WHO Global Vaccine Safety

A collaborative effort to prepare for COVID-19 vaccines PV

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## Current safety work and deliverables – WHO

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| **Product related safety & pharmacovigilance**    | • 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 | • R&D blueprint  
• Prequalification unit  
• Regulatory system strengthening unit  
• Regulatory convergence and network unit  
• Norms and standards (ECBS)  
• Immunisation dpmt (IVB)  
• Emergency dpmt  
• WHO Regional Offices |
| **Vaccine safety system (national, regional, global levels)** | • 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 | • R&D blueprint  
• Prequalification unit  
• Regulatory system strengthening unit  
• Regulatory convergence and network unit  
• Norms and standards (ECBS)  
• Immunisation dpmt (IVB)  
• Emergency dpmt  
• WHO Regional Offices |
| **AESIs**                                         | • 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 | • R&D blueprint  
• Prequalification unit  
• Regulatory system strengthening unit  
• Regulatory convergence and network unit  
• Norms and standards (ECBS)  
• Immunisation dpmt (IVB)  
• Emergency dpmt  
• WHO Regional Offices |
| **Safety communications**                         | • 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 | • R&D blueprint  
• Prequalification unit  
• Regulatory system strengthening unit  
• Regulatory convergence and network unit  
• Norms and standards (ECBS)  
• Immunisation dpmt (IVB)  
• Emergency dpmt  
• 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
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

Mandate: Focus on COVID19 vaccine safety and risk communication strategy/plan
WHO efforts in preparing for COVID-19 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 database** is maintained by either NIP or NRA or PV Centre (It's 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**