Safety data management systems, methods of post-introduction evaluation & assessing performance in countries using COVID-19 vaccines & Some examples of eData solutions
Learning objectives: The learner should be able to

01 Explain how data generation can provide information for action

02 Demonstrate the impact of sharing of data

03 Map the stakeholders using vaccine safety data

04 Use eData solutions for data management
Presentation structure

01 Generate data and obtain information for action
02 Sharing of data
03 Mapping of stakeholders using vaccine safety data
04 Generic data sharing approach
05 Some examples of eData solutions
From data generation to information for action

Source of AEFI data

Feedback
- Use data to explain the logic of the decision to the public and stakeholders

Decision
- Based on need slice and dice data further
- Look at the graphs, tables and line lists

Analysis/interpretation
- Look at the graphs, tables and line lists

Processing/data cleaning
- Review the data entered and check for mistakes and inconsistencies

Data entry into database
- In country software, Complete reporting form

Transmission
- Send the completed form to the next level in hierarchy

Notification
- Complete reporting form.

Transmission
- In country software, Complete reporting form

Analysis
- Look at the graphs, tables and line lists

Investigation
- Based on need slice and dice data further

Review the data entered and check for mistakes and inconsistencies.

Causality assessment
- Based on need slice and dice data further

Reporting
- Send the completed form to the next level in hierarchy

Interview patient or parent, look at records, logistics etc.

Complete reporting form.

AEFI Detection
- Interview patient or parent, look at records, logistics etc.

AEFI reporting
- Complete reporting form.

AEFI notification
- Complete reporting form.

AEFI data source
- Interview patient or parent, look at records, logistics etc.

Transcription
- Complete reporting form.

Process/data cleaning
- Review the data entered and check for mistakes and inconsistencies.
Impact of data sharing

National:
- Data in some countries will be reported through multiple channels, with programmes working on data from the same patients and sometimes via the same health care professional, but with different goals and pathways.

Regional and global:
- Maximizes resources and capacity to enable efficient responses and decision-making.
- Improves Signal detection capacity and ability to identify rare events.
- Data transformation is usually required to facilitate data sharing.
# Outcome of data sharing

<table>
<thead>
<tr>
<th>Data source</th>
<th>Outcome of data sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data from passive and enhanced passive AEFI surveillance systems</td>
<td>Detect signals, monitor immunization programme activities, monitor events that could be related to defective, un-registered or counterfeit COVID-19 vaccines.</td>
</tr>
<tr>
<td>Data from active surveillance systems</td>
<td>Verify and confirm the post-licensure safety profiles of COVID-19 vaccines, test hypotheses (epidemiologic associations between AEFIs and COVID-19 vaccines), detect signal with an accelerated time from reporting to detection</td>
</tr>
<tr>
<td>Data from COVID-19 vaccine manufacturers</td>
<td>Bi-directional sharing of data with COVID-19 vaccine manufacturers will help ensure that data collection is complete and avoid double counting of events. In addition, the manufacturers may be aware of data from other countries or sources that can help in the evaluation of AEFIs.</td>
</tr>
<tr>
<td>Data from other sources such as disease surveillance data, vaccine distribution and utilization data</td>
<td>Generate rapid alerts to trigger common responses from a geographical territory, know the implementation level, know the quality of surveillance at the national level to plan for improvement strategies, understand the distribution of different COVID-19 vaccines and to compare with distribution of the disease for interpreting patterns observed during data analysis.</td>
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</tbody>
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### Mapping Stakeholders and data

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Current data mapping (variable in different contexts)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>District/Subnational level</strong></td>
<td></td>
</tr>
<tr>
<td>Health care institutions</td>
<td>- Individual Case AEFI Reports</td>
</tr>
<tr>
<td></td>
<td>- Case Report Form for ad-hoc studies</td>
</tr>
<tr>
<td>Disease surveillance offices</td>
<td>- Investigation information to complete Individual Case AEFI report</td>
</tr>
<tr>
<td></td>
<td>- Data on local epidemiological behaviour of infectious diseases</td>
</tr>
<tr>
<td>Immunization programme offices</td>
<td>- Data on immunization activities</td>
</tr>
<tr>
<td></td>
<td>- Individual Case AEFI reports</td>
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<td><strong>National level</strong></td>
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</table>
| Disease surveillance Responsible | ▪ Data on infectious and non-infectious diseases  
▪ Data on AEFI surveillance |
| National Immunization Programmes / Expanded Programmes for Immunization | ▪ Data on immunization activities: Administrative data and distribution activities  
▪ Data on AEFI surveillance. |
| National Regulatory Authorities | ▪ Data on AEFI surveillance from primary health care workers and citizens  
▪ Data on AEFI surveillance from manufacturers  
▪ Data on Adverse Event reports from clinical trials |
| Health information systems units | ▪ Data from all sources in the country |
| Research institutions/Clinical Research Organization | ▪ Individual Case Safety (Adverse Events) Reports from clinical trials  
▪ Data on diseases considered as AESI/AEFI |
| Vaccine manufacturers or marketing authorization holders | ▪ Individual Case AEFI report |
| Clinical Research Sponsors | ▪ SUSAR from clinical trials |
## Mapping Stakeholders and data

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<tr>
<td><strong>Regional and Global Level</strong></td>
<td></td>
</tr>
<tr>
<td>WHO regional offices</td>
<td>▪ WHO-UNICEF JRF</td>
</tr>
<tr>
<td></td>
<td>▪ Individual case reports on infectious disease surveillance</td>
</tr>
<tr>
<td></td>
<td>▪ Access to WHO UMC Global ICSR/ AEFI database</td>
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<tr>
<td>WHO Headquarters</td>
<td>▪ WHO-UNICEF JRF</td>
</tr>
<tr>
<td></td>
<td>▪ Individual case reports on infectious disease surveillance</td>
</tr>
<tr>
<td></td>
<td>▪ Access to WHO UMC Global ICSR/ AEFI database</td>
</tr>
<tr>
<td>WHO PIDM/VigiBase</td>
<td>▪ Individual Case AEFI report</td>
</tr>
<tr>
<td>(maintained by UMC)</td>
<td>▪ WHO UMC Global ICSR/ AEFI database</td>
</tr>
</tbody>
</table>
1. Hard copies directly submitted to districts
2. EDI (electronic data interchange eg DHIS2 & Medsafety APP for AEFI)

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

- Data transformation to E2B (R3) format
  - Ready for Vigiflow
  - Under development for DHIS2 for AEFI & Medsafety App for AEFI
Some examples of eData solutions
DHIS2

National DHIS2 Database
Vigiflow
The Med Safety app is a free smartphone app for reporting suspected adverse effects (or adverse drug reactions) to National Competent Authorities. This simple tool lets you report adverse effects to medicines, keep track of previously reported information and receive official news and alerts about medicines you are taking or interested in.
COVID19 Solutions under development...

- Medsafety app
- National Database
- E2B (R3) Bridge
- AEFI Specific modifications
- ADR Reporting
- National DHIS2 Database
- VigilFlow
- E2B (R3)
Key points to remember

- Data is generated to obtain information that leads to action
- Actionable data is obtained only when data is shared, processed and interpreted and decisions taken.
- Data standards and harmonization are mandatory for data sharing particularly when eData solutions are used to handle large volumes of data
References

- VigiBase: https://www.who-umc.org/vigibase/vigibase/
Every country should have locally appropriate software solutions!

Thanks for listening!