Global Vaccine Safety Blueprint 2.0

Developing a strategic action plan for 2021-2030
Events unexpected at time of licensure:

- Polio following IPV
- Intussusception following rotavirus vaccine
- Narcolepsy and H1N1 vaccination

Known vaccination problems and vaccine reactions:

- Immunization errors
- Anaphylaxis
- VAPP

Rumours, poor science and over-reaction:

- HPV vaccine coverage in Denmark
- Multiple sclerosis and hepatitis B vaccine in France
- OPV and chronic diseases in Nigeria
- Thiomersal and neuro-developmental disorders
- Pentavalent vaccine in Asian countries
Vision for the 2012 Global Vaccine Safety Blueprint

Effective vaccine pharmacovigilance systems are established in all countries
Minimal capacity

Managerial principles

- Regulatory framework
- Lines of accountability
- Institutional development plan
- Commitment to share information

PV resources

- AEFI surveillance
  - Core variables
  - Stimulated reporting
  - National database
- Independent experts
- Communication strategy
8 strategic objectives support the first Blueprint main goals

AEFI Detection: To strengthen vaccine safety monitoring in all countries

Investigation of Safety Signals: To strengthen the ability of countries to investigate vaccine safety signals

Vaccine Safety Communication: To develop vaccine safety communication plans at country level

Tools and Methods: To develop internationally harmonized tools and methods to support country vaccine safety activities

Regulatory Framework: To promote a legal, regulatory and administrative framework for the safety of vaccines at national, regional and international levels

Global Analysis and Response: To provide expert advice on vaccine safety issues at national, regional and international levels

Public-Private Information Exchange: To put in place systems for appropriate interaction between national governments, multilateral agencies, and manufacturers

Technical Support and Trainings: To strengthen regional and global technical-support platforms that meet countries’ expressed needs

Technical objectives

Enabling objectives
Expanding partnership around GVSI
Progress to date

7 GVSIP meetings of collaborators and plans

Tools
Guidelines
AEFI systems

Global Vaccine Safety Observatory
GVSI - Measuring progress

- AEFI reporting ratio in surviving infants from a country per year (using JRF)

A country is said to have minimal capacity if it reports at least 10 cases per 100,000 surviving infants per year.
% and number of countries reporting* at least 10 per 100000 AEFI cases by WHO Region 2010, 2016, 2017 and 2018

<table>
<thead>
<tr>
<th>Region</th>
<th>2010</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>African</td>
<td>40</td>
<td>25</td>
<td>27</td>
<td>20</td>
</tr>
<tr>
<td>Americas</td>
<td>14</td>
<td>11</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>13</td>
<td>11</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>European</td>
<td>19</td>
<td>16</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>South-East Asia</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>21</td>
<td>16</td>
<td>14</td>
<td>15</td>
</tr>
</tbody>
</table>

* Reporting >= 10 cases/100000 surviving infants (all colored)
Not reporting at least 10 cases per 100000 surviving infants
Countries meeting GVAP indicator, 2010

Countries meeting GVAP indicator, 2018

Cumulative AEFI reports from WHO/UNICEF joint reporting 2000-2017
Vaccine Safety Net

- Linking websites and web analytics for data driven vaccine safety information and communication
- Referencing from the global digital platforms

- Social media catalyzer (Twitter, Fb, blogs)
- International research in communication for vaccines
2019 landscape analysis

The largest stakeholder type represented was government, followed by industry and global agencies.

The most common WHO regions represented overall were South-East Asia (SEARO), followed by the Americas (AMRO/PAHO) and Europe (EURO).
Utility of the Blueprint and GVSI

Utility of Support

- PPI Exchange
- Global Analysis and Response
- Technical Support and Trainings
- Regulatory Framework
- Tools and Methods
- Vaccine Safety Communication
- Investigation of Safety Signals
- AEFI Detection

Legend:
- Extremely Useful
- Somewhat Useful
- Not Useful
- Not Applicable
Key Insight: Post-2020 Strategic Objectives

Participants recommended revisiting some of the current strategic objectives of the Blueprint, particularly vaccine safety communication and public-private information exchange, as well as prioritizing some new areas in the post-2020 strategy.

**Public-Private Information Exchange**
- Only 22% of respondents found GVI’s support of public-private information exchange extremely useful, with over 10% finding it not useful at all.
- Both industry and non-industry respondents noted that they want more timely and consistent information sharing between those two groups, with WHO serving as the convener to do this.

**Regulatory Framework**
- Only 36% of respondents found GVI’s support for a regulatory framework extremely useful.
- Industry in particular noted that they view WHO as playing a critical role to assist regulatory bodies with setting up frameworks.

“I know WHO developed global benchmark tool for regulatory strengthening, but not sure it is the regulatory framework.”

**Global Analysis and Response**
- Over 20% of respondents view global analysis and response as a primary focus for GVI. However, 8% of respondents found GVI’s support of global analysis and response not useful at this time.
- Many respondents noted that WHO can fill critical data analysis gaps regarding adverse events and serve as a “trusted source of information” for vaccine safety information and analysis of global trends.

“I think the vaccine safety communication needs to be revisited seriously…”

**Vaccine Safety Communication**
- 18% of respondents would like to see vaccine safety communication prioritized in the post-2020 strategy.
- Many respondents noted that the WHO communication materials are theoretical and need more practical examples, particularly considering the changing landscape.

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# From minimal capacity to maturity levels

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Level 1 sub-indicators</th>
<th>Level 2 sub-indicators</th>
<th>Level 3 sub-indicators</th>
<th>Level 4 sub-indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal provisions, regulations and guidelines required to define regulatory framework of vigilance</td>
<td>Legal provisions for a national vigilance system exist. They require the manufacturers to set up a vigilance system of their medical products and periodically report data and reliance on vigilance-related decisions from other bodies</td>
<td>Legal provisions allow NRA to require manufacturers to conduct specific safety studies</td>
<td>Legal provisions require manufacturers to designate an individual person in charge of vigilance. Guidelines available for planning, conducting, monitoring, and reporting of vigilance activities</td>
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<tr>
<td>Arrangement for effective organization and good governance</td>
<td>Defined organizational structure with clear roles and responsibilities</td>
<td>Documented procedures to ensure among all relevant stakeholders</td>
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<tr>
<td>Human resources to perform vigilance activities</td>
<td>Sufficient competent staff with adequate job descriptions, training plan implemented and documented.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Procedures established and implemented to perform vigilance activities</td>
<td>Staff access to relevant information resources is ensured</td>
<td>Procedures for collection, investigation and assessment of AEFIIs are implemented, include a risk approach and access to expert committees for review of serious concerns</td>
<td>Standard procedures are implemented for the national vigilance system, include regular assessment of risk-benefit balance and active vigilance activities</td>
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<tr>
<td>Regular performance monitoring</td>
<td>Vigilance information used in timely manner to update regulatory decisions</td>
<td>Performance indicators for vigilance activities implemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transparency, accountability and communication</td>
<td>Vigilance activities appropriately communicated to the public</td>
<td>Mechanism for regular feedback complemented with a risk communication plan and data shared with international partners</td>
<td></td>
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</tbody>
</table>
Strategic areas for Blueprint 2.0

**Technical**
- Surveillance of adverse events following immunization (AEFI)
- Enhanced communication
- Fragile states

**Enabling**
- Regulatory framework
- Governance and systems development
- Coordination of safety systems
- Funding and Financing

*Chapter substantially rewritten*
*New chapter*
Coordination of safety systems:

More timely and consistent information sharing between those two groups, with WHO serving as the convener to do this

Objective 1  Strengthened coordination and exchange of information between vaccine manufacturers and national regulatory authorities at local, regional and global level

Strategies:

*Enforce* mechanisms for systematic and timely exchange of vaccine safety related information (individual case reports, safety signals, findings from post-marketing studies and any changes about benefits and risk profile of the vaccine) between vaccine manufacturers and public health authorities at local, regional and global level

*Develop* mechanisms for systematic and timely exchange of vaccine safety related information (individual case reports, safety signals, findings from post-marketing studies) from public health authorities to the relevant vaccine manufacturer to ensure that the manufacturer can maintain the safety profile of its products, at local, regional and global level
Blueprint 2.0 development: Overview of activities & timelines

- Landscape analysis (survey) initiated
- GACVS review of survey
- Landscape analysis finalized
- Blueprint 2.0 draft 1 developed
- Draft 1 Ext review
- SAGE updated
- Blueprint 2.0 Draft 2 developed
- Vaccine Safety SUMMIT and GACVS
- Blueprint 2.0 final
- WHO clearance
- SAGE Endorsed


**Completed Activities**
- Draft 1
- Draft 2
- Draft 3
- Approvals

**Ongoing Activities**

**Pending Activities**

**Independent reviews or clearance**

Deadline for comments on draft 1: 25 October 2019
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