Safety Surveillance of COVID-19 vaccines

Member State Briefing

4 March 2021

World Health Organization

Presentation objectives

1. Contrast how the safety surveillance of Covid-19 vaccines differs from other vaccines
2. Highlight early learnings that can lead to broader improvements to safety surveillance
3. Confirm Member State support for safety surveillance efforts

Safety surveillance of Covid-19 vaccines: unique circumstances require innovative approaches

Current context

- Safety surveillance is **essential to maintaining positive benefit-risk profile and public confidence** in authorized products
- **6 unique circumstances:**
  1. Unprecedented speed, scale, complexity of rollout
  2. Routine detection methods insufficient to manage volume of reports
  3. Knowledge gaps (e.g., incomplete data sets)
  4. Priority populations including elderly, frail and co-morbidities – what is 'fake'/real signal?
  5. Ability to link events to specific batches (vaccine, diluent, adjuvant)
  6. Intense media and public attention
- WHO has long played a **leadership role in promoting smart safety surveillance practices**

Implications

- WHO **is adopting innovative approaches to address safety issues** associated with COVID-19 vaccines (***see next page***)
- COVID-19 is serving as a **catalyst for broader safety surveillance innovations**

From data to decision: the safety process

Safety surveillance of vaccines

In « normal » times

Adverse Event/Data	Signal	Action
Passive reporting Active surveillance Manufacturers	National Regional Global	National Regional Global

NEW

Additional measures in a pandemic

Daily Intelligence Reviews

Databases
Networks
Studies
Literature

Triage

Expert committee

Assessment

Watch list

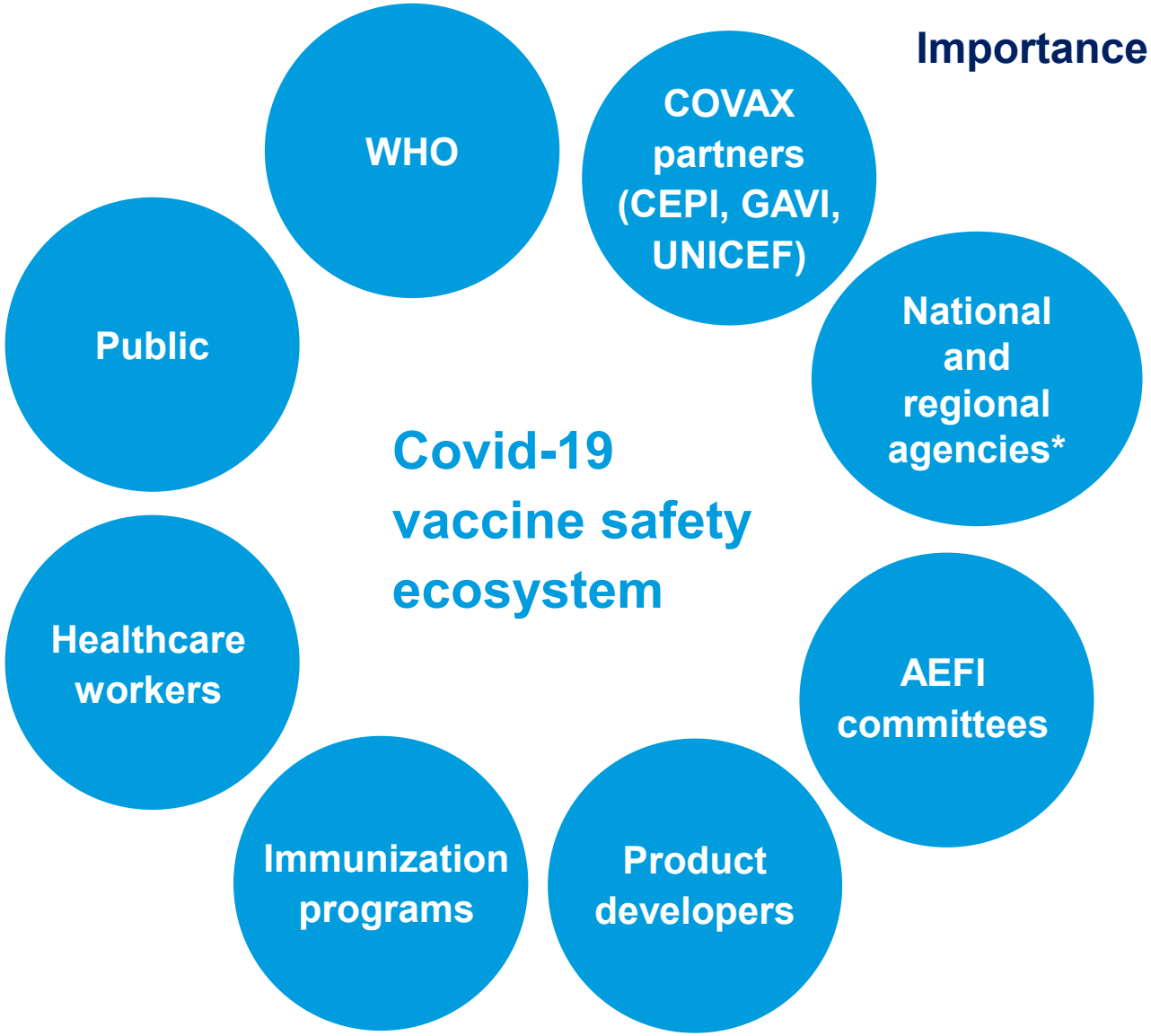
Communication (e.g., public briefings, alerts)

Recommendations for Policies (e.g., SAGE) **and product labelling**

Key take-aways

- **More pro-active**
- **Enabling real-time data collection and assessment**
- **Leveraging more data sources** (incl. informal sources such as social networks)
- **Greater coordination and joint action** (e.g., through regulatory networks)
- **Ongoing evaluation and adjustment** to meet evolving needs

Overview of the COVID-19 vaccine safety ecosystem



Importance of enhanced collaboration to power the system

Examples of collaborations to date

- GAVI: support to facilitate adverse event reporting
- CEPI/SPEAC: list of adverse events of special interest (AESI)
- UNICEF: budgeting for country adverse event surveillance
- Bilaterals: between WHO and EMA

In progress…

CEPI - WHO WG:

- support small developers to meet safety obligations
- improve data flow (developers - countries - WHO)

Regulatory networks:

- real-time information exchange
- joint work on emerging safety signals, background rates
- risk management measures and public communications

* Regulators, public health agencies, CDCs

WHO C19 Vaccines safety strategy: *drawing results as designed*

GACVS subcommittee
(bi-weekly and ad hoc, as required)

- **Reviews emerging 'signals'. Examples include**
  - **Anaphylaxis: stabilized- input to SAGE**
  - **Deaths – *as expected in the age group* – influential Statement**
  - **Flu-like reactions – as expected – statement being prepared**

WHO PVG Daily Situation Huddles

- **Identifies emerging signals; public concerns; prepare briefings as needed**
- **Maintains *Watch List*: hypertension, myocarditis, Bells Palsy...**
- **Feeds into GACVS subcommittee agenda**

WHO Global Database
(weekly)

- **Weekly review: over 177,000 individual case safety reports (as on 28 Feb)**
- **Snapshot:**
  - **39% of reports in age group - 18 – 44 y; 33% in 45- 64y**
  - **More events reported in women (75%)**

Five early learnings in terms of vaccine safety surveillance
The value of…

1. **Ongoing, real-time monitoring –** e.g., lower anaphylaxis rates than the initial signal
2. **Having the right tools and guidance to monitor safety in specific sub-populations** – e.g., frail people and pregnant women
3. **Exposure data and background rates** – putting events into context (the “Norway experience”)
4. **Networks –** Earlier detection, better informed decisions and more coordinated response
5. **An agile scientific committee –** e.g., GACVS subcommittee and statement on deaths

WHO welcomes interventions on:

- How Member States could provide political support for the strategy and approach described
- Additional suggestions WHO could consider to address challenges associated with COVID-19 vaccine safety
- Measures Member States are adopting to further strengthen safety surveillance efforts for COVID-19 vaccines

Back-up

Issues/opportunities

- Leverage the HCW cohort to implement active surveillance using LIMC appropriate protocols
- Safety surveillance and risk management plans for non-major markets: the challenges of product developers and countries
- Accessing clinical safety data prior to WHO EUL to inform appropriate safety measures
- Effective use of regulatory reliance: what does it look like?
- What are the greatest opportunities ahead? How can COVID be a driver for permanent change?

WHO safety surveillance strategy for COVID-19 vaccines

Scope

- **Addresses all countries and vaccines**
- **Inclusive of all stakeholders**
- **Routine/active surveillance and specific studies**
- **1st wave rollouts: opportunity to rapidly collect quality data from HCW cohort and apply lessons to subsequent waves**

Principles

- **Reliance/work-sharing (smart approach)**
- **Collaboration with leading regulators/networks**
- **Proactive E2E approach (clinical trials to post-introduction)**
- **Builds on solid foundation of existing guidance, tools and platforms**
- **Catalyst for broader safety surveillance innovations**

Elements

- **Guidance (data-knowledge-decision)**
- **Tools & enablers (to collect, manage adverse event data; protocols; signal review committees; communication networks)**
- **Training: (competency based; function-driven)**

Vaccine safety dataflow for COVID19

Generic data sharing model

Subnational

National

Global

NRA (province - few)

EPI (province)

Disease Surveillance

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

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

Manufacturers

National Database

National EPI

NRA

District program manager

AEFI reporting form

❶

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

Multiple sources

Staging

Data Warehouse

Data transformation

Merging

Cleansing

❹

Relevant Committees

World Health Organization

PQ Team

PV Team

Manufacturers

Global Database (WHO PIDM)

❹ Transformation to E2B (R3) format

- Ready for Vigiflow
- Under development for DHIS2 for AEFI & Medsafety App for AEFI