Extraordinary Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization

Dr Shanthi Pal

Team Lead (a.i), Pharmacovigilance (PVG), WHO

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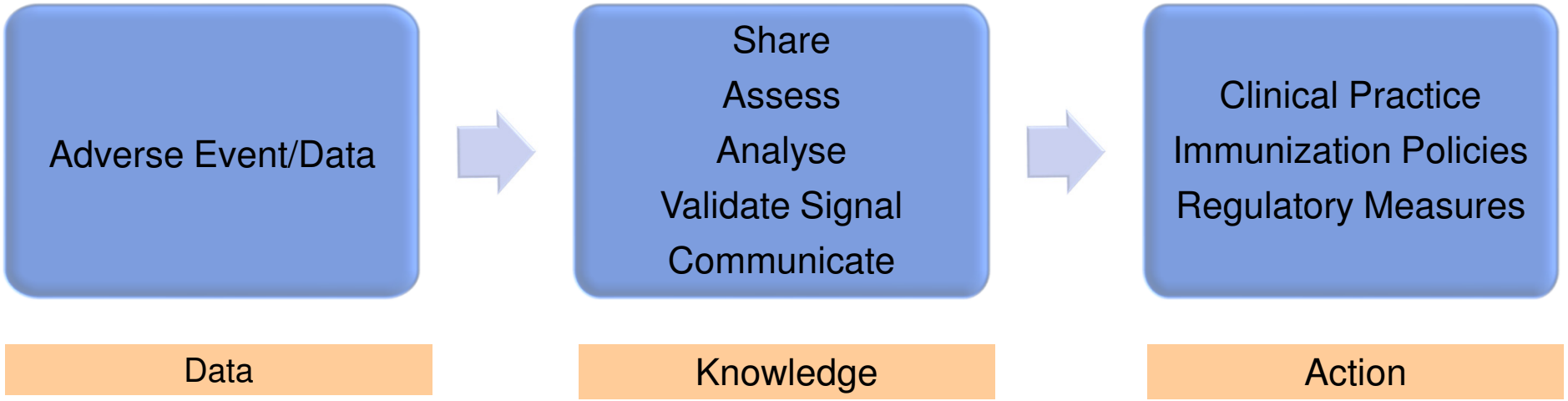
Vaccine Safety

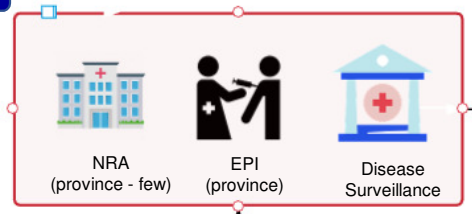
From data to decision: a high level overview of the PV process



Vaccine safety workflow

Different levels
Multiple stakeholders
Different functions
Different competencies

Subnational



❷

eTools eg DHIS2, Vigiflow for vaccines or country developed tools supported by email

❷

District program manager

❶

AEFI reporting form

❶

1. Hard copies directly submitted to districts
2. EDI (electronic data interchange eg DHIS2 & Medsafety APP for AEFI)

National

❸

eTools eg DHIS2, Vigiflow for vaccines or country developed tools supported by email

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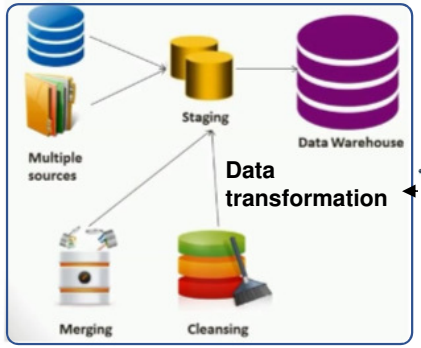
Manufacturers

National Database

National EPI

NRA



Global

Relevant Committees

World Health Organization

PQ Team

Manufacturers

PV Team

Global Database (WHO PIDM)

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Transformation to E2B (R3) format
- Ready for Vigiflow
- Under development for DHIS2 for AEFI & Medsafety App for AEFI

Simplifying the approach

Objective

- Unknown (and long-term) Events
- Events of Special Interest
- Missing information (safety in pregnancy)

Methods

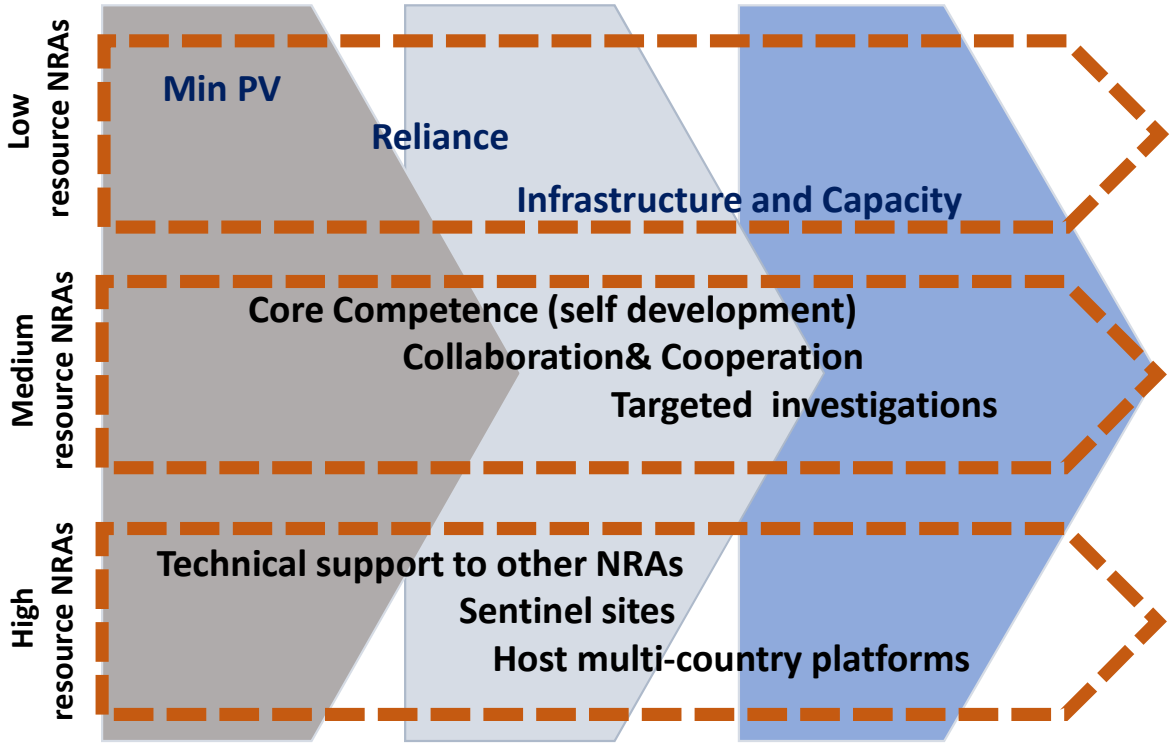
- Spontaneous Reporting
- Active surveillance
- Studies

Tools

- Paper forms
- E-Reporting
- App-based
- Databases
- Data-Bridges
- Communication platforms

World Health Organization

Optimal use of resources through reliance: Smart PV



WHO safety surveillance strategy for COVID-19 vaccines

Elements of the strategy:

- Guidance (data-knowledge-decision; targeted; function-based)
- Tools & enablers (to collect, manage AE data; protocols; Signal Review Committees; Communicate/VSN)
- Training: (competency based; function-driven)

Principles of the strategy

- reliance/work-sharing (smart PV approach): NRA, EPI, Developer
- collaboration with leading regulators/networks
- proactive (CTs to post-introduction), etc.
- builds on solid foundation of existing guidance, tools and platforms

Scope

- COVID work serving as catalyst for broader safety surveillance innovations
- Scope broader than COVAX – must address/support all countries and vaccines
- RMP and role of industry (addressing the 'delta')
- First wave rollout: opportunity to rapidly collect quality data from HCW cohort and apply lessons to subsequent waves

Shanthi

COVID-19 Vaccine Safety: progress update

Area of work	Update
Country and Regional Support	• **WHO COVID-19 Vaccine Safety Manual and Training Tools**, launched 15 Dec 2020 • **DHIS2 AEFI tracker* developed and rolled out in Africa**, Nov 2020 • **African Advisory Committee on Vaccine Safety launched,** Dec 2020 • **AESI Study protocol** by mid-Jan • **Guidance on Safety in Pregnancy,** expected by Q1 2021
Information Exchange	• **ICMRA PV sub-group bi-weekly meetings** • **EMA PV bi-weekly meetings** • **Vaccine Safety Network**
Global Safety Review and Signal Detection	• **GACVS COVID19 sub-committee**: first meeting 23 Dec, weekly starting Jan 2021 • **US CBER and CDC to submit weekly safety reports** into WHO VigiBase, 18 Dec

*AEFI package launch, 09 Dec: https://www.youtube.com/watch?v=bep50f2F1lE&feature=youtu.be
Data-driven deployment of COVID-19 vaccines, 03 Dec: https://www.youtube.com/watch?v=xmifLCuZy50

AFRO Implementation

❖ **DEC 2020**

- Sensitization of regional and national stakeholders on regulatory and safety preparedness through webinars on National Deployment and Vaccination Plan
- Inaugural meeting of Regional African Advisory Committee on Vaccine Safety – 14th Dec
- Regional and National Stakeholders invited to Orientation session on Global Webinar on 15th Dec 2020

❖ **JAN-FEB 2021**

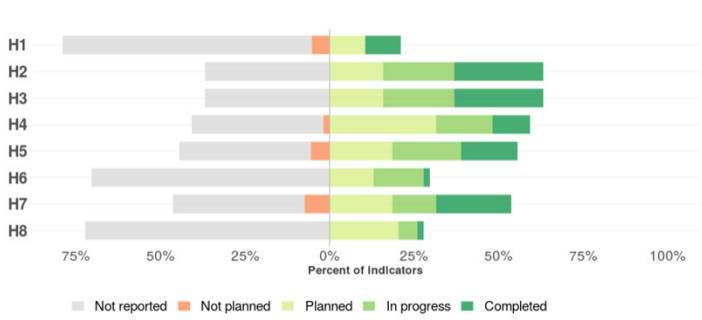
- IST level virtual trainings of trainers (ToT) of key country stakeholders conducted on each module in two separate sessions
- This to be followed by country level in-person trainings of national and provincial level stakeholders
- *- Training the national AEFI committees to review COVID-19 Vaccine safety data (e.g., causality assessment of serious AEFI, clusters of AEFI, AESI, signals, emerging safety concerns etc.)*
- *Capacity building on active surveillance of specific COVID-19 vaccine related adverse events in select countries*
- *National stakeholders meetings to discuss and approve on intensified roles and responsibilities as per Global manual*
- *Preparations to introduce DHIS 2 AEFI tracker tool to capture & share case-based safety data from district to national level*

EURO Implementation

- Mapping out support needs & developing TA plans for MICs – 15 Jan'20
  - Updating the Regional plan
- AVSS and AESI surveillance:
  - Régional webinar – 30 Jan'20
  - TA for in-country support Jan-Jun'20
- Enhancing passive AEFI surveillance (Feb):
  - AEFI reporting & Signal detection webinar
  - Rapid response/case investigation webinar
  - Causality assessment webinar
- TA to support development of vaccine safety chapters of NDVPs – end Feb'20
- Country specific TA to facilitate case management and global reporting (Mar'20)

Regional monitoring system on country preparedness for COVID-19 vaccination started in Nov'20

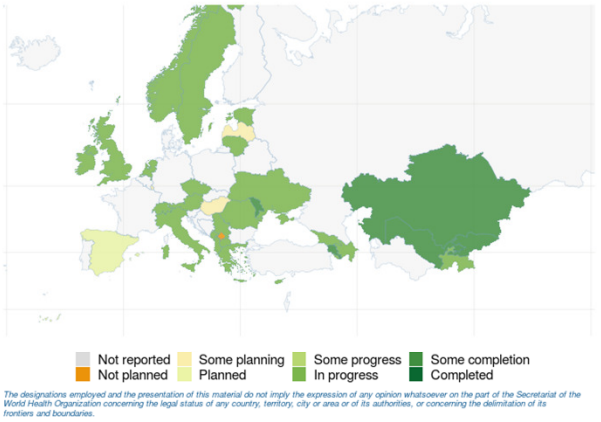
Proportion of countries by reported status for each indicator within impetus area H: Vaccine Safety Monitoring



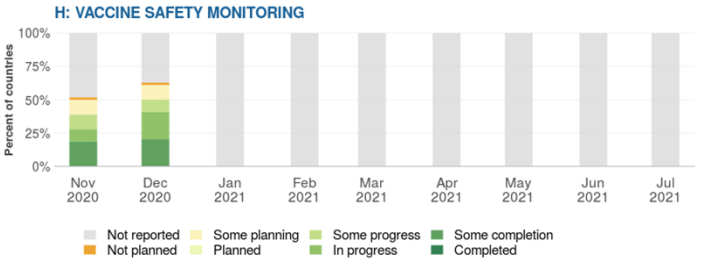
Indicators for impetus area H	
H1[1,2]	Regulatory provisions in place for manufacturers to implement risk management plans
H2[2]	Responsibilities, procedures and tools for passive surveillance of Adverse Events Following Immunization, or AEFIs, following COVID-19 vaccination defined
H3[2]	Responsibility defined and capacity for signal detection, i.e. monitoring AEFI reporting rates and clusters, established
H4	Rapid response mechanism to detect safety signals and crisis communication plan established
H5	Mechanisms for active surveillance of AEFI in place
H6[1]	Procedures to monitor, or access to data, such as background rates for Adverse Events of Special Interest, or AESIs related to COVID-19, in place
H7	National, independent, mechanism in place to assess causality of AEFIs
H8[1]	Functional mechanism for real-time vaccine safety data sharing through global or regional vaccine safety databases in place

[1] Reporting against this indicator began in December, 2020

Current status of country preparedness for overall impetus area H



Regional progress by month



PAHO Implementation plans

- For launching the Global Manual for COVID-19 Vaccines Introduction, a joint Launch along with the Regional Manual for AEFI Surveillance launching is planned

- This will be conducted the **last week of February 2021** and following activities planned*:*

•Regional meeting with all member states
•Interactive Webinar with WHO experts

- **March – June 2021**

•Sub-regional workshops to launch the following tools:
•Release of new WHO tools (investigation and causality assessment)
•PAHO's online course for AEFI surveillance

- **February – June 2021**

•Media Plan to promote the launch of PAHO Social Communication Strategy.
•Specific Social Communication strategy for Health Care Workers

SEARO implementation

❖**Global safety guidelines manual will be the technical basis**

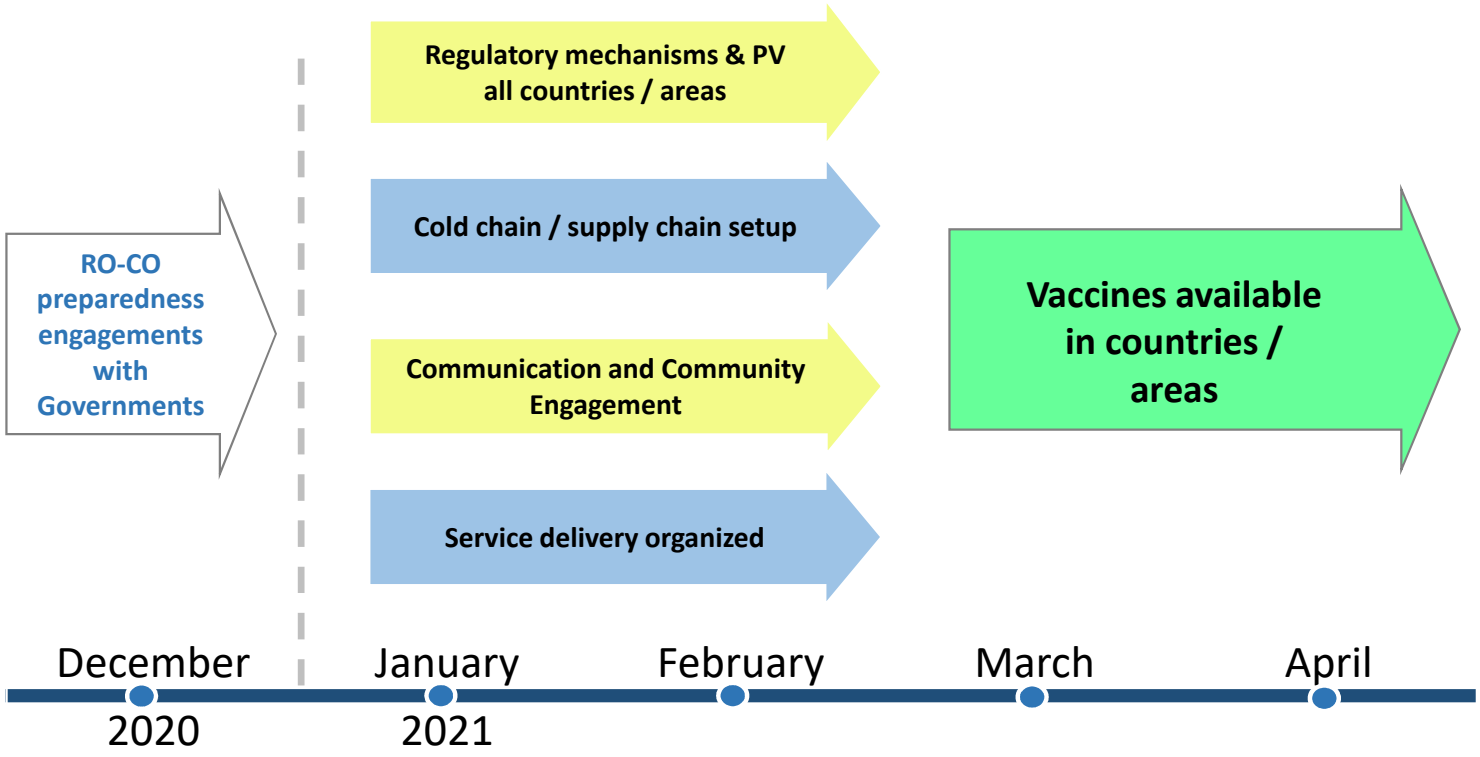
- Presentations are being developed for the regional webinars

❖**Regional workshop on safety surveillance for COVID-19 vaccines 22-23 December 2020 (Virtual)**

- Objectives
  - Identifying key activities for safety surveillance that need to be accomplished before, during and after COVID-19 vaccine deployment
  - Guidance on inclusion of comprehensive vaccine safety surveillance in national vaccine deployment and vaccination plans for COVID-19 vaccines

- Fine tune the training materials based on inputs from the participants and 5-6 country workshops will be conducted

Timeline: COVID-19 Vaccines Operational Plan in WPR



Note: Some countries may start vaccine introduction as early as in January –February 2021

Pfizer/BioNTech COVID-19 vaccination doses administered, Jan 3, 2021

Country	Doses administered*
United States	4,225,756
Israel	1,090,000
United Kingdom	944,539
Germany	188,553
Canada	112,246
Italy	72,397
Poland	47,600
Denmark	32,368
Mexico	24,998
Portugal	16,701
Romania	13,242
Chile	8,648
Croatia	7,864
Oman	7,231

Country	Doses administered*
Austria	6,000
Hungary	5,110
Iceland	4,875
Bulgaria	4,739
Greece	3,001
Kuwait	2,500
Estonia	2,487
Lithuania	2,270
Ireland	1,800
Finland	1,767
Luxembourg	1,200
Latvia	573
France	352
Costa Rica	55
World total	6,828,872

(* For the United State and Canada, the number is shown as a total of Pfizer/BioNTech vaccine and Moderna vaccine.)

(Source https://ourworldindata.org/covid-vaccinations)

Anaphylaxis reports

US CDC (18 Dec) *: 6 confirmed cases of anaphylaxis reported; one had a history*

EMA database: (3 Jan)

- *39 reports of MedDRA PT 'anaphylactic reaction'*
- *3 reports of 'anaphylactoid reaction'*
- *4 reports of 'anaphylactic shock'*

Other unconfirmed reports

Approximately 1 case per 100 000 dose

EMA: CHMP discussion and final Opinion (1) (Comirnaty)

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Hypersensitivity and anaphylaxis Events of anaphylaxis have been reported.

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination.

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Comirnaty.

(Ref : https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf)

Algorithm for the triage of persons presenting for Pfizer-COVID-19 vaccine

https://www.cdc.gov/vaccines/acip/meetings/index.html

	PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** •Immunocompromising conditions •Pregnancy •Lactation **ACTIONS** •Additional counseling* •15-minute observation period	**CONDITIONS** •Moderate/severe acute illness **ACTIONS** •Risk assessment •Potential deferral of vaccination •15-minute observation period if vaccinated	**CONDITIONS** •None **ACTIONS** •N/A
ALLERGIES	**ALLERGIES** •History of food, pet, insect, venom, environmental, latex, etc., allergies •History of allergy to oral medications (including the oral equivalent of an injectable medication) •Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) •Family history of anaphylaxis **ACTIONS** •15-minute observation period	**ALLERGIES** •History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) •History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication **ACTIONS:** •Risk assessment •Potential deferral of vaccination •30-minute observation period if vaccinated	**ALLERGIES** •History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** •Do not vaccinate

Some additional considerations

- GACVS sub-committee, 23 Dec 2020
- Rates of anaphylaxis high compared with what is ‘expected’
- Duration of observation period would be critical
- An allergy specialist may have to be co-opted to GACVS-sub committee, for more clear/definitive advice
- Identification of event only the first step
- Risk minimization and management plan would be paramount and need to be tailored for the setting (LMIC)
- Effectiveness of RMM should be monitored

Acknowledgement

- ICMRA
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