

# COVID19 Vaccine Safety: Challenges and Opportunities

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# COVID19 Vaccines: unprecedented x 4

- Development - 6-12 months
- Deployment - Billions of doses over 12-18 months
- New technologies- never approved in vaccines for human use
- Potentially many different vaccines

# More than ever a need for

- systems to rapidly detect and minimise serious risks to patients
- near real-time data
- proactive vigilance: hot pursuit of safety concerns of special interest
- collaboration, to come together, to share knowledge, experience and information
- stemming unfounded safety concerns

# But, we are not starting from scratch



We have leverage

- Platforms
- Partners
- Presence
- Precedence



# WHO Programme for International Drug Monitoring

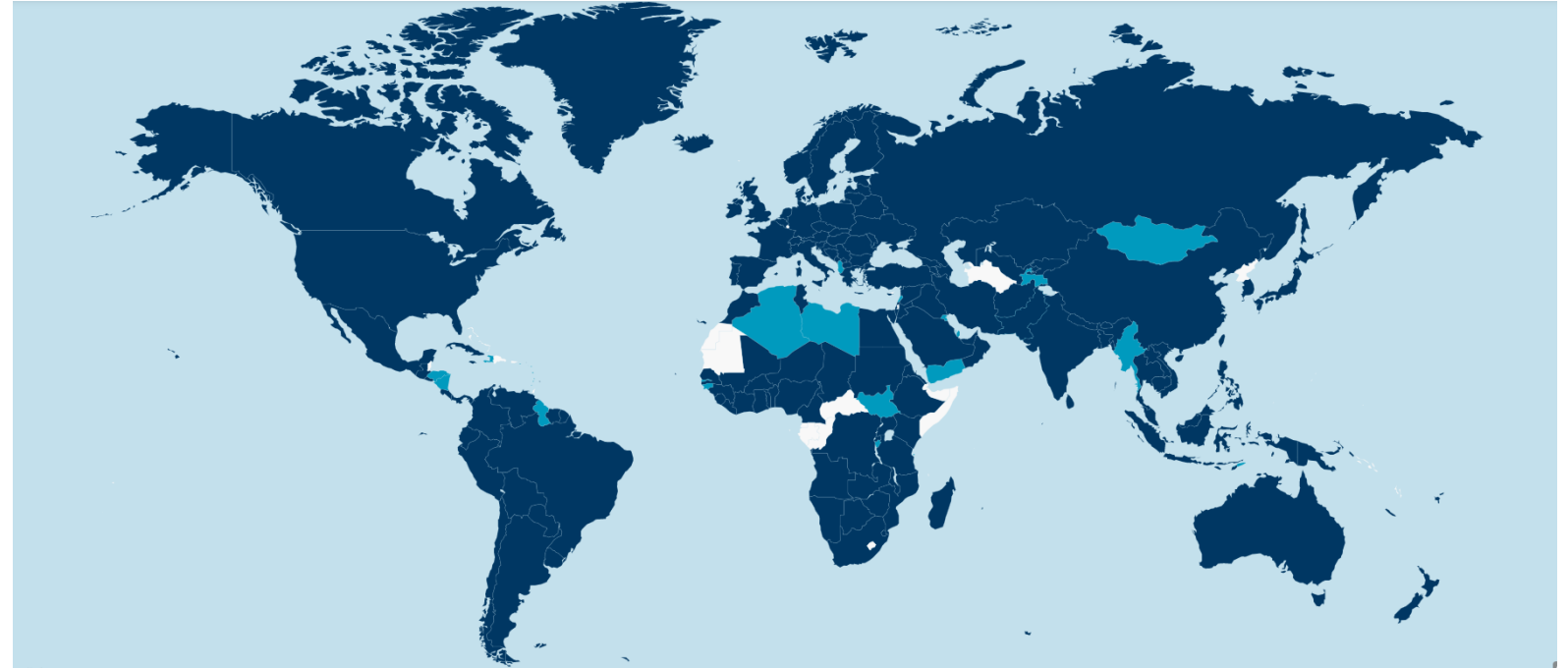


**WHO Global Adverse Events database has**

- **23+ million reports**
- **1 528 421 AEFI reports**

**100+ Member States supported with a national database, VigiFlow**

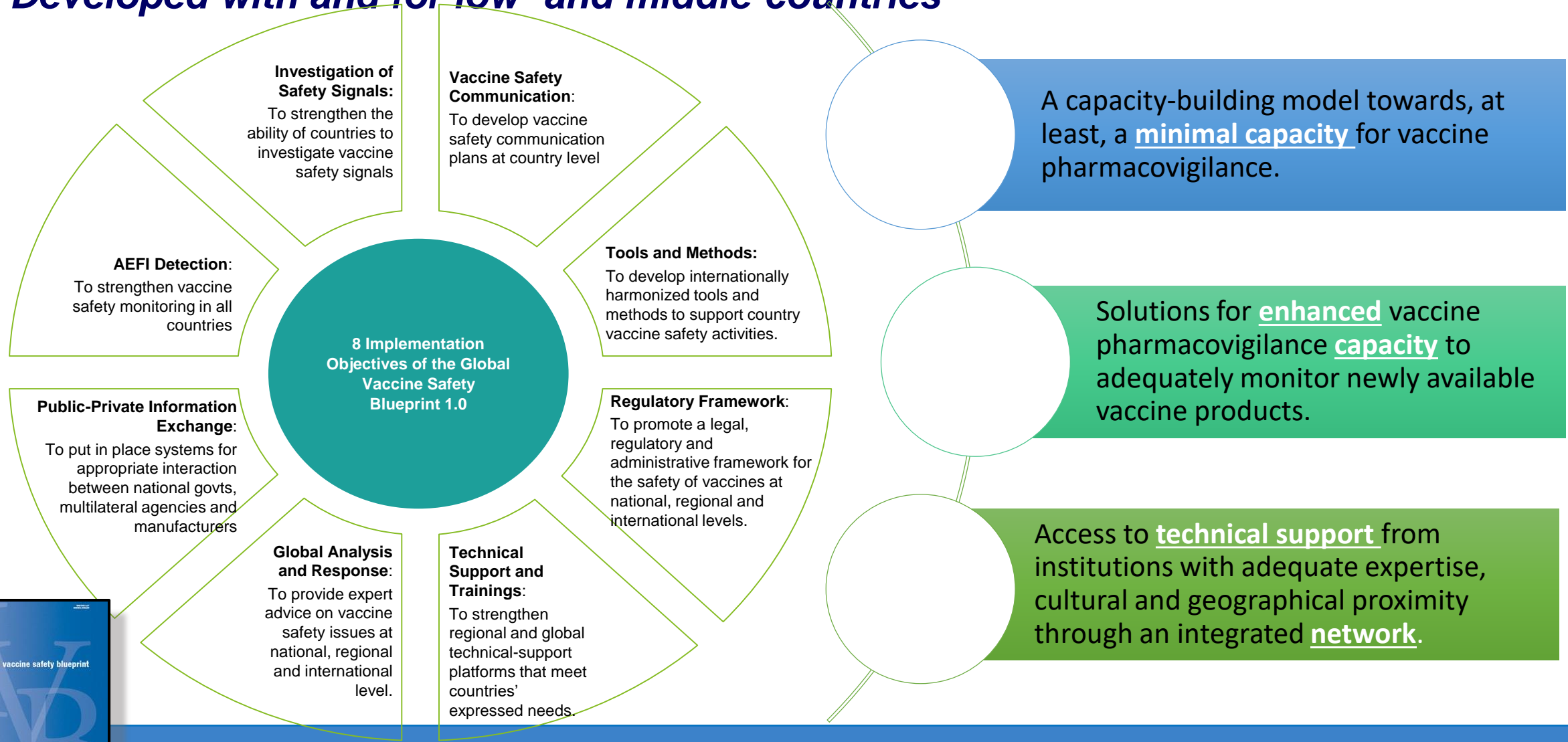
**Reporting tools available: paper-based, e-Reporting, App-based, web-based....**



**As on 26 August 2020: 170 Member States of the WHO PIDM have PV systems**

# Global Vaccine Safety Blueprint

*Developed with and for low- and middle-countries*



# GVS blueprint implemented through a large collaborative partnership: Global Vaccine Safety Initiative



Agence de Médecine Préventive  
www.aamp.org



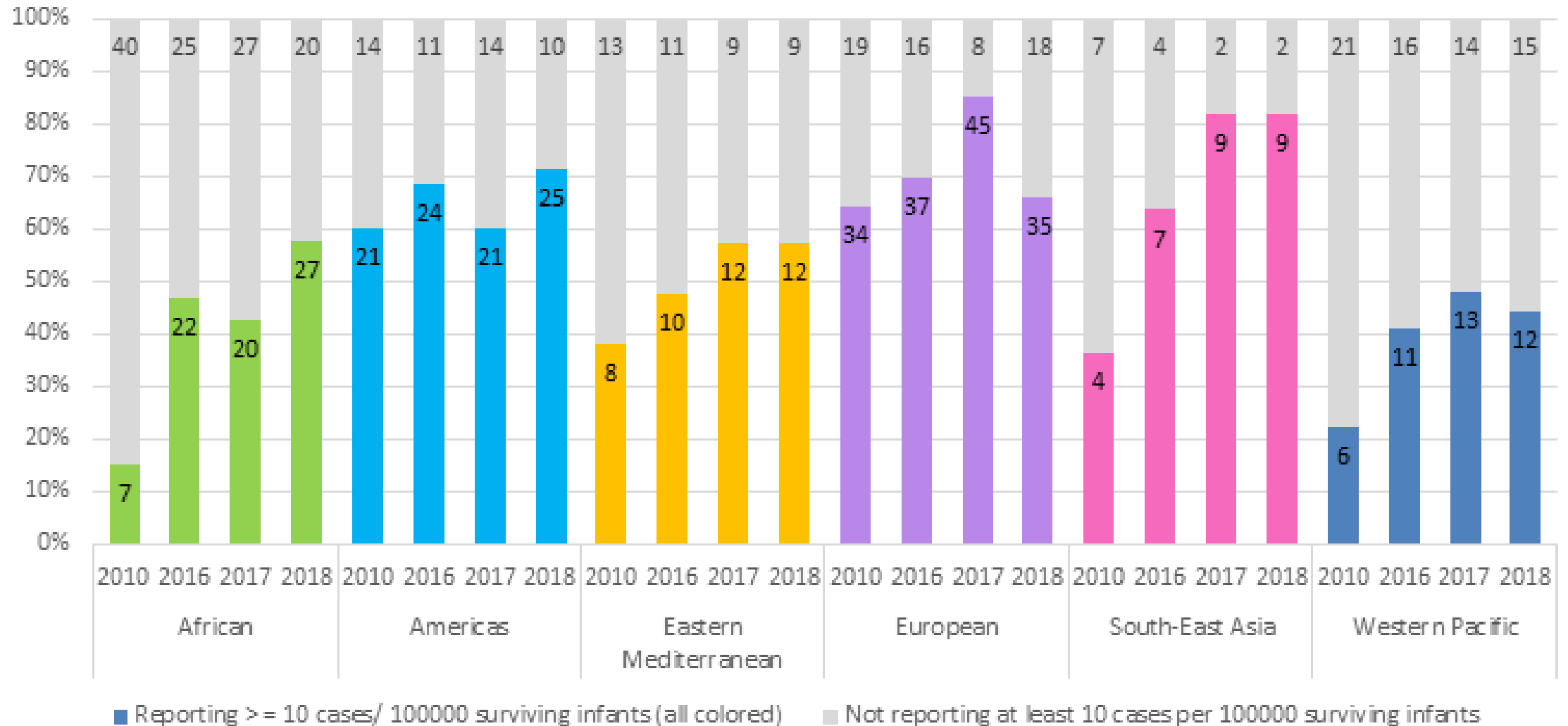
BILL & MELINDA GATES foundation



Paul-Ehrlich-Institut



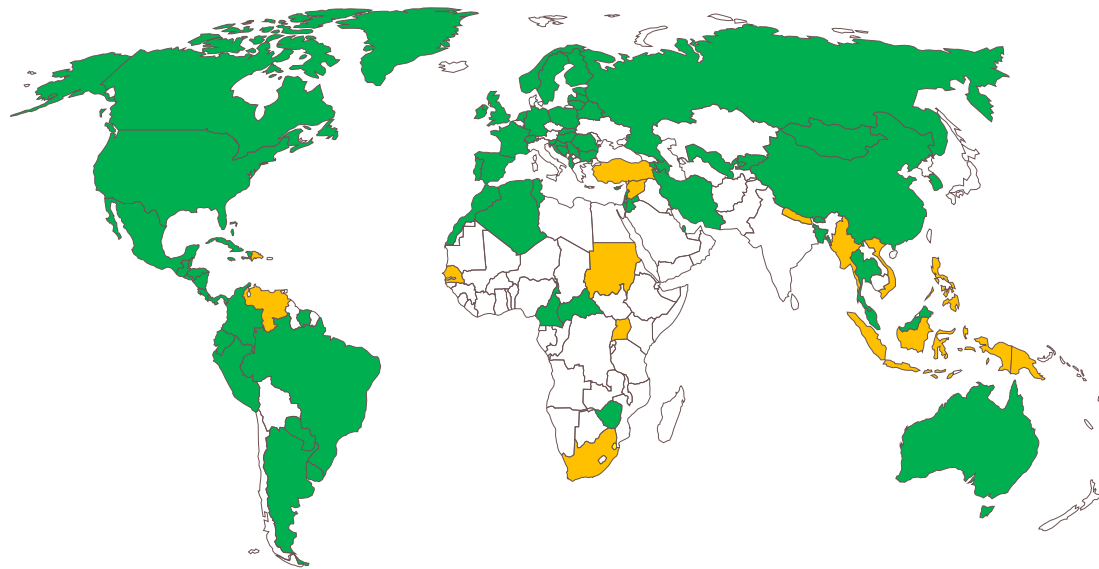
## % and number of countries reporting\* at least 10 per 100000 AEFI cases by WHO Region 2010, 2016, 2017 and 2018



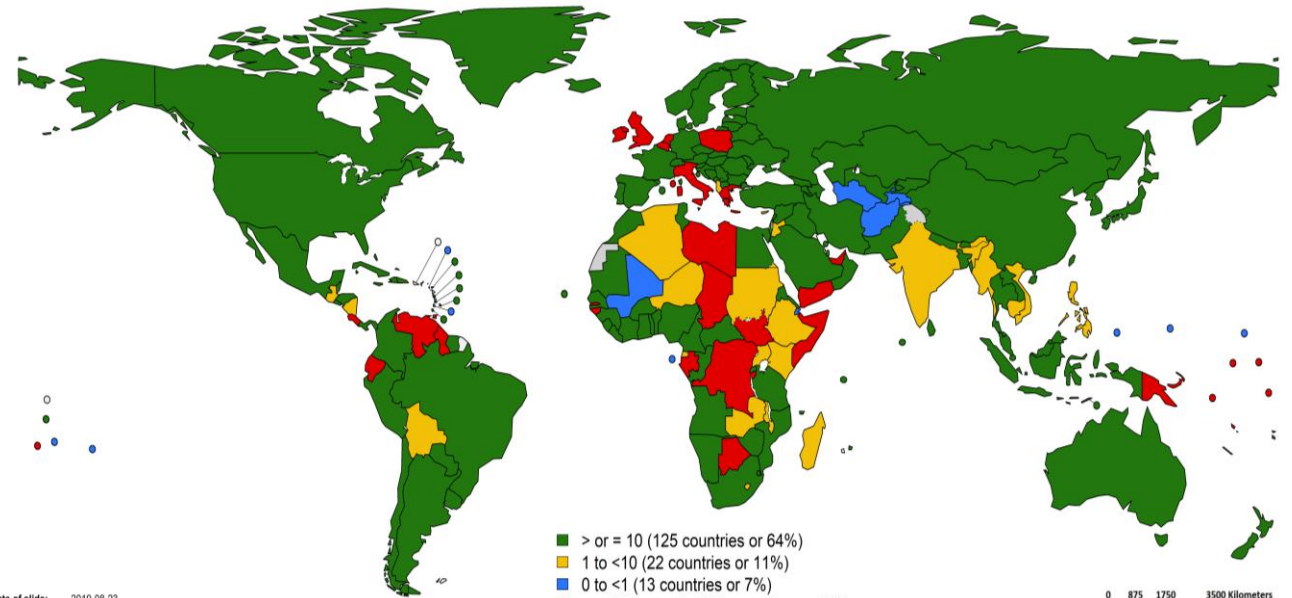


# GVSI - Measuring progress AEFI reports 2010 & 2018

## Countries meeting GVAP indicator 2010



## Countries meeting GVAP indicator 2018



GVAP indicator: a country is said to have minimal capacity if it reports at least 10 (AEFI) cases per 100,000 surviving infants per year

**Date of slide:** 2019-08-23  
**Map production:** Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)  
**Data source:** Data reported to WHO & UNICEF from the Member States through the Joint Reporting Form, as at 23/08/2019

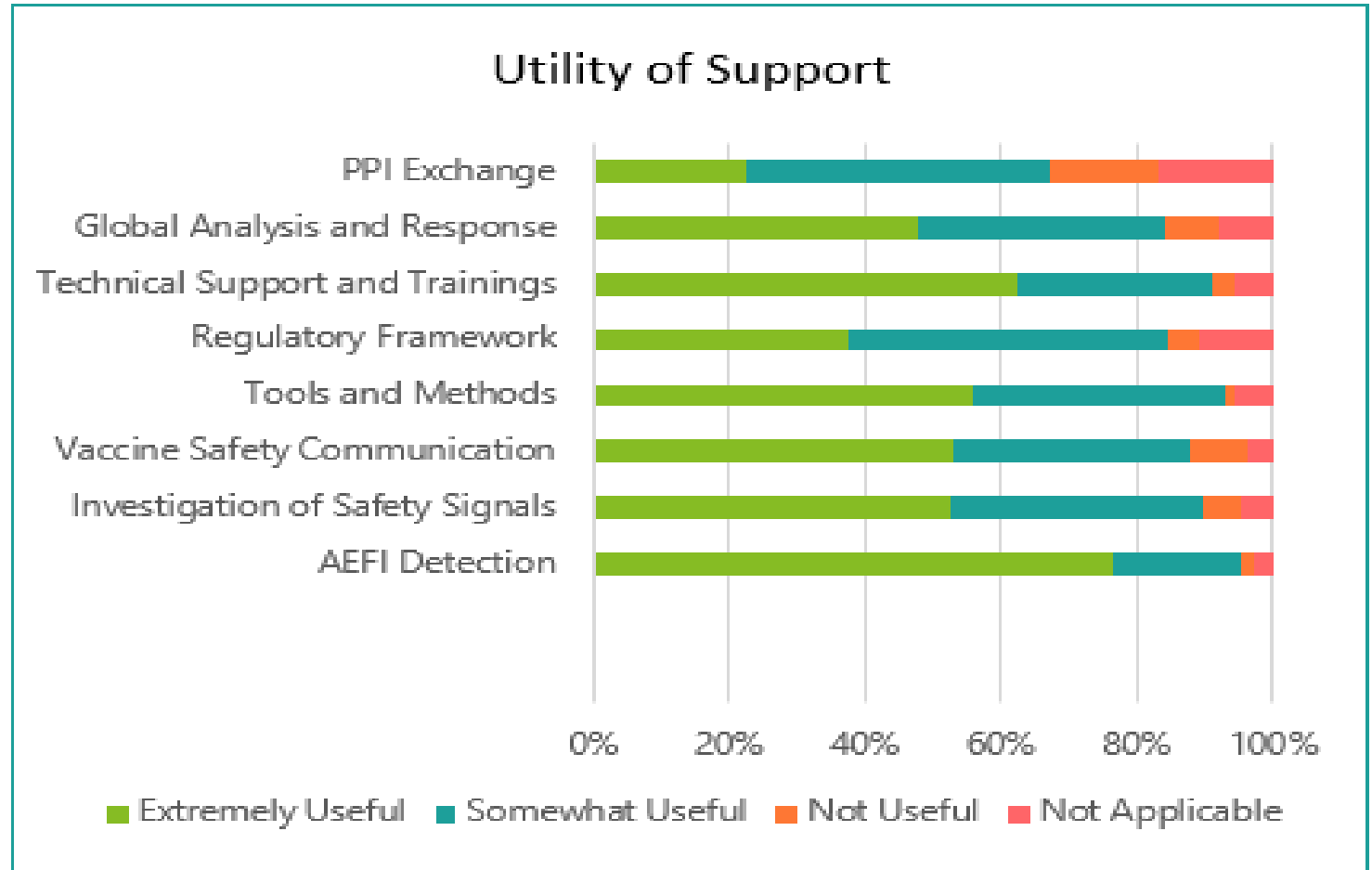
**Disclaimer:**  
 The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area nor of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.  
 World Health Organization, WHO, 2019. All rights reserved.

# Utility of the Blueprint and GVSI

## GLOBAL VACCINE SAFETY BLUEPRINT 2.0 BACKGROUND RESEARCH

July 2019

Prepared by Deloitte Consulting LLP



# Global Vaccine Safety Blueprint 2.0 – What is different?

Moving from minimal/enhanced capacity to a maturity level concept

- Aligns with the WHO NRA benchmarking tool



- Aligns with the Immunization Agenda 2030

# Global Advisory Committee on Vaccine safety (GACVS)

## Background and mandate

GACVS

- **Risk Assessment** of vaccines and provides recommendations to the SAGE\* that makes policy decisions
- Advices on **vaccine safety monitoring** systems, tools and studies
- Significant role in composing scientific messages for use by **risk communicators**

- Established in 1999
- Provides independent, authoritative, scientific advice to WHO on vaccine safety issues of *global* or *regional* concern with the potential to affect in the short or long term national immunization programmes:

# Global Advisory Committee on Vaccine Safety (GACVS)

## Standing committee:

- 15 global experts
- Meets twice a year
- Regular consultation and interaction between members during the year (working groups)
- GACVS alert

## Agenda developed/proposed by:

- The secretariat and current/former members
- Strategic Advisory Group of Experts (SAGE) on Immunization

## Recommendations

- Published in the Weekly epidemiological record and disseminated through WHO web site and electronic newsletter

**Contents**

25 Global Advisory Committee on Vaccine Safety, 4-5 December 2019

**Global Advisory Committee on Vaccine Safety, 4-5 December 2019**

The Global Advisory Committee on Vaccine Safety (GACVS), an independent

**Comité consultatif mondial pour la sécurité des vaccins, 4-5 décembre 2019**

Le Comité consultatif mondial pour la sécurité des vaccins (GACVS) est un organe consultatif

### Global Vaccine Safety

**Global Vaccine Safety**

Global Vaccine Safety Initiative

Global Advisory Committee on Vaccine Safety

**Topics**

Committee reports

**Reference documents and publications**

### Global Vaccine Safety

**Global Vaccine Safety**

Global Vaccine Safety Initiative

Global Advisory Committee on Vaccine Safety

**Topics**









Committee reports

**Safety of human papillomavirus vaccines**

**Committee reports**

- 24 January 2020 - Human papillomavirus vaccines and infertility (from meeting of 4-5 December 2019)
- 12 July 2019 - Communication about the safety of human papillomavirus vaccines (from meeting of 5-6 June 2019)
- 14 July 2017 - Safety update of HPV vaccines (from meeting of 7-8 June 2017)
- 22 January 2016 - Safety of HPV vaccines (from meeting of 2-3 December 2015)
- 14 February 2014 - Human papillomavirus vaccines safety (HPV) (from GACVS meeting of 11-12 December 2013)
- 19 July 2013 - Update on human papillomavirus vaccines (from meeting of 12-13 June 2013)
- 7 August 2009 - Safety of human papillomavirus vaccines (from meeting of 17-18 June 2009)
- 30 January 2009 - Safety of human papillomavirus vaccines (from meeting of 17-18 December 2008)
- 20 July 2007 - Safety of human papillomavirus vaccine (from meeting of 12-13 June 2007)

**Statements**

-  GACVS Statement on Safety of HPV vaccines - 17 December 2015  
 pdf, 112kb
-  GACVS Statement on the continued safety of HPV vaccination - 12 March 2014  
 pdf, 173kb
-  GACVS Safety update on HPV Vaccines, Geneva - 17 December 2013  
 pdf, 19kb
-  GACVS Safety update on HPV Vaccines - 13 June 2013  
 pdf, 230kb

Page last updated on 20 February 2020

# Extraordinary meeting of GACVS on COVID19 Vaccine Safety, May 2020



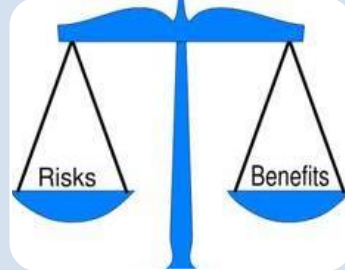
The COVID-19 vaccines in the pipeline and current lead candidates under consideration



Potential adverse events of special interest (AESI) with COVID vaccines



Regulatory perspectives and approaches in the context of COVID-19 vaccine introduction



The application of standardized templates for risk/benefit assessment of vaccines



COVID-19 vaccine risk-benefit communication and infodemic management during COVID-19 response.

**GACVS Recommendations published**



<https://www.who.int/wer/2020/wer9528/en/>



# To conclude

- Introducing, on a very large scale, different COVID-19 vaccines with new technologies will create new challenges
- WHO has a network of AEFI reporting countries and a Global Advisory Committee; these should be leveraged to meet COVID19 Vx safety challenges
- Pharmacovigilance methods, tools and databases exist; these should be adapted to meet COVID19 AE issues (collecting, reporting, analysis, data management..)
- Collaboration between different actors is key (regulators, public health authorities, vaccine manufacturers, international organisations, others)

**Thank you**