Global Vaccine Action Plan
Secretariat Annual Report 2017
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Abbreviations

AEFI	adverse events following immunization
ANC1	first antenatal visit
AFP	acute flaccid paralysis
BCG	Bacille Calmette–Guérin (vaccine)
CI	confidence interval
CCI	Composite Coverage Index
CDC	United States Centers for Disease Control and Prevention
cMYP	comprehensive multi-year plan
COIA	Commission on Information and Accountability for Women's and Children's Health
CRS	congenital rubella syndrome
CSO	civil society organization
CTC	controlled temperature chain
cVDPV	circulating vaccine-derived poliovirus
DHS	Demographic and Health Survey
DoV	Decade of Vaccines
DTP	diphtheria–tetanus–pertussis (vaccine)
EIA	enzyme immunoassay
EPI	Expanded Programme on Immunization
EQA	external quality assessment
EWEC	Every Woman Every Child (Strategy)
Gavi	Gavi, the Vaccine Alliance
GACVS	Global Advisory Committee on Vaccine Safety
GAPIII	WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use
GGE	general government expenditure
GPEI	Global Polio Eradication Initiative
GNI	gross national income
GVAP	Global Vaccine Action Plan
HEAT	Health Equity Assessment Toolkit
HepB	Hepatitis B
Hib	*Haemophilus influenzae* type b
HIC	high-income countries
HPV	human papillomavirus
IB-VPD	invasive bacterial vaccine-preventable disease
IHR	International Health Regulations
IMB	Independent Monitoring Board
IPAC	Immunization Practices Advisory Committee
IPV	inactivated polio vaccine
IVB	Immunization, Vaccines and Biologicals Department (WHO)
JRF	(WHO-UNICEF) Joint Reporting Form (on Immunization)
M&E/A	monitoring and evaluation/accountability
MenAfriVac	Serogroup A meningococcal conjugate vaccine
MCV	measles-containing vaccine

MDG	Millennium Development Goal
MICS	Multiple Indicator Cluster Surveys
MIC	middle-income country
MR	measles–rubella (vaccine)
MMR	measles–mumps–rubella (vaccine)
MNT	maternal and neonatal tetanus
MNTE	maternal and neonatal tetanus elimination
MSF	Médecins Sans Frontières
NAC	national authority for containment
NGO	nongovernmental organization
NIAID	National Institute of Allergy and Infectious Diseases
NITAG	National Immunization Technical Advisory Group
NRA	national regulatory authority
NVC	(Measles) National Verification Committee
OPV	oral polio vaccine
PATH	Program for Appropriate Technology in Health
PAB	protected at birth (against neonatal tetanus)
PAHO	Pan American Health Organization
PCV	pneumococcal conjugate vaccine
polio	poliomyelitis
PDVAC	Product Development for Vaccines Advisory Committee
PMNCH	Partnership for Maternal, Neonatal and Child Health
PQS	performance, quality and safety
QC	quality control
R&D	research and development
RCV	rubella-containing vaccine
RF	(PAHO) Revolving Fund
RV	rotavirus vaccine
RSV	respiratory syncytial virus
RTAG	regional technical advisory group
RVC	(Measles) Regional Verification Commission
SAGE	Strategic Advisory Group of Experts (on immunization)
SAR	Special Administrative Region
SDG	Sustainable Development Goal
SIA	supplementary immunization activity
SO	(GVAP) Strategic Objective
TAC	TaqMan Array Card
TAG	Technical Advisory Group
TB	tuberculosis
TBE	tick-borne encephalitis
TPP	target product profile
TSE	total systems effectiveness
Td	tetanus diphtheria
TT	tetanus toxoid
TTCV	tetanus toxoid-containing vaccines
UN	United Nations
UNFPA	United Nations Population Fund

UNICEF	United Nations Children's Fund
UNICEF-SD	United Nations Children's Fund Supply Division
V3P	Vaccine Product, Price and Procurement (project)
VPD	vaccine-preventable disease
WG	working group
WHO	World Health Organization
WPV	wild poliovirus
WUENIC	WHO-UNICEF estimates of national immunization coverage
YF	yellow fever

Introduction

The Global Vaccine Action Plan and process for monitoring progress

The Global Vaccine Action Plan (GVAP) is a framework adopted by all the World Health Organization (WHO) Member States at the Sixty-fifth World Health Assembly in May 2012 to achieve the vision of the Decade of Vaccines (DoV) 2011–2020 of "a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases".[1] The GVAP's mission is to "improve health by extending by 2020 and beyond the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live".

The GVAP has articulated five goals and six strategic objectives to achieve this mission, as shown in Table 1. The Sixty-fifth World Health Assembly requested the WHO Director-General to monitor progress and report annually, using an accountability framework, in order to guide immunization discussions and future actions.[2] In response, the DoV partners developed a Monitoring & Evaluation/Accountability (M&E/A) Framework that identifies specific indicators to measure progress for each goal and strategic objective. The DoV partners also agreed to a process for an annual independent review of progress. The need for this annual reporting mechanism has been re-emphasized in resolution WHA70.14 at the Seventieth World Health Assembly in May 2017.

Table 1: The GVAP Monitoring and Evaluation/Accountability Framework: goals, strategic objectives and indicators to evaluate progress

Goal /Strategic objective	Indicators
GOALS	
1. Achieve a world free of poliomyelitis	G1.1 Interrupt wild poliovirus transmission globally
	G1.2 Certification of poliomyelitis eradication
2. Meet global and regional elimination targets	G2.1 Maternal and neonatal tetanus elimination
	G2.2 Measles elimination
	G2.3 Rubella/Congenital rubella syndrome (CRS) elimination
3. Meet vaccination coverage targets in every region, country and community	G3.1 By 2015, reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis-containing vaccines

[1] The GVAP can be found at: http://www.who.int/immunization/global_vaccine_action_plan/en/.
[2] Resolution WHA65.17, available at: http://apps.who.int/gb/or/e/e_wha65r1.html.

Goal /Strategic objective	Indicators
	G3.2 By 2020, reach 90% national coverage and 80% in every district or equivalent administrative unit for all vaccines in national programmes, unless otherwise recommended
4. Develop and introduce new and improved vaccines and technologies	G4.1 Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases **Note:** this indicator is included in the "research and development" section, but there is no R&D chapter in the report this year
	G4.2 Licensure and launch of at least one platform delivery technology **Note:** this indicator is included in the "research and development" section, but there is no R&D chapter in the report this year
	G4.3 Number of low-income and middle-income countries[3] that have introduced one or more new or under-utilized vaccines **Note:** this indicator is included in the "immunization coverage" section
5. Exceed the Millennium Development Goal 4 target for reducing child mortality and Integration indicators	G5.1 Reduce under-five mortality rate
	G5.2 Integration of health care interventions and immunization activities
STRATEGIC OBJECTIVES (SOs)	
1. Ensuring country ownership of immunization	SO1.1 Increasing domestic expenditures for immunization per person targeted **Note:** this indicator is included in the "sustainable financing and supply for immunization" section
	SO1.2 Presence of an independent technical advisory group that meets the defined criteria
2. Demand for immunization	SO2.1 Percentage of countries that have assessed the level of hesitancy in vaccination at a national or subnational level
	SO2.2 Reasons for vaccine hesitancy

[3] World Bank country classification by income level: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

Goal /Strategic objective	Indicators
	SO2.3 Percentage of countries that include in their immunization programme actions to promote or sustain public demand for vaccines and vaccination services
3. The benefits of immunization are equitably extended to all people	SO3.1 Percentage of districts with 80% or greater coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine **Note**: this indicator is included in the narrative of "Immunization coverage" section, Goal G3.1
	SO3.2 Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s) **Note**: this indicator is included in "Immunization coverage" section, Goal G3.1
4. Strong immunization systems are an integral part of a well-functioning health system	SO4.1 Dropout rates between first dose (DTP1) and third dose (DPT3) of diphtheria–tetanus–pertussis-containing vaccines **Note**: this indicator is included in the "Immunization coverage" section, Goal G3.1
	SO4.2 Sustained coverage of diphtheria-tetanus-pertussis-containing vaccines 90% or greater for three or more years **Note**: this indicator is included in the narrative of the "Immunization coverage" section, Goal G3.1
	SO4.3 Immunization coverage data assessed as high quality by WHO and UNICEF **Note**: *This indicator is no longer monitored*
	SO4.4 Number of countries meeting established surveillance standards with case-based surveillance for vaccine-preventable diseases and with viral and bacterial laboratory confirmation of suspect or probable cases
5. Stock-out and access to sustained supply of vaccines of assured quality	SO5.1 Percentage of doses of vaccine used worldwide that are of assured quality **Note:** this indicator is included in the "Sustainable financing and supply for immunization" section.
	SO5.2 Number of countries reporting a national-level stock-out of at least 1 vaccine for at least 1 month **Note:** this indicator is included in the "Sustainable financing and supply for

Goal /Strategic objective	Indicators
	immunization" section
6. Country, regional and global research and development innovations maximize the benefits of immunization	SO6.1 Progress towards development of HIV, TB and malaria vaccines
	SO6.2 Progress towards a universal influenza vaccine (protecting against drift and shift variants)
	SO6.3 Progress towards institutional and technical capacity to carry out vaccine clinical trials
	SO6.4 Number of vaccines that have either been re-licensed or licensed for use in a controlled-temperature chain (CTC) at temperatures above the traditional 2–8°C range **Note:** this indicator is included in the "Sustainable financing and supply for immunization" section
	SO6.5 Number of vaccine delivery technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline **Note:** All indicators in strategic objective 6, except SO6.4 and SO6.5, are part of the "Research and development" section; *they have not been reported on this year*
7. Access to sustainable financing and supply for immunization (in response to WHA Resolution on Sustained access to affordable Vaccines (WHA68.6, 2015)	- Immunization Financing (SO1.1) - NRA strengthening and in-country registration process improvements - Pre-qualification - Vaccines Shortages - Vaccines Research and development - Domestic expenditures for immunization - Vaccine Prices (VP) - Number of vaccine delivery technologies (devices and equipment) that have received WHO prequalification (SO6.5) - Stock-outs - Number of vaccines re- licensed for use in a controlled-temperature chain (CTC) - % of doses of vaccine used worldwide that are of assured quality (SO5.1) - **Note:** All those indicators are included in the "Sustainable financing and supply for immunization" section

This report, prepared by the Secretariat for the Decade of Vaccines Global Vaccine Action Plan, serves as the basis for the independent review. As was the case in previous years, this report reviews progress against each of the indicators in the GVAP Monitoring and Evaluation/Accountability Framework. In addition it contains a narrative report on sustainable supply and financing for immunization, a report on the situation of middle-income countries with regard to immunization and independent voluntary submissions from various partners on the activities they conducted under the GVAP umbrella.

Updates to the GVAP Secretariat report 2017

This report includes a few new features from the 2016 edition, as outlined below.

1. The report does not strictly follow the structure of the GVAP, but rather follows a thematic order. As an example, all results relating to immunization coverage are compiled into one section of the report, even though they come under separate goals or strategic objectives. Grouping results in this way also meets the request from the Strategic Advisory Group of Experts (SAGE) on immunization that certain original indicators be considered as part of the overall report on progress with immunization coverage, rather than as independent indicators.

2. All the indicators and reports related to i) improving global vaccine security; ii) strengthening procurement and its transparency; iii) enhancing national funding for immunization; and iv) strengthening national supply chain systems have been gathered under a single chapter "Sustainable financing and supply for immunization". This includes the section of last year's chapter plus indicators on stock-outs and controlled temperature chain. This is done to detail the activities initiated in response to World Health Assembly resolution WHA68.6[4] in 2015.

3. In line with World Health Assembly resolution WHA70.14 and a SAGE recommendation, a separate chapter has been added to describe the particular situation of middle-income countries.

4. The chapter on vaccine hesitancy includes for the first year an indicator (SO2.3) on the demand for immunization and has been renamed "Vaccine hesitancy and demand for immunization".

5. Progress on the GVAP research and development indicators, which is to be reported biennially and was included in the 2016 report, has not been reported on this year.

6. The annex "Priority Country reports on progress towards GVAP-RVAP goals" provides an update on the initial seven countries selected for review. An additional four new country reports have been included, from India, Madagascar, Papua New Guinea and Yemen.

Data Visualization of GVAP Indicators via its new portal: http://apps.who.int/gho/cabinet/gvap.jsp

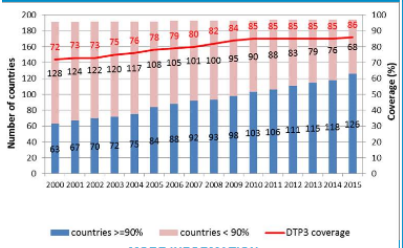
[4] http://apps.who.int/gb/ebwha/pdf_files/WHA68-REC1/A68_R1_REC1-en.pdf#page=27

GLOBAL VACCINE ACTION PLAN

Access the GLOBAL VACCINE ACTION PLAN Website >

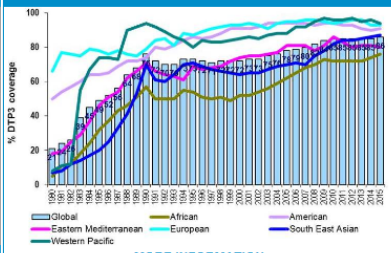
All analysis published on the GVAP portal are based on 2015 data. The global 2016 update will be available by October 2017.

DTP3 COVERAGE ACCESS AND DROPOUT



MORE INFORMATION >

COUNTRIES WITH SUSTAINED COVERAGE



MORE INFORMATION >

GLOBAL VACCINE ACTION PLAN MONITORING INDICATORS

GOALS OF THE DECADE OF VACCINES

Polio eradication >	Elimination targets >	Immunization coverage >	New vaccines introduction >	Reduced mortality >

STRATEGIC OBJECTIVES INDICATORS

Country ownership >	Vaccine hesitancy >	Vaccine surveillance >	Vaccine supply >	Financing >	Vaccine safety >	Research and development >

Monitoring results: goals, strategic objectives and indicators

1. Disease elimination

GOAL 1: ACHIEVE A WORLD FREE OF POLIOMYELITIS (Indicators G1.1 and G1.2)

G1.1: INTERUPT WILD POLIOVIRUS TRANSMISSION GLOBALLY
TARGET: 2014
G1.2: CERTIFICATION OF POLIOMYELITIS ERADICATION
TARGET: 2018

For the definition of each indicator, description of data sources, comments on data quality, description of results, narrative and highlights please refer to the documents listed in Box 1.

Box 1: Descriptions of indicators, results, data sources and highlights

1. For context, see the GPEI status reports available at: http://www.polioeradication.org/Resourcelibrary/Strategyandwork/Annualreports.aspx
2. To review the real-time updates on polio cases worldwide, see: http://www.polioeradication.org/Dataandmonitoring.aspx
3. To review the August 2016 report of the Independent Monitoring Board (IMB) of the GPEI, please visit: http://polioeradication.org/tools-and-library/policy-reports/imb-resources/reports/
4. Report by the Secretariat to the World Health Assembly, April 2017: http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_14-en.pdf

Highlights

- The Global Polio Eradication Initiative (GPEI) is sustaining strong progress on several fronts, new cases in Nigeria highlight the fragility of this progress.
- In 2016, only 37 cases of wild poliovirus have been detected, halving the number of reported cases compared to 2015.
- Only one wild serotype (poliovirus type 1) continues to be detected; wild poliovirus type 2 was officially declared eradicated in 2015 and no case of paralytic poliomyelitis due to wild poliovirus type 3 has been detected anywhere since November 2012.
- In Afghanistan and Pakistan substantial progress has been made toward interruption of wild poliovirus transmission. In Pakistan, two of the three core reservoirs of poliovirus (Karachi and Peshawar) have demonstrated encouraging progress in 2016.
- The year 2016 saw only three countries affected by circulating vaccine-derived poliovirus (cVDPV) outbreaks: Lao People's Democratic Republic, Nigeria and Pakistan. However, in 2017 (as of 30 June), new cVDPV type 2 cases were reported from the Syrian Arab Republic and the Democratic Republic of the Congo.

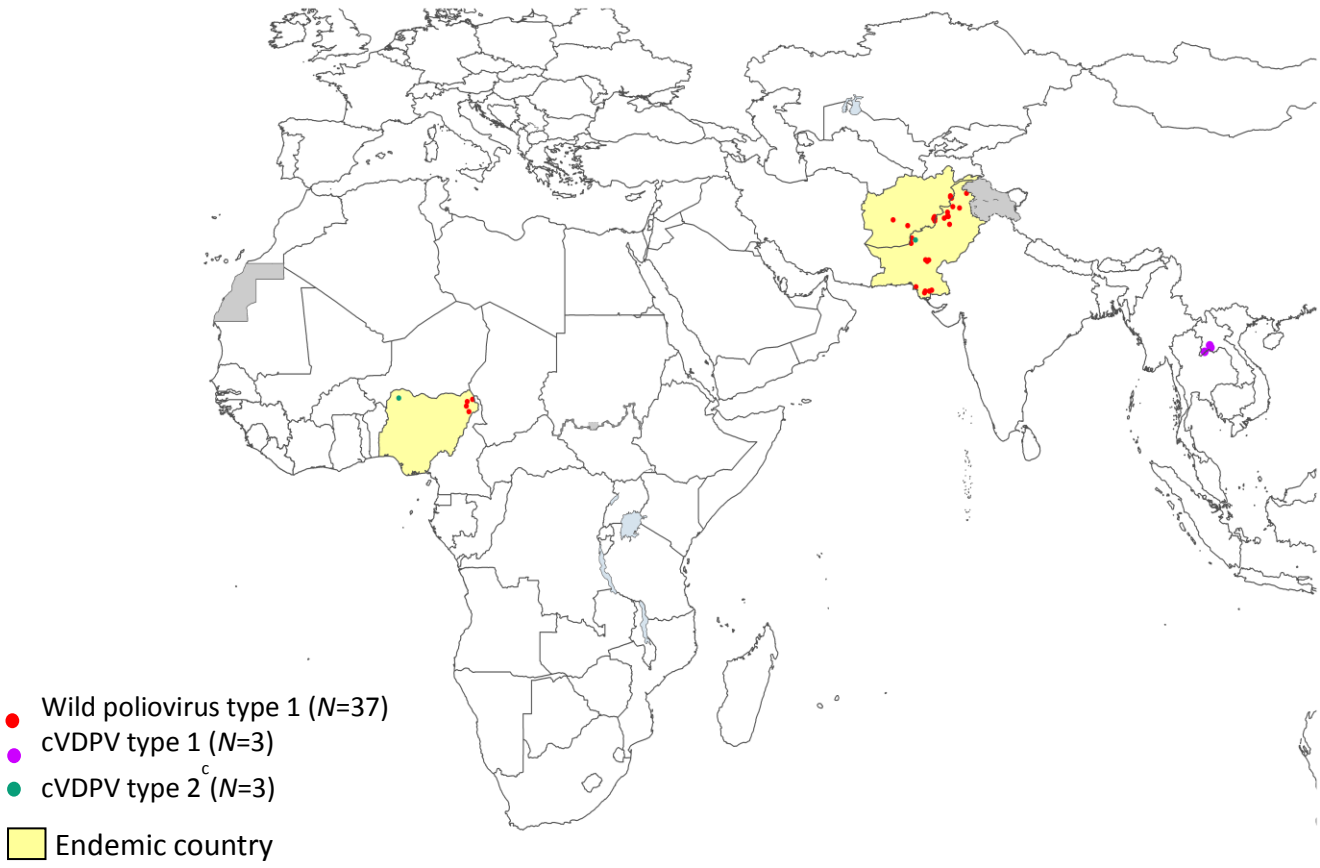
- To address an ongoing US$ 1.5 billion funding need to secure a lasting polio-free world and achieve global certification, global leaders united in June 2017 at the Rotary Convention in Atlanta, United States of America. Public and private sector donors pledged a collective US$ 1.2 billion towards the effort, leaving a gap of US$ 300 million for 2017–2020.
- In July and August 2016, Nigeria confirmed 4 cases of paralytic poliomyelitis due to wild poliovirus in Borno State, related to a strain last detected in 2012. Nigeria and Africa had not confirmed any new cases for two years between July 2014 and July 2016.
- Two separate circulating vaccine-derived polioviruses type 2 have been detected in Borno and Sokoto States, Nigeria. Vaccine-derived poliovirus found in Borno had been circulating undiscovered for almost two years.
- At its meeting in October 2016, the Strategic Advisory Group of Experts on immunization (SAGE) noted both the reduction in supplies of inactivated polio vaccine (IPV), due to technical difficulties that manufacturers have encountered in scaling up production, and the expectation that the global vaccine supply will remain fragile through 2018.

Interruption of wild poliovirus transmission

Thirty-seven cases of paralytic poliomyelitis (polio) due to wild poliovirus with onset of paralysis had been reported globally in 2016, compared to 74 for 2015. All the cases were reported from Pakistan, Afghanistan and Nigeria and were caused by wild poliovirus type 1 (Fig. 1.1).

On 20 September 2015, the Global Commission for the Certification of Poliomyelitis Eradication declared global eradication of wild poliovirus type 2. Wild poliovirus type 3 has not been detected globally since November 2012.

Fig. 1.1. Global wild poliovirus and cVDPV[a] cases [b, c] in 2016



[a] cVDPV is associated with ≥ 2 AFP cases or non-household contacts. VDPV2 cases with ≥ 6 (≥ 10 for type 1) nucleotides different from Sabin in VP1 are reported here.
[b] Excludes viruses detected from environmental surveillance.
[c] In Nigeria, 1 cVDPV2 from a healthy child contact of WPV1 case (specimen collected 26 Aug 2016).
Source: WHO; data as of June 2017.

Endemic countries – Afghanistan, Pakistan and Nigeria

Owing to continued cross-border transmission, Afghanistan and Pakistan continue to be treated as a single epidemiological block. In Pakistan, 20 cases were reported in 2016, compared to 54 in 2015. In Afghanistan, 13 cases were reported, compared to 20 in 2015. The two countries demonstrated strong progress over the past nine months and technical advisory groups concluded that rapid interruption of transmission of wild poliovirus was feasible in both countries.

Pakistan

In Pakistan, the number of polio cases continues to decline. The year 2016 saw the lowest-ever annual number of polio cases in the country but environmental surveillance continues to detect poliovirus over a wide geographical range, indicating ongoing transmission. Two of the three core reservoirs of poliovirus (Karachi and Peshawar) have demonstrated encouraging progress in 2016. A national emergency action plan for the disease is being overseen directly by the Office of the Prime Minister. Emergency operations centres at federal and provincial/regional levels ensure almost real-time monitoring of activities,

implementation of corrective action and increased accountability at all levels. Efforts are focused on interrupting the remaining core reservoir in Quetta, Balochistan, and to address cross-border reservoirs with neighbouring Afghanistan.

Afghanistan

In Afghanistan, the number of polio cases continues to decline steadily with cases reported from just four districts. Polio eradication is a priority of the Afghanistan Government's health agenda: In 2015 and 2016, the Government scaled up its efforts to accelerate polio eradication nationally amid multiple complex challenges, including increasing conflict and insecurity in many parts of the country. The National Emergency Action Plan continues to serve as the guiding document for its polio eradication activities. Emergency operation centres at the national and regional levels are aligned under this plan, as are efforts of all partners. The Government also coordinates activities with Pakistan to address cross-border reservoirs.

Nigeria

In Nigeria, four cases of poliomyelitis due to wild poliovirus type 1 were confirmed in July and August 2016 from Borno State, the first reported from the country since July 2014. Genetic sequencing of the isolated viruses indicate they are most closely linked to a wild poliovirus type 1 last detected in Borno State in 2012. High-quality vaccination and surveillance in many areas of the State is impossible due to conflict, which is likely the reason why this strain has circulated undetected since that time. The Government of Nigeria immediately launched an aggressive outbreak response according to revised international outbreak response protocols, with five rounds of large-scale supplementary immunization activities (SIAs) to deliver additional doses of bivalent oral polio vaccine (OPV) at short intervals. The Government declared the outbreak to be a national public health emergency. At the same time, additional measures are being implemented to increase the sensitivity of subnational surveillance. The response is part of a broader regional outbreak response, coordinated with neighbouring countries, in particular the Lake Chad subregion, including northern Cameroon, parts of the Central African Republic, Chad and southern Niger. At the sixty-sixth session of the Regional Committee for Africa (Addis Ababa, 19–23 August 2016), health ministers declared the polio outbreak to be a regional public health emergency for countries in the Lake Chad subregion.

International spread of wild poliovirus

Episodes of international spread of poliovirus continued in 2016 with the poliovirus circulating across the shared border of Afghanistan and Pakistan. Minimizing the risk and consequences of further international spread requires the full implementation of the eradication strategies in the remaining infected areas; comprehensive application of the Temporary Recommendations issued by the WHO Director-General under the International Health Regulations (2005) (IHR); and heightened surveillance and outbreak response preparedness plans by all Member States in order to facilitate a rapid response to new cases of poliovirus. During its teleconference (7 February 2017), the Emergency Committee of the IHR (2005) recommended extending the Temporary Recommendations for a further three months.

Vaccine-derived poliovirus outbreaks

Circulating vaccine-derived polioviruses type 1

The Lao People's Democratic Republic was affected by a circulating vaccine-derived poliovirus outbreak (type 1) in 2015 but no new cases have been reported from that country since 11 January 2016.

Circulating vaccine-derived polioviruses type 2

In Nigeria, one case of poliomyelitis due to circulating vaccine-derived poliovirus type 2 (cVDPV2) was reported in Sokoto State. A separate circulating vaccine-derived poliovirus type 2 was confirmed in Borno State; it was isolated from an environmental sample during strengthened surveillance activities in the area (collected in March 2016) and stool specimens (collected in August 2016) from a healthy contact of one of the cases of polio due to wild poliovirus type 1. Genetic sequencing of this strain indicates that it has been circulating for almost four years in the area and was last detected in northern Nigeria in November 2014. The Government of Nigeria responded fully and immediately, in line with new protocols established for the detection of vaccine-derived poliovirus type 2 in the period following the switch from use of trivalent OPV.

2017 Update

In June 2017, in the Syrian Arab Republic, a circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak was confirmed. The virus strain was isolated from acute flaccid paralysis (AFP) cases from two different governorates. Outbreak response following internationally-agreed response protocols is being implemented to stop circulation of this strain.

In May 2017 two separate, genetically unrelated, circulating vaccine-derived poliovirus type 2 (cVDVP2) were detected in two provinces of the Democratic Republic of the Congo. Following a risk analysis by the Ministry of Health, supported by WHO and partners of GPEI, outbreak response in the affected and high-risk provinces of the country was implemented in July 2017.

Emergence of such strains underscore the risks associated with subnational vaccination coverage gaps, and of the need to phase out use of OPV following the global eradication of wild poliovirus. This process has already started with the switch from trivalent OPV to bivalent OPV that began in April 2016.

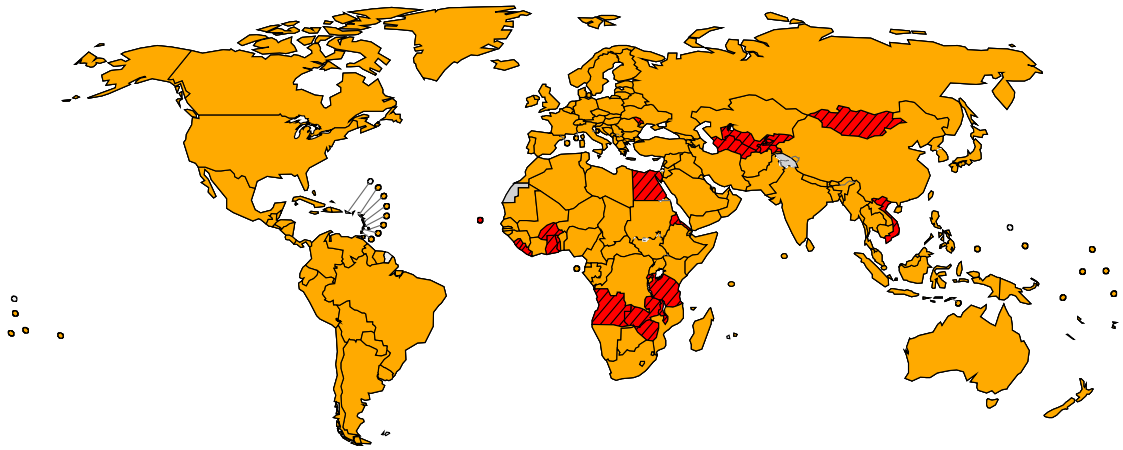
Phased removal of oral polio vaccines

The successful switch from trivalent to bivalent OPV was a milestone; it was the largest-ever withdrawal of one vaccine and associated introduction of another. To prepare for the switch to bivalent OPV, all countries had committed themselves to introduce at least one dose of IPV into their routine immunization programmes. By end-September 2016, all Member States had confirmed completion of the switch (Fig. 1.2)[5]. This achievement is a tribute to

[5] Since January 2013, the following countries have introduced IPV: Kazakhstan, Peru & Singapore (July 2013); Micronesia (August 2013); Libya (April 2014); Albania & Panama (May 2014); Nepal & Tunisia (September 2014); Philippines (October 2014); China (December 2014); Comoros, Senegal & Serbia (January 2015); Colombia & Nigeria (February 2015); Bangladesh & Maldives (March 2015); DR Congo, DPR Korea & The Gambia (April 2015); Madagascar (May 2015); Cote d'Ivoire, Grenada, Kiribati, Morocco, St Vincent and the

the extraordinary commitment, leadership and engagement of all Member States. Cessation of the use of OPV is necessary to eliminate the very rare long-term risks of vaccine-derived polioviruses associated with its use, and is a key strategy of the Polio Endgame Plan, which had been endorsed by SAGE and the World Health Assembly.

Fig. 1.2. Countries using IPV vaccine to date and countries having made a formal decision to introduce



[a] **Including partial introduction in India.**

At its meeting in October 2016, SAGE noted the reduction in supplies of inactivated polio vaccine due to technical difficulties that manufacturers have encountered in scaling up production. Currently, IPV manufacturers have only supplied less than 50% of the originally-awarded contracts by the United Nations Children's Fund (UNICEF) since 2014 *(1)*. As a result, 33 Tier 3 and 4 countries[6] will have no supply of IPV for their routine immunization programme until at least 2018.

The GPEI is exploring with Member States the feasibility of instituting dose-sparing strategies, such as using intradermal administration of fractional-dose inactivated poliovirus

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Grenadines & Sudan (June 2015); Bhutan, Cameroon, Niger, Pakistan, Philippines & Sri Lanka (July 2015); Benin, Chad, Papua New Guinea, The Former Yug. Rep. of Macedonia (August 2015); Afghanistan, CAR, Dominica, Guyana, Iran, Jamaica, Seychelles & Solomon Islands (September 2015); Bahamas, Lao People's Dem Rep, Nauru, Samoa (October 2015); Antigua and Barbuda, Botswana, Burundi, Cook Islands, Guinea, India, Mauritania, Mauritius, Mozambique, Namibia, Nicaragua, St Lucia, Suriname, Tuvalu, Vanuatu & Yemen (November 2015); Algeria, Belize, Cambodia, Dominical Rep, Ecuador, Ethiopia, Fiji, Gabon, Georgia, Honduras, Kenya, Myanmar, Paraguay, St Kitts & Nevis, S. Sudan, Thailand, Tonga & Trinidad & Tobago (December 2015); Cuba, El Salvador, Guatemala, Haiti, Iraq & Venezuela (Bolivian Rep of) (January 2016); Azerbaijan, Bolivia & Timor-Leste (February 2016); Chile & Mali (March 2016); Argentina, Congo, Djibouti, Lesotho, Sao Tome & P., Uganda (April 2016); Armenia, Guinea-Bissau, Indonesia & Swaziland (July 2016); Eq. Guinea (August 2016)

[6] Definition and Rationale of risk Tiers for IPV Introduction:
http://www.who.int/immunization_standards/vaccine_quality/4a_risk_tiers_for_ipv_introduction.pdf

vaccine. SAGE also strongly recommended that countries start preparing for use of a fractional intradermal dose of inactivated poliovirus vaccine in a two-dose schedule, in lieu of a single intramuscular full dose, a recommendation further stressed by the body's Polio Working Group at its recent meeting in Geneva, 9–10 February 2017). Some Member States, notably Bangladesh, India, and Sri Lanka, have already adopted fractional-dose schedules in their immunization programmes in order to ensure that sufficient quantities of IPV are available for continued vaccination of the full birth cohort. Following SAGE recommendations, regional technical advisory groups (RTAGs) have started to strongly encourage Member States to consider use of fractional-dose inactivated poliovirus vaccine. WHO is facilitating the discussions among regional and national technical advisory groups on the introduction of fractional-dose inactivated poliovirus vaccine; it is monitoring IPV supply and negotiating with suppliers to increase it as well. WHO is also collaborating with countries in the WHO region of South-East Asia (e.g. India, Sri Lanka) to document the experiences and lessons learned with the use of fractional-dose inactivated poliovirus vaccine.

Containment

Efforts to contain poliovirus type 2 have progressed in 2016, following the publication of the *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use* (GAPIII) *(2)*. Currently in 2017, 175 countries and territories reported that they no longer had wild- or vaccine-derived poliovirus type 2, 18 reported that they did and 12 were completing reports. Thirty countries have designated 77 poliovirus-essential facilities to retain type 2 polioviruses, but some of them still have to nominate the national authority for containment (NAC) that will be responsible to certify that these facilities meet the containment requirements described in GAPIII. In support of Member States' efforts to complete Phase I of GAPIII, guidance is being developed to help facilities identify samples that are likely to harbour type 2 polioviruses, recommending their destruction, transfer or safe and secure storage and handling. In support of the implementation of Phase II, the GPEI Secretariat has raised awareness about poliovirus containment, particularly with non-polio networks, and strengthened national capacity by training stakeholders, including national authorities and poliovirus-essential facilities about GAPIII implementation and certification. In October 2016, WHO published the *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment (3)*, which is aimed at guiding NACs in their efforts to certify facilities' compliance with the requirements of GAPIII, in consultation with the Global Commission for the Certification of the Eradication of Poliomyelitis. Furthermore, training is currently offered to auditors expected to participate in containment audits of poliovirus-essential facilities. With this support, concerned Member States are expected to complete Phase I and progress with Phase II of GAPIII, formally engaging concerned facilities in the poliovirus containment certification process.

Polio transition planning

In its 2016 Assessment Report, SAGE recommended that "*Countries with large numbers of staff and resources issued from the Global Polio Eradication Initiative are requested to describe, in their polio transition plan, how they propose to maintain and fund critical immunization, laboratory and surveillance activities that are currently supported with polio funding and staff" (4)*.

Preparing for the transition away from GPEI funding is particularly important in the 16 countries that collectively account for over 90% of GPEI resources.[7] These countries are making plans to identify and mitigate the risks associated with the downsizing of the polio programme and the eventual closure of the GPEI. Based on the decreasing polio budgets for 2016–2019 provided by the GPEI, the 16 countries are now in various stages of developing national transition plans that will have to fulfil three goals: i) ensure that functions essential to maintaining a polio-free world after eradication are sustained and integrated into existing public health programmes; ii) ensure that the lessons learned from polio eradication activities are captured and widely disseminated; and iii) where feasible and appropriate, plan for the transfer of polio capabilities, assets and processes to support other health priorities in countries. The progress in developing these national plans is being monitored by the GPEI's Transition Independent Monitoring Board.

At the WHO Executive Board in January 2017, Member States called on WHO to develop and submit a report to the World Health Assembly on the financial, human resources, programmatic and operational implications of the scaling down of the polio programme for WHO as a whole. The report *(5)* highlighted the support provided by polio-funded staff and infrastructure to immunization programmes in the 16 priority countries and the very significant risks posed to immunization goals, including GVAP targets, from the planned polio transition. The report noted that the development of the African business case for immunization – involving countries on the African continent in both the African and Eastern Mediterranean Regions – provides an opportunity to carefully identify the programmatic gaps in countries resulting from polio transition, and the advocacy and financing support that will be needed from bilateral and multilateral donors to address these risks. In addition, the report also noted the role of national governments in providing increased domestic resources, or advocating for other bilateral assistance to replace some of the GPEI funding that had been supporting immunization and surveillance activities in these countries.

During the Seventieth World Health Assembly in May 2017, Member States stressed the importance of careful planning, both to protect their long-standing investments for polio eradication, and to sustain progress in key health programmes (like immunization) that have benefited from polio resources. They requested the Director-General to prepare a detailed strategic action plan on polio transition by the end of 2017, to be submitted to the Executive Board in January 2018. This action plan will include detailed country-by-country analysis of the programmatic risks, including for Immunization, and propose mitigation efforts and the financing needed to implement them.

[7] http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/transition-planning/country-transition-planning/

To support the transition planning efforts, GPEI is developing a post-certification strategy that will outline the high level technical standards for essential functions that need to be sustained after certification to keep the world polio free, including the financial requirements that are needed to maintain these functions. The post-certification strategy will be finalized before the end of 2017, to be submitted to the Executive Board and the World Health Assembly in 2018. The post-certification strategy will also help guide countries in developing their nationals plans for sustaining essential immunization, surveillance and laboratory activities, and also identify the polio-funded assets that are non-essential, and can be re-purposed to support other health priorities.

Finance and management of the GPEI

Thanks to the generous continuing support of the international development community, including Member States (especially the countries where poliomyelitis is endemic), multilateral and bilateral organizations, development banks, foundations and Rotary International, the budget for planned activities for 2016 was fully financed. Efforts are under way to mobilize the additional US$ 1.5 billion needed to fully fund the implement the Polio Eradication and Endgame Strategic Plan and to secure a lasting polio-free world and global certification. To address this ongoing funding need, global leaders united in June 2017 at the Rotary Convention in Atlanta, USA. Public and private sector donors pledged a collective US$ 1.2 billion towards the effort, leaving a gap of US$ 300 million for 2017–2020.

Table 1.1. Acute flaccid paralysis (AFP)/polio case count in 2016, by WHO region

WHO region	AFP cases reported	Non-polio AFP rate	AFP cases with adequate specimen (%)	Wild poliovirus confirmed cases	cVDPV confirmed cases
African	32 254	8.08	95	4	1
Americas	2 302	0.98	71	0	0
Eastern Mediterranean	15 987	7.62	90	33	1
Europe	1 770	1.14	86	0	0
South-East Asia	50 801	9.43	87	0	0
Western Pacific	7 029	1.93	90	0	3

Source: WHO; data as of June 2017.

Table 1.2. Breakdown of confirmed wild poliovirus and cVDPV cases in 2016, by country

	WPV1	cVDPV type 1	cVDPV type 2
Afghanistan	13		
Pakistan	20		1
Lao People's Democratic Republic		3	
Nigeria	4		1

Source: WHO; data as of June 2017.

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3. The Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment (GAPIII-CCS). Geneva: World Health Organization; 2017 (http://polioeradication.org/wp-content/uploads/2017/02/CCS_2016EN.pdf, accessed 8 June 2017).
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5. Resolution WHA70.14 Add.1. Polio transition planning. Report from the Secretariat. In: Seventieth World Health Assembly, Geneva, 24 April 2017. Provisional agenda item 12.3, Geneva: World Health organization; 2017 (A70/14; http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_14Add1-en.pdf, accessed 9 June 2017).

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- Global Polio Eradication Initiative. Polio Eradication and End Game Strategy Plan 2013–2018. Geneva: World Health Organization; 2013 (http://polioeradication.org/wp-content/uploads/2016/07/PEESP_EN_A4.pdf, accessed 19 June 2017).

GOAL 2: MEET GLOBAL AND REGIONAL ELIMINATION TARGETS: ACHIEVE MATERNAL AND NEONATAL TETANUS ELIMINATION (INDICATOR G2.1)

DEFINITION OF INDICATOR	An incidence of < 1 case of neonatal tetanus per 1000 live births per year in all districts or similar administrative units of a country[8]; the neonatal tetanus indicator acts as proxy for maternal tetanus. To monitor sustainability of elimination, the routine Expanded Programme on Immunization (EPI), reproductive health and surveillance data will be used, as sustainability is directly linked to health system strengthening with a focus on routine delivery of immunization, antenatal care (ANC), clean delivery, clean cord care practices and surveillance activities. The draft guidelines for sustaining MNTE once achieved have been finalized and they are now awaiting final review by the SAGE Working Group on MNTE and the Director-General before publication and dissemination.
DATA SOURCES	• WHO-UNICEF Joint Reporting Forms (JRFs). • Country health management information system (HMIS) reports. • Country disease surveillance reports. • Immunization coverage survey reports. • Multiple Indicator Cluster Survey (MICS) reports, Demographic and Health Survey (DHS) reports and any other reports of immunization and reproductive health programme reviews. • Reports of maternal and neonatal tetanus elimination validation surveys.

HIGHLIGHTS

- It was noted in last year's report that the GVAP target for maternal and neonatal tetanus elimination (MNTE) for 2015 was not achieved. In 2015 (the latest year with data) about 34 000[9] neonates were estimated to have died from tetanus.

- In 2016, three additional countries eliminated MNT: Equatorial Guinea, Indonesia and Niger, in addition to the Punjab province of Pakistan.
- A success story of 2016 was Indonesia's achievement of MNTE, the last remaining country in the South-East Asia Region to do so. The focus in this region has now turned to the efforts required to sustain the countries' elimination status.
- Since 2010, 22 of the 40 countries required to meet the GVAP milestone for 2015 had achieved elimination.

[8] Please refer to GVAP Secretariat Report 2013 for more information: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_secretariat_report_2013.pdf?ua=1

[9] http://www.who.int/immunization/diseases/MNTE_initiative/en/

- A total of 41 of the 59 priority Member States (70%) had achieved MNTE as of December 2016.
- At the end of 2016, maternal and neonatal tetanus (MNT) still continued to be a public health problem in 18 Member States[10]. These countries have developed their MNTE plans of action as part of comprehensive multi-year planning. Competing health priorities, however, are a challenge to the timely implementation of the planned activities.

Introduction and background

Tetanus is an acute, potentially fatal disease caused by a neurotoxin produced by the bacterium *Clostridium tetani* that is commonly found in the soil and in the intestinal tracts of animals and humans. As such, the disease cannot be eradicated. Maternal and neonatal tetanus (MNT) are forms of generalized tetanus affecting mothers during pregnancy, due to unclean abortion or delivery, and infants during the first month of life. Neonatal tetanus (NT) infection begins when *C. tetani* spores are introduced into the umbilical tissue during delivery. The organisms produce a neurotoxin at the site of the umbilical cord wound which passes into the blood-stream of the newborn infant and into the central nervous system. This results in motor neuron hyperactivity, hypertonia and muscle spasms. Death occurs as a result of paralysis of the respiratory muscles and/or inability to feed.

The global estimate of neonatal tetanus deaths declined from over 780 000 in 1988 *(1)* to 34 000 in 2015 *(2)*, a 96% reduction over 27 years—a result of implementing the recommended strategies. SAGE commented on the guidelines for sustaining MNTE. These comments will be addressed in the latter half of 2017 and the guidelines disseminated thereafter. This will provide a number of options to Member States on appropriate responses that may be required following periodic desk reviews of MNT risk indicators. The updated WHO position paper on tetanus was published in February 2017 *(3)* to reflect updates from SAGE, which included aligning it with the diphtheria and tetanus position papers, emphasizing the booster doses including in the second year of life, and stressing the need to shift from tetanus toxoid (TT) to tetanus diphtheria (Td) vaccine starting from 4 years of age.

Results

Since 2010, the total number of countries that achieved elimination is 22 of the 40 required to meet the GVAP milestone for 2015. As of December 2016, a total of 41[11] of the 59 priority Member States (70%) had achieved MNTE (see Table 1.3 and Fig. 1.3).

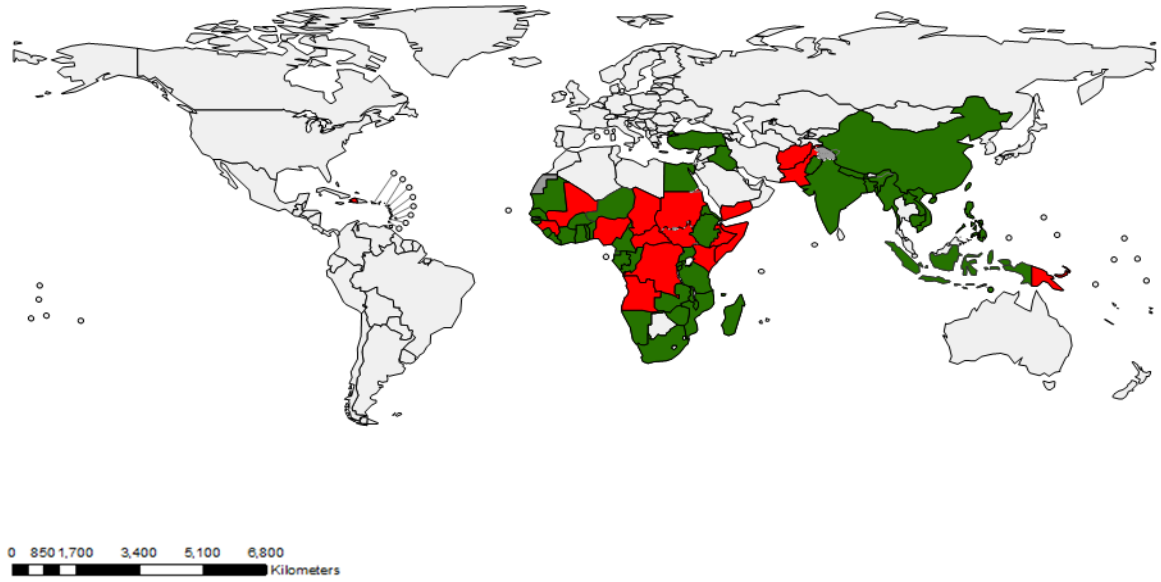
[10] Afghanistan, Angola, the Central African Republic, Chad, the Democratic Republic of the Congo, Ethiopia (Somali Region), Guinea, Haiti, Kenya, Mali, Nigeria, Pakistan, Papua New Guinea, Philippines (Autonomous Region of Muslim Mindanao), Somalia, Sudan, South Sudan and Yemen.

[11] Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Cameroon, China, Comoros, Congo, Côte d'Ivoire, Egypt, Equatorial Guinea, Eritrea, Gabon, Ghana, Guinea Bissau, India, Indonesia, Iraq, Lao People's Democratic Republic, Liberia, Madagascar, Malawi, Mauritania, Mozambique, Myanmar, Namibia, Nepal, Niger, Rwanda, Senegal, Sierra Leone, South Africa, Timor-Leste, Turkey, Togo, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

Table 1.3: Timeline of MNT elimination, 2011–2016

2011	Four Member States were validated as having achieved MNTE in 2011 (Ghana, Liberia, Senegal and Uganda) in addition to Ethiopia (excluding the Somali Region) and Indonesia (the third of the four phases)
2012	Six Member States (Burkina Faso, Cameroon, China, Guinea Bissau, Timor-Leste and the United Republic of Tanzania) were validated as having eliminated MNT
2013	Five additional Member States (Cote d'Ivoire, Gabon, Iraq, Lao People's Democratic Republic and Sierra Leone) and three additional areas in India (Mizoram and Uttarakhand States and Delhi Union Territory) achieved elimination bringing the total number of areas that achieved elimination in India to 18 out of 35 at the time
2014	Madagascar eliminated MNT as did 12 additional states of India (Andaman & Nicobar Islands, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Daman & Diu, Jharkhand, Madhya Pradesh, Odisha, Rajasthan, Tripura and Uttar Pradesh)
2015	Three Member States (Cambodia, India and Mauritania) and 16 of 17 regions of the Philippines achieved MNTE
2016	Three Member States (Equatorial Guinea, Indonesia and Niger) and Punjab Province (the largest province in Pakistan) achieved MNTE

Fig. 1.3: Member States with validated elimination of neonatal tetanus (as of December 2016)[a]



[a] This includes Ethiopia (except the Somali Region), 16 of 17 regions in the Philippines and the Punjab Province of Pakistan.

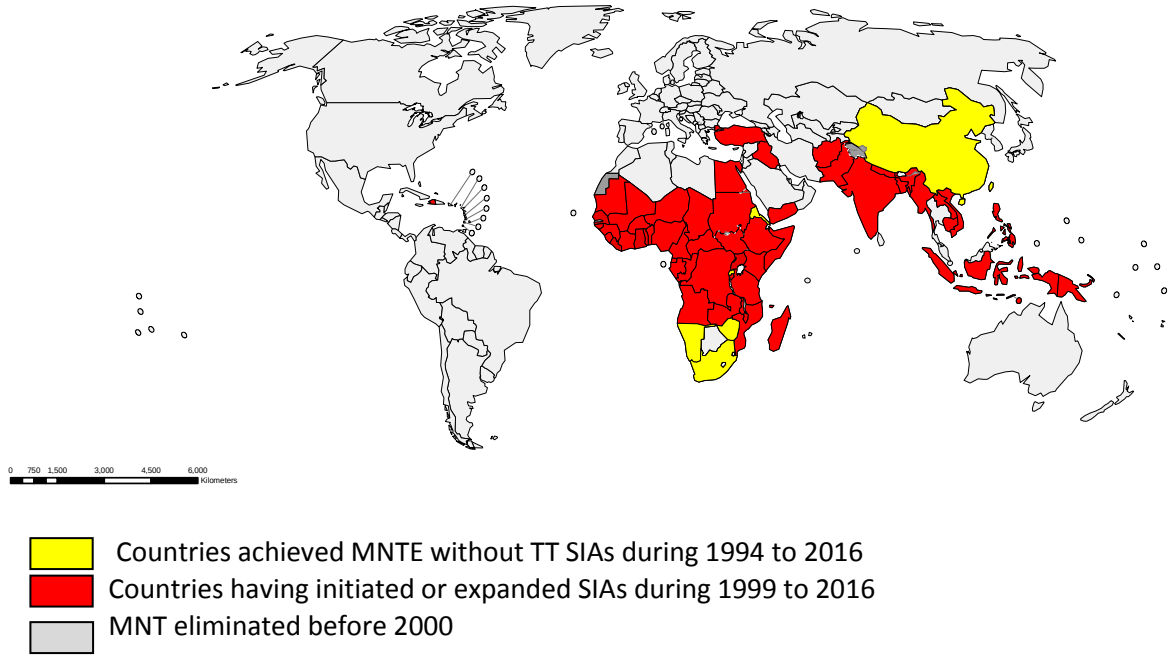
- Not eliminated
- Eliminated prior to 2000
- Eliminated since 2000

Source: WHO-UNICEF database, 6 July 2017.

In addition in 2016, TT vaccination campaigns targeting women of reproductive age (15–49 years) were conducted in 10 Member States[12] maintaining the total number of countries that have implemented TT SIAs from 1999 to 2016 to 53 (Fig. 1.4).

[12] Chad, Ethiopia, Guinea, Kenya, Nigeria, Pakistan, Papua New Guinea, Philippines, South Sudan, Sudan.

Fig. 1.4: The 53 Member States that implemented TT SIAs between 1999 and 2016



Source: WHO-UNICEF database, as of 6 July 2017.

Discussion: Areas requiring focus in order to keep progress on track towards the attainment of "MNTE in all countries"

In September 2016 SAGE provided recommendations *(4)* to ensure that the remaining priority countries attain MNT elimination, and that all countries that have achieved elimination receive the necessary guidance to sustain it. The issue of gender and geographic inequity in access to tetanus toxoid-containing vaccines (TTCV) is also to be addressed by SAGE, as well as the US$ 125 million (inclusive of TT Uniject cost of US$ 33 million) funding gap that is a serious challenge to the global goal for achieving MNTE. Contributions and advocacy from national governments have proved instrumental in the achievements thus far recorded, as has funding from the private sector – Kiwanis International, Procter & Gamble and Pampers – and other international organizations such as the UNICEF National Committees. To maintain this momentum, it is now the time for individual and collaborative fundraising efforts by all MNTE partners to tap bilateral and multilateral donors.

Targeted campaigns for women of reproductive age in high-risk areas with TTCV have protected over 180 million women globally (Fig. 1.5). However, 58 million women of reproductive age still remain to be reached through SIAs in the remaining 18 countries that have not yet attained MNTE. Timely availability of resources including funds has been dictating the phase of work in terms of reaching more women of reproductive age with protective doses of TTCV during SIAs (Fig. 1.6), and this will be critical to the implementation of countries' action plans.

The reflection of MNTE plans in the comprehensive multi-year plan (cMYP) shows national commitments, but the execution of the plans depends on prioritization and allocation of

resources by national governments. The target date for the attainment of MNTE cannot therefore be ascertained based on TT vaccination plans in the cMYP. However, it is envisaged that almost all of the remaining 18 countries will achieve elimination by the DoV target of 2020 – if the implementation challenges are addressed.

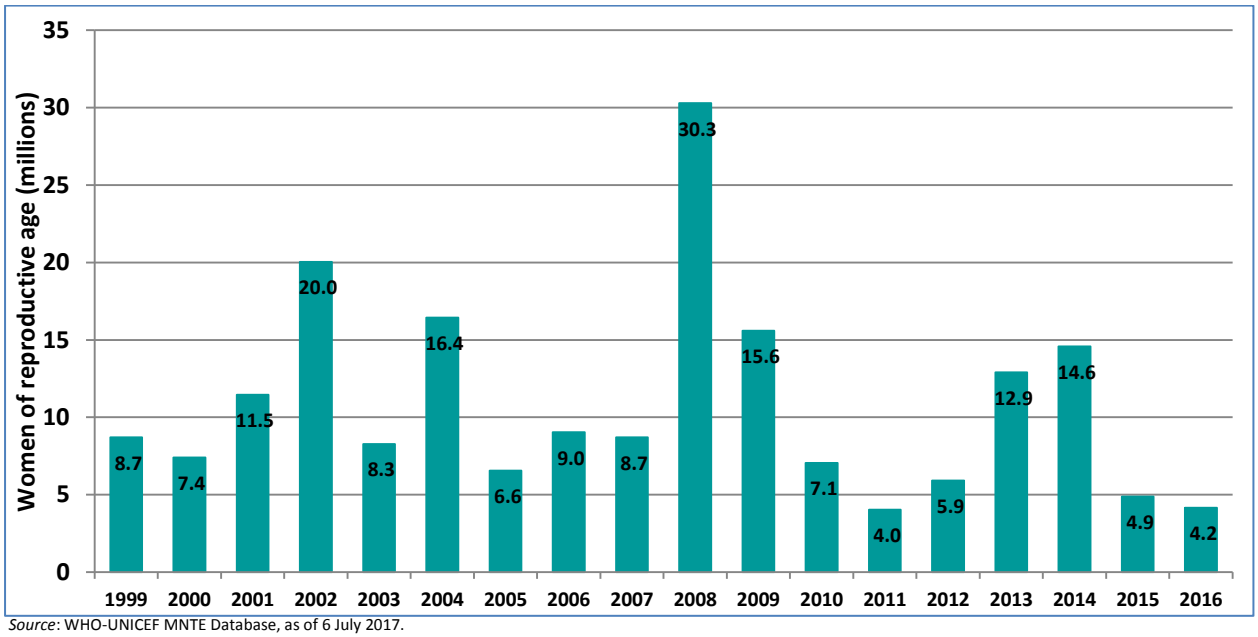
One of those challenges is vaccinating high-risk populations, primarily due to geographical difficulties and/or security challenges. Nine of the 18 countries that have yet to attain MNTE have such populations: Afghanistan, the Central Africa Republic, Chad, Mali, Nigeria, Pakistan, Somalia, Sudan, South Sudan and Yemen. TT Uniject is required in these countries. The use of TT Uniject by lay health workers after brief training in Afghanistan, Pakistan, Ghana, Mali and Somalia in the past attained coverage levels of at least 80% for TT3 *(5)* and an assessment of the experiences of the use by the Program for Appropriate Technology in Health (PATH) found that the vaccine was correctly administered, safe injection techniques were applied and no serious side-effects reported *(5).*

Integration of the Expanded Programme on Immunization (EPI) with guidelines on antenatal care (ANC) needs to be enhanced within Initiatives such as the Reaching Every Child approach or the Mother & Child Health Days. A package of high-impact interventions can be integrated into these efforts to support the most underserved communities. WHO now recommends at least eight ANC visits to give adequate opportunity for a pregnant woman to reduce perinatal mortality and improve her experience of care. This will allow a woman to receive all her due doses of TTCV based on her tetanus vaccination status, alongside other life-saving interventions.[13] Coverage levels for ANC (https://data.unicef.org/topic/maternal-health/antenatal-care/) and institutional delivery (https://data.unicef.org/topic/maternal-health/delivery-care/) show the most recent data from surveys (updated in December 2016).

These important aspects of MNTE rely heavily on the performance of health systems and often progress slowly unless there is a concerted effort by governments. For example in China and India national resources were used to provide incentives to mothers to deliver in health facilities, an approach that is most sustainable when governments invest the use of domestic resources.

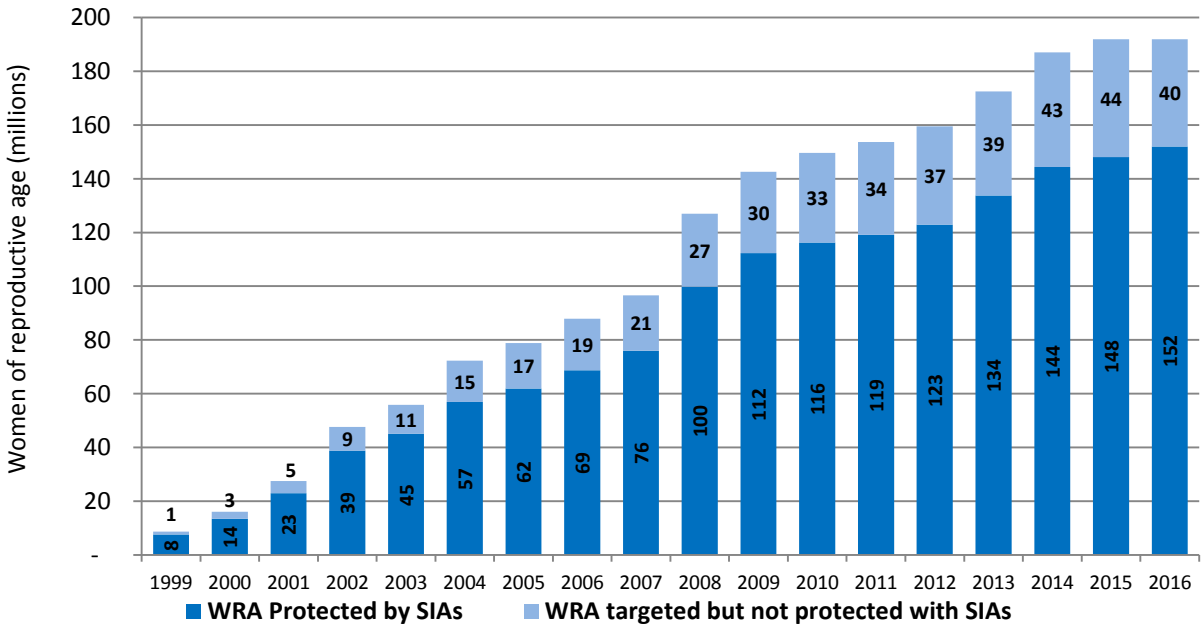
[13] WHO recommendations on antenatal care for a positive pregnancy experience. I.World Health Organization. ISBN 978 92 4 154991 2
http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1

Fig. 1.5: Number of women of reproductive age targeted during TT SIAs, by year



Source: WHO-UNICEF MNTE Database, as of 6 July 2017.

Fig. 1.6. Cumulative number of women of reproductive age protected with at least 2 doses of TT during SIAs, by year



Source: WHO-UNICEF MNTE Database, as of 6 July 2017.

2017 update

In 2016, the SAGE Working Group on Maternal and Neonatal Tetanus Elimination and Broader Tetanus Prevention proposed actions and timelines to achieve MNTE by 2020, which were endorsed by SAGE in October of that year. The countries that SAGE considered being likely to eliminate MNT by 2018 include Angola, Chad, Ethiopia, Haiti, Kenya, the Philippines and South Sudan. Of those, Ethiopia and Haiti sought validation of the elimination of MNT in June 2017 (see Annex 1.1).

There remain 16 priority countries yet to achieve MNTE, among which two have partially eliminated MNT: Pakistan (Punjab Province) and the Philippines (16 of 17 regions, except ARMM). All the remaining 16 countries are eligible for support from Gavi, the Vaccine Alliance (Gavi) support, except the Philippines.

Validation surveys are planned for the Philippines and the southeastern region of Nigeria in 2017. A pre-validation assessment of another region has also been conducted in Nigeria in 2017 and more of these assessments are planned for later in the year in Chad, the Democratic Republic of the Congo, Kenya and Pakistan (Sindh Province).

Chad, Kenya and the Philippines have completed planned activities and are close to achieving elimination. Angola and the Democratic Republic of the Congo are planning corrective activities in order to maintain the momentum towards MNTE.

A significant part of Nigeria, a significant part of Pakistan, Papua New Guinea and Sudan are lagging in their efforts to eliminate MNT, despite their relatively stable political situation (see Annex 1.2). South Sudan made significant progress towards eliminating MNT soon after its independence in 2011, and is one of the countries projected to achieve elimination before the end of 2018. The recent resurgence of fighting and increasing insecurity do, however, put the country at risk of missing the 2018 deadline. Other countries affected by political instability include Afghanistan, the Central African Republic, Mali, Somalia and Yemen. Efforts must be made to lobby donors to fund innovative approaches like TT Uniject to reach the vulnerable populations in these countries.

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Annex 1.1: Update on the status of implementation of the October 2016 SAGE recommendations

	SAGE recommendation	Progress so far
1	*"Achieve elimination targets for maternal and neonatal tetanus, measles, rubella and congenital rubella syndrome. The Maternal and Neonatal Tetanus and Measles and Rubella Initiatives are each requested to develop an investment case that specifies the additional funding required to achieve and sustain elimination targets in routine immunization programmes and use the investment case to solicit necessary support from donors and national governments by the end of July, 2017."*	The MNTE investment case is currently being developed in collaboration with UNICEF, WHO and the United Nations Population Fund (UNFPA) and support from contractors. The initial output on the investment case focusing on the needs of the remaining priority countries is expected by September 2017.
2	"UNICEF, UNFPA, and WHO should make all efforts to secure timely supply of the available WHO prequalified TT vaccine in compact single-dose pre-filled auto-disable injection devices to facilitate vaccination of inaccessible populations by community workers."	A proposal has been submitted to the Gavi Alliance Policy and Programme Committee requesting financial assistance to support the production and availability of this critical pre-filled device. A concept note is being finalized in the context of using this initiative as a test case to assess the total system effectiveness to support the use of TT in the Uniject presentation to achieve public health objectives. The total system effectiveness in the context of innovation and markets is new and the Bill & Melinda Gates Foundation is actively involved in this effort.
3	*"UNICEF, United Nations Population Fund (UNFPA), and WHO should support countries in securing the necessary resources to implement their national elimination plans, including procurement of Td vaccine and operational costs for SIAs."*	A stakeholder's meeting was convened at the end of November 2016 to follow up on this and the existing partners reiterated their commitment until 2019–2020. The concept note produced was to secure funding for TT Uniject from Gavi, with active collaboration of the Bill & Melinda Gates Foundation. The final draft of MNTE investment case to facilitate resource mobilization to help support countries to implement their elimination activities is expected September 2017.
4	*"UNICEF, UNFPA and WHO should work with countries to generate and sustain political commitment to maintaining*	All opportunities including the Regional Immunization Technical Advisory Group meetings and Immunization Managers'

	SAGE recommendation	Progress so far
	elimination of MNT, in order to guard against complacency once a country has been declared to have achieved elimination."	meetings are being utilized to advocate countries sustain their MNTE status. MNTE was discussed in 2017 in the Regional Immunization Technical Advisory Group meetings of the African, South-East Asia and Western Pacific Regions. Additionally, efforts are being made to finalize and disseminate the guidelines on sustaining MNTE to ensure that countries are guided through the appropriate steps to sustain their achievements.
5	*"Where feasible, the use of sero surveys to validate assessment of risk identified from other data sources should be considered to guide vaccination strategies, especially in high-risk districts. Close attention should be paid to sampling strategies and laboratory methods to ensure that results are valid and interpretable."*	This recommendation has not yet progressed much as yet. Discussions initiated between UNICEF and CDC on the feasibility of combining some of the MNTE validation surveys with serosurvey.

Annex 1.2: Status of MNT elimination in countries

Country category and definition	***List of countries in this category***	**Progress**
Countries at likely to attain MNTE by 2018	Angola, Chad, Democratic Republic of the Congo, Ethiopia, Guinea, Haiti, Kenya, Philippines, South Sudan	Ethiopia and Haiti were validated as having attained MNTE in June 2017. Chad, the Philippines and Kenya have completed planned activities and assessments are planned to begin at the end of 2017. Angola and the Democratic Republic of the Congo are planning corrective actions in some areas, to prepare for assessments. South Sudan is affected by conflict, however, the country is on course to attain MNTE, with completion of third round of SIAs in 2017. Guinea is reviewing the MNTE risk status of districts and planning further implementation of SIAs.
Countries likely to attain MNTE by 2019	Papua New Guinea, Sudan	Implementation efforts in Papua New Guinea and Sudan are lagging; implementation is on hold in Papua New Guinea due to upcoming elections and some logistical issues in Sudan.
Countries likely to achieve MNTE by 2020	Afghanistan, Central African Republic, Somalia, Mali, Nigeria, Pakistan, Yemen	Afghanistan, Central African Republic and Somalia: Implementation of MNTE activities has stalled due to a mix of low commitment and insecurity, requiring advocacy and preferably TT Uniject devices to the meet validation timeline of 2020. Mali is planning TT SIAs in the northern part of the country following a risk assessment; a pre-validation assessment for the south is under discussion with the country team. Nigeria has conducted pre-validation assessments in the southeast and southwest regions of the country. The validation survey for the southeast zone is scheduled for 9–30 Oct 2017 while a few areas are conducting corrective activities in the southwest prior to conducting a validation survey. Nigeria's South South geopolitical zone is reviewing risk to commence implementation of TT SIAs early next year. The remaining three northern regions will be reviewed early next year to plan implementation of MNTE activities in a phased manner to meet the goal by 2020. Pakistan has embarked on a province-by-province approach. Punjab Province achieved MNT elimination in 2016. Sindh province has completed TT SIAs and is preparing for a pre-validation assessment. Further MNTE activities are planned in another two at-risk provinces

		with larger populations (Balochistan and Khyber Pakhtunkhwa). Yemen has resumed implementation of SIAs in a phased approach with the aim of achieving MNTE by 2020. The country has completed the 1st round in 46 districts and is planning the 2nd round for October 2017.

GOAL 2: MEET GLOBAL AND REGIONAL ELIMINATION TARGETS: ACHIEVE MEASLES ELIMINATION

(Indicator G2.2)

DEFINITION OF INDICATOR	Framework for verification of measles elimination *(1)* lists the following. • Measles eradication: worldwide interruption of measles virus transmission in the presence of a surveillance system that meets specified performance indicators. • Measles elimination: the absence of endemic measles transmission in a defined geographical area (e.g. region or country) for ≥ 12 months in the presence of a well-performing surveillance system. Note: Verification of measles elimination takes place after 36 months of interrupted endemic measles virus transmission.
DATA SOURCES	• WHO-UNICEF Joint Reporting Forms (JRFs) for disease incidence and WHO-UNICEF estimates of national immunization coverage (WEUNIC) data for coverage rates. • Progress reports of the regional verification commissions from the Regions of the Americas, Europe, and the Western Pacific for outbreak data and status of countries with regard to elimination as of 31 December 2016.
COMMENTS ON DATA QUALITY	• JRFs and WUENIC data are subject to the same limitations as all other data submitted via the JRFs, as described in the 2016 GVAP Secretariat report *(2)*. • Regional verification commission reports are only available from four regions: European Region, Region of the Americas, South-East Asia Region and the Western Pacific Region.
MILESTONES	• Measles elimination goals by WHO region *(3)*: – Region of the Americas: last endemic case in 2002 and verified as having eliminated measles in 2016 – Western Pacific Region: elimination by 2012 – European Region: elimination by 2015 – Eastern Mediterranean Region: elimination by 2020 – African Region: elimination by 2020 – South-East Asia Region: elimination by 2020.

Highlights

- In 2016, 41% and 26% of Member States globally reached the respective MCV1 and MCV2 targets of at least 95% coverage. MCV1 coverage has stagnated at the same level for the past five years. The global MCV1 and MCV2 coverage levels were 85% and 64%, respectively – both short of the programme targets.
- Since 2010, global measles incidence has decreased 62% from 50 cases per million population in 2010 to 19 in 2016. However, only 88% of Member States reported measles surveillance data in 2016 compared to 97% in 2010. The 2016 global measles incidence is substantially higher than the global 2015 target of fewer than 5 cases per million population.
- Between 2000 and 2015[14], estimated measles deaths decreased by 79% (from 651 600 in 2000 to 134 200 in 2015); compared with no measles vaccination, an estimated 20.3 million child deaths were prevented by measles vaccination during this period. However, the target of a 95% mortality reduction by the end of 2015 was not met.
- The 2015 global milestones for MCV1 coverage and measles incidence were still not achieved in 2016. The 2015 goal for measles mortality reduction was not achieved on time either.
- In 2016, 20.8 million infants did not receive the first dose of MCV1. In decreasing order, the following six large Member States had the highest numbers of unvaccinated infants: India, Nigeria, Pakistan, Indonesia, Ethiopia, and the Democratic Republic of the Congo.
- An external mid-term review of the Global Measles and Rubella Strategic Plan 2012–2020 was conducted in 2016 and its findings reported to SAGE in October 2016.
- For Member States with routine measles coverage < 90% nationally (71 Member States in 2016), reaching and sustaining ≥ 95% coverage will require substantial additional investments over a sustained period.

Background and progress

The impact of the measles vaccine on global public health has been tremendous. Before 1963, most of the world's population had been infected with measles virus by their 15th birthday, resulting in an estimated 100 million cases and more than 2 million deaths annually *(4)*. By 2000, four decades of steadily increasing use of the vaccine had led to a dramatic reduction in the number of cases to just over half a million annually. In 2016, the Region of the Americas was verified as having eliminated measles.

The sixty-third World Health Assembly in 2010 endorsed three global measles targets for 2015 as milestones towards global eradication of measles;[15] however, progress in meeting them has been slow.

[14] The mortality estimates for 2016 were not available at the time of writing this report.

[15] The global milestones endorsed are to: 1) exceed 90% coverage with the first dose of MCV nationally and exceed 80% vaccination coverage in every district or equivalent administrative unit; 2) reduce annual measles incidence to fewer than 5 cases per million and maintain that level; 3) reduce measles mortality by 95% or more in comparison with 2000 estimates.

Between 2010 and 2016, global routine measles vaccine coverage stagnated at 85% – well below the 2015 target of ≥ 90% (**Table 1.4**). Three of the six WHO regions have sustained measles-containing vaccine (MCV1) coverage above 90% (Region of the Americas, European Region and Western Pacific Region), one region achieved coverage between 80 and 90% (South-East Asia Region) and two regions failed to reach 80% coverage (African Region and Eastern Mediterranean Region). The number of Member States achieving the global MCV1 coverage target at the national level has decreased in 2016 as compared to 2010; 123 Member States achieved the ≥ 90% MCV1 national coverage target in 2010 but only 120 achieved the target in 2016[16] **(Table 1.4 and Fig. 1.7**). Middle-income countries without Gavi support have MCV1 national coverage rates comparable with high-income countries (94%), see **Table 1.5**.

[16] It should be noted that the 90% MVC1 coverage target for 2015 is a milestone towards elimination. In order to achieve the regional elimination targets, vaccination coverage needs to be > 95% for two doses of MCV administered through routine immunization or routine immunization and SIAs. To prevent measles outbreaks, this high level of coverage needs to be achieved uniformly across all districts and across people in all age groups born since the introduction of measles vaccine.

Table 1.4: Number of measles cases and incidence by WHO region, 2014–2016 and baseline 2010

WHO region	WHO-UNICEF estimates for MCV1 national coverage (%)					Percentage of Member States reporting confirmed measles cases in their JRF[a]				Measles incidence per million population					Percentage of Member States with incidence less than 5 per million population				
	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	% change 2010–2016
African	72	72	72	73	-1	96	98	100	98	37	53	76	232	-84	51	52	51	30	+70
Americas	92	92	92	93	-1	94	97	100	100	0	1	2	0	0	100	97	97	100	0
Eastern Mediterranean	77	75	75	81	-5	86	100	90	90	10	33	29	17	-41	44	38	21	40	-10
European	93	94	94	93	0	85	89	77	98	5	30	19	34	-85	84	72	58	69	+21
South–East Asia	87	86	85	83	5	100	100	91	100	14	25	23	30	-53	27	45	50	36	-25
Western Pacific	96	96	96	96	0	67	63	63	92	31	35	71	27	-15	37	59	35	68	-45
Total	**85**	**85**	**84**	**85**	**0**	**88**	**91**	**87**	**97**	**19**	**29**	**40**	**50**	**-62**	**69**	**65**	**57**	**60**	**+15**

[a] Excludes Antigua and Barbuda, Israel, Kuwait, Monaco, Niue, Nauru, Poland, Portugal, Singapore and Switzerland, which did not report measles data in the JRF.

Source: JRF data, as of 23 June 2017.

Since 2010, global reported measles incidence has decreased by 62% from 50 cases per million population in 2010 to 19 in 2016 with only one region (Region of the Americas) meeting the global 2015 target of fewer than 5 cases per million population (Table 1.4 and Fig. 1.8). During the same period, there was a 13.3% increase in the number of Member States (69% of Member States in 2016 compared to 60% Member States in 2010) meeting the global incidence target for 2015.

Between 2000 and 2015, estimated measles deaths decreased by 79% (from 651 600 in 2000 to 134 200 in 2015) and all regions reported substantial reductions in estimated measles mortality. However, the progress since 2010 has been too slow and the target of 95% mortality reduction was not achieved.

Disease burden remains considerable among middle-income countries not supported by Gavi, with an incidence of 12 cases per million population, compared to 3 cases per million population among the high-income countries group (Table 1.9). However, 92% of middle-income countries not supported by Gavi had introduced MCV2 by the end of 2016, which helped to boost global coverage of MCV2 to 64% (compared to 39% in 2010) (Fig. 1.9). And four additional Member States have introduced a second dose of MCV into their routine immunization programmes since 2015 (to 85% – an increase of 15% of those offering the vaccine in 2010).

An external mid-term review of the Global Measles and Rubella Strategic Plan 2012–2020 was conducted in 2016 *(5)* and reported its findings to SAGE in October 2016. SAGE endorsed the main recommendations *(6)* – in particular, that the basic strategies in the strategic plan are sound, and that failure to reach global targets is mainly due to lack of country accountability and global political will, as reflected in insufficient resources. SAGE also supported the key recommendations from the mid-term review for strengthening disease surveillance, among other key recommendations shown below.

- Although all six regions have measles elimination goals with the ultimate vision of a world free of measles, it is premature to set a date for eradication at this point.
- Strengthening immunization systems is critical to achieving regional elimination goals. Working to achieve measles and rubella elimination can help strengthen health systems in general and immunization systems in particular.
- The report recommends a shift from primary reliance on supplementary immunization activities (SIAs) to routine immunization services to assure two doses of MCV are delivered to the target population. Regular high-quality SIAs will still be necessary while routine immunization services are being strengthened.
- The report recommends that the measles/rubella vaccination programme be considered an indicator for the quality of the overall immunization programme and that measles/rubella incidence and measles and rubella vaccination coverage be considered as primary indicators of immunization programme performance.

In October 2016, SAGE removed the introduction criterion for the routine administration of MCV2 stressing that the addition of MCV2 in the second year of life reduces the accumulation of susceptible children by immunizing those who did not respond to MCV1 or did not receive the first dose. This measure has the further advantages of potentially lengthening the period between campaigns, helping to establish a routine visit during the second year of life to ensure the well-being of the child and reducing the risk of outbreaks.

Among countries that provide MCV2 to infants less than 2 years of age *and* have reported coverage both for MCV1 and MCV2, the difference between MCV1 and MCV2 has gradually declined: 15% drop out in 2014; 14% drop out in 2015; 11% drop out in 2016.[17] Although progress is being made to reduce the MCV1 to MCV2 coverage gap, the data highlight the missed opportunities and routine system weaknesses that contribute to suboptimal population immunity and the inability to interrupt measles virus transmission.

Many countries regularly supplement routine efforts through the use of SIAs. In 2016, 39 preventive SIAs vaccinated more than 119 million children in 24 Member States, with six of those (25%) providing one or more additional child health interventions during the SIA. Coverage was reported as ≥ 95% in 56% of the 39 SIAs conducted in 2016 (based on doses administered); however, among the eight countries conducting post-SIA coverage surveys in 2016, only three estimated coverage at ≥ 95%.

Given these gaps in coverage and population immunity, it is not surprising that outbreaks continue to threaten the achievement and sustainability of regional elimination goals.

Regional review

In the African Region, eight countries (Congo, the Democratic Republic of the Congo, Equatorial Guinea, Ethiopia, Gabon, Liberia, Nigeria, South Sudan) experienced quite high incidence of measles in 2016. The highest was documented in Equatorial Guinea, with incidence rates of 1881 per million population, while Nigeria reported the largest number of confirmed measles with 17 136 measles cases. Outbreaks are mainly the result of suboptimal MCV1 coverage levels, poor-quality SIAs in many countries and epidemiological susceptibility to measles in older age children and adolescents. In Nigeria in particular, it was noted that the incidence was 112 per million in the Northern States, while it was 2.8 in the Southern States. On the other hand, the age-specific incidence of measles in the Northern States was 527 per million in the under-5 age group, and 152 per million in the 5–9 years age group, indicating the large immunity gaps persisting into school age.

During the Pan American Health Organization's (PAHO) 55th Directing Council on 27 September 2016, the International Expert Committee for Documenting and Verifying Measles and Rubella Elimination announced that after reviewing all of the epidemiological evidence presented by the Member States for the period 2011–2016, the Region of the Americas had eliminated measles. The Region reached the goal of eliminating endemic transmission of the measles virus in 2002 and has maintained this status for over a decade, despite constant importations of the virus from other regions in the world. However, maintaining the status in an increasingly interconnected world will be an ongoing challenge

[17] For each calculation year, countries that had not introduced the vaccine for one full year were excluded.

in the coming years because countries are constantly at risk of importing and reintroducing the viruses and thus undoing the progress they have made. During 2016, 93 confirmed cases of measles were reported in three countries of the Region of the Americas, reaching the lowest incidence rate in the history of the Americas (0.093 per million population). However, in that same year, there was a significant decrease in the reporting rate of suspected cases, reaching its lowest point with 1.9 per 100 000 population. The confirmed measles cases were reported in Canada (11 cases), Ecuador (1 case) and the United States (80 cases, not reported through the JRF). Thirty per cent of the cases affected adults aged 20–39 years old. Four countries conducted follow-up campaigns during 2016, achieving between 94–99% of coverage nationwide.

PAHO will propose a plan of action at the next Pan American Sanitary Conference to guarantee the sustainability of measles and rubella elimination during the period 2018–2023. The plan's objective is to maintain a high level of immunity against these viruses in the general population and maintain high-quality surveillance systems to avoid the re-establishment of endemic transmission.

The Eastern Mediterranean Region has seen a significant decrease in the reported numbers of cases in 2016 (6139 cases) compared to 2015 (21 418 cases). In 2016, outbreaks occurred in Afghanistan, Pakistan, Sudan and Yemen. The majority of the reported outbreaks affected children under 10 years of age, indicating poor implementation of routine vaccination and poor quality of SIAs.

In the European Region, 2016 saw the lowest number of measles cases in the Region (4167 cases) reported in 45 countries that submitted measles data (including zero reporting) through the JRF. However, transmission and outbreaks continued in a number of countries. Romania and Italy had the most cases (64%) and the highest incidence of the disease. The majority of the reported cases in 2016 were of unvaccinated people. One third of the cases were among children aged 1–4 years.

The South-East Asia Region has made significant progress towards measles elimination in 2016. Countries of the Region have initiated implementation of activities outlined in the Strategic Plan for Measles Elimination and Rubella and Congenital Rubella Syndrome Control in the South-East Asia Region[18]. India continued to report the most cases (17 250) of measles followed by Indonesia (6962), of the 82 006 cases reported in the South-East Asia Region overall. In 2016, the measles virus continued to circulate in most countries of the Region, except in Bhutan, the Democratic People's Republic of Korea and the Maldives. (While 45 cases were reported in Bhutan in 2016, these were attributed to importations, based on epidemiological and virological investigations.) While the completeness and quality of investigations of suspect cases varied among countries, it is clear that the main cause of continued measles cases in most countries of the Region was low coverage with measles vaccine, despite two doses of MCV being a part of the routine schedule in all 11 countries of the Region. Coverage with MCV1 in routine immunization has increased to 87% in 2016. However, nearly 4.5 million children remain unvaccinated with MCV annually (2.9

[18] Strategic plan for Measles Elimination and Rubella and Congenital Rubella Syndrome Control in the South-East Asia Region 2014-2020:
http://www.searo.who.int/entity/immunization/documents/sear_mr_strategic_plan_2014_2020.pdf

million in India and 1.2 million in Indonesia). Around 6.8 million children were reached with measles/rubella-containing vaccine (M/RCV) in 2016 through mass-vaccination campaigns. Phased, wide-age range, mass-vaccination campaigns with measles-rubella vaccine are planned for India and Indonesia during 2017–2018, targeting more than 470 million children aged 9 months to 15 years. Approximately 3260 suspected outbreaks were reported in the Region in 2016, 63% of which were investigated (compared to 57% investigated in 2015). All countries investigated 100% of the reported outbreaks except India (55%) and Indonesia (70%). The measles rubella laboratory network in the Region has expanded from 23 laboratories in 2012 to 39 WHO-accredited laboratories in 2016, with an additional six laboratories foreseen to join the network in 2017. Nearly 35 000 samples were tested by the network in 2016.

Following a historically low level of measles transmission in 2012, the Western Pacific Region has experienced a resurgence of measles in 2013–2016. Measles incidence, however, started to decline after 2014 (Table 1.4). In 2016, 57 879 measles cases including confirmed and compatible cases were reported. Of these, 30 273 cases (52%) were from Mongolia and 24 820 cases (43%) were from China. In September 2016, 28 countries or areas in the region were verified by the (measles) regional verification commission (RVC) to have interrupted endemic measles virus transmission for at least 36 months.

These events illustrate the need for sustained efforts to raise and maintain high levels of immunization coverage even in areas where elimination-level control has previously been attained. Every opportunity to address system bottlenecks and to increase routine immunization coverage should be seized. The introduction of a routine second dose of MCV and SIAs provide such opportunities. For example, SIAs have been shown to contribute to strengthening the routine immunization programme through improving several aspects including health-worker skills and knowledge, social mobilization, cold chain and logistics and integration of other public health interventions *(7,8)*. The establishment of RVCs for measles elimination and their corresponding national verification committees (NVCs) has helped to refine the understanding of the barriers to elimination and build stronger national commitment to achieving elimination goals (Table 1.5).

Regional verification commissions

The Region of the Americas has the longest standing RVC. In September 2016, the regional verification commission in the Americas Region declared the Region free of endemic Measles (Table 1.6) *(9)*.

At the Western Pacific Region RVC meeting in 2016 (Table 1.7), Australia, Brunei Darussalam, Cambodia, China, Hong Kong Special Administrative Region (SAR), China, Macao SAR, Japan and the Republic of Korea were verified as having achieved or sustained measles elimination based on a verification-standard epidemiological surveillance system supported by accredited laboratories.

In the European Region (Table 1.8), 51 of 53 Member States have established NVCs and at the RVC meeting in October 2016, 24 (45%) Member States were documented to have interrupted endemic measles transmission for more than 36 months.

In the Eastern Mediterranean Region, a regional verification guide was drafted but no RVC has yet been established. However, NVCs were established in 9 of 22 Member States. Three

countries or areas in the region (Bahrain, Oman and the West Bank and Gaza Strip) are ready for verification once the RVC is established.

The South-East Asia Region has established an RVC and the framework for verification of measles and control of rubella/CRS has been finalized in 2016. In 2017, the RVC has verified two countries as having eliminated measles (Bhutan and the Maldives).

In 2016, the African Region has started the process of establishing the RVC and the first RVC meeting is scheduled for 2017. Compared to 2015, there has been some progress globally in terms of the number of regions with RVCs and significant progress in the number of Member States that have established NVCs, particularly in the South-East Asia Region.

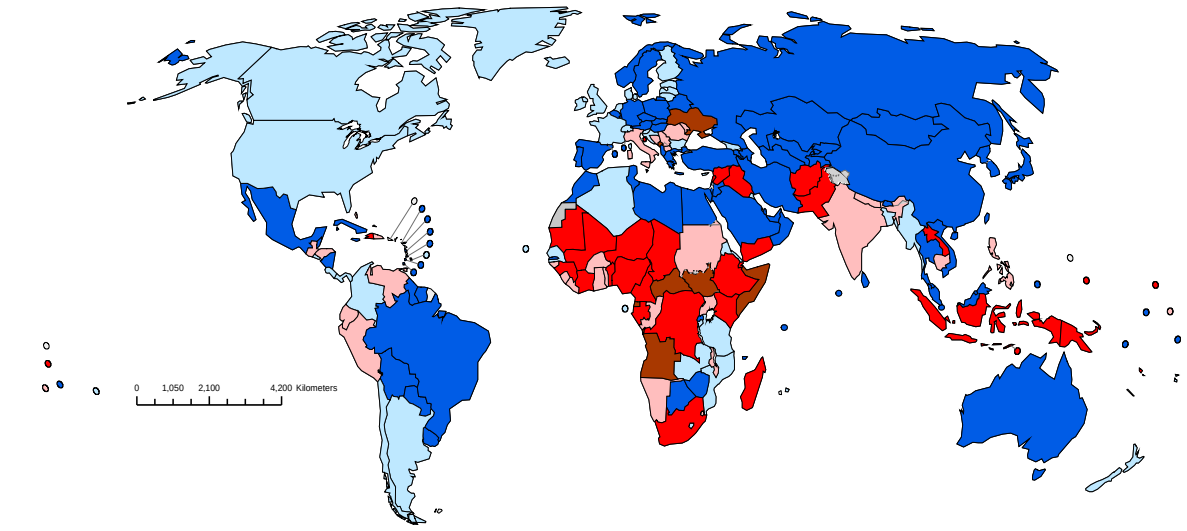
Conclusion

The year 2016 has seen some improvement in global measles incidence, in the proportion of countries achieving the global 2015 incidence targets, in MCV2 coverage levels (**Fig. 1.9**) and in the number of RVCs and NVCs established. However, coverage with MCV1 has remained stagnant and major outbreaks continue to occur in five of the six WHO regions. Many of the outbreaks are affecting school-aged children and adults making it more challenging for countries to close the immunity gaps and prevent outbreaks. The 2015 global targets and remaining regional targets remain off track.

In decreasing order, the following six large Member States had the highest number of infants that did not receive the first dose of MCV1 in 2016: India, Nigeria, Pakistan, Indonesia, Ethiopia, and the Democratic Republic of the Congo (Fig. 1.10). For these countries, one could highlight the importance of strengthening health systems to achieve higher immunization coverage. Routine MCV1 coverage in these countries has either shown little progress or has declined since 2010, and the reported measles incidence remains high. In addition, discrepancies between administrative data and survey data on immunization coverage, particularly for SIAs, remain a problem. Immunization coverage reported from administrative sources is often much higher than the coverage reported from surveys.

Measles is a highly infectious disease, and its elimination requires very high and homogeneous population immunity and a high-quality surveillance system. Without a robust routine programme, elimination is very difficult to achieve and cannot be sustained. For Member States that are now at < 90% coverage nationally, reaching ≥ 95% coverage will require substantial additional investments over a sustained period. The gap between MCV1 and MCV2 coverage highlights the missed opportunities and routine system weaknesses that contribute to suboptimal population immunity and the inability to interrupt measles virus transmission.

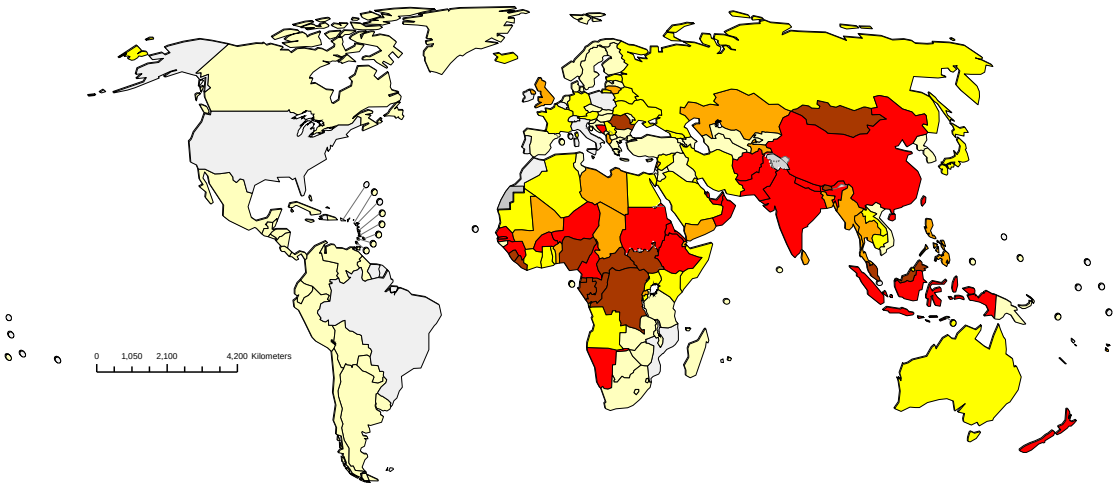
Fig. 1.7. Immunization coverage (%) with first dose of MCV1 in infants per country, 2016



< 50% *(7 countries or 4%)*
50–79% *(32 countries or 16%)*
80–89% *(32 countries or 16%)*
90–94% *(43 countries or 22%)*
≥ 95% *(80 countries or 41%)*
Not available
Not applicable

Source: WHO-UNICEF coverage estimates 2016 revision, July 2017.

Fig.1.8. Reported measles incidence rate[a] per country, 2016

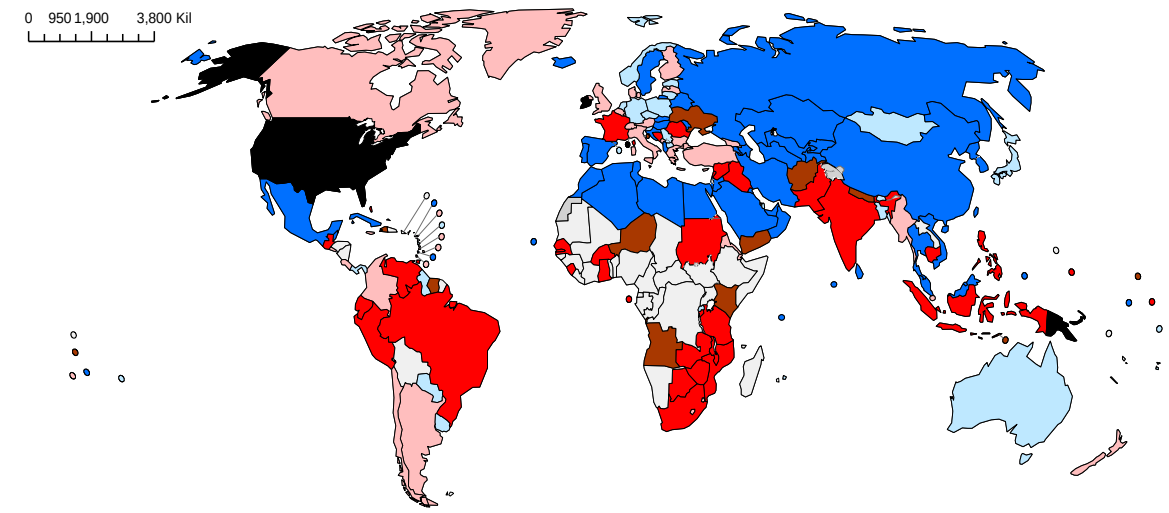


< 1 (86 countries or 44%)
> 1 to < 5 (30 countries or 15%)
> 5 to < 10 (19 countries or 10%)
> 10 to < 50 (21 countries or 11%)
≥ 50 (13 countries or 73%)
Not available/No data reported to WHO headquarters (28 countries or 14%)
Not applicable

[a] Per million population

Source: JRF data, as of 23 June 2017.

Fig. 1.9: Immunization coverage with routine MCV2 by national schedule for infants, 2016



< 50% (13 countries or 7%)
50–79% (35 countries or 18%)
80–89% (35 countries or 18%)
90–94% (27 countries or 14%)
≥ 95% (50 countries or 26%)
Second dose of measles-containing vaccines in schedule but no coverage data available (4 countries or 2%)
Not available/Not introduced (34 countries or 18%)
Not applicable

Source: WHO-UNICEF coverage estimates, 2016 revision.

Table 1.5: Progress towards measles elimination, by WHO region (as of 31 December 2016)

WHO region	Target year for measles elimination in region	RVC established	Regional measles elimination verification report provided for 2015 and 2016 data	Member States that have established an NVC *n* (% of total)	Established NVCs that submitted annual status reports *n* (% of total)[a]	Member States that were verified free of endemic measles based on 2016 reporting *n* (% of total)[b]
African	2020	No	No	None	Not applicable	Not applicable
Americas[e]	2000	Yes	Yes	24 (100%)	24 (100%)	44/44 (100%)
Eastern Mediterranean	2020	No	No	9 (43%)	Not applicable	Not applicable
European	2015	Yes	Yes	51 (96%)	51 (100%)	24 (79%)[c]
South-East Asia	2020	Yes	Yes	11 (100%)	11 (100%)	2 (18%)
Western Pacific	2012	Yes	Yes	27[d] (100)	17 (100)[d]	7[f] (26%)

[a] Percentage represents the total number of established NVCs, not the total number of Member States.

[b] Percentage represents the total number of Member States, not the total number of established NVCs.

[c] 24 of these countries were verified as having been free of endemic measles for 36 months or longer. An additional 13 were documented to have interrupted endemic measles transmission for at least 12 months. As of September 2017, 33 of these countries were verified as having been free of endemic measles for 36 months or longer. An additional 9 were documented to have interrupted endemic measles transmission for at least 12 months.

[d] 13 Pacific Island countries formed one joint subregional verification committee (they are: Cook Islands, Fiji, Kiribati, Marshall Islands, Micronesia (Federated States of), Nauru, Niue, Palau, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu). China, Hong Kong SAR and China, Macao SAR established their own Committees in addition to the Chinese NVC. There are a total of 16 NVCs and 1 SRVC for the 27 Member States in the Western Pacific Region.

[e] Countries in the Americas are not providing annual reports to NVCs as both measles and rubella have been eliminated. In 2016, 22 of 24 NVCs submitted (for the second time) verification reports with 2012–2015 data.

[f] In September 2016, 7 countries or areas were verified as having achieved or sustained measles elimination: Australia, Brunei Darussalam, Cambodia, China, Hong Kong, SAR, China, Macao SAR, Japan and the Republic of Korea.

Table 1.6: Progress towards measles elimination in the Region of the Americas (as of 31 December 2016)

Status according to Pan American Health Organization (PAHO) Region definitions [a]	Number of countries/territories (% of total)	Countries/territories
Measles elimination verified	44 (100)	35 countries + 6 British Overseas Territories + 3 Netherland Antilles

[a] Pan American Health Organization (PAHO) Region definitions:

- Measles elimination verified: Verify interruption of endemic measles, rubella and congenital rubella syndrome cases in all countries of the Americas for a period of at least 3 years from the last known endemic case, in the presence of high-quality surveillance.
- Interrupted endemic transmission for ≥12 months: Absence of endemic measles transmission for a period equal or greater than 12 months, in the presence of a well-performing surveillance system.

Table 1.7: Progress towards measles elimination in the Western Pacific Region (as of 31 December 2016)

Status according to Western Pacific Region definitions[a]	Number of countries (% of total)	Countries or areas
Elimination verified	7 (26%)	Australia, Brunei Darussalam, Cambodia, China, Hong Kong SAR, China, Macao SAR, Japan, Republic of Korea
Possibly ready for verification, but additional data required	3 (11%)	New Zealand, Singapore, Pacific islands subregion
Does not yet fulfil the criteria for verified elimination	6 (22%)	China[b], Lao People's Democratic Republic, Malaysia, Papua New Guinea, Philippines, Viet Nam

[a] Western Pacific Region definitions:

- Elimination verified: The interruption of endemic measles virus transmission for ≥36 months in the presence of verification-standard surveillance and genotyping evidence that supports the interruption of endemic measles virus transmission. Australia, China, Macao SAR, Mongolia and the Republic of Korea were verified again in March 2015 (as well as in March 2014) as having interrupted measles virus transmission for more than 3 + 1 years. Brunei Darussalam, Cambodia and Japan were verified in March 2015 as having interrupted measles virus transmission for more than 3 years. Note: During the 2016 RVC meeting, it was confirmed that the measles outbreak in Mongolia that started in March 2015 and lasted until June 2016 was from endemic transmission of an H1 virus that had re-established itself in Mongolia.
- Possibly ready for verification, additional data required: After reviewing the first reports prepared by the NVCs, the RVC determined that interruption may have been achieved, but more detailed epidemiological data were needed to verify measles elimination.
- Endemic transmission: The existence of continuous transmission of indigenous or imported measles virus that persists for ≥ 12 months in the nation.

[b] Data apply to all parts of China excluding China, Hong Kong SAR and China, Macao SAR.

Table 1.8: Progress towards measles elimination in the European Region (as of 31 December 2016)[a]

Status using European Region definitions[b]	Number of countries (% of total)	Countries or areas
Interrupted endemic transmission for ≥ 36 months	24 (45)	Albania, Andorra, Armenia, Azerbaijan, Belarus, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Hungary, Israel, Latvia, Luxembourg, Malta, Netherlands, Norway, Portugal, Republic of Moldova, Slovakia, Slovenia, Sweden, Tajikistan, Turkmenistan
Interrupted endemic transmission for ≥ 12 months but < 36 months	13 (25)	Austria, Croatia, Denmark, Greece, Iceland, Ireland, Lithuania, Montenegro, Russian Federation, Spain, The former Yugoslav Republic of Macedonia, United Kingdom of Great Britain and Northern Ireland, Uzbekistan
Endemic transmission	14 (26)	Belgium, Bosnia and Herzegovina, France, Georgia, Germany, Italy, Kazakhstan, Kyrgyzstan, Poland, Romania, Serbia, Switzerland, Turkey, Ukraine
No report submitted	2 (4)	Monaco, San Marino

[a] As of September 2017, 33 of these countries were verified as having been free of endemic measles for 36 months or longer. An additional nine countries were documented to have interrupted endemic measles transmission for at least 12 months.

[b] European Region definitions:

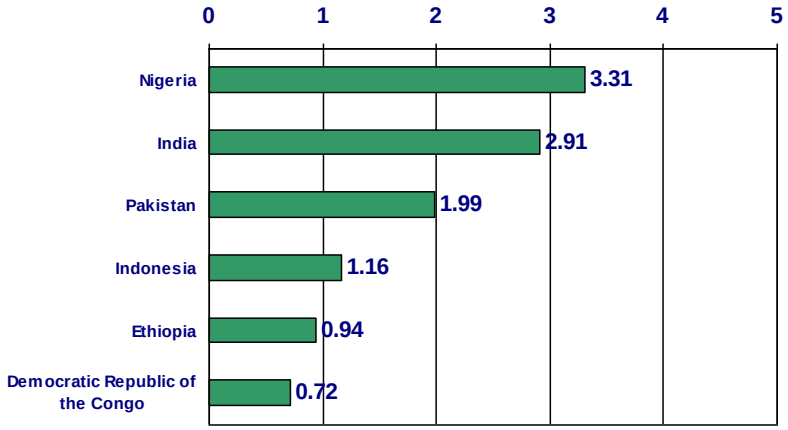
Interrupted endemic transmission for ≥ 36 months: Absence of endemic measles transmission from 2012–2014 in the presence of a well-performing surveillance system.

Interrupted endemic transmission for ≥ 12 months but < 36 months: Absence of endemic measles transmission at least in 2014 in the presence of a well-performing surveillance system.

Endemic transmission: Continuous transmission of indigenous or imported measles virus that has persisted for a period of 12 months or more in the Member State. (Note: this definition differs from that stated in the WHO Weekly Epidemiological Record.)

No report submitted: Not available because the country does not have a functioning NVC or failed to submit the annual status report.

Fig. 1.10: Countries with the largest numbers of infants unvaccinated with MCV1, in millions, 2016



Source: WHO-UNICEF coverage estimates 2016 revision.

Table 1.9: MCV1 coverage and measles incidence per million population, by income category and Gavi support, 2014–2016 and baseline 2010

Income group and Gavi support	WHO-UNICEF estimates for MCV1 national coverage (%)					Percentage of Member States reporting confirmed measles cases in their JRF				Measles incidence per million population					Percentage of Member States with incidence less than 5 per million population				
	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	% change 2010–2016
Gavi-supported countries	78	78	78	78	0	97	99	96	99	28	46	47	81	65	54	51	50	40	33
Middle-income countries, no Gavi support	94	94	93	95	1	90	86	87	97	12	20	46	32	59	75	70	65	72	4
High-income countries	94	94	94	93	-1	75	89	79	96	3	4	5	8	63	86	78	59	72	19
Total	**85**	**85**	**84**	**85**	**0**	**88**	**91**	**87**	**97**	**19**	**29**	**40**	**50**	**62**	**68**	**65**	**57**	**60**	**15**

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GOAL 2: MEET GLOBAL AND REGIONAL ELIMINATION TARGETS: ACHIEVE RUBELLA AND CONGENITAL RUBELLA SYNDROME ELIMINATION

(Indicator G2.3)

DEFINITION OF INDICATOR	• Rubella and CRS elimination: The absence of endemic rubella virus transmission in a defined geographical area (e.g. region or country) for ≥ 12 months and the absence of CRS cases associated with endemic transmission in the presence of a well-performing surveillance system. Note 1: There may be a time lag (up to 9 months) in occurrence of CRS cases after interruption of rubella virus transmission has occurred. Evidence of the absence of continuing rubella transmission from CRS cases is needed because CRS cases excrete rubella virus for up to 12 months after birth. Note 2: Verification of rubella elimination takes place after 36 months of interrupted rubella virus transmission.
DATA SOURCES	• WHO-UNICEF Joint Reporting Forms (JRFs) for disease incidence and WHO-UNICEF estimates of national immunization coverage (WUENIC) data for coverage rates are subject to the same limitations as all other data submitted via the JRFs, as described in the 2013 report of the GVAP Secretariat *(1)*. • Coverage estimates for the first dose of rubella-containing vaccine are based on WHO and UNICEF estimates of coverage of measles-containing vaccine.
COMMENTS ON DATA QUALITY	• None
MILESTONES	• Region of the Americas: Rubella eliminated in 2009 and the International Expert Committee for Measles and Rubella Elimination verified the Region as rubella and CRS free in April 2015 • European Region: Rubella elimination by 2015 • Western Pacific Region: Rubella elimination pledged but no target date set • South-East Asia Region: Rubella control by 2020 • African Region: No target • Eastern Mediterranean Region: No target.

Highlights

- The number of countries using rubella-containing vaccine (RCV) in their national programme continues to steadily increase. As of December 2016, 152 Member States had introduced rubella vaccines; coverage, however, varies from 13% to 96% depending on the region. Only 42 Member States had not introduced RCV into their routine immunization programme.
- An external mid-term review of the Global Measles and Rubella Strategic Plan 2012–2020 *(2)* was conducted in 2016 and its findings reported to SAGE in October 2016. SAGE endorsed the main recommendations of the review, including the following.
  - The incorporation of rubella vaccination into the immunization programme needs to be accelerated – it should be accorded equivalent emphasis as measles.
  - Congenital Rubella Syndrome (CRS) surveillance should be implemented either at sentinel or national level, especially in countries using measles–rubella vaccine (MR).
- Two WHO regions (the African Region and the Eastern Mediterranean Region) still do not have rubella elimination or control targets.
- Rubella and CRS surveillance systems are weak and cases remain underreported, particularly in Member States that have not yet introduced RCV and/or do not have rubella control or elimination goals. Hence, global rubella and CRS surveillance data do not reflect the true burden of these diseases.
- Failure to fully integrate prevention of rubella and CRS with measles elimination activities represents a major missed opportunity for immunization and integrated disease surveillance.

Background and progress

As of December 2016, 152 (78%) Member States had introduced RCV, with 42 Member States yet to introduce the vaccine. Average coverage globally has steadily increased from 35% in 2010 to 47% in 2016; coverage, however, varies from 13% in the African Region to 96% in the Western Pacific Region[19] (Table 1.10). In 2017 an additional 16 countries will introduce rubella vaccine into their routine schedules after having completed MR catch-up campaigns.

In 2016, the global incidence of rubella was estimated to be 4.03 per million population (reported by 163 (84%) Member States, (Table 1.10 and Fig. 1.11). Rubella surveillance is weak in many countries, especially among the countries that have not yet introduced the vaccine. Further, the total number of Member States reporting rubella incidence to WHO has decreased since 2010 (170 Member States (88%), which may also partly explain the decreasing reported incidence (Table 1.10).

In total, the number of Member States that reported CRS figures in 2016 (122, 63%) has remained basically the same since 2015 (128, 66%) (Table 1.11). The very low reported global incidence is probably more a sign of the lack of/weak CRS surveillance systems outside the Americas and Europe, so the true global burden of disease is unknown.

[19] Calculation of coverage takes into account all birth cohorts regardless of the introduction status of RCV.

Encouragingly, a growing number of Member States outside these two regions are establishing CRS surveillance systems.

Regional review

The Region of the Americas achieved rubella and congenital rubella syndrome elimination in 2009; the last endemic rubella case was reported in 2009 in Buenos Aires, Argentina and the last endemic CRS case was reported in 2009 in Brazil. In 2015, the Region was verified as having eliminated rubella and CRS. In 2016, two rubella cases were confirmed in Canada and the United States respectively. Genotype 2B was identified in the rubella case reported by the United States, likely imported from India. No genotype was identified in the case reported by Canada. In 2016, the United States reported 2 confirmed CRS cases of one female and one male born in the states of Illinois and Maryland respectively. The mothers of these two cases are from Nigeria and Pakistan; genotypes 1G and 2B were identified.

Fifty-two of the Member States in the European Region use the combined measles–mumps–rubella vaccine (MMR), while Tajikistan is using MR vaccine in a two-dose schedule. Based on JRF data, the number of rubella cases reported in the region dropped by 97% between 2010 (*n*=10 551) and 2016 (*n*=358). Twenty-four Member States (45%) were verified as having eliminated rubella in 2016. In addition, 11 Member States (21%) had interrupted rubella transmission for more than 12 months but less than 36 *(3)*. In 2016, most of the rubella cases occurred in Poland even though no cases were reported on the JRF. Countries that reported cases through the JRF in 2016 included the Ukraine (*n*=150) and Germany (*n*=95).

In 2014, the Regional Committee for the Western Pacific endorsed the Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific Region and its specified immunization goals, including the regional rubella elimination goal (target date to be determined). The number of reported rubella cases has been declining in the Western Pacific Region since 2011 (from 76 022 in 2011 to 5446 in 2016) with the majority of cases being reported from China, Viet Nam, Japan and the Philippines. Reported CRS cases in the Region have increased since 2015 (5 in 2015 and 19 cases in 2016) with most cases being reported from Viet Nam (4 in 2015 and 18 in 2016, respectively). Very few countries in the Region have established CRS surveillance.

The South-East Asia Region has made significant progress towards rubella and CRS control. RCV has been introduced in eight of 11 Member States. Of the remaining three Member States, India and Indonesia have started to introduce RCV in 2017, while the Democratic People's Republic of Korea is yet to finalize a plan to introduce rubella vaccine in routine immunization. In 2016, 10 361 confirmed cases of rubella were reported. India continued to report the most confirmed cases (8274), followed by Indonesia (1238) and Nepal (656). Surveillance for CRS only started as a WHO-supported activity after the September 2013 Regional Committee resolution. Eight of the 11 Member States have initiated sentinel site CRS surveillance; the other three conduct CRS surveillance as part of an integrated disease surveillance programme. A total of 319 confirmed cases of CRS were reported in 2016 with Indonesia reporting the highest number (174) followed by Bangladesh (87) Nepal (33) and India (25).

Although the Eastern Mediterranean Region has not yet set a rubella elimination goal, 13 countries (60%) have set a national target for rubella/CRS elimination and 11 countries are now implementing CRS surveillance. In 2016, 1981 confirmed cases of rubella were reported by the countries of the Eastern Mediterranean Region. The majority of these (90%) were reported from three countries (Sudan 996), Pakistan (648) and the United Arab Emirates (132), two of which (Sudan and Pakistan) have not yet introduced RCV. So far, only one of the six countries eligible for Gavi support (Yemen) has benefited from Gavi support to conduct SIAs of RCV with introduction completed in 2015.

The African Region does not yet have a rubella elimination target. However, countries are being supported to use the opportunity of the implementation of measles elimination strategies to address rubella and CRS. In 2016, the Region reported 4157 rubella cases through the JRF. As of December 2016, nine countries have introduced RCV in their routine immunization schedules. In 2017, an additional 14 Member States[20] will introduce rubella vaccine into their routine schedules after having completed MR catch-up campaigns.

Conclusion

A new phase of accelerated rubella control and CRS prevention has begun, marked by a 2011 WHO position paper, which recommended a strategy consistent with rubella and CRS elimination *(4)*, the inclusion of rubella elimination in five WHO regions by 2020 as a disease control target in the Global Vaccine Action Plan (2012), and Gavi support for the introduction of rubella vaccine in countries meeting the eligibility criteria. As All WHO regions have measles elimination goals, in countries that meet the rubella introduction criteria, it would be a missed opportunity not to include rubella elimination as a disease target. This is because similar strategies are used to eliminate rubella and measles – rubella vaccine is combined with measles vaccine (as MR/MMR or MMRV), and fever and maculopapular rash surveillance is used for the detection of both measles and rubella.

Fig. 1.12 and 1.13 describe the global and regional rubella vaccine coverage rates. The coverage with RCV increases with increasing income; the lowest coverage is reported in countries eligible for Gavi support, but these countries have made the most progress since 2010. This is largely attributed to the increased numbers of these countries that have introduced the vaccine since 2010 (Table 1.12).

Several key challenges remain.

- Building support for additional regions to adopt elimination goals. This includes ensuring that all Member States can achieve and maintain the minimum coverage (≥ 80%) through routine services and/or in SIAs required for introduction of RCV.

- Advocating for resources and a secure vaccine supply needed to meet the European Region's elimination goal.

[20] Angola, Benin, Botswana, Burundi, Congo, Cote d'Ivoire, Kenya, Lesotho, Malawi, Mauritania, Mozambique, Namibia, Swaziland and Zambia.

- Ensuring high routine coverage (≥ 95%) of RCV1 and RCV2 (the same figure used for measles coverage is used here because RCV is bundled with MCV as MR or MMR).

- Ensuring high-quality MR SIAs that reach at least 95% of targeted children, as verified through surveys.

- Strengthening synergies between rubella and measles surveillance and expanding CRS surveillance – commitment at all levels of government as well as involvement of the private sector is needed to address these challenges.

For countries eligible for Gavi support, the challenge is in capitalizing on the available resources for RCV introduction while ensuring sufficient political and financial commitment to assure the sustainability of the programme.

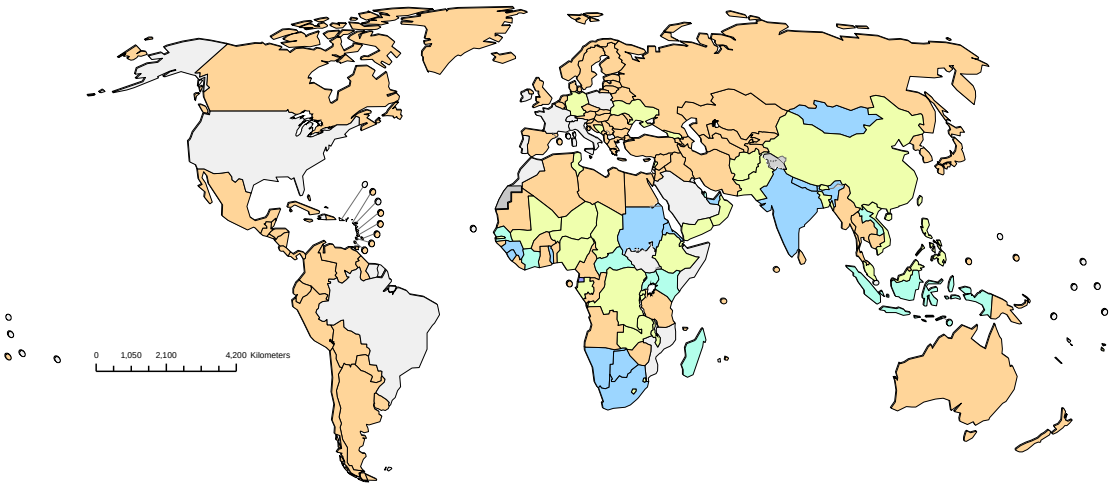
Financial support from Gavi together with the leadership, coordination and technical expertise from the Measles & Rubella Initiative, provide an opportunity for Member States and regions to accelerate progress in rubella control and CRS prevention. Rubella elimination has been achieved and verified in the Americas and the European Region is the next region closest to achieving rubella elimination. Substantially greater commitment and investment by Member States and the global immunization community will be required to reach the GVAP target of rubella elimination in five WHO regions by 2020.

Table 1.9: Rubella cases[a] and incidence by WHO region, 2014–2016 and baseline 2010

WHO region	RCV1 national coverage (%)					Percentage of Member States reporting on rubella in their JRF				Rubella incidence per million population					Percentage of Member States with incidence less than five per million population				
	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	% change 2010–2016
African	13	12	9	0		94	94	94	79	4.25	5.54	7.82	3.87	10	68	66	52	70	-3
Americas	93	92	92	92	1	86	100	100	100	0.002	0.005	0.01	0.02	-90	100	100	100	100	0
Eastern Mediterranean	46	45	42	38	21	81	86	91	81	3.42	2.99	4.65	3.53	-3	82	83	79	65	26
European	93	94	94	93	0	83	83	72	93	0.497	0.83	0.98	14.22	-97	100	93	95	86	16
South-East Asia	15	15	13	3	400	100	100	100	82	7.42	3.38	5.09	26.11	-72	64	73	82	33	94
Western Pacific	96	96	89	61	57	63	56	59	85	2.9	5.04	6.92	25.75	-89	88	73	81	83	6
Total	**47**	**47**	**44**	**35**	**34**	**84**	**86**	**84**	**88**	**4.03**	**3.32**	**4.8**	**14.93**	**-73**	**86**	**83**	**80**	**80**	**8**

[a] Coverage estimates for the 1st dose of rubella-containing vaccine are based on WHO and UNICEF estimates of coverage of measles-containing vaccine.
Source: JRF data, as of 12 July 2017.

Fig. 1.11: Reported rubella incidence rate[a] per country, 2016



< 1 case per million (108 countries or 56%)
≥ 1 to < 5 (32 countries or 16%)
≥ 5 to < 10 (10 countries or 5%)
≥ 10 to < 50 (12 countries or 6%)
≥ 50 (1 country or 1%)
Not available/No data reported to WHO headquarters (31 countries or 16%)
Not applicable

[a] Per million population

Source: JRF, as of 23 June 2017.

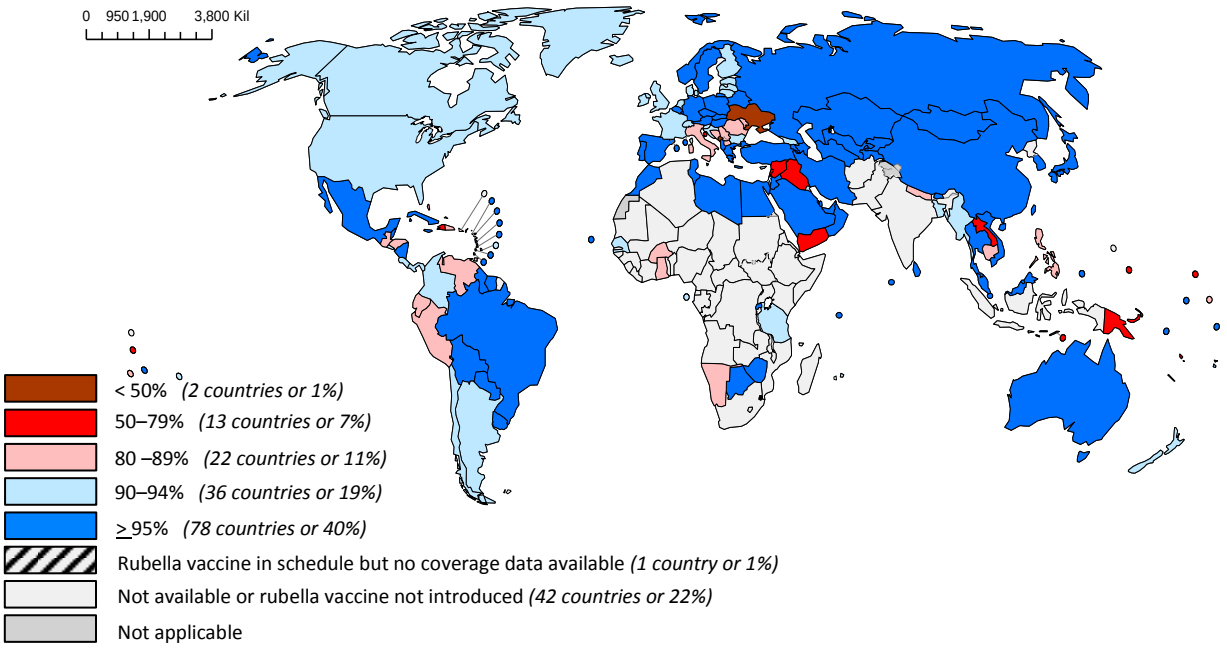
Table 1.10: Congenital rubella syndrome cases[a] and incidence by region, 2014–2016 and baseline 2010

WHO region	Percentage of Member States reporting on CRS in their JRF				CRS incidence per million population					Percentage of Member States with incidence less than five per million population				
	2016	2015	2014	2010	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	% change 2010–2016
African	45	49	36	32	0.04	0.28	0.08	0.13	-69	100	100	100	94	6
Americas	86	97	100	100	0	0.002	0	0	0	100	100	100	100	0
Eastern Mediterranean	43	48	38	48	0.05	0	0.01	0.03	67	100	100	100	90	11
European	77	77	68	83	0.009	0.018	0.045	0.003	200	100	100	100	100	0
South-East Asia	82	82	73	36	0.09	0.32	0.28	0.09	0	100	100	100	100	0
Western Pacific	44	41	44	70	0.06	0.02	0.04	0	0	100	100	100	100	0
Total	63	66	60	65	0.05	0.09	0.05	0.01	400	100	100	100	98	2

[a] Coverage estimates for the 1st dose of rubella-containing vaccine are based on WHO and UNICEF estimates of coverage of measles-containing vaccine.

Source: JRF data, as of 12 July 2017.

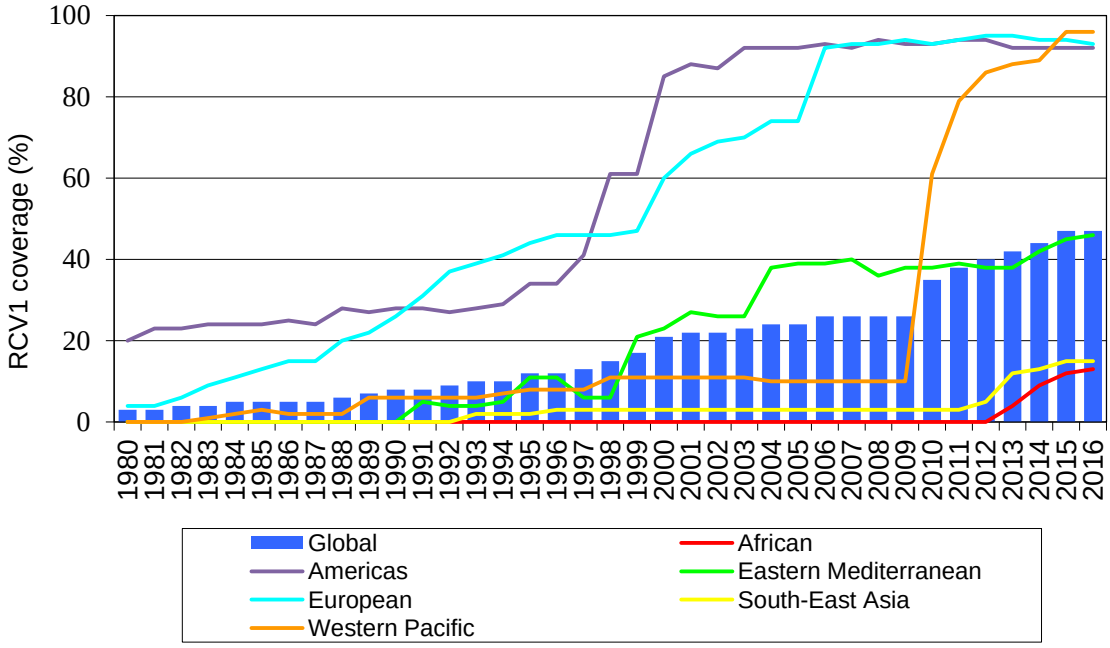
Fig. 1.12: Immunization coverage with rubella-containing vaccines[a] in infants, 2016



[a] Coverage estimates for the 1st dose of rubella-containing vaccine are based on WHO and UNICEF estimates of coverage of measles-containing vaccine.

Source: WHO-UNICEF coverage estimates 2016 revision.

Fig. 1.13: Rubella-containing vaccine coverage[a] by WHO region, 1980–2016



[a] Coverage estimates for the 1st dose of rubella-containing vaccine are based on WHO and UNICEF estimates of coverage of measles-containing vaccine.

Source: WHO-UNICEF coverage estimates 2016 revision

Table 1.11: Coverage of RCV and rubella incidence, by income category and Gavi support, 2014–2016 and baseline 2010

Income group and Gavi support	RCV1 national coverage (%)					Percentage of Member States reporting on rubella in their JRF				Rubella incidence per million population				
	2016	2015	2014	2010	% change 2010–2016	2016	2015	2014	2010	2016	2015	2014	2010	% change 2010–2016
Gavi-supported countries	17	17	12	4	325	92	90	92	82	6.03	4.17	5.93	14.7	-59
Middle-income countries, no Gavi support	94	94	94	93	1	75	84	75	91	0.71	0.498	0.66	4.98	-86
High-income countries	90	89	89	74	22	83	83	83	91	2.25	3.36	4.9	18.77	-88
Total	**47**	**47**	**44**	**35**	**34**	**84**	**86**	**84**	**88**	**4.03**	**3.32**	**4.8**	**14.93**	**-73**

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2. Immunization coverage

NOTE TO THE READER

Progress against the GVAP goals and strategic objectives related to immunization coverage has been consolidated into a single report, as was done in the previous reports based on a recommendation from the SAGE Decade of Vaccines working group.

As in the previous report, and as per the SAGE working group recommendation, the data for the following indicators are no longer reported as separate indicators, but included in the overall progress with coverage:

- Indicator SO3.1: percentage of districts (or equivalent administrative units) with 80% or greater coverage with three doses of vaccine containing diphtheria–tetanus–pertussis (DTP)
- Indicator SO4.2: 3 years sustainability of DTP3 national coverage > 80%
- Indicator SO3 4.1: DTP1-DTP3 dropout rate for national coverage

It has to be noted that the SAGE Decade of Vaccines working group also recommended no longer monitoring Indicator SO4.3: "Immunization coverage data assessed as high quality by WHO and UNICEF" as the information provided was not relevant to the quality of data provided by the countries but rather to the level of confidence of WHO and UNICEF in their own estimates.

The three major sources of data for this report include the following.

- The WHO/UNICEF Joint Reporting Form on Immunization (JRF), which collects national-level data from countries on reported cases of selected vaccine-preventable diseases; recommended immunization schedules; immunization coverage; vaccine supply; and other information on the structure, policies and performance of national immunization systems
- The WHO/UNICEF estimates of national infant immunization coverage (WUENIC), which are derived from various data sources including reported coverage data from the JRFs.
- The WHO Health Equity Monitor of the Global Health Observatory data repository: data from Demographic and Health Surveys (DHS) and Multiple Indicator Cluster Surveys (MICS).

The estimates are based on data and information available to WHO or UNICEF as of 15 July 2017. The data are available from both WHO and UNICEF web sites: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/ and http://www.data.unicef.org/child-health/immunization.
An explanation of how to interpret the country profiles is also available: http://www.who.int/entity/immunization/monitoring_surveillance/routine/coverage/User_Ref_Country_Reports.pdf .

The GVAP assessment compares progress against indicators across time and using different country classifications. However, it has to be noted that the list of WHO Member States[1], the World Bank country classification[2] as well as the list of Gavi-eligible countries[3] have evolved over the time periods under consideration, affecting, to different degree, comparisons of indicators' results by regions, income groups and Gavi eligibility. Thus, within the GVAP reports of 2015–2017, comparisons over the years were reduced to the most relevant ones that were not widely impacted by these differences in classification.

Readers need also to be aware that the entire time series of coverage estimates may be updated for certain countries, based on the availability of new data that affect the coverage estimates over a period of time, for example a new coverage survey, an update sent by a Member State or data submitted late in the previous year. Thus, the estimates of coverage for 2015 in this report may not be the same as that in the previous report. The coverage estimates for 2016 must, therefore, be compared with the 2015 estimates in the updated time series.[4] [5] [6]

For more information about the JRF and WUENIC coverage data, please refer to GVAP Secretariat Report 2013, Annex 1 on "Understanding immunization coverage data: WHO/UNICEF JRF and WUENIC". Pages 133–137 (http://www.who.int/entity/immunization/global_vaccine_action_plan/GVAP_secretariat_report_2013.pdf?ua=1).

The vaccines coverage punch cards, by WHO region and country are presented in the Immunization Coverage Score Cards; the 2017 edition is available through the GVAP website under the GVAP Secretariat reports: http://www.who.int/immunization/global_vaccine_action_plan/en/

1 List of WHO Member States is available at: http://www.who.int/countries/en/

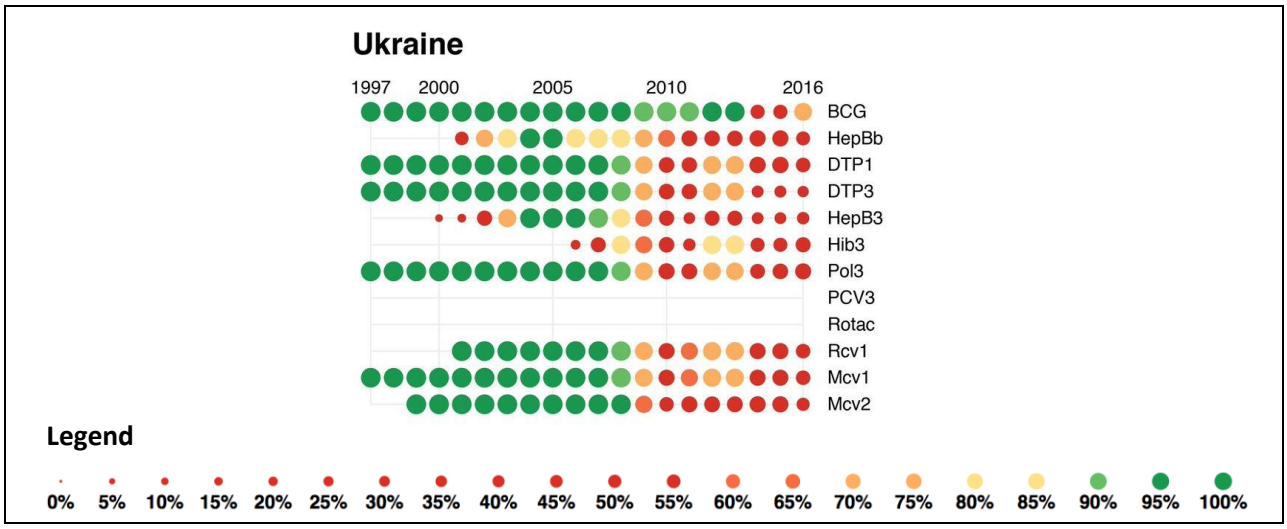
2 World Bank country classification is available at: http://data.worldbank.org/about/country-and-lending-groups

3 List of Gavi-eligible countries is available at: http://www.gavi.org/support/apply/countries-eligible-for-support/

4 Burton A, Monasch R, Lautenbach B, Gacic-Dobo M, Neill M, Karimov R, et al. WHO and UNICEF estimates of national infant immunization coverage: methods and processes. Bull World Health Organ. 2009; 87(7):535-41 (http://www.who.int/bulletin/volumes/87/7/08-053819/en/, accessed 23 September 2017).

5 Burton A, Kowalski R, Gacic-Dobo M, Karimov R, Brown D. A formal representation of the WHO and UNICEF Estimates of National Immunization Coverage: a computational logic approach. PLoS ONE 2012;7(10):e47806. doi:10.1371/journal.pone.0047806 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3485034/pdf/pone.0047806.pdf, accessed 23 September 2017).

6 Brown D, Burton A, Gacic-Dobo M, Karimov R. An Introduction to the Grade of Confidence in the WHO and UNICEF Estimates of National Immunization Coverage. The Open Public Health Journal. 2013; 6:73–76 (http://www.who.int/immunization/monitoring_surveillance/routine/coverage/TOPHJ673.pdf?ua=1, accessed 23 September 2017).



GVAP COVERAGE INDICATORS

Goal/Strategic Objective	Indicators
Goals	
G3 **Meet vaccination coverage targets in every region, country and community**	G3.1 Reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria–tetanus–pertussis-containing vaccines
	G3.2 Reach 90% national coverage and 80% in every district or equivalent administrative unit for all vaccines in national programmes, unless otherwise recommended
Strategic Objectives (SOs)	
SO3 **The benefits of immunization are equitably extended to all people**	SO3.1 Percentage of districts with 80% or greater coverage with three doses of diphtheria–tetanus–pertussis-containing vaccine **Included in the G3.1 coverage indicator section.**
	SO3.2 Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s)
SO4	SO4.1

Goal/Strategic Objective	Indicators
Strong immunization systems are an integral part of a well-functioning health system	Dropout rates between first dose (DTP1) and third dose (DPT3) of diphtheria–tetanus–pertussis-containing vaccines **Included in the G3.1 coverage indicator section**
	SO4.2 Sustained coverage of diphtheria–tetanus–pertussis-containing vaccines 90% or greater for three or more years **Included in the G3.1 coverage indicator section**
	SO4.3 Immunization coverage data assessed as high quality by WHO and UNICEF **This indicator is no longer monitored as recommended by the SAGE DoV working group (WG)**

GOAL 3: MEET VACCINATION COVERAGE TARGETS IN EVERY REGION, COUNTRY AND COMMUNITY

DTP3 coverage of 90% nationally and 80% in every district (Indicator G3.1) (also includes indicators SO3.1, SO4.1, SO4.2)

TARGET	2020 in all Member States
DEFINITION OF INDICATOR	National coverage data based on WHO-UNICEF estimates of national immunization coverage (WUENIC). For district-level coverage, the data are considered valid only if the WUENIC estimates and administrative data from the JRF are the same or if the WUENIC estimates are ≥ 90%.
DATA SOURCES	• WUENIC estimates. • Administrative data from WHO-UNICEF Joint Reporting Forms (to compare with WUENIC estimates as a check of validity).

HIGHLIGHTS

- In total 130 Member States (67%) reached national DTP3 coverage of ≥ 90% in 2016, as compared to 128 Member States, 2015. This represents 86% of the world's children, though there has not been a significant increase in coverage since 2010.
- In order to reach the target of at least 90% DTP3 vaccination coverage worldwide, an additional 9.9 million children would need to be vaccinated in 64 countries; innovative strategies are required to vaccinate these children and meet the GVAP goal, particularly in eight countries which had less than 50% DTP3 coverage and are affected by emergencies and/conflict: Central African Republic, Chad, Equatorial Guinea, Nigeria, Somalia, South Sudan, Syrian Arab Republic and Ukraine.
- The number of countries that have achieved and sustained coverage ≥ 90% over the past three years was 115.
- The estimated number of un- and under-vaccinated infants in 2016 for DTP was 19.5 million. This is the lowest reported in the past five years. Of these, 12.9 million children, nearly 1 in 10, did not receive any vaccination in 2016.
- There were 146 countries that reported coverage estimates at the district level for 2016. Of those, 108 Member States had DTP3 district-level data considered valid, as compared to 122 in 2015.
- Worldwide, over half of the 108 countries with valid district-level data available in 2016 did not reach 100% of the districts or achieve 80% coverage for DTP3.
- While WHO and UNICEF estimates showed that 130 countries had DTP3 coverage of 90% or more at the national level, only 46 of these countries had coverage of 80% or more in all districts (and valid district data) and therefore were meeting the GVAP target.

Data availability and quality

For detailed information about the JRF and WUENIC coverage data, please refer to the GVAP Secretariat Report 2013, Annex 1 "Understanding immunization coverage data: WHO-UNICEF JRF and WUENIC", pp. 133–37 (http://www.who.int/entity/immunization/global_vaccine_action_plan/GVAP_secretariat_report_2013.pdf?ua=1).

By the end of 2016 most countries had begun using combination vaccines that include diphtheria–tetanus–pertussis, *Haemophilus influenzae* type b, hepatitis B (DTP–Hib–HepB) or DTP–Hib–IPV or DTP–Hib–HepB–IPV; therefore the generic term "DTP" is used in the report to refer to all DTP-containing vaccines.

Though WUENIC data are available every year and can be used to monitor progress against achievement of target coverage at the national level, full assessment of progress in national DTP3 coverage is limited by the availability of valid district-level coverage data. In this assessment, district-level coverage data were considered valid if WUENIC estimates were identical to the administrative coverage data reported by national authorities on the JRF, or if the WUENIC estimates of national coverage were 90% or greater.

Using this definition, 108 Member States (56%) had valid DTP3 district-level coverage estimates in 2016. Of the remaining 86 Member States, 38 have WUENIC estimates that differed from the JRF administrative data and were therefore not considered valid, and 48 did not report district-level coverage (Table 2.1). The number of countries that did not report district-level coverage increased from 34 in 2015 to 48 in 2016, while the number of countries with invalid district-level coverage data in 2016 was unchanged from that in 2015.

Table 2.1. National coverage and valid district-level coverage data availability for DTP3, 2016

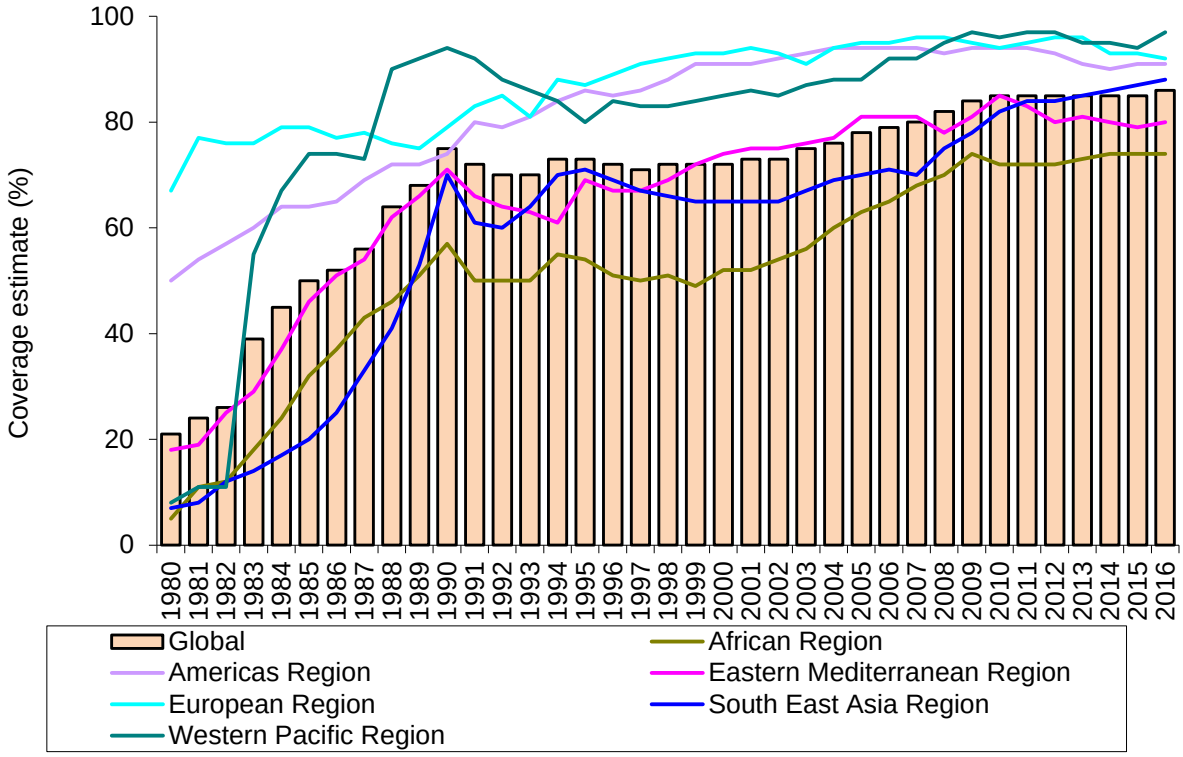
National DTP3 coverage	District data valid and ≥ 80% in all districts	District data valid, but not achieving 80% in all districts	District data not valid or not reported	Total
≥ 90%	46	47	37	130
< 90%	2	13	49	64
Total	48	60	86	194

Results

National DTP3 immunization coverage

Globally, the average coverage with three doses of DTP-containing vaccine (DTP3) remained at 86%, with no significant change during the past year. This falls short of the global immunization coverage target of 90% (Fig. 2.1).

Fig. 2.1. Global and regional average coverage rate with DTP3, 1980–2016



Source: WHO/UNICEF coverage estimates 2016 revision.

Of the 194 Member States, 130 (67%) have achieved a national DTP3 coverage rate of ≥ 90% in 2016. The distribution was uneven between WHO regions. As compared to 2015, the 2016 data showed an increase in the number of countries that attained DTP3 coverage of ≥ 90% in the African Region (+3 countries) and Western Pacific (+1 country) while coverage levels in the Region of the Americas, Eastern Mediterranean and South-East Asia Regions remained unchanged. The coverage level in the European Region remained high, 89% (Table 2.2). There were 45 countries meeting the target in 2016 as compared to 47 countries in 2015.

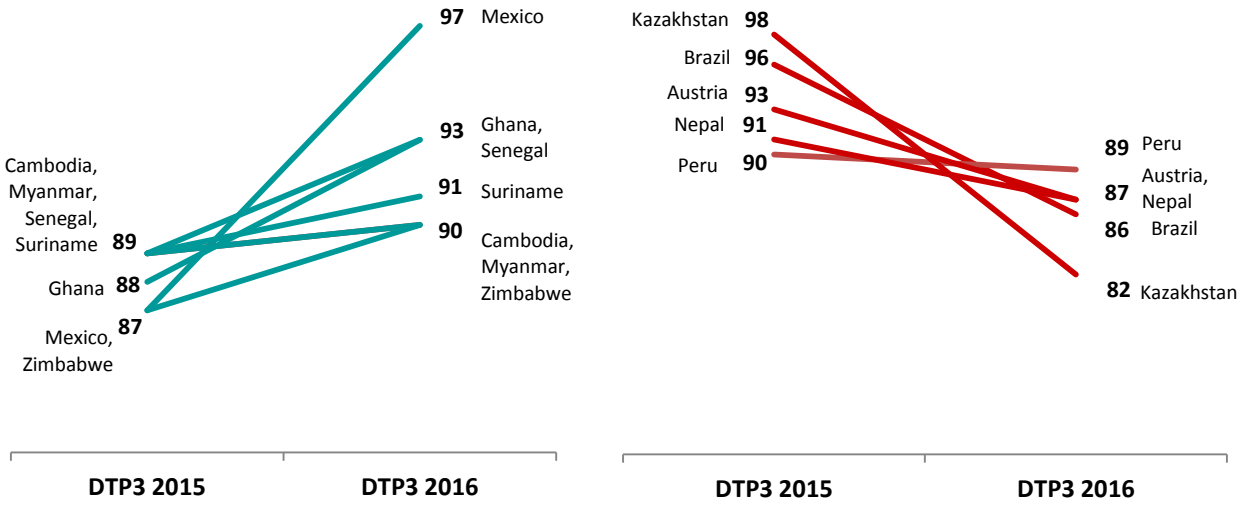
Table 2.2. Distribution of all 194 Member States by level of national DTP3 coverage rate and WHO region, based on WUENIC estimates, 2016

WHO region	DTP3 ≥ 90% in 2015		DTP3 ≥ 90%		DTP3 70–89%		DTP3 50–69%		DTP3 < 50%		Total
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*
African	17	36%	20	43%	17	36%	5	11%	5	11%	47
Americas	27	77%	27	77%	7	20%	1	3%	0	0%	35
Eastern Mediterranean	13	62%	13	62%	4	19%	2	10%	2	10%	21
European	47	89%	45	85%	6	11%	1	2%	1	2%	53
South-East Asia	7	64%	7	64%	4	36%	0	0%	0	0%	11
Western Pacific	17	63%	18	67%	6	22%	3	11%	0	0%	27
Global	128	66%	130	67%	44	23%	12	6%	8	**4%**	**194**

Source: WHO/UNICEF coverage estimates 2016 revision.

Seven countries – Cambodia, Ghana, Mexico, Myanmar, Senegal, Suriname and Zimbabwe – which in 2015 had national DTP3 coverage rates below the 90%-threshold, reached or exceeded the threshold in 2016 (Fig. 2.2a). Conversely, five countries – Austria, Brazil, Kazakhstan, Nepal and Peru – which in 2015 had national DTP3 coverage rates above the threshold, dropped below the 90%-threshold in 2016; the first three Member States lost over 5 points between 2015 and 2016 (Fig. 2.2b). There was a significant increase in DTP3 coverage (over 10 points) as compared to 2015 in the following three countries: Liberia, Mexico and the Philippines.

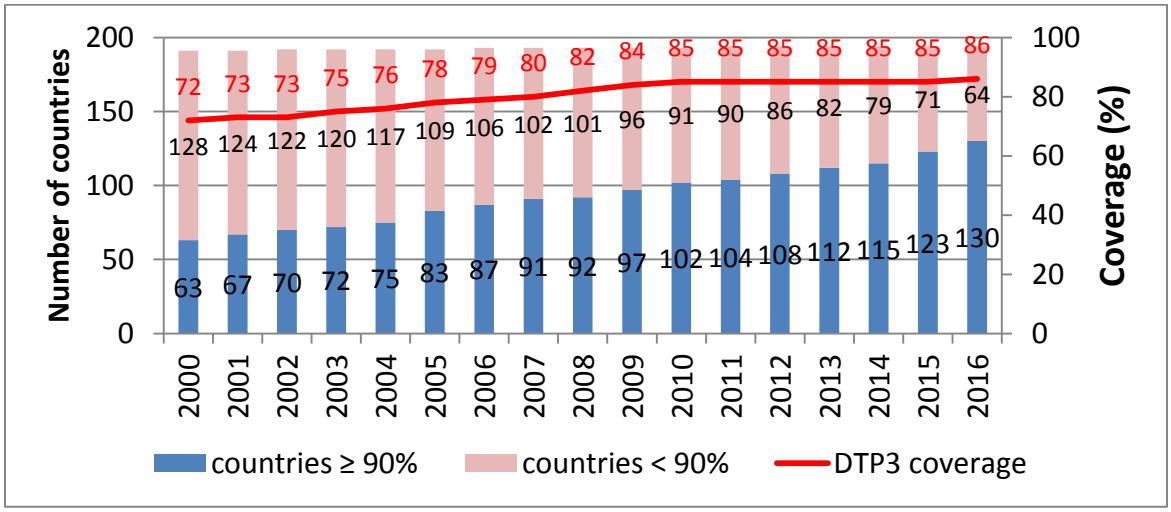
Fig. 2.2a and 2.2b. National DTP3 coverage between 2015 and 2016 in per cent for (a) countries reaching the 90%-coverage threshold and (b) countries dropping below the threshold



There are eight countries that had less than 50% DTP3 coverage in 2014 throughout 2016, including the Central African Republic, Chad, Equatorial Guinea, Nigeria, Somalia, South Sudan, the Syrian Arab Republic and Ukraine.

One hundred fifteen countries sustained DTP3 coverage ≥ 90% for three years in 2016 (Fig. 2.3), as compared to 112 countries in 2015 (indicator SO4.2). Since 2010, 102 Member States sustained their national level coverage at 90% or higher.

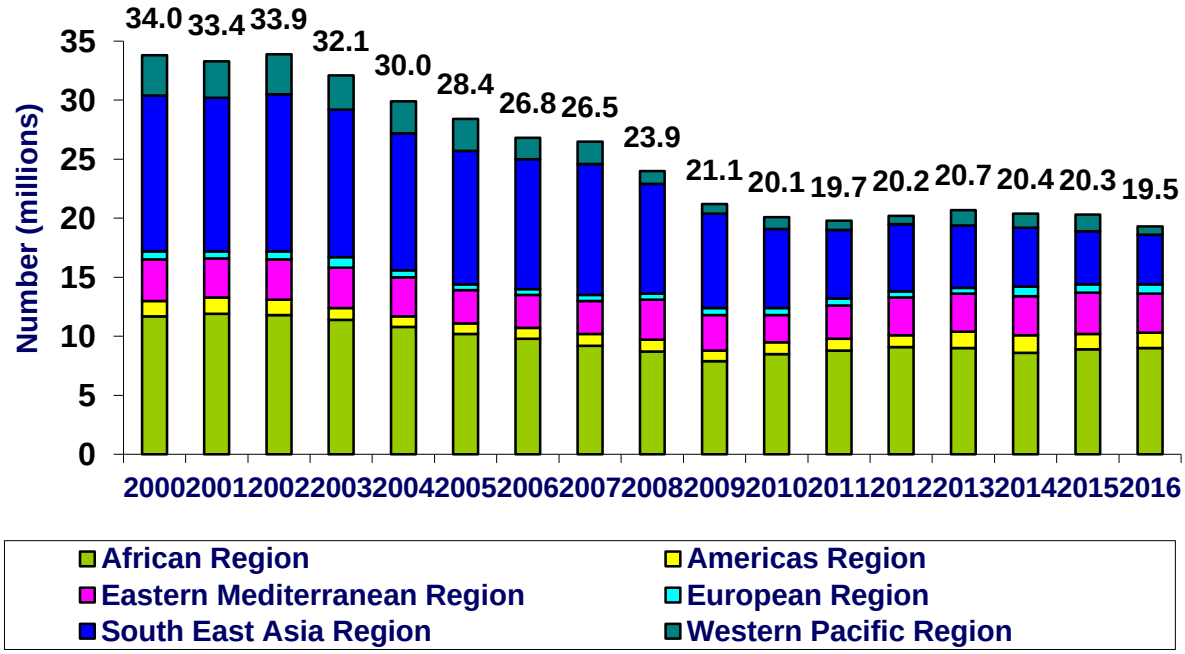
Fig. 2.3. Number of countries that have reached and sustained ≥ 90% DTP3 coverage since 2000, and global DTP3 coverage in 2016[a]



[a] Data in this table should be read as follows: "In 2016 (last column), 130 countries have reached and sustained DTP3 ≥ 90% DTP3 for 1 year; 123 for 2 years, 115 countries for the past 3 years and 63 have reached and sustained it for 16 years".
Source: WHO/UNICEF coverage estimates 2016 revision.

While DTP1 and DTP3 coverage rates are used as GVAP indicators, it is important to correlate these figures with absolute numbers of children who did not receive full vaccination to measure adequately the extent of the challenges immunization programmes in countries face. Hence, 86% of global DTP3 coverage rate in 2016 corresponds to roughly 19.5 million children who have received less than three doses of DTP vaccine. This figure was 20.3 million in 2015 (Fig. 2.4).

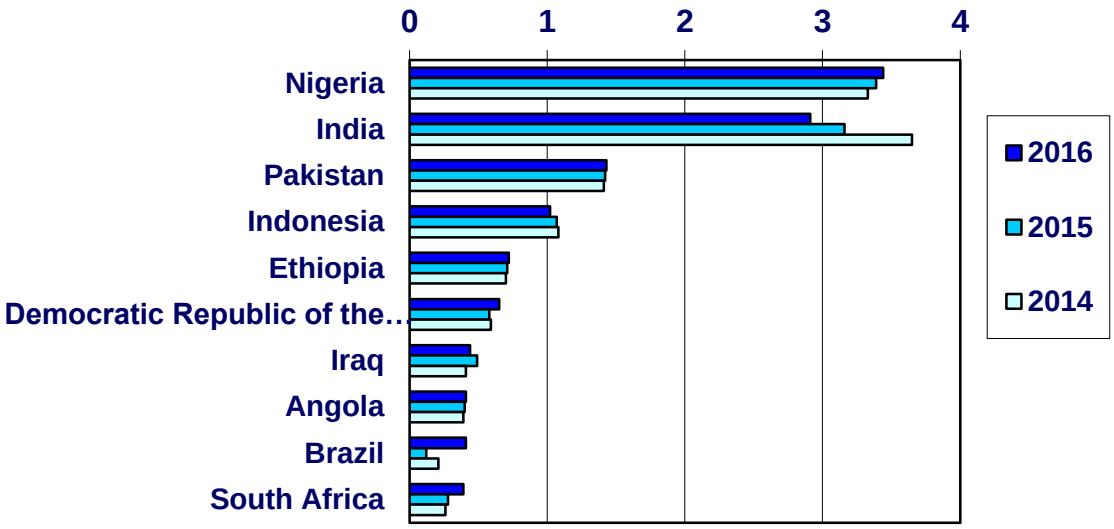
Fig. 2.4. Number of children un- or under-vaccinated with DTP by year and WHO region, 2000– 2016



Source: WHO/UNICEF coverage estimates 2016 revision. United Nations Department of Economic and Social Affairs, Population Division. World population prospects: the 2017 revision [CD-ROM]. New York (NY): United Nations; 2017.

Improvements between 2015 and 2016 on reducing un- or under-vaccinated children were measurable in a number of countries, in particular the Philippines (~605 000), India (~244 000) and Mexico (~229 000). Conversely Brazil and South Africa observed the highest increase in the number of DTP3 un- or under-vaccinated children, respectively +289 000 and +106 000. The major causes were vaccine stock-outs at national and district levels. The countries with the highest number of children who received less than three doses of DTP-containing vaccine during the past three years are shown in Fig. 2.5.

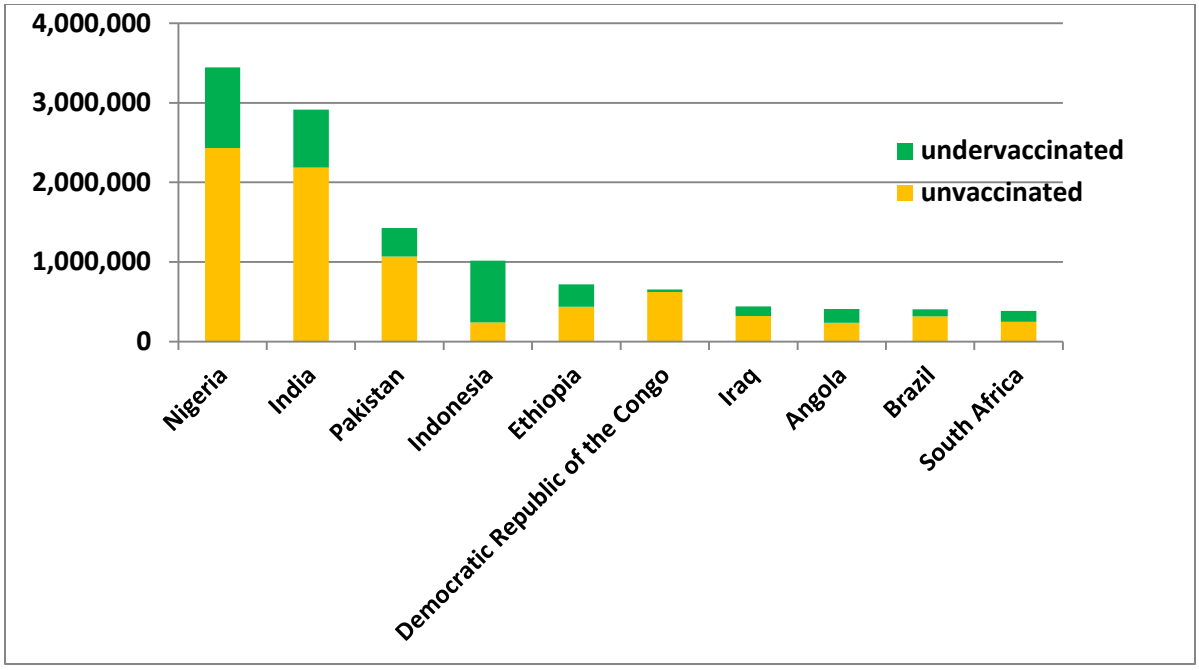
Fig. 2.5. Countries with the highest number of children un- or under-vaccinated with DTP, 2014–2016 (in millions)



Source: WHO/UNICEF coverage estimates 2016 revision. United Nations Department of Economic and Social Affairs, Population Division. World population prospects: the 2017 revision [CD-ROM]. New York (NY): United Nations; 2017.

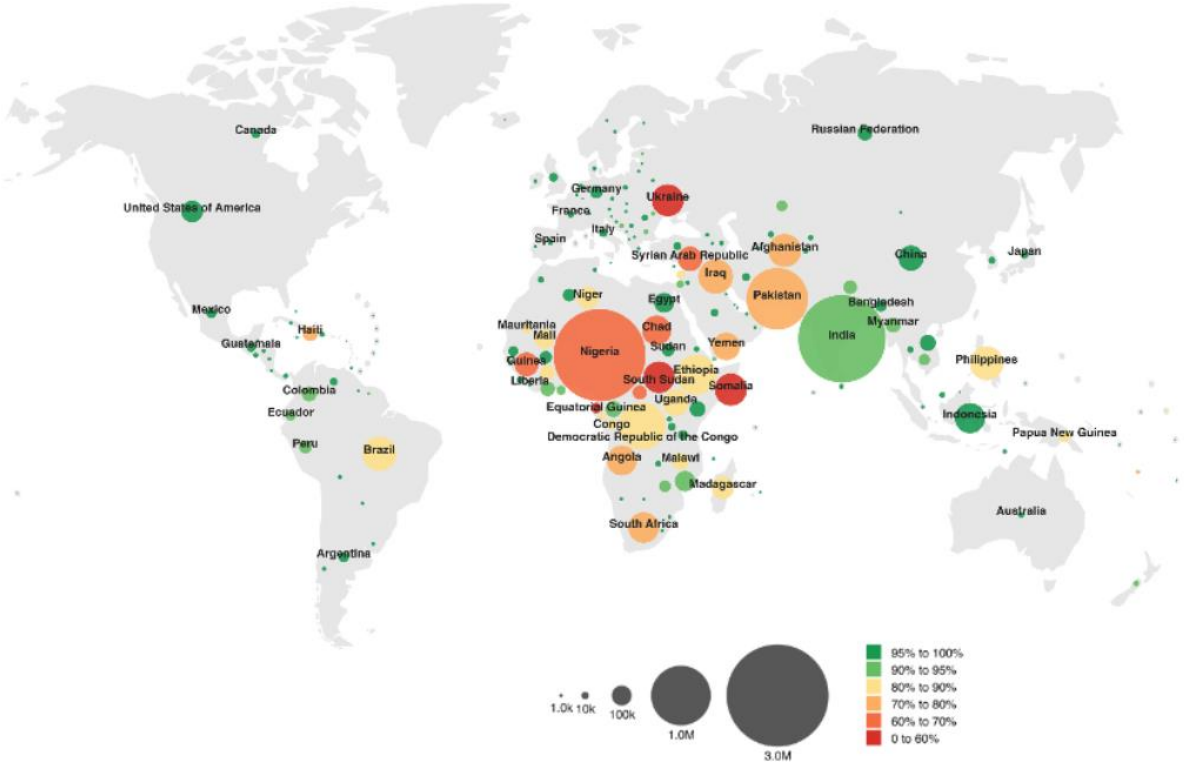
Details on the distribution of children who have not received any dose of DTP vaccine and those who have received one or two doses in 2016 are presented in Fig. 2.6 and 2.7.

Fig. 2.6: Top 10 countries with highest number of children un- or under-vaccinated with DTP, 2016



Source: WHO/UNICEF coverage estimates 2016 revision.

Fig. 2.7: DTP1 coverage and numbers of children who did not receive any dose of DTP vaccine, by country, 2016



Source: WHO/UNICEF coverage estimates 2016 revision.

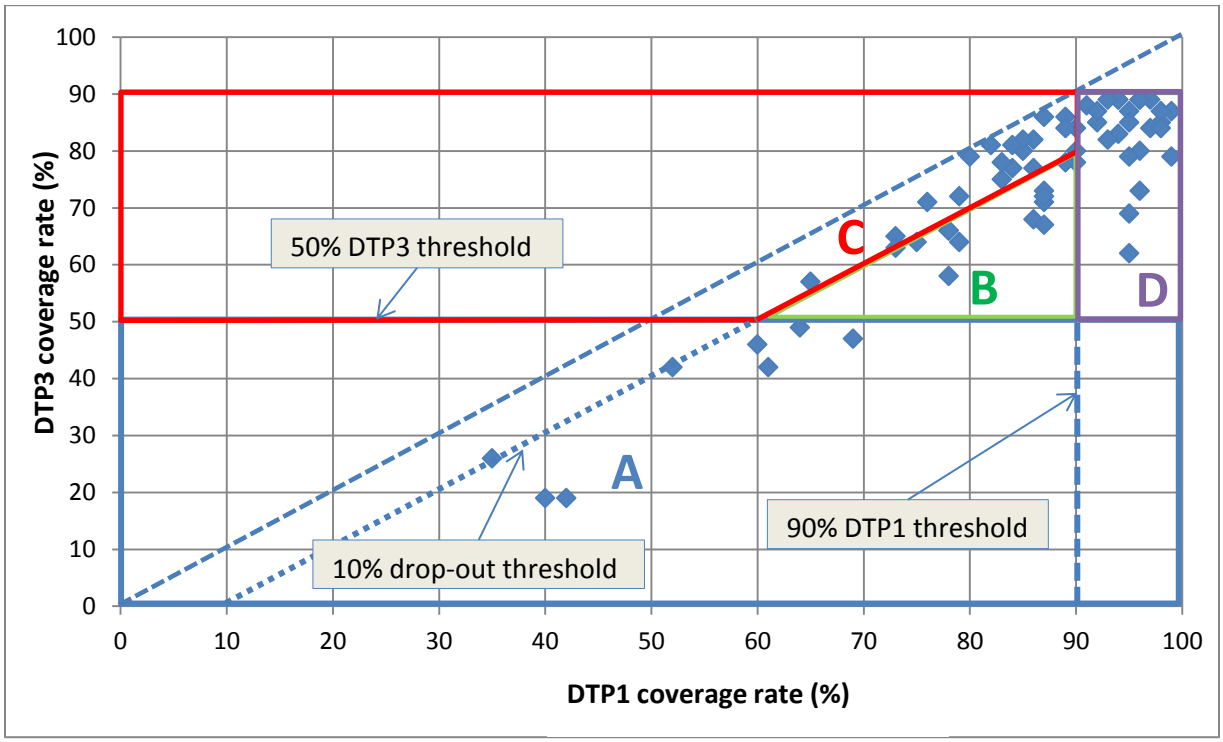
If all countries are to reach at least 90% DTP3 vaccination coverage, 9.9 million additional children would need to be vaccinated in 64 countries. Of these children, 7.3 million live in "fragile states", that is, those countries affected by conflict and/or humanitarian crises; 4 million of these children live in just three countries – Afghanistan, Nigeria and Pakistan – where access to routine immunization services is critical to achieving and sustaining polio eradication as well[7]. According to 2016 data, of these 64 countries, 23 are non-Gavi eligible lower-middle-income countries (representing 1.2 million infants), 39 are supported by Gavi (with 8.6 million un- and under-vaccinated) and two are high-income countries.

DTP1–DTP3 drop-out rates

Countries where DTP3 coverage was less than 90% in 2016 can be split into four groups based on their DTP1 and DTP3 coverage rates and their DTP1–DTP3 drop-out rate (Fig. 2.8). For each of these groups, different mechanisms and recommendations to increase coverage apply, adapted to their specific situation (Table 2.3).

[7] 1 in 10 infants worldwide did not receive any vaccinations in 2016. Joint news release UNICEF/WHO: http://www.who.int/mediacentre/news/releases/2017/infants-worldwide-vaccinations/en/

Fig. 2.8: Classification of the 64 Member States for which DTP3 national coverage is less than 90% into four groups based on their DTP1 and DTP3 coverage (and recommendations adapted to their specific situation)[a]



[a] Note: Recommendations for the four groups include the following:
A: Countries need to improve the **overall health system** (DTP3 < 50%)
B: Countries need to improve **access and address drop out** (DTP1 < 90%, DTP3 ≥ 50% and drop-out rate ≥ 10%)
C: Countries need to improve **access** (DTP1 < 90%, DTP3 ≥ 50% but drop-out rate < 10%)
D: Countries need to improve **drop-out** rate (DTP1 ≥ 90% but DTP3 < 90%)

Source: WHO/UNICEF coverage estimates 2016 revision.

Table 2.3: Classification of Member States for which DTP3 national coverage is less than 90% into four groups based on their DTP1 and DTP3 coverage (and recommendations adapted to their specific situation), 2016

Group	Definition	Countries	Proposed strategies to increase DTP3 coverage
A	**DTP3 < 50%**	Central African Republic, Chad, Equatorial Guinea, Nigeria, Somalia, South Sudan, Syrian Arab Republic and Ukraine	Most countries in this group are experiencing acute emergencies. A WHO framework for decision-making was developed in 2013 to address immunization activities for populations affected by acute emergencies[8]. **Strengthen the overall health system.**
B	**DTP3 of 50–89%, DTP1 < 90% and drop-out rate ≥ 10%**	Afghanistan, Angola, Ethiopia, Guinea, Haiti, Iraq, Mali, Marshall Islands, Mauritania, Niger, Papua New Guinea, San Marino, South Africa, Uganda and Vanuatu	**Improve access** through social mobilization, generation of demand and targeting hard-to-reach populations. **+** **Improve quality and predictability of service delivery,** and reduce missed opportunities.
C	**DTP3 of 50–89%, DTP1 < 90% and drop-out rate < 10%**	Benin, Brazil, Congo, Democratic Republic of the Congo, Gabon, Kiribati, Lao People's Democratic Republic, Lebanon, Madagascar, Malawi, Pakistan, Philippines, Tonga and Yemen	**Improve access** through social mobilization, generation of demand and targeting hard-to-reach populations.
D	**DTP3 of 50-89% and DTP1 ≥ 90%**	Austria, Bosnia and Herzegovina, Cameroon, Côte d'Ivoire, Djibouti, Dominican Republic, Ecuador, Guatemala, Guinea-Bissau, India, Indonesia, Kazakhstan, Kenya, Liberia, Micronesia (Federated States of), Montenegro, Mozambique, Nepal, Panama, Peru, Republic of Moldova, Romania, Samoa, Sierra Leone, Timor-Leste, Togo and	**Improve quality and predictability of service delivery**, and reduce missed opportunities.

[8] The framework recognizes that acute emergencies pose specific challenges to which guidelines developed for use in non-emergency settings may not apply. For example, acute emergencies may result in sudden changes in the burden of vaccine-preventable diseases (VPDs), either in their incidence or their case–fatality ratio, or both, as well as in an increased risk of epidemics and changes in the usual geo-distribution patterns: http://www.who.int/hac/techguidance/tools/vaccines_in_humanitarian_emergency_2013.pdf

		Venezuela (Bolivarian Republic of)	

District-level DTP3 coverage (G3.2)

In 2016, there were 108 (56%) Member States with valid and available district-level coverage estimates representing an 11% decrease from the 122 (63%) countries in 2015. Forty-eight countries (24%) did not provide district-level coverage data and 38 provided data that were considered not valid (Table 2.4). Among the 108 with valid district-level data, only 46 had achieved national level coverage of ≥ 90% and coverage of ≥ 80% in every district (or equivalent administrative level), meeting the indicator G3.2 target. This was less than the previous year, when 54 Member States reached this goal. Table 2.4 shows the data on a global and regional level.

Table 2.4: Distribution of Member States by national and district-level DTP3 coverage achievements, by WHO region, 2016

WHO region	Countries with DTP3 district coverage data available and valid								DTP3 district coverage data not available		DTP3 district coverage data available but not valid		Total
	DTP3 coverage national ≥ 90% & all districts ≥ 80%		DTP3 coverage national ≥ 90% but not all districts ≥ 80%		DTP3 national coverage < 90%		Total						
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	N
African	4	9%	16	34%	4	9%	24	47%	4	9%	19	40%	47
Americas	9	26%	14	40%	4	11%	27	77%	5	14%	3	9%	35
Eastern Mediterranean	6	29%	3	14%	0	0%	9	43%	4	19%	8	38%	21
European	17	32%	8	15%	4	8%	29	55%	22	42%	2	4%	53
South-East Asia	5	45%	1	9%	0	0%	6	55%	3	27%	2	18%	11
Western Pacific	5	19%	5	19%	3	11%	13	48	10	37%	4	15%	27

Global	46	24%	47	24%	15	8%	108	56%	48	24%	38	20%	194

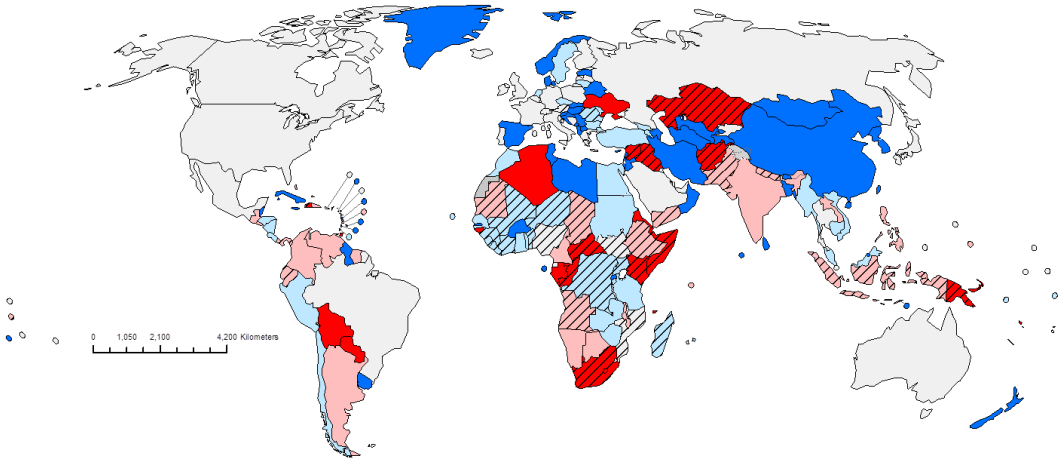
When examining district-level coverage in more detail it appears that, among the 108 countries with valid district-level coverage data, 31 countries had between 80% and 99% of their districts achieving DTP3 coverage of ≥ 80% in 2016 (indicator SO3.1), 18 countries had between 50% and 79% of their districts achieving DTP3 coverage of ≥ 80%, while nine countries had < 50% of districts achieving coverage of ≥ 80% (Table 2.5). Fig. 2.9 presents Member States according to DTP3 district-level coverage indicators.

Table 2.5: Distribution of Member States by percentage of districts achieving ≥ 80% coverage for DTP3, by WHO region, 2016

WHO region	Countries with DTP3 district coverage data available and valid										DTP3 District coverage data not available		DTP3 District coverage data available but not valid		Total
	100% districts with DTP3 ≥ 80%		80–99% districts with DTP3 ≥ 80%		50–79% districts with DTP3 ≥ 80%		0–49% districts with DTP3 ≥ 80%		Total						
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*
African	4	9%	9	17%	6	11%	5	11%	24	47%	4	9%	19	40%	47
Americas	9	26 %	6	17%	9	26%	3	9%	27	77%	5	14%	3	9%	35
Eastern Mediterranean	6	29 %	3	14%	0	0%	0	0%	9	43%	4	19%	8	38%	21
European	19	36 %	9	17%	0	0%	1	2%	29	55%	22	42%	2	4%	53
South-East Asia	5	45 %	1	9%	0	0%	0	0%	6	55%	3	27%	2	18%	11
Western Pacific	5	19 %	5	19%	3	11%	0	0%	13	48	10	37%	4	15%	27
Global	48	25 %	31	17%	18	9%	9	5%	108	56%	48	24%	38	20%	194

Source: WHO/UNICEF coverage estimates 2016 revision.

Fig. 2.9: Member States by the percentage of districts with DTP3 coverage ≥ 80%, 2016



< 50% (23 Member States (12%), 14 of which the administrative coverage DTP3 data is considered not valid)

50-79% (28 Member States (14%), 10 of which the administrative coverage DTP3 data is considered not valid)

80-99% (44 Member States (23%), 11 of which the administrative coverage DTP3 data is considered not valid)

All districts (51 Member States (26%), 3 of which the administrative coverage DTP3 data is considered not valid)

Not available (48 Member States (25%), 7 of which the administrative coverage DTP3 data is considered not valid)

Not applicable

WHO-UNICEF (WUENIC) estimate is < 90% or differs from country administrative coverage reported on the JFR and therefore district data are not considered valid (38 Member States or 20%)

Source: WHO/UNICEF coverage estimates 2016 revision.

90% coverage nationally of all vaccines in national schedule and 80% in every district (INDICATOR G3.2)

TARGET	2020 in all Member States
DEFINITION OF INDICATOR	Indicator includes the following vaccines: • Three doses of DTP, polio and the first dose of MCV for all Member States • BCG for Member States where included in the schedule (i.e. not limited to high risk populations) • Three doses of HepB, Hib, PCV and rotavirus last dose (2nd or 3rd dose, depending on the vaccine) when part of the national immunization schedule. National coverage data are included only for vaccines that have been introduced into the immunization schedule for at least one full year before the JRF reporting year (e.g. coverage reported for the full calendar year 2016 for a vaccine introduced nationwide in 2015) and in countries that have reported these data.
DATA SOURCES	WHO-UNICEF estimates of national immunization coverage (WUENIC). Administrative data from WHO-UNICEF Joint Reporting Forms (JRFs).

HIGHLIGHTS

- Globally, 83 countries (43%) reached this target for all vaccines, as compared to 2015 when 82 Member States reached the target.
- A total of 111 Member States (57%) have yet to achieve this goal; most are Gavi-eligible countries (45%) and middle-income countries (32%) that are not eligible for Gavi support.
- A total of 47 Member States (24%) met DTP3 national coverage goals but failed to meet the ≥ 90% coverage targets for all vaccines in national programmes, while 64 Member States (33%) failed to meet both targets.
- The number of countries that reached 90% national coverage for all vaccines in national programmes and 80% coverage in every district for DTP3 dropped to 39 Member States in 2016, from 41 countries in 2015 and 48 countries in 2014.

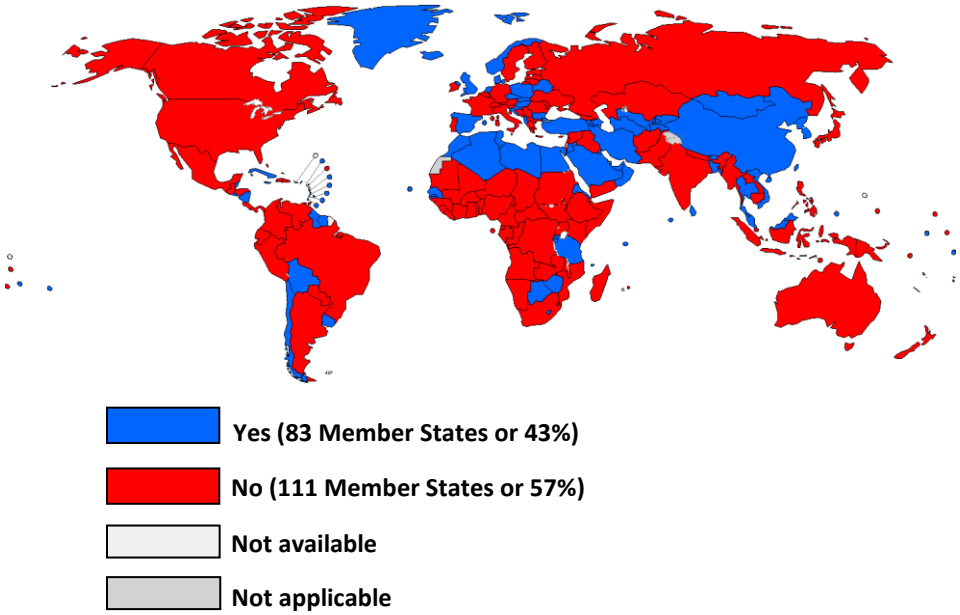
Data availability and quality

At this point, it is only possible to measure adequately progress against the target for national-level coverage, since district-level administrative data are currently available only for DTP3 and measles-containing (MCV1) vaccines. For the purposes of this analysis, it should be noted that the lowest coverage rate for any one particular vaccine that is part of the national immunization programme is used to determine whether the country has met the national indicator target. For the analysis of the district-level component of the indicator, DTP3 district-level administrative coverage data are used as a proxy for all district-level coverage data.

Results

Countries achieving in 2016 national coverage of 90% or greater for all vaccines in their immunization schedule are shown in Fig. 2.10. In 2016, 83 countries (43%) reached this target for all vaccines while the remaining 111 (57%) Member States did not.

Fig. 2.10: Member States that have achieved national coverage of ≥ 90% for all vaccines included in the national infant immunization schedule in 2016[a]



[a] Basket of infant vaccines for this indicator includes infant vaccines that are universally introduced, not infant vaccines used for risk groups and/or infant vaccines introduced in some parts of the country only.

Source:: WHO/UNICEF coverage estimates 2016 revision.

Over the past several years progress has stalled in reaching ≥ 90% national coverage for all vaccines in national programmes. In 2016, just over half of the countries in the Eastern Mediterranean and South-East Asia Regions met the GAVP goal, while fewer than half of countries in the Western Pacific, Americas and European Regions met the goal. And in the African Region fewer than a third of the countries met the goal. Fluctuations in the past three years have been minor in all regions (Table 2.6).

Table 2.6: Number of Member States that achieved ≥ 90% national coverage for all the vaccines included in their national immunization schedule[a], by WHO region, 2014–2016

WHO region	2014		2015		2016	
	n	(%)	*n*	(%)	*n*	(%)
African	15	32%	12	26%	14	30%
Americas	16	46%	18	51%	16	46%
Eastern Mediterranean	10	48%	10	48%	12	57%
European	28	53%	23	43%	23	43%
South-East Asia	6	55%	6	55%	6	55%
Western Pacific	12	44%	13	48%	12	44%
Global	87	45%	82	42%	83	43%

[a] Basket of infant vaccines for this indicator includes infant vaccines that are universally introduced, not infant vaccines used for risk groups and/or infant vaccines introduced in some parts of the country

Source: WHO/UNICEF coverage estimates 2016 revision.

Among the 111 countries that are yet to achieve this target, 24 of them[9] (22%) have only one of their antigens falling under the 90% threshold (data not shown). Reasons for this could be due to a number of causes:

- recent introduction of a new vaccine into the national programme – such as pneumococcal conjugate vaccine third dose (PCV3) in Cyprus, Lithuania, the Solomon Islands and Slovenia;
- data quality and validation problems – such as the PCV3 coverage estimate in the Russian Federation, Bacille Calmette–Guérin vaccine (BCG) in Ireland and Japan, HepB3 estimates in France, rotavirus estimates in Australia, Estonia, Israel and New Zealand;
- vaccine stock-outs – in Mexico, for example, the immunization programme reported district level stock-outs of unknown duration for rotavirus vaccine in 2016.

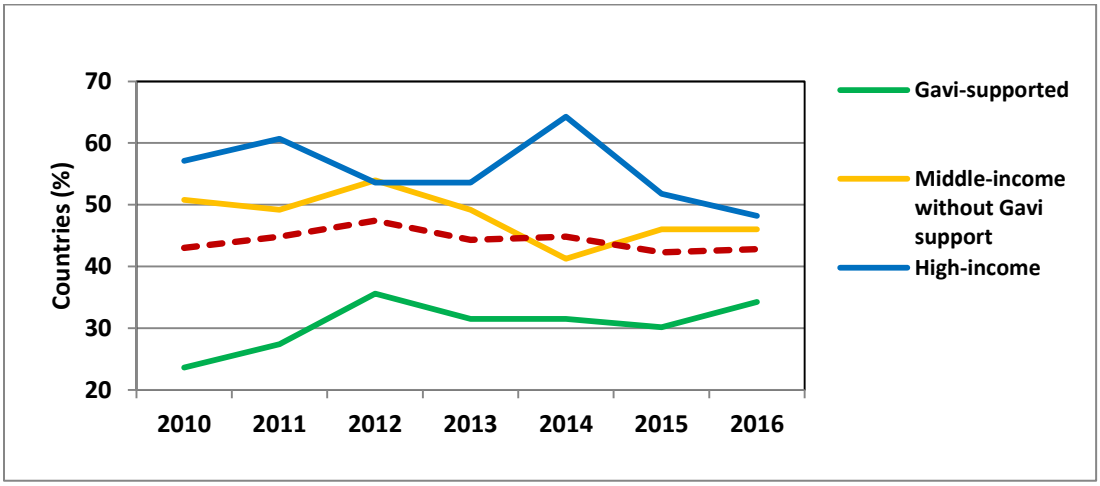
Forty-seven Member States (24%) met DTP3 national coverage goals but failed to meet the ≥ 90% coverage targets for all vaccines in national programmes, while 64 nations (33%) failed to meet both targets. A variety of causes could account for coverage of some vaccines being lower than that of DTP3. These causes are not identifiable by examining data available at the global level. Countries in this category need to examine their own data carefully to understand the underlying causes for lower coverage with one or more vaccines and take the necessary corrective actions.

When considering World Bank income groups and Gavi eligibility criteria, it appeared that 27 of 56 high-income countries (48%) reached the target of 90% coverage for all vaccines in the

[9] Australia, Belgium, Cyprus, Costa Rica, Estonia, France, Greece, Ireland, Israel, Japan, Lithuania, Luxembourg, Mauritius, Mexico, Monaco, New Zealand, Portugal, Russian Federation, Singapore, Slovenia, Solomon Islands, Sweden, Switzerland and United States of America.

national schedule. A similar number of middle-income countries[10] reached the target (29 of 63; 46%), while only 25 of 73 Gavi-eligible countries (34%) did so (Fig. 2.11).

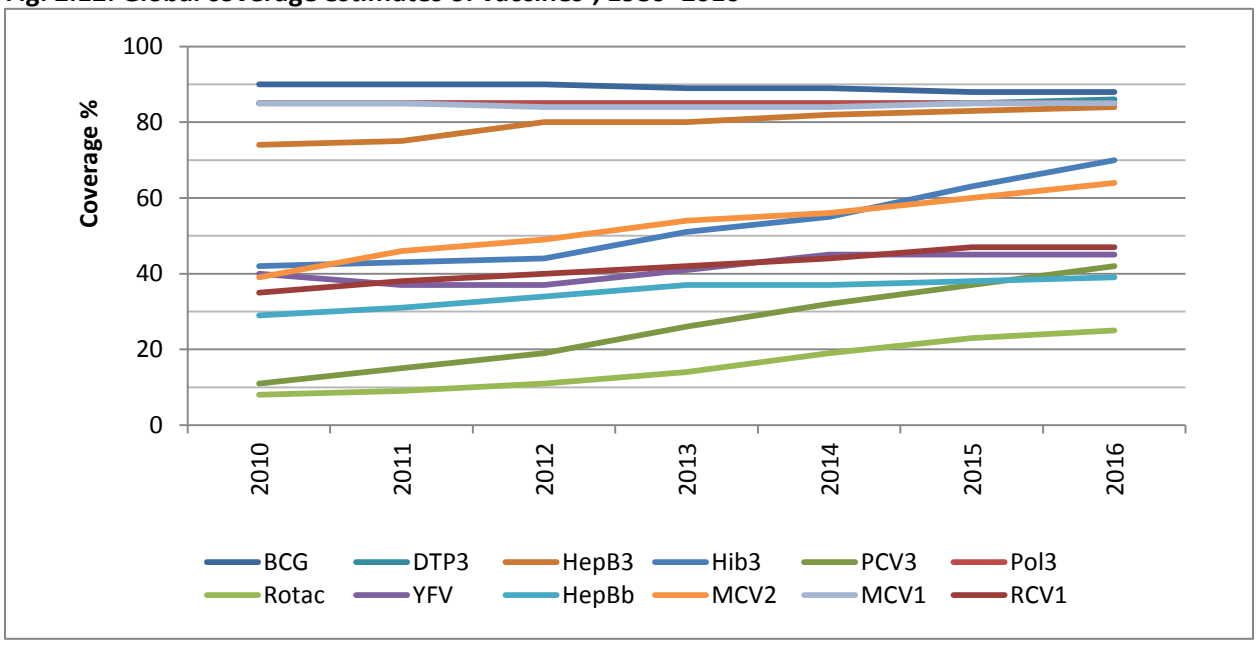
Fig. 2.11: Percentage of countries reaching ≥ 90% national coverage for all vaccines in national programme, 2010–2016



The global coverage of individual vaccines varies from one vaccine to another. While global coverage for BCG, DTP3, HepB (third dose), polio and MCV1 are all above 80%, global coverage for Hep B birth dose, rubella-containing vaccines (RCV1), MCV2 and new vaccines like rotavirus, PCV and Hib remains low (Fig. 2.12). Many countries are yet to introduce these vaccines in their national programmes.

[10] According to the World Bank: http://www.worldbank.org/en/country/mic

Fig. 2.12: Global coverage estimates of vaccines[a], 1980–2016



[a] BCG, DTP3, MCV1 & MCV2, HepB (birth and 3rd doses), Hib (3rd dose), Pol 3rd dose (either OPV or IPV), PCV3, RCV1, rotavirus vaccine (last dose) and yellow fever vaccine (YFV).

Source: WHO/UNICEF coverage estimates 2016 revision.

District-level coverage for all vaccines in the national programme

As mentioned in the section on data availability above, DTP3 district-level coverage data are currently used as proxy for district coverage of all vaccines. In 2016 39 Member States reached 90% national coverage for all vaccines in the national programme and 80% coverage in every district for DTP3 (Table 2.7). The trend in coverage and reaching the GVAP target is shown in Table 2.8.

Table 2.7 Number of countries meeting the GVAP target for national level coverage for all vaccines in the national schedule, and district-level coverage for DTP3, 2016

National coverage of all vaccines	No. of countries where district DTP3 data valid and ≥ 80% in all districts	No. of countries where district DTP3 data valid, but not achieving 80% in all districts	No. of countries where district DTP3 data not valid or not reported	Total
≥ 90%	39	28	16	83
< 90%	9	32	70	111
Total	48	60	86	194

Table 2.8 Number of countries meeting the GVAP target for national level coverage for all vaccines in the national schedule, and district-level coverage for DTP3, 2014–2016

	2014	**2015**	**2016**
No. of countries where national coverage for all vaccines ≥ 90% and district DTP3 data valid and ≥ 80% in all districts	48	41	39
No. of countries with valid DTP3 district-level coverage data	113	122	108

Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s) (INDICATOR SO3.2)

TARGETS	Increasing trend in equity in immunization coverage Proportion of Member States with < 20% difference in DTP3 coverage between the lowest and highest wealth quintile: 60% by 2015 75% by 2020.
DEFINITION OF INDICATOR	• DTP3 immunization coverage among 1-year-olds distributed by wealth quintiles for the period 2008–2015 • Determination of wealth index as defined in DHS and MICS • Data are to be measured at least twice (by special study or survey), with an early and late measure.
DATA SOURCES	WHO Health Equity Monitor Database of the Global Health Data repository,[11] which contains data on more than 30 reproductive maternal, neonatal and child health indicators disaggregated by child's sex, place of residence (rural versus urban), wealth quintile and educational level. Consolidated data come from DHS and MICS conducted in 102 Member States, 100 of which are from low- or middle-income countries. The Health Equity Assessment Toolkit (HEAT) helps visualize data from the WHO Health Equity Monitor Database and allows for comparison between countries[12].

Highlights

- Data from Demographic and Health Surveys (DHS) or Multiple Indicator Cluster Surveys (MICS) conducted between 2008 and 2015 on national diphtheria–tetanus–pertussis (DTP3) coverage rates by wealth quintiles were available for 84 Member States (43%) compared to 64 Member States in the previous year's report; only 58 of the 75 "Countdown" countries[13] (77%) have DTP3 coverage rates by wealth quintiles available.
- Coverage in 66 Member States (79%) was generally higher in the wealthiest quintile than in the poorest quintile.
- Of the 84 countries with available data, 59 (70%) have met the target of < 20% difference in immunization coverage between the highest and lowest wealth quintiles (including 18 for which DTP3 national coverage for the richest is lower than for the poorest population).
- Among the 41 countries with the interquartile difference between 0 and 20% (meeting the target), only half had DTP3 coverage above 90%.

[11] The database can be found at: http://apps.who.int/gho/data/node.main.HE-1540?lang=en.
[12] The tool can be found at: https://whoequity.shinyapps.io/HEAT/
[13] http://countdown2030.org

- Twenty-five countries (30%) had a quintile differential ≥ 20% and have thus failed to meet the target. Of those, none of the countries had DTP3 coverage ≥ 90%, meaning that all 25 countries have failed to meet both targets.

Data availability and quality

Data for this indicator were derived from a re-analysis of publicly available[14] DHS and MICS data. Standard indicator definitions as defined in DHS and MICS documentation for economic status and immunization coverage were used. Health inequality data, particularly the proxy methods used by DHS and MICS, have several limitations and must be interpreted with caution[15]. Since estimates of household wealth and immunization coverage are only available through DHS and MICS, which are conducted periodically, these data cannot be generated for each country on an annual basis. The analysis was limited to surveys conducted from 2008 to 2015 (data from surveys conducted in 2016 or later are not yet published or reanalysed).

There may be minor discrepancies for a few countries between the data reported here and in previous DHS or MICS country reports, owing to small differences in the definition and calculation of some indicators. More information about the indicator criteria is available in the WHO Indicator and Measurement Registry.[16]

DHS and MICS provide data on children aged 12–23 months, meaning the birth year of the cohort is the year before the surveys were conducted (i.e. a DHS conducted in 2008 corresponds to the 2007 birth cohort). DTP3 coverage data used for each country correspond to the birth year of the cohort and not the year the national surveys were conducted.

Since two thirds of countries only had a single survey for the descriptive analysis, if multiple years of survey data were available within the relevant time period, data from the most recent survey were chosen for inclusion in the analysis. For example, surveys were conducted in Cambodia in 2010 and in 2014, but only the data from the survey conducted in 2014 were included in this analysis. At the time of this report, 84 countries had data on DTP3 coverage rates by wealth quintiles between 2008 and 2015. Data availability has improved since last year, with completed and reanalysed surveys from 20 additional countries[17].

To identify trends, at least two time points are required. In total 28 countries had two or more surveys conducted since 2008. For those Member States that have not conducted a survey since 2008, a new survey will be needed to establish a baseline. The United Nations (UN) Secretary-General's Global Strategy for Women's and Children's Health recommends household surveys every three years for the 75 "Countdown" Member States (countries with the highest

[14] Immunization: DTP3 Equity: wealth quintile, data by country (http://apps.who.int/gho/data/node.main.HE-1590?Lang=en).

[15] See the "Handbook on health inequality monitoring with a special focus on low- and middle-income Member States" (http://apps.who.int/iris/bitstream/10665/85345/1/9789241548632_eng.pdf)

[16] www.who.int/gho/indicator_registry/en/).

17 Afghanistan, Dominican Republic, El Salvador, Guatemala, Guinea Bissau, Jamaica, Mexico, Montenegro, Myanmar, Namibia, Panama, Republic of Moldova, Serbia, South Sudan, Sudan, Tunisia, Turkmenistan, Ukraine, Yemen and Zambia.

child mortality). Therefore it is expected that at least these Member States will collect three sets of data during the decade, to monitor reduction in coverage inequities.

Results

Baseline data on DTP3 coverage rates for the highest and lowest wealth quintile from DHS and MICS conducted from 2008 to 2015 in 84 Member States was used to calculate the quintile differential defined as the lowest wealth quintile's coverage rate subtracted from the highest wealth quintile's coverage rate. The mapping of Member States with DTP coverage data by wealth quintiles available between 2008 and 2015 is presented in Fig. 2.13. The quintile differentials for all countries with ≥ 10% quintile difference are displayed in Fig. 2.14.

Of the 84 countries with data, 59[18] (70%) have met the target of < 20% difference in immunization coverage between the highest and lowest wealth quintiles. Among those 59 countries, 18 Member States (31%) had higher coverage in the poorest quintile than in the wealthiest quintile. As this analysis addresses the inequalities in DTP3 coverage in the poorest wealth quintile, the negative difference in coverage between the richest and poorest quintiles in these 18 countries will not be addressed. It should be noted that 12 countries (20%) reached the target of a quintile differential < 20% but still had ≥ 10% difference between the richest and poorest quintiles, and 29 countries (49%) had a quintile differential < 10% but ≥ 0% (Tables 2.9 and 2.10).

Although the 12 countries with a quintile differential < 20% but ≥ 10% have met the goal, additional efforts to lower the quintile differential to below 10% are needed. These should include efforts to meet the DTP3 national coverage target of ≥ 90% as only two[19] of the 12 countries have national coverage of ≥ 90% (Table 2.9). Guatemala, Guinea Bissau, Panama, the Philippines, Senegal and Zambia have DTP3 national coverage ≥ 80% and < 90%. Those Member States with a quintile differential of ≤ 10% are shown in Table 2.10.

[18] Albania, Armenia, Bangladesh, Belize, Bolivia (Plurinational State of), Bosnia and Herzegovina, Burkina Faso, Burundi, Chad, Colombia, Costa Rica, Dominican Republic, Egypt, El Salvador, Gabon, Gambia, Ghana, Guatemala, Guinea Bissau, Guyana, Haiti, Honduras, Jamaica, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Malawi, Maldives, Mauritania, Mexico, Mongolia, Montenegro, Namibia, Nepal, Panama, Peru, Philippines, Republic of Moldova, Rwanda, Sao Tome and Principe, Senegal, Serbia, Sierra Leone, Suriname, Swaziland, Tajikistan, The former Yugoslav republic of Macedonia, Timor-Leste, Togo, Tunisia, Turkmenistan, Uganda, Ukraine, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

[19] Bangladesh and United Republic of Tanzania.

Table 2.9: DTP3 national coverage, DTP3 coverage by wealth quintile, and quintile differential for 12 Member States having a quintile differential of ≥ 10% and < 20%

Category	Country (survey year)	DTP3 coverage	Quintile 1 (poorest)	Quintile 5 (richest)	Quintile differential
DTP3 ≥ 90% ***n*=2 (2%)**	Bangladesh (2014)	91	81	97	16
	United Republic of Tanzania (2015)	90	81	95	15
DTP3 < 90% ***n*=10 (12%)**	Timor-Leste (2009)	66	55	73	18
	Chad (2014)	34	29	45	17
	Senegal (2015)	89	82	99	17
	Mauritania (2011)	60	53	68	16
	Panama (2013)	81	78	94	16
	Guinea Bissau (2014)	83	75	91	16
	Philippines (2013)	86	79	93	15
	Zambia (2013)	87	80	95	15
	Haiti (2012)	63	55	68	13
	Guatemala (2014)	85	79	90	11

Source: Data from DHS or MICS conducted between 2008 and 2015.

Table 2.10: DTP3 national coverage, DTP3 coverage by wealth quintile, and quintile differential for 29 Member States having a quintile differential of ≤ 10% but > 0%

Category	Country (survey year)	DTP3 coverage	Quintile 1 (poorest)	Quintile 5 (richest)	Quintile differential
Quintile differential <10% but >0% and DTP3 ≥90% n = 17 (20%)	Armenia (2010)	95	88.3	96.9	8.6
	Bosnia and Herzegovina (2011)	93	92.3	93.8	1.5
	Burkina Faso (2010)	90	83.4	92.9	9.5
	Colombia (2010)	91	84.9	92.5	7.6
	Costa Rica (2011)	94	89.8	97.2	7.4
	Egypt (2014)	97	93.7	99.1	5.4
	Guyana (2014)	92	90.4	93.8	3.4
	Honduras (2011)	96	96.4	98.1	1.7
	Jordan (2012)	98	96.2	99.1	2.8
	Kenya (2014)	90	83.7	92.8	9.2
	Malawi (2015)	93	92.1	92.8	0.6
	Mongolia (2010)	93	91.2	96.2	5.0
	Montenegro (2013)	92	86.6	93.7	7.2
	Rwanda (2014)	98	95.7	98.9	3.3
	Sao Tome and Principe (2014)	95	91.8	96.5	4.7
	Swaziland (2014)	92	91.3	96.2	4.9
	Tunisia (2011)	96	96.1	99.6	3.5
Quintile	Bolivia (Plurinational State of) 2008	86	85.7	86.1	0.4

Category	Country (survey year)	DTP3 coverage	Quintile 1 (poorest)	Quintile 5 (richest)	Quintile differential
differential <10% but >0% and DTP3 <90% n =12 (14%)	Dominican Republic (2014)	63	55.2	64.7	9.5
	Gabon (2012)	73	62.2	71.8	9.7
	Ghana (2014)	89	88.1	91.9	3.8
	Mexico (2015)	72	74.9	77.4	2.6
	Nepal (2014)	89	88.7	94.7	6.0
	Peru (2012)	84	83.4	88.6	5.1
	Togo (2013)	83	84.0	90.9	6.9
	Uganda (2011)	72	74.5	74.8	0.3
	Ukraine (2012)	75	68.2	69.9	1.8
	Viet Nam (2013)	89	83.3	91.8	8.6
	Zimbabwe (2015)	84	80.5	85.8	5.3

Source: Data from DHS or MICS conducted between 2008 and 2015.

The remaining 25 countries (30%) had a quintile differential > 20% and none have reached the target for DTP3 coverage of ≥ 90% (Table 2.11). Therefore they have met neither the DTP3 national coverage target nor the wealth quintile coverage gap reduction target. In this group, Cambodia is the one country to have reached a DTP3 coverage ≥ 80%; the quintile difference was 24.6% in 2014 and the DHS figure for the same year shows 84% for national DTP3 coverage. For these 25 Member States, a strategy to increase the overall national coverage, while targeting the populations in the lowest wealth quintile, will be essential in making progress towards both goals.

In general, Member States with high DTP3 national coverage were likely to have smaller differences in coverage between wealth quintiles. Seventeen[20] of the Member States with national DTP3 coverage rates of ≥ 90% had a quintile differential < 10% but ≥ 0%.

From the 28 countries where at least 2 data points were available in time, 15 decreased the equity gap, for five there were no significant changes observed and for eight countries the equity gap increased. Six of the 28 counties still have more than a 20% gap between poorest and richest wealth quintiles. The overall trend seems to indicate a minor reduction in inequity, although this trend could not be observed for all countries (Table 2.12).

[20] Armenia, Bosnia and Herzegovina, Burkina Faso, Colombia, Costa Rica, Egypt, Guyana, Honduras, Jordan, Kenya, Malawi, Mongolia, Montenegro, Rwanda, Sao Tome and Principe, Swaziland and Tunisia.

Table 2.11: DTP3 national coverage, DTP3 coverage by wealth quintile and quintile differential for 25 Member States having a quintile differential of > 20%

Category	Country (survey year)	DTP3 coverage	Quintile 1 (poorest)	Quintile 5 (richest)	Quintile differential
DTP3 < 90% *n*=25 (30%)	Nigeria (2013)	38	7	80	72
	Pakistan (2012)	65	30	88	58
	Lao People's Democratic Republic (2011)	56	37	81	45
	Central African Republic (2010)	32	18	61	43
	Cameroon (2011)	69	45	88	43
	Yemen (2013)	60	43	84	41
	Madagascar (2008)	73	54	93	39
	Ethiopia (2011)	37	26	64	38
	Sudan (2014)	75	52	90	38
	Myanmar (2015)	63	50	84	35
	Democratic Republic of the Congo (2013)	63	48	83	35
	Indonesia (2012)	72	53	85	33
	Guinea (2012)	50	32	63	31
	Niger (2012)	69	53	84	31
	Côte d'Ivoire (2011)	64	52	81	29
	Mali (2012)	64	49	78	29
	Iraq (2011)	70	56	83	28
	Benin (2011)	74	59	86	27
	Congo (2011)	69	55	82	27
	Comoros (2012)	73	58	84	26
	Cambodia (2014)	84	72	96	25
	South Sudan (2010)	15	6	31	24
	Afghanistan (2015)	58	49	70	22
	Mozambique (2011)	77	65	88	22
	Liberia (2013)	72	58	79	21

Source: Data from DHS or MICS conducted between 2008 and 2015.

Table 2.12: DTP3 national coverage, DTP3 coverage by wealth quintile, and quintile differentials for countries with data points from multiple years[a]

Country	Y 1	QD	Y 2	QD	Y 3	QD
Afghanistan	2010	24	2015	21		
Bangladesh	2011	8	2014	16		
Cambodia	2010	19	2014	25		
Chad	2010	17	2014	17		
Democratic Republic of the Congo	2010	32	2013	35		
Dominican Republic	2013	35	2014	10		
Egypt	2008	2	2014	5		
Ghana	2008	4	2011	1	2014	4
Guyana	2009	10	2014	3		
Kazakhstan	2010	-2	2015	-7		
Kenya	2008	12	2014	9		
Kyrgyzstan	2012	-19	2014	-6		
Lesotho	2009	15	2014	-7		
Malawi	2010	3	2013	4	2015	1
Mozambique	2008	30	2011	22		
Nepal	2010	13	2011	10	2014	6
Nigeria	2008	68	2011	64	2013	72
Peru	2010	-5	2011	13	2012	5
Philippines	2008	22	2013	15		
Rwanda	2010	3	2014	3		
Sao Tome and Principe	2008	5	2014	5		
Senegal	2012	14	2014	6	2015	17
Sierra Leone	2008	17	2010	3	2013	-7
Sudan	2010	44	2014	38		
Swaziland	2010	-7	2014	5		
Togo	2010	22	2013	7		
Viet Nam	2010	25	2013	9		
Zimbabwe	2010	14	2014	10	2015	5

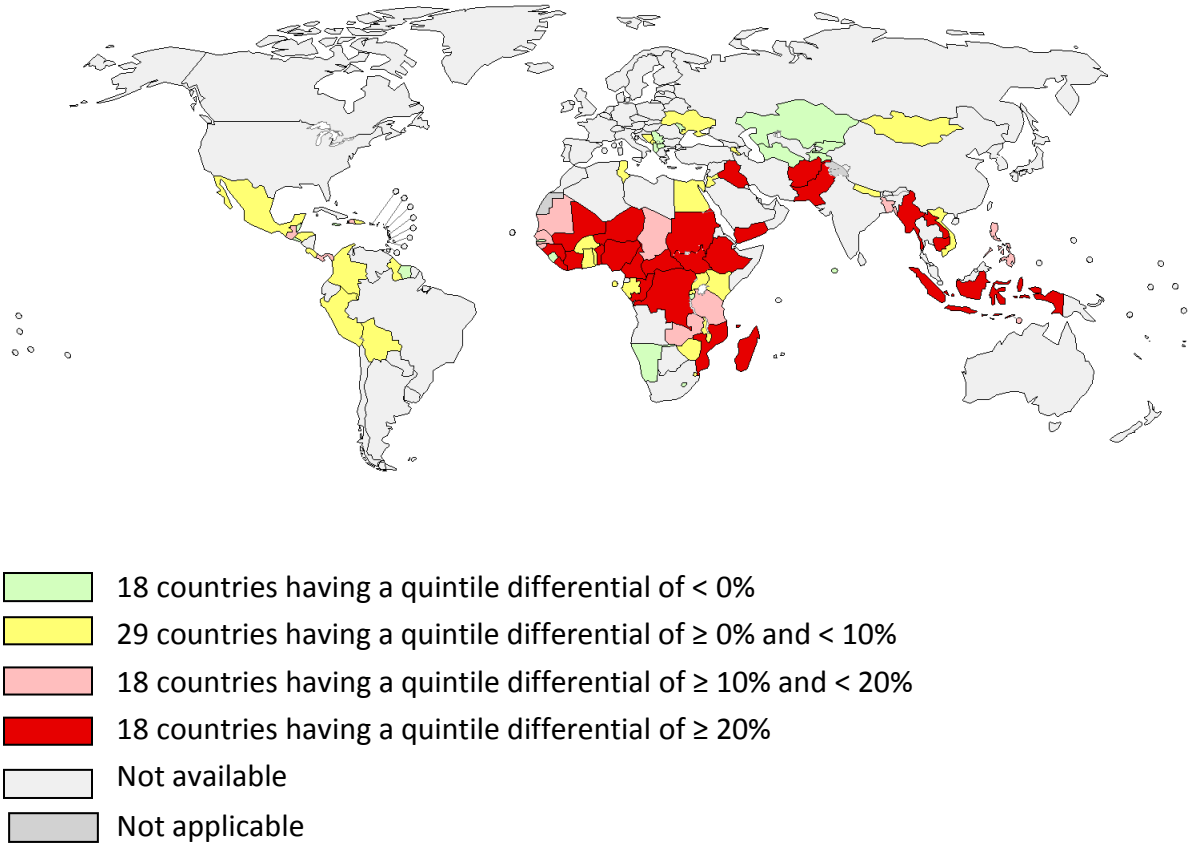
QD, quintile differential.

[a] Showing latest three years available.

Source: Data from DHS or MICS conducted between 2008 and 2015.

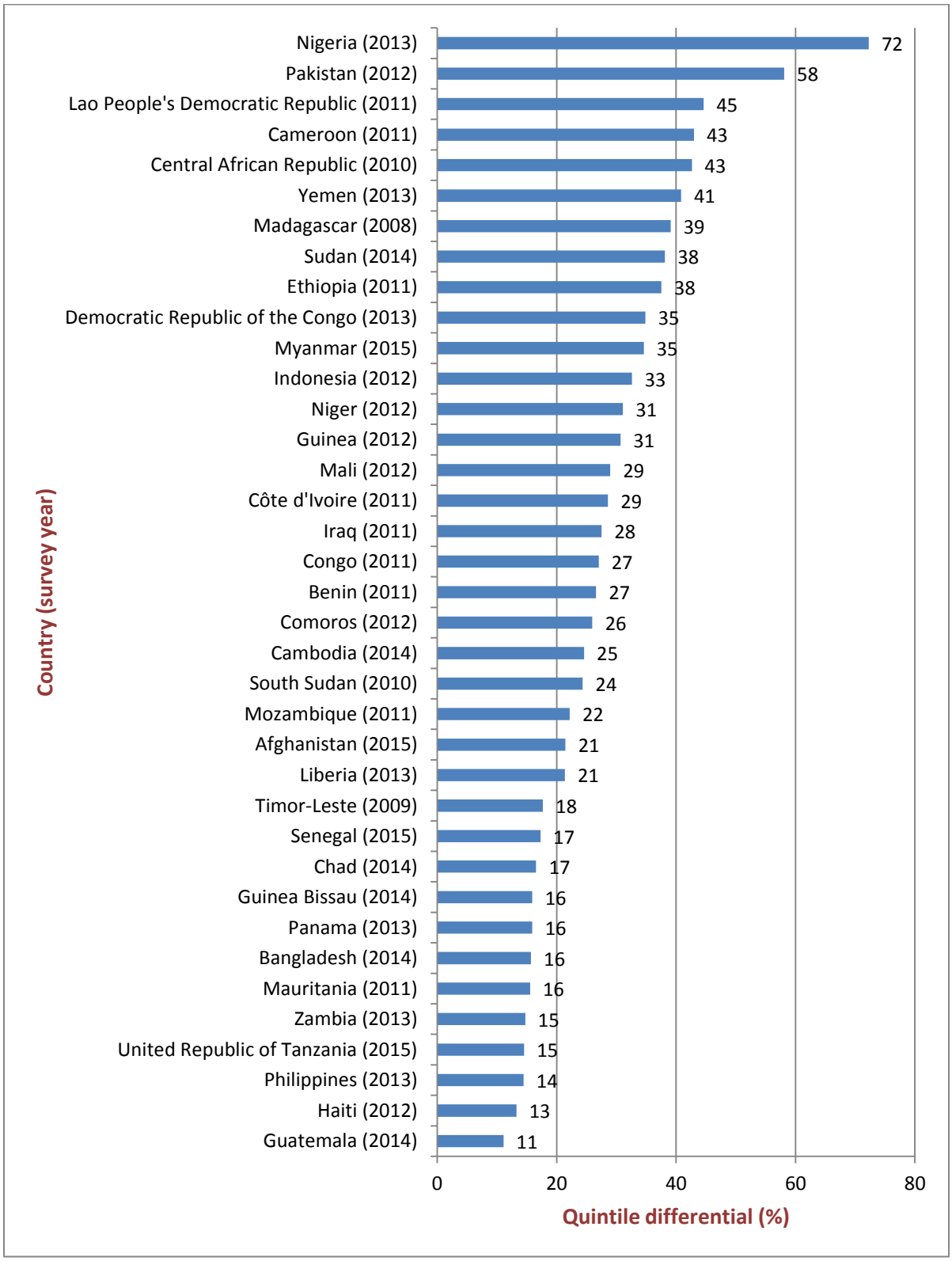
It should be noted that this indicator cannot be properly assessed globally until all countries conduct at least 2 DHS or MICS. As it stands, the underlying target for all countries to have baseline data by 2015 has not been met. Preliminary results indicate that countries with DTP3 coverage below 90% have a tendency to have greater wealth quintile differentials; it is therefore important for those countries with lower national coverage to assess equity in immunization coverage.

Fig. 2.13: Member States with DTP coverage data by wealth quintiles available between 2008 and 2015



Source: Data from DHS or MICS conducted between 2008 and 2015.

Fig. 2.14: DTP3 quintile differential for 37 Member States having a quintile differential of ≥ 10%



Source: Data from DHS or MICS conducted between 2008 and 2015.

GOAL 4: DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNOLOGIES

Number of low-income and middle-income countries that have introduced one or more new and under-utilized vaccines (Indicator G4.3)

TARGET	2015: At least 90 low- and middle-income Member States 2020: All low- and middle-income Member States This year, the GVAP classifications of Gavi-eligible and non-Gavi-eligible middle-income countries have been used, representing 138 countries. The data from high-income countries are not included as they are not applicable to the indicator.
DEFINITION OF INDICATOR	A vaccine is added to the national immunization schedule and used for a sustained period of at least 12 months. New and under-utilized vaccines are all vaccines that were not previously included in the national immunization schedule. Introduction of a single dose of IPV as part of the polio eradication end-game strategy is not considered as an inclusion criterion for this indicator.
DATA SOURCES	WHO-UNICEF Joint Reporting Forms (JRFs).
DATA AVAILABILITY AND QUALITY	The limitations of JRF and WUENIC coverage data were discussed in the GVAP Secretariat report 2013[21].

HIGHLIGHTS

- There has been significant progress over the past six years in the introduction of new vaccines.
- The 2015 goal for introduction of new or underutilized vaccines in low- and middle-income countries was already achieved, exceeding the target with 99 low- and middle-income countries having introduced at least one new and under-utilized vaccine to their national immunization programme and sustained vaccine use for at least 12 months by the end of 2014.
- By the end of 2015, a total of 193 vaccine introductions took place in 108 of the 138 low- and middle-income countries worldwide during the first six years of the Decade of Vaccines. (These countries account for more than two thirds of the low- and middle-income Member States).
- Many vaccine introductions took place in Gavi-eligible countries; 90% of Gavi-eligible countries (66 of 73 countries) introduced at least one new or under-utilized vaccine during this time frame (61% of the 108 low- and middle-income countries where new or under-utilized vaccines were introduced).

[21] For more information about the JRF and WUENIC coverage data, please refer to the GVAP Secretariat report 2013, Annex 1. http://www.who.int/entity/immunization/global_vaccine_action_plan/GVAP_secretariat_report_2013.pdf?ua=1

Note: Since the indicator reviews sustained use (full calendar year) of vaccine, reporting on this indicator reviews data on vaccines introduced at latest by the end of December 2015. Hence, a vaccine introduced in 2015 will have completed its first full calendar year over the current 2016 reporting period.

RESULTS

In the first six years of the Decade of Vaccines – January 2010 to December 2015 – 108 of the 138 low- and middle-income countries added at least one new and under-utilized vaccine to their national immunization programme and sustained vaccine use for at least 12 months, i.e. until December 2015 (Table 2.13). These vaccines include: Hib-containing vaccine, pneumococcal conjugate vaccine (PCV), rotavirus vaccine, human papillomavirus vaccine (HPV), rubella and Japanese encephalitis. These 108 countries represent more than 70% of the world's population living in low- and middle-income countries.

Table 2.13: Number of low- and middle-income Member States that introduced a new and under-utilized vaccine between January 2010 and December 2015 and sustained its use for at least 12 months, by vaccine and Gavi eligibility

Country classification	Total no. of countries by category	Member States having introduced at least one vaccine	Vaccines					
			Hib	PCV	Rota virus	HPV	Rubella	JE
Countries eligible for Gavi support[a]	73	66 (90%)	14	52	35	3	15	4
Middle-income countries, no Gavi support	65	42 (65%)	14	22	13	17	4	0
Total	138	108 (78%)	28	74	48	20	19	4

JE, Japanese encephalitis.

[a] Includes countries eligible for Gavi support for new vaccines in 2015, but excludes countries transitioning out of Gavi support that year.

Forty-three of these low- and middle-income countries introduced one vaccine from 2010 to 2015, while 65 countries (45 of which are middle-income countries eligible for Gavi support and

20 are not) introduced more than one vaccine. A total of 193 vaccine introductions took place in these 108 low- and middle-income countries during the first six years of the Decade of Vaccines. Tables 2.14 and 2.15 show the breakdown by WHO region.

An increase in new and under-utilized vaccine introductions during recent years was seen with pneumococcal vaccines, which 54% of low- and middle-income countries introduced. Additionally, 35% of low- and middle-income countries introduced rotavirus vaccines between 2010 and 2015. During the same period, 19 low- and middle-income countries had introduced and sustained rubella vaccine, and 20 had introduced and sustained the use of HPV through 2015 (only three of which – Lesotho, Rwanda and Uganda – are supported by Gavi). It is expected that the number of low- and middle-income countries introducing HPV will increase due to the Gavi policy supporting routine HPV introduction.

Table 2.14: Number of Gavi-supported Member States that have added one or more new and under-utilized vaccines[a] to their national immunization schedule, by year and WHO region

WHO region	Number of Gavi-supported countries/ total Member States in region (2015)	Number of Gavi-supported countries having introduced at least one vaccine					
		2010	2011	2012	2013	2014	2015
African	37/47	0	10 (27%)	8 (22%)	12 (32%)	19 (51%)	9 (24%)
Americas	6/35	2 (33%)	2 (33%)	1 (17%)	0	2 (33%)	0
Eastern Mediterranean	6/21	0	2 (33%)	2 (33%)	2 (33%)	3 (50%)	1 (17%)
European	8/53	1 (13%)	1 (13%)	2 (25%)	3 (38%)	3 (38%)	2 (25%)
South-East Asia	9/11	0	2 (22%)	4 (44%)	1 (11%)	1 (11%)	4 (44%)
Western Pacific	7/27	2 (29%)	0	1 (14%)	5 (71%)	0	6 (86%)
Total	73/194	5 (7%)	17 (23%)	18 (25%)	23 (32%)	28 (38%)	22 (30%)

[a] Excluding IPV.

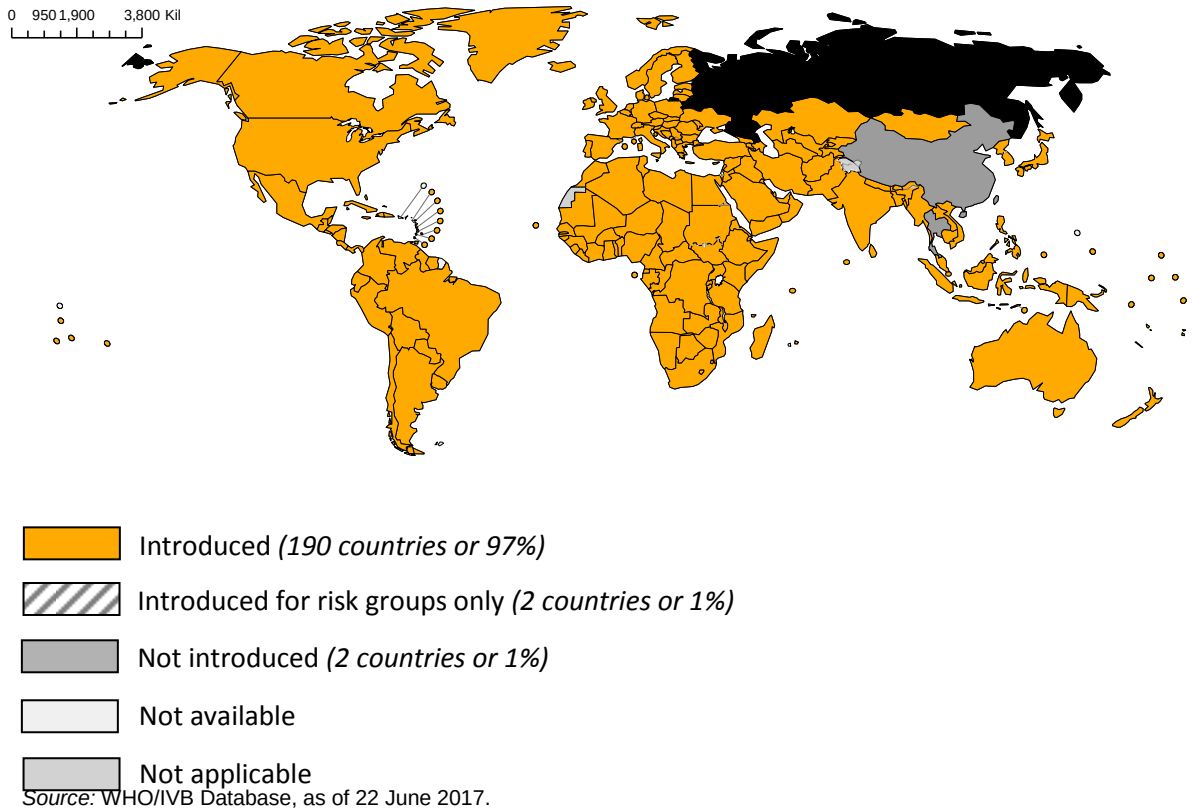
Table 2.15: Number of middle-income Member States not supported by Gavi that have added one or more new and under-utilized vaccines[a] to their national immunization schedule, by year and WHO region

WHO region	Number of middle-income countries without Gavi support/total Member States in region (2015)	Number of middle-income countries without Gavi support having introduced at least one vaccine					
		2010	2011	2012	2013	2014	2015
African	9/47	2 (22%)	1 (11%)	1 (11%)	1 (11%)	3 (33%)	3 (33%)
Americas	20/35	6 (30%)	3 (15%)	6 (30%)	3 (15%)	3 (15%)	1 (5%)
Eastern Mediterranean	9/21	1 (11%)	1 (11%)	1 (11%)	1 (11%)	3 (33%)	2 (22%)
European	12/53	3 (25%)	1 (8%)	0	1 (8%)	1 (8%)	0
South-East Asia	2/11	0	0	0	1 (50%)	0	0
Western Pacific	13/27	3 (23%)	2 (15%)	2 (15%)	2 (15%)	0	1(8%)
Total	65/194	15 (23%)	8 (12%)	10 (15%)	9 (14%)	10 (15%)	7 (11%)

[a] Excluding IPV.

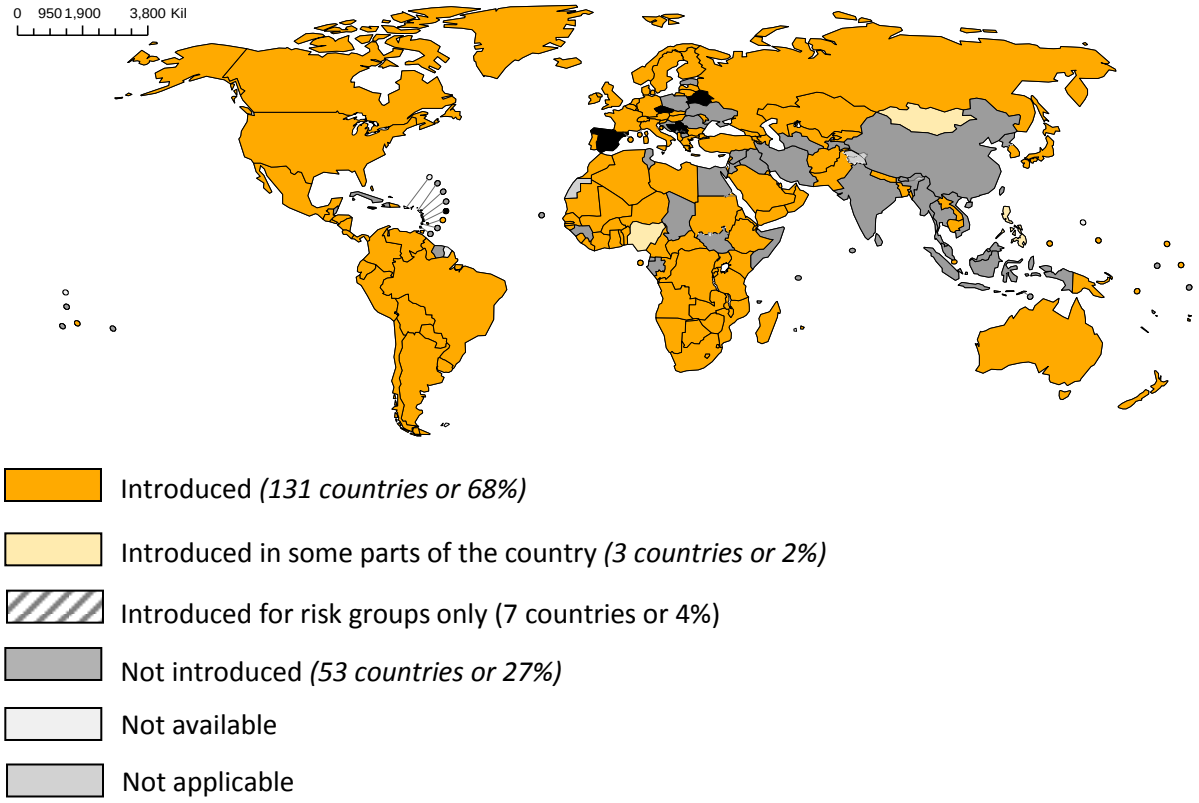
Fig. 2.15–2.18 show the status of the use of Hib-containing, pneumococcal conjugate, rotavirus and HPV vaccines in national immunization programmes worldwide. Note that the maps include vaccines introduced before 2010 and after 2015, and represent the most current data available.

Fig. 2.15: Member States with Hib-containing vaccine in their national immunization programme



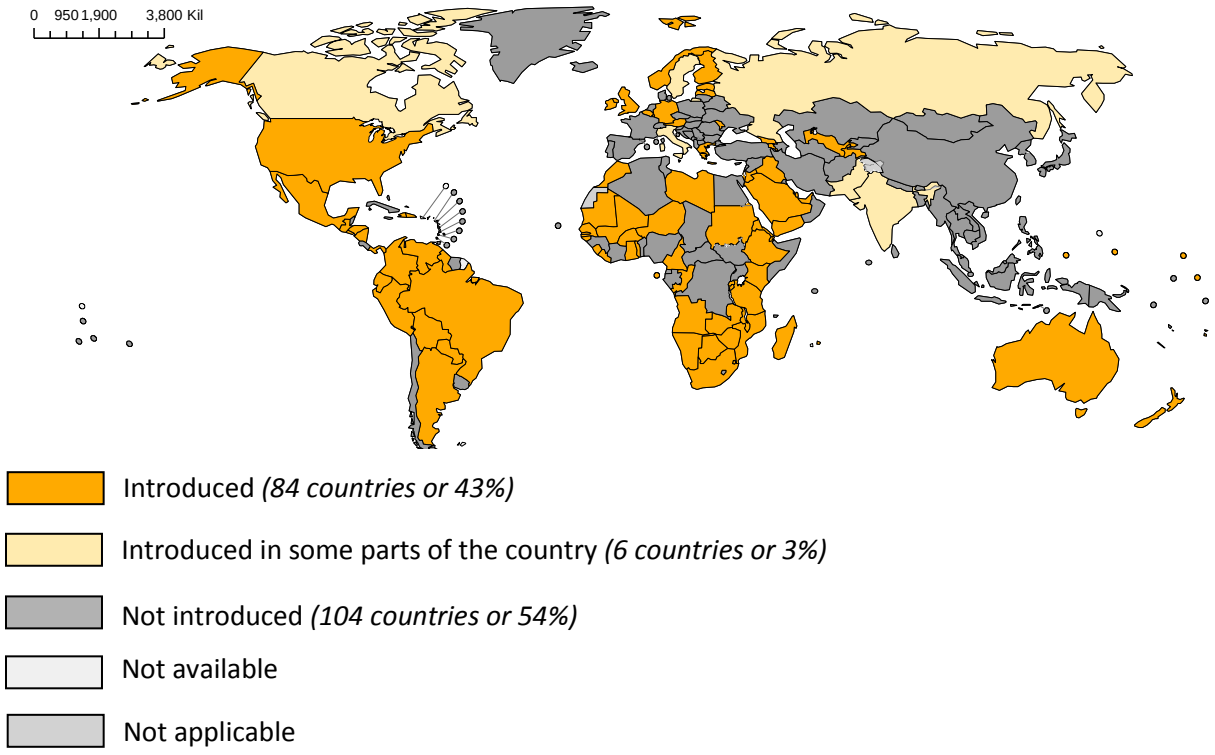
Source: WHO/IVB Database, as of 22 June 2017.

Fig. 2.16: Member States with pneumococcal conjugate vaccine in their national immunization programme



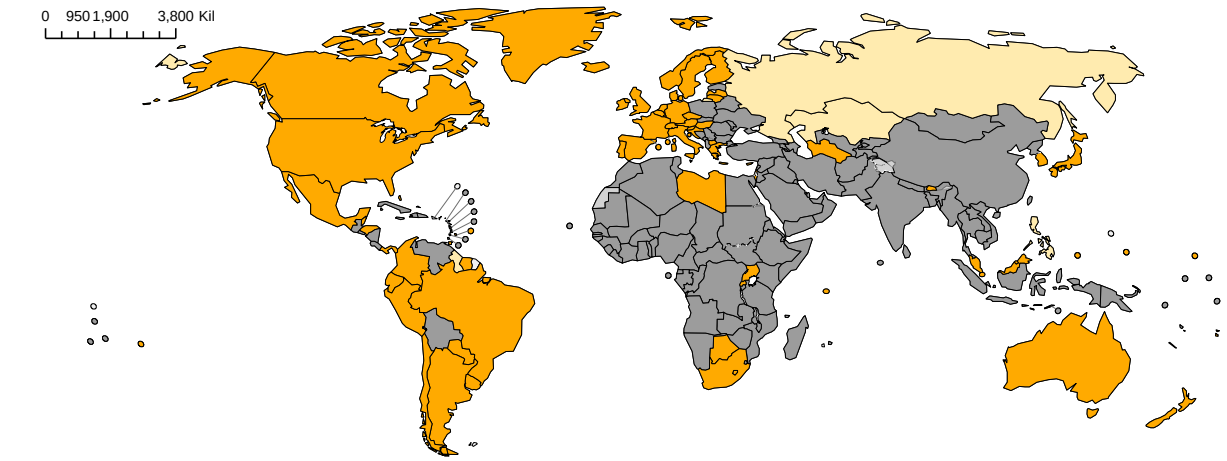
Source: WHO/IVB Database, as of 22 June 2017.

Fig. 2.17: Member States with rotavirus vaccine in their national immunization programme



Source: WHO/IVB Database, as of 22 June 2017.

Fig. 2.18: Member States with HPV vaccine in the national immunization programme



Introduced *(70 countries or 36%)*

Introduced in some parts of the country *(4 countries or 2%)*

Not introduced *(120 countries or 62%)*

Not available

Not applicable

Source: WHO/IVB Database, as of 22 June 2017.

3. Reduction in under-five mortality and integration indicators

GOAL 5: EXCEED THE MILLENIUM DEVELOPMENT GOAL 4 TARGET FOR REDUCING CHILD MORTALITY

In its 2016 assessment report *(1)*, the SAGE DoV working group recommended countries to "(…) expand immunization services beyond infants and children to the whole life course, and determine the most effective and efficient means of reaching other age groups within integrated health service provision. New platforms are urgently needed to reach people during the second-year-of-life, childhood, adolescence, pregnancy, and into later adulthood".

The integration of health services is "the organization and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money". *(2)* However, measuring integration remains a complex issue and difficult to measure with simple indicators.

Reduction in under-five mortality is among the goals of the GVAP. This is aligned with the target in the Global Strategy for Women's, Children's and Adolescents' Health, the Millennium Development Goal (MDG) 4 for 2015, and the Sustainable Development Goals (SDGs): "By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births" (SDG 3.2).

The integration indicator was not originally part of the GVAP monitoring and accountability framework, but it was felt that integrated delivery of services across the continuum of care was instrumental for the health and well-being of women, children and adolescents. Hence, the integration indicator that shows the composite coverage with key interventions across the continuum of care is presented along with the report on progress in reducing under-five mortality.

Reduce under-five mortality rate (Indicator G5.1)

TARGET	2015: Two thirds reduction compared to 1990 2020: Exceed 2015 target of two thirds reduction in under-five mortality rate.
DEFINITION OF INDICATOR	Under-five mortality rate per 1000 live births.
DATA SOURCES	United National Interagency Group on Mortality Estimates.

HIGHLIGHTS

- Substantial progress has been made towards achieving Millennium Development Goal 4. Worldwide, the number of deaths among children under age five has halved. Yet, in 2015[1], an estimated 5.9 million children under age five died.
- About one third of countries worldwide have reduced their under-five mortality by two thirds or more and achieved the MDG 4 target set in 2000. Among them are 24 low- or lower-middle-income countries.
- Under-five mortality remains a concern in many parts of the world, with pockets of high mortality in many countries, particularly in the African and Eastern Mediterranean Regions.

Under-five mortality is one of the key indicators used to monitor progress on the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030) *(3)*. Mortality data for 2016 were not available at the time of the finalization of this year's GVAP secretariat report. Analyses are based on 2015 figures, which were also used by the 2017 progress report on the Global Strategy for Women's and Children's Health.

Member States committed to implementing the Global Strategy for Women's and Children's Health and requested the WHO Director-General to report regularly on progress towards women's, children's and adolescents' health as endorsed by the Sixty-Ninth World Health Assembly resolution WHA69.2 in 2016. To help monitor progress the Global Health Partnership (H6) and other partners have created an open-access online data portal publishing the latest available country data on the 60 relevant indicators, including on immunization[2]. This portal was launched in May 2017 on the WHO Global Health Observatory website. In addition, WHO collaborated with partners in Every Woman Every Child and the Partnership for Maternal, Newborn & Child Health on a 2017 progress report *(4);* highlights from the report are excerpted in Box 3.1.

Box 3.1: Main messages from *Progress in partnership: 2017 progress report on the Every Woman Every Child Global Strategy for Women's, Children's and Adolescents' Health*

Globally, the health and well-being of women, children and adolescents are improving faster than at any point in history, even in many of the poorest nations. The transformation is due in great measure to one of the most successful global health initiatives in history: Every Woman Every Child (EWEC). The EWEC movement puts the EWEC Global Strategy into practice through country-led, multi-stakeholder engagement and collaboration, and mutual accountability for

[1] Mortality data for 2016 were not available at the time of the finalization of this year's GVAP Secretariat report.
[2] Data portal for the Global Strategy for Women's, Children's and Adolescents' Health (http://apps.who.int/gho/data/node.gswcah).

results, resources and rights. Its core partners include H6[3], the Partnership for Maternal, Newborn and Child Health (PMNCH) and the Global Financing Facility.

"Survive, Thrive and Transform": progress towards the EWEC Global Strategy's objectives

Survive

The number of preventable deaths among women, children and adolescents, and also of stillbirths, remains high. For example, while the world's maternal death rate has fallen by 44% since 1990, an estimated 303 000 women died from preventable causes during pregnancy and childbirth in 2015, with more than half of maternal deaths occurring in sub-Saharan Africa. From 1990 to 2015, death rates of children aged under 5 declined by 53%. But still an estimated 5.9 million children aged under 5 died in 2015, mainly of avoidable causes, among which were 2.7 million newborns who died within 28 days of birth. Stillbirth also remains a major neglected problem, with 2.6 million stillbirths estimated in 2015.

Thrive

Multiple barriers to high-quality health care and health-enhancing services prevent millions of women, children and adolescents from realizing their full potential and their human right to the highest attainable standard of health and well-being. For example, in low- and middle-income countries, 250 million children are at risk of suboptimal development due to poverty and stunting. Additionally, poor-quality health services and inequities in accessing care are major obstacles to improving health outcomes. Gaps are also exacerbated by the worldwide shortage of qualified health workers: global projections to 2030 estimate that an additional 18 million health workers will be needed to meet the requirements of the SDGs. Furthermore, many women and girls do not have access to comprehensive sexual and reproductive health services and rights, including modern contraceptive methods, safe abortion (where legal), treatment and prevention of infertility, and prevention of sexual violence.

Transform

Issues such as lack of civil registration of children at birth, poverty, gender inequality, lack of education, lack of adequate water, sanitation and hygiene, air pollution, gender-based violence and discrimination constitute both violations of rights and barriers to progress. For example, the number of out-of-school children of primary school age declined globally from 99 million in 2000 to 59 million in 2013. However, progress has stalled since 2007. Just 1% of the poorest girls in low-income countries complete upper secondary school. Worldwide, almost one third of all women who have been in a relationship have experienced physical and/or sexual violence by their intimate partner, and 30% of adolescent girls (aged 15–19 years) have experienced physical and/or sexual violence by an intimate partner. Issues such as poverty, gender inequality, poor education, discrimination and violence often intersect, leading to even greater vulnerabilities and increased risks of preventable death, illness and injury.

Commitments to the EWEC global strategy

[3] https://www.everywomaneverychild.org/2016/03/03/h6/

EWEC has mobilized continued support from governments and a diverse group of nongovernmental stakeholders. Commitments, whether financial, in-kind or shared value interventions (policy, advocacy, etc.) have increased since 2015. Between September 2015 and December 2016, 215 commitments were made to the EWEC Global Strategy, totalling US$28.4 billion (excluding the value of non-financial commitments, which is considerable but hard to quantify). Governments of low- and lower-middle-income countries committed an estimated US$ 8.5 billion – more than half the sum committed by high-income countries. By number of commitments, governments account for 28%; the private sector, 24%; civil society organizations and nongovernmental organizations, 23%; UN agencies, 7%; and joint partnerships, 4%. For example, The Government of Afghanistan committed in 2015 to improve the quality of education for midwives, and to enhance medical services and supplies in hard-to-reach and insecure areas. It has also committed to creating a multisectoral movement to strengthen gender equity and women's empowerment, improving peace and security in Afghanistan.

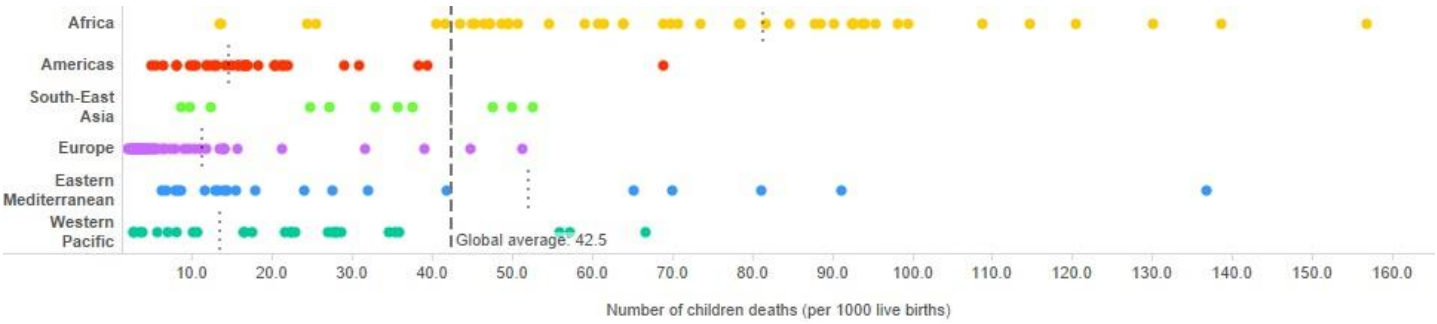
Advancing EWEC partners' framework for 2018–2020

To support countries in the implementation of their national plans and accelerate progress in achieving the EWEC Global Strategy and the SDGs, partners have identified six areas requiring more focused attention and better aligned multi-stakeholder action: early childhood development; adolescent health and well-being; quality, equity and dignity in health services; sexual and reproductive health and rights; empowerment of women, girls and communities; and humanitarian and fragile settings. The five common deliverables are: political commitment; integrative, sustainable financing; multi-stakeholder and cross-sectoral partnership; improved management systems and capacities; and strengthened data and information systems and accountability at all levels.

In a time of increased conflicts, refugee and migrant crises, shifting political agendas, widespread human rights violations, and persisting and emerging dangers, the need to harness the power of partnership and work together with a common vision for change has never been more urgent. The rewards are great: investing in health and well-being of women, children and adolescents produces healthier and more inclusive communities, vibrant economies and more peaceful societies.

In the absence of 2016 estimates of under-five mortality, additional analysis of the 2015 under-five mortality data has been done, to show the extreme spread of mortality rates across WHO regions and countries (Fig. 3.1). More details are available in the interactive online version.

Fig. 3.1: Under-five mortality rate per 1000 live births in 2015, by WHO region[a]

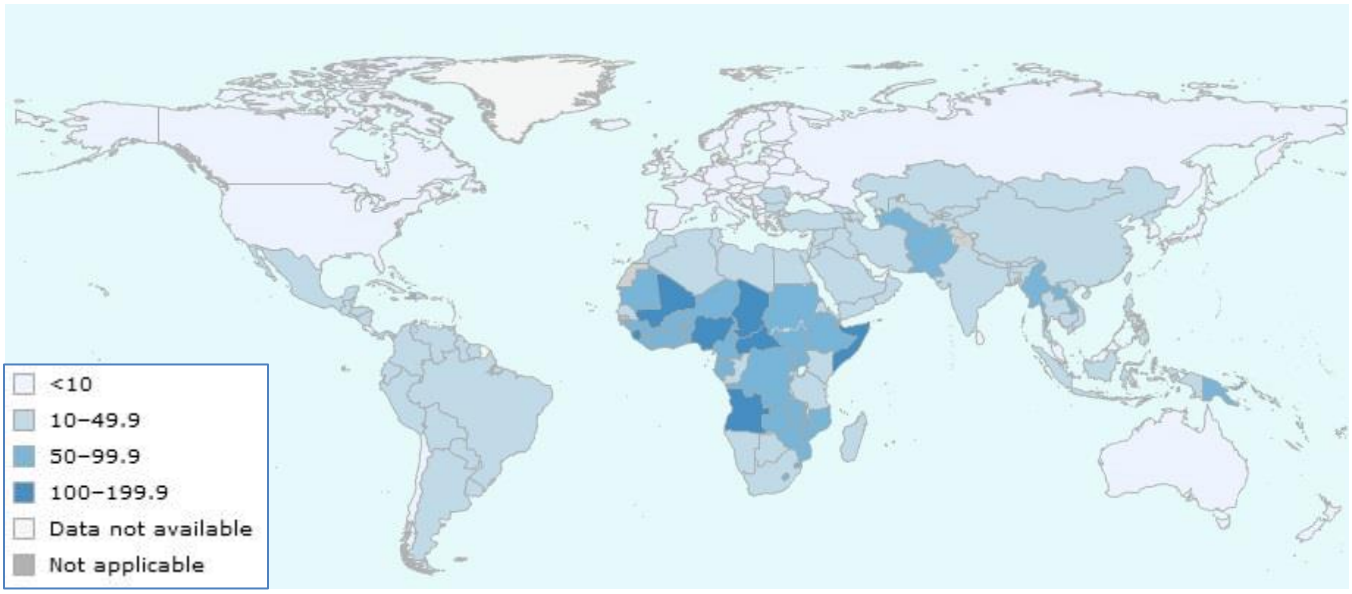


[a] Each dot represents the average rate for one country.
NB: The dotted grey line indicates the regional average, and the dashed grey line indicates the global average.
Source: WHO Global Health Observatory data portal on the Global Strategy for Women's, Children's and Adolescents' Health.

It is noteworthy that all countries, without exception, have seen their under-five mortality rate decline over the past 25 years (globally a drop of 53%), some at an accelerated pace such as in sub-Saharan Africa. And yet, high average under-five mortality rates still remain a concern in many parts of the world (see Fig. 3.2):

- In the African Region: Angola, Chad, the Central African Republic, Sierra Leone, Mali and Nigeria have under-five mortality rates above 100 per 1000 live births.
- In the Eastern Mediterranean Region: Somalia, Afghanistan, Pakistan and Sudan have under-five mortality rates above 70 per 1000; Yemen and Iraq also have high rates (42 per 1000 and 32 per 1000, respectively).
- In the Region of the Americas: Haiti, Guyana, the Plurinational State of Bolivia, the Dominican Republic and Guatemala have under-five mortality rates at least twice above the regional average of 15 per 1000 live births.
- In the Western Pacific Region: the Lao People's Democratic Republic, Papua New Guinea, Kiribati and to a lesser extent Cambodia and the Philippines have, on average, under-five mortality rates at least twice above the regional average of 14 per 1000 live births.
- In the European Region: Turkmenistan, Tajikistan, Uzbekistan, Azerbaijan, Kyrgyzstan have under-five mortality rates at least twice above the regional average of 11 per 1000 live births.

Fig. 3.2: Under-five mortality per 1000 live births in 2015, globally



Source: (5)

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2. Integrated health services - What and why? Geneva: World Health Organization; 2008 (Technical brief No. 1; http://www.who.int/healthsystems/technical_brief_final.pdf, accessed 29 August 2017).

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4. Progress in partnership: 2017 progress report on the Every Woman Every Child Global Strategy for Women's, Children's and Adolescents' Health. Geneva: World Health Organization; 2017 (http://gsprogressreport.everywomaneverychild.org/wp-content/uploads/2017/07/GS-update-2017.pdf, accessed 29 August 2017).

5. Levels and trends in child mortality: report 2015. Estimates developed by the UN Inter-agency Group for Child Mortality Estimation. New York (NY): United Nations Children's Fund; 2015 (http://www.childmortality.org/files_v20/download/IGME%20report%202015%20child%20mortality%20final.pdf, accessed 29 August 2017).

Integration of health care interventions and immunization activities (Indicator G5.2)

DEFINITION OF INDICATOR	**Indicators proposed by the DoV Secretariat:** a) Composite Coverage Index (CCI)[4] *(1)*, which is a weighted average of eight preventive and curative interventions for the 75 Countdown countries; and b) Comparative coverage by country of the CCI component interventions in four stages of the continuum of care (family planning, maternal and newborn care, immunization and case management of sick children), stratified by countries with CCI < 60, CCI 60–70, CCI > 70
TARGET	No target set
DATA SOURCES	Countdown 2015 equity data by country[5], recent WHO-UNICEF estimates of national immunization coverage (WUENIC) for DPT3, MCV1 and BCG[6] and Demographic Health Surveys (DHS)[7] and Multiple Indicator Cluster Surveys (MICS)[8]

Background

Following recommendations from the SAGE DoV working group in 2015, a revised integration indicator focusing on immunization with other health interventions was presented in the 2016 GVAP Secretariat report *(2)*. The objective of this revised indicator was to measure country efforts in reducing the number of missed opportunities for any preventive interventions to reduce mother and child mortality and to also highlight opportunities for integration.

Findings from the 2016 GVAP Secretariat report of the integration indicator found the lowest CCI component interventions were *case management of sick children* or *family planning needs satisfied*. In addition, across all three categories of CCI, there were wide variations in coverage of the four CCI component interventions in several countries *(2)*. This highlighted inequality between and within countries but also opportunities to address the low coverage interventions during visits with higher-performing health interventions e.g. immunization and maternal and newborn care.

This chapter presents an update of the CCI and its component interventions combined into four stages of the continuum of care – *family planning needs satisfied; maternal and newborn care;*

[4] The CCI is based on the weighted average of coverage of a set of eight preventative and curative interventions; the CCI gives equal weight to four stages in the continuum of care: family planning, maternal and newborn care, immunization, and case management of sick children. The weighted average for a group (e.g., a country or a wealth quintile) is calculated as

$$\frac{1}{4}\left(\mathrm{FPS}+\frac{\mathrm{SBA}+\mathrm{ANCS}}{2}+\frac{2\mathrm{DPT3}+\mathrm{MSL}+\mathrm{BCG}}{4}+\frac{\mathrm{ORT}+\mathrm{CPNM}}{2}\right)$$

FPS is family planning needs satisfied, SBA is skilled birth attendant, ANCS is antenatal care with skilled provider, DPT3 is three doses of diphtheria–pertussis–tetanus vaccine, MSL is measles vaccination, BCG is BCG (tuberculosis) vaccination, ORT is oral rehydration therapy for children with diarrhea, and CPNM is care seeking for pneumonia.

[5] Data available at http://countdown2030.org/documents/2015Equity/Countdown_Full_Equity_Profiles_ICEH.xlsx

[7] Data available at http://dhsprogram.com/Publications/Publications-by-Country.cfm

[8] Data available at http://mics.unicef.org/surveys

immunization; and case management of sick children – to measure potential missed opportunities between immunization and other health services.

Data availability and quality

The CCI data are derived from the Countdown 2015 equity data by country,[9] updated with more recent data from DHS[10], MICS[11] and recent WUENIC for DPT3, MCV1 and BCG[12], time matched with other CCI component data for accurate comparability. Analyses were limited to available data from 2010 onward. Therefore, CCI data were unavailable for 17 of the 75 Countdown countries due to lack of data since 2010 or missing data. Twenty-four countries had recent household data available since 2016. The CCI scores of 10 countries[13] whose CCI were presented in the GVAP 2016 report and which have recent data were compared. The CCI results are stratified by countries with CCI < 60 (weak health systems), CCI 60–70 (less weak health systems), CCI > 70 (stronger health systems).

Results

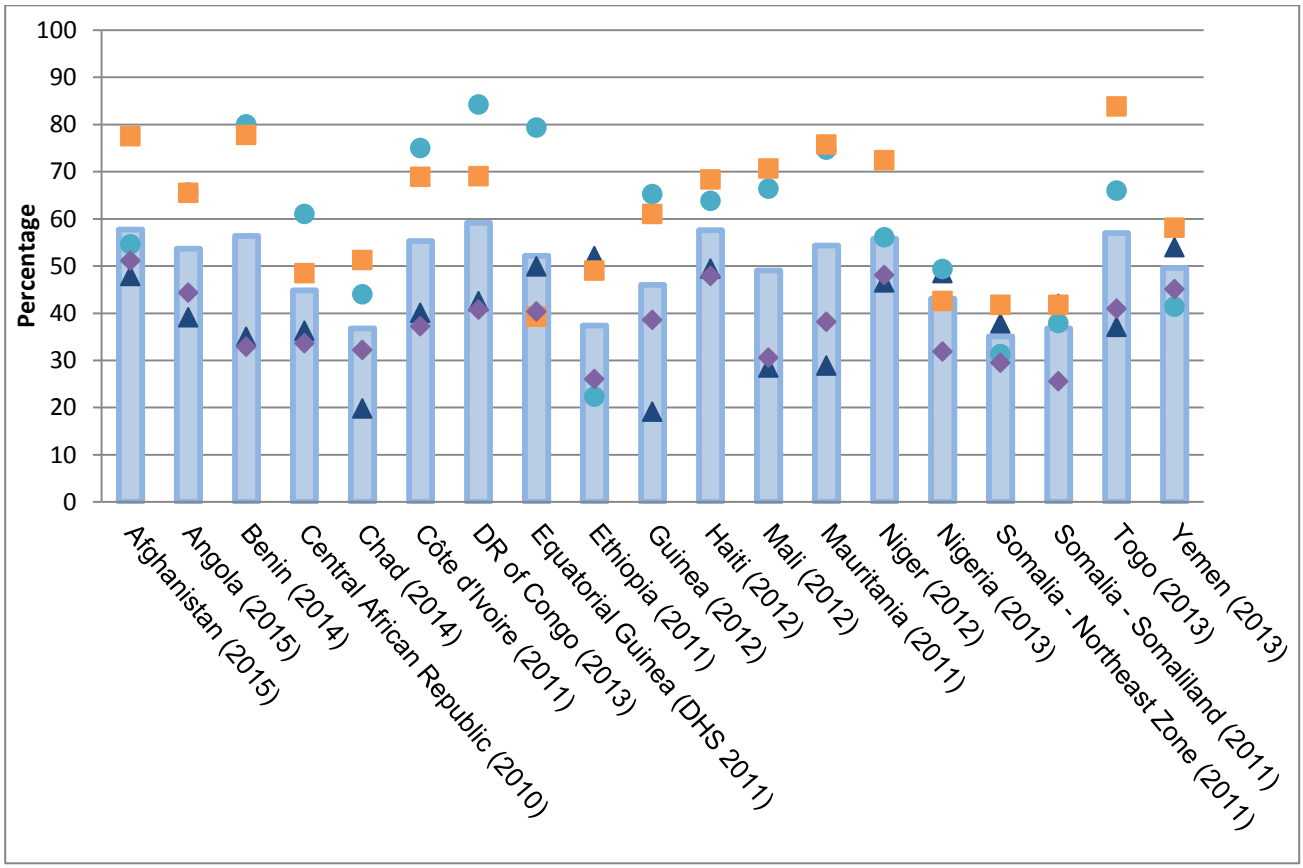
Fig. 3.3–3.5 show the CCI and its four stages of component interventions among 58 Countdown countries, stratified by CCI < 60, CCI 60–70, CCI > 70. Irrespective of CCI category, disparity among the four stages of continuum of care components remains evident. The highest CCI component interventions in the majority of Countdown countries were *maternal and newborn care* and *immunization,* while for countries with CCI < 60 or CCI 60–70, *family planning needs* and *case management of sick children* were particularly low (Table 3.1).

Immunization had the highest coverage among countries with CCI 60–70, while among three countries with CCI < 60 (Central African Republic, Democratic Republic of Congo and Equatorial Guinea) and two countries with CCI > 70 (the Congo and Gabon) *maternal and newborn care* was 13–40% higher than *immunization* coverage.

In Fig. 3.6, 10 countries presented in the 2016 GVAP Secretariat report *(2)* and with a recent round of household survey data are compared. Over a short time span of 1–4 years, the CCI and the four stages of continuum of care components have slightly improved or remained unchanged in the majority of these Countdown countries, with the exception of two countries (Benin and Zimbabwe), which saw minor decreases. Both Bangladesh and Rwanda made improvements in *maternal and newborn care* coverage, while Cameroon made improvements in both *immunization* and *family planning needs satisfied* coverage.

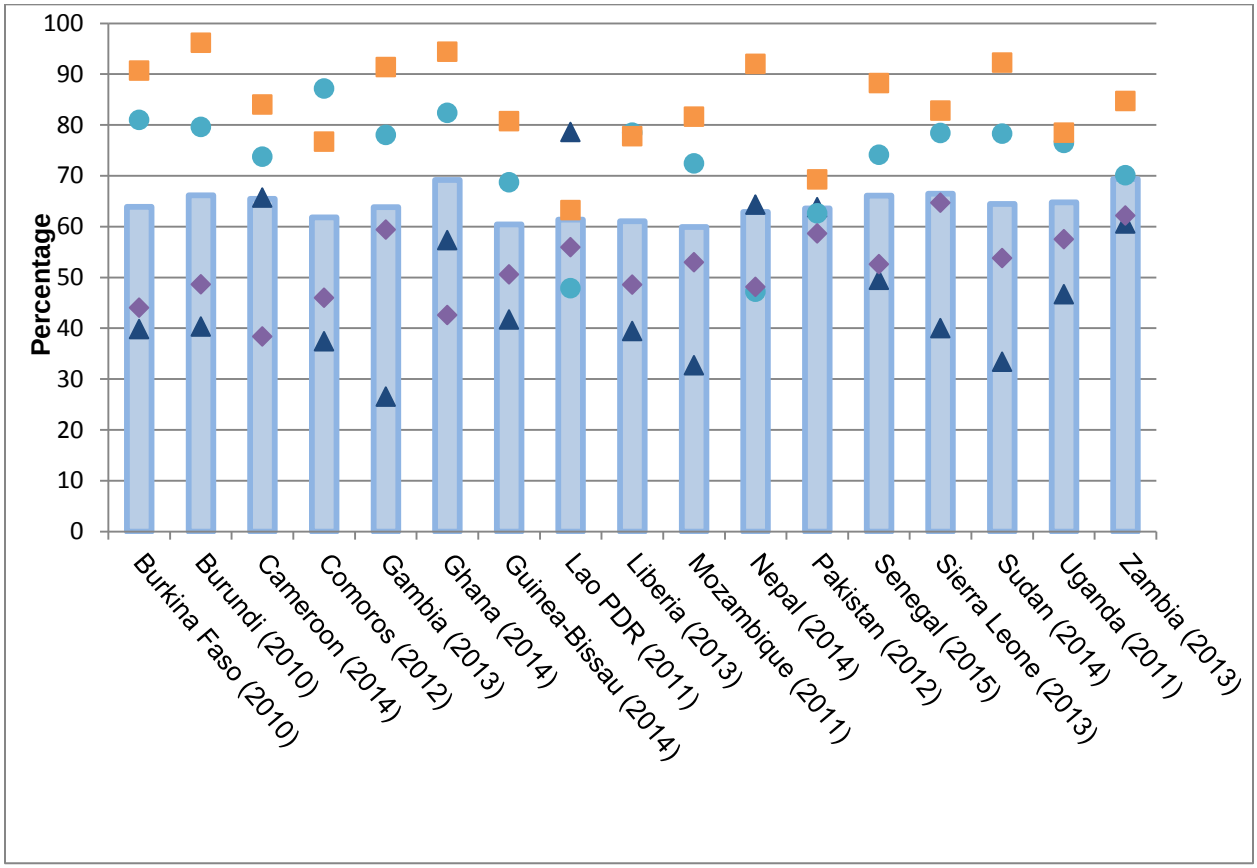
[9] Data available at http://countdown2030.org/documents/2015Equity/Countdown_Full_Equity_Profiles_ICEH.xlsx
[10] Data available at http://dhsprogram.com/Publications/Publications-by-Country.cfm
[11] Data available at http://mics.unicef.org/surveys
[12] Data available at http://www.who.int/immunization/monitoring_surveillance/routine/coverage
[13] Bangladesh, Benin, Cameroon, Chad, Malawi, Peru, Rwanda, Senegal, Swaziland, and Zimbabwe

Fig. 3.3: CCI and coverage for four CCI components in Countdown countries[a] with a CCI < 60% (year of data collection indicated for each country)



[a] Countdown countries with available data since 2010.
Source: Data from Countdown to 2015 report *(3)*, WUENIC, DHS and MICS.

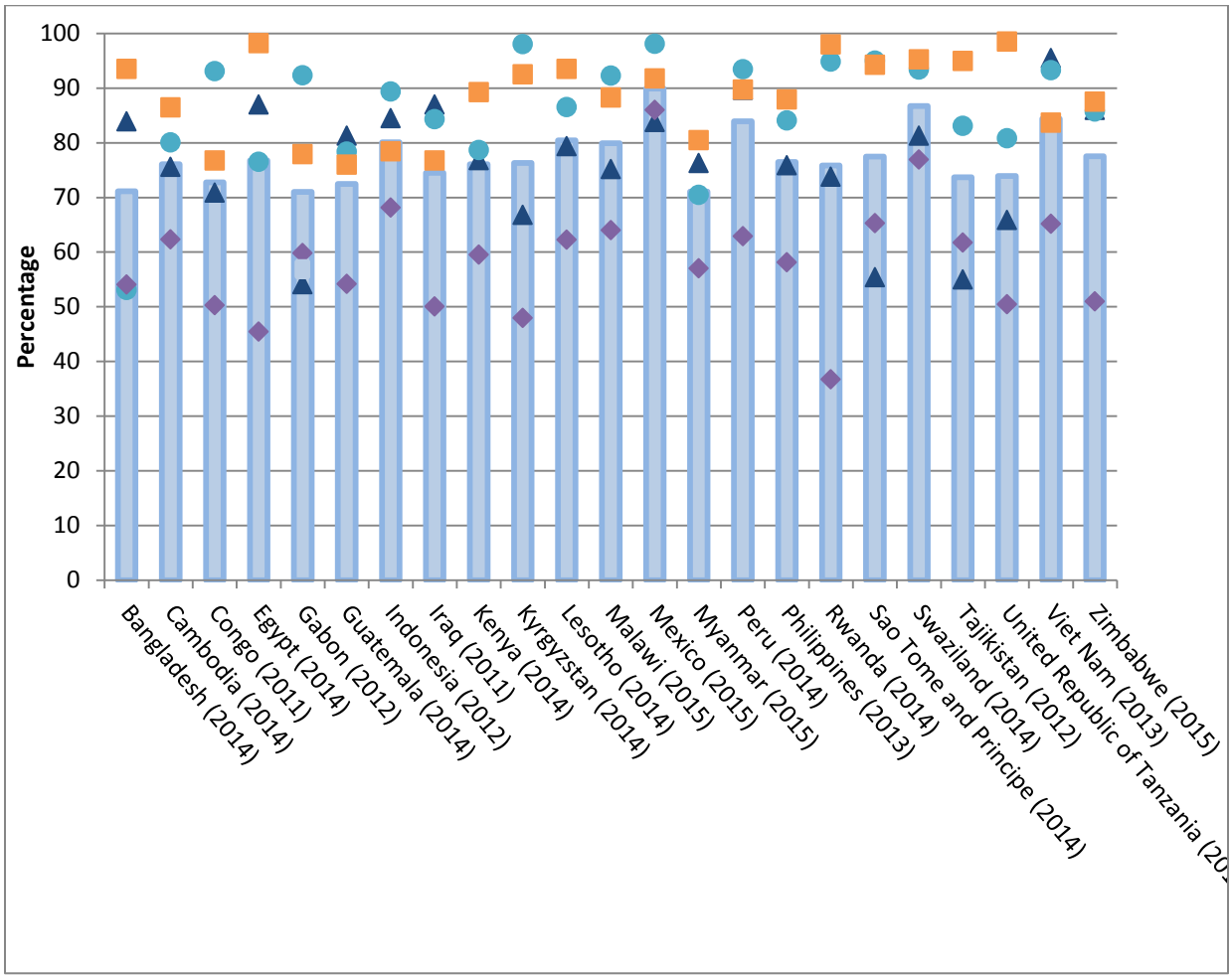
Fig. 3.4: CCI and coverage for four CCI components in Countdown countries[a] with a CCI 60–70% (year of data collection indicated for each country)



[a] Countdown countries with available data since 2010.

Source: Data from Countdown to 2015 report *(3)*, WUENIC, DHS and MICS.

Fig. 3.5: CCI and coverage for four CCI components in Countdown countries[a] with a CCI > 70% (year of data collection indicated for each country)



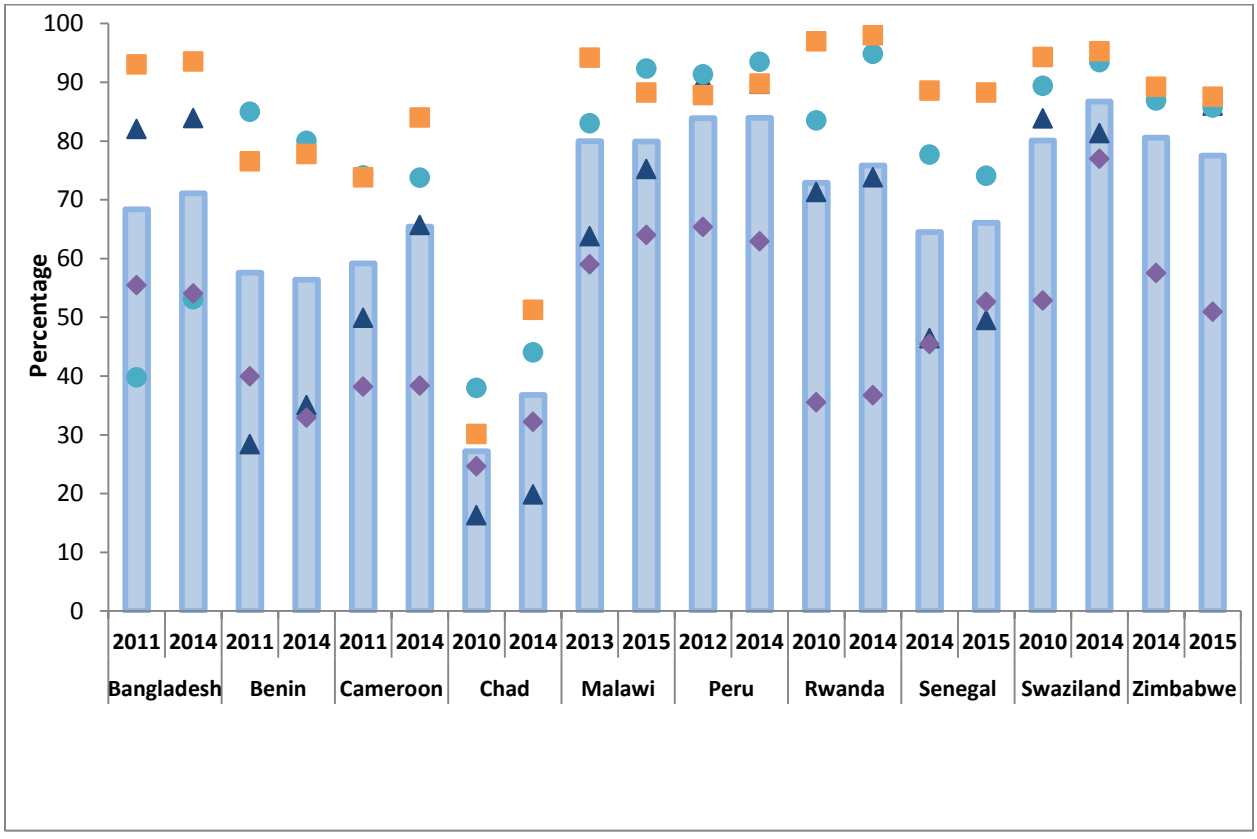
[a] Countdown countries with available data since 2010.

Source: Data from Countdown to 2015 report *(3)*, WUENIC, DHS and MICS.

Table 3.1: Median coverage of the four CCI components in Countdown countries with a CCI < 60%, 60–70%, and > 70%

CCI components	Median across all countries	Median across countries with CCI < 60%	Median across countries with CCI 60–70%	Median across countries with CCI > 70%
Family planning needs satisfied	54%	40%	42%	77%
Maternal and newborn care	78%	64%	76%	87%
Immunization	81%	66%	84%	89%
Case management of sick children	50%	38%	53%	60%

Fig. 3.6: Comparison of CCI and coverage for four CCI components in 10 Countdown countries[a] with two rounds of data since 2010 (year of data collection indicated for each country)



[a] Countdown countries with available data since 2010.

Source: Data from Countdown to 2015 report *(3)*, WUENIC, DHS and MICS.

Both *immunization* and *maternal and newborn care* continued to have the highest coverage in the majority of Countdown countries. However, *maternal and newborn care* was higher than *immunization* in nine countries with CCI < 60 and 10 with CCI > 70. For many of these countries, coverage differences between *immunization* and *maternal and newborn care* were small. Nonetheless, it highlights that there are opportunities for reminders about the importance of child immunization during antenatal care, which could lead to improvements in coverage. Also, integration of lower-coverage component interventions with higher-coverage component interventions could potentially reduce missed opportunities for any preventive interventions aimed at reducing mother and child mortality. Expressed differently, these figures demonstrate the existence of yet untapped opportunities of contact of children and mothers with the health system to implement additional preventive interventions and increase overall coverage of those preventive measures (see example in Box 3.2).

Box 3.2: Integrating immunization and family planning activities: example from Madagascar

Both immunization and family planning services are important components of primary health care. Offering family planning services to postpartum women through infant immunization contacts is one of several "promising" high-impact practices in family planning identified by a technical advisory group of international experts. A promising practice has limited evidence, with more information needed to fully document implementation experience and impact.

Evidence suggests that an integrated model is acceptable to clients and service providers. In an assessment conducted in Madagascar, almost all women who were interviewed expressed interest in receiving family planning services during immunization visits. Likewise, 74% of providers and 89% of managers were supportive of integrating family planning services with immunization. However, functioning health systems are needed to support integrated service delivery. Studies have shown that integrated models are most successful when immunization programmes have high coverage rates, sufficiently trained staff, an adequate supervision and monitoring system and stakeholder support. Political and community support are critical to building a supportive environment for integration.

Source: (4)

Disclaimer: The WHO Department of Reproductive Health and Research has contributed to the development of the technical content of documents such as that described here, which is viewed as a summary of evidence and field experience. It is intended that these briefs be used in conjunction with WHO family planning tools and guidelines, available from the WHO Sexual and reproductive health website, Clinical guides and counselling tools: http://www.who.int/topics/family_planning/en/.

The limitations of using the modified CCI as an indicator for integration were previously described in the 2016 GVAP Secretariat Report *(2)*. As stated above, 17 Countdown countries were not reviewed, as they did not have household survey data available since 2010 or were missing data.

Countdown countries presented in this report formed part of the final report of the *Countdown to 2015: a decade of tracking progress for maternal, newborn, and child survival*, published in

2016 *(3)*. The 75 Countdown countries were monitored over a 10-year period and major reductions in maternal and infant deaths were achieved through increasing coverage of cost-effective and evidence-based health interventions. However, it is evident that wide inequalities remain between and within Countdown countries and continued investments are required to achieve global targets and reduce inequalities *(3)*. Health equity is a priority of WHO, particularly as countries work towards achieving SDGs. CCI are available for 102 countries at subnational level and by economic status and place of residence via the Global Health Observatory[14]. WHO's Health Equity Assessment Toolkit (HEAT)[15] is a user-friendly tool that enables health inequality comparisons of numerous maternal child indicators (including CCI) within and across countries using data from the WHO Health Equity Monitor database. In addition, HEAT Plus will be released in 2017, which will allow users to upload and work with their own data[16]. This benchmarking tool might offer an additional incentive for countries to perform national equity analyses on CCI to better target interventions *(5)* and identify areas for improved integration of services.

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4. Country ownership: NITAGs

Presence of an independent technical advisory group that meets the defined criteria (Indicator SO1.2)

TARGET	Functional NITAGs in all Member States by 2020.
DEFINITION OF INDICATOR	A functional NITAG has been defined as one that meets all of the six following process indicators agreed upon in 2010 by WHO and its partners involved with the strengthening of NITAGs: 1. Legislative or administrative basis for the advisory group 2. Formal written terms of reference 3. At least five different areas of expertise represented among core members 4. At least one meeting per year 5. Circulation of the agenda and background documents at least one week prior to meetings 6. Mandatory disclosure of any conflict of interest. These six indicators do not guarantee the functionality of the NITAG but have been agreed upon as a minimum set of indicators that will allow for monitoring of progress at the global level. A more comprehensive set of indicators has been published for use at national level *(1)* and a more in-depth performance evaluation tool that reviews the critical aspects of functioning, quality, and integration is available at the NITAG Resource Center[1].
DATA SOURCES	Process indicators related to the establishment of NITAGs have been included in the WHO-UNICEF Joint Reporting Forms (JRFs) since 2011 and in that year data were collected for 2010. In this summary information from Member States regarding the existence of a NITAG, the specific criteria are derived from the 2016 JRF and compared with JRF data collected for previous years. For those Member States that did not submit or fully complete the JRF for 2016, information from the previous year's JRF was used to give a more comprehensive picture of the situation. The denominator used to calculate the proportion of NITAGs

[1] http://www.nitag-resource.org

in existence is the number of Member States that completed the NITAG-related section of the JRF. The results are presented by WHO region, World Bank income classification, Gavi eligibility and population size. Population figures used are those from the UN Population Division *(2).*

HIGHLIGHTS

- A total of 83 Member States (including 27 middle-income countries that are eligible for Gavi support and 26 that are not) reported access to a NITAG that met six process indicators, representing a 102% increase over the 41 reported in 2010. The 83 countries are accounting for 61% of the global population.
- A total of 122 (64%) Member States reported the existence of a National Immunization Technical Advisory Group (NITAG) with an administrative or legislative basis (accounting for 91% of the global population).
- Between 2015 and 2016 there has been only a small increase in the number of countries meeting the six functionality criteria[2] – a net gain of three countries since 2015. In 2016 12 new countries have reported meeting the six functionality criteria, while nine countries reported they no longer do so.
- Efforts need to be strengthened to support NITAGs to achieve the GVAP 2020 target.
- The Seventieth World Health Assembly resolution WHA70.14[3] in 2017 gives new impetus to the establishment and strengthening of NITAGs and immunization partners'.
- Formalization of approaches to allow small Member States to benefit from subregional or other Member States' advisory groups is still lagging and need prioritization. Progress in this regard has been accomplished in the Region of the Americas but efforts still need to be accelerated in the Western Pacific Region.
- At the first international NITAG meeting (May 2016), there was a strong call by countries to proceed with the establishment of a global NITAG network. This network was formally established during the second international NITAG Network meeting (June 28–29 2017); it will facilitate exchange of information between NITAGs and accelerate progress in reaching the target.
- The emphasis of established NITAGs has shifted to increasing capacity for evidence-based review.

[2] In last year's report it was reported that 77 countries were meeting the six functionality criteria, but since then information was received that led to six countries being subsequently added to the list (Albania, Benin, Bhutan, Ireland, Senegal and Turkey) and three others removed (Andorra, Iraq and Luxembourg) in the final reporting for 2015.

[3] http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R14-en.pdf

DATA LIMITATIONS

As highlighted in the GVAP Secretariat's previous report *(3)*, these results are subject to data limitations including some lack of data completion, the absence of a systematic data validation process with national counterparts and some confusion with the Inter-agency Coordinating Committee (ICC). This confusion was documented but has been minimized over time. An increasing number of countries have corrected the information provided during previous years and corrections were retrospectively applied to the reported data for the previous years concerned. In order to assess the evolution of NITAG implementation and functionality since 2010, data were thoroughly cleaned cleaning based on consistency of responses on the overall time trend with final approval at country level.

When Member States report the existence of a NITAG with formal terms of reference or the existence of a NITAG with a formal administrative or legislative basis, data should be less susceptible to reporting bias than the mere reporting of the existence of a NITAG, and therefore the number of such groups should be closest to the actual number with respect to the existence of a NITAG. The number of Member States reporting the existence of a NITAG that complies with all six process indicators is also less susceptible to reporting bias/error.

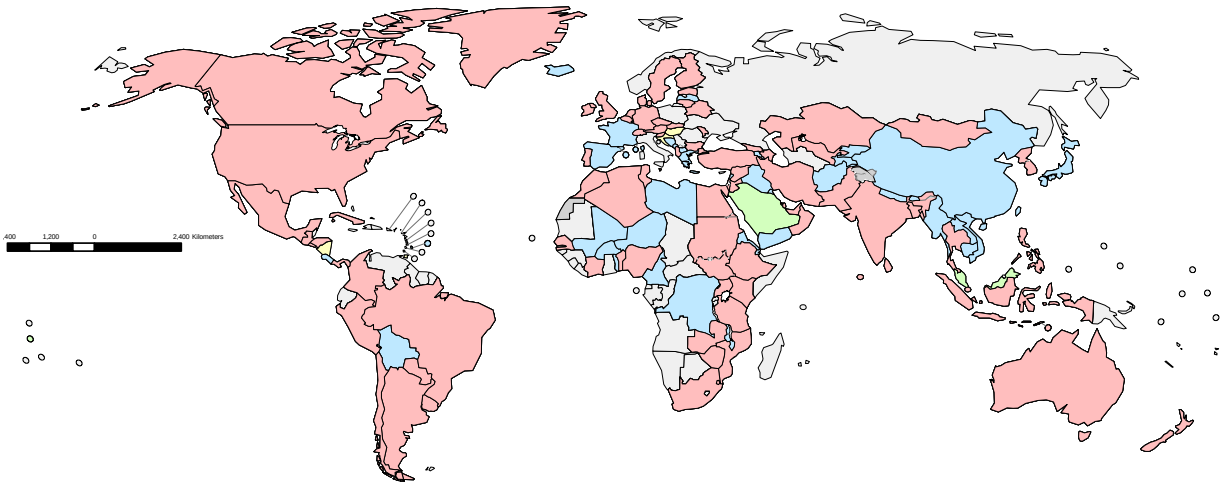
RESULTS

As of 23 June 2017, 184 Member States (95%) had completed the 2017 JRF[4] reporting immunization-related data for 2016 and 178 (92%)[5] provided a response to at least one of the NITAG-related JRF questions. Among the 16 Member States that did not submit their JRF or their NITAG-related data for 2016, all but two of them had reported NITAG data in the past two years' JRF (i.e. data for 2014 and 2015[6]). Therefore, data from 2014 and 2015 were used in the 2016 data set for the remaining 14 Member States. The Government of Monaco indicated it worked with the French NITAG, and therefore data from France were included in the data set for Monaco.

Data for 192 Member States were available for the analysis as presented in Fig. 4.1 and Table 4.1. Table 4.1 presents the 2016 NITAG-related indicators status at the global and regional levels. Fig. 4.2 presents the 2010–2016 trajectory in the establishment of NITAGs and highlights the need for acceleration of progress to reach the GVAP NITAG target. The comparison between 2010 and 2016 is only provided at global level as progress encountered in some regions prior to 2010 could lead to spurious interpretation of the trends when disaggregated by region.

[4] As of 23 June 2017, Member States that have yet to submit 2017 JRF data for 2016 include Antigua and Barbuda, Israel, Kuwait, Monaco, Nauru, Niue, Poland, Portugal, Singapore and Switzerland.
[5] Member States that have not completed the NITAG portion of JRF include Bolivia (Plurinational State of), Brazil, Ireland, Luxembourg, Mozambique, and The former Yugoslav Republic of Macedonia.
[6] The two countries that did not report data from 2014 are Luxembourg and Poland.

Fig. 4.1: National Immunization Technical Advisory Groups (NITAGs) in 2016



83 countries meeting the six NITAG criteria

122 countries having a NITAG with administrative or legislative basis

122 countries reporting the existence of a NITAG with terms of reference

129 countries reporting the existence of a NITAG

No NITAG/Not available

Not applicable

Source: WHO/UNICEF Joint Reporting Form database.

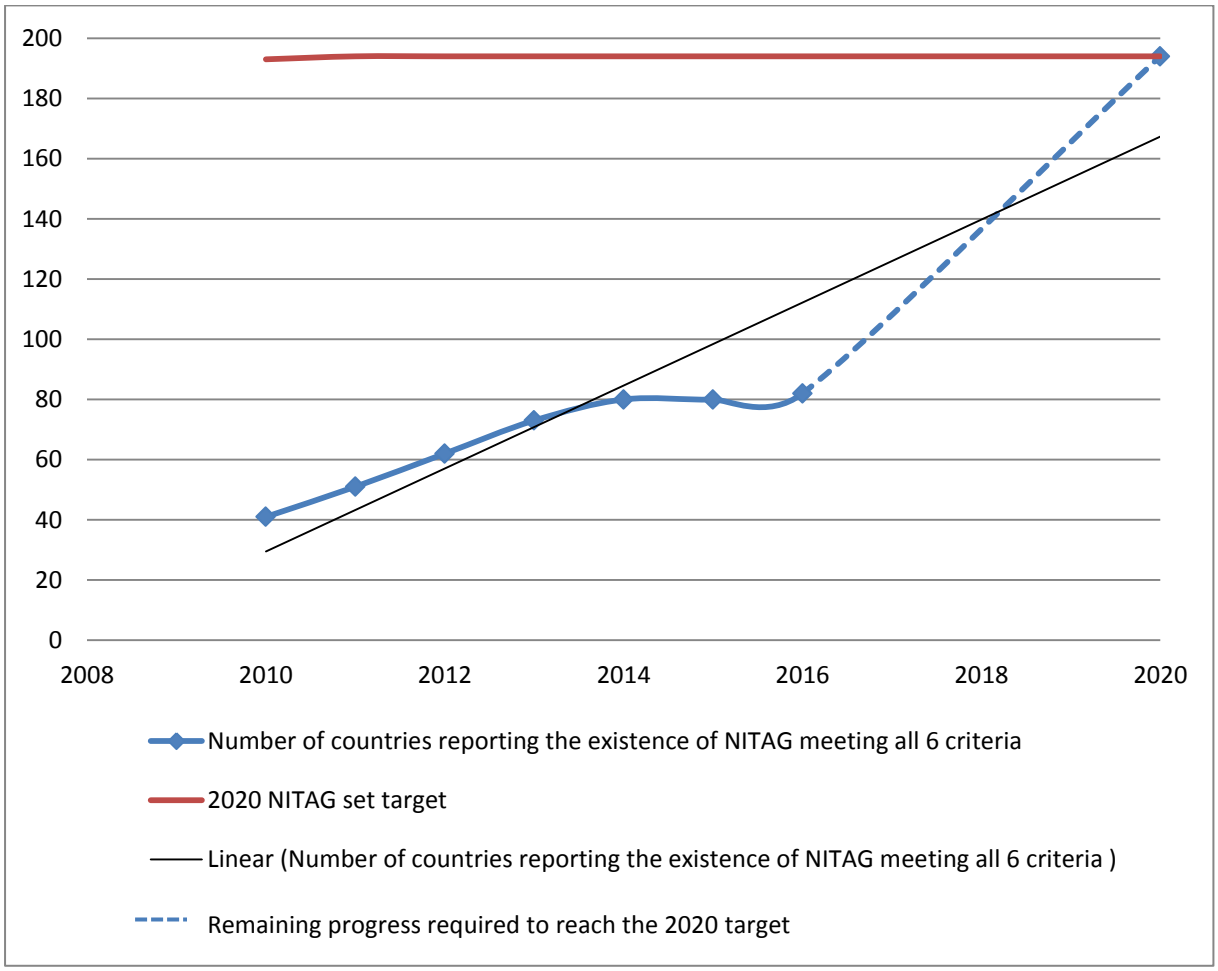
Table 4.1: Analysis of the NITAG JRF 2016 data at global level, by WHO region, World Bank income group and eligibility for Gavi support

		WHO region[a]							Gavi support/Income classification		
INDICATOR		**Overall**	**African**	**Americas**	**Eastern Mediterranean**	**European**	**South-East Asia**	**Western Pacific**	**Gavi supported-countries**	**Middle-income countries, no Gavi support**	**High-income countries**
	No. of Member States with NITAG data available /WHO Member States (%)	192/194 (99)	47/47 (100)	35/35 (100)	21/21 (100)	51/53 (96)	11/11 (100)	27/27 (100)	73/73 (100)	63/63 (100)	54/56 (96)
Existence of a NITAG	No. of responding Member States reporting the existence of a NITAG (%)	129 (67)	23(45)	20 (57)	20 (95)	42 (82)	11 (100)	13 (48)	48 (66)	35 (56)	44 (81)
	Percentage of population covered by a NITAG	91	83	92	98	64	100	99	93	91	94
NITAG meeting all six process indicators	No. of Member States reporting existence of a NITAG meeting all six process indicators/	83/129 (64)	15/23 (65)	15/20 (75)	12/20 (60)	27/42 (64)	8/11 (73)	6/13 (46)	27/48 (56)	25/35 (71)	30/44 (61)

	No. of Member States reporting existence of NITAG (%)										
	Percentage of responding Member States with a NITAG meeting all six process indicators	43	32	43	57	53	73	22	37	38	56
	Percentage of the entire population covered with a NITAG meeting all six process indicators	61	64	90	75	47	96	10	78	39	67

[a] For 14 Member States, data from 2014 or 2015 have been used.
[b] Two Member States are not classified by the World Bank income classification and are not eligible for Gavi support: Niue and the Cook Islands.

Fig. 4.2: Time trend (2010–2016) in the establishment of NITAGs meeting all six process criteria with remaining progress required to reach the 2020 target



There has been notable progress in achieving this target between 2010 and 2016; 122 Member States overall (64%) reported the existence of a NITAG with a formal legislative or administrative basis, among the 192 Member States included in the analysis. In 2016, there were 83 Member States[64] with a NITAG that met all six process indicators, which includes 53 low- and middle-income countries. This is a 102% increase compared to 2010, when only 41 countries reported having a NITAG meeting all six process indicators.

However, the global trend over the past year shows very little progress in the number of countries meeting the six functionality indicators. While 12[65] new countries reported meeting the six functionality criteria in 2016, nine countries currently on the list failed to do so. The main cause of these dropouts is the fact that the NITAGs in five of these countries did not meet in 2016. Nevertheless, remarkable progress was made in the African Region between 2015 and 2016 – 64% of the Region's total population is now living in a country with a NITAG meeting the six criteria of functionality (up from 47% in 2015).

Further regional review shows that the South-East Asia Region, where all countries have established a NITAG, had the highest proportion of Member States reporting the existence of a NITAG that met all six process indicators (73%) and the Western Pacific Region the lowest (22%). The South-East Asia Region had the greatest percentage (100%) of Member States that had a NITAG based on a formal legislative decree; percentages for the other regions include: 49% in the African Region, 41% in the Western Pacific Region and 51% in the Region of the Americas (percentages within the latter two regions are affected by a substantial number of small Member States), 78% in the European Region and 90% in the Eastern Mediterranean Region. The number of countries with NITAGs in the European Region increased significantly over the past 10 years – only eight countries there do not currently have a NITAG. It should be noted that although only 64% of the population living in the European Region appears to be covered with a NITAG, this is due to the fact that the Russian Federation – the most populous country in the region – does not have a NITAG at the moment. This should not diminish the efforts undertaken by countries, WHO, and partners in establishing NITAGs and the progress achieved in the Region overall.

In 2016, 61% of the global population lived in a country with a NITAG that meets all six process indicators. This metric was also met by 37% of Gavi-eligible countries, 41% of middle-income countries not eligible for Gavi support and 54% of high-income countries. When reviewed by population size of countries, 28% of Member States with small populations (less than the median population of all responding Member States) reported meeting this metric, compared with 58% of more populous Member States.

[64] Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Belarus, Belgium, Benin, Brazil, Bulgaria, Canada, Chile, Colombia, Côte d'Ivoire, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Egypt, El Salvador, Estonia, Ethiopia, Finland, Georgia, Germany, Guatemala, Honduras, India, Indonesia, Iran (Islamic Republic of), Ireland, Israel, Jordan, Kazakhstan, Kenya, Lithuania, Maldives, Malta, Mexico, Mongolia, Morocco, Mozambique, Netherlands, New Zealand, Nigeria, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Portugal, Qatar, Republic of Korea, Republic of Moldova, Senegal, Singapore, Slovakia, Slovenia, South Africa, South Sudan, Sri Lanka, Sudan, Sweden, Swaziland, Switzerland, Syrian Arab Republic, Thailand, Timor-Leste, Tunisia, Turkey, Uganda, the United Arab Emirates, the United Kingdom, United Republic of Tanzania, the United States, Uruguay, Uzbekistan, Zambia and Zimbabwe.

[65] These 12 countries are Austria, Belarus, Ethiopia, Georgia, Morocco, Panama, South Sudan, Swaziland, Sweden, United Republic of Tanzania, Zambia and Zimbabwe.

NARRATIVE

Progress has been made in achieving this indicator since 2010, notwithstanding the relative stagnation towards success over the past year. However, progress should be accelerated if the 2020 target is to be achieved. It should be noted that what appears as limited progress is due in part to the fact that several NITAGs were unable to meet all six process indicators in 2016. At least a few of these instances were due to temporary circumstances (e.g. no NITAG meeting organized in 2016 in France). However, the sustainability of the NITAGs is a clear area of concern (which was also raised in last year's assessment report).

In all WHO regions there is now a clear commitment to establish NITAGs and all regional technical advisory groups (RTAGs) have made strong statements with regard to the need to strengthen existing NITAGs. As a result countries are issuing requests to partners for technical assistance to establish and/or strengthen NITAGs. In 2016, 16 countries eligible for Gavi support (13 in the African Region) identified and prioritized NITAG support in their targeted country-assistance requests to Gavi. Work is ongoing to bring together NITAG chairpersons, immunization managers and other stakeholders (such as colleagues from health ministries) at regional TAG meetings (facilitated in all but one region to date). Country and intercountry NITAG workshops/meetings continue to be very successful where organized and serve as catalysts of further progress and collaboration. However, collaboration and the sharing of information (e.g. of NITAG recommendations) with all stakeholders can still be improved. Formal documentation of this collaboration and its effectiveness on improving the capacity of NITAGs is also needed.

Positive developments over the past year include the accelerated progress and efforts in the African and Western Pacific Regions; for example, an RTAG workshop in the Western Pacific Region in the last quarter of 2017 is planned. In addition, several country-specific workshops have taken place that focus on strengthening NITAGs and evidence-based review processes – to begin to build that formal documentation that is still needed. In the Region of the Americas, advances have been made for the Caribbean islands with respect to uniting them within subregional advisory groups. Conversely, the progress toward solutions for the small island nations in the Western Pacific Region is less tangible. A draft proposal will be discussed at the March 2018 meeting of the Pacific Island countries immunization managers meeting on how to mutualize experience and best practices.

It should be noted that although it seems that the NITAG initiative in middle-income countries not eligible for Gavi support is only slightly more advanced than in Gavi-eligible countries, this must be contextualized; middle-income countries not eligible for Gavi support have the largest proportion of small countries (whatever the cut-off applied of total population < 500 000, < 1 million or even < 2 million), compared with Gavi-eligible and high-income countries, which affects the figures.

Stakeholders have also renewed their commitments to achieving this target. As requested by partners, a specific session on NITAGs took place at the April 2017 SAGE meeting *(5)*. A background document prepared for the SAGE meeting reviewed in detail the situation, partners' contributions as well as challenges and opportunities *(6)*. As SAGE highlighted, there are myriad challenges that countries face in establishing, strengthening and sustaining NITAGs. Notable among these are lack of assessments of conflicts of interest, insufficient

training on evidence-based review processes and recognition of the NITAG by respective health ministries. The absence of systematic declaration of interests by core members remains problematic in some countries due to historical and cultural influences and is certainly the main limiting factor for a number of countries, for which the NITAG would otherwise meet all six process indicators; SAGE emphasized that this lack of transparency could undermine the credibility of NITAGs and their recommendations.

SAGE also recommended that tailored guidance, tools, training, mentoring programmes and sharing of information are needed to assist NITAGs, particularly in the area of expanding their scope beyond introduction of new vaccines to include critical review (and optimization) of vaccines already introduced in national programmes. SAGE noted that fostering collaborations between countries and at regional and global level was essential for success and stressed that initiatives such as the Global NITAG Network (GNN) *(8)* and the NITAG Resource Center *(7)* are essential, and that these would require dedicated financial and human resources.

The second international meeting of the GNN took place 28–29 June 2017, during which the GNN strategic document was endorsed and the Network officially launched *(8,9)*. The meeting also identified priority activities for the GNN and its global partners including inter alia the issuance of off-label recommendations, interaction with manufacturers, handling of declarations of interest, issue of NITAGs in federal states, consideration of unpublished literature, development and use of software applications to communicate about NITAG recommendations, anti-immunization lobby, addressing comments on draft recommendations, and disseminating information or how to use existing systematic reviews. The last point is of particular importance; it was stressed at the meeting that NITAGs should not reinitiate systematic reviews, but rather capitalize as much as possible on existing reviews.

WHO will provide the central GNN secretariat functions and facilitate the core network activities while NITAGs will be expected to also provide some in-kind contribution to these activities. WHO will now also assume responsibility for the maintenance and development of the NITAG Resource Center web platform.

Additional NITAG-related tools have been finalized by the WHO Collaborating Centre on "Evidence-informed immunization policy-making" at the Agence de Médecine Préventive (AMP) – Health policy and Institutional development unit (AMP-HPID) and made available on the NITAG Resource Center website. This includes guidance on the management of declaration of interests. Challenges with securing funding are impacting AMP-HPID, unfortunately, and threatening its sustainability as a WHO Collaborating Centre; therefore limited progress with regard to implementation of evaluations, provision of technical support and necessary developments of the NITAG Resource Center (e.g. development of an internal search engine) has been made.

SAGE has further specifically mentioned NITAGs in its GVAP midterm review *(10)*:

1. Governments are encouraged to enact laws that guarantee access to immunization, establish National Immunization Technical Advisory Groups (NITAGs) or equivalent groups, ensure that sufficient budgets are allocated

to immunization each year and create mechanisms to monitor and efficiently manage funds at all levels (including those from the private sector).

2. National immunization programme managers should report each year to their NITAGs or equivalent groups on progress made, lessons learnt and remaining challenges toward implementing National Immunization Plans and show how these plans are aligned to Regional and Global Vaccine Action Plan goals.

These recommendations are specifically reflected in the Seventieth World Health Assembly resolution WHA70.14[66] in 2017, which

> urges Member States to demonstrate stronger leadership and governance of national immunization programmes by: strengthening national processes and advisory bodies for independent, evidence-based, transparent advice including on vaccine safety and effectiveness, such as health intervention and technology assessments and/or National Immunization Technical Advisory Groups working in collaboration with national regulatory authorities … [and by] "reviewing periodically, through the National Immunization Technical Advisory Groups or equivalent independent groups, the progress made, including immunization coverage, lessons learned and possible solutions for dealing with remaining challenges.

The resolution further requests the WHO Director-General to "support Member States in strengthening National Immunization Technical Advisory Group or equivalent mechanisms cooperating with regulatory authorities to inform national decisions based on national context and evidence to achieve national immunization goals".

SAGE stressed the importance of NITAGs in light of their contribution to the improvement of national immunization programmes as a core institution of well-functioning immunization programmes and urged that countries, WHO, partners and donors continue to provide support and facilitate the work of NITAGs and their secretariats in order to meet the GVAP 2020 goal.

[66] http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R14-en.pdf

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5. Vaccine hesitancy and demand for immunization

STRATEGIC OBJECTIVE 2: INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUES OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY

Vaccine hesitancy: percentage of countries that have assessed the top three reasons for vaccine hesitancy (Indicator SO2.1) and assessments of the level of hesitancy in vaccination at a national or subnational level in the past five years (Indicator SO2.2)

TARGET	Assess the top three reasons for vaccine hesitancy in the country in the past year to monitor determinants of vaccine hesitancy over time. Monitor the trend in the percentage of Member States that have assessed the level of hesitancy towards vaccination at national or subnational level in the previous years.
DEFINITION OF INDICATOR	**Indicator 1: Reasons for vaccine hesitancy** • Question 1: what are the top three reasons for not accepting vaccines according to the national schedule? • Question 2: is this response based on or supported by some type of assessment, or is it an opinion based on your knowledge and expertise? **Indicator 2: Percentage of countries that have assessed the level of hesitancy towards vaccination at the national or subnational level in the previous five years.** • Question 1: has there been some assessment (or measurement) of the level of hesitancy in vaccination at national or subnational level in the past (< 5 years)? • Question 2: if yes, please specify the type and year and provide assessment title(s) and reference(s) to any publication or report.
DATA SOURCES	All 194 countries within the six WHO regions included both indicators in their 2017 WHO-UNICEF Joint Reporting Form (JRF) to collect country data for 2016 (referred to as 2016 JRF data).

HIGHLIGHTS

- For the first time, trends across the three years of data are provided.
- Since 2014, the year in which the two indicators were first included globally into the WHO-UNICEF JRF, the response rate to the vaccine hesitancy indicators has been steadily increasing – 73% in 2014, 79% in 2015 and 83% in 2016.
- In 2016, 82 of the 184 countries (45%) that submitted the form reported having undertaken an assessment of vaccine hesitancy within the past five years, while 63 (34%) reported that no assessment had been undertaken and 39 (21%) did not respond to the question.

- The JRF data between 2014 and 2016 show that the top three most-frequently listed determinants for vaccine hesitancy globally have been consistent across the three years, although their ranking and frequency have changed. These three determinants are: a) risk–benefit (scientific evidence perception); b) lack of knowledge and awareness of vaccination and its importance; c) religion, culture, gender and socioeconomic issues, in particular religious reasons.

Background

The Strategic Advisory Group of Experts on Immunization (SAGE) endorsed two indicators to assess vaccine hesitancy worldwide as part of the Decade of Vaccines Global Vaccine Action Plan (GVAP). After pilot testing, these indicators were first introduced in the 2014 JRF and thus, to date, three years of data have been collected – 2014, 2015 and 2016. This has provided the opportunity to assess how vaccine hesitancy reasons have changed over time.

Results

Response rate

As of 23 June 2017, 184 WHO Member States had submitted their 2016 JRF data. Of these 184 countries, 152 provided at least one reason for vaccine hesitancy. Between 2014 and 2016, the number of countries that provided at least one reason for vaccine hesitancy has increased by 10%, from 73% to 83% (Table 5.1).

Although the overall response rate has increased, this is not consistent across all WHO regions. In four of the six WHO regions – the European Region, Eastern Mediterranean Region, South-East Asia Region and Western Pacific Region – the response rate has decreased compared with 2015, while the African Region saw a large increase in response between 2015 and 2016 – from 70% to 94%.

Table 5.1: Response rates for reasons for vaccine hesitancy by WHO region, 2014–2016

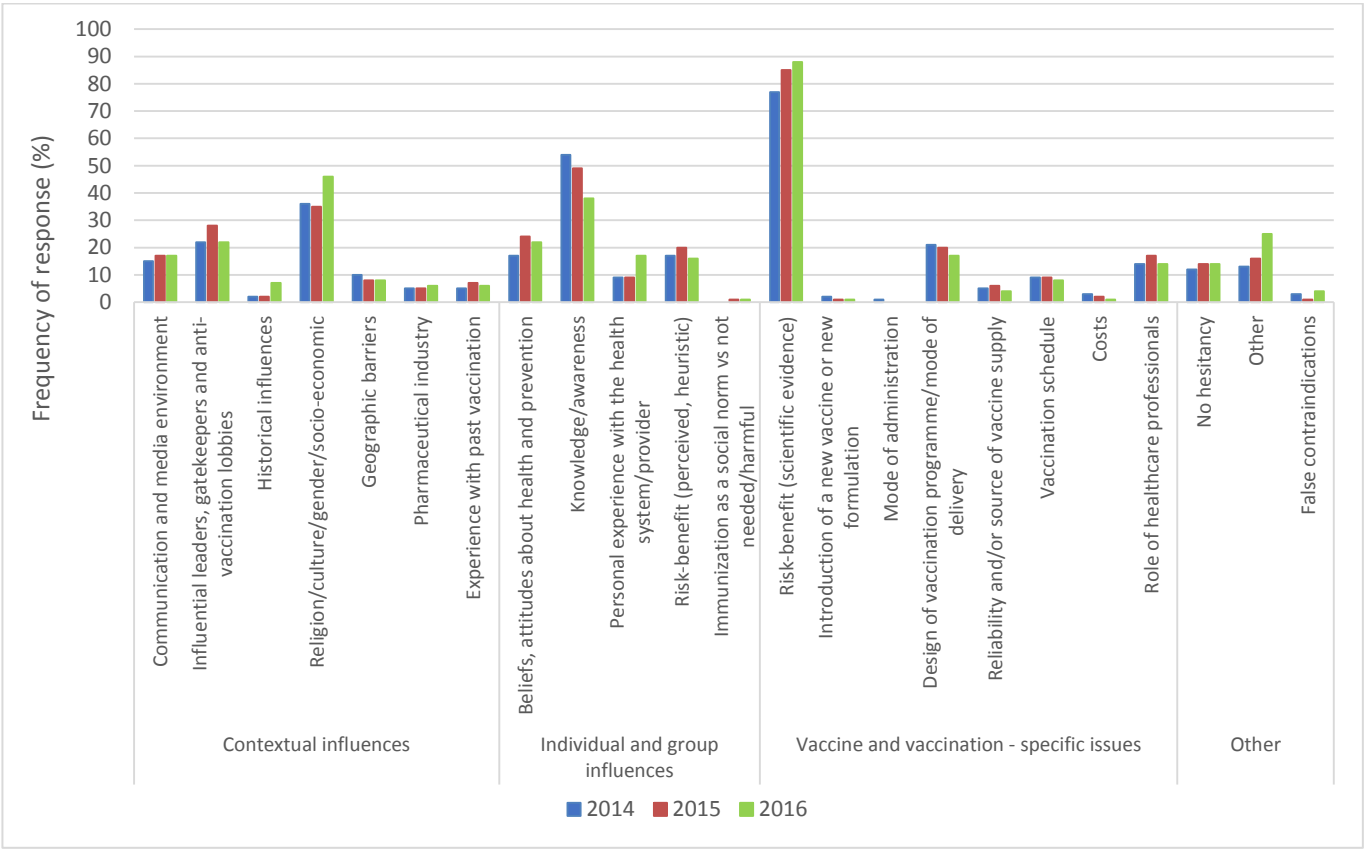
WHO region		Any reason given *n* (%)	Question not completed *n* (%)	No. of countries that submitted JRF
All regions	2014	131 (73)	49 (27)	180
	2015	146 (80)	37 (20)	183
	2016	152 (83)	32 (17)	184
Americas	2014	25 (76)	8 (24)	33
	2015	31 (89)	4 (11)	35
	2016	30 (88)	4 (12)	34
African	2014	33 (70)	14 (30)	47
	2015	33 (70)	14 (30)	47
	2016	44 (94)	3 (6)	47
European	2014	34 (76)	11 (24)	45
	2015	38 (84)	7 (16)	45
	2016	40 (83)	8 (17)	48
Eastern Mediterranean	2014	14 (67)	7 (33)	21
	2015	15 (75)	5 (25)	20
	2016	14 (70)	6(30)	20

South-East Asia	2014	11 (100)	0 (0)	11
	2015	11 (100)	0 (0)	11
	2016	10 (91)	1 (9)	11
Western Pacific	2014	14 (61)	9 (39)	23
	2015	18 (72)	7 (28)	25
	2016	14 (58)	10 (42)	24

Top three reasons for vaccine hesitancy (Indicator 1)

The top three reasons provided for vaccine hesitancy were grouped according to the matrix of determinants *(1)* of vaccine hesitancy, which assembles the reasons into three major categories, each with subgroups: contextual influences, individual and group influences as well as vaccine/vaccination-specific influences. Reasons were then ranked based on their frequency (Fig. 5.1).

Fig. 5.1: Top three reasons for vaccine hesitancy globally, 2014–2016



The top three reasons for vaccine hesitancy across all WHO regions has consistently been: a) risk–benefit (scientific evidence); b) lack of knowledge and awareness of vaccination and its importance; and c) religion, culture, gender and socioeconomic issues for all three years of data. However, the rank order has changed across 2014–2016 with risk–benefit (scientific evidence) significantly increasing and knowledge/awareness decreasing as a reason (Table 5.2).

Table 5.2: Top three reasons for vaccine hesitancy globally, 2014–2016

Rank	Reasons, 2014 (*n*)	Reasons, 2015 (*n*)	Reasons, 2016 (*n*)
1	Risk–benefit (scientific evidence) (77)	Risk–benefit (scientific evidence) (85)	Risk–benefit (scientific evidence) (88)
2	Knowledge/awareness (54)	Knowledge/awareness (49)	Religion/culture/gender/ socioeconomic (46)
3	Religion/culture/gender/ socioeconomic (36)	Religion/culture/gender/ socioeconomic (35)	Knowledge/awareness (38)

The reported reasons were compared by country income level (low income, lower-middle income, upper-middle income and high income, according to the World Bank classification)[1] (Table 5.3). Knowledge/awareness was frequently ranked in the top three reasons in low-income and middle-income countries, while it never was listed among the top three reasons in high-income counties across these three years. Risk–benefit (scientific evidence) was in the top three reasons all three years across all country income levels; and it has consistently been the top reason for vaccine hesitancy in high-income countries. The religion/culture/gender/socioeconomic determinant was only listed in the top three in low- and middle-income countries in 2014 and 2015 but in 2016 it tied for third most-frequently cited reason in high-income countries.

Table 5.3: Top three reasons for vaccine hesitancy by country income level, 2014–2016

[1] http://www.data.worldbank.org/indicator

	2014		2015		2016	
Income group	**Determinant**	**Frequency (*n*)**	**Determinant**	**Frequency (*n*)**	**Determinant**	**Frequency (*n*)**
Low income	Knowledge/awareness	14	Knowledge/awareness	11	Religion/culture/gender/ socioeconomic	10
	Risk–benefit (scientific evidence)	11	Risk–benefit (scientific evidence)	7	Other	10
	Religion/culture/gender/ socioeconomic	7	Religion/culture/gender/ socioeconomic Design of the vaccination program/mode of delivery	6 6	Risk–benefit (scientific evidence)	9
Lower-middle income	Knowledge/awareness	17	Knowledge/awareness	21	Risk–benefit (scientific evidence)	21
	Risk–benefit (scientific evidence)	17	Risk–benefit (scientific evidence)	20	Knowledge/awareness	15
	Religion/culture/gender/ socioeconomic	9	Religion/culture/gender/ socioeconomic	8	Religion/culture/gender/ socioeconomic	13
Upper-middle income	Risk–benefit (scientific evidence)	19	Risk–benefit (scientific evidence)	19	Risk–benefit (scientific evidence)	27
	Knowledge/awareness	15	Religion/culture/gender/ socioeconomic	13	Religion/culture/gender/ socioeconomic	15
	Religion/culture/gender/ socioeconomic	11	Influential leaders, gatekeepers and anti-vaccination lobbies	12	Knowledge/awareness	14
High income	Risk–benefit (scientific evidence)	30	Risk–benefit (scientific evidence)	38	Risk–benefit (scientific evidence)	31
	Beliefs, attitudes about health and prevention	10	Beliefs, attitudes about health and prevention	14	Beliefs, attitudes about health and prevention	10
	Risk–benefit (perceived, heuristic)	10	Risk–benefit (perceived, heuristic)	13	Risk–benefit (perceived, heuristic)	9

Although the categorization of a country's responses as classified by the matrix of determinants stayed the same from year to year, the actual reason provided varied in some countries. This is due to the fact that many different reasons can be categorized the same way. For example, in 2016 one country reported "worry of adverse reactions" as a reason for vaccine hesitancy. This was categorized as "risk–benefit (scientific evidence)". The previous year the same country reported "sceptical about the effectiveness of vaccines" as a reason for vaccine hesitancy. This reason was put in the same category. The responses provided by this country varied yet the categorization remains the same. This is an important consideration when looking at trends across time.

When stratified by WHO region, risk–benefit (scientific evidence) is in the top three for all regions in all three years except for the Eastern Mediterranean Region. Knowledge/awareness is in the top three reasons for at least one of the three years of data in all regions except for the Americas. Religion/culture/gender/socioeconomic never placed in the top three reasons in either the European or South-East Asia Regions (Table 5.4).

Table 5.4: Top three reasons for vaccine hesitancy by WHO region, 2014–2016

	2014	2015	2016

WHO region	Determinant	Frequency (*n*)	Determinant	Frequency (*n*)	Determinant	Frequency (*n*)
Americas	Religion/culture/gender/ socioeconomic	11	Risk–benefit (scientific evidence)	16	Religion/culture/gender/ socioeconomic	15
	Risk–benefit (scientific evidence)	11	Influential leaders, gatekeepers and anti-vaccination lobbies	11	Risk–benefit (scientific evidence)	15
	Communication and media environment	6	Religion/culture/gender/ socioeconomic	9	Communication and media environment	8
African	Knowledge/awareness	18	Knowledge/awareness	14	Religion/culture/gender/ socioeconomic	17
	Risk–benefit (scientific evidence)	14	Risk–benefit (scientific evidence)	10	Risk–benefit (scientific evidence)	16
	Religion/culture/gender/ socioeconomic	13	Religion/culture/gender/ socioeconomic	9	Other	12
European	Risk–benefit (scientific evidence)	34	Risk–benefit (scientific evidence)	40	Risk–benefit (scientific evidence)	36
	Knowledge/awareness	8	Risk–benefit (perceived, heuristic)	11	Knowledge/awareness	11
	Risk–benefit (perceived, heuristic)	8	Communication and media environment; Beliefs, attitudes about health and prevention	10 and 10	Communication and media environment; Beliefs, attitudes about health and prevention; Other	8 and 8 and 8
Eastern Mediterranean	Knowledge/awareness	8	Knowledge/awareness	8	Knowledge/awareness	7
	Influential leaders, gatekeepers and anti-vaccination lobbies	4	Religion/culture/gender/ socioeconomic	5	Religion/culture/gender/ socioeconomic	5
	Beliefs, attitudes about health and prevention	4	Beliefs, attitudes about health and prevention	4	Influential leaders, gatekeepers and anti-vaccination lobbies Risk-benefit (perceived, heuristic)	3 3
South-East Asia	Knowledge/awareness	6	Knowledge/awareness	6	Risk–benefit (scientific evidence)	5
	Risk–benefit (scientific evidence)	6	Risk–benefit (scientific evidence)	6	Knowledge/awareness	3
	Design/vaccination programme/Mode/delivery	4	Other	4	Religion/culture/gender/ socioeconomic	2
Western Pacific	Risk–benefit (scientific evidence)	10	Risk–benefit (scientific evidence)	12	Risk–benefit (scientific evidence)	15
	Knowledge/awareness	9	Knowledge/awareness	6	Knowledge/awareness	6
	Geographic barriers	5	Religion/culture/gender/ socioeconomic Role of healthcare professionals	4 4	Beliefs, attitudes about health and prevention	4

Analysis was conducted on reasons provided from Gavi-supported and non-Gavi supported countries. No major differences were observed of the top three determinants of vaccine hesitancy.

The number of countries where no hesitancy was noted has stayed relatively consistent across the three years of data with a slight increase from 2014 (*n*=12) to 2015 (*n*=14). In 2016 this stayed the same with 14 countries stating vaccine hesitancy was not a problem in their country. In the Eastern Mediterranean and South-East Asia Regions, “No vaccine hesitancy” was listed most frequently.

Assessments of vaccine hesitancy (Indicator 2)

A total of 145 of the 184 Member States that submitted their JRF (79%) responded to the second indicator. The number of countries that reported having completed an assessment related to vaccine hesitancy in the past five years increased from 29% (52/180) in 2014 to 36% (65/183) in 2015 but decreased slightly in 2016 to 33% (63/84). The rate of assessments varied across WHO regions (Table 5.5)

Table 5.5: Reported assessments of vaccine hesitancy by WHO region, 2016

WHO region	Year	No assessment *n* (%)	Assessment *n* (%)	Question not completed *n* (%)	No. of countries that submitted JRF
All regions	2016	82 (45)	63 (34)	39 (21)	184
Americas	2016	25 (73)	6 (18)	3 (9)	34
African	2016	17 (36)	21 (45)	9 (19)	47
European	2016	19 (40)	21 (44)	8 (16)	48
Eastern Mediterranean	2016	7 (35)	7 (35)	6 (30)	20
South-East Asia	2016	6 (55)	2 (18)	3 (27)	11
Western Pacific	2016	8 (33)	6 (25)	10 (42)	24

Discussion

The response rate to the questions about the vaccine hesitancy indicator has increased from 2014 to 2016. While this is encouraging, the increase is not consistent between regions, with four regions – European, Eastern Mediterranean, South-East Asia and the Western Pacific – witnessing a slight decrease in their response rate over the past year.

The JRF vaccine hesitancy response data show the value of yearly collection to determine the top reasons for vaccine hesitancy to monitor trends over time and across regions and across countries. Of note: only a minority of countries reported not experiencing any vaccine hesitancy.

In 2016, the top three reported determinants for vaccine hesitancy across all regions were (a) risk–benefit (scientific evidence); b) lack of knowledge and awareness of vaccination and its importance; c) religion, culture, gender and socioeconomic issues in particular religious reasons. These have stayed consistent from 2014 to 2016. With respect to risk–benefit (scientific evidence), many of the responses were concerns about vaccine safety, efficacy and fear of side-effects. Given the consistency of this response, addressing these concerns globally, regionally and within countries must continue to be a priority.

Limitations to this analysis were observed when categorizing Indicator 1 by the matrix of determinants. In some instances answers fit in more than one category. Moreover,

imprecision of the information provided demonstrated challenges for grouping. Furthermore, the classification of the provided reasons may be subject to personal perception. In order to mitigate potential bias, reasons were grouped by the same person across the three years following an underlying comprehensive framework.

Knowledge/awareness was a common concern particularly in low- and middle-income countries, demonstrating the need for increased education in regards to vaccines and vaccine-preventable diseases in these countries. What is encouraging is that country efforts to improve knowledge appear to be working, as the frequency of this reported reason for vaccine hesitancy has been decreasing since 2014.

In high-income countries risk–benefit (perceived, heuristic) was ranked high. This determinant refers to reasons related with complacency towards the risk of vaccine-preventable diseases. Thus, this determinant being listed frequently by high-income countries may indicate that complacency is developing in regards to vaccine-preventable diseases.

The majority of the reasons cited for vaccine hesitancy within the contextual influences category – which includes the subgroup religion, culture, gender and socioeconomic issues; see Fig. 5.1 – were related to religion, and were especially prominent in low- and middle-income countries. The frequency of this response has been increasing over the past three years and is now the fourth most commonly-cited reason by high-income countries.

A comprehensive analysis of responses by Gavi-supported versus not-supported countries was not depicted in this summary, as Gavi support was assumed not to be an influencing factor for vaccine hesitancy.

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1. MacDonald N, the SAGE Working Group on Vaccine Hesitancy. Vaccine hesitancy: definition, scope and determinants. Vaccine. 2015; 33(34):4161–4.

Demand for Immunization: Percentage of countries that include in their immunization programme actions to promote or sustain public demand for vaccines and vaccination services (Indicator SO2.3)

TARGET	Assess what the country's immunization programme does to promote or sustain public (individuals' and communities') demand for vaccines and vaccination services and what other activities were implemented to stimulate and sustain public demand for vaccines and vaccination services.
DEFINITION OF INDICATOR	**Indicator 1: In 2016, what did the country's immunization programme (at the national or lower levels) do to promote or sustain public (individuals' and communities') demand for vaccines and vaccination services (directly or indirectly; alone or in coordination with/through partner agencies and/or CSOs[2])?** • Question 1: Implementing activities (e.g. training) to prepare for, prevent, manage or communicate about adverse events following immunization (AEFIs) or other vaccine-related events (e.g. address rumours)? (Yes/No) • Question 2: Partnering with local leadership and/or CSOs to enhance the quality and accountability of services, including assessment of community concerns? (Yes/No) • Question 3: Training health workers on interpersonal communication skills? (Yes/No) **Indicator 2: Did the country's immunization programme (at the national or lower levels) implement any other activities (directly or indirectly; alone or in coordination with/through partner agencies and/or CSOs), do anything else to stimulate and sustain public demand for vaccines and vaccination services? Please describe up to three activities.** • Question 1: Please describe up to three activities. (Free text fields)
DATA SOURCES	All 194 countries within the six WHO regions included both indicators in their 2017 WHO-UNICEF Joint Reporting Form (JRF) to collect country data for 2016 (referred to as 2016 JRF data).

HIGHLIGHTS

- These two new demand indicators elicited a very high response rate, despite being included for the first time (2016 reporting period) in the JRF. In total, 166 of 184 of those countries (90%) having submitted the JRF responded to either of the questions.

[2] CSO, civil society organization.

- A limitation is that no precise definition of the demand indicator was provided. Therefore, countries may have interpreted the questions differently and comparisons between countries and regions can only be made with limited confidence.

Background

To assess the demand component of Strategic Objective 2, an informal working group on vaccine demand was established, under the oversight of SAGE GVAP working group. It developed two indicators to be included for the first time in the 2017 WHO/UNICEF JRF. The indicators aim to assess the actions taken by the national immunization programmes to build and sustain demand for vaccination and provide the possibility for countries to elaborate on these activities *(1)*.

Results

Response rates

As of 23 June 2017 184 WHO Member States had submitted their 2016 JRF data. Of these, 166 (90%) provided at least one response to either of the two indicators. Response rates were high across all WHO regions (Table 5.6). The global response rate to the vaccine demand portion/the JRF rate was 86%, Two WHO regions had response rates below the global average: the European (72%) and Western Pacific Regions (70%).

Table 5.6: Response rate of countries to either of the two demand indicators, by WHO region

WHO region	Any answer given, *n* (%)	Questions not completed, *n* (%)	Total
All regions	166 (86)	28 (14)	194 (100)
African	46 (98)	1 (2)	47 (100)
Americas	34 (97)	1 (3)	35 (100)
Eastern Mediterranean	19 (90)	2 (9)	21 (100)
European	38 (72)	15 (28)	53 (100)
South-East Asia	10 (91)	1 (9)	11 (100)
Western Pacific	19 (70)	8 (30)	27 (100)

Further, the response rate was high across all World Bank income groups. The lowest response rate was noted from high-income countries (72%) *(2)*.

The positive response rate to the three questions in Indicator 1 – conducting implementing activities related to addressing AEFI, partnering, and training activities to promote or sustain demand for vaccines – varied considerably by region. The global average response to the first question was 69%, with a low of 47% in the European Region and a high of 87% in the African Region. This suggests that countries take seriously the issue of AEFI, and are working to address it. The global positive response rate to partnering activities was 56%, with a low

of 43% in the European Region and a high of 76% in the Eastern Mediterranean Region. The global positive response rate to training activities was 59%, with a low of 37% in the Western Pacific Region and a high of 85% in the African Region (Table 5.7).

Table 5.7: Affirmative responses to the three questions included in Indicator 1

WHO region	Number of countries responding "yes" to question 1: Implementing (%)	Number of countries responding "yes" to question 2: Partnering (%)	Number of countries responding "yes" to question 3: Training (%)
Global	134 (69)	109 (56)	114 (59)
African	41 (87)	38 (81)	40 (85)
Americas	27 (77)	18 (51)	18 (51)
Eastern Mediterranean	18 (86)	16 (76)	16 (76)
European	25 (47)	18 (34)	23 (43)
South-East Asia	9 (82)	9 (82)	7 (64)
Western Pacific	14 (52)	10 (37)	10 (37)

The response rates to Indicator 2 regarding countries' indication on the use of other activities meant to stimulate and sustain public demand for vaccines was 93%; however, only 56%of countries responded positively (i.e. they did conduct other demand-stimulation activities). The lowest positive response rates were in the European (30%) and Western Pacific (33%) Regions. The highest positive response rate (85%) was from the African Region (Table 5.8).

Table 5.8: Response rate and affirmative response rate to Indicator 2

WHO region	Number of countries providing responses to demand activities (%)	Number of countries responding "yes" to demand-stimulation activities (%)
Global	181 (93)	108 (56)
African	42 (89)	40 (85)
Americas	33 (94)	23 (66)
Eastern Mediterranean	12 (57)	12 (57)
European	20 (38)	16 (30)
South-East Asia	8 (73)	8 (73)
Western Pacific	10 (37)	9 (33)

The most frequent themes noted in Indicator 2 were:

- media and communication activities (*n*=61): e.g. radio announcements, journal articles, TV and radio shows, online advertisements;

- vaccination activities around World, Regional or National Immunization Weeks (*n*=22): e.g. Africa Vaccination Week in April 2016, World Immunization Week, followed by National Immunization Month, Promotion of World Immunization Week through webpage of the country's national institute/public health;
- community involvement activities (*n*=12): e.g. implementation of a community approach to the promotion of vaccination, raising awareness among the members of a community to vaccinate unimmunized children.

Discussion

Demand for vaccines and vaccination is a complex concept that encompasses the interaction between human behaviours and system structure and dynamics *(1)*. Demand for vaccines is defined as

> the actions of individuals and communities to seek, support, and/or advocate for vaccines and immunization services. Demand is dynamic and varies by context, vaccine, immunization services provided, time, and place. Demand is fostered by governments, immunization program managers, public and private sector providers, local leadership, and civil society organizations hearing and acting on the voices of individuals and communities" *(1)*.

As no definition of vaccine demand has been included in the JRF, the concept of demand for vaccine may have been interpreted differently by each country. Inclusion of the definition in future JRFs would ensure a common understanding of the concept.

Additional indicators from the JRF, including DTP3 and MCV1 coverage and MCV1 timeliness could help provide a broader perspective on vaccine demand in each country. However, multiple factors contribute to these indicators, and they do not have direct, causal relationships with vaccine demand, so their relationship should be interpreted with caution.

In general, the response rate to the two demand indicators, despite being included in the JRF for the first time in 2016, was very high: 166 of the 184 countries which submitted a JRF form responded to either or both of the two indicators (86% of all countries globally). This response rate is higher than other newly-included indicators, such as those on vaccine hesitancy, for which during the first year of inclusion only 79% of countries globally provided any information *(2).*

To date no matrix for the classification of the responses to Indicator 2 has been developed, unlike for vaccine hesitancy *(3)*. A formalized matrix would facilitate grouping and analysis of the different themes listed by countries in response to the query.

References

1. Hickler B, MacDonald NE, Senouci K, Schuh HB, the informal Working Group on Vaccine Demand (iWGVD) for the Strategic Advisory Group of Experts on immunization (SAGE) Working Group on Decade of Vaccines. Efforts to monitor global progress on individual and community demand for immunization: development of definitions and indicators for the Global Vaccine Action Plan Strategic Objective 2. Vaccine. 2017; 35(28):3515–19

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3. MacDonald N, the SAGE Working Group on Vaccine Hesitancy. Vaccine hesitancy: definition, scope and determinants. Vaccine. 2015; 33(34):4161–4 (http://www.sciencedirect.com/science/article/pii/S0264410X15005009, accessed 4 September 2017).

6. Surveillance

STRATEGIC OBJECTIVE 4: STRONG IMMUNIZATION SYTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

Number of countries meeting established surveillance standards with case-based surveillance for vaccine-preventable diseases and with viral and bacterial laboratory confirmation of suspect or probable cases (Indicator SO4.4)

TARGET	Seventy-five per cent of low- and middle-income countries have sentinel hospital surveillance that meets surveillance standards for rotavirus diarrhoea or other national priority vaccine-preventable diseases.
DEFINITION OF INDICATOR	Number of countries meeting established surveillance standards with case-based surveillance for vaccine-preventable diseases and with viral and bacterial laboratory confirmation of suspect or probable cases. For this report the focus is on sentinel surveillance for rotavirus and invasive bacterial vaccine-preventable diseases.
DATA SOURCES	Data reported annually through the WHO-UNICEF Joint Reporting Form (JRF); data reported by countries participating in WHO-coordinated surveillance networks (namely the global rotavirus and invasive bacterial vaccine-preventable disease surveillance networks).

Highlights

- The global invasive bacterial vaccine-preventable and rotavirus disease surveillance networks have built and maintain national, regional, and global surveillance and laboratory capacity for identifying and monitoring circulating strains of *Streptococcus pneumoniae, Haemophilus influenzae*, *Neisseria meningitidis* and rotavirus from countries in all six WHO regions.
- Most (> 70%) countries that reported rotavirus and invasive bacterial vaccine-preventable disease (IB-VPD) surveillance data to WHO as part of the global networks in 2016 met minimum surveillance standards.
- The surveillance networks is being leveraged to test for additional vaccine-preventable diseases and diseases with vaccines in development, such as typhoid and other enteric pathogens such as norovirus, *Shigella*, and enterotoxigenic *Escherichia coli* (ETEC).
- Continued and sustainable surveillance is critical to meet ongoing data needs at the country, regional and global levels.

Overview of the global invasive bacterial vaccine-preventable and rotavirus disease surveillance networks and other IB-VPD and rotavirus surveillance

In 2008, WHO brought together existing regional surveillance to establish standardized global sentinel hospital surveillance networks for rotavirus disease and invasive bacterial vaccine-preventable diseases (IB-VPDs). These active, syndromic sentinel site surveillance networks report case-based clinical and laboratory data for children aged under 5 years hospitalized with acute gastroenteritis (to monitor rotavirus) and IB-VPDs (meningitis, pneumonia or sepsis to monitor *S. pneumoniae*, *H. influenzae* and *N. meningitidis*). The main objectives of the networks are to describe disease burden to make decisions about rotavirus and pneumococcal conjugate vaccine (PCV) introduction, to monitor short- and long-term trends to show rotavirus and pneumococcal conjugate vaccine impact globally and especially in regions with surveillance gaps, and to leverage the surveillance platform to monitor other vaccine-preventable diseases (VPDs), such as typhoid, and diseases with vaccines under development, such as ETEC and *Shigella*.

The role of WHO in VPD surveillance is to:

- generate and monitor VPD surveillance trends globally;
- lead, coordinate, and advocate for surveillance activities with countries and partners, including coordinating external quality assessment (EQA) and quality control (QC) in partnership with organizations such the United States Centers for Disease Control and Prevention (CDC) and Public Health England;
- set global norms and standards for surveillance;
- support countries with technical assistance and in evidence-based policy decisions;
- support research, vaccine impact and policy decisions through the use of surveillance data.

WHO provides managerial oversight, technical assistance and limited financial support to countries for surveillance activities, with a focus on countries eligible for Gavi support. WHO has established networks of sentinel hospitals and national laboratories supported by regional and global reference laboratories, and conducts an annual EQA programme that targets participating laboratories; conducts sentinel site assessments and regional workshops for laboratory capacity building in molecular techniques; provides technical advice and laboratory supplies to sites; and shares data semi-annually via a global surveillance bulletin[1].

In 2016, the Global Rotavirus Surveillance Network (GRSN) comprised 133 sentinel surveillance sites in 58 countries (Table 6.1 and Fig. 6.1) and the Global IB-VPD Surveillance Network (GISN) comprised 124 sentinel sites in 57 countries (Table 6.2 and Fig. 6.2). Most countries have one or two surveillance sites, though some have as many as nine; 83% of countries reporting rotavirus surveillance through the GRSN and 81% of countries reporting IB-VPD surveillance through the GISN were eligible for Gavi support.

In addition, there were at least 67 countries that conducted rotavirus surveillance (Table 6.1 and Fig. 6.1) and 86 countries that conducted IB-VPD surveillance (Table 6.2 and Fig. 6.2) outside of networks; of these, 18% of countries conducting rotavirus surveillance and 20%

[1] http://www.who.int/immunization/monitoring_surveillance/resources/NUVI/en/

of those conducting IB-VPD surveillance were eligible for Gavi support. These countries may have either conducted surveillance according to the WHO-recommended methodology but not reported data to WHO, or they may have conducted surveillance using an alternate method that is not the method recommended by networks. This includes aggregated data instead of case-based, laboratory-based instead of syndromic surveillance, or a method limited to one pathogen, such as *S. pneumoniae*. WHO does not currently have the resources or capacity to assess the quality of surveillance of sites not participating in the WHO-coordinated network. However, some of these countries participate in WHO-organized training activities, EQA, collaborative projects and meetings. These additional surveillance activities have been identified through a number of sources: a 2016 supplemental JRF surveillance survey, a 2016 survey of meningitis laboratory surveillance capacity conducted by the University of Edinburgh, and country participation in other regional and global surveillance networks (e.g. Enhanced Surveillance of Meningitis, MenAfriNet, and SpIDNet for IB-VPDs, and EuroRotaNet for rotavirus).

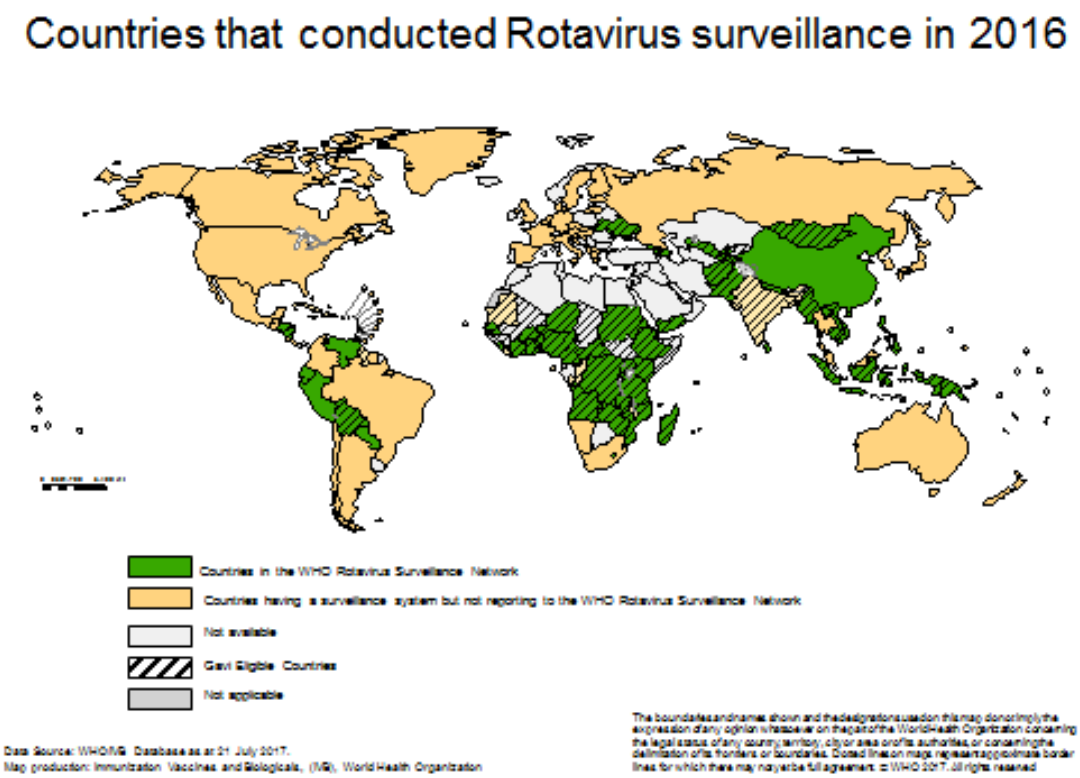
Table 6.1: Number of countries with rotavirus surveillance, by year, income level and type of surveillance, 2016

	Income level and eligibility for Gavi support			
	Gavi-eligible	**Middle income, not Gavi-eligible**	**High income**	**Total**
Part of WHO-coordinated GRSN	48	9	1	58
Conducts rotavirus surveillance but not part of GRSN	12	22	33	67
No reported surveillance	13	34	22	69
Total	73	65	56	194

Table 6.2: Number of countries with IB-VPD surveillance, by year, income level and type of surveillance, 2016

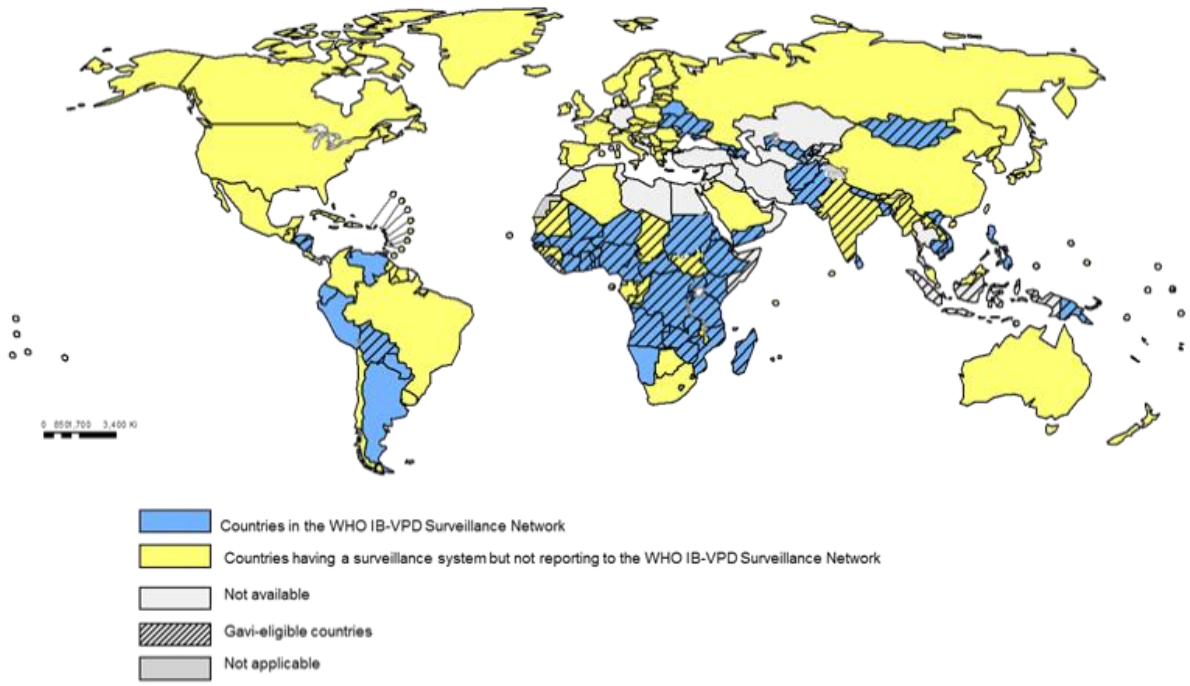
	Income level and eligibility for Gavi support			
	Gavi-eligible	**Middle income, not Gavi-eligible**	**High income**	**Total**
Part of WHO-coordinated Global IB-VPD Surveillance Network (GISN)	46	11	0	57
Conducts IB-VPD surveillance but not part of GISN	17	28	41	86
No reported surveillance	10	26	15	51
Total	73	65	56	194

Fig. 6.1: Countries conducting rotavirus surveillance, 2016



Source: WHO/IVB 2017

Fig. 6.2: Countries conducting IB-VPD surveillance, 2016



Source: WHO/IVB 2017

Report on SO4.4 indicator and target

WHO monitors the performance of sites and countries that participate in GRSN and GISN on four performance indicators. In addition, affiliated sentinel hospital laboratories and laboratories that process surveillance specimens participate in the global EQA.

The performance indicators for the rotavirus disease sentinel surveillance sites are as follows.

1. Consistent reporting throughout year (minimum standard is green or yellow for this indicator)
    a. Green: 12 months and confirmed zero reporting if no cases
    b. Yellow: 10–11 months and confirmed zero reporting if no cases
    c. Red: < 10 months and confirmed zero reporting if no cases
2. Minimum number of cases reported annually (minimum standard is green or yellow for this indicator)
    a. Green: ≥ 100 suspected diarrhoea
    b. Yellow: ≥ 80–99 suspected diarrhoea cases
    c. Red: < 80 suspected diarrhoea cases
3. Suspect cases with specimen collected
    a. Green: ≥ 90%
    b. Yellow: ≥ 80–89%
    c. Red: < 80%
4. Specimens tested for rotavirus by enzyme immunoassay (EIA)

a. Green: ≥ 90%
b. Yellow: ≥ 80–89%
c. Red: < 80%

The performance indicators for the IB-VPD sentinel surveillance sites are as follows.

1. Consistent reporting throughout year (minimum standard is green or yellow for this indicator)
    a. Green: 12 months and confirmed zero reporting if no cases
    b. Yellow: 10–11 months and confirmed zero reporting if no cases
    c. Red: < 10 months and confirmed zero reporting if no cases
2. Minimum number of cases reported annually (minimum standard is green or yellow for this indicator)
    a. Green: ≥ 100 suspected meningitis; ≥ 500 meningitis + pneumonia/sepsis
    b. Yellow: ≥ 80–99 meningitis; ≥ 400–499 meningitis + pneumonia/sepsis
    c. Red: < 80 meningitis; < 400 meningitis + pneumonia/sepsis
3. Suspect cases with specimen collected
    a. Green: ≥ 90%
    b. Yellow: ≥ 80–89%
    c. Red: < 80%
4. Laboratory-confirmed cases with serotype/group
    a. Green: ≥ 80%
    b. Yellow: ≥ 60–79%
    c. Red: < 60%

Most countries (at least 80%) that reported rotavirus surveillance data to WHO as part/GRSN met minimum surveillance standards (at least one surveillance site per country reporting for at least 10 months with a minimum number of cases as defined above; **Table 6.3**). This was stable if slightly increasing from 2015 to 2016. The number of surveillance sites that met the four performance indicators has increased from 2013 to 2016, with the majority meeting all four indicators (**Fig. 6.3**).

A slightly lower but still high number (at least 70%) of countries that reported IB-VPD surveillance data to WHO as part of GISN met minimum surveillance standards (at least one surveillance site per country reporting for at least 10 months with a minimum number of cases as defined above; **Table 6.4**). This was stable if slightly decreasing from 2015 to 2016. The number of surveillance sites that met the four performance indicators was high for specimen collection requirements, medium for consistent reporting and minimum number of cases, and low for serotyping and serogrouping (Fig. 6.4). In general, the number of sites meeting each criterion has been stable from 2013 to 2016.

In 2016, a total of 116 laboratories participated in the IB-VPD EQA that tested for Gram stain, species identification by culture, genotypic identification (when applicable) and an optional exercise to test antimicrobial susceptibility. Among these, 100 laboratories (86%) passed. In the same year, a total of 119 laboratories participated in the rotavirus EQA that tested their ability in diagnosing rotavirus by EIA. All 119 laboratories (100%) passed. A total of 60 laboratories were tested for their performance in rotavirus genotyping. Among these, 53 laboratories (88%) passed.

Table 6.3: Number and percentage of countries reporting rotavirus surveillance data that meet minimum standards[a] to WHO as part of GRSN

Income level and eligibility for Gavi support	2015	2016
Gavi-eligible	38/45 (84%)	43/48 (90%)
Middle income, not Gavi-eligible	8/10 (80%)	9/9 (100%)
High income	1/1 (100%)	0/1
Total	47/56 (84%)	52/58 (90%)

[a] At least one surveillance site per country reporting for at least 10 months with a minimum number of cases as defined in the text above.

Table 6.4: Number and percentage of countries reporting IB-VPD surveillance data that meet minimum standards[a] to WHO as part of GISN

Income level and eligibility for Gavi support	2015	2016
Gavi-eligible	35/44 (80%)	35/46 (76%)
Middle income, not Gavi-eligible	8/11 (73%)	8/11 (73%)
High income	None	None
Total	43/55 (78%)	43/57 (75%)

[a] At least one surveillance site per country reporting for at least 10 months with a minimum number of cases as defined in the text above.

Fig. 6.3: Surveillance sites reporting rotavirus surveillance data to WHO as part of GRSN that met four performance indicators, 2013–2016

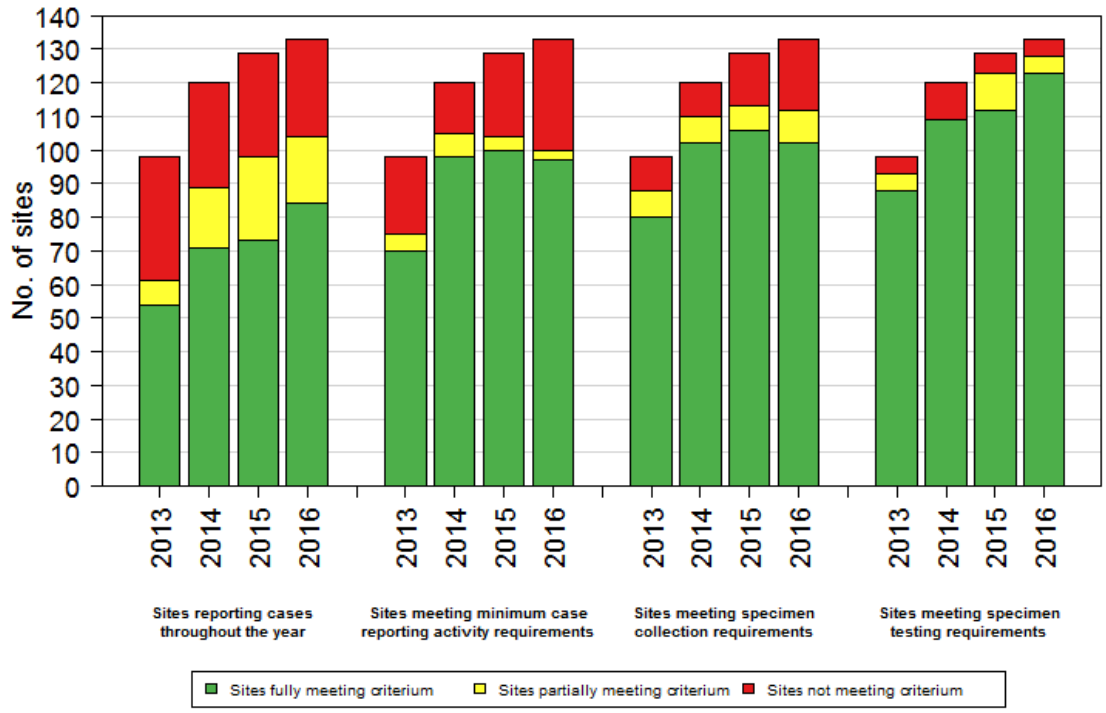


Fig. 6.4: Surveillance sites reporting IB-VPD surveillance data to WHO as part of GISN that met four performance indicators, 2013–2016

The future of IB-VPD and rotavirus surveillance

WHO recommends surveillance for rotavirus and IB-VPD to define burden of disease and monitor impact of vaccination. Long-term, high quality surveillance is needed after vaccine introduction to monitor the impact of the vaccination programme and the changes in disease; one important example of this is pneumococcus, especially for potential pneumococcal serotype replacement. In addition, maintaining surveillance and laboratory capacity allows countries to leverage the infrastructure to monitor other vaccine-preventable and non-vaccine preventable diseases, to monitor antimicrobial resistance and to identify and respond to outbreaks and epidemics.

The global invasive bacterial vaccine-preventable and rotavirus disease surveillance networks have adopted these objectives and the sites within the networks have matured into strong, long-standing surveillance systems that are a critical part of basic VPD surveillance in many countries. In addition, a large number of countries conduct surveillance for these diseases outside the WHO-coordinated networks. Although there are high-performing sites in all regions, performance of some sites needs to be strengthened, especially for consistent reporting, laboratory confirmation of organisms and monitoring of strains. This underscores the need for consistent support and funding of surveillance at country level and for continued coordination and monitoring at regional and global levels. One of the largest obstacles for maintaining the network is sustainable funding, both at the country level and for external support through WHO and other partners. The surveillance networks will therefore need to advocate at the country level for sustainable support for surveillance and determine sources of funding in addition to Gavi, especially for countries

transitioning out of Gavi support and middle-income countries that are not eligible for Gavi support.

For rotavirus, there is an ongoing need to monitor the impact of vaccination that has expanded across much of the African Region, and to generate disease burden and early vaccine impact data from Asia, where rotavirus vaccine is not yet widely used. GRSN is also being leveraged to monitor other priority childhood enteric diseases, especially those with vaccines in development, such as norovirus, *E. coli* and *Shigella*. The Global Pediatric Diarrhea Surveillance project (formerly referred to as Global Pediatric Diarrhea TAC Array Study) uses a novel diagnostic test, the TaqMan Array Card (TAC), to test specimens from a subset of more than 30 sites that are part of the GRSN for more than 25 enteric pathogens in addition to rotavirus. With support from the Bill & Melinda Gates Foundation and partners at the University of Virginia and the CDC, TAC laboratory testing capacity was built at five regional references laboratories globally and is expanding to another in 2017. More than 1200 specimens were tested from 11 countries in Africa, Asia and the Americas in 2015 and showed that this novel diagnostic testing platform could be used successfully in many laboratories globally to identify the causes of diarrhoea in children *(1)*.

For IB-VPD, surveillance needs to monitor long-term changes after vaccine introduction, such as for pneumococcal serotype replacement, and to address new policy questions, such as for alternate and reduced PCV schedules. Antimicrobial resistance has also become a global concern that can be addressed through these networks. For example, the laboratories participating in the IB-VPD EQA have an optional exercise that allows them to test antimicrobial susceptibility against the pathogens that cause invasive bacterial diseases. The laboratories that are part of this and other surveillance networks have supported outbreak response for large-scale pneumococcal outbreaks that have occurred in the African meningitis belt. Current sentinel surveillance may not be sufficient to answer all of these questions adequately, so each type and level of surveillance that is needed must be evaluated to maximize the use of PCV. Pilot testing of integrated typhoid surveillance at four IB-VPD surveillance sites (Bangladesh Ghana, India and Uganda) is under way and will be completed at the end of 2017.

Being part of global VPD surveillance networks can provide benefits to countries: technical support and training on epidemiology, laboratory and data management; EQA/QC; linkages with partners; opportunities for network activities and studies (e.g. Global Pediatric Diarrhea Surveillance project), and in some cases funding. One of the most urgent needs is to encourage sustainable surveillance by building national surveillance and laboratory capacity while maintaining needed support from global and regional partners. WHO will continue to support and work with countries to strengthen their surveillance systems in order to maintain high-quality data that can be analysed and made available at the country, regional and global level.

References

1. Operario DJ, Platts-Mills JA, Nadan S, Page N, Seheri M, Mphahlele J, et al. Etiology of severe acute watery diarrhea in children in the Global Rotavirus Surveillance Network using quantitative polymerase chain reaction. J Infect Dis. 2017; 216(2):220–7

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7. Sustainable financing and supply for immunization

Introduction

In 2016, adequate financing and access to vaccine supply continue to remain major obstacles for countries to achieve and sustain national, regional and global immunization goals. Within countries these financing and supply bottlenecks exist both at national and subnational levels. Several countries are reporting challenges getting both traditional and "new" vaccines in the quantities needed as well as accessing sufficient financial resources to meet the increasing costs of paying for vaccines and their delivery through national immunization programmes (in particular due to high vaccine prices). The reliable access to vaccines at service levels require that national supply chain systems can ensure timely distribution of vaccines in a strong cold chain system to safeguard vaccine potency up to the point of administration. Unfortunately, the supply chain systems in many countries continue to underperform and countries are unable to meet WHO standards for effective vaccine management. One of the common results is that countries experience vaccine stock outs.

The year 2015 marked a change in the GVAP Secretariat report: the main accomplishments across several strategies and resolutions of WHO's work in the area of sustainable financing and supply for national immunization programmes were reported on for the first time. A chapter provided updates on the actions taken by WHO to respond to the World Health Assembly resolution WHA68.6 of 2015.

Expanding on this change, Section 7 of the 2017 GVAP Secretariat report provides updates on the following activities: i) improving global vaccine security; ii) safeguarding sustainable financing for vaccines and immunization; iii) strengthening procurement and its transparency; and iv) strengthening national supply chain systems. Note that more detailed quantitative analyses related to these updates are available in subchapters of this section.

Improving global vaccine security

Improving country regulatory environment for vaccine introduction (see also Subchapter 1)

Efficient regulatory mechanisms with streamlined processes and predictable timelines facilitate access to vaccines. As of June 2017, WHO reported that there are 43 vaccine-producing countries worldwide, 36 of which have a functional national regulatory authority (NRA). As of end 2016, 21 of the vaccine-producing Member States were producing one or more WHO-prequalified vaccines.

The WHO dedicated programme for regulatory systems strengthening within the WHO Essential Medicines and Health Products Department has been working on several fronts to enhance country regulatory environments for vaccine introductions. In particular, following two WHO international consultations conducted in Geneva in January and December 2015, WHO developed further the NRA Global Benchmarking Tool in 2016 and 2017. This tool is a means by which WHO evaluates regulatory systems that oversee medical products including vaccines and health technologies in Member States. The WHO NRA Global Benchmarking Tool incorporates the concept of maturity levels from ISO 9004:2009, *Managing for the sustained success of an organization -- a quality management approach (1)*. The concept has

been extensively discussed within the WHO as well as during two WHO international consultations conducted in Geneva in January and December 2015. By applying the concept of maturity levels according to a well-defined algorithm, NRAs are able to ascertain their performance status and existing regulatory capacity with the object of attaining required maturity level. The concept of maturity level also allows for the definition of more advanced systems that in turn should facilitate reliance and greater regulatory cooperation.

Among the WHO achievements in 2016–2017, are field visits, training and workshops in Viet Nam, Mexico, India and the Russian Federation to successfully follow-up on recommendations for NRA's assessments and their recommendations for improvement. Of note: the Mexican regulatory authority (COFEPRIS) has declared its interested to establish a centre of excellence to support other NRAs in the region and to build regulatory capacity in Asia-Pacific Economic Cooperation (APEC) member economies. Also, the re-benchmarking of the Indian NRA took place in February 2017 – India scored well in all of these functions. Remarkable improvements in the regulatory system have been observed since the previous assessment in 2012. The NRAs of Kazakhstan and Serbia will be assessed in 2017.

In the context of WHO's support to Member States in strengthening their regulatory systems, WHO conducted a workshop on sensitization towards a quality management system for NRAs from 13 to 17 June 2016 in Bangkok, Thailand. Twenty-five participants from ten countries from the South-East Asian Region, one country from the Region of the Americas and one observer from the WHO Country Office in Viet Nam from the Western Pacific Region also attended the workshop. WHO is in the process of planning required technical support and capacity building activities to address the gaps in the countries identified during the workshop in order to improve the overall quality management system of the NRAs. At least one similar workshop will be conducted in the WHO African Region in 2017.

It is important to note that even with functional NRAs, inefficient and widely varying processes for registering vaccines, including WHO-prequalified vaccines, create an important obstacle to vaccine introduction, lengthening timelines and driving up costs for countries and suppliers. WHO is working to facilitate registration or acceptance of WHO prequalified vaccines by enhancing understanding, reliance and trust in the WHO prequalification process in key priority countries, particularly for priority vaccines. In 2015–2016, the vaccines assessment group received four rotational fellows from NRAs in Nigeria, Saudi Arabia, the United Republic of Tanzania and Zambia. The rotational fellowship programme has been effective in facilitating vaccine registration in countries.

Prequalification process (see also subchapter 2)

WHO prequalification offers manufacturers a well-established and robust means of accessing markets for products that meet internationally-accepted quality norms and standards. A total of 147 vaccines (including several presentations) had been prequalified as of December 2016. Seven vaccines were prequalified and evaluation of 12 additional vaccines took place in 2016. With regards to vaccine delivery technologies, a total of 310 products had been prequalified as of end December 2016 compared to 163 in 2010,

corresponding to a 90% increase between 2010 and 2016. Details of product specifications and summary assessment and inspection reports are published on the WHO/PQT website.[1]

The WHO Emergency Use and Assessment Listing (EUAL) procedure developed in 2015 is currently being revised. This procedure is used in the event of a public health emergency caused by a sudden outbreak of any epidemic-prone diseases. Affected countries may face challenges to assess quality, safety and efficacy of the available products with less than usual data regarding potential use. In the context of a public health emergency and in the absence of the usual package of information required for marketing authorization or WHO prequalification listing, NRAs with the technical assistance/support of WHO would be obliged to make decisions on the potential use of candidate products based on a risk–benefit analysis of existing, but not comprehensive, data. Several infectious diseases may pose an epidemic or pandemic risk, including smallpox (in case of a terrorist attack), severe acute respiratory syndrome (SARS) or SARS-like disease, Ebola virus disease (EVD), Zika virus, pandemic influenza, among others.

Recent outbreaks (e.g. yellow fever and meningitis) and insufficient supply of some vaccines (e.g. inactivated polio vaccine) triggered the needs to identify potential additional sources of vaccines for international supply. These vaccines need to be prequalified through implementation of an expedited evaluation process or fast-track prequalification mechanism.

Pre-empting and managing vaccine shortages

Vaccine shortages occur when global supply of a vaccine cannot meet the full demand from countries. Depending on the severity, vaccine shortages can translate into national vaccine stock outs and in suspension of immunization activities.

Over the past couple of years, several countries across regions and World Bank income groups[2] have reported being confronted with shortages of vaccines and the trend seems to be on the rise. Given the growing concern related to global vaccine shortages, the 2016 SAGE meeting discussed this topic at length and highlighted an important gap in ongoing work to address supply shortages. This is a gap in information collection, analysis and exchange on supply availability, related regulatory matters, country demand and access risks. Investment in this area could enhance informed decisions for both countries (e.g. vaccine introduction, product choice) and manufacturers (e.g. facility improvement, capacity investment). The issue was highlighted particularly with regards to self-procuring countries not supported by targeted intelligence efforts. SAGE recommended that WHO plays a key role to address this gap by enhancing dialogue between countries and manufacturers on global demand predictability, supply availability and potential threats to vaccine supply, particularly for vaccines and countries not supported by the UNICEF Supply Division, the Pan American Health Organization (PAHO), or Gavi *(2)*.

Against this background, WHO has initiated a vaccine shortage project. The aim of the project is to provide concrete proposals on WHO's role and actions to enhance information sharing for pre-empting and managing vaccine supply shortages. Existing information from WHO and immunization stakeholders has been mapped to identify gaps and opportunities.

[11] http://www.who.int/immunization_standards/vaccine_quality/pq_revision2010/en/

[2] https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

Two global market assessments, one for Bacille Calmette–Guérin vaccine (BCG) and one for diphtheria- and tetanus toxoid-containing vaccines are being used to prototype an operating model for WHO in this project. The model will be submitted for feedback to immunization stakeholders by the end of 2017 and thereafter to donors for funding consideration.

Vaccine research and development

During 2016–2017, the WHO R&D Blueprint strategy to prevent epidemics has progressed substantially. WHO has updated its list of priority pathogens[3] likely to cause major epidemics (and will continue to do so, on an annual basis). Ebola vaccines have progressed to the stage of regulatory assessment for licensure. For Middle East respiratory syndrome coronavirus (MERS-CoV) WHO has developed a global R&D roadmap as well as vaccine target product profiles (TPPs), and a vaccine is now in clinical testing. A TPP for Zika virus vaccine has also been published and numerous other vaccines are in early-phase clinical evaluation. Other vaccine TPPs have been developed as well, including for Nipah and Lassa viruses. To foster an enabling environment for research on vaccines, drugs and diagnostics for outbreak response, a number of tools have been developed including draft material transfer agreements that guide the sharing of samples, and an agreement with stakeholders for rapid sharing of data. A global coordination mechanism has been established to map out stakeholder activities and priorities and to ensure coordinated R&D activities during outbreaks.

In January 2016, WHO recommended that pilot implementation of RTS,S – the first malaria vaccine to achieve the equivalent of licensure – occur in parts of 3–5 sub-Saharan African countries, administering 3 doses of the vaccine to children aged from 5 months with a fourth dose 15–18 months later. Since then US$ 50 million has been committed by Gavi, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and Unitaid to enable the pilot implementation programme, which is due to start early 2018 in Ghana, Kenya and Malawi. These studies will generate critical evidence to enable decision-making about the potential wider scale use of this vaccine.

A dengue vaccine (CYD-TDV or Dengvaxia) has been registered in several countries, and in 2016 WHO issued a position paper on its use. Since then another dengue vaccine (TV003) has entered phase III trials in Brazil.

A typhoid conjugate vaccine dossier has been submitted for prequalification in 2017, and evidence to support policy collected. This will be presented to SAGE in October 2017 for policy recommendation.

Numerous other vaccines have proceeded in clinical development: the HIV vaccine (HVTN 702) started phase IIb/III trials in South Africa, with efficacy results expected in 2020; The candidate (tuberculosis) TB vaccine M72/AS01 has entered phase IIb studies for prevention of TB in endemic countries; a recombinant BCG (VPM1002) has entered phase III studies in infants and adults; and several respiratory syncytial virus (RSV) candidate vaccines have entered phase III studies including in elderly patients and in pregnant women.

[3] http://www.who.int/blueprint/priority-diseases/en/

Safeguarding sustainable financing for vaccines and immunization (see also subchapter 3)

Ensuring adequate and reliable access to sustainable financing for vaccines and vaccinations remains a chronic issue in many countries despite greater global investments in support of immunization and health systems strengthening.

To support countries to develop an overview of expenditures and financing for immunization and to help them better plan and budget for needs to meet goals and targets, WHO and UNICEF have been providing technical assistance to countries. These comprehensive multi-year plans (cMYPs) provide multi-year costed strategies and operational plans for immunizations. During 2016, a total of 65 countries had updated their national cMYP, 35 of which were middle-income countries. That same year, 18 countries developed new immunization plans.

For those specific countries that are transitioning out of Gavi support, WHO is working closely with national and global immunization partners to advocate for increased domestic financing in order to sustain immunization gains once Gavi support ends. Despite very limited resources, WHO has also been active in supporting countries that recently transitioned from Gavi support to explore options for continued programme funding and strengthening. Attracting immunization donors' interest beyond Gavi-supported countries has been more difficult than foreseen; this has stalled donor investments in the middle income strategy for immunization endorsed by SAGE in April 2015[4].

In 2016, as part of national immunization assessments (Expanded Programme on Immunization, EPI, reviews) WHO has been supporting the development and the testing of a new immunization financing assessment module. The testing of this module has been carried out in several countries over the past five years: in low-income countries, countries in transition out from Gavi support and also in middle-income countries not eligible for Gavi support. Given the positive results achieved over 2016–2017, this immunization financing assessment is being integrated into the EPI review as a dedicated assessment module. This will improve the EPI review by now allowing countries to assess immunization financing and financial sustainability bottlenecks prior to the development of cMYPs.

Lastly, in order to improve the monitoring of immunization financial flows, efforts have been made to strengthen the linkages between immunization financing tracking efforts and the System of Health Account (SHA) framework at country level by facilitating the exchange of information and methodologies to track expenditures. Alignment in methodologies and processes will contribute to improve the quality of data being reported on immunization-specific expenditure and financing.

Strengthening procurement and its transparency

Improving and sustaining country vaccine procurement systems

Inefficient procurement is an important barrier preventing a reliable supply of affordable vaccines (both new and traditional). To support countries in improving procurement, the

[4] http://www.who.int/immunization/sage/meetings/2015/april/Cernuschi_MIC_Strategy_SAGE_Apr2015.pdf?ua=1&ua=1

WHO regional offices have been providing as much technical assistance as is possible under the current capacity constraints to improve the accuracy of national vaccine forecasts; to enhance demand-consolidation activities (such as the harmonization of product requirements across countries); and to improve procurement legislations.

Following up on specific World Health Assembly recommendations for exploring benefits of pooled procurement, four of the six WHO regional offices – for Africa, the Eastern Mediterranean, Europe and the Western Pacific – have been supporting countries currently self-procuring vaccines to consider procuring through alternative mechanisms, such as UNICEF Supply Division, for enhanced access to affordable vaccines. Of note, the first successful inter-country joint vaccine procurement took place in the European Region in 2016: a partnership agreement on joint procurement and lending of medicinal products and medical devices was signed by health authorities of the three Baltic States – Latvia, Estonia and Lithuania. Following this, Latvia and Estonia jointly procured rotavirus vaccine, which resulted in securing a vaccine supply for both countries at lower cost than procuring alone.

All regional offices have been investing time and resources in encouraging country participation in the WHO Vaccine Product, Price and Procurement (V3P) project[5], which provides a platform for accessing procurement information. Results of this work are outlined below.

The revolving fund of PAHO has continued to procure vaccine on behalf of over 40 countries and territories in the region.[6]

Pricing and procurement transparency (see also subchapter 4)

In 2016–2017, the number of countries sharing vaccine procurement information with the V3P project has increased. The V3P database contains data about price, products, manufacturers, volumes, procurement mechanisms, contract lengths, currencies and sources of funding; it is a crucial source of global vaccine market information. This demonstrates the proactive response of Member States to resolution WHA68.6 (2015) on the GVAP that called for all countries to share their vaccine price information with WHO. In 2017, 144 countries directly shared price information with V3P, a 180% increase compared to 2016 (51 countries) and a 450% increase since the launch of the V3P initiative in 2014. The data available in the V3P database, provided by individual countries, PAHO and UNICEF, covers about 84% of all the countries in the world, making vaccine price transparency a concrete reality.

The V3P initiative was created to respond specifically to the needs for vaccine price transparency expressed mainly by middle-income countries not supported by either Gavi or PAHO, which faced critical challenges affording vaccine. It is important to note that 90% of this group of countries are now sharing price information (only five countries have yet to participate). Alongside the great efforts of countries, other initiatives by WHO and partners have also contributed to more transparency and better access: for example, the publication

[5] http://www.who.int/immunization/programmes_systems/procurement/en/

[6] http://www.paho.org/hq/index.php?option=com_content&view=article&id=1864&Itemid=40713&lang=en

of the first edition of the Access to Vaccines Index[7] by the Access to Medicine Foundation and the organization of the 2017 Fair Pricing Forum by WHO[8].

Timely access to affordable supply in humanitarian emergencies

In order to address the specificity of immunization in crisis-affected populations, WHO published in 2013 *Vaccination in acute humanitarian emergencies: a framework for decision making (3)*. Despite the available technical guidance, experience from partners showed that a key barrier to protecting crisis-affected populations from vaccine-preventable diseases was affordable and timely access to vaccines *(4)*.

In its mid-term GVAP assessment report in 2016 *(5)*, SAGE urged international agencies, donors, vaccine manufacturers and national governments to work together to alleviate the financial burden placed on countries to buy and deliver vaccines for displaced populations at high risk of vaccine-preventable diseases and ensure a timely supply of affordable vaccines in humanitarian crisis situations.

As a response, WHO, UNICEF, Médecins Sans Frontières (MSF) and Save the Children developed and launched a "Humanitarian Mechanism" in May 2017 *(6)*. This framework sets forth requirements for vaccine supply in emergencies and the elements for effective and efficient vaccine procurement among others. The mechanism's "main aim is to facilitate timely access to affordable supply for entities such as Civil Society Organizations, Governments or UN Agencies who are procuring on behalf of populations facing humanitarian emergencies otherwise unable to have access to affordable vaccines" *(6)*. It should be noted that other mechanisms already exist for accessing supply of certain vaccines where risk of disease is considered high, such as the International Coordination Group for meningococcal vaccine, oral cholera vaccine and yellow fever vaccine, or at lowest market prices for some vaccines through UNICEF procurement on behalf of populations facing humanitarian emergencies.

Currently, pneumococcal conjugate vaccine (PCV) from the two available manufacturers is offered under the mechanism for procurement through civil society organizations and UN agencies. The mechanism's partners encourage more suppliers to join this effort, making commitments to offer their lowest global vaccine prices to governments and/or organizations serving the needs of people caught in humanitarian emergencies. It is acknowledged that while this mechanism aims to facilitate timely access to affordable vaccines in humanitarian crises, the challenge remains for many middle-income countries to introduce life-saving vaccines into their routine immunization programmes, also due to price barriers.[9]

Strengthening national supply chain systems (see also subchapter 5)

Vaccine access continues to be an important issue in 2017, especially at national level with countries struggling to ensure an uninterrupted supply of vaccines to the local level. WHO continues to work closely both at national and subnational levels to collect and analyse stock-out data. Since 2014, an increasing number of countries have reported interruptions

[7] https://accesstovaccinesindex.org/

[8] http://www.who.int/medicines/access/fair_pricing/en/

[9] http://www.who.int/immunization/programmes_systems/sustainability/mic_strategy/en/

in vaccination services due to vaccine stock outs at subnational levels. In 2016, a total of 70 countries reported at least one stock out of vaccines for at least one month, up from 50 countries in 2014. The upward trend strongly signals that national immunization supply chain systems face growing difficulties in securing access to vaccines when needed. While the impact on coverage and equity remains unclear, WHO is studying the impact of national stock outs on programme performance and ways to mitigate such stock outs.

Following a call for action from SAGE's GVAP assessment report in 2016 to redesign supply chains and information systems, WHO and UNICEF have been working in tandem with other partners to support countries to improve their vaccine supply and cold chain systems with transformative solutions through the WHO-UNICEF Effective Vaccine Management initiative. Under the umbrella of the Gavi immunization supply chain strategy launched in 2014, various initiatives by Alliance partners are leading to improvements in the ability of countries to ensure vaccine availability at the local level and mitigate stock outs; to safeguard vaccine potency in optimized and end-to-end temperature-managed cold chain systems; and to increase data driven vaccine management efficiencies to reduce avoidable wastage. Since early 2016 progress has been made in strengthening the immunization supply chains in 37 of 47 priority countries. Of these, six countries have attained the WHO benchmark standards for effectively managing vaccines from end-to-end.

Scaling up innovative products and thermostability (see also subchapter 6)

Encouraging progress continues to be made in support of the controlled temperature chain (CTC), with recognition that advocacy and partner engagement are factors underpinning the successful experiences with and supply of vaccines labelled for this delivery approach outside of the cold chain. A working group dedicated to the CTC was established under WHO's Immunization Practices Advisory Committee (IPAC) in mid-2016 with a view of convening key stakeholders to define a common vision and strategy around CTC, as well as determine the critical threats to the programme and associated solutions. Among the important outputs from this working group has been a statement distinguishing the use of vaccines out of the cold chain from those used in a CTC, which highlights the importance of on-label use of vaccines.

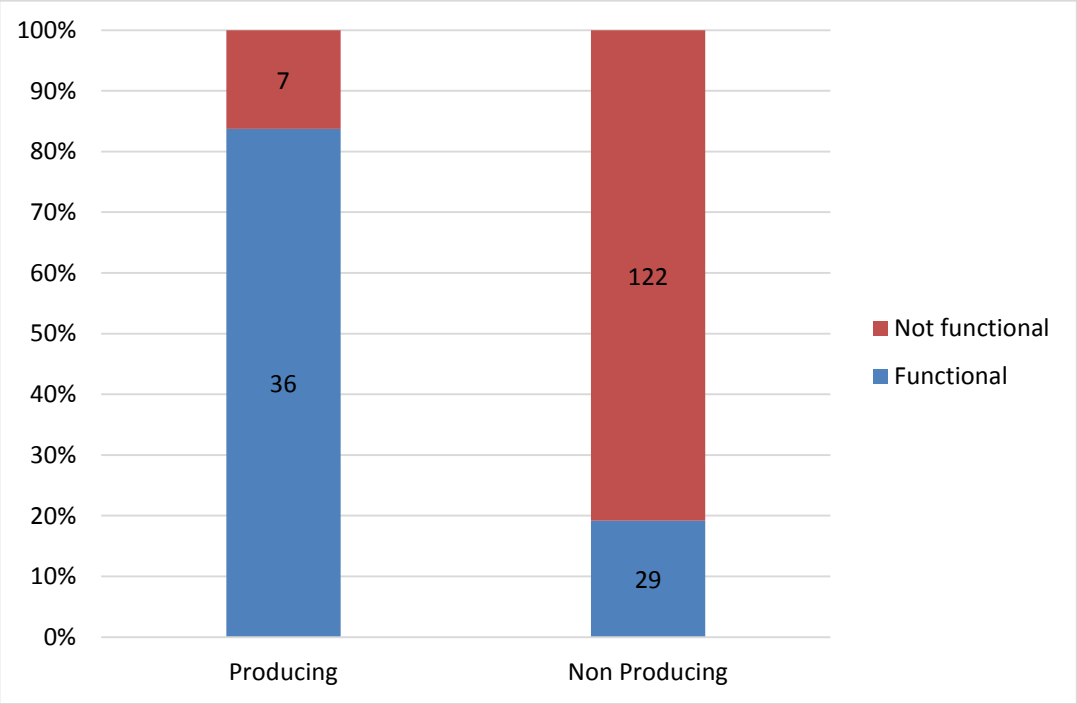
In addition, in February 2017, the working group identified four priority vaccines on which CTC licensure and implementation efforts should be concentrated, namely: human papillomavirus (HPV) vaccine, oral cholera vaccine (OCV), tetanus toxoid (TT)-containing vaccine and birth dose of hepatitis B vaccine. A strategic roadmap is under development to define the specific steps and resources required to move these four vaccines through the CTC agenda. While the efforts around HPV and OCV concern mainly the broadening of evidence characterizing the potential benefits of CTC, the proposed activities in support of CTC with TT and birth dose of hepatitis B vaccine are at the supply level, to facilitate licensure and availability of these vaccines for use in a CTC.

Subchapter 1: Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies: percentage of doses of vaccine used worldwide that are of assured quality (indicator SO5.1)

Results

As of June 2017, WHO reported there were 43 human vaccine-producing countries (according to the WHO definition[10]), of which 36 had a functional national regulatory authority (NRA), as assessed by WHO (compared to 37 countries in June 2016) (Fig. 7.1). Similarly, the number of functional NRAs of vaccine non-producing countries is 29 countries (compared to 30 countries in 2016). Twenty-two of the vaccine-producing Member States were producing one or more WHO-prequalified vaccines by the end of 2016 (same as 2015).

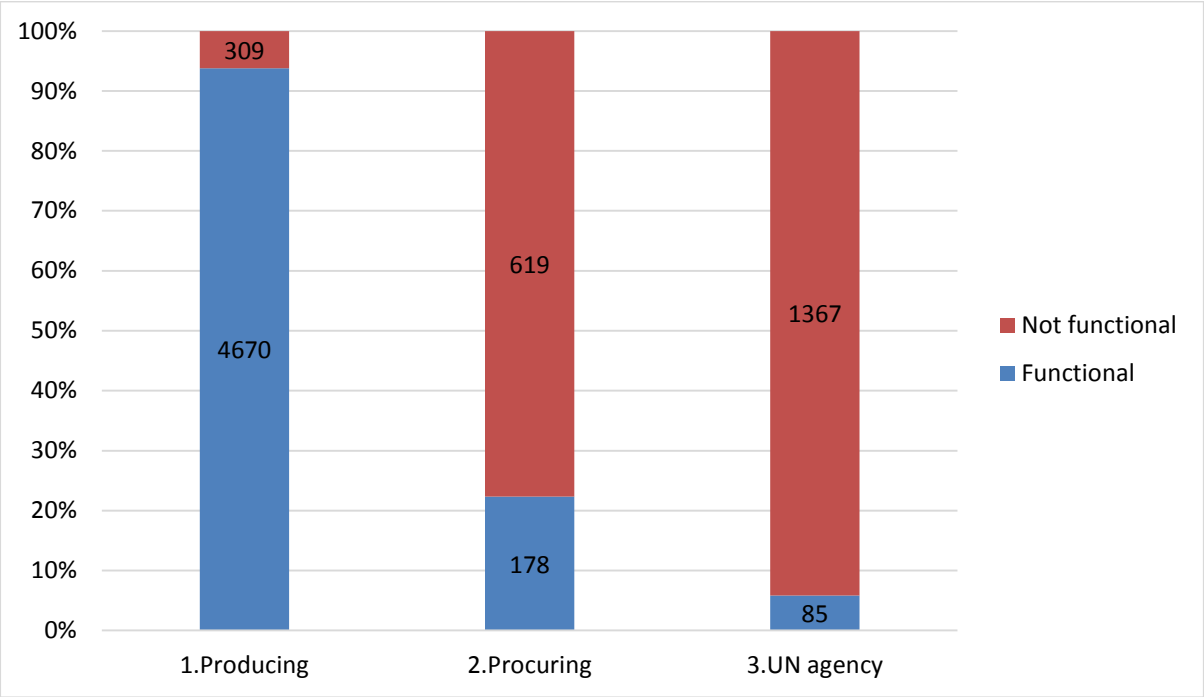
Fig. 7.1: Number and percentage of Member States (vaccine-producing and non-producing) with an NRA assessed as functional as of June 2017



In terms of global population, there was no significant change compared to 2015 – 68% (4.9 billion people) still live in the 65 countries where there is direct oversight by a functional NRA (Fig. 7.2). However Fig. 7.3 shows that even in the countries without functional NRAs, the majority of the world's population have access to WHO-prequalified vaccines through their national immunization programmes.

[10] WHO has defined "vaccine producing country" as a country that is able to produce human vaccine for at least 5% of national demand.

Fig. 7.2: Proportion of the global population living in countries with functional regulatory oversight for vaccine in 2016 (in millions)

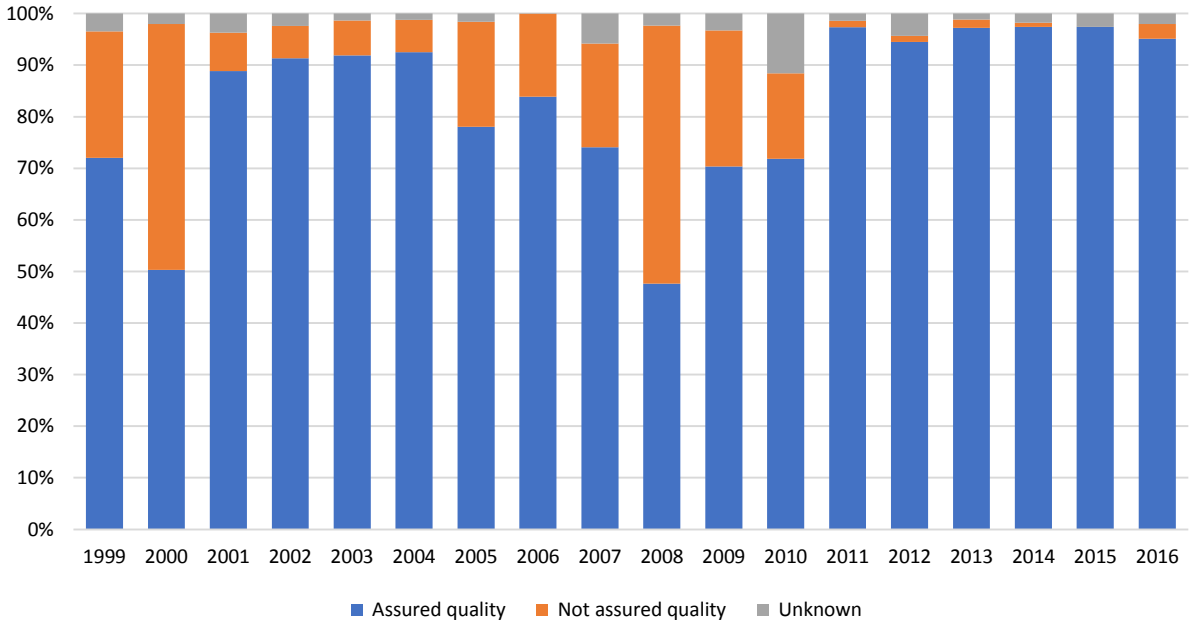


Producing: Main source of vaccine comes from a vaccine-producing country; procuring: Main source of vaccine is self-procurement; UN agency: Main source of vaccine comes through a UN agency.

Source: WHO Health Systems and Innovation, Regulatory Systems Strengthening, as of June 2017.

Overall, 95% (2% less than in 2016) of the global doses of vaccines used in national immunization programmes are of assured quality (Fig. 7.3). WHO is working closely with all Member States to meet the target of assured quality of 100% of vaccine doses used by national immunization programmes by 2020.

Fig. 7.3: Percentage of assured (blue) versus non-assured (orange) quality vaccines used worldwide, 1999–2016[a]



a Doses of vaccines reported mainly from country's lot release and WHO/UNICEF JRF.

Source: World Health Organization/Essential Medicines and Health Products, as of 1 June 2017.

Subchapter 2: Immunization programmes have sustainable access to predictable funding, high-quality supply and innovative technologies: number of vaccine delivery technologies (devices and equipment) that have received WHO prequalification (indicator SO6.5)

TARGET	None specified
DEFINITION OF INDICATOR	The number of products (cold chain equipment, injection devices and others) that have been prequalified by the WHO performance, quality and safety (PQS) specification system as of 31 December 2016, as compared to the number of prequalified products on 31 December 2010, which was 163 products. Note: The definition does not take into account the number of products that might have entered the list and been withdrawn in the interim period. Therefore, it is just the difference between two data points.
DATA SOURCES	The WHO PQS database.
COMMENTS ON DATA QUALITY	Data reflect the difference of the number of products that were listed in the PQS as prequalified on 31 December 2010 and those as of 31 December 2016. The recording of the date after each change of a product's status ensures the quality of data.

HIGHLIGHTS

- A total of 310 products had been prequalified as of 31 December 2016 compared to 163 in 2010, a 90% increase between 2010 and 2016.
- Specifications have been developed for freeze-free vaccine carriers and cold boxes as well as for energy-harvesting controls for solar direct drive (SDD) cooling devices.
- Specifications for refrigerated vehicles have been drafted and contact with manufacturers is ongoing to enable inputs for finalization.
- A generic field evaluation protocol was published in 2016. This protocol serves as a template for the field testing of new technology. The aim is to enable quick generation of field performance data before full prequalification of new technology.

BACKGROUND

The performance, quality and safety scheme for the prequalification of equipment determines the immunization equipment to be purchased by UN agencies. It requires manufacturers comply with criteria of performance, quality and safety based on an assessment by independent, WHO-accredited laboratories. For more details please refer to the 2016 GVAP Secretariat report or to the PQS website[11].

RESULTS

Innovation

The PQS Secretariat and partners have been exploring the need for large cold rooms (> 40 m^3) in countries with significantly large populations. WHO is partnering with UNICEF Supply Division to provide advice to the Democratic Republic of the Congo during development of the specifications for their super large cold room (400 m^3). The project is ongoing in Kinshasa and two other regional hubs. WHO is also working with PATH and UNICEF to develop specifications for solar cold rooms. New specifications for freeze-safe cold boxes for vaccine storage are published and field testing of the first candidate is under way.

In 2014, a multi-partner PQS specifications working group was established that included WHO, UNICEF, PATH, the Clinton Health Access Initiative, Solar Electric Light Fund and Gavi, with the objective of developing TPPs for innovative solutions and the revision of existing specifications. This working group met four times in 2015, three times in 2016 and has met twice in 2017 (as of 1 August 2017). Between 2015 and 2017 this group addressed the following items:

- standard definitions for net and gross volumes to be included in vaccine management handbooks;
- development of standards for calculating freezing capacity of SDD freezers;
- specifications for freeze-free vaccine carriers and cold boxes;
- specifications and verification protocol for voltage stabilizers;
- development of specifications for energy harvesting controls for SDD refrigerators;
- specifications for solar cold rooms;
- specifications for large cold rooms (> 40 m^3);
- specifications for vaccine vial monitors and other chemical indicators.

Products

Procurement agencies today can choose between 310 PQS prequalified products from 75 manufacturers, a 90% increase from the 163 products that were available on 31 December 2010. Product availability has been increasing steadily since 2010 (Table 7.1 and Fig. 7.4).

Table 7.1: Number of prequalified products per year and per category between 2008 and 2017[a]

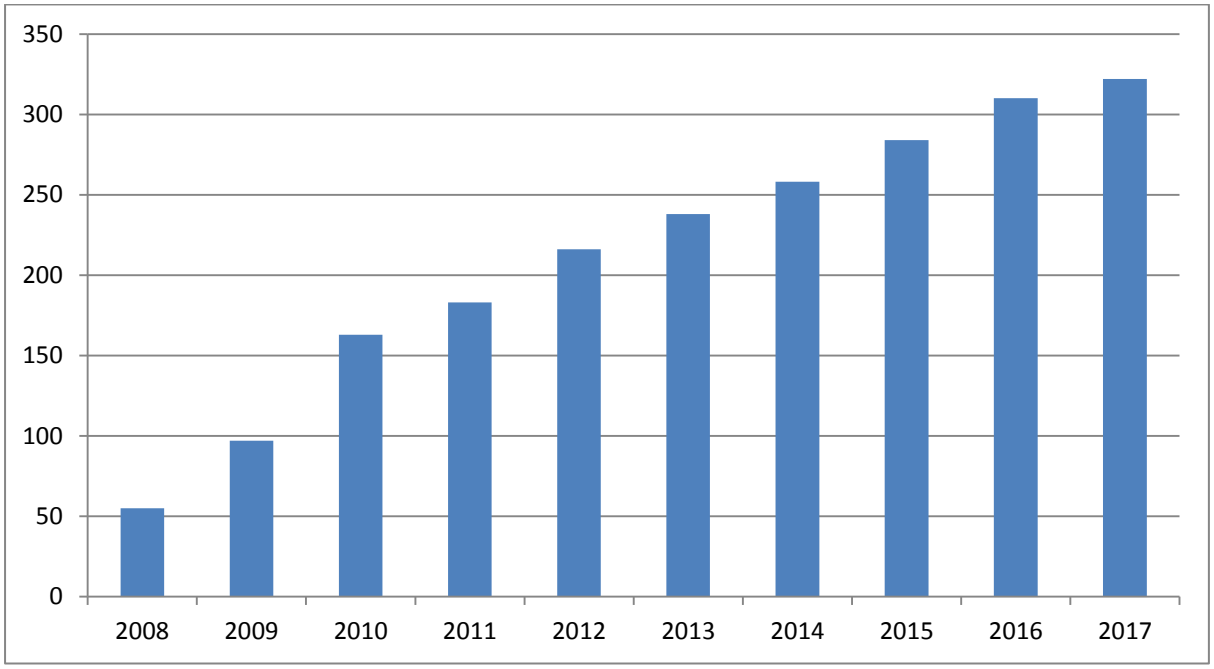
Prequalified products	Year	Increase (%)

[11] http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2010–2016
Cold rooms and related equipment	0	1	3	3	3	3	3	4	4	4	33%
Refrigerators and freezers	0	8	14	23	33	36	44	51	74	6	429%
Cold boxes and vaccine carriers	0	2	31	32	34	37	39	41	42	2	36%
Water packs	0	1	15	16	18	17	17	17	17	0	13%
Temperature monitoring devices	7	10	11	12	17	22	24	31	33	1	200%
AD syringes for immunization	21	31	30	27	29	33	36	39	39	3	30%
Waste management equipment	5	9	10	10	10	10	11	12	12	0	20%
Therapeutic injection devices	22	35	49	60	72	80	84	89	89	0	82%
Total	55	97	163	183	216	238	258	284	310	16	90%

[a] As of 30 June 2017.

Fig. 7.4: Cumulative number of prequalified products, 2008–2017[a]



[a] As of 30 June 30 2017.

Subchapter 3: All Member States commit to immunization as a priority: domestic expenditures for immunization per person targeted (Indicator SO1.1)

Strategic objective	All Member States commit to immunization as a priority
Target	Increasing trend in country allocation to national immunization programmes.
Definition of indicator	Domestic expenditures for immunization are considered all recurrent expenditures financed by domestic resources (from national and subnational government budgets) for immunization-specific activities carried out for both vaccine procurement and immunization delivery. Supplemental immunization activities are excluded, as are extra-budgetary expenditures from development partners, capital expenditure, out-of-pocket and private expenditures. The number of live births is used as a proxy for persons targeted as standard denominator available for all countries.
Data sources	1. The WHO-UNICEF Joint Reporting Form (JRF) financing indicators: government expenditure on routine immunization; government expenditure on vaccines 2. World Bank: income classification 3. Gavi: Gavi co-financing country grouping 4. UN Population Division: live birth data.

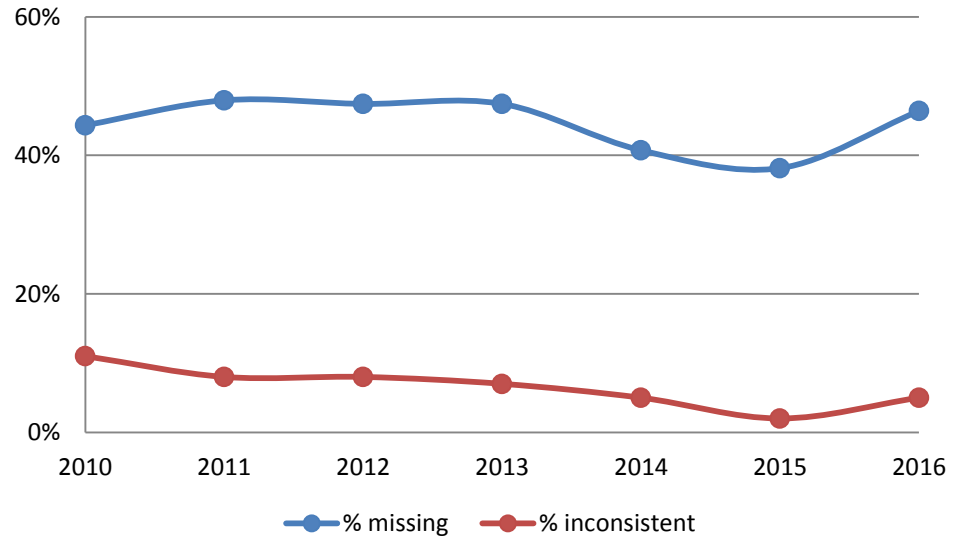
Highlights

- Of the 127 countries included in the analysis, 84 countries reported an increase in government expenditure on routine immunization compared to the baseline level. The global average increased by 27%, from US$ 31 to US$ 39 per live birth.
- Across the WHO regions, various trends are noted. A substantial increase was seen in the African Region while a decrease in expenditure was seen in the European Region. Relatively low, but increasing expenditures per live birth are reported in the African Region, Eastern Mediterranean Region and South-East Asia Region while the Region of the Americas and the European Region reported higher average expenditures.
- These various trends in government expenditure on routine immunization have been confirmed by the JRF data (indicator on government expenditures on vaccines). Further analyses at regional and country levels are required to assess if the financial resources allocated to immunization are adequate to achieve the GVAP target.
- The quality of the data submitted by countries remains a concern. Various efforts are ongoing to advocate that countries reaffirm their commitment to improving the quality of data and reporting of financing indicators on the JRF. This includes cooperation between national governments and the WHO National Health Account and EPI teams, which is expected to contribute to improved data quality of the JRF financing indicators.

Data quantity and quality

Through 2015, the quantity and quality of information submitted by Member States on government expenditure for routine immunization in the JRF has been improving steadily. That changed in 2016, as the amount of missing and inconsistent data increased (Fig. 7.5). An unexpected increase in missing data was observed in three regions[12] (Table 7.2). Inconsistency was identified when the government expenditure on routine immunization indicator showed highly divergent reported values (compared to the trend) or when criteria of internal consistency among JRF financing indicators were not met. Six criteria have been used to check internal consistency *(7)*. It is assumed that complete and consistent entries result in higher data quality and accuracy. Additional efforts are required to encourage country submission of the GVAP financing indicators and to stress the importance of reporting consistent JRF data.

Fig. 7.5: Percentage of countries with inconsistent data and missing data on government expenditure on routine immunization, 2010–2016



Source: JRF (2010–2016)

[12] South-East Asia Region: Bhutan, Democratic People's Republic of Korea, Indonesia, Sri Lanka, Thailand.
Region of the Americas: Antigua and Barbuda, Bahamas, Bolivia (Plurinational State of), Canada, Dominican Republic, El Salvador, Guatemala, Haiti, Mexico, Panama, Peru, Saint Kitts and Nevis, Saint Lucia, Trinidad and Tobago, USA, Uruguay.
Western Pacific Region: Lao People's Democratic Republic, Malaysia, Marshall Islands, Niue, Viet Nam

Table 7.2: Number of countries with missing and inconsistent data for government expenditure on routine immunization per region, 2010–2016

WHO region	2010	2011	2012	2013	2014	2015	2016
African	16	17	18	14	11	11	9
Americas	7	6	7	9	5	4	16
Eastern Mediterranean	11	13	12	12	12	10	9
European	39	40	38	39	37	34	33
South-East Asia	1	2	3	2	0	1	5
Western Pacific	12	15	14	16	14	14	18
Total no. of countries with missing data	86	93	92	92	79	74	90
% missing	44%	48%	47%	47%	41%	38%	46%
Total inconsistent data	21	16	16	14	9	4	9
% inconsistent[a]	11%	8%	8%	7%	5%	2%	5%

a An inconsistency was reported when the government expenditure on routine immunization indicator showed divergent reported values (compared to the trend) or when the criteria of internal consistency were not met.

Source: JRF (2010–2016)

Feedback to countries has been provided on the quality of data by highlighting possible inconsistencies, identified through cross-checking data based on the reported trend and data sources. In approximately 20–40 cases each year, inconsistencies or missing data are replaced by WHO estimates based on the reported trend, by the average of data from the previous and subsequent year or by using additional sources of information, like cMYP and Gavi co-financing requirements. For 2016, 16 of the 90 countries with missing data have responded to the queries and/or confirmed the WHO estimates.

Various efforts are ongoing to advocate that countries reaffirm their commitment to improving the quality of data and reporting of financing indicators on the JRF. This includes cooperation between national governments and the WHO National Health Account and EPI teams, which is expected to contribute to improved data quality of the JRF financing indicators, particularly by ensuring consistency between the two sources of information: data from national health accounts and immunization-specific expenditure reported in the JRF.

As countries encounter difficulties in identifying and reporting government expenditure on routine immunization, the JRF financing indicator on government expenditure on vaccines[13] has been included to complement the analysis. Generally, this indicator has been considered more reliable with fewer missing data as it addresses clearly defined expenditure items, which are the procured vaccines used in routine immunization.

[13] JRF indicator on government expenditure on vaccines used in routine immunization (excluding vaccines used in supplementary immunization activities)

Methodology

Compared to the 2016 GVAP Secretariat report, the methodology for the 2017 report has been slightly changed to improve the reliability of data and the number of countries included in this analysis: the baseline remains the same (average of 2010–2011) while the comparison period is given by the average of the two most recent years (2015–2016) instead of the three most recent years as described in the 2016 GVAP Secretariat report. This change aims to ensure the comparability of the time periods, which should contain the same intervals. To be included in the analysis, a country needs to meet the following criteria:

1. have reported data on government expenditure on routine immunization from at least one year (2010–2011);
2. have reported data on government expenditure on routine immunization from at least one year (2015–2016).

The average of each two-year period is used for comparison: averages of the baseline period 2010–2011 are compared with the averages of the period from 2015–2016. A total of 127 Member States are included in this year's report. The 2016 GVAP Secretariat report included 104 Member States in the analysis and the 2015 GVAP Secretariat report included 92 countries: the sample size for the analysis has progressively increased each year.

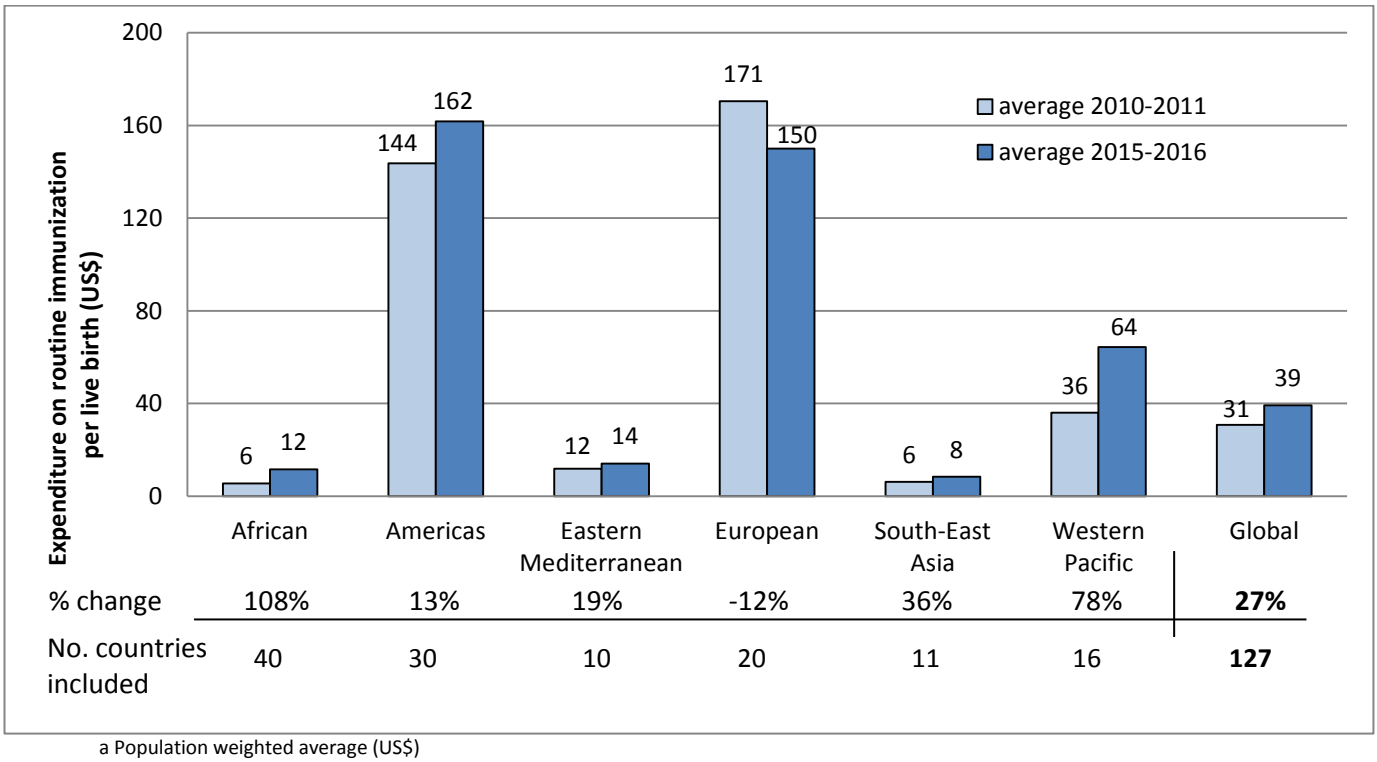
In order to include a complementing analysis of the government expenditure on vaccines, the same sample size of the government expenditure on routine immunization indicator is used. However, of the 127 countries responding to the above criteria, four countries – Denmark, Myanmar, South Sudan and Zimbabwe – did not reported data on vaccine expenditure in the years 2010–2011 and/or 2015–2016. This resulted in a sample size of 123 countries for the complementing analysis of the JRF indicator on government expenditure on vaccines.

In addition to global analysis, countries were grouped and analysed by WHO region, World Bank income classification and Gavi co-financing status to highlight specific trends in government spending for immunization. Government expenditure on routine immunization per live birth is calculated as the main indicator of analysis, supplemented by government expenditure on vaccine per live birth. The group average is weighted by live births to take into account country size. All government expenditures are expressed in nominal terms.

Results

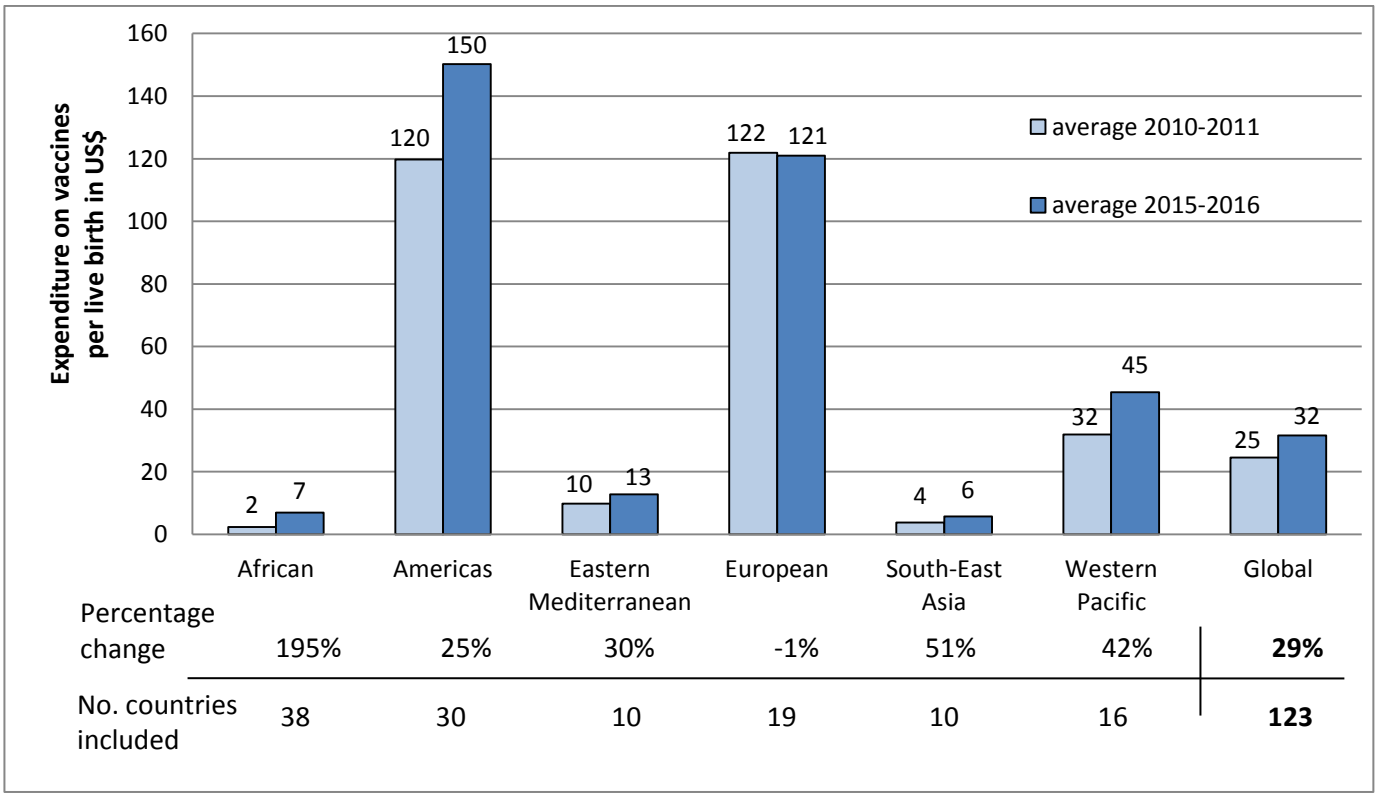
Globally government expenditure on routine immunization and on vaccines per live birth has increased, compared to the 2010–2011 baseline. For routine immunization the increase was 27% (from US$ 31 to US$ 39 per live birth) and for vaccines 29% (from US$ 25 to US$ 32 per live birth); see Fig. 7.6a and Fig. 7.6b. This represents an annual increase of around 5%. According to World Bank's world development indicator database, global inflation for 2010 to 2016 was on average 3.02% per year. Hence, government expenditure on both vaccines and routine immunization grew more than the inflation, which indicates an increase in real terms.

Fig. 7.6a: Government expenditure[a] on routine immunization per live birth, by WHO region



a Population weighted average (US$)

Fig. 7.6b: Government expenditure[a] on vaccines per live birth, by WHO region



a Population weighted average (US$)

An increase in government expenditure is observed in all regions for both indicators, except for the European Region. The African Region had the highest increase in spending with a doubling of government expenditure on routine immunization between 2010–2011 and 2015–2016 and government expenditure on vaccine has almost been tripled[14]. The Western Pacific Region is ranked in second place in terms of government expenditure increase, with 78% for government expenditure on routine immunization. The European Region is the only region that experienced a decline in government expenditure on routine immunization as well as vaccines, the former reduced by 12% and the latter by 1%. The region of the Americas, Eastern Mediterranean Region and the South-East Asia Region had relatively modest increases in government expenditure (Fig. 7.6b). Detailed data on government expenditure on routine immunization by country are available in Annex 7.1.

In addition to the substantial differences in expenditure variation between baseline and years 2015–2016 across regions, the absolute expenditure amount also varies widely. In 2015–2016, the African, Eastern Mediterranean and South-East Asia Regions spent approximately US$ 11 on routine immunization per live birth (population weighted average), while the Western Pacific Region spent approximately five times more. Expenditures on routine immunization in the Regions of the Americas and Europe were even higher – approximately US$ 150 per live birth (population weighted average).

Table 7.3 provides further information about the variation of government expenditure within each WHO region (minimum, maximum, median, 1st and 3rd quartile values). Between countries, the expenditure varies from a minimum of US$ 0.6 to a maximum of US$ 1357 per live birth, with a high variation especially in the 3rd quartile and maximum values[15]. On a regional level, the major variance is present in the European and Western Pacific Regions, with a range of around US$ 5 to US$ 1300 per live birth. The presence of outliers is a possible explanation for certain regional differences between the average expenditures, presented in Fig. 7.6a and the median presented in Table 7.3. See Annex 7.1 for detailed data per country.

Table 7.3: Variation of government expenditure (US$) on routine immunization per live birth, by WHO region, 2015–2016

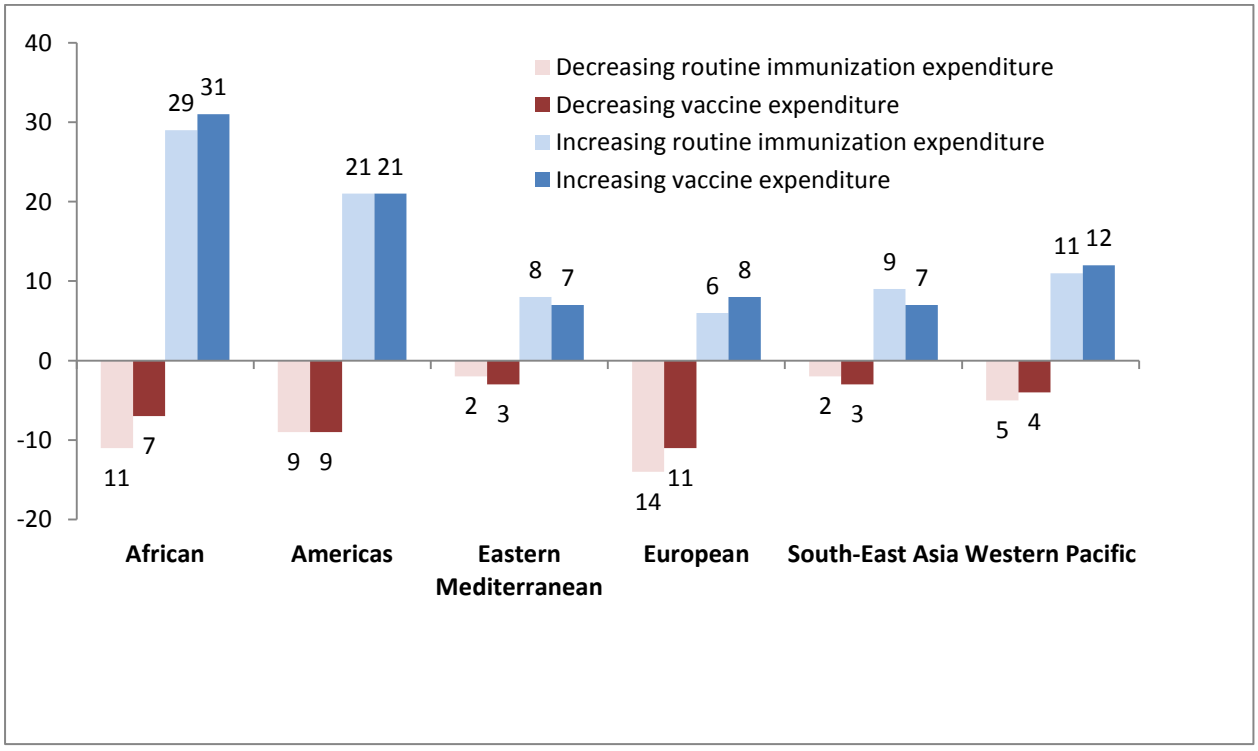
WHO region	Sample size	Min.	Quartile 1	Median	Quartile 3	Max.
African	40	0.6	4.1	7.3	17.4	154
Americas	30	19.8	64.1	115.9	196.3	401
Eastern Mediterranean	10	1.0	4.4	25.1	71.7	124
European	20	4.9	44.2	169.2	285	1286
South-East Asia	11	4.7	11.4	13.4	19.0	82
Western Pacific	16	5.2	15.3	29.4	262	1357
Global	127	0.6	8.7	30.6	129.1	1357

[14] The increase in government spending on routine immunization is mainly driven by the expenditure growth in Equatorial Guinea, Senegal, Botswana and Nigeria (Table A1.1).
[15] The countries with major outlier values are Australia, Denmark, Ireland and New Zealand.

In term of share of government financing on total expenditure on routine immunization[16], countries in Region of the Americas show high independence – on average 95% of the expenditure on routine immunization was financed by government in 2015–2016 (94% in 2010–11). The African Region shows the highest dependency on external funding, with the government financing 41% of the total expenditure on routine immunization in 2015–2016 (49% in 2010–11). In other regions government funding represents more than half of the total expenditure on routine immunization, however the share is declining over the period of study because external rather than government funds are increasingly being used for this.

Globally, the number of countries with an increased or decreased trend in government expenditure on routine immunization and vaccines are quite similar, with a slightly higher proportion of countries with an increasing trend in vaccine expenditure (Fig. 7.7). The African Region has the largest proportion of countries with an increase in expenditures on routine immunization while the South-East Asia Region has the largest proportion of countries with an increased trend on vaccine expenditures. For both indicators, the European Region is the only region where the number of countries with decreased government expenditure exceeds the number of countries with increased expenditures.

Fig. 7.7: Number of countries with increasing/decreasing trends of government expenditure on routine immunization and vaccines, by WHO region



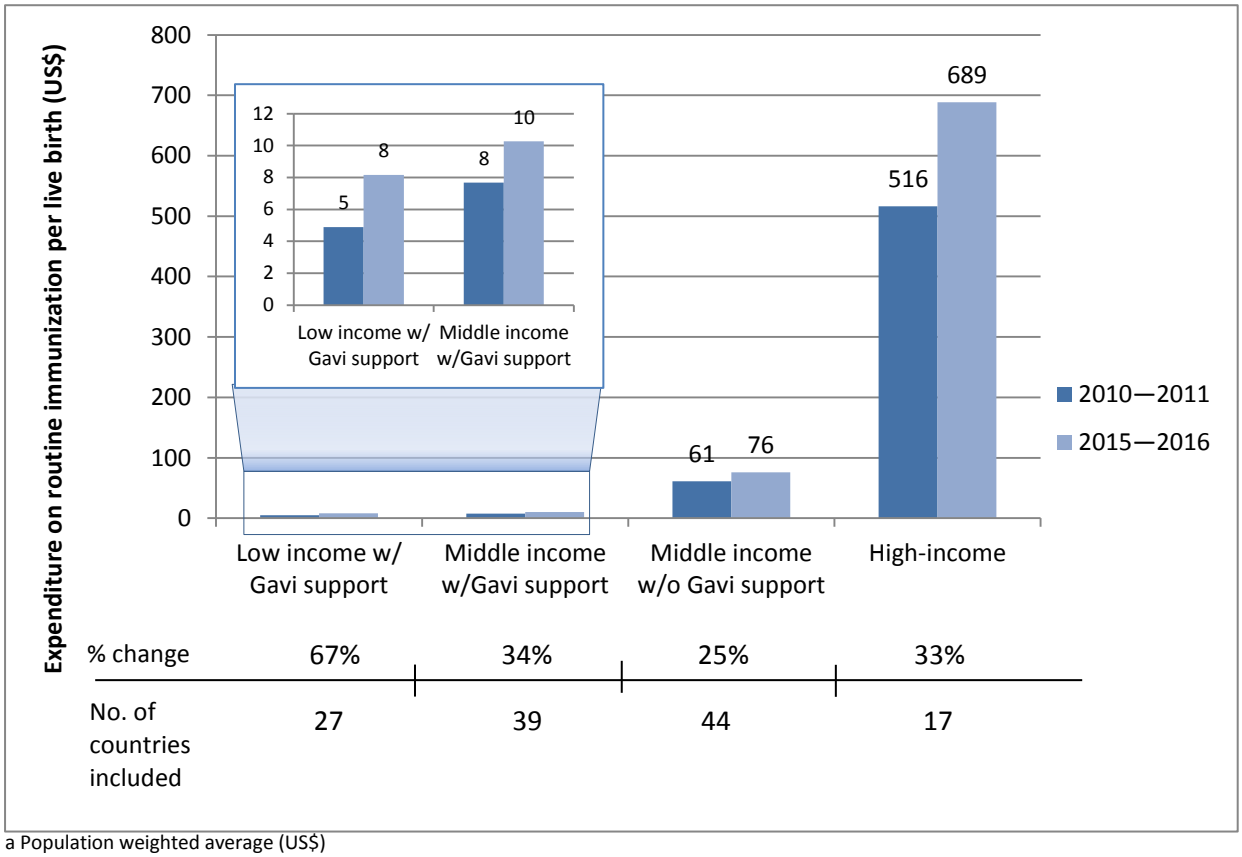
[16] Data on percentage of government financing expenditure on routine immunization and vaccines are also collected by JRF and available at:
http://www.who.int/immunization/programmes_systems/financing/data_indicators/en/

Analysis by income and Gavi classification

All country income groups reported an increase in government expenditures on routine immunization, however, to varying degrees (Fig. 7.8). Countries eligible for Gavi support had an average population-weighted expenditure per live birth of US$ 7 in 2010–2011 and US$ 10 in 2015–2016, which represents a percentage increase of 43%.

When the Gavi-eligible countries included in the sample are classified by World Bank income group the percentage increase varies widely: the highest increase is found in the low income group (27 countries) with an increase of 67% (from US$ 5 to 8 per live birth). Middle-income countries without Gavi support (44 countries included in the analysis) have a government expenditure of around seven times the expenditure of middle-income countries with Gavi support. High-income countries' governments (17 countries) have the highest absolute expenditure on routine immunization of around 60 times the expenditure of middle-income countries with Gavi support.

Fig. 7.8: Government expenditure[a] on routine immunization per live birth, by income group and Gavi support



a Population weighted average (US$)

Acknowledgements

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Annex 7.1: Tables on GVAP financing indicators by country, WHO region and World Bank income classification

Table A1.1: Government expenditure (US$) on routine immunization[a] by country, African Region

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Equatorial Guinea	UMC	1.37	9.82	617
Senegal	LIC	4.62	30.59	563
Botswana	UMC	24.86	153.61	518
Nigeria	LMC	4.02	22.79	467
Uganda	LIC	2.03	9.39	362
Namibia	UMC	32.72	113.22	246
Madagascar	LIC	0.88	2.81	220
Sierra Leone	LIC	1.70	4.58	169
Niger	LIC	1.75	4.72	169
Congo	LMC	3.76	8.64	130
Mali	LIC	7.95	17.88	125
United Republic of Tanzania	LIC	4.82	9.82	104
Burundi	LIC	0.79	1.46	85
Democratic Republic of the Congo	LIC	0.63	1.07	72
Côte d'Ivoire	LMC	5.85	9.43	61
Seychelles	HIC	24.84	39.23	58
Mauritius	UMC	99.38	153.66	55
Rwanda	LIC	6.15	9.03	47
Swaziland	LMC	59.72	84.24	41
Zimbabwe	LIC	15.74	22.17	41
Ethiopia	LIC	10.67	14.33	34
Mauritania	LMC	4.95	6.60	33
Eritrea	LIC	2.89	3.80	32
Guinea-Bissau	LIC	1.15	1.48	29
Mozambique	LIC	3.87	4.74	22
Benin	LIC	5.90	7.06	20
Chad	LIC	3.86	4.16	8
South Sudan	LIC	1.24	1.28	3
Sao Tome and Principe	LMC	66.83	68.62	3
Burkina Faso	LIC	5.88	5.60	-5

Togo	LIC	18.67	17.23	-8
Kenya	LMC	4.37	3.95	-10
Lesotho	LMC	9.28	7.49	-19
Central African Republic	LIC	0.74	0.58	-21
Cameroon	LMC	7.37	5.47	-26
Guinea	LIC	2.50	1.78	-29
Zambia	LMC	34.67	14.72	-58
Comoros	LIC	14.49	5.24	-64
Malawi	LIC	5.86	1.35	-77
Gabon	UMC	43.94	7.51	-83
Population-weighted average		5.56	11.57	108

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

a Population-weighted average in US$ per live birth.

Table A1.2: Government expenditure (US$) on routine immunization[a] by country, Region of the Americas

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Saint Lucia	UMC	29.81	130.43	338
Guatemala	LMC	32.30	103.99	222
Guyana	UMC	64.70	157.00	143
Barbados	HIC	215.99	386.22	79
Saint Vincent and the Grenadines	UMC	21.86	35.11	61
Bahamas	HIC	119.91	191.48	60
Argentina	UMC	164.40	243.12	48
Paraguay	UMC	96.09	138.33	44
Bolivia (Plurinational State of)	LMC	49.06	70.10	43
Panama	UMC	296.26	406.70	37
Dominica	UMC	27.05	35.89	33
Dominican Republic	UMC	16.80	22.10	32
Brazil	UMC	200.37	260.46	30
Grenada	UMC	45.67	58.06	27
Venezuela (Bolivarian Republic of)	UMC	63.88	80.41	26
Uruguay	HIC	161.19	196.99	22
Nicaragua	LMC	74.99	91.54	22
Cuba	UMC	173.14	208.85	21
Honduras	LMC	55.72	62.73	13

Belize	UMC	60.82	68.27	12
El Salvador	LMC	114.21	127.84	12
Peru	UMC	182.99	200.63	10
Chile	HIC	218.84	194.37	-11
Ecuador	UMC	157.29	131.79	-16
Colombia	UMC	102.09	82.16	-20
Costa Rica	UMC	283.89	220.03	-22
Saint Kitts and Nevis	HIC	26.13	19.78	-24
Mexico	UMC	127.55	87.59	-31
Jamaica	UMC	124.94	42.21	-66
Suriname	UMC	112.73	24.29	-78
Population-weighted average		143.63	161.82	13

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

a Population-weighted average in US$ per live birth.

Table A1.3: Government expenditure (US$) on routine immunization[a] by country, Eastern Mediterranean Region

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Iran (Islamic Republic of)	UMC	12.33	30.83	150
Djibouti	LMC	34.87	85.38	145
Lebanon	UMC	40.67	88.16	117
Jordan	UMC	65.44	123.88	89
Sudan	LMC	2.69	4.01	49
Afghanistan	LIC	2.13	2.66	25
Tunisia	LMC	21.97	26.80	22
Egypt	LMC	24.01	23.48	-2
Pakistan	LMC	9.12	5.77	-37
Yemen	LMC	4.93	1.00	-80
Population-weighted average		11.93	14.15	19

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

a Population-weighted average in US$ per live birth.

Table A1.4: Government expenditure (US$) on routine immunization[a] by country, European Region

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Armenia	LMC	16.78	70.97	323
Kazakhstan	UMC	82.98	186.86	125
Republic of Moldova	LMC	15.77	26.34	67
Uzbekistan	LMC	9.03	13.78	53

Georgia	UMC	55.39	81.02	46
Kyrgyzstan	LMC	6.50	8.42	29
Finland	HIC	419.33	414.38	-1
Netherlands	HIC	644.73	592.10	-8
Hungary	HIC	300.47	272.38	-9
Turkey	UMC	192.04	168.80	-12
Ireland	HIC	1496.58	1285.69	-14
Andorra	HIC	750.56	642.95	-14
Tajikistan	LMC	5.78	4.90	-15
Azerbaijan	UMC	37.29	31.42	-16
Belarus	UMC	67.87	54.89	-19
Estonia	HIC	211.91	169.55	-20
Iceland	HIC	323.89	250.70	-23
Bulgaria	UMC	350.06	262.47	-25
Ukraine	LMC	79.01	49.14	-38
Denmark	HIC	981.60	326.74	-67
Population-weighted average		170.53	149.99	-12

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

a Population-weighted average in US$ per live birth.

Table A1.5: Government expenditure (US$) on routine immunization[a] by country, South-East Asia Region

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Myanmar	LMC	0.89	12.78	1340
Thailand	UMC	29.84	81.63	174
Democratic People's Republic of Korea	LIC	8.90	23.46	163
Nepal	LIC	6.41	13.69	113
Maldives	UMC	20.79	30.60	47
Bangladesh	LMC	7.59	10.40	37
India	LMC	3.93	4.70	19
Timor-Leste	LMC	12.70	13.39	5
Indonesia	LMC	11.99	12.40	3
Bhutan	LMC	14.98	6.19	-59
Sri Lanka	LMC	35.71	14.57	-59
Population-weighted average		6.19	8.40	36

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

a Population-weighted average in US$ per live birth.

Table A1.6: Government expenditure (US$) on routine immunization[a] by country, Western Pacific Region

Countries	World Bank income group	Average 2010–2011	Average 2015–2016	% change
Lao People's Democratic Republic	LMC	1.82	52.67	2793
Republic of Korea	HIC	110.52	816.39	639
Malaysia	UMC	83.78	369.15	341
Niue	NA	140.39	227.27	62
Viet Nam	LMC	6.19	9.82	59
Mongolia	LMC	22.11	34.70	57
New Zealand	HIC	878.12	1356.93	55
China	UMC	17.76	24.59	38
Philippines	LMC	23.35	31.58	35
Vanuatu	LMC	18.30	20.47	12
Australia	HIC	1055.14	1038.17	-2
Cambodia	LMC	7.97	6.92	-13
Tonga	LMC	18.82	16.28	-14
Papua New Guinea	LMC	6.52	5.18	-21
Marshall Islands	UMC	100.73	27.81	-72
Solomon Islands	LMC	59.59	12.55	-79
Population-weighted average		36.07	64.37	78

LIC, low-income country; LMC, lower-middle-income country; UMC, upper-middle-income country; HIC, high-income country.

[a] Population-weighted average in US$ per live birth.

Note: For countries with only one data point for the 2010–2011 or 2015–2016 periods, this number is included as estimation of the respective 2-year average.

Table A1.7: Government expenditure on vaccines as percentage of government expenditure on routine immunization,[a] by WHO region, Gavi eligibility status and World Bank income classification

Region or classification	2010–2011	2015–2016
African Region	55%	67%
Region of the Americas	81%	80%
Eastern Mediterranean Region	65%	77%
European Region	82%	86%
South-East Asia Region	52%	65%
Western Pacific Region	70%	77%
Global	68%	75%
Low-income country with Gavi support	52%	54%
Middle-income country with	53%	71%

Gavi support		
Middle-income country, no Gavi support	83%	87%
High-income country	87%	80%

[a] Population-weighted average in US$ per live birth.

Subchapter 4: Vaccine price & procurement report 2017

GVAP vaccine price indicators

Indicator	Goal
1 – Transparency: number of countries sharing price information by WHO region.	Monitor country progress in sharing price data over time.
2 - Annual average or unit vaccine prices as data permits a) Price trends: evolution of annual average price over time; b) Volume & price: relationship of vaccine prices with volumes purchased, segmented by level of income; c) Price segmentation: relationship between income level and vaccine prices. Minimum–maximum price range by country level of income.	This indicator aims to: • facilitate country planning for the introduction of new vaccines; and • increase country and global knowledge of the vaccine market and price trends.

Highlights

- A total of 144 countries have shared vaccine price information, three times as many countries as in 2016 (51 countries). Reported data for 2016 represents a total value of US$ 7.8 billion for a total volume of 3.2 billion doses purchased from 73 manufacturers.
- In just four years after its launch, the V3P Initiative has created price transparency for 84% of all WHO Member States, representing 95% of the world birth cohort. In response to calls for action from the Sixty-eighth World Health Assembly in 2015 resolution WHA68.6 and SAGE, Member State participation has increased in all WHO regions, particularly in the African Region, Eastern Mediterranean Region and South-East Asia Region, while countries from the Region of the Americas have participated for the first time.
- Data show that vaccine prices are stable or declining over time.
- No clear association could be observed between volume and price. More sophisticated analyses will be needed to further explore this relationship.
- There is a moderate to strong association between gross national income (GNI) per capita and price, with large price ranges visible among middle-income countries and high-income countries, indicating a segmentation of the vaccine markets and high price differentiation: in middle-income countries not supported by Gavi, the maximum price for a vaccine type is 14 times higher, on average, than the minimum price reported in the same category; in high-income countries it is almost 30 times higher; while in countries supported by Gavi it is 6 times higher.

Background

The global call for greater vaccine price transparency and affordability has been relayed through several resolutions and recommendations in recent years.[17] In particular, the Sixty-eighth World Health Assembly resolution WHA68.6 in 2015 on the Global Vaccine Action Plan [18] called on Member States to share vaccine price data with WHO through the Vaccine Product Price and procurement (V3P) initiative[19]. V3P aims to enhance Member States' planning and budgeting for vaccines and to inform their procurement decisions and

[17] The Global Vaccine Action Plan objective 5 (WHA65.17, 2012); the SAGE-endorsed Middle Income Country Strategy for immunization (SAGE, 2015) and the African Ministerial Declaration in February 2016 (link).
[18] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R6-en.pdf
[19] WHO. Vaccine Product Price and Procurement (V3P) database. Available from: www.who.int/immunization/v3p.

strategies, particularly in the areas of new vaccine introduction and understanding the factors that can influence price.

The objective of this subchapter is to present an updated view of the GVAP price indicators and key findings from the most recent data available through the V3P initiative.[20] All the data and many analyses are available on the V3P website: www.who.int/immunization/v3p.

Note: Data, vaccine types[21] and countries included in each analysis may vary to ensure that relevant data are used to respond to each indicator. Note that the analyses in this subchapter do not aim to exhaustively represent all of the factors that can influence vaccine prices but were done with the purpose of tracking the GVAP price indicators. Additional price, procurement and market information per vaccine is available in the section *Other information on products, prices and procurement* of this subchapter.

GVAP price and procurement indicators

Throughout this subchapter, countries will be grouped to reflect elements that have an important link to price: financing (i.e. whether or not they receive Gavi financial support for vaccine purchase), income (to reflect ability to pay) and procurement policy (i.e. whether or not they procure vaccines through the PAHO Revolving Fund). The categories below will be used:

1. "Gavi countries"[22,23] – This refers to countries that receive support from Gavi to procure vaccines.
2. "Non-Gavi, non-PAHO middle-income countries (MICs)"[24] – This refers to middle-income countries (either lower-middle or upper-middle income as per World Bank classification) that neither receive Gavi support nor are located in the Region of the Americas.
3. "High-income countries (HICs)"[25] – This refers to high-income countries.
4. "PAHO middle-income countries"[26] – This refers to middle-income countries within the Region of the Americas using the PAHO Revolving Fund.

Indicator 1: Transparency: number of countries sharing price information by WHO region

A total of 144 countries from all WHO regions reported vaccine prices in 2017[27], three times as many countries as last year (51 countries had shared price data in 2016) and five times as

[20] Data collected in 2017 through the WHO/UNICEF JRF are from 2016. PAHO and UNICEF have provided 2017 data.

[21] A vaccine type is defined as one or a combination of antigen(s) active against specific disease(s). For instance: DT, DTP and DTP–Hib–HepB are considered three distinct vaccine types. For each vaccine type, many distinct products and presentations can exist.

[22] This category includes the 73 countries that are or have been eligible for Gavi support since 2000, regardless of whether they are currently still eligible for support, in transition to self-financing or fully self-financing.

[23] This category includes six countries in the Region of the Americas (Haiti, which benefits from Gavi support, and five middle-income countries that are transitioning to self-financing or are fully self-financing: Bolivia (Plurinational State of), Cuba, Guyana, Honduras, Nicaragua.

[24] This category includes one middle-income country in the Region of the Americas, (Mexico), as the country does not procure through the PAHO Revolving Fund.

[25] This category includes two high-income countries in the Region of the Americas (Canada and the USA), as they do not procure through the PAHO Revolving Fund.

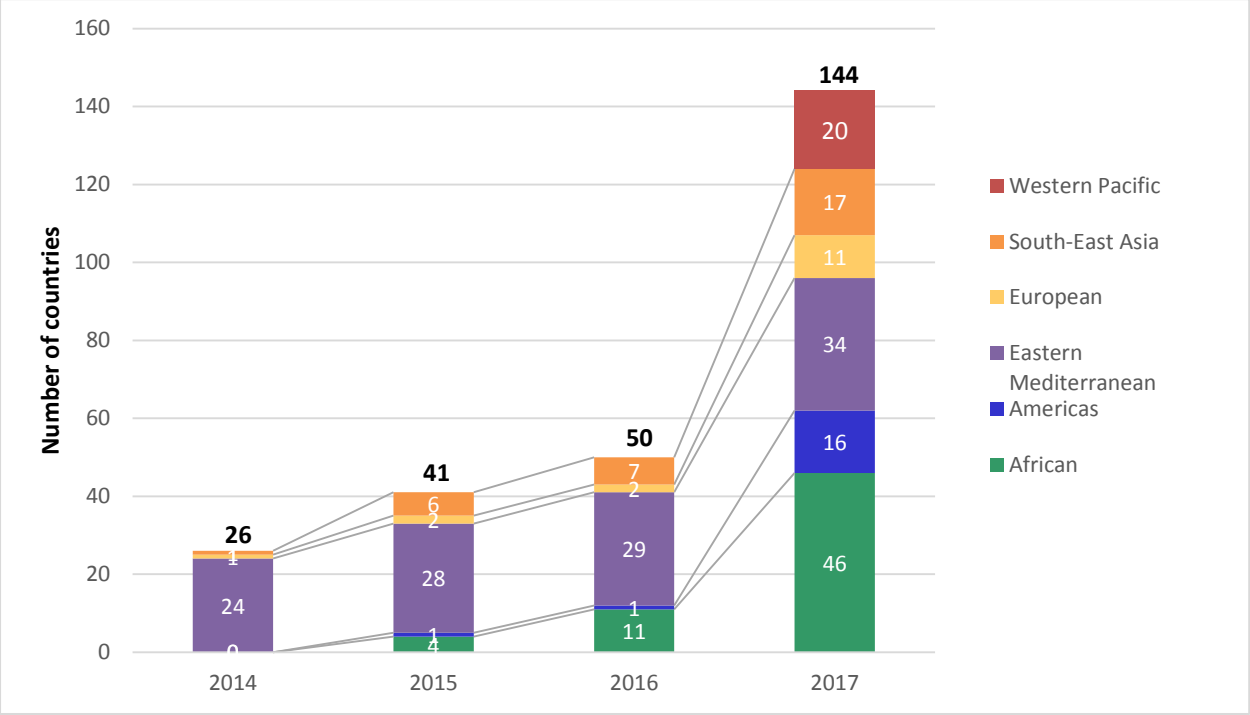
[26] This category includes all countries in the Region of the Americas *except* those countries mentioned in the above footnotes.

[27] These are only the countries that have provided vaccine price information in the JRF, including two countries with low-quality data, which could not be included in the V3P database. Countries that purchase vaccines through the PAHO Revolving Fund were given the

many countries since the launch of the V3P initiative in 2014 (Fig. 7.9). Participation has increased in all WHO regions, thanks to the efforts of WHO regional offices and further integration of the data collection process within the JRF.

Of the 32 "non-PAHO and non-Gavi countries" (26 high-income countries and six middle-income countries) that did not share price information, 10 reported not being able to share because of confidentiality issues, and three because procurement was not done by the central government. The other 19 countries did not indicate why the information was not shared.

Fig. 7.9: Number of countries[27] reporting vaccine price data over time, by WHO region, and year of reporting[a]

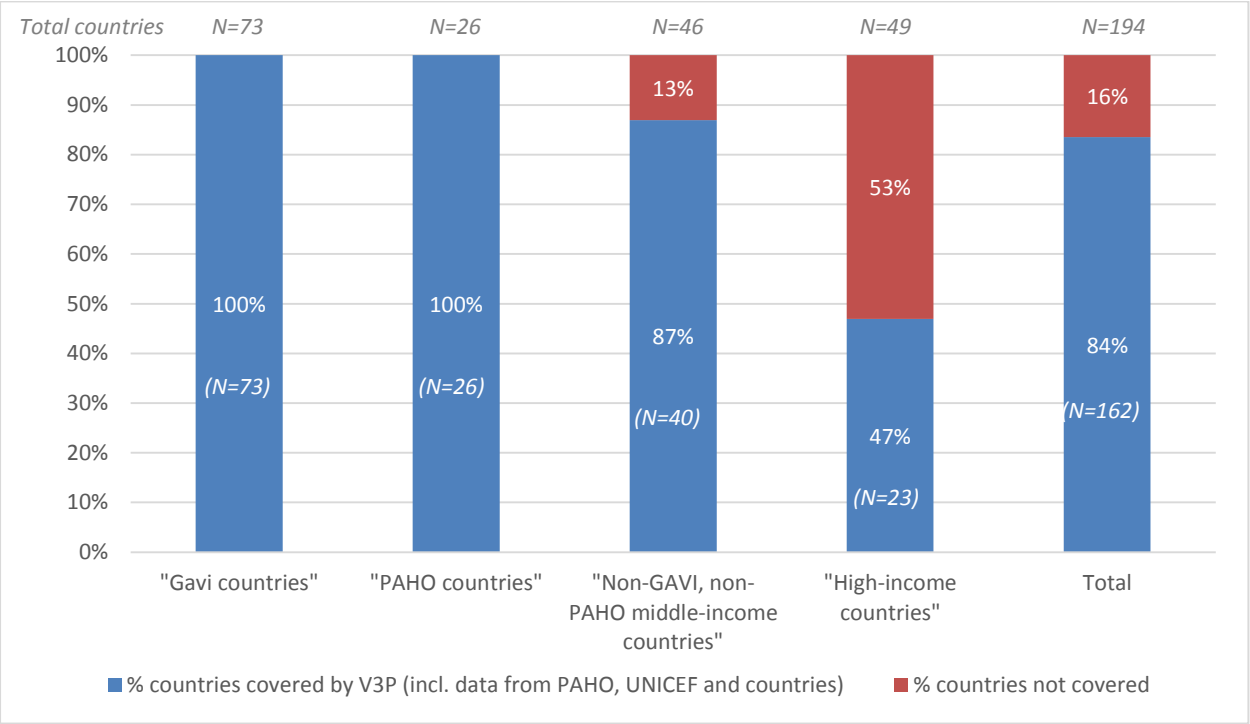


[a] The graph represents all countries that have directly shared price data with V3P, regardless of the quality of the data, from all WHO regions.

In addition to country data, the V3P database also collects price information from the PAHO Revolving Fund and UNICEF Supply Division. At the end of 2016, the V3P database contained vaccine price information covering 84% of the countries in the world (Fig. 7.10), corresponding to 95% of the global birth cohort.

option to provide their procurement information but not the price, as the revolving fund directly shares price information with V3P. As a result, 10 countries in the Region of the Americas shared information about procurement but not price and 20 countries shared information on both.

Fig. 7.10: Country coverage of vaccine price data in the V3P database 2017, by the four categories under review[a]



[a] Percentage based on the number of countries in each category.

Indicator 2a: Price trends: evolution of annual average price over time

The change in prices over time for countries, PAHO and UNICEF was analysed and compared to the annual average of the global inflation rate over the same period of time. Country data were analysed for the period 2013–2016, while data from UNICEF and PAHO were analysed for the period 2010–2017. The average global annual inflation rate *(Ir)* was used as the threshold to define the three ranges presented in Table 7.4: 2.19% per year for the period 2013–2016 and 3.02% per year for the period 2010–2017.[28] Increase or decrease in average vaccine price *(P)* was then compared to the inflation rate, to determine how both nominal and real prices have evolved over time.[29]

Table 7.4: Evolution of average vaccine price over time, by procurement mechanism and vaccine type

	Self-procurement		**Pooled-procurement**	
Number and types of vaccine (%)	**"Non-Gavi, non-PAHO countries" (2013/14–2016)** *Data source: JRFs*		**"PAHO countries" (2010–2017)** *Data source: PAHO*	**"Gavi countries" (2010–2017)** *Data source: UNICEF*
	High-income countries	**Middle-income countries**		

[28] Annual average of the global inflation rate, consumer prices (annual %), as available from the World Bank World Development Indicators. extracted on 7 July 2017. Available from: http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators#

[29] Note that the analysis is based on the global inflation rate but does not consider the fact that inflation may vary by region or income group.

Increase in average price[a]	Four vaccine types (21%): BCG; IPV; Td; Tdap	Three vaccine types (27%): DTaP–HepB–Hib–IPV; Td; TT	Ten vaccine types (42%): BCG; DT; DTaP; DTP; HepA (adult); MMR; MR; Td; varicella; YF	Six vaccine types (43%): DT; MenA; MMR; Td; TT; YF
Stable average price[b]	Three vaccine types (16%): HepB (adult); DTaP–Hib–IPV; pneumo ps	Three vaccine types (27%): BCG; DTP; MMR	Four vaccine types (17%): HepA (ped); pneumo ps; rabies; rotavirus	Four vaccine types (29%): BCG; bOPV1,3; measles; MR
Decrease in average price[c]	Twelve vaccine types (63%): DTaP–HepB–Hib–IPV; DTaP–IPV; HepA (adult); HepB (ped); Hib; HPV; influenza (adult); MenC; MMR; PCV; rabies; TT	Five vaccine types (45%): DT; DTP–HepB–Hib; HepB (ped); PCV; rotavirus	Ten vaccine types (42%): DTP–HepB–Hib; DTP–Hib; HepB (adult); HepB (ped); Hib; HPV; influenza (adult); influenza (ped); IPV; PCV	Four vaccine types (29%): DTP; DTP–HepB–Hib; HepB (ped); PCV
Total in the analysis	Nineteen vaccine types (100%)	Eleven vaccine types (100%)	Twenty-four vaccine types (100%)	Fourteen vaccine types (100%)

Notes:

- In the first column with country data the analysis only includes countries in the categories "Middle-income countries outside of the Americas Region and not supported by Gavi" and "High-income countries", as defined at the beginning of the subchapter, with vaccine price data available for 2013 (or 2014) and 2016. These country data are considered as proxy for "self-procurement", as 96% of the countries in the analysis self-procure all or part of their vaccines. Prices are public sector prices. There are 25 countries included in this analysis. Note that the database in 2013 and 2014 contained mainly data shared by countries of the European Region (they represented 92% and 70% of the participating countries in 2014 and 2015, respectively). The analysis includes 23 vaccine types for which at least three records were registered by countries in both 2013 and 2016 (representing 19 vaccine types for high-income countries and 11 for middle-income countries).
- The analyses presented in the second and third columns of the table are based on 14 and 24 vaccine types purchased by UNICEF and PAHO, respectively, in both 2010 and 2017.

pnuemo ps, pneumococcal polysaccharide vaccine; YF, yellow fever.

[a] Inflation rate < average vaccine price: both real and nominal prices have increased.

[b] 0 ≤ average vaccine price ≤ inflation rate: nominal price has increased but real price has decreased..

[c] Average inflation rate < 0: both real and nominal prices have decreased.

In high-income countries and middle-income countries, 63% and 45% of vaccine types included in the analysis have shown a clear decline in price over the three- or four-year period, respectively. Outliers with strong price increase or decrease are often responsible for the fluctuation of the average, usually due to a product switch that drastically changes the price that a country pays from one year to another. For instance, one high-income country in the European Region saw the price of its Td vaccine jump from US$ 0.95 per dose in 2014 to US$ 8.74 per dose in 2015 when it switched from a 10-dose vial procured from a local manufacturer to a 1-dose prefilled syringe procured from a multinational company.

For PAHO and UNICEF, the trend is slightly different, with a clear price increase seen for almost half of the vaccine types included in the analysis. One of the main reasons as to why the prices are evolving differently for PAHO and UNICEF compared to self-procuring countries may be that prices paid by PAHO and UNICEF are already the lowest available in the world, leaving little room for further price decrease. Also, both organizations wish to strike a balance between affordability and vaccine security, ensuring multiple manufacturers

are awarded at each tender, and not purchasing solely from the manufacturer offering the lowest price.

Main reasons that can explain a change in price include: product market maturity, level of competition, increased demand on low profitability markets, fluctuations in forecasting and poor predictability of demand, manufacturers' pricing strategies, fluctuations in costs of production, contracting and tendering practices, change in presentation purchased, etc.

Indicator 2b: Volume & price: relationship of vaccine prices to volumes purchased, segmented by level of income

To better understand the relationship between vaccine price and volume purchased, an analysis of linear correlation between volume and price was conducted on 102 vaccine types differentiated by presentation sizes (e.g. 10- and 20-dose BCG). These were analysed separately by country category ("Gavi countries", "non-Gavi, non-PAHO middle-income countries" and "high-income countries"). Of these 102 vaccines, only seven showed a statistically significant correlation between volume purchased and price.[30]

- A negative correlation[31] was found in the "non-Gavi, non-PAHO middle-income countries" category for four vaccines: DT-10; Td-10; IPV-1; PCV1.
- A positive correlation[31] was found in the "high-income countries" category for three vaccines: HepB (ped)-1; HPV-1; Tdap-1.

Additional statistical analyses were conducted to try clarify a potential association between volume and price but they did not show a clear linear association. The positive or negative correlations presented above seem to be mainly driven by outliers.

Therefore, statistical analyses show inconclusive evidence about the relationship between volume and price. Conducting further analyses on the data, including regression analyses, could help identify the weight of the volume factor and its influence on price. Of note, the Access to Medicine Foundation published the 18 factors that companies consider when setting their prices, and only one out of six companies listed "volume to be purchased" as one of them (and only in conjunction with other factors, such as duration of contract and target population coverage) *(8)*.

While the volume/price relationship remains unclear, there is enough evidence proving that pooled-procurement systems, such as those of PAHO and UNICEF, do manage to secure lower prices for their vaccines. These mechanisms purchase higher volumes, but they also use other levers to secure low prices, such as long-term commitments, payment guarantees, payments in hard currencies, etc. Countries that consider creating or joining a pooled-procurement mechanism should keep in mind that a pooled procurement system is much more than just combining volumes. A recent successful effort from the Baltic States in the European Region is illustrated in Box 7.1.

[30] Only vaccines purchased at the national level through self-procurement and self-funding were included in the analysis. The correlation analysis was only conducted when at least 10 observations ($N \geq 10$) were available and the result considered statistically significant when returning a P-value less than or equal to 0.05 ($P \leq 0.05$).

[31] The correlation is considered negative when the correlation coefficient r associated with the number of observations N is lower than the threshold of -0.3, such as: $r(N) \leq -0.3$. The correlation is considered positive when $r(N)$ is higher than the threshold of +0.3, such as: $r(N) \geq 0.3$. When $-0.3 \leq r(N) \leq 0.3$, it is considered that there is little to no association (no value in this analysis was found in this range).

Indicator 2c: price segmentation: relationship between income level and vaccine prices. Minimum–maximum price range by country level of income

An analysis of correlation between GNI per capita and price was conducted on 57 vaccine types and 61 "non-Gavi, non-PAHO middle-income countries" for which a GNI per capita was available from the World Bank.[32] Results are presented in Table 7.5.

Table 7.5: Correlation between GNI per capita and vaccine price in "non-Gavi, non-PAHO middle-income countries", 2016

Indicator	Vaccine type (*N*=number of records in the analysis)		
Strongly positive correlation *r ≥ 0.6*	HepA (ped) *(N=26)*	HepB (ped) *(N=60)*	Rabies *(N=15)*
➔ **6 vaccine types**	Rotavirus *(N=18)*	Td *(N=36)*	YF *(N=14)*
Moderately positive correlation *0.3 ≤ r ≤ 0.6*	BCG *(N=57)*	DT *(N=29)*	DTP–HepB–Hib *(N=27)*
	HepB (adult) *(N=43)*	Hib *(N=17)*	HPV *(N=30)*
	IPV *(N=40)*	MenACYW-135 (conj) *(N=16)*	MMR *(N=59)*
➔ **12 vaccine types**	PCV *(N=42)*	Tdap *(N=21)*	TT *(N=26)*

Note:

- Does not take into consideration other important elements such as the manufacturer, product characteristics, presentation size and form or procurement mechanism. The table only focuses on countries that have never been eligible for Gavi support, as Gavi support allows countries to access lower prices for many vaccines.
- *r(N)*: where *r* is the Pearson correlation coefficient associated with *N*, the number of observations. The correlation is considered moderately positive when the correlation coefficient *r* associated with the number of observations *N* is between +0.3 and +0.6. The correlation is considered strongly positive when *r(N)* is higher than the threshold of +0.6.
- The correlation analysis was only conducted when at least 10 observations ($N \geq 10$) were available and the result considered statistically significant when returning a *P*-value less than or equal to 0.05 ($P \leq 0.05$). Therefore, the above table presents results for 18 vaccine types. For 27 vaccine types there were too few records ($N < 10$). For 12 of the 18 vaccine types reviewed, the correlation was not statistically significant ($p > 0.05$).

All vaccine types analysed in Table 7.5 show a positive correlation between GNI per capita and price; as the GNI per capita of a country increases, the price the country pays for its vaccines increases as well.

As in past reports, Table 7.6 shows that the price range is wider for higher-income groups (in high-income countries, the average maximum price is 28.7 times higher than the minimum price). On the contrary, in general countries supported by Gavi reported a more unified price range, with differences mainly for vaccines that are not in Gavi's portfolio (e.g. BCG, DT, TT).

Table 7.6: Average multiplier factor between the lowest and highest price of a vaccine type, by country category, 2016

Category	Average multiplier between lowest and highest price across vaccine types
"Gavi countries"	6.2
All "non-Gavi, non-PAHO middle-income countries"	13.9

[32] GNI per capita, Atlas method (current US$), as available from the World Bank World Development Indicators. Extracted on 4 July 2017. Available from: http://data.worldbank.org/indicator/NY.GNP.PCAP.CD

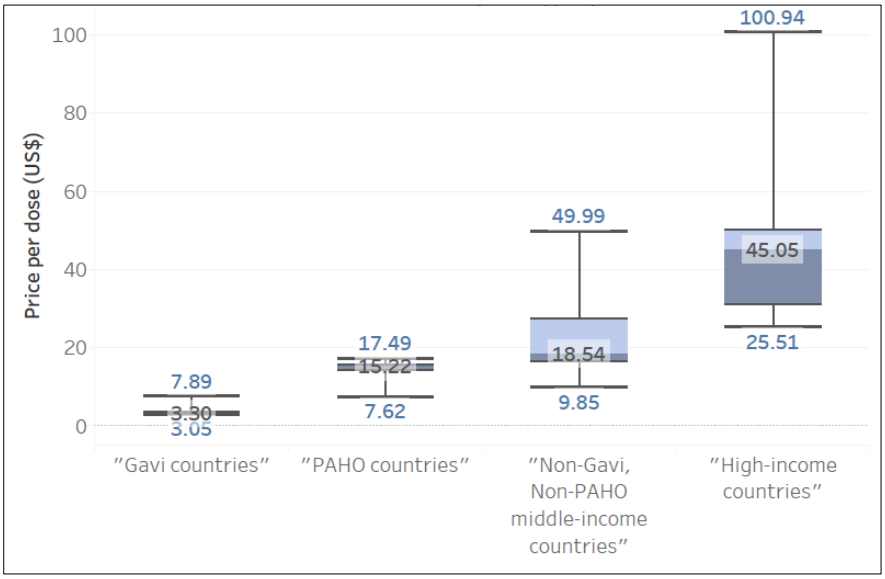
All "high-income countries" (incl. those using the PAHO RF)	28.7
Across all income levels	15.8

Note:

- The analysis was only conducted on 32 vaccine types for which there were more than four data points available per income category
- Does not take into consideration other important elements such as the manufacturer, product characteristics, presentation size and form or procurement mechanism.
- This analysis is very sensitive to the values of outliers.

Findings from Table 7.5 and Table 7.6 show that both eligibility for Gavi support and GNI per capita strongly associate with the range of prices that countries pay for their vaccines. This is aligned with findings of the Access to Vaccines Index 2017 which stated that "When setting prices, all companies consider countries' Gavi status – most also consider GNI per capita" for at least some countries. This association was present even if the Index also found that this varied by manufacturer and that middle-income countries are not systematically addressed *(8)*.

Fig. 7.11: Minimum, maximum and median price by country category for PCV, 2016[a]



[a] The boxes on the graph show the median (centre of the box), a box above and below the median for the nearest quartiles and a set of "whiskers" that extend to the entire data range.

Box 7.1 - Price transparency and joint procurement in action: the example of the Baltic States

In 2012, health authorities of the three Baltic States – Estonia, Latvia and Lithuania – signed a partnership agreement on joint procurement and lending of medicinal products and medical devices in order to improve both product availability and affordability (see https://likumi.lv/doc.php?id=248008). Procurement of selected vaccines was conducted using the joint system: BCG (2015), rotavirus (2016) and PCV (2017). Each time, a lead country was assigned to coordinate the tender process. Through the first tender, the Baltic States learned what worked and what did not, and improved the process by harmonizing procurement, programmatic and market authorization requirements to expand the supplier base. In addition, procurement teams became more knowledgeable of vaccine markets and prices by leveraging data available through the V3P website and improved demand predictability through multi-year contracting. Countries worked in a well-coordinated and flexible way to align demand requirements and address supply challenges. The second joint tender on rotavirus was successful, resulting in 17–25% lower price per immunization course than individual countries had been previously paying.

Though it is still too early to draw conclusions, the results obtained through the joint procurement system are very encouraging.

Fig. 7.11 is an illustration of price differentiation for PCV (for graphs on other vaccines, please visit the V3P website[33]). The graph shows that for this vaccine, the price range is higher and wider for the categories "Non-Gavi, non-PAHO middle-income countries" and "high-income countries", even if price ranges overlap between categories. Also, the graph shows that within these two categories, the range is driven by a few outliers paying high prices, but the majority of countries pay close to the median price of US$ 18.54 in "Non-Gavi, non-PAHO middle-income countries" and US$ 45.05 in "high-income countries", indicating some level of consistency within each country category.

Price segmentation can be actively pursued by manufacturers (e.g. through tiered pricing strategies) but can also be generated by the demand side, for instance as a consequence of countries' product preferences (e.g. a high-income country preferring to buy a more expensive prefilled syringe instead of a multidose vial).

Other information on products, prices and procurement

The V3P data can be used to inform procurement decisions and strategies. This chapter provides a quick overview of the type of information that can be extracted from the V3P database to enhance market knowledge and support procurement strategies.

The 2016 data reported by countries[34] represents a total value of US$ 7.8 billion for a total volume of 3.2 billion doses purchased from 73 manufacturers. Table 7.7 provides additional detail on selected vaccines, prefaced with the following comments.

- Price trends show that nominal vaccine prices have gone down compared to the world inflation rate in the past 3–4 years for data shared by countries and in the past 7 years for data shared by PAHO and UNICEF.
- The vaccine type with the highest volume purchased by countries is bivalent OPV (bOPV); it represents 44% of all vaccine doses purchased in 2016, but only 3% of the total market value.
- The vaccines with the highest market values are all newer vaccines: PCV (18%), HPV (15%) and rotavirus (10%).
- Price ranges for all vaccines are very wide, indicating high price differentiation.
- Vaccines that are mainly purchased by high-income countries may be under-represented in the table, as only 47% of the world's high-income countries are covered by the V3P database.

[33] V3P website: www.who.int/immunization/v3p
[34] Based on 142 countries with data.

Table 7.7: Information on supply, demand, pricing and procurement for selected vaccines[a]

Vaccine type	No. of countries reporting price data (2016)	% of countries self-procuring[e] (2016)	Price trend: annual evolution of average nominal price compared to world inflation rate (*Ir*) over the same period[b]				Reported price in 2016: lowest (presentation size) / highest (presentation size) and median (US$)	No. of different products[d] procured (2016)	No. of manufacturers (2016)	Market value in US$ millions (% of total market value) in 2016	Market volume in million doses (% of total market volume) in 2016
			"Non-PAHO HICs"[c], 2013–2016	"Non-Gavi, non-PAHO MICs"[c], 2013–2016	"PAHO countries" (PAHO data, 2010–2017)	"Gavi-countries" (UNICEF data, 2010–2017)					
BCG	127	34.6	↑	↑	↑	↓	$ 0.05 (10 dose) / $ 6.93 (10 dose) / $ 0.14	23	17	$ 233 (4%)	306 (13%)
bOPV	107	22.4	NA	NA	NA	↓	$ 0.05 (20 dose) / $ 2.02 (20 dose) / $ 0.14	15	10	$ 175 (3%)	1 065 (44%)
DTaP–HepB–Hib–IPV	23	82.6	↓	↑	NA	NA	$ 17.56 (1 dose) / $ 90.50 (1 dose) / $ 35.92	3	2	$ 244 (4%)	11 (0.5%)
DTaP–Hib–IPV	24	87.5	↓	NA	NA	NA	$ 6.97 (1 dose) / $ 41.89 (1 dose) / $ 20.56	5	3	$ 195 (3%)	16 (1%)
DTP–HepB–Hib	97	14.4	NA	↓	↓	↓	$ 0.17 (10 dose) / $ 6.31 (5 dose) / $ 1.70	19	11	$ 457 (8%)	290 (12%)
HepA (adult)	15	80.0	↓	NA	↑	NA	$ 8.23 (1 dose) / $ 44.41 (1 dose) / $ 21.22	6	4	$ 3 (1%)	0.2 (0%)
HepB (ped)	73	46.6	↓	↓	↓	↓	$ 0.06 (10 dose) / $ 15.00 (10 dose) / $ 0.47	20	13	$ 76 (1%)	46 (2%)
Hib	21	61.9	↓	NA	↓	NA	$ 1.95 (1 dose) / $ 17.94 (1 dose) / $ 5.90	5	4	$ 71 (1%)	8 (0.5%)
HPV	41	61.0	↓	NA	↓	NA	$ 3.74 (1 dose) / $ 154.13 (1 dose) / $ 17.69	8	4	$ 850 (15%)	22 (1%)
IPV	86	32.6	↑	NA	↓	NA	$ 0.80 (10 dose) / $ 41.99 (1 dose) / $ 2.15	11	8	$ 187 (3%)	54 (2%)
JE	9	100.0	NA	NA	NA	NA	$ 0.45 (5 dose) / $ 27.15 (1 dose) / $ 1.39	6	5	$ 51 (1%)	67 (3%)
MenACWY (conj)	16	68.8	NA	NA	NA	NA	$ 8.11 (10 dose) / $ 89.16 (1 dose) / $ 37.10	5	4	$ 397 (7%)	6 (0%)
MenC (conj)	12	100.0	↓	NA	NA	NA	$ 12.55 (1 dose) / $ 37.09 (1 dose) / $ 22.60	3	3	$ 377 (7%)	30 (1%)
MMR	74	52.7	↓	↓	↑	↑	$ 0.60 (10 dose) / $ 40.00 (1 dose) / $ 3.66	11	5	$ 221 (4%)	57 (2%)
PCV	91	35.2	↓	↓	↓	↓	$ 3.05 (2 dose) / $ 100.94 (1 dose) / $ 7.76	5	2	$ 1 035 (18%)	157 (7%)
Rabies	27	55.6	↓	NA	↓	NA	$ 4.44 (1 dose) / $ 101.43 (1 dose) / $ 11.96	7	7	$ 38 (1%)	4 (0%)
Rotavirus	58	25.9	NA	↓	↓	NA	$ 1.07 (1 dose) / $ 86.75 (1 dose) / $ 3.00	4	3	$ 591 (10%)	98 (4%)
Seasonal influenza (adult)	41	61.0	↓	NA	↓	NA	$ 1.01 (1 dose) / $ 7.92 (1 dose) / $ 3.75	17	11	$ 503 (9%)	155 (6%)
Typhoid	11	90.9	NA	NA	NA	NA	$ 2.58 (1 dose) / $ 47.26 (1 dose) / $ 8.07	4	3	$ 1 (0%)	0.4 (0%)
Yellow fever	50	26.0	NA	NA	↑	↑	$ 0.84 (10 dose) / $ 82.53 (1 dose) / $ 1.20	7	4	$ 18 (0.5%)	14 (1%)

HICs, high-income countries; MICs, middle-income countries.

[a] Selected vaccines includes only those vaccines recommended by WHO for routine immunization, as presented in the Summary of WHO position papers (http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1). Vaccines available in several combinations are presented only in one type of combination, except if there is a specific interest in presenting more than one combination. Therefore, vaccines selected here for presentation are: BCG, HepB, bOPV, IPV, DTP–HepB–Hib, DTaP–Hib–IPV, DTaP–HepB–Hib–IPV, Hib, PCV, rotavirus, MMR, HPV, JE, YF, typhoid, MenC, MenACWY, HepA, rabies, seasonal influenza. OCV, MMRV, MenA, MenB and tick-borne encephalitis (TBE) could not be included in the analysis due to insufficient data.

[b] The average global annual inflation rate (Ir) is: 2.19% per year for the period 2013–2016 and 3.02% per year for the period 2010–2017.28 For the country trend analysis, only vaccine types for which at least three records were registered both in 2013/14 and 2016 are included in the trend analysis. ⬇= the annual average price variation is equal to or below Ir / = the annual average price variation is above Ir.

[c] Only for countries providing data for at least 2013/2014 as well as 2016 (note that many will be European countries).

[d] A vaccine product is defined as the unique combination of the following characteristics: vaccine type, manufacturer, presentation form and presentation size.

[e] Procurement done outside of UNICEF, PAHO or other pooled procurement systems.

Conclusion

With price transparency now significantly improved, efforts should focus on enhancing the use of vaccine price data, particularly to help governments employ the data for planning and budgeting, as well as for procurement decisions and strategies. The Baltic States are a good example of countries using data to enhance their procurement skills. The information of the V3P database can also greatly support regional and international activities and is currently already used to inform international policy, analyse price trends, support vaccine-shortage models and market-shaping strategies as well as to inform discussions on fair pricing.

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Subchapter 5: Stock outs: Availability of vaccines for routine immunization at national (Indicator SO5.2) and subnational levels including country performance towards supply chain fundaments

Indicator SO5.2: Availability of vaccines for routine immunization at national level (stock outs)	
Target	Two thirds reduction in countries reporting national-level stock outs by 2020 (from 2010 level).
Definition of indicator	Number of countries reporting a national-level stock out of at least one vaccine for at least one month[a].
Data sources	WHO-UNICEF Joint Reporting Form (JRF).

[a] A stock-out event is defined when a stock out of a vaccine occurred for a duration of at least one month at national level. This indicator is a proxy measure of a stressed immunization supply chain system – a shortage of vaccines at national level is not a desirable situation and indicates that recommended three-month safety stocks have been depleted and vaccine availability for lower levels of the system could be compromised. If a stock out in one country was reported for two vaccines, it would be considered as two stock-out events for that country. Note that events are defined by antigen. In the case of one national stock out of a pentavalent vaccine, this would be considered a stock out of several antigens of that one vaccine. As such, the number of events is adjusted by antigen. To improve cross-country comparisons, the analysis focused on select vaccines common to all national immunization schedules. These include: BCG; DTP and measles-containing vaccines (e.g. DTP–HepB–Hib or MMR); and polio (e.g.: OPV and/or IPV)
For more information on the definitions, methods and data sources, please consult the 2014 GVAP Secretariat report.

Highlights

- The year 2016 marks a setback towards the GVAP target of a two thirds reduction in countries reporting national-level stock outs by 2020: a total of 73 countries reported 131 national level stock-out events for at least one vaccine and for an average duration of 51 days. The 73 countries account for 38% of WHO Member States and represent 34% of the world's birth cohort.
- In 2016, 37% of national stock-out events concerned DTP-containing vaccines and were primarily (70%) due to in-country factors (inaccurate forecasts, orders not being met in full, stock management issues, funding or procurement delays).
- Similarly, polio-containing vaccines accounted for another 37% of all stock-out events reported in the 73 countries. In 75% of cases, these stock outs concerned IPV vaccines as a result of the global supply shortages. The remaining 25% of cases concerned OPV vaccines and were due to in-country factors (inaccurate forecasts, orders not being met in full, stock management issues, funding or procurement delays).
- The incidence of stock outs was concentrated primarily in the European Region, the Region of the Americas and in East & Southern Africa.
- Countries of all income groups reported at least one national-level stock-out event in 2016, respectively 51% of Gavi-eligible countries, 38% of middle-income countries not eligible for Gavi support and 20% of high-income countries.
- Overall causes of stock outs for all vaccines are primarily linked to inaccurate forecasts or stock management issues in Gavi-eligible countries; to procurement delays in middle-income countries not eligible for Gavi support; and product availability on the vaccine market (global shortage) in high-income countries.
- The root-cause analysis indicates that in 2016, overall, product availability on the global market (especially due to global shortages of IPV) accounted for 34% of national-level stock outs in the 73 countries. The remaining proportion – 66% of all national-level stock outs – was due primarily to national funding or procurement delays, poor forecasting and/or stock management issues.

- The situation at subnational level has been worsening since 2014. Of the 65 countries with district-level stock outs, 54 countries experienced interruption of vaccination services because of the lack of vaccines. In other words, in 83% of cases, a district-level stock out lead to the interruption of vaccination services in concerned countries.

National-level stock outs

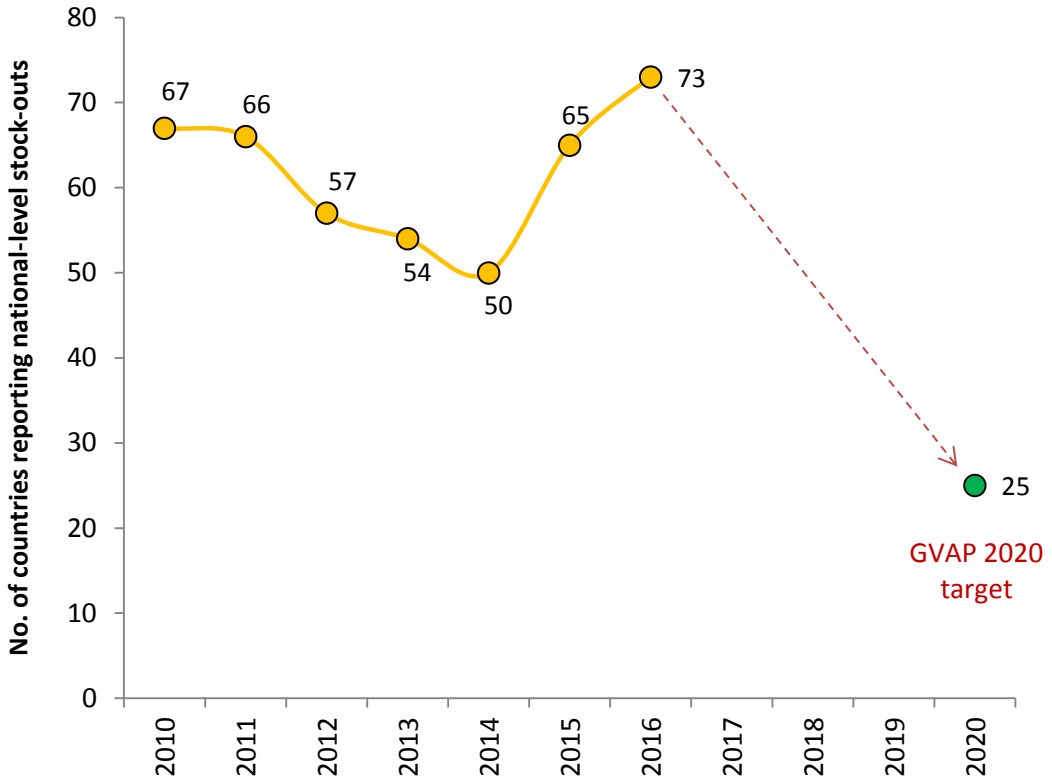
In 2016 a total of 73 countries (or 38% of Member States) reported a national-level stock out for at least one vaccine and for at least one month. Compared to 2015, this represents a worsening of the situation where 65 countries (or 34%) had reported national-level stock outs (Table 7.8).

Table 7.8: Summary statistics for countries reporting at least one national level stock-out event[a]

	2016	Trend 2015 – 2016	2015	2014	2013	2012	2011
Total number of countries reporting stock outs	73	↑	65	50	54	57	66
% countries reporting stock outs	38%	↑	34%	26%	28%	29%	34%
Total number of stock-out events	131	↑	113	111	112	120	148
% of stock-out events[b, c]							
BCG vaccine	18%	↓	34%	25%	33%	34%	28%
DTP-containing vaccines	37%	↓	51%	40%	35%	42%	45%
Measles-containing vaccines	8%	↑	5%	14%	14%	9%	14%
OPV/IPV vaccines	37%	↑	10%	22%	18%	15%	13%
Average number of stock-out events[c]	1.79	↑	1.74	2.22	2.07	2.11	2.24
Average duration of a stock-out event (days)[c]	51.5	↑	47.0	59.7	36.0	35.5	33.0

[a] For BCG and DTP, measles- and polio-containing vaccines.
[b] Some countries reported multiple stock outs in a given year which is why this number is higher that the number of countries reporting stock outs.
[c] For countries reporting stock outs.

Fig. 7.12: Trend towards the GVAP 2020 target

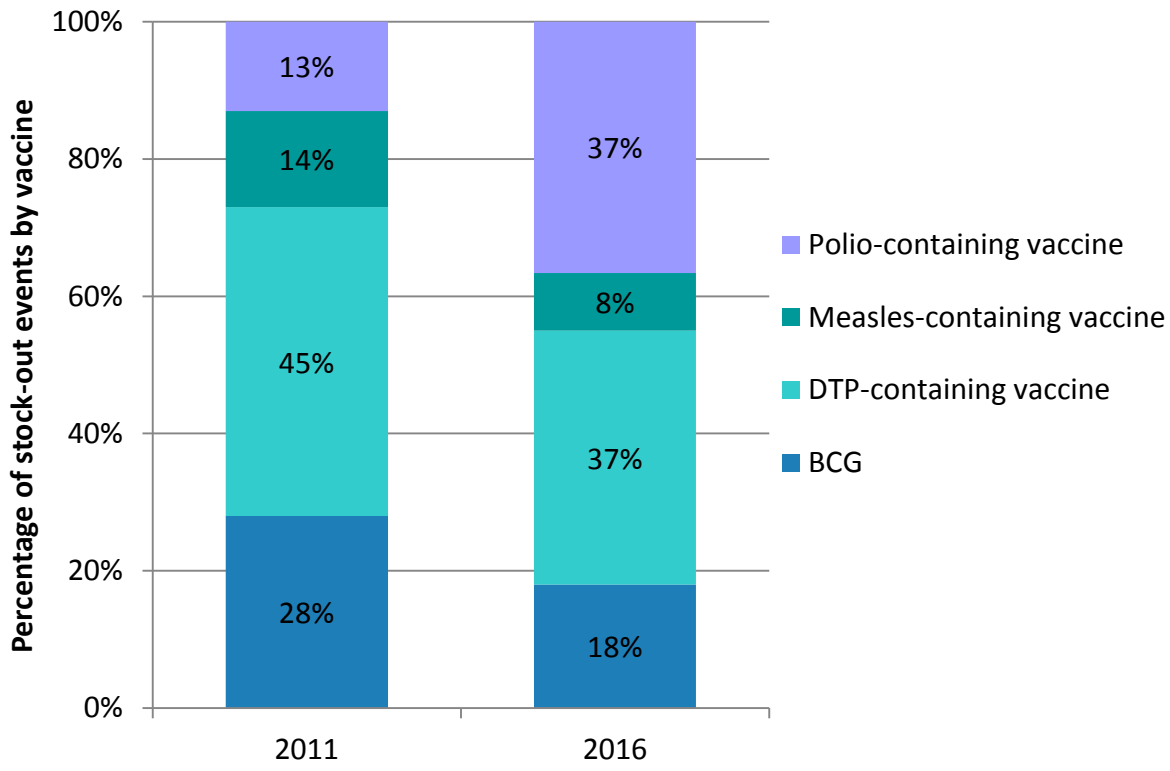


Achieving the GVAP target of two thirds reduction of countries reporting national-level stock outs by 2020 is off track. As shown in Fig. 7.12, national-level stock outs have been increasing over the past two years. In fact, 2016 is the year that marks a peak since 2010 in the total number of countries reporting national-level stock outs. One has to go back a decade to 2006 in order to see more countries reporting stock outs.

For these countries reporting national-level stock outs, multiple events often occur within the year if one or more vaccines are affected. In 2016, a total of 131 stock-out events were reported in the 73 countries. In other words, countries averaged 1.79 stock-out events in 2016 – an average that has slight increased since 2015. The average duration of a stock-out event in days was estimated at 51 (the median duration is 38 days). While multiple stock outs within a year are not uncommon, the majority of countries (42 or 58%) reported only one stock-out event at national level in 2016. There were, however, 10 countries in 2016 that reported 4 or more stock-out events.

Analysis by vaccine indicates that 37% of the stock outs concerned DTP-containing vaccines – a slight improvement from 2015. Stock outs of polio-containing vaccines represented 37% of all national level stock-out events in 2016 (Fig. 7.13). This reflects a worsening situation from 2015, specifically related to stock outs of IPV. Measles-containing vaccines represented 8% of all national-level stock outs in 2016 – a slight increase from a year earlier. On the other hand, the proportion of stock outs of BCG vaccines dropped between 2015 and 2016 – from 34% of all stock-out events in 2015 to 18% in 2016.

Fig. 7.13: Proportion of national level stock-out events by vaccine, 2011 and 2016



A review of stock outs by WHO region and World Bank income group reveals the following findings.

1. The incidence of national-level stock outs in 2016 was greatest in the European Region (17 countries affected or 23%), in the Americas Region (12 countries or 16%) and in East & Southern Africa (11 countries affected or 15%) (Table 7.9). In 2015, more countries in East & Southern Africa (AFR E&S), the Eastern Mediterranean Region and South-East Asia Region reported national-level stock outs.

2. Although national-level stock outs were reported by countries of all income groups, the concentration is greatest in middle-income countries – 63% of stock-out events occurred in lower- and upper-middle-income countries. Also of notice, there was a significant fluctuation of the proportion of countries reporting stock outs in all income groups over the past years (Fig. 7.14).

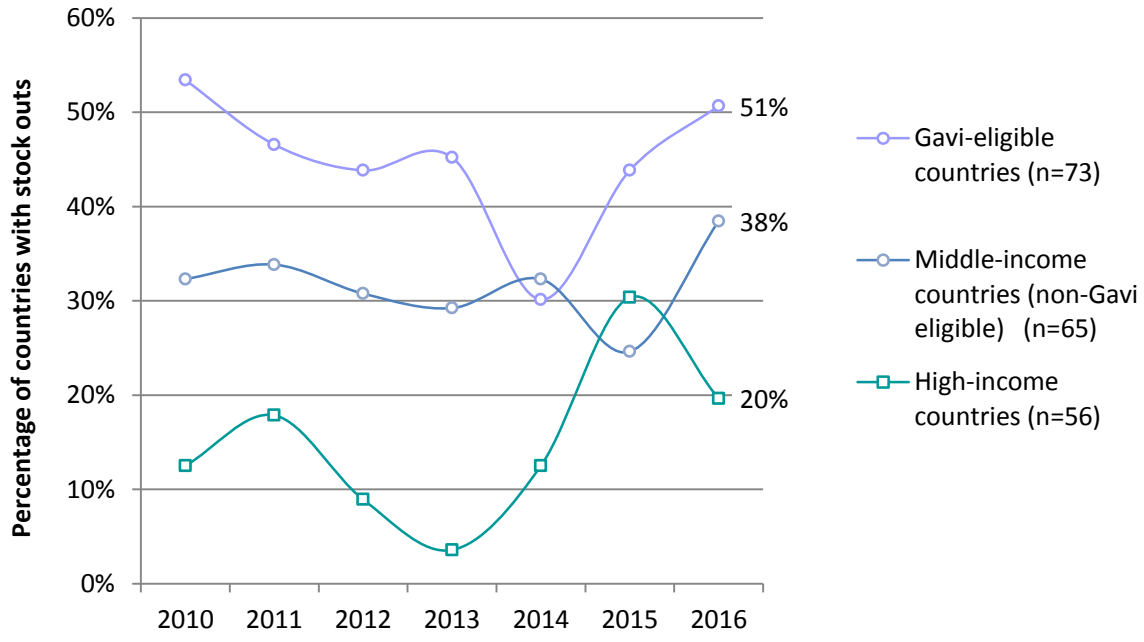
3. Over 60% of countries reporting a national-level stock out have medium to large birth cohorts.

Table 7.9: Percentage of countries experiencing a national stock-out event, by WHO region, income classification and population[a]

[b]	2016	Trend	2015	2014	2013	2012	2011
Grouping by WHO region							
Region of the Americas	16%	↓	17%	32%	17%	16%	18%
African Region, West	10%	↓	15%	8%	19%	11%	9%
African Region, Central	8%	↓	11%	6%	11%	7%	8%
African Region, East and South	15%	↑	8%	18%	17%	21%	21%
Eastern Mediterranean Region	11%	↑	9%	6%	6%	5%	12%
European Region	23%	↓	26%	14%	7%	18%	17%
South-East Asia Region	8%	↑	5%	4%	7%	5%	2%
Western Pacific Region	8%	↓	9%	12%	17%	18%	14%
Grouping by income classification[c]							
Low income	23%	↑	20%	26%	26%	23%	23%
Lower-middle income	30%	↑	28%	24%	41%	35%	29%
Upper-middle income	33%	↑	28%	36%	30%	32%	32%
High income	14%	↓	25%	14%	4%	11%	17%
Grouping by population size[d]							
< 100 000	37%	↓	43%	38%	43%	49%	39%
> 100 000 < 500 000	25%	↑	22%	20%	22%	18%	21%
> 500 000	38%	↑	35%	42%	35%	33%	39%

[a] Percentage of countries that experience at least one stock-out event for at least one vaccine during at least one month.
[b] This column represents the breakdown of the 194 Member States by region, income and population size.
[c] According to the World Bank classification of countries.
[d] As expressed by the number of births in the country.

Fig. 7.14: Proportion of countries with national stock-out events by adjusted income group



Causes of national-level stock outs

In 2016, the information being collected through the WHO/UNICEF JRF mechanism was expanded to include information on the causes of national-level stock outs. For those countries that reported a national stock out for a particular vaccine, the reasons of the stock out had to be indicated by choosing among the following eight causes: i) funding delays; (ii) inaccurate forecasts; iii) orders not met in full; iv) stock management issues; v) procurement delays; vi) global vaccine shortages; vii) quality issue of the vaccines; viii) other reasons not identified.

The results of this analysis indicate that in 2016, overall, product availability on the global market (especially due to global shortages of IPV) accounted for 34% of the causes of national-level stock outs in the 73 countries. The remaining proportion of stock outs (66%) was primarily due to national funding or procurement delays, poor forecasting and/or stock management issues.

When analysed by adjusted income grouping (Fig. 7.15), the data reveal specific reasons for stock outs.

- Stock outs in Gavi-eligible countries are primarily due to inaccurate forecasts or stock management issues and also affected by global shortages.
- Stock outs in non-Gavi middle-income countries are due to procurement and funding delays, as well as issues of inaccurate forecast and/or stock management. For self-procuring countries, the main reason is procurement delays.
- Stock outs in high-income countries are principally caused by lack of product availability on the vaccine market (global shortage).

Analysis by vaccine reveals that national stock outs of BCG, measles-containing vaccine and OPV were mainly caused by funding or procurement delays. Stock outs of DTP-containing vaccines were mainly the result of procurement delays, inaccurate forecasts or stock management issues. Lack of product availability and global shortages on the vaccine market was the dominant cause of IPV stock outs reported at national level (Fig. 7.16).

Fig. 7.15: Causes of national stock out by adjusted income group, 2016

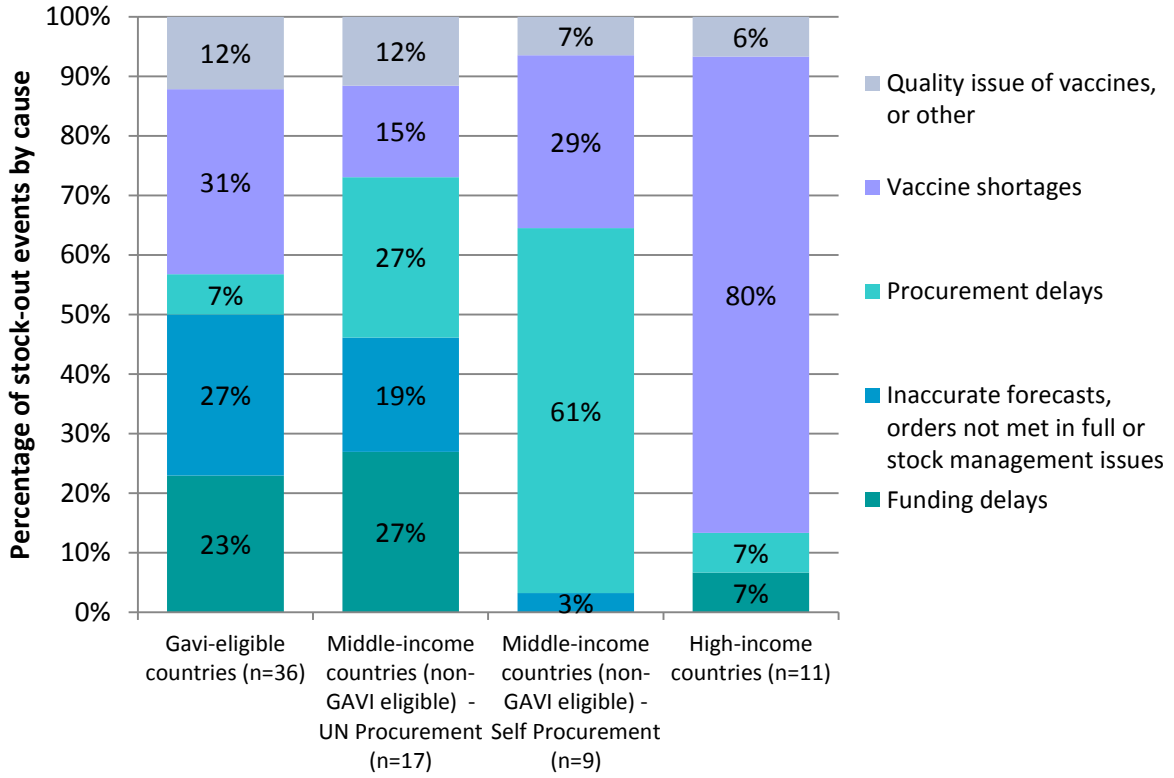
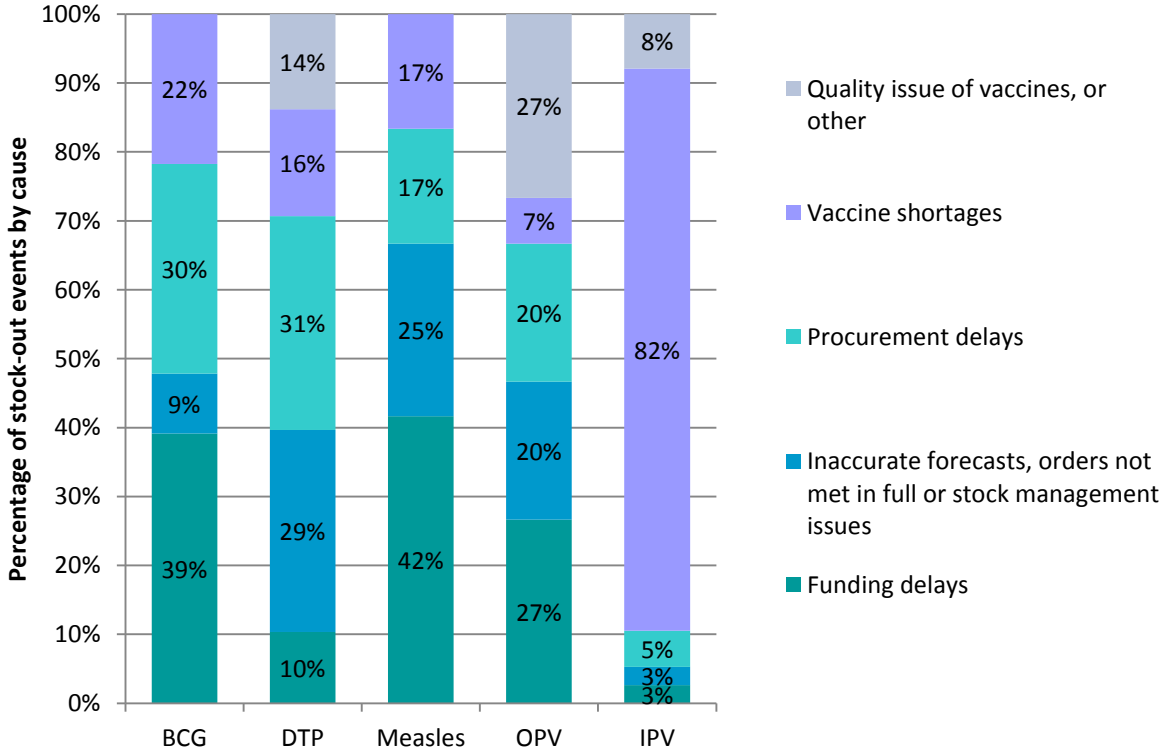


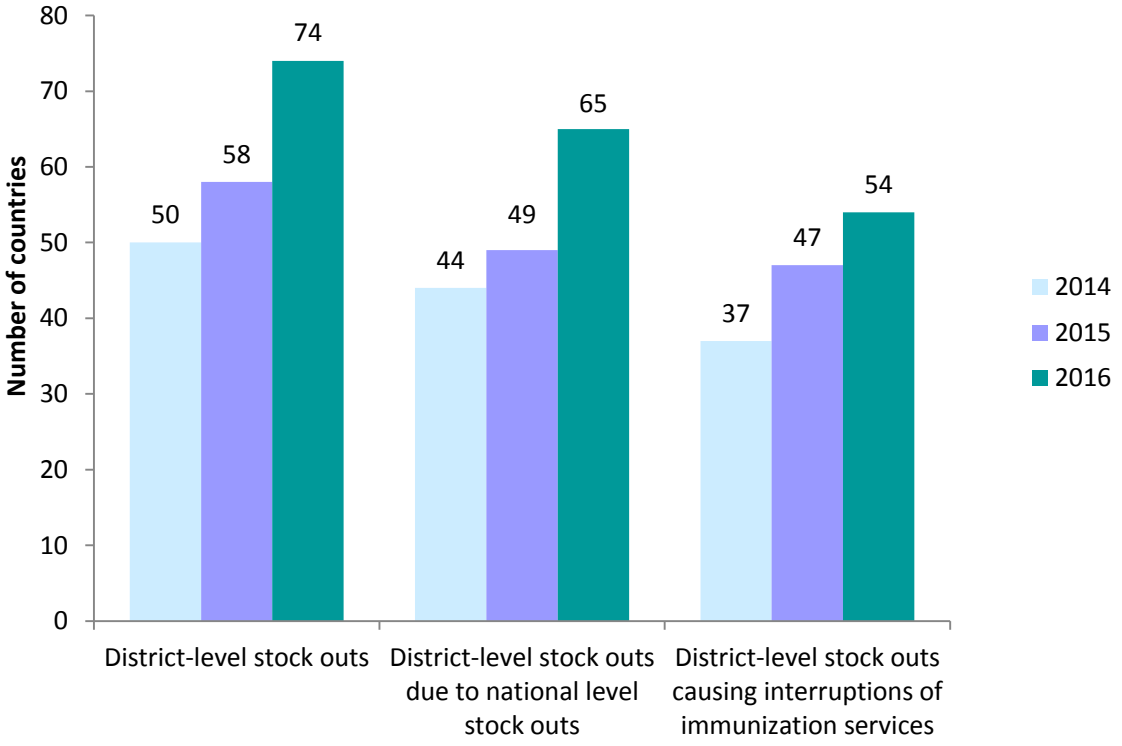
Fig. 7.16: Causes of national stock out by vaccine, 2016



Subnational-level stock outs

A total of 74 countries reported experiencing stock outs at subnational level. Of these 74 countries, 88% of them (65 countries) indicated that the district and national-level stock outs were linked – that the national stock out resulted in vaccines being unavailable at district level (Fig. 7.17). For the remaining 12% of countries that reported a district-level stock out, these were caused by other factors – for example, a breakdown of the distribution system, orders not being met in full or poor stock management at lower levels of the supply chain.

Fig. 7.17: Vaccine stock outs at subnational level, 2014–2016



More concerning however, is the fact that district-level stock outs led to an interruption of vaccination services in 54 countries. This implies that there is an 83% chance that a district level stock out will cause an interruption of immunization services in the concerned districts.

The situation since 2014 has been worsening, with more countries reporting district-level stock outs and interruptions of vaccination services due to those stock outs.[104]

[104] While the subnational stock out indicators provide valuable insights, the magnitude of the problem is difficult to gauge without an understanding of how many districts were affected.

Performance of the immunization supply chain

Global Immunization stakeholders endorsed the need to strengthen five fundamental aspects of the supply chain of national vaccine systems, as part of achieving the goals of the GVAP. These aspects are shown below.

1. Robust plans and strategies to strengthen the immunization supply chain, to guide improvements by 2020[105].
2. Dedicated vaccine supply chain managers at national level to ensure compliance with effective practices of vaccine handling and management throughout the supply chain.
3. Optimized cold chain systems that include continuous temperature monitoring devices instead of standard thermometers.[106]
4. Better data to manage vaccine stocks throughout the supply chain using an electronic stock management system.[107]
5. Supply chain systems designed to improve efficiency.[108]

From 2014 onward proxy indicators to these five fundamental aspects were inserted in the WHO/UNICEF JRF. While these are not among the GVAP indicators, the key findings from these are provided in this subchapter as complementary analyses. The key findings include the following points (also shown in Table 7.10).

- A total of 57% of countries reported having an immunization supply chain improvement plan and 65% of countries reported having a dedicated immunization supply chain manager.
- Only 35% of countries have at least 50% of their subnational cold chain equipped with continuous temperature monitoring devices (but 25% of countries have 100% of their subnational cold chain equipped with continuous temperature monitoring devices).
- Over a quarter of countries (27%) reported having an e-stock management system at district level.
- Under a quarter of countries (24%) reported having practices of supply chain integration, where vaccines are stored or transported with other health commodities.

[105] The JRF indicator is: Y/N to whether a country has an immunization supply chain improvement plan, and whether there is a dedicated supply chain manager at national level to oversee the immunization supply chain and the implementation of the plan.

[106] The JRF indicator is the % of cold chain equipment at subnational levels of the supply chain in a country that is equipped with continuous temperature monitors (CTM). Keeping vaccines in the correct temperature ranges is vital to ensure that their potency is preserved up until the point of vaccination. The assumption behind this indicator is that having the cold chain equipped with devices for continuous temperature monitoring will mitigate the risks associated with temperature breaks in the cold chain that can compromise vaccine potency.

[107] The JRF indicator is Y/N to whether a country has an electronic stock management system at district level and below. It is assumed that if a country has electronic stock management systems, higher levels of the supply chain can have better visibility on vaccine stocks at lower levels allowing managers to better plan distribution and avoid having too much vaccine at one location (leading to overstocking) or not enough in another location (leading to stock outs).

[108] Y/N to whether there is a practice in the country of storing and/or transporting other temperature-sensitive pharmaceuticals in the vaccine cold chain at any level of the vaccine supply chain. From a system design perspective, this indicator points to potential efficiency gains from integrated storage and/or transport of vaccines with other health commodities.

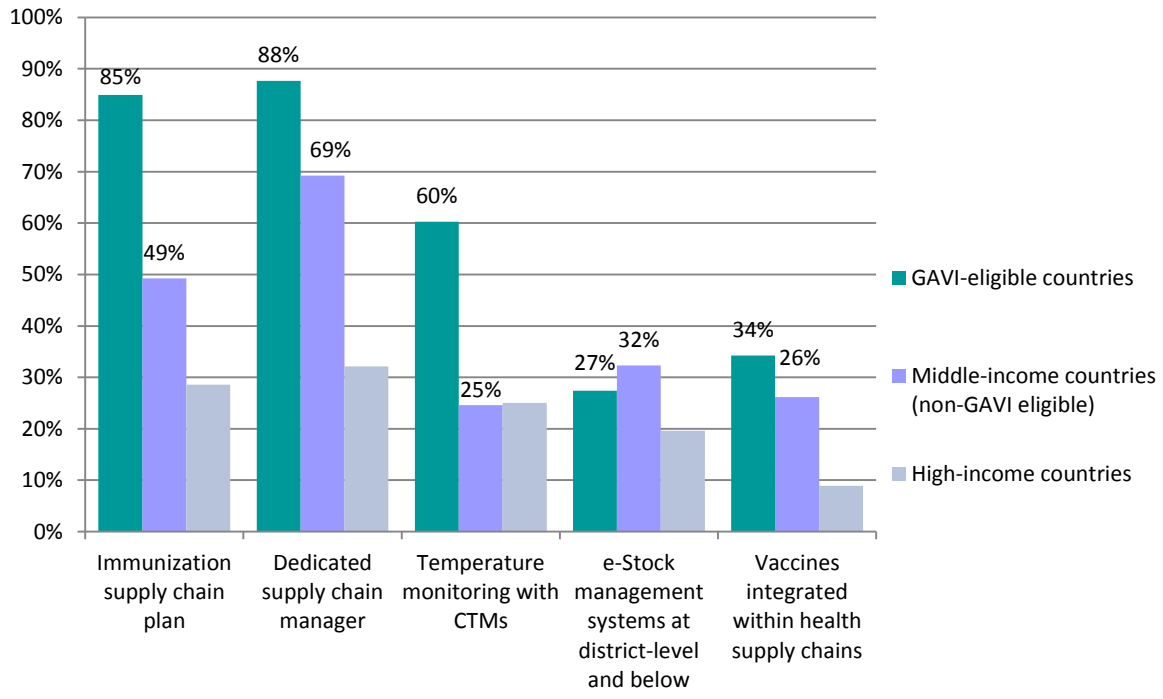
Table 7.10: Performance in meeting the five fundamental aspects of an immunization supply chain, 2016

	2016	Trend	2015	2014
Percentage of countries with an immunization supply chain improvement plan	57%	↑	52%	51%
Percentage of countries with dedicated immunization supply chain manager	65%	↔	65%	61%
Percentage of countries where 50% or more of their Subnational cold chain is equipped with continuous temperature monitoring devices	38%	↑	28%	28%
Percentage of countries with an electronic stock management system at district level and below	27%	↔	26%	21%
Percentage of countries reporting a practice of integrated storage and transport of vaccines[a]	24%	NA	-	-

[a] Item only included in JRF for 2016 data.

The fundamental aspects of the supply chain were analysed by adjusted income grouping as well. Data indicate that for the most part, Gavi-eligible countries outperform both middle-income (non-Gavi eligible) and high-income countries (Fig. 7.18). The aspect where non-Gavi-eligible countries are most significantly lagging behind other Gavi-eligible countries is on adequately managing temperatures in the cold chain with continuous monitoring devices.

Fig. 7.18: Performance of countries against the fundamental aspects of the supply chain, 2016



Subchapter 6: Number of vaccines that have either been re-licensed or licensed for use in a controlled-temperature chain at temperatures above the traditional 2–8 °C range (Indicator SO6.4)

HIGHLIGHTS

- The number of vaccines licensed for CTC has not increased since the licensure of the quadrivalent HPV vaccine, Gardasil from Merck USA in June 2016.
- As of 31 December 2016, only two vaccines (MenAfriVac and Gardasil) are licensed under CTC conditions. (The manufacturer of the 13-valent PCV that was licensed for CTC in 2015 decided to remove this indication in 2016.)
- In October 2016, the CTC working group, a subgroup of IPAC, issued a statement on the use of vaccines out of the cold chain and in a controlled temperature chain (CTC), advocating strongly in favour of the latter and encouraging manufacturers to accelerate efforts toward licensing and labelling vaccines consistent with CTC usage.
- In line with CTC working group conclusions, SAGE strongly urged all prequalified vaccine manufacturers of monovalent hepatitis B vaccine to pursue regulatory approval for CTC labelling in order to facilitate administration of the birth dose of the hepatitis B vaccine, for which coverage is significantly lagging in most countries.
- According to a survey conducted in 2016 in the African and Western Pacific Regions, 72% of responding countries believed that CTC would facilitate the provision of the birth dose of hepatitis B vaccine, and most of these would favour a product labelled for use in a CTC.
- In February 2017, the CTC working group identified four priority antigens for CTC: HPV, OCV, TT, and hepatitis B, and is actively drafting a strategic CTC roadmap.

Definition of the indicator

This indicator remains unchanged. It measures the number of vaccines used in low- and middle-income countries that are licensed for use in a CTC for a limited period of time at ambient temperatures of up to 40 ^{o}C. It should be noted that since the establishment of the indicator, it has been recognized that this is not the most appropriate metric of progress with this area of work, since much can be accomplished in support of CTC without the number of licensed vaccines increasing year to year.

WHO continues to define CTC as follows.

- Allowing vaccines to be kept and administered at ambient temperatures, up to at least 40 ^{o}C, as per the conditions specified on their product label and with the appropriate temperature monitoring tools.
- A single excursion for a limited period of time (length of time will vary by antigen and setting, though a minimum of three days is preferred by WHO) immediately preceding administration.
- Up until this excursion, the vaccine should continue to be kept in the traditional 2–8 ^{o}C cold chain. CTC therefore does not imply an approach that replaces the cold chain, but rather one that extends it to locations and populations who might not otherwise be as easily within reach of health services.

- Through the development of the 2015 WHO *Guidelines on stability evaluation of vaccines under extended controlled temperature conditions* (ECTC) *(9),* ECTC was coined to distinguish regulatory requirements from programmatic requirements – the latter apply only to CTC.

Data quality

Reliable data continue to be obtained through the following means:

1. coordination between the WHO teams responsible for managing EPI, which drives the CTC programmatic agenda, and responsible for the prequalification of vaccines;
2. direct dialogue maintained with respective vaccine manufacturers who are undertaking thermostability studies with a view to an eventual label variation submitted to the NRA and prequalification in support of a CTC approach;
3. oversight and technical support of country-level operational research and surveys linked to CTC implementation and advocacy efforts;
4. collaboration with partner institutions increasingly engaged in the CTC agenda, such as PATH, MSF, Gavi, and UNICEF;
5. strategic guidance and technical outputs emerging from the CTC working group, which is a subgroup to IPAC.

Results

Over the past year improvements in strategic coordination and visibility of the CTC programme, primarily due to the establishment of the CTC working group created under IPAC represents important progress. The CTC working group advocates for CTC licensure and makes policy and programmatic recommendations, each fully endorsed by IPAC and the WHO Department for Immunization, Vaccines and Biologicals (IVB). This allows for a more clearly defined strategic direction for the programme and improved communications and engagement across partnering institutions. Of particular value has been the consensus reached around the role of each stakeholder, all of which are represented on the CTC working group. These include global partner agencies such as UNICEF, Gavi and PATH, as well as WHO regional and country representatives. The pharmaceutical industry is involved as well, represented by the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Countries Vaccine Manufacturers Network (DCVMN). With a renewed and concentrated engagement on the part of these various stakeholders, the CTC agenda has benefited from more productive dialogue and a clearer path forward marked by specific commitments, such as the mention of CTC in relevant UNICEF tender efforts and the consideration of how CTC fits within Gavi's work on the Healthy Markets Framework.

In October 2016, following the preparatory efforts of the CTC working group, IPAC released a statement on the use of vaccines out of the cold chain and in a controlled temperature chain (CTC), advocating strongly in favour of the latter and encouraging manufacturers to accelerate efforts toward licensing and labelling consistent with CTC usage *(10)*. The document distinguishes between the two approaches, highlighting the different steps towards regulatory review and approval, as well as implementation methods and conditions. In view of the stricter requirements associated with CTC, the statement encourages countries to abide by CTC standards as much as possible, even when resorting to use of vaccines outside the cold chain. Subsequent discussions by SAGE, deliberating on the

thermostability evidence supporting the use of hepatitis B vaccine out of the cold chain, led to the SAGE recommendation that countries pursuing such a policy, do so following this guidance from IPAC. In recognition of the available evidence and strong advantages CTC could offer hepatitis B vaccination efforts, especially for the timely administration of a birth dose of the vaccine, SAGE also "strongly [urged] all the pre-qualified vaccine manufacturers of monovalent hepatitis B vaccine to pursue regulatory approval for Controlled Temperature Chain (CTC) as soon as possible"*(11)*.

Facilitating the delivery of birth doses of hepatitis B vaccine through CTC has been an appealing concept for many years, and one of the initial drivers of the CTC agenda. Despite regular calls for enabling CTC in the hepatitis B vaccination programme, evidence documenting the demand for a CTC-licensed birth dose of hepatitis B vaccine has been lacking and vaccine manufacturers have been reluctant to commit. To better inform manufacturers and renew their interest to pursue CTC labelling for hepatitis B vaccines, WHO conducted a survey between May and November of 2016 assessing country-level interest in this type of product. Though all WHO regions were invited to participate, only countries in the African and Western Pacific Regions found the survey directly relevant. A total of 25 countries from these two regions responded to the survey (eight from the Western Pacific Region and 17 from the African Region), 72% of which reported that CTC would facilitate delivery of birth dose of hepatitis B vaccine. Current policy for birth dose of hepatitis B vaccine in each of the responding countries was not a factor affecting response rates, however interest in the CTC concept was more pronounced among countries that had already introduced the birth dose but which struggled to achieve high coverage.

The CTC working group met on 13 February 2017 to consider the results of the survey, among other topics, and develop a shared vision and work plan for partners and CTC stakeholders. Using the criteria of thermostability profile, feasibility to achieve licensure, combined with favourable potential for public health impact, the working group agreed to focus on the following four vaccines: HPV, TT-containing vaccines, OCV and hepatitis B vaccine (birth dose). A strategic roadmap is being developed to articulate the specific steps and resources required to move the CTC agenda forward over the next four years (2017–2020). This will align with GVAP time frames and the overarching CTC programme goals: increased stakeholder engagement, characterizing both the value proposition and demand for CTC, generating more evidence on CTC to inform guidance, and supporting the licensure and prequalification of the priority vaccines.

Discussion

The activities around the four named priority vaccines will focus on downstream, programmatic activities and upstream, supply-oriented efforts. For CTC-labelled and fully approved (licensed and prequalified) vaccines, the principal focus will be increasing country-level awareness and using best practices to scale up implementation of CTC. This includes building the evidence base on the impact, benefits and opportunities offered by CTC and clarifying the value proposition. The HPV vaccine, which is slotted for use with CTC during quarter 4 of 2017 in at least one sub-Saharan African country will be the test case from which to learn lessons on demand generation. Contingent upon prequalification, OCV will likely also provide opportunities to learn and document CTC implementation in various countries.

Upstream dialogue and facilitation efforts defined in the draft CTC priority vaccines strategic roadmap *(12)* focus on the birth dose of hepatitis B vaccine and TT-containing vaccines. As necessary, manufacturers may also be engaged on HPV and OCV products. Work will focus on facilitating supply through demand assessment and identifying candidate products and pathways to CTC licensure and prequalification. During the roadmap's four-year time frame, additional vaccine candidates for CTC use will be identified and a proactive approach to CTC licensure during product development will be encouraged. Other vaccines, such as for rotavirus and rabies, have already been noted as having promising prospects for CTC licensure.

To ensure programmatic focus, a number of vaccines have had to be de-prioritized, such as meningitis A vaccine and PCV (the latter was de-prioritized given that PCV is only delivered in combination with vaccines that still require the cold chain). Products for both of these antigens were early trailblazers for CTC licensure and represented important milestones for the CTC programme. However, neither vaccine has optimal field conditions for capitalizing on CTC flexibility and benefits and it was agreed that programme efforts should be concentrated elsewhere. Consequently, the manufacturer of the previously-prequalified PCV product elected to not pursue a CTC indication on its recently developed multidose presentation of this vaccine; in the interest of consistency and by request of the relevant regulatory authorities, it was decided to remove the CTC indication from the single-dose presentation. It should be noted that the data in support of this product's thermostability status remain valid and compatible with CTC requirements.

The use of CTC must always be considered in the context of the structure, needs and challenges of immunization programmes and the advantages measured against any potential risks. The relative infancy of this innovation means processes and decisions around CTC are carefully nurtured through a cautious pace and strategic planning to ensure appropriate progress and true impact. The long-term success of CTC depends on the experience with CTC being consistently positive and associated with a context in which there is a clear added value of its use. The CTC programme seeks to demonstrate, optimize and further develop that value proposition and communicate and seek consensus across global immunization partners.

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8. GVAP progress: addressing the group of middle-income countries not eligible for Gavi support

Highlights

- Middle-income countries not eligible for Gavi support ("non-Gavi MICs") have made great progress toward global eradication of maternal and neonatal tetanus elimination. Sustaining this progress is crucial.

- Non-Gavi MICs contribute to about a third of the reported cases of measles globally and progress towards disease elimination is slower than in other countries.
- Approximately 37% of the world's population unvaccinated with DTP3 reside in non-Gavi MICs, and several non-Gavi MICs had a sharp drop in DTP3 coverage over the past six years.
- Many non-Gavi MICs are lagging behind other countries in new vaccine introduction, as evidenced by the examples of PCV and rotavirus vaccine.
- Only 38% have a functional NITAG in place to inform decision-making on vaccine introduction and other areas of immunization policy based on evidence.
- National financial resources for non-Gavi MICs, while growing, are doing so at a much slower rate than in countries outside of this group: half of upper-middle-income countries' governments show spending comparable to that of lower-middle-income countries.
- Non-Gavi MICs pay considerably higher prices than lower income groups for several vaccines. Price differentiation within the non-Gavi MIC group is also large.
- Thirty per cent of non-Gavi MICs have difficulties accessing vaccines and report national-level stock outs, caused mainly by procurement delays.
- Very limited technical assistance is available to non-Gavi MICs and international immunization agencies struggle to provide minimal support through peer learning, advocacy and political engagement.
- Despite various recommendations and a global strategy, supporting the non-Gavi MICs remains an unfunded mandate and will become a growing issue as more countries transition out of being supported by Gavi.

Background

The global immunization community continues to debate the question as to whether middle-income countries[109] are being left behind in the path towards the 2020 Goals of the GVAP *(1,2)*. Due to their economic growth and development status, middle-income countries have a less clear claim on external development aid and assistance, under the assumption that their immunization systems are strong and they are wealthy enough to pay for vaccines and their delivery. This debate is all the more important given that middle-income countries are home to two thirds of the world's poorest people and account for two thirds of under-five mortality *(3,4,5)*.[110]

In response to these concerns, the World Health Assembly and SAGE have repeatedly called for rigorous investigation of obstacles to sustainable access to vaccines in middle-income countries. In June 2014, WHO convened a Middle-Income Country Task Force that was mandated to develop a global strategy and plan of action to strengthen immunization

[109] Currently defined by the World Bank as those with Gross National Income (GNI) per capita between US$ 1,006 and US$ 12,235: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.
[110] State of inequality. Reproductive, maternal, newborn and child health, WHO 2015: http://apps.who.int/iris/bitstream/10665/164590/1/9789241564908_eng.pdf?ua=1&ua=1.

systems within the context of middle-income countries.[111] Following this, a shared partner strategy for middle-income countries was endorsed by SAGE in April 2015 (the "MIC Strategy") proposing a focus on three key pillars: i) strengthening evidence-based decision-making; ii) enhancing political commitment and ensuring financial sustainability of immunization programmes; iii) improving access to timely and affordable supply *(6)*.[112] The strategy targets 63 of the 105 middle-income countries that are not supported by Gavi, and do not receive support from several other immunization initiatives.[113] The Middle-Income Country Task Force defined this group as "non-Gavi MICs". The strategy is also meant to support countries that lose Gavi financial support over time.

In line with the MIC Strategy and objective, this chapter provides an update on non-Gavi middle-income countries' performance against some of the key indicators of GVAP. After a review of these countries' progress against disease elimination, their performance on immunization coverage and new vaccine introduction is presented. The chapter then studies non-Gavi middle-income countries challenges vis-à-vis the three key pillars of the MIC Strategy.

As relevant, achievements of non-Gavi middle-income countries will be compared with those of all countries supported by Gavi (73) and that of high-income countries (Annex 8.1 shows the 194 Member States of WHO by region and status in GVAP analysis). Where useful, additional comparisons will be discussed, e.g. between countries procuring through UN agencies or self-procuring, or across income level within the non-Gavi middle-income country group.

The chapter will also discuss recent efforts to support non-Gavi MICs towards reaching GVAP targets.

Disease control goals

Non-Gavi MICs have made great progress towards global polio eradication in recent years and no polio cases were reported in 2016. Nevertheless these countries remain at risk for the introduction of wild polioviruses and the emergence of vaccine-derived polioviruses. For instance, the Syrian Arab Republic is experiencing an outbreak of circulating vaccine-derived poliovirus (CVDPV2) and the Russian Federation reported cases of VDPV2 in 2016 and 2017. Also, in 2015–2016, the European Region faced an outbreak of circulating vaccine-derived poliovirus in Ukraine.

With regard to polio eradication, the issue for non-Gavi MICs is thus one of sustainability, for instance in relation to the move towards a more expensive two-dose schedule of IPV vaccine and in the context of polio transition (see GOAL 1: Achieve a world free of poliomyelitis). It is worth noting that non-Gavi MICs diligently used crucial financial aid (US$ 45 million) exceptionally approved by the Polio Oversight Board of the Global Polio Eradication Initiative to support IPV introduction in non-Gavi MICs. Ultimately, only 18 of

[111] Please see Annex I of the MIC Strategy for a comprehensive list of the MIC Task Force members http://www.who.int/immunization/sage/meetings/2015/april/Cernuschi_MIC_Strategy_SAGE_Apr2015.pdf?ua=1&ua=1.

[112] A fourth area defined as "enhancing demand for and equitable delivery of immunization services" was also included in the MIC Strategy, as well as other challenges less specific to the middle-income country group.

[113] Please see Annex III of the MIC Strategy for a comprehensive mapping of ongoing support activities in middle-income strategies.

the 25 eligible countries requested support (for a total of US$ 16 million), as the other seven countries mobilized their own resources *(7)*.

For maternal and neonatal tetanus – all non-Gavi MICs with exception of the Philippines have reached the elimination target (see GOAL 2: Meet global and regional elimination targets: Achieve maternal and neonatal tetanus elimination). Having completed all planned Td supplementary immunization activities in high-risk areas in the Autonomous Region of Muslim Mindanao, the Philippines is also on track to attain maternal and neonatal tetanus elimination before the end of 2017. Nevertheless, as for polio, the issue of sustainability arises with regard to disease surveillance, data use and maintenance of low risk status.

In relation to measles and rubella, in 2016, non-Gavi MICs perform better than Gavi-supported countries, but still lag behind high-income countries (see

GOAL 2: Meet global and regional elimination targets: Achieve Measles Elimination). Disease burden remains considerable with an incidence of 13 per million population, compared to 3 per million population among the high-income country group. The non-Gavi MICs contribute to about a third of the reported cases globally (26% for non-Gavi MICs; 72% for Gavi-eligible countries; and 1.5% for the high-income countries) and some large outbreaks occurred in Equatorial Guinea and Romania in 2016. Further, large numbers of cases continue to be reported from China.

Very importantly, the non-Gavi MICs clearly lag behind both the Gavi-eligible and high-income countries in terms of percentage increase in the number of Member States that have achieved the 2015 global target of < 5 cases per million population. Similarly, the progress made in terms of introduction of measles second dose and rubella-containing vaccine is much higher among the Gavi-supported than the non-Gavi MICs**.** While this is partially expected given already higher performance of this group, it also denotes clear challenges. The Measles and Rubella Initiative is raising funds to provide technical assistance for countries in this group that are nearing elimination and for the countries in which measles and rubella are endemic.

Immunization coverage

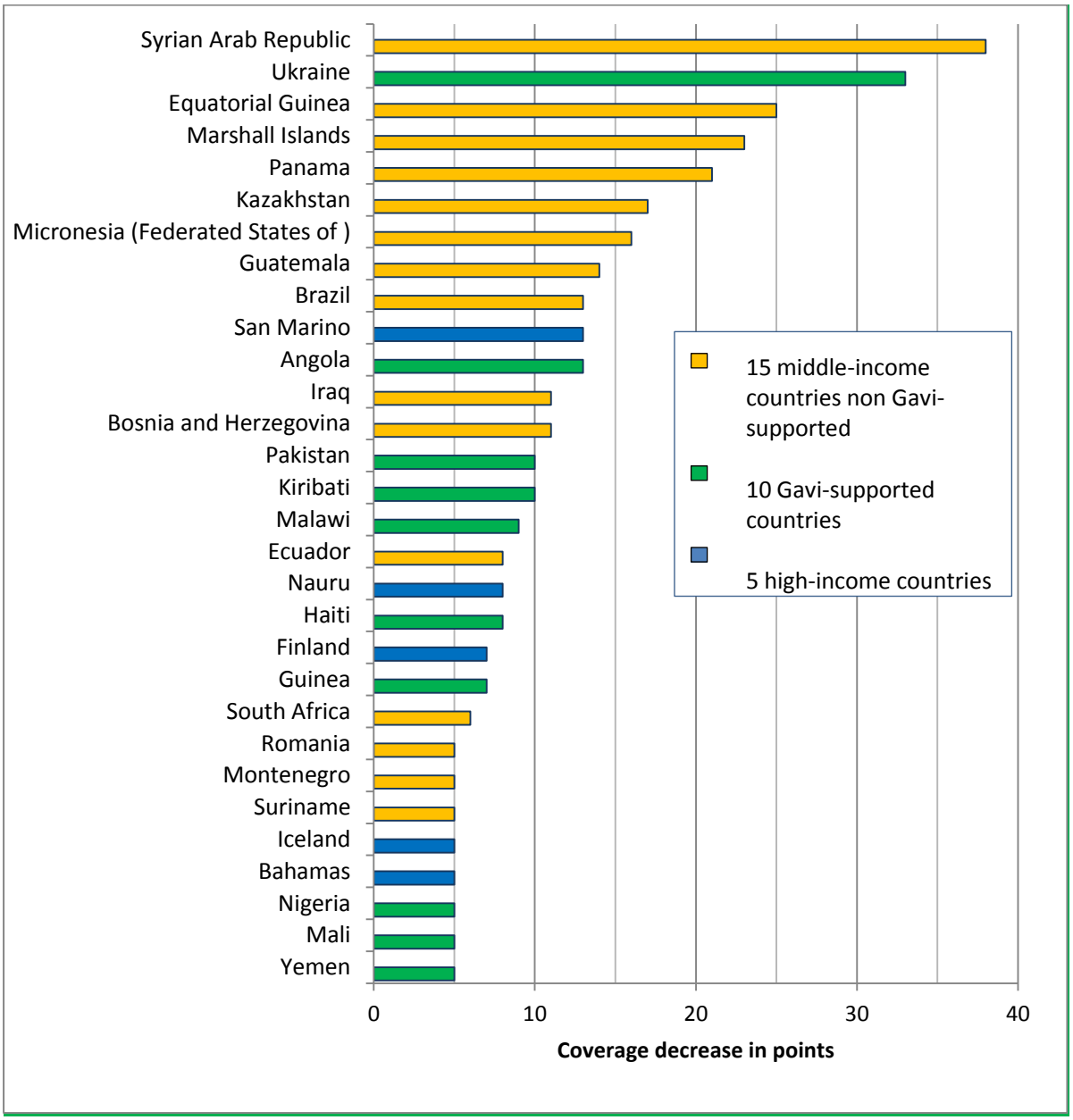
DTP3 coverage is used as an indicator of the overall strength of immunization systems. Within non-Gavi MICs DTP3 coverage is approximately the same level as that of high-income countries (at 93%). Nevertheless, non-Gavi MICs are still home to 3.1 million children unvaccinated with DTP3 (16% of world's unvaccinated).[114]

In addition, some worrying trends have been identified, such as non-Gavi MICs representing 50% of countries with declining DTP3 coverage from 2010 to 2016 (Fig. 8.1). Fifteen non-Gavi MICs had a drop in DTP3 coverage of 10 points or more over this period.[115] Equity in coverage is also an issue with non-Gavi MICs accounting for 27 (47%) of the 57 countries for which valid district-level coverage data were available and not meeting the 80% target across all districts.

[114] The main countries contributing to the number of children not receiving 3 doses of DTP-containing vaccines are Iraq (0.44), Brazil (0.41), South Africa (0.39), Philippines (0.33), Syrian Arab Republic (0.23), China (0.17), and Egypt (0.12).

[115] Kiribati, Pakistan, Bosnia and Herzegovina, Iraq, Angola, San Marino, Brazil, Guatemala, Micronesia (Federated States of), Kazakhstan, Panama, Marshall Islands, Equatorial Guinea, Ukraine, Syrian Arab Republic.

Fig. 8.1: Countries with at least a 5-point decline in DTP3 coverage between 2010 and 2016



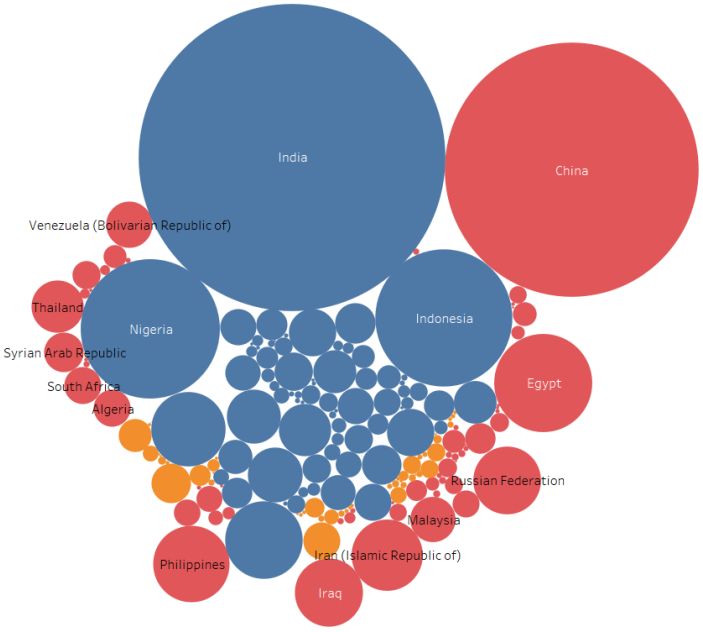
Source: WHO/UNICEF coverage estimates 2010 and 2016.

New vaccine introduction

Non-Gavi MICs represent an important share of children unvaccinated with PCV3 as well – almost 30 million children corresponding to 37% of unvaccinated children worldwide (Fig. 8.2). These numbers are largely driven (90%) by 10 countries[116].

[116] India, China, Nigeria, Indonesia, Egypt, Philippines, Russian Federation, Iraq, Islamic Republic of Iran, Thailand.

Fig. 8.2: Infants not immunized with PCV3, 2016[a]

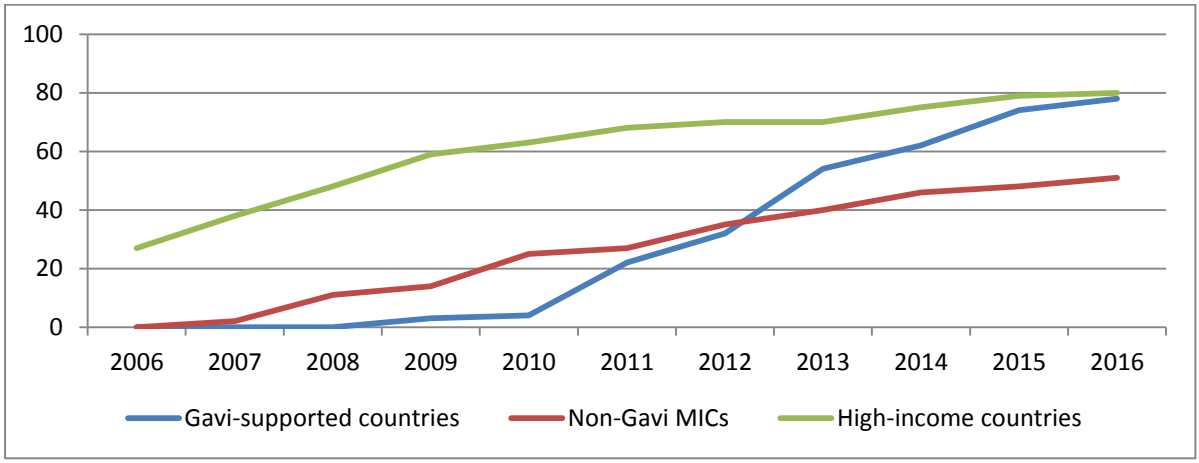


[a] This figure includes countries that have introduced and not introduced PCV. In red: non-Gavi MICs; in blue: Gavi-supported countries; in orange: high-income countries.
Source: WHO/UNICEF coverage estimates 2016 revision. United Nations Department of Economic and Social Affairs, Population Division. World population prospects: the 2017 revision [CD-ROM]. New York (NY): United Nations; 2017.

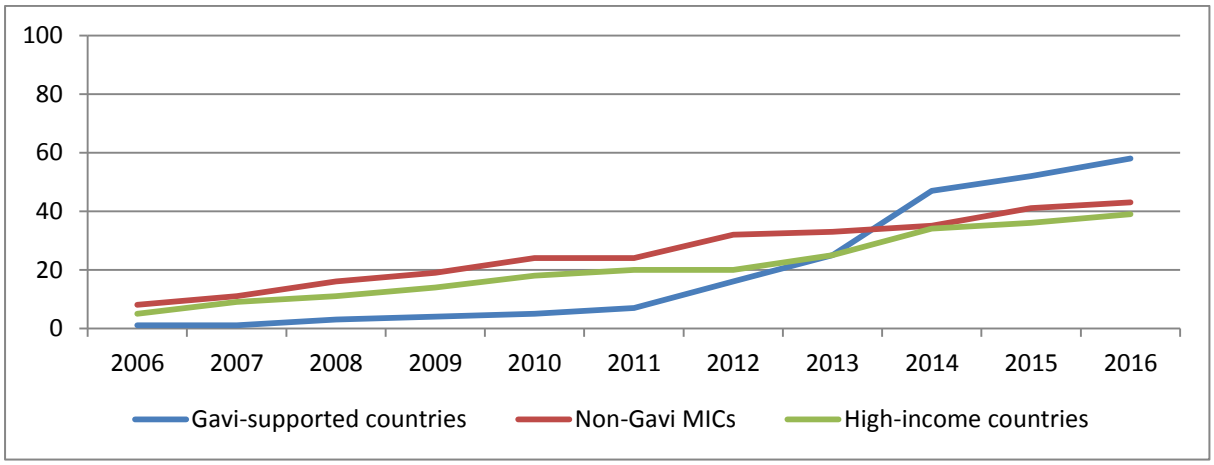
Indeed, with the exception of HPV (Fig. 8.3), non-Gavi MICs are lagging behind both high-income and Gavi-supported countries with regard to introduction of new vaccines. While it is important to acknowledge that this may reflect independent evidence-based decision-making, this also highlights obstacles to access.

Fig. 8.3: Percentage of countries with PCV, HPV, rotavirus vaccines in the immunization schedule

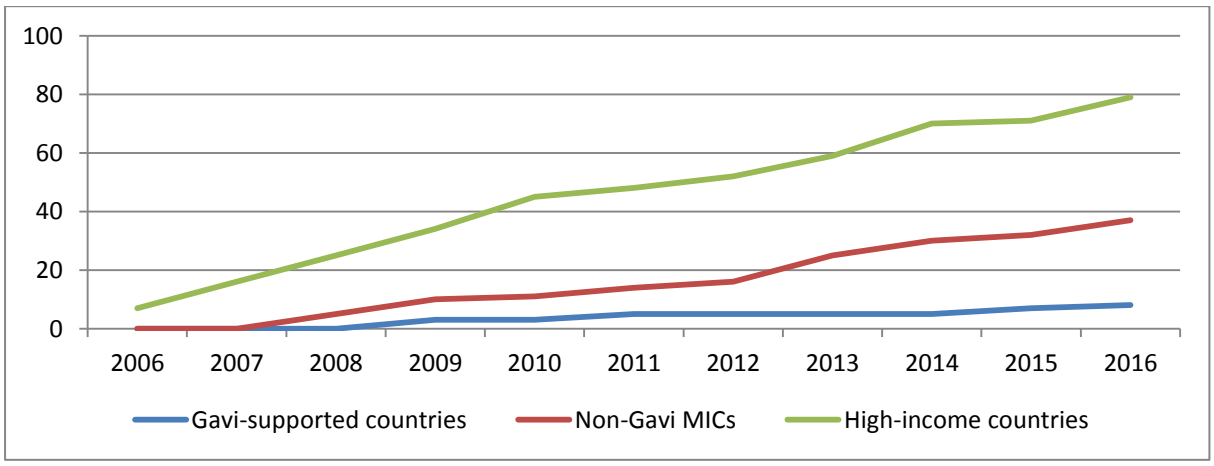
PCV



Rotavirus



HPV



Source: WHO-UNICEF JRF, as of 23 June 2017.

Evidence-based decision-making, access to adequate and predictable financial resources and timely access to affordable supply – in addition to a growing anti-vaccine agenda and conflicts – are understood to be the main challenges to improved immunization performance in non-Gavi MICs. The next sections will review these areas in some detail.

Strengthened decision-making for timely and evidence-based immunization policy

Progress against targets

Informed decision-making on vaccine introduction and other areas of immunization policy is crucial for all countries, but especially important for countries that fully fund their immunization programmes. In these countries, adoption and related decisions are likely to be less reliant on international recommendations and strong cases need to be made to secure sufficient domestic resources to sustainably fund programmes. This is particularly the case where resources are more limited, as in the case of middle-income countries.

Immunization partners have agreed that national immunization technical advisory groups (NITAGs) are important structures of the decision-making process and GVAP calls on all countries to put in place functional NITAGs by 2020. Unfortunately, at present only 56% of non-Gavi MICs have a NITAG in place and only 38% have a functional NITAG meeting all process indicators agreed upon in 2010 by WHO and its partners. By comparison, 81% of high-income countries have an existing NITAG (56% with functional NITAG) as do 66% of Gavi-supported countries (37% with functional NITAG). Functional NITAGs cover only 39% of the population residing in non-Gavi MICs.

On an encouraging note, there is a clear increase between 2010 and 2016 in the number of countries having a functional NITAG in non-Gavi MICs (+92%). Nevertheless this progress remains much more moderate than in Gavi-supported countries (+286%) reflecting a clear focus of the international donor community on countries with lower GNI.

Partner interventions

Several partners are indeed active in strengthening national decision-making processes through supporting evidence-based policy recommendations, disease burden measurement, economic analysis, tools development, training, advocacy, technical assistance; and recent analyses have documented the impact of these efforts *(8,9)*. Global efforts – such as recommendations and guidance documents – and regional support workshops can benefit all countries, particularly where national efforts alone cannot. In 2017, for example, WHO supported the establishment of a NITAG in the Philippines: following a mission to the country of the Middle-Income Country Task Force and as a result of a targeted NITAG training workshop, the country made important progress towards formalizing the NITAG terms of reference and operating procedures. This can have far-reaching implications given the country's struggle to maintain and raise immunization coverage in big part due to difficulties with immunization planning and its implications on procurement.

Similarly, while the creation of both a global network of NITAGs and regional networks to facilitate sharing of experiences and peer learning could substantially support non-Gavi MICs, participation by these countries can and should be enhanced. Isolated – but very promising – examples include members of the Chinese NITAG participating in a study tour in the USA and Canada, and benefitting from lessons learned from the United Kingdom and Germany. A similar example comes from Panama where institutional enhancement was possible through the first meeting of the Global Network of NITAGs and support from PAHO.

Enhancing political commitment and ensuring financial sustainability of immunization programmes

Progress against targets

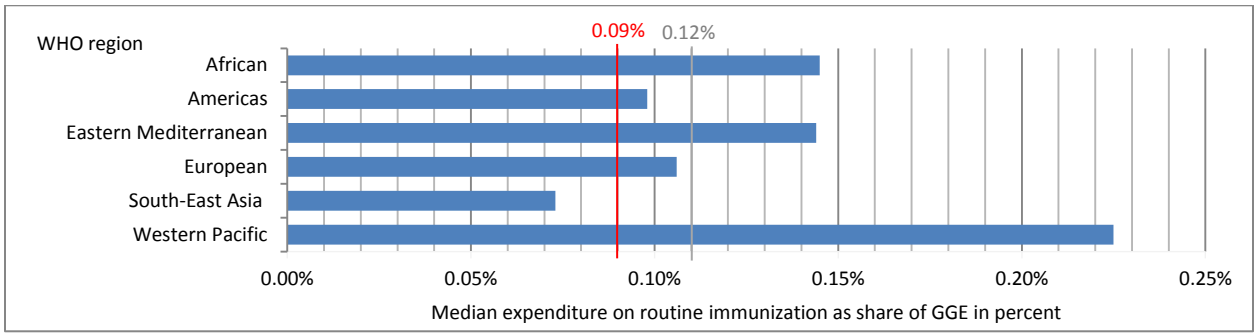
Non-Gavi MICs must rely primarily or exclusively on domestic resources to purchase vaccines and fund immunization services. Inadequate national financing – in some cases reflecting insufficient political will – as well as inefficient use of available resources may limit both new vaccine introduction and immunization coverage. This issue has been raised several times by countries and agencies in the context of consultations with the Middle-Income Country Task Force.

Data on domestic immunization expenditures in non-Gavi MICs are limited and of mixed quality. Yet some insights can be derived from the data available. Looking at the share of routine immunization in general government expenditure (GGE),[117] it is observed that 64% of non-Gavi MICs meet or exceed the median share of GGE spent on immunization in the Region of the Americas (0.09%), which is used as a reference in the absence of an agreed target (Fig. 8.4 below provides information by WHO region).[118] Nevertheless, government resources devoted to the purchase and delivery of vaccines vary widely across non-Gavi MICs.

[117] Government expenditure on routine immunization was calculated as a percentage of 2012–2015 average GGE using data from the WHO-UNICEF JRFs and the International Monetary Fund's World Economic Outlook Database. This analysis excludes 27 Non-Gavi MICs due to insufficient data. Of note, JRF data on government expenditure on routine immunization does not include shared costs.

[118] The Region of the Americas was chosen because of its high performance in vaccine coverage and introduction of new and under-utilized vaccines.

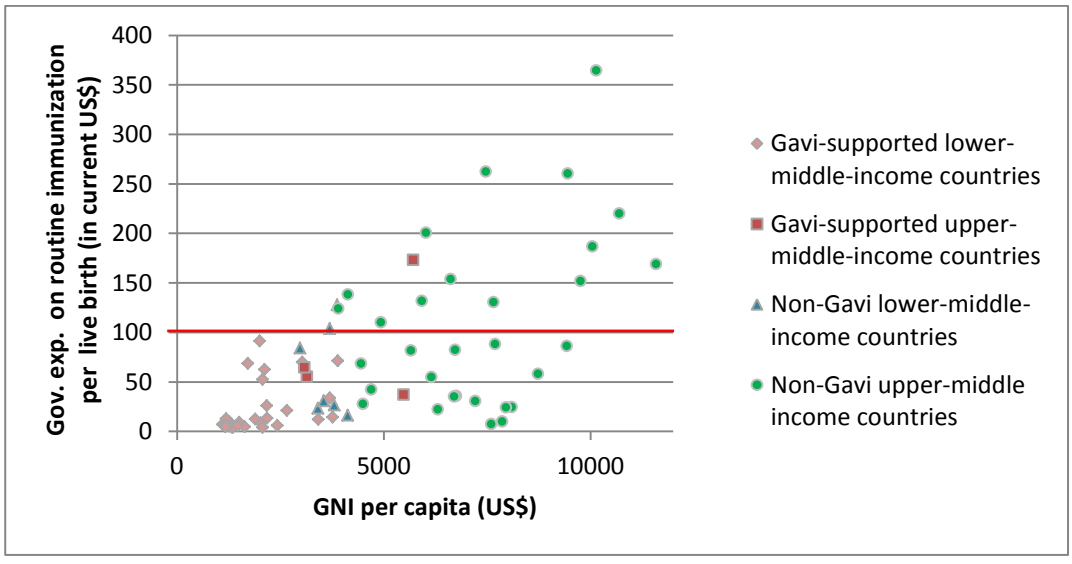
Fig. 8.4: Non-Gavi MICs government expenditure on routine immunization as share of GGE (regional median)[a]



a Red line represents the median share of immunization in GGE for the Region of the Americas. The grey line is the median share of immunization in GGE for the non-Gavi MICs group. The Region of the Americas is the most represented in the sample. For the South-East Asia Region, only two countries had data available. Data come from WHO-UNICEF JRF and the International Monetary Fund's World Economic Outlook Database.

Reviewing government expenditure on routine Immunization per live birth shows that expenditure tends to increase with income (Fig. 8.5). However, large variations are again observed particularly for upper-middle-income countries that have potential to invest further: half of upper-middle-income countries' governments show spending comparable to that of lower-middle-income countries.

Fig. 8.5. Distribution of government expenditure on routine immunization per live birth by GNI per capita among middle-income countries, 2015–2016[a]

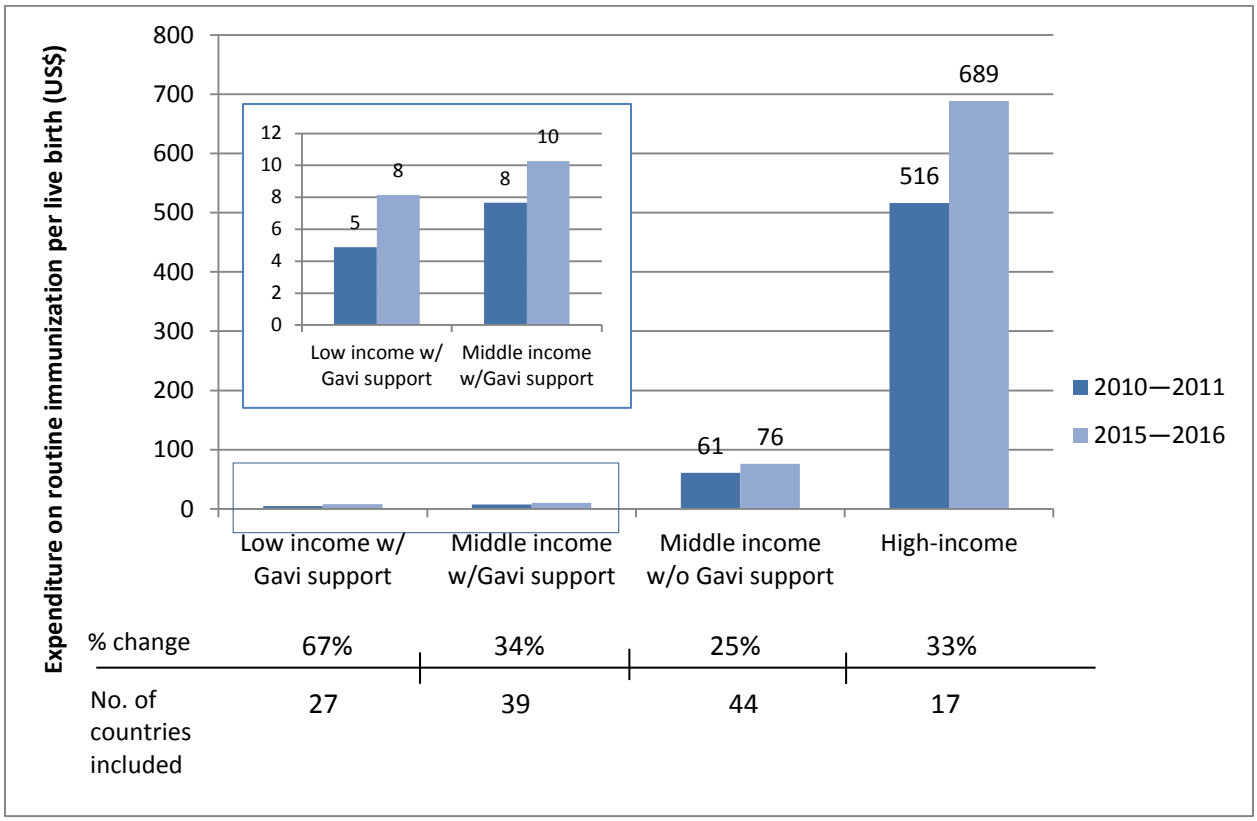


[a] Red line at US$ 100 per live birth represents maximum spending for lower-middle-income countries.

Source: WHO-UNICEF JRF.

With regard to GVAP targets, 75% of non-Gavi MICs (40 of 53)[119] have standard budget line items for vaccines and immunization programmes in their national or health sector budgets, which can contribute to higher and more predictable immunization funding *(10)*. A total of 72% of non-Gavi MICs also reported increased domestic expenditure on immunization, as required by the target on indicator SO1.1 (among these several large countries).[120] While this performance is very encouraging and comparable to what was observed in Gavi-supported countries (both eligible and in transition to self-financing), the increase in domestic expenditure seems lower in non-Gavi MICs (25%) and in countries soon to be joining this group (Gavi-transitioning countries – 4%) compared to other groups of countries (Fig. 8.6).[121]

Fig. 8.6: Government expenditure[a] on routine immunization per live birth, by income group and Gavi support



a Analysis is based on the government expenditure on routine immunization comparing the baseline (average of 2010–2011) with the comparison period (average of 2015–2016). Inclusion of countries is based on the criteria to have at least one reported data point in 2010–2011 and at least one data point reported in 2015–2016.

[119] Fifty-three is the number of non-Gavi MICs for which data were available from the 2016 JRF.

[120] Thirty-one of 43 countries for which trend data – comparing the baseline (average of 2010–2011) with the comparison period (average of 2015–2016) – were available from the 2017 JRF.

[121] The non-Gavi MICs group was further split into "PAHO" and "non-PAHO" countries where the following increases in immunization expenditure were observed respectively: 13% and 45% (reflecting among others a higher level of immunization expenditure in "PAHO" countries).

Source: WHO-UNICEF JRF

Partner interventions

The immunization community can support non-Gavi middle-income countries to build on current efforts. Consultations with immunization partners and non-Gavi MICs (as part of the MIC Strategy development process) strongly reinforced the importance of helping countries to mobilize additional domestic resources for immunization. While several agencies support through advocacy, technical assistance, peer exchanges, and training, here again, these activities primarily benefit Gavi-supported or PAHO countries *(11)*.[122]

WHO is supporting countries for financial assessments and financial sustainability strategies and the Regional Office for Europe has been making important progress to support countries in the European Region in defining and implementing resource mobilization strategies. However requests for support are increasing significantly and dedicated tools to assist are limited.[123]

Improved access to affordable and timely supply

Progress against targets

Consultations with WHO regional offices and countries during the work of the Middle-Income Country Task Force included particular emphasis on the issue of affordability of vaccines, especially for non-Gavi MICs and countries soon to lose Gavi support.

As presented in the Sustainable financing and supply for immunization chapter, the considerable data now available on vaccine prices through the WHO V3P initiative show a clear association between GNI per capita and price with middle-income countries paying considerably higher prices than lower-income countries (Fig. 8.7 presents an example of PCV). This is believed to be one of the major obstacles to quicker introduction of more expensive new vaccines, such as PCV.

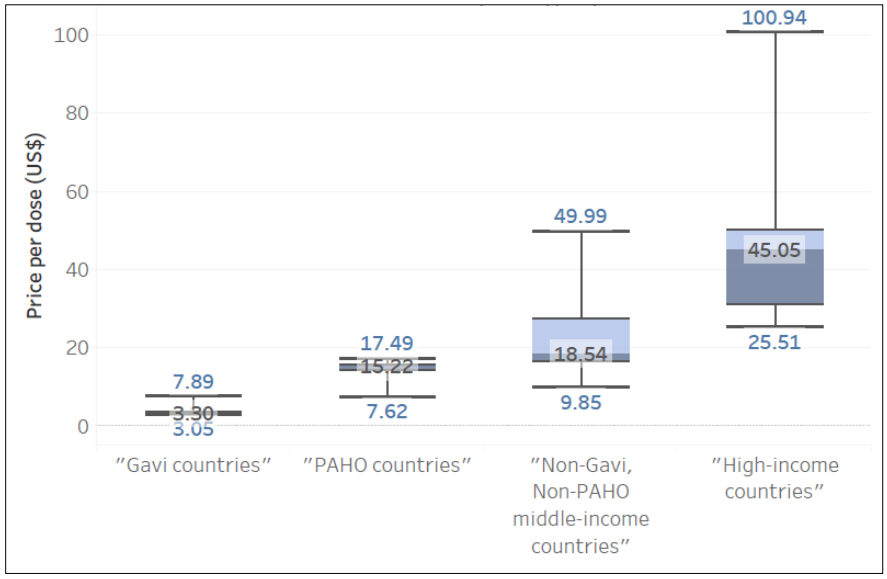
Analysis also shows high price variance for higher-income groups – see

[122] Information on the European Region's work with Gavi-transitioning countries was obtained from Osman Niyazi Cakmak, MIC Task Force member.

[123] WHO headquarters received direct requests for support from Botswana, Jordan, Namibia and Thailand in 2017. These were in addition to further requests received by the regional offices.

Indicator 2c: price segmentation: relationship between income level and vaccine prices. Minimum–maximum price range by country level of income. In particular, non-Gavi lower-middle-income countries have an average multiplier between minimum and maximum price paid at 10.68 and non-Gavi upper-middle-income countries a multiplier of 14.68. This variance shows that it should be possible to improve transparency of pricing strategies targeting middle-income countries and develop policies encouraging fair pricing as a way to strengthen access to vaccines.[124]

Fig.8.7: Minimum, maximum and median price by country category for PCV, 2016

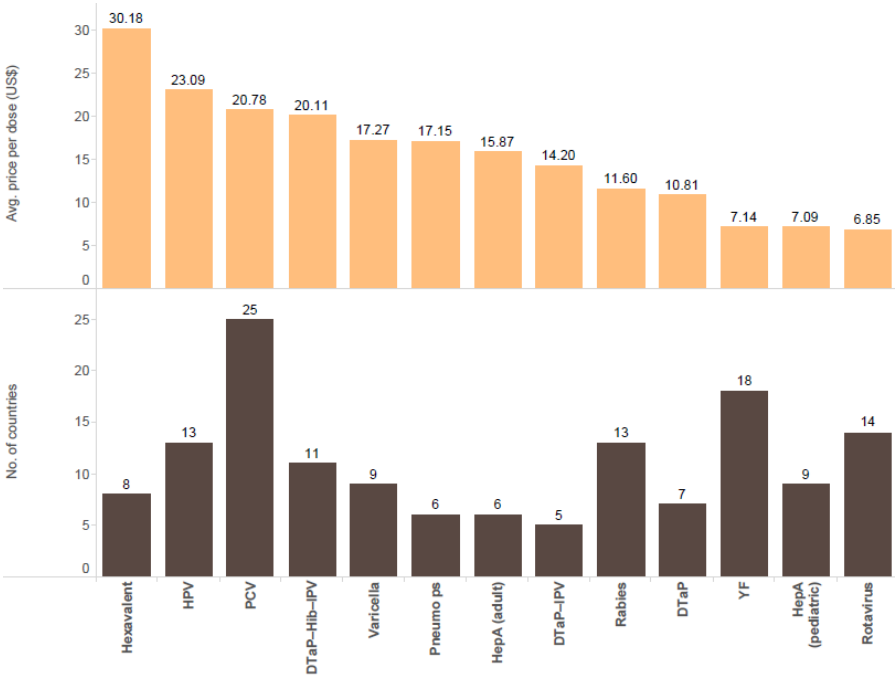


Note: The boxes on the graph show the median (centre of the box), a box above and below the median for the nearest quartiles, and a set of "whiskers" that extend to the entire data range.

The most expensive vaccines for non-Gavi MICs are hexavalent (DTaP-Hib-IPV-HepB) and pentavalent (DTaP–Hib–IPV) vaccines, HPV, PCV, varicella, pneumococcal polysaccharide (Fig. 8.8).

[124] The analysis was only conducted on 32 vaccine types for which there were more than four data points available per income category. It does not take into consideration other important elements such as the manufacturer, product characteristics, presentation size and form or procurement mechanism. This analysis is very sensitive to the values of outliers.

Fig. 8.8: Average price per dose (US$) in non-Gavi MICs for selected vaccines, 2016[a]



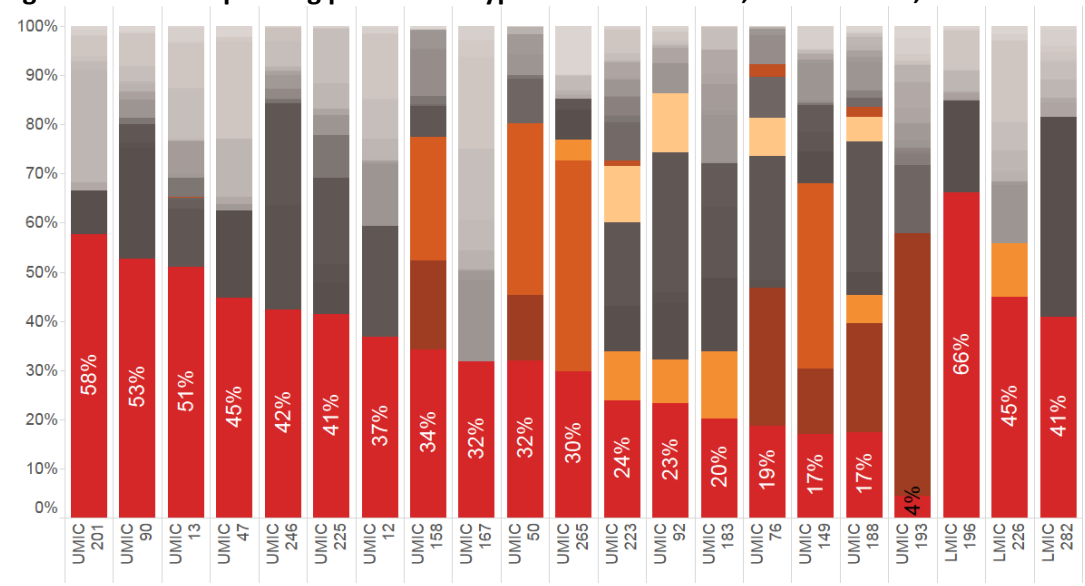
a This only includes vaccines for which more than four records were reported.

Source: V3P data (extracted 18 July 2017).

Analysis shows that budgets of non-Gavi MICs increase drastically when countries introduce a new vaccine. This is particularly the case for PCV, which represents on average 34% of the vaccine budget of non-Gavi MICs (but can require as much as 66% of vaccine spending); this denotes a particular burden for non-Gavi lower-middle-income countries (Fig. 8.9).[125]

[125] Rotavirus and HPV represent smaller shares: rotavirus is usually used in a two-dose schedule, while HPV only targets girls.

Fig. 8.9: Share of spending per vaccine type in non-Gavi MICs, focus on PCV, 2016[a]

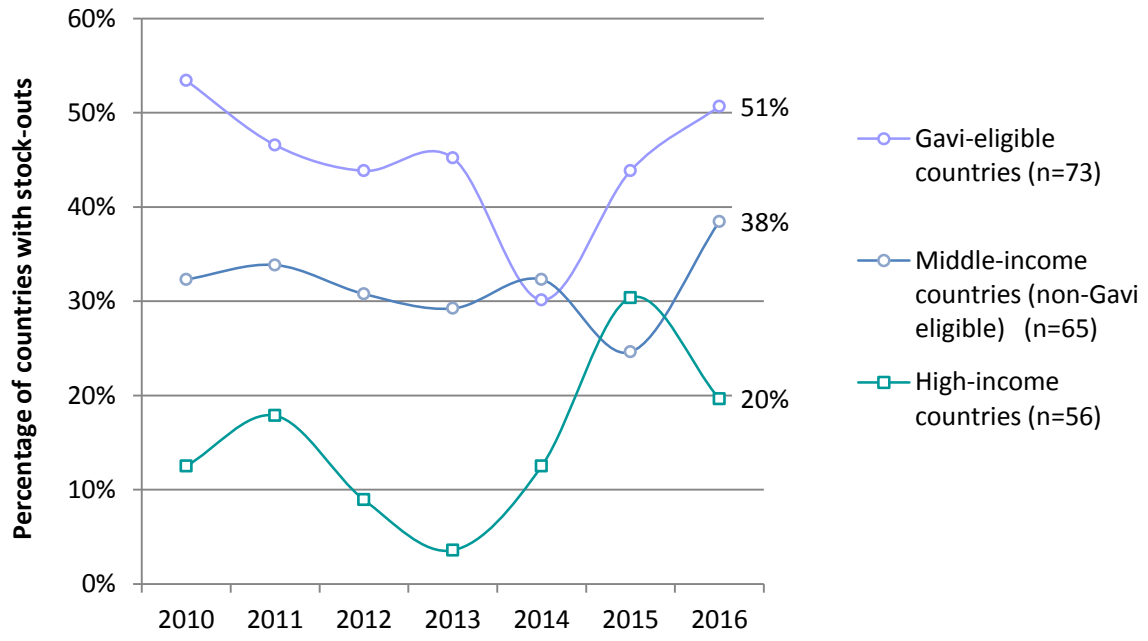


[a] Each bar represents a country (grouped by World Bank income group and anonymization number, e.g. UMIC 223). Figure only includes records with volumes > 10 and countries that have reported a price for PCV. Calculated as: [Price per dose of a vaccine] x [Volume of same vaccine] / [sum of [price per dose] x [Volume] for all vaccines. Used as a proxy for spending on vaccine purchases. In red: PCV. In orange from darkest to lighter (most expensive vaccines for non-Gavi MICs): DTaP–IPV–Hib, pneumococcal polysaccharide, hexavalent vaccines, HPV, varicella. In grey all other vaccines.

Source: V3P data (extracted 18 July 2017).

Besides the issue of affordability, timely access to vaccine supply was also noted as a barrier during the Task Force's consultations with countries. In 2016, 40% of non-Gavi MICs reported at least one national level stock-out event for at least one vaccine and for at least one month in duration. The year 2016 marks the highest number of non-Gavi MICs reporting national-level stock outs since 2010; the problem seems to be particularly acute in countries self-procuring vaccines relative to those procuring through UN agencies, although historical trends show that both categories of countries have experienced difficulties (Fig. 8.10).

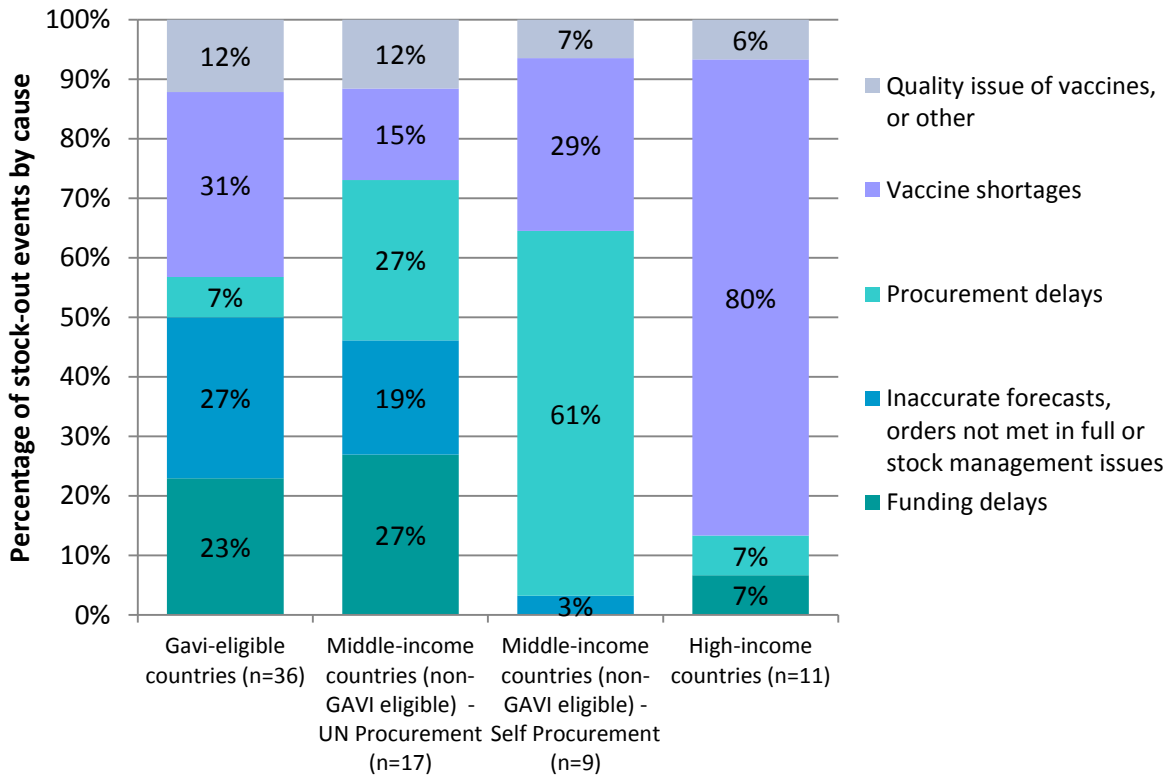
Fig. 8.10: Percentage of countries reporting stock-out events by income group and Gavi support, 2010–2016



Source: WHO-UNICEF JRF 2017.

New data from the JRF also allows for an analysis of causes of stock-out events. Fig. 8.11 shows that in self-procuring non-Gavi MICs, procurement issues are the leading factor behind over 70% of stock outs, while it represents a minor problem in both Gavi-supported and high-income countries and less of an issue in countries using UN procurement services. Global vaccine shortages are the second leading cause recorded by self-procuring non-Gavi MICs. For non-Gavi MICs procuring through UN agencies, funding delay is another considerable factor.

Fig. 8.11: Causes of stock outs, 2016



Source: WHO-UNICEF JRF 2017.

As in high-income countries, stock outs in non-Gavi MICs were predominantly for DTP-containing vaccines (including with HepB and Hib) and for polio vaccines (in Gavi-supported countries OPV or IPV represent the main vaccines out of stock). Each represented respectively 39% and 34% of all stock-out events reported.

With regard to implementing fundamental aspects of a vaccine supply chain, available data show that non-Gavi eligible countries significantly lag behind other countries in adequately managing temperatures in the cold chain with continuous monitoring devices. Without such devices it is difficult to safeguard the potency of vaccines throughout the cold chain and protect these against (undetected) damaging temperature exposures – particularly against freezing of expensive liquid vaccines. Both high-income countries and non-Gavi MICs are outperformed by Gavi-supported countries on establishment of all fundamental aspects of the supply chain.

Partner interventions

As proposed under the MIC Strategy, immunization partners are beginning to address the issue of timely and affordable vaccine supply through improved procurement skills and knowledge at country level. Facilitating this process is peer learning among countries, development of missing tools (such as updated procurement guidelines & assessment tools) and provision of targeted technical assistance to countries most in need. Currently, the effort is very limited due to unclear roles and responsibilities and limited capacity. Nevertheless, UNICEF has promoted

peer-to-peer exchange forums for middle-income country procurement practitioners at the global level, while some WHO regional offices have been able to give continuity to these efforts at the regional level (e.g. Regional Offices for Europe and South-East Asia). Both initiatives were met with enthusiasm and active participation by countries.

Another proposed area of intervention under the MIC Strategy is increased vaccine market transparency, in particular of vaccine pricing. Section 7 on sustainable financing and supply for immunization has described the important progress towards vaccine market transparency in the past few years. Of note, all but five of the 65 non-Gavi MICs are now sharing price information (representing 90% of all non-Gavi MICs). This represents important progress and shows that countries are willing to engage in low cost, sustainable peer-exchange platforms that directly respond to their needs. Further efforts are needed to assist countries in making use of the data and to develop policies encouraging fair pricing as a way to strengthen access to vaccines. WHO has started to engage in this latter area through the organization of a Fair Pricing Forum[126] in May 2017 in collaboration with the Government of the Netherlands.

Assurance that suppliers will be paid on time is important to obtain lower vaccine prices, but some middle-income countries face uncertainties in their annual budgetary allocation processes or legal restrictions on prepayment, while others have difficulty accessing hard currency *(REF?)*.[127] Revolving funds such as those used by PAHO and the UNICEF Vaccine Independence Initiative provide a line of credit to member countries unable to pay for a vaccine purchase at the time needed; this allows countries greater flexibility in payment terms and prevents supply disruptions. UNICEF has more than doubled the capital base of the Vaccine Independence Initiative revolving fund to US$ 35 million (as of July 2017) providing important opportunities for both Gavi-transitioning countries and non-Gavi MICs, which has been strongly encouraged by the Middle-Income Country Task Force. Countries are already starting to take advantage of this new opportunity.

Another barrier to access is distinct and sometimes onerous registration requirements, particularly for lower-cost manufacturers (that have fewer resources to negotiate these processes) with possible negative impact on price competition.[128] While work is ongoing to streamline and align requirements for vaccine registration regionally and globally this remains limited in scope (see Sustainable financing and supply for immunization section).

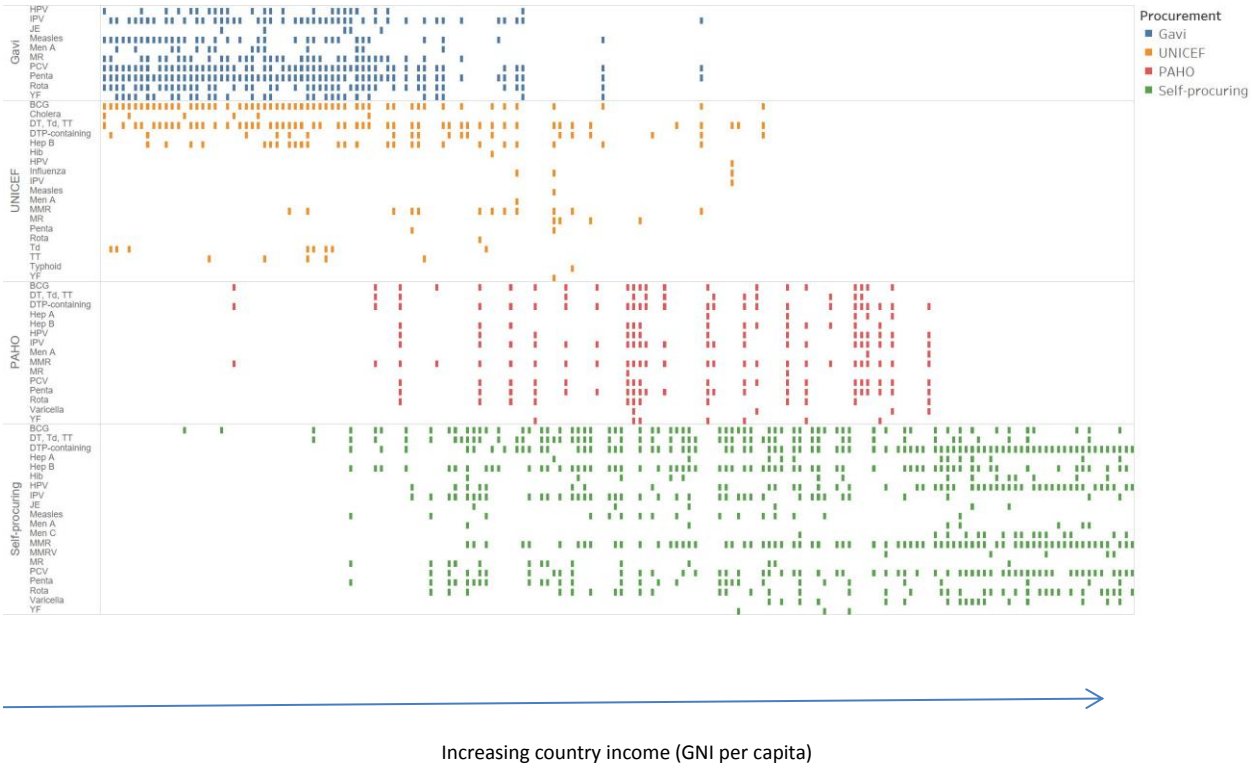
External procurement services, for example through UNICEF Supply Division, can also be a useful option for middle-income countries that have limited procurement capacity. UNICEF recently negotiated supply arrangements for pentavalent vaccines on behalf of non-Gavi MICs at significantly reduced prices (at parity with those prices paid by Gavi). Discussions with countries and manufacturers continue, with a focus particularly on pneumococcal conjugate vaccines (PCV) – and plans are in place by UNICEF Supply Division to launch a new tender on behalf of middle-income countries later in 2017.

[126] http://www.fairpricingforum2017.nl/home

[127] Gavi. Country needs assessment of Access to Appropriate Pricing for Gavi graduates and non-Gavi LMICs.

[128] Consultation with DCVMN at annual conference, November 2014.

Fig. 8.12: Vaccine market segmentation by procurement/funding agencies[a]



[a] The scope of the exhibit is global. Each mark represents known country use of a vaccine. Countries are ordered along the x-axis by GDP per capita. Procurement method (or support, i.e. Gavi) is based on 2016 data. Marks labelled as "Gavi" are known to procure through UNICEF Supply Division, but emphasis is placed on Gavi support for the specific countries and antigens. The graphic is intended as an illustration of procurement routes, not a definitive mapping of Member States' antigen purchasing. All data are subject to change.
Source: Linksbridge; reproduced with permission. Data used to populate the graphic come from WHO-UNICEF JRF, Gavi, UNICEF SD and the PAHO Revolving Fund.

Measures to influence vaccine markets as a way of increasing access to timely and affordable supply are also explored. In this area, some WHO efforts described in the Sustainable financing and supply for immunization section show potential for middle-income countries. Among these are the newly-launched Humanitarian Mechanism and the workstream on vaccine shortages. Non-Gavi MICs represent an important share of the vaccine market – 29% of volumes and 36% of the value of vaccine purchased in 2016 according to the V3P data. Yet these countries are de facto excluded from many initiatives to share information, and coordinate and shape the market, which focus on markets supported by Gavi, the PAHO Revolving Fund and UNICEF Supply Division (Fig. 8.12).

Conclusion

Following repeated calls from the World Health Assembly and SAGE, WHO convened a time-limited task force to develop a coordinated strategy and plan of action to enhance sustainable immunization efforts in middle-income countries.

The Middle-Income Country Task Force concluded that while 42 of the 105 middle-income countries are well supported by the international donor community including Gavi, 63 countries neither benefit from much donor support nor a unified international strategy. In these 63 countries (the non-Gavi MICs), vaccine-preventable disease burden and numbers of unvaccinated children are lower than in Gavi middle-income countries, but nonetheless remain substantial and unacceptable. In addition, as several Gavi-supported countries transition out of Gavi support in the next few years, the non-Gavi MICs group will become home to the highest disease burden and highest number of unvaccinated children.

This chapter confirmed slow progress in elimination of measles in non-Gavi MICs and highlighted worrying trends in immunization coverage (i.e. DTP3 coverage) in a group already home to a large share of the world's unvaccinated children. A review of the introductions of new vaccines also showed a lag in protecting populations with new antigens in this group of countries.

Weak decision-making processes, limited financial resources and obstacles accessing timely and affordable vaccine supply are understood to be the main challenges to improved immunization performance for non-Gavi MICs. As reviewed here, a large proportion of these countries do not have functional independent institutions using evidence to shape immunization policies and vaccine introduction decisions. However, several countries have the potential to increase their immunization spending further. In addition, there is an opportunity to improve transparency of manufacturers' pricing strategies for enhanced access. Efficiency and efficacy of procurement procedures can also be strengthened to this aim.

Through extensive consultations with countries, WHO regional offices, UN agencies, international civil society organizations, donors and the vaccine industry, the MIC Task Force and partners have developed a MIC Strategy, which was endorsed by SAGE in April 2015. The Strategy proposes a clear focus on three key pillars to address the challenges facing non-Gavi MICs: i) strengthening evidence-based decision-making; ii) enhancing political commitment and ensuring financial sustainability of immunization programmes; iii) improving access to timely and affordable supply.

The strategy proposes a "light touch approach" to implementation: coordinated advocacy by international partners aimed at boosting each country's own investments, country learning through peer platforms and some key initiatives to enhance access to vaccines. Yet, partners and countries are struggling to make progress in these areas, as the Strategy remains largely unfunded.

As reviewed in this section, the experience with the limited initiatives available – such as the exceptional support for IPV introduction, the Global Network of NITAGs, procurement peer learning opportunities and the vaccine price transparency platform – show that countries are eager to engage and address challenges. To scale up such initiatives, the Middle-income Country Task Force has called for a paradigm shift in official development assistance in immunization: away from an "all or nothing" approach and towards wider and nuanced support to all countries based on their different abilities and needs.

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ANNEX 8.1: CLASSIFICATION OF COUNTRIES ACCORDING TO THEIR WORLD BANK INCOME STATUS AND GAVI ELIGIBILITY USED THROUGHOUT THE REPORT

Member State (WHO)	WHO region	Status in GVAP analysis
Afghanistan	Eastern Mediterranean	Gavi
Albania	European	MIC_non-Gavi
Algeria	African	MIC_non-Gavi
Andorra	European	HIC
Angola	African	Gavi
Antigua and Barbuda	Americas	HIC
Argentina	Americas	MIC_non-Gavi
Armenia	European	Gavi
Australia	Western Pacific	HIC
Austria	European	HIC
Azerbaijan	European	Gavi
Bahamas (the)	Americas	HIC
Bahrain	Eastern Mediterranean	HIC
Bangladesh	South-East Asia	Gavi
Barbados	Americas	HIC
Belarus	European	MIC_non-Gavi
Belgium	European	HIC
Belize	Americas	MIC_non-Gavi
Benin	African	Gavi
Bhutan	South-East Asia	Gavi
Bolivia (Plurinational State of)	Americas	Gavi
Bosnia and Herzegovina	European	MIC_non-Gavi
Botswana	African	MIC_non-Gavi
Brazil	Americas	MIC_non-Gavi
Brunei Darussalam	Western Pacific	HIC
Bulgaria	European	MIC_non-Gavi
Burkina Faso	African	Gavi
Burundi	African	Gavi
Cabo Verde	African	MIC_non-Gavi
Cambodia	Western Pacific	Gavi
Cameroon	African	Gavi
Canada	Americas	HIC
Central African Republic (the)	African	Gavi
Chad	African	Gavi
Chile	Americas	HIC

Member State (WHO)	WHO region	Status in GVAP analysis
China	Western Pacific	MIC_non-Gavi
Colombia	Americas	MIC_non-Gavi
Comoros (the)	African	Gavi
Cook Islands	Western Pacific	
Congo (the)	African	Gavi
Costa Rica	Americas	MIC_non-Gavi
Cote d'Ivoire	African	Gavi
Croatia	European	HIC
Cuba	Americas	Gavi
Cyprus	European	HIC
Czech Republic (the)	European	HIC
Denmark	European	HIC
Djibouti	Eastern Mediterranean	Gavi
Dominica	Americas	MIC_non-Gavi
Dominican Republic (the)	Americas	MIC_non-Gavi
DPR Korea	South-East Asia	Gavi
Democratic Republic of the Congo	African	Gavi
Ecuador	Americas	MIC_non-Gavi
Egypt	Eastern Mediterranean	MIC_non-Gavi
El Salvador	Americas	MIC_non-Gavi
Equatorial Guinea	African	MIC_non-Gavi
Eritrea	African	Gavi
Estonia	European	HIC
Ethiopia	African	Gavi
Fiji	Western Pacific	MIC_non-Gavi
Finland	European	HIC
France	European	HIC
Gabon	African	MIC_non-Gavi
Gambia (the)	African	Gavi
Georgia	European	Gavi
Germany	European	HIC
Ghana	African	Gavi
Greece	European	HIC
Grenada	Americas	MIC_non-Gavi
Guatemala	Americas	MIC_non-Gavi
Guinea	African	Gavi

Member State (WHO)	WHO region	Status in GVAP analysis
Guinea-Bissau	African	Gavi
Guyana	Americas	Gavi
Haiti	Americas	Gavi
Honduras	Americas	Gavi
Hungary	European	HIC
Iceland	European	HIC
India	South-East Asia	Gavi
Indonesia	South-East Asia	Gavi
Iran (Islamic Republic of)	Eastern Mediterranean	MIC_non-Gavi
Iraq	Eastern Mediterranean	MIC_non-Gavi
Ireland	European	HIC
Israel	European	HIC
Italy	European	HIC
Jamaica	Americas	MIC_non-Gavi
Japan	Western Pacific	HIC
Jordan	Eastern Mediterranean	MIC_non-Gavi
Kazakhstan	European	MIC_non-Gavi
Kenya	African	Gavi
Kiribati	Western Pacific	Gavi
Kuwait	Eastern Mediterranean	HIC
Kyrgyzstan	European	Gavi
Lao People's Democratic Republic (the)	Western Pacific	Gavi
Latvia	European	HIC
Lebanon	Eastern Mediterranean	MIC_non-Gavi
Lesotho	African	Gavi
Liberia	African	Gavi
Libya	Eastern Mediterranean	MIC_non-Gavi
Lithuania	European	HIC
Luxembourg	European	HIC
Madagascar	African	Gavi
Malawi	African	Gavi
Malaysia	Western Pacific	MIC_non-Gavi
Maldives	South-East Asia	MIC_non-Gavi
Mali	African	Gavi
Malta	European	HIC
Marshall Islands (the)	Western Pacific	MIC_non-Gavi
Mauritania	African	Gavi

Member State (WHO)	WHO region	Status in GVAP analysis
Mauritius	African	MIC_non-Gavi
Mexico	Americas	MIC_non-Gavi
Micronesia (Federated States of)	Western Pacific	MIC_non-Gavi
Monaco	European	HIC
Mongolia	Western Pacific	Gavi
Montenegro	European	MIC_non-Gavi
Morocco	Eastern Mediterranean	MIC_non-Gavi
Mozambique	African	Gavi
Myanmar	South-East Asia	Gavi
Namibia	African	MIC_non-Gavi
Nauru	Western Pacific	HIC
Nepal	South-East Asia	Gavi
Netherlands (the)	European	HIC
New Zealand	Western Pacific	HIC
Nicaragua	Americas	Gavi
Niger (the)	African	Gavi
Nigeria	African	Gavi
Niue	Western Pacific	NA
Norway	European	HIC
Oman	Eastern Mediterranean	HIC
Pakistan	Eastern Mediterranean	Gavi
Palau	Western Pacific	MIC_non-Gavi
Panama	Americas	MIC_non-Gavi
Papua New Guinea	Western Pacific	Gavi
Paraguay	Americas	MIC_non-Gavi
Peru	Americas	MIC_non-Gavi
Philippines (the)	Western Pacific	MIC_non-Gavi
Poland	European	HIC
Portugal	European	HIC
Qatar	Eastern Mediterranean	HIC
Republic of Korea	Western Pacific	HIC
Republic of Moldova (the)	European	Gavi
Romania	European	MIC_non-Gavi
Russian Federation (the)	European	MIC_non-Gavi
Rwanda	African	Gavi
Saint Kitts and Nevis	Americas	HIC
Saint Lucia	Americas	MIC_non-Gavi

Member State (WHO)	WHO region	Status in GVAP analysis
Saint Vincent and the Grenadines	Americas	MIC_non-Gavi
Samoa	Western Pacific	MIC_non-Gavi
San Marino	European	HIC
Sao Tome and Principe	African	Gavi
Saudi Arabia	Eastern Mediterranean	HIC
Senegal	African	Gavi
Serbia	European	MIC_non-Gavi
Seychelles	African	HIC
Sierra Leone	African	Gavi
Singapore	Western Pacific	HIC
Slovakia	European	HIC
Slovenia	European	HIC
Solomon Islands	Western Pacific	Gavi
Somalia	Eastern Mediterranean	Gavi
South Africa	African	MIC_non-Gavi
South Sudan	African	Gavi
Spain	European	HIC
Sri Lanka	South-East Asia	Gavi
Sudan (the)	Eastern Mediterranean	Gavi
Suriname	Americas	MIC_non-Gavi
Swaziland	African	MIC_non-Gavi
Sweden	European	HIC
Switzerland	European	HIC
Syrian Arab Republic (the)	Eastern Mediterranean	MIC_non-Gavi
Tajikistan	European	Gavi
Thailand	South-East Asia	MIC_non-Gavi
The former Yugoslav Republic of Macedonia	European	MIC_non-Gavi
Timor-Leste	South-East Asia	Gavi
Togo	African	Gavi
Tonga	Western Pacific	MIC_non-Gavi
Trinidad and Tobago	Americas	HIC
Tunisia	Eastern Mediterranean	MIC_non-Gavi
Turkey	European	MIC_non-Gavi
Turkmenistan	European	MIC_non-Gavi
Tuvalu	Western Pacific	MIC_non-Gavi
Uganda	African	Gavi
Ukraine	European	Gavi
United Arab Emirates (the)	Eastern Mediterranean	HIC
United Kingdom of Great Britain and Northern Ireland (the)	European	HIC
United Republic of Tanzania (the)	African	Gavi
United States of America (the)	Americas	HIC
Uruguay	Americas	HIC
Uzbekistan	European	Gavi
Vanuatu	Western Pacific	MIC_non-Gavi
Venezuela (Bolivarian Republic of)	Americas	MIC_non-Gavi
Viet Nam	Western Pacific	Gavi
Yemen	Eastern Mediterranean	Gavi
Zambia	African	Gavi
Zimbabwe	African	Gavi

Gavi, Gavi-supported country; HIC, high-income country;. MIC, middle-income country.

9. Vaccine safety

TARGET	The target is currently set at a ratio of 10 based on an empirical analysis of JRF data since 2000.
DEFINITION OF INDICATOR	Number of AEFI reported by country per 100 000 surviving infants.
DATA SOURCES	WHO-UNICEF joint reporting forms (JRFs).
DATA AVAILABILITY AND QUALITY	Please see below.

Highlights

- The reporting ratio of adverse events following immunization (AEFI) reported by country per 100 000 surviving infants has been used to identify countries where AEFI reporting appears to be established.
- In 2016, 107 countries reported at least 10 or more AEFI cases for 100 000 surviving infants. This is an 18% increase since 2015, and a 39% increase since 2010.
- In 2016, based on the data in the JRF received, a majority of countries from Regions of the Americas (23/34 or 68%), Eastern Mediterranean (10/20 or 50%), European (36/48 or 75%) and South-East Asia (7/11 or 64%) met the AEFI indicator. Less than half of the countries in the African (21/47 or 45%) and Western Pacific (10/24 or 42%) Regions met the indicator.

Background

The indicator "Number of AEFI reported by country per 100 000 surviving infants per year and per country" proposed by the Global Advisory Committee on Vaccine Safety (GACVS) was adopted by the SAGE Decade of Vaccines working group to encourage reporting of AEFI particularly from low- and middle-income countries, where vaccine safety surveillance is frequently non-functional. Countries are encouraged to report all AEFI without distinguishing benign and serious AEFI; or differentiating reports related to routine immunization activities from those obtained through supplementary activities. Since 2016, this indicator is being actively monitored at the global and national levels. Data limitations were discussed in the GVAP Secretariat report 2016.

Narrative

Since the introduction of the indicator, Member States in all WHO regions have made substantial efforts to enhance AEFI reporting. This is demonstrated by enhanced reporting seen in all WHO regions since 2010. The increase is particularly evident in the African Region between 2015 and 2016 where the number of countries reporting at least 10 AEFI cases per 100 000 surviving infants has increased from 13 in 2015 to 21 in 2016 (Fig. 9.1).

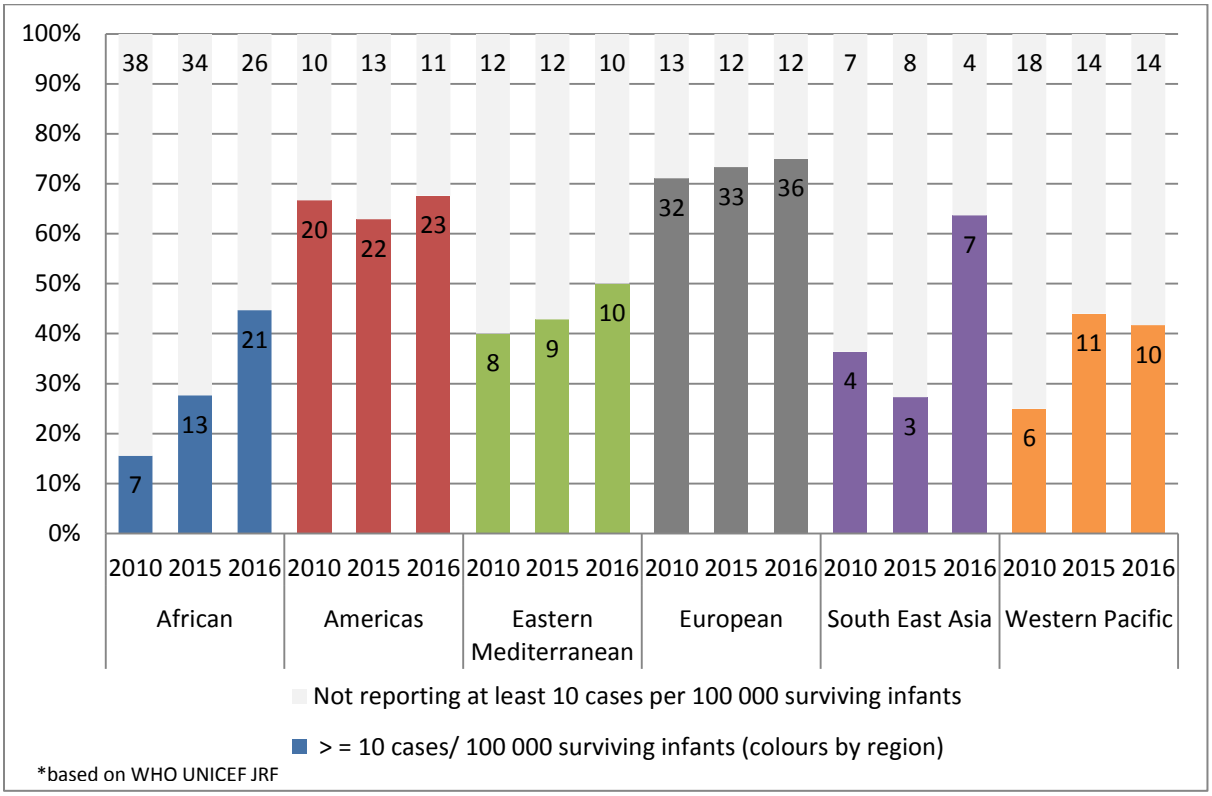
The impact of capacity-building efforts undertaken in 2015 and 2016 to increase AEFI reporting from Gavi-eligible countries is most visible in the African and South-East Asia Regions. Impact of

such efforts are also evident both in the Gavi-eligible and middle-income countries in the European Region as well. A large number of upper-middle-income and high-income countries from all regions continue to meet the minimum reporting indicator requirement (Fig. 9.2). Fig. 9.3–9.5 show the number of AEFI reported per 100 000 surviving infants by Member State, for the years 2010 (baseline), 2015 and 2016.

In 2016 additional efforts were undertaken to improve AEFI reporting particularly in lower-middle-income countries based on the framework of the Global Vaccine Safety Blueprint *(1)*. This included greater focus on country-level activities such as development of vaccine safety implementation work plans and capacity building. The establishment of national AEFI committees by several lower-middle-income countries that provided guidance on developing national AEFI guideline documents in line with the global standard played an important role in increasing awareness and stimulating AEFI reporting. This is clearly evident in the African Region where efforts have also been made to bridge the gaps in information sharing between the national regulatory authorities and national immunization programmes. Opportunities such as malaria vaccine introduction in selected countries in Africa and dengue vaccines in Asia have been used as opportunities to strengthen vaccine safety systems. Strengthening vaccine safety communication has been awarded high priority in several countries, particularly after the HPV vaccine-related safety incidents reported from several developed countries in Europe and Asia.

With improved AEFI reporting, countries now need to strengthen the subnational performance (in all districts) to ensure homogeneity by encouraging at least 80% of districts to report 10 AEFI per 100 000 surviving infants or more. The use of electronic technology-based AEFI reporting processes with emphasis on good-quality data collection and data handling will address the urgent need for making effective decisions. This is of particular importance when new vaccines are introduced and challenges are faced when addressing a vaccine safety crisis. The quality of information that is obtained, particularly during investigation of serious AEFI cases, has great implications on improving AEFI causality assessment and decision-making processes at subnational and national levels.

Fig 9.1: Percentage and number of countries reporting[a] at least 10 per 100 000 AEFI cases, by WHO region, 2010, 2015–2016



a Based on annual number of WHO-UNICEF JRFs received.

Fig 9.2: Countries reporting at least 10 per 100 000 AEFI cases, by Gavi eligibility & World Bank income classification, 2010, 2015–2016

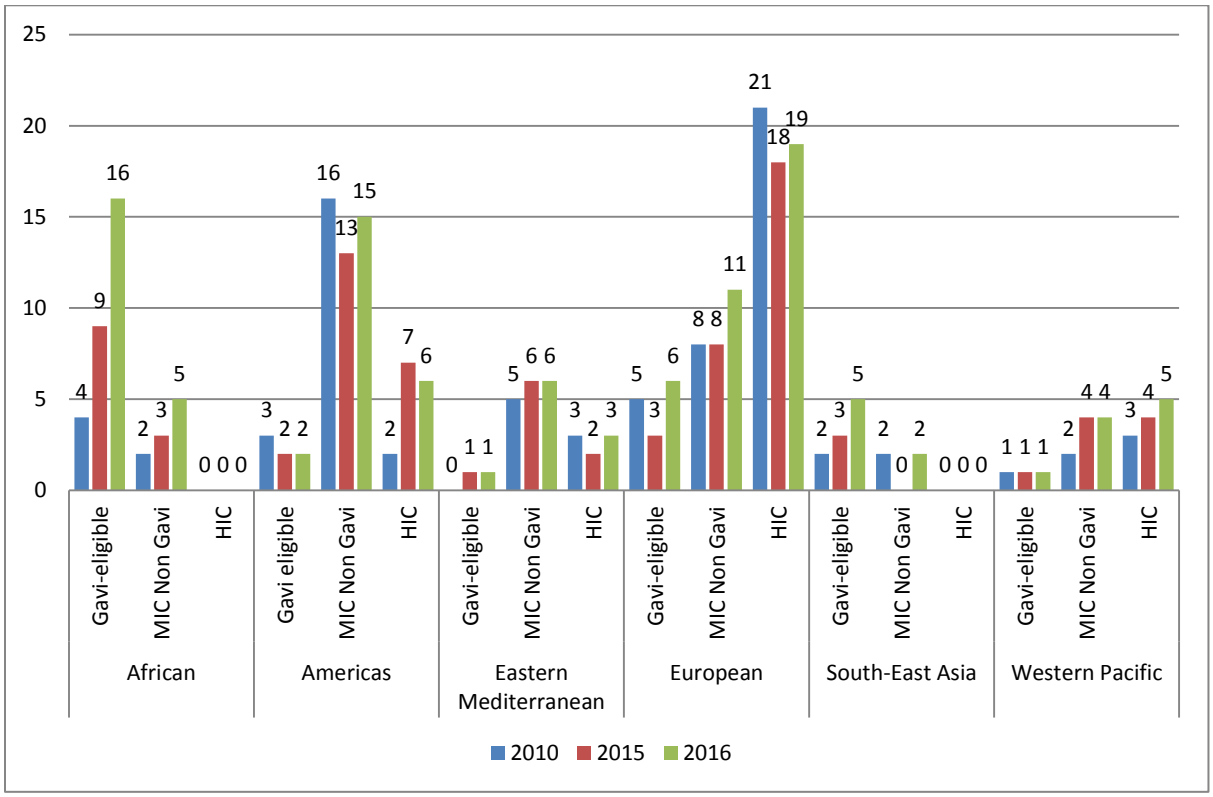


Fig. 9.3: Number of AEFI reported per 100 000 surviving infants by Member State, 2010

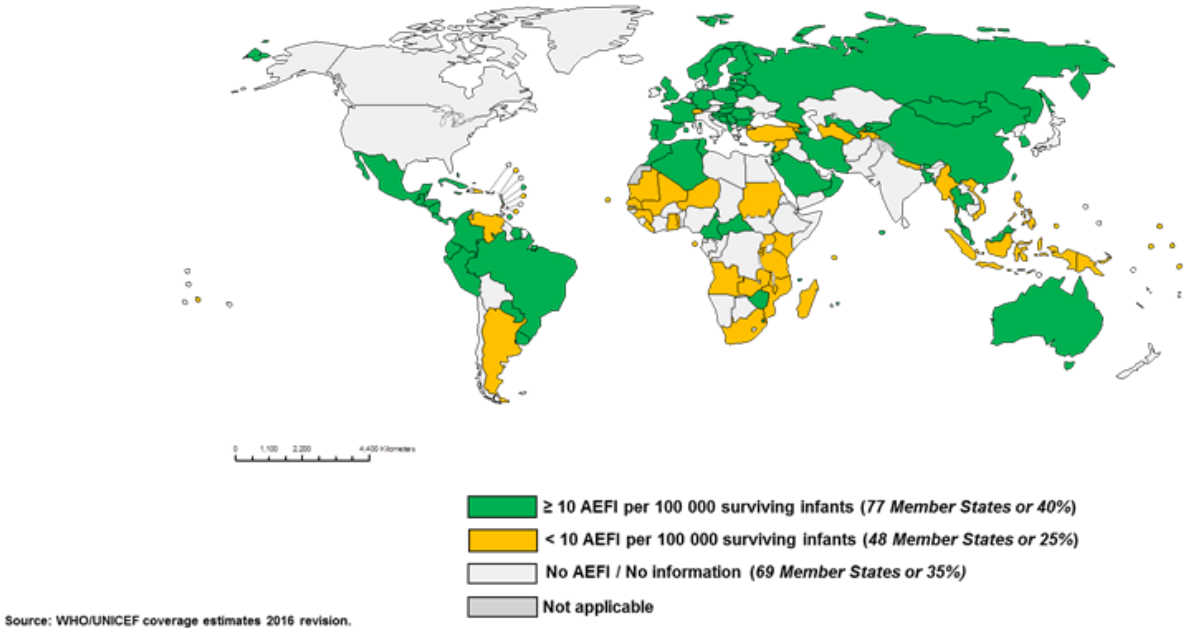
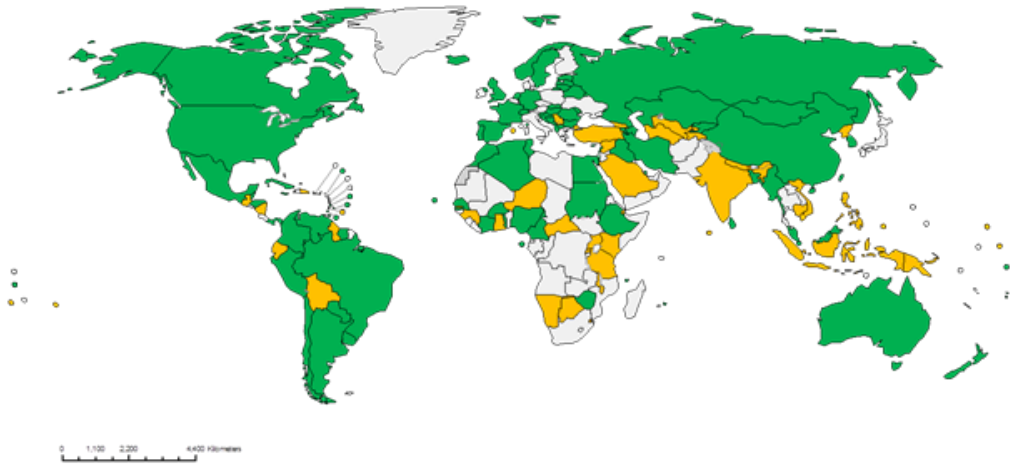
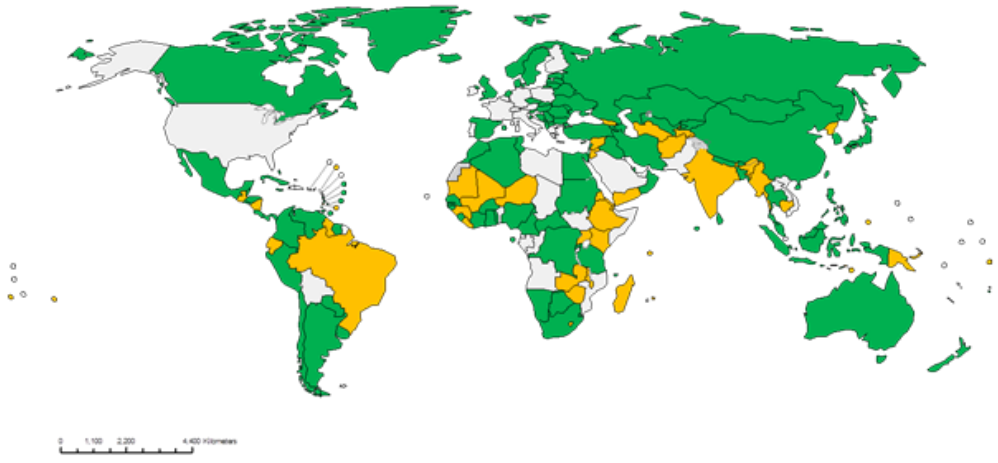


Fig. 9.4: Number of AEFI reported per 100 000 surviving infants by Member State, 2015



Source: WHO/UNICEF coverage estimates 2016 revision.

Fig. 9.5: Number of AEFI reported per 100 000 surviving infants by Member State, 2016



Source: WHO/UNICEF coverage estimates 2016 revision.

References

1. Global vaccine safety blueprint. Geneva: World Health Organization; 2012 (http://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf?ua=1, accessed 21 September 2017).

Tracking resources invested immunization: report on health account activities

WHO's Department of Health Governance and Financing is releasing, for the first time this year, data on health spending by disease categories on its Global Health Expenditure Database. It contains a dataset on immunization-related expenditures from 30 countries, with data from a five-year period. The database is available for download: http://www.who.int/health-accounts/ghed/en/.

Documenting and monitoring commitments for immunization

No report submitted for 2016 period.

Case studies and report for the GAVI CSO constituency

Civil society case studies

ETHIOPIA: Raising awareness of immunization through the use of innovative tools

Hanan Rahma providing routine immunization, March 2017

Hanan Rahma is a health extension worker (HEW) who has been working in the Sherkole Afendu Health Post for the last three years. Sherkole Afendu is located 50 km from Assosa town and is one of the hard-to-reach kebeles in Assosa woreda.

Conducting routine immunization used to be difficult in this kebele, according to Hanan, due to the inaccessibility of some villages and low awareness in the community. One time a mother asked Hanan to promise her that the vaccine that Hanan was administering would not kill her child. Hanan reassured her that the vaccine could actually save her child.

Awareness of the benefits of immunization has increased significantly due to the efforts of the International Rescue Committee (IRC). IRC introduced two tools to Hanan's community – the *Enat Mastawesha* and the *defaulter tracing tool (DTT)*. *Enat Mastawesha* is a color-coded health calendar distributed to all eligible households (i.e. houses with pregnant women or infants) in the village and used by HEWs and the Health Development Armies (HDAs) during home visits. These calendars serve as visual aids when explaining critical maternal and child health services including immunization. The *DTT* is a simple carbon-copy registration form used at the Health Post to record basic infant/caregiver information and missed vaccines in the community.

An HDA explaining the use of Enat Mastawesha and upcoming immunization appointments to a caregiver

Using these tools, and with the support of community leaders, Hanan says that HEWs have been able to mobilize the community for routine immunization. Hanan was also able to trace defaulter children in a timely manner, in order for the HEWs to get them caught up on missed vaccinations. In 2016, her Health Post performed well, achieving Pentavalent 3 coverage of 95%, with Pentavalent 1 – Pentavalent 3 dropout rate of just 4%.

Hanan feels fulfilled in her job and has seen how caregiver attitudes towards immunization in her community have been transformed for the better. Hanan has seen firsthand how the immunization tools have made her community more informed about the value of immunization in protecting their children and keeping them safe from vaccine-preventable illnesses.

Source: International Rescue Committee; article developed for World Immunization Week, April 2017

GHANA: Rewarding community members for their success in completing immunization schedules – a motivation for others

With support from Gavi, the Ghana Coalition of NGOs in Health (GCNH) has been able to expand their health and immunization promotion activities across the country. One innovative way to mobilize communities has been through recognition awards to community members. One example was an award given to a community member, Mr. Benji, who was recognized by GCNH for completing his daughter's immunization schedule at the child welfare clinics in the Abura Community of Cape Coast. At the award presentation, Mr. Benji said:

"Because of the motivation that I got from this immunisation programme organised by the Ghana Coalition of NGOs in Health, I have decided to be committed to it and champion it in my community. I will also encourage fathers to send their children to the child welfare clinic. I have received a lot of education from the nurses, which really motivated me, and as a result, I am committed to ensuring that my child is sent to the appropriate facility whenever she is due for immunisation. I am very grateful to you for this great opportunity and hope that it will serve as an opportunity for others to also emulate and do same."

The "best caregiver" award being presented to Mr. Benji by Dr. Daniel Asare, CEO of Cape Coast Teaching Hospital for completing his child's full immunization schedule for the year

Immunization at community-based child welfare clinics

This is just one of many activities conducted by the Ghana Coalition of NGOs in Health. In recent years, coalition members have helped to expand immunization coverage in six regions. Best practices such as strengthening community systems and structures, increasing male involvement in the demand for immunization, and utilizing innovative approaches to improve the quality of health care services have been implemented in over 100 communities to increase immunization coverage to over 90%. Through GCNH's

efforts, immunization services are now reaching areas previously classified as “hard-to-reach communities.”

Source: Ghana Coalition of NGOs in Health; article developed for World Immunization Week, April 2017

MALAWI: Utilizing innovative approaches to deliver multi-dose vaccines to hard-to-reach communities

The logistical challenge of ensuring that vaccines are delivered safely, on time and to the right people is especially difficult for communities who live in hard-to-reach areas, in temporary homes or who move around frequently. This is the case for the large community of fishermen who live and work on Lake Chilwa in Malawi. Known for being a hotspot for cholera outbreaks since the 1980s, the lake, which borders Mozambique, is home to almost 90 000 people. During the fishing season from March to May the lake sees a massive influx of fishermen, who settle along the shore, on the islands, or in floating homes on the lake, called *zimboweras*. This community's lifestyle makes it difficult for them to access safe water and sanitation, making them even more vulnerable to the disease and logistically more difficult to vaccinate.

A major outbreak starting in December 2015 prompted the Malawi Ministry of Health to ask for support from Agence de Médecine Préventive's (AMP) Vaxichol team and a group of international partners (MSF, UNICEF and WHO) to carry out an oral cholera vaccine (OCV) immunization campaign to control the outbreak. The community's remoteness and mobility made this effort particularly challenging given that OCV requires two doses, 14 days apart. The team determined that they needed an immunization strategy designed to reach people where they lived – the harbor, the islands, or the floating homes.

For the approximately 70 000 residents living in the harbor areas located on the shore, the two doses were given under medical supervision. On the islands, community leaders took charge of distributing the second dose, which had been delivered to them in cold boxes at the end of the first round. The islanders, more than 6,500, showed their immunization cards and those of other household members in order to receive the doses, which they took home and distributed. Those living in the *zimboweras*, estimated at about 6,000 at this time received the second dose in a plastic bag during the first round and were told to keep it at home and take it two weeks later.

Undoubtedly there were concerns about the islanders and those living in floating homes taking the doses without medical supervision. Almost half of the fishermen on the floating homes were worried about storing the vaccine so they decided that a solution would be to give their second dose to the owner of a cluster of floating homes for storage and distribution. The responsibility for the second dose rested with the community itself. Although this had never been done before, the campaign strategy worked.

The two doses of OCV reached the most people possible. Overall, 180 000 vaccines were delivered in a community where many of its citizens would have missed out on their second dose due to a logistical challenge. The approaches used in this campaign demonstrated immediate success in reaching mobile and hard-to-reach communities and is currently being studied to assess further impact.

Source: Agence de Médecine Préventive's (AMP); developed for World Immunization Week, April 2017

PAKISTAN: Understanding a mother's perspectives on immunization

In Pakistan, Civil Society Human and Institutional Development Program (CHIP), conducted interviews with mothers of children less than two years of age to gain an understanding of their perspectives on the benefits of immunization. This interview took place in the village of Baba Je Keli in Nowshera district, Khyber Pakhtunkhwa province.

Awareness-raising on importance of immunization under strict social norms and values

Interviewer (Sania): Hello. I am Sania and work with a humanitarian organization, CHIP. We are working in your area for the improvement of health of children under 23 months. You must have seen us working in your area? We meet every day in the house of the local health worker and I deliver sessions to the community about nine different deadly vaccine preventable diseases. Can you please tell me your name please?

- ***Interviewee (Tahira):*** *Hello! I am Tahira. I am a housewife and have 3 children. One of them is 11 months old. Yes, I have seen you in the house of health worker and also on the street while you were visiting people's homes.*

Sania: Can I ask you some questions related to the immunization of your children?

- ***Tahira:*** *Yes, sure, but I don't have much knowledge about immunization.*

Sania: It's ok! I just want to know the reason behind your decision to not vaccinate your elder daughter but to vaccinate your younger son?

- ***Tahira:*** *I will be honest with you. Iqra was my first child and at that time I was young. We used to live in a village, which was quite far away from the health center. My husband is a farmer and he used to spend his whole day in the fields. I wasn't aware of what vaccination was and why people vaccinate their children. When Hamad was born, I visited the health center with my neighbor who was taking her three-months old son to be vaccinated. On our way back, I asked my neighbor why she was getting her child vaccinated as her child was completely fine. Farhat, my neighbor, then told me that it's a protection against nine diseases that are deadly for children.*

Sania: So have you started vaccinating your children?

- ***Tahira:*** *Well it's still a new thing for me. I did not get Hamad vaccinated after seeing my friend's son get a severe fever the day after he was vaccinated. This created a question in my mind about whether it benefits or affects the health of child.*

Sania: So it means that you did not get Hamad vaccinated?

- ***Tahira:*** *I did get Hamad vaccinated regularly and he has now received five vaccines.*

Sania: Wow! So what actually encouraged you to get your child vaccinated? How were you convinced?

- ***Tahira:*** *Well two ladies visited our house. They were social workers who invited me to attend a session in which a health worker briefed us about the health of mothers and children.*

Sania: So what did you learn in that session?

- ***Tahira:*** *It was a very informative session. The health worker told us that every year millions of children die and the reason behind this are those nine diseases. She told us that every year the government spends a lot of money just to make sure children are vaccinated to prevent diseases. She further told us that after the child is vaccinated he/she might get ill for a day or two but will recover soon and it's a sign that the child is now safe. Even if a specific disease does infect the child, the strength of that disease will not be that strong as compared to a non-vaccinated child.*

Sania: So, did it convince you?

- ***Tahira:*** *Yes. Both me and my husband. I took my children to the health center.*

Sania: How do you feel after visiting the health facility?

- ***Tahira:*** *It was not a very pleasant experience. One person who was sitting in the hospital was very rude. One of the staff members asked us to come back again on Saturday in order to get my child vaccinated. This infuriated us as my husband had left his work to get our child vaccinated. We took a rickshaw to come to the health facility, which charged us PKR.200/-, and being poor, we can't afford it every day.*

Sania: *S*o did you go to the hospital next Saturday?

- ***Tahira:*** *Yes, I visited again but this time I went with my mother-in-law. She accompanied me, and this time Hamad was vaccinated. The doctor gave us a sheet of paper, which had two dates on it and asked us to visit again on those dates.*

Sania: Did you take Hamad again to the hospital on those dates?

- ***Tahira:*** *No*

Sania: Why?

- ***Tahira:*** *I did not take Hamad to the health facility again due to three reasons. Firstly, the hands of the children get swollen which really disturbs us. Secondly, I lost the paper, which had the two dates on it. Thirdly, I had no one to accompany me or take me to the hospital.*

Sania: So then how did Hamad get the remaining doses?

Woman is interviewed by local health worker according to local norms and values

- ***Tahira:*** *One day while I was busy doing household chores, I heard a loud speaker with the message to bring all children less than two years for vaccination to a communal place. Soon after that two ladies visited us, who had our names (my husband's, Hamad's and mine) and asked me to bring Hamad for vaccination. I told them that I had lost that page to which they smiled and told me not to worry. They gave me a colorful card and instructed me to keep it safe for the next time.*

Sania: So did this mean you got Hamad vaccinated then?

- ***Tahira:*** *Yes, I took Hamad again for vaccination and this time the staff were very polite. They referred to me as sister and requested I bring Hamad back again next month. They informed me that Hamad might get a temperature but there was nothing to worry about and he would be okay soon afterwards.*

Sania: So how was your experience of getting Hamad vaccinated and do you have any suggestions?

- ***Tahira:*** *It was a good experience overall. I suggest that the staff members should be trained how to talk to and behave with females, on what guidance to give to mothers, as well as ensuring health facilities have the basic equipment. The government should send doctors/vaccinators to areas that are away from hospitals.*

Source: Pakistan CSOs Coalition for Health and Immunisation (PCCHI); interviews conducted in conjunction with World Immunization Week, April 2017

UGANDA: Improving immunization services by listening to community voices

With an immunization utilization rate of only 33% and immunization coverage of 48% (HMIS, 2017), Namalemba village is one of the riskiest places in Uganda to be a child. However, in the past year, community members decided to change that. With the help of Synergy Uganda, a member of the

Uganda Civil Society Immunization Platform (UCSIP), a series of community dialogues was organized to gain perspectives on why Namalemba lagged behind other communities in immunization. These dialogues included officials from the District Health Team, health service providers (health workers and village health teams), community members and religious leaders. During these dialogues, participants learned about the new immunization law, which mandates immunization of children. Participants also shared their experiences accessing immunization services and discussed possible solutions to resolve issues, especially on how immunization defaulters could be identified and immunized.

Together, the participants highlighted several issues affecting the quality and utilization of immunization services in Namalemba:

- Inadequate mobilization of the community for immunization activities
- Inadequate sensitization about the benefits of full/complete immunization
- Stock out of some of the vaccines
- Inadequate follow up of immunization defaulters
- Poor record management and misinformation about immunization by some religious groups

Following the dialogues, workable solutions that could lead to improvement were discussed and an action plan developed. A quality improvement committee consisting of six representatives who took part in the dialogues was set up to monitor implementation.

"As a result, community members have been empowered to identify and report immunization defaulters to health workers and local leaders. In addition, health workers have reduced the waiting time for mothers when they bring their children for immunization by vaccinating children as they are brought to the health facility. This has impacted positively on the immunization indicators of Namalemba village" said Mr. Wateta George, Executive Director, Synergy Uganda.

With community members showing interest and concern in immunization, health workers have found helpful partners in identifying and following up on un-immunized children and those who have dropped out of the regular immunization schedule. This type of collaboration has been critical in raising the quality standard of immunization services and has set Namalemba on a path to increasing immunization utilization and coverage.

Community dialogue meeting at Namalemba Village
(*Photo by Tracy Namayanja*)

Source: Synergy Uganda; article developed for World Immunization Week, April 2017

GAVI CSO constituency and steering committee report

INTRODUCTION

The 2016 Midterm Review of the Global Vaccine Action Plan (GVAP) by the Strategic Advisory Group of Experts on Immunization (SAGE) noted significant concern that at the midpoint of the GVAP (2012-2020), progress towards reaching goals to eradicate vaccine preventable diseases (VPD) and increase access to vaccines is too slow – with the global average for immunization coverage growing at only 1% since 2010.[129] The report highlighted that only 16 countries have made measurable progress since 2010 including countries with the highest numbers of unvaccinated people – Democratic Republic of the Congo, Ethiopia and India.

Serious efforts on the part of all immunization partners will be needed to reach the GVAP goals by 2020 for all countries. To help guide this effort, the SAGE made nine recommendations with specific sub-recommendations attached to each. As part of recommendation five to, "Enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans," the SAGE specifically recommended that "Civil society organizations should describe how their work maps against different national immunization plans in their 2017 GVAP report, so that the geographic and programmatic scope of their work is more visible. Where possible, CSOs should also measure and share the impact of their work."

The Gavi CSO Constituency and Steering Committee welcomes the above SAGE recommendation and in response is leading the development of a "CSO reporting framework" with the input of WHO, UNICEF, Gavi, members of the SAGE GVAP reporting working group, and a wide range of immunization actors. This effort will culminate in the development of a set of tools to be used by CSOs at the country level to report their attributable contributions to their country's National Immunization Plan, and, by proxy, to the GVAP. In-country testing will take place in summer 2017 with Gavi-supported local CSO platforms in Burkina Faso, India and Sierra Leone, with virtual pre-testing run in Kenya and Nigeria prior to that. The resulting draft framework will be presented to the SAGE GVAP working group in the end of August, 2017.

While waiting for the development of the CSO reporting framework, the Gavi CSO Constituency and Steering Committee moved forward with its regular submission to the GVAP Secretariat report.

The purpose of this year's independent civil society report is to:

Summarize activities by civil society in support of countries' national immunization plans
Highlight key findings from the 2016 Gavi CSO Constituency Survey
Provide a status update on the 2016 CSO recommendations

The civil society report focuses on 15 focus countries identified by the World Health Organization (WHO). These include countries from three WHO regions:

1. Africa region (AFRO) – Benin, Burkina Faso, Ethiopia, Ghana, Kenya, Madagascar, Malawi, Mali, Nigeria, Sierra Leone, Togo, Uganda and Zambia
2. Eastern Mediterranean (EMRO) – Pakistan

[129] 2016 Midterm Review of the Global Vaccine Action Plan: Strategic Advisory Group of Experts on Immunization - http://www.who.int/immunization/global_vaccine_action_plan/sage_assessment_reports/en/

3. South East Asia (SEARO) – India

METHODOLOGY

Similar to the independent civil society submissions to the annual GVAP Secretariat reports since 2014, the Gavi CSO Constituency Coordinator and the Gavi CSO Steering Committee directed and oversaw the work of an external consultant who prepared this report. The work of the consultant was funded by the Immunization, Vaccines and Biologicals (WHO/IVB) Department of the World Health Organization (WHO).

The consultant carried out a desk review of civil society documents, reports and national immunization plans. These included civil society materials prepared for World Immunization Week (April 2017), results from the 2016 Gavi CSO Constituency survey, and current national comprehensive multi-year immunization plans (cMYPs).

SUPPORT FOR CIVIL SOCIETY IN COMPREHENSIVE MULTI-YEAR NATIONAL IMMUNIZATION PLANS

In order to understand the country-specific contexts in which civil society is working, comprehensive multi-year national immunization plans (cMYP) in effect in 2016 for the 15 focus countries were reviewed for mention of key words related to support for civil society-implemented immunization activities and their various roles in immunization service delivery.[130][131]

Key words searched for:

- "civil society"
- "community"
- "CSO" (civil society organization)
- "NGO" (non-governmental organization)
- "CBO" (community-based organization)
- "FBO" (faith-based organization)

The review revealed the range of activities by civil society in the implementation of national immunization programs. Countries whose plans were developed after 2013 were guided by the GVAP checklist[132], which includes several suggested civil society activities in support of GVAP strategic objectives (SOs) 1-3:

- SO1) Support local civil society organizations and professional associations to contribute to national discussions on immunizations and health.
- SO2) Engage, enable and support in-country CSOs to advocate to local communities and policy-makers and in local and global media regarding the value of vaccines.
- SO2) Create national or regional advocacy plans that involve in-country CSOs.
- SO3) Involve CSOs in community outreach and planning.
- SO3) Train health workers and CSOs on how to engage communities, identify influential people who can assist in planning, organizing and monitoring health and immunization programs, identify community needs and work with communities to meet those needs.

[130] Gavi Alliance website – http://www.gavi.org/country/

[131] Country Planning Cycle Database, A World Health Organization Resource - http://www.nationalplanningcycles.org/

[132] WHO-UNICEF guidelines for developing a comprehensive multi-year plan (cMYP), update September 2013 - http://www.who.int/immunization/programmes_systems/financing/tools/cmyp/en/

Many comprehensive multi-year immunization plans (cMYPs) describe how civil society organizations (CSOs) contribute to implementation (see Section II below). CSOs are recognized as important partners in many of the national immunization plans, but challenges remain insofar as ensuring access to sustainable funding, and support to monitor their activities, including documenting and reporting data in a systematic way that aligns with countries' timelines and methods for annual national data collection and reporting.

Overall, activities conducted by civil society as described in national cMYPs include surveillance of vaccine preventable diseases (VPD), social and community mobilization, immunization promotion, advocacy, and community-based monitoring of adherence to immunization schedules. Table 1 includes a summary of CSO activities that are described in national cMYPs. cMYPs not available for 2016 are indicated in *italics.*

It is important to note that while these activities are listed in cMYPs, the extent to which they have been realized has not been verified by in-country CSOs or an external evaluator. This reinforces the need for CSOs to be funded and supported by governments, and donor and technical partners to be able to monitor effectively their contributions to national cMYPs.

Table 1. Country cMYPs in effect in 2016 where civil society roles are noted

Country	cMYP timeframe	Support for and roles of civil society organizations as described in cMYPs
AFRO (13)		
Benin	2014-2018	• Community is involved to help identify treatment defaulters using the Reaching Every District (RED) approach. • Civil society supported to raise community awareness of VPD. • Government works with religious leaders in campaigns to promote immunization. • Community support networks funded to conduct community-based surveillance of Maternal and Neonatal Tetanus (MNT) cases, promote routine immunization especially among parents who have not brought their children in for immunization. • Civil society conducts social mobilization for greater community participation in immunization. • Government establishes contracts with NGOs to implement the immunization program.
Burkina Faso	*2011-2015*	• *Community-based associations involved in VPD surveillance, communication activities to promote immunization.*
Ethiopia	2016-2020	• CSOs and NGOs involved in community-based surveillance of VPD. • NGOs engaged in delivery of immunization services at district and health facility levels.
Ghana	2015-2019	• CSOs engaged to promote demand and sustain the uptake of immunization services through social mobilization, advocacy and communication activities at community level as well as in hard-to-reach areas. • CSOs provide direct immunization services including supplementary immunization activities.
Kenya	2013-2017	• NGO- and FBO-run facilities supported to deliver immunization services. • Community members and NGOs engaged to conduct advocacy, communication and social mobilization activities such as community meetings and drama to increase demand for immunization.
Madagascar	2012-2016	• Communities, NGOs and civil society involved in immunization promotion activities and participate in the active surveillance of EPI priority diseases. • Community workers and NGOs trained and equipped to conduct social mobilization activities to improve immunization coverage especially in hard-to-reach areas using mobile and other strategies.
Malawi	2012-2016	• Community members and NGOs engaged to conduct advocacy, communication and social mobilization activities such as community meetings and drama to

		increase demand for immunization.
Mali	2012-2016	• NGOs supported to conduct social mobilization activities and immunization campaigns to raise awareness of the benefits of immunization using the RED approach. • Community associations manage and operate community-level health facilities.
Nigeria	2016-2020	• Local CSOs and professional associations supported to contribute to national discussions of immunizations and health. • CSOs trained on the use of tools to track and report immunization activities (as part of the accountability framework developed under the previous cMYP to strengthen accountability at all levels of the routine immunization system). • NGOs and CBOs involved in social and community mobilization to create awareness, participation and demand for routine immunization at community level • CBOs engaged to mobilize caregivers to access and utilize integrated services and assist in newborn / defaulter tracing and follow-up in their communities. • Government trains CBOs to build their capacity in community surveillance of VPD.
Sierra Leone	2012-2016	• NGOs conduct refresher EPI trainings, and participate in surveillance, and in routine and supplemental immunization service delivery. • NGOs support mobile teams for hard-to-reach communities. • NGOs play a role in transportation of EPI materials and supplies. • NGOs, CBOs and FBOs supported to carry out home visits, identify unreached children and conduct defaulter tracing.
Togo	*2011-2015*	• *NGOs involved in surveillance as part of an integrated monitoring effort with political and traditional authorities and traditional healers.* • *NGOs conduct advocacy, communication for behavior and social change and social mobilization activities.*
Uganda	2012-2016	• CSOs and professional associations supported to contribute to national discussions on immunizations and health. • CSOs engaged, enabled and supported to advocate to local communities and policy-makers and in local and global media regarding the value of vaccines. • CSOs involved in community outreach and planning. • CSOs trained to engage communities, identify influential people who can assist in planning, organizing and monitoring health and immunization programs, identify community needs and work with communities to meet those needs.
Zambia	*2011-2015*	• *Civil society involved in community awareness on VPD to increase immunization demand and utilization of immunization services.*
EMRO (1)		
Pakistan	2014-2018	• CSOs and professional associations supported to contribute to national discussions on immunizations and health. • CSOs involved in raising awareness about the value of vaccines among communities, policy makers, local and global media. • CSOs are part of national and regional advocacy plans. • CSOs participate in monitoring EPI activities and conduct community outreach and planning. • CSOs contracted to carry out social marketing and behavior change activities especially in urban slums. • CSOs trained to engage communities, identify influential people who can assist in planning, organizing and monitoring health and immunization programs, identify community needs and work with communities to meet those needs.
SEARO (1)		
India	2013-2017	• CSOs advocate for policy changes and greater transparency to hold governments and other healthcare stakeholders to account. • CSOs provide direct immunization services. • CSOs conduct community education and mobilization to increase acceptance of

		vaccines and immunization demand through the introduction of Accredited Social Health Activists (ASHA) as community health workers. • CSOs conduct community-based VPD surveillance and reporting.

2016 Gavi CSO Constituency Survey

An annual survey was administered to CSO members of the Gavi-supported national civil society immunization platforms in 14 of the 15 focus countries. The survey was not administered in Pakistan owing to logistical challenges on the part of the survey administrators. A summary of contributions by the Pakistan national civil society immunization platform is included in Section V below. Administration of the survey in the 14 countries was led by trained survey focal points that oversaw data collection by trained enumerators in each country.

All 14 countries, with the exception of Ghana, were sent the *same* survey tool. Ghana piloted the survey and the results informed the tool's revision. In the end, the tool was shortened and included more pre-defined responses. Due to time and logistics issues, Ghana was unable to re-administer the survey using the final version; therefore, Ghana used the earlier version of the survey.

A sample size of CSOs associated with each national platform was pre-determined using Raosoft sample size calculator. Of the total sample size, 994 CSOs responded for an overall response rate of 81%. It is important to note that one completed survey represents one CSO platform member.

The response rate for Madagascar, Nigeria and Togo was 100% and for Benin and Sierra Leone, the response rate was above 100% - for these countries, the number of CSOs participating in the survey was higher than the determined sample size. The response rate for Burkina Faso, Ethiopia, Ghana, Malawi, Mali, Uganda, Zambia and India was above 50%. For Kenya, the response rate was below 50%. Major reasons for non-response in all countries were: outdated membership lists and/or inaccurate contact information; and poor Internet connectivity. Table 2 provides a complete country-by-country summary of the number of CSOs that participated in the survey.

Table 2. CSOs participating in the 2016 Gavi CSO Constituency Survey (in # and % as indicated)

Country	Total # of CSO platform organizational members	# CSOs targeted by the survey (95% CI)	# of CSOs participating in survey	*% of CSOs in sample size participating in survey*
AFRO (13)				
Benin	95	77	83	***107.79***
Burkina Faso	35	33	28	***84.85***
Ethiopia	28	28	23	***82.14***
Ghana*	467	159	103	***64.78***
Kenya	98	79	21	***26.58***
Madagascar	178	51	51	***100.00***
Malawi	44	40	34	***85.00***
Mali	1467**	229	214	***93.45***
Nigeria	26	26	26	***100.00***
Sierra Leone	219	140	143	***102.14***
Togo	26	26	26	***100.00***
Uganda	291	166	97	***58.43***
Zambia	40	40	30	***75.00***
EMRO (1)				

Pakistan***	81	N/A	N/A	N/A
SEARO (1)				
India	198	131	115	***87.79***
TOTAL	3212	1225	**994**	***81.14***

* Ghana used an earlier version of the survey.

** The Mali platform combines three sub-networks of organizations at each administrative level – community, district and regional. There are hundreds of community health associations, which manage community-level health facilities. They are linked by organizations in each district and region, and coordinated by the national Mali platform. This highly decentralized system is why there are over 1000 CSO platform members.

*** The survey was not administered in Pakistan due to logistical challenges by survey administrators.

Survey Results

For this year's CSO independent submission, several key results from the survey are summarized in the Tables below. It is important to note that the majority of CSOs self-identified primarily as community associations and NGOs although the other choices for types of organizations, including academia, charity, professional association, advocacy group, foundation and religious organization, also applied. The survey defined a community association as "a nongovernmental association of participating members of a community, such as a neighborhood, village, condominium, cooperative, or group of homeowners or property owners in a delineated geographic area." A nongovernmental organization (NGO) was defined in the survey as a non-profit organization that is independent from states and international governmental organizations; usually funded by donations but some avoid formal funding altogether and are run primarily by volunteers.

Responses to survey questions were based on the perspectives and experiences of the individual completing the survey on behalf of his/her CSO, many of whom was the director of the CSO.

1. Has your CSO ever encountered any children who had never been vaccinated?

The survey asked if the CSO had encountered children who had never been vaccinated. All CSOs in Nigeria who completed the survey responded yes. More than 85% of CSOs in Burkina Faso, Ethiopia, Kenya, Madagascar, Sierra Leone and Togo responded yes. For CSOs responding "yes", the survey asked CSOs to indicate their follow up actions based on a pre-defined list. Table 3 captures the percent of CSOs responding "yes" to the question for each country, and subsequently the percent of CSOs participating in the survey that indicated a specific follow up action.

Table 3. CSOs encountering children who had never been vaccinated and follow up actions (in %)

Country	Yes	Initiated an immunization catch up schedule	Referred them to the nearest health center	Adequately counseled the caregivers on steps to take
AFRO (13)				
Benin	79.52	6.02	28.92	44.58
Burkina Faso	85.71	3.57	28.57	53.57
Ethiopia	86.96	21.74	39.13	21.74
Ghana	N/A*	N/A*	N/A*	N/A*
Kenya	90.48	14.29	38.10	33.33
Madagascar	96.08	5.88	68.63	17.65
Malawi	67.65	2.94	41.18	17.65
Mali	42.72	7.04	7.51	27.70
Nigeria	100.00	3.85	46.15	42.31

Sierra Leone	85.31	9.79	57.34	18.18
Togo	88.46	30.77	34.62	23.08
Uganda	71.13	7.22	38.14	22.68
Zambia	70.00	13.33	50.00	6.67
EMRO (1)				
Pakistan	N/A	N/A	N/A	N/A
SEARO (1)				
India	64.35	23.48	19.13	21.74

* This question was not included in the earlier version of the survey completed by Ghana platform members.

2. Why were the children not vaccinated?

The survey asked the CSO to indicate why children were not vaccinated based on their experiences and interactions with caregivers. A defined list of reasons given for children not being vaccinated were provided in the survey and organized around three main categories: 1) due to lack of information (Table 4); 2) due to lack of motivation (Table 5); and 3) other obstacles (Table 6). The categories and their related reasons were drawn from the October 2009 *Literature Review: Reasons children are not vaccinated in low and middle-income countries* which was carried out by the USAID-funded IMMUNIZATION basics project at the request of the SAGE and commissioned by WHO.

In Table 4, for unvaccinated children due to lack of information, the top three reasons were that caregivers were unaware of the need for vaccination, fear of side effects and caregivers had wrong ideas about contraindications. In Table 5, for unvaccinated children due to lack of motivation, cultural and religious beliefs and rumors about the effects of immunization were the top reasons. Finally, other obstacles in Table 6, far distances to reach the place of immunization and caregivers being too busy, were the main reasons that children were not vaccinated.

The percent totals at the bottom of each table represent the percent of CSOs responding to a particular reason among all CSOs who completed the survey (i.e. 994 CSOs).

Table 4. CSOs reporting children were not vaccinated due to lack of information

Country	Fear of side effects	Misunderstanding of available information	Place and/or time of immunization unknown	Unaware of need for vaccination	Wrong ideas / perceptions about contraindications
AFRO (13)					
Benin	29	18	23	29	37
Burkina Faso	8	8	6	14	8
Ghana	40	43	23	41	49
Ethiopia	8	10	8	14	11
Kenya	5	9	9	12	11
Madagascar	19	9	3	9	8
Malawi	6	4	4	10	10
Mali	7	47	23	26	14
Nigeria	8	8	4	12	8
Sierra Leone	64	49	26	52	58
Togo	10	9	7	8	11
Uganda	32	21	13	29	33
Zambia	11	7	4	12	10
EMRO (1)					

Pakistan	N/A	N/A	N/A	N/A	N/A
SEARO (1)					
India	52	20	15	61	30
TOTAL # CSOs	**299**	**262**	**168**	**329**	**298**
% of CSOs participating in the survey	**30.08**	**26.36**	**16.90**	**33.10**	**29.98**

Table 5. CSOs reporting children not vaccinated due to lack of motivation

Country	No faith in immunization (cultural/religious reasons)	Personal grudges between caregivers & vaccinator	Postponed until another time	Rumors
AFRO (13)				
Benin	23	8	13	37
Burkina Faso	12	0	3	11
Ethiopia	2	2	5	5
Ghana	33	16	14	34
Kenya	11	4	9	4
Madagascar	17	4	3	37
Malawi	13	0	2	5
Mali	0	2	1	4
Nigeria	9	3	4	5
Sierra Leone	47	26	36	25
Togo	12	2	14	11
Uganda	36	5	14	21
Zambia	8	0	2	5
EMRO (1)				
Pakistan	N/A	N/A	N/A	N/A
SEARO (1)				
India	40	8	27	43
TOTAL # CSOs	**263**	**80**	**147**	**247**
% of CSOs participating in the survey	**26.46**	**8.05**	**14.79**	**24.85**

Table 6. CSOs reporting children not vaccinated due to other obstacles

Country	Caregiver too busy	Child ill; brought but not given immunization	Child ill; not brought	Family problems (e.g. illness of caregiver)	Long waiting time	Place of immunization too far	Time of immunization inconvenient	Vaccinator not available	Vaccine not available
AFRO (13)									
Benin	27	7	15	15	12	31	15	4	2
Burkina Faso	9	2	2	4	5	5	4	1	3
Ethiopia	5	1	4	5	1	12	8	7	8
Ghana	27	6	13	27	26	27	25	6	9
Kenya	9	1	5	7	4	12	8	3	7
Madagascar	20	1	2	2	8	29	7	7	4
Malawi	3	0	1	2	0	13	3	4	5

Mali	1	0	0	1	0	1	2	2	3
Nigeria	4	0	2	2	4	6	2	2	4
Sierra Leone	73	1	5	13	33	57	30	15	26
Togo	11	3	5	6	6	8	5	2	6
Uganda	16	2	11	17	13	22	13	4	14
Zambia	0	0	0	0	3	15	0	1	4
EMRO (1)									
Pakistan	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SEARO (1)									
India	9	6	29	46	2	31	20	8	12
TOTAL # CSOs	**214**	**30**	**94**	**147**	**117**	**269**	**142**	**66**	**107**
% of CSOs participating in the survey	**21.53**	**3.02**	**9.46**	**14.79**	**11.77**	**27.06**	**14.29**	**6.64**	**10.76**

3. Which of the following activities does your organization do?

The survey asked CSOs a series of Yes/No questions about their involvement in specific, pre-defined activities that were organized around GVAP strategic objectives (SO) 1-4. For SO1, CSOs mostly carried out immunization-related information sharing for better CSO coordination and implementation of promising practices; a lesser number of organizations participated in national-level discussions on immunization and health. For SO2, CSOs indicated that most of their activities were in community education on immunization followed by advocacy towards local and national authorities and least, social research on immunization delivery. For SO3, CSOs mainly mobilized communities and raised awareness and interest in immunization through sensitizations and education and to a lesser extent conducted direct administration of vaccines. Finally for SO4, CSOs carried out the majority of activities in tracking community members who had defaulted on their immunization schedule. Country-by-country details for each SO and related activities are provided in the following Tables 7-10.

Table 7. Strategic Objective 1 (SO1): All countries commit to immunization as a priority (% CSOs responding)

Country	Participate in national-level discussions on immunization and health	Share immunization-related information with other CSOs, such as best practices related to immunization	Work with local, district or national level EPI to do joint planning
AFRO (13)			
Benin	27.71	87.95	20.48
Burkina Faso	64.29	71.43	39.29
Ethiopia	73.91	82.61	82.61
Ghana	N/A*	N/A*	N/A*
Kenya	71.43	57.14	71.43
Madagascar	52.94	84.31	70.59
Malawi	52.94	61.76	91.18
Mali	77.57	86.45	82.24
Nigeria	34.62	88.46	73.08

Sierra Leone	83.92	96.50	83.22
Togo	30.77	69.23	61.54
Uganda	54.64	90.72	86.60
Zambia	76.67	96.67	93.33
EMRO (1)			
Pakistan	N/A	N/A	N/A
SEARO (1)			
India	29.57	90.43	51.30

* This option was not given in the earlier version of the survey completed by Ghana platform members.

Table 8. Strategic Objective 2 (SO2): Individuals and communities understand the values of vaccines and demand immunization as both their right and responsibility (% CSOs responding)

Country	Educate communities, households, & individuals on immunization	Advocate to local, district or national level leaders & policy makers on the importance of vaccination	Conduct social research to improve the delivery of immunization services
AFRO (13)			
Benin	98.80	50.60	37.35
Burkina Faso	92.86	71.43	28.57
Ethiopia	73.91	60.87	39.13
Ghana	56.31	67.96	3.88
Kenya	76.19	61.90	28.57
Madagascar	98.04	98.04	21.57
Malawi	73.53	73.53	17.65
Mali	98.60	97.66	77.10
Nigeria	96.15	96.15	61.54
Sierra Leone	100.00	91.61	48.25
Togo	100.00	23.08	19.23
Uganda	95.88	90.72	41.24
Zambia	100.00	83.33	46.67
EMRO (1)			
Pakistan	N/A	N/A	N/A
SEARO (1)			
India	97.39	66.09	24.35

Table 9. Strategic Objective 3 (SO3): The benefits of immunization are equitably extended to all people (% CSOs responding)

Country	Work with underserved & marginalized groups to increase their interest and ability to access vaccination (e.g. sensitization & mobilization; education on immunization-related myths & taboos; immunization campaigns in hard to reach areas)	Address gender-related barriers to immunization	Mobilize communities to participate in vaccination campaigns or other immunization-related events	Administer vaccines to underserved and marginalized populations (routine vaccination)	Administer vaccines to underserved and marginalized populations (vaccine campaigns)
AFRO (13)					
Benin	85.54	57.83	95.18	9.64	13.25
Burkina Faso	75.00	50.00	89.29	14.29	14.29
Ethiopia	69.57	39.13	65.22	21.74	6.80
Ghana	N/A*	41.75	77.67	N/A*	N/A*
Kenya	76.19	57.14	76.19	33.33	33.33
Madagascar	96.08	82.35	98.04	15.69	29.41
Malawi	73.53	73.53	76.47	17.65	17.65
Mali	83.64	88.79	94.39	84.58	85.05
Nigeria	96.15	88.46	100.00	23.08	38.46
Sierra Leone	97.90	88.81	97.20	5.59	4.90
Togo	80.77	57.69	88.46	61.54	57.69
Uganda	92.78	82.47	92.78	30.93	36.08
Zambia	93.33	93.33	90.00	0.00	0.00
EMRO (1)					
Pakistan	N/A	N/A	N/A	N/A	N/A
SEARO (1)					
India	96.52	83.48	95.65	5.22	7.83

* This option was not given in the earlier version of the survey completed by Ghana platform members.

Table 10. Strategic Objective 4 (SO4): Strong immunization systems are an integral part of a well functioning health system (% CSOs responding)

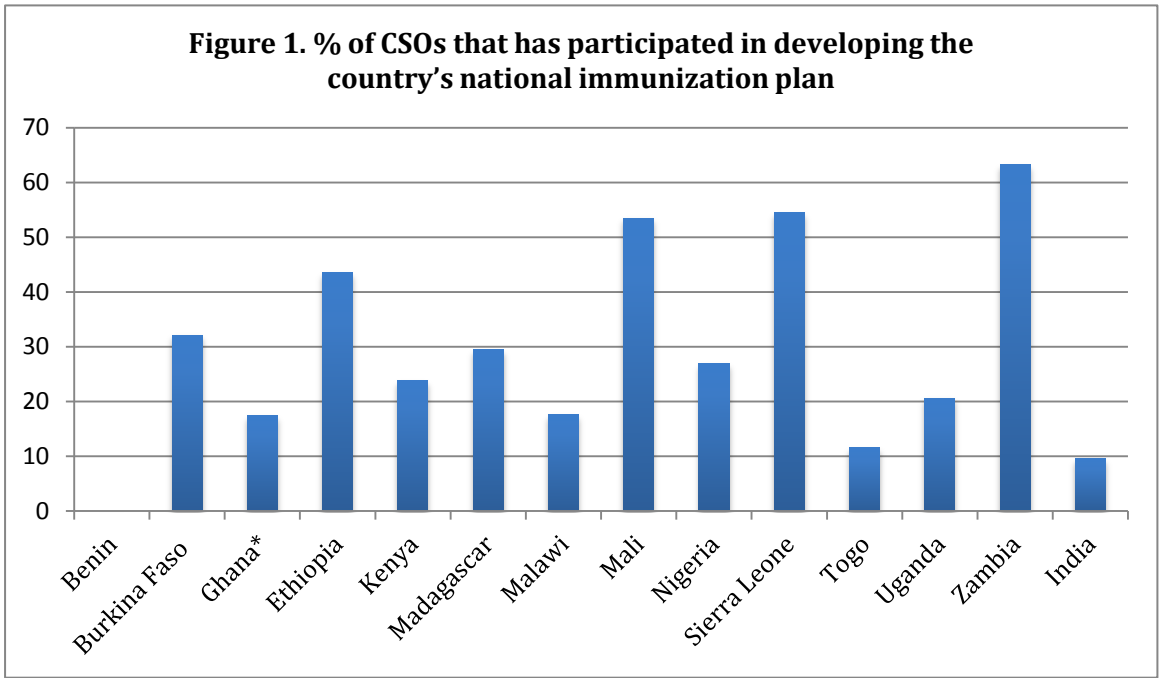
Country	Administer vaccines to populations that are NOT underserved or marginalized (routine vaccination)	Track and follow up with clients who have defaulted on their vaccinations	Train health care workers or community health volunteers in immunization-related topics	Assistance in transporting vaccines from the main center to the site where they are administered
AFRO (13)				
Benin	8.43	55.42	20.48	7.23
Burkina Faso	10.71	46.43	25.00	7.14

Ethiopia	17.39	60.87	91.30	60.87
Ghana	N/A*	29.13	N/A*	8.74
Kenya	33.33	33.33	71.43	47.62
Madagascar	9.80	62.75	62.75	43.14
Malawi	8.82	50.00	26.47	35.29
Mali	86.92	90.19	99.53	97.66
Nigeria	26.92	92.31	84.62	38.46
Sierra Leone	4.90	62.94	20.28	13.99
Togo	53.85	73.08	57.69	50.00
Uganda	26.80	61.86	59.79	46.39
Zambia	0.00	76.67	70.00	60.00
EMRO (1)				
Pakistan	N/A	N/A	N/A	N/A
SEARO (1)				
India	6.09	65.22	80.87	12.17

* This option was not given in the earlier version of the survey completed by Ghana platform members.

4. Has your organization ever participated in developing your country's national immunization plan?

The survey posed a question on CSOs' participation in the development of national immunization plans. This went beyond a question on whether CSOs were invited to a meeting where the national immunization plan was presented and discussed, but to actual direct involvement in the plan's development. India CSOs indicated the lowest participation while Mali, Sierra Leone and Zambia indicated over 50% involvement. While this information is interesting to give a sense of the extent of CSO participation in plan development, the true level of participation is difficult to measure given that CSOs are organized into platforms so that they are able to create one unified voice and have representatives speak on their behalf. The establishment of national platforms was grounded in the need to coordinate and organize CSOs, which is especially important in countries with hundreds of CSOs operating at all administrative levels. National platform representatives are most likely involved whereas individual organizational members may have not. Figure 1 includes country-by-country percentages of CSOs reporting participation in national plan development out of the total number of CSOs participating in the survey for each country.



* The question in the survey completed by the Ghana platform was "Has your organization ever been invited to a country-level GVAP planning meeting?" [The figure indicates the percentage of CSOs responding "yes" to being invited and attending the meeting out of the total number of CSOs completing the survey (103).]

I. PAKISTAN NATIONAL CIVIL SOCIETY IMMUNIZATION PLATFORM

Established informally in 2011, the Pakistan CSOs Coalition for Health and Immunization (PCCHI) serves as the national civil society immunization platform. PCCHI currently has 81 member CSOs from four provinces: Balochistan, Khyber Pakhtunkhawa (KPK), Punjab and Sindh, and received formal registration in 2016 as an independent not-for-profit and non-government organization. Similar to other national civil society immunization platforms, PCCHI members carry out independent community development programs in their geographic areas in addition to their immunization activities in order to serve their communities based on a range of health and development needs.

PCCHI is a member of the National Interagency Coordination Committee (NICC), which meets quarterly to carry out the following; however PCCHI and CSOs highlight that they never directly participated in the development of national immunization plans, which should be noted is contrary to what is indicated in the country's cMYP (see Section III above):

- Coordinate support at national level from government and partner agencies to strengthen EPI and polio eradication activities in Pakistan.
- Mobilize the national government and NGOs to eradicate polio and control other vaccine-preventable disease.
- Assist Pakistan in becoming self-sufficient in its immunization programs.
- Establish a forum for exchange of information and dialogue on immunization programs in the country and facilitate that dialogue by making data information sources readily available.
- Ensure the availability of appropriate policies, advice and tools to the Pakistan government.
- Assist the international and national community in identifying and developing support for new disease control programs when appropriate intervention tools, such as new vaccines become available.
- Advise the government in specific areas related to EPI and Polio Eradication where partner agencies have specialized expertise.

- Review progress towards Polio Eradication. Improving EPI and plans for further activities.

Since 2011, Pakistan CSOs have been working to strengthen routine immunization. PCCHI has conducted a range of immunization activities including:

1. Secondary desk research studies on status and barriers to immunization
2. Advocacy on the importance of immunization through print media and radio spots
3. Primary research on the status and barriers to immunization in urbans slums of Sindh and Punjab
4. Demand promotion activities at different events like Pneumonia Day and World Immunization Week
5. Vaccination of children in partnership with District EPI Teams

II. STATUS ON 2016 CIVIL SOCIETY RECOMMENDATIONS

In the 2016 Gavi CSO Constituency independent submission for the GVAP report, the Gavi CSO Constituency proposed three recommendations. These recommendations and a status update are included below.

Recommendation 1: A meeting should be organized with the Gavi CSO Steering Committee and the SAGE GVAP working group to discuss how recommendations from 2014 and 2015 can be supported, implemented and monitored as appropriate and relevant at the country, regional and global levels.

STATUS: While representatives from the Gavi CSO Steering Committee are regularly invited to observe SAGE GVAP working group meetings, there has not yet been a discussion specifically around recommendations made by CSOs in their 2014, 2015, and 2016 submissions, and how these recommendations can be acted upon.

Recommendation 2: Guidance should be made available to country-level immunization and Health Systems Strengthening (HSS) staff regarding how to work with CSOs to strengthen immunization and health programs, with a focus on engaging local CSOs. As this guidance does not currently exist, the Gavi CSO Steering Committee would welcome an opportunity to collaborate with WHO, the SAGE GVAP working group and the GVAP Secretariat to produce it.

STATUS: Partially implemented. From the CSO side, CRS has conducted a SMILER training with each Gavi- supported CSO platform to strengthen their M&E capacity and facilitate them to create an M&E system, including tools and procedures. SMILER is explained here: https://www.crs.org/our-work-overseas/research-publications/propack-iii. From the government and WHO side, we are not aware of whether this recommendation has been implemented.

Recommendation 3: Provide support to, and work with, in-country CSOs to help them regularly collect data that they analyze and report on in order to clearly communicate their contributions to immunization- and health-systems strengthening. Small grants should be provided for CSO trainings on data collection, analysis, monitoring and reporting.

STATUS: The Gavi CSO Constituency with the active involvement of a broad range of immunization stakeholders is developing a framework for CSO reporting on attributable contributions to national Immunization plans. It is hoped that this will be a first step to achieving the above-mentioned recommendation. This effort also responds to the SAGE recommendation in the 2016 Midterm Review of the GVAP.

Independent submissions

American Red Cross - Independent Submissions from other Stakeholders

Nairobi, Kenya - April 2016

In 2016 the American Red Cross as part of the Measles & Rubella Initiative (MRI) contributed towards Goals 2, 3, and 5 of the Global Vaccine Action Plan (GVAP), activities focused on Strategic Objective 2 Demand for Immunization. Working through the Red Cross Movement formal partnerships with Red Cross national societies were established to train and mobilize volunteers to support measles and rubella vaccination campaigns within targeted areas. Volunteers conducted social mobilization activities providing information to communities and encouraging caregivers to bring eligible children to vaccination posts, thereby increasing demand within supported areas.

Social mobilization campaigns coincided with measles/measles and rubella Supplemental Immunization Activities (SIA) in four countries Kenya, Namibia, Zambia, and the Democratic Republic of the Congo. In general the activities conducted by the volunteers focused on house to house visits within intervention areas. Volunteers were mobilized within their own communities to provide a built-in level of trust that enables them to better engage community members and increase demand through education and encouragement. The table below provides an overview of the activities conducted in each of the supported countries.

National Society Supported by American Red Cross	Supplementary Immunization Intervention*	Number of Subnational Areas Targeted	Households Visited	Number of Volunteers Recruited	Targeted Population
Kenya Red Cross Society	MR	3	225,989	1,548	2,237,376
Namibia Red Cross Society	MR	9	164,163	1,191	1,436,916
Zambia Red Cross Society	MR	1	196,544	1,365	832,215
DRC Red Cross Society	M	1	421,785	2,163	800,866
Total		**14**	**1,008,481**	**6,267**	**5,307,373**

*M = measles vaccine; MR = combined measles rubella vaccine

Through informal comparison of data from Red Cross supported versus unsupported geographic areas in a country, an average increase of up to 10% in coverage rates has been observed in Red Cross supported areas. Additionally convenience sample interviews of caregivers at vaccination posts found that information provided by Red Cross volunteers one of the most frequently cited sources of information about the vaccination campaigns. American Red Cross has begun a formal analysis with the U.S. Centers for Disease Control and Prevention to better quantify these results.

CDC's global immunization activities focus on supporting global and regional immunization goals, and national immunization programs, that prevent death, disability and disease through the delivery of safe and effective vaccines. These investments in global immunization contribute to the goals of the Decade of Vaccines and the Global Vaccine Action Plan (GVAP).

Goal 1—Achieving a Polio-Free World

- CDC is the U.S. lead scientific agency[133] in the global effort to eradicate polio. CDC is a core partner of the Global Polio Eradication Initiative (GPEI) along with the WHO, UNICEF, Rotary International, and the Bill and Melinda Gates Foundation (BMGF). GPEI works with Ministries of Health and partners to achieve polio goals.
- CDC is working to support GPEI efforts to interrupt poliovirus transmission in the three remaining polio endemic countries – Afghanistan, Pakistan, and Nigeria; end vaccine-derived poliovirus outbreaks; and to prevent, detect, and respond to poliovirus importations in polio-free countries.
- CDC's Global Reference Laboratory for polio: plays a significant role in providing quality assurance, diagnostic confirmation, and genomic sequencing of samples obtained worldwide, as well as formulating the standards for laboratory containment of poliovirus.
- CDC is leading GPEI's work on a containment activities to minimize the risk of accidental or intentional poliovirus release from laboratories and vaccine production facilities.
- CDC is leading GPEI efforts to document and transition the knowledge, lessons learned, assets and infrastructure accumulated by the initiative to address other health goals, while sustaining polio functions still needed after polio eradication is achieved.

Goal 2—Meet Global and Regional Elimination Targets

- **Measles and Rubella:** CDC is the U.S. lead scientific agency[134] for the Measles and Rubella Initiative. CDC's programmatic support for measles is also provided through the Global Health Security Agenda's immunization package for which measles vaccination coverage is the performance measure for immunization program improvement.
- **CDC's Global Measles Reference Laboratory** serves as one of the leading reference laboratory for measles and rubella worldwide. It provides confirmatory testing of specimens as well as training for country and regional laboratory personnel, conducts essential measles and rubella research, and provides global public health laboratories access to molecular testing and molecular proficiency testing
- CDC works with WHO regions to monitor measles incidence and risk through developing and analyzing surveillance data, estimating burden of disease and deaths, and participates in verifying national and regional elimination. CDC also helps partners monitor **rubella and congenital rubella syndrome** disease burden through seroprevalence surveys.

[133] http://www.cdc.gov/polio/why/
[134] http://www.measlesrubellainitiative.org/learn/about-us

Goal 3—Meet Vaccination Coverage Targets at Every Level

- CDC helped develop the Global Routine Immunization Strategies and Practices companion document to the GVAP which highlights routine immunization service delivery as the foundation for sustained decreases in morbidity and mortality from vaccine preventable diseases (VPDs) across the lifecycle of all individuals.
- CDC supports country efforts to increase vaccination coverage through routine immunization services by developing and advocating for the scale up of interventions to: 1) address community- and health sector-based barriers to vaccine access and utilization; 2) minimize missed opportunities for vaccination; and 3) provide catch-up vaccination (e.g., school-entry record checks and follow-up vaccination).
- CDC supports interventions to increase equity and coverage by using planning and implementation of vaccination campaigns to identify under-vaccinated children for referral to routine immunization services.
- **CDC develops and supports implementation of strategies to link planning, delivery, and monitoring of vaccination with other related health interventions administered across the life span (e.g., Second Year of Life project piloted in Ghana).**
- **CDC supports initiatives that increase demand for vaccination by addressing vaccine hesitancy and increasing community demand for vaccines through innovations in communication strategies; and by promoting policies, regulations, and laws that facilitate vaccine demand and utilization.**
- CDC provides expertise and consultation to develop immunization information systems (IIS) which are able to collect, analyze, and report high-quality, immunization-related data to support management of immunization programs. CDC assesses and enhances the ability of IIS to ensure high-quality collection, management, and use of data by developing interventions to improve the quality and use of data and IIS at regional and country levels. These interventions include appropriate technologies to track and improve vaccine delivery across the life course, and approaches to improve target population estimates.
- **CDC partners with the Global Vaccine Safety Initiative and ministries of health to build capacity for vaccine safety assessment and response. This includes developing technical documentation to monitor and characterize adverse events following immunization, and developing risk management and communication strategies for rapid response to emerging vaccine safety data.**
- CDC supports accurate estimates of vaccine coverage by developing new tools and approaches to increase accuracy as well as by developing guidelines for use and interpretation of vaccination coverage surveys.
- CDC conducts and supports studies to identify barriers to vaccine acceptance and demand in order to develop strategies to overcome those barriers and increase vaccine uptake.

Goal 4—Develop and Introduce New, Improved Vaccines & Technologies

- CDC works to increase the development, introduction, and use of new and underused vaccines to prevent diseases of global and regional public health importance.
- Recent vaccine introductions CDC has supported include: Cholera, *Haemophilus influenzae* type b, human papillomavirus (HPV), influenza, Japanese encephalitis, meningococcus A, pneumococcal conjugate (PCV), inactivated polio, rotavirus, and typhoid vaccines.
- CDC scientists are actively involved in the development of disease burden studies and clinical trials of new vaccines for dengue, Ebola, malaria, and Zika virus.
- CDC supports efforts to use vaccine introduction to strengthen other disease prevention and control initiatives includes linking rotavirus and pneumococcal conjugate vaccine introductions with implementing the Global Action Plan for Prevention of Pneumonia and Diarrhea, HPV vaccine with cervical cancer prevention, and malaria vaccine with other malaria control and elimination strategies.
- CDC laboratories serve as global specialized reference laboratories supporting global and regional surveillance networks used to assess burden of disease and impact from new vaccine introductions.
- CDC works to strengthen immunization policy bodies, which play important roles in reviewing technical, operational, and programmatic evidence for new vaccine introduction, and in developing immunization goals, policies and guidelines.

JSI GVAP Submission 07/14/17

JSI is dedicated to improving and promoting public health in the United States and across the globe. JSI works across a full range of public and community health areas, strengthening health systems to improve services—and ultimately, people's health.

Working with partners, JSI strengthens routine immunization (RI) systems, supports introduction of new vaccines, contributes to the achievement of disease control targets, and informs regional and global policies and strategies. In 2016, JSI supported the achievement of the objectives of the Global Vaccine Action Plan through a wide range of activities and programs described below:

Strategic Objective 1: Country Commitment

- In 2016, JSI efforts alongside the African Union, WHO, UNICEF, BMGF, and other partners, contributed substantially, to the passage of the Addis Declaration on Immunization (ADI). The ADI calls for countries to increase political and financial investments in their immunization programs. The ADI was a major outcome of the groundbreaking Ministerial Conference on Immunization in Africa in February 2016, in which all 54 African countries participated. JSI supported the design and implementation of the Conference and advised on the Declaration.

Strategic Objective 3: Equity

- JSI supported country efforts to identify and reach underserved populations to improve equitable coverage as part of the Reaching Every District (RED) approach in all 19 countries mentioned under Objective 4. JSI also supported countries to learn how to transition from RED to Reaching Every Child (REC).
- Over the past decade, JSI provided technical assistance (TA) for 71 new vaccine introductions in 15 countries, including vaccines against polio (IPV), measles (2nd dose), rubella, cervical cancer (HPV), pneumonia (PCV), rotavirus (RVV), and cholera (OCV). JSI also supported post introduction evaluations in many countries.

- JSI provided TA for the initial RVV introduction in India in four states in 2016 and the subsequent scale-up across five additional states in 2017. JSI is also documenting lessons learned to inform pan India scale-up.
- Through the Rotavirus Accelerated Vaccine Network (RAVIN) project, JSI provided TA to country teams in Afghanistan, Bangladesh, Benin, Cambodia, Democratic Republic of Congo (DRC), Myanmar, and Nepal in planning for and conducting situational assessments (SAs). JSI also worked with EPI teams and partners on developing country applications to Gavi for RVV introduction support.
- JSI technically supported WHO/AFRO in revising the RED guide to include a greater focus on equity, community engagement, integration, and urban populations.
- JSI is providing TA, with funding by Gavi, to the MoH in Haiti to design an urban immunization service model for Cite Soleil that could be applicable in other urban settings in Haiti and around the globe. A situation and landscape analysis have been completed while a service model has been approved.
- JSI is working in partnership with the International Organization for Migration, to create a curriculum for the US Refugee Assistance Program to support immunization of incoming refugees from satellite intake centers located throughout the globe.

Strategic Objective 4: Strong Immunization Systems

- JSI provided TA to strengthen RI systems as an integral part of the broader health system and/or introduce new vaccines in Benin, DRC, Ethiopia, Guinea, Haiti, India, Kenya, Liberia, Malawi, Madagascar, Mozambique, Nepal, Niger, Nigeria, Pakistan, South Sudan, Tanzania, Uganda, and Zimbabwe.
- JSI contributed to the annual Gavi Joint Appraisals in eight countries (Nigeria, Zimbabwe, Tanzania, Kenya, Malawi, Pakistan, Madagascar, and Mozambique) and was partially involved in two countries (Uganda and Haiti). Through this joint effort by partners, these countries assessed progress, identified TA gaps and priorities, and strengthened multiyear planning.
- JSI, through the USAID-funded Maternal Child Survival Program's (MCSP), provided TA to 11 countries in the historic WHO-led global polio vaccine Switch. JSI's efforts resulted in effective planning, logistical, and monitoring arrangements and ensured that health care workers were trained and supervised to administer the new vaccine.

Strategic Objective 5: Sustainable Access to Predictable Funding, Quality Supply and Innovative Technologies

- JSI assisted the government of Niger in assessing the country's existing cold chain equipment capacity in preparation for the upcoming installation of further cold chain equipment.
- With support from Gavi, JSI is providing TA to the Ministry of Health and Family Welfare (MoHFW) in India): (1) To review the immunization incentive system for Accredited Social Health Activist scheme, and to document opportunities and challenges, develop standard operating procedures, and provide recommendations in reaping the full benefit of these incentive systems; and (2) to prepare a standard package of Frequently Asked Questions on Immunization that can be customized for Medical Officers, health workers, mobilisers, and parents/caregivers.

Strategic Objective 6: Research and Innovation

- JSI, through USAID's MCSP in Nigeria, is pursuing a study to determine whether engaging traditional barbers and other community resource persons can be an effective way to identify and refer newborns to RI services, with the aim of reducing left-outs and improving timeliness of vaccinations.
- JSI's published more than a dozen peer-reviewed articles. For example, our Dose Per Container Project published an article summarizing the published knowledge on the programmatic impact of vaccine presentations and suggesting areas of current and future

research to ultimately improve decision making around vaccine doses per container and increase understanding of how this decision relates to other program goals.

The Network for Education and Support in Immunisation (NESI), based at the University of Antwerp in Belgium, is an international multidisciplinary network with the mission to strengthen immunisation programmes in low- and middle-income countries. Through partnerships with WHO, academic institutions, Ministries of Health and other interested parties, NESI focuses on capacity building, education and training, and institutional strengthening, in order to complete its mission.

During 2016, NESI contributed to two of the six Strategic Objectives of the Global Vaccine Action Plan.

SO1: Country ownership – *Strengthen national capacity to formulate evidence-based policies*.

Two **regional forums with peer-to-peer exchange of information, best practices and tools related to new vaccine introduction** were organised:

- Workshop "Implementing HPV vaccination in Africa: opportunities for strengthening adolescent health" with participation of 8 Eastern and Southern African countries, organised in collaboration with the South African Vaccination and Immunisation Centre (SAVIC)/Sefako Makgatho Health Sciences University, South African Medical Research Council (SA-MRC), University of Nairobi and Kenya Paediatric Association and with support from WHO/AFRO (Nairobi, Kenya, March 2016).
- Symposium "Strengthening HPV vaccination and adolescent health programmes in Africa" with participation of 16 Eastern and Southern African countries, organised in collaboration with the South African Vaccination and Immunisation Centre (SAVIC)/Sefako Makgatho Health Sciences University, South African Medical Research Council (SA-MRC), with support from WHO/AFRO (Johannesburg, South Africa, November 2016).

SO4: Strong immunisation systems – *Strengthen capacity of managers and frontline workers*.

NESI's pre- and in-service educational programmes are tailored to the needs of the immunisation programmes in the respective partner countries, with country ownership as guiding principle.

In-service training:

In-service vaccinology courses are key to building national vaccinology expertise by strengthening the capacity of academics in vaccinology and to guide NITAGs and policy-makers to make evidence-based recommendations and decisions on vaccines and immunisation. Mid-level management courses targeting EPI managers and other EPI staff contribute to efficient management of immunisation programmes and to maintaining public trust in vaccination through effective communication with individuals and communities.

- Co-organiser and co-facilitator in “TropEd Advanced Vaccinology Course”, Berlin, Germany (January 2016), as partner of the Institute of Tropical Medicine and International Health.
- Co-facilitator in “Vaccinology course for Health Professionals”, Kampala, Uganda (July 2016), organised by the East Africa Centre for Vaccine and Immunisation (ECAVI).
- Co-organiser and co-facilitator in “Inter-country EPI Mid-Level Management course for Anglophone African countries”, Pretoria, South Africa (October 2016), as partner of WHO/AFRO.

Pre-service training:

Pre-service health training institutions are crucial in delivering medical and nursing staff deployable in immunisation programmes capable of addressing complex situations, sustaining routine immunisation, and introducing new vaccines and technologies. Clinical and public health training that incorporates the learning objectives of EPI will enable students to develop a firm basis of EPI core knowledge and skills.

- Contributed to the finalisation of EPI prototype curricula for medical and nursing/midwifery schools in the African Region, as partner of WHO/AFRO.
- Country support given to Indonesia, Kenya and Morocco to strengthen EPI training at medical faculties and nursing schools.

PATH

PATH

Driving Global Vaccine Action Plan (GVAP) progress through innovation

For more than 20 years, PATH has successfully developed and delivered lifesaving vaccines for the most vulnerable children and communities around the world, spanning the spectrum of discovery to development to delivery. From preclinical research on novel vaccine candidates and technologies through pivotal clinical evaluations and, ultimately, innovative approaches for vaccine introduction, sustainable access, and integrated systems, PATH is committed to working with partners to advance GVAP objectives.

OBJECTIVE 1: COUNTRY COMMITMENT

PATH bolsters policymakers' capacity to make evidence-based immunization decisions through technical assistance, peer learning, and advocacy. Recent work includes:

- Assisting the governments of 16 low-resource countries in Africa and Asia in the planning, implementation, and evaluation of human papillomavirus vaccine delivery.
- Continuing to cultivate an African-led, member-owned, peer-to-peer learning network to inform national and global decision-making around immunization data.
- Convening two rotavirus vaccine cost-effectiveness analysis training workshops to build economic capacity among decision-makers in Asia and Eastern Europe.
- Assisting the Democratic Republic of the Congo to support immunization through a new national public health law and edicts in two provinces.
- Assisting Uganda to establish an immunization fund.

OBJECTIVE 2: DEMAND

To build demand for vaccines, PATH generates evidence on their efficacy, impact, safety, and cost-effectiveness and disseminates findings through advocacy and training. Recent work includes:

- Collaborating with the Ministry of Health, Regional Health Bureaus, Regional Islamic Affairs Offices, and other groups in pastoral Ethiopia to revitalize social mobilization committees to generate immunization demand and coverage.
- Building demand for Japanese encephalitis (JE) vaccine through the development and dissemination of a decision-making guide for vaccine introduction.

OBJECTIVE 3: EQUITY

To help ensure vaccines are within reach for all, PATH works at global, regional, and country levels to test and scale innovations that improve coverage and health equity. Recent work includes:

- Advancing maternal immunization strategies to protect infants and mothers against diseases such as Group B *Streptococcus,* respiratory syncytial virus, influenza, and pertussis.
- Continuing to study the long-term impacts of MenAfriVac®—a meningitis A vaccine by PATH, the World Health Organization (WHO), and Serum Institute of India, Pvt. Ltd. (SIIPL) delivered to over 270 million Africans.

OBJECTIVE 4: STRONGER IMMUNIZATION SYSTEMS

PATH works alongside countries to advance innovative solutions that strengthen immunization systems as part of integrated health systems. Recent work includes:

- Partnering with the governments of Tanzania and Zambia to develop and roll out interventions to improve immunization data collection, quality, and use—including an electronic immunization registry.
- Collaborating with global, national, and regional institutions to strengthen disease monitoring and surveillance systems to generate more accurate vaccine impact and safety data.
- Compiling the latest evidence on next-generation supply chains in a special edition of *Vaccine* and supporting Uganda to take up Effective Vaccine Management improvements.

OBJECTIVE 5: SUSTAINABLE ACCESS, FUNDING, AND SUPPLY

PATH helps predict, measure, and ensure a sustainable supply of safe, effective, and affordable vaccines in partnership with manufacturers and procurers. Recent work includes:

- Partnering with a Chinese manufacturer to support country introduction of a WHO-prequalified JE vaccine at an affordable price, with more than 260 million doses delivered.

OBJECTIVE 6: RESEARCH AND DEVELOPMENT

PATH leads research and development of innovative vaccines, formulation, packaging, devices, and delivery strategies to increase the impact of immunization. Recent work includes:

- Working with WHO and other stakeholders to prepare for pilot implementation of GlaxoSmithKline's RTS,S malaria vaccine in Ghana, Kenya, and Malawi, beginning in 2018.
- Advancing research into whether, by reducing and/or delaying the administration of vaccine doses, RTS,S has the potential to aid malaria elimination efforts.
- Partnering to begin clinical development of two novel oral polio vaccines candidates against type 2 polio.
- Conducting a Phase 1/2 trial of a trivalent non-replicating rotavirus vaccine candidate, a novel approach that may improve rotavirus vaccine protection.
- Supporting SIIPL in the development of a low-cost rotavirus vaccine, Rotasiil®, licensed in India in 2016.
- Initiating Phase 3 trials of SIIPL's low-cost pneumococcal conjugate vaccine candidate in The Gambia and of two locally made influenza vaccine candidates in Vietnam.
- Moving a vaccine candidate against multiple kinds of meningococcal meningitis into early clinical development.
- Working with WHO and other stakeholders to expand the availability of vaccines qualified for controlled temperature chain (CTC) use and to assist countries with CTC introduction.
- Improving the availability of optimal cold chain equipment through assistance to manufacturers and WHO and laboratory and field evaluations.
- Collaborating with a range of partners to advance novel immunization delivery technologies.
- Participating in WHO's Immunization Practices Advisory Committee, Immunization Supply Chain Task Force, and Product Development Vaccine Advisory Committee; and supporting the start-up of the Coalition for Epidemic Preparedness Innovations.

Save the Children activities in 2016 supporting progress on the GVAP:

Save the Children is committed to supporting progress on the GVAP towards achieving universal immunisation coverage. We advocate at global, regional, and national levels to ensure that Every Last Child has access to immunisation as an early priority in building Universal Health Coverage. We also work with Ministries of Health and national immunisation programmes to strengthen routine immunisation, as part of our integrated maternal and child health programmes, ensuring that immunisation is an essential part of a well-functioning health system. Our activities in 2016 supported GVAP goals 1, 2, 3 and 4, and strategic objectives 2, 3, 4 and 5.

- We **advocated at global, regional, and national levels** for accelerated action to equitably improve immunisation coverage, calling for strengthened health systems that can deliver immunisation and other primary health services in reach of Every Last Child. For example, we published a new report, *Further, Faster, Fairer: Reaching Every Last Child with Immunisation*, and an *Immunisation Equity Scorecard*, highlighting inequalities in coverage and calling for action. We also used opportunities such as World Immunisation Week and the World Health Assembly to call for progress, through various advocacy activities and social media outreach. At regional level, we supported efforts towards the adoption of the Addis Declaration on Immunisation. At national level, we advocated for and supported policies and action to improve equitable immunisation coverage in Nigeria, Indonesia, Ethiopia, and DRC.
- We supported and advocated for **improved and sustainable domestic financing** for immunisation and health. This has been a core call within our advocacy work at global, regional, and national levels. In Nigeria, for example, we carried out a budget analysis and advocated for an increased allocation for routine immunisation and are part of the National Immunisation Financing Task Team in Nigeria to support improved sustainable immunisation financing in the country.
- We supported the **delivery of routine immunisation** services as part of national immunisation programmes in several countries, including Afghanistan, DRC, Ethiopia, Kenya, Myanmar, Niger Nigeria, Sierra Leone, Somalia/Somaliland, South Sudan, and Yemen.
- We supported immunisation programmes to **reach excluded areas and communities** to help ensure immunisation is equitably extended to all people. For example, we supported mobile outreach services for children in nomadic communities in Somalia and "mop-up" campaigns for children living in hard to reach areas in India.

- We helped improve the **capacity of health workers and EPI coordinators** to deliver quality immunisation services and effectively manage EPI programmes. For example, we carried out trainings in Malawi on Reaching Every Child and data monitoring and stock management.
- We provided essential **equipment and supplies for immunisation** and rehabilitated infrastructure where needed. For example, we supported County Health Departments in areas of South Sudan through transportation of vaccines, procurement and delivery of ice packs, and maintenance of refrigerators and EPI equipment. In Malawi, we procured monitoring and evaluation tools and immunisation refrigerators, while also providing back up fuel to assist with the collection and distribution of vaccines and EPI commodities in hard to reach areas.
- We strengthened **supply chains**, providing support to improve vaccine management and cold chain systems. For example, we supported zonal and district health authorities with vaccine supply chain management in Somalia, including on forecasting, procurement and delivery of vaccines, and maintenance of cold chain equipment. We also supported the maintenance of cold chain equipment in India. Together with partners and government, we introduced a rapid SMS mobile phone application (EPI cStock) to help with supply chain logistics in Malawi.
- We increased **awareness and empowered communities** on the value of immunisation and to demand access to services. For example, in Nigeria we supported demand creation and mobilisation of caregivers during immunisation outreach sessions in hard to reach communities, in addition to building the capacity of and supporting local Ward Development Committees on the benefits of routine immunisation, monitoring service quality and strengthening their voice and accountability skills, thereby improving accountability between local communities and the primary health care system. In Somalia, we supported Community Health Workers to mobilise communities to come to Primary Health Units and outreach sites for vaccination.
- We supported the **introduction of new vaccines**. For example, we advocated for the introduction and rollout of PCV vaccine in Bangladesh and rotavirus vaccine in India, in the latter making the case for States with a higher burden of diarrhoeal disease to be prioritised. In Nigeria, we supported a pilot rollout of the rotavirus vaccine in preparation for the government's national rollout, including strengthening the cold chain, introducing a rotavirus introduction training manual, and training health workers. In Malawi, we supported training on rotavirus and pneumococcal vaccines.
- We supported **polio activities** as part of our work to strengthen routine immunisation. For example, we supported the CORE Group Polio Project in Ethiopia and Nigeria, including training and supervising community health volunteers to conduct social mobilisation activities and community-based surveillance; building local health worker capacity; mobilising community and religious leaders to support immunisation and surveillance activities; and providing logistics support for immunisation and surveillance activities. We also supported County Health Departments in South Sudan during National Immunisation Days for Polio.
- We supported **immunisation campaigns**. For example, we conducted a Measles campaign in several areas of Yemen and supported Measles Rubella campaigns in districts of Malawi. In South Sudan, we supported the national integrated meningitis vaccination campaign.
- We supported the delivery of routine immunisation services and responded to disease outbreaks as part of our response in **humanitarian contexts**. For example, we provided technical and financial assistance to support immunisation delivery in north-west Syria. We also supported the yellow fever response in DRC, and the response to the measles outbreaks in Mandera, Kenya and in South Sudan. Together with WHO, UNICEF and MSF, we developed a Humanitarian Mechanism to support the procurement of more affordable vaccines in humanitarian contexts.

Task Force for Global Health

GVAP Stakeholder Survey Project

Background: In 2016, in its GVAP midterm assessment report, WHO's Strategic Advisory Group of Experts (SAGE) determined the current pace of global progress must change if all the GVAP goals are to be achieved by 2020 and provided a set of recommendations. With support from the U.S. Centers for Disease Control and Prevention, The Task Force for Global Health (TFGH)[135] has developed a two-phase project to get ideas and suggestions from key immunization stakeholders on how to make greater progress toward achieving the GVAP goals. The focus is to develop specific recommendations, priorities, and innovative ideas to improve the likelihood of successfully meeting the GVAP goals and provide them to the SAGE Decade of Vaccines (DOV) Working Group.

Phase 1: Global Stakeholders (Q2-3, 2017) - A survey was developed with input solicited from partners including WHO, UNICEF, PATH and others. The SurveyMonkey survey was open for 3 weeks (June 16-July 7, 2017). The survey link was sent to ~90 potential respondents via email (2 separate mailings) describing background, purpose, process, and dissemination plans. Recipients included the American Academy of Pediatrics (AAP), American Red Cross, Bill & Melinda Gates Foundation, CDC, Gavi, International Federation of Red Cross/Red Crescent Societies, John Snow, Inc., PATH, Rotary, Save the Children, UNICEF, USAID, WHO, WHO/UNICEF regional offices and other partner organizations.

The survey consisted of 17 questions assessing familiarity and organizational support of GVAP goals, perceptions of progress made toward achieving GVAP goals and recommendations, and suggestions for increasing the likelihood of improving progress toward achieving those goals. Questions included multiple choice, drop-down matrix, allocation/prioritization and free-text/open ended types. The survey could not be taken more than once from the same device and contact information.

A summary of preliminary results is shown below.

Phase 2: Country Stakeholders (Q4, 2017-Q1, 2018) - A second survey will be conducted to assess country perception around GVAP recommendations, identify factors contributing to country progress toward achieving GVAP goals (or lack thereof), and make additional recommendations for improvement. Countries in the progressing, static, and declining vaccine coverage categories (as per SAGE's midterm assessment report) will be identified, selected, and surveyed. Best practices will be shared by utilizing existing global or regional meetings to present survey findings and hold panel discussions for countries to share successes, challenges, country needs and recommendations toward achievement of GVAP goals. Ongoing advocacy will take place throughout the project.

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[135] The Task Force for Global Health (www.taskforce.org), a 501(c)(3) nonprofit organization, was founded in 1984. The Task Force programs include work in three sectors: immunization and vaccines, health systems strengthening, and neglected tropical diseases. In each area, the Task Force works with partners and communities around the world to provide and improve the resources necessary for better global health for those in need.

GVAP Stakeholder Survey Project – Preliminary results, Phase 1

Responses were received from 38 respondents; 24 were complete. This summary is a preliminary analysis of closed-ended questions. For purpose of analysis, SAGE recommendations were grouped into three categories and results below are grouped in these categories. SAGE recommendations are listed in Annex A. Respondents were asked to characterize global progress to date and were also asked to prioritize recommendations through a question requiring allocation of 100 dollars across each of the recommendations in each category. Results of the prioritization are presented listing the top 3 recommendations. In each category, the top 3 garnered >50% of resources. It is not possible to compare across categories.

Overall results: 92% of respondents were somewhat or very familiar with GVAP goals. Only 2 of 7 goals (new or under-utilized vaccine introduction and development and introduction of new and improved vaccines) were felt "very likely to be achieved" by >50% of respondents whereas 3 (polio eradication, measles and rubella elimination, and increasing national immunization coverage) were felt "unlikely to be achieved" by >60% of respondents.

Leadership, governance, and sustainability: Of the 9 recommendations, only 1 (NITAGs) was felt to "have made good progress" since the GVAP midterm assessment in implementing the recommendations to achieve GVAP goals by as many as 40% of respondents. The 3 highest priorities for support (in rank order) were:

- getting more countries to make greater investments in routine immunization programs, especially those transitioning from Gavi support;
- getting more countries to make greater investments in disease surveillance; and
- getting more countries to upgrade systems, protocols and policies necessary to achieve and sustain high immunization coverage.

Sustainability, data quality, and immunization system strengthening: None of the 6 recommendations was felt to have made good progress by as many as 30% of respondents. The 3 highest priorities for support (in rank order) were:

- greater implementation of improved interventions in countries with DPT3 national coverage levels below 80% (e.g., integrated health services, human resource development, improved quality and use of data);
- getting more countries to use up-to-date data, such as disease surveillance, coverage and program delivery data to guide their immunization program decisions; and
- improving vaccine delivery and supply chain systems in more countries (e.g., cold chain storage, inventory systems, and vaccine transportation).

Accountability, elimination targets, and supply in humanitarian crisis situations: Only 1 of the 7 recommendations (greater use of social mobilization and engagement of Civil Society organizations as advocates for vaccines and immunization) was felt to have made good progress by as many as 20% of respondents. The three highest priorities (in rank order) were:

- greater use of social mobilization and engagement of Civil Society organizations as advocates for vaccines and immunization;

- greater or more advocacy by global immunization partners for the urgency and value of accelerating global progress toward achieving GVAP goals by 2020; and
- more efforts by international agencies, donors, vaccine manufacturers, and national governments to assist countries with large displaced populations or in humanitarian crisis situations.

Annex A: SAGE midterm review recommendations assessed in survey
Leadership, governance and sustainability

1. Getting more countries to make greater investments in routine immunization programs, especially those transitioning from Gavi support
2. Getting more countries to make greater investments in disease surveillance
3. Having more country ministers become strong immunization advocates within their country and region
4. Having more countries undertake efforts to build public trust and confidence in vaccines and immunization programs
5. Getting more governments to enact laws that guarantee ongoing access to immunization for all recommended vaccines for all children
6. Having all countries establish National Immunization Technical Advisory Groups (NITAGs) or equivalent groups
7. Having national immunization program managers report annually to NITAGs or equivalent groups on progress made, lessons learned and remaining challenges toward implementing National Immunization Plans
8. Getting more countries to upgrade systems, protocols and policies necessary to achieve and sustain high immunization coverage
9. Getting countries with large numbers of staff and resources funded by the Global Polio Eradication Initiative to develop a transition plan detailing how critical immunization, laboratory and surveillance activities will be maintained and funded when external polio funding decreases

Sustainability, data quality and immunization system strengthening

1. Getting more countries to expand immunization services beyond infants and children to the entire life course
2. Greater implementation of improved interventions in countries with DPT3 national coverage levels below 80% (e.g., integrated health services, human resource development, improved quality and use of data)
3. Getting more countries to make greater investments in disease detection and notification systems, data reporting systems, and laboratory capacity
4. Getting more countries to establish a clear process for investigating and confirming cases of vaccine preventable diseases and responding to and confirming outbreaks
5. Improving vaccine delivery and supply chain systems in more countries (for example, cold chain storage, inventory systems, and vaccine transportation)
6. Getting more countries to use up-to-date data, such as disease surveillance, coverage and program delivery data to guide their immunization program decisions

Accountability, elimination targets and supply in humanitarian crisis situations

1. Greater or more advocacy by global immunization partners for the urgency and value of accelerating global progress toward achieving GVAP goals by 2020
2. Greater use of progress reviews of Global and Regional Vaccine Action Plans by WHO Regional Directors
3. Greater use of social mobilization and engagement of Civil Society organizations as advocates for vaccines and immunization
4. More efforts directed toward achievement of elimination targets for measles

5. More efforts directed toward achievement of elimination targets for maternal and neonatal tetanus
6. More efforts directed toward achievement of elimination targets for rubella and congenital rubella syndrome
7. More efforts by international agencies, donors, vaccine manufacturers, and national governments to assist countries with large displaced populations or in humanitarian crisis situations

Vaccine manufacturers

No contribution