

# Report from Gavi, the Vaccine Alliance

Meeting of the Strategic Advisory Group of  
Experts on Immunisation (SAGE)

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Dr. Seth Berkley, CEO  
23 October 2018, Geneva



# 1

## Update on Gavi vaccine programmes

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# Typhoid conjugate vaccine: update on countries' appetite for introduction

## Approved TCV support

### Pakistan

- Large outbreak of extremely drug-resistant (XDR) *Salmonella typhi* strain in Sindh
- Phased catch up (at-risk, urban areas) and RI (~35M doses)

### Zimbabwe: outbreak response (~300k doses)

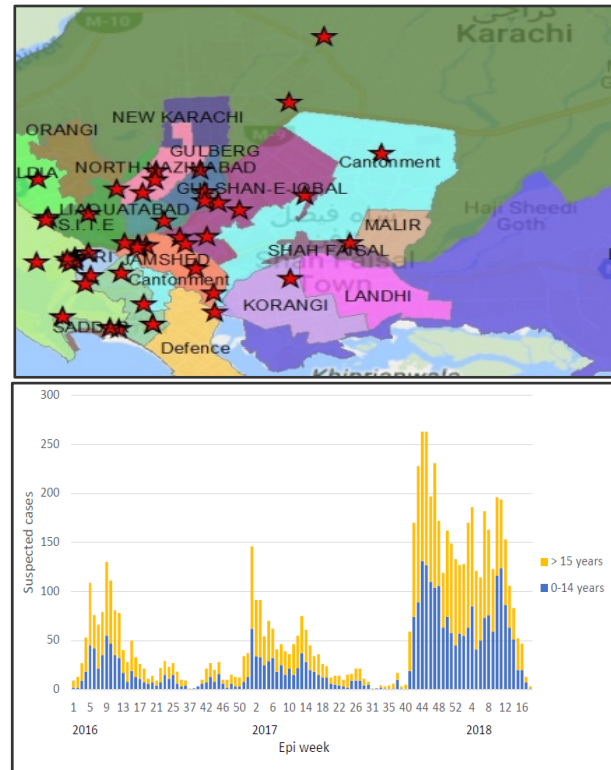
- >70% of isolates resistant to ciprofloxacin
- First public sector, non-research use of TCV in Africa

### Interest from:

**Liberia, Malawi, Zambia, Lao, Nepal and Bangladesh**

SAGE October 2018

Confirmed typhoid cases Hyderabad, Feb 2018



Suspected typhoid cases, Harare city, Jan.'16 to Apr. '18

# How do we align an effective outbreak response with targeted routine immunisation?

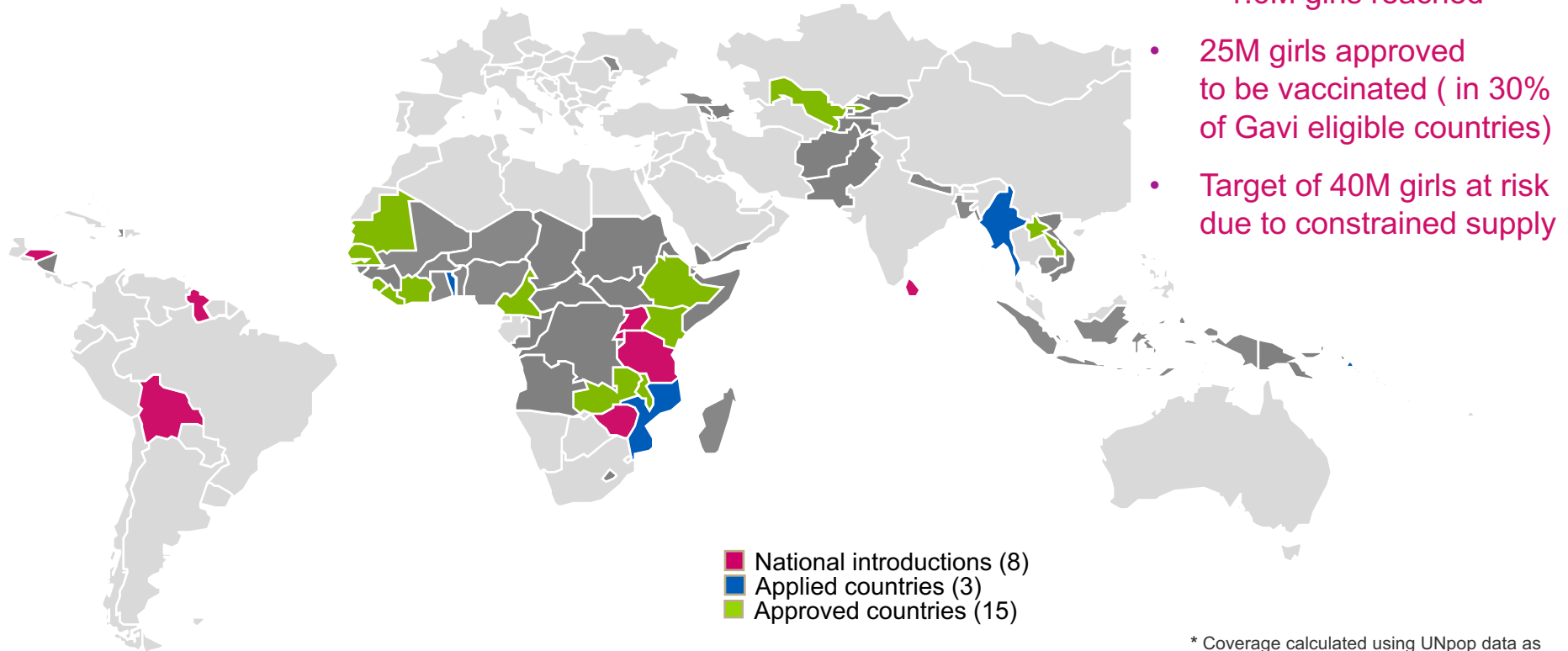
## Technical guidance needed to facilitate TCV introduction

- Criteria for review of applications
- Strengthened surveillance
- Tools to assess risk in absence of laboratory-confirmed data
- Outbreak and risk-based use case scenarios; urban centric vs pockets of poverty
- Real world impact of vaccine could be component of learning agenda to complement BMGF-funded TyVac





# How do we ensure HPV supply in lower income countries as global demand increases?



- ~ 1.6M girls reached
- 25M girls approved to be vaccinated ( in 30% of Gavi eligible countries)
- Target of 40M girls at risk due to constrained supply

\* Coverage calculated using Unpop data as denominator and JRF (dose 2) as numerator

# HPV: Implications of FDA approval of expanded age range for vaccination?

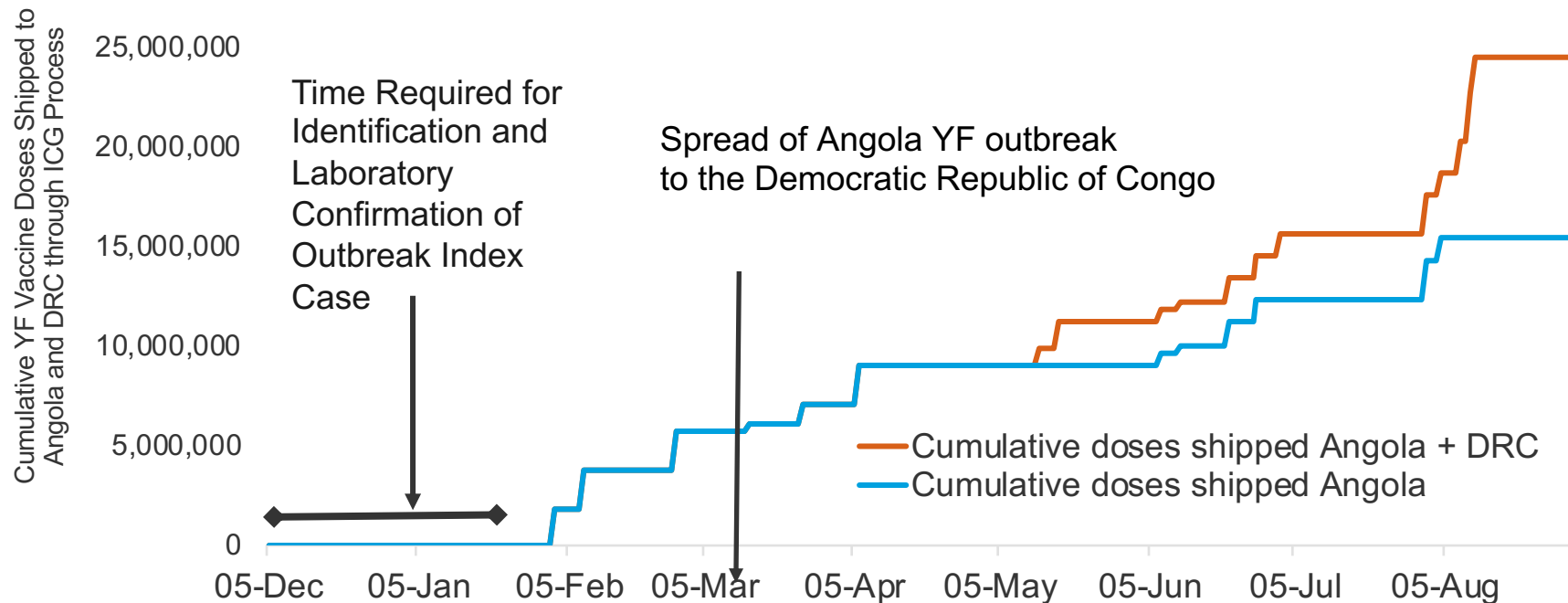
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HPV vaccine  
expanded  
for people  
ages 27 to 45



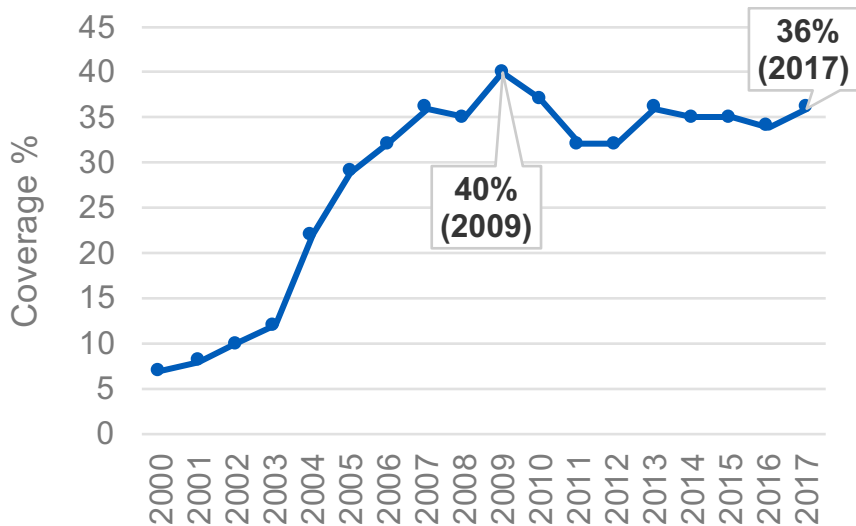
About 14 million women and men become infected with the human papillomavirus each year in the United States, according to the Centers for Disease Control and Prevention.  
Keith Bedford/The Boston Globe, via Getty Images

# More rapid yellow fever outbreak detection and response may allow more efficient vaccine use



# Accelerating improvements in coverage in countries eligible for yellow fever vaccine support

## YFV routine coverage



Source: WUENIC 2017

## Opportunities to accelerate

- Further focus on increasing RI coverage
- Improved supply and planning
- Improved surveillance and diagnostics: current 'yellow fever diagnostics' proposal to the Gavi Board

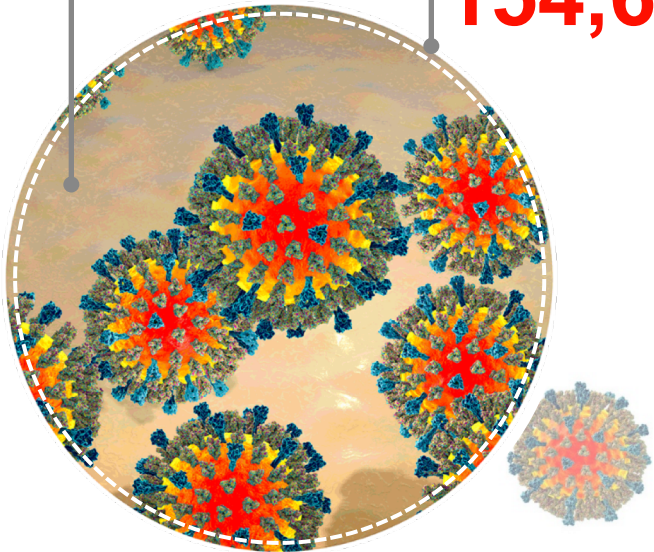
# Measles continues to surge

Total cases  
in 2017:

149,357

Cases in 2018  
(to end of September):

154,603



BBC Sign in News Sport Weather Shop Reel Travel Mo

NEWS

Health

## Measles cases hit record high in Europe

20 August 2018

f b t e Share



## Resurgence of deadly measles blamed on low MMR vaccination rates

More than 41,000 cases of measles reported in the EU in six months to June - almost double the number over the whole of 2017

Aug 20, 2018, 07:00am

## Outbreak Or Not, Measles Is A Growing Threat Globally

09/08/18

## Crisis in Venezuela threatens region's measles-free status



Prevention of measles is based on immunisation with two doses of the MMR vaccine for each child under the age of five. Copyright: FAHO



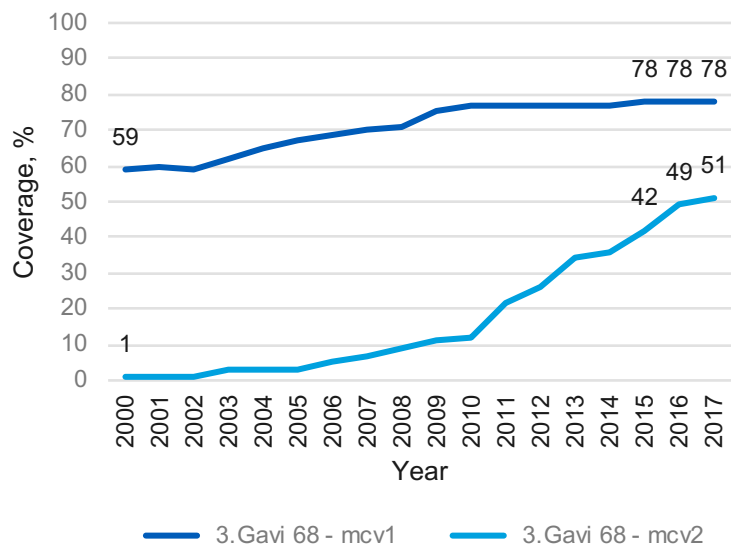
Forbes



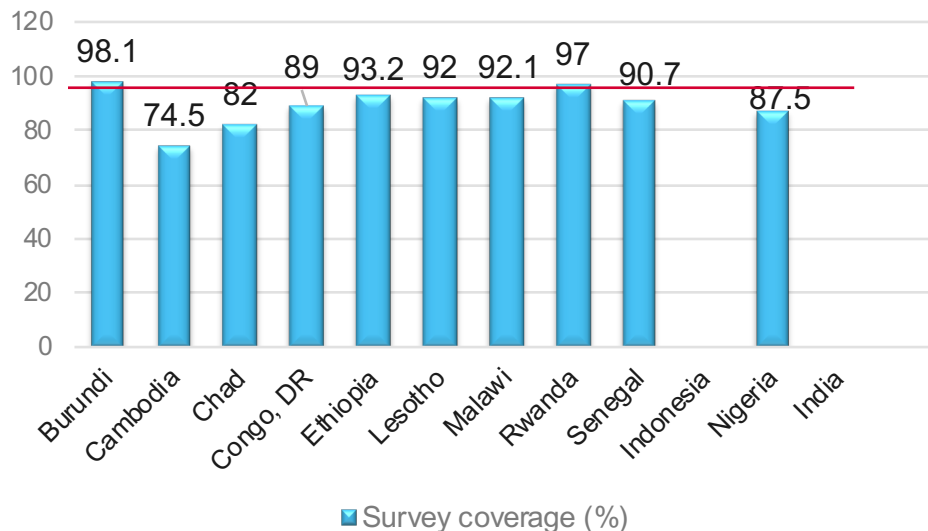
on at the Princess of Wales Hospital in Bridgend. Photograph:

# How do we design sustainable measles vaccination strategies to reduce transmission?

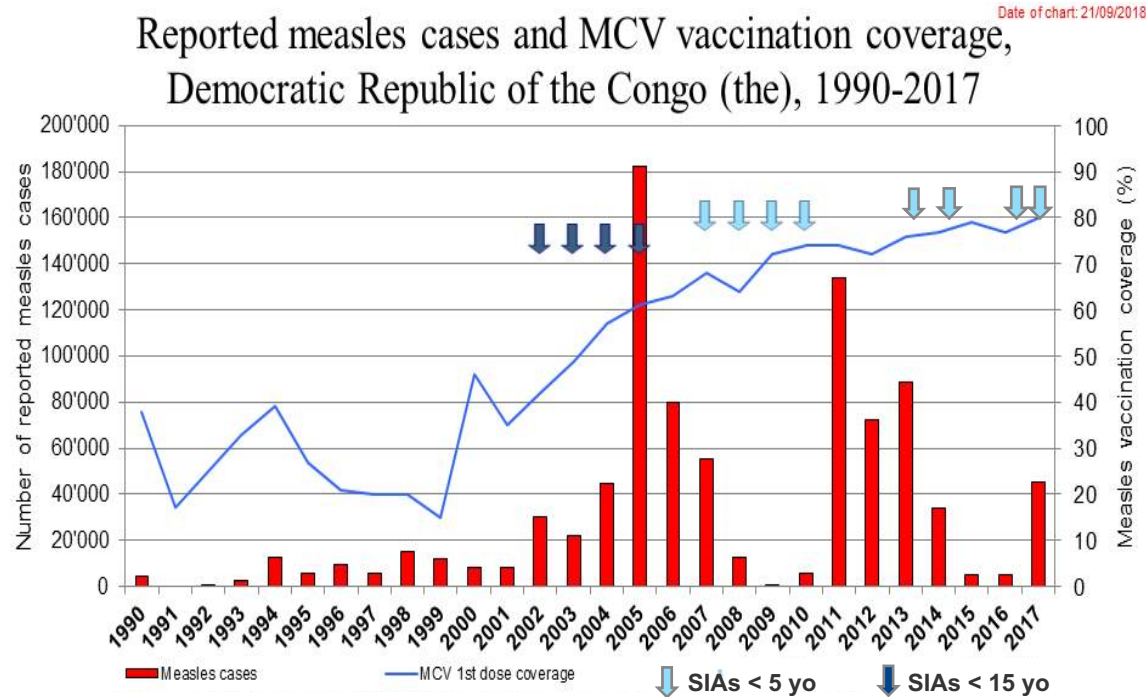
**MCV1 and MCV2  
coverage trend, WUENIC**



**Gavi supported campaigns in 2017,  
survey coverage**



# Outbreaks continue following frequent SIAs in DRC

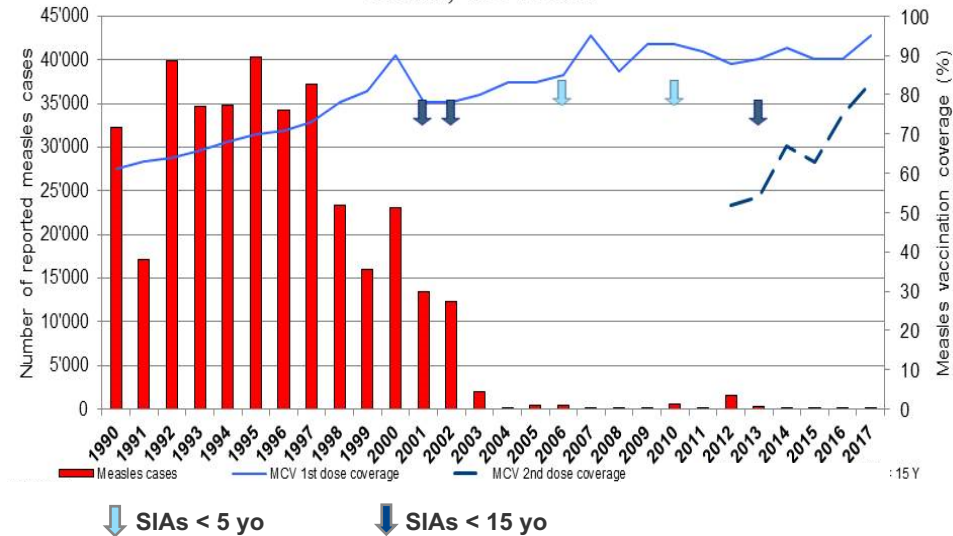




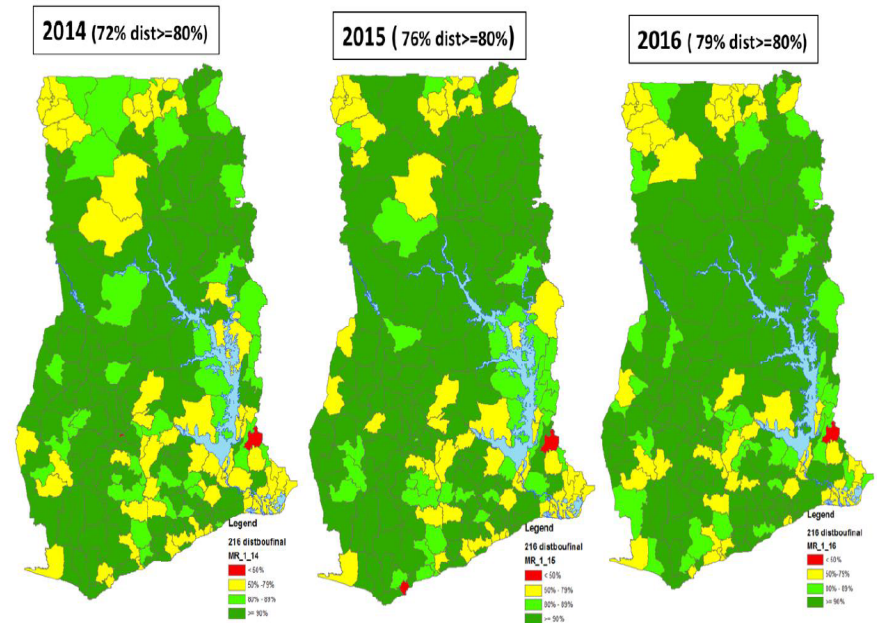
# Ghana: national coverage masks subnational disparities

Reported measles cases and MCV vaccination coverage,  
Ghana, 1990-2017

Date of chart: 21/09/2018

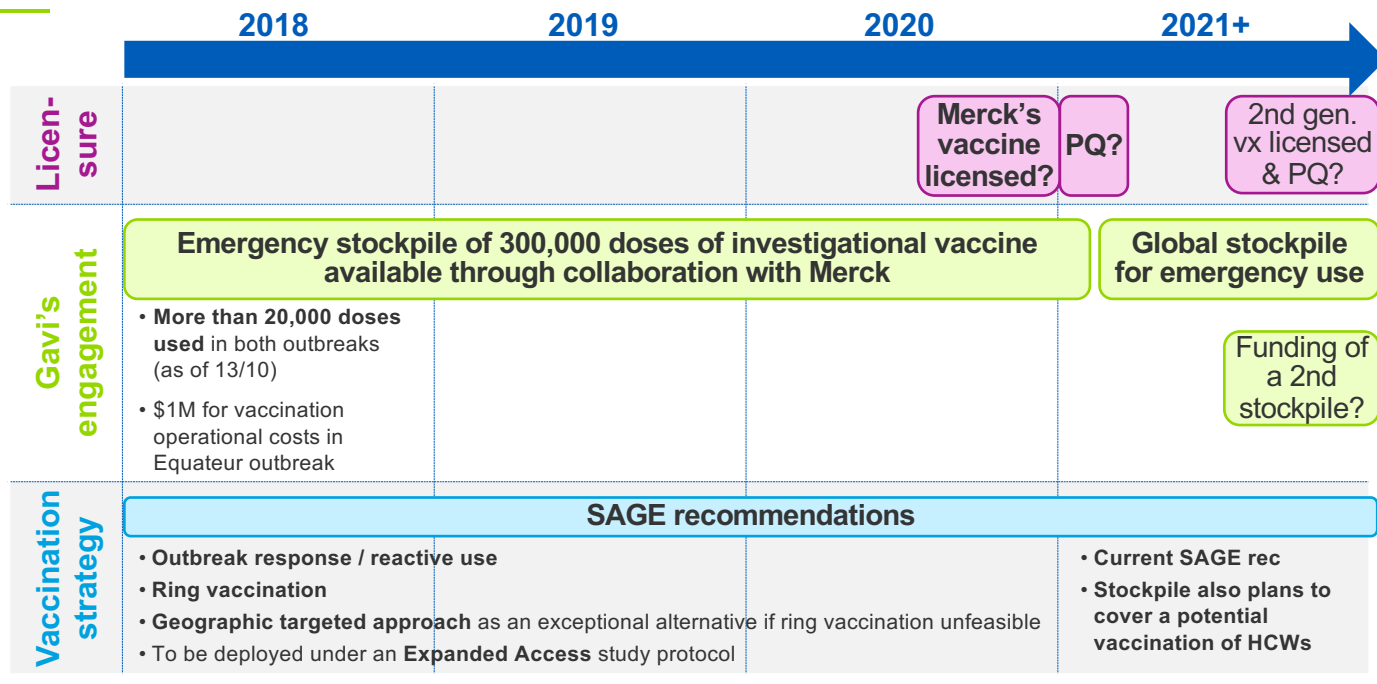


Trend of MCV1 subnational coverage, 2014-2016, Ghana





# As licensure of Merck Ebola vaccine nears, Gavi is preparing for funding a global stockpile



## Gavi looks forward to:

- Further insights from modelling work on scenarios involving potential **geographical targeted vaccination**
- SAGE WG discussing **preventive use** once more data is available

# Vaccine Investment Strategy: evidence-based process to assess candidates for potential investment

## 1. WHO landscape analysis

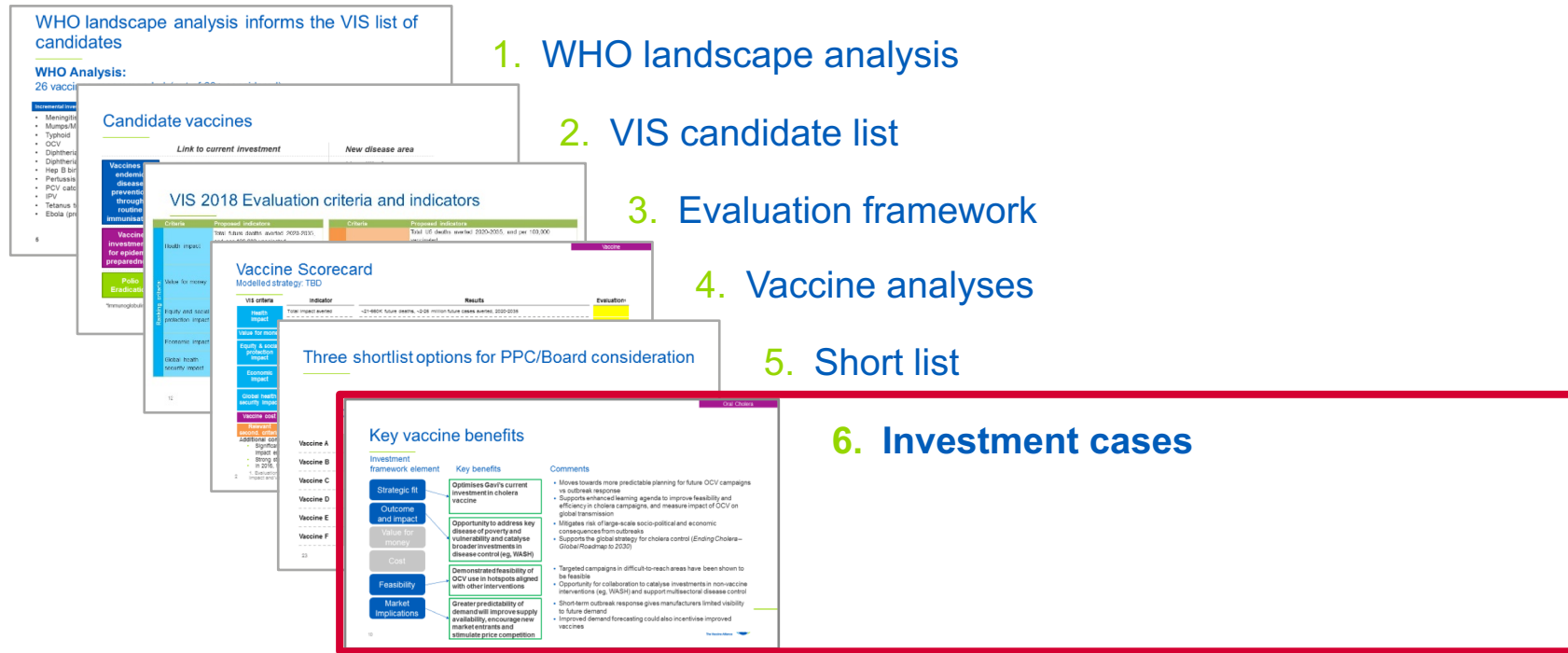
## 2. VIS candidate list

## 3. Evaluation framework

## 4. Vaccine analyses

## 5. Short list

## 6. Investment cases



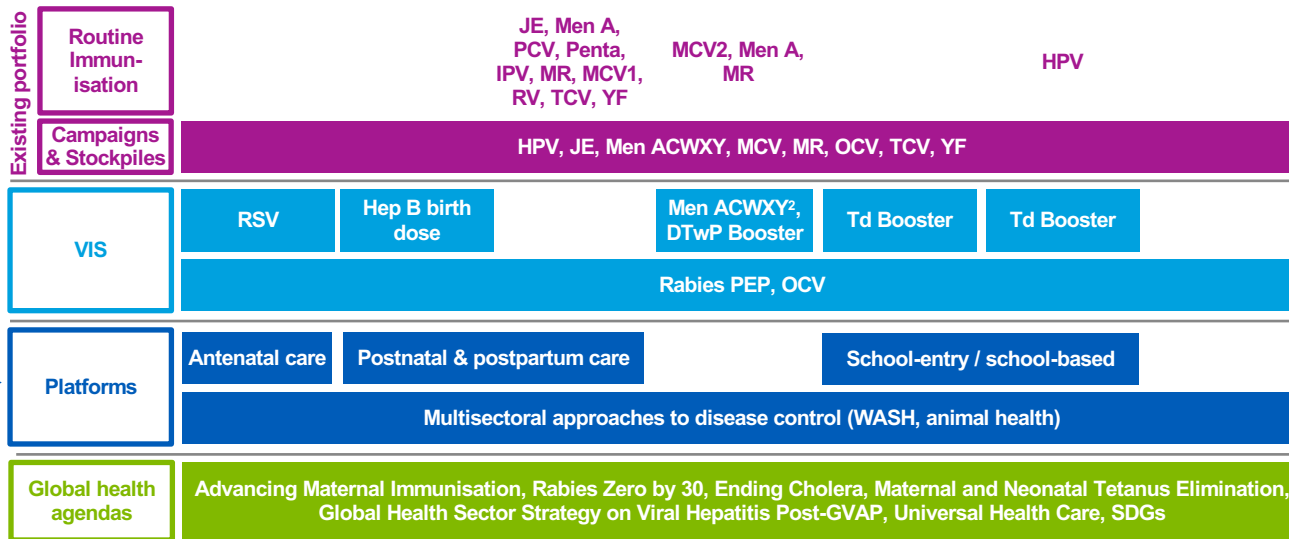
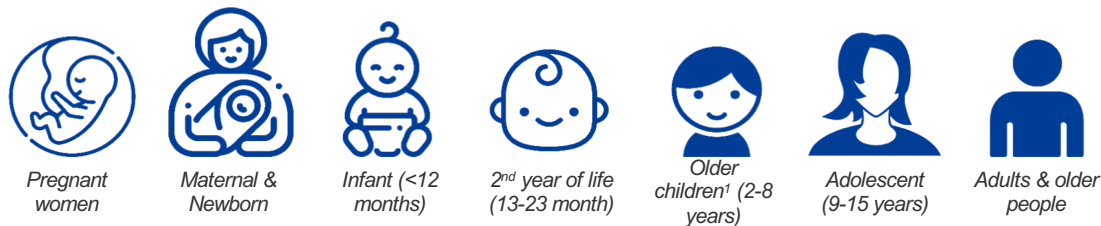
# Six investment cases for vaccines for endemic disease are put forward in the Vaccine Investment Strategy for 2021+

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## Further guidance or information would maximise impact

|  |  |
|--|--|
| <b>D, T &amp; P-containing boosters</b>                              | Incremental impact of each booster?<br>RI to mitigate diphtheria outbreaks?  |
| <b>Hepatitis B birth dose</b>  | Most effective delivery strategy for non-institutional births?   |
| <b>Oral cholera vaccine</b>  | Impactful periodic campaigns, aligned with WASH interventions? Perverse incentives?  |
| <b>Rabies post-exposure prophylaxis</b>                              | Key elements of successful integrated human and animal rabies control strategy?  |
| <b>Multivalent meningococcal vaccine</b>                             | Most impactful, cost-effective vaccination strategy to reach highest risk pop?   |
| <b>Respiratory syncytial virus vaccine and monoclonal antibodies</b> | Which pre-introduction activities to ensure uptake of a vaccine in LICs?<br>Impactful, future cost-effective strategy for use of mAbs? |

# VIS candidates expand the reach of immunisation and support integration of health programmes



Strengthen life-course approach with new immunisation time-points

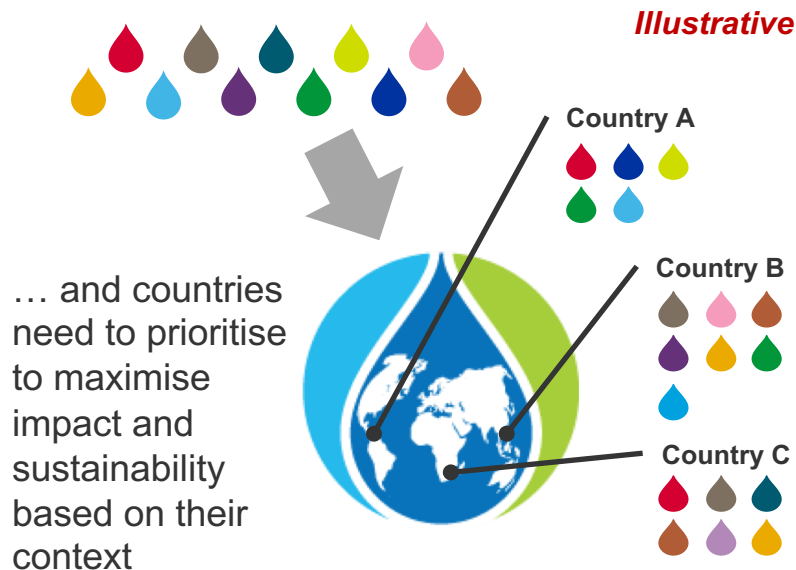
Align with global agendas on health and development

Catalyse multisectoral approaches to disease control and service delivery

1. Mostly corresponds to school entry; In theory, Gavi is supporting MCV2 at school entry, but Gavi countries have so far chosen to introduce MCV2 in the second year of life 2. Assumed 1 dose (15-18 months)

# VIS vaccines will require strong technical and policy guidance at global level

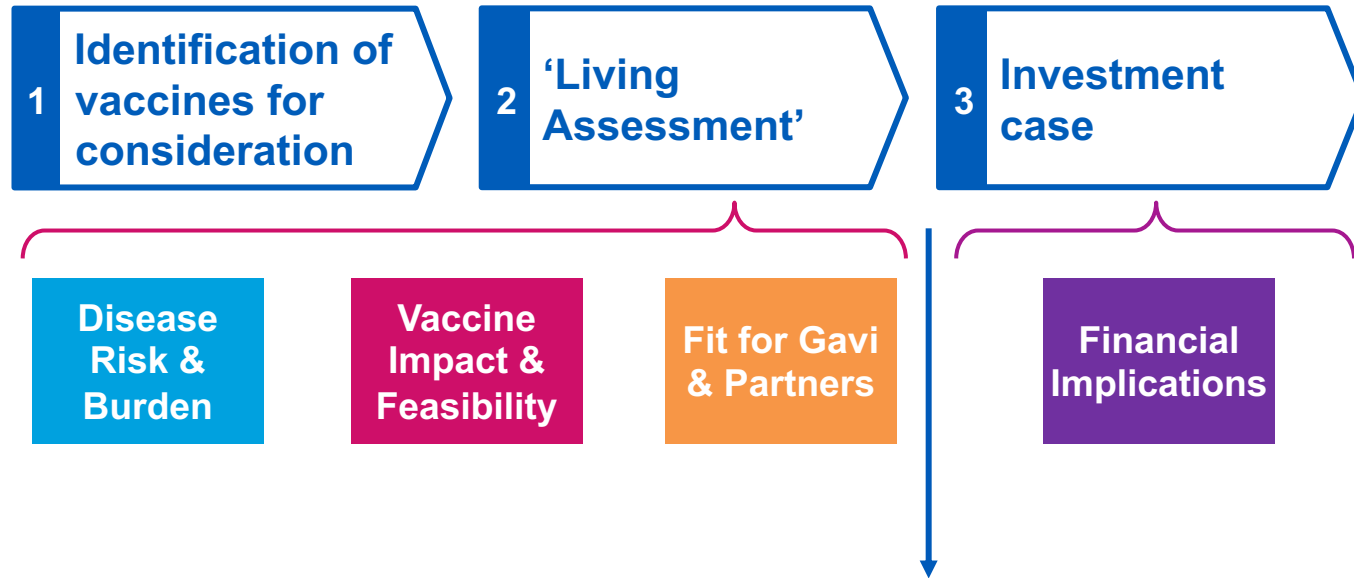
As Gavi's portfolio evolves, vaccines increasingly have different value for each country ...



What capabilities and evidence will countries need to make informed decisions on choice and timing of vaccine introductions?

# Gavi will also monitor the vaccine landscape for epidemic preparedness and response

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*In this VIS, Gavi Board will consider a learning agenda investment for routine influenza vaccination of health care workers in context of pandemic preparedness*

# Gavi's increasing engagement with GPEI

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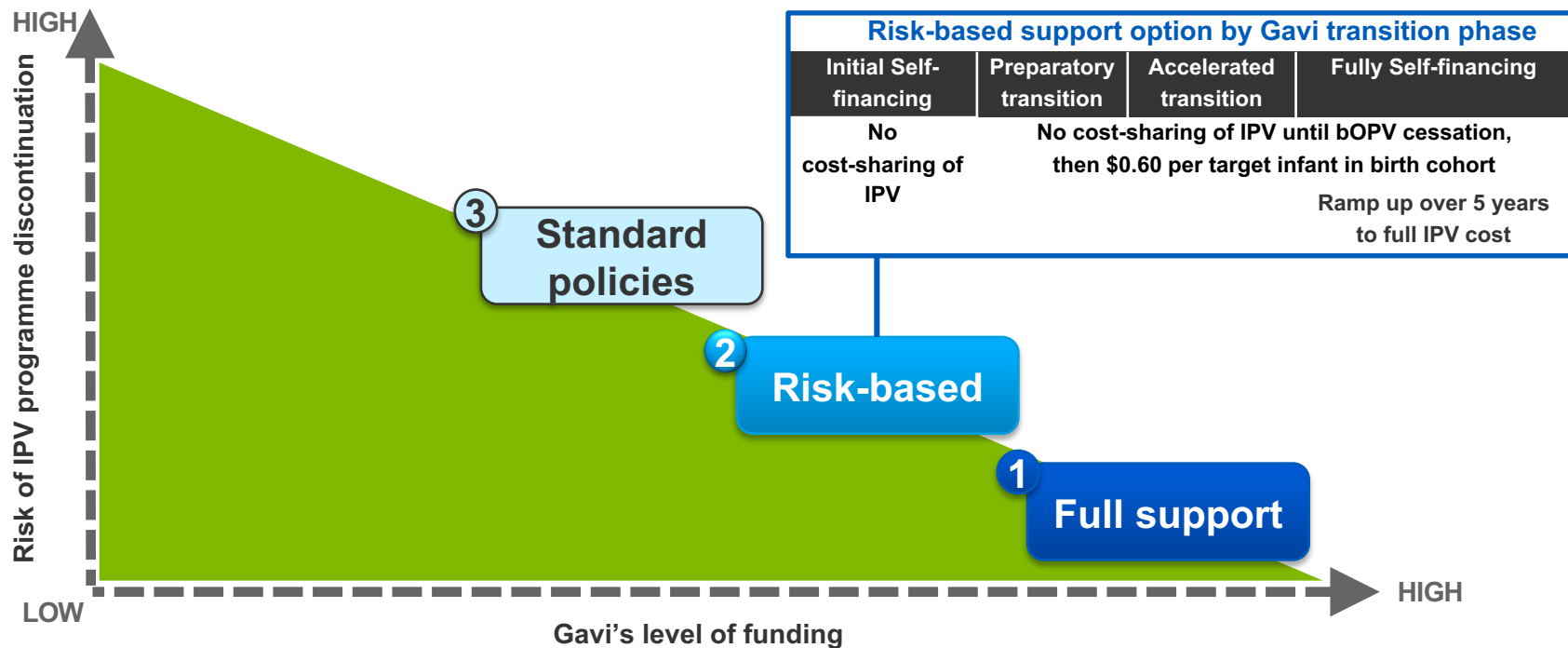
## **June 2018 Gavi Board:**

- Decision to fund IPV with core resources (US\$200M) for 2019-20 period
- Endorsed increased engagement with country-level polio transition and planning for a post-polio eradication world

## **November 2018 Gavi Board will consider continued IPV support post-2020**

**Strengthening Gavi and GPEI's strategic and programme alignment:**  
especially given global situation with VDPVs

# Risk of IPV discontinuation differs across support scenarios





# The Alliance is making progress on the Vaccine Innovation Prioritisation Strategy (VIPS)



An Alliance wide effort to drive product innovation to better meet country needs and improve coverage and equity



## **Vaccine product innovations**

*in delivery technologies,  
primary containers,  
formulation, labelling,  
packaging*

## **By end 2019**



The Alliance will have assessed and **prioritised a long list of vaccine product innovations** using an evaluation framework incorporating country inputs

## **Beyond 2019**



As a next step, the Alliance will also consider how to **support the prioritised innovations beyond prioritisation and signalling**, e.g. in terms of development, procurement and country uptake

# AMR drives urgency to address tuberculosis burden

- Estimated 25% of the world's population is infected with TB; 1.6M deaths annually
- Multidrug-resistant TB remains a public health crisis & a health security threat
- New vaccine: phase 2b preliminary trial results show 54% protection against activation of TB in infected individuals

THE NEW ENGLAND JOURNAL OF MEDICINE

## ORIGINAL ARTICLE

### Phase 2b Controlled Trial of M72/AS01<sub>E</sub> Vaccine to Prevent Tuberculosis

O. Van Der Meeren, M. Hatherill, V. Nduba, R.J. Wilkinson, M. Muyoyeta, E. Van Brakel, H.M. Ayles, G. Henostroza, F. Thienemann, T.J. Scriba, A. Diacon, G.L. Blatner, M.-A. Demoitie, M. Tameris, M. Malahleha, J.C. Innes, E. Hellström, N. Martinson, T. Singh, E.J. Akite, A. Khatoon Azam, A. Bollaerts, A.M. Ginsberg, T.G. Evans, P. Gillard, and D.R. Tait

## ABSTRACT

### BACKGROUND

A vaccine to interrupt the transmission of tuberculosis is needed.

### METHODS

We conducted a randomized, double-blind, placebo-controlled, phase 2b trial of the M72/AS01<sub>E</sub> tuberculosis vaccine in Kenya, South Africa, and Zambia. Human immunodeficiency virus (HIV)-negative adults 18 to 50 years of age with latent *M. tuberculosis* infection (by interferon- $\gamma$  release assay) were randomly assigned (in a 1:1 ratio) to receive two doses of either M72/AS01<sub>E</sub> or placebo intramuscularly 1 month apart. Most participants had previously received the bacille Calmette-Guérin vaccine. We assessed the safety of M72/AS01<sub>E</sub> and its efficacy against progression to bacterio-

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Van Der Meeren at GlaxoSmithKline, 20 Fleming Ave., 1300 Wavre, Belgium, or at [olivier.van-der-meeren@gsk.com](mailto:olivier.van-der-meeren@gsk.com).

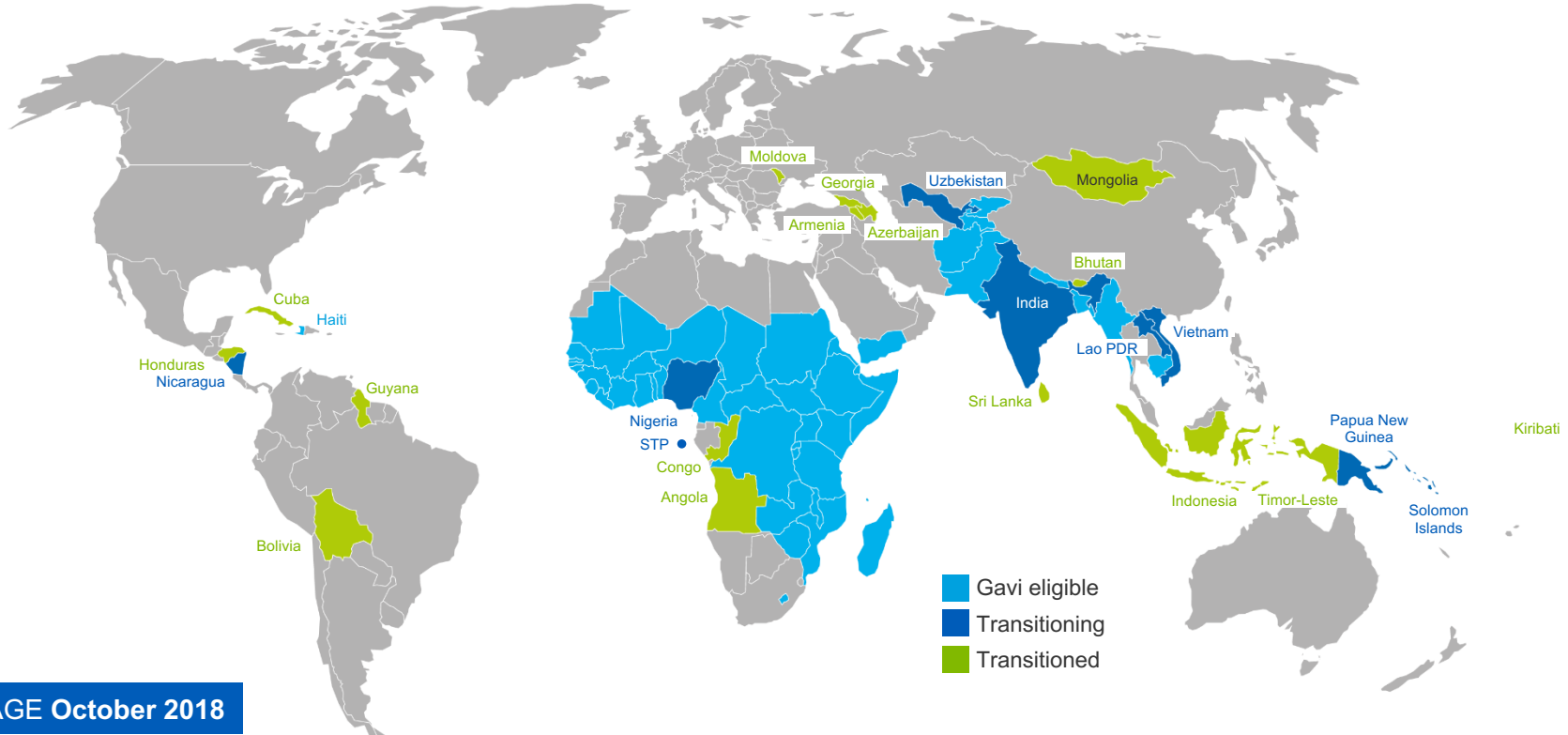
Drs. Van Der Meeren and Hatherill and Drs. Gillard and Tait contributed equally to this article.

This article was published on September 25, 2018, at [nejm.org](http://nejm.org).

# 2

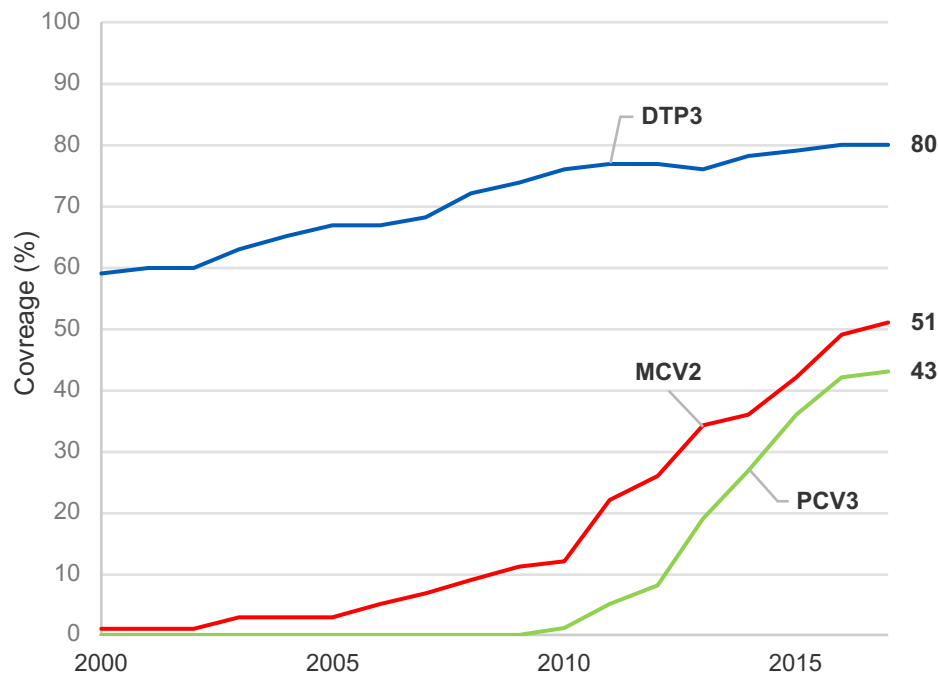
## Update on key activities

# 16 countries have already transitioned and 9 countries are still in transition



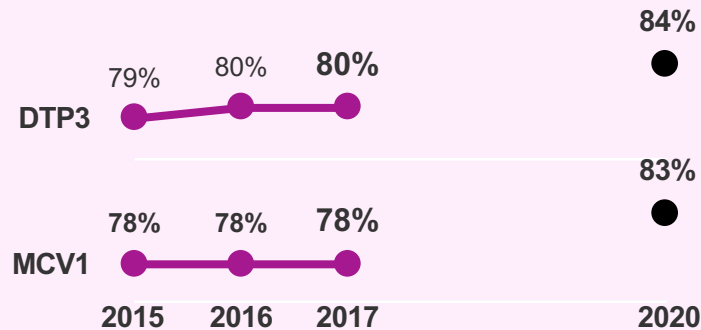
# Progress towards SDG immunisation targets but more work needed to ensure no one left behind

Gavi-supported countries (68)

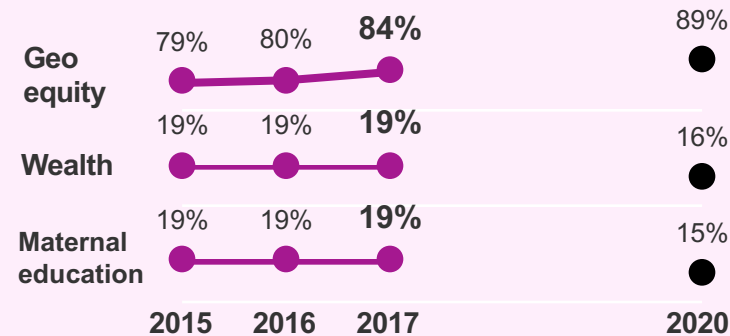


SAGE October 2018

## COVERAGE



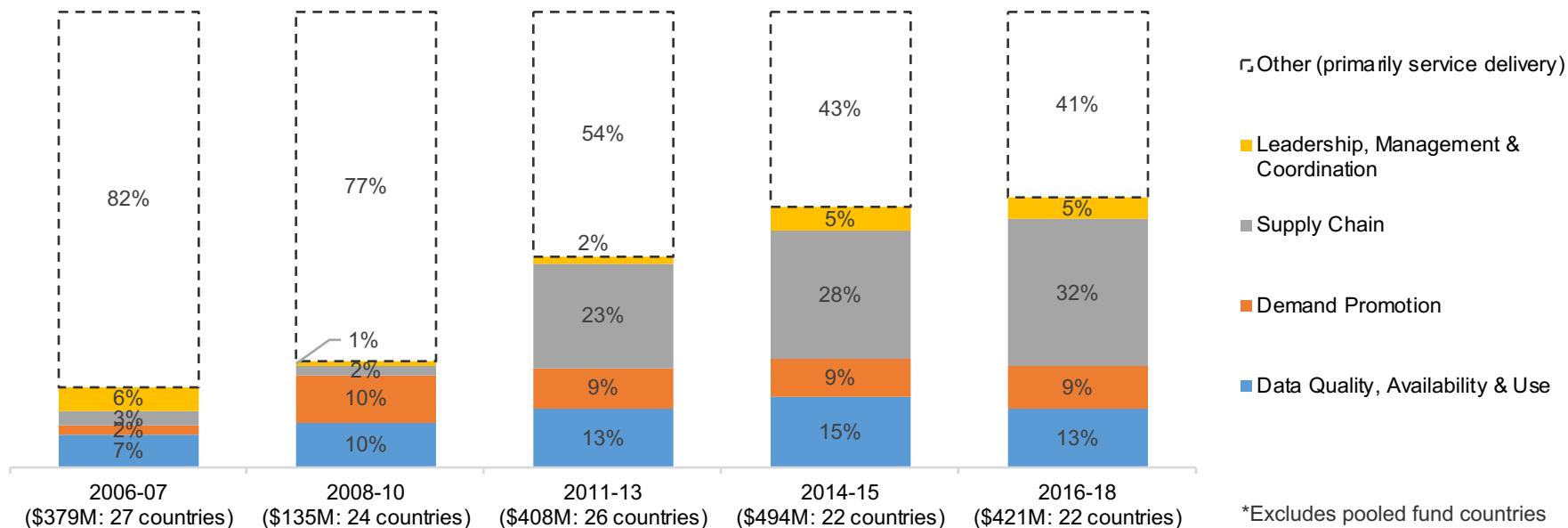
## EQUITY



# HSS investments increasingly targeted at drivers of coverage & equity

## Growing share of Gavi HSS Investments targeted at SFAs

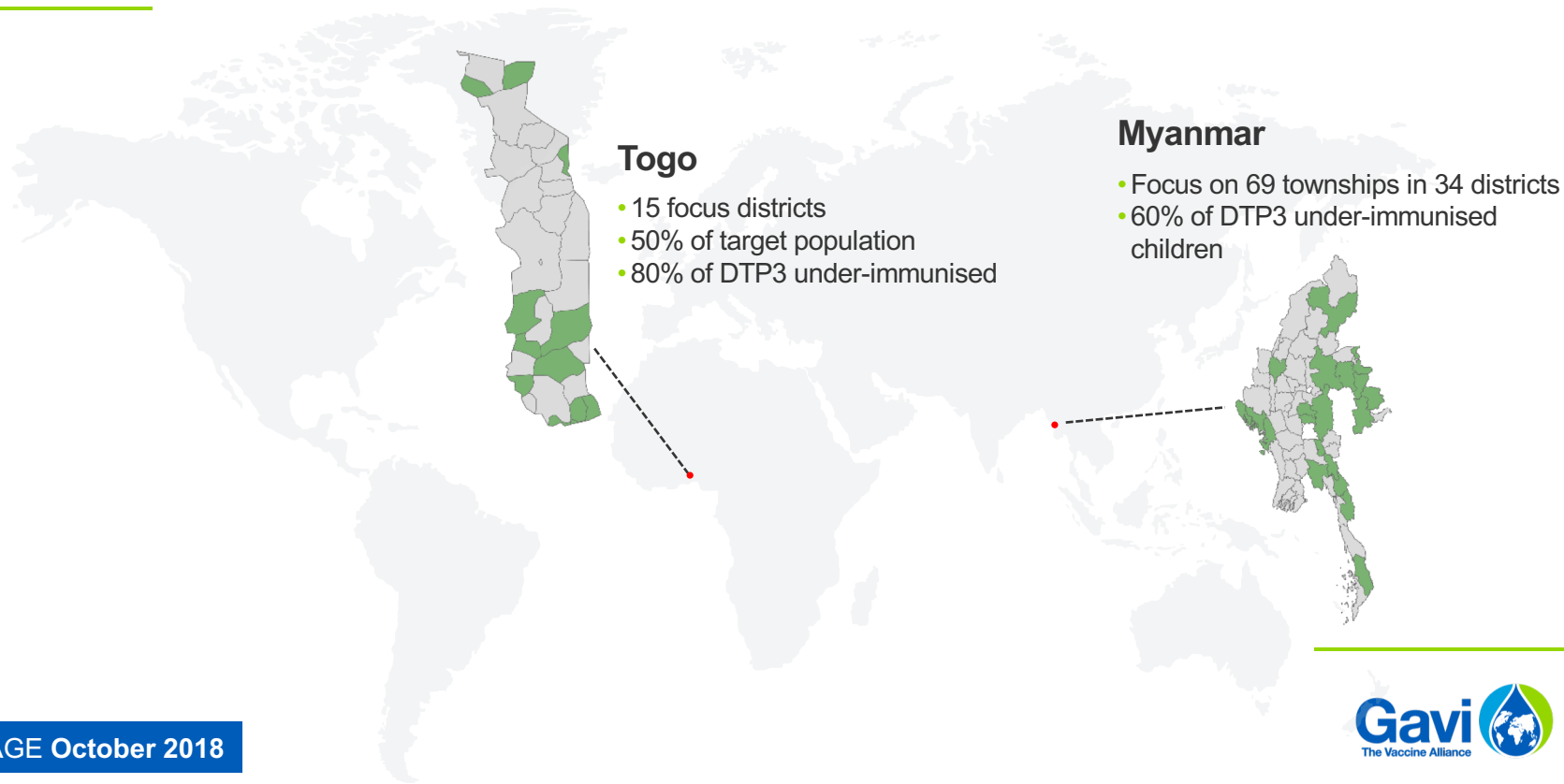
Approved HSS proposal budgets in reference years



**All 10 countries approved in 2016-2018 through the Country Engagement Framework had interventions targeted at specific sub-populations with low coverage and/or large numbers of under-immunised children**

# Subnational focus enabling prioritisation of investments towards improved immunisation coverage & equity

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# Leadership, Management & Coordination: building institutional capacity to increase coverage and equity

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## Menu of interventions (depending on country context and need):

- Embedded 'EPI Management Partner'
- Enhancing EPI performance management
- EPI south-to-south twinning
- EPI Management training programme (Yale-UGHE)
- Strengthening Coordination Forums (e.g. ICC, HSCC)



# Building political will: Translating in-country political commitment to improve immunisation programmes

Alliance adopting a **more systematic approach** to:

1

**Strengthen legislative and regulatory framework**

2

**Sustain immunisation financing**

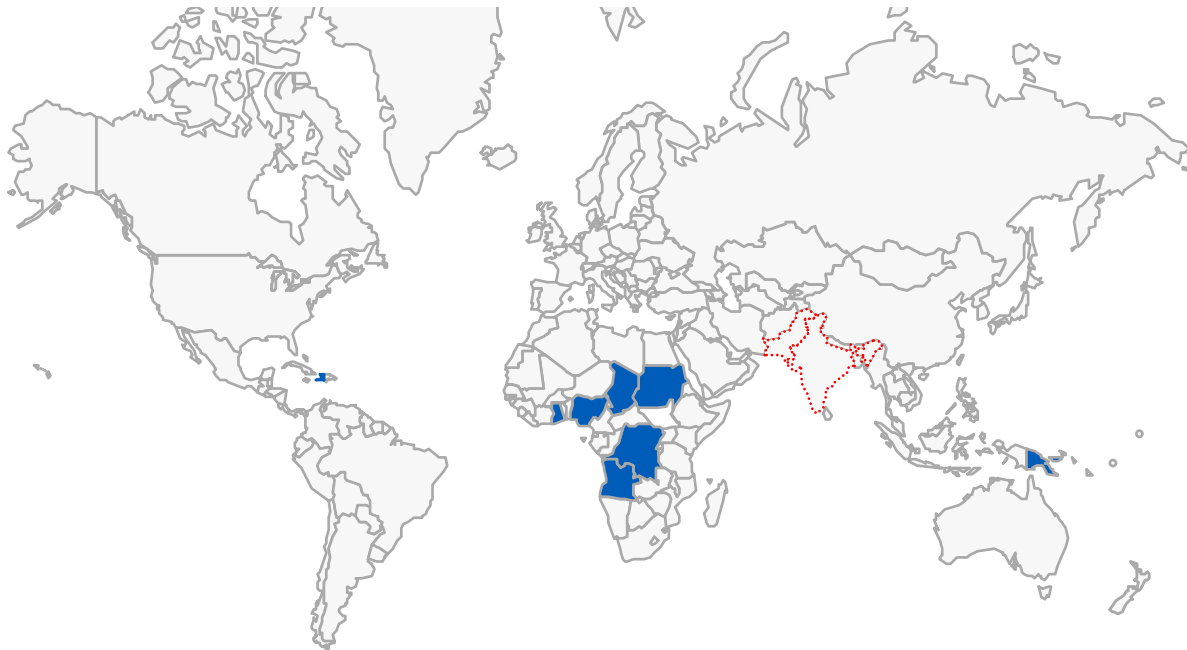
3

**Build vaccine confidence**

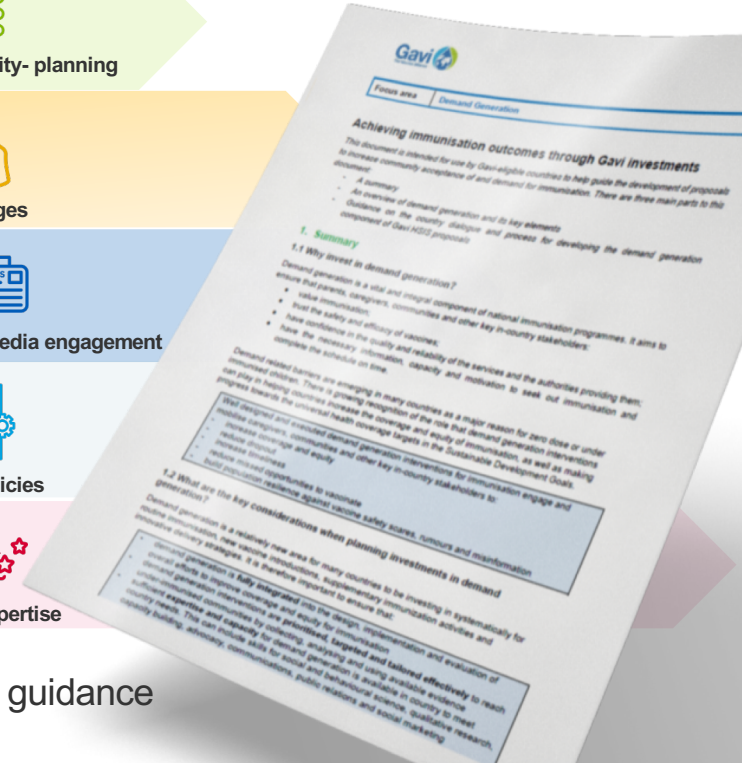
4

**Strengthen EPI leadership**

## First wave of prioritised countries



# New partner framework for demand generation



# Learning and testing: current partnership pipeline

**AUDACIOUS ALLIANCE**  
Tech enabled frontline workers. In development  
UGANDA, KENYA, LIBERIA



**CROWDBREAKS Social**  
Listening collaboration  
with EPFL, Sabin, WHO



**ZM SMS 'Nudge'**  
Reminders  
PAKISTAN



Gavi-Unilever experiential  
marketing in UP - underway



**Africa United – Africa**  
Cup of Nations - New  
phase



"M-Vaccin Côte  
d'Ivoire"  
SMS Nudges  
COTE  
D'IVOIRE -  
underway



Branding and  
empowerment for HPV  
MALAWI RWANDA,  
ETHIOPIA - underway



**LIONS Phase 2 –**  
starting soon – 5  
African countries



Reaching children in urban  
slums – experiential  
marketing/branding/mobile/  
fundraising/influencing  
Initial ideation and scoping –  
ready for feasibility testing

# Updated countries identified as facing fragility in 2018

With removal of **Nigeria and Ethiopia**, fragile countries comprise only 18% of the under-immunised, compared to 48% in 2017

**Syria** classified as low-income



No longer classified as fragile



Accelerated transition

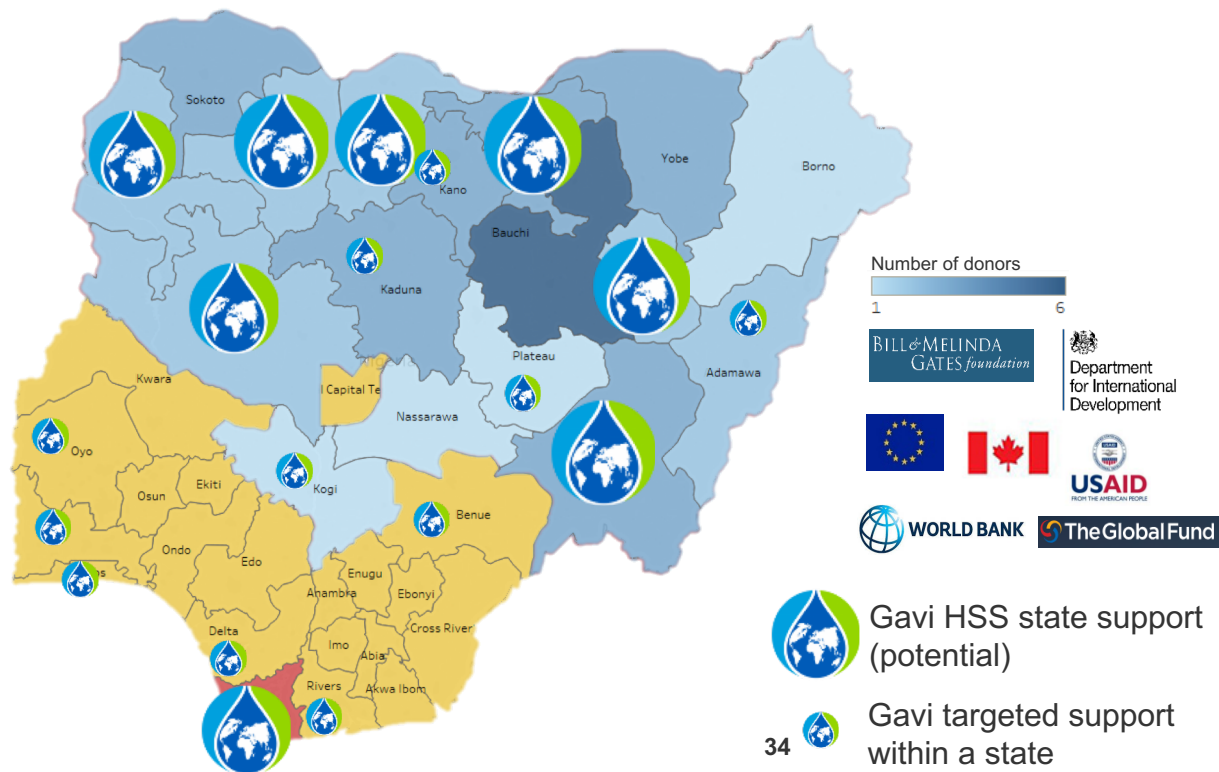
# Nigeria: Gavi to potentially support an additional US\$461M in vaccine financing\* through 2028

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- Extended acceleration transition period to improve coverage and mitigate risks in fiscal situation
- Target to achieve 84% coverage of third dose of pentavalent and introduce new vaccines
- Focus tailored to context of reaching under-immunised
- Accountability framework and annual review to be implemented

**Gavi's total vaccine support is US\$773M from 2018-2028**  
**The government co-financing will be US\$1.9B**

# Nigeria: Gavi's potential state level focus – will be dynamic through the transition period



## Priority states:

- low performance
- high # under-immunised children
- identified funding gaps
- political will

Achieved through collaboration with other partners

# 3

## Beyond 2020: Gavi 5.0

# Immunisation in the context of broader global health agendas

ASTANA, KAZAKHSTAN  
25-26 OCTOBER 2018



GLOBAL  
CONFERENCE  
ON PRIMARY  
HEALTH CARE

SAGE October 2018

## Towards a Global Action Plan for Healthy Lives and Well-being for All

Uniting to accelerate progress towards  
the health-related SDGs

Phase 1 - October 2018

A joint initiative of the following organizations:



Vaccines to tackle drug  
resistant infections

An evaluation of R&D opportunities



BCG  
THE BOSTON CONSULTING GROUP





# Given evolving environment, Gavi has started to explore four key themes to inform its post-2020 Strategy

1

## How does Gavi continue its efforts reaching every child in remaining eligible countries?

19 million under-immunised remaining in 2020; at current pace, U5 mortality SDG target will be missed.

3

## How can Gavi be more intentional about its contribution to global health security?

Number of recorded outbreaks has grown steadily from 1980 to 2010, over 3-fold increase.

2

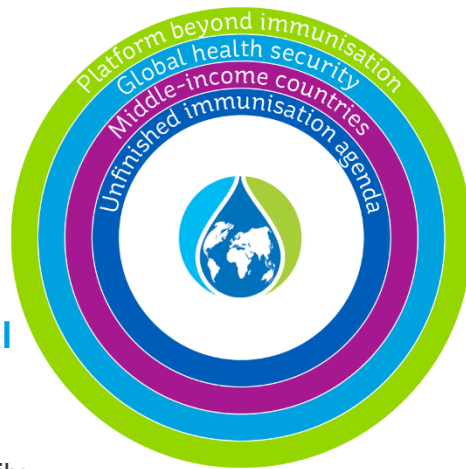
## How can Middle Income Countries accelerate their vaccine agenda?

More than 80% of world's vulnerable live in MICs today; almost 70% of underimmunised in MICs in 2030.

4

## How to leverage Gavi platform for other health / non health interventions?

Immunisation has the highest coverage rates among health interventions; it could be further leveraged to strengthen primary healthcare.

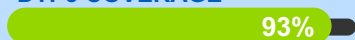


# As countries transition out, increasingly contrasted situations in Gavi portfolio

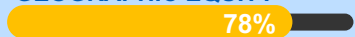
## Cambodia: “Strong performance”



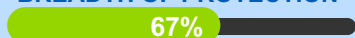
### DTP3 COVERAGE



### GEOGRAPHIC EQUITY



### BREADTH OF PROTECTION



### EFFECTIVE VACCINE MANAGEMENT



## Guinea: “Weak systems”



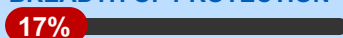
### DTP3 COVERAGE



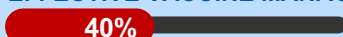
### GEOGRAPHIC EQUITY



### BREADTH OF PROTECTION



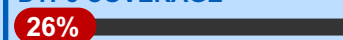
### EFFECTIVE VACCINE MANAGEMENT



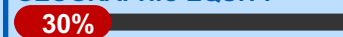
## South Sudan: “Widespread conflicts”



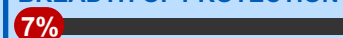
### DTP3 COVERAGE



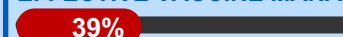
### GEOGRAPHIC EQUITY



### BREADTH OF PROTECTION



### EFFECTIVE VACCINE MANAGEMENT



# The Alliance's post-2020 model requires more targeted approaches

Post-2020 Gavi portfolio of 49 countries\*

Immunisation  
Barriers

Low

Medium

High

Widespread  
Conflicts

**Weak systems  
with low  
performance**

**2. Weak systems** (n=14)

Kenya

71%

52%

**1. Strong performers** (n=29)

Burkina Faso  
Bangladesh  
Cote d'Ivoire  
Ghana  
Cambodia  
Rwanda

Tajikistan  
Eritrea  
Zimbabwe  
Burundi  
Sudan  
And 13 more

13%

41%

**High  
performance  
with relatively  
strong system**

Chad  
Djibouti  
Nigeria

Guinea  
Haiti  
Mali  
Pakistan

Comoros  
Niger  
Congo DRC

Madagascar  
Mauritania  
Ethiopia

Cameroon  
Liberia  
Mozambique

Myanmar  
Sierra Leone

**3. Widespread Conflicts** (n=6)

Afghanistan  
CAR  
Somalia

South Sudan  
Syria  
Yemen

**Ongoing  
acute crises /  
failing states**

**Average DTP3 coverage:**  
1. Strong performers: 92%  
2. Weak systems: 65%  
3. Widespread conflicts: 54%

Low

Medium

High

**Coverage and Equity**

x%

Share of under-immunized in 2025

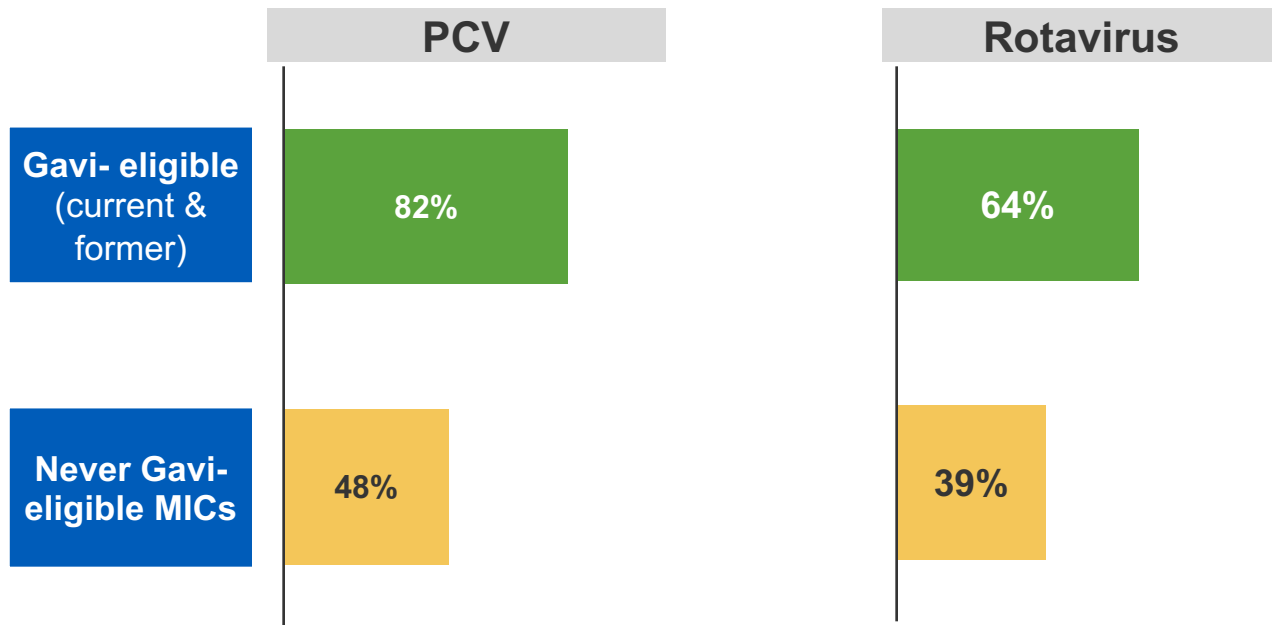
x%

Share of birth cohort in 2025

\*Includes countries eligible for the entire 2021 / 2025 period

# Never-Gavi MICs lagging behind Gavi-eligible countries on PCV and Rota introductions

Percentage of countries where vaccine is introduced as of 2018



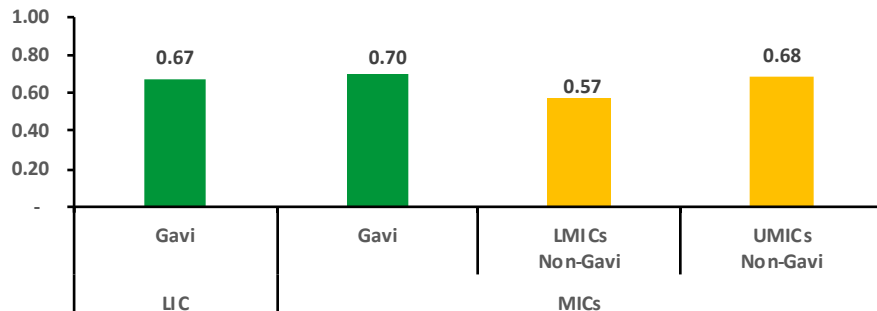
**Note:** Gavi-Eligible refers to Gavi 72 and Never-Gavi refers to countries not part of Gavi 72

**Source:** Vaccine Launch Database for Gavi-eligible countries; JHU IVAC View-Hub for PCV, Rota and PATH Global Overview for HPV for non-Gavi countries; Includes Phased/ Subnational and Regional introductions; Gavi Eligible excludes Syria

# Programmatic and institutional capacities lagging in MICs

Effective vaccine management composite score

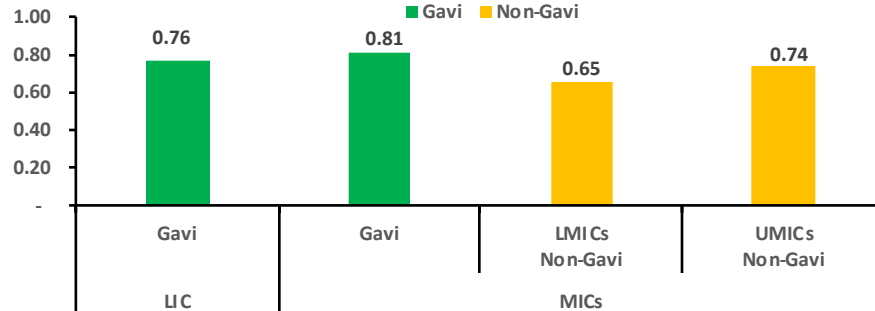
■ Gavi ■ Non-Gavi



National level EVM score

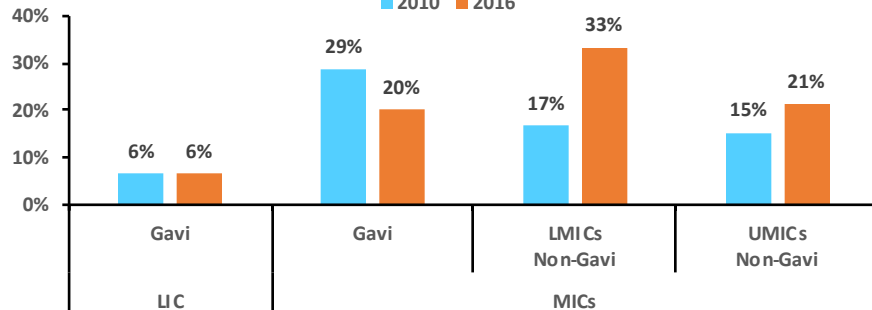
(criteria: storage capacity, maintenance, stock management, vaccine management)

■ Gavi ■ Non-Gavi



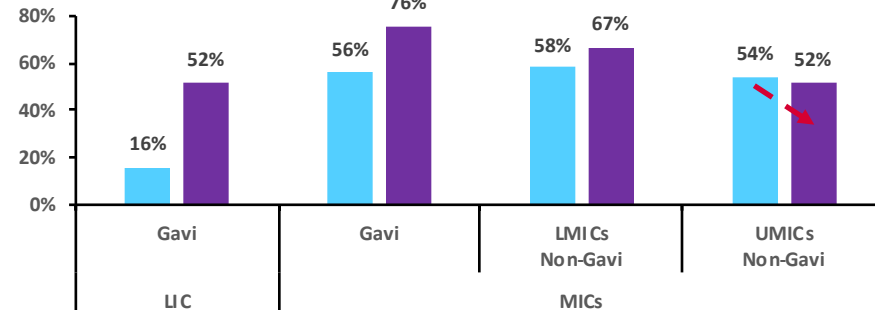
% of countries with a national stock out for at least one month (DTP, PCV, Rota and measles)

■ 2010 ■ 2016



Establishment of NITAG

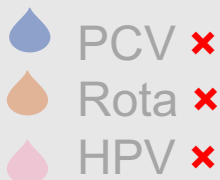
■ 2010 ■ 2016



# Non-Gavi eligible Middle Income Countries facing different types of challenges



## Introductions



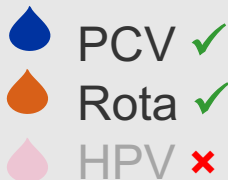
## DTP3 Coverage

## Geographic Equity

GEOGRAPHIC EQUITY

91%

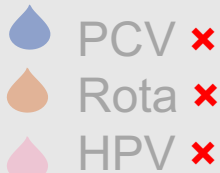
Strong health system, missing vaccines



GEOGRAPHIC EQUITY

63%

Country in chronic crisis, coverage lagging behind



GEOGRAPHIC EQUITY

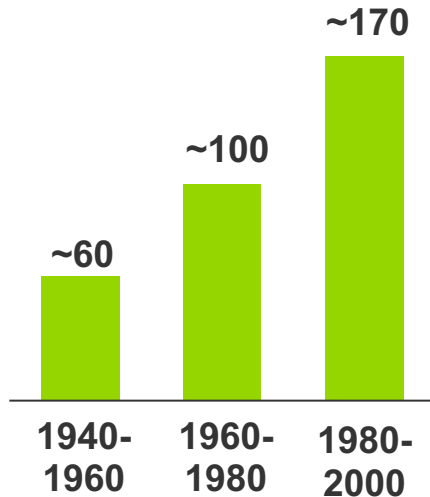
49%

Slipping coverage and lacking introductions

# Outbreaks are on the rise

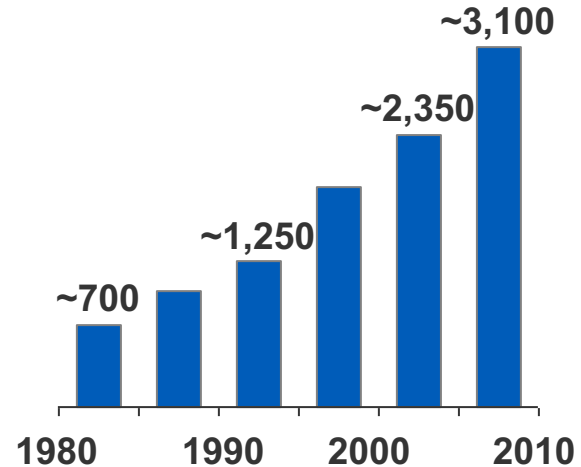
## New pathogens increasingly emerging...

*New pathogen events*



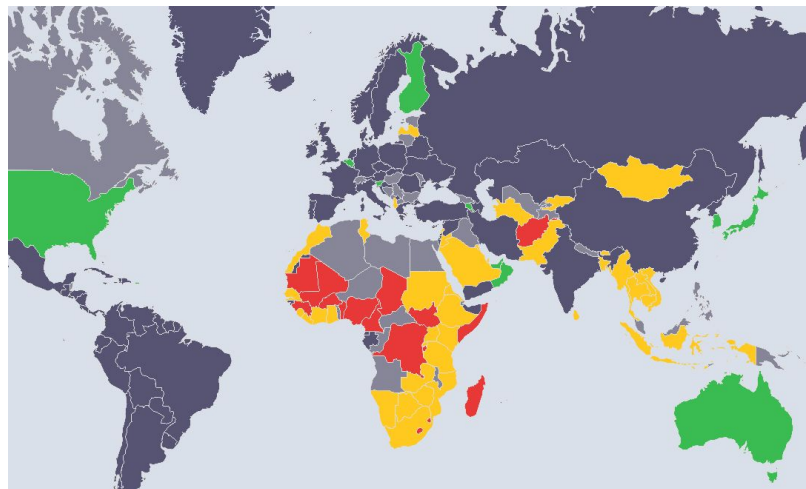
## ...and more outbreaks recorded

*Infectious disease outbreaks*

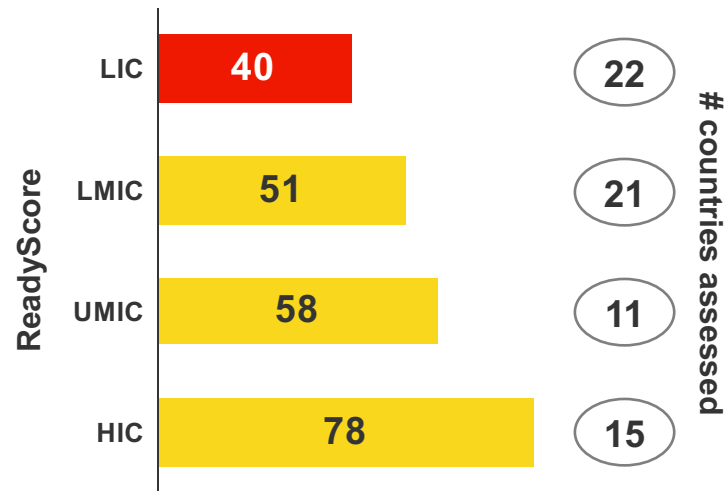


# Gavi countries not well prepared to respond to potential outbreaks

## JEE assessment - overview



## Country breakdown

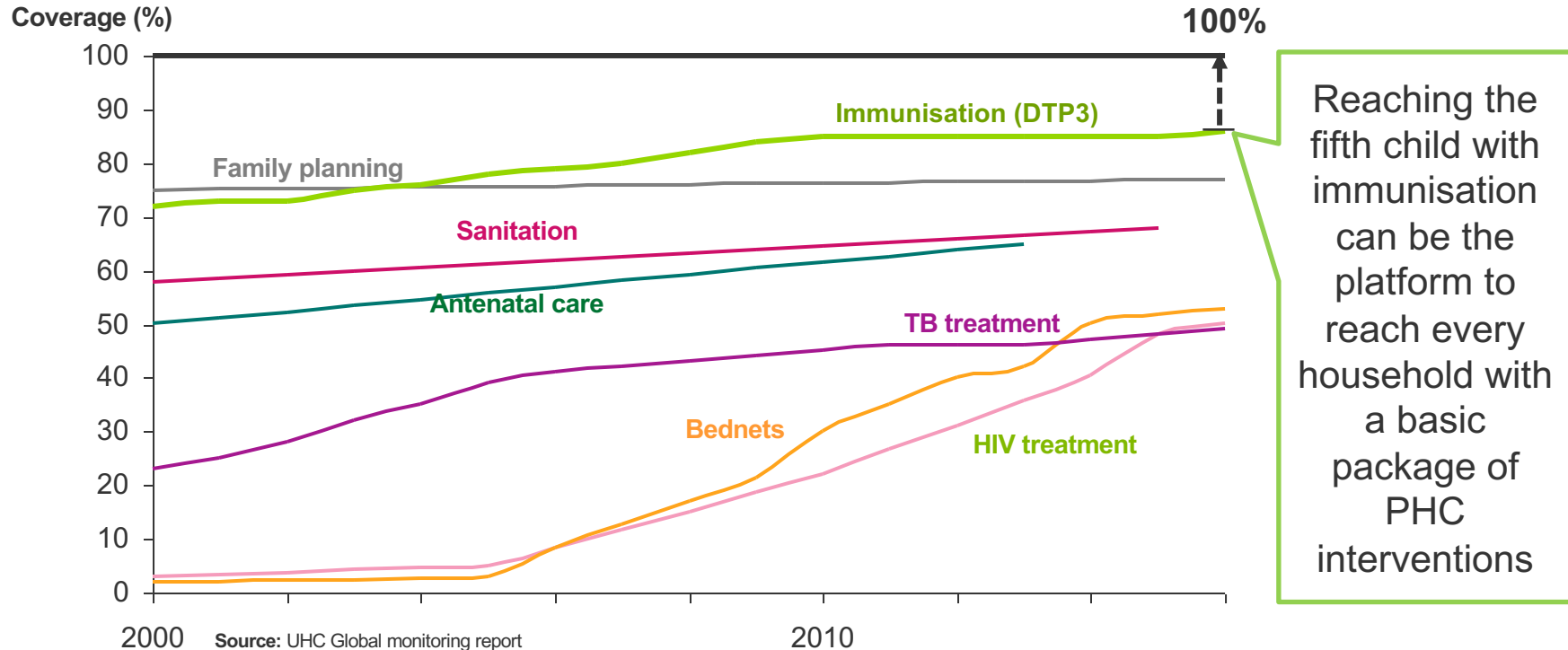


**ReadyScore<sup>1</sup>:** ■ Better prepared (> 80) ■ Work to do (>40-80) ■ Not ready (<=40) ■ Unknown ■ In progress



# Immunisation has the highest coverage rates among key health interventions

## Global coverage of UHC tracer indicators for health interventions



# GHC, our new home

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# THANK YOU

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Reach every child

[www.gavi.org](http://www.gavi.org)