COVID-19 Vaccines: Safety Surveillance Manual

Module: Safety data management systems in countries using COVID-19 vaccines

Contents

Abbreviations

AACVS	African Advisory Committee on Vaccine Safety
ACE	Angiotensin-converting enzyme
ADEM	Acute disseminated encephalomyelitis
ADRs	Adverse drug reactions
AEFI	Adverse event following immunization
AESI	Adverse event of special interest
ARDS	Acute respiratory distress syndrome
AVSS	Active vaccine safety surveillance
CEM	Cohort event monitoring
CEPI	Coalition for Epidemic Preparedness Innovations
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus disease 2019
DCVMN	Developing Countries Vaccine Manufactures Network
DL	Data linkage
DNA	Deoxyribonucleic acid
EH	e-Health
EPI	Expanded programme on immunization
GACVS	Global Advisory Committee on Vaccine Safety
GBS	Guillain-Barré syndrome
GVAP	Global vaccine action plan
HCW	Health care worker
ICD	International classification of diseases
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
ISoP	International Society of Pharmacovigilance
ISRR	Immunization stress-related response
MAH	Marketing authorization holder
MedDRA	Medical dictionary for regulatory activities
MH	m-Health
MoH	Ministry of Health
mRNA	Messenger RNA
NIP	National Immunization Programme
NITAG	National Immunization Technical Advisory Group
NRA	National regulatory authority
PBRER	Periodic benefit-risk evaluation report
PHEIC	Public health emergency of international concern
PLSS	Post-licensure safety studies
PSUR	Product safety update report
PV	Pharmacovigilance
QPPV	Qualified person responsible for pharmacovigilance
RITAG	Regional Immunization Technical Advisory Groups
RMP	Risk management plan
RNA	Ribonucleic acid
SAGE	Strategic Advisory Group of Experts (for immunization)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SKG	Significant knowledge gap
SIA	Supplementary immunization activities
SS	Sentinel surveillance
TGA	Therapeutic Goods Administration (Australian Ministry of Health)
VAED	Vaccine-associated enhanced disease
VLP	Virus-like particles
VPD	Vaccine preventable disease
WHO	World Health Organization

Glossary

Adjuvant	A pharmacological or immunological agent added to a vaccine to improve its immune response.
Adverse event following immunization (AEFI): general definition	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.
• AEFI by cause: coincidental events	• An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
• AEFI by cause: immunization anxiety-related reaction	• An AEFI arising from anxiety about the immunization (see immunization stress related responses).
• AEFI by cause: immunization error-related reaction	• An AEFI that is caused by inappropriate vaccine handling, prescribing or administration, that, therefore, is preventable.
• AEFI by cause: 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 (e.g. adjuvant, preservative or stabilizer).
• AEFI by cause: 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 its administration device as provided by the manufacturer.
Adverse event of special interest (AESI)	A preidentified 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.
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 that are temporally associated may not necessarily be causally associated.
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.
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.
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.
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.
Immunization	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

Immunization safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse event surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.
Immunization safety surveillance	A system for ensuring immunization safety through detecting, reporting, investigating, and responding to AEFI.
Immunization stress related responses (ISRR)	Stress response to immunization that may manifest just prior to, during, or after immunization.
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 creation of dangerous waste is prevented. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
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 also be carefully monitored because they may signal a potentially larger problem with the vaccine or vaccination or have an impact on the vaccination acceptability; in general.
Risk management plan (RMP)	A risk management plan is a document that describes the current knowledge about the safety and efficacy of a medicinal product. The RMP provides key information on plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine or vaccine. It also describes measures to be undertaken to prevent or minimise risks associated with the use of the product in patients.
Safe injection practice	Practices that 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 in-patient 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	Vaccine reactions can be mild, moderate or severe. Severe reactions may include both serious and non-serious reactions.
Signal (safety signal)	Information (from one or more sources) that suggests a new and potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verification.
Surveillance	The continual, systematic collection of data that are analysed and disseminated to enable decision-making and action to protect the health of populations.
Trigger event	A medical incident following immunization that stimulates a response, usually a case investigation.
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
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.

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 pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFI and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or vaccination.
Vaccination failure	Vaccination failure can 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) because the vaccine did not produce its intended effect
Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.
Vaccine safety	The process that maintains the highest efficacy of, and lowest adverse reaction to, a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunization safety.

1.   Introduction

WHO's Global manual on surveillance of AEFIs[1] provides guidance on the purpose of data analysis at different level. For example, who should analyse data, how it should be analysed and interpreted and its use for estimating relative and attributable risks. In the context of COVID-19 vaccine AEFI surveillance, the same principles and approaches should be applied, with some adaptation to allow for different vaccination strategies, vaccine target populations, types of vaccines and the surveillance systems available in different countries.

Guidance on vaccine safety surveillance systems and responding to AEFIs and AESIs to address the unique challenges from COVID-19 vaccine introduction is given in separate modules [link to AEFI and AESI modules to be added]. Once surveillance systems are operational, the efficiency and effectiveness of the system are determined by the outputs and outcomes from the system. First, the raw data generated by the system needs to be collated, then transmitted, processed and interpreted and, finally responded to systematically and scientifically. This module will provide guidance on how COVID-19 vaccine safety data should be processed and made actionable.

2.   Sharing COVID-19 vaccine safety data

At the national level, the guarantee the integrity and validity of the COVID-19 vaccine safety data generated, data loss and duplication should be minimized. This can be achieved through data sharing between stakeholders such as national immunization programmes (NIPs) and expanded programmes for immunization (EPIs), national regulatory agencies (NRAs), pharmacovigilance centres, Ministries of Health (MoHs), AEFI committees, private sector, vaccine marketing authorization holders (MAHs). Data in some countries will be reported through multiple channels, with programmes working on data from the same patients and sometimes via the same health care professional, but with different goals and pathways.

At regional and global levels, data sharing maximizes resources and capacity to enable efficient responses and decision-making. Also, signal detection capacity would be increased, as would the ability of detecting and analysing very rare adverse events. Data transformation is usually required to facilitate data sharing from different sources.

2.1.   Rationale for data sharing

Data sharing at all levels is important to increase knowledge rapidly that can inform decisions about COVID-19 vaccine introduction and continuation strategies. Uncertainty about the frequency AEFI and clinical presentation will be expected due to the fast-track development processes for COVID-19 vaccines, with short time frames for data collection and regulatory review. The rationale for sharing data from four main sources are outlined below:

- Data from passive and enhanced passive AEFI surveillance systems: to detect signals, monitor immunization programme activities, monitor events that could be related to defective, un-registered or counterfeit COVID-19 vaccines.

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[1] WHO Global Manual on Surveillance of AEFI. Available from:
https://www.who.int/vaccine_safety/publications/Global_Manual_on_Surveillance_of_AEFI.pdf. Accessed 29 October 2020.

- Data from active surveillance systems: to verify and confirm the post-licensure safety profiles of COVID-19 vaccines, test hypotheses (epidemiologic associations between AEFIs and COVID-19 vaccines), detect signal with an accelerated time from reporting to detection.

- Data from COVID-19 vaccine manufacturers: bi-directional sharing[2] of data with COVID-19 vaccine manufacturers will help ensure that data collection is complete and avoid double counting of events. In addition, the manufacturers may be aware of data from other countries or sources that can help in the evaluation of AEFIs.

- Data from other sources such as disease surveillance data, vaccine distribution and utilization data can help generate rapid alerts to trigger common responses from a geographical territory, know the implementation level, know the quality of surveillance at the national level to plan for improvement strategies, understand the distribution of different COVID-19 vaccines and to compare with distribution of the disease for interpreting patterns observed during data analysis.

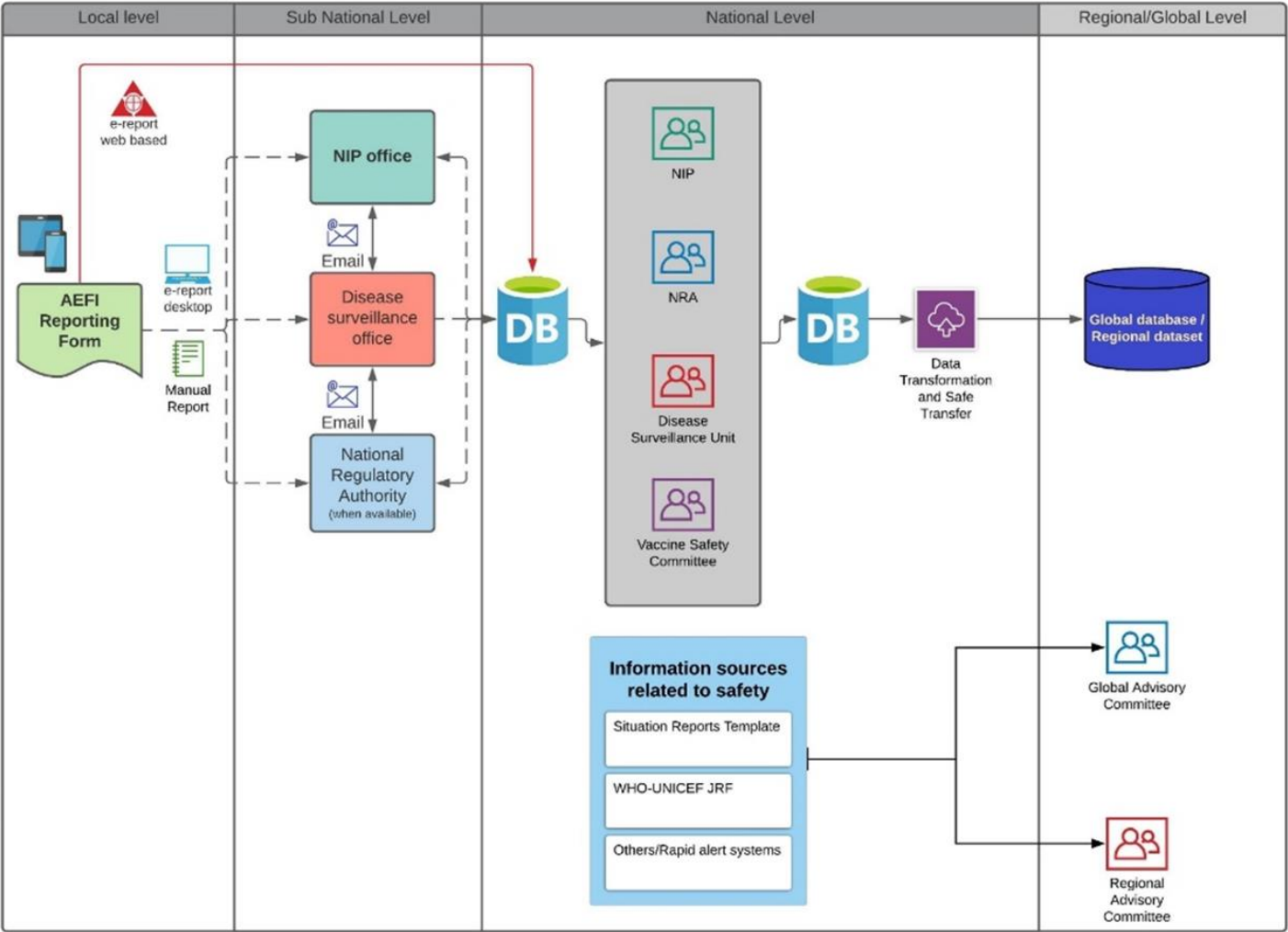## 2.2. Ethics in safety data sharing and collaboration

The key ethical considerations for data sharing include data confidentiality, data security, autonomy, sovereignty and benefits for those providing and sharing data.

2.3. Generic data sharing model

Fig 1 shows a schematic representation of the structure of a generic model for data sharing at the local, subnational, national and global levels. Each country must adapt the generic systems to their local context.

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[2] MAH inform the NRAs of the AEFI occurring in other parts of the world and the NRA needs to share AEFI data from their country with the MAH.

59   Fig 1: Schematic representation of the structure for data sharing at the local, subnational, national and global levels

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2.4. Stakeholders mapping for AEFI data sharing

The potential stakeholder mapping is summarized in Table 1. It is important to consider who will be producing or managing COVID-19 vaccine AEFI data when a data sharing strategy will be developed.

Table 1: Potential stakeholder mapping of COVID-19 vaccine AEFI data sharing

Stakeholder	Current data mapping (variable in different contexts)
District/Subnational level	
Health care institutions	▪ Individual Case AEFI Reports ▪ Case Report Form for ad-hoc studies
Disease surveillance offices	▪ Investigation information to complete Individual Case AEFI report ▪ Data on local epidemiological behaviour of infectious diseases
Immunization programme offices	▪ Data on immunization activities ▪ Individual Case AEFI reports
National level	
Disease surveillance Responsible	▪ Data on infectious and non-infectious diseases ▪ Data on AEFI surveillance
National Immunization Programmes / Expanded Programmes for Immunization	▪ Data on immunization activities: Administrative data and distribution activities ▪ Data on AEFI surveillance.
National Regulatory Authorities	▪ Data on AEFI surveillance from primary health care workers and citizens ▪ Data on AEFI surveillance from manufacturers ▪ Data on Adverse Event reports from clinical trials
Health information systems units	▪ Data from all sources in the country
Research institutions/Clinical Research Organization	▪ Individual Case Safety (Adverse Events) Reports from clinical trials ▪ Data on diseases considered as AESI/AEFI
Vaccine manufacturers or marketing authorization holders	▪ Individual Case AEFI report
Clinical Research Sponsors	▪ SUSAR from clinical trials
Regional and Global Level	
WHO regional offices	▪ WHO-UNICEF JRF[3] ▪ Individual case reports on infectious disease surveillance ▪ Access to WHO UMC Global ICSR/ AEFI database[4]
WHO Headquarters	▪ WHO-UNICEF JRF ▪ Individual case reports on infectious disease surveillance ▪ Access to WHO UMC Global ICSR/ AEFI database
WHO PIDM/VigiBase (maintained by UMC)	▪ Individual Case AEFI report ▪ WHO UMC Global ICSR/ AEFI database

2.5. Data sources

There are different data sources with different data formats that can be applied to the COVID-19 pharmacovigilance. Some considerations for country capacity for data sharing include:

- timely availability of individual AEFI case reports with at least the 25 core variables;

- data centralized in a database with variables coded with a pre-defined data standard;

- completeness and accuracy of data (quality);

- technology available to implement safe data transfer;

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[3] https://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/
[4] https://www.who-umc.org/vigibase/vigibase/

73 • data governance frameworks that define rules for data sharing with external institutions.

2.5.1. Individual case safety reports (individual AEFI case reports)

75 Different levels of information systems exist in different countries. This information is usually
76 collected from passive AEFI surveillance systems however, it could also be collected from active
77 sentinel surveillance sites. Individual reports could also come from COVID-19 vaccine trials that
78 would be assessed by a scientific committee established for the purpose. The WHO global database
79 VigiBase, contains ICSRs and AEFIs from all Member States in the WHO Programme for International
80 Drug Monitoring. The source can be used to perform quantitative calculations at national, regional
81 and global levels to detect signals and safety concerns.

2.5.2. Aggregated safety data from different sources

83 All countries routinely share aggregated safety data to help characterize vaccine safety e.g., WHO-
84 UNICEF JRF, SITREP, IDSR, regulatory authorities' networks reports, academic initiatives etc.

2.5.3. Ad-hoc research

86 Ad hoc research projects or specific studies could be performed by networks of health care institutes
87 using data transferred to national institutes and to the data warehouse of the institute doing the
88 final analysis. The platform selected by the study coordination and described in the study protocol
89 will impact the database. It is necessary to perform a careful analysis of availability data for the event
90 and its quality, and for the vaccination status of the patients to be included in the study before
91 initiating ad-hoc studies. Patient diagnosis registration systems and vaccination registries should be
92 available.

2.6. Data standards

94 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for
95 Human Use (ICH) standardises the definition of the data elements used in the electronic transmission
96 of different types of Individual Case Safety Reports (ICSRs), regardless of source and destination. The
97 standard adopted by the ICH for electronic transmission of ICSRs is described in the ICH E2B(R3)
98 message standard. Additional information is available at https://www.ich.org/page/electronic-
99 standards-estri.

100 Data should satisfy agreed international standards for successful data sharing, so that both the
101 transmitter and the receiver have identical information. Multiple data standards are available for
102 specific coding and for whole database structures and data formats. For clinical diagnosis coding,
103 some standards have been developed e.g. Medical Dictionary for Regulatory Activities (MedDRA) and
104 ICD. It is important to use a standard for identifying the specific vaccine that is being evaluated.
105 Whenever available, the anatomical therapeutic chemical (ATC) standard[5] should be used. For active
106 surveillance systems, data standards are defined by the study protocols.

2.7. Data transformation

108 If the database used country does not comply with a standard as outlined above, data
109 transformation is essential before data can be shared. the ICH E2B(R3) message standard should be
110 used for data transformation and transmission in a standard transmission format. This requires
111 coding as outlined in MedDRA and Identification of Medicinal Products (IDMP). Data science

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[5] WHO. The ATC/DDD Methodology. Available from: https://www.who.int/medicines/regulation/medicines-safety/toolkit_methodology/en/. Accessed 299 October 2020.

112 techniques should be applied for converting the source database format into the target format of the
113 international database, using tools such as, ETL (Extract, Transform and Load). Countries are
114 encouraged to contact WHO country offices for guidance if needed.

2.8. Repositories

116 The following are examples of repositories that are collecting and processing information on AEFI and
117 enabling decision making at national, regional and global levels:

118 • examples of national databases: Vaccine Safety Datalink (US), Canadian Adverse Event
119   Following Immunization Surveillance System (CAEFISS);

120 • example of regional databases: EudraVigilance;

121 • global databases;

122   o for aggregate data: the WHO/UNICEF Joint Reporting Process; and

123   o for case-based data, the WHO Vigibase, maintained by UMC.

2.9. Performance indicators

125 So that all counties can verify that their safety assessments for-19 vaccines, indicators have been
126 adapted from existing immunization indicators where possible, but specific indicators have been
127 developed to adapt to the current COVID-19 situation. Programme managers should take into
128 consideration the fact that vaccine safety surveillance systems are for all vaccines, not just the
129 COVID-19 vaccine and that routine vaccination will continue during COVID-19 deployment.

130 This section describes indicators obtained by extracting data on COVID-19 vaccine from
131 pharmacovigilance monitoring and evaluation systems. The objectives of these indicators specific to
132 COVID-19 vaccines are:

133 • at the national level:

134 • help national AEFI committees, NRAs and NIPs/EPIs to identify any subnational
135   programmatic issues, vaccine safety signals, crisis in a timely manner and to make
136   decisions for correction;

137 • identify if the country's vaccine safety system is sensitive enough to identify signals and
138   respond to them;

139 • improve the quality of reporting, investigations and causality assessment; and

140 • enable comparison of national safety performances with regional and global standards.

141 • at the subnational level:

142 • help provincial governments to identify districts where surveillance is poor (low
143   reporting);

144 • identify and respond to programme and immunization errors early;

145 • identify capacity gaps in specific districts, particularly those with vulnerable populations;
146   and

147 • allocate resources for building local training capacity.

148 • at the local level:

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149   •   Identify zones with high COVID-19 coverage but poor AEFI reporting.

150 Since COVID-19 vaccines are novel, it has been suggested that a separate report generated monthly
151 for them, based upon these indicators. Three types of indicators have been proposed:

152   •   key COVID-19 pharmacovigilance indicators include: total AEFI rate/100,000 COVID-19
153   vaccine doses administered/distributed; serious AEFI (SAE) rate per 100,000 doses of COVID-
154   19 vaccine administered/distributed (Table 2);

155   •   six indicators for monitoring the functionality of pharmacovigilance systems in the COVID-19
156   context include (Appendix 3.1):

157   o   % of districts with silent COVID-19 AEFI reporting:

158   o   % of districts not submitting monthly Reports;

159   o   % of districts with >10 COVID-19 related AEFI reports/ 100,000 doses of COVID
160   vaccines doses administered;

161   o   % of serious AEFI after COVID-19 vaccination investigated;

162   o   % of serious AEFI after COVID-19 vaccination investigated within 2 days of
163   notification

164   o   Proportion of identical AEFI reports available with the NRA and the EPI (i.e. NRA
165   reports =EPI reports).

166   •   five indicators for monitoring the quality of pharmacovigilance systems in the COVID-19
167   context include (Appendix 3.2):

168   o   % of case based AEFI reports shared between NRA and EPI <7 days of receipt;

169   o   % Completeness of AEFI reporting forms with the critical variable;

170   o   % of AEFIs reported within 48 hours of notification:

171   o   % of serious AEFI cases with causality assessed within 14 days of investigation;

172   o   % of AEFI cases with causality assessment done where feedback was provided within
173   7 days of case classification.

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175 **Table 2:** Key COVID-19 vaccine safety surveillance indicators

Indicator	Calculation	Information source	Measurement	Primary collector
Total AEFI rate per 100,000 doses of COVID-19 vaccine doses administered / distributed*	No of AEFI reported at xx level / No of doses of COVID-19 vaccines Administered/ Distributed at the same level X 100,000	Numerator: Case based AEFI reports from linelist or reporting forms Denominator: Vaccination Records at the local level	If the reporting rate of AEFI differs from the ones available in clinical trials	Numerator: HW reporting AEFI Denominator: District immunization program manager
Serious AEFI rate per 100,000 doses of COVID-19 vaccines doses administered / distributed*	No of serious AEFI reported at xx level / No of doses of COVID-19 vaccines Administered/ Distributed at the same level X 100,000	Numerator: Case based serious AEFI reports from linelist or reporting forms Denominator: Vaccination Records at the local level	If the reporting rate of serious AEFI differs from the ones available in clinical trials	Numerator: HW reporting serious AEFI Denominator: District immunization program manager

176 *To consider the type of vaccine at the time of calculation.

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178 **3. Appendices**

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180 **3.1.** **Appendix 3.1: Indicators and targets for monitoring the functionality of pharmacovigilance**
181 **systems in COVID-19 context**

Indicator	Target	Calculation	Information source	Measure	Main responsible
% of districts with silent COVID-19 AEFI reporting.	<10%	Number of districts where COVID-19 related AEFI was zero in the month of XX / No of Districts X 100	Reports submitted with zero AEFIs. during the previous month.	Identification of silent districts / areas within a province	District immunization programme manager sending periodic reports
% of districts not submitting monthly Reports	<10%	Number of districts where monthly COVID-19 related reports AEFI was not sent for a particular month / No of Districts X 100	Monthly (including zero) reports submitted by districts	Identification of delinquent reporting districts in a province	District immunization programme manager sending periodic reports
% of districts with ≥10 COVID-19 related AEFI reports/ 100,000 doses of COVID vaccines doses administered	>80%	No of districts with ≥ 10 AEFI reported for 100,000 doses of COVID-19 vaccines Administered / No of Districts X 100	Calculated from AEFI reporting form submitted by the districts following COVID-19 vaccination and Immunization registries	District performance on AEFI monitoring	District immunization programme manager sending AEFI reporting form and data on administered doses
% of serious AEFI after COVID-19 vaccination investigated	100%.	Number serious AEFI investigated / Number of serious AEFI X 100	AEFI reporting form and AEFI investigation form	The quality of investigation of serious AEFI	District immunization programme manager coordinating the AEFI investigation

% of serious AEFI after COVID-19 vaccination investigated within 2 days of notification	>80%	Number serious AEFI investigated within 2 days of notification / Number of serious AEFI X 100	AEFI reporting form and AEFI investigation form	The timeliness of investigation of serious AEFI	District immunization programme manager coordinating the AEFI investigation
Proportion of identical AEFI reports available with the NRA and the EPI (i.e. NRA reports =EPI reports).	1 for all months.	No of AEFI reports with NRA in the month of XXXX / No of AEFI reports with EPI in the month of XXXX	AEFI reporting forms available with EPI or NRA following COVID-19 vaccination	Data sharing between the immunization programme and the regulators	Regulators and EPI programme managers

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183 **3.2.** **Appendix 3.2: Indicators and targets for monitoring the quality of pharmacovigilance systems**
184 **in COVID19 context**

Indicator	Target	Calculation	Source of information	Measure	Main responsible
% of case based AEFI reports shared between NRA and EPI <7 days of receipt	100%	Number AEFI reports shared between NRA and EPI within 48 hrs. of receipt / Number of AEFI reports X 100	AEFI reporting forms available with NRA and EPI or matching number of cases in linelist	Quality of data sharing	NRA and EPI programme managers
% Completeness of AEFI reporting forms with the critical variables	>80%	Number AEFI reports with complete critical variables* / Number of AEFI reports X 100	AEFI reporting forms	Quality of AEFI data collected	EPI programme managers
% of AEFIs reported within 48 hours of notification	>80%	Number AEFI reports sent to next level within 48 hours of notification / Number of AEFI reports X 100	AEFI reporting forms	Speed of response to AEFI notification	EPI programme managers
% of serious AEFI cases with causality assessed within 14 days of investigation	>80%	Number serious AEFI reports with causality assessed within 14 days of investigation / Number of serious AEFI reports X 100	AEFI reporting forms	Speed of response to AEFI investigation	NRA and EPI programme managers

% of AEFI cases with causality assessment done where feedback was provided within 7 days of case classification	>80%	Number causality assessed cases with feedback provided within 7 days of case classification / Number of AEFI reports with causality assessment done X 100	Documentation of feedback of AEFI causality assessment	Speed of response to AEFI causality assessment	NRA and EPI programme managers

185   * Italics in reporting form

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