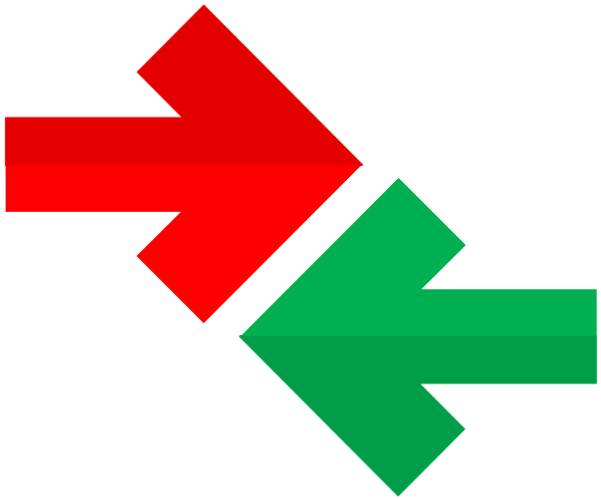
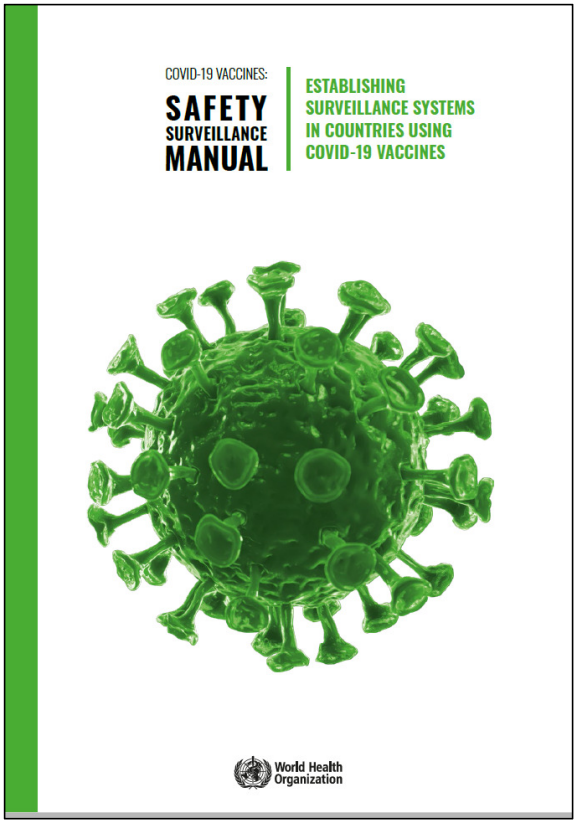
Establishing surveillance systems in countries using COVID-19 vaccines





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Learning Objectives: The learner should be able to …

Objective 1
Describe the activities rrecommended for AEFI surveillance for all countries introducing COVID-19 vaccination

Objective 2
Identify the best vaccine safety surveillance approaches based on the existing systems within a country.

Objective 3
Propose the appropriate vaccine safety strategy best suited in the context of COVID19 vaccine introduction.

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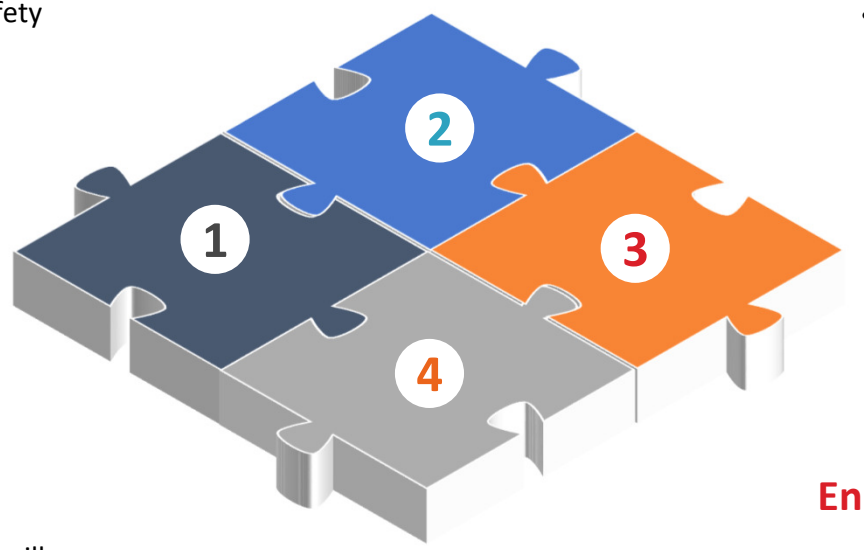
Presentation Structure

Overarching approach

- For all countries
- For countries with advanced safety surveillance systems



Recommended surveillance activities

- To strengthen routine passive AEFI surveillance, investigate AEFIs causing concern, AEFI causality assessment, clustering and safety signals, respond to any COVID-19 vaccine-related event and address concerns of stakeholders

Surveillance strategies

- Active, Passive and sentinel surveillance
- Application of these strategies in different contexts

Enhancing country capacity

- Guidance for countries with partially established systems, well established systems and excellent systems with potential to detect signals
- Approach to death as an AEFI

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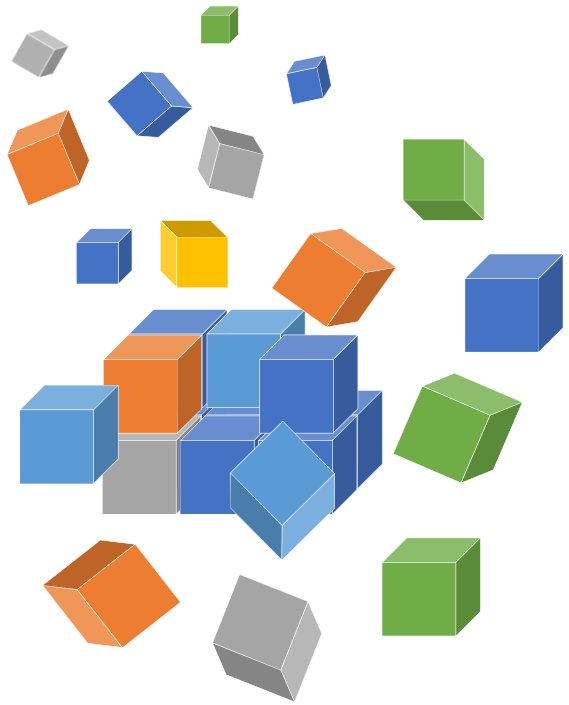
Goals of COVID-19 vaccine safety surveillance



01 Detect serious AEFIs/AESIs rapidly

02 Generate data to characterize safety of the COVID-19 vaccines

03 Identify, investigate, assess, validate and respond to safety signals

04 Ensure high quality safety surveillance

05 Maintain public and stakeholder confidence in vaccines

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Objectives of vaccine safety surveillance for all countries

Strengthen routine passive surveillance reporting systems

Detect and investigate potential safety signals - clustering of serious events, immunization errors, community concerns etc.

Perform systematic causality assessments for AESIs

Plan and respond rapidly to any COVID-19 vaccine-related events

Address concerns expressed by health care professionals and maintain community confidence

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Additional considerations for countries with advanced safety surveillance systems

Implementing active surveillance systems for AESIs

Research on identified or newly observed vaccine safety concerns

Improve the use of local and national safety data to generate information on the safety of the COVID-19 vaccines being used

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How to enhance current vaccine safety surveillance systems to COVID 19 vaccines?

Capacity to identify and respond to larger numbers of AEFI cases

Follow up vaccinated cohort for at least one year

Ability to cover non-traditional (adult) populations

Communicating in a timely, appropriate and systematic manner

Ability to identify the vaccine brand, manufacturer, batch number and other identifiers of the vaccine received

Special training of national AEFI committees to address the novel challenges related to comorbidities, non-traditional (adult) populations, novel vaccines etc

Sharing of information and coordination among stakeholders

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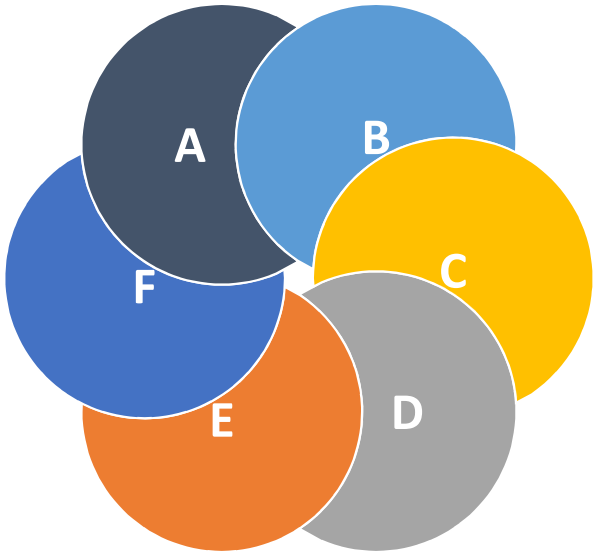
Recommended AEFI surveillance activities for all countries introducing COVID-19 vaccination



- **A** — Strengthen routine passive AEFI surveillance
- **B** — Investigate potential AEFIs causing concern
- **C** — Perform systematic AEFI causality assessment
- **D** — Address concerns of health care professionals and maintain community confidence
- **E** — Plan and respond to any COVID-19 vaccine-related event
- **F** — Detect clustering and safety signals

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A. Strengthen routine passive AEFI surveillance

Training on identification and reporting of AEFI

Update, print and distribute AEFI surveillance tools.

Stimulate AEFI reporting and perform real time safety data analyses.

Innovate processes for timely reporting, review and data sharing nationally, regionally and globally

Develop standard operating procedures (SOPs) for the coordination process between stakeholders including novel ones e.g. Public Health Emergency Units.

Consider setting up AEFI committees at relevant levels.

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B. Investigate potential AEFIs causing concern

Prepare investigation teams and train them.

Update, print and distribute AEFI investigation tools.

During investigation, collect and document all relevant data for causality assessment (AEFI reporting and investigation forms, clinical case record, laboratory reports, autopsy reports, etc.)

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C. Perform systematic AEFI causality assessment

Constitute an national AEFI committee to review, guide and respond to AEFI safety signals and public concerns.

Provide training on causality assessment processes.

Provide regular updates to the Committee members on COVID-19 vaccine development and safety data.

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Foster and use the committee's expertise to identify AEFI cases in need of further investigation, such as AESIs

Anticipate and plan for increased number of AEFI reports that will need to be assessed.

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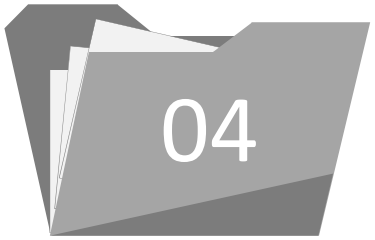
D. Detect clustering and safety signals

Regularly review and process AEFI surveillance data, particularly those conditions identified during pre-licensure.

Explore the use of disease surveillance data to complement AEFI surveillance systems for the detecting of AESIs

Consider use of early signal detection methods (e.g. data mining), especially for certain AESIs.



Identify "silent areas" where AEFI reporting is poor and investigate

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E. Plan and respond to any COVID-19 vaccine-related event

Outline roles and responsibilities (including the private sector) for safety surveillance activities and response

Update stakeholders on COVID-19 vaccine safety information

Communicate with WHO Country offices, regions and globally and share data on outcomes of AEFIs and AESIs in a rapid, timely and regular manner.

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F. Address concerns of health care professionals and maintain community confidence

Create and share a COVID-19 vaccine safety communication plan with relevant stakeholders.

Train and support personnel to address concerns before, during and after COVID-19 vaccine introduction.

Develop, print, and distribute messages concerning the safety COVID-19 vaccines.

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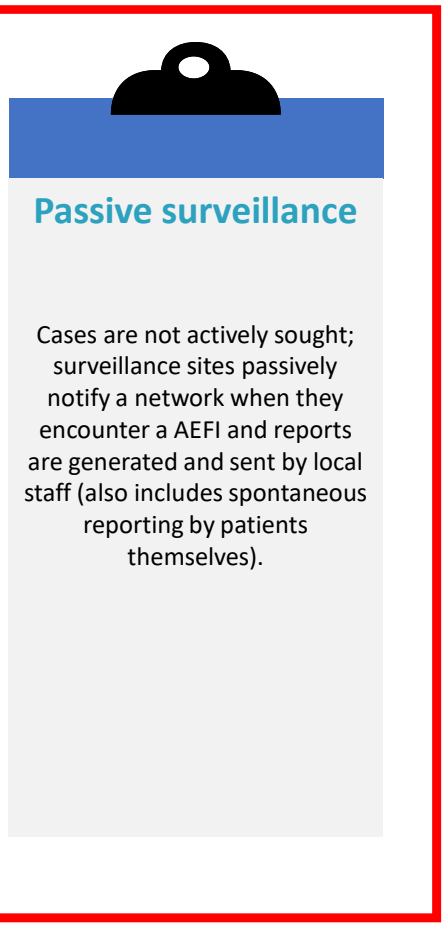
Surveillance strategies

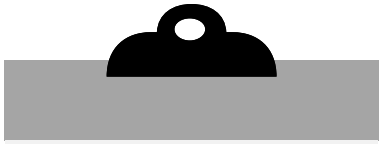


Passive surveillance

Cases are not actively sought; surveillance sites passively notify a network when they encounter a AEFI and reports are generated and sent by local staff (also includes spontaneous reporting by patients themselves).

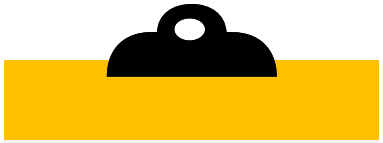
Active surveillance

Using a standard protocol, designated staff visit health care facilities, talk to health-care professionals, reviewing medical records, identify suspected cases of AESI, collect and analyse data.



Cohort event monitoring

Health care providers are trained and encouraged to report and follow-up of those vaccinated through defined channels, e.g., phone call, email, home visit report AEFIs.



Sentinel surveillance

Selected reporting units, with a high probability of seeing patients with the disease, good laboratory facilities and experienced well-qualified staff, identify and report cases. It deliberately collects data from only a limited network of carefully selected reporting sites

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Passive (routine) surveillance approaches for AEFI

N°	Criteria	Operationalisation
1	Purpose of information collection	To identify AEFIs and assess their severity and perform causality assessment
2	Relevant for	HCPs, EPI managers, NRAs, surveillance and information managers, epidemiologists, surveillance and information managers, media, vaccine safety partners, including the community
3	Method for data collection	Through spontaneous reporting or detection by HCPs
4	Initiated by	Pre-existing system
5	Responsibility	NIPs/EPIs, NRAs and MoHs
6	Data sharing	NIPs/EPIs, NRAs, MoHs, WHO (VigiBase), MAHs
7	Preparedness assessment	Preparedness checklist
8	Stakeholder training	All frontline immunization staff in healthcare facilities (public and private); and other relevant staff in reporting, investigation, data analysis, and causality assessment

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Active surveillance approaches for AESI

N°	Criteria	Operationalisation
1	Purpose of information collection	To identify predefined specific (rare) events and assess if associated with COVID-19 vaccination
2	Relevant for	Sentinel site staff, NIP/EPI managers, NRAs, epidemiologists, national AEFI committees, study teams
3	Method for data collection	As per specific protocol for AESIs by sentinel site surveillance of cases or electronic health record using various methods
4	Initiated by	Countries or regions wants to investigate significant knowledge gaps
5	Responsibility	Principal Investigator appointed by the country
6	Data sharing	NIP/EPI, NRAs, MoHs, WHO (VigiBase), MAHs
7	Preparedness assessment	Protocol review by the NITAG/ National AEFI committee
8	Stakeholder training	Sentinel site staff-Immunization Staff and clinicians in sentinel sites and predefined active surveillance systems, EPI Mangers, NRA, research staff, AEFI national committee

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Surveillance approaches for manufacturers and MAHs

N°	Criteria	Operationalisation
1	Purpose of information collection	To provide safety information missing at the time of licensure
2	Relevant for	NRAs, NIP/EPI, MAHs
3	Method for data collection	As per study protocol designed by MAH and approved by relevant authorities
4	Initiated by	Vaccine manufacturer or MAH
5	Responsibility	Vaccine manufacturer or MAH with oversight from relevant authorities
6	Data sharing	MAHs, NIP/EPI, NRAs
7	Preparedness assessment	Based on criteria for site selection by NRA, NIP/EPI and MAHs
8	Stakeholder training	Principle Investigator at Study Site

Deaths following COVID19 vaccination

Countries should define specific protocols for investigating deaths following COVID-19 vaccination.

Guidance on investigating deaths following vaccination are provided in the global manual on surveillance of AEFI (page 58 section 6.9).

All deaths in individuals who have received COVID-19 vaccination should be investigated.

Whenever possible autopsies should be conducted and tissue samples collected for in-depth pathologic, virologic and genetic testing.

If an autopsy is not done, a complete verbal autopsy using standard protocol should be conducted.

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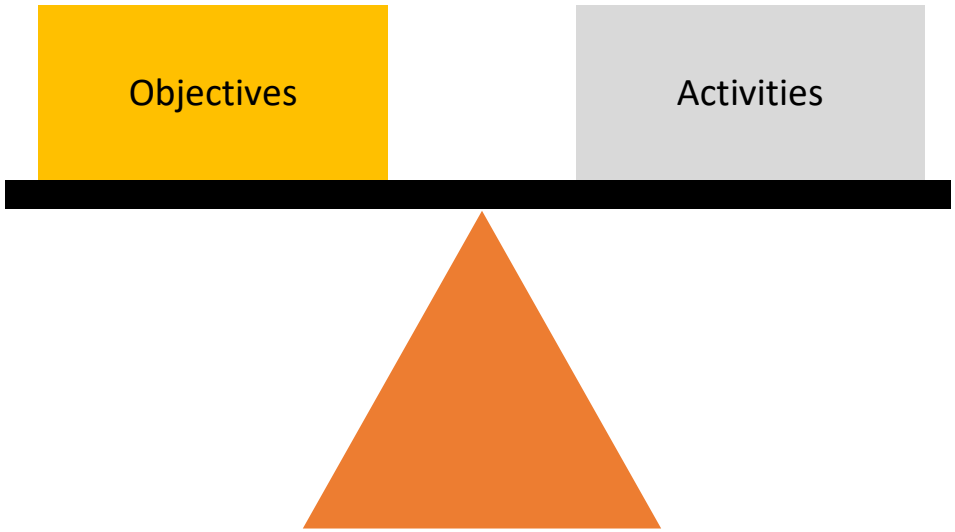
Enhancing current in-country safety surveillance systems

In countries with established passive surveillance ➔ partially functioning systems

Objectives

- improve the use of local and national safety data to generate information for action
- continuously update the safety profile of COVID-19 vaccines being used; and
- implement active surveillance for AESI.



Activities

- assess the functionality of the existing AEFI surveillance system to identify key gaps and opportunities
- strengthen National AEFI committee capacity
- consider active surveillance for AESIs if there is capacity.

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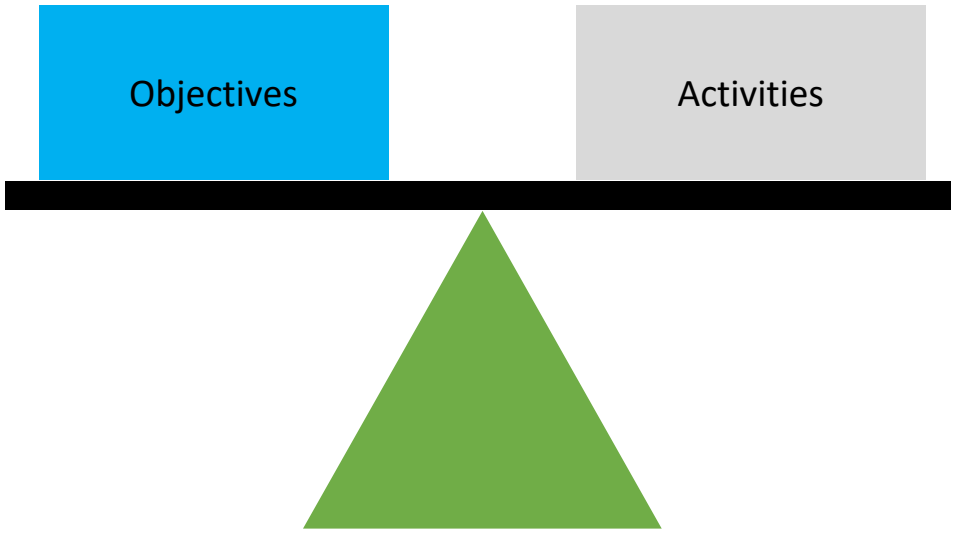
Enhancing current in-country safety surveillance systems

Objectives

- implement active surveillance for AESIs
- improve the use of local and national safety data to generate information for action and
- continuously update the safety profile of COVID-19 vaccines being used.

In countries with established passive surveillance ➔ fully functioning systems



Activities

- establish active AESI surveillance at selected sentinel sites
- inform the national AEFI committee about potential concerns for COVID-19 vaccines
- share information within the region & function as resource for neighbouring countries with less capacity
- review sources of epidemiological information at the national and subnational level that could provide information on background rates of selected AESIs

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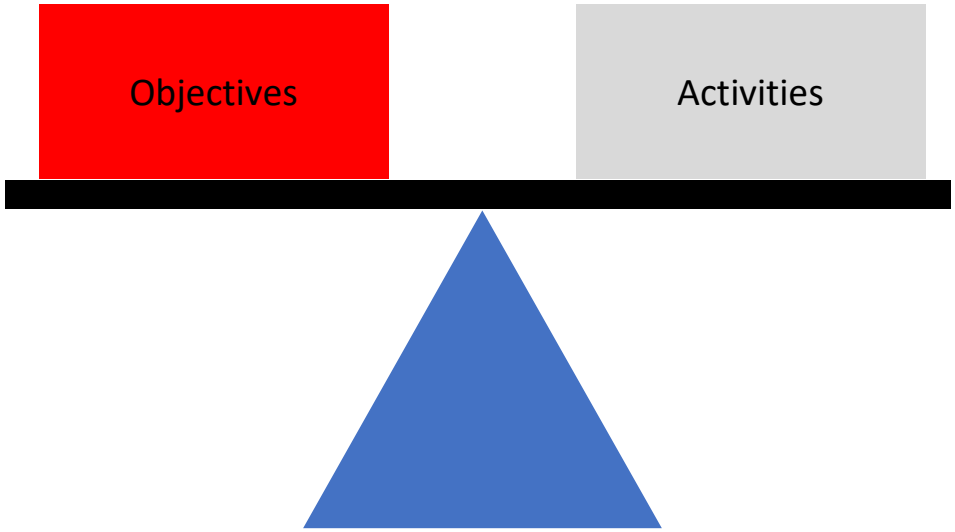
Enhancing current in-country safety surveillance systems

Objectives

- implement active surveillance for AESIs
- conduct research on vaccine safety concerns e.g., VAED
- improve the use of local and national safety data to generate information for action
- continuously update the safety profile of COVID-19 vaccines being used.

In countries with well established passive & active surveillance systems and ability to detect signals



Activities

- inform the National AEFI committee about potential concerns for COVID-19 vaccines
- consider which AESIs should be monitored using active surveillance
- establish background rates for the selected AESIs
- consider participation in regional and global safety surveillance data networks
- countries could act as resource for neighbouring countries with less capacity
- consider specific studies, for example, plan to identify and evaluate VAED in context of vaccine failure.

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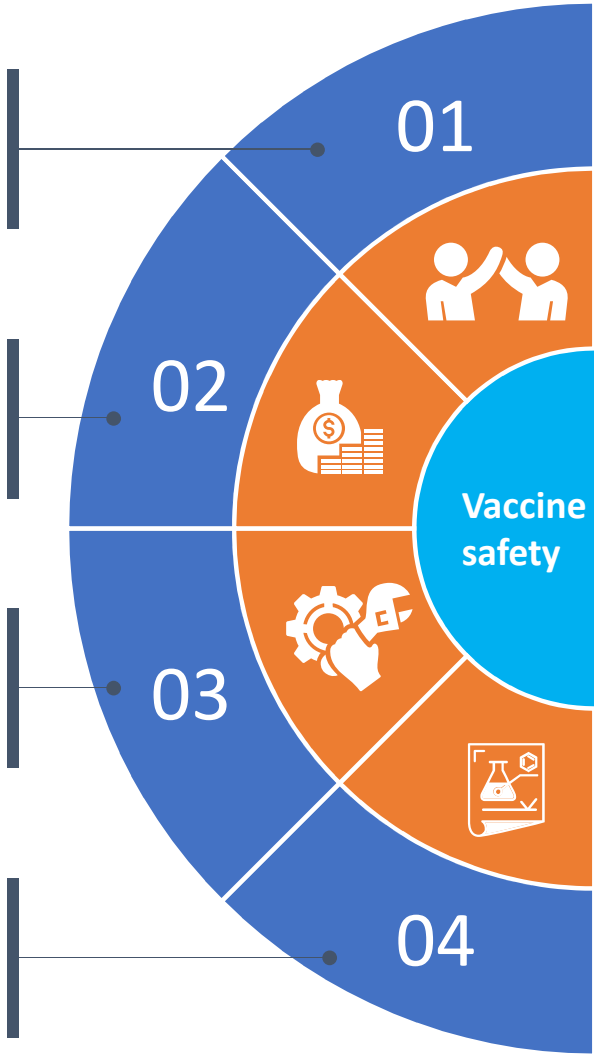
Key points to remember…

There are primarily 4 surveillance strategies, **passive (spontaneous)**, active, CEM and sentinel.

All countries need to enhance their exiting vaccine safety surveillance systems for AEFI.

Countries with better systems need to consider AESI surveillance.

All stakeholders should be involved in strengthening vaccine safety surveillance.



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- CIOMS Guide to Active Vaccine Safety Surveillance. Available from:
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- Passive surveillance
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- Active surveillance & Accelerated disease control
  https://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/active/en/

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