

@GaviSeth

# Report from Gavi

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Seth Berkley, CEO  
Meeting of the Strategic Advisory Group of  
Experts on Immunization  
April 2016



# Why SAGE matters to Gavi

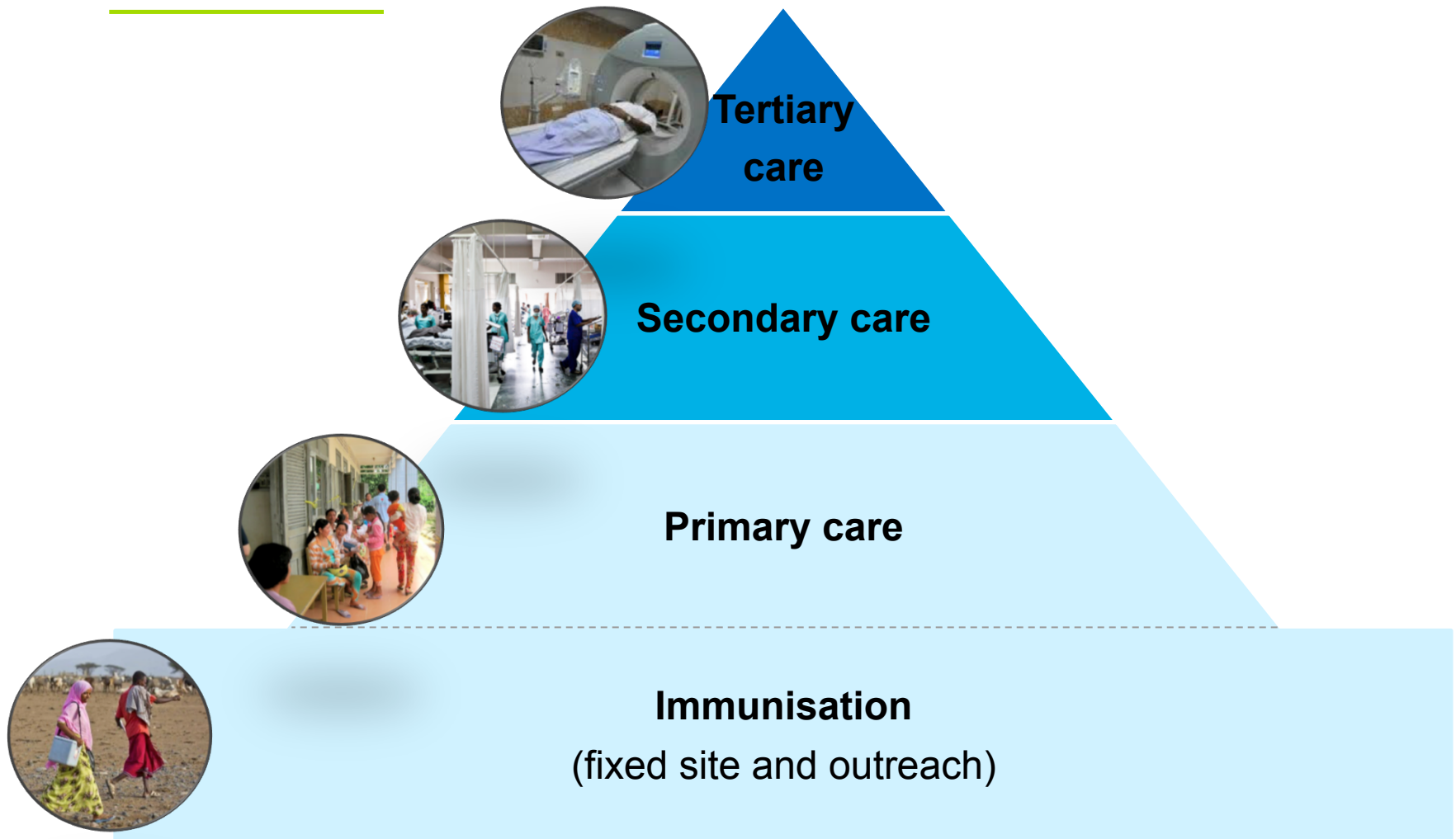
- **Gavi relies on SAGE technical guidance for decision-making**
  - Gavi Board decisions follow SAGE guidance
  - SAGE Chair is a non-voting member of Gavi Policy & Programme Committee
- **A number of upcoming Board decisions contingent on SAGE recommendations**

# Vaccines in the global context

- Midpoint of Decade of Vaccines
- More kids immunised than ever
- 86% coverage by DPT3 containing vaccine (81% Gavi countries)
- 70 introductions 2015
- New Gavi Strategic Period 2016-2020
- One year on from replenishment
- Vaccines and Global Health Security

# Immunisation: a platform for universal health coverage

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# AGENDA 2030: monitoring framework – a missed opportunity

3.8.1 Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population)

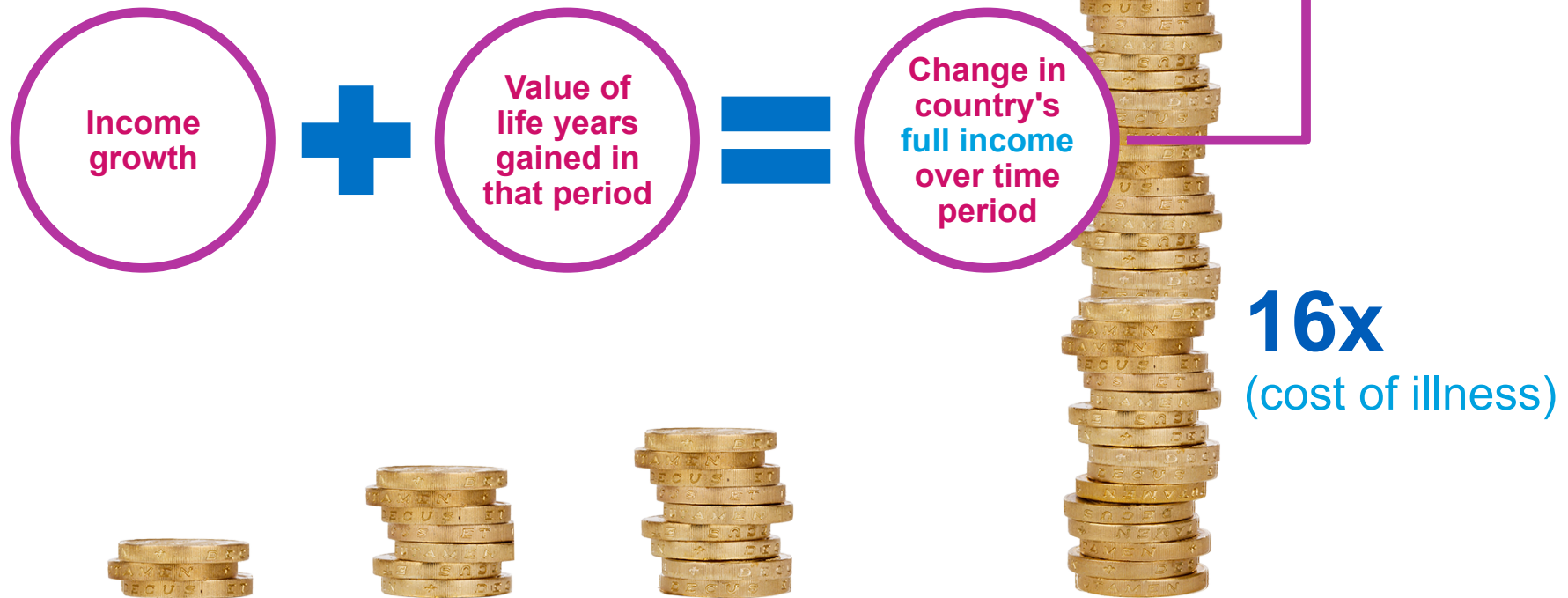
Based on the Global Vaccine Action Plan:

“Reach and sustain 90% national coverage and 80% in every district with all vaccines in national programmes”

*The Board was shocked to learn that perhaps the single most relevant indicator in the health sector, **immunisation coverage**, is not currently being considered as an individual item in the SDG monitoring framework.*



# RETURN ON INVESTMENT



Public  
infrastructure



The Economic Benefits of Public  
Infrastructure Spending in Canada.  
The Centre for Spatial Economics,  
September 2015

Pre-school  
education



The rate of return to the HighScope  
Perry Preschool Program.  
Department of Economics, University  
of Chicago, April 2009

Community  
health workers



Strengthening primary health care  
through community health workers...  
Dessalegn H, Chambers R, Clinton  
C, Phumaphi J, Sirleaf J, Evans T, et  
al. 2015

Immunisation



Return on investment from childhood  
immunizations in low- and middle-income  
countries, 2011-20.  
Health Affairs. 35(2):199-207. Ozawa S, Clark S,  
Portnoy A, Grewal S, Brenzel L, Walker D. 2016

# Board Chair: Ngozi Okonjo-Iweala

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## TAKING ACTION

1. **Prioritise** investment in immunisation
2. Ensure vaccine line-item in health budgets
3. **Focus on equity** by investing in health to fully immunise every child
4. **Act now** to achieve the 2030 SDG's and be on track for Agenda 2063
5. Become an immunisation **champion**



30



African  
Development  
Week 2016

AU-ECA Conference  
of Ministers

Semaine du  
développement  
africain 2016

Conférence  
des ministres  
UA-CEA

Semaine du  
développement  
africain 2016

Conférence  
des ministres  
UA-CEA

HAZARD ABDELKADIR  
Ministre de la Santé Publique et de l'Hygiène

CARLOS LOPES  
Ministre de la Santé et de l'Hygiène

H. J. GONÇALVES  
Ministre de la Santé et de l'Hygiène

# Recent studies underway on vaccine impact

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- Over 20 studies
- Across Sub-Saharan Africa and Asia
- Supporting impact assessment of pneumococcal conjugate and rotavirus vaccines in a variety of settings
- Supporting cholera and rabies studies through VIS learning agenda

# PCV, The Gambia: The impact of the vaccines on severe pneumococcal pneumonia, sepsis, and meningitis

## Pneumococcal conjugate vaccine impact study



MRC  
The Gambia Unit

Pneumococcal disease surveillance with

**14,650**  
patients

PCV in The Gambia **reduced** severe pneumococcal pneumonia, sepsis and meningitis in children by



**55%**



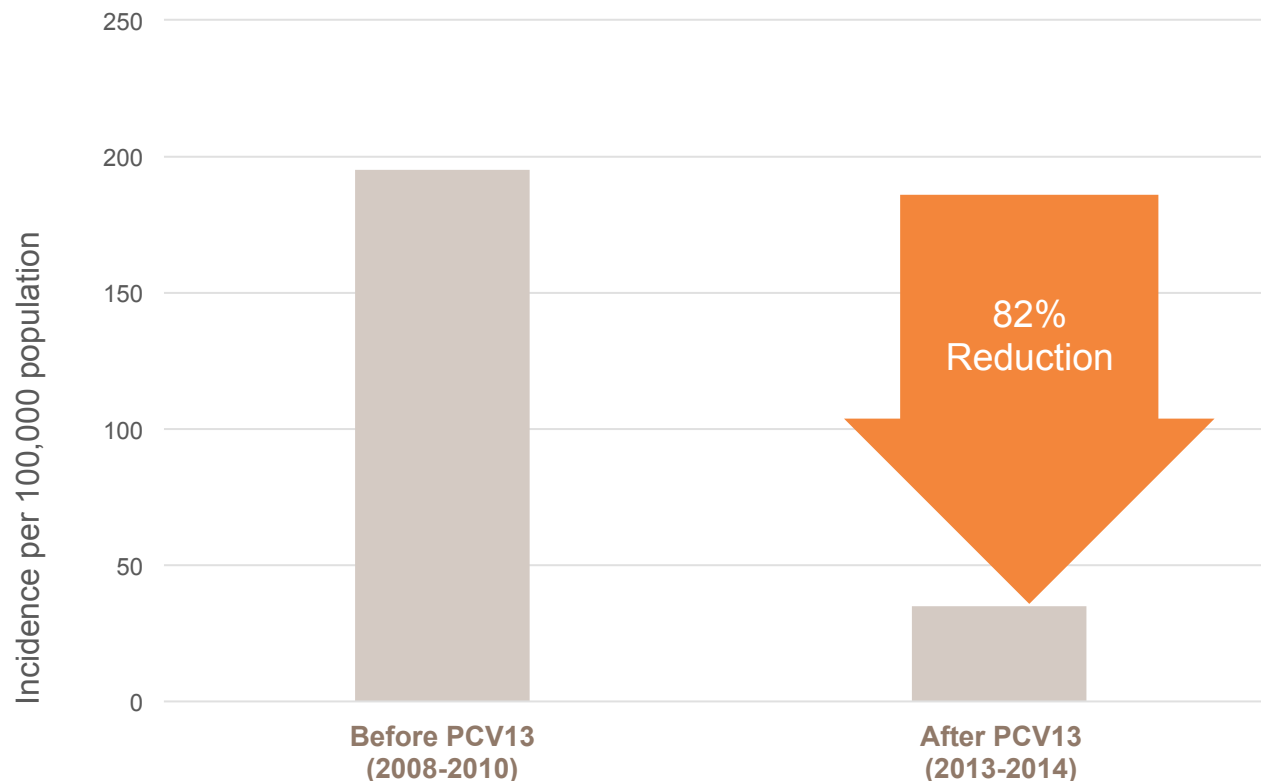
“If children in The Gambia develop serious pneumococcal pneumonia, sepsis or meningitis they have a **1 in 7** chance of dying”

Mackenzie GA et al. Effect of the Introduction of Pneumococcal Conjugate Vaccination on Invasive Pneumococcal Disease in The Gambia: Population-Based Surveillance. Lancet Infectious Diseases, Published online February 17 2016.

# PCV, The Gambia: Vaccine-type invasive pneumococcal disease incidence in children under 2, the Gambia

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## Before and after pneumococcal vaccine introduction (PCV13)

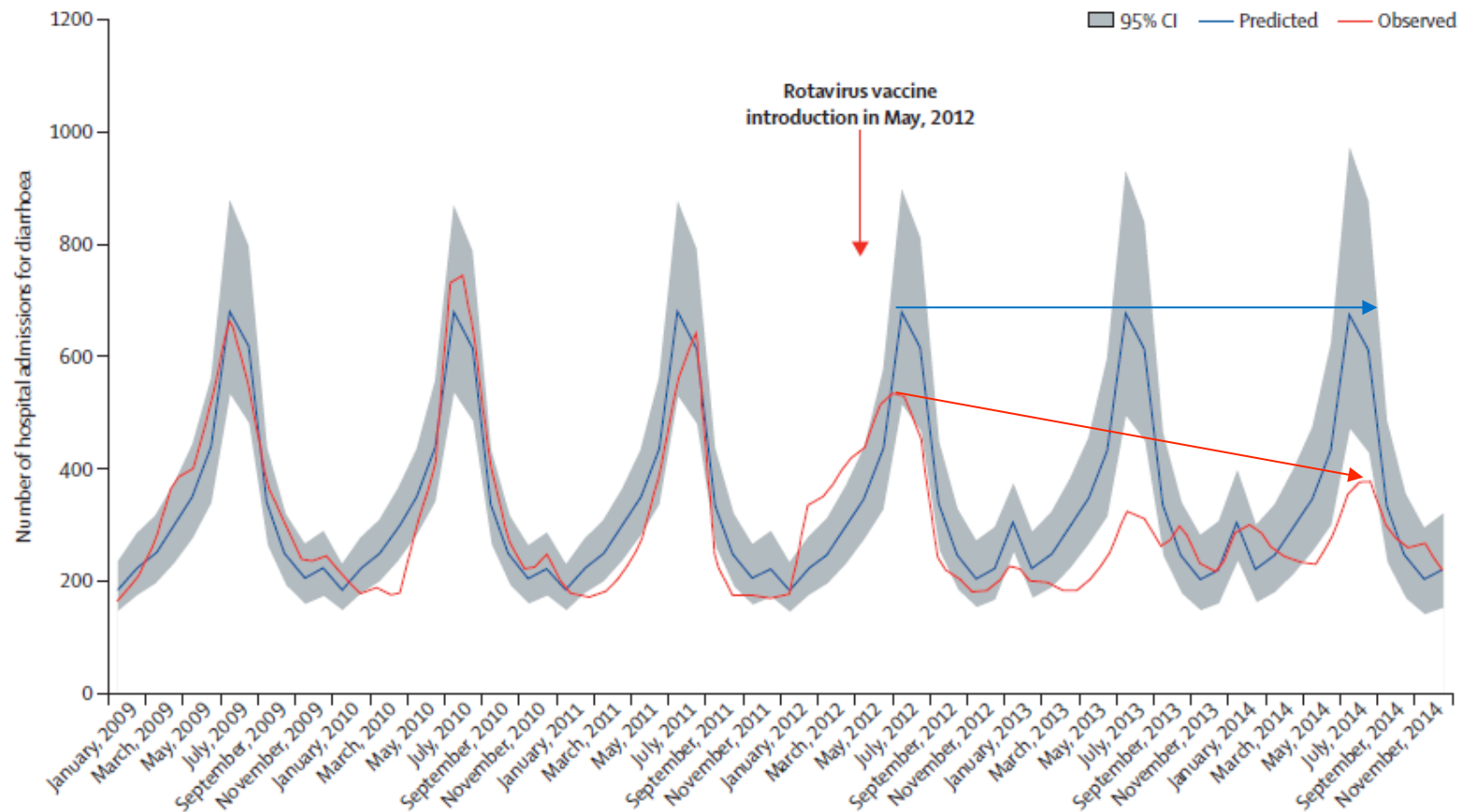


Mackenzie GA et al. Effect of the Introduction of Pneumococcal Conjugate Vaccination on Invasive Pneumococcal Disease in The Gambia: Population-Based Surveillance. Lancet Infectious Diseases, Published online February 17 2016.

**Note** - other age groups available: 2-4 years, 5-14 years, >15 years; also: PCV7 type only, PCV 13 type only, NVT, and all-type. Data here (PCV13 type , under 2) show highest impact.



## Rotavirus, Rwanda: Hospital admissions for diarrhoea before and after rotavirus vaccine introduction, Rwanda



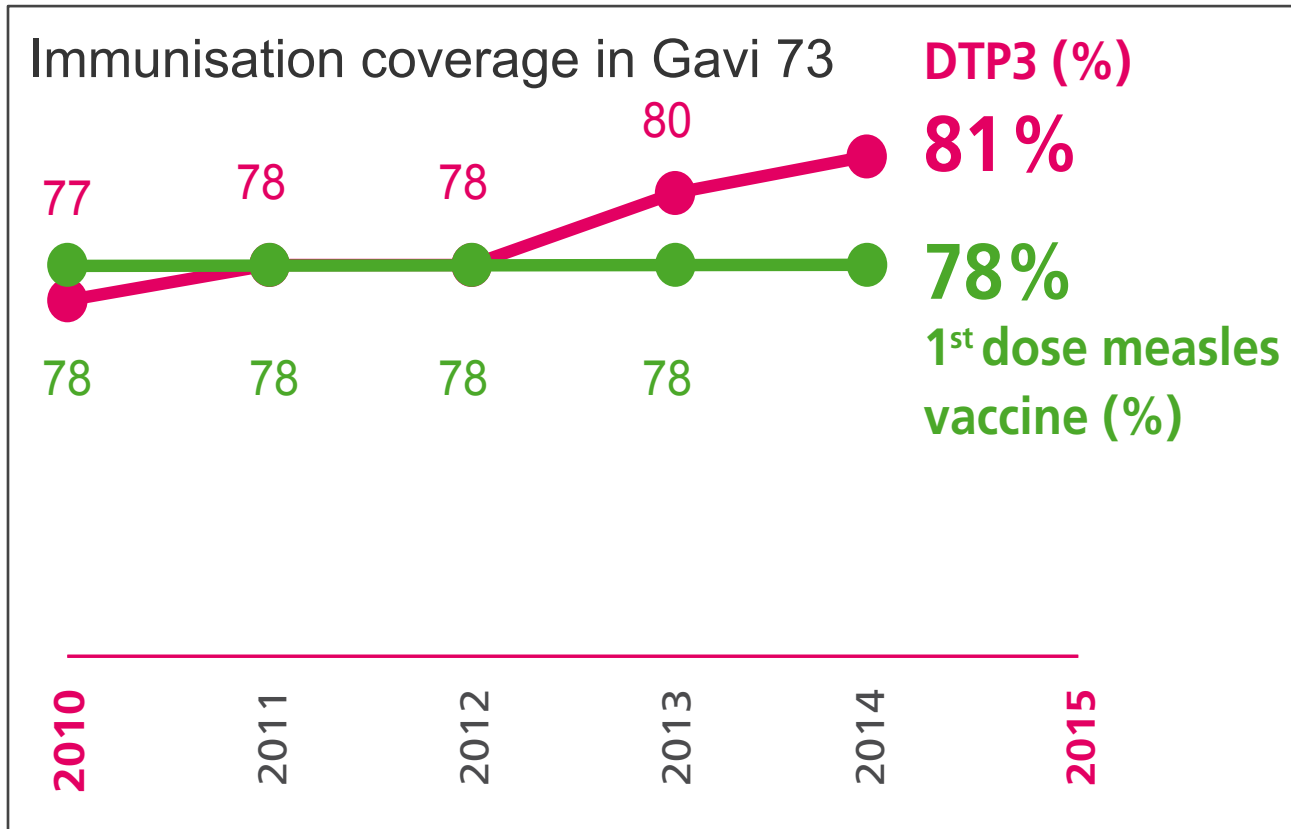
Ngabo F et al. Effect of pentavalent rotavirus vaccine introduction on hospital admissions for diarrhea and rotavirus in children in Rwanda: a time-series analysis. *The Lancet Global Health*, Volume 4, Issue 2, e129 - e136.

# Gavi programme update

## Key Board decisions – December 2015

- **Gavi's Measles and Rubella strategy**
- **Alliance Partnership Strategy with India, 2016-2021**
- **Partners' Engagement Framework**
- **Data strategic focus area**

# Measles immunisation coverage has stagnated



- **MCV1 coverage also flat globally since 2010**
- **MCV2 38% in Gavi 73**

Source: WHO/UNICEF Estimates of National Immunization Coverage, 2015.

# Measles and rubella: Enhanced engagement (up to \$800M for 2016-20)

## Current Gavi support

**Routine Measles second dose**  
for 5 years

**Measles SIAs**  
in 6 high risk countries  
for under-5s

**MR campaigns**  
for under-15s before  
routine introduction

**Outbreak response fund**  
to MRI until 2017

## Proposed changes

Routine Measles 2<sup>nd</sup> dose and MR as normal co-financed vaccines

Extend support to all Gavi countries that need measles SIA before introducing MR

Support follow-up campaigns where required

Consider supporting 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

# India strategy: Approved up to \$500 million in investments

## Indicative vaccine/cash allocation

	Scope of support	Number of children immunised (million)	Cost estimates (\$ million)
<b>Vaccines support</b>			
Rota	20% cohort for 3 years	15	~\$80
Pneumo	20% cohort for 3 years	15	~\$180
MR (campaign)	2 out of 4 phases	170	~\$110
HPV*	~15% cohort for 1 year	2	~\$30
<b>Cash support</b>			~\$100
<b>Total</b>			\$500

**Health impact: Additional ~440,000-860,000 future deaths averted**

\* Subject to NTAGI recommendation and Government approval for new vaccine introduction

# Country focus: A bottom-up approach

1

## **Understanding country needs**

- **72 in-country Joint Appraisals (JAs) in 2015**
- **Articulation of key barriers and needs**

2

## **Responding to country needs**

- **Proposals from UNICEF/WHO seek to respond to JAs**
- **Initial submissions include ~200 'boots on the ground'**

3

## **Countries at the design table**

- **Improved harmonisation**
- **Greater transparency**
- **Enhanced accountability**



# Data strategy: What the Alliance aims to achieve by 2020

Focus areas



Immunisation  
Delivery, Coverage  
& Equity (DCE)



VPD surveillance



Vaccine safety

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

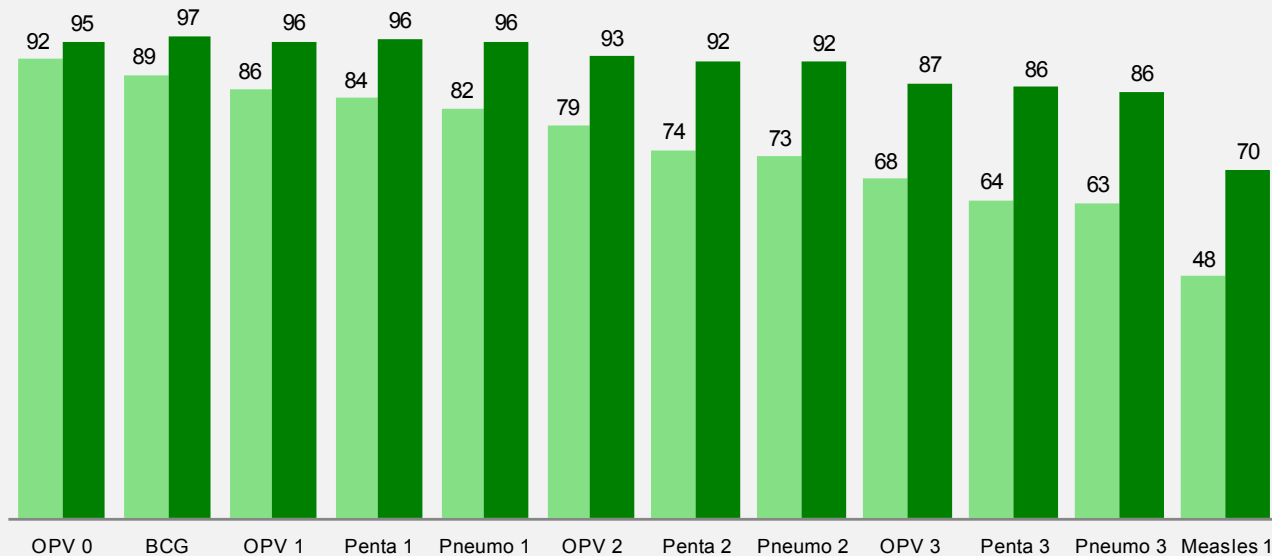
Ability to **identify and investigate** signals of severe AEFIs, **respond** efficiently and effectively and **address public concerns** on safety

# Punjab, Pakistan: Using data for accountability and results

## A province-wide third-party survey has confirmed the progress

December 2015  
December 2014

Antigen coverage (children aged 12 months)  
%



***Penta3 and  
MCV1  
increased  
>20  
percentage  
points in  
one year***

NOTE: Based on record and recall reporting of immunizations received in children aged 49-52 weeks within the larger Nielsen sample of children aged 0-12 months.

SOURCE: Nielsen (Dec 2014 & Dec 2015)

1

# Key issues on Gavi agenda

# Gavi's engagement in Ebola



- Gavi and Merck announced advanced purchase commitment (APC) for Ebola vaccines
- Gavi prepayment of US\$5M for future procurement of licensed Ebola vaccine
- In return, Merck committed to:
  - Have EUAL application accepted by WHO by December 2015
  - Make available 300,000 investigational doses by May 2016
  - Submit for licensure by December 2017
- Other manufacturers declined APC, but engagement continuing

# Angola yellow fever outbreak a reminder of potential epidemic threat



# Gavi's growing role in outbreak preparedness and response

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**Yellow fever**  
vaccine stockpile



**Measles outbreak**  
response



**Meningitis vaccine**  
stockpiles



**Oral cholera**  
vaccine stockpile



**Ebola vaccine**  
stockpile



# Outbreak response and preparedness: Strategic questions cover 4 potential areas of engagement

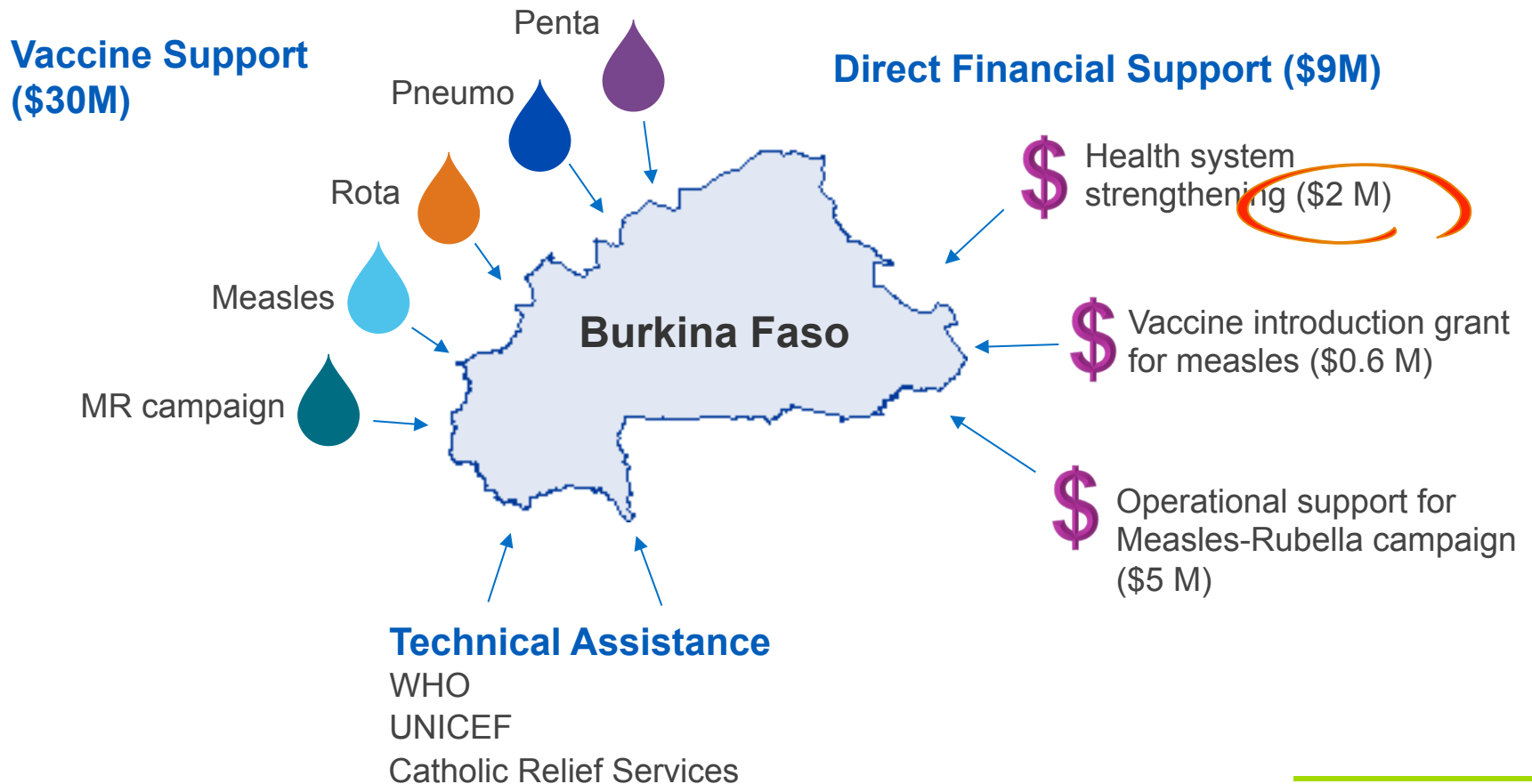
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1	<b>Stockpile Investments</b>	To what extent should Gavi develop a more comprehensive and engaged strategy with regard to Gavi-supported vaccine stockpiles used in outbreak response?
2	<b>Existing Vaccines/Flu</b>	What role, if any, should Gavi have in preparedness and response for outbreak diseases where there exists vaccines which Gavi currently does not support such as pandemic influenza?
3	<b>Vaccines in Development</b>	For vaccines in development for emerging infectious diseases, what role, if any, should Gavi have?
4	<b>Country Capacity</b>	To what extent should Gavi take a more deliberate approach to support countries to strengthen core capacities to prevent, detect and respond to disease outbreaks?



# Gavi HSS and other Direct Financial Support critical for improving immunization coverage and equity

*Example: Alliance support to Burkina Faso in 2014*



# Shaping vaccine markets is a key responsibility for the Alliance

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## Objectives:

- **Supply security**
- Sustainable price
- Innovation



## Ambitious new market shaping goals for 2016-2020

- 13 vaccine markets in scope and suggestion that Gavi should seek to shape all markets where it funds procurement (including stockpiles)
- Achieve 'healthy market dynamics' in 5 markets

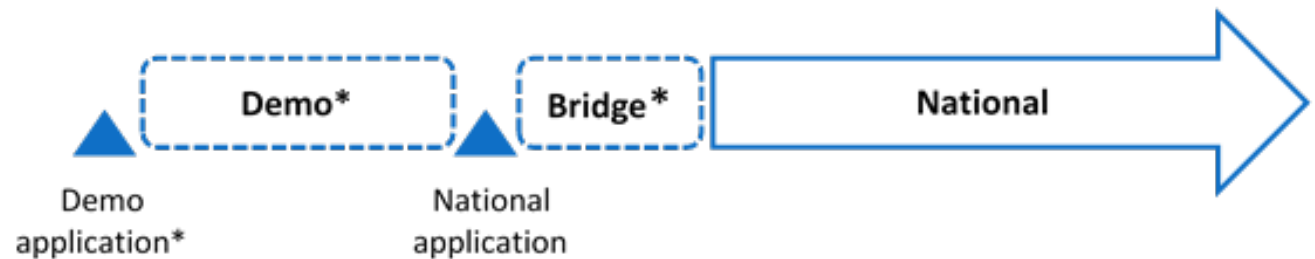
## Review of Supply and Procurement Strategy: Gavi Board decisions in June

- **Healthy markets:** balance trade-offs between supply/price/innovation, tailored risk tolerance for stockpile procurement
- **Longer term view:** monitor externalities, support country transition
- **Innovation for equity:** vaccines and cold chain equipment

# HPV new way forward: shift to single pathway

Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
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Old HPV  
Programme  
Framework



Sep 2016 New  
HPV Programme  
Framework

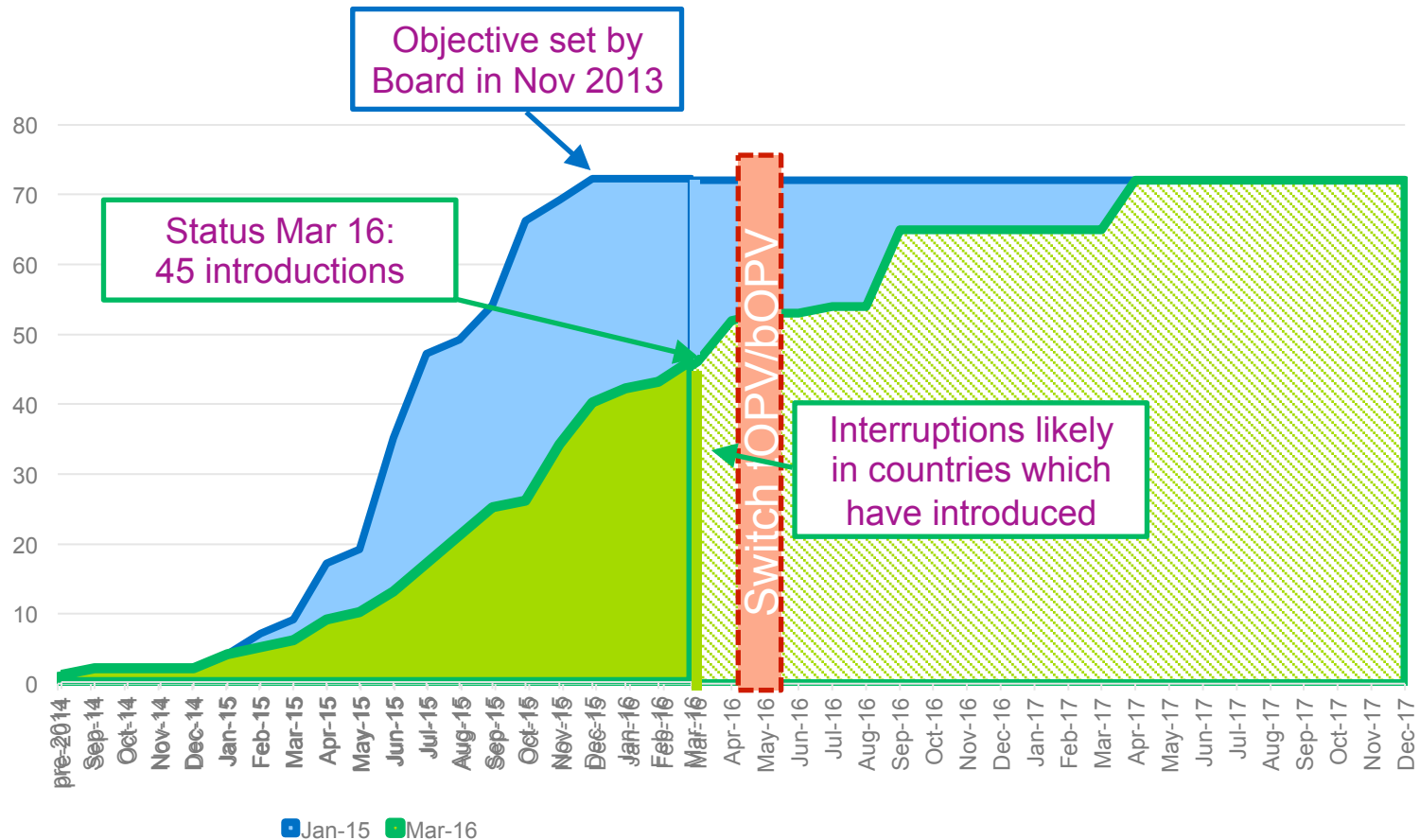


## Mandatory Pre-application workshop:

- Reduce risk of delivery approach discrepancy btw Demo and National – ***Learn to scale-up***
- EPI ownership, utilization of existing infrastructure

# Issues on the SAGE agenda

# 71 IPV introductions: Jan.15 vs Mar.16 plans




# **Gavi's support for IPV approved post-2018 contingent on additional funding**

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- **Gavi committed to support IPV through 2018 when Board will review**
- **Board approval was dependent on resources provided by GPEI and their donors**
- **Extension of Endgame to 2019 raises questions of how IPV will be supported post-2018**
- **SAGE recommendation on IPV across different scenarios and timelines, and possible revised IPV dose schedule, will facilitate global planning**

# Gavi's engagement in polio legacy



Report to the Board  
2-3 December 2015

**SUBJECT:** COUNTRY PROGRAMMES STRATEGIC ISSUES

**Report of:** Hind Khatib-Othman, Managing Director, Country Programmes

**Authored by:** Stefano Mahvotti; David Salinas, Alan Brooks, Santiago Cornejo

**Agenda item:** 13

**Category:** For information

**Strategic goal:** SG1 - Vaccines, SG2 - Health systems, SG3 - Financing

1. Executive Summary

1.1. This is a cover note to the Country Programmes update that was submitted to the Programme and Policy Committee (PPC) in October 2015. It provides information on several strategic issues raised during the PPC's discussion of the Country Programmes update and poses questions to the Board for its deliberation. More detailed information on the Alliance's in-country operations, activities, achievements and challenges and particularly on the Alliance's work to increase coverage, equity and sustainability in the Gavi supported countries is provided in the attached Country Programmes update to the PPC, as well as in its Annexes A through D. The Annexes also provide more detail on the implementation of each of the Strategic Goals 1, 2 and 3 as well as an update on the Alliance's operations in 4 key countries, the Democratic Republic of Congo, India, Nigeria and Pakistan. A further annex to this cover note (Annex 1) gives an overview of the World Bank Group's engagement through the Gavi Alliance, January 2015-November 2016.

1.2. The Secretariat has also taken note of the comments and opinions expressed by PPC members with respect to the content and structure of the Country Programmes update to the PPC. In order to provide further guidance to the Secretariat the PPC has agreed that it would take time to discuss and align among PPC members on the content and structure of future updates at a PPC retreat which will be held before the May 2016 PPC meeting.

2. Content

Introductions

2.1. During the current strategic period the Alliance has focused strongly on delivering on the objectives of the 2011-2015 strategy, in particular to accelerate the uptake and use of underused and new vaccines. All

Board-2015-Mtg-3-13

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## Approach approved by Gavi Board

- Country-driven, country-specific approach
- Resources integrated in national programmes
- No resources/mandate to take over partners' full human resources/assets
- Focus on equitable and sustainable immunisation coverage
- Health system strengthening and Partners' Engagement Framework are key instruments for support

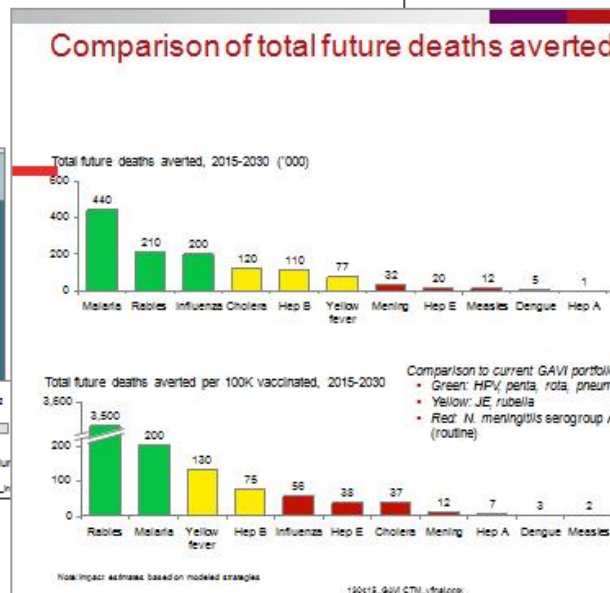
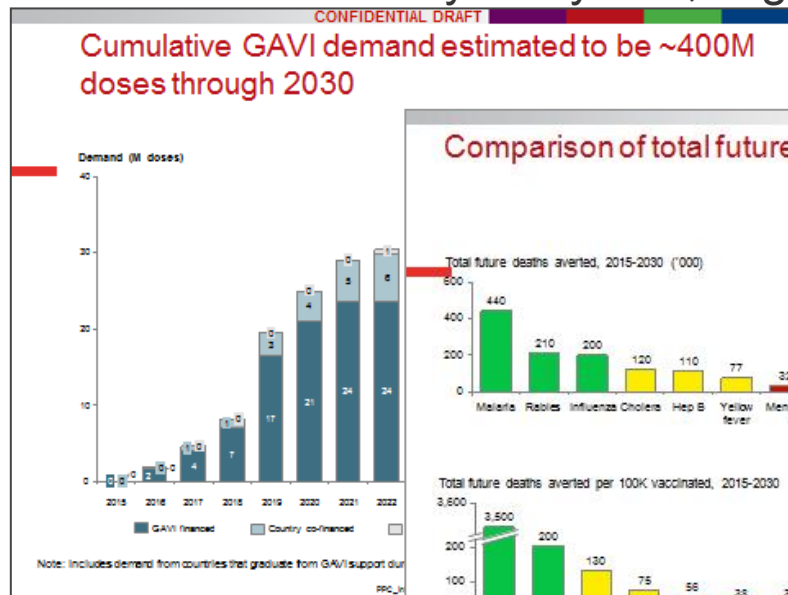


# New vaccines for Gavi investment

## Malaria, dengue, RSV...

## The Vaccine Investment Strategy (VIS) defines evidence-based new vaccine priorities for Gavi support

- Evidence review, analyses, stakeholder consultations, independent expert advice
- Once every five years, aligned with strategic cycle



**CONFIDENTIAL DRAFT**

**Hepatitis E Phase I Scorecard**  
Baseline: Routine immunization at 10 years

Category	VIS Criteria	Phase I Indicator	Phase I Evaluation
Health Impact	Impact on child mortality	0 US future deaths averted, 2015-2030 (vaccination at age 10)	0 US future deaths averted per 100K vaccinated population
	Impact on overall mortality	<20,000 total future deaths averted, 2015-2030	<20,000 total future deaths averted per 100K vaccinated population
	Impact on overall morbidity	<1.0M total future cases averted, 2015-2030	<1.0M total future cases averted per 100K vaccinated population
Additional impact considerations	Epidemic potential	No long-term sequelae	Limited epidemic potential
	Global or regional public health priority	No global or regional resolution on elimination or eradication	No global or regional resolution on elimination or eradication
	Herd immunity	Insufficient evidence on herd immunity	Insufficient evidence on herd immunity
	Availability of alternative interventions	Water and sanitation improvements possible for disease control	Water and sanitation improvements possible for disease control
	Socioeconomic inequity	Hepatitis E is associated with inadequate water supplies and poor sanitation and hygiene	Hepatitis E is associated with inadequate water supplies and poor sanitation and hygiene
Implementation feasibility	Gender inequity	Disease burden concentrated in pregnant women (~40% case fatality rate)	Disease burden concentrated in pregnant women (~40% case fatality rate)
	Disease of regional importance	Planned expansion well below GAVI demand; 1 manufacturer	Planned expansion well below GAVI demand; 1 manufacturer
	Capacity and supplier base	Significant potential to influence market (GAVI market is ~4x planned capacity)	Significant potential to influence market (GAVI market is ~4x planned capacity)
	GAVI market shaping potential	Packed volume cannot yet be determined; manufacturer would switch from prefilled syringe to single-dose vial to serve GAVI market	Packed volume cannot yet be determined; manufacturer would switch from prefilled syringe to single-dose vial to serve GAVI market
Cost and value for money	Ease of supply chain integration	Ease of programmatic integration	Not aligned with other vaccine schedules
	Vaccine efficacy and safety	>100% efficacy; no evidence of causal link to serious adverse events	>100% efficacy; no evidence of causal link to serious adverse events
	Vaccine procurement cost <sup>1</sup>	~\$350M from 2015-2030	~\$350M from 2015-2030
	In-country operational cost	High incremental cost: three doses delivered outside of health system	High incremental cost: three doses delivered outside of health system
	Procurement cost per event averted <sup>2</sup>	~\$18,000 per future death averted, \$350 per future case averted	~\$18,000 per future death averted, \$350 per future case averted

<sup>1</sup> Procurement cost includes vaccine, syringe, safety box, and freight. <sup>2</sup> Scoring based on cost per future death averted.

**GAVI ALLIANCE**

# Malaria vaccine (RTS,S)

## **Shortlisted in 2013 VIS**

- Board requested final review after trials and WHO recommendation

## **Dec 2015: Board update on WHO pilot recommendations**

- concerns around potential Gavi role in implementation research (safety, fit with mandate, timing)

## **May 2016: PPC review of WHO request for pilot funding**

- exploring Gavi – UNITAID – Global Fund cost-sharing though not in budget
- WHO leading (sovereign) donor initial outreach
- outstanding questions on budget and technical validation of pilot approach

# Dengue assessment 2013

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**Considered in 2013 VIS alongside 14 other vaccines**

## **Reasons for low ranking**

- At the time, significant uncertainty about efficacy of lead candidate, timing and availability of an effective vaccine
- Lack of burden data from Gavi countries and uncertain demand
- Relatively high expected cost and relatively low health impact compared with other vaccines

# VIS 2018

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## Criteria to be developed with stakeholders

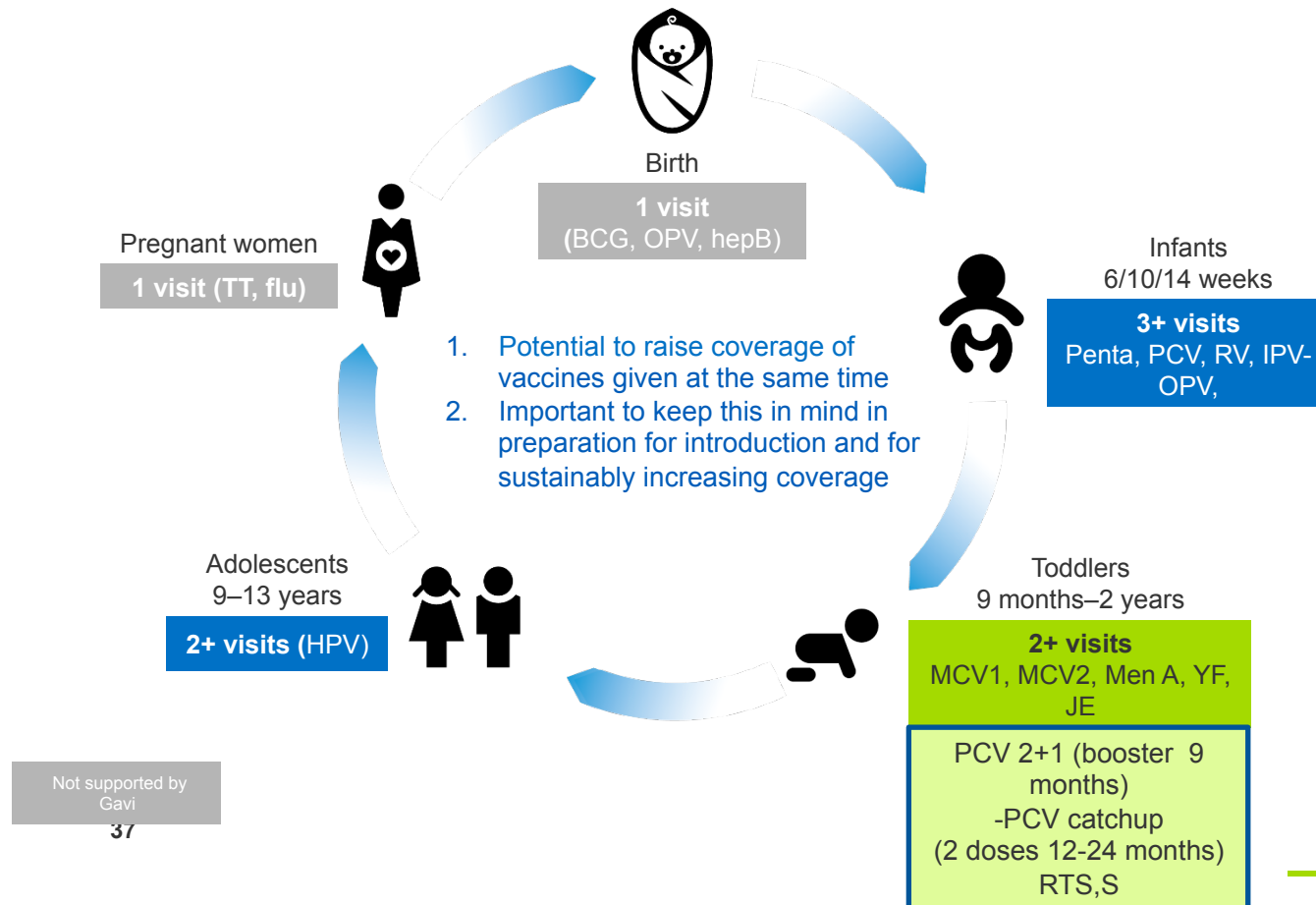
- Normally direct health impact. Other potential criteria: equity impact, implementation feasibility, cost, outbreak preparedness, maternal immunisation, 2<sup>nd</sup> year of life platform

## Vaccines likely in scope for consideration

- **For re-assessment:** dengue, Oral Cholera Vaccine, (maternal) influenza, rabies PEP, meningococcal multivalent, Hepatitis E, DTP booster, Hepatitis B birth dose, Typhoid conjugate
- **New:** RSV, Group B Streptococcus, norovirus, ...?

## Process starts mid 2017

# Many vaccines supported by Gavi given in "second year of life" immunisation platform





# Immunisation ever higher on the political agenda



# vaccineswork

**THANK YOU**

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