is then sent to the MCAZ for verification and sent back to the ministry of health for circulation to relevant partners by the EPI manager. This verification process is essential in order to harmonize the all AEFI reports reported in Zimbabwe every quarter. Below is the up to date WHO AEFI Line list template.

S. No	Patient Name/ Identifier	AEFI Reporting ID number	Patient Location (Village/Town)	Patient Location (District)	Sex(M/F)	Age (Date of brith or age at onset)	Vaccine/s	Manufacturer	Vaccine Batch No	Diluent Batch No	Adverse Event	Date of Vaccination (DOV)	Date of onset (DOO)	Date of Notification (DON)	Date of Reporting (DOR)	Serious (Yes/No)	Reason for Serious	Outcome	Autopsy conducted in case of death (Y/N/NA)	Reported by	Reporter Location 1	Reporter Location 2	Investigation Planned (Y/N)	Date report recd. at Natl Level	Causality Assessment*
1																									
2																									
3																									
4																									
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	A1	A2	A3	A4	B1	B2	C	D
*Causality Assessment codes	Vaccine-product related	Vaccine quality defect related	Immunization error-related	Immunization anxiety-related	Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event	Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	Coincidental	Inadequate information to classify

Appendix IX: Importance of AEFI reporting form completeness

Table 2. Important information to be included on AEFI form for valid AEFI causality assessment and benefit-risk assessment.

Information on AEFI report	**Reason for Importance**	**Consequences of missing data**
Patient Information		
Age of patient	Indicates a valid patient and Possibly different risk	Risk of incorrect conclusion about a single patient. Not possible to make age-specific analyses/ stratification.
Sex of patient	Indicates a valid patient and possibly different risk.	Risk of incorrect conclusion about a single patient. Not possible to make gender-specific analyses/ stratification.
Medical history and past medication and/or vaccine history of the patient	Indicates valid comorbid condition(s) and/or interactions	Risk of missing out key risk factors that might have caused likelihood of AEFI reaction. Risk of incorrect causality assessment.
Death information	Helps to characterize reaction/event. Gives information on the seriousness of the case. Helps to focus on the more important issues.	Risk of incorrect conclusions about a single patient but also about a possible drug problem. Risk of focusing on less important issues
Seriousness	Helps to characterize reaction/event. Gives information on the seriousness of the case. Helps to focus on the more important issues.	Risk of incorrect conclusions about a single patient but also about a possible drug problem. Risk of focusing on less important issues.
Parent-child information	Identify parent drug exposure resulting in reaction/event in foetus/child.	Risk of missing safety issues related to parent-child exposure.
Reaction information		
Reaction/event	As precise and correct description of the reaction/event as possible is of utmost importance for evaluation.	Risk of incorrect conclusions about a single patient but also about a possible drug problem.
Date of onset of reaction /event	Needed to calculate time to onset, in order to evaluate the time relationship between vaccine and reaction/event.	Unable to confirm the time relationship between drug and reaction/event; cannot do complete causality assessment.

Outcome of reaction/event	Indicates the seriousness of the reaction/event and further characterizes a clinical event. Needed to determine outcome of dechallenge when drug was withdrawn.	Unable to confirm a relationship between drug and reaction/event and assess impact. Risk of focusing on less important issues
Laboratory findings	Help to verify and characterize the reaction/event.	Lead to incorrect conclusion about a single patient but also about a possible medicine problem.
Vaccines information		
Medicines	As precise and correct description as possible of the medical product, including Trade name and medicines/vaccines characterization (suspected / interacting/ concomitant), is of utmost importance for evaluation.	Risk of incorrect conclusion about a single patient but also about a possible medicines problem.
start-and stop dates	Needed to calculate time to onset and duration of treatment. Stop date might be an indication that the reaction prompted cessation of treatment.	Unable to confirm time relationship between drug and reaction/event; cannot do complete causality assessment.
Time to onset	Time to onset reported as the time interval between start of drug and reaction onset is important if drug start-and reaction start dates are missing. Needed to evaluate the time relationship between drug and reaction/event.	Unable to confirm time relationship between drug and reaction/event; cannot do complete causality assessment.
Medicine/vaccine Vaccine administration data	Identify problems related to form, strength or route of administration of a medicinal product	Unable to investigate certain hypothesis based on influence of form, strength or route of administration on a reaction/ event.
Dose	Important from a pharmacological point of view. Identify non-optimal use of medicine, resulting in reaction/ event.	Lead to incorrect conclusion about a single patient but also about a possible medicine problem.
Indication	The reaction/event may be influenced by the indication; i.e. the patient's underlying disease. Especially important if the drug may be used for very different indications. May give hint on route of administration, of importance if the route of administration data is missing. May identify off label use	Risk of incorrect conclusions if drug is used for very different indications; confounding by indication should always be considered.

Dechallenge	Crucial as a positive dechallenge indicates association between drug and reaction/event especially important when information on time to onset is missing.	Unable to confirm medicine/vaccine - adverse reaction relationship.
Rechallenge	Crucial as a positive rechallenge strongly indicates association between drug and reaction/event	Risk of missing very important drug problems reported very rarely but with strong evidence of causality

Appendix X: WHO Presentation_ Module 4: COVID-19 Vaccination Training for Health Workers

At the end of this module, the health worker should be able to:

i. identify an adverse event following immunization (AEFI);
ii. describe how to identify and respond to AEFI; and
iii. explain how to report AEFI following COVID-19 vaccination

What is an AEFI?

An AEFI is any untoward medical occurrence which follows immunization; does not necessarily have a causal relationship with vaccine usage; may be an unfavourable symptom about which a vaccine recipient complains; and may be abnormal laboratory finding, sign or disease found by medical staff.

What can be the cause of an AEFI?

i. Vaccine product related reactions
ii. Vaccine product defect related reaction
iii. Immunization error-related reaction
iv. Immunization anxiety-related reaction
v. Coincidental event

How can vaccine reactions be classified?

i. A1- Vaccine product-related reaction: caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product even when vaccine has been prepared, handled and administered correctly.
ii. A2- Vaccine quality defect-related reaction: caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer

By intensity, vaccine reactions can be classified into minor reactions or severe reactions. Both minor and severe reactions can be serious or non-serious.

What are immunisation error related reactions?

A3- Immunization error-related reaction: caused by inappropriate vaccine handling or administration
May occur due to human error such as:

i. reconstitution error (e.g. use of incorrect diluent, diluent mistakenly substituted with a drug vial)
ii. contamination of vaccine and/or syringe (e.g. touching the needle or the rubber cap of the vial with hand or other object, using the reconstituted vaccine after the maximum recommended time)
iii. administration error (e.g. incorrect vaccination technique)

They can cause severe reactions, and may also lead to serious AEFI and result in death.
These errors are PREVENTABLE.

What are Immunisation Anxiety Related reactions?

A4- Immunization anxiety-related reaction: arising from anxiety about the immunization and fear of injection.
Different factors can contribute to anxiety-related reactions such as different vaccination environment, novelty of the vaccine, fear of injection.
To help prevent fainting and injures that could occur from a fall, vaccinated individuals should stay seated for about 15 minutes after vaccination.

What are coincidental events?

C. Coincidental event: event that happens after vaccination but is not caused by vaccine or vaccination process

Adult and elderly populations with chronic diseases may develop conditions irrespective of vaccination that may be attributed to vaccine.

Similar events may occur in healthy individuals where higher frequency of a specific condition, including any communicable disease, can be expected based on age, sex, geographic location or ethnic background.

Other important terms and definitions

AEFI can be classified by seriousness as:

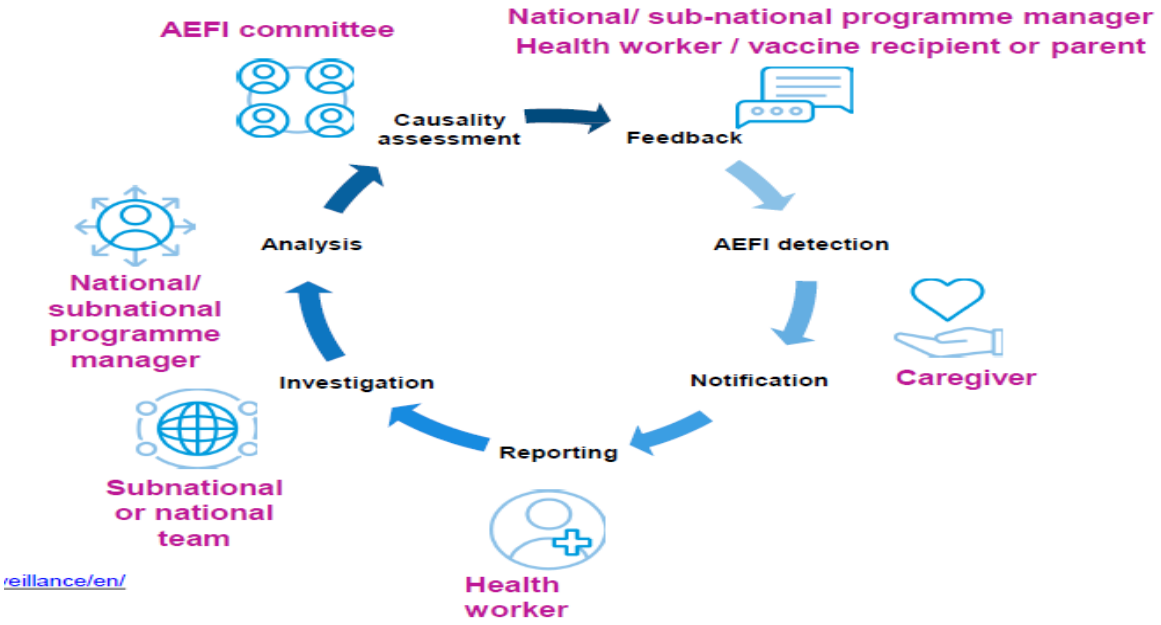
i. serious AEFI – results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability, or is a congenital anomaly/birth defect
ii. non- serious AEFI – does not pose a potential risk to the health of the recipient

Cluster – two or more cases of the same or similar events related in time, place/geography, and/or vaccine administered. Coincidental events can occur as clusters. Immunization stress-related responses (ISRR) can occur in clusters. Clusters should be reported.

How can you prevent immunization error-related AEFI?

i. Do not store and/or pack other diluents or medications together with the COVID-19 vaccine.
ii. Always check the labels of vaccines and diluents before reconstitution – vaccines and diluents should be from the same manufacturer.
iii. Follow manufacturer's recommendations on storage, vaccine preparation, route and technique of administration, and contraindications and precautions.
iv. Draw the auto-disable (AD) syringe just before vaccination.
v. Do not touch the needle.
vi. Do not touch the rubber cap of the vaccine vial.
vii. If reconstituted, never carry vaccines from one place to another.
viii. Do not cover the vaccine carrier with the lid while the reconstituted vaccine vial is in the foam pad.
ix. Discard the vaccine if it was reconstituted before the maximum recommended time or at the end of the session, whichever comes first.
x. When in doubt, contact your supervisor for clarification. Do not hesitate to report issues or concerns when identified.

AEFI Monitoring key players and roles



What AEFIs should you report and how?

Report all AEFI that are brought to your notice.
Complete the reporting forms and send them to your supervisor.
Use the COVID-19 reporting form.
Include all available information as accurately as possible.
Report all non-serious AEFI according to your country's policy.
In case of serious AEFI, inform your supervisor and/or AEFI focal person immediately (over telephone) and complete the reporting form within 24 hours.

AEFI after COVID-19 vaccines from clinical trials

Known minor AEFI from COVID-19 vaccines are similar to other injectable vaccines and include injection site pain, headache, fatigue, muscle pain.
Other minor AEFI include fever, chills, nausea, arthralgia (pain in a joint).
General precaution/contraindication for any vaccine is possible allergic reaction, including anaphylaxis, to a vaccine component.

What are extremely rare safety events the health worker should be prepared for?

Anaphylaxis
In general anaphylaxis is a very rare (estimated as <1/1 000 000) but severe and potentially fatal reaction.
Proper diagnosis and urgent treatment and management are essential.
When sudden loss of consciousness occurs >5–10 minutes after immunization, anaphylaxis should be considered as a possible diagnosis, in addition to fainting (vasovagal syncope).
More on differences between anaphylaxis, general acute stress response and fainting is available at:
https://www.who.int/publications/i/item/978-92-4-151594-8

Distinguishing acute stress response and anaphylaxis

	Acute stress response (vasovagal syncope – VVS)	Anaphylaxis
At onset	VVS and general: occurs suddenly, before, at time of or soon after injection	Seconds to minutes after exposure, almost all cases within 1 hour
Skin	VVS and general: pale, cold, sweaty/clammy	Red, raised itchy rash, swollen eyes and face, generalized rash
Respiratory	VVS: normal to deep breaths General: rapid deep breathing	Noisy breathing, wheeze or stridor, persistent cough
Heart	VVS: slow pulse, transient hypotension General: normal or fast pulse or hypertension	Fast pulse, hypotension
Gastro–intestinal	VVS: nausea, vomiting General: nausea	Abdominal cramps, vomiting, nausea
Neurologic	VVS: transient loss of consciousness reversed by supine position General: fearfulness, dizziness, numbness, weakness, tingling around lips, spasms in hands and feet	May develop loss of consciousness not relieved by supine position

https://www.who.int/immunization/diseases/measles/SIA-Field-Guide.pdf

Summary of key points

1. The known safety profile of COVID-19 vaccines is similar to the existing injectable vaccines.
2. Report all AEFI brought to your notice and ensure adequate medical intervention/ referral as needed.
3. Fill in the COVID-19 reporting form in a complete, accurate and timely manner, and forward to your supervisor.
4. Because this is a new vaccine, it is essential to notify any safety concerns and provide support during any investigations.