@GaviSeth

Report from Gavi

Seth Berkley, CEO
Meeting of the Strategic Advisory Group of Experts on Immunization
October 2015

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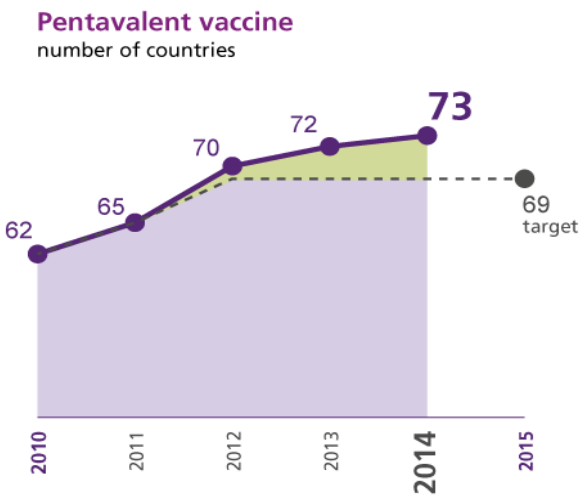
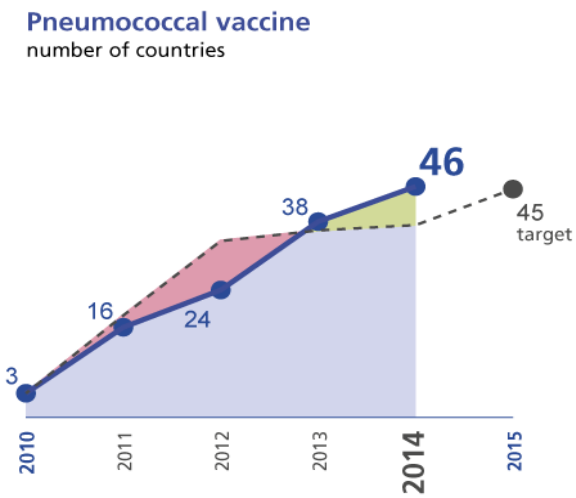
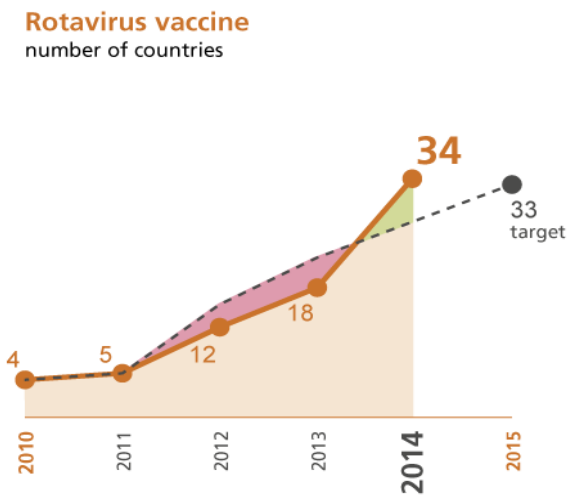
Delivering on Gavi's strategy for 2016-2020

Gavi surpassed its 2011-15 introduction targets a year ahead of schedule







Source: Gavi 2011-15 strategy key performance indicators; Gavi data

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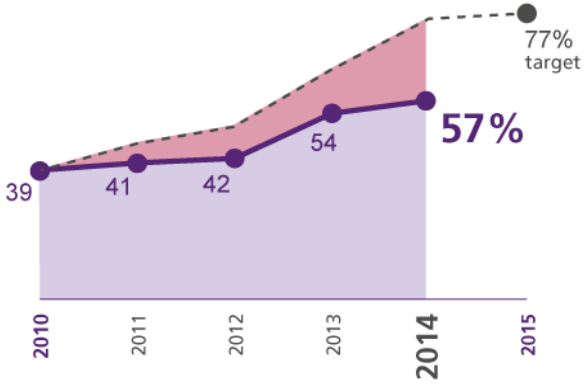
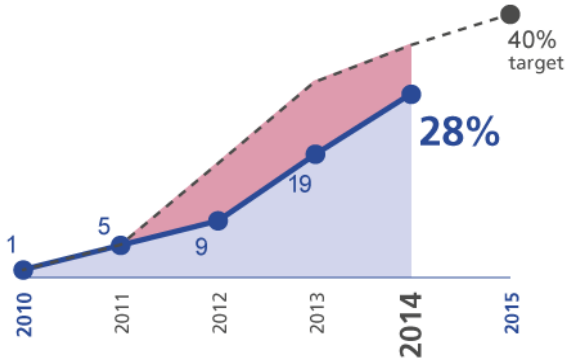
However, we are not on track to achieve our targets for coverage of new vaccines

Pentavalent vaccine, 3rd dose
coverage (%)



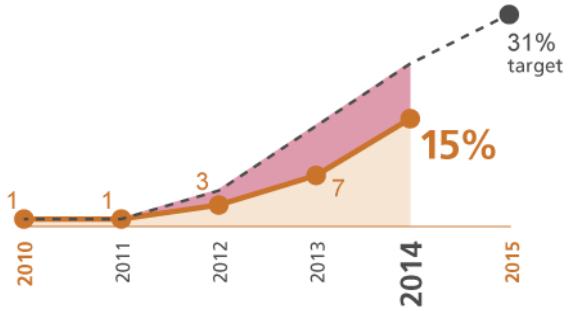
- Slower roll-out in large countries

Pneumococcal vaccine, 3rd dose
coverage (%)



- Country readiness
- Slower roll-out in large countries
- Supply

Rotavirus vaccine, last dose
coverage (%)



- Supply
- Country preference

Source: Gavi 2011-15 strategy key performance indicators; WHO/UNICEF Estimates of National Immunization Coverage 2014 revision, July 2015

= reasons for slow uptake

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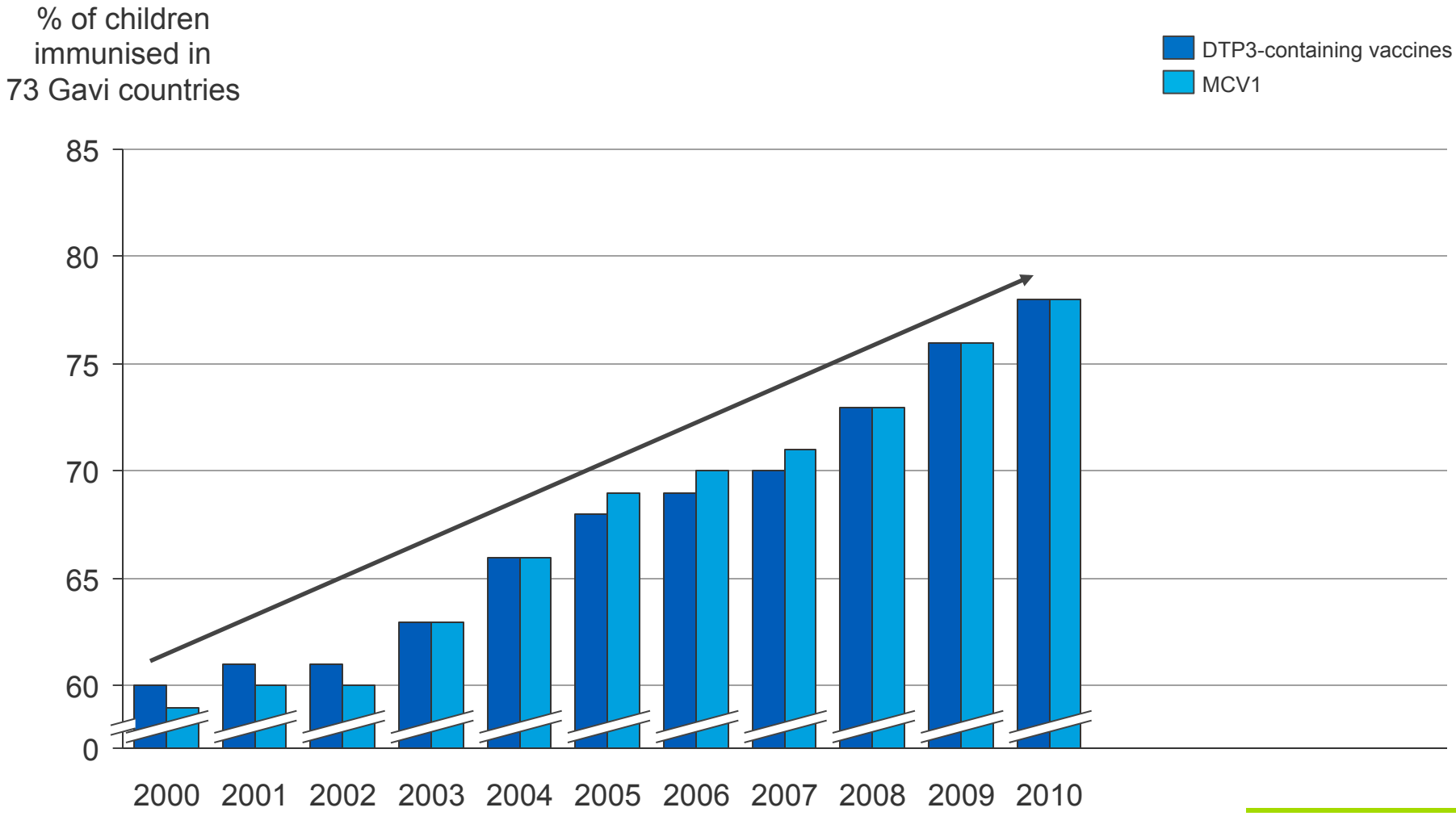
Average coverage across the Gavi 73 increased nearly 20 points in Gavi's first decade…



Source: WHO/UNICEF Estimates of National Immunization Coverage 2014 revision, July 2015

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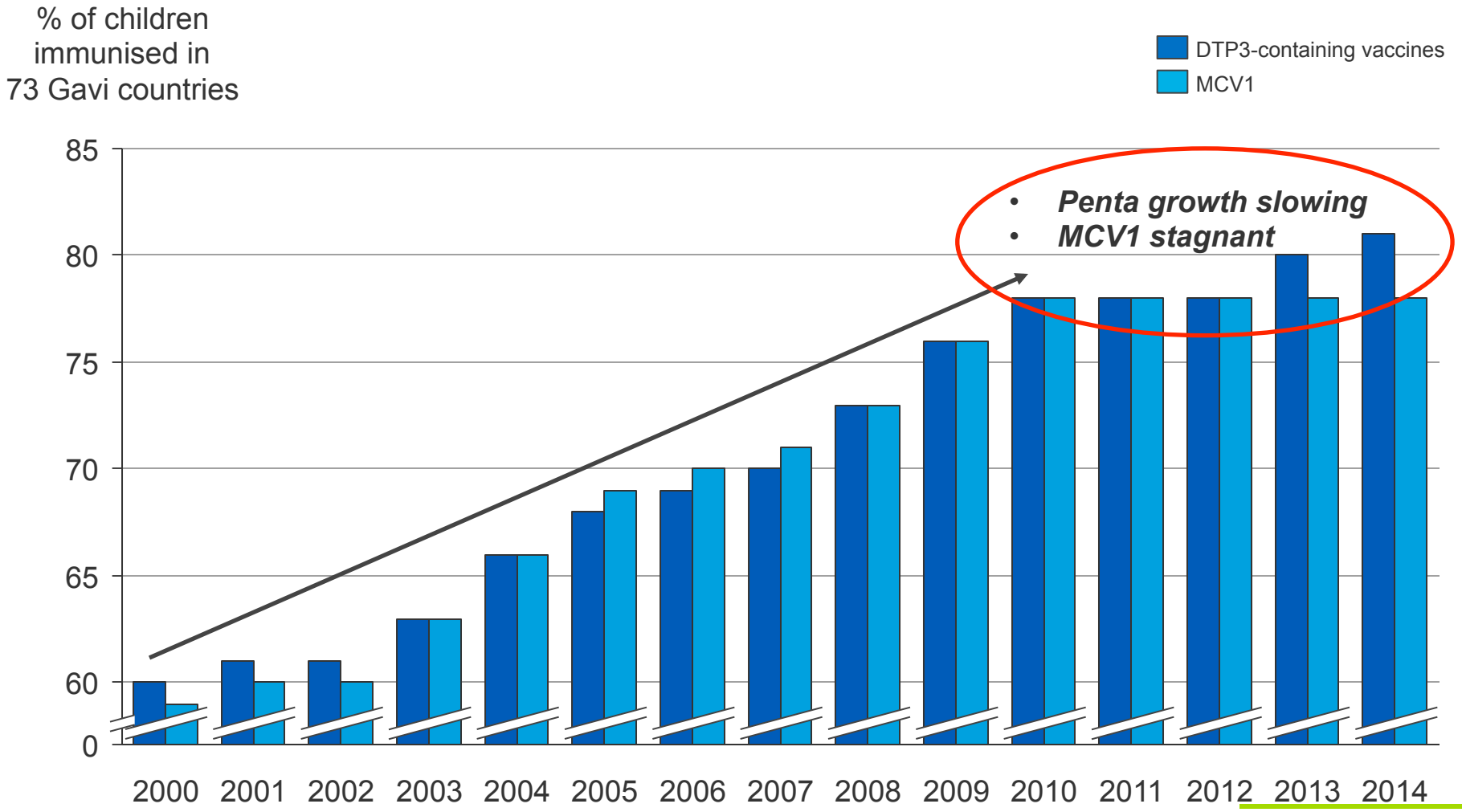
…but has plateaued in recent years



Source: WHO/UNICEF Estimates of National Immunization Coverage 2014 revision, July 2015

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Routine immunisation coverage has increased rapidly in many Gavi countries

1999

<50% 17 countries	50-59% 13 countries	60-69% 4 countries	70-79% 14 countries	80-89% 11 countries	90%+ 12 countries
Afghanistan	Cambodia	Mozambique	Azerbaijan	Bangladesh	Armenia
Angola	Cameroon	Nepal	Benin	Georgia	Bhutan
Burkina Faso	Côte d'Ivoire	Papua NG	Bolivia	Guyana	Cuba
Cent Afr Rep.	DPR Korea	Senegal	Burundi	Kenya	Eritrea
Chad	India		Comoros	Lesotho	Honduras
Congo Rep.	Lao PDR		Cambia	Malawi	Kyrgyzstan
DR Congo	Liberia		Ghana	Rwanda	Mongolia
Djibouti	Madagascar		Indonesia	Solomon Isl.	Moldova
Ethiopia	Mauritania		Kiribati	Tajikistan	Sri Lanka
Guinea	Pakistan		Myanmar	Zambia	Ukraine
Guinea-Bissau	Sudan		Nicaragua	Zimbabwe	Uzbekistan
Haiti	Togo		Sao Tome		Vietnam
Mali	Uganda		Tanzania		
Niger			Yemen		
Nigeria					
Sierra Leone					
Somalia					

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Routine immunisation coverage has increased rapidly in many Gavi countries

2004

<50% 8 countries	50-59% 5 countries	60-69% 13 countries	70-79% 15 countries	80-89% 15 countries	90%+ 16 countries
Angola	Afghanistan	Congo Rep.	Azerbaijan	Bhutan	Armenia
Chad	Cent Afr Rep.	Côte d'Ivoire	Benin	Bolivia	Bangladesh
Ethiopia	DR Congo	Djibouti	Burkina Faso	Burundi	Eritrea
Lao PDR	Haiti	Guinea	Cameroon	Cambodia	Guyana
Liberia	Timor-Leste	Guinea-Bissau	Comoros	Cuba	Honduras
Niger		India	DPR Korea	Gambia	Kyrgyzstan
Nigeria		Kiribati	Georgia	Ghana	Lesotho
Somalia		Mali	Indonesia	Malawi	Moldova
		Pakistan	Kenya	Mozambique	Mongolia
		Papua NG	Madagascar	Myanmar	Sao Tome
		Sierra Leone	Mauritania	Nepal	Solomon Isl.
		Uganda	Nicaragua	Rwanda	Sri Lanka
		Zimbabwe	Sudan	Senegal	Ukraine
			Togo	Tajikistan	Tanzania
			Yemen	Zambia	Uzbekistan
					Vietnam

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Routine immunisation coverage has increased rapidly in many Gavi countries

2009

<50% 3 countries	50-59% 2 countries	60-69% 6 countries	70-79% 16 countries	80-89% 17 countries	90%+ 28 countries
Cent Afr Rep.	Ethiopia	Afghanistan	Angola	Azerbaijan	Armenia
Chad	Guinea	Haiti	Benin	Cameroon	Bangladesh
Somalia		Lao PDR	Congo Rep.	Comoros	Bhutan
		Mauritania	DR Congo	Côte d'Ivoire	Bolivia
		Nigeria	India	Djibouti	Burkina Faso
		Papua NG	Indonesia	Georgia	Burundi
			Madagascar	Guinea-Bissau	Cambodia
			Mali	Kenya	Cuba
			Mozambique	Kiribati	DPR Korea
			Niger	Liberia	Eritrea
			Pakistan	Moldova	Gambia
			Timor-Leste	Nepal	Ghana
			Togo	Senegal	Guyana
			Uganda	Sierra Leone	Honduras
			Ukraine	Sudan	Kyrgyzstan
			Zimbabwe	Tanzania	Lesotho
				Yemen	Malawi
					Mongolia
					Myanmar
					Nicaragua
					Rwanda
					Sao Tome
					Solomon Is
					Sri Lanka
					Tajikistan
					Uzbekistan
					Vietnam
					Zambia

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Routine immunisation coverage has increased rapidly in many Gavi countries

2014

<50%	50-59%	60-69%	70-79%	80-89%	90%+
5 countries	2 countries	4 countries	14 countries	16 countries	32 countries
Cent Afr Rep.	Guinea	Côte d'Ivoire	Afghanistan	Angola	Armenia
Chad	Liberia	Niger	Benin	Cameroon	Azerbaijan
Haiti		Nigeria	Djibouti	Comoros	Bangladesh
Somalia		Papua NG	Ethiopia	DR Congo	Bhutan
South Sudan			Indonesia	Guinea-Bissau	Bolivia
			Kiribati	Honduras	Burkina Faso
			Madagascar	India	Burundi
			Mali	Kenya	Cambodia
			Mozambique	Lao PDR	Congo Rep.
			Myanmar	Mauritania	Cuba
			Pakistan	Senegal	DPR Korea
			Timor-Leste	Sierra Leone	Eritrea
			Uganda	Solomon Isl.	Gambia
			Ukraine	Togo	Georgia
				Yemen	Ghana
				Zambia	Guyana
					Kyrgyzstan
					Lesotho
					Malawi
					Moldova
					Mongolia
					Nepal
					Nicaragua
					Rwanda
					Sao Tome
					Sri Lanka
					Sudan
					Tajikistan
					Tanzania
					Uzbekistan
					Vietnam
					Zimbabwe

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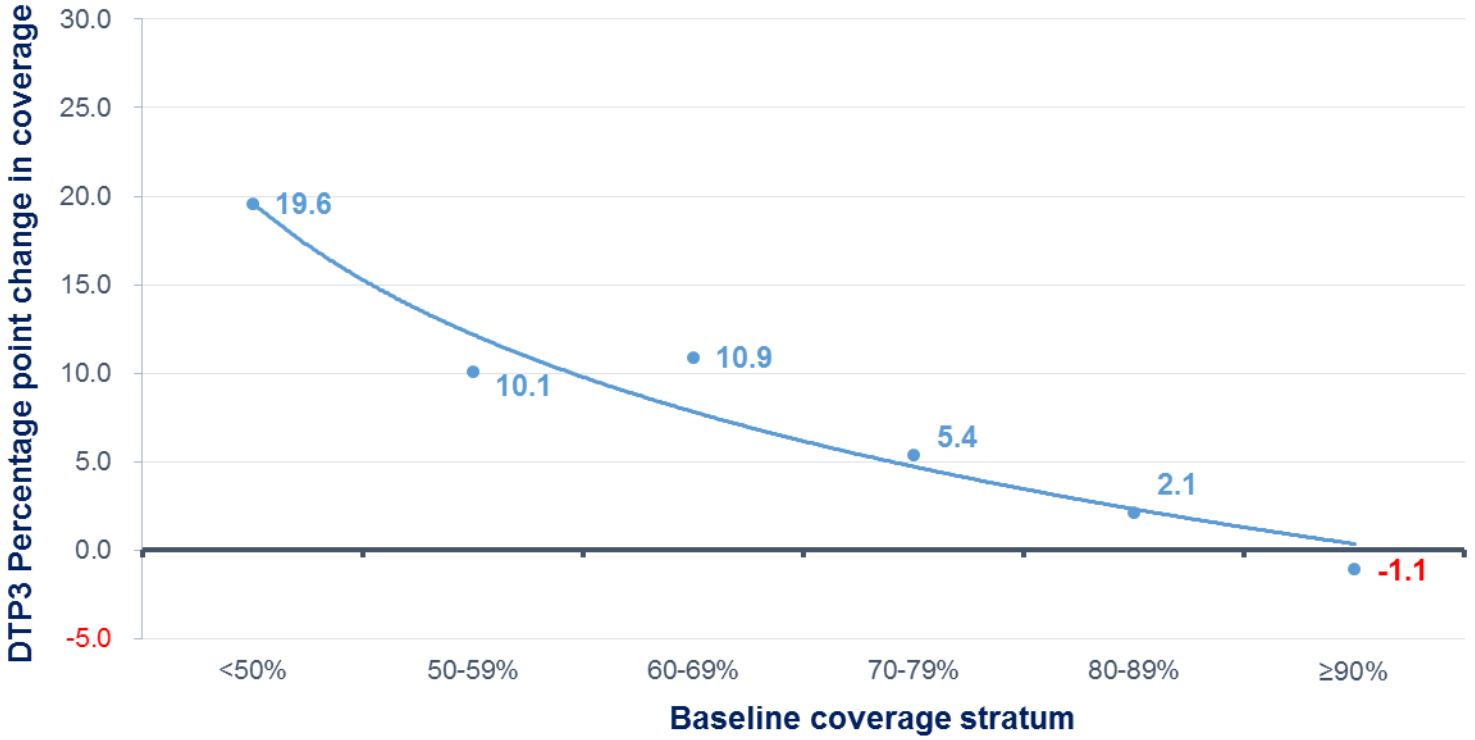
As coverage increases, countries are encountering a “ceiling” effect

Average percentage point change in 5 year period by baseline coverage level, third dose of DTP-containing vaccine



1999-2014 trend observations from 53 countries divided into three five-year groups (2000-2004, 2005-2009, 2010-2014) with prior year serving as baseline

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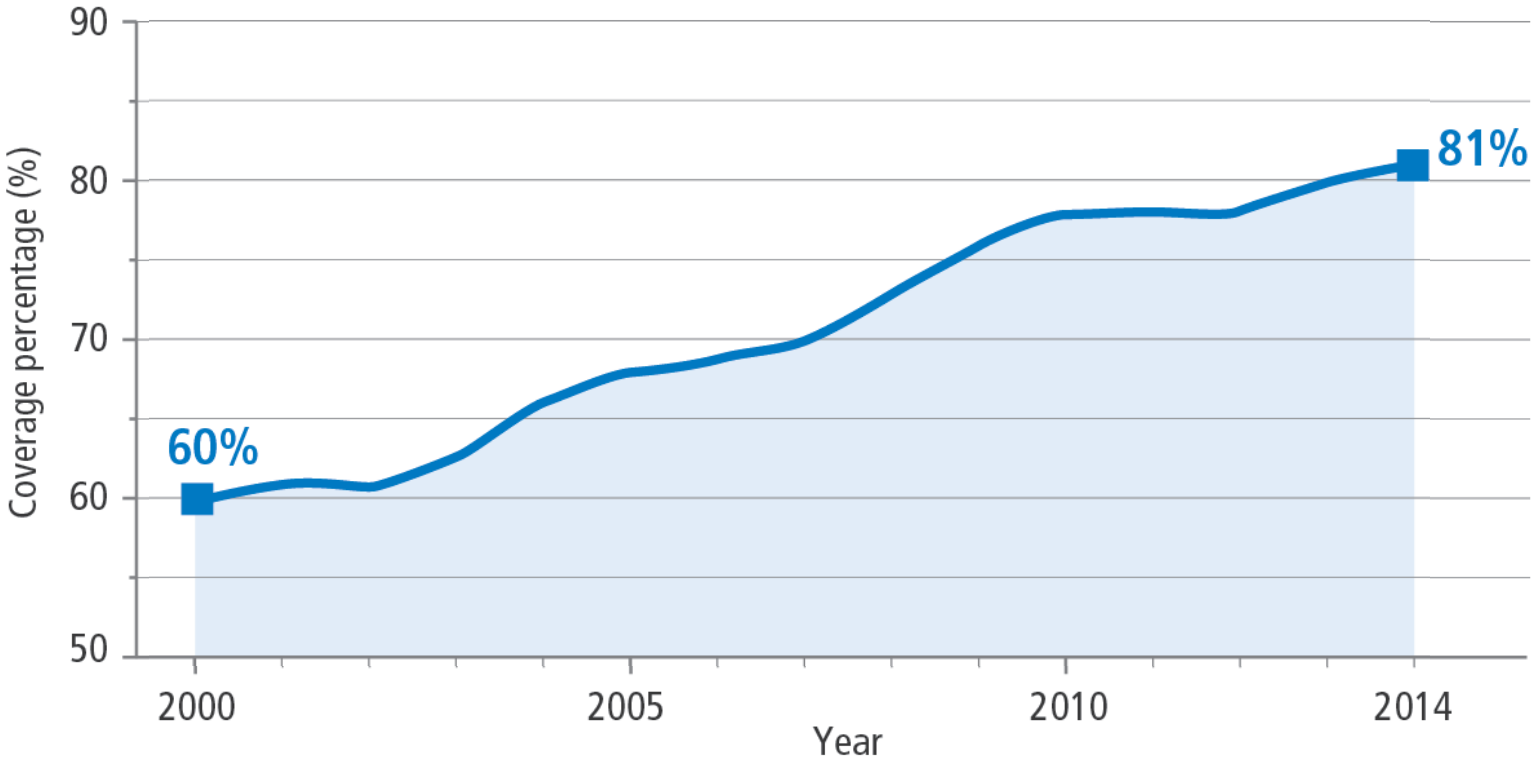
Immunisation coverage in 73 Gavi-supported countries



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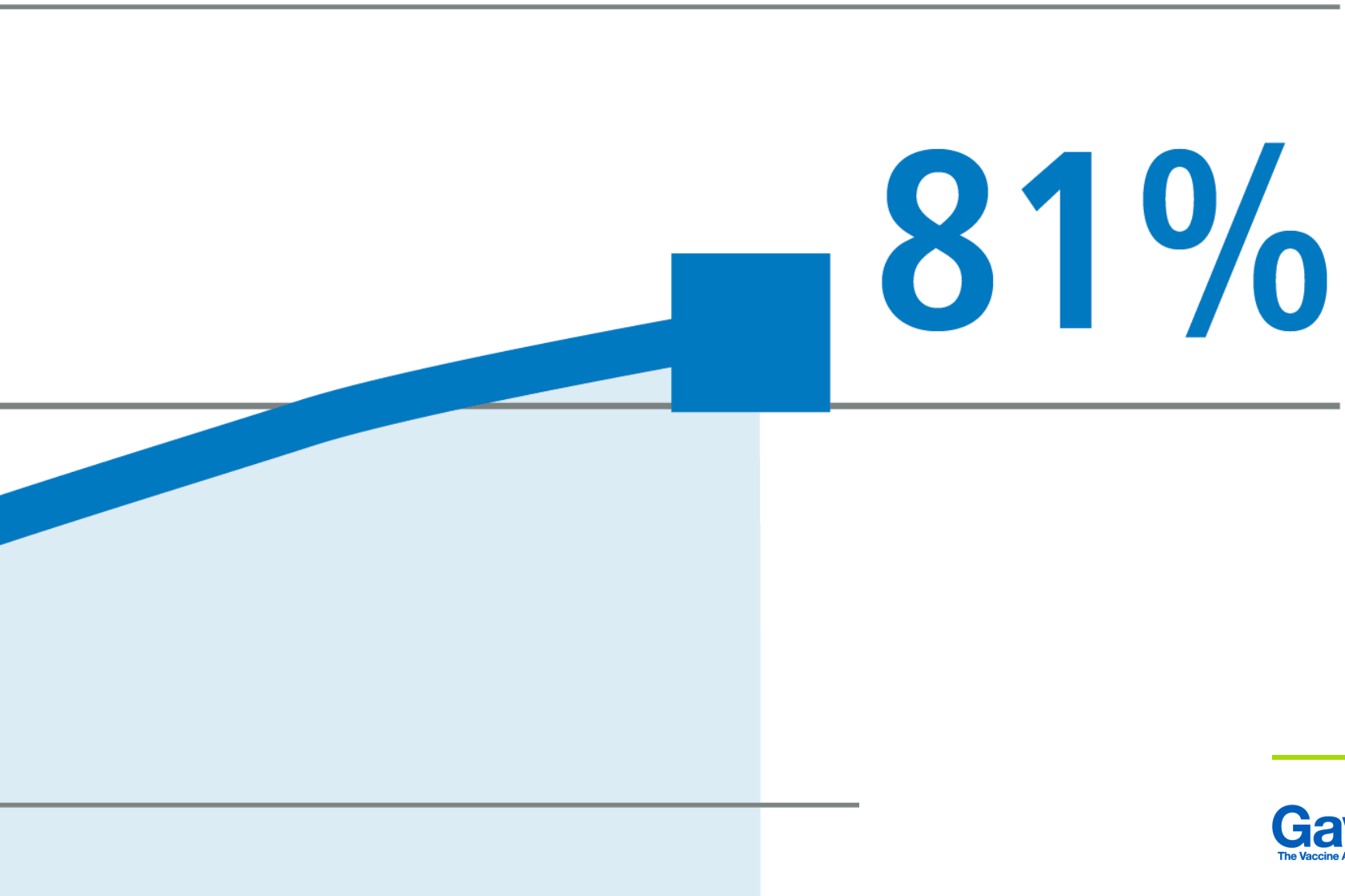
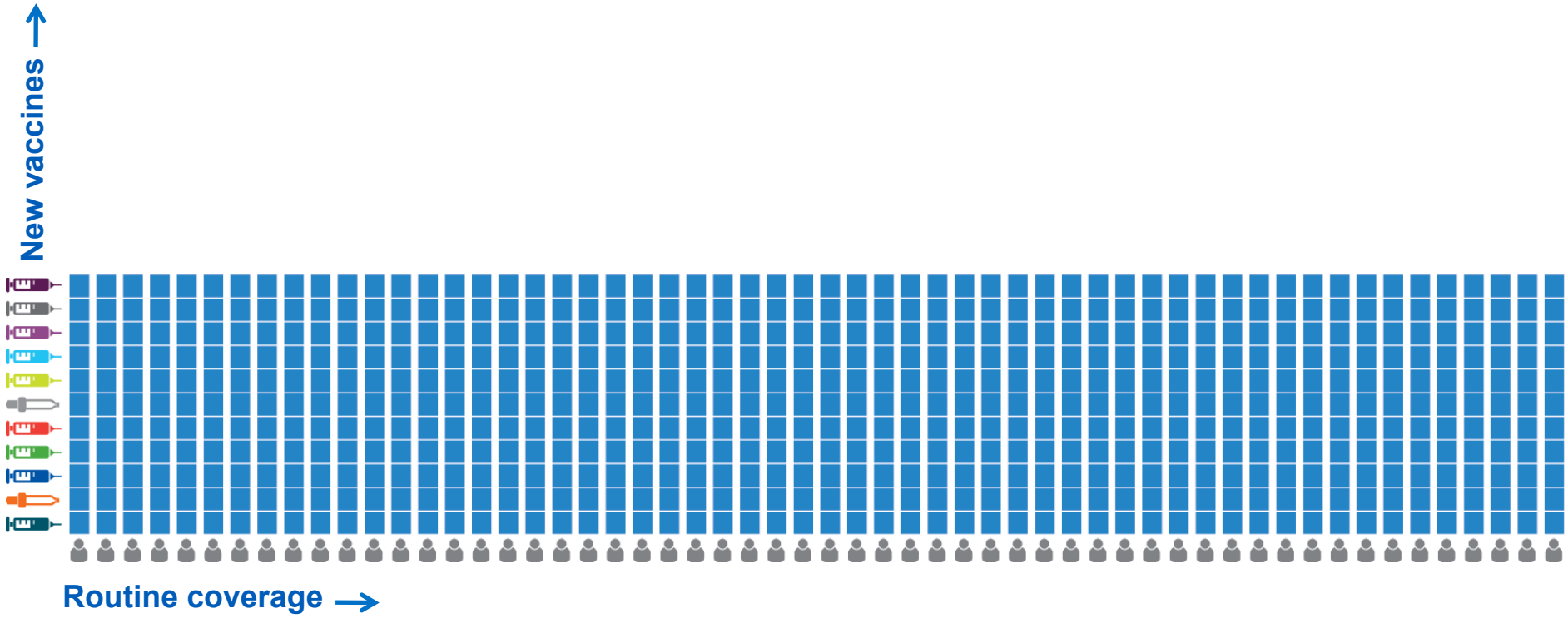
A closer look...



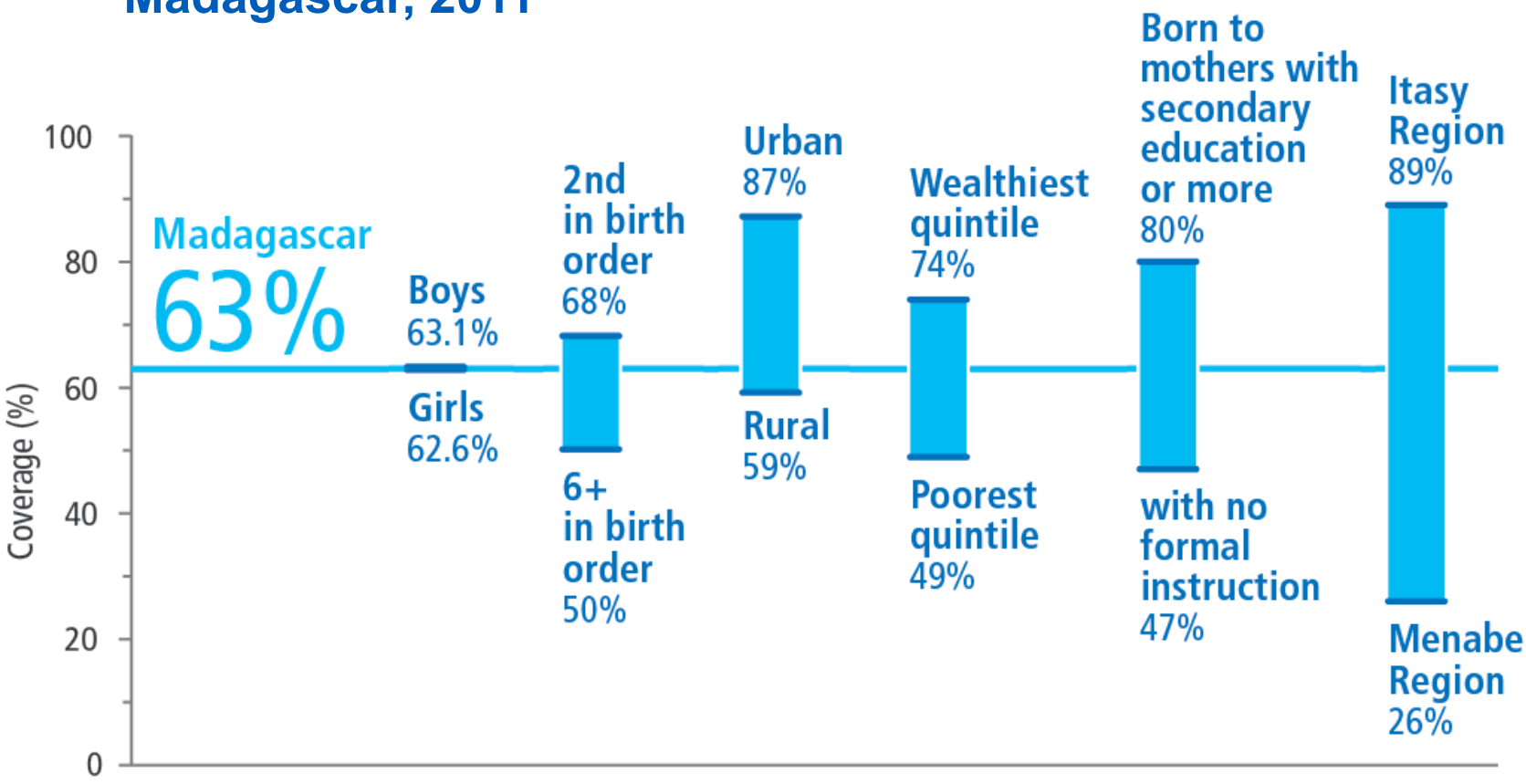
A closer look...

A closer look...



In addition, significant inequities persist in many countries

Immunisation inequities by population characteristics, Madagascar, 2011



Source: unicef

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Gavi 2016-20 strategy focused on accelerating progress on coverage & equity and sustainability

Gavi's four strategic goals 2016-20

1 Accelerate **equitable uptake and coverage** of vaccines

2 Increase **effectiveness and efficiency of immunisation delivery** as an integrated part of strengthened health systems

3 Improve **sustainability** of national immunisation programmes

4 **Shape markets** for vaccines and other immunisation products

Source: Gavi 2016-20 strategy

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How will Gavi measure coverage & equity?

	2016-20 strategy indicators	Recommended 2016-20 targets
Reach of RI coverage	• 3rd dose of pentavalent vaccine • First dose of measles vaccine	+5 percentage points
Breadth of protection	• Average coverage across all Gavi supported vaccines	• +32 points
Equity of RI coverage	Difference in penta3 coverage by • Geography (by district) • Wealth • Education status of mother / female caregiver	+10 percentage points

Gavi 2016-20 strategy targets to be approved by Board in December

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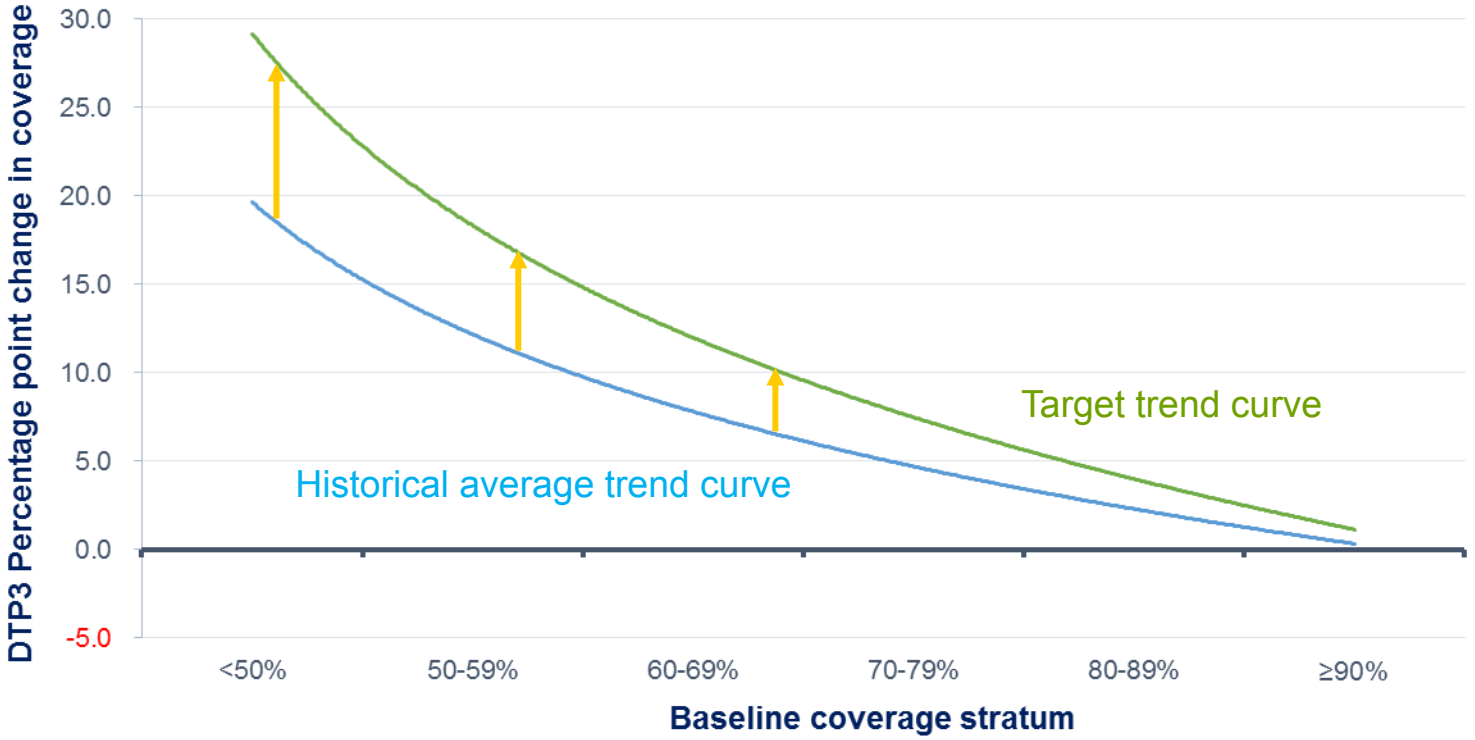
Coverage target will require 50% acceleration in rate of coverage growth for each country strata

Average percentage point change in 5 year period by baseline coverage level, third dose of DTP-containing vaccine



1999-2014 trend observations from 68 countries divided into three five-year groups (2000-2004, 2005-2009, 2010-2014) with prior year serving as baseline

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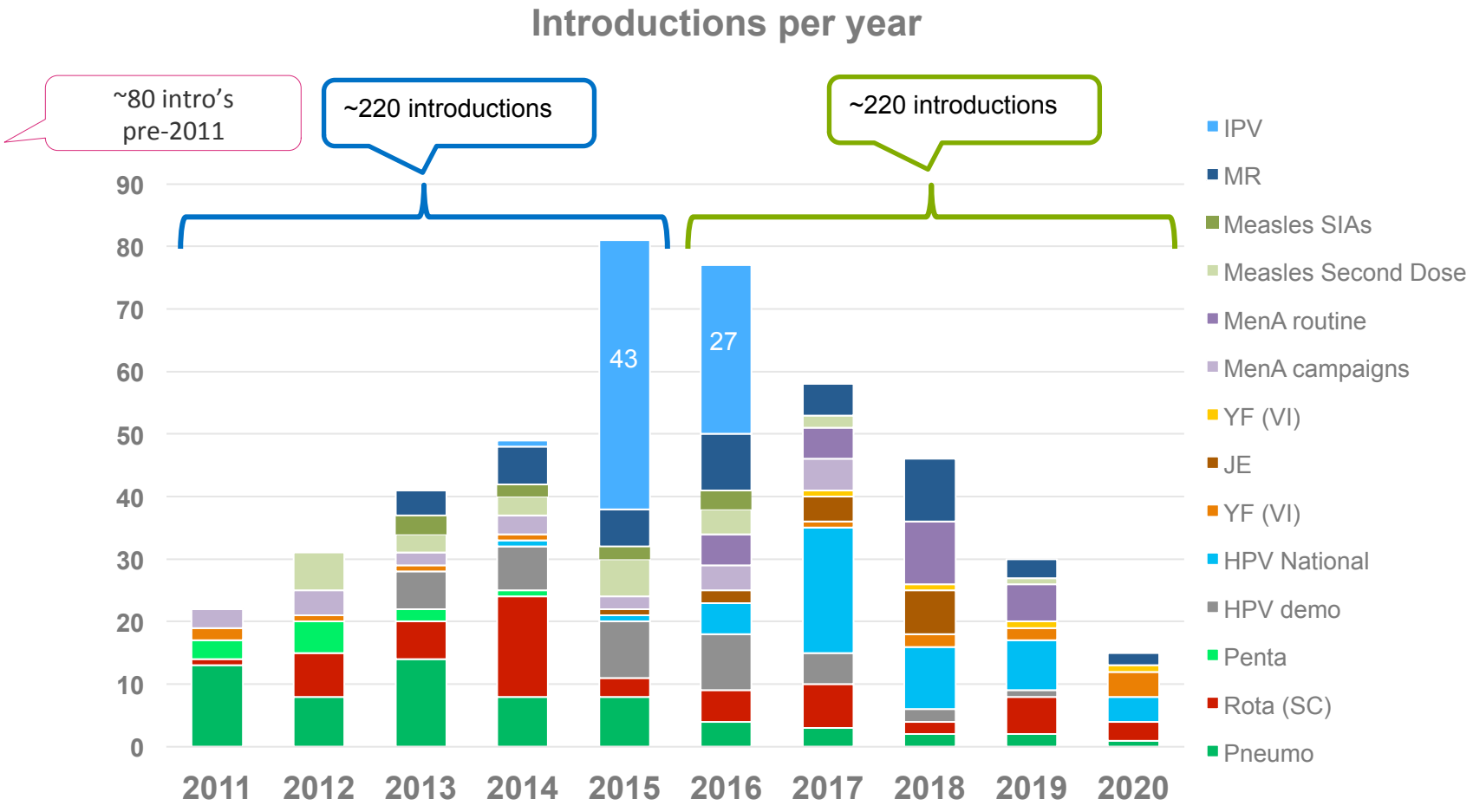
Continued focus on new vaccine introductions to address inequities in access between countries



Source: Vaccine Implementation data; data as of 15 September 2015 (SDFv11). Unconstrained introduction dates were used for all vaccines except yellow fever and rotavirus vaccines.

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Four key elements of new approach to strengthen coverage and equity

1 **More proactive and country-tailored grant management**

- *Direct funding support review*
- *GAMR (incl. JAs and HLRP)*
- *Translation of strategy into frontline actions (& linkage to Gavi support)*

2 **New ways of working with Partners**

- *Partners' Engagement Framework (incl. RFI for expanded partners)*

3 **Transformational engagement in SFAs**

- *Supply chain*
- *Data*
- *Sustainability*
- *Demand promotion*
- *Political will*
- *Leadership, mngmt & coord.*

4 **Differentiated approach prioritizing 20 countries**

- *Focus on 20 priority countries*
- *Intensified engagement with countries ('C&E approach')*
- *Country-specific strategies (e.g. India)*

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1 A new country-centric process to design, monitor and review grants

New approach

Integrated package of support to meet country needs

- New and under-used vaccines
- Health system strengthening
- Country-driven technical assistance
- Transition planning

Design support, with country lens

Review & evaluate support

Routine monitoring

- Country-driven joint appraisals
- Performance frameworks
- Country level KPIs for partners

High Level Review Panel (HRLP)

Impact evaluation

- Small area estimations
- Grant evaluation

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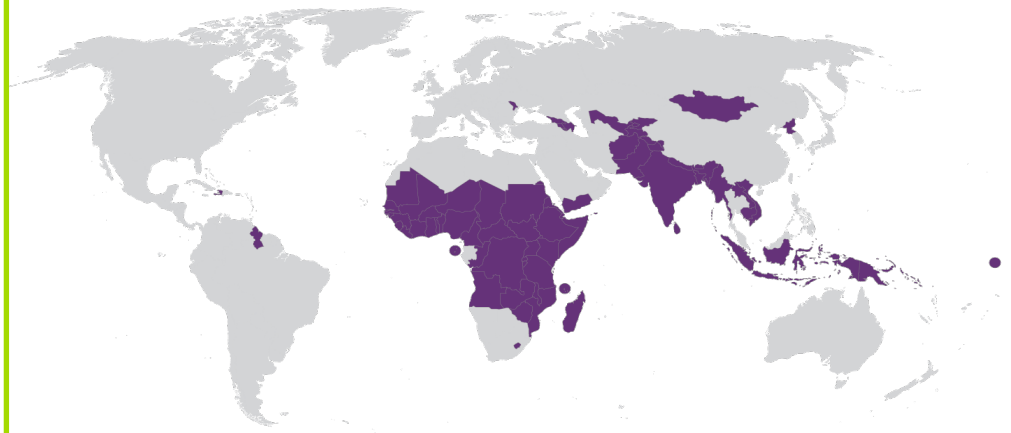
2 A new Partners' Engagement Framework to provide targeted technical support

1 **Targeted country assistance:**
Country-driven assistance plan
Prioritisation of countries
Assistance to include management support



2 **Special investments in strategic focus areas:**

- Supply chain
- Data
- Demand generation
- Sustainability
- Political will
- Leadership, management and coordination

3 **Foundational support:** Long-term funding for core partners (WHO, UNICEF, World Bank, CDC, CSO) for coordination in key programmatic areas

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3 Six “Strategic Focus Areas" identified as first priorities for transformational work

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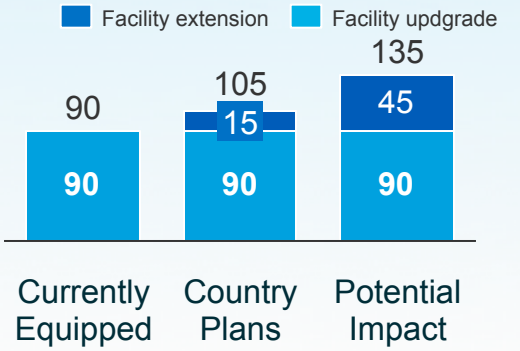
3 SFA example: Supply Chain
Three objectives of CCE Optimisation platform

CCE available everywhere it's needed

Vision: Equip 90,000 facilities with upgraded equipment and extend CCE to 45,000 unequipped facilities over the next 5-7 years

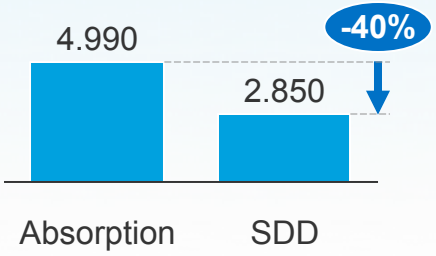
Facilities impacted by Platform[1], #



Right technology for each facility

- *Incentivise manufacturers to develop higher performing / lower cost technologies*
- *Help countries to choose the right technology for their needs*

Total cost of ownership[2], USD



Reliable and robust equipment performance

Improve technology design to mitigate common failures (e.g., voltage regulators) and enhance CCE maintenance

1: Estimations for 55 countries eligible for platform funding based on Board presentation (excluding India)
2: Based on Board presentation assuming a Dometic RCW 50EG (24L) as absorption and a BFRV15 (15L) as SDD
Source: CCEM, Country EVM assessments (2011-2014), IEA, World Energy Outlook 2012, Interviews with Country SCMs and external consultants

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3 SFA example: Data
What the Alliance aims to achieve in data by 2020

Focus areas

Goals for 2020

Measurable improvements in availability, quality, use and transparency of data to **improve immunisation coverage and equity**

Quality and timely data on VPD to **strengthen programme management, inform decisions** and provide **evidence** for measurement of impact and risk

Ability to **identify and investigate** signals of severe AEFIs, **respond** efficiently and effectively and **address public concerns** on safety

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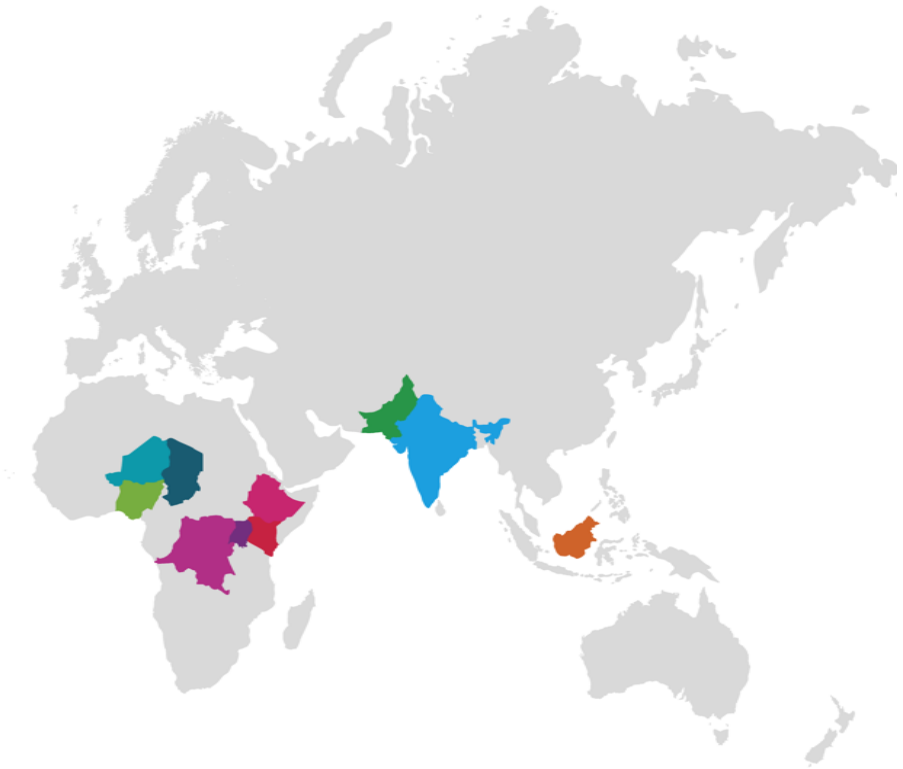
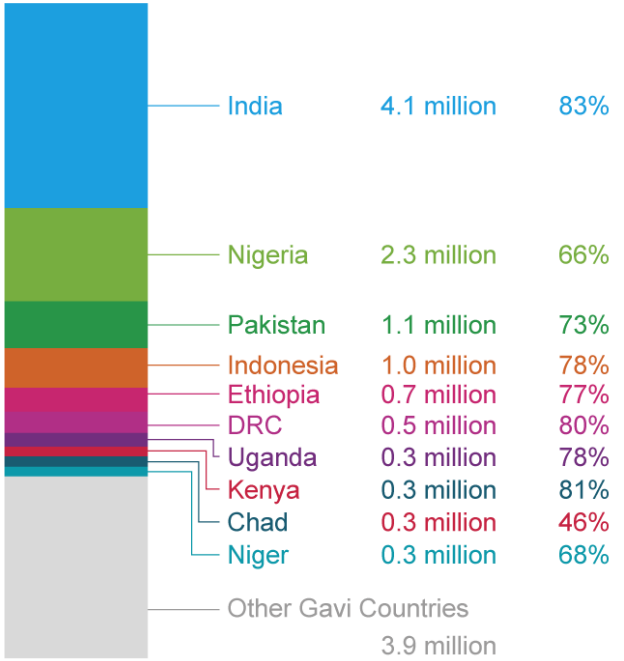
4 Critical to accelerate progress in selected large and fragile countries



Number of under-immunised children + DTP3 Coverage



- **~75% of under-immunised children* in Gavi countries are in 10 large or fragile states**
- **Accelerating progress in these countries critical to drive global improvement in coverage**

* Based on children receiving three doses of a DTP-containing vaccine

Source: Gavi analysis based on WHO/UNICEF Estimates of National Immunization Coverage 2014 revision, July 2015

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4 20 countries have been prioritised for more intensified engagement and tailored support

10 countries with most under-immunised children	10 countries with high inequities[1] or conflict
• Afghanistan	• Central African Republic
• Chad	• Haiti
• DR Congo	• Madagascar
• Ethiopia	• Mozambique
• India	• Myanmar
• Indonesia	• Niger
• Kenya	• Papua New Guinea
• Nigeria	• Somalia
• Pakistan	• South Sudan
• Uganda	• Yemen

20 prioritised countries account for >80% of under-immunised children in Gavi 73

[1] High inequity is defined as >20% coverage difference between highest and lowest wealth quintile in DHS surveys after 2010.

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4 Progress in India critical to global coverage and equity agenda

1 Coverage and equity

Increase immunisation coverage and equity in India through targeted support to strengthen the routine immunisation system

2 New vaccines

Maximise health impact by accelerating adoption of new vaccines in India

3 Market shaping

Maximise procurement savings and vaccine supply security by sharing information, coordinating tactics and building a long-term strategy that strengthens local public and private sector manufacturers

4 Sustainability

Ensure that vaccine programmes in India will be sustainable beyond 2021 by supporting the government to plan for the transition and advocating for increased domestic spending on immunisation

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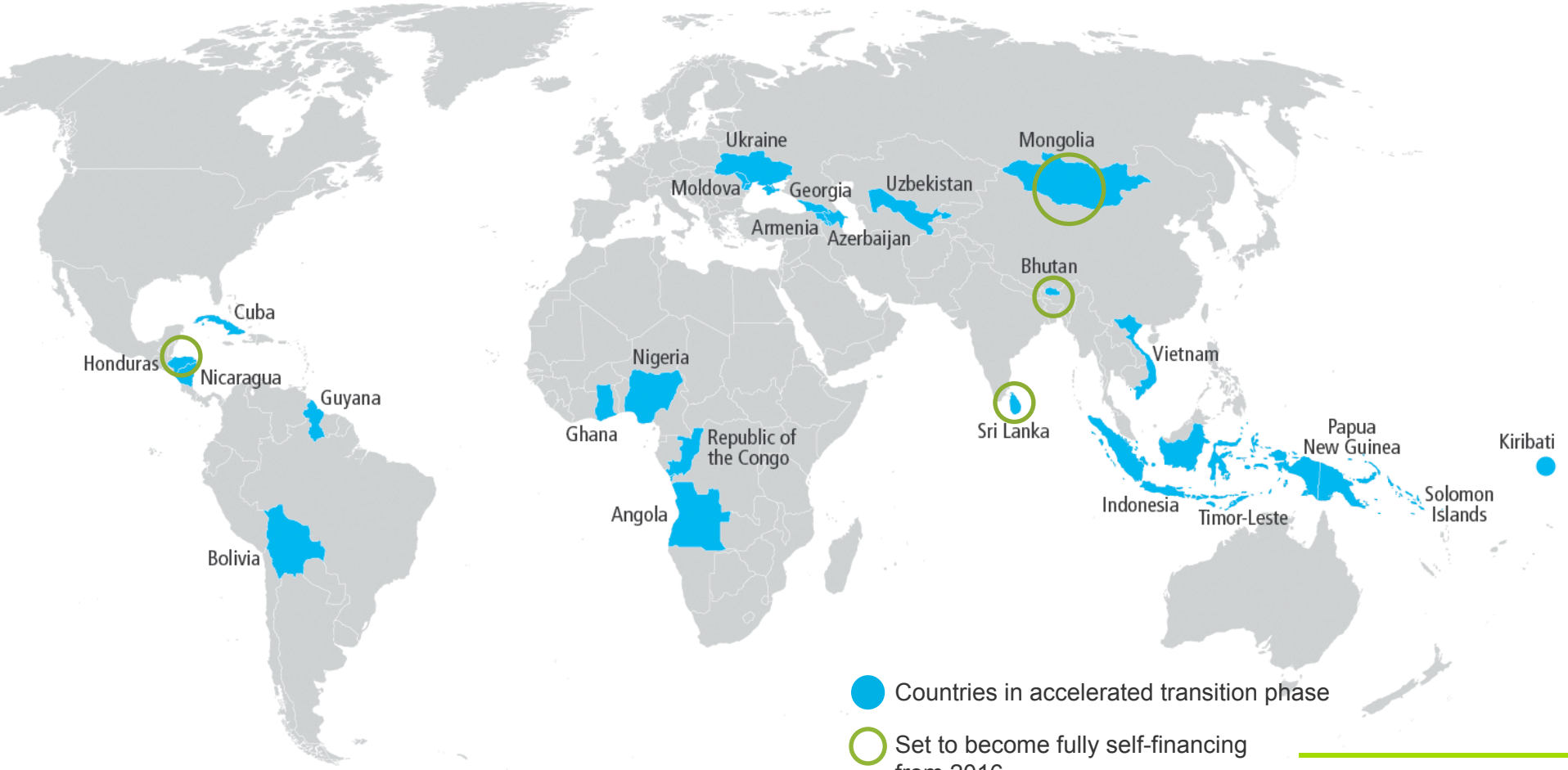
24 countries in accelerated transition phase, 4 set to become fully self-financing from 2016



Note: Cuba and the Ukraine are no longer receiving Gavi vaccine support.

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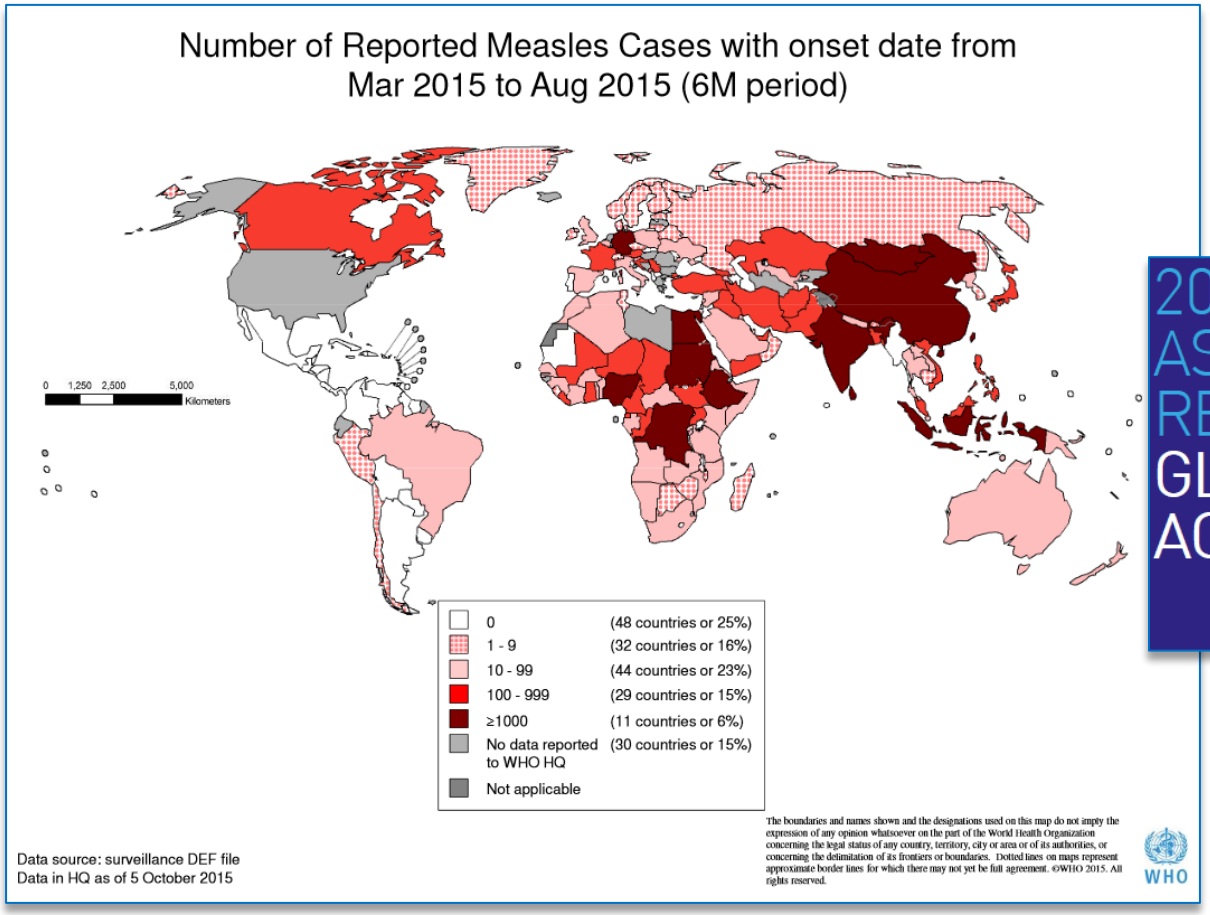
Key updates on programmes

Measles and rubella: Global control and eradication efforts off track



GVAP
OFF TRACK
MID-POINT TARGET

2015 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN

STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION

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Measles and rubella: Gavi's current support fragmented and limited in scope and time

Past: Gavi-IFFIm provided US$ 176M to M&RI in 2004-2008

Current direct support ($1.3 Billion Programmed):

Routine measles second dose (duration of 5 years)	Measles-Rubella campaigns (below 15 years) before start of routine
Measles SIA 6 high risk countries for population below 5 years of age	Outbreak response fund to Measles - Rubella Initiative (US$ 55m through to 2017)

Indirect support:

- Performance-based funding with measles coverage indicator, as part of HSS

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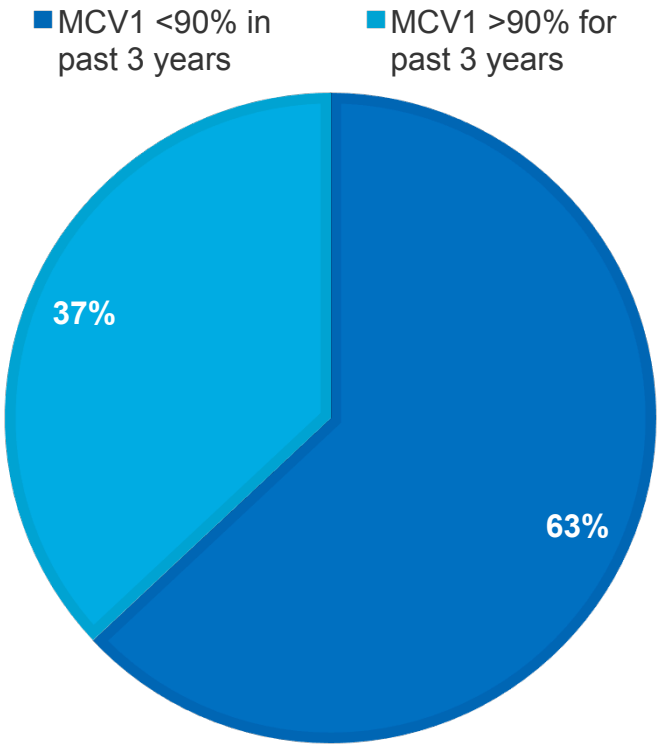
Strengthened measles control critical as first step before focusing on elimination

What is realistic foundation for eliminating measles…

…90% routine MCV1 coverage for 3 years?

Gavi 73 countries



3 regions targeting elimination in 2015

Number of countries in each region with MCV1 coverage >90% for past 3 years:

- **EURO:** 42 out of 53 (79%)
- **EMRO:** 12 out of 21 (57%)
- **WPRO:** 19 out of 27 (70%)

#add your hashtag

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Measles and rubella: Gavi Board to consider enhanced engagement (up to $800M for 2016-20)

Current Gavi support	Proposed changes
Routine **Measles second dose** for 5 years	Routine Measles 2nd dose and MR as normal co-financed vaccines
Measles SIAs in 6 high risk countries for under-5s	Extend support to all Gavi countries that need measles SIA before introducing MR
MR campaigns for under-15s before routine introduction	Support follow-up campaigns where required
Outbreak response fund to MRI until 2017	Continue to support outbreak response beyond 2017

Key conditions of Gavi support:

- Countries develop 5-year M and R plan as part of national RI plan
- Countries finance routine first dose of measles vaccine or equivalent
- Better use of data and independent monitoring to target and strengthen SIAs

NOTE: Gavi already projected to invest ~US $600M in measles and rubella 2016-20

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Ebola: Gavi supporting recovery of routine immunisation and health systems

- Immediate restoration of EPI services:
  - Catch-up and strengthen vaccination campaigns (US$ 12,561,015 approved and disbursed; several DTP3, MCV1, MenA, Measles & Polio campaigns conducted in 2015)
  - Restore population confidence in health systems via engagement with CSOs (US$ 500,000 of which 275,000 has been disbursed)
  - Fast-track reprogramming of existing HSS grants (US$ 3M in total)
  - Rapid recruitment & training of healthcare workers
  - Plans for upgrade of supply chain have been initiated
- Medium/long-term recovery of health system:
  - HSS proposals with doubled ceilings as per Dec 2014 Board decision. Preparation of HSS proposals will start as of Q1 2016
  - Ensure complementarity of support across agencies

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Ebola vaccine – critical priorities today for use

- Availability of doses in case of resurgence or new outbreak
- Emergency Use Authorisation Listing pathway
- Manufacturer commitment to pursue full licensure
- Continue product development towards improved vaccine profile

Gavi to procure doses for stockpile after licensure and WHO recommendation

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Gavi's growing role in outbreak preparedness and response

Yellow fever
vaccine
stockpile

Meningitis ACWY-containing
vaccine stockpiles

Oral **cholera**
vaccine
stockpile

Ebola?

Others?

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IPV: Significant delays in introduction due to supply constraints

- 25 IPV introductions in Gavi countries to date
- 28 IPV introductions in Gavi supported countries delayed to 2016 due to supply constraints, 8 delayed after the switch
  - Delays in manufacturer production scale-up
  - Increased use of IPV in campaigns
- Gavi engaged in polio legacy discussions to support strategic integration of relevant assets into RI

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Malaria: Preparing for recommendation from SAGE/ MPAC; Close collaboration with Global Fund

- RTS,S among shortlisted vaccines analysed in Vaccine Investment Strategy 2013
- Board deferred decision until after finalisation of trials and WHO recommendation
- Timeline for Gavi review:
  - 12 November: Programme and Policy Committee guidance
  - 2/3 December: Board guidance on potential Gavi engagement
- Close collaboration with Global Fund

Malaria vaccine: How good is good enough?

By Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance, and Dr Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria

How effective does a vaccine have to be before it should made available? This is far from straightforward. Clearly it needs to be capable of preventing disease, but to what extent? None are 100% effective. So in the cold light of day, for most countries it comes down to a complex calculation based on the cost effectiveness, lives saved, illness avoided and the availability of other effective interventions. For highly effective vaccines – ones which offer a high level of immunity – this normally proves uncontentious, but what about ones that are less effective? How much protection do they need to provide in order to justify their use?

Such is the question World Health Organization (WHO) experts will now be preparing to ask themselves as they consider whether or not to recommend the world's first malaria vaccine for use in affected countries in Africa. That's because today the European Medicines Agency effectively gave the GlaxoSmithKline vaccine – called as Mosquirix – a green light, meaning that the 250,000-page application has now passed every regulatory bar required of it for WHO to consider it. Its decision is expected in October.

With nearly 200 million cases of malaria every year, resulting in the deaths of around 1,200 children every day, this may seem like a no brainer. However the decision is a complex one. Clinical trial data suggests that Mosquirix offers only partial protection, preventing one-in-three cases of clinical malaria, a relatively low success rate compared to other approved vaccines. What's more the clinical trials were carried out with the vaccine used in conjunction with high use of other interventions, such as long-lasting insecticide treated bednets and antimalarial drugs.

So we don't really know how effective the vaccine is by itself or how well it would perform outside the controlled setting of a clinical trial. In fact there are still many unknowns. We don't know, for example, if the vaccine will give people a false sense of security and lead to reduction in the use of bednets and other interventions. Given the progress that has been made since 2000 in halving the number of malaria deaths, that would be tragic.

Similarly, the effectiveness is very much dependent upon infants receiving an additional booster shot, after an initial three doses. Without this protection starts to wane significantly from 36% efficacy with the booster to around 28% in older infants, the equivalent of preventing one-in-four cases, and even lower in younger children. The obvious answer is to make sure everyone gets that booster, but that's easier said than done. With vaccinations half the challenge is making sure everyone gets the full course. That's all very well in the controlled setting of clinical trials but in practice what sort of dropout rate can we expect for that booster shot, particularly since this will be given outside of the normal childhood immunisation schedule?

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