

Update from the GAVI Alliance

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*Strategic Advisory Group of Experts on Immunization
(SAGE)*
Geneva, Switzerland, 1-3 April 2014



Overview

- Recap of recent Board decisions
- Programmatic update
- GAVI 2016-2020 Strategy update
- Policy update
- Looking forward to Replenishment

Key Board decisions reached during the November 2013 meeting in Cambodia

- The opening of a funding window for **Japanese Encephalitis** vaccine for support beginning in 2014
- Agreement to begin providing support for the introduction of **IPV as part of routine immunisation programmes**
- Under the Vaccine Investment Strategy, the approval of support for additional **yellow fever campaigns** and a contribution towards the global **cholera stockpile**
 - The Board noted that a **case for future support for a malaria vaccine will be considered** if and when a vaccine is licensed, recommended for use and PQ'd
 - The Board concluded that further evidence is needed prior to approving support for vaccines for rabies and influenza in pregnant women
- Approval of a revised Gender Policy
- Approval of a revised Transparency and Accountability Policy

Programmatic update

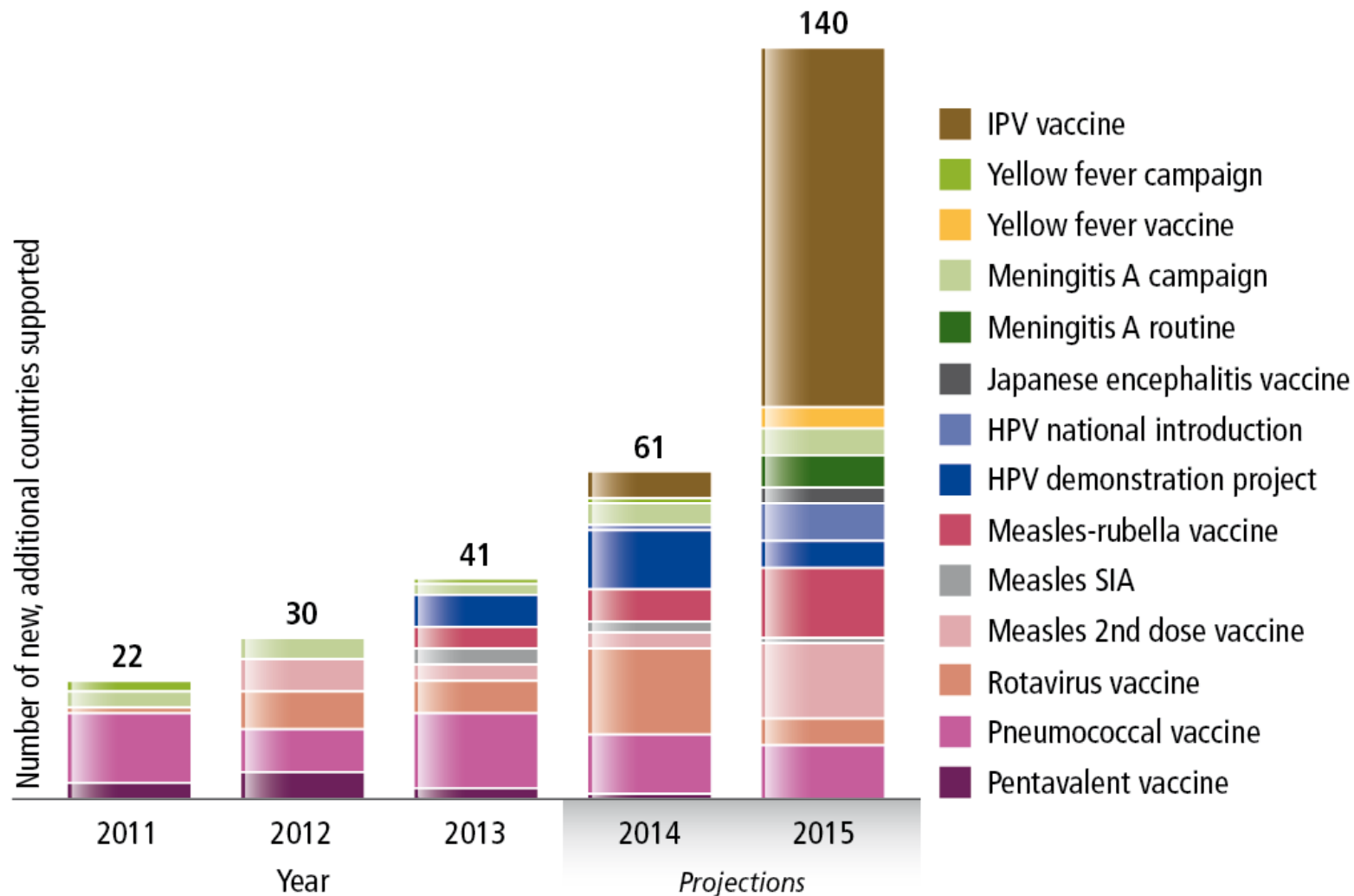
Improving GAVI's Grant Management

- Part of broader strengthening of GAVI Alliance country support
- Board approved June 2013. Implementation 2014-15
- Key principles:
 - Greater country ownership & alignment with their processes
 - Lower transaction costs & better use of Alliance resources
 - Better alignment of HSS & vaccine support
 - Improved transparency and fiduciary oversight
- Initial improvements:
 - Country 'Expression of Interest' for support enables better Alliance dialogue and TA in application development
 - Greater use of country plans than current GAVI application form
 - High Level Alliance Review Panel increases Alliance flexibility (meeting 3 times a year) and accountability

The IRC Terms of Reference have been amended to reflect the GAMR changes

- New TORs include:
 - Holistic review by IRC of all requests for new funding and extensions to funding for next full strategy and planning cycle
- These changes provide more detail on the IRC's operating modalities, including:
 - Clarification of the roles and responsibilities of Chair and Vice Chair

New GAVI vaccine support, 2011–2015: routine programme introductions and campaigns



Source: GAVI Alliance Strategic Demand Forecast version 8, as of November 2013.
 Note: Only the first phase of introductions and campaigns is included. IPV projections are only partially based on country input.

GAVI – GPEI complementary partnership

GAVI Alliance Board decisions in 2013

- Recognising the **Global Polio Eradication Initiative's (GPEI) responsibility for eradicating polio**, emphasised
 - Objective is to **improve immunisation services** in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the **complementary strengths of GAVI and GPEI in support of countries**
 - Importance of **strong partnership** between GAVI and GPEI based on a **mutually agreed understanding of roles, responsibilities and results** in countries
 - GAVI playing a lead role in coordinating the financing and the introduction of **IPV into the routine immunisation programs** in eligible and graduating GAVI countries.

GAVI and GPEI began working closely from 2013 to improve coordination, strengthen routine immunisation services and plan for IPV introduction

IPV vaccine financing and supply

UNICEF awarded a tender for IPV vaccines in February 2014, which makes sufficient quantities of affordable IPV available

IPV pricing as of 28 February 2014

	Ten-dose vials	Five-dose vials	Single-dose vials
GAVI-supported countries	EUR 0.75 per dose (approx. USD 1.00 per dose at current exchange rates)	USD 1.90 per dose	USD 2.80 per dose
Middle-income countries	EUR 1.49-2.40 (approx. USD 2.04 - 3.28 at current exchange rates)		

GAVI Support for IPV

GAVI Alliance Board decisions - **November 2013**

Eligibility and Policy Exceptions

Eligibility

All GAVI eligible and graduating countries.**

Immunisation coverage filter

Requirement to have 70% DTP3 coverage before applying for vaccine support does not apply.

Duration of support

Until 2024 (subject to funding beyond 2018).

Application submission window

Applications will be accepted until June 2015, with introduction targeted by end of 2015.

Co-financing

All countries exempted, although co-financing is encouraged. Countries can apply even if they are in default on co-financing requirements of other vaccines.

Introduction grant

All GAVI countries eligible for vaccine introduction grant.

*All policy exceptions will be reviewed by the Board in 2018.

**Support for IPV introduction in India would be considered separately by the GAVI Board.

IPV Application Process

- 1. Intent to apply:** Countries should regularly inform GAVI Secretariat and Alliance partners of their application and introduction plans to assist with planning of technical assistance and vaccine supply.
- 2. Application submission:** Applications accepted from December 2013 until June 2015.
- 3. Frequent Independent Review Committee (IRC) evaluations.**
- 4. Recommendations to approve or not will be made by the IRC to the GAVI CEO.**
 - If approved, **decision letters** will be sent within 4 weeks of the IRC review.
 - **Vaccine introduction grants** to be disbursed within 6 weeks of the decision letter.
- 5. IPV introduction:** Countries must target introduction by end of 2015.

10 applications received by March 30 deadline, 4 tier one countries (Afghanistan, Ethiopia, Nigeria, Yemen); 4 in 2014; 6 in 2015

GAVI 2016-2020 Strategy update

The GAVI Alliance currently supports countries where most of the world's poor people reside

Selected countries with largest poor populations

Ineligible and graduated
 Eligible for full GAVI support
 GAVI graduating

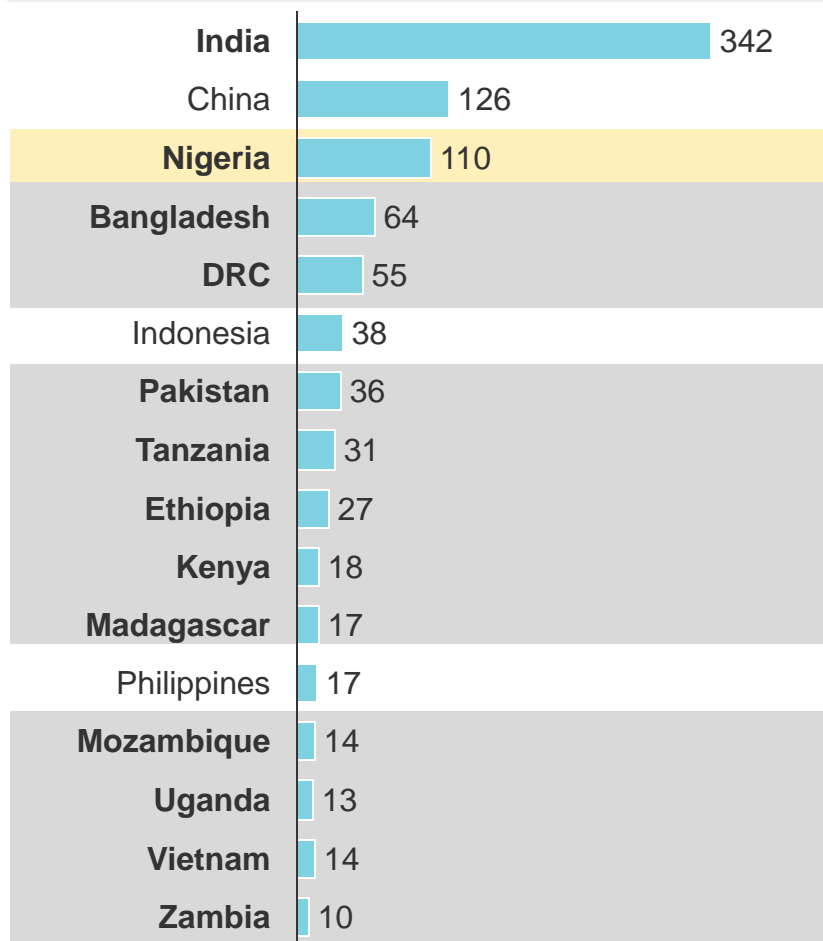
People living with less than 1.25\$ a day		% of population (poverty rate)		Children not receiving DTP3		DTP3
Million, all countries for which data available				Thousand		
India	404	33%	6,203	72%		
China	159	12%	158	99%		
Nigeria	115	68%	3,125	41%		
Bangladesh	67	43%	111	96%		
DRC	58	88%	763	72%		
Indonesia	40	16%	1,520	64%		
Pakistan	38	21%	828	81%		
Tanzania	32	68%	186	92%		
Ethiopia	28	31%	1,150	61%		
Kenya	19	43%	166	83%		
Madagascar	18	81%	72	86%		
Philippines	18	18%	442	86%		
Mozambique	15	60%	917	76%		
Vietnam	15	17%	71	97%		
Uganda	14	43%	251	78%		
Brazil	12	6%	117	96%		

- **The Alliance currently supports countries that include close to 80% of the world's poor**
- **Non Alliance countries with large number of poor people have relatively robust routine immunisation**

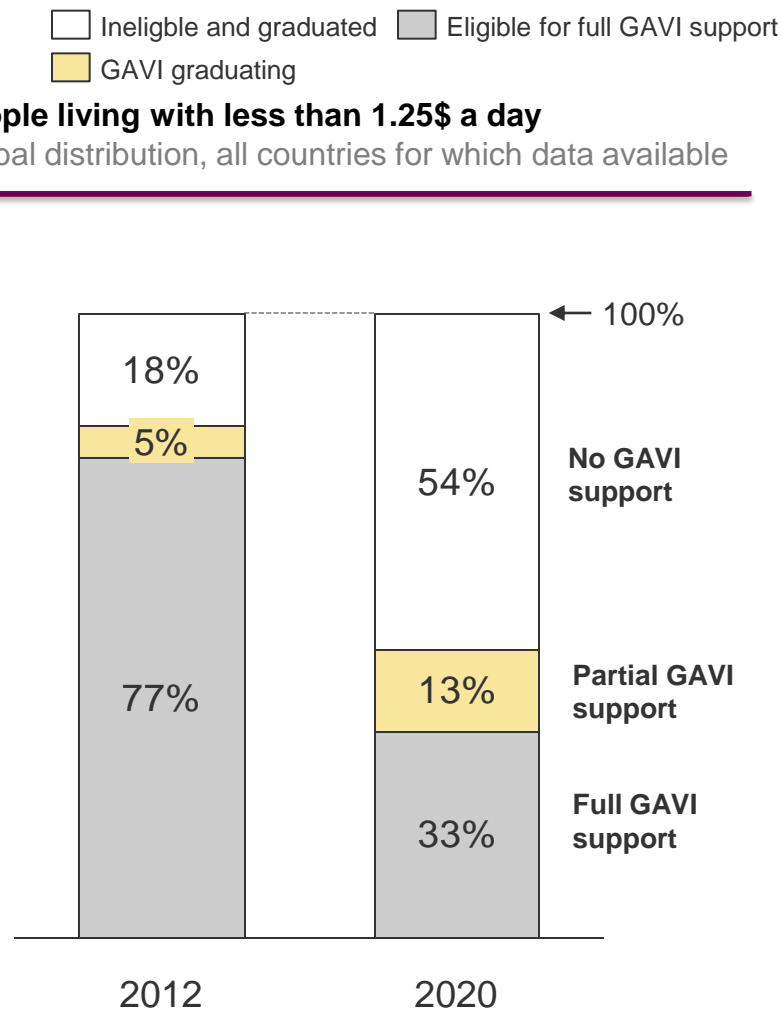


However, under current eligibility policy, share of poor people living in GAVI-supported countries would decrease, with a drop starting in 2020 and mainly driven by India and Nigeria

People living with less than 1.25\$ a day by 2021
Million, selected countries



People living with less than 1.25\$ a day
Global distribution, all countries for which data available



Sources: UN population division (2020 projections), Projections of future poverty rates based on World Bank latest available poverty rates, crossed with estimated future poverty rate changes for India and China illustrated in Chandy, Ledlie and Penciakova (Brookings Institution), The Final Countdown: Prospects for Ending Extreme Poverty by 2030, Brookings Policy paper 2013-04 (mid-point estimates (2014) applied to the period 2012-2020)

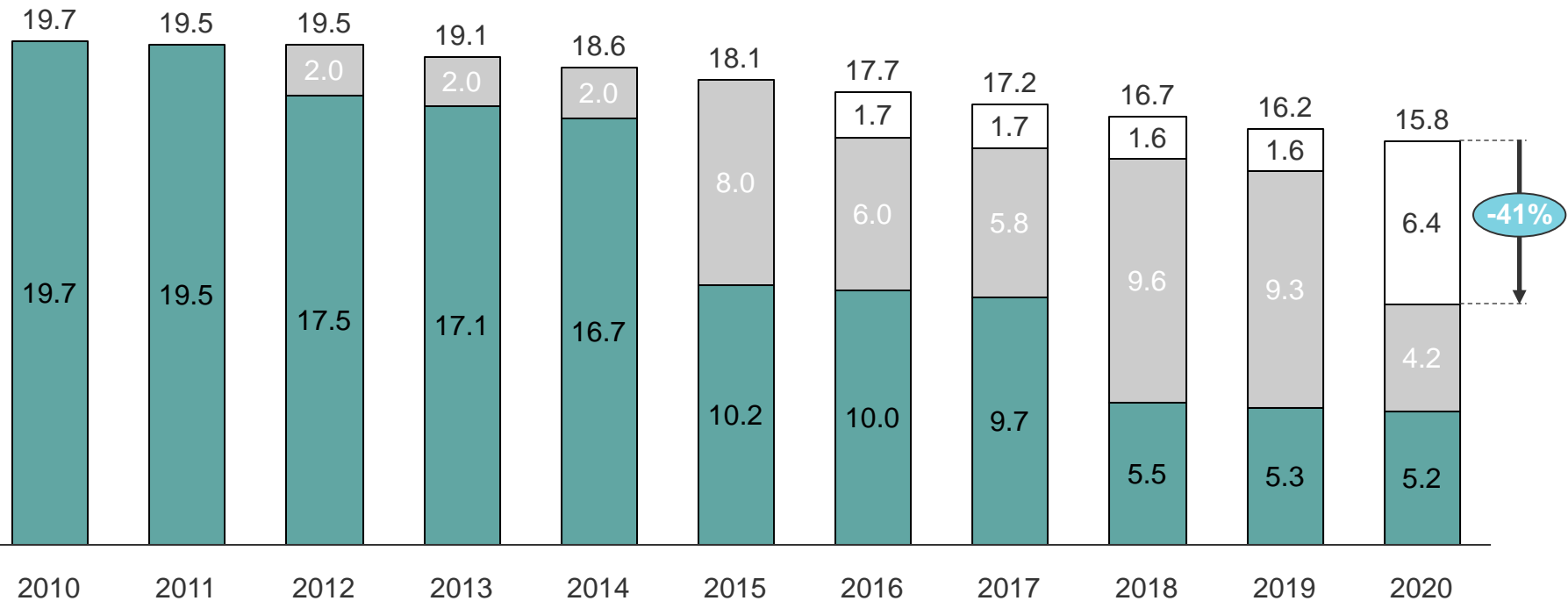
... and in terms of underimmunised children, GAVI Alliance would progressively stop supporting countries with a majority of them

Million children, GAVI 73

Unimmunised people living in countries where:

- Graduation completed
- In the graduation process
- Eligible for full GAVI support

Children not receiving DTP3



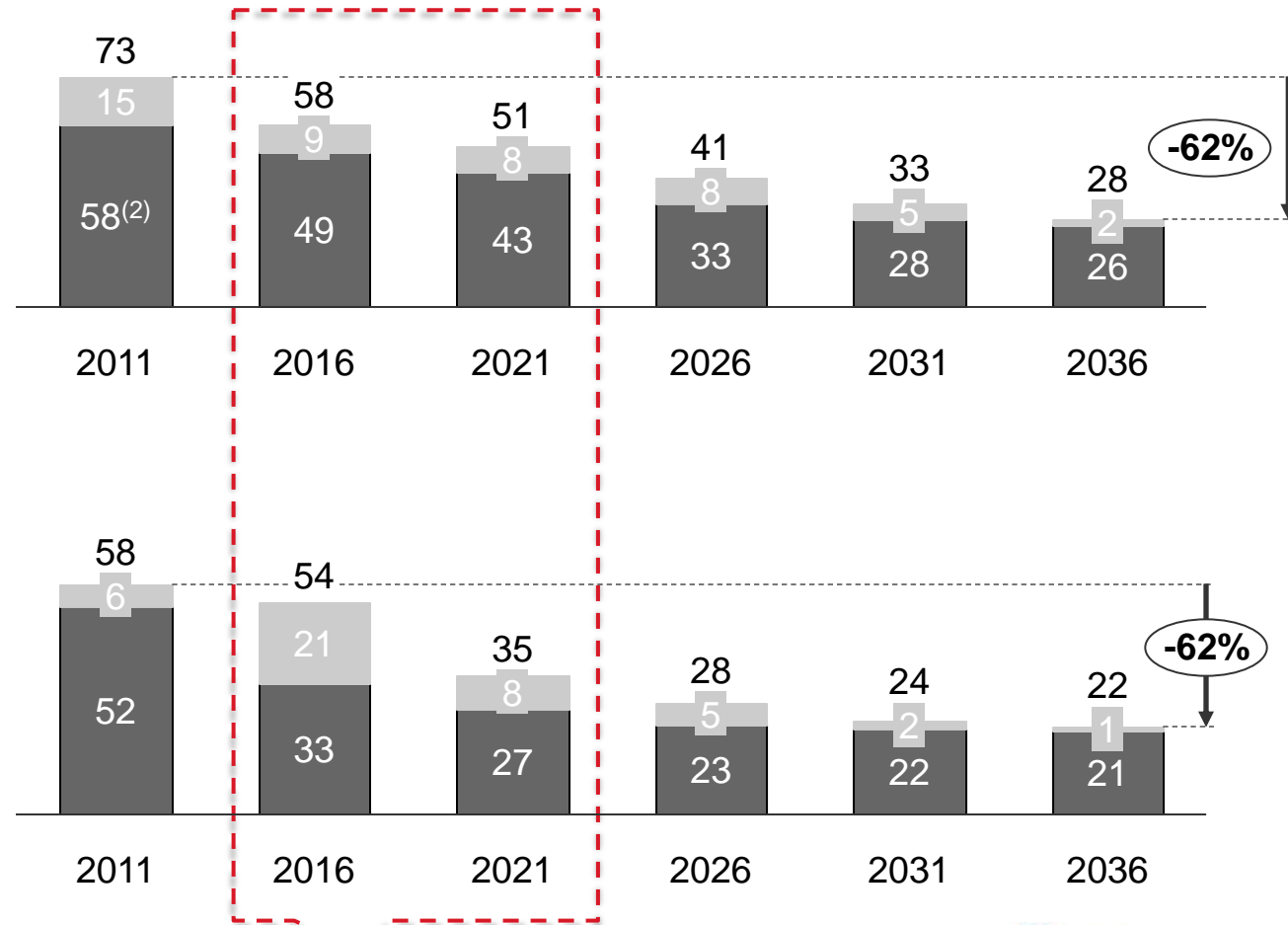
1 Countries able to apply for NVS in reference year (incl. «grace period» for countries that have just entered graduation) -- 2 Countries that have entered graduation, no longer able to apply for NVS, but not yet fully financing vaccines -- 3 Countries that have completed graduation process

Under current eligibility policy, by 2036, GAVI birth cohort will stabilise to ~40% of what it is today, with a major drop after 2020

In the graduation process
 Eligible for full GAVI support

Number of GAVI supported countries

% of global birth cohort in GAVI-supported countries

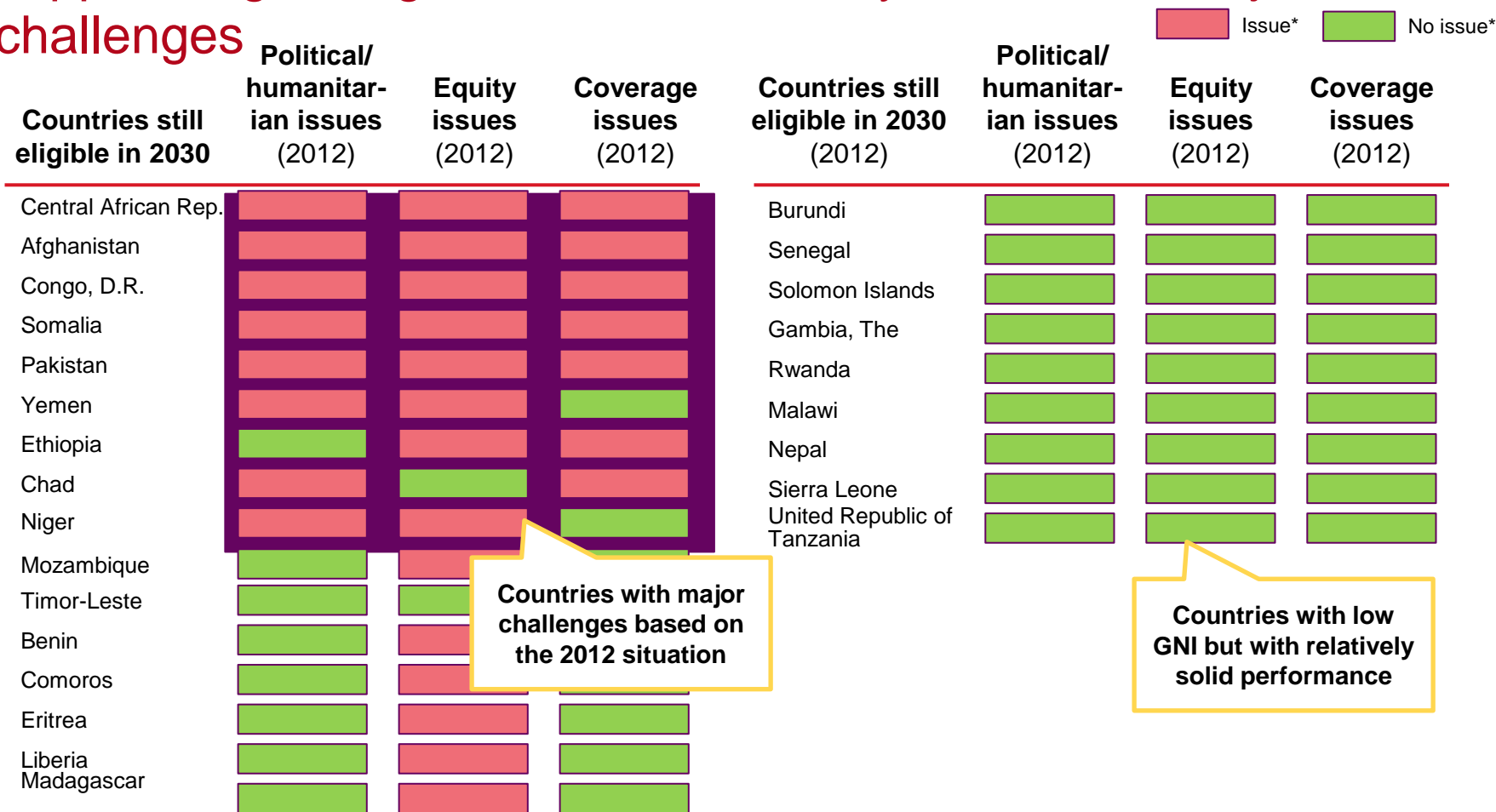


Next strategic period



1. Data based on year country reaches eligibility threshold
 2. Counting North and South Sudan as two countries
 Source: SDF8

By 2030, several countries will still be eligible for full GAVI support, a growing share of which likely to still face major challenges



- How could GAVI Alliance best respond to the needs of countries with major challenges?
- How should GAVI Alliance support evolve for high performing countries?
- Should GAVI Alliance consider an exit strategy for vaccines that become affordable with stable supply in the long term?

* Criteria aligned on GAVI Fragile states policy”, criteria. Political / humanitarian issues = Humanitarian emergencies and/ or UN OCHA indicator and/ or top category for Failed States Index by the Fund for Peace and/ or complete devolution of MOH from the central level to regional levels. Equity issues = wealth inequity in immunisation coverage and/ or >50% of districts reporting DTP3 coverage <50% and/ or country statistical different in female versus males coverage. Coverage issues = 10 GAVI-eligible countries with largest un-immunised populations of children, and/ or national DTP3 coverage less than 70%; Source: GNI projections July 2012

Some countries may not be able to overcome significant challenges before they graduate

NON EXHAUSTIVE

	Size of birth cohort (2016, Millions)	DTP3 coverage (2012)	Vaccines introduced before graduation process completed (1)	Fiscal space (2)	Under 5 mortality rate, per 1000	
Currently graduating	Angola	0.8	91%	Penta, Pneumo, Rota, YF	0.82%	163.5
	Azerbaijan	0.2	75%	Penta, Pneumo, HPV	0.36%	35.2
	Bhutan	0.0	97%	Penta; HPV	0.29%	44.6
	Bolivia	0.3	80%	Penta, Pneumo, Rota, YF, HPV	0.60%	41.4
	Congo, Rep.	0.2	85%	Penta, Pneumo, Rota, YF	1.23%	96
	Honduras	0.2	88%	Penta, Pneumo, Rota, HPV	0.64%	22.9
	Indonesia	4.1	64%	Penta	0.59%	31
	Papua N.G.	0.2	63%	Penta, Pneumo, Rubella catchup	0.62%	63
	Timor-Leste	0.1	67%	Penta	0.78%	56.7
	Ukraine	0.5	76%	Penta	NA	9
Countries entering the graduation phase (2015-2020)	Cote d'Ivoire	0.7	94% ⁽³⁾	Penta, Pneumo, Rota, YF, HPV, Rub. catchup	2.32%	107.6
	Ghana	0.8	92%	Penta, Pneumo, Rota, YF, HPV, Rub. catchup	2.06%	72
	India	26.5	72%	Penta (all st.), Pneumo (5 st.) Rota (all states)	NA	56.3
	Lao PDR	0.1	79%	Penta, Pneumo, Rota, HPV	1.92%	71.8
	Lesotho	0.1	83%	Penta, Pneumo, Rota, HPV, Rubella catchup	0.40%	99.6
	Nigeria	7.1	41%	Penta, Pneumo, Rota, HPV, Rubella catchup	2.84%	123.7
	Vietnam	1.4	97%	Penta, Pneumo, Rota, HPV, Rubella catchup	0.57%	23
	Sudan: North	1.2	92%	Penta, Pneumo, Rota, YF, HPV demo	3.14%	73.1
	Zambia	0.7	78%	Penta, Pneumo, Rota, HPV, Rubella catchup	0.82%	88.58

- Some (large) countries may graduate before having built strong **health systems for immunisation** (e.g. Indonesia, India and Nigeria)
- Some countries may **miss the opportunity** to apply for needed **GAVI supported vaccines** (e.g. HPV in Bolivia, PCV in Mongolia)

(1) By the time of graduation. Italic shows vaccines introduced but not paid by the Alliance; (2) Defined as the country's expenditure for vaccine costs (GAVI co-financing for NUV+ government spend for "traditional" vaccines) / government health expenditure. Less than 1% is considered sufficient fiscal space; Between 1% and 2% is considered ambitious, and more than 2% is considered challenging (3) Mainly driven by campaigns in 2012. 2011 estimated DTP3 coverage was 62%

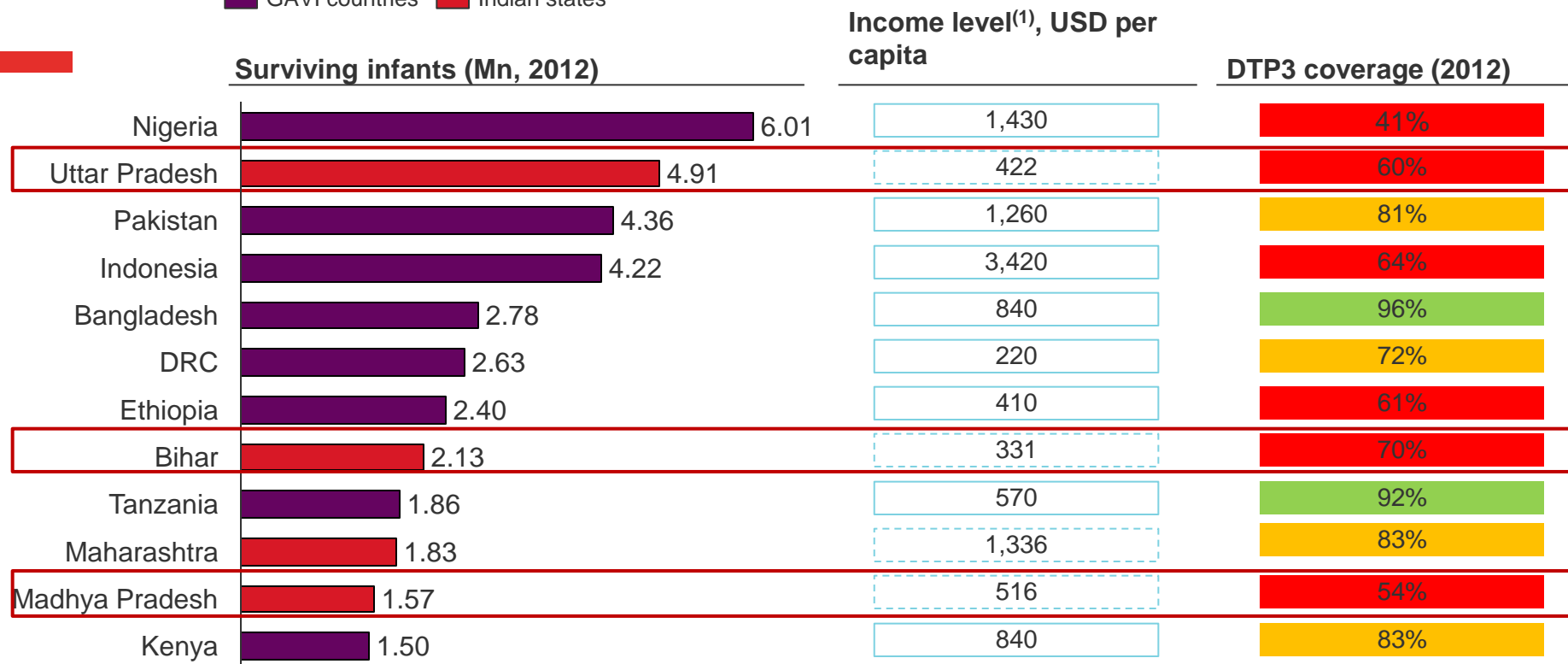
Sources: birth cohort projections from UN population division, 2012 coverage data (WUENIC July 2013), SDF v8.0 introduction dates, IGME mortality data for 2012



Should large countries with significant needs be considered for targeted investments outside basic eligibility?

Some of largest Indian states comparable to GAVI countries in terms of magnitude, income level and vaccine coverage

■ GAVI countries ■ Indian states



India accounts for more than:

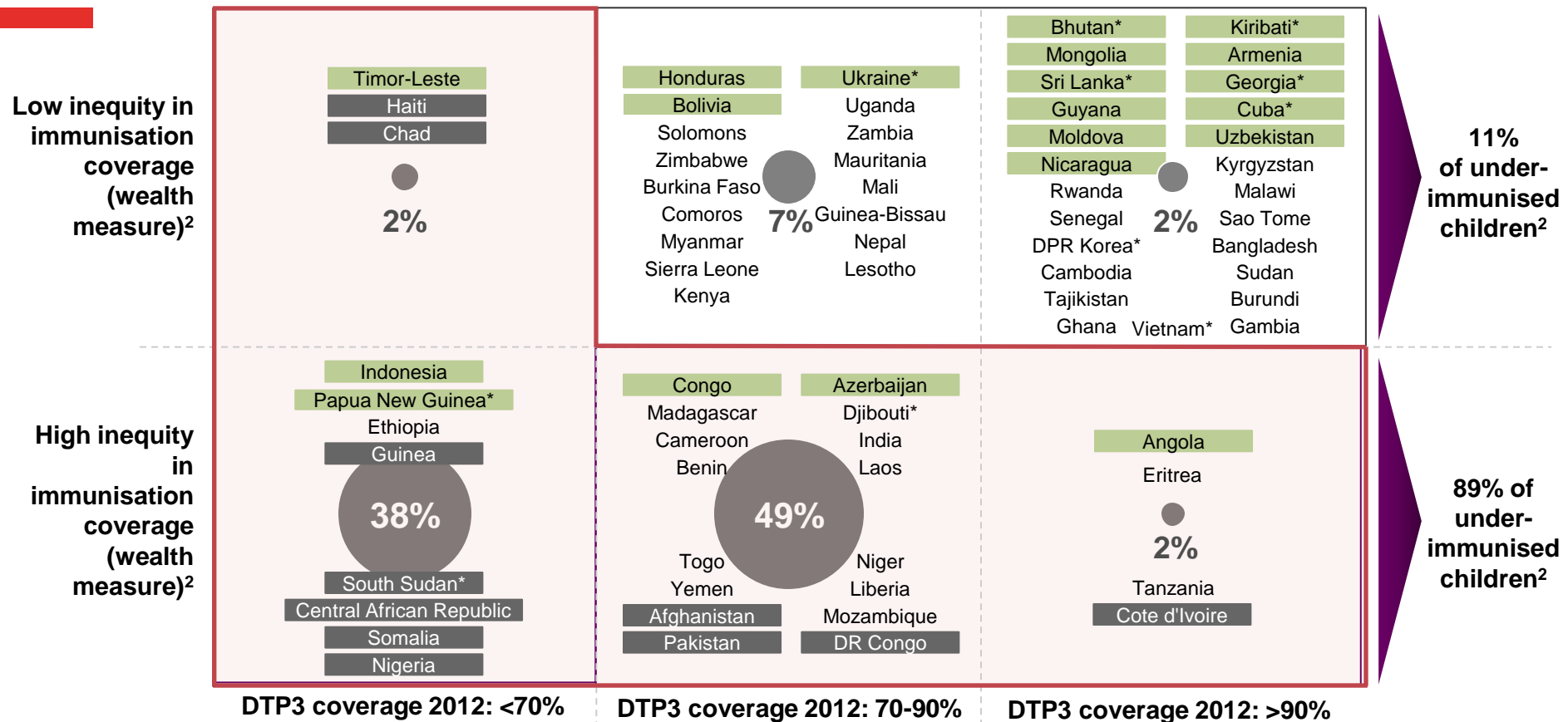
- 30% of the world's under-immunised children (2012)
- 17% of global child deaths from pneumococcal pneumonia (2000)
- 23% of global child deaths from rotavirus diarrhea (2004)

(1) WB estimate of GNI per capita for 2012 for GAVI countries, GDP per capita for 2010-11 for Indian states, assuming exchange rate of 0.016 USD per rupee. GNI and GDP are not fully comparable metrics, but provide an illustrative sense of income levels
 Source: World Bank; Ministry of statistics and Program Implementation Govt. Of India; disease burden data from Laxaminarayan & Ganguly (2011), India's Vaccine Deficit: Why more than half of Indian children are not fully immunised and what can – and should be done, Health Affairs 30(6), 1096-1103 (quoting WHO 2000, 2004)

91% of underimmunised children live in countries with high inequity and/or low coverage¹

Equity helps immunise unreached children and increase coverage

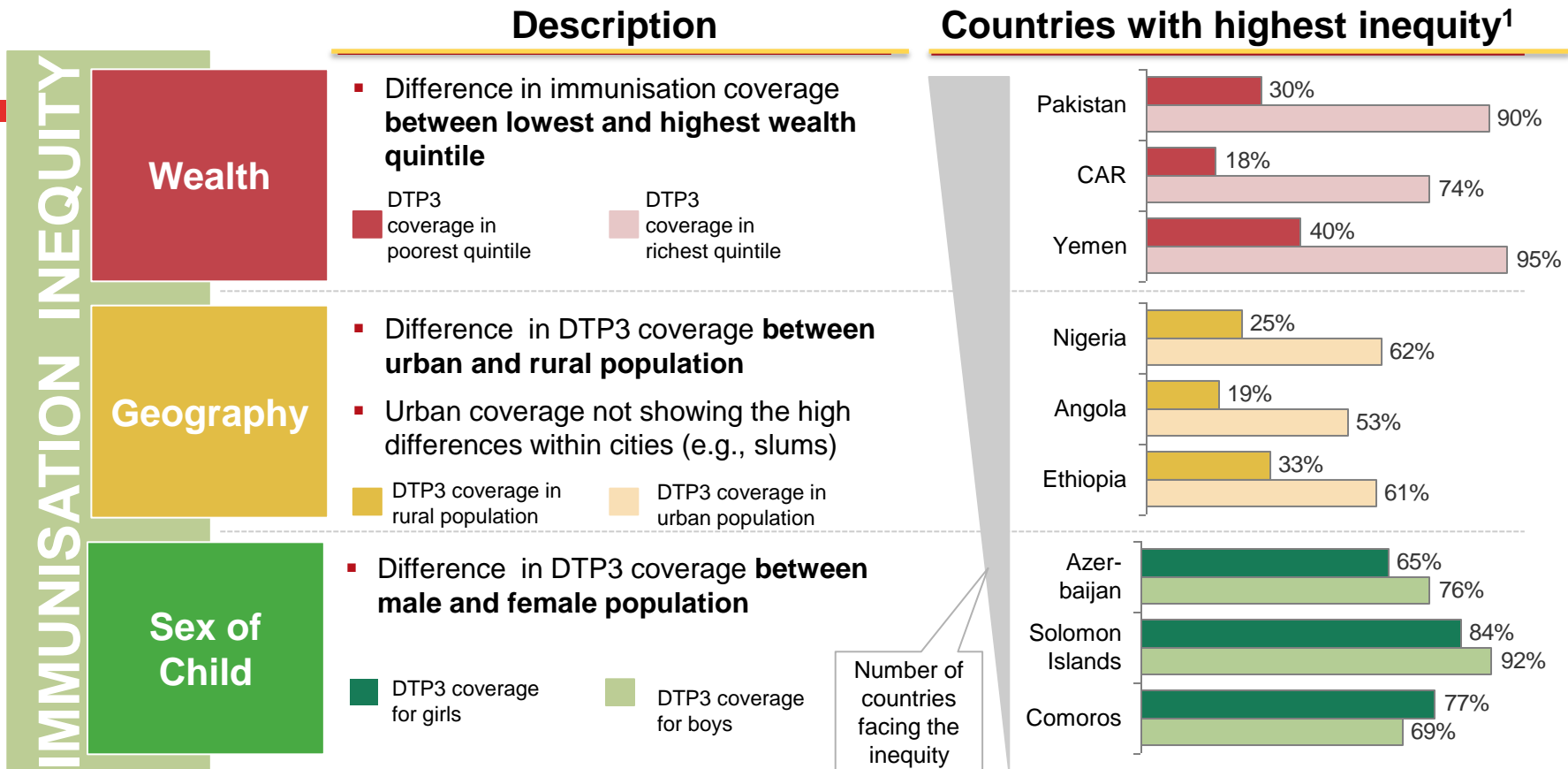
■ Graduating countries
 ■ Countries under current fragility policy
 ● Bubble size represents number of underimmunised children, percentage indicates distribution across GAVI 73 countries



* Lacking or questionable data on equity, distribution to high or low wealth inequity based on expert opinion; 1. Excl. underimmunised children in countries not supported by the Alliance; 2. High wealth inequity defined as DTP3 coverage in lowest wealth quintile is more than 20 %-points lower than in highest quintile
 Source: WHO for DTP3 coverage data, latest DHS or MICS for equity data, BCG analysis, DHS and MICS



Inequity in immunisation coverage is highest when looked at through the wealth and geography lenses



- Major determinants of inequity in immunisation coverage are wealth and geography; These also tend to be determinants of highest mortality and morbidity from vaccine preventable diseases
- Sex of child is rarely a determinant of inequity in immunisation coverage

1. Based on the latest available Demographic & Health Surveys (DHS) and Multiple indicator cluster survey (MICS)
 Source: Pakistan: DHS (2012/13), Nigeria, MICS4 (2011, wealth) & DHS (2013, geography), CAR: MICS4 (2010), Angola: MICS3 (2008/09), Azerbaijan: DHS (2006), Solomon Islands: DHS (2006/07), Guinea: DHS (2011/12)

While most countries face barriers to immunisation in all categories, the challenges vary by country

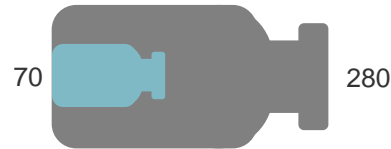
		Country 1	Country 2	Country 3	Country 4	
a	Supply chain	▪ Poor cold chain management / maintenance	●	●	●	●
		▪ Poor stock management	●	●	●	●
		▪ Lack of standards/skills for monitoring, vaccine storage, wastage	●	●	●	●
b	Service delivery	▪ Insufficient / poor supportive supervision of workers	●	●	●	●
		▪ Staff vacancies / low staff levels	●	●	●	●
		▪ Insufficient quantity and use of services	●	●	●	●
c	Demand generation	▪ Social and cultural barriers	●	●	●	●
		▪ Mobile / migrant population	●	●	●	●
		▪ Lack of engagement of local leaders & community	●	●	●	●
d	Data for decision-making	▪ Poor data systems / tools / equipment	●	●	●	●
		▪ Poor recording and reporting of data (incl. falsification)	●	●	●	●
		▪ Low use of health information / lack of effective analysis	●	●	●	●
e	Leadership, management & coordination	▪ Inadequate financing	●	●	●	●
		▪ Poor coordination between sectors, levels and partners	●	●	●	●
		▪ Weak / poorly organized health system	●	●	●	●
f	Country context	▪ Security	●	●	●	●
		▪ Socio-political instability	●	●	●	●
		▪ Anti-vaccination groups / adverse media reporting	●	●	●	●

Each country is facing a different set of barriers, so the Alliance will need to maintain country-driven flexibility in its approach

● Country reports this barrier
● Country does not report this barrier

As part of modernising immunisation systems – and due to the rapid growth in doses and higher volume of vaccines – supply chain improvements are needed

Storage volume (cm³)
(vaccinations per child¹)



↑ 4x

Increasing number of
doses in GAVI countries²



↑ ~6x

Introduction of more
expensive vaccines³



↑ ~5x

Increase in stock keeping
units per year for GAVI
Vaccines⁵



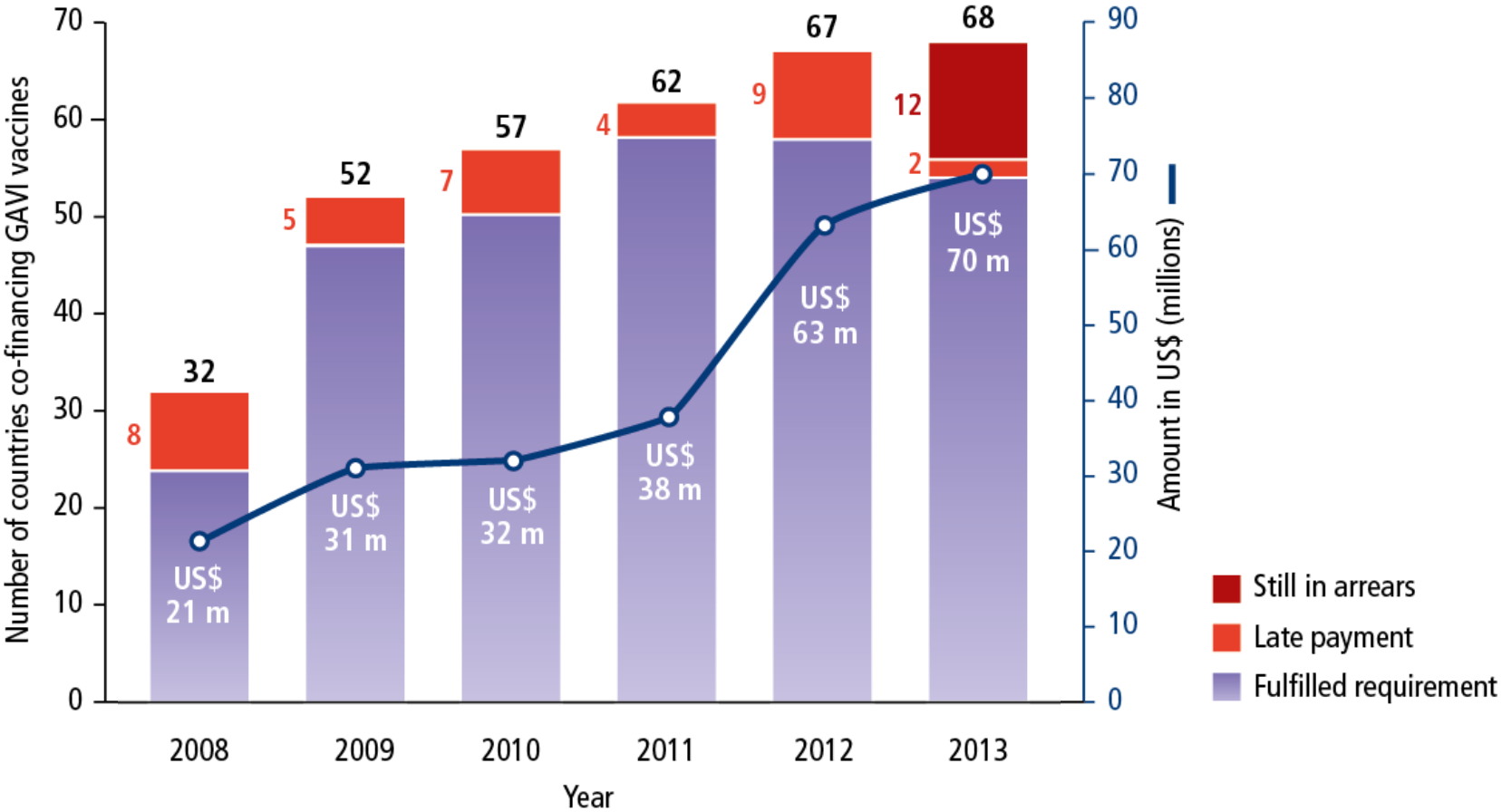
↑ ~2x

GAVI supply chain requirements

■ 2010 ■ 2020

1. UNICEF Supply 2012 Financial report, WHO data for Pneumo and Rota vaccines, and HPV (only for girls); 2. 2010: GAVI Shipment Data; 2020: GAVI SDF Forecast; Including volume for GAVI future graduated countries; 3. Comparison based on 2013 Price; 2020 Vaccines include: Rota, Pneumo; HPV; 2010' vaccines include: YF, Measle, DPT, OPV (UNICEF SD); 4. Very high heat sensitivity Vx: 2010: Pneumo (small amount); 2020: Pneumo & Rota (Milstien, J. TechNet21 Consultation, PATH Vx stability study) share based on 2010 & 2020 Vaccines program GAVI Budget; 5. GAVI Background SDF Information; 2010': estimates based on 2009 data; 2020: estimates based on 2013 forecast;

Co-financing: countries taking ownership



Source: GAVI Alliance as of March 2014



Co-financing performance

- Countries are stepping up their share of vaccine costs
 - Co-financing in the period 2011–2015 ~ **US\$ 470 M**
- Co-financing in the period 2016–2020 ~ over **US\$ 1 B**
- Some countries still experience challenges and/or don't prioritize financing immunisation
 - 21 countries not paying for traditional vaccines
 - Delays with co-financing payments
- Piloting a tailored strategy with DRC to gradually increase their expenditure on “traditional” vaccines and co-financing
- Now looking comprehensively at immunisation financing, not just GAVI

Scaling up engagement with graduating countries

- 20 countries are on the path to graduate from GAVI
 - In these countries, the fiscal space not the main challenge
 - Procurement and programmatic challenges predominant
- The Alliance has expanded its engagement with graduating countries to include programmatic and financial sustainability aspects in assessments and plans
 - Time limited catalytic investments to support graduation plans
 - Opportunity to apply for HSS for countries in graduation when they are below 90% coverage
- The correlation between poor people, poor countries, and poor health is less rigid than it once was

Some summary points from Board workshop (1/2)

GAVI in the long term

- **Need to clarify & optimise the Alliance model**, both at global and at country level, including roles and responsibilities of all partners and operating model
- **Fragile countries** will be an increasingly important issue, but not clear yet what changes in the model might be required to best support them
- **Graduated (Alumni) countries** (and potentially non eligible): GAVI definitely will have a **continuing non-financial role** to play: priorities include market shaping, access to price and technical assistance to ensure sustainability after graduation
- **Breakthrough vaccines**: We should keep the Alliance infrastructure to support access when these vaccines come on board; Eligibility and support model might then have to be adapted

Some summary points from Board workshop (2/2)

Eligibility and graduation

- Overall **model** is good; do not change eligibility
- For graduating countries with continued challenges, **tailor** the **graduation** process to protect results and sustainability
 - Consider flexible exit criteria based on robust, transparent and comparable **data**
 - Careful not to introduce **perverse incentives**
- Market shaping and **access to price** key for graduated countries
- Consider strategic, **catalytic investments** outside basic eligibility for special cases, but clear scope and boundaries

Coverage and equity

- **Focus efforts more** on countries with issues on coverage and equity, while avoiding the creation of perverse incentives
- **Country ownership will be critical**, and GAVI will need to support countries through access to tools and mechanisms leveraging the comparative advantage of the Alliance
- **Consider complementing the flexibility of HSS with further targeted support**, particularly on data, supply chain and demand side, developed through an Alliance-wide process and emphasising immunisation's integration with other primary health care services



Policy update

Overview of GAVI programmatic policies and strategies

	Programmatic policies
Approved	Gender Policy
Approved	Transparency and Accountability Policy
Approved	Policy on Fragility and Immunisation
Approved	Prioritisation Mechanism
Approved	Vaccine Investment Strategy
Approved	Vaccine Donation Policy
Approved	Vaccine Supply and Procurement Strategy for 2011 – 2015
Approved	Performance-based Funding
Policy up for review 2014	Country Eligibility Policy
Policy up for review 2014	Graduation Policy
Policy up for review 2014	Revised Co-Financing Policy
Policy up for review 2014	Vaccine Introduction Grant and Operational Support for Campaigns Policy (mini review of funding levels)
New – in development 2014	Risk policy

- Approved
- Policy up for review 2014
- New – in development 2014

Four GAVI Alliance policies and strategies were revised in 2013

Gender Policy

- Evidence shows gender influences demand, access and utilization of health services; to reach the hard-to-reach, *gender-related barriers* for caretakers of children must be addressed
- Revised policy aims to support countries to analyse and address gender-related barriers to accessing immunisation services

Transparency and Accountability Policy (TAP)

- Revised policy covers vaccines in addition to cash-based support
- Stronger focus on prevention of misuse

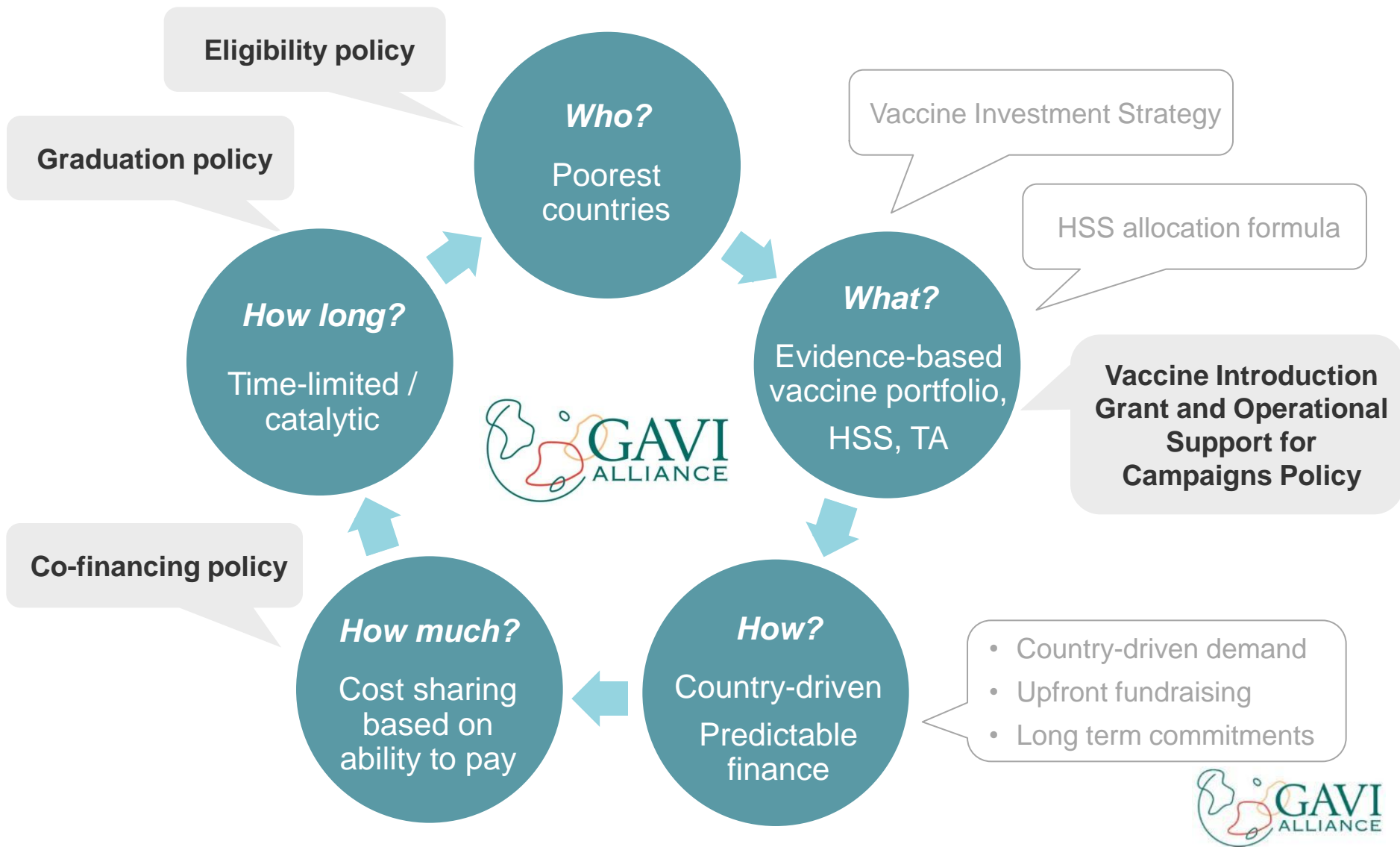
Prioritisation Mechanism

- Improved metrics for health impact and financial sustainability indicators

Vaccine Investment Strategy (VIS)

- Expanded support for yellow fever campaigns
- Time-limited investment in global cholera stockpile
- Malaria vaccines to be re-assessed in 2016
- Rabies study to fill evidence gap
- Monitoring maternal influenza developments

Several core policies underpinning the GAVI Alliance country funding model under review in 2014-2015



A GAVI Alliance 'Risk Policy' will be developed for Board approval in December 2014

- GAVI Alliance Board requested a risk policy at its November 2013 meeting, in line with recommendations from an Enterprise Risk Management audit
- The policy aims to articulate:
 - Agreement within the Alliance on risk appetite and risk tolerance
 - Agreement within the Alliance on definitions of different types of risk
 - Agreement within the Alliance on accountability structures for different types of risk
 - Including high level mapping of current risk mitigation processes

Consultations with Alliance partners and other relevant stakeholders in June-August 2014

Update on Country Tailored Approach (CTA)

Objectives

- Improve coverage in countries with particularly challenging circumstances
- Protect immunisation systems and existing GAVI support in case of emergency events

Implementation:

- 11 countries identified for tailored approach
- 2 CTAs finalised: DRC, Nigeria
- 4 CTAs under development for countries with on-going challenges: Pakistan, Afghanistan, Haiti, Cote d'Ivoire
- 1 CTA under development for country in emergency situation: CAR
- Remaining 4 CTAs to be finalised in 2014: Chad, Guinea, Somalia, South Sudan

2014 WHO/SAGE position on acellular pertussis vaccine will be critical guide for countries and GAVI Alliance

- GAVI supports whole cell pertussis vaccine as part of pentavalent vaccine
- Acellular pertussis vaccine combinations not currently in scope for GAVI procurement
 - No WHO pre-qualified aP containing pentavalent vaccine
 - aP-hexa (with IPV) pre-qualification anticipated in 2014; not consistent with GAVI Board decision to support monovalent IPV
- Should GAVI provide financial support (i.e. penta equivalent) towards national *self-procurement* of aP-containing combo's?
 - Significantly higher price (~5-10x) → sustainability?
 - Public health risks of aP versus wP?
 - Programmatic implications as boosters may be required?
 - Penta / IPV market shaping implications?
 - Policy implications for other countries

Improving access to vaccines through tiered pricing



Seth Berkley

Immunisation is now widely recognised as one of the most efficient, successful, and cost-effective health investments in history, but despite a substantial effort over the past 50 years, nearly one in five deaths of children younger than 5 years is still caused by a vaccine-preventable disease. With more than 22 million children in the world still unimmunised against common but life-threatening diseases (as measured by a vaccine containing a third dose of diphtheria-tetanus-pertussis [DTP]), almost all in developing countries, there is clearly still a long way to go.

In addition to the traditional and inexpensive vaccines

procured by GAVI through UNICEF Supply Division. This process reduces transaction costs, allowing for even further savings. To give a sense of the scale of procurement, in 2012 UNICEF procured more than \$790 million worth of vaccines from ten manufacturers on behalf of GAVI countries. GAVI and its Alliance partners also use push and pull mechanisms to incentivise manufacturers. For example, the Bill & Melinda Gates Foundation has provided developing-country manufacturers with investments to support product development and manufacturing scale-up in return for lower vaccine prices when they begin

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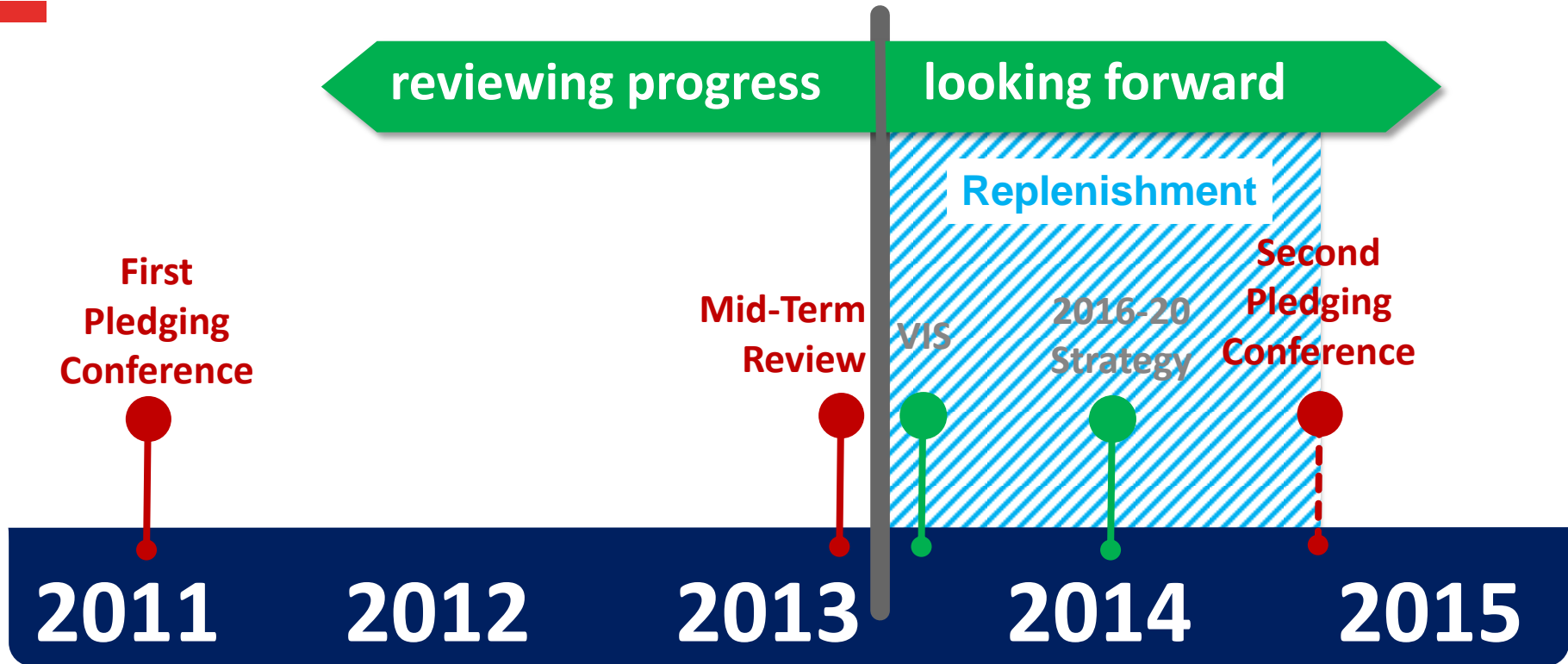
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Looking forward to Replenishment

Road to Replenishment



Thank you



GAVI/2011/Ed Harris



www.gavialliance.org