

WHO Global Vaccine Safety

A collaborative effort to prepare for COVID-19 vaccines PV

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Current safety work and deliverables – WHO

Content topic	Description of deliverables	Collaborative WHO departments/units
Product related safety & pharmacovigilance	<ul style="list-style-type: none"> • Specific monitoring requirements part of each clinical trial approval • Risk management plans for each vaccine required as part of any emergency or other authorization • Product specific roadmaps, incl. safety monitoring expectations 	<ul style="list-style-type: none"> ▪ R&D blueprint ▪ Prequalification unit
Vaccine safety system (national, regional, global levels)	<ul style="list-style-type: none"> • Guidance to countries and regions on prerequisites for vaccine safety preparedness that could be adapted to local country contexts as part of vaccine introduction plans • Alignment of COVID-19 vaccine safety preparedness and leveraging of existing national AEFI surveillance systems as far as possible • Check list for country preparation • Dash board on country readiness • Practical guidance on operationalizing the principles of regulatory reliance to PV concepts of work-sharing to promote collaboration between countries on active surveillance in a country setting. • Adequate data management systems, aligned with international standards • Identify regional and global platforms for AEFI data sharing 	<ul style="list-style-type: none"> ▪ Regulatory system strengthening unit ▪ Regulatory convergence and network unit ▪ Norms and standards (ECBS)
AESIs	<ul style="list-style-type: none"> • Basic AESI list, incorporating specific case definitions when Brighton Collaboration definitions do not exist for the prioritized AESI in the list • Minimum institutional capacity in place in countries for their identification 	<ul style="list-style-type: none"> ▪ Immunisation dptmt (IVB) ▪ Emergency dpmt
Safety communications	<ul style="list-style-type: none"> • Roadmap for safety communications on COVID-19 that incorporates vaccines benefits/risks communication plans. • Practical and scenario-based suggestions for how to manage vaccine safety concerns (pre-licensure, launch, roll out). • Compilation of useful resources for countries 	<ul style="list-style-type: none"> ▪ WHO Regional Offices

WHO COVID-19 Vaccine PV preparedness guidance manual



Being developed with GACVS guidance → 4 working groups* → meeting weekly

GACVS members
(chair each working group)

SAGE COVID19 working group representative

SPEAC members

Regulators from all regions
(US FDA, EMA, China NMPA, Chile, Uganda, Ghana)

Immunisation programme and PV center (US CDC, ECDC, China CDC, Nigeria, Benin, Ethiopia, India, Australia, Chile, Vietnam..)

Academia

WHO collaborating centers
(Sweden, Morocco)

WHO regional offices vaccine safety focal points

* Members selected through a Global Call for expression of interest

GACVS Working Groups, Deliverables and Status

Current status



- + Brainstorming framework
- + Developing subsections
- + Creation of subsection contents
- + Subsection contents consolidated, reviewed, refined and **zero draft developed**
- + Final draft developed

Mandate: Focus on COVID19 Vaccine platforms, their known immunity profile and known Adverse events following immunization (AEFI) and Adverse events of special interest (AESI)

Chapter 1

COVID19 vaccines:
Description, access
and use



Chapter 2

COVID-19 vaccines and
adverse events - Adverse
Events Following
Immunization (AEFI) and
Adverse Events of Special
Interest (AESI)



Mandate: Focus on global and regional preparedness for COVID vaccine introduction, and responding to an AEFI after COVID vaccination

Chapter 3

Global and Regional
preparedness for
COVID19 vaccine
introduction



Chapter 4

Stakeholders and
resources for COVID19
Vaccine Safety



Mandate: Focus on AEFI Surveillance in countries using COVID vaccines and AEFI data management and performance indicators

Chapter 5

Establishing AEFI Surveillance systems in countries using COVID19 vaccines



Chapter 6

Responding to adverse events following COVID19 vaccination



Chapter 7

Data management and monitoring safety surveillance performance



Mandate: Focus on COVID19 vaccine safety and risk communication strategy/plan

Chapter 8

Safety communication
in the context of
COVID-19 vaccination

Synthesizes evidence from vaccine safety and risk communication applying them to the COVID-19 vaccine context. It does not cover communication to support vaccine acceptance and uptake



WHO efforts in preparing for COVID19 vaccine PV

Implementation by Region/ Countries

Operationalizing COVID-19 vaccine pharmacovigilance



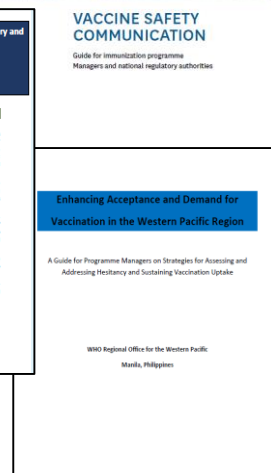
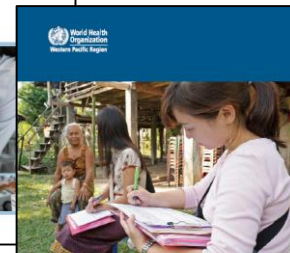
Needs

- **Enhance passive surveillance/ sentinel surveillance** to generate vaccine safety information
- Implementing **active surveillance** (*Where resources are available*) for detection of potential signals /AESI
- **Constitute a national expert committee** (sub-national for larger countries) to review and respond to AEFI safety signals and public concerns
- Conduct **research** to test hypothesis (*Where resources are available*)

Operationalizing COVID-19 vaccine pharmacovigilance

Regional support in the Western Pacific

- Vaccine PV training for WHO CO staff (EPI, NRA and Communication) in April 2019
- 19 in country vaccine PV training workshops in 14 countries during 2016-2020
 - Joint country support activities by EPI(VDI) and Regulatory (EMT) teams
 - Assessment of PV capacity using a modified WHO GBM/PV tool for the regional/country context
 - Introduced WHO methodology and e-tool for causality assessment
- Vaccine PV is a mandatory component of SIA and new vaccines introduction plan
- Virtual Regional Training on Vaccine and Immunization Safety 17-19 Nov (Non-PICS) and 24-26 Nov (PICs) 2020
- Capacity building will be driven by Global guidance developed by GACVS working groups



Operationalizing COVID-19 vaccine pharmacovigilance:



Country preparedness in the Western Pacific Region

Enhanced AEFI surveillance in China (1.39 billion population)

- Supported by legal framework
- Clear guide and SOPs
- Well trained staff
- Efficiently used information technology
- Very high AEFI reporting rates
- Data analysis at both national and subnational level
- Periodic safety update reports

Functional AEFI committee in Mongolia (3 million population)

- Independent experts including non medical
- Follows WHO methodology for causality assessment
- Every case review not limited to the investigation report findings and but supported by published evidence
- Produce comprehensive review reports

*AEFI surveillance system is in place in 29 Countries and Areas; 14 Countries and Areas having a functional AEFI committee

**Source WHO-UNICEF JRF 2018-2019*

Data sharing at country, regional and Global levels

Needs



Diversity with COVID-19 vaccines

- Different vaccine platforms
- Different target population; young/adults/elderly; healthy vs unhealthy (with chronic co-morbidities)

Sensitivity with COVID-19 vaccines

- Interest for vaccine is beyond the health; economic and political
- Risk for overall trust and demand for vaccines and immunization

COVID-19 safety profile

- AESI/ Signals

It would be a challenge to assess COVID-19 vaccines safety profile on standalone ONE country data.

Data sharing at country, regional and Global levels

Opportunities

Country database

- **Country AEFI data base** is maintained by either NIP or NRA or PV Centre (Its country specific)
- **Disseminating PV data through published monthly/quarterly/annual reports** (e,g: China, Malaysia) - This can initiate with COVID-19 data followed by sharing all other vaccines used in NIP



Regional database

- **Regional Alliance for NRA for Vaccines in the WPR is a potential platform** for sharing COVID-19 vaccine PV data
- Regional database will help NRA and NIP **to monitor safety profile of COVID-19 vaccines use in the region**
- Regional data base will be a **reliable source of vaccine safety information for all vaccines**



Global database

Located in the WHO program for international drug monitoring

- Benefit of the **global database in the context of COVID-19 vaccines is significant.**
- Vaccine safety data of one or more COVID-19 vaccines across the world will provide valid comparisons of safety profile supporting evidence based decisions in response to safety events



Conclusions

- COVID-19 vaccines present unique challenges never faced before
- Collaborative and coordinated approach is critical for successful COVID-19 vaccines safety monitoring
- WHO is uniquely placed to coordinate the global effort through:
 - **Strong presence** in all countries through regional and countries offices
 - **Convening power**
 - Well **established and comprehensive internal mechanisms** (Prequalification, Global Advisory Committee on Vaccine safety, SAGE, ...)
 - The **Global Vaccine Safety Initiative**