

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

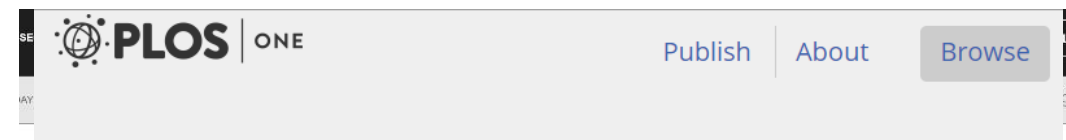
Known vaccination problems and vaccine reactions:

- 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

What we worry about



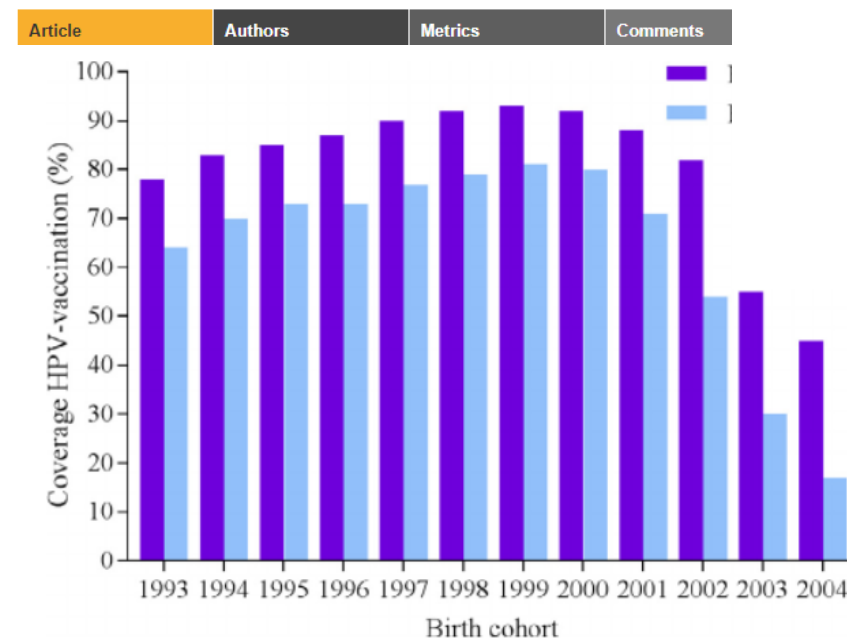
OPEN ACCESS

RESEARCH ARTICLE

Increased Incidence and Clinical Picture of Childhood Narcolepsy following the 2009 H1N1 Pandemic Vaccination Campaign in Finland

Markku Partinen, Outi Saarenpää-Heikkilä, Ismo Ilveskoski, Christer Hublin, Miika Linna, Päivi Olsén, Pekka Nokelainen, Reija Alén, Tiina Wallden, Merimaaria Espo, Harri Rusanen, Jan Olme, Heli Sätälä, [...], Turkka Kirjavainen [view all]

Published: March 28, 2012 • <https://doi.org/10.1371/journal.pone.0033723>



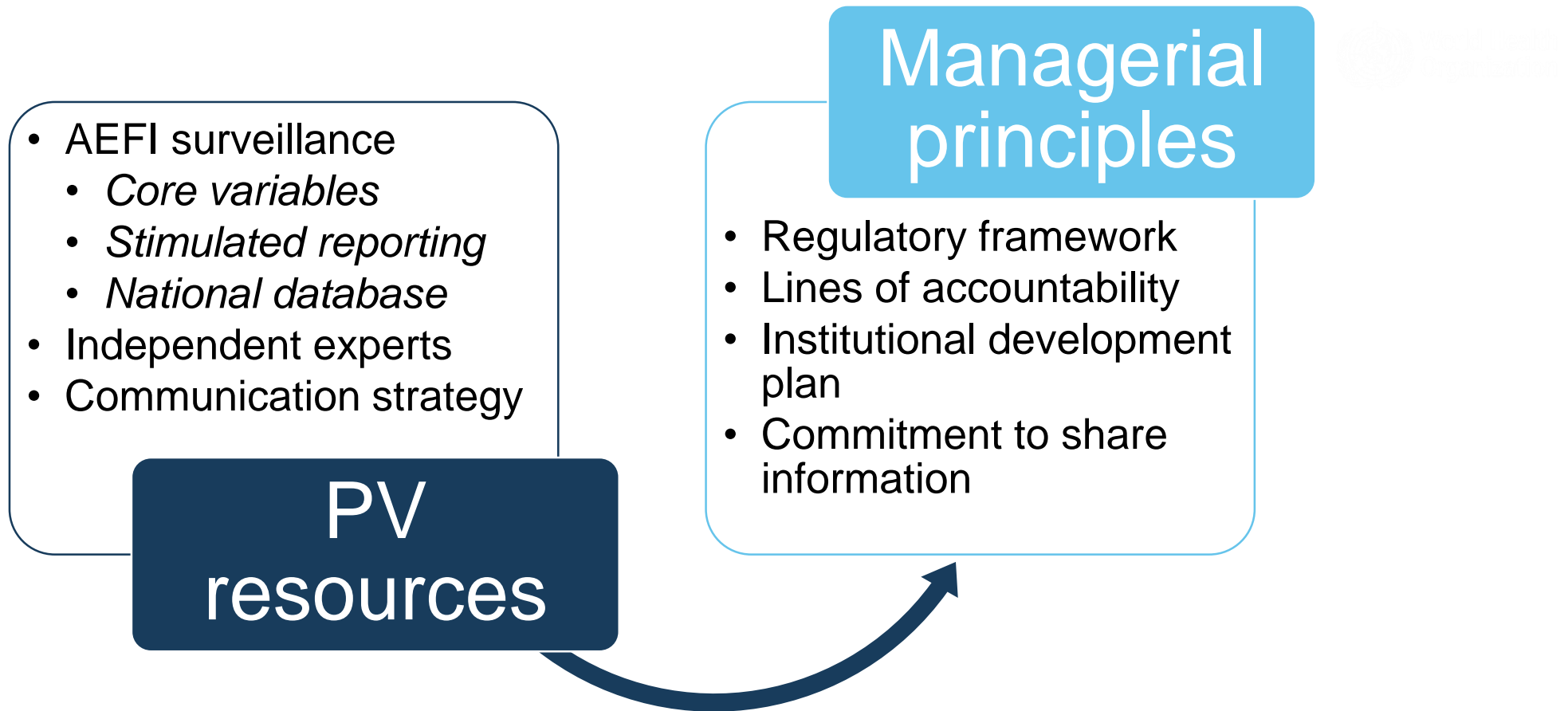
HPV-vaccination coverage in Denmark. Source: Data retrieved from Statens Serum Institute [25].

Vision for the 2012 Global Vaccine Safety Blueprint



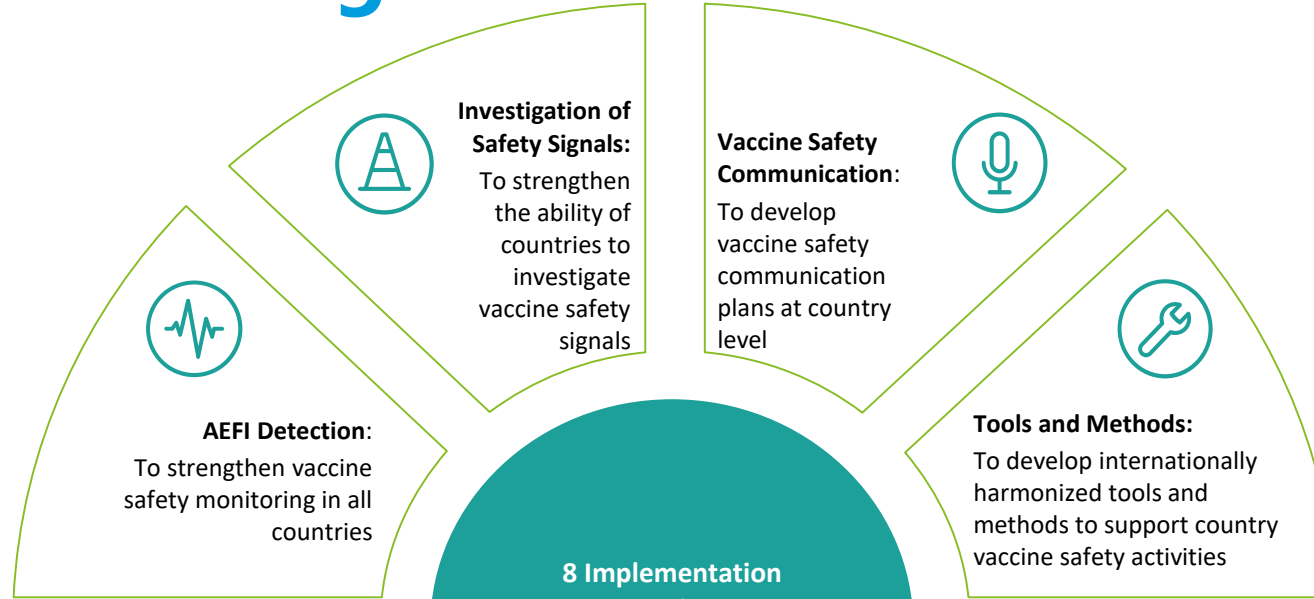
*Effective vaccine
pharmacovigilance systems are
established in all countries*

Minimal capacity



8 strategic objectives support the first Blueprint main goals

Technical objectives



Enabling objectives

Expanding partnership around GVSII



7 GVSI meetings of collaborators and plans

Tools

Guidelines

AEFI systems

Training

Investigation

Global Vaccine Safety Observatory

GVSI - Measuring progress

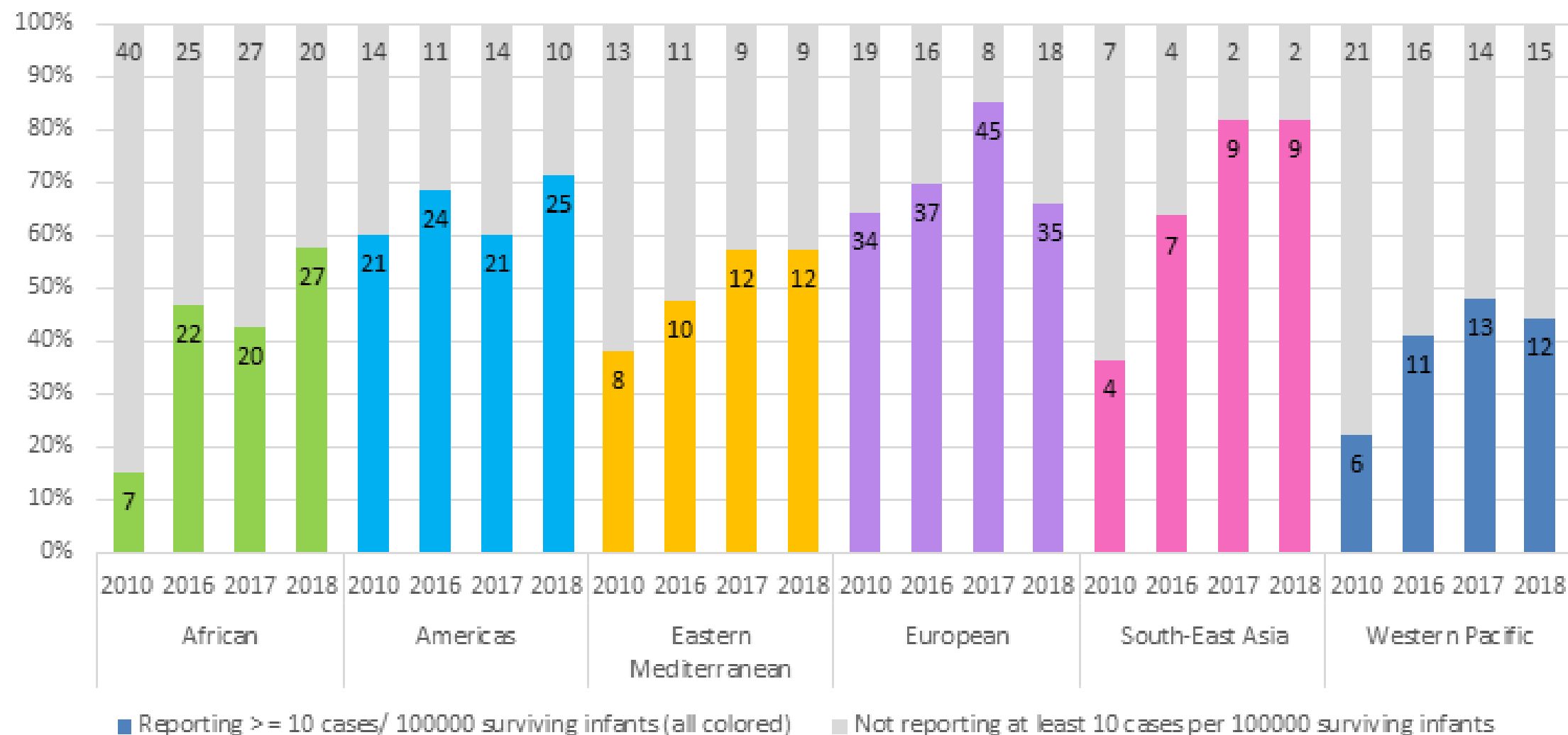
GVAP* indicator

*Global Vaccine Action Plan

- **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.

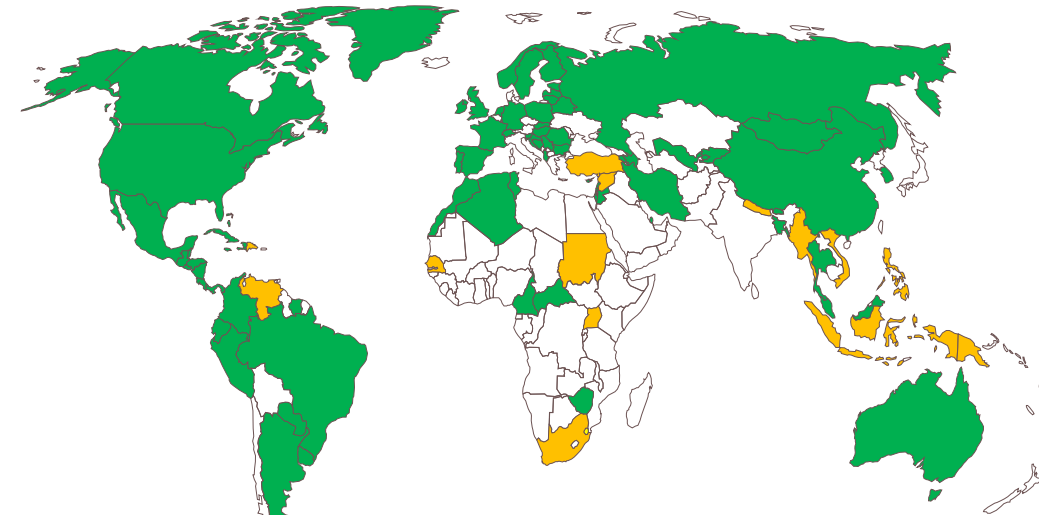
% and number of countries reporting* at least 10 per 100000 AEFI cases by WHO Region 2010, 2016, 2017 and 2018



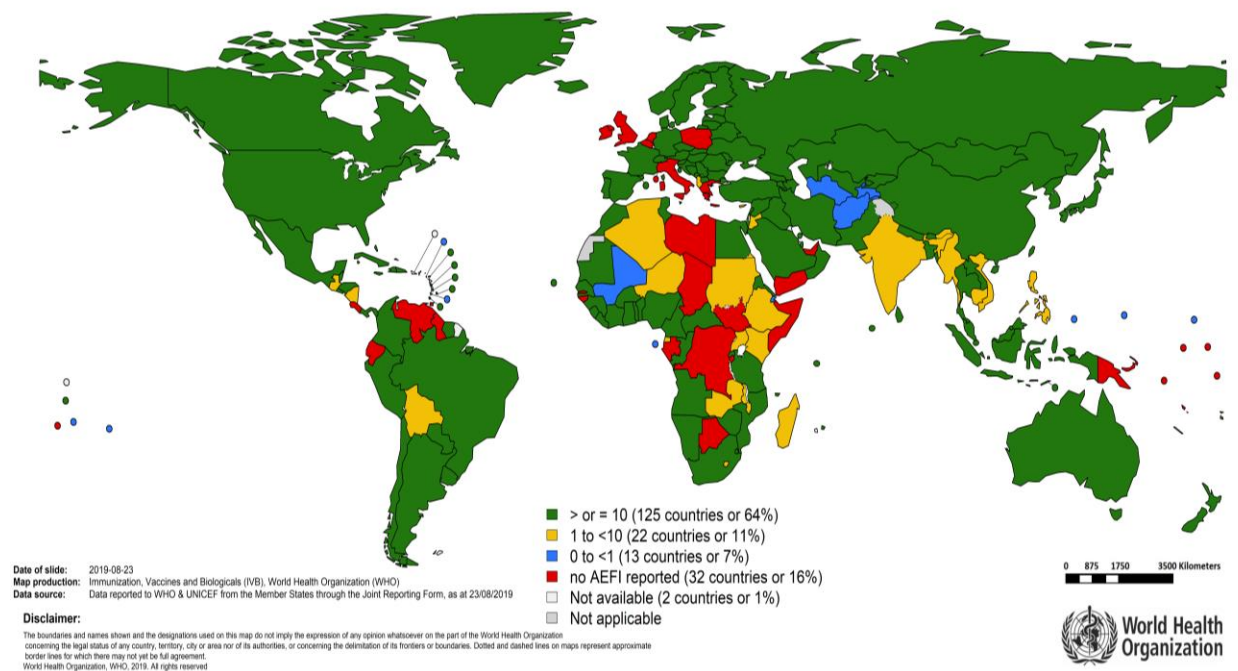
AEFI reports 2010 & 2018



Countries meeting GVAP indicator,
2010

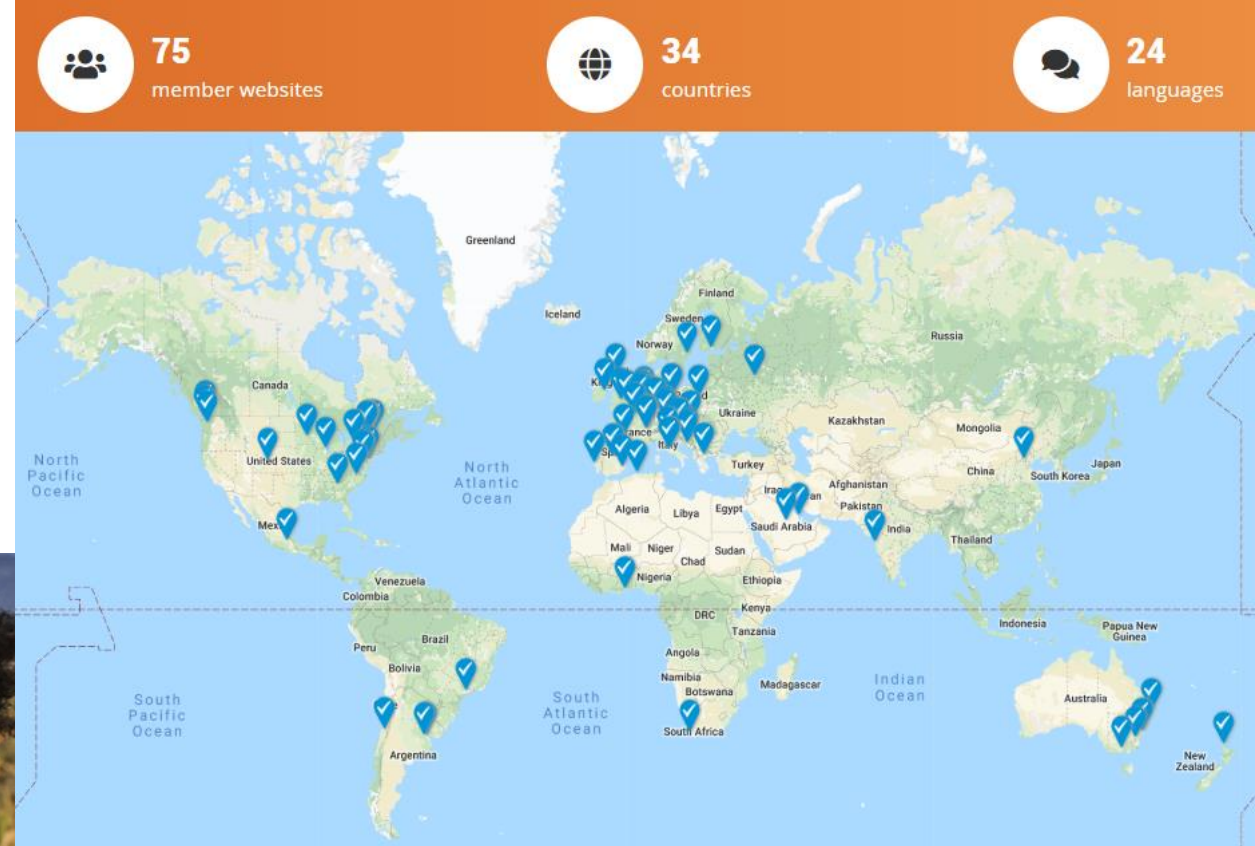


Countries meeting GVAP indicator
2018



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

GLOBAL VACCINE SAFETY BLUEPRINT 2.0 BACKGROUND RESEARCH

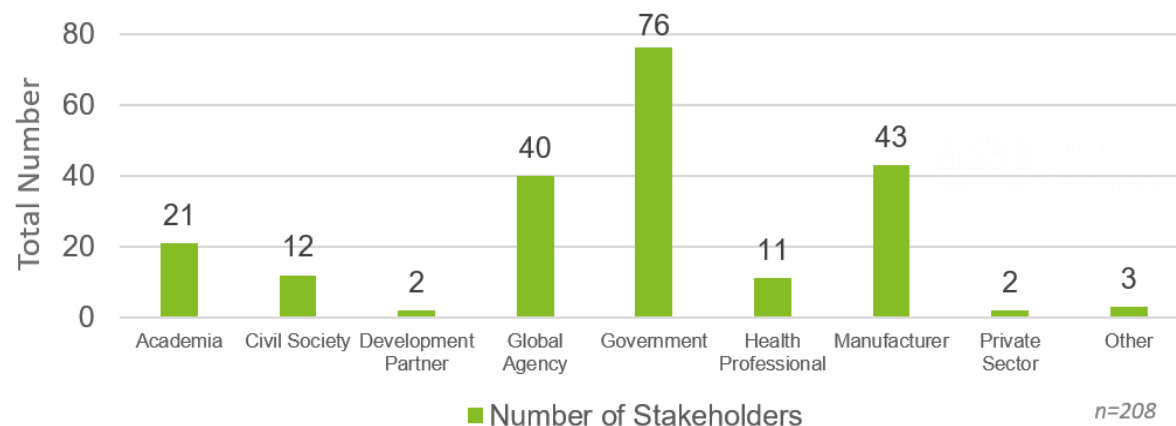
July 2019

Prepared by Deloitte Consulting LLP

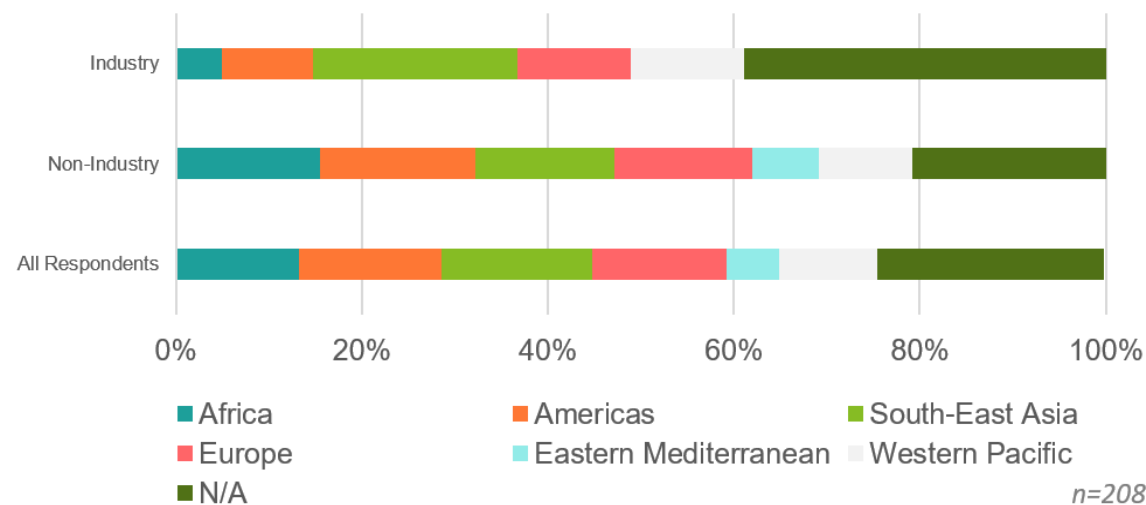
The **largest stakeholder type** represented was government, followed by industry and global agencies.

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

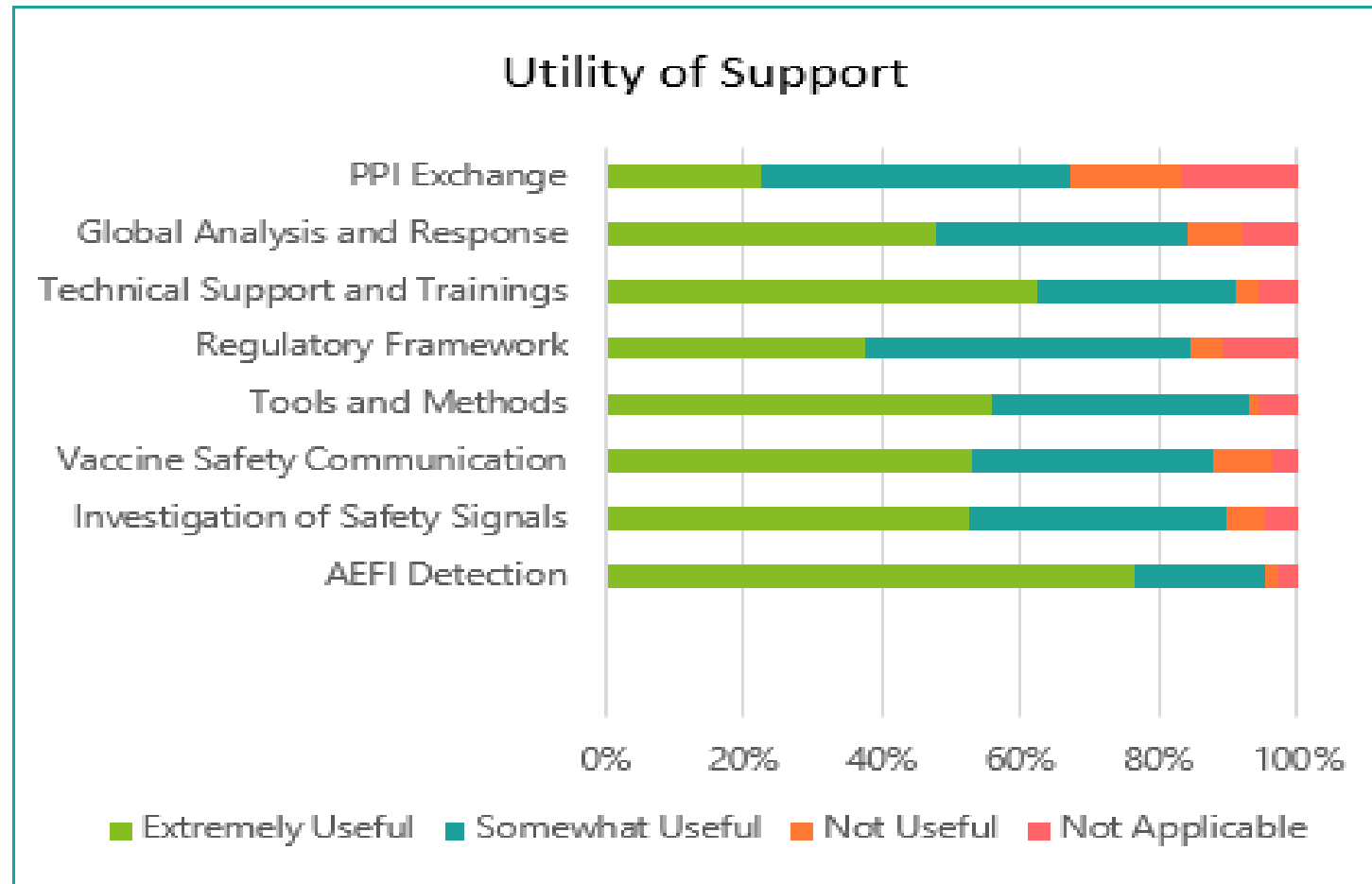
Breakdown by Stakeholder Type



Respondent Primary WHO Region



Utility of the Blueprint and GVSII



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 GVSI'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 GVSI'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 GVSI. However, 8% of respondents found GVSI'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



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
- "I think the vaccine safety communication **needs to be revisited seriously...**"*

From minimal capacity to maturity levels

Indicators	Maturity levels			
	Level 1 sub-indicators	Level 2 sub-indicators	Level 3 sub-indicators	Level 4 sub-indicators
Legal provisions, regulations and guidelines required to define regulatory framework of vigilance	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	Legal provisions allow NRA to require manufacturers to conduct specific safety studies	Legal provisions require manufacturers to designate an individual person in charge of vigilance. Guidelines available for planning, conducting, monitoring, and reporting of vigilance activities	
Arrangement for effective organization and good governance		Defined organizational structure with clear roles and responsibilities	Documented procedures to ensure among all relevant stakeholders	
Human resources to perform vigilance activities			Sufficient competent staff with adequate job descriptions, training plan implemented and documented.	
Procedures established and implemented to perform vigilance activities	Staff access to relevant information resources is ensured		Procedures for collection, investigation and assessment of AEFIs are implemented, include a risk approach and access to expert committees for review of serious concerns	Standard procedures are implemented for the national vigilance system, include regular assessment of risk-benefit balance and active vigilance activities
Regular performance monitoring			Vigilance information used in timely manner to update regulatory decisions	Performance indicators for vigilance activities implemented
Transparency, accountability and communication		Vigilance activities appropriately communicated to the public	Mechanism for regular feedback complemented with a risk communication plan and data shared with international partners	

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

Consolidated with
investigation,
tools and training

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

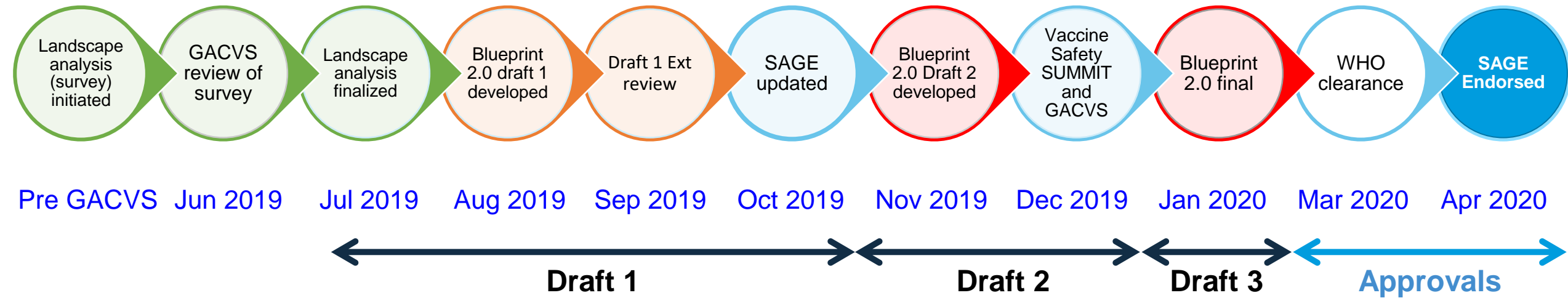
Objective 1 **Strengthened coordination and exchange of information between vaccine manufacturers and national regulatory authorities at local, regional and global level**

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



**Deadline for comments on draft 1
25 October 2019**

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